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Patient safety at odds with patient privacy? The case of national and regional quality registries fo incapacitated elderly in Sweden

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O Centro de Direito Biomédico, fundado em 1988, é uma associação privada sem fins lucrativos, com sede na Faculdade de Direito da Universidade de Coimbra, que se dedica à promoção do direito da saúde entendido num sentido amplo, que abrange designadamente, o direito da medicina e o direito da farmácia e do medicamento. Para satisfazer este propósito, desenvolve acções de formação pós-graduada e profissional; promove reuniões científicas; estimula a investigação e a publicação de textos; organiza uma biblioteca especializada; e colabora com outras instituições portuguesas e estrangeiras.

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PRESENTATION

Guilherme de Oliveira

The IV EAHL Conference on European Law and Patient Safety has been held in Coimbra, Portugal (9-11 October, 2013). This event has offered the opportunity to celebrate the 25th anniversary of the Faculty of Law's Biomedical Law Centre.

*"How familiar are you with the concept of **patient safety**? Hundreds of thousands of patients are harmed or die each year due to unsafe care, or get injured inadvertently when seeking health care." (WHO).*

What is the contribution that law and legal experts can give to ensure that access to health care is done in ever more secure ways? What is the contribution we can make to the patient to obtain better and faster reparation?

What can legislation and legal doctrine do, so that errors constitute an opportunity to build more secure health systems?

Attendants have had the opportunity to choose among over eighty presentations, covering many aspects of Patient Safety in several relevant topics.

Here are some of the papers presented at the conference.

This Lex Medicinae's special issue aims to promote the interest on Law and Patient Safety amidst legal experts.

THE SUICIDE OF MENTAL PATIENTS AND THE DUTIES OF CARE OF THE MENTAL HEALTH INSTITUTIONS

Ana Pereira de Sousa [1] / *José Pais do Amaral* [2] / *André Dias Pereira* [3]

Abstract: *The suicide of mental patients is a world serious problem. Mental health institutions have been accused by Courts of Law as being negligent as far as their patients' security is concerned. Many legal cases all over the world have addressed and judged situations of mental patients' suicide and the problems caused by this issue to the institutions in which these patients were hospitalised. Portugal has published in 2013 the National Suicide Prevention Plan, but a lot more needs to be done. Moreover, it is defended that an intra-hospital plan of mental patients' suicide prevention should be created and implemented around the world. Legislation should be updated and adapted to regulate and control the mental patients' suicide problem.*

Key-words: *mental health institutions, mental patients, suicide, legislation, suicide prevention, follow-up procedures, awareness, training, education.*

I. Introduction

Not long ago it was defended that, in general, the only way in effect susceptible of preventing suicide was the immediate hospitalisation of the patients in a closed regime. A good example of this is the American study dated from 1959 that analysed 134 suicide cases successfully committed by patients confined to a hospital or recently discharged from it [4].

However, the potential harmful consequences of this approach and the fear of the stigmatising institutionalisation inherent to it have encouraged the mental health institutions to find new ways of taking care of their psychiatric patients [5].

In the beginning of the 1960s, the *open door* policy has been created, characterised since its debut by a fast admission and a vigorous medical treatment [6], in which the patient has a broad movement freedom, being able to wander inside the hospital facilities which do not have ditches or walls [7] [8].

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[4] Mainly maniac-depressive and chronic alcoholic individuals, who showed suicidal ideas, cf. Eli Robins *et al*., *Some clinical considerations in the prevention of suicide based on a study of 134 successful suicides* in *American Journal of Public Health and the Nations Health*, 1959, 895-897.

[5] Cf. M. Vand Der, L. Bowers/ J. Jones/A. Simpson/K. Haglund, *Locked doors in acute inpatient psychiatric: a literature review* in *Journal of Psychiatric and Mental Health Nursing*, England, 2009, p. 294.

[6] We are still following Vand Der *et al*., *ob. cit.,* p. 293.

[7] Therefore in opposition to the big walled buildings, located in the cities' proximities, packed with *locked* mental patients and frequently with few resources, in a style close to the *psychiatric asylums* (cf. Vand Der *et al*., *ob. cit*., p. 293), in which the patients' human will was, as it is known, broken by the doctor's *autorictas* (Foucault).

[8] Avoiding, for example, that the patients feel like they were arrested or object of punition, instead of feeling like they were object of care, as intended, cf. Vand Der *et al*., *ob. cit*., p. 297.

This is a remarkable paradigm change, which has been being applauded by the modern psychiatry [9] and it has been defined by some authors as the most important change in the mental hospitals [10]. But, as it happens in life, a change carries new risks and challenges.

II. Getting closer to the problem

A. In general

Suicide is a very serious world health problem, being the first death cause out of ten around the globe, and being the second of the causes that create it [11].

Annually, about one million people put an end to their lives, which makes one death per each forty seconds [12]. In the last four decades, the suicide rates substantially increased — more than 60% [13]. Additionally, but always among the top results, the suicide rate among the young people has become an even more serious issue [14].

In order to deal with this problem, in 1989 the World Health Organisation (WHO) defined the suicide prevention as an absolute priority [15], having the United Nations in the 1990s encouraged the governments to implement and to develop suicide prevention strategies [16].

Extensive programs and strategies that tend to prevent suicide at a national and/or regional level have been adopted by different countries [17], all of them sharing common topics: the population education/awareness, a responsible information service on behalf of the media, the introduction of this topic in school syllabuses, the detection and the depression treatment and other mental disor-

[9] A several number of advantages (and disadvantages) of the adoption of this regime opposing to the closed doors one can be perused in the Vand Der *et al.*, *ob. cit.*, pp. 295 and following.

[10] Cf. Adams B., *Locked doors or sentinel nurses?* in *Psychiatric Bulletin*, 2000, pp. 327-328 *apud* R. Ashmore, *Nurse´s accounts of locked ward doors: ghosts of the asylum or acute care in the 21st century*, *Journal of Psychiatric and Mental Health Nursing*, 2008, England, p. 175.

[11] Cf. Merete Nordentoft, *Crucial elements in suicide prevention strategies* in *Progress in Neuro-Psychopharmacology & Biological Psychiatry*, 2001, p. 848.

[12] Cf. Tetsuya Matsubayashi/Michico Ueda, *The effect of national suicide prevention programs on suicide rates in 21 OECD nations* in *Social Science & Medicine*, 2011, Elsevier, p. 1395.

[13] Cf. Kirsten Windfuhr, *Issues in designing, implementing and evaluating suicide prevention strategies* in *Psychiatric*, Vol. 8, 2009, Elsevier, p. 272.

[14] In Canada, for example, suicide continues to be the second death cause, after the road accidents, among the young people between 15 and 19 years-old, cf. White, Jennifer/Morris, Jonathan, *Precarious spaces: risk, responsibility and uncertainty in school-based suicide prevention programs* in *Social Science and Medicine*, 71, 2010, p. 2187.

[15] In fact, the WHO has developed several activities calling attention for the need of the suicide prevention and to put it in the every country's national agenda, being a recent example the *Mental Health Declaration for Europe: Facing the Challenges, Building Solutions*, particularly its 5th aim: *to develop and implement measures to reduce the preventable causes of mental health problems, comorbidity and suicide*(http://www.euro.who.int/document/mnh/edoc06.pdf).

[16] Based essentially on six specific vectors: the existence of governmental policies; the creation of an indicator model of the intervention areas (in which the 1st level of intervention aims the prevention of the population in general, the 2nd one concerns the groups considered to be of high risk, and the 3rd one aims the high risk individuals); the definition of clear and measurable goals (key ideas of the path that the strategy will follow, which resources need to be mobilized and in which terms the progress will be measured); the identification of entities that will implement the aims; and, finally, the monitoring and the assessment of the planning (with the essential aim of verifying if, in fact, the planned program is according to the defined aims and ends), cf. Kirsten Windfuhr, *ob. cit.*, pp. 272 and following. See also in this regard, the Danish study of Merete Nordentoft, *Crucial elements…, cit.,* pp. 848 and following and specifically about the regional prevention programs established in France, cf. Martine Marie Bellanger/Alain Jourdain/Agnes Batt-Moillo, *Might the decrease in the suicide rates in France be due to regional prevention programmes?* in *Social, Science & Medicine* 65, 2007, Elsevier, pp. 431 and following.

[17] Finland has been the first country to develop a strategy of national suicide prevention (1992). Then, Norway (1994), Sweden (1995), Australia (1995), Denmark (1998), France (1998), New Zealand (1998), Ireland (2001), the USA (2001), England (2002) and Germany (2003) have followed the example, cf. Tetsuya Matsubayashi/Michico Ueda, *ob. cit.,* pp. 1395-1396.

ders, the need of double attention concerning the alcohol and drugs abusers, the access reinforcement to the mental health services, the improvement of follow-up procedures concerning individuals who have tried to commit suicide, the implementation of labour policies and the growing training of the health professionals, the reduction to lethal means' access,... [18][19].

And, although there existed some *limitations* in the way they have been implemented [20], it is certain that researches recently undertaken have concluded that, after the introduction of these preventive governmental programs, the suicide rate has decreased [21].

Unfortunately, there are several countries which have not yet defined the suicide prevention as a priority. Portugal, precisely and until now, seemed to be one of them, having however recently created the named *2013/2017 National Suicide Prevention Plan*.

B. More specifically

In this context, which we believe not to be surprising, the suicide of hospitalised psychiatric patients consubstantiates, also in a worldly scale, a perfectly dramatic situation: this is the second [22] most frequent *sentinel event* reported to the Joint Commission International (JCI) since 1995 [23].

And, even more seriously, an event that has as main cause the existence of *failures* in the clinical treatment of these patients: in 60% of the suicide cases occurred, the risk has not been adequately treated or the *designed* risk level was below the imposed precautions [24].

This meets the scope of several studies undertaken in the meantime concerning the suicide topic, in particular the ones that denounce the existence of mental disorders that are simply not treated or that are improperly treated [25].

[18] Cf. Anderson & Jenkins, 2005, p. 249 *apud* Tetsuya Matsubayashi/Michico Ueda, *ob. cit.,* p. 1396.

[19] See the very interesting suicide prevention plan in force in Oregon, whose target group is the young people, in http://public.health.oregon.gov/PreventionWelness/Safeliving/SuicidePrevention/2000plan/Pages/plan.aspx

[20] As an example and according to Kirsten Windfuhr (*ob. cit.*, p. 274), the strategy for Ireland has not established clear aims, Sweden has not clarified the implementation process and few are the strategies that, contrarily to what has happened in Scotland, have incorporated an evaluative procedure as an integral part. Equally criticising the way the strategies launched by Quebec (mainly due to the lack of a synergetic collective approach and the existence of high suicide rates), by Thailand and by Australia (whose relative inefficacy might be due to the big amount of time passed since the decision of its adoption until its practical and concrete implementation), cf. Martine Marie Bellanger *et al.*,*ob. cit.,* p. 432.

[21] Cf. Tetsuya Matsubayashi/Michico Ueda, *ob. cit.*, pp. 1397 and following, in particular, p. 1399, authors who illustrate this conclusion with the case, among others, of Germany, a country in which it was possible to prevent about 1350 suicides.

[22] After the wrong practice of chirurgical procedures.

[23] Cf. Jeffrey S. Janofsky, *Reducing inpatient suicide risk: using human factors analysis to improve observation practices* in *The Journal of the American Academy of Psychiatry and the Law*, 37, 2009, p. 15; also cf., http://www.jointcommission.org/assets/1/18/SE_General_Info_1995_4Q2012.pdfhttp://www.jointcommission.org/assets/1/6/CAMLTC_2012_Update2_20_SE.pdf

[24] Defending that one of the fundamental concerns of the *Standing Nursing and Midwifery Advisory Committee* (1999) is, precisely and in order to prevent suicide, based on the mental patients safety procedures, in particular in the deficiencies related to the detection, by the staff, of the risk, or to the need of specific observation of these patients, cf. L. Bowers *et al.*, *Safety and security policies …, cit.,* p. 428.

[25] Cf. Zoltán Rihmer, *Strategies of suicide prevention: focus on health care* in *Journal of Affective Disorders*, vol. 39, 1996, Elsevier, p. 84, with wide quotations of researchers pointing to this precise way; cf., also, ZoltánRihmer/XeniGonda/Peter Torzsa/Laszlo Kalabay/Hagop S. Akiskal, *Affective temperament, history of suicide attempt and family history of suicide in general practice patients* in *Journal of Affective Disorders*, vol. 149, 2013, Elsevier, p. 350; Louis Appleby, *Suicide in Psychiatric Patients: Risk and Prevention* in *British Journal of Psychiatric*, 1992, pp. 755-756, an author who highlights, for example, the conclusion reached in a study then undertaken, and that defended that 70% of depressed patients, besides being in contact with medical services, was not receiving the adequate portion

Therefore, all of this dictated the (depressing) conclusion that at least some of the committed suicides could have been avoided [26].

What are then the concerns that the mental hospitals (or hospitals with mental units) should always and in every case have present and how should they put them in practice in order to prevent the suicides? This is what we seek to answer.

III. The risk assessment and the prevention: the standardisation

A. Previous premises

As we can see, the answer to the posed question is necessarily linked to factors commonly related to the suicide of hospitalised mental patients.

Those factors, according to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), are three in total [27]: the first one is linked to the failures detected in the safety procedures [28]. The second one concerns the assessment made to the patient, frequently based on an incomplete management of the suicide risk right after their admission, or on the absence or incompletion of the situation's reassessment in which the patient is involved [29]. The third one has to do with the institution's human resources and with its staff who, most of the times, is not enough, has a lack of guidance and training, being therefore common to exist inadequate care plans and observations records that, when they do exist, are incomplete, offering a short availability of concrete data about the patients [30].

10

of antidepressants, and many of them were not even receiving treatment; also cf. Judit Balázs/Franco Benazzi/Zoltán Rihmer/Annamária Rihmer/K. K. Akiskal/H. S. Akiskal, *The close link between suicide attempts and mixed (bipolar) depression: Implications for suicide prevention* in *Journal of Affective Disorders*, n.º 91, 2006, Elsevier, p. 137 and Makiko Kaga/Tadashi Takeshima/Toshihiko Matsumoto, *Suicide and its prevention in Japan* in *Legal Medicine*, vol. 11, 2009, Elsevier, p. 20.

[26] In fact, if it is unequivocal that it is not possible to prevent all the suicides, it is also undeniable that many — or at least some of them — could be avoided. See, in this sense, the *National Prevention Strategy* created by the *U.S. Department of Health & Human Services* in http://www.surgeongeneral.gov/initiatives/prevention/index.html and also, H. G. Morgan, *Can suicide be prevented? Prevention is possible if doctors are taught how* in *British Medical Journal*, 309, 1994, pp. 861-862. We then believe that the ideas defended by B. Barraclough/J. Bunch/B. Nelson/P. Sainsbury (*A hundred cases of suicide: clinical aspects in British Journal Psychiatric*, 125, 1974, p. 355), when they declared that "historically, have doctors not always shown to know that they have the obligation to prevent suicide, in part because they shared the essential idea that the majority of suicides was caused by a moral crisis, and therefore this was not their concern or task", is nowadays totally overcome.

[27] Cf. Carl L. Tishler/Natalie Staats Reiss, *Inpatient suicide: preventing a common sentinel event* in *General Hospital Psychiatric*, vol. 31, 2009, Elsevier, pp. 102-103.

[28] There are few available studies about the safety procedures regarding the hospitalised mental patients (and their visitors), as concerning to their detection, the alarms use and modern technology use or the control of entries and exits of people in the hospital, cf. L. Bowers *et al.*, *Safety and security policies ..., cit.,* pp. 427- 429; there are authors who state that, according to the British Royal College of Psychiatrists (1998), there is the need for 24/7 security staff in the hospitals and for the establishment of clear criteria about the kind of patient in case. According to L. Tishler/Natalie Staats Reiss (*ob. cit.,* p. 106), the facilities remodeling (if possible), the redesign or reinforce of the existent safety strategies, the patients' monitoring, the alarms use and the non-breakable glass and not opening to the outside windows installation, are several aspects that should be taken into account to fulfill this aim.

[29] Cf. L. Bowers *et al.*, *Safety and security policies …, cit.,* p. 103 (these are authors who add that it is common to detect failures in the identification and removal of means that can be used for self-aggression) and, similarly, there is the work of Louis Appleby, *ob. cit.,* pp. 756-757. *Pointing the finger to the uncertainties,* concerning the specific diagnosis of the individuals' mental state right before their death, the inexistence of a follow-up treatment after the patients' discharge, or still, the hospitalisation motivated more by the type and localisation of the institution than by the concrete characteristics and needs of the ill individuals, cf. Irene M. K./Ovenstone, Norman Kreitman, *Two Syndromes of Suicide* in *The British Journal of Psychiatric*, 1974, pp. 339-340 and Jennifer L. Hughes/Joan R. Asarnow, *Enhanced Mental Health Interventions in the Emergency Department: Suicide and Suicide Attempt Prevention* in *Clinical Pediatric Emergency Medicine*, 2013, Elsevier, p. 29.

[30] Cf. L. Bowers *et al.*, *Safety and security policies …, cit.,* p. 103. In this sense, we call attention for the fact that the mental health teams do not have at their disposal enough amounts of psychologists, nurses, social service technicians, occupational therapists and other non-medical professionals.And the majority of the teams keep the traditional pattern of the psychiatric hospitalisation services rather than the pattern followed by the modern mental health services. In order to

Because of this (non despicable) group of reasons, in 2007 the Joint Commission's National Patient Safety Goal wrote the following prescription: a risk's assessment that can identify the patient's specific characteristics and the functional aspects that can increase or decrease the suicide risk shall be undertaken [31]. It is necessary to assess the risk, so that next it can be possible to define the safety precautions (or care patterns) to be adopted: this is watchword [32]. And how can we do this? We can do this by creating a rigorous hospital plan of suicide risk prevention [33]. A plan that has as background the causes, the predictors and the treatments that could have been applied and, in this sense, that has present a very concrete pre-understanding of the risk factors (and also a recognition of the high risk individuals) [34]. Along with this, the plan should include previously used methods [35] or, if preferable, the plan that, having as its previous and fundamental basis the profile of the individual who intends to commit suicide in a psychiatric institution, should objectively and undoubtedly stipulate which are the *care rules* that must be observed [36] [37].

This is not, obviously, an easy task; but it is possible to be undertaken, or better, this is something that undoubtedly imposes itself, since it is only possible to create action patterns from this data, especially as far as the surveillance and safety of the hospitalised mental patients are concerned [38]. Let us now see the possible contribution that we wish to make to this aim.

B. The suicidal profile and methodology

As Carl L. Tishler and Natalie Staats Reiss point out, if it is unequivocal that the hospitalised mental patients are a unique population group — because the suicidal risk factors of this group are not necessarily the same that define the other groups —, it is not less certain that, having this present, it is not possible, as it is, to build the profile of the person who intends to commit suicide in a psychiatric institution [39].

know more about the fact that the services' quality is, according to the assessment made with the professionals' participation, below the reasonable stage, and that the most critical areas regarding the criteria and quality patterns' unfulfilling are the ones concerning the human resources (donation, distribution, and interdisciplinary staff's composition), and the administrative organisation, cf. the 2007/2016 Mental Health National Plan in http://www.adeb.pt/destaque/legislacao/cnsm_planonacionalsaudemental2007-2016__resumoexecutivo.pdf

[31] Cf. Peter D. Mills/Vince Watts/Steven Miller/Jan Kemp/Kerry Knox/Joseph M. De Rosier/James P. Bagian, *A checklist to identify inpatient suicide hazards in veterans affairs hospitals* in *The Joint Commission Journal on Quality and Patient Safety*, Vol. 36, 2010, p. 88.

[32] Cf. Jennifer L. Hughes/ Joan R. Asarnow, *Enhanced Mental Health Interventions in the Emergency Department: Suicide and Suicide Attempt Prevention* in *Clinical Pediatric Emergency Medicine*, 2013, Elsevier, p. 29.

[33] Cf. Carl L. Tishler/Natalie Staats Reiss, *Inpatient suicide: preventing…, cit.,* p. 102 and Jeffrey S. Janofsky, *Reducing inpatient suicide risk…, cit.,* p. 17.

[34] Cf. James A. Mercy (*Building a Foundation for Suicide Prevention — The Contributions of Jack C. Smith* in *Am J. Prev. Med*, 2000, Elsevier Science Inc., 2000, pp. 26-27).

[35] The suicidal methodology applied is, in fact, of fundamental importance and it cannot be underestimated. For example, all bibliography that is dedicated to the topic of weapons access restrictions concluded that there is a strong link between the possession of a fire gun and the suicide committed with such a gun. Moreover, in the USA, 60% of the committed suicides are undertaken using this kind of guns, cf. Merete Nordentoft, *Crucial elements in suicide prevention…, cit.,* p. 850.

[36] See the interesting *guidelines* available by the *Suicide Prevention Resource Center* about how to program a strategic action plan in http://www.sprc.org/brp

[37] See the 4th edition of the *Joint Commission International Accreditation Standards for Hospitals* (or *Manual of Hospital Patterns*) *in* http://www.google.pt/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=11&ved=0CCwQFjAAOAo&url=http%3A%2F%2Fwww.jointcommissioninternational.org%2Fcommon%2FDocuments%2FHospital%2FFourth_Edition_Hospital_Manual_Portuguese_Translation.pdf&ei=9AkuUqjrOcKq7Qa7qYCIBQ&usg=AFQjCNG-E1Q9cZNLkNU36zH-3km78AOaLOw&sig2=K_kqmTWuh7oj4Abm6aZezQ

[38] Cf. L. *Bowers et al.*, *Safety and security policies …, cit.,* p. 428.

[39] Cf. Carl L. Tishler/Natalie StaatsReiss, *Inpatient suicide..., cit.*, p. 105.

Hence, this is generally a male, young and single person with a common diagnosis that includes depression, schizophrenia, personality disorders, dual diagnosis and/or psychotic symptoms. This is also a person who, generally speaking, had an admission to the hospital preceded by an attempt to commit suicide or who, while this admission, showed the idea of committing suicide. Probably, this person has a history of previous suicide attempts and a history of a mental disease, sometimes so serious that they had to be hospitalised in the past.

Adding to this, this kind of patient will probably have a family history of psychiatric problems and even a close relative who had also committed suicide. Normally, this is an unemployed person and their family relationships are poor and, in the group of chronic risk factors, there will be, among others, elements of serious hopelessness, a progressive suicide idealisation and a history of alcohol or drug abuse [40]. Finally, the method that this person will use to put an end to their life will very probably be extremely violent [41].

C. The checklist

We have already seen that one of the fundamental concerns that a mental institution should have present is based on the surveillance of the mental patients who it has under its care and, in this specific context, the suicide risk assessment is vital.

In this scope, we have then listed the different risk factors that commonly originate the death of this kind of patients. The way of how to list these same patients in terms of the risk (in order to be possible to stipulate the very concrete care rules to be observed) is, so far, the crux of the matter [42], because as there is not a sole way of decreasing all

[40] Cfr. Carl L. Tishler/Natalie Staats Reiss, *Inpatient suicide…, cit.*, pp. 105-106; B. Barraclough *et al.*, *ob cit.*, pp. 356 and following; Irene M. K. Ovenstone/Norman Kreitman, *ob. cit*, pp. 336 and following; Louis Appleby, *ob. cit.,* pp. 749 and following; Zoltán Rihmer, *Strategies of suicide prevention…, cit.*, pp. 83 and following (an author who, based on a vast scientific bibliography and close to the studies that we have quoted so far, clearly defends that the existence of a mental disease and a previous suicide attempt are the strongest suicide predictors); Zoltán Rihmer*et al.*, *Affective temperament, history of suicide attempt and family history…, cit.,* pp. 350 and following; Kirsten Windfuhr, *ob. cit.,* p. 273; Merete Nordentoft, *ob. cit.,* pp. 850 and following; J. M. G. Williams/C. Crane/T. Barnhofer/A. J. W. Van der Does/Z. V. Segal, *Recurrence of suicidal ideation across depressive episodes* in *Journal of Affective Disorders*, n.º 91, 2006, Elsevier, pp. 189 and following and Robert D. Dvorak/Dorian A. Lamis/Patrick S. Malone*, Alcohol use, depressive symptoms, and impulsivity as risk factors for suicide proneness among college students* in *Journal of Affective Disorders*, 2013, Elsevier, pp. 326 and following; J. M. G. Williams/C. Crane/T. Barnhofer/A. J. W. Van der Does/Z. V. Segal, *Recurrence of suicidal ideation across depressive episodes* in *Journal of Affective Disorders*, n.º 91, 2006, Elsevier, pp. 189 and following.

[41] According to Louis Appleby, *Suicide in Psychiatric Patients: Risk and Prevention* in *British Journal of Psychiatric*, 1992, pp. 753-754, there is a general consensus among the researchers that the hospitalised mental patients resource to more violent methods to put an end to their lives. Therefore, and normally, the male patients hang themselves or jump from tall buildings; women frequently drown or poison themselves; patients with an alcohol or drug abuse diagnosis normally use the overdose method, not excluding the fact that, in the patients suffering from depression, an extrinsic factor susceptible of influence the suicide can be the inherent toxicity of the prescribed antidepressants. Accordingly, there are other cases reported to the JCO between 1995 and 2005 that corresponded to the ones in which the patients who left the institution (with or without permission) ended up in drowning themselves or jumping from buildings, or dying by having caused a car accident, cf. Carl L. Tishler/Natalie Staats Reiss, *ob. cit.*, p. 105.

[42] According to Carlos Eduardo Leal Vidal/Eliane Costa Dias Macedo Gontijo/LúciaAbelha Lima, the first contact of the health services with an individual who has attempted to commit suicide is an excellent opportunity to identify the potential risk level and its reduction; however, not always this opportunity is taken, either because of the service characteristics or due to the lack of training and difficulty in dealing with suicidal patients, being observed that, in the majority of the cases, there is not a serious risk of death, only existing then *bureaucratic* guidance, cf. AA. *cit.*, *Tentativas de suicídio: fatores prognósticos e estimativa do excesso de mortalidade* in *Cadernos de Saúde Pública*, Vol. 29, n.º 1, Rio de Janeiro, 2013 *in* http://www.scielo.br/scielo.php?pid=S0102-311X2013000100020&script=sci_arttext

patients' suicide potential — since it depends on several variables, such as the concrete characteristics of the hospital in case, for example — there is not either a sole way of dealing, objectively and directly, with the risk that each one of the patients presents.

However, among the scientific bibliography that we have read, there was a study which has particularly raised our attention. We mean the standardised checklist that has been developed in the Veterans Affairs Hospitals (2007-2008) by a multidisciplinary team (which not only integrated its own mental department staff, but also, and namely, it integrated architects and engineers with experience in designing and building mental health units).

This team, that was born based on the collected elements and on its vast experience concerning suicides (and their attempts) committed by hospitalised patients, having as its basis clear guidelines respecting what was necessary to implement and observe, has additionally created a model-system of the risk identification by levels (in a scale from 1 to 5, in which level 1 means a minimum risk, and level 5 represents a critical risk demanding immediate reaction), each one reporting probable events (see annex I) [43].

All of this, obviously, with the ultimate aim of decreasing the number of suicides and also the injuries associated with the suicide attempts [44]. And this, at least, will allow the staff who works in a mental institution to objectively know what is the effective risk that the patient that they have before them has, and what concrete precautions will they consequently have to adopt [45].

Clearly these precautions have also to be defined and formalised, which depends again on the concrete content of the adopted intra-hospital prevention plan that naturally shall not be too different from the many standards in force abroad (such as the need of monitoring the patients who have a comorbidity diagnosis, the need of having psychiatric/psychological appointments with daily visits by the respective professionals, of using protocols of continuous observation, of existing clear rules also concerning the observation timings and the replacement of who is observing the detailed monitoring of behavioural signs and of the patient's symptoms with reference to the suicide indicators...) [46].

But the advantages of the creation of a plan of this nature (that is, a standardised, clear and objective plan) do not end here. On the contrary, we believe that the implementation of a measure

[43] Cf. Peter D. Mills *et al.*, *ob. cit.,* pp. 87-88.

[44] We need to mention that there is a limitation to this study. Although this checklist has inherent to it all the known bibliography about the suicide attempts by hospitalised patients, there is the fact that it is still very early to verify if this checklist use has reached the mentioned aims, cf. Peter D. Mills *et al.*, *ob. cit.,* p. 92.

[45] Another interesting standardised surveillance model, a very detailed one, can be analysed in the study of Jeffrey S. Janofsky, *ob. cit.,* pp. 20-22.

[46] Cf. Carl L. Tishler/Natalie Staats Reiss, *ob. cit.*, pp. 107-108, authors who, besides these express care recommendations specifically for the patient, defend that the recommendations concerning the hospital measures shall be based on 1) the establishment of a compulsory monitoring way of the suicide risk that includes specific register means of the observations about changes in the patient's behaviour, their appearance, and risk level; 2) the staff training to recognise the risk increase and the patient's "deterioration"; 3) the establishment and/or updating of the treatment measures of the patients' risk, including the rules determination about the patient's observation and the authorised leavings; 4) the establishment or updating of proceedings aiming to sensitise the visitors about the patients' suicide risks and the visitors' role; 5) the updating of the information in the patients' transfer procedures; 6) the creation of guidelines aiming the administration of adequate medication and the right portions in order to treat the conditions that contribute for the suicide risk; 7) the confirmation that all these measures are being followed.

like this makes easier to know if the functioning of a concrete hospital administrative *apparato* respected the average behaviour patterns to which it was linked or if, instead, it did not and, therefore, functioned abnormally (*service responsibility*) [47].

If it has been observed some responsibility, mainly a civil one, it needs to be imputed; if it has not been observed, the scenery is inverted (*rectius*: it has necessarily to be inverted): the injured parties (for example, the victim's relatives) shall be indemnified [48].

This would undoubtedly have advantages in the legal safety plan and in three different vectors: the citizens would benefit from it (they would know when they would have the right for an indemnity or not, avoiding this way the proliferation of actions destined to ruin); the Administration would benefit, as well as the efficiency of its performance (because if it was known what to do and what not to do in order to avoid problems concerning the civil responsibility, it would be very much probable that it would act this way); and the judges would benefit, to whom certainly the jurisdictional function,and the function of the Administration's good functioning control in particular, would be made easier [49].

D. Practical-concrete relevance

Having arrived to this point, we shall not think that all that we have previously mentioned — the implementation of an intra-hospital plan of mental patients' suicide prevention, being these patients confined to the guardianship and surveillance [50]

[47] The *service responsibility*, present in the article no 7, section 4, of the Portuguese Regime of the State Non-contractual Civil Responsibility and the other Public Entities (Law no 67/2007 of 31/12), has its origin in the French legal system, and it emerged as a way of preventing that, in all those situations in which something in the administrative machine has gone wrong and generated damage, it can pass unpunished because it is not possible to detect the authorship of that problem, and therefore, if it was person A or person B who is the responsible for such a behaviour (active or passive). We then defend that, whenever an administrative system did not work well or did work well but in a defective or late way, being far away from the patterns that are legally expected in a modern and minimally efficient system, such a situation implies the responsibility of the public powers, which can only be released in *concrete cases*. Similarly, and although the responsibility in case is not objective, it is easier then to find the faulty employee, having the jurisprudence evolved in the sense that, in the cases in which the surveillance duty is under threat, the fault shall be attributed to the Administration, inverting the burden of proof. This is what precisely happens in the cases such as the one explained, and therefore, in the situations of damages suffered by mental patients hospitalised in public institutions. The objective fault of a person is declined, in order to assess if, in the concrete circumstances of the case, the administrative board has respected the demanded standards: the negligence, omissions, mistakes and deficiencies are analysed, as well as the problems that could have been avoided if the correct diligence had been used (Hauriou), and therefore the judge would have at their disposal enough time to evaluate the case. Adopted by the majority of the European legal systems, we then face a progressive improvement of the faulty administrative responsibility, and hence this is closer of the objective responsibility, being it anonymous, uncharacterised, fictitious or organisational. For a general analysis of this creation in France, Spain, Italy and Germany, see, among others and respectively, Michel Paillet, *La faute du service public on droit administratif français*, Paris, LGDJ, 1980 and *La responsabilité administrative*, Paris, Dalloz, 1996; Fernando GarridoFalla, *Responsabilidad de la AdministraciónPública* in *La responsabilidad patrimonial de los poderes públicos*, Madrid/Barcelona, Marcial Pons, 1997, pp. 23 and following; Marcello Clarich, *La responsabilitédelle P.A. per attività di vigilanza, ispettiveelo autorizzati* in *Le responsabilità pubblichecivile, amministrativa, disciplinare, penale, dirigenziale*, Padova, CEDAM, 1998, pp. 161 and following and Fritz Ossenbühl, *Die Haftung des Staates für hoheitliche Akte der Legislative, Adminstrative un Judikative* in *Responsabilidade civil extracontratual do Estado — Trabalhos Preparatórios*, Gabinete de Política Legislativa e Planeamento, Coimbra, Coimbra Editora, 2002, pp. 169 and following.

[48] As wittingly Lindsay M. Hayes underlines (*Suicide Prevention in correctional facilities: Reflections and next steps* in *International Journal of Law and Psychiatric*, n.º 36, Elsevier Ltd., 2013, p. 194), the conclusion that it had not been possible to prevent a suicide can only exist after the services (in the case, the prison services) have efficiently shown that their facilities started and kept in practice an adequate and reasonable program of suicide prevention.

[49] Cf. Ana Pereira de Sousa, *A culpa do serviço no exercício da função administrativa* in *ROA*, Lisboa, OA, ano 71, Jan./Mar. 2012, p. 352.

[50] A surveillance that shall remain after the hospital discharge (cf. Zoltán Rihmer, *Strategies of suicide prevention…, cit.*, p. 83; Louis Appleby, *Suicide in Psychiatric Patients…, cit.,* p. 753. It needs to be mentioned that it is in the 3 months following the hospital discharge that the period to commit suicide is

of a health institution governed by imperative and objective observation rules, such as the ones linked to suicide risk assessment and the precautions created for each one of the designed levels — lacks of relevance, especially, legal relevance. That is not the case.

In fact, what practice has shown is that many (the great majority) of the mental health institutions which possess what they define as acting *protocols* are nothing less, in reality, than a group of highly vague rules without a binding nature (essentially in relation to the visiting times, some behaviour rules that should be respected by the visitors, phone contacts and a few more, not to mention the *individual therapeutic programs* that, when filled out, could not be more generic than they actually are). They have not, therefore, a clear and rigorous *formalisation* of the rules and care procedures to which they are attached [51].

In fact, how many among us — as users, relatives, friends or even professionals — have already consulted a protocol that indicates who are the patients who are in risk of committing suicide and which are the treatment measures of that risk? Or who can explain (or even mention) whose patients shall be monitored, what kind of observation shall be done and by whom (if in a continuous way, with breaks, their timings, by the nurse x,...) or which are the specific means of the concrete collected observations register about the risk level that must and are being used? [52] Or who can mention how many daily visits should the psychiatrist, the psychologist and the social worker, among others, pay and also, what are the (clear, coherent and articulated) acting procedures in cases of crisis or escape of these patients (concrete responsible people for their surveillance, means to be employed and definition of third entities to be involved) [53]?

And if we add to all this the Portuguese jurisprudential portrait in this context, we face an extremely upsetting scenery. Let us give three examples: according to the scientific bibliography, as we have already mentioned above, the profile of a mental patient hospitalised in a psychiatric institution normally corresponds to a man in his 30s, a mental patient (in general, with several diagnosis), single, with a hospitalisation history and one or more previous suicide attempts, unemployed and an alcohol abuser [54].

particularly critical and Jennifer L. Hughes/Joan R. Asarnow, *ob. cit.*, p. 29, alert for the fact that about 66% of the teenagers in suicide risk are inconsequently discharged and, therefore, they do not have any follow-up procedure). But this is a topic that outreaches ours.

[51] We need to mention that, although the JCO underlines the need for an around-the-clock observation of the patients with a high suicide risk, not only the existent bibliography about this observation is not abundant, but there are not systematic studies either, or even recommendations, about the best practices to be adopted. Some institutions describe in their observations the elements that they consider as critical in the suicide prevention, others have as basis the symptoms collected by the nurses, and still others do not know how to qualify or describe the patients' observation levels, cf. Jeffrey S. Janofsky, *Reducing Inpatient Suicide Risk…, cit.,* p. 15. According to this author, and as it has already been mentioned, the standardisation of the surveillance procedures is the best way of reducing the existence of mistakes, and these should be simplified in their key-aspects.

[52] Already in 1989, the mental patients had, in 58% of the cases, suicide thoughts, but only in 28% of them the suicide risk has specifically been mentioned in the medical reports, and 21% in the nurses' reports; in no more than in 11% there were *special* observations, Louis Appleby, *Suicide in Psychiatric Patients…, cit.,* p. 755.

[53] At least since the 1980s that in the USA it is defended a metal detectors' system, as the one used in the airports, that has as target not only all those who enter the hospital, but also the patients who return to it after an authorised leave. The reason for this *modus operandi* is that the hospital administration has the duty to protect both the patients and the workers and visitors from possible violent acts, cf. L. Bowers *et al.*, *Safety and security policies …, cit.,* p. 428.

[54] The mental disease cocktail (as depression or schizophrenia, for example), alcohol abuse, history of parasuicide is, in fact, explosive, being a very clear predictor of the mental patients' suicide. We have to highlight that, as Robert

The process number 251/03 concerned a mental patient hospitalised in a psychiatric institution who precisely united these characteristics (and his clinical record, which has been extremely difficult to have access to, proved it) [55].

This patient, who felt marginalised and powerless to fulfil a life project, preferred to die [56], used to leave the hospital without permission but the institution knew about it, coming back to it willingly or with her mother, and who saw his doctor leaving the hospital for her holidays without leaving any record telling that the patient needed an added and special surveillance, committed suicide in less than one month after his hospitalisation.

He did this a few hours after he had run away from the hospital and after, in the meantime, having had drunk alcohol (which, inclusively, had been the motive for his hospitalisation in such an accredited institution), having thrown himself to the railways that are located near the hospital where he was. He knew this hospital very well, because he lived next to it since he was a child, entering and leaving it all the time, together with his relatives, friends and staff.

The Court has exonerated the defendant hospital, taking into consideration that nothing could foresee that this patient would commit suicide. However, the entire situation, as we could have seen, pointed to the opposite end, which, unfortunately, ended up happening.

It has then been useless the appeal made to several and different legal systems, because, when they are confronted with situations like these (with the existence of a diagnosis of comorbidity linked to a previous suicide attempt), they do not hesitate in holding the health institutions responsible for them, both due to an omission in the surveillance duty, and due to an abnormal service functioning.

Actually, in France [57], conscious that a hospital's main responsibility source is the lack of surveillance, mainly in what respects the mental patients whose suicide the hospital did not avoid, and bearing in

D. Dvorak *et al.* state in their very recent study (*Alcohol use…, cit.,* p. 326 and following), in the USA the students have been identified as a risk group, bearing in mind the harmful alcohol consumption and its close relation to suicide, potentiated by the fact that there is a risk of becoming mental patients. Moreover, and specifically regarding the University students, approximately 17% of them are developing depressive symptoms and 9% already have major depression symptoms. Similarly, also in Canada relatively recent studies show the growing concern towards the young people, mainly towards those who suffer from the borderline disorder.And it is defended that, when these young people show comorbidity (for example, episodes of major depression with substances abuse, alcohol included), the risk for them to commit suicide seems, in fact, to be high, cf. Paul S. Links/ Brent Gould/RuwanRatnayake, *Assessing Suicidal Youth With Antisocial, Borderline, or Narcissistic Personality Disorder* in *Can J Psychiatry*, Vol. 48, n.º 5, 2003, pp. 301 and following (authors who, as it is imperious, list the four steps that, in their point of view, the doctors shall take in order to monitor the suicide risk for this kind of patients).

[55] A process that proved, as far as we are concerned, the lack of organisation that ruled in that hospital (moreover, this hospital had been frequently mentioned by the media due to suicides), with several pages left to fill out, with references to other patients rather than the patient in case, with unfilled plans, with no allusions to the existent dangers and to the ways to avoid them, etc.

[56] Hopelessness that, according to Carlos Saraiva, is the first indicator of the suicidal intention, cf. A. *cit.*, *Para-suicídio: contributo para uma compreensão clínica dos comportamentos suicidários recorrentes*, PhD thesis in Psychiatry presented to the Faculty of Medicine of the University of Coimbra, Coimbra, 1997, p. 89.

[57] In this legal context, the hospitals' responsibility regarding their organisation conditions and/or services functioning — a responsibility that, since 1966 (with the Hawezak judgment of the 6th January) ceased to be subordinated to the existence of a *faute lourde* (clear fault and of particular seriousness), being enough, in order to take place, the existence of a *faute simple* (a negligence) — will happen, for example, in that case in which a doctor, at the moment of a mental patient's entry in the hospital, examines them and concludes — bearing in mind the patient's state and attitude — that there is no suicide risk. Therefore, he does not prescribe any particular surveillance. A few hours later, the patient commits suicide. The appreciation mistake is blatant, even if it is more a prognosis mistake than a diagnosis mistake. The will also happen in the cases where the patient has tried to commit suicide before, cf. René Chapus, *Droit Administratif Général*, Paris, Montchrestien, 1995, pp. 322 e 1177.

mind that the administrative fault consideration that is made by the judge (despite being able to defend some appreciations in general) is undertaken by reference to the case, linked to the service diligence habits, the doctrine and the jurisprudence have early started to define certain elements of the concretisation of the appreciation made by the judge in that fault finding, among which it is highlighted the damage predictability. Hence, the predictability of the context in which the Administration works is one of the appreciation standards that has particular relevance in the context of the mental hospitals' functioning: if a patient escapes or commits suicide, it will be analysed if their behaviour would have made the event foreseeable [58]. Then, in the cases where the Administration has as mission to prevent an individual's behaviour, there will not be fault if the circumstances show that the damage was foreseeable — a predictability that is understood as the existence of a risk, in the sense of a danger, which implies the obligation to adopt precautions [59].

Along with this, also in Spain the Supreme Court had the opportunity to express itself (in 28/02/1995) about a similar case, namely about an indemnity action undertook by the relatives of a mental patient who died in a car accident after having escaped from the public institution in which he was hospitalised. Having examined if the service functioning had or had not been adequate (concerning the patient's state, his escape's record, the number of staff who habitually undertook the surveillance tasks and the number of people who were doing that task in the escape's day), having verified that there were elements that could foresee a possible escape and that, although the patients' care was undertaken by seven or eight employees — on that day, there were four of them —, the Court has considered that the service performance was below the demanded standards, being this an abnormal functioning of the public service and therefore, "su muerte (la del enfermo) tuvo su causa en la falta de una necessária e imprescindible vigilância por parte del personal del Centro (...) el fallecimiento no hubiera ocurrido de existir en el Centro la atención exigible" [60].

The next example (process number 038737 of 25/11/1998) tells the story of an indemnity action taken by the husband of a lady who, with a diagnosis of major depression and following two previous suicide attempts in a period of 15 days, has been hospitalized and, three days later, has thrown herself from one of the hospital's stories without,

[58] Cf. Michel Paillet, *La responsabilité …,cit.,* pp. 112 e 113.

[59] "The best way of defining the danger knowledge is to prove that the Administration has already been warned. (…) Then, the real knowledge of the danger is not a necessary condition of fault: the simple predictability is, in most cases, enough, as it makes presumable the real knowledge from the moment in which the Administration can and must assure the danger absence. (…) When an activity is involved under the direction of the Administration, it has as limit the unpredictability of the participant's behaviour. The behaviour predictability notion intervenes when the danger does not come out from the activity in which the individual does not participate, but from the individual's own behavior. (…) The fault in the surveillance of the mental patients is the most invoked one, mainly when they commit suicide. In these cases, the judge seeks to know if the attitude was foreseeable or not, taking into account their antecedents and the patient's pathologic state.", cf. Laurent Richer, *La faute du service dans la jurisprudence du Conseil d'Etat,* Paris, Economica, 1978, pp. 53-54.

[60] Cf. Mariano MagideHerrero, *El critério de imputación de la responsabilidad in vigilando a la Administración, especial referencia a la responsabilidad de la Administración en su actividade de supervisión de sectores económicos* in *La responsabilidad patrimonial de los poderes públicos*, Madrid/Barcelona, Marcial Pons, 1997, pp. 377 and 378.

however, having actually died. The damages have been devastating and she became paraplegic. The Supreme Administrative Court has considered that no responsibility should be put over the hospital for omission of the surveillance duty, basically because that hospital had in force the open door regime. The lady, on the day in which she tried to commit suicide, was feeling normal and her husband did not tell the services that, on the day before, she had told him that she had self-destruction ideas.

Once more, and for the reasons that we have just presented, we do not agree with the Court's decision: this outcome was, in fact, predictable [(61)]. Moreover, the fact that that was an open door regime and the circumstance that the lady, on that day, appeared to be normal are irrelevant: the first one, and as the German jurisprudence well states, does not release the hospital to keep surveillance (and, in this particular case, a close surveillance) regarding a mental patient, mainly when, as it was the case, the same patient had tried to commit suicide twice, 15 days before her hospitalisation [(62)] [(63)]; the second one, pointing to the same direction, as there are cases in which a suicide attempt is preceded by serenity moments and not by impulsivity ones — the decision is already made, and itonly needs to be undertaken [(64)]. Not to mention the fact that the husband did not tell a word to the services about his wife's ideas of putting an end to her own life; this has been, by the way, the decisive element of her hospitalisation, having this taken place three days before this last suicide attempt... The third case is about the process number 08532/12 in which it was discussed a hospital's surveillance duty concerning an old patient who suffered from Alzheimer's and who disappeared from that hospital and was

[(61)] "The mortality among those who try to commit suicide is extremely high", cf. Keith Hawton/Joan Fagg, *Suicide, and Other Causes of Death, Following Attempted Suicide* in *British Journal of Psychiatric,* 152, 1988, p. 365.

[(62)] Let us see the case of a patient who, after several suicidal episodes, saw herself confined to a maximum safety room. This patient was systematically surveilled from the outside, having to ask for help to leave the room, as it was not possible to open the room's door from the inside. An important detail: it was not allowed to smoke inside the room and, if she wished to smoke, she had no other alternative than to leave the room. Some days later, the patient leaves the room, she goes to the toilet, and the nurse has not made any personal control. In the bathroom, she puts fire to her vest, made of synthetic material, and she suffers serious burns. The hospital has been sentenced. According to the German court, the fundamental issue was that the patient should have been searched when she left the room. The lack of proof of the adoption of these measures determined the hospital's sentence. According to this, and to the German legal system, the fact that the mental patients are in open door departments does not imply that the psychiatric staff should not surveil them. It has been because of this that, following these rules, the German Supreme Court judges sanctioned (due to deficient custody) a hospital where a woman has been hospitalised suffering from depression and with previous suicide attempts, as she has managed to leave the institution with no control, having thrown herself into a railway and losing one of her legs. It is said here that the condemnation has been entirely justified, cf. Paolo Cendon/Giuseppe Citarella, *Disagio Psichico e risarcimento del danno* in http://www.personaedanno.it/attachments/allegati_articoli/AA_000304_resource1_orig.pdf.

The authors state that these criteria, regarding the surveillance duty, are applicable to other non-specialised institutions that, taking care of these patients, are not mental hospitals. It is the case of a mental patient who had not immediately been transferred to a mental hospital suffering from schizophrenia, with a previous suicide attempt which had motivated his hospitalisation in that first institution.

[(63)] Whatever the psychiatric service regime or the training of their health professionals is, H. G. Morgan mentions (*Suicide Prevention — hazards on the fast lane to community care* in *British Journal of Psychiatric*, 160, 1992, p. 150), there are certain clear and defined rules and a clear discipline inherent to the consultancy and management of the suicide risk. And it is always necessary to bear in mind the personal and socio-demographic risk factors, the collection of clinical elements, the problem's categorisation and the correspondence between the finding and the risk factors, an approach that has to overcome the simply theoretical models.

[(64)] Cf. Carlos Saraiva, *ob. cit.*, p. 89: "Poldinger (1968) estabelece um processo suicida em três fases:…3. Decisão, por vezes seguida de uma *serenidade*". See also in this sense a widower's personal communication presented at the *WHO European Ministerial Conference on Mental Health*, which took place between the 12th and the 15th January 2005 in Helsinki *in* http://www.renepca.com/docs1/who_helsinki.pdf

found dead several days after [65]. In this case, it was discussed if, as defended by the authors, there would be some legal or regulation norm, or some technical or common prudence rule that would threat the surveillance of a patient in conditions like those.

The courts have answered negatively to this question. They have analysed the main applicable norms — The Health and Hospital Status Act (Decree-Law number 48357 of 27/04/1968) — and concluded that none of the diplomas contemplated such a duty. In the same way, although the Patients Rights and Duties Chart mentions the right to receive adequate care to their health state, it has been understood that this norm did not guarantee the invoked intention either, as it seems, because it was too generic regarding the medical behaviour extracted from it. And, in fact, the authors recognised the absence of a written rule in that sense, alleging a violation of the common prudence rules. They have still invoked that, even if it has not been clear if the doctor had been told by the patient's relatives about his disease, still this doctor knew (or should have known) about her patient's health state, mainly that he suffered from Alzheimer's, with loss of consciousness states and even senility, and that he should not leave the hospital without permission, like it was imposed by the common prudence rules. However, the Court understood (such as the first section did) that it had not been proved that the doctor knew the patient's clinical state and that the mere fact that he was of an advanced age did not justify — bearing in mind the common prudence rules and in the absence of a legal or regulation norms that would state the opposite — an added surveillance duty, except if the doctor knew the patient's particular situation [66].

As the doctrine states, the proposed justification (the one which defends that the doctor had not perceived the patient's clinical state) cannot pass (*rectius*: could not pass). In fact, if the hospital did not have any information about the patient's state, who inclusively had needed the hospital services before, it should have had (it was the minimum accepted) [67]. Moreover, this patient had a clinical condition that inspired serious care (he was 83 years-old and suffered from Alzheimer's, belonging to what the scientific bibliography defines as *a high risk group*) [68]. Finally, the fact that it did not exist any legal or regulation norm does not, not even it could, constitute an obstacle to a demand for responsibility towards the hospital. If it was like this, the way of the public administration to never be legally confronted with would have been found: it would be enough not to legislate or regulate... [69]

[65] Cf. Vera Lúcia Raposo, *Do ato médico ao problema jurídico*, Coimbra, Almedina, 2013, p. 201.

[66] Cf. Vera Lúcia Raposo, *Do ato médico…*, *cit*., p. 201.

[67] This is an omission case of the surveillance duty, due to an omission of the record duty; a violation that is not personalised in a concrete individual, but resulting from a weak service functioning.

[68] We need to mention that, although the suicide is not mentioned in this process, in the undertaken study the majority of the senior people who had committed suicide suffered from Alzheimer's, cf. Ana Rubio/Alice Lee Vestener/John M. Stewart/Nicholas T. Forbes/Yeates Conwell/Christopher Cox, *Suicide and Alzheimer's Patology in the Elderly: A Case Control Study* in *Biological Psychiatry*, 49, 2001, pp. 861-862.

[69] Also in Brazil, there are dozens of sentencing decisions against mental institutions, both public and private, due to an unfulfilling of the care duty towards the mental patients who they have under their charge.

And here we find the importance that a concrete and binding intra-hospital suicide prevention plan gets [70]: it is intended to serve as a guideline also to the Portuguese justice, mainly while the verification of the *results average patterning* takes place [71]. This quite often is dictated based on statements of third people with links to the institution, in such a way that it even seems to demand the existence of a written norm that can foresee the concrete behaviour to which a hospital is bound as a unique path to fulfil its responsibility –this way forgetting that the legal system is formed not only by rules, but also by principles [72].

Fortunately, however, and as we had the opportunity to highlight, in the comparative law perspective, the scenery is different: countries like France, Spain, Brazil or the United States of America [73] do not hesitate in condemning the mental hospitals (or hospitals with mental units) whenever these do not function as expected. This idea meets what the European Court of Human Rights defends on this subject — a court that has a major power [74].

[70] Clearly defending the creation of standards elaborated according to the social demands, to the limitations, the political orientations and the non-renounceable contents imposed by the Constitution of the Republic and the common laws. Of which, the elaboration of medical protocols — in which there could be present the proofs and analysis that should be done to the patients according to their symptoms — are a simple example, and how and with what intensity the several kinds of patients should be surveilled (patients with more or less serious problems, with suicidal tendencies…), Oriol Mir Puigpelat, *La responsabilidad patrimonial de la administración, hacia um nuevo sistema*, Madrid, Civitas, 2002, pp. 261-262 e 273-274.

[71] Cf. *The mentioned art.* 7th, number 4 oftheLRCEE: *Existe funcionamento anormal do serviço quando, atendendo às circunstâncias e a padrões médios de resultado, fosse razoavelmente exigível ao serviço uma actuação susceptível de evitar os danos produzidos.*

[72] Cf., Ronald Dworkin, *Los Derechos En Serio*, Barcelona, Editorial Ariel, S.A., 1989, e Robert Alexy, *Teoria dos Direitos Fundamentais*, S. Paulo,Malheiros Editores, 2008.

[73] In the USA, the courts also pay attention to the clinical record of the patient, mainly to their previous suicide attempts. Examples of sentencing of mental hospitals are the cases *Comiskey vs. State* (in which a mental patient had committed suicide throwing himself under the underground. The court has decided that the surveillance this patient was subject to was not enough, that any measure has been taken by the hospital staff, who even knew about this patient's suicidal intentions). Also the case of *Hawthorne vs. Blythewood* (the institution has been sentenced due to a failure in the surveillance standard of a maniac-depressive patient who has drowned himself, cf. Paolo Cendon/Giuseppe Citarella, *ob. cit.*. These authors tell another case that took place in this country: a case in which a patient, after two unfruitful defenestration tries, saw the surveillance over him increased and the tranquilisers and anti-psychotic pharmacologic portion has also been increased. It was then understood that the patient could stay in the freer part of the facilities. However, he did eventually commit suicide, having the hospital been sentenced. This sentence has been determined by the lack of adequate safety measures to such a serious disease and by the lack of professional skills on behalf of the nurses.

[74] See the Act of 13/0372012, stated by the 4th Section under the process number 2694/2008 (*Reynolds Case against the United Kingdom*), in conjunction with other stated cases. This was about a patient who suffered from schizophrenia and, by being already known to the hospital services, has been indicated as having a low suicide risk. This patient has thrown himself from a window and has died. The Court understood that the hospital had not sufficiently protected the patient, having sentenced it. See, about this, the Act of 03/05/2012, stated by the 1st Section in the process number 40657/2004,*Kleyn and Aleksandrovich Case against Russia* (it is about the death of a victim placed under the police custody and who ended up in throwing herself from a window and died. The State has been sentenced, since there was an unfulfilling of the obligations of conducting a complete and efficient investigation about the circumstances of this death, including the suicide possibility); the Act of 11/01/2011, stated by the 2nd Section under the process number 4611/2005 -*ServetGündüz Case and Others against Turkey* (about a soldier's suicide during the military service, it has been verified the unfulfilling of the State obligation to proportionate an adequate treatment and military conditions to the soldiers who presented psychological disorders. It had been verified an omission in the necessary measures to avoid the suicide of a soldier who suffered from drugs abuse, being him prevented from having access to weapons. The State has been sentenced). And the Act of 06/12/2011, stated by the 1st Section under the process number 8595 -*Donder and De Clippel Case against Belgium* (this was about the suicide of a young man suffering from a mental disease who had been placed in a prison and who has committed suicide. The State has been sentenced, having been considered that the articles 2th and 5th of the ECHR and the right to life, to freedom and to safety had been violated. It has then been decided that the State should take adequate measures in order to safeguard the lives of the people under its care. Therefore, and being this a case in which a young man suffered from paranoid schizophrenia, with an especially high risk of committing suicide, the authorities should have taken preventive measures to protect him, which has not happened).

IV. Finalising

We are obviously powerless to avoid all the suicides. Suicides do exist, as we all know, and they are shockingly increasing [75]. We also talk about suicides almost only in a perspective faced to the health professionals, as these are the people who have the mental patients under their charge [76] [77].

However, these are not the only ones who are responsible for decreasing the suicide rate [78]: each and every one of us while human beings must also be [79] [80] (a topic that, yet, is out of ours' scope). And it is because of that that the National Suicide Prevention Plan, by defining the *alarm signs* which demand a special attention (without disregarding the extremely important Portuguese Association of Suicidology, located in Coimbra) [81] [82], must be

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[75] As Lindsay M. Hayes well underlines, *Suicide Prevention…, cit.,* p. 192, with a total pertinence towards what is discussed here, even if his study focuses on the suicides in prisons, the fact there are few, or even none, inmates who do not have any suicide precautions can be a red flag. And its inexistence can never be interpreted as the inexistence of suicidal inmates, nor can it function as a barometer of the suicide prevention practices. Corroborating the idea that the deaths caused by suicide are superior in number to the ones pointed out by the statistics, cf. Christina W. Hoven/Danuta Wasserman/Camila Wasserman/Donald J. Mandell, *Awareness in nine countries: A public health approach to suicide prevention* in *Legal Medicine*, 11, 2009, Elsevier, p. 14.

[76] Included in these professionals, there are naturally the General Practitioners, mainly when the previous detection is made, and when it is necessary to intervene in a case of a possible proximity to a suicidal behaviour after a careful analysis of the patient's family record, signalising the ones who are under a serious risk of committing suicide, cf. Zoltán Rihmer *et al*., *Affective temperament …,cit*., 353. Bearing in mind that these doctors' training in terms of suicide prevention in the Gotland Island, it implied a decrease in the suicides rate, cf. H. G. Morgan/K. Hawton, *Suicide prevention by general practitioners* in *British Journal of Psychiatry*, 1993, p. 422 and *Suicide Prevention* in *British Journal of Psychiatry*, 1994, pp. 126-127.

[77] In our opinion, the very updated study from Sheri A. Nsamenang/Jon R. Webb, Kelly C. Cukrowicz, Jameson K. Hirsch (*Depressive symptoms and interpersonal needs as mediators of forgiveness and suicidal behavior among rural primary care patients* in *Journal of Affective Disorders*, n.º 149, 2013, Elsevier, pp. 282 e ss.) is extraordinary. By underlining the importance of the primary cares as a source of timely detection and prevention of the suicidal behaviour, mainly in the rural areas (where the suicide rates are higher), it mentions that forgiveness (a common aspect, but not the only one, in every religion) can, in fact, affect the interpersonal functioning and decrease the suicidal behaviour risk.

[78] We need to highlight that currently there is a meeting between the health professionals (psychologists, psychiatrists, occupational therapists, social workers, nurses, co-workers…) where they share situations that they have had with patients and the emotional impact that those situations had in those patients. Basically, this is an exchange between professionals to which it has been given the name of *Schwartz Rounds.* It has started in the USA with the story of a cancer patient. The last one took place on the 27/07/2013, at the *Derbyshire Healthcare Foundation Trust*, in England, and it has been told by a nurse (the story was about the suicide of one of the patients hospitalised in the psychiatric unit), who shared the psychological scars that this event opened on him.

[79] As Zoltán Rihmer well states (*Strategies of suicide prevention…, cit*., p. 83), the health professionals can only help the patients with whom they contact, and therefore, the public education of the symptoms, dangers and the psychiatric diseases (such as the depression), treatment is extremely important.

[80] The group of interventions can be, or it is, multiple. For example, a study made about patients who have refused treatment after having tried to commit suicide, found out that sending letters regularly (4 times in a year) during 5 years significantly decreased the suicide rate of the contacted group in comparison with the one which has not been contacted. Also, a study made in Verona, Italy, concluded that contacting the elder population by phone one month after the suicide attempt reduced the suicide rate. Another investigation confirmed that the phone contact one month after the suicide attempt decreased the number of tries one year later, cf. Merete Nordentoft, *Crucial elements…, cit.,* p. 852.

[81] For the information that several are the studies that show that regions which have centers for suicide prevention saw the suicide rate decrease in the following 10 years, cf. Zoltán Rihmer, *Strategies of suicide prevention…, cit*., p. 86. See, because of this topic and for curiosity, the *Strategic Direction for the Prevention of Suicidal Behavior* created by the *Center for Disease Control and Prevention* in http://www.cdc.gov/ViolencePrevention/pdf/Suicide_Strategic_Direction_Full_Version-a.pdf, entity whose creation and essential contribution is the responsibility of Jack Smith, who since the beginning defended that the effort in the suicide prevention should have as basis the improvement of the capacity of monitoring the suicide and the suicidal behavior through surveillance systems, cf. James A. Mercy, *Building a Foundation…, cit*., pp. 26 and following. Pointing some of the factors that foresee the suicide (or Danish *crisis center*), cf. Ping Qin/Bente Hjorth Madsen/Preben Bo Mortensen, *Characteristics of clients to a suicide prevention centre — An epidemiological analysis of the users over a 10-year period* in *Journal of Affective Disorders*, n.º 115, 2009, Elsevier, pp. 339 and following.

[82] In 2006, Japan, which inclusively made into law the *Basic Act on Suicide Countermeasures*, started to count with the named Suicide Prevention Center, an entity that has as aim to support the governmental measures of suicide prevention. Its most important missions are the academic research, information giving, human resources training, networking, private sector support and presentation of political proposals, along with the undertaking of psychological autopsies (suicidal epidemiology section), cf. Makiko Kaga *et al*., *Suicide and its prevention…, cit.,* p. 20.

applauded. But there is still a lot to do [83] [84]. The public education concerning this matter is, in fact, one of those things that must be done [85]. The elaboration of intra-hospital suicide risk prevention plans, with clear and coherent rules and of mandatory observation is, in this context that we have been narrating, important as well. After all, we are talking about human life.

V. Conclusions

1. Suicide is the number one cause out of the 10 most frequent causes of death. Therefore, and like other diseases that by their nature cease to be limited to the patient's intimacy, it should get a priority approach on behalf of the State and of the several knowledge communities with which it is directly involved.

2. Opposite to what happens in certain deaths, which Medicine seems to be powerless to prevent, in the death caused by suicide (as experience and statistics conclude) it is possible to intervene, decreasing its occurrence.

3. Portugal seems to have put into practice in a late stage (but, as it is commonly said, it is better late than never) what the World Health Organisation had a long time ago asked the States: it has published in 2013 a national suicide prevention plan.

4. Bearing in mind the general nature of this proclamation, but recognising its merit, it is important to move forward into two further plans, with the aim of reducing this kind of deaths.

5. A hospital prevention plan is needed, that is, a plan designed to function in the hospital unit context;

6. And another plan of individual prevention (related to the patient's diagnosis), which necessarily implies (existing already serious works on this topic) the classification of the suicide risk in an alert scale, resulting from the identification of the suicidal person's profile and from the existent clinical information (being this precise and updated) and to which the staff, who interacts and surveils the potential suicidal person, must have a total access.

7. What has been defended so far already exists in a certain way, maybe except the intermediate hospital plan, but, in our perspective, what really matters is this comprehensive vision of suicide prevention — which has its start in the parameters to which the national plan alludes — it is then consolidated in hospital parameters (that will be found, among other aspects, in the physical space organisation, in the visitors' regulation, in the definition

[83] Many important issues are, in fact, still to be solved. For example, why the men have suicide rates motivated by lethal means and women have higher rates of non-lethal attempts, or why the white people commit more suicides than the black or the Hispanics, cf. James A. Mercy, *Building a Foundation …, cit.,* p. 29.

[84] It is worth mentioning that one of the tasks to be adopted by the Japanese society as a way of preventing suicide is, simultaneously with the launching of campaigns to decrease the death due to excess of work, the removal of harmful information coming from websites, a measure that assumes a close articulation with the local police authorities in removing that information, cf. Makiko Kaga *et al*., *Suicide and its prevention…, cit.,* p. 20.

[85] A context in which the media have a prominent role and which, obviously, must be performed in a responsible way. Cf., related to this topic, the study of Makiko Kaga *et al.* (*Suicide and its prevention…, cit.,* p. 19), which corroborates this need with a case that took place in 1996 and which had been broadcasted by the media in a sensationalist way: a 18 year-old well-know singer jumped from a building and died. In the following two weeks, 30 young people have committed suicide in the same way. Curiously, in Portugal, there is little information about suicide, seeming to exist a pact among the journalists for not covering this issue. This is exactly the opposite of what happens in Denmark, in Belgium and in Australia, countries that have encouraged the media coverage according to the WHO prescriptions, cf. http://www.who.int/mental_health/prevention/suicide/resource_media.pdf

of rules for the patient's follow-up period, in the establishment of previous reaction procedures, such as the escape, etc.), and it is materialised individually and therapeutically in the patient, always involving, in a dynamic and informed way, all those who interact with the potential suicidal person (doctors, nurses, co-workers,...).

8. In Portugal, there are rare, or even none, legal decisions that, in what is really important to us (except concerning the public mental institutions and the diagnosis mistakes, in which the fault problems have already an efficient and defined treatment), condemn the State in the event of a suicide; and there is not either a clear legal framework that, in this domain of the civil responsibility, can have, however, simple categories that can explain it: the suicide predictability and the adaptation to the means applied (being these material or human) and that tend to avoid it.

9. The legislation is powerless to, through general normative impositions, intervene seriously and efficiently in such sensitive, specific and individual situations, such as are the ones related to the (physical and human) conditions and behaviour that can explain the suicide (a truth evidenced by the legal emptiness and by the statistical analysis).

10. Therefore, we defend that the legality parameter (in this new task to which the Law never gave a satisfactory answer) is dynamically constituted through the establishment of guidelines that get gradually more specific until they reach the suicidal person, starting from the national plan rules, continuing to the hospital plan and finishing in the individual plan; and also establishing conditions and acting lines of the involved agents whose violation forces, or would force, to conclude the verification of the assumptions upon which the civil responsibility existence depends.

11. Hence, we are positive that this way those who defend an inconvenient and limited objective responsibility, those who manage without the reality defending the reversions in the burden of proof, or sustaining the presumptions recognition would successfully have their answer.

12. We are then convinced that it is through this parametrical intervention in those three dimensions (whose stability would decrease) that we would answer, in an updated and dynamic way, to the fault problem and to the sense of causality in this kind of responsibility, adapting the legal answer to the phenomenon that is of great care to us: the illicit act prevention and the repair of its effects.

Chapter 1: Preventive environment and measures

HEALTH CARE DISCIPLINARY CASES: PREVENTION VS. ROUTINIZATION

Søren Birkeland [1]

Abstract: Keeping health care individuals to their professional responsibility is one way to decrease erroneous health care. Non-compensation disciplinary measures may exercise a 'preventive' function by different means but traditionally the health professional's dependence on 'appreciation' and absence of blame has played a crucial role — no matter if it is in the highly specialized university hospital unit or in the general practice clinic. This implies in itself that health care provision, which might be considered erroneous, is averted and health care is optimized so that, in any disciplinary case, it can be defended. Still, these preventive functions have presupposed that, from the disciplinary perspective, negligence be considered something 'exceptional' (and *not* inevitable) and a high degree of trust is preserved that 'finally (disciplinary) justice is done'.

By reference to the development in Denmark, it is problematized that the mechanisms may be changing; parallel to a massive increase in the number of patients lodging a complaint with the disciplinary system (<200 in 1975 and > 2000 in 2011; 1/4 result in a 'reprimand' and 1/1000 in criminal prosecution), the disciplinary handling has been moved to a board with a simplified investigation and decision structure (e.g. case handling in written; one solitary expert witness assessment; a substantial proportion solely completed by a judge). The option of administrative appeal has been eliminated and only one per thousand decisions is appealed for the courts. Error (and negligence) prevention functions are discussed in the light of complaint system structures.

Introduction

> "….While I continue to keep this oath unviolated, may it be granted to me to enjoy life and the practice of the art, respected by all men at all times; but should I trespass and violate this oath, may the reverse be my lot" (The Oath of Hippocrates, late 5th century BC).

Quality improvement of health care provision and maintaining patient safety and professional standards are important tasks of malpractice law and the health care professional bodies (Elango 2003; O'Rourke & Holl-Allen, 2010). One way to maintain appropriate standards of health care is to 'discourage' from erroneous practicing and keep health professionals to their professional responsibility and repute.

As it is problematized in the following, health professional disciplinary measures may exert preventive functions by different means. One matter-of-fact means of prevention comes from the actuality that disciplinary proceedings can lead to authorization withdrawal and removal of the professional from health care provision. Other preventive functions may be due to the fact that disciplinary proceedings are known to demand a lot of human (and

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sometimes economic) resources [2]. Not least importantly, however, the mechanism that health care professionals are kept to their professional 'pride' may serve a substantial preventive function [3]. In various aspects proper health care provision is dependent upon health professionals being kept to their career self-esteem so to speak. Recognition is better than blame; no matter if it is in university hospital settings or in the general practice clinic. No matter if the health care giver concerned is a specialized neuro-oncologist or a gradual medical student. And no matter if he or she is a medical doctor, a psychologist or a nurse.

In the following, a discussion is provided about patient safety maintenance (and avoidance of treatment errors) through the health care professional disciplinary measures' preventive effects. Emphasis is put on the last decades of development in the Danish disciplinary system. By way of introduction the authorization scheme is described as it is closely connected to the disciplinary (patient complaints) system.

The Danish Authorization Scheme

In Denmark, most groups of health care workers (medical doctors, midwifes, chiropractors, nurses, etc.) are authorized by the Danish Health and Medicines Authority (*Danish:* 'Sundhedsstyrelsen') [4]. Authorization ensures e.g. a title protection and monopoly for specified kinds of treatment. Not least important, however, it follows from the Danish Act on Authorization of Health Professionals (877, dated 04/08/2011) that authorization serves to "*enhance patient safety and promote the quality of health services*" (Para 1). Among other things, this intention is achieved by requiring medical doctors (and other authorized health professionals) to exercise "diligence" in their professional career. Such a duty was previously found in the acts of the various health professions (including the former Act on Medical Doctors, paragraph 6, 1976). Now it is stated collectively in the Act on Authorization of Health Professionals, Para 17.

> This paragraph (in Chapter 5, concerning Health Professionals' Duties etc.) states that "In the exercise of health care, an authorized health professional is required to act carefully and conscientiously. This requirement also pertains to the use of assistance, the economic prescription of drugs, etc."

The duty to act carefully and conscientiously has been commonly referred to by the authorities (especially the disciplinary system) as performance

[2] Moreover disciplinary cases (and the risk thereof) may largely impact the relationship between health professionals and patients (see e.g. Cunningham and Dovey, 2000; Mabeck, 2001; Birkeland et al. (b), 2013). Likewise there is increasing evidence available pointing towards a direct connection between health professionals' concern about disciplinary cases and 'defensive medicine' (aggressive diagnostic testing, overuse of antibiotics etc.; see e.g. Carrier et al., 2013). Hence, even if the disciplinary system aims at improving health care, it may sometimes result in altered practice towards defensive medicine which imply withdrawing from providing some services and 'avoiding malpractice liability rather than considering a risk-benefit analysis for both investigations and treatment' (Cunningham and Dovey, 2000). This can result in decreased quality due to inappropriate decision-making, increased costs, and unfavorable patient outcomes.

[3] Satisfaction gained by performing the job to the best etc. See about 'professional pride', e.g. James (1989), Grol (2001), and Spooner, Chapple, and Roland (2001).

[4] Psychologists are authorized and under supervision by the Danish Board of Psychologists under the Ministry of Social Affairs.

within the "norm of generally recognized professional standards". The latter norm is particularly connected to the disciplinary judgment carried out with the patient complaints system. This individualized duty of authorized health professionals is supervised by various authorities. Supervision both constitutes a general means, as according to Para 213 of the Act on Health Care (Act 913), the Danish Health and Medicines Authority should "monitor health conditions", but also implies an individual supervision according to Para 215. According to the latter provision, "The Danish Health and Medicines Authority monitors the health care provided by persons within the health care system." Not least, a legal control with quality of health care is exercised through means of the access for patients to lodge a complaint with the disciplinary system if the quality of health care delivered by an authorized health care professional, from the patient's perspective, is found unacceptable.

The Danish Disciplinary System

Forty years ago, disputes on professional conduct and disciplinary cases were rare occurrences in Danish health care. Management of such cases was placed with the traditional judicial institutions (mainly the central administrative hierarchy with the Danish Health and Medicines Authority and the courts).

During the last decades specialized patient complaint systems have been established in many countries (Irvine, 2006; Stolper et al., 2010; Johansson *et al.*, 2004; Bismark *et al.*, 2006; Birkeland et al., 2013 (a,b)) [5] as is the case with Denmark. Because of, among other things, a wish for enhanced representation of judicial expertise and lay-person perspectives, the management of disciplinary cases was placed with a specialized 'Patient Complaints Board' in the late 1980es. In this connection, the disciplinary handling was separated from the compensation system ('Patientforsikringen'). At the same time, the system aimed at providing an easily accessible, economic, 'fast-track' opportunity for complaints handling.

Over the years, the board structure has slightly changed but basically the case handling is unaltered. Currently the system works as follows. Most *disciplinary* board cases are initiated through means of a *patient complaint*; complaints have to be lodged within 2 years after the time of suspicion of wrong treatment and — in all instances — within five years after the day the treatment occurred (Act 706, Para 4). The case is clarified by the disciplinary board's secretariat which gathers relevant documents etc. The involved parties receive a copy of the complaint and are allowed to receive copies of

[5] According to the "Patients' Role"-recommendations and Recommendation (2000)5 of the Committee of Ministers to member states ("On the development of structures for citizen and patient participation in the decision-making process affecting health care", subsection 15), "..Patients and their organisations should be granted access to adequate mechanisms for enforcement of their rights in individual cases, which could be complemented by a supervision mechanism by an independent body. In order to be effective these mechanisms should have a broad range, providing for forms of conciliation and mediation. Formal complaints procedures should be straightforward and easily accessible. Financial barriers to equal access to these mechanisms should be removed, either by making access free of charge or by subsidizing people with low incomes who wish to use them". Such recommendations are commonly referred to as "soft law" which, from a traditional legal dogmatic perspective, is not legally binding. Nonetheless, they usually provide valuable information about notable and internationally acknowledged legal principles.

documents during the case management. The defendant health professional is asked to produce a report and provide medical records, X-ray material etc. Also other health professionals might be requested to contribute in order to clarify the complaint case. All involved health professionals have a duty to provide any relevant information for case clarification. Subsequently a proposal is made for decision: typically, in those cases not only concerning patients' formal legal rights, this proposal is based upon written evaluations made by one of the board's experts. For instance, complaints against nurses are assessed by nurses and complaints about cardiologists are assessed by cardiology experts. The Board's decision is made by a five-person committee consisting of 2 public representatives, 2 representatives of the health profession concerned (nurses if case about a nurse, medical doctors if case about medical doctor etc.), and a chairperson who is a judge. The chairperson can however make the decision in those cases giving rise to no doubt that there is no basis for criticism; in 2007 almost half of cases (47.2%) were completed this way (Sundhedsvæsenets Patientklagenævn, 2007).

The Board has the authority to conclude that a concrete case provides no basis for criticism but otherwise the board may conclude that the health professional concerned must be criticized because he or she has violated the law by not acting 'within the norm of generally recognized professional standards' (e.g. by reference to the aforementioned obligation for 'carefulness and conscientiousness', Act on Authorization, Para 17). It is not considered whether the patient has received the best possible treatment, but — as indicated — it is clarified whether performance was within the area of the just acceptable health care provision. The board may also inculcate the health professional to be more careful and conscientious in his or her future work — a criticism with injunction. Additionally the health professional concerned can be brought for the prosecuting authority. The latter competence is only rarely used; in 2011, 1 case was conveyed to the prosecuting authority (Patientombuddet Årsberetning, Sundhedsvæsenets Disciplinærnævn, 2011).

The decision (with an explanation) is sent to the complainant and the involved health professional (-s). Also, decisions are sent to the Health and Medicines Authority in order to identify, e.g., health professionals which represent a threat to patient safety. So the decision may be the first step in a more thorough examination of the health professional which may finally result in authorization withdrawal through the courts. Anyway decisions on criticism result in the Health and Medicines Authority to establish a permanent file connected to that health professional. Similarly, the local authorities receive a copy of the final decisions. In case of repeated criticism of a concrete health professional (at least 3 times within 5 years) or if a criticism with injunction is issued, name and identification code are made public (on the board's homepage). Also, a selected variety of anonymous decisions is published on the Disciplinary Board's homepage (www.patientombuddet.dk).

There is no possibility to complain about the final decision to other administrative authorities, although the case can be reopened if the board receives additional information considered likely to have resulted in the Board making another decision. Board decisions may be brought to the Danish

Ombudsman (see Patientombuddet Årsberetning, Sundhedsvæsenets Disciplinærnævn, 2011), who may also on his own initiative perform investigations on the board's customary case handling. Ultimately, decisions can be brought before the courts.

From 2011 onwards, the Danish disciplinary (complaints) board is placed in connection with the "Patientombuddet" institution and currently, the complaints system is based upon Act on Complaints and Compensations in the Healthcare System (see Act 706, 25/06/2010) and Rules of Procedure 1447, 15/12/2010.

Additionally complainants have an opportunity to file a complaint with the Patientombuddet concerning concrete health care, without intending named health professionals to be disciplined (Act 706, Para 1). In those cases, it can be concluded that the health care delivered by that health care unit was criticizable. It is also possible to complain about certain groups of health professionals without an authorization (see Para 2, subsection 2 in Act 706, and Ministerial Order 1448, Para 1). Likewise as a new incentive, patients are offered an opportunity to have a 'dialogue' with the regional municipality in order to clarify the course of concrete health care (Act 706, Para 1, subsection 3). If the patient is not satisfied with this dialogue he or she may decide to file a complaint against the health professional or the health care unit concerned (according to the disciplinary board or Patientombuddet procedures, see above).

Complainants who wish compensation are helped to file their claim to the separate compensation system ('Patientforsikringen'). Parallel, according to law, 'unintended adverse events' must be reported and followed up through the no-fault system. Regional public patient advice offices have been established in order to guide people through the complaint system (Act on Health Care, Chapter 11).

Preventive Functions of the Disciplinary System

From the perspective of penal law, criticism (formal reproof) can be considered among the least severe sanctions. Anyhow as it has been already mentioned, disciplinary cases may both be very resource demanding and have a large impact on, e.g., doctor-patient relationship. So it is reasonable to examine the purpose and effects of the disciplinary system.

By reference to penal law, the usually mentioned means of justification for legal sanctions are, e.g., retribution, rehabilitation, incapacitation, and deterrence [6]. The latter mentioned measure — deterrence (or prevention) implies preventing people from future wrongdoing. From this point of perspective, disciplinary responsibility may serve as an incentive for health professionals to do their best (deterrence from negligence); a general preventive measure for the broad group of health professionals and an individualized preventive measure for those complained about (See Birkeland et al, (a) 2013) [7]. Hence, preparatory works on the Act on Complaints

[6] Sanctions can, however, also be explained in terms of prevention and reinforcement theories to signal what are the norms and what is 'acceptable'. Thus the reproof may imply some behavior being more or less publicly expressed as 'wrong' (or criminal); community's anger is recognized while the wrongdoer is somewhat stigmatized and presumably discouraged from future misconducts (compare the 'pillory' mechanism).

[7] See about preventive effects of disciplinary and tort law measures in health care von Eyben (1985).

and Compensations (which regulates the disciplinary board) explicitly maintained that there are two main purposes for the complaint system; first the system aims to clarify whether the "…*health person has violated health legislation in order to protect against repeated criticizable behavior*" and second to "… *contribute to the continuing quality improvement in the health care sector*" (see Bill LSF 75, note section 3.1.1). The system rationales are both providing a preventive instrument and a patient safety and quality improvement tool (see also Authorization Act, Para 1). The preventive function has been repeatedly explicated. Afterwards "Patientombuddet" (Patientombuddet Årsberetning, Sundhedsvæsenets Disciplinærnævn, 2011) stated that "*there is no doubt that those health professionals receiving a criticism for health care provision will become more attentive in future similar situations*". This preventive aim can be claimed to be of particular importance in settings like in Denmark where the risk of being sued for monetary compensation in connection with stated negligence is negligible [8].

To sustain its preventive functions, the disciplinary systems must keep their 'authoritative' appearance. This necessitates that disciplinary proceedings are somewhat 'non-ordinary' (something not inevitable, something that one must not necessarily 'anticipate') rather than mirroring e.g. the common knowledge that 'to err is human'. This preventive function implies another facet as well. As mentioned in the introduction, traditionally, the health professional's dependence on 'appreciation' and absence of blame has played a crucial role. Professional pride in itself implies that health care provision which might be considered erroneous is averted. Additionally care can be optimized so that, in case of disciplinary proceedings, health care provision can be defended [9].

Furthermore, health care professionals (as well as patients and the publics) must keep the trust that finally disciplinary justice let be done and that unpredictability in disciplinary case decisions is minimized. Health professionals must keep the trust that if exercising enough 'carefulness and conscientiousness' no disciplinary case arise, or if so, criticism can be finally avoided.

From Sporadic Malpractice Investigation to Disciplinary Trial Routinization

Ever since the establishment of the specialized patient complaints board, there has been a consid-

[8] It should, however, be mentioned that if the health professional has acted grossly negligent, he or she can be brought to the courts and according to the Act on Authorization (Para 75) can be issued a fine or even be sentenced to imprisonment (up to 4 months).

[9] As it was indicated in the introduction, professional pride has close connections to biomedical ethics. From the perspective of later ethical theory, the principles of beneficence and non-maleficence could be mentioned (see Beauchamp and Childress, 1989 and Gillon, 1994). It is central to health care provision that it is done for the benefit of others (that is, prevention or removal of harm or — at least — improving the patient's situation). A major goal of health care provision is promotion of patients' welfare and health care professionals are expected to help their patients and refrain from causing harm. In this regard health care professionals should possess skills and knowledge in order to assist patients. Harms should be prevented, removed or decreased and possible benefits must be weighed against risks so as to produce net benefit. Correspondingly non-maleficence implies "not to do harm." In other words health care professionals must refrain from treatments that are only harmful and abstain from ineffective treatments. As mentioned above patients must be only purposefully harmed if the action is balanced by proportional benefit. Ultimately, the patient him- or herself must make the decision whether potential benefits outweigh harms (respect for autonomy); the intervention's potential benefit must outweigh the risks in order for the health care provision to be 'ethical'.

erable increase in the annual number of complaint (disciplinary) cases. Thus in 1975 less than 200 were completed by the Danish Health and Medicines Authority (White Paper 866, 1979) and in 2011 more than 2000 were completed by the Disciplinary Board (Patientombuddet Årsberetning, Sundhedsvæsenets Disciplinærnævn, 2011). Currently, approximately one fourth results in a 'reprimand' and no more than one per thousand cases results in criminal prosecution (Patientombuddet Årsberetning, Sundhedsvæsenets Disciplinærnævn, 2011). Authorization withdrawal rarely follows. By way of example, authorization was withdrawn from approximately 50 among a total of more than 25,000 medical doctors by end September 2013 (Danish Health and Medicines Authority, 2013; DADL, 2012).

Even though there is limited knowledge about the proportion of health professionals which have ever been involved in disciplinary cases, a previous study from New Zealand (disciplinary system comparable to the Danish one) suggests that the proportion may be rather high: one third of health professionals had ever been involved in disciplinary proceedings (Cunningham, 2003). Likewise a recent Danish study of disciplinary decisions against general practitioners (GPs) during one year suggested that — even though some groups appeared to have higher odds of involvement in disciplinary cases (especially the more senior GPs), complaint case frequencies suggested that the average GP is involved in a disciplinary case every 5 year (Birkeland et al., (a)). This increase might have a number of implications. It could be argued that it ought to be possible for health professionals to run a professional life without being brought before the disciplinary board. Nonetheless, within many professions, it seems increasingly unrealistic to avoid involvement in at least a few disciplinary cases throughout the career [(10)].

To sum up, it appears from the above mentioned that the development has been away *from* disciplinary cases being a) something non ordinary, b) something dishonorable (causing health professionals to do their best) c) something that is within the means of health professionals to avoid, d) something which the 'proud' health professional will ultimately take to the court. Now the situation is that i) disciplinary cases are increasingly common, ii) being involved in disciplinary cases is very unpleasant and resource-demanding but health professionals must recognize that a complaint case is 'something that one must anticipate' ('those who perform sometimes fail' etc.), iii) it is doubtful if health professionals can fully avoid disciplinary cases, as they can be initiated by any patient who can refer to a concrete health care episode and problematize care provision, iv) health professionals are aware that roughly one in four disciplinary cases result in criticism, appeal to the courts is very costly and in reality is an almost non-existing possibility (only 1 decision among more than 2000 was taken to the courts in 2011; Patientombuddet Årsberetning, Sundhedsvæsenets Disciplinærnævn, 2011).

The latter mentioned gives rise to another kind of objections; that is legal rights considerations and compliance with claims about fair trial etc.

[(10)] Alongside, some would provocatively argue that those who succeed to avoid disciplinary proceedings are not necessarily the very best health professionals but sometimes rather are those whose main professional focus becomes 'to watch the back' (see above about defensive medicine).

As mentioned above the disciplinary handling has been moved to a board with a simplified investigation and decision structure (e.g. case handling in written; one solitary expert witness assessment; a substantial proportion solely completed by a judge). Furthermore, the option of administrative appeal has been eliminated [(11)]. Bearing in mind that only one or two disciplinary decisions are appealed for the courts every year could possess a problem because this model *de facto* provides no more than a one-instance trial with limited procedural protection. In many cases decisions are based upon the opinion of one single expert witness, frequently concluded by one judge (or the 5-person committee), and without the possibility of hearing of witnesses, etc. It should be kept in notice that disciplinary board decisions are often the cornerstones in any further initiative from the Health and Medicines Authority (see above). That is, e.g. 'intensified surveillance' and, in the longer run, authorization limitation or withdrawal. Not least, afterwards it will be very difficult to argue against a decision made by the ('health care specialized') disciplinary board and it comes naturally that — during subsequent administrative case handling — the Health and Medicines Authority will be very disinclined to shed any doubt about disciplinary board decisions [(12)].

Future

According to Danish law, citizens should be provided means of proceedings when any doing related to the public sector is supposed to be wrongful. Likewise, it comes naturally that, in order to prevent e.g. abuse of power, legal means of "user remonstration" and public monitoring must be established where persons are professionally working in the service of the community. So far, within the health care sector, the specialized disciplinary board satisfies these purposes [(13)]. Correspondingly, international obligations demand patient complaints structures to be arranged; the Council of Europe recommendations have already been mentioned. It appears that these prerequisites are offered according to the Danish Act on Complaints and Compensations. It has, however, been problematized above that disciplinary proceedings have more or less become a 'companion' in the everyday work life of health care persons (almost "like having a parking ticket") and concurrently the potential preventive purposes of the health professionals' disciplinary system may be increasingly challenged.

Furthermore, from the perspective of patient safety, a crucial point lies with the Health and Medicines Authority's follow-up on disciplinary

[(11)] In this connection it could be mentioned that disciplinary cases concern a wide variety of issues including e.g. the responsibility of patients themselves in connection with follow up during the course of illness, patients' rights and possibilities of keeping to international treatment guidelines, the requirements of health professionals to refer to scientific evidence in choice of treatments, and the disciplinary boards competence to — broadly defined — be 'law-making' etc.

[(12)] Further topics concern legal rights considerations in those disciplinary cases which result in criminal litigation (se Para 75, Act on Authorization). Criminal court decisions should be based, e.g., upon statements made according to criminal law procedures ('with the legal rights of the accused') rather than hearing material produced for the disciplinary board's case management.

[(13)] Patient complaint measures might serve other functions in addition to safeguarding patients' legal rights. Thus they may serve as a means of influencing the standards of health care provision set forth by the central authorities (by e.g. increasing the requirements with regard to educational skills before performing particular kinds of surgery, specifying requirements concerning patients' informed consent etc.). Likewise they provide a means of harmonization of health care provision among various specialties and geographical areas.

board reprimands. Hence the Health and Medicines Authority has to determine which among a large number of disciplinary reprimands should lead to further investigations, 'intensified surveillance' and perhaps finally an authorization withdrawal. In this regard, the material from the disciplinary board's decision will very often be a very important cornerstone.

The advantages of the current system have been already mentioned in terms of a 'rapid' and relatively inexpensive disciplinary process with involvement of the perspectives of lay men, lawyers, and health professionals. As summarized in this article, there may be some drawbacks as well. Striking the right balance between preventive functions, economic costs, human resource efforts, and legal rights claims can be a difficult task.

However, the new Patientombuddet institution provides some fresh points of entries. Some crucial requirements are met including the need for having an opportunity to complain about health care provision through an easily accessible 'one-string' system without any need for complainants to have particular knowledge in health care matters in order to pinpoint specific health care persons.

Furthermore it could be argued that, in some respects, Patientombuddet provides a more powerful means of quality improvement and patient safety tool than does the individual-disciplinary approach. Patientombuddet maintains the possibility of issuing a criticism yet, due to the less personal nature of investigation and decision-making, any defensive behavioral position of health professionals concerned is likely to be weakened. The health care providing unit may possibly be more motivated to see any form of criticism from a distance and 'realistically' consider both their standards of health care provision, difficulties with communication within the organization and with patients etc. Cooperation with Patientombuddet's case handling might be more matter-of-fact and reveal less emotional response to the content of the case. Correspondingly, by way of comparison, within other areas of the public services, complaint handling does not commonly imply the routine element of individualized disciplinary assessment.

It remains to be determined how far the new parallel "no-name, no-blame" systems perform with regard to improving patient safety and quality in health care [(14)]. Additionally, future will show if the advantages of the Patientombuddet institution may be used in connection with further revisions of the complaint system. That is, for example in connection with giving this institution the competence -through means of a combined health expert, lawyer, and lay person evaluation — to initiate person-focused disciplinary proceedings [(15)]. In this regard the disciplinary proceedings in those expected fewer cases could be intensified (and more 'court--like') — allowing for hearing of witnesses, further appeal possibilities etc. Placement of disciplinary proceedings exclusively with a 'court-like' board would safeguard a more thorough clarification for the sake of those disciplinary cases which must be followed up by further proceedings, sanctions etc.

[(14)] Equally this pertains to the above mentioned reporting of unintended adverse events.

[(15)] Perhaps after an initial screening whether criminal investigation is merited (in order to offer appropriate legal rights of the accused).

This possibly would re-introduce the perception that disciplinary negligence is something *more* than 'to err is human', preclude the issuing of 'mass-disciplinary--reprimands' and ensuing risks of undermining of preventive functions. Furthemore focus could be more effectively — and perhaps more quickly — directed towards those health care professionals actually being a risk to patient safety.

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LEGAL REGULATION OF THE HEALTH CARE SPHERE AND PATIENTS' RIGHTS IN UKRAINE

Zinoviy Hladun [1]

The aim of this research is scientific study of the legal regulation of the patients' rights in the sphere of medical service and health care. "Health", "health care" and "patients' rights", as legal terms, are widely used in modern law. However, there is no unified legislation which would regulate the relations in this area in Ukraine. Thus, it is necessary to examine a range of issues that are arisen from the formation of modern legislation which regulates relations in the field of recognition and observance of patients' rights in the process of providing them with medical care; to offer some suggestions for improving the regulation of these issues and the adoption of new legislation.

An analysis of recent researches and publications. Health legislation (or legislation on health care) is developing rapidly in Ukraine during recent years. It is a complex branch of law and a system of legislative acts, which regulate the organizational, economic and personal relations that are arised from the provision of medical care (patients) and the activities for the protection of individual and public health. However, scientific and legal research of issues in the sphere of medical law and relations is developing quickly. The works of the young generation of Ukrainian researchers in the sphere of health care appeared in recent years. Among them: S. Antonov, S. Buletsa, I. Vynogradova, T. Volynets, V. Galai, R. Hrevtsova, L.Deshko, N. Illarionova, O. Prasov, V. Samsonov, I. Senyuta, O. Kashyntseva, N.Kopachovets, O. Krylov, P. Livak, B. Lohvynenko, K. Narovska, O. Starchenko, D. Karamyshev, T.Tyhomyrova, J. Shatkovskyi etc. It should be noted that the names of the authors of the first Ukrainian textbook on medical law (2008) are S.Stetsenko, V. Stetsenko and I. Senyuta [1]. Each of these authors researched specific issues of legal regulation of relations in the health care sphere. However, there is still no entire work on the analysis of the regulation of patients' rights in the sphere of medical service and health care in Ukraine.

Legal content of "human health" and "public health" categories

The key concept of this research is the term "human health" and therefore it is extremely important to understand it a properly. The term

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"human health» is a diverse one, so there are many definitions of it as professionals of various disciplines understand it differently and used different approaches to explain and reveal the essence of this phenomenon. Health is a natural property of human. Health is given to human with his life as a "gift of God" and a state and society can't influence on this process. However, they have influence on the creation of favorable conditions for health life, work, education and recreation through the formation of common public interest in health care sphere and strengthening of health, the development of public policy in this area and adaptation of appropriate legislation.

The term "human health" means "a dynamic process of complete physical, mental and social well being and not only the absence of disease or infirmity". This is the most universal definition which was stated in the Preamble to the Constitution of the World Health Organization (1948, revised in 1998) [2]. This definition is also imperfect and quite controversial because the term "total social welfare" is extremely broad and depends firstly on the level of society, in particular social, economic and cultural relations, and, secondly, social usefulness of human is not always determined by his biological condition. However, such meaning of this term was stated in the Article 3 of the Fundamentals of the Legislation of Ukraine on Health Care. It states that "health is a state of a complete physical, mental and social well being and not merely the absence of diseases and disabilities" [3]. However, talking about human health and its legal protection and security, we are dealing with not one, but two different concepts of health — individual health and public health. In the scientific literature and in law the terms "public health" and "public health" are often used as identical one. There are lots of reasons for this. Individual health and public health (health of certain groups of people (for example employees or any particular areas — drivers, miners, civil servants and others) or population (village, town, district, region, countries) in general) is a real-life phenomenon, with its normative definition and legal content.

These terms are widely used in modern legislation, including the Constitution of Ukraine, the Fundamentals of the Legislation of Ukraine on Health Care, Civil and Criminal Code, the Code of Administrative Offences, numerous laws which regulate the relations in this area, as well as in acts of international health law.

According to a number of important international legal acts, including the Universal Declaration of Human Rights, the International Pact on Economic, Social and Cultural Rights, which was ratified by Ukraine and the European Social Charter (revised) (Council of Europe, 1996 p.), signed by Ukraine on May 7, 1999, and numerous conventions and recommendations of the International Labour Organization (most of them were ratified by Ukraine), the duty of the state is to take care of human health and ensure its protection.

The review of Ukrainian legislation on health care and patients' rights

A state regulation of relations in the sphere of health care occurs mainly through the implementation of legal rules, that is, through the development and adoption of an appropriate legislation. As in a

life, in practice, there is no phenomenon that can be regulated by the rules of only one area of law. Thus, the area of health care also includes various relationships that are regulated by different norms of law. According to the division of the norms of law on public and private law, the next should be noted. Public health, as a set of national and community measures which aim is to strengthen the health of people and which are carried out by public (state and municipal) authorities, is a subject of private (civil, labor part) as well as public law (constitutional, administrative, financial, and others). One can also talk on the legal protection of health by means of civil, labor, criminal and other areas of law (together with the civil and administrative legal protection of health).

However, under the conditions of state and municipal public health care system, exactly the norms of public law dominate quantitatively and qualitatively in the legal regulation of public relations in the field of both individual and public health. Thus, this research is dedicated to them.

The legal basis for the legal regulation of relations in the field of health care, including patients› rights, is a valid legislation that is a set of legal acts which regulate such matters. Ukrainian legislation on health care can be divided into two parts, which, however, are closely connected with each other. The first one is theacts of international law which are ratified by the Verkhovna Rada of Ukraine; the second one — Ukrainian legislative acts.

The first group should include the Universal Declaration of Human Rights, the International Covenants on civil, political, social, economic and cultural rights, the Declaration of Rights of the Child, as well as the acts that regulate certain issues of health care and medicine — Lisbon Declaration on the rights of patients (Lisbon, Portugal, September-October 1981), the Regulation on the protection of the rights and privacy of the patient (Budapest, Hungary, October 1993), the Regulation and views of the World psychiatric Association on the rights and legal protection of the mentally ill people (Athens, Greece , 17 October 1989), the Declaration on the Rights of Persons with Disabilities (December 9, 1975), the Declaration on the transplantation of human organs (Madrid, Spain in October 1987), the Declaration on the roles of physicians in solving of the environmental and demographic problems (Vienna, Austria in September 1988) as well as a significant number of similar acts which were adopted by the World Health Organization, the World medical Association, World Association of Nurses and several other international organizations.

The second group of Ukrainian legislative acts includes: primarily, the constitutional norms that reinforce the human right to health protection, medical service and health insurance, leisure, social security and other social benefits; the norms of backbone Law — The Basics legislation of Ukraine on health care, «On Prevention of Acquired Immunodeficiency Syndrome (AIDS) and Social Protection of Population» [4], «On protection of population against infectious diseases» [5], «On Medicines» [6], «The blood donation and it›s components» [7], « On the transplantation of organs and other anatomical human materials» [8], «On the implantation of artificial cardiac pacemakers» [9], «On psychiatric care» [10] etc.

The regulatory and legal framework for the protection of individual and public health, which

consists of 170 laws, 135 presidential decrees, 505 Government›s regulations, 2931 decrees of Ministry of Health of Ukraine has been formed in Ukraine since independence [11]. They all, to a greater or lesser extent, meet the requirements of international law and, in particular, the EU legislation on health care. Such conclusion is made by Ukrainian and foreign experts on these issues [12, 132].

Legislation of any country, regulating the issue of human health or public health, set the measures of the legal health care according to the legal standards. Therefore, **health care**, as indicated in the mentioned above Article 3 of the Fundamentals of the Legislation of Ukraine on Health Care, is a "system of measures aimed at ensuring, maintaining and developing of the physiological and psychological functions, the optimum working capacity and social activity of the person at the maximum biologically possible individual duration of life". One of the measures as to the health care (along with organizational, financial, staffing etc.) is legal one. This indicates the legal measures on health care. Therefore, **legal protection of public health** is a set of legal measures and means that are intended to preserve, strengthening and restore of individual and public health. For example, a law determines the rights of citizens in health care sphere, including patient's rights, legal grounds and procedures for granting different types of care, conducting a variety of medical procedures and manipulations, the order of selection of the attending physician, the procedure which deals with medical information, receiving of various medical documents etc.

An individual, according to the the civil law (Article 284 of the Civil Code of Ukraine) [13], who reached 14 years and applies for the provision of medical aid has the right to choose a doctor and treatments in accordance with his recommendations, and has personal and property rights, while staying at a medical facility.

According to the foregoing, the «protection of individual and public health» as a legal category is characterized by the following features:

- is one of the internal functions of the modern state, the base of a state, regional and local social policy;
- is a certain kind of professional human activities (mainly medical), intellectual and teamwork which provides various means and measures for treatment of illness and rehabilitation of health as well as a compensation for the damage to human health;
- the purpose of this activity is the preventive measures and treatment of people, strengthening of their health;
- the main subject in this activity are individuals (citizens, foreigners, stateless persons, refugees) who are accompanied by the medical activities during the whole life from birth until death; other subjects are medical and pharmaceutical workers, health facilities, state and local governments that administer in this area.

One should distinguish between legal health care and **legal protection of health**. Unlike the first one, the second one has an active character. The legal protection of health (both individual and social) is the sum of the applicable legal order

authorized by legal ways and means to eliminate the illegal encroachments on individual and public health, redress participants healthcare relationships and apply to persons who have committed offenses against the person's health (or public health) measures of legal liability. The subjects of these activities can be either public (Ministry of Health of Ukraine, the administration of public health services, police, prosecutors etc.), communal (health authorities of local self- administration of municipal hospitals) and non-governmental bodies (professional medical associations, public patients' organizations etc.). The need to protect the right for health care arises from the law's infringements [14, 25].

The protection of rights, according to M. Boiaryntseva, is a subjective and self-reliant right that reflects a legal possibility of the empowered person to use special means of law enforcement character. The protection of rights, freedoms and legal interests is such form of their ensuring that displays the act of this mechanism which aims at: ending violations of rights, freedoms and legitimate interests of citizens; liquidation of any obstacles which appeared during their implementation; restoration of rights, freedoms and legitimate interest; instituting criminal proceedings against person who is guilty [15, 161]. An example of this activity is a complain on Administration of medical facility for incompleteness, bad quality of medical service or wrong diagnose and prescribed treatment. It should be noted that patient has the right to assess the actions of not only a physician who treats him but also of other members of the medical staff.

It should be determined the next relations according to legal analysis. The private and public relations for the provision of medical care to individuals as well as to protect public health belong to the sphere of legal regulation (population health).

The sphere of public relations includes: the organization of public health care; the establishment and work of the health care system as a whole and its individual parts; medical institutions and their licensing and accreditation; a state sanitary- epidemiological supervision; the relations in the sphere of medical and pharmaceutical workers' training, their admission to the profession; identifying and securing human and civil rights, in particular, patient's right in the health care sphere; the procedure for providing of various types of medical aid; the provision of the variety of medical procedures and manipulations, including medical examination; the delivery of the documents and spreading of the of information on the state of patient's health; the realization of state and public control in this area etc.

The private relations in the health care sphere include: the relationships that occur between patients and health care workers of first aid and relate to the choice of a doctor, medical facilities and treatments; possibility of the patients to get the information about their health and preservation of this information in a secret; have possibility to be visited by other medical professionals, family members, guardians, notary, lawyer and priest etc.

They assume the character of the relations that are regulated by law on the basis of the law's norms. The evidence of the legal nature of this relationship is that, firstly, in terms of content, they are either private law or public law as they are regulated by the health issues with both private and public interest. Secondly, they arise on the basis of the rules of

private and public law, thirdly — these relationships are characterized as legal equality of the parties (based on private law) as well as legal inequality of the parties (on the basis of the public law), fourthly — they are regulated by numerous law acts (laws, decrees, regulations, rules, instructions, lists, clinical protocols, medical forms, guidelines etc.), which were adopted by Parliament or the President, approved by the Cabinet of Ministers, Ministry of Health of Ukraine and other central bodies of executive authorities. Today, the relations in this sphere are regulated, approximately, by over 5500 legal acts [16, 92].

The legal norms, which can be found in the acts of legislation, are the means of establishing a specific legal regime in the relevant sphere of relations**. The legal regime of relations** in the health care sphere consists in establishing for the members of this relationship, especially for patients and medical staff persons, as well as health care facilities, the obligatory rules which relate to the prevention, diagnosis, treatment and rehabilitation of persons who were suffering from these diseases, and the prohibition of certain types of activities. Thus, law established the prohibition of certain activities. For example, persons who suffer infectious disease can't work in the sphere of catering [3, 30].

The reasons for application of legal health care measures are:

— **For an individual** — a visit to the medical profession or medical facility for medical care, giving of such aid in the exceptional cases or participation in a medical experiment;

— **For the groups of individuals or population** — the spread of viral diseases, for prevention and ceasing of which is necessary to use administrative and legal methods of dealing with them, in particular, a mass examination of populations for detection of ill persons and their isolation, mass vaccination against diseases that are transmitted by air, the massive use of drugs for preventive measure, the announcement of quarantine in certain areas etc.

The subject of legal regulation of the relations in the sphere of health care is not human health, because it is a natural weal, but the recognition of human rights in its comprehensive protection and security by a state. Thus, the object of legal regulation is the protection of human health and the subject is the social relations in this sphere.

The objects of legal regulation of relations in the health care sphere can be divided into material and non-material. The material objects of legal regulation include: medical facilities, their medical staff, medicines, main funds (buildings, vehicles, medical equipment, communications equipment, etc.). The non-material objects are official links between subjects of this relationship, the relationship between patients and health care professionals, professional level of medical staff etc.

The main and most important object of legal regulation is health of population and its state, which can be affected by improving it. One of the most important objects of legal regulation is a health care system that unites multiple health care institutions of all forms of property (facilities management)

and subordination, executive authorities and local self-government (subjects of administration) which govern in this area, and the relationship between them. Health care institution (medical facilities) is the main and primary link of all national system of health care. They can be classified according to various criteria: by the type of medical services (therapeutic, surgical, obstetric, etc.), which are available at them; by the capacity, which is calculated or by the number of beds in hospitals, or by the number of persons who may be received by doctor at clinics; by the level of medical services that can be provided in health care institutions — first, second (specialized) or third (highly specialized) aid; eventually, by name — hospitals, clinics, primary care centers, diagnostic center, dispensary, outpatient clinic, first aid stations etc. [17].

Every person, who considers to be harmed or whose rights have been violated, has the right to complaint on such actions or decisions within the established procedure. This concerns the patients too. A civilized human community realizes the need for the recognition of patients' rights and the establishment of state and public control over medical practice.

The idea of respect for patients' status as full-fledged participants in the relationship of health care sphere, which arise from providing them with medical care during treatment, lies on the basis of patients' rights. Accordingly, one can not provide medical care forcibly (except for a few cases where there is a question of saving human life) and to carry out medical intervention in a patient's body without his agreement [18, 23].

In Ukraine, the patient's rights to health are defined more fully in Article 6 of the Fundamentals of the Legislation of Ukraine on Health Care. It states that a patient has right to a qualified medical care, including a free choice of doctor, a choice of therapies in accordance with his recommendations and healthcare facility, accurate and timely information about their state of health and public health, including existing and potential risk factors and their degree; legal protection against any illegal discrimination related to health, compensation for health's damage, an appeal against illegal decisions and actions of the mediacal staff, facilities, health authorities and others.

These rights are defined even more fully in the European Charter of Patients' Rights [26], which provide 14 universal patient's rights — from the preventive measures' right to the right to compensation for damage to health.

However, Ukrainian legislation in some laws provides certain rights of patients in certain areas of medical practice or in the treatment of certain diseases. In particular, the Law of Ukraine «On protection of population against infectious diseases» [5], provides certain restrictions on the free movement of people and communication among themselves in order to prevent and suppress the spread of infections, the Law of Ukraine «On the transplantation of organs and other anatomical human materials» [8] provides special rights of the donor and recipient. The Law of Ukraine «On psychiatric care» is complete and detailed [10]. The article 25 of the mentioned law set up in details the rights of persons to whom psychiatric care are provided and that includes respectful and human treatment that eliminates the humiliation of honor and dignity. They can also receive the information about their

rights related to the provision of mental health care and stay in a psychiatric hospital only for the time necessary for examination and treatment etc. This is understandable, since the sphere of human mental activity is very unclear and vague for the diagnosis of mental illness and has no clear boundaries and criteria of normal human mental activity and its variations. Thus, more abuses in this sphere are possible. That is why this sphere requires a clear legal regulation and intensified control in this area.

One of the most common offences in this area is a violation of the patients' rights to the complaint by medical personnel. Article 13 of the European Charter of Patients' Rights provides that «everyone has the right to complain about caused suffer and losses and the right to receive an answer or other appropriate response» [19]. Annually, the Ministry of Health of Ukraine and local health receives more than 120 thousand complaints from patients who complain of bad quality and incompleteness of the provided medical aid, low professional level of the medical stuff and their rude and tactless behaviour and their extortion. Typically, these complaints are examined but without much result.

State protection of patients' rights

Judicial protection of the right to health care (including patient rights) should be carried in the manner which is prescribed by law according to Article 6 of the Fundamentals of the Legislation of Ukraine on Health Care. Thus, one of the most important rights of the patient is his right to appeal the actions and decisions of his physician as well as other health care professionals and healthcare administration. Less than 0.5 % of these "medical" cases, according to the estimations, reach trial, which, in our opinion , is the most objective and impartial mechanism for resolving such conflicts in this area (as it doesn't depend on the service order of medical administration). One can assert with certain assumptions that the patients which are desperated by the indecision and helplessness of medical administration in 20 % of cases appeal to protect their rights to the prosecuting magistracy, and in 10 % of cases — to the police.

The legislation of most countries, including Ukraine, has two main ways to appeal decisions and actions of medical staff — administrative and judicial. Each of them has its advantages and disadvantages. The advantage of the trial of the patient's complain, which is carried out by the Court, that doesn't depend from medical administration, is objectivity in accordance with the principles of judicial procedure. Its weak point is a long terms of solving it. The existing law provides the order of administrative trails of statements and complaints of patients and their relatives (by medical administration) in accordance with the laws of Ukraine «On citizens' appeals» [20], «On Protection of Consumer Rights» [21], «On access to public information» [22] etc. However, the patient's desire to appeal the actions of physicians is a necessary condition for the trial of the patient's complaint. At the same time, every practicing lawyer knows that complaining to the doctor, particularly to the doctor who treated you yesterday is very difficult from the moral, ethical, psychological considerations, as well as from purely legal considerations. In addition to this, an elementary human inertia and laziness and

lack of faith in the possibility to achieve justice through mutual guarantee in the medical community also have influence on this. Taking into consideration the narrowing of the sphere of so-called general supervision of prosecuting magistracy over abidance by law, a procurator's own initiative on the patients' rights is doubtful too. This concerns also, to some extent, Ministry of Internal Affairs' bodies, which act in such cases only after victim's statement. It is clear that in the area of abidance of patients' rights, most of these infringements remain without a proper response. This is a negative phenomenon that contributes to the ignorance of law by medics and spreads the atmosphere of impunity and low level of moral and legal culture in their professional environment.

However, the presence of some perfect legislation can not, by itself, provide a perfect legal regulation of relations in this area, including, for example, the rights of patients and health professionals. This requires that the legislative acts be supplemented by the institutional measures, i.e. to create relevant authority (or empower the already existing one). It seems that the easiest option of the institutional support for patients' rights is to empower the central executive body, the Ministry of Health of Ukraine, to ensure the rights of patients and to define it as a prior task. The Department of the patient's rights could be created as part of the ministry apparatus, which could headed by the official who could have a status of an official authorized for patients' rights (ombudsman) [23, 205].

It is quite possible that some physicians, having certain advantages on their side, may be tempted to abuse their rights for their advantage, or even to break the patient's rights, especially, when nobody knows them. Our life shows us numerous cases of such violation, including the commission of crimes. The patient is either «run» in a circle of various expensive examinations, which are not necessary for his illness and for which he need to pay, or under the guise of «working therapy», mentally ill patients are forced to work in the gardens or yards of their doctor or hospital manager, or under the guise of some «modern» medicine patient is recommended to buy some «dummy» medicines from chalk, or ablate some organ for transplantation from just died one, who didn't give his consent for this etc. It is impossible to list all ways of fraud in medicine! More and more ways appear every day! The modern living conditions need to strengthen control over the health care sphere from society and state's side, including departmental and non-departmental oversight and control, and also the control from the institutions and civil society organizations' sides, including the ascertainment and broadening of all types of legal amenability for the offenses that are committed in this area.

In Ukraine there is a tendency to create a separate law and to form an independent state agency for its enforcement in order to solve some important social problem. Thus, the State Sanitary and Epidemiological Service was created in accordance with the Law of Ukraine «On Ensuring Sanitary and Epidemiological Welfare of the Population» (1994), the Committee on Drug Control was created in accordance with the Law of Ukraine «On narcotic drugs, psychotropic substances and precursors» (1995), the State Service for pharmaceutical drug — in accordance with the Law of Ukraine «On

pharmaceutical drug» (1996) etc. All of the agencies have the status of public governance bodies and are ruled by the Ministry of Health of Ukraine.

If one seriously put the problem of the recognition and respect for patients' rights in Ukraine, one should be interested in the existing global positive experience within this issue. This experience shows the possibility for the creation of a special state agency (institution) that would be involved in the control of the observance of the patients' rights in health care sphere, that is, it would have a special powers. In some countries (Australia, Poland, New Zealand, Germany, UK) [32], such agency is a Commissioner of Parliament or Government for patients' rights. This position has not been provided yet by the current Ukrainian legislation. However, the need for such an institute exists. Therefore, he should be created sooner or later if take into consideration the need to improve the legislation as a whole and improve the quality of medical care and the procedure of trial of patients' complaints.

It is needed a number of preconditions in order to implement such an institution in Ukraine. The most important of these preconditions is the political will of the President and the Supreme Council of Ukraine in order to implement it. If take into consideration that it is not been provided by the Constitution and current legislation now, it can be done in one of two ways. The first one is to approve the appropriate Law of Ukraine «On the Supreme Council of Ukraine commissioner on patients' rights» and to nominate a person on this position by the appropriate decision of the Supreme Council of Ukraine and provide funding for that agency by a separate line item in the State Budget of Ukraine.

The second way is the possibility of the President of Ukraine, in accordance with 15 paragraph of 106 Article of the Constitution, to create by his decree such a body and appoint it's head (Commissioner of the President of Ukraine for patient's rights) [4]. The second way is more realistic if take into consideration the already existing precedent that is the introduction of the post of Commissioner of the President of Ukraine for the children's rights. Thus, there are two ways to solve the problem of the establishment of such institution in this sphere, which provide two different legal status of this body. In the first case, the Commissioner of the Supreme Council of Ukraine for patients' rights and the Supreme Council gives it the appropriate authority. In the second case the Commissioner of the President of Ukraine for patients' rights and only the President may allot it the respective power.

We will talk now about the scope of power of this body. According to a number of norms of the Constitution of Ukraine, the powers which a new-created body may be endowed by the Supreme Council of Ukraine are broader then the powers which this body may be endowed by the President. So, it all depends on who will take advantage of this initiative earlier — Parliament or the President of Ukraine? According to the author, whoever will use it, it is necessary to introduce this State Institute. It is socially beneficial and its activities will promote professional and cultural level of Ukrainian medicine (because the observance of the patients' rights is a necessary part of the professional medical practice), professional culture of providing the quality medical care, strengthening the legal culture in a professional medical environment.

As to the content of the powers which the commissioner for patients' right should be endowed, it is clear that in his activities, he can replace neither the judiciary nor the medical administration. His main tasks are: to detect violations of the patients' rights, to give them a proper legal evaluation and through existing legal mechanisms to eliminate these violations, to call perpetrators to account and to restore law and order in this area. Therefore, the maximum authority of this Commissioner for patients' rights may be carrying out the official inspections (internal investigations) and, in case of violations, transferring these materials to agencies which conduct pre-trial investigation, or if the case is quite obvious and has a civil nature, directing it to the court.

In accordance with the powers, the status of the Commissioner may have either «strong» or «weak» character. He can be «strong» in the case when he will have the power of pre-trial investigation and the possibility of giving a legal assessment of the actions and decisions of health care professionals and health administration (including the decisions of health care authorities) that would have legal significant for the last one. However, if take into consideration some legal traditions that emerged in the process of state- and law-making, he will have, probably, a «weak « character , that is he will be empowered to hear complaints of patients and will put question of the removal of existing disorders or patients' rights in front of health care bodies and health administration. He will have to contact the police or the court in order to make a final decision. However, this way will meet the requirements, principles and ideas of law-governed state. Thus, it seems that exactly this way will be the most acceptable to the introduction of the Commissioner for patients' rights in Ukraine.

Accordingly, a person, who will be appointed on the position of Commissioner for patients' rights, will be responsible to the authority which formed the institution and appointed him, that is, to the Parliament or to the President of Ukraine. The thing is a political responsibility. As for the legal liability of any official, it is governed by numerous norms of current legislation and provides disciplinary, administrative, civil and criminal amenability for the committed offenses. Thus, the mentioned questions, according to the author of this research, can be resolved by the adoption of «On the patients' rights» law which would not only regulate in detail all the issues of recognition and realization of patients' rights in Ukraine, but also the issues which concern the Commissioner for patients' rights. It would also set a legal procedure for appealing the actions and decisions of medical workers, health administration, and other issues of legal protection of patients' rights.

Today, the need for a legislative solution to this problem is understood by everyone, but not everyone understands its importance and priority. The Ukrainian healthcare system will not take the character of the civilized and European medicine without a solution to the problem of the patients' rights. 5 bills on the rights of patients was made and registered in the Supreme Council of Ukraine but none of them was adopted during the last 15 years [26]. Why?

Besides the political reasons of the lack of interest of the deputies of the Supreme Council of Ukraine to this problem and to medical sphere in

general, another reason for the rejection of the long-awaited law is the sphere of relations by itself in which it has to operate. According to the majority of MPs and government officials, the sphere of health-care is typically costly public sector, which only «spend» budget, not «earn» anything in contrary to any other areas of the economy — energy, industry, transport, agriculture economy, trade and others.

Legislative Support of Healthcare Reform in Ukraine

The state policy of Ukraine in the area of public health consists in improving and promoting the health of the nation, meeting EU standards in health care sphere. This, in turn, entails the need to reform and enhance the quality and efficiency of the entire health care system, and, thus, adherence to international standards of medical care and patient's rights.

Large-scale implementations of medical reforms were set up in Ukraine in 2010. The reform of the national health care system was vitally important since independence. However, the important changes in this area over these years have not been done. Today, the sphere of health care in Ukraine is in a deep crisis. This is demonstrated directly and indirectly by the low quality of medical service, inadequate financing of health facilities, the low doctors' salaries, and, most importantly — dissatisfaction of physicians and patients by this state of affairs. Sociological polls, that are conducted from time to time, show consistently a steady dissatisfaction of Ukrainians with the work of health services (90%), the number of dissatisfied among health care workers is over 60 % [27]. The main drawbacks of the national health care system is the old organization of medical service, imperfect health care structure, insufficient provision of modern medical equipment and technology, and lack of funding. Thus, Ukrainian medicine year after year is losing ground among similar medical services of the international community. All these are reasons for the deterioration of the health of the nation, depopulation, and, thus, the deterioration of the indicators of socio -economic development and quality of life.

It is not surprising that these and some other circumstances have forced the current government finally take on health care reform and declare it one of the priorities of its activities. The directions of the reforms are defined by the Decree of President of Ukraine on January 27, 2010 (N.º 70 /2010 «On additional measures to improve medical care» [28]). It began from the decision of the Cabinet of Ministers of Ukraine on February 17, 2010 (N.º 208 «On certain issues improving health system») in which the major conceptual areas of health system reform were approved [29].

On July 7, 2011, the changes and complements to the Basic Laws of Ukraine on health care for the improvement of provision of medical service to the population of the country were amended [30]. At same day, the Parliament of Ukraine adopted the Law of Ukraine «On the procedure for health care system reform in Vinnytsia, Dnipropetrovsk, Donetsk and Kyiv regions» [31]. On July 5, 2012 the Law of Ukraine «On emergency medical care», which initiated the reorganization of this important health care service, was adopted [32]. The process of legislative support of health care reforms in Ukraine has begun with the adoption of these regulations.

The European vector of Ukraine's state policy allows, in certain assumptions, to consider that the proposals of this research, despite all the difficulties, will soon be adopted. Thus, Ukraine will have a modern health care system, detailed legislation and Ukrainian patients — a Public Guardian of their rights.

Conclusions. «Health care» and «protection of health» are universal legal categories, the basis of which is «human health» term. They are widely used as a legal terms, in particular, in current Ukrainian legislation and regulations of international law. The relations that arise in this area are complex and regulated by almost all areas of law, though, the norms of administrative and civil law are dominant among them.

Personal health care differs from public health care, especially according to their object, which in the first case is health of individual, and the second is public health, ie health of a certain group of people. The subjects of this activity are an individual who receive medical aid as well as medical staff and medical facilities, that provide medical care and carry out other measures to protect health, and the executive authorities and local governments that administer these activities.

The relations concerning the provision of medical aid to individuals as well as the protection of public health (population's health) are a subject of legal regulation of the administrative law that gives the reason to speak on the administrative and legal health care. One should distinguish administrative and legal protection of health which is the sum of the applicable legal order authorized by legal ways and means to eliminate the illegal encroachments on individual and public health, redress participants healthcare relationships and apply to persons who have committed offenses against the person's health (or public health) measures of legal liability. This demonstrates the important role of the norms of administrative law in the process of legal regulation of the relations in the health care sphere. The question on the establishment of the State Institute of Patients' Rights in Ukraine should be solved. It is possible to do this by empowering the appropriate authority of the Ministry of Health of Ukraine as well as by establishing the post of Commissioner of patients.

Today, one can not state that Ukrainian legislation in this sphere has taken its complete form and there is no reason for further improvement. Currently, a number drafts of legislations «On the rights of patients» are under the discussion in the Parliament of Ukraine, the scientific literature raised the question of the need to prepare the next laws: «On medical institutions», «On the legal status and guarantees of the activities of medical and pharmaceutical workers in Ukraine», «On the guaranteed level of health care by the state», «On obligatory state medical insurance», «On primary health care and family medicine», «On specialized medical care», «On private medical practice» etc. Due to the increasing number of legal acts, which regulate the relations in the sphere of health care, it would be important to combine related legal rules in a single act, which would regulate them systematically and comprehensively. Medical and Sanitary Codes of Ukraine can be such acts.

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RIGHT TO MEDICAL INFORMATION IN THE NATIONAL COURT PRACTICE AND IN THE JUDGEMENTS OF THE EUROPEAN COURT OF HUMAN RIGHTS

Iryna Senyuta [1]

Preface

Ukraine belongs to the continental law system, where judicial precedent is not recognized as a source of law. As defines I. Ilchenko, precedent law in Ukraine, will probably never take the same place among the sources of law as it takes in the anglo-saxon legal family, but still it is not worth objecting to some of the precedent's law perspectives in the national legal system [2].

Societal development, change of normative mechanisms, courts institutional reorganizations, doctrinal modification change the role of a judicial precedent in a national legal system, which gives reasons to assert that judicial precedent becomes a non-typical (quasi-source of law) source of law, which can potentially transform into a source of Ukrainian law.

Legislative changes and institutional renovations in the judicial system were an important stage in the formation of this source of law. According to Article 38 of the Law of Ukraine "On Judicature and Judges' Status", Supreme Court of Ukraine is the highest judicial body in the system of courts of general jurisdiction, which among its other powers is entitled to review cases on the grounds of dissimilar application by the courts (court) of cassation of the same legal norm of material law to analogous relations as it is foreseen by the procedural law.

It is worth highlighting that according to Article 360-7 of the Civil Procedural Code of Ukraine, judgement of the Supreme Court of Ukraine, which was delivered as a result of considering the application as regards to reviewing the court decision on the grounds of dissimilar application by the court of cassation of the same legal norms of material law in the analogous relations, is binding for all subjects of state power, which apply legal acts that comprise this legal norm in their activity and for all courts of Ukraine. Courts shall make their case-law be in conformity with the Supreme Court of Ukraine judgement.

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[2] Ільченко І. Деякі питання застосування Конвенції про захист прав людини і основоположних свобод та практики Європейського суду з прав людини (Ilchenko I. Certain Aspects of Application of the Convention for the protection of Human Rights and Fundamental Freedoms and Case-law of the European Court of Human Rights)/ [Електронний режим доступу] http://www.minjust.gov.ua/14103.

Another type of court decisions, which can be referred to quasi sources of law are the judgements of the Constitutional Court of Ukraine, judgements that have often generated scientific debates. It should be noted that judgements of the Constitutional Court of Ukraine have a binding force on the whole territory of Ukraine, are final and cannot be appealed against. Analysis of Articles 61 and 65 of the Law of Ukraine "On the Constitutional Court of Ukraine" gives reasons to assume that legal acts of the Constitutional Court of Ukraine are normatively binding for all legal relations participants. As defines the scholar in the sphere of constitutional law I.A. Ivanovs'ka, a research of peculiarities of the Constitutional Court of Ukraine acts enables to ascertain that these acts have legal nature and foresee legal regulation of the most important social relations, are designated for all subjects of legal relations or for a part of these subjects as well as can be applied for numerous times when regulating social relations [3].

This judicial institution is the only body which has the powers to interpret the Constitution of Ukraine. In the aspect of the above-mentioned, quite well inherent seem to be the words of the head of the Supreme Court of the USA Charles Hughes (1862 — 1948) that "Constitution of the USA — is what the Supreme Court will say about it [4].

Very specific role in the national legal system plays case-law of the European Court of Human Rights (hereinafter — ECtHR) and the Convention for the Protection of Human Rights and Fundamental Freedoms (hereinafter — Convention), which application became most topical with the adoption of the Law of Ukraine "On Execution of the Judgements and Application of the Case-law of the European Court of Human Rights" of 23 February 2006. (hereinafter — the Law of 2006).

Article 2 of the Law of 2006 foresees that judgements of the ECtHR are binding and are to be executed by Ukraine according to Article 46 of the Convention. One of key articles of the Law of 2006 is Article 17, which foresees that national courts shall apply the Convention and case-law of the European Court as a source of law when hearing cases. Analysis of the definitions of the Law of 2006 affirms that case-law of the Court is a case-law of the European Court of Human Rights and European Commission of Human Rights; hence, this means that the case-law of the ECtHR which concerns other states than Ukraine, shall be applied by national courts when solving disputes.

Format of the European Convention and the mechanism owing to which the Convention is enforced — case-law of the European court, create peculiar legal circle i.e. the Convention cannot exist without its being interpreted by the European Court, and the European Court cannot function without the Convention[5].

Taking this legal circle into account let us analyze one of the most important rights in the sphere of health care — right to medical information, the

[3] Івановська А., Юридична природа актів Конституційного Суду України (Ivanovska A. Legal Nature of the Acts of Constitutional Court of Ukraine) // Університетські наукові записки. — 2005. — № 4 (16). — С. 42-50.

[4] Ільченко І. (I. Ilchenko), supra note 2.

[5] Ibidem.

realization of which is closely connected with other rights, in particular right to medical interference, right to refuse from medical interference, right to confidentiality of one's state of health.

Conflicts of laws, discrepancies of laws' application, problematic legal application issues raise the need to work out a scientific and practical way, directed at optimization of the whole range of problems. On the one hand this will simplify realization of the right to medical information and on the other hand, in case of violation of this right, this will favor an effective protection of human rights. In order to illustrate law-enforcement mechanisms we shall take use of not only court decisions, which can be considered as a quasi-source of law, but also other case-law examples, which explicitly highlight problems which an individual faces when exercising his rights.

Regulation of the Right to Medical Information under the Laws of Ukraine

Analyzing the right to medical information in the light of case-law either national or the one of the ECtHR it is important to elucidate the way this right is regulated by the laws, which will illustrate a range of issues, including those which raise the necessity of applying to courts.

In Ukraine, Convention has the same status as other legal acts and it is a part of national legislation of Ukraine according to Article 9 of the Constitution, which foresees the following:

> "International treaties that are in force, agreed to be binding by the Verkhovna Rada of Ukraine, are part of the national legislation of Ukraine. Conclusion of international treaties that contravene the Constitution of Ukraine is possible only after introducing relevant amendments to the Constitution of Ukraine"

Article 8 of the Convention foresees the right to respect for private and family life, which ECtHR applies when trying cases connected with violation of the right to medical information.

A constitutional basis of this right is fixed in Articles 32 and 34 of the Constitution of Ukraine, which provides for the right to examine information about oneself that is not a state secret or other secret protected by the law, at the bodies of state power, bodies of local self-government, institutions and organisations.

Such possibility is regulated in detail in Article 285 of the Civil Code of Ukraine (hereinafter — Civil Code) and paragraph "e" of Article 6 and Article 39 of the Law of Ukraine "On Principles of Ukrainian Health Care Legislation" (hereinafter — Principles).

In particular Article 39 of the Principles foresees that:

> "Article 39 Responsibility to provide medical information
>
> A patient who has reached the age of majority is entitled to receive accurate and complete information about his/her health, including familiarization with relevant medical documentation regarding his/her health.
>
> Parents (adoptive parents), guardians, custodians have the right to obtain information about the state of health of the child or the ward.
>
> A health care employee shall provide a patient with information about his/her health, purpose of proposed examination and treatment, possible prognosis for the disease, including risks to life and health, in an accessible form.

> In case information about patient's disease can worsen his state of health or worsen state of health of persons enumerated in paragraph 2 of this Article, harm the process of treatment, medical staff can provide non-complete information about state of health of a patient, restrict a possibility to familiarize with certain medical records. In the case of death of a patient, members of his family or other persons authorized by them may be present when the causes of his/her death are examined and become acquainted with the conclusions about the causes of death and have the right against these conclusions in the court."

In the context of defining legal boundaries of the right to medical information one should not evade regulation of this right by other social regulator — bioethical norms, which are foreseen in the Code of Ethics of Ukrainian Doctor, which was adopted and signed during All-Ukrainian meeting of doctors' organizations and at the X meeting of All-Ukrainian Doctors' Association (27 September 2009) (hereinafter — Code of Ethics).

Subparagraph 3.7 of the Code of Ethics foresees that a patient has the right to exhaustive information about his health, but a patient can refuse from it or appoint a person, who should be informed about patient's state of health. Information can be concealed from a patient in cases when there are substantial reasons to consider that such information can cause serious harm to a patient. But in case a patient insists on providing him such information a doctor shall provide a patient with exhaustive information. In case of unfavourable prognosis for a patient a doctor should inform him about it delicately and carefully, by leaving a hope to continue the life and possibly a successful result.

Legal Application and Legal Realization Issues

I. As Regards to Conceptual and Categorical Apparatus

Article 39 of the Principles most exhaustively regulates the right to medical information, but, as we can observe, it foresees the right through the prism of a responsibility to provide such information, which is elucidated in the name of Article. It should be noted that when enumerating patients' rights in the Principles the lawmaker didn't follow the lawmaking unification, since, for example, Article 39-1 of the Principles, which guarantees the right to medical confidentiality has the title "Right to confidentiality of one's state of health". Notwithstanding the norms, which are fixed in Article 285 of the Civil Code and Article 39 of the Principles by their content are practically the same, Article of the Civil Code was defined through the right — "Right to information about ones state of health". Again there arises a question: what is the correlation between notions "medical information" and "information about the state of health"? In order to provide the answer to this question we should analyze part 3 of Article 39 of the Principles, which on the one hand foresees a responsibility of a medical professional to provide medical information and on the other hand — from this norm there evolves a definition of the notion "medical information". Hence, the text of this norm provides that information about the state of health is a composite element of medical information.

When carrying out a "normative section" of the right to medical information, of course one of the most important things is clarification of the defini-

tion "medical information". For the first time this term was defined in the judgement of the Constitutional Court of Ukraine in the case as regards to official interpreting of Articles 3, 23, 31, 47, 48 of the Law of Ukraine "On Information" and Article 12 of the Law of Ukraine "On Public Prosecution" (case of K.H. Ustymenko) of 30 October 1997 (hereinafter — judgement in the case of Ustymenko)

> "Medical information that is information about state of health of a person, history of his /her disease, aim of a proposed examinations and medical measures, prognosis of a possible development of disease including availability of a risk to life and health, by its legal regime belongs to confidential information, that is information with limited access. A doctor is obliged to provide such information at the request of a patient, members of his family or legal representatives completely and in accessible form".

Constitutional Court of Ukraine did not simply suggest a definition of the term and thus played a role of a "quasi-lawmaker", but also precisely established the regime of information and a range of subjects, who are entitled to medical information. But it should be noted at once that the interpretation was conducted basing on the wording of Principles which existed at the time the judgement was passed. Of course it doesn't impact the validity of this judgement. As it is defined in the doctrine of the constitutional law legal standpoints of the Constitutional Court of Ukraine are fixed in the acts on official interpretation and in case legal acts were abolished these standpoints can become a legal basis for adoption of a new act instead of the old one and need to be similarly interpreted, hence the importance of the Constitutional Court of Ukraine interpretations may be preserved [(6)]. To prove this statement it should be highlighted that a new wording of the Principles, which is valid today, absorbed the legal standpoint of the Constitutional Court of Ukraine in the judgement of Ustymenko case.

II. As Regards to Access to Medical Information and Getting Familiar with Medical Records.

When realizing the right of a patient to medical information, which is foreseen by Article 285 and Article 39 of the Principles one of the most complicated issues is the aspect of getting familiar with certain medical records, which concern patient's health. Normative regulation of this issue through the prism of a phrase "get familiar" does not explicitly foresee the right to make copies of primary medical records, hence there are numerous difficulties, which patients face when realizing this right.

Often applying to health care facilities with requests to receive copies of necessary medical records does not bring successful results and patients or their legal representatives or their family members, who get familiar with medical information about the person who is under guardianship or about a deceased family member, under the norms of the legislation are ineffectual. Hence the number of cases as regards to protection of this right in courts increased.

In the judgement in the case of Ustymenko Constitutional Court of Ukraine stated that in cases of refusal to provide or in cases of deliberate concealing information from a patient, members of

[(6)] Івановська А. (Ivanovska A.), supra note 3

his family or legal representatives, such actions or omissions to act can be appealed against either to the court, health care facility or state body in the sphere of healthcare at person's choice.

One of the interesting decisions is the decision of Pershotravnevyi district court of the town C. (2012). A plaintiff applied to the court with a claim against the respondent as regards to providing copies of medical records. In her claim plaintiff referred to the fact that on September 9, 2011 she applied to the chief doctor of the Regional clinical hospital as regards to provision of copies of medical records of her husband X, who stayed on in-patient treatment in that health care facility in the resuscitation department from 27 June 2011 till 28 July 2011. Later on, plaintiff received a reply, where it was stated that "primary medical records should not be given out to private persons". The plaintiff indicated that she didn't ask to provide her "primary records", as it was stated in the answer letter to her application, but on the contrary she asked for a copy of her husband medical history. Besides this, plaintiff also applied to regional communal institution "Hospital of Emergency Medical Care" as regards to providing her copies of medical history of her husband X., who was admitted to the urological department on the 20 of June, 2011 and was discharged from the resuscitation ward on the 27 of June, 2011. Similarly in this case plaintiff received the response to her application, by which she was refused of receiving copies of her husband medical history.

Having tried the case, Pershotravnevyi district court of the town of C. satisfied the complaint and obliged Regional clinical hospital and Hospital of Emergency Medical Care to provide copies of medical history of X. completely and found the actions of the respondents to be unlawful. When passing a decision the court basically relied on Article 285 of the Civil Code of Ukraine, which foresees the right of the deceased person family members to be present and observe the process of examining reasons for death of a person and get familiar with the conclusion as regards to the persons death. In its decision the court also referred to the standpoint of the Constitutional Court of Ukraine, fixed in its judgement in Ustymenko case of 30 October 1997, where it goes about doctor's obligation to provide medical information completely and in accessible manner upon patient's request or request of patient family members.

Very important is the standpoint of the ECtHR, which was expressed in judgement in case of K.H. and others v. Slovakia (2009) [7], when the ECtHR noted that the complaint in issue concerned the exercise by the applicants of their right of effective access to information concerning their health and reproductive status. Such information under the Court's point of view was linked to the applicants' private and family lives within the meaning of Article 8. In this case the ECtHR noted the following:

> "Bearing in mind that the exercise of the right under Article 8 to respect for one's private and family life must be practical and effective, the Court takes the view that such positive obligations should extend, in particular in cases like the present one where personal data are concerned, to the making available to the data subject of copies of his or her data files".

[7] *K.H. and Others v. Slovakia*, no. 32881/04, ECHR, 2009.

> The applicants in that case obtained judicial orders permitting them to consult their medical records in their entirety, but they were not allowed to make copies of them under the Health Care Act 1994.
>
> Although it was not for the applicants to justify the requests for copies of their own medical files, the Court would nevertheless underline that the applicants considered that the possibility of obtaining exclusively handwritten excerpts of the medical files did not provide them with effective access to the relevant documents concerning their health. The original records, which could not be reproduced manually, contained information which the applicants considered important from the point of view of their moral and physical integrity as they suspected that they had been subjected to an intervention affecting their reproductive status.
>
> The Court also observes that the applicants considered it necessary to have all the documentation in the form of photocopies so that an independent expert, possibly abroad, could examine them, and also in order to safeguard against the possible inadvertent destruction of the originals are of relevance.
>
> There has therefore been a failure to fulfill the positive obligation to ensure effective respect for the applicants' private and family lives in breach of Article 8 of the Convention".

Of course such legal standpoint of the ECtHR, which is a source of law for Ukraine, definitely resolved the problem as regards to correct understanding of competent state bodies' obligation to provide for effective realization of the right to information in the aspect of receiving copies of medical records.

Within the above-mentioned legal standpoints of judicial instances it is worth making several scientific and practical comments as regards to these issues.

1. Right to medical information, including the right to get familiar with medical records belongs to an adult patient. Before the age of 18 such right should be vested with his/her parents or other parents, who are acting in his/her interests. To realize ones right to get familiar with medical records a person should apply legal guarantees, which are fixed in the Law of Ukraine "On Personal Data Protection" in addition to provisions, foreseen in part 1 of Article 285 of the Civil code, part 1 of Article 39 of the Principles. According to Article 8 of the Law of Ukraine "On Personal Data Protection", a subject of personal data (i.e. a patient in our case) has the right to access his personal data. Personal non-property rights to personal data, which are enjoyed by every person, are inalienable and inviolable.
2. To receive personal data, in particular, copies of medical records, it is necessary to prepare a request for access to personal data, which should be then submitted to the owner of personal data (or administrator, who acts according to the contract, which was concluded with the owner in written form), in particular health care facilities notwithstanding their form of property, according to Article 2, part 2 of Article 4 of the Law of Ukraine "On Personal Data Protection".
3. Request for access to personal data shall meet the established requirements as regards to its content. A patient should indicate:

    1) Full name, place of residence (abiding-place) and details of the document proving his identity (for instance passport);

2) Information on the basis of personal data in respect of which the request is submitted, or information about the owner or manager of personal data (the patient should clearly indicate the health care facility, where his personal data are preserved, place of registration of the legal entity, etc.);
3) A list of personal data, which are requested (it is worth clearly indicating which copy of medical records the patient needs, including for example, the number of medical card, since the patient at discharge gets discharging epicrisis, where this number is indicated);
4) The purpose and/or the legal basis for the request (a person should indicate not only the basic legal norms governing access to personal data, but also necessary legal acts, which fix the right to medical information).

4. It is worth paying attention to the decision, passed by the Pershotravnevyi district court of the town of C. Which when hearing the case applied the Law of Ukraine "On Access to Public Information". Basically the dispute had been resolved correctly, but on the same time a wrong legal basis was chosen, since in that case the court should apply provisions of the Law of Ukraine "On Personal Data Protection", which had been in force at the material time of the legal relations.
5. A request of a patient should be satisfied within the time period of 30 calendar days, starting from the day such request was received. An access to personal data can be postponed to a maximum of 45 calendar days, about what an applicant should be informed.
6. A refusal in access to personal data should be conducted in written from, where reasons for such refusal must be indicated. A refusal can be permitted in case the access to such data is forbidden by the law.
7. It should be noted that under part 1 of Article 19 of the Law of Ukraine "On Personal Data Protection" access of patients' personal data is free of charge.
8. It is worth paying attention to one more mechanism of receiving access to personal data, which is fulfilled owing to other authorized persons, for instance, lawyers, which happens quite seldom in practice. A lawyer has a specific legal instrument — lawyer's request. Order of lawyer's request execution is regulated by Article 24 of the Law of Ukraine "On Advocacy and Advocate's Activity". In this aspect it is worth pointing out several accents:

8.1. One should keep in mind that copies of two documents verified by the lawyer shall be added to the lawyer's request a) certificate for advocate's activity; b) warrant or a proxy granted by the body of state power, authorized to provide free legal aid.
8.2. A reply to lawyer's request shall be provided not later than 5 days starting such request was received. A term of providing reply to lawyer's request can be pro-

longed for not more than 20 workdays with taking into account information that is requested (for instance, preparation of a big amount of information).

8.3. If replying to lawyer's request foresees preparation of copies of documents amounting more than ten pages, a lawyer shall compensate for actual expenses for making copies and printing.

8.4. A lawyer is entitled to receive upon his request information or copies of documents with the exception of information with limited access and copies of documents, which include information with limited access. According to Article 21 of the Law of Ukraine "On Information" there are three types of information with limited access, i.e. confidential, secret and official (service) information. Medical information belongs to confidential. Taking into account the above mentioned we can sum up that a lawyer can only demand information about his client, with whom he concluded a legal aid agreement or who authorized a lawyer to represent his interests by granting a proxy. In this case a client should grant his lawyer such a power — receive access to personal data.

First of all it is worth highlighting that right to medical information, within the context of protection from illegal disclosure, is closely connected with the right to confidentiality of a state of health, which is the guarantee of the first right.

Hence, it is relevantly to figure out national laws, which foresee one more patient's right — right to confidentiality of a state of health, in particular Article 286 of Civil Code and Article 39-1 of the Principles:

> "A patient has the right to confidentiality regarding one's state of health, the fact of seeking medical assistance, diagnosis and the information obtained during one's medical examination.
>
> One may not demand and provide information about the diagnosis and treatment of an individual at his/her place of work or study".

One more legal norm in this context is foreseen in Article 40 of the Principles, which is called "Medical Confidentiality", which explicitly provides for a responsibility of medical professionals and other persons, who in the course of fulfilling their professional or service duties got to know about a disease, medical examination, medical survey and its results, intimate and family sides of a person, not to disclose such information, with the exception of cases foreseen by the law.

In the judgement in Ustymenko case Constitutional Court of Ukraine defined a rule of applying information about person's state of health: medical secret — information about the patient and medical information is information for the patient. As we can see the preposition changes essence of a phrase. With the view of the above mentioned, in order to point out joint legal application segments in each of these rights we suggest one more rule: medical secret = medical information + information of non-medical character. Hence, there is no doubt as regards to the fact that the grounds for research as

well as intertwining of mechanisms of these rights realization and protection are common.

National court practice is full of examples, where on the one hand a subject of an application thinks that he has the right to medical information and demands such information lawfully, while on the other hand — such provision of information can bear unlawful character and so violate the right of other person to confidentiality of his/her state of health. Lack of knowledge of the peculiarities of these rights realization raises numerous problems and court cases in practice.

For instance, in June 2012 X. applied to the court with a lawsuit against central district hospital A. and asked the court to find actions of the respondent hospital illegal and oblige the respondent to execute certain actions. X. substantiated her claims by the following facts: when she stayed on in-patient treatment in the central district hospital A. on the 19th of February 2012 C. committed against X. a transgression. At lawyer's request, who represented interests of X. as regards to the period of C's staying in the hospital and reasons for staying in the hospital, her diagnosis and her state of health as well as reasons for terminating treatment, respondent hospital provided a response indicating that C. was discharged from hospital for violating rules of the hospital. Referring to the fact that X. didn't receive full response, X. asked the court to find actions of the Central district hospital illegal and oblige a hospital to provide her full response at her lawyer's request as regards to treatment of C. By the decision of B. district court of 30 October 2012 X. was refused in satisfying her lawsuit.

By resolution of the court of appeal of S. region (2012) an appeal of X. was rejected and decision of the B. district court was left without changes.

Of course in this case the lawyer exceeded his powers and by his request wanted to obtain information about the state of health of a person, who wasn't his client, which is illegal. Information about C. is confidential, and hence should not be disclosed to a lawyer. We cannot exclude the fact that the lawyer needed such information in order to fulfill his professional duties, but he would be able to receive such information at the court's order, by submitting a petition, when the case was already tried by the court.

Another example is: D. filed a lawsuit against central district hospital No. 1. In order to prove his claims, plaintiff indicated that the respondent upon lawyer of C. request disclosed information about D's applying to the first-aid center on 2 March, 2002 and D's diagnosis without D's prior consent. This information was used against D. and caused him material and moral damages. D. asked the court to find actions of the central district hospital No. 1 as regards to providing lawyer of C with information about D's state of health illegal and oblige a respondent hospital compensate D. 235,5 hryvnias for material damages and 10000 hryvnias for moral damages. By decision of the F. district court of the city of H. of 21 March 2011a lawsuit was left without satisfaction.

Appellate court of R. region (2011) after hearing the appeal of D. repealed a first instance court decision in part where the first instance court refused finding actions of the respondent hospital illegal and thus in this part, appellate court satisfied claims of

a D. and found actions of the respondent hospital illegal.

When passing its decision the first instance court referred to the norms of the Law of Ukraine "On Advocacy" of 12 December 1992 (was current at the material rime of a dispute), in particular Article 6 of this law, which provided for the right of a lawyer to collect data about facts, which can be used as evidence in civil, commercial and criminal cases when carrying our his duties of providing legal aid. Appellate court did not agree with such position of the first instance court and referred to Article 39-1 of the Law of Ukraine "On Principles of Ukrainian Health Care Legislation", which foresees the right of patient to confidentiality of his state of health, the fact of seeking medical assistance, diagnosis and the information obtained during one's medical examination. Appellate court put into the basis of his decision part 2 of Article 11 of the Law of Ukraine "On information", which forbids collecting, storing, applying and disseminating confidential information about a person, except other is foreseen by the law.

It is worth noting that Appellate court of R. region correctly defined a conflict between the right to medical information and right to medical confidentiality, when satisfying claims of D. since in this case the lawyer was not entitled to receive information about D's state of health, as he wasn't empowered for representing interests of D. In this case a right to medical confidentiality of one's state of health was violated and the court of appeal in its turn provided for protection of this right.

In this context it is worth pointing out rich case-law of the ECtHR. In its judgement in case of M.S. v. Sweden (1997) [8] ECtHR highlighted the following:

> "Protection of personal data, particularly medical data, is of fundamental importance to a person's enjoyment of his or her right to respect for private and family life as guaranteed by Article 8 of the Convention. Respecting the confidentiality of health data is a vital principle in the legal systems of all the Contracting Parties to the Convention. It is crucial not only to respect the sense of privacy of a patient but also to preserve his or her confidence in the medical profession and in the health services in general. The domestic law must afford appropriate safeguards to prevent any such communication or disclosure of personal health data as may be inconsistent with the guarantees in Article 8 of the Convention".

In its judgement in case Z v. Finland (1997) [9] the ECtHR noted the following:

> "Court will take into account that the protection of personal data, not least medical data, is of fundamental importance to a person's enjoyment of his or her right to respect for private and family life as guaranteed by Article 8 of the Convention. Respecting the confidentiality of health data is a vital principle in the legal systems of all the Contracting Parties to the Convention. It is crucial not only to respect the sense of privacy of a patient but also to preserve his or her confidence in the medical profession and in the health services in general.
>
> Without such protection, those in need of medical assistance may be deterred from revealing such information of a personal and intimate nature as may be necessary in order to receive appropriate treatment and, even, from seeking such assistance, thereby endangering their own health and, in the case of transmissible diseases, that of the community.

[8] *M. S. v. Sweden*, no. 74/1996/693/885, ECHR, 1997.
[9] *Z. v. Finland,* no. 22009/93, ECHR, 1997.

> The domestic law must therefore afford appropriate safeguards to prevent any such communication or disclosure of personal health data as may be inconsistent with the guarantees in Article 8 of the Convention.
>
> The above considerations are especially valid as regards protection of the confidentiality of information about a person's HIV infection. The disclosure of such data may dramatically affect his or her private and family life, as well as social and employment situation, by exposing him or her to opprobrium and the risk of ostracism. For this reason it may also discourage persons from seeking diagnosis or treatment and thus undermine any preventive efforts by the community to contain the pandemic. The interests in protecting the confidentiality of such information will therefore weigh heavily in the balance in determining whether the interference was proportionate to the legitimate aim pursued. Such interference cannot be compatible with Article 8 of the Convention unless it is justified by an overriding requirement in the public interest.
>
> In view of the highly intimate and sensitive nature of information concerning a person's HIV status, any State measures compelling communication or disclosure of such information without the consent of the patient call for the most careful scrutiny on the part of the Court, as do the safeguards designed to secure an effective protection".

Quite positive seem to be guarantees, foreseen by the national laws, in particular Law of Ukraine "On Resistance to Diseases Caused by Human Immunodeficiency Virus (HIV), and Legal and Social Protection of People Living with HIV" for people, who are living with HIV, in particular those, which are connected with protection of their medical information. Part 1 of Article 13 of this Law provides that all people living with HIV enjoy the right to unimpeded getting familiar with information about one's state of health, which is stored in health care facilities.

In the meaning of the abovementioned Law, medical information comprises such data: a) information about the results of testing in order to detect HIV; b) whether a person is or is not infected with HIV. Medical professionals are obliged to take all necessary steps to secure proper storage of confidential information about persons, who are living with HIV and protection of such information from being disclosed. The laws provide for explicit range of subjects whom a medical professional can disclose such data lawfully:

1) A person, who underwent testing;
2) As regards to patients, who are under 14 — their parents or other legal representatives of such person;
3) Other medical professionals and health care facilities — only if such disclosure is connected with treatment of such person and upon an informed consent of this person provided in written form.
4) Other persons — only under the court decisions and in cases foreseen by the law.

Not less important is a legal standpoint of the ECtHR, which was elucidated in its judgement in the case I v. Finland (2008) [(10)].

> "Between 1989 and 1994 the applicant worked on fixed-term contracts as a nurse in the polyclinic for eye diseases in a public hospital. From 1987 she paid regular visits to the polyclinic for infectious diseases of the same hospital, having been diagnosed as HIV-positive.

[(10)] *I. v. Finland,* no. 20511/03, ECHR, 2008.

Early in 1992 the applicant began to suspect that her colleagues were aware of her illness. At that time hospital staff had free access to the patient register which contained information on patients' diagnoses and treating doctors. Having confided her suspicions to her doctor in summer 1992, the hospital's register was amended so that henceforth only the treating clinic's personnel had access to its patients' records.

The Court observes that it has not been contended before it that there was any deliberate unauthorized disclosure of the applicant's medical data such as to constitute an interference with her right to respect for her private life. Nor has the applicant challenged the fact of compilation and storage of her medical data. She complains rather that there was a failure on the part of the hospital to guarantee the security of her data against unauthorized access, or, in Convention terms, a breach of the State's positive obligation to secure respect for her private life by means of a system of data protection rules and safeguards.

The protection of personal data, in particular medical data, is of fundamental importance to a person's enjoyment of his or her right to respect for private and family life as guaranteed by Article 8 of the Convention. Respecting the confidentiality of health data is a vital principle in the legal systems of all the Contracting Parties to the Convention. It is crucial not only to respect the sense of privacy of a patient but also to preserve his or her confidence in the medical profession and in the health services in general. The above considerations are especially valid as regards protection of the confidentiality of information about a person's HIV infection, given the sensitive issues surrounding this disease. The domestic law must afford appropriate safeguards to prevent any such communication or disclosure of personal health data as may be inconsistent with the guarantees in Article 8 of the Convention.

The Government has not explained why the guarantees provided by the domestic law were not observed in the instant hospital. The Court notes that it was only in 1992, following the applicant's suspicions about information leak, that only the treating clinic's personnel had access to her medical records. The Court also observes that it was only after the applicant's complaint to the County Administrative Board that a retrospective control of data access was established. Consequently, the applicant's argument that her medical data were not adequately secured against unauthorized access at the material time must be upheld.

The Court notes that the mere fact that the domestic legislation provided the applicant with an opportunity to claim compensation for damages caused by an alleged unlawful disclosure of personal data was not sufficient to protect her private life. What is required in this connection is practical and effective protection to exclude any possibility of unauthorized access occurring in the first place. Such protection was not given here. There has therefore been a violation of Article 8 of the Convention".

National health care system is being also transferred to electronic database of personal data of patients starting from the pilot region of the state (city of Kyiv, Dnipropetrovs and Vinniza regions), where this system is being experimentally reformed. According to the resolution of the Cabinet of Ministers of Ukraine "On Approving a Regulation on Electronic Register of Patients" of 6 June, 2012 No. 546, register is a unitary information system of storing, updating, using and circulating by way of disseminating, realization and transferring as well as destroying data about a natural person and medical care, which was provided to him/her. Owners of the register (health care facilities) if there exists a patient's consent to processing of his/her personal data, include information to the register, process this information and provide for protection of personal data, which are included to the register.

The Law of Ukraine "On Personal Data Protection" implemented an important application construction — consent to processing of personal data. In the sphere of health care there had been devel-

oped a typical form "Informed Voluntary Consent of a Patient to Processing of Personal Data" which was normatively fixed in two by-law acts, in particular in Order of the Ministry of Health of Ukraine "On Approving Forms of Primary Registration Records and Instructions of their Filling in, which Are Used in Health Care Facilities Notwithstanding their Form of Property and Subordination" of 14 February 2012 No. 110 and in Order of the Ministry of Health "On Approving Forms of Primary Registration Records and Instructions of their Filling in, which Are Used in Health Care Facilities that Provide Out-patient and Policlinic and In-patient Treatment to the Population Notwithstanding their Form of Property and Subordination" of 25 May, 2013 No. 435. Each of these forms is used together with normatively fixed medical records.

Issue of getting familiar with relevant medical records, which are a source of medical information, is full of practical questions and raises a necessity for legal regulation through the prism of securing the right of a patient not to get familiar, but to make copies of relevant medical records, which concern his/her health.

III. As Regards to Peculiarities of Medical Information

Analysis of current legislation enables to enumerate peculiarities of medical information, these are: a) accessibility; b) accuracy; c) completeness; d) timeliness [(11)].

Accessible form of information has two aspects. External, which lies in patient's or his legal representative's or any person, authorized by them (for instance, lawyer) access to such information, that is by filing a request and as a consequence receiving such information. Internal — providing information in an understandable for a patient or other competent subject manner.

Accuracy of information means providing information, contained in medical records.

Completeness of information shall be considered in two variants: the first one lies in providing information according to a request, which was formulated in a procedural document of a competent subject, request of a patient for access to personal data, request of a legal representative, lawyer's request. A second one lies in doctor's providing information before carrying out medical interference, hospitalization etc, in amount caused by a specific situation when receiving informed, and voluntary consent of a patient to diagnostics procedure, treatment, carrying out surgical operation and anaesthetize. A form of such consent was normatively stipulated in order of the Ministry of Health of Ukraine "On Approving Forms of Primary Registration Records and Instructions of their Filling in, which Are Used in Health Care Facilities Notwithstanding their Form of Property and Subordination" of 14 February 2012 No. 110

Timeliness of information manifests itself in two forms of exercising the responsibility of providing medical information, in particular: a) providing information requested within a timeframe set by the law; b) providing medical information prior to the moment medical care is provided.

[(11)] Byrne I., Ezer T., Cohen J., Overall J., Senyuta I. Human Rights in Patient Care: A Practitioner Guide/ Under scientific editing of Senyuta I. — L'viv: LOBF Publishing House «Medicine and Law», 2012. — 497 p. — P. 381.

In the judgement in case R.R. v. Poland (2011) [12] the ECtHR defined:

> "The right of access to such information falling within the ambit of the notion of private life can be said to comprise, in the Court's view a right to obtain available information on one's condition. The significance of timely access to information concerning one's condition applies with particular force to situations where rapid developments in the individual's condition occur and his or her capacity to take relevant decisions is thereby reduced.
>
> In the same vein, in the context of pregnancy, the effective access to relevant information on the mother's and foetus' health, where legislation allows for abortion in certain situations, is directly relevant for the exercise of personal autonomy. On the 18th week of the applicant's pregnancy there was carried out an ultrasound scan. Later a physician estimated that it could not be ruled out that the foetus was affected with some malformation and informed the applicant thereof. The applicant told him that she wished to have an abortion if the suspicion proved true.
>
> In the present case the essential problem was precisely that of access to medical procedures, enabling the applicant to acquire full information about the fetus' health.
>
> The Court observes that the nature of the issues involved in a woman's decision to terminate a pregnancy is such that the time factor is of critical importance. The Court is of the view that there was ample time between week 18 of the pregnancy, when the suspicions first arose, and week 22, the stage which is regarded as time-limit for legal abortion when genetic testing could have been performed.
>
> As a result, the applicant was unable to obtain a diagnosis of the fetus' condition, established with the requisite certainty, by genetic tests within the time-limit for abortion to remain a lawful option for her.
>
> The Court concludes that it has not been demonstrated that Polish law as applied to the applicant's case contained any effective mechanisms which would have enabled the applicant to seek access to a diagnostic service, decisive for the possibility of exercising her right to take an informed decision as to whether to seek an abortion or not.
>
> The Court concludes that the authorities failed to comply with their positive obligations to secure to the applicant effective respect for her private life and that there has therefore been a breach of Article 8 of the Convention".

It seems that every peculiarity of medical information can raise a necessity for the protection of a person's rights both by national and international instruments.

Every peculiarity serves for better understanding of the amount of the right to medical information as well as its legal application features and if it is necessary its protection.

Concluding Remarks

When researching different elements of the right's to medical information structure we can figure out several remarks, which will favor optimization of legal realization and legal application:

1. It is worth changing the formulation of ability in the legislation from the right to information about one's state of health into right to medical information, which is more correct within the frameworks of correlation between notions, since medical information — is the entirety and respectively, information about a state of one's health is its integral part.
2. Wording of Article 39 of the Principles should be changed: name of Article should

[12] *R.R. v. Poland,* no. 27617/04, ECHR, 2011.

be elucidated through the prism of a right instead of an obligation as it is today, which in its turn will provide for normative uniformity as well.

3. On the level of Civil Code and Principles it is necessary to guarantee the right to receive copies of medical records, which concern state of health of a patient, instead of right to get familiar with medical records.
4. Legal standpoints of the ECtHR and other courts, legal acts of which are considered as quasi-sources of law shall be researched in order to effectively secure the right of a person by all court instances and in order to improve national laws of Ukraine.
5. Doctrinal and practical research was carried out in order to focus the attention on the necessity of uniform and correct application of material norms which regulate relations, connected with realization of the right to medical information by the courts.
6. It is the court practice that explicitly "uncovers" problems, which shall be resolved in a complex way both legislatively and by way of effective judicial and other law-enforcement procedures.

PATIENT SAFETY AT ODDS WITH PATIENT PRIVACY? THE CASE OF NATIONAL AND REGIONAL QUALITY REGISTRIES FOR INCAPACITATED ELDERLY IN SWEDEN

Titti Mattsson [1]

1. Introduction

Different methods exist for measuring and developing operational quality within health and medical care services. In Sweden, the national and regional quality registries [2] play an increasingly large role in this development. According to the Health and Medical Services Act (1982:763) Section 31, the quality of Swedish health and medical care should be systematically and continuously improved and assured. Working with quality registries is one way of fulfilling this legislative requirement. In the registries, patient-related data is gathered from many different care givers about diagnosis, measures taken, results of treatment etcetera. The collected health data is processed, compared and analysed, and used to increase the quality of health and medical care on different levels. For example, with the data, a successful treatment or procedure for a particular patient group — say, stroke patients — may be found, and this knowledge can be used to change routines and procedures at health clinics in Sweden to create better and safer health care for stroke patients. The purpose of the quality registries is exactly this: to develop and ensure the quality of care and patient safety. The personal data may also be processed for certain other purposes, such as for research.

Sweden has unique opportunities for quality registers because it has comprehensive population registers and unique personal identification numbers. Sweden has a tradition of maintaining national, individual-based registers. The population register dates back to the 18th century. The personal identity number was introduced in the middle of the 20th century and covers the whole population. The number is used by the health care authorities in medical records and it provides secure identification of all individuals. Since the 1970s, there has been continuous development of nationwide quality registries to assess health care in Sweden. The first quality register, the Swedish Knee Arthroplasty Register, started in 1975 [3]. There are currently 106 national

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[2] In addition, there are local quality registries with data from the one care giver; however, these registries are not discussed in the article.

[3] See http://www.knee.nko.se/english/online/thePages/contact.php. Retrieved 24 January 2014.

quality registers funded by the state and the county councils. [4] These registries have various origins and purposes. For example, some registries have been developed to describe geographic variations in the use of different treatment methods. Other records are designed to highlight differences in health care utilisation and medical practice. There are also records based on individual procedures (such as knee replacement or hip surgery), on specific diagnoses (such as dementia or diabetes) and on particular areas where there are known risks (e.g. fall risks for the elderly) [5].

Since 2008, national and regional quality registries are regulated by the Patient Data Act (2008:355). According to the Act, care givers are allowed to collect and process personal data in a registry for the primary purpose of developing and securing the quality of health and medical care. Since some years back, the expansion and addition of quality registries has been promoted by the government, which pushes the development forward with economic incentive to the care givers.

It is considered also that people with limited or no decision-making capacity need to be addressed in the national and regional quality registries. The argument is that regular controls of accidents or successful treatments experienced by patients with cognitive impairments at regional health units could increase patient safety and care quality for the patients of the future. For example, to develop successful health care for dementia, related health care needs to be evaluated regularly, and this requires the participation of patients with dementia. However, there is an ethical problem in gathering data about people without decision-making capacity and using this data for clinical evaluations and in research. Unlike many other patient groups, these individuals are often unable to refuse the data collection. According to law, registration in national and regional quality registers is not a mandatory duty for the patients [6]. The Patient Data Act Chapter 7 Section 2 gives the individual the possibility to avoid being registered in a quality registry and this right also applies after the processing of personal data has commenced. However, for natural reasons the right to refuse is limited to those with enough cognitive capacity to do so.

This article deals with the personal privacy of patient groups suffering from severe cognitive impairments, with particular focus on the incapacitated elderly. I argue that there is a risk that the data collection into national and regional quality registries conflicts with the right to privacy of this group. This article discusses the problem of collecting data with the aim of increasing patient safety while simultaneously doing so in the absence of consent from the patient. After an initial discussion about the topic as such, attention is given to the case in Swedish legislation when a person, due to severe cognitive impairments, lacks the capacity to refuse

[4] Riksrevisionen, *RiR 2013:20 Statens satsningar på nationella kvalitetsregister — Leder de i rätt riktning?* (Stockholm: Riksrevisionen, 2013), p. 4.

[5] *Ibid.*

[6] Reporting to the National Board of Health and Welfare (Socialstyrelsens) five national health data registers (the Patient Register, the Medical Birth Registry, the Cancer Registry, the Drugs Registry and the Dental Health Registry) is mandatory according to law. Registration in the national and regional quality registers, however, is optional for health care entities.

participation in data collection in the national and regional quality registries. In addition, the regulation and practice of allowing registry-based research on incapacitated elderly persons is examined. The concluding part contains a few reflections about the need for protective legislation to avoid the conflict between the general aim to promote patient safety and the vulnerable individual's right to privacy.

2. National and regional quality registries

2.1. Regulation and organisation

In the Patient Data Act, quality registries are defined as automatic and structured collections of personal data with the purpose of systematically and regularly developing and ensuring the quality of health care (Chapter 7 Section 1). The aim of the regulation is both to facilitate enhanced patient safety and maintain a strong protection of privacy [7]. The registries are developed through collection of patients' personal data from several care givers in order to make comparisons of health care on a national and regional level [8]. The data is often retrieved from the patients' medical records [9]. The Patient Data Act regulates the processing and use of this data [10]. In addition, there are some general provisions in the Personal Data Act (1998:204); this means that when the Patient Data Act does not contain any relevant rules, the provision of the Personal Data Act will apply.

In Swedish health care, the presumption is for secrecy and confidentiality of the medical records and other personal data of the patients [11]. However, under certain conditions the data can be disclosed. The regulation may be designed as a duty or a possibility to disclose data [12]. Reporting to quality registries is voluntary for the care giver. According to the Public Access to Information and Secrecy Act (2009:400) Chapter 25 Section 11, a public care giver is allowed to disclose data to a national or regional quality registry for the purpose of quality assurance of care. In the preparatory works, it is stated that this regulation should naturally apply to private care givers as well [13]. Every registry must have a national or regional health care authority within the health sector which is responsible for the use of the personal data that is collected in the registry. Often it is a county council or a national authority which has this responsibility. Each hospital, or other local care giver, that collects data for a registry is responsible for its local register process. For example, the party who is the personal data

[7] Prop. 2007/08:126 Patientdatalag m.m. p. 177.
[8] *Ibid,* p. 176.
[9] *Ibid,* p. 195.
[10] SOU 2006:82 p. 36.

[11] Public Access to Information and Secrecy Act (2009:400), Ch. 25 Sec. 1.

[12] There are numerous statutes in Sweden issued by the government and the parliament that require data to be disclosed. This situation is criticised in legal doctrine; see U. Sandén, *Sekretess och tystnadsplikt inom offentlig och privat hälso- och sjukvård. Ett skydd för patientens personliga integritet*, (Umeå: Skrifter från juridiska institutionen vid Umeå universitet nr 27, 2012). She argues that the situation is unacceptable from the perspective of patient privacy. It is impossible for a patient in Sweden to know what personal data has been disclosed to other persons or authorities without his or her consent or knowledge.

[13] *Supra* note 7 p. 197. However, extended use of a rule exempting sensitive data from secrecy so private care givers may have access to the data is not desirable from a right-to-privacy perspective. See Sandén, *supra* note 12, p. 208.

controller has the duty to ensure that the person who is being registered receives information about the processing of personal data.

A national strategic group makes decisions concerning the overall development of quality registries in Sweden [14]. The group consists of representatives from the government and the municipalities [15]. In addition to the strategic group, there is an operative unit and an expert group with more practical duties, such as managing funding of the registry centres [16]. Since 2012, there is a National Registry Service at the National Board of Health and Welfare (Socialstyrelsen). The aim is to contribute to high quality of the registries and to make them useful for the clinical community and researchers. This board is also supposed to assist when researchers need to merge or cross-check data in registries, for example between a national quality registry and one of the national registries of the National Board of Health and Welfare, such as the Health Data Registry or the Patient Registry.

There is a strong desire on the part of the Swedish government to develop the national and regional quality registries further. The registries are considered to be very important tools for health care to provide patient care and safety in Sweden. To encourage the development of the national and regional registries, the caregivers receive financial compensation for each registration. As mentioned above, it is not mandatory for a care giver to report data to a quality registry [17]. The quality registries are therefore dependent on the interest of the care giver to supply the registries with data. The use of quality registries has increased significantly after the government approved high levels of compensation. In 1990, the government distributed SEK 2 million to five national quality registers. State funding has increased significantly from 2010 onwards. In 2013 the government allocated SEK 600 million for investments relating to national quality registers [18]. In addition, the county councils have a separate reimbursement system for the regional registers [19]. However, in a recent report, the Swedish National Audit Office questions whether the Swedish state investments in the registers strengthen the development of quality of care in practice [20].

2.2. Health data from incapacitated elderly

From a patient safety perspective, many registries provide information that helps health care workers to identify risks and proactive working methods to

[14] For more information, see http://www.kvalitetsregister.se/om_kvalitetsregister/quality_registries. Retrieved 21 January 2014.

[15] Handbok för kvalitetsregister med SLL som huvudman, Karolinska institutet and Stockholms läns landsting, Stockholm 2012 p. 4.

[16] There are eight registry centres; QRC Stockholm, EyeNet Sweden, Registercentrum Syd, KCP (Kompetenscentrum för psykiatriska och andra kvalitetsregister Örebro Uppsala), UCR (Uppsala Clinical Research Center), Registercentrum norr, Registercentrum Västra Götaland and RCSO (Registercentrum Sydost); see http://www.kvalitetsregister.se/om_kvalitetsregister/quality_registries. Retrieved 20 January 2014.

[17] For other kinds of registries, there may be a statutory duty to report health data in Sweden. According to the Health Data Registry Act (1998:543) Section 6, public and private care givers have a duty to report certain health data to the National Board of Health and Welfare.

[18] *Supra* note 4.

[19] See http://www.demenscentrum.se/Nyheter/kvalitetsregister. Retrieved 2 December 2014.

[20] *Supra* note 4. The National Audit Office is part of the central control power of the Swedish Riksdag (Parliament) with the duty to perform an independent audit of all state finances.

prevent health damage. The contents of the registries are the basis for the open reporting of content and outcomes of care. However, a prerequisite for this is that the current data is available and can be followed over time. In addition, the national quality registries need to have a significant range to be useful for systematic improvement in health care. If data from persons with impaired decision-making capacity is missing in the records, the data may become less reliable. Then there is a risk that the effect on improving patient safety diminishes. Therefore participation of all groups is considered necessary, including incapacitated elderly.

Many quality registers focus on specialised care and specific treatments, but during the last ten years they have also started to address a broader patient population, including elderly people with multiple diseases and elderly with cognitive impairments. Some examples of national registries are Senior Alert, Swedish Dementia Registry (SveDem), BPSD (Behavioural and Psychological Symptoms of Dementia) and the Swedish Stroke Register Riks-Stroke. *Senior Alert* focuses on risk prevention for the elderly and collects data on accidents or risk of accidents, malnutrition, oral hygiene, weight loss, pressure ulcers etcetera. The registry has most county councils and municipalities connected to the registry in over 12 000 health units. The registry has data on 358 000 elderly in Sweden [21]. *The Swedish Dementia Registry, SveDem*, is a national quality registry for dementia disorders. Currently 93 per cent of all memory clinics in Sweden are participating in SveDem [22]. The aim of the registry is to improve the quality of diagnostics, treatment and care of patients who suffer from dementia disorders. Patients diagnosed with such disorders are registered and are then followed up every year. In the registry, parameters such as age, gender, heredity, BMI, MMSE scores, diagnoses, dementia work-up investigations, medical treatment, support from the community, time from referral to diagnosis etcetera are collected [23]. Almost 34 000 patients were registered and around 18 000 were followed up in September 2013 [24]. *BPSD* is a registry with the aim of improving the quality of care of patients with dementia and to achieve a national standard of care for these patients throughout Sweden [25]. The registry collects data on the frequency and severity of BPSD, current medical treatment, possible causes of BPSD etcetera. The registry has been operating since 2010 and is in use throughout many regions of Sweden [26]. Finally, *Riks-Stroke* started in 1994 and is one of the world's largest stroke registers. All hospitals in Sweden with acute stroke patients participate in the registry. The aim of the register is to support high-quality care for stroke patients throughout the country [27].

As mentioned above, participation in national and regional quality registries in Sweden is volun-

[21] See http://www.lj.se/infopage.jsf?nodeId=40605. Retrieved 24 January 2014.

[22] See http://www.ucr.uu.se/svedem/index.php/about-svedem. Retrieved 20 January 2014.

[23] *Ibid.*

[24] *Ibid.*

[25] http://www.bpsd.se/in-english/. Retrieved 24 January 2014.

[26] *Ibid.*

[27] http://www.riks-stroke.org/?content=&lang=eng&text=. Retrieved 20 January 2014.

tary. Before personal data is treated in a registry, the responsible authority has to give information to the patient. Information is to be provided in accordance with the Patient Data Act, Chapter 8, Section 6. This includes information such as which national or regional health care authority is responsible for the use of the personal data, the aim of the registry, which data will be stored and the possibility to refuse to provide data to the registry. In addition, according to Chapter 7 Section 3, patients must also be informed about their right to request at any time that all personal data be erased. For cases in which it is not possible to provide the information before personal data processing is started, it must be provided as soon as practicable thereafter in accordance with the same section. The patient may always oppose the registration. The law imposes no requirement on any consent from the individual. Instead, the patient is given an opportunity to object to the processing of the data. This is sometimes referred to as "opting out" where the person's privacy is protected by his or her right to refuse registration of the information provided. In the preparatory works it is also described as a quiet consent from the patient [(28)].

How, then, does the system of registering incapacitated persons work in order to include these groups? The rights to information and to oppose registration presuppose personal capacity to understand the information provided and to be able to form an opinion about whether or not to participate. The legal framework does not regulate this situation [(29)]. For a long time, the situation was not an issue, and registering was taking place without an investigation of the legality of the procedures. During recent years, this situation has led to several critical remarks by the Data Inspectorate (the supervisory body). A couple of years ago, the authority criticised some municipalities for having recorded information about dementia in an unacceptable way. The demented persons did not have a legal representative who could object to the registration. In September 2011, the same authority made a formal statement that it is illegal to record information about dementia (and other long-term lack of decision-making capacity) in a national quality registry unless the person has a legal representative who can act on behalf of the incapacitated person. However, some care givers have continued with the practices. Consequently, in 2013 the authority again criticised some municipalities for registering incapacitated elderly in Senior Alert only by virtue of relatives' statements.

The current legal state in Sweden is that if a person permanently lacks decision-making capacity and therefore cannot understand the information to be provided for registration, no registration can legally be made without a legal representative for the patient. Only a small number of incapacitated persons in Sweden have such legal support [(30)]. There-

[(28)] *Supra* note 7 p. 196.

[(29)] If legal representatives exist, for example custodians for children or trustees for incapacitated individuals, these representatives decide on behalf of the person according to the Child and Parental Code (1949:381). Few persons with cognitive impairments in Sweden have a legal representative, because relatives do not automatically get this role and instead a power of attorney is often used.

[(30)] This is also a very problematic situation for the health and medical care of incapacitated individuals. Therefore, the government has appointed a Govern-

fore, the practical situation is considered problematic in respect to the uncertain future of the registries which include incapacitated persons.

2.3. The legal situation

As a response to the uncertainties in the legislation, the Swedish government did initiate an Inquiry concerning the problem about the right to information in health and social care [31]. In a commission report in June 2013, a draft law on new rules in the Patient Data Act was put forth which will enable the processing of personal data of incapacitated persons without their agreement [32]. More specifically, the Inquiry on the right information in health and social care proposes an amendment which opens up the possibility also to record personal information from incapacitated persons under certain conditions. Due to this proposal, in October 2014 the Patient Data Act will have a new provision that states that data collection is allowed if the patient, if possible, has been consulted, and if there are no reasons to believe that the patient does not consent the processing of personal data. The health personnel shall assess whether the patient lacks the capacity to respond to personal data processing. If the staff find that such ability is absent, the person making the assessment should try to ascertain the past attitude of the individual, for example by talking to relatives. If there are no reasons to believe that the person would have opposed the data registration if he or she had been able to give an opinion on the issue, the registration may be performed [33].

The planned new legislation has, so far, led to little discussion about the pros and cons of registering these groups of patients and the risk of privacy breaches this could entail. For example, it ought to be investigated further whether the bill is consistent with the requirements in the European Convention on Human Rights and Biomedicine (the Oviedo Convention), which expresses a requirement that a legal representative be provided adult decisions incapable patients [34].

3. Registry-based research

3.1. Quality registers for research

During the last years there has been a strong governmental aim of strengthening Sweden's competitiveness in research. The quality registries are considered unique and powerful tools for research and there is an interest in using the quality registers to support research. In March 2007, the Ministry of Education appointed a commission to make a report on the clinical research situation that would take into account the needs of both health care and research [35]. The report highlighted quality registers

ment Committee to propose new legislation; Dir. 2012:72. Beslutsoförmögna personers ställning i hälso- och sjukvård, tandvård, socialtjänst.

[31] S 2011:13.

[32] SOU 2013:45 Rätt information — Kvalitet och patientsäkerhet för vuxna med nedsatt beslutsförmåga.

[33] Prop. 2013/14: 202 Förbättrad informationshantering avseende vissa patienter inom hälso-och sjukvården.

[34] Sweden has signed the European Convention on Human Rights and Biomedicine (the Oviedo Convention) but not yet ratified it, because the issue of a legal substitute for persons who lack capacity to consent has not been solved in the Swedish legislation.

[35] Dir 2007:39, *Utredning av den kliniska forskningens behov och villkor samt förslag till åtgärdsplan.*

as a crucial instrument for clinical research, both now and in the future [36].

In the following, I will turn to the accessibility of data in the quality registers. In the article, it is relevant to ask this question: under what conditions is registry-based research on elderly persons with cognitive impairments allowed? Many national and regional quality registries contain very attractive material to use for different studies in health and medicine but also in other kinds of research, including the behavioural and social sciences.

The key requirement in most codes of research ethics is that certain kinds of research can be conducted only if the person has given his or her informed consent. Corresponding provisions requiring informed consent can be found in several international regulations and codes of ethics regarding research on humans, such as the Declaration of Helsinki (World Medical Association's code of ethics for research involving human subjects), European Convention on Human Rights and Biomedicine (the Oviedo Convention), as well as guidelines CIOMS (the Council for International Organizations of Medical Sciences, initiated by WHO and UNESCO). All of these regulations state that biomedical research may be conducted only if the research subject is informed about the study and given the opportunity to voluntarily decide whether they wish to participate. To give informed consent according to these documents, the patient must understand the request of the research team, the nature of the procedure (examination, using information in personal records etcetera) and the risk — and possible benefits — of participation. Thus, informed consent demands a fairly competent person who can understand the information provided and the choices involved in whether or not to participate. Not everyone, including incapacitated elderly, has such a degree of capacity.

Swedish regulation is influenced by these international rules. A law has been in force since 2004 which deals with vetting the ethics of research that involves humans, the Act (2003:460) concerning Ethical Review (Ethical Review Act). It encompasses research involving living persons, but it also covers such areas as research on the deceased, biological material from people, and research that involves dealing with sensitive information about people or personal information concerning criminal offences. This Act is the principal legislation governing the requirements for research involving human subjects in Sweden. If the research requires permission in accordance with the Ethical Review Act Section 4 1-3, the rules of informed consent apply. Such research involves either physical intervention on the subject of the research, or research conducted using methods designed to affect the subject mentally or physically, or research that poses a clear risk for physical or mental harm to the subject. If the study instead is subject to permission according to Section 3, the Ethics Review Board determines the applicable provisions regarding information and consent for each research project [37]. The Act governs the

[36] SOU 2008:7, *Världsklass! Åtgärdsplan för den kliniska forskningen* and SOU 2009:43, *Klinisk forskning — ett lyft för sjukvården.*

[37] For practical reasons, informed consent is not always requested for registry-based research. The registries may contain data for several thousand persons and it is considered difficult to handle procedures for informed consent for

basic requirements of information and consent that must be met for such research on patients. Section 3 covers many areas of research, including social sciences, law and medical research, including research based on registries. According to Section 3, an ethical review is requested if the research includes the processing of sensitive personal data (as defined by the Personal Data Act) or personal data relating to offences against the law involving crime, criminal convictions, coercive measures or administrative detention.

3.2. Accessibility of data from incapacitated elderly persons

In accordance with other legislation containing consent requirements, a valid informed consent can only be provided by persons who have certain abilities. For example, a person who is severely demented cannot give informed consent to participate in research. If the requirement to obtain informed consent from the research subjects is made unconditional, it will have the consequence that research involving such persons can never take place. An absolute ban is problematic and eliminates possibilities to prevent, treat and relieve sickness and ill health of groups without ability to consent. For this reason, the most influential research ethics regulations make exceptions for this group [38]. In addition, the Swedish regulation permits persons without ability to consent to be involved, under certain circumstances, in research. According to the Ethical Review Act Section 20, research on adults may be carried out without the consent "if illness, mental disorder, weakened state of health or some other similar circumstance prevents the subject of the research from expressing an opinion." However, such research assumes that certain special protection conditions are fulfilled. According to Section 21, research may be performed only if the research can be expected to a) result in knowledge that is not possible to obtain through research using informed consent, and b) result in direct benefit to the subject who is the subject of the research. Apart from this main rule, the same section states another possibility to do research without informed consent, i.e. *if* the purpose is to contribute to a result that may be beneficial to the person who is the subject of the research or someone else suffering from a similar disease or disorder, and *if* the research involves a minimal risk for injury and only slight discomfort to the subject. Even though the research subject lacks capacity for informed consent, the person shall be informed individually, to the greatest possible extent, about the research [39]. In addition, the person's next of kin shall be consulted (and in some cases the trustee). The research may not be conducted if the research subject in any way demonstrates that he or she does not want to participate or if any of those consulted opposes the research participation.

everyone. Instead, the ethical boards often request that the researchers advertise in newspapers and other media about the project in order to make people aware of the research and be able to drop out of the study. By contacting the research group, the person will be excluded from the study.

[38] Another exception is children under 18 years of age. Special provisions exist for this group as well.

[39] Ethical Review Act Sec. 22.

The regulation opens up for many questions about its application. Ethical review is being conducted by six regional ethical review boards. Appeals are handled by the Central Ethical Review Board (the Central Board) [40] In the following, some results form a study of cases from the Central Board will be presented [41].

3.3. Cases from the Central Ethical Review Board

In addition to the regulation mentioned above, case law becomes important for understanding the legal practice and the conditions under which research may take place on persons, when these persons lack the capacity to consent to research participation, due to illness or severe cognitive impairments. The study covers all cases from 2004 to 2012 from the Central Board which focus on elderly persons with cognitive impairments in research — 15 cases in all [42]. The cases include both individuals who are patients in health care and individuals who are using other care, such as assisted housing services.

Informed consent, voluntary participation and information confidentiality are central concepts in many cases. The concept of patient safety, on the other hand, is rarely directly discussed in the cases. However, the ethical discussions often concern patient safety related to risk for injury or discomfort in one way or another. According to the regulation described earlier, the prerequisite for accepting a research project is that it should be expected to result in direct benefit to the subject, *or* result in something that may be beneficial to the person and, at the same time, involve only a minimal risk for injury and only minor discomfort to the subject of the research.

The overall question for the study involves the conditions under which the Central Board agrees to include incompetent elderly in research studies. The main reason expressed repeatedly in the cases reviewed is *the importance of including elderly with cognitive impairments as a group for scientific reasons and knowledge gain*. One such case is a longitudinal and cross-disciplinary project intended to study the determinants of disease, functional dependency and health care utilisation among the elderly [43]. The overall project objective is to study how various factors in older people's lives affect their physical and mental function. The study includes interviews with personnel and relatives as well as a physician's examination of each patient. The Regional Board requires that the study adds one condition, which is that persons who have a legal representative should not be included in the study (without explaining

[40] The Central Board is regulated in *Förordning (2007:1068) med instruktion för Centrala etikprövningsnämnden*.

[41] There is very little legal research done on cases from the Central Board. On children, see T. Mattsson, "Delaktighet i vård, omsorg och forskning — Barns beslutsförmögenhet i relation till ålder, mognad och hälsa", in: Statens institutionsstyrelse, *Tvångsvård ur ett juridiskt perspektiv* (Stockholm: Institutionsvård i Fokus, 2014) and J. Schiratzki, "Etik och samtycke i barnforskning", *Förvaltningsrättslig tidsskrift* 1 (2011). On incapacitated persons, see L. Broström, M. Johansson, T. Mattsson, "Vilka personer saknar förutsättningar att ge informerat samtycke till att delta i forskning? En rättslig och etisk diskussion rörande etikprövningslagens regler och tillämpning", *Förvaltningsrättslig tidskrift* 1 (2014).

[42] The Central Board has decided a total of 400 cases since its start in 2004.

[43] Central Board decision Ö 26-2007, dated 2007-09-20.

the reason for this restriction). The Central Board objects to this and argues that if people with trustees or guardians are not allowed to participate in the study, the consequence will be that the aim of the study will be distorted. The Central Board finds that the inclusion of persons with severe cognitive impairment has a clear scientific value. It is argued that the invasion of privacy inclusion entails for the research subject would be minimised by the patient's relatives giving permission, and by that some parts of the participation (like blood tests) are not to be done on people with very severe cognitive impairment. Thus, the gains of including people with impaired decision-making competence outweigh the possible invasion of privacy for the individual [(44)]. In similar cases, the Central Board comes to the conclusion that the risks are small and may be outweighed by the knowledge gain [(45)].

The Central Board sometimes has to deal indirectly with the question of patient safety for incapacitated persons. One such case is about a randomised, double-blind, placebo-controlled multicentre study studying the effect of a new antidepressant compound. The study is to take place at an elderly care institution, with elderly who are incapacitated. The Regional Board does not want to allow the research because of patient safety reasons. They argue that the study presents high risks for suicide (as a third of patients with diagnosed depression will receive a placebo and one-third of patients a still relatively untested drug). However, the Central Board is of another opinion. The Central Board argues that specialists will specifically assess the patient's suicide risk, and in case of assessed increase in risk the subject's participation in the study will cease and the patient will be treated with proven medicines. For this reason, the Central Board finds that the experimental design offers a sufficient degree of patient safety [(46)].

Several research projects get approval only after *excluding persons without capacity to consent*. [(47)] One such application [(48)] concerns an open clinical evaluation of an ointment to be applied around the genitourinary area twice a day on 50 female patients older than 65 years, who live in retirement homes and who, during the last six months, had at least one clinically diagnosed urinary tract infection. The ointment contains ingredients which according to the study hypothesis is assumed to protect users from urinary tract infections. The Central Board accepts the study only after the study design is changed so that only competent decision-making persons will be included in the study. The decision contains no discussion about how patients' decision-making powers should be examined. In another case, the Central Board makes the same suggestion not to include incapacitated persons [(49)]. In order to make a correct selection, the Central Board proposes that all patients who wish to participate in the research study will undergo a structured dementia test. Patients with dementia will then be excluded

[(44)] Compare Central Board decision Ö 45-2005, dated 2006-01-26 and Ö 42-2004, dated 2005-01-25.

[(45)] See for example Central Board decision Ö 2-2010, dated 2010-03-04.

[(46)] Central Board Decision Ö 7-2009, dated 2009-04-20.

[(47)] See for example Central Board decision Ö 22-2011, dated 2011-07-29 and decision Ö 25-2011, dated 2011-09-22.

[(48)] Central Board decision Ö 22-2011, dated 2011-07-29.

[(49)] Central Board decision Ö 45-2005, dated 2006-01-26.

from the research study. Several cases demonstrate the same theme, i.e. that the Central Board accepts a study only after a revision of the application so that the research will no longer include incapacitated persons.

A research project may not result in direct benefit to the patient, but according to the regulation described above it should at least involve only a minimal risk for injury and only slight discomfort. In several cases, the research is *denied completely* because the risks of the research methods in the study *are considered to be able to cause harm*. For example, in one case the researchers want to contact by phone such persons older than 70 years. Because of the likelihood that the persons are socially isolated people, a risk is considered to exist that the method will result in an increased mental strain for at least some persons [(50)]. For this risk of harm, the Central Board comes to the conclusion that this risk outweighs the potential gain and therefore rejects the research application.

4. Concluding discussion

People live longer today in many parts of the world, thanks to better medical care which cures illnesses that have historically been fatal. Longer life for a larger proportion of the population has in turn led a situation where many elderly live in some degree of physical or mental disability. They may get good treatment that alleviates many of the symptoms of illness, but not all. Common problems such as reduced physical vigour, declining vision, poor memory, and hearing loss may be compensated with technical devices at home and assistance with personal care and home services. However, other conditions may lead to increasing dependency and loss of autonomy. The most prevalent condition for the very old is dementia [(51)]. Other similar problems may arise from strokes and certain impairments like Alzheimer's disease. It is considered crucial for a modern welfare state to have a health care system which can accommodate the increasing numbers of these elderly who often need different forms of care.

In Sweden, one solution for meeting the increasing demands in health and medical care is to develop and offer the use of national and regional quality registries for quality assurance and research. The national political efforts to expand this sector are very strong and unanimous. However, the simultaneous development of aiming for patient safety for the community as a whole may have negative implications for the individual participant. Reflections on the individual's vulnerability are therefore relevant.

In this article, my focus has been on the incapacitated elderly. The legal system seldom focuses on the elderly. The principles and rules in health care provide legal protection to the elderly, just as they do for the rest of the population. The older population is seen as one integrated part of the rest of society with rights equal to those of younger persons. This egalitarian approach is positive regarding the general status of the elderly population [(52)]. On the

[(50)] Central Board decision Ö 22-2010, dated 2010-11-09.

[(51)] L.A. Frolik, "Later Life Legal Planning", in: I. Doron (ed.) *Theories on Law and Ageing: The Jurisprudence of Elder Law* (Berlin, Springer; 2010) pp. 13.

[(52)] I. Doran, "A Multi-Dimensional Model of Elder Law", in: *ibid.,* p. 61.

other hand, the same approach can make the legal system difficult to apply to the elderly. For example, some situations may have a negative effect on the positions of an older person — an effect which may not arise for many others. As shown in the article, the person may have limited possibility to decline participation in collecting data for a registry, due to personal impairments such as declining mental capacity. The situation of vulnerability demands certain legal considerations [(53)]. There are several ways that improvements of a vulnerable situation can be achieved. Sometimes the legislation can affect elderly individuals by extending some *benefits* to them or promoting certain rights, such as participation and representation. At other times the law can affect individuals by providing *protection* for them, such as protection against negligence, poverty or exploitation [(54)].

In the case of the development of national and regional registries, the legislation aims to benefit different patient groups, including incapacitated elderly, and promote patient safety and security when patients are in contact with health and medical care. This is a very honourable ambition in line with the general health and medical care regulation in Sweden. One problem, however, seems to be the risk of breach of privacy rights for the same group. The situation today in Sweden, with the unsatisfactory legal situation regarding collection of data about incapacitated individuals, is a problem that needs to be resolved with protective legislation for this group. However, the upcoming legislation opens up seemingly too broad an opportunity for very easily registering information about incapable persons. Apart from the economic incentive, the care givers usually have an interest in developing their business in both the short and long term, and nursing staff who will conduct the assessment may experience requirements from the employer to obtain the most widespread registration possible. Such interests from the care provider side can also potentially affect the information to be given to patients, deputies and family members, which in turn could affect their ability to make sound decisions on the issue of "opting out". It is problematic that the care givers have multiple interests in the management of information about a person, and are to determine whether or not registration should be done.

In general, research does not aim to benefit the subject of the study. Thus, subjects often participate in research for reasons other than personal gain [(55)]. A very difficult issue is how to deal with the participation of incapacitated persons. As discussed above, there is an ethical dilemma embedded in the problem of involving persons in research without their consent, and therefore the ways of recruiting such persons for research projects are limited. This dilemma deserves a thorough discussion. The study of the decisions by the Central Ethical Review Board does not provide assurance about how the data will

[(53)] Compare M. Albertson Fineman, "The vulnerable subject: Anchoring equality in the Human Condition", *Yale Journal of Law & Feminism* 20(1), pp. 1-24.

[(54)] *Supra* note 50, p. 62.

[(55)] However, in some cases the patient may have fears about not receiving equally good care if he or she does not participate in a study offered when entering the hospital or other care facility. In that sense, the person may get involved merely to allay fears about inferior care.

be used by the researchers. Although one tendency is that there is a certain unwillingness on the part of the Board to accept research studies with incapacitated elderly as research subjects, another tendency is to allow them if the scientific value is deemed to be sufficient. Thus, one conclusion to be drawn from the cases is that data collection from national and regional quality registries may very well be used in research in Sweden. This conclusion calls for proper and strictly regulated data collection.

The risk is that the principle of the right to privacy for incapacitated elderly can be overshadowed with promises of patient safety for all. Sweden is known for its recordkeeping. One undesirable situation is if incapacitated elderly participate simply because they do not have the capacity to say no. This possible tension between the medical interest in good data as a basis for patient safety and the individual's right to privacy needs to be resolved through protective legislation.

THE MEDICAL PRACTITIONERS TRIBUNAL SERVICE: ONE YEAR ON [1]

Dr Kartina A. Choong [2] *& Dr Martin Barrett* [3]

Abstract: *In June 2012, the General Medical Council (GMC) instituted a series of new rules that reformed their fitness to practise work. The most significant change to disciplinary proceedings was the formation of a Medical Practitioners Tribunal Service (MPTS) which is led by a former Deputy High Court Judge. Aimed at safeguarding patient safety, the MPTS is an autonomous part of the GMC which will now adjudicate on all cases relating to doctors whose fitness to practise is called into question. With the new development, the GMC will continue to collect evidence and carry out the investigations, but the cases will be adjudicated by the tribunal which is empowered to impose sanctions against doctors' registration. The fitness to practise panels which sit on these hearings are made up of medical and lay members who receive specific training and are regularly appraised. The hearings are conducted in public and the tribunal is accountable to Parliament. The GMC had hoped that the change would bolster public and professional confidence that these hearings are impartial, fair and transparent. They have described the change as "the biggest shake-up of fitness to practise hearings since they were first established in 1858" (GMC Press Release, 11 June 2012). This paper takes a look at the profile of the cases which the MPTS heard in the first year of its operation and assesses its scope for improving patient safety.*

I. Introduction

> "[T]he General Medical Council (GMC) was 'doctor-centred'. It appeared to assume that all doctors were good, competent and conscientious until proved otherwise. It would deal with the profession's 'bad apples' for the sake of the profession. It would do so in its own way and did not welcome scrutiny. Its procedures were designed to be fair to doctors and to ensure that no doctor would lose his/her right to practise without very good cause. It did not focus on the reasonable expectations of the public and it did not see itself as having a duty to ensure that all members of the medical profession were willing and able to provide a proper professional service [4]."

This was the stern verdict of the Shipman Inquiry which was set up in 2001 to investigate the issues arising from how a British general practitioner — Dr Harold Shipman — managed to kill, without detection, more than 200 of his patients over a period of 24 years (1974-1998). In its report, the Inquiry highlighted that since the GMC is the only authority that can erase or suspend a doctor's right to practise medicine in the country, its Fitness to Practise (FTP) procedures are effectively the "teeth"

[1] An earlier version of this paper was presented at the 4th European Conference on Health Law, Coimbra, 9-11 October 2013. We thank the participants of the conference for their helpful comments and Jessica Hair for research assistance.

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[4] Smith, J., *The Shipman Inquiry: Fifth Report — 'Safeguarding Patients: Lessons from the Past — Proposals for the Future'*, Command Paper Cm 6394 (2004), chapter 15, paragraph 47.

behind all other monitoring and disciplinary structures available in the health care system [5].

The Council has since introduced a number of changes to its FTP procedures [6] in order to restore public faith in its ability to safeguard patient safety and to counter the perception that it is overly protective of doctors. One of the most recent initiatives was the setting up of the Medical Practitioners Tribunal Service (MPTS) in June 2012. Led by a former Deputy High Court Judge, with panels that consist of medical and lay members who receive specific training and who are regularly appraised, the MPTS would be an autonomous part of the GMC that adjudicates on all FTP cases that are brought to the Council's attention. For this, it would be accountable to Parliament. The service, which was launched with the declared aim of protecting patients by making independent and impartial decisions concerning a doctor's fitness to practise [7], has been described by the Council as "the biggest shake-up of fitness to practise hearings since they were first established in 1858 [8]." This paper studies the profile of the FTP cases that were heard in the first year of its operation (i.e from 1st August 2012 to 31st July 2013). Through this, it aims to assess the MPTS' potential and limitations in protecting patients.

The next section will provide an overview of the historical development of professional discipline in British Medicine. It seeks to show that although the GMC was authorised to discipline doctors from its inception in 1858, the approaches taken have largely been doctor-centred until the end of the 20th century. It was only in the 21st century that a more patient-centred orientation was adopted and that this led to the creation of the MPTS in 2012. Section III will analyse the profile of the cases which the MPTS has sat on in its first year. It assesses its scope and limitations in enhancing patient safety before bringing the discussion to a close in Section IV.

II. The Historical Development of Professional Discipline

The connection between professional discipline and patient protection has not always been clear nor consistent throughout the history of the medical profession in the UK. In the early days, public protection was predicated on the integrity of the professional. This was illustrated by the Royal College of Physicians (RCP)'s founding charter of 1518 which described the college's formation as "necessary to withstand in good time the attempts of the wicked, and to curb the audacity of those wicked men who shall profess medicine more for the sake of their avarice than from the assurance of any good conscience, whereby very many inconveniences may ensue to the rude and credulous populace [9]." However, since the primary drive behind the establish-

[5] *Ibid.*, Summary, paragraph 3.

[6] See discussion below.

[7] MPTS, 'The role of the MPTS', available at http://www.mpts-uk.org/about/1595.asp.

[8] GMC Press Release 11 June 2012, available at http://www.gmc-uk.org/news/13286.asp.

[9] The Founding Charter from King Henry VIII, 1518 in G.N. Clark & A.S.A. Briggs, *A History of the Royal College of Physicians of London: Volume 4* (Oxford : Oxford University Press, 2005) p. 1573.

ment of the college was to ensure that power was vested in leading physicians of the time to grant licences to those qualified to practise Medicine [10], it would appear that the sentiments captured in the charter was as much about professional self-interest as it was about patient safety.

With the inauguration of the GMC in 1858 [11] as the regulatory body of the medical profession in the UK, the public was able to distinguish between the "legally qualified or duly qualified [12]" doctors from those who are unqualified, through the Medical Register which this statutory body maintained. Although the Council was authorised to take actions against the doctor's registration, this part of the discussion seeks to highlight that it was not until the 21st century that a shift began to be made to a more patient-centred approach to professional discipline.

A. The 19th and 20th Centuries

The GMC was known as the General Council of Medical Education and Registration of the United Kingdom [13] when it was set up in 1858. The name reflects its two chief duties: to establish proper educational standards for the medical profession and to maintain a register of qualified practitioners [14]. From the outset, it was authorised to erase the names of those convicted of a criminal offence or those judged, after due inquiry by the Council's Disciplinary Committee, to have been guilty of infamous conduct in any professional respect [15]. Whilst acknowledging that it was impossible to compile an exhaustive list of what could amount to "infamous conduct in a professional respect", the GMC indicated that there were a number of misconducts that could raise disciplinary issues. [16] They included: adultery with patients; breach of medical confidentiality; the provision of untrue or misleading certificates; the commercialisation of a secret remedy; gross neglect in diagnosis or treatment; and improper attempts at profit at the expense of professional colleagues (e.g. by canvassing for patients and advertising for the doctor's own professional privilege) [17]. All these, interestingly, gave rise to the belief on the part of the public that the primary concern of the Council was with professional ethics and discipline [18].

Irvine nevertheless identified the role of the Council between 1858 and 1979 as being that of the traditional regulator — reactive, passive, extremely protective of doctors and unwilling to deal with poor medical practice [19]. The few disciplinary

[10] Royal College of Physicians (RCP), 'History of the RCP', available at http://www.rcplondon.ac.uk/about/history.

[11] By the Medical Act 1858.

[12] *Ibid*., section XXXIV.

[13] The name was changed to the General Medical Council in 1951.

[14] Poynter, F.N.L., 'The centenary of the General Medical Council' (1958) *British Medical Journal* 1245 at 1246.

[15] Section XXXIX, Medical Act 1858.

[16] GMC, 'Functions, procedure, and disciplinary jurisdiction' (1965) pp. 7-8.

[17] As is clear from their focus, acts and omissions which did not take place in a professional respect (other than criminal offences), were not issues that merited disciplinary attention — see S. Mills, *et. al*., *Disciplinary Procedure in the Statutory Professions* (West Sussex: Bloomsbury Professional, 2011) pp. 39-41. This, as will be seen below, stands in stark contrast to the approach adopted by the MPTS.

[18] Finch, E., 'The centenary of the General Council of Medical Education and Registration in relation to medical education' (1958) 23(5) *Annals of the Royal College of Surgeons of England* 321.

[19] Irvine, D., 'A short history of the General Medical Council' (2006) 40 *Medical Education* 202.

charges it dealt with were concerned with criminal behaviour, adultery with patients and breaches of professional etiquette [20]. Regarding the latter, the fact that canvassing for patients and advertising were deemed as professional offences signified that the emphasis of ethical conduct at the time was also directed towards issues between doctors [21]. There were no guidelines drawn up to inform doctors and the public about what constituted good practice. The Council had instead preferred to use case law as the basis for advising doctors about misconduct [22]. This allowed the profession itself to decide on what constituted a "good doctor" — and he was someone who complied with the professional norms [23] i.e. doing what was normally done, rather than what should ideally be done. Public protection was therefore not the Council's priority then [24].

Some changes were subsequently made to their disciplinary procedures in the period from 1980 to the end of the 20th century. This was in response to the hundreds of complaints which started to be received yearly from patients and official bodies about the behaviour of doctors [25]. Complaints to the GMC would now be directed through a number of committees. Cases involving conduct would undergo a three-stage process. At the first stage, a medical screener would decide whether the case should go no further or be referred for investigation. If the latter, the case will then be managed by the Preliminary Proceedings Committee (PPC) (stage two) which decided if there was sufficient merit in the case being referred to the Professional Conduct Committee (PCC)(stage three). The PCC was empowered to hold the hearing in public. A doctor whose conduct was found to have amounted to "serious professional misconduct" (SPM) can be reprimanded, be given conditions, suspended or have his name erased from the medical register [26]. Cases involving the health of the practitioner (e.g. mental illness and alcohol and/or drug abuse) would be referred to the Health Committee which would arrange a medical examination of the doctor to determine whether his health seriously impeded his ability to practise medicine. If found proved, the doctor may be reprimanded; given conditions; or suspended; but not face erasure from the register [27]. Cases involving performance were managed by an Assessment Panel that would determine if there was Seriously Deficient Performance (SDP) [28]. The doctor could accept a statement of progress and he would be supervised until it was determined that his performance was satisfactory. Failure to comply or continued unsatisfactory performance would result in referral to the Committee on Professional Perfor-

[20] *Ibid*., p. 204.

[21] Stacey, M., *The Sociology of Health and Healing* (London: Unwin Hyman, 1988) p. 85.

[22] Irvine, D., *op. cit*., p. 205.

[23] See e.g. *Allinson v. General Council of Medical Education and Registration* [1894] 1 QB 750, *per* Lopes LJ at 763 and *Bolam v. Friern Hospital Management Committee* [1957] 1 WLR 582, *per* McNair J. at 587. For discussion, see J.B. Fanning, 'Uneasy lies the neck that wears a stethoscope: some observations on defensive medicine' (2008) *Professional Negligence* 93 and D. Thomas, 'Peer review as an outmoded model for health practitioner regulation' in I. Freckelton (ed.), *Regulating Health Practitioners* (New South Wales: The Federation Press, 2005) pp. 58-59.

[24] Irvine, D., *op. cit*., p. 204.

[25] Hill, D., 'The General Medical Council: frame of reference or arbiter of morals?'(1977) 3 *Journal of Medical Ethics* 110.

[26] Section 36 of the Medical Act 1983.

[27] Section 37 of the Medical Act 1983.

[28] Medical Professional (Performance) Act 1995.

mance (CPP). Sanctions available to the Committee included suspension and placing conditions on the doctor's practice [29].

The meaning of "serious professional misconduct" [30], however, was difficult to ascertain. The GMC had never published agreed standards or the criteria and thresholds by which decisions could be taken. In time, the term had come to mean "professional misconduct of such a degree that the PCC considers it to be serious" [31]. This is a circular definition [32]. The PCC would acquit and take no action against a doctor if the available evidence did not satisfy the criminal standard of proof. According to the Shipman Inquiry, "the concept of negligence even if serious does not fit comfortably with Serious Professional Misconduct [33]." The PCC's need to feel "sure" (i.e. beyond reasonable doubt) about the culpability of the doctor meant that many doctors were allowed to continue unrestricted practice irrespective of how poor their clinical practice had been [34]. Professional discipline's concern about being "fair to doctors" thereby left patients and the public insufficiently protected [35]. Further, the presence of 3 separate routes for professional discipline was also deeply confusing for the public. This deterred complaints or caused those who did complain to grow weary as a consequence of having to "negotiate something of an obstacle course [36]".

B. The 21st Century

It was not until the 21st century that the balance between protecting doctors on the one hand and the public on the other, started to tip towards safeguarding patients. This change of emphasis was prompted by the escalation in the number of complaints received by the GMC and the emergence of a string of high profile cases which came to light at around the same time as the Shipman case. These included the scandal at the Bristol Royal Infirmary where substandard cardiac surgery on infants as performed by 2 surgeons resulted in high rates of death; the case of Dr Richard Neale who did not provide appropriate care to his patients and which resulted in 2 deaths; the case of Dr Clifford Ayling who committed indecent assault on a number of his female patients; and the case of Drs William Kerr and Michael Haslam — 2 psychiatrists who sexually abused their female patients over many years [37].

Consequently, the Fitness to Practise Rules 2004 were created [38]. The 3 types of hearing (conduct,

[29] For further discussion, see A. Samanta & J. Samanta, 'Regulation of the medical profession: fantasy, reality and legality' (2004) 97 *Journal of the Royal Society of Medicine* 211 at 216.

[30] A term which was brought in to replace "infamous conduct in a professional respect".

[31] Dalton, K. J., 'Physician licensing and disciplining in England and Europe' in American College of Legal Medicine, *Legal Medicine* (Philadelphia: Mosby, 2004) p. 690.

[32] *Ibid*.

[33] Smith, J., *op. cit.*, p. 110.

[34] Dalton, K.J., *op. cit.*, p. 690.

[35] Smith, J., *op. cit.*, chapter 6.

[36] Baker, R., 'Patient-centred care after Shipman' (2004) 97 *Journal of the Royal Society of Medicine* 161 at 164.

[37] For further discussion, see e.g. M. Dixon-Woods *et. al.*, 'Why is UK medicine no longer a self-regulating profession? The role of scandals involving "bad apple" doctors' (2011) 73(10) *Social Science & Medicine* 1452; M. Davis, *Medical Self-Regulation: Crisis and Change* (Hampshire: Ashgate Publishing Ltd., 2007) pp. 121-242.

[38] GMC, 'Reform of the fitness to practise procedures at the GMC: Changes to the way we deal with cases at the end of an investigation' (Consultation paper) p. 11.

health and performance) were amalgamated into a single test of impaired fitness to practise (FTP). The GMC would investigate the complaints received, collect evidence and hear those cases. If a doctor's fitness to practise is found impaired, then sanctions can be applied that ranged from no further action, through to warnings, conditions, suspension and erasure from the medical register. The Council also published *Good Medical Practice* which represents a set of duties jointly regarded as important by doctors and the public [39]. The document was to be the new set of guidelines against which fitness to practise was judged [40].

In 2012, the Medical Practitioners Tribunal Service (MPTS) was established by Parliament. It provides a hearing service that is fully independent in its decision-making and separate from the investigatory role of the GMC. Now, in a three stage process, the GMC sets out the allegations against the doctor and presents evidence. The case continues if, in a private session, the MPTS panel finds the facts proved. Stage two commences where the panel hears, in public evidence, from the GMC as to whether the doctor's fitness to practise is impaired. At the final stage of the proceedings, the panel makes a decision on sanctions.

Although the panellists can exercise their discretion as to the sanctions to be exercised, they are required to refer to the guidance developed by the GMC on this matter [41]. This, according to the GMC, is for purposes of promoting consistency and transparency in decision-making. [42] The primary aim of sanctions is "the protection of patients and the wider public interest (i.e. maintenance of public confidence in the profession and declaring and upholding proper standards of conduct and behaviour) [43]". According to the guidance, if a doctor's fitness to practise is not found to be impaired, the panel could conclude the case by either taking no action or by issuing a warning. When a warning is issued, this would be because the doctor's performance has departed significantly from *Good Medical Practice* or where it has given rise to significant cause for concern following an assessment [44]. The warning, which would be in relation to the doctor's future conduct or performance (rather than his health), would need to be disclosed to the complainant, the doctor's employer and any other enquirer [45]. It would also be published on the GMC website for a period of 5 years [46].

Where a finding is made that the doctor's fitness to practise is impaired, four options are available to the panel. One would be to take no action against a doctor's registration if the doctor has demonstrated considerable insight into his/her behaviour and has already undergone and completed any remedial actions which he/she would otherwise be required by the panel to undertake [47]. The panel can also impose conditions [48] on the doctor's registration

[39] Irvine, D., *op. cit.*, p. 207.
[40] *Ibid.*
[41] GMC, 'Indicative Sanctions Guidance for the Fitness to Practise Panel', April 2009 (with 7 August 2009 revisions, March 2012 revisions and March 2013 revisions).
[42] *Ibid.*, p. 4.
[43] *Ibid.*, p. 8.
[44] *Ibid.*, p.12.
[45] *Ibid.*
[46] *Ibid.*
[47] *Ibid.*, p. 14.
[48] E.g. restricting the doctor's employment to NHS posts; disallowing him from carrying out a particular procedure; or making him undergo remediation or retraining — *ibid.*, p. 17.

for a period of up to three years (but renewable for up to 36 months thereafter); suspend the doctor's registration for up to 12 months; and erase the doctor's name from the register [49]. Although the panel maintains that its "decision is not intended to be punitive" [50], it concedes that the sanctions "may have a punitive effect [51]".

III. The MPTS and Patient Safety

A. Cases from 1 August 2012 to 31 July 2013

The MPTS heard 173 cases in the period between 1st August 2012 and 31st July 2013. The hearings are open to the public. The details and outcomes of those hearings are published on the MPTS website and members of the public can access them without charge. From these, it is possible to identify, *inter alia*, the decisions of the panel as to whether impairment was present; the sanctions taken; the grounds for the investigation; the year that the registrable qualification was obtained; and the institution granting the registrable qualification.

As can be seen from the table below, the MPTS decided to take no further action for 39 of the cases heard, and 10 registered practitioners were given a warning. Thus in over 70% of the cases heard last year, the doctors' fitness to practise was found to be impaired. Conditions were imposed on the registration of 18 of those doctors while 53 others were suspended. The most serious sanction, i.e. erasure, was also applied to the registration of 53 doctors.

Outcome	Numbers	Percentage
No action taken	39	22.54
Warnings issued	10	5.78
Conditions imposed	18	10.40
Suspension of registration	53	30.64
Erasure from register	53	30.64
Total	173	100

Table 1: Outcomes of cases heard by the MPTS between 1/8/2012 and 31/7/2013

In the majority of the cases that came before the MPTS in this period (i.e. up to 119 or 69%), the medical practitioners have been qualified for 15 up to 35 years. This strongly indicates that questions over their fitness to practise bears little relation to lack of professional experience. Another notable factor is that up to 107 or 62% of the overall cases heard concerned overseas doctors i.e. those who received their medical degree from outside the UK. This seems to be a continuation of an ongoing trend. As far back as 1989, Smith has noted that although overseas doctors were under represented on the GMC, they were over represented among those appearing before the Professional Conduct Committee [52]. Other commentators have also commented on this trend in the 1990s and early 21st century [53].

[49] *Ibid.*, p. 13.
[50] *Ibid.*, p. 7.
[51] *Ibid.*

[52] Smith R, 'Profile of the GMC: Overseas doctors: diminishing controversy' (1989) 298(6685) *British Medical Journal* 1441.
[53] See e.g. F. Goodlee, 'The GMC, racism and complaints against doctors' (1996) 312 (7042) *British Medical Journal* 1314; P. Moszynski, 'GMC to look into higher number of complaints against overseas trained doctors' (2007) 335 *British Medical Journal* 320.

There is nevertheless no clear association between ethnicity and the tendency to appear before an FTP panel among UK-qualified doctors [54].

B. Patient Protection: Potential and Limitations

1. Potential

As regards the MPTS' potential for public protection, it is undoubtedly the case that a complaint dealt with within the MPTS' FTP framework has greater potential to protect the public especially when compared to the malpractice framework. For one, whilst there is a need to prove that an alleged wrongdoing has led to injury when pursuing a medical negligence case against a doctor, there is no equivalent requirement for any harm or damage to have occurred before a doctor can be disciplined by the MPTS. Taking a closer look at the profiles highlighted above, incidents which have resulted in sanctions being applied include where the doctor has: kept diaries which contained derogatory and sexualised information about his patients; [55] accessed pornographic material at work [56]; created pornographic images purporting to be of a male patient with female colleagues [57]; left another doctor who should have been under his direct supervision unsupervised [58]; demonstrated a cavalier attitude to patient care [59]; and amended his patient's medical records a number of times after receiving a letter from a solicitor regarding a possible medical negligence claim [60]. Other cases include where the doctor has: treated his patient in a brusque, uncaring and rude fashion [61]; displayed a dismissive attitude to criticism [62]; did not carry professional indemnity insurance [63]; produced a dishonest and exaggerated report for a patient's insurance claim that was not based on a clinical assessment of the patient [64]; provided dishonest information to obtain employment [65]; accepted paid clinical work as a locum general practitioner elsewhere when on authorised sick leave at his place of work [66]; rewrote and replaced some pages of a patient's medical records; [67] and demonstrated inappropriate and sexually motivated behaviour towards his colleagues [68].

Although those incidents may not have produced any direct and discernible injury to the doctors' patients, they demonstrate that MPTS' FTP hearings do not wait until something has gone wrong before actions are taken. Rather, they identify risks from the doctors' behaviour and take appropriate action proactively. Thus unlike malpractice law which acts retrospectively and offers remedies after

[54] Humphrey, C., *et. al.*, 'Clarifying the factors associated with progression of cases in the GMC's Fitness to Practise procedures' (2009) RES-153-25-0101 p. 32.
[55] Case number 2654896.
[56] *Ibid.*
[57] *Ibid.*
[58] Case number 2803157.
[59] *Ibid.*
[60] Case number 1711880.
[61] Case number 4271938.
[62] Case number 6109941.
[63] Case number 5194517.
[64] Case number 6034254.
[65] Case number 5180486.
[66] Case number 4160133.
[67] Case number 4277886.
[68] Case number 4330468.

an incident has resulted in injury [69], these hearings tend to look forward and not back [70], This preventative posture [71] also has the capacity to protect the safety of a wide pool of patients. In a successful medical negligence suit, the finding of liability would only benefit one patient (i.e. through the award of monetary compensation to the one who instituted the claim) [72]. MPTS actions, by putting a stop on acts and omissions which do not constitute good professional practice, stand to benefit everyone who is likely to be treated by the doctor in the present and the future.

Additionally, the cases heard in the first year of the MPTS' operation also demonstrate that FTP hearings deal not only with clinical, but also non-clinical matters. Cases for which sanctions were applied include situations where the doctor has: posted obscene photos of his ex-girlfriend on Facebook [73]; falsified qualifications on his CV [74]; shown paedophile tendencies [75]; taken indecent photos of women in public without their consent [76]; taken part in violent disorder at a public protest [77]; and falsely claimed on his CV that he was a contributing author on a number of publications [78]. Some of those cases came to the attention of the GMC because the offences had been dealt with by the criminal justice system [79].

In regulating doctors' behaviour both during work and outside of work, the MPTS is, as highlighted earlier, of the view that the public interest extends beyond public protection to embrace the maintenance of public confidence in the profession, and the upholding of proper standards of conduct and behaviour. The significance of this is underlined by the fact that registered medical practitioners are entrusted with clinical and non-clinical responsibilities [80]. These duties may range from signing prescriptions and death certificates, through to various other certificates such as verifying the details on passport applications. Clearly a doctor with impaired integrity in those areas that the ordinary individual might assume to be private, will always be subject to suspicions that his professional life could be compromised [81]. Consequently, *Good Medical Practice* [82] and the MPTS (and now the revalidation process [83]) all place integrity as an important component in maintaining public trust.

[69] Geraghty, C., 'Advancing patient safety in Ireland: the American model and cultural change' (2009) *Medico-Legal Journal of Ireland* 27 at 28.

[70] *Meadow v. General Medical Council* [2006] EWCA Civ 1390 *per* Sir Anthony Clarke MR at paragraph 32.

[71] Geraghty, C., *op. cit.*, p. 31.

[72] Timms, M., 'Referring a doctor to the General Medical Council' (2006) *Journal of Personal Injury Law* 36 at 39.

[73] Case number 5180080.

[74] Case number 6046047.

[75] Case number 6024833.

[76] Case number 7079875.

[77] Case number 6110813.

[78] Case number 3679731.

[79] It is mandatory for doctors to notify the GMC if they come into contact with the criminal justice system as offenders — see GMC, 'Guidance on convictions, cautions and determinations' (April 2013).

[80] Hesketh, W., 'The police-health professions' protocol: a review' (2012) *Police Journal* 203 at 205; McFarlane, G., 'Clinical negligence disputes' (2003) *Journal of Personal Injury Law* 71 at 77.

[81] The MPTS' stance on this is similar to that of the Rehabilitation of Offenders Act 1974. Although this statute protects offenders from having to disclose their previous criminal convictions when applying for jobs and insurance after a rehabilitation period, this provision does not apply to doctors.

[82] GMC, *Good Medical Practice* (March 2013), paragraph 1.

[83] See e.g. GMC, 'Supporting information for appraisal and revalidation' (2012) pp. 3-4.

2. Limitations

The MPTS' role in safeguarding patient safety is nevertheless compromised on a number of fronts. Firstly, the MPTS seems to be following a redemptive model. When determining the appropriate sanction for a doctor's wrongdoing, the MPTS panels are expected to consider mitigating factors in two circumstances: where the doctor has demonstrated insight into the problem and his/her attempts to address it [84]; and evidence of his/her overall adherence to important principles of good practice [85]. Also of relevance are testimonials, personal hardship, work-related stress, lack of training and supervision at work [86]. The "insight" expected is for the doctor to be "able to stand back and accept that, with hindsight, they should have behaved differently, and that it is expected that he/she will take steps to prevent a recurrence" [87]. Assessing insight is always difficult, but in a redemptive model where the severity of sanction is linked to the degree of insight, it is important that the insight and remorse are genuine and not just words and attitudes superficially displayed to lessen any penalty that might be meted out. It goes without saying that testimonials, support and remedial training will have little effect on future practice if the doctor does not fully understand the reasons behind the initial complaint or comply with strategies to improve performance [88].

Secondly, whether a doctor's impaired fitness to practise actually comes to the GMC's and MPTS' attention depends on the assistance and cooperation of others. This means that a problem can go undetected if patients, employers, colleagues and/or other bodies are unwilling to come forward and report the doctor to the GMC [89]. Here it is pertinent to note that *Good Medical Practice* directs practitioners who have concerns that a colleague may not be fit to practise, to ask for advice from a colleague, their defence body or the GMC. If their concerns have not been addressed, they are to report the matter in accordance with GMC guidance and their workplace policy [90]. However, doctors are generally reluctant to criticise and report one another because of a sense of shared vulnerability [91]. Indeed, as pointed out recently by Robert Francis QC in the Report of the Public Inquiry into the Mid Staffordshire NHS Foundation Trust [92], there is a culture of professional disengagement among health care practitioners where many, including Consultants, had preferred to keep their heads down and not challenge or manage

[84] These could include admission of what took place; apologies extended by the doctor to the complainant; and efforts made to prevent such behaviour recurring or to rectify any deficiencies in performance — GMC (2009), *op. cit.*, p. 8.

[85] E.g. by keeping up to date; and working within his/her area of competence. Consideration could also be taken of his/her character; the circumstances leading up to the incidents; and whether this is the first time that a finding has been made against him/her — *ibid.*

[86] *Ibid.*

[87] *Ibid.*, p. 10.

[88] Case, P., 'The good, the bad and the dishonest doctor: the General Medical Council and the "redemption model" of fitness to practise' (2011) 31(4) *Legal Studies* 591 at 611-612.

[89] Baker, R., 'Patient-centred care after Shipman' (2004) *Journal of the Royal Society of Medicine* 161; Davies, A.C.L., 'Mixed signals: using educational and punitive approaches to regulate the medical profession' (2002) *Public Law* 703 at 722.

[90] *Good Medical Practice*, *op. cit.*, paragraph 25(c).

[91] Davies, M., *op. cit.*, p. 249.

[92] Francis, R., *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry* (2013), Executive Summary.

with any vigour [93]. He recognised that whilst it cannot be suggested that such a passive and disengaged culture "are present everywhere in the system all of the time,… their existence anywhere means that there is an insufficiently shared positive culture [94]" which prioritises patient safety.

And neither does the current set-up, which holds hearings in public, has a punitive effect and makes available the outcomes of hearings on the internet, incentivise doctors to openly admit and voluntarily report their own substandard clinical practices, wrongdoings, mistakes or adverse incidents. For one, they would expose themselves to the possibility of fitness to practise hearings and/or legal reprisals. More importantly, as pointed out by commentators, any system which names and shames encourages secrecy and cover-up, rather than the candour needed to improve patient safety [95]. Further, since many errors in medical practice (including medication, procedures and diagnosis) can be externally induced [96] and arise from the complexity of the healthcare delivery system itself [97], the FTP hearings conducted by the MPTS that can only address an individual doctor's practice may not adequately address patient safety where the problem is of a systemic nature [98].

IV. Conclusion

The GMC, in its role as the regulator of the medical profession in the UK, has been vested since its inception in 1858 with the power to discipline doctors by taking action against their registration. However, this power has been used sparingly throughout its history and when exercised, it was not always driven by concerns over patient safety or protection. Neither have the processes involved always been clear and transparent to the public. The Shipman case and a number of other high-profile cases which emerged in the full glare of media publicity at the beginning of the 20th century have drawn attention to questions about how the GMC reacts to the increase in the number of unethical and incompetent doctors [99]. Keen to assuage rising criticism that it is overly protective of doctors, fitness to practise underwent a profound change in the last 10 years or so. One of the most recent and significant reforms is the launch of the MPTS as an independent adjudicatory body in June 2012.

In the first year of its operation, the MPTS heard 173 cases. In over 70% of those cases, the doctors' fitness to practise was found to be impaired and sanctions were meted out. These were over issues that arose in medical practice and in the doctors' private lives. As discussed, the MPTS' will-

[93] *Ibid*., paragraph 1.8.

[94] *Ibid*., paragraph 1.117.

[95] Quick, O., 'Patient safety and the problem and potential of law' (2012) *Professional Negligence* 78; Haynes, K., 'Clinical risk management: reality or rhetoric? Experience from the UK — a personal view' (2003) *Medico-Legal Journal of Ireland* 83 at 86.

[96] Reason, J., *Human Error* (Cambridge: Cambridge University Press, 1990) p. 15.

[97] Kopec, D., *et. al*., 'Human errors in medical practice: a systematic classification and reduction with automated information systems' available at http://www.scibrooklyn.cuny.edu/~kopec/research/new/Final_J_Med_Sys_10_16_02.pdf/.

[98] Timms, M., *op. cit*., p. 37.

[99] Lowe, M., *et. al*., 'Is it possible to assess the "ethics" of medical school applicants?' (2001) 27 *Journal of Medical Ethics* 404.

ingness and ability to take action in both of these spheres could certainly engender a safer environment for patients. By holding its hearings in the open and by publishing the details and outcomes of its FTP hearings on the internet, these also make the process transparent to the public and could serve as a strong incentive on the part of doctors to avoid irresponsible and unacceptable behaviour. However, the earlier discussion also expressed concern that this "name and shame" approach could be detrimental to patient safety as could the redemptive model adopted which may encourage exaggerated or feigned remorse or insight to escape a heavier penalty.

It is therefore difficult to predict, on the basis of its first year's work, whether the current framework is the best solution to the call for more effective public protection. It is too early to tell and the MPTS should be given the opportunity to prove its worth. The potential to evolve new processes, however, gives rise to optimism that the GMC can indeed meet the challenges of changes both in society and the delivery of medical services.

Chapter 1: Preventive environment and measures

PATIENT SAFETY IN E-HEALTH AND TELEMEDICINE

Alexandre Dias Pereira [1]

Abstract*: Information and communication technologies provide opportunities for medical practice at a distance, including medical information, consulting, diagnosis, or even surgeries. Technologies can overcome physical distances and boundaries and promote wider access to health care. However, telemedicine raises issues of patient safety. The risk of malpractice may increase as both doctors and patients are not physically present, technologies may be unreliable or at least require special training to be operated by electronic means at a distance. Safety and confidentiality of communications are also sensitive questions. How does the legal system cope with the technological challenge? Are there specific rules for telemedicine? This paper addresses the European and national legal framework on telemedicine concerning licensing requirements, reimbursement, jurisdiction and applicable law. It has supported the communication to the IV European Conference on Health Law, which took take place in Coimbra, Portugal, from October 9th to 11th, 2013,*

1. Introduction

1.1. *Telemedicine projects.* Telemedicine is emerging as an alternative or a complement to traditional medical practice. In the European Union, the strategic document 'A Digital Agenda for Europe' [2], aims widespread deployment of telemedicine by 2020. In the US the American Telemedicine Association [3] presents itself as 'the leading international resource and advocate promoting the use of advanced remote medical technologies', and the U.S. Department of Health and Human Services' Health Resources and Services Administration (HRSA) Office for the Advancement of Telehealth has funded the Telehealth Resource Centers (TRCs) [4].

On this side of the Atlantic, Norway has launched a leading project on telemedicine as a response to problems of very low population density, long distances to see a doctor, and ageing population. The Norwegian Centre for Telemedicine (NST) is located in the city of Tromsø in the north of Norway. The Centre's mission is to produce and provide knowledge about telemedicine and e-health, both nationally and internationally. The goal is to ensure the integration of telemedicine services into health care. It is internationally well-known and has been a World Health Organization (WHO) Collaborating Centre for Telemedicine since 2002 [5].

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[2] COM(2010)245 final.

[3] http://www.americantelemed.org/

[4] http://www.telehealthresourcecenter.org/. There are a total of 14 TRCs which include 12 Regional Centers, all with different strengths and regional expertise, and 2 National Centers which focus on areas of technology assessment and telehealth policy.The webiste of TRCs has a module on legal and regulatory concerns raised by Telehealth, especially regarding cross-state practice and reimbursement.

[5] http://www.ehealthservices.eu/project_partners/nst

In Portugal, telemedicine is already connecting five districts in the Centro Region, notably Guarda, Coimbra, Viseu, Aveiro and Leiria, networking circa 50 units of healthcare. The telemedicine program also provides access to medical specialities, in particular pediatry, cardiology, imagiology, dermatology, endocronology, and psiquiatric medicine. There are also specialized private operators, such as the Institute of Telemedicine LLP ("Instituto de Telemedicina, Lda."), which provides medical services and consulting, diagnosis and therapeutics, by telemedicine [6].

1.2. *Advantages of telemedicine and the emerging market for eHealth services.* Telemedicine has many advantages for healthcare systems, in particular reducing hospitalisation costs, saving on unnecessary emergency visits, shortening waiting times, improving access to healthcare by patients living in remote areas, and facilitating across border healthcare.

Telemedicine is also a new economic opportunity. The global market for eHealth is estimated to have a potential value of €60 billion, of which Europe represents one third, i.e. €20 billion. The combined global value of the telehome and telehospital market in 2011 was estimated at €8.8 billion, which will climb to €20.7 billion in 2016, according to a BCC Research study of March 2012 [7].

1.3. *Definition of telemedicine and e-health services and the problem of lack of legal security.* Telemedicine is defined as "the provision of healthcare services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients" [8]. Examples of telemedicine services are teleradiology, teleconsultation, telemonitoring, teleophtalmology, telesurgery and teledermatology. In broad sense telemedicine also includes other e-health services, notably health information portals, online pharmacy [9], electronic health record systems, electronic transmission of prescriptions or referrals (e-prescription, e-referrals), and e-prescription.

There is no uniformity of regulations among EU Member States concerning telemedicine services. This lack of legal security is considered an obstacle to the development of eHealth market. [10] Most Member States do not have legal instruments specifically dealing with telemedicine, and only a few have adopted national regulations or professional and ethical guidelines concerning the provision of telemedicine

[6] http://www.i-telemedicina.pt/

[7] Commission Staff Working document on the applicability of the existing EU legal framework to telemedicine services, SWD(2012) 414 final, Brussels, 6.12.2012.

[8] See Commission Communication on telemedicine for the benefit of patients, healthcare systems and society, COM(2008)689; and Commission Staff Working document on the applicability of the existing EU legal framework to telemedicine services, SWD(2012) 414 final, Brussels, 6.12.2012.

[9] In Portugal online pharmacy has been authorized by Decree-Law No 307/2007 of 31 August, implemented by Ministerial Order No 1427/2007 of 2 November.

[10] Legal concerns raised by telemedicine include, notably, licensing requirements for delivering cross-border telemedicine (1), compliance with data protection regulations (2), conditions and rights for reimbursement (3), liability (4), jurisdiction and applicable law (5).

services. Some national legal systems, such as Poland, require the physical presence of the patient and health professional at the same time and in the same place, for a medical act to be legally valid [11] [12].

2. The principle of freedom to provide telemedicine services in the internal market

2.1. *General rule.* Telemedicine is a service and as such falls under the provisions of the Treaty on the Functioning of the European Union (TFEU). [13] The European Court of Justice has consistently held that health services fall within the scope of the freedom to provide services (Article 56 TFEU) [14] and that neither the special nature of health services nor the way in which they are organised or financed removes them from the scope of this fundamental freedom [15]. This includes citizens' freedom to seek and receive health and care services from another Member State, regardless of how the service is delivered, i.e. including through telemedicine, as the Court expressly recognised that the freedom to provide services applies to services, which a provider supplies without moving from the Member State in which he is established, to recipients in other Member States [16].

2.2. *Possible restrictions.* Member States are, however, allowed to maintain or introduce restrictions to the free movement of services, provided that these are justified by imperative reasons of public interest (e.g. public health), do not exceed what is objectively necessary for that purpose and that the same result cannot be achieved by less restrictive rules [17].

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[11] EU legal framework to telemedicine services, SWD(2012) 414 final. This paper provides a synopsis of the document, addressing legal issues of telemedicine such as the free provision of services in the internal market, telemedicine as cross-border healthcare and information society services, licensing, and jurisdiction.

[12] Albeit not covered by this paper, protection of data and privacy in electronic communication is also a relevant issue of telemedicine. In fact, telemedicine by its nature involves personal data processing through the generation and/or transmission of personal data related to health. Article 8 of the EU Charter of Fundamental Rights, which has become legally binding, guarantees the fundamental right to the protection of personal data and it is enshrined in Article 16(1) of the Treaty on the Functioning of the EU (TFEU). According to the Directive on the application of patients' rights in cross-border healthcare the Member State of treatment must ensure that the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.

Directive 95/46/EC (currently under review) is the general EU law on the protection of personal data, which sets the rights of data subjects and establishes criteria for the legitimacy of processing personal data, including "personal data on health". It prohibits the processing of personal data related to health unless certain conditions are fulfilled (Article 8 of the Directive). According to the European Court of Justice, the notion of "data concerning health" must be given a wide interpretation, so as to include information concerning all aspects, both physical and mental, of an individual's health (European Court of Justice, Judgment of 6 November 2003, Case C-101/01 — *Bodil Lindqvist*, 50 and 51).The Article 29 Data Protection Working Party provided further interpretation of this concept by recommending that health data should cover: a) any personal data closely linked to the health status of a person only, such as genetic data or data on consumption of medicinal products, alcohol or drugs; b) any other data contained in the medical documentation concerning the treatment of a patient — including administrative data (social security number, date of admission to hospital, etc.), so that any data that is not relevant for the treatment of the patient, should not be included in the medical files. On the other hand, Directive 2002/58/EC lays down specific requirements in connection with the provision of publicly available electronic communications services in public communications networks to ensure confidentiality of communications and security of their networks.

[13] EU legal framework to telemedicine services, SWD(2012) 414 final.

[14] ECJ judgment of 31 January 1984 in joined cases 286/82 and 26/83 *Luisi and Carbone.*

[15] See in particular ECJ judgment of 28 April 1998, in case C-158/96 *Kohll;* ECJ judgment of 12 July 2001 in case C-368/98, *Vanbraekel;* ECJ judgment of 13 May 2003 in case C-385/99, *Müller-Fauré and Van Riet*; ECJ judgment of 12 July 2001 in case C-157/99, *Smits and Peerbooms*; ECJ judgment of 16 May 2006 in case C-372/04, *Watts*.

[16] ECJ judgement of 10 May 1995 in case C-384/93 *Alpine Investments*.

[17] ECJ judgment of 02 March 2011 in case C-108/91 *Ker-Optika*, 58 until 76. ECJ judgement of 4 December 1986 in case 205/84, *Commission v Germany*, paragraphs 27 and 29; ECJ judgment of 26 February 1991 in case C-180/89, *Commission v Italy*, paragraphs 17 and 18; and ECJ judgement of 20 May 1992 in case C-106/91, *Ramrath*, paragraphs 30 and 31.

It means, in short, that, in principle, Member States should not adopt any national law, which would prevent service providers from exercising their freedom to provide telemedicine services. Any obstacle to the freedom to provide services across borders is prohibited, unless it is justified by imperative reasons of public interest, for example on grounds of public health. Administrative and reimbursement difficulties might represent obstacles in this regard, and Member States should prove that they are justified.

Does telemedicine have sensitive concerns which may justify, under the rule of reason, protective regulations at national level against cross-border telemedicine?

2.3. *The Portuguese Deontological Regulation of Telemedicine.* In Portugal, the Medical Deontological Code [(18)] has a chapter on telemedicine. Telemedicine is not prohibited, but it does not appear to be a preferential or privileged mode of medical practice.

To begin with, the Code provides the principle of freedom of doctors to use telemedicine. This principle is enshrined in a provision on doctor's liability (Art. 95), and means that doctors are free and completely independent to decide whether to use or to refuse telemedicine (Art. 95/1). A doctor who asks the opinion from a colleague is liable for treatment as well as for decisions and recommendations given by him to the patient (Art. 95/2). Moreover, tele-consulted doctors have no obligation to issue an opinion where they have not knowledge or enough information on the patient to give a reasoned opinion, but they are liable for it if they give it (Art. 95/3).

On the other hand, the Code provides that telemedicine must respect the doctor-patient relationship (Art. 94), preserving mutual trust, independence of doctor's opinion, patient's autonomy and confidentiality (Art. 94/1). Where the patient requests a supervision consultation by means of telemedicine, this must not replace the doctor-patient relation and shall only be given if the doctor has a clear and justifiable idea of the clinical situation of the patient (Art. 94/2).

Then, doctors who use means of telemedicine and do not physically observe the patient in presence must carefully evaluate the received information, and they can only give opinions, recommendations or take medical decisions where the quality of the received information is enough and relevant (Art. 94/3). In telemedicine emergency situations it is allowed that the opinion of the tele-consulted doctor be based upon incomplete information, but the assistant doctor shall be liable for the decision to be taken (Art. 94/4).

On the other hand, the Code contains a special provision of patient's security in telemedicine (Article 96). It provides that doctors shall only use telemedicine provided that they make sure that the team in charge of its performance assures a level of quality sufficiently high which works in a proper way and complies with established regulations (Art. 96/1). In particular, doctors must use supporting systems, quality controls and evaluation procedures to monitor the accuracy and the quality of the

[(18)] Enacted by Regulamento n.º 14/2009 of 13 January 2009 — http://dre.pt/pdf2sdip/2009/01/008000000/0135501369.pdf

received and transmitted information (Art. 96/2). Moreover, doctors can only use telemedicine once they have made sure that the system used and its users assure medical secret, namely by means of encryption of names and other identifying data (Art. 96/3).

Confidentiality is a sensitive issue of telemedicine. Concerning collaborators who are not doctors and take part in the transmission or reception of data, doctors must make sure that the education and skills of such professionals are adequate, so that they can assure an appropriate use of telemedicine and the preservation of medical secret (Art. 95/4). Telemedicine practitioner doctors clarify the patient and obtain his consent according to Articles 44 to 48 of the Deontological Code (Art. 95/5), and they must assure the application of security measures established to protect the patient's confidentiality (Art. 95/6).

Concerning clinical records, doctors using telemedicine must register in the clinical file the methods of identification of the patient as well as information requested and information received (Art. 97/1). Tele-consulted doctors must register in the clinical file the opinions which they have issued and the information upon which they have based their opinions (Art. 97/2). Computerized methods of storage and transmission of the patient's data may only be used where enough measures have been adopted to protect confidentiality and security of stored or exchanged information (Art. 97/3).

In short, the deontological Code allows doctors to use telemedicine, provided that it respects the doctor-patient relation, patient's security and confidentiality.

Do these special concerns of the deontological Code prevent the provision of telemedicine by doctors established in another Member State to patients located in Portugal?

In principle it should not have a restrictive effect on the freedom to provide medical services within the internal market. But it is possible that the telemedicine concerns may justifiably obstacle an absolute freedom of telemedicine.

3. Telemedicine as (possible) cross-border healthcare and as information society service

3.1. EU Directive 2011/24 on the application of patients' rights in cross-border healthcare [(19)], due to be transposed by 25 October 2013 [(20)], codified the jurisprudence of the European Court of Justice on EU patients' rights to be reimbursed for medical treatment in other EU Member States [(21)], including through eHealth and telemedicine [(22)].

Telemedicine services fall within the scope of this Directive when they are health services provided by health professionals [(23)]. It contains two express

[(19)] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

[(20)] A proposal for the implementation of Directive 2011/24/EU has been open to public discussion — http://www.portaldasaude.pt

[(21)] E.g. judgment of 27 October 2011, C-255-09, Commission v. Portugal.

[(22)] EU legal framework to telemedicine services, SWD(2012) 414 final.

[(23)] Health care professional, as defined in Article 3(f) of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, "means a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment".

references to telemedicine (Article 3(d) and Article 7(7)) and its scope covers "the provision of healthcare to patients, regardless of how it is organised, delivered or financed" (Article 1(2)). This Directive clarifies patients' rights to be reimbursed for the provision of cross-border health services, including cross-border telemedicine services. The key applicable provisions are the following:

a) Rights are established to ensure that the essential information on prices, quality and safety of care are accessible to the patient to ensure an informed decision;
b) The Member State of treatment (that in case of telemedicine is the Member State where the service provider is established) must ensure that the healthcare in question is provided in accordance with its legislation (Article 4(1));
c) The principle of non-discrimination with regard to nationality is recognised and applies both to access and to fees charged for medical services (Article 4(3) and (4)).
d) In principle, the Member State of affiliation of the patient ('home-country') shall reimburse the costs of cross-border healthcare if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation.

3.2. EC Directive 2000/31 on electronic commerce [24] creates a legal framework to ensure the free movement of information society services. It sets information requirements for information society service providers, rules on commercial communications, contracts concluded by electronic means and the liability of intermediary service providers [25].[26]

In order for a telemedicine service to qualify as an information society service, it needs to be a "service normally provided for remuneration, at a distance, by electronic means, at the individual request of a recipient of service" [27].

[24] Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce').

[25] The specific liability regime of intermediaries of information society services provided for the eCommerce Directive does not apply to the providers of telemedicine services as they are not considered "intermediaries" in the meaning of Articles 12-15 of the eCommerce Directive.

[26] See Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee — First Report on the application of Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce), COM(2003)702 final.

[27] Article 2(a) and Article 1(2) of Directive 98/34/EC (Regulatory Transparency Directive) and whereas 17 of eCommerce Directive. The notion of information society services has four elements: for remuneration (1), at a distance (2), by electronic means (3), at the individual request of a recipient (4). "Remuneration" is to be considered in relation to the service in question, regardless of who effectively pays for the telemedicine service. "At a distance" means that the service is provided without the parties being simultaneously present. All telemedicine services are by definition provided at a distance. "By electronic means", i.e. the service also has to be sent initially and received at its destination by means of electronic equipment for the processing (including digital compression) and storage of data, and entirely transmitted, conveyed and received by means of wire, radio, optical means or other electromagnetic means. This means that the following health services are not information society services: a) services provided in the physical presence of the provider and the recipient, such as medical examinations at a doctor's premises, even if using electronic equipment; b) services which are not using online telecommunication services, such as a telephone or telefax medical consultation or medical call-centers providing services through traditional *voice telephony*. "At the individual request of a recipient" means that services falling under the definition of information society service are those provided in response to an individual request from the recipient. Telemedicine services are usually provided at the individual request of a recipient. Patients *being* treated by a doctor using telemedicine services (e.g. teleradiology), implicitly accept such services and this constitutes the individual request. Examples of services supplied on individual request can be found in the Vade-mecum to the Regulatory Transparency Directive, which include "*doctors (computer medicine), etc., access to databases, data and file management, consultation, diagnosis etc.*"

The main provisions of the eCommerce Directive that apply to cross-border telemedicine are the following:

a) The *country of origin principle* provides that the law applicable to an information society service will be the law of the Member State in which the service provider is established, i.e. the place in which a service provider effectively pursues an economic activity using a fixed establishment for an indefinite period. The Member States may however under certain circumstances and procedural conditions and on a case-by-case basis take measures to restrict the provision of a particular online service from another Member State (Article 3).

However, according to the Regulatory Transparency Directive [(28)], Member States wishing to adopt a regulation on telemedicine services as information society services will have to notify it to the Commission and to other Member States before adoption. This requirement seeks to verify that the future regulation will not create obstacles to the free movement of information society services and to the freedom of establishment (of information society service providers) within the internal market.

b) The principle of *free access to the electronic market* means that Member States cannot subject the taking up and the pursuit of the activity of an information society service provider to prior authorisation or any other requirement having an equivalent effect (Article 4 (1)).

c) Concerning *duties of information and freedom of commercial communications***,** information society service (ISS) providers, including telemedicine providers, have to render easily, directly and permanently accessible to the recipients of the service a set of information, such as their identity and contact details on their website. Regulated professions have to provide additional information concerning, for instance, their professional body or registered institution, professional title and the Member State where it has been granted.

Telemedicine providers have to comply with some specific requirements when using commercial communications for the promotion of e-Health services or products (Articles 6 and 7), for instance, ensuring they are clearly and unambiguously identifiable as such. The rules on unsolicited commercial communications were complemented by new rules in Directive 2002/58, amended by Directive 2009/136 [(29)]. The principle is the requirement of prior consent and the right to opt-out.

Members of regulated professions may use commercial communications online, subject to compliance with such professional rules governing the independence, honour and dignity of the pro-

[(28)] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, as modified by Directive 98/48/EC.

[(29)] Directive 2009/136/EC of the European Parliament and of the Council of 25 November 2009 amending Directive 2002/22/EC on universal service and users' rights relating to electronic communications networks and services, Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector and Regulation (EC) No 2006/2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws.

fession. Restrictions are allowed but a total ban of commercial communications is to be removed by Member States according to Article 24(1) of Directive 2011/24/EU on services in the internal market.

4. Licensing

In order to provide telemedicine cross-border within the EU, do healthcare professionals also need to be licensed or registered in the Member State of the patient? The 'country-of-origin principle' answers to this question.

4.1. Licensing is required at the source, i.e. in the country of origin. In most Member States, the competence to accredit professionals wishing to deliver health services is delegated to an appointed licensing or registration body.

In Portugal this body, concerning doctors, is the *Ordem dos Médicos* (Doctors' Association). Registration is restricted to graduates in medicine by a Portuguese medical school or, where recognized, by a foreign medical school. Upon being licensed/registered, the health professional will have to abide by the rules and regulations established by the licensing authority (the professional body) and to be subject to disciplinary sanctions in case of non-compliance.

4.2. The Member State of establishment is the Member State of provision of telemedicine. In fact, Directive 2001/24/EU provides that the Member State of treatment is that of the service provider's Member State of establishment, and that "healthcare is considered to be provided in the Member State where the [telemedicine] healthcare provider is established" (Articles 3 (d) and 4(1)(a)).

The application of the legislation of the service provider's Member State of establishment (as the 'country-of-origin principle') is also enshrined in the e-Commerce Directive (Article 3(1) and 3(2) of Directive 2000/31/EC). It means that Directive 2005/36/EC on the recognition of professional qualifications [30] does not apply to healthcare professionals providing cross-border telemedicine. [31] Article 5(2) of this Directive provides that it is only applicable to situations where the service provider actually moves to the territory of a host Member State to pursue a regulated profession. As indicated above, telemedicine services are provided without the actual movement of the telemedicine provider health care professional.

5. Reimbursement

Cross-border telemedicine services are, in principle, entitled to reimbursement. According to Directive 2011/24/EU, patients are entitled to be reimbursed by their Member State of affiliation, for the healthcare received in another EU Member State, if the healthcare in question is among the benefits to which the insured person is entitled in his home country.

The Directive 2011/24/EU makes it clear that cross-border healthcare services using e-Health services are also to be reimbursed (Recital 26). The

[30] Directive 2005/36/EC of the Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications.

[31] EU legal framework to telemedicine services, SWD(2012) 414 final

Member State of affiliation may impose on an insured person seeking reimbursement of the costs of cross-border healthcare, including healthcare received through the use of telemedicine, the same conditions, criteria of eligibility and regulatory and administrative formalities as it would impose if this healthcare were provided on its territory (Article 7(7)).

On the other hand, reimbursement of cross-border healthcare, cannot, as a rule, be subject to prior authorisation (Article 7(8)). Member States may however introduce a system of prior authorisation only for certain types of healthcare and under strict conditions (Article 8(2)), such as planning requirements and the use of highly specialised and cost-intensive medical infrastructure or medical equipment. Such a system has to be restricted to what is necessary and proportionate to the objective to be achieved. Member States should notify to the European Commission of the set-up of a prior authorisation system and make publicly available which healthcare is subject to such system.

The Directive also limits the conditions under which the Member State of affiliation may refuse to grant prior authorisation to an insured person (Article 8(6)).

6. Jurisdiction and applicable law in case of damage

An important issue is the determination of the competent court and the applicable law where the patient seeks compensation for damages suffered due to telemedicine [32].

6.1. For civil and commercial matters, the rules determining the *competent jurisdiction* in a cross-border situation are provided in Regulation 44/2001 [33].

To begin with, parties are free to designate, by written agreement, which court should be competent to resolve a possible conflict arising between them (Article 23). However, consumer protection limits the possibility for such a designation in the case of a consumer/ professional contractual relationship (Article 17).

Where parties do not contractually define the court of their choice, as a general rule jurisdiction is to be exercised in the Member State in which the defendant is domiciled, regardless of his/her nationality. However, in certain circumstances a defendant may be sued in the courts of another Member State.

In matters involving a non-contractual relationship, the competent courts are those of the place where the harmful event occurred or may occur (Article 5(3)). This includes the place where either the act causing harm or the direct damage occurs. In cross-border telemedicine, the place where the act causing the damage occurs is located in the Member State where the professional is when delivering the service (a); and the place where the damage arises is located in the Member State where the patient was when he received the medical advice or treatment (b).

In matters involving a contractual relationship a distinction is made between contracts between

[32] EU legal framework to telemedicine services, SWD(2012) 414 final.

[33] Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters hereinafter "Regulation Brussels I".

professionals only (B2B) and contracts between professionals and consumers (B2C).

In B2B contracts, the competent courts are the courts in the Member State where, under the contract, the services were provided or should be provided (Article 5(1)(b)). In B2C contracts, where the professional's activity is 'directed to the Member State of the consumer's domicile or to several States including that Member State', the consumer may only be sued (e.g. over a dispute concerning an unpaid bill) before the competent courts of the Member State of his domicile, and he has a choice to sue either in the Member State where the other party is domiciled or in the Member State where he is himself domiciled (Article 15(1)(c) and Article 16). In the rulings *Alpenhof* and *Pammer* [34], the European Court of Justice clarified the notion of 'directed activities' in the context of the internet, holding that to determine whether a trader's website is 'directing' its activity to the Member State of the consumer's domicile, it should be ascertained whether, before the conclusion of any contract, it was apparent from the website and the trader's overall activity that he was foreseeing business opportunities in that Member State [35]. Accordingly, "the mere accessibility of the trader's or the intermediary's website in the Member State in which the consumer is domiciled is insufficient", for ex. where a Portuguese consumer requests from a Swedish telemedicine provider services available only in Swedish.

If the activity is not directed to the Member State of the consumer's domicile, the competent courts are the courts in the Member State where, under the contract, the services were provided or should be provided (Article 5(1)(b)). In cross-border telemedicine scenarios, it is argued by the European Commission that, by analogy with the case-law concerning the delivery of goods, it could be reasonably be the Member State where the patient was when he received the advice or treatment [36]. However, according to Directive 2011/24/EU: "In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established" (Article 3(d)).

6.2. Concerning *law applicable to contracts***,** Regulation Rome I [37] provides rules on the applicable law to civil and commercial contracts.

Concerning contracts between professionals (B2B), the general rule is the freedom of choice of the parties, meaning that the applicable law to the contract will be the one expressly chosen by the parties. In the absence of choice, the default rule for services contracts shall apply, according to which contracts for the provision of services are governed

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[34] ECJ Rulings C-144/09 and C-585/08 of 7 December 2010.

[35] The Court also formulates a non-exhaustive list of matters from which it may be concluded that the trader's activity is directed to the Member State of the consumer's domicile: "*the international nature of the activity, mention of itineraries from other Member States for going to the place where the trader is established, use of a language or a currency other than the language or currency generally used in the Member State in which the trader is established, mention of telephone numbers with na international code, outlay of expenditure on an internet referencing service to facilitate access to the trader's site or that of its intermediary by consumers domiciled in other Member States etc.*".

[36] EU legal framework to telemedicine services, SWD(2012) 414 final.

[37] Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I Regulation).

by the law of the Member State where the service provider has his habitual residence (Article 4(1)(b)), i.e. the home-country of the telemedicine provider.

Concerning contracts between professionals and consumers (B2C), the parties are also free to choose the applicable, but the consumer may not be deprived of the protection afforded to him by the provisions of the law of his country that cannot be derogated from (due to their importance) through agreement. In case there's no choice of law agreement, the law applicable is either the law of the country where the consumer has his habitual residence (Article 6) in case the healthcare professional directs its activities to the Member State where the consumer has his habitual residence or to several countries including that country (i), or the law of the Member State where the service provider has his habitual residence (Article 4(1) b)) in case the healthcare professional does not direct its activities to the Member State where the patient has his habitual residence (ii).

6.3. As for *law applicable to torts*, Regulation Rome II [38] applies to situations involving a conflict of laws regarding non-contractual obligations in civil or commercial matters.

The law applicable to torts is the law of the country in which the damage occurs, i.e. the Member State where the patient was when he received the treatment. This law applies irrespective of the country in which the event giving rise to the damage occurred (i.e. the Member State where the healthcare professional was when he delivered the advice/treatment) and irrespective of the country or countries in which the indirect consequences of that event occur (Article 4(1)). Notwithstanding, under certain conditions, the parties may choose another applicable law by an agreement entered into after the event giving rise to the damage occurred (Article 14).

In what concerns the relationship between the applicable law and the country-of-origin principle, Article 4 of Directive 2011/24/EU provides that cross-border healthcare shall be provided in accordance with the legislation of the Member State of treatment and the standards and guidelines on quality and safety laid down by that Member State (Article 4 of Directive 2011/24/EU), i.e. treatment must be carried out in a way that complies with the provider's local law. 105

However, this does not derogate from the rules set out in the Rome I and II Regulations on applicable law (Article 2(q) of the Directive2011/24/EU), as the law applicable to civil liability may be of a different Member State than the one of the healthcare provider. The scope of Article 4 of Directive 2011/24/EU is limited to public law issues, and goes hand-in-hand with Article 17 of the Rome II Regulation, according to which in assessing the conduct of the person claimed to be liable, account shall be taken of the rules of safety and conduct in force in the place of the event giving rise to liability [39]. For example, if the Member State of

[38] Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II Regulation).

[39] EU legal framework to telemedicine services, SWD(2012) 414 final.

treatment is Portugal because it is the country of origin of the telemedicine provider but the parties have chosen Spanish law, the latter will apply to civil liability between the parties despite the standards imposed by Portuguese law are still relevant in determining whether a surgeon has complied with local requirements on standards and guidelines on quality and safety applicable to telemedicine.

Chapter 1: Preventive environment and measures

PATIENT'S RIGHTS IN POLAND

Katarzyna Syroka-Marczewska [1]

Introduction

Patient's rights constitute integral part and substantiation of human rights and arise from common feel of threat to subjective rights and person's dignity [2]. It is extremely dynamic field, therefore it requires legislator's reaction for changing reality. Several recent years have brought new legal regulations regarding and numerous domestic, European and international acts of law made patients' rights the center of interest for governments, organizations, foundations and associations.

Patients' rights vary in different countries and in different jurisdictions, often depending upon prevailing cultural and social norms. Different models of the patient-physician relationship — which can also represent the citizen-state relationship — have been developed, and these have informed the particular rights to which patients are entitled [3].

The goal of this paper is to explore the legal context and Polish regulation about patient's right and try to answer how it work in practice. I will give a short overview of international documents and guidelines with regard to the legal aspects of patient safety, after which I will analyse the patient rights. In addition I will try to examine new extended functions of the Office of the Polish Ombudsman as an independent central administrative body.

The activity of the World Health Organization

The activity of the World Health Organization, development of health systems and easy access to health care services have had a great impact on the development of patient's rights [4]. In 1994, the World Health Organization introduced the Declaration on Promotion of Patients' Rights in Europe (hereinafter referred to as: the Declaration). The Declaration constitutes a common European framework for action and should be interpreted as an enhanced entitlement for citizens and patients to improve partnership in the process of care with health care providers and health service managers. According to this Declaration national situations

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[2] Ewa Kujawa, Patient Rights — a new reality, a new moral dilemmas, [:] Grażyna Rogala-Pawelczyk: Patient rights and professional ethics of nurses and midwives, 27-30 (1998); Grażyna Iwanowicz-Palus, Patient Rights in Poland, Law and Medicine, 80, 8 (2000).

[3] World Health Organization, http://www.who.int/genomics/public/patientrights/en/

[4] Mirosław Nestorowicz, Medical Law, 16-20 (9th edition 2010).

vary in respect of legal frameworks, health care systems, economic conditions, and social, cultural and ethical values, but there are some common approaches, which can be appropriately adapted to the circumstances in each country, related to the following components:

- legislation or regulations, specifying the rights, entitlements and responsibilities of patients, health professionals and health care institutions;
- national colloquia and conferences to bring the parties together in order to create and promote the sense of common understanding
- medical codes and other professional codes, patients' charters and similar instruments, drawn up in the light of common agreements between representatives of citizens, patients, health professionals and policy--makers, and periodically revised in response to changing circumstances;
- networking between and among patients and health care providers, recognizing the distinction between citizen and user participation;
- government support for the establishment and effective management of nongovernmental organizations (NGOs) in the field of patients' rights;
- involvement of the media in informing the public, stimulating constructive debate and maintaining awareness of the rights and responsibilities of patients and users and their representative organs;
- improved training in communication and advocacy skills for health professionals as well as for patients and other users, for further development of a proper understanding of a perspective and role of all parties;
- promotion of researching to evaluate and document the effectiveness of provisions — legal and other, and various initiatives undertaken in different contexts of different countries [5].

Patient's rights: Polish legal regulation

The Declaration serves as guidelines that shall be applied in particular countries. The reference can be found in the Polish Charter of Patient's Rights, which was presented and publicized in 1998 by the Minister of Health. Simultaneously, Health Maintenance Organizations (HMO) established the institution of the contemporary Ombudsman of Patient's Rights, which was still present after formation of National Health Fund (NFZ). Another step towards protecting and executing patient's rights was establishment of the Office for Patient's Rights in 2002 — under the regulation of the Minister of Health of December 28, 2001, — as a single budget entity and the spokesperson for patient's rights at psychiatric hospitals. All the initiatives mentioned above had limited scope of action, which led to the need of establishing a new institution that would operate in Poland to protect patients' rights, and

[5] http://www.who.int/genomics/public/eu_declaration1994.pdf

would be independent from the Minister of Health, NFZ and medical governments [6].

It was decided to regard the Ombudsman of Patient's Rights as the central body of governmental administration, competent in cases regarding protection of patients' rights. Consequently, on November 6, 2008, Parliament passed the act on the patient's rights and the Ombudsman of Patient's Rights [7] (hereinafter referred to as Apr), which became effective on June 5, 2009. On October 2, 2009, the Prime Minister, Donald Tusk, appointed Krystyna Barbara Kozłowska to the position of the Ombudsman of Patient's Rights. The Office of the Ombudsman is an independent central administrative body in Poland. In addition the Patients Ombudsman can cooperate with governmental and non-governmental organizations, produce and disseminate educational materials, as well as take legislative initiative on behalf of a better protection of the rights of patients [8].

The Apr try to regulated patient's rights in a comprehensive manner, but we also have to bear in mind other legal regulations in this regard, for example: the act on the professions of physician and dentist [9], the act on healthcare services financed from public funds [10], the act on medical activity [11], the act on mental health [12].

The Apr regulates the following areas:

- the right to receive health care (right to medical care of good quality)
- the right to information
- patient's right to medical confidentiality
- patient's right to give consent (to grant health care)
- the right of respect to intimacy and dignity
- patient's right to medical records
- right to respect for patient's family and private life
- patient's right to pastoral care
- patient's right to keep valuable goods in the deposit
- the right to inform about the side effects of medical products
- patient's right to raise objection against physician's opinion or decision

The right to receive health care (right to medical care of good quality)

The patient is entitled to receive health care, which are in compliance with the current state of medical knowledge. In the case of limited possibilities of granting certain health care benefits, to

[6] The need was also indicated in the recommendations, presented at the Polish conference "Biały Szczyt" on March 19, 2008 — there is a need of establishing an institution, which would deal with the protection of patient's rights. It would monitor patients' situation in the healthcare system, represent them in public institutions and address public institutions in systemic cases, regarding solutions improving protection and enforcement of patient's rights.

[7] Act dated November 6, 2008 on the patient rights and the Ombudsman of Patient Rights (Journal of Laws**, No. 52, Item 17).**

[8] Maria Sokalska, Patients' safety as seen from the perspective of the implementation of Poland's Law on Patients' Rights and the Ombudsman, Book of Abstracts, Fourth European Conference on Health Law, 9-11 October 2013 r., Coimbra, 79.

[9] Act dated December 5, 1996 on professions of doctor and dentist (Journal of Laws of 2011, No. 277, Item).

[10] Act dated August 27, 2004, on healthcare services financed from public funds (Journal of Laws, No 164, Item 1027).

[11] Act dated April 15, 2011 on medical activity (Journal of Laws of 2013, Item 217).

[12] Act dated August 19, 1994 on mental health (Journal of Laws, No 231, Item 1375).

objective, based on medical criteria, procedure establishing order of access to these benefits. Above mentioned entitlement has got temporary limitation, as "the legislator (...) anticipated an admissibility of so called medical queue — also due to limited financial resources"[13]. However, because of threat to patient's health or life, he's got the right to be immediately provided with health care benefits. Notwithstanding, in the cases of threat to health or life, the patient has got the right to be immediately provided with health care benefits, and in the event of delivery, the patient is entitled to receive health care benefits which are in connection with the childbirth. Health care benefits shall be granted with due diligence by the subjects providing health care benefits in the conditions that meet professional and sanitary expectations described in separate provisions. When health care benefits are being granted, persons performing medical profession, shall foremost take into consideration professional ethics, specified by the bodies competent for such professions.

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Patient's right to be informed

Patient, including minor, who is over 16 or his social representative, have got the right to receive understandable information on the patient's health condition, diagnosis, suggested and possible diagnostics and treatment methods, possible to foresee results of their application and omission, treatment outcomes and prognosis. Patient has also right to not be informed, at their explicit request. After receiving above, he's got the right to present his opinion on the topic to the physician. Moreover, the patient is entitled to receive from the nurse or midwife, understandable information on his nursing and nursery treatment. On diagnosis of the disease constituting threat to life, the physicist shall inform gently and tactfully but honestly and exhaustively if possible; suppression of such information is forbidden ;however, limitation of provided information is acceptable [14].

The Slater case in England from 1767 reflected enlightenment medicine principles, when disclosure of medical information was first suggested and the court said, that It is reasonable that patient should be told what is about to be done to him [15]. Many years later in the USA the Mohr case along with the American Code of Medical Ethics first ordered physicians to inform their patients and obtain their consents to surgery: "The free citizen's first and great right — the right to himself this right necessarily forbids a physician …. to violate without permission the bodily integrity of his patient" [16].

[13] Court of Appeal 29.06.2004, I ACa 1/04, LEX **146712**

[14] Małgorzata Świderska, Patient right to be informed, (in: M. Nesterowicz, Patient Rights Act and the Patient Ombudsman. Commentary, 81, 2009

[15] Slater v. Baker and Stapleton case, 2 Wils. K.B. 358.

[16] Mohr v. Williams case 104 N.W. 12. Decision of the Minnesota Supreme Court authored by Calvin L. Brown. for almost a century, this case has been used in first-year Torts classes in American law schools to teach students about consent. Dr. Williams was a physician and surgeon and Mrs. Mohr was a patient who came to Dr. Williams complaining of trouble with her right ear. Dr. Williams examined her right ear and he discovered that there was a large perforation in the eardrum, that there was a large polyp in the middle ear, and that the ossicles of the middle ear were probably diseased. Dr. Williams also examined Mrs. Mohr's left ear, but he was unable to make a full examination because of a foreign substance in the left ear. On Dr. Williams' recommendation, Mrs. Mohr agreed to have surgery on her right ear to remove the polyp and diseased ossicles. Anesthetics were used during the operation. After the patient was unconscious, Dr. Williams made a full examination of Mrs. Mohr's left ear and discovered that it was in a worse state than her right ear: there was a small perforation high up in

In my opinion information should be communicated to the patient in a way appropriate to the latter's capacity for understanding, minimizing the use of unfamiliar technical terminology.

In practise it doesn't work in Poland properly, because usually patients are not properly advised about risks, possible results and alternatives to a proposed treatment. They do not share responsibility for their treatments in the way they were meant to. I agree with Eduardo Dantas, that one of the main problems in providing excellence in health care is not lack of money but lack of information [(17)].

Patient's right to medical confidentiality

Patient's right to medical confidentiality is strictly connected with the right to information. In my opinion it is of a crucial importance. Physician — patient privilege constitutes the found of trust towards physician and observance of the rule is strictly connected with the importance of this profession. Very often physicians are the ones who see people who they are for real, not who they want everyone else to think they are. The scope of described provision include all the data concerning patient, which have been obtained by the persons granting health care benefits, in relation to medical profession performance — this note refers to information given by the patient and individually observed by the benefit provider as well. Worth mentioning is the fact that information received from the third parties during medical profession activities performance is the subject to medical confidentiality. This obligation is still valid at the moment of the patient's death, which does not exclude any restrictions. Above mentioned exceptions have been regulated in apr in detail. Confidential information can only be disclosed if the patient gives explicit consent or if the law expressly provides for this.

Patient's right to give consent to grant health care

Patient's consent to grant health care benefits is of a crucial importance in the field of health protection. Relying medical intervention possibility on receiving appropriate consent gives the guarantee of respect for the patient's autonomy, and in wider perspective — respect of human's dignity, referred to in Article 30 of Polish Constitution. The consent shall be thus an act executing the protection of patient's autonomy in terms of basic personal interests [(18)]. It cannot be expressed under duress, mistake or in mental condition which makes conscious decision making impossible. Provisions of law do not regulate explicitly form in which patient or his statutory representative should give consent; however, due to evidence reasons,

the drum membrane, hooded and with rough edges, and the bone of the inner wall of the middle ear was diseased and dead. Dr. Williams also examined the right ear and found that it was not in as bad a condition as he had anticipated. He therefore decided to operate on the left ear instead of the right, performing an ossiculectomy, removing a part of the drum membrane and scraping away the diseased portion of the inner ear. Mrs. Mohr later brought suit against Dr. Williams, claiming that he had damaged her hearing and seriously injured her person, and that, because she had not consented to surgery on her left ear, his actions were wrongful and unlawful and constituted an assault and battery.

(17) Eduardo Dantas, Informational negligence: information as a prevention tool for patients and physicians, Book of Abstracts, Fourth European Conference on Health Law, 9-11 October 2013 r., Coimbra, 50.

(18) Marek Safjan, Law and Medicine, 35, 2009.

the most safe form is to give consent in writing. Moreover, in the event of operation, applying treatment method or diagnostics, which can precipitate higher risk for the patient, he consent shall be also given in writing. The content of the consent shall be explicit and must not refer to any medical procedures (*in blanco* method) — it must be clear to whom and for what action it is given.

The patient's consent should be preceded with appropriate information to which he's got the right to claim for. The Supreme Court has rightly noticed that the obligation of providing correct information by the physician is necessary circumstance in giving legally binding consent for particular type of treatment (referred to as "explained", "informed" and "realized" consent) and ineffectiveness of consent caused by granting inappropriate information can be seen as physicist's illegal action[19].

Making a medical procedure without the patient's consent is one of the offences against freedom. The Polish Penal Code of 1997 [20] has introduced in Article 192 new type of offence, which states that any person who performs medical procedure without the patient's consent, shall be liable with fine, penalty of limitation of freedom or imprisonment up to 2 years. According to Article 16 apr, the patient is entitled to give consent to particular health care benefits or refusal of such, after receiving understandable information from the physician. Due to age or mental condition, the patient cannot independently enjoy all the rights that he is entitled to. If the patient is a minor, the physician must be given so called substitute consent from the patient's statutory representative in order to conduct examination or provide other health care benefits [21]. In the case of a person fully incapacitated, the consent shall be given by the patient's statutory representative. If such person is able to provide factual-based opinion about the examination, receiving this person's consent is a must.

In the event of lack of statutory representative, the real guardian is entitled to give consent for undertaking the examination of a minor, fully incapacitated or unable to consciously give consent patient. If statutory representative of a minor, incapacitated or person unable to consciously give consent, does not give consent to conducting by physician operation or providing certain treatment or diagnostics and which would lead to higher risk for a patient and necessary for dismissal of threat for losing patient's life or serious injury or serious deterioration of health, physician can perform such activities after receiving consent from custodial court.

A minor, who is over 16, incapacitated person or mentally ill patient, or mentally handicapped, however disposing of sufficient factual-based knowledge on the issue is entitled to express objection as for health care benefits, despite the consent given by statutory representative or real guardian. In such case, permission from a custody court is a must.

[19] Supreme Court 18.01.2013, IV CSK 431/12, LEX nr 1275006

[20] Journal of Laws**, No. 88, Item 553**

[21] Eleonora Zielińska (red.), The act on the professions of physician and dentist . Commentary, 469, 2008.

The right of respect to intimacy and dignity of a patient

The right of respect to intimacy and dignity belongs to the filed of personal goods an constitutes, in connection with jurisdiction of the Supreme Court [22], the subject of protection provided in the Civil Code [23]. The patient's intimacy, which is closeness, shall be perceived in terms of any feeling and actions related to granting health care benefits [24]. According to W. Drabik, violation of intimacy is in connection with the feeling of shame [25]. On the other hand, "dignity is the personal good, which reflects internal feeling of self-esteem and importance as an individual. It is violated when some other person gives lower esteem than expected, which triggers off recipient's justified mental discomfort" [26]. This right also includes the right to die in peace and dignity. Terminally ill patient is entitled to health care benefits, which will lessen the pain and suffering in general.

Patient's right to medical records

The subject granting health care benefits, should make medical records available for the patient, his statutory representative or person authorized by the patient. After patient's death, the person authorized to his medical records is the person who was given such right by the patient. Medical records is made available:

- for inspection, including databases regarding health protection, in the seat of the subject granting health care benefits.
- by making extracts, duplicates or copies;
- by issuing an original with delivery receipt and reservation of return if entitled body or subject requires making original records available.

Patient has the right of access to medical files and technical records and to any other files and records pertaining to their diagnosis, treatment and care and to receive a copy. If the patient obliges return medical files, there is possibility to receive original.

Right to respect for patient's family and private life

The patient of the subject performing medical activity in the form of stationary or twenty-four-hour health care, has got the right to personal or phone contact as well as written correspondence with other persons. Moreover, he's entitled to receive supplementary nursing, which is additionally paid by the patient. There can be no intrusion into a patient's private and family life unless and only if, in addition to the patient consenting to it, it can be justified as necessary to the patient's diagnosis, treatment and care

[22] Supreme Court 18.01.1984, CR 400/83, OSNC 1984/11/195, "Intimacy and dignity are the personal goods of every

[23] Act of April 23, 1964 (Journal of Laws 64 No. 16, Item 93 with further amendments).

[24] Ibidem.

[25] W. Drabik, The right of respect to intimacy, Puls 1996, nr 7-8.

[26] Supreme Court 30.10.2003, IV CK 149/02, LEX nr 209289.

The right to inform about the side effects of medical products

Since November 25, 2013, as a result of amendment of pharmaceutical law, patient, his statutory representative or real guardian is entitled to report on side effects of a medical product to persons performing medical profession, President of the Office for Registration of Medicinal Products, Medical Devices and Biocide Products or to any subject responsible for introducing a medical product on the market . It is a new patients right in Poland, but in my opinion very important. Patient safety concerns also medical product.

Patient's right to raise objection against physician's opinion or decision

The European Court of Human Rights in Alicja Tysiąc case [27], found that the Polish legal framework did not provide an effective mechanism to resolve disagreements as to the availability or legality of therapeutic termination in any case, either between a pregnant woman and doctors or between medical staff themselves. The Regulation of the Minster of Health and Social Care of 22 January 1997 [28] on the professional qualifications of physicians', empowering to abort pregnancy and decide whether the pregnancy constitutes a threat to woman's life of health or indicates a real possibility of serious and irretrievable foetus defects or terminal illness constituting threat to its life [29] has been criticized by the European Court of Human Rights because it does not contain any appeal mechanism from the physician' decision refusing abortion. By 6 votes to 1, European Court of Human Rights held that there was a violation of Article 8 European Convention on Human Rights [30] (right to private life), as it is not the Court's task in the present case to examine whether the Convention guarantees a right to have an abortion and it has not been demonstrated that Polish law as applied to the applicant's case contained any effective mechanisms capable of determining whether the conditions for obtaining a lawful abortion had been met in her case the provisions of the civil law on tort as applied by the Polish courts did not afford the applicant a procedural instrument by which she could have vindicated her right to respect for her private life. The civil law remedy was solely of a retroactive and compensatory character. It could only, and if the applicant had

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[27] Tysiac v Poland case, application no. 5410/03

[28] According to the Regulation

§ 1. 1. Pregnancy abortion may be induced, with reservation to section 2, by a physician having: 1) first level medical specialty in obstetrics and gynaecology 2) title of a specialist in obstetrics and gynaecology 2. A physician attending specialization training, in order to obtain first level of specialization in obstetrics and gynaecology, performs pregnancy abortion in the presence and under supervision of a physician empowered to abort pregnancy, hereinafter referred to in section 1.

§ 2. 1. Circumstances indicating that the pregnancy constitutes threat to pregnant woman's health or life shall be stated by the physician having specialty in the field of pregnant woman's disease. 2. Circumstances indicating real possibility of a serious and irretrievable foetus defect or terminal illness constituting threat to its life shall be stated by the physician with a specialist title, stating on the genetic abnormality on the basis of genetic examinations or the physician with a speciality in obstetrics and gynaecology, stating on the foetal genetic disorder on the basis of medical ultrasonography (USG) imaging in pregnant woman.

[29] Journal of Laws of January 22, 1997

[30] The European Convention on Human Rights (ECHR) (formally the Convention for the Protection of Human Rights and Fundamental Freedoms) is an international treaty to protect human rights and fundamental freedoms in Europe. Drafted in 1950 by the then newly formed Council of Europe, the convention entered into force on 3 September 1953. All Council of Europe member states are party to the Convention and new members are expected to ratify the convention at the earliest opportunity.

been successful, have resulted in the courts granting damages to cover the irreparable damage to her health which had come to light after the delivery. Crucially, the examination of the circumstances of the case in the context of criminal investigations could not have prevented the damage to the applicant's health from arising. The same applies to disciplinary proceedings before the organs of the Chamber of Physicians.

Patient's right to raise objection against physician's opinion or decision constitutes implementation of these judgement.

According to Article 31 apr patient or his statutory representative may raise an objection against opinion or decision described in Article 2 Section 1 of an act on the professions of physician and dentist if opinion or decision has got an impact on patient's rights or obligations resulting from legal provisions and lack of appeal procedure stipulated by the separate provisions. Objection shall be raised to the Medical Board, which operates at the Ombudsman of Patient Rights, through its medium. The date to raise an objection shall be 30 days from opinion or decision delivery by the physician announcing the patient's health condition. Moreover, the objection requires justification, including indication of the provisions of law which contain above mentioned rights and obligations. In my opinion, the formalities went too far, as the patients fail to have legal knowledge regarding provisions in force.

Medical Board consists of three physicians, the two of whom must be of the same specialization as the physician who delivered contested opinion or decision. Members of the Medical Board are appointed by the Ombudsman of Patient Rights yearly updated list of physicians in particular speciality of medicine. Issues regarding Medical Board's way of operating have been regulated in detail by the Regulation of the Minister of Health in the case of Medical Board operating at the Ombudsman of Patient Rights Ombudsman of Patient Rights [(31)], (further: Regulation). Appropriately to the content of para 3 of the Regulation, there is a possibility of excluding a member of the Medical Board from participation in the proceedings, ex officio or upon the patient's or his legal representative's motion, for instance if the member delivered contested opinion or decision, he is a spouse or relative of a physician, who delivered contested opinion or decision or if the contested opinion or decision has been delivered by the physician whose professional relation towards him is of subordinate or superior nature. New member of the Medical Board shall be appointed within 3 days of the date of excluding the previous one. Moreover, the Medical Board shall proceed at the sessions, in which the patient or his statutory representative is allowed to participate. What's more, the patient (or his statutory representative) is entitled to provide information and explanations during the proceedings, except for the session, when the panel meeting and voting upon decision takes place (para 4 of the Regulation). During the proceedings, the Medical Board can make a decision on the need of patient's examination, in such case the President of the Medical Board shall indicate the date, taking into consideration patient's health

[(31)] Regulation of the Minister of Health of March 10, 2010 on the Medical Board operating at the Ombudsman of Patient Rights (Journal of Laws 2010, No. 41, Item 244),

condition and the circumstances that have an impact on exercising patient's rights and obligations. The President of the Medical Board informs the patient or his statutory representative on the date of the Medical Board's session or on the date, place and the scope of examination on his mail address, via electronic correspondence or on the phone number indicated by the patent or his statutory representative. Decision regarding particular case is delivered by the Medical Board with unanimous decision in the presence of all of its members has got the basis in medical records and, if needed, is delivered after the patient's examination. It contains justification in writing and should be signed by all the members of the Medical Board and immediately delivered, with this justification, to the patient or his statutory representative and if they did not participate in the Medical Board's session — no later than within 7 days after decision delivery. The justification should contain description of the course of the session, including information on the decision of the opinion or decision, which was the subject to the objection, and circumstances, which led to conducting patient's examination.

The Medical Board, which is each time appointed by the Ombudsman of Patient Rights to hear an appeal in patient's individual case, is obliged to immediate delivery of decision, no longer than within 30 days since the date of its file. (Article 31, section 5, apr). Duration of the Medical Board's proceedings depend on the level of complexity and type of case. It must be emphasized that appeal against Medical Board's decision is impossible. Moreover, according to Article 1, section 8 apr, in proceedings concerning Medical Board's activities, the provisions of Code of Administrative Procedure shall not be applied. Medical Board's activities are financed from the national budget.

The patient or his statutory representative may raise an objection against opinion or decision described in Article 2 Section 1 of an act on the professions of physician and dentist if opinion or decision has got an impact on patient's rights or obligations resulting from legal provisions and lack of appeal procedure stipulated by the separate provisions, but it unfortunately doesn't work properly in practice. Since 2009 (on November 6, 2008, Sejm of the Republic of Poland passed a Law on patient's rights and the Ombudsman of Patient Rights which entered into force on the June 5, 2009), it has been just few cases, but most of them don't meet the requirements: the objection was raised after the date (the date to raise an objection shall be 30 days from opinion or decision delivery by the physician announcing the patient's health condition) or separate regulation has appeal procedure. In 2013 there were two cases which concerned disagreements as to the availability or legality of therapeutic termination between a pregnant woman and doctors. In one of them (the case similar to Alicja Tysiąc case) the Medical Board claimed that the doctor's opinion was appropriate. In the second case, the Medical Board questioned the doctor's opinion and claimed that the patient may raise an objection, but it is not official information from Ombudsman's of Patient Rights Report (the official report 2013 is still being prepared).

Summary

The development of patient's rights was thus natural consequence of changing reality, where medical paternalism lost its domination, and the patients became much more aware of their rights, abandoning the model of being only passive participants of the treatment process. Due to the development of regulations which stay in connection with the rights of a patient in Poland, the growing numbers of legal cases have been noticed, and, as a result, the time of waiting for the court's decision has been lengthened. Polish legislator, taking above into account, decided to reduce the load of common courts of law and introduced new model of extra-judicial way of claims enforcing. Provincial commissions adjudicating on medical events operate in Polish legal order since January 2012. New regulations regarding extra-judicial claim for redress or compensation are applied only in the case of so called medical events. The concept does not occur in the separate legal regulations and it is understood in the Act as infection of a patient with pathogenic biological factor, body injure, deterioration of health or patient's death as a result of diagnosis contrary to the current medical knowledge on the diagnosis (if it caused inappropriate treatment application or delayed general treatment, caused disease development) treatment, including performing of an operation and the application of a treatment product or medical device being the result of health care benefits in the hospital in the light of provisions on medical treatment activity.

It was based on French and Scandinavian experiences. This type of action has facultative and alternative character. Entitled entity has got the possibility to file a motion to commission on adjudicating on medical events or to direct the claim to the court. The rules and mode of enforcing of claims resulting from medical events has been regulated in chapter 13 apr.

As I mentioned, patient's rights are extremely dynamic field, therefore it requires legislator's reaction for changing reality. The law should serve to commonly recognized moral values and if the legal norms will be supported by the values, application of law will be more ascertained and will lack intuitive adjudicates — in accordance with unspecified criteria — dilemmas of an ethic nature [(32)].

In my opinion in the light of contemporary medicine achievements, the tasks set to the legislator are extremely difficult to perform. Undoubtedly, the possibilities of medicine and physicians' action have been primary to the legal regulation, which aren't always compatible with the reality, thus, respecting legal norms in force is necessary, especially in the field of health and patient's rights.

[(32)] Agnieszka Krajewska, Current Legal Issues Concerning, 37, 2004.

NO-PATIENT SAFETY IN REPRODUCTIVE MEDICINE [1]

Guilherme de Oliveira

I. Introduction

In Europe and The United States of America, restrictions are being formulated on couples' access to reproductive medicine services which go beyond those expressly imposed by law. It can be said that these restrictions of access are based in some cases on the futility of intervention, in others where there are clinical risks for the mother and for the future child, or even where the future child is at risk of psychological and social harm resulting from the incompetence of their progenitors. These restrictions are made by doctors within reproductive medicine services, some of whom are questioning law and jurists if their objections to granting access to certain couples are licit.

The fact that the question is being asked is in itself of some interest. In truth, until a few dozen years ago, perhaps doctors could not even remember ever asking such questions of law [2]. The point is that over much of the previous three centuries, doctors and social workers developed what is known as 'medical policing', aiming to foster 'hygienism' as a ruling practice in Europe, with the goal of 'purification' and 'health of the people' [3]. It was certainly the case that they had power to decide everything necessary to control family relations, including the permanent removal of the children, based on their interpretation of what was in the children's best interests [4]. This medicalisation of child protection, in specific terms, rested upon efforts to remove children from families of alcoholics in order to give them better alimentation and conditions of health. This was how, over the course of a century, around 100,000 children were sent out of the United Kingdom to the colonies, having no say in the matter and with many having been falsely informed that their parents had died. In the context in which this movement unfolded, it is probable that those who took these decisions were convinced that they were the right ones [5].

The practice of separating children from their parents out of sanitary concerns appears to have been common in Europe. It is only recently, in the

[1] This article is part of another text entitled *Restrições no acesso à parentalidade*

[2] In view of other types of restrictions and of parental privations prior to the emergence of reproductive medicine.

[3] Bruno Barreiros, *O discurso higienista no Portugal do século XVIII: tradição e modernidade*. In «Adelino Cardoso, *et. al.* coord., Arte Médica e Imagem do Corpo: de Hipócrates ao final do século XVIII», Lisboa, Biblioteca Nacional, 2010, p. 123-136.

[4] Eekelaar, *Family Law and Personal Life*, Oxford, Oxford University Press, 2007, p. 9ff

[5] *Op.cit.,* p. 14.

final two decades of the twentieth century, that it became necessary and habitual to ask of the law and jurists how the best interests of the child might be defined... [6]. In the middle of the twentieth century a movement gained force which opposed the excessive regulatory power of the state in favour of individual autonomy. This movement found juridical expression in the rise in both the number and importance of fundamental rights enshrined in the constitutions of various countries. At the same time as this, sociologists were revealing how the greatest violence was taking place within the so-called 'family sanctuary', while radiologists were able to verify how babies suffered fractures which had been caused deliberately within the family [7].

The result of these tendencies was, naturally, the transference to laws and courts of the decision-
120 making powers of doctors and social workers. That is to say, laws now came to define the types of cases in which it is legitimate to intervene within families in order to determine how citizens conduct their lives, and the courts had to interpret these laws and determine concrete cases; and while it is true that such deliberations had to be based upon the reports of health providers, the power of final decision was transferred to the realm of law.

In Portugal, the Constitution of the Republic states that "parents have the right and the duty to educate and support their children" (art. 36, No. 5) and, furthermore, that "children cannot be separated from their parents, except when parents have failed to fulfil their fundamental duties towards them and always by means of judicial ruling" (No. 6).

In addition, within the sphere of ordinary law[8], the ways in which the State can intervene are well defined and, amongst other limitations, can be found the obligation to ensure that intervention is minimal (art. 4. *d*), proportional (*e)* and gives prevalence to measures which maintain the integration of the child within the family (*g)*).

Nowadays, therefore, prevalence is given to fundamental rights; and *the question is put between the State and the individual rights of citizens*: to what extent can laws and courts limit the fundamental rights of citizens? To what extent — and under what conditions — can public services restrict rights? Concretely: does the fundamental right to procreate and form a family have limits? Who has legitimacy to define and impose limits? Can health authorities and doctors restrict access to health services which have evident consequences in parentage?

II. Fundamental rights involved

a) The right to the free development of personality

The right to development of personality, while establishing a "general tutelage of personality", enshrines a "general freedom of action", a "freedom of behaviour" in the sense of individual autonomy and self-determination, "granting each person the

[6] *Op. cit.,* p. 16.
[7] *Op. cit.*, p. 15.

[8] Particularly Law No. 147/1999, of September 1st, (child protection and children at risk regulation).

freedom to draw up their own plan of life" [9]. Every citizen is granted this right.

The right to free development of personality should be considered within the framework of discussion of this topic [10]. The truth is that the decision to procreate has great implications across a number of domains — psychological, physiological, sanitary, economic — and such a decision must be seen as a structural constituent of individual autonomy and personal freedom.

b) The right to form a family

The "right to form a family" granted to all persons, married or not, by art. 36, No. 1, 1st part, Constitution of the Portuguese Republic is, indisputably, a right to procreate [11]. In this way, norms which had the following characteristics would probably be considered inconstitutional: those which enforced sterilisation upon persons carrying certain diseases; which penalized unmarried persons with children; which established, under Malthusian demographic policy, a maximum number of children which couples could have and which sanctioned persons, married or unmarried, who had children exceeding this number. A norm which prohibited certain couples from conceiving children would also probably be considered inconstitutional.

c) The right to health protection (64.º CRep)

One of the dimensions of the right to health protection is the right to demand of the State services aimed at preventing and treating illness.

Ever since The World Health Organisation defined infertility as a global public health issue [12], there is no doubt that health institutions should provide services aimed at curing the condition [13]. Having said this, all kinds of guarantees associated with the realization of these types of social rights are present particularly within the national system of health; this is true, above all, in the case which interests us, that of universality, which prevents discrimination in citizens' access [14].

[9] Paulo Mota Pinto, *O direito ao livre desenvolvimento da personalidade*, in Separata de "Portugal-Brasil, ano 2000", Boletim da Faculdade de Direito, Coimbra Editora, 2000, p. 149-246.

[10] And of other topics related to reproductive medicine and with filiation in general. Thus, when it is argued whether adopted children have the right to legally know biological links still unknown (cfr. art. 1987 CCiv) or the right to know the identity of their already recognised progenitors; or when it is discussed, in a parallel case, if children born by artificial insemination using donor gametes have the right to know who provided the eggs or the sperm which contributed to the conception; or even, in a case twice as difficult, we might say, if a child born from a donated embryo can know the identity of the couple who produced and donated this embryo. These rights can also be invoked in order to counteract the deadlines which limit judicial actions necesary to establish filial links which have not yet been recognised or to refute juridical arguments that might be contrary to biological truth.

[11] And, secondly, it is *a right to establish corresponding relations of paternity and maternity*. In violating this second dimension of the above mentioned right, norms, in particular, which prohibited the father from adopting or the mother from declaring maternity of an adulterou sor incestuous child would also be considered inconstitutional. What would also be considered inconstitutional are norms which, conversely, prohibited a child born out of wedlock from establishing his filiation by bringing a paternity test action, or from regulating such actions, as in legislation prior to the Reform of 1977, demands which are not justified by the diversity of conditions surrounding the birth of the child; but the inconstitutionality of such norms would become clearer in art. 36, No. 4, of the Constitution of the Portuguese Republic.

[12] http://www.who.int/reproductivehealth/topics/infertility/perspective/en/index.html

[13] The very existence of Law No. 32 of 2006 suggests that such services should be rendered by the National Health System.

[14] Canotilho, JJ; Moreira, V., *Constituição da República Portuguesa anotada*, vol. I, 4th ed., Coimbra, Coimbra Editora, 2007, p. 827.

III. Restrictions of access to parentage

The question which is asked is the following: for reasons of safety, to avoid risks for the mother and/or the child, should medical services add new restrictions to the right to accede to parentage — in addition to those already enshrined in law [15] — by means of reproductive medicine practice?

aa) Restrictions due to *futility*

The notion of "futile intervention" developed within the framework of the end of life; and the question has also been discussed in the case of severely handicapped new-born babies [16]. It is understandable that doctors would wish to use all the technical means at their disposal, and it is also easy to imagine how families are unwilling to accept loss and prefer the continuation of treatment. In certain cases, however, doctors are faced with the possibility of intervention which is not going to produce any effects or which could be prejudicial to the interests of the patient [17]. In spite of all the difficulties and the extent to which everything depends on the assessment of concrete cases, it is now accepted that doctors are not obliged to proceed with treatment, nor should they do so, when it is felt that their actions are likely to be therapeutically futile.

More recently, there has been discussion of the futility of treatment in relation to reproductive medicine [18]. Doctors have tried to define the cases in which the condition of the couple, and above all the woman, give rise to a very low probability of success in using techniques designed to assist reproduction. In some of these cases — and in spite of "not having clear quantitative indicators" — the probability of success can be lower or equal to 1%. In such cases, intervention can be considered futile, and health providers can refuse to proceed, as in all domains of medical practice. After all, here as in any other area of medicine, the rendering of futile care generates more risks for the patient than the advantages offered [19]. The technical laws of the profession — the *leges artis* — justify the abstention of care, in other words, justify the restriction of access to attempts to achieve parentage.

It should be admitted, however, that here also it is possible to recognise the concepts of "physiological futility" and "normative futility" [20]: while the former concerns the consideration of the risks and physical advantages a patient might experience, the latter also takes into account the psychological advantages which improve the health of the patient. In certain cases it can be understood that the patient will come to gain considerable benefits, in spite of the very poor prognosis regarding the goal of possibly having a child [21]. In such cases, a global view of the patient can recommend the practice of treatment physiologically futile but psychologically effective.

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[15] Law No. 32 of 2006, of 26 de Julho, arts. 4 and 6.

[16] Mason; Laurie — *Law and Medical Ethics*, 8th ed., Oxford, Oxford University Press, 2011, p. 475.

[17] *Idem*.

[18] ASRM —*Fertility treatment when the prognosis is very poor or futile: a committee opinion, 2012,* In «Fertility and Sterility», vol. 98, No. 1, p. 6-9.

[19] In addition to consuming resources which may be lacking in another sector of the health system.

[20] Mason; Laurie — *Law and Medical Ethics, cit.*, p. 476.

[21] In this sense, the ethics committee of the American Society of Reproductive Medicine, cit., p. 7.

bb) Restrictions due to low probability of success and/or due to risks to the mother and/or the future child. Imposition of life style [22]

Reproductive medicine doctors identify cases in which there is a relatively poor prognosis of a baby being born; these are cases in which the age of the mother and certain physiological conditions greatly diminish the chances of success; the American Society of Reproductive Medicine estimates that the percentage of success of interventions will be between one and five per cent [23].

Once more, there should be a consideration of risks/benefits, according to the *leges artis*: the intervention is justified, in spite of a poor prognosis, if the risks for the woman are fewer than the advantages she is likely to gain; conversely, the refusal of treatment is justified when the probability of causing harm outweighs the expectation of success.

Again here there is the need to appreciate the emotional needs of a couple who are aware of the poor prognosis but who are particularly determined to try everything. These needs might lead the doctor to intervene with little hope of success, but with important advantages from the point of view of the couple's equilibrium. These interventions, however, should respect the limits imposed by the *leges artis*, even if understood in a way that understands the couple's mental health, which obliges the doctor not to subject the patients to risks that outweigh the advantages of intervention.

Lastly, I believe that the consideration of all the risks and benefits is the only criterion which should guide doctors when deciding whether to intervene or not. By this I mean that the intense pressure exercised by the couple cannot justify the doctor passing beyond the limits of the *leges artis*; they can simply abstain whenever the intervention can be considered *bad medical practice*, after having considered both the risks and the physiological and emotional benefits. After all, in this area, there are no special rules which overrule the general deontological norms and medical law.

In many cases in which the consideration of risks/benefits does not favour intervention, doctors are aware of the causes of the initial poor prognosis. In fact, "life styles" which involve excess of weight, consumption of tobacco and alcohol, are factors which increase various risks for the mother and for new-born babies [24]. The document referred to above of the European Society of Human Reproduction and Embriology is highly elucidating regarding the technical advantages which can be obtained through alterations in "life style": the risks for the health of the mother and the newborn are lowered and the success rates of interventions rise. In the cases of excess weight and consumption of tobacco, a significant alteration in habits can even restore spontaneous fertility and dispense with the need for medical assistance [25].

[22] ASRM —*Fertility treatment when the prognosis is very poor or futile: a committee opinion, 2012;* ESHRE Task Force on Ethics and Law 17: *Lifestyle-related factors and access to medically assisted reproduction, 2010.*

[23] *Fertility treatment …* p. 8.

[24] ESHRE Task Force on Ethics and Law 17: *Lifestyle-related factors and access to medically assisted reproduction,* In «Human Reproduction», Jan 2010, p. 1-6.

[25] *Op. cit.*, p. 5.

On the basis of this technical knowledge, doctors tend to demand the adoption of healthy habits by women and couples as a *prior condition* for initiating treatment. These demands, however, can be seen as an unacceptable intrusion into the individual freedom of women and couples. Could it be that there are suficient reasons to restrict in some way the freedom to conduct life as you wish? And to what extent would it be reasonable to do so?

Firstly, it should be borne in mind that doctors are obliged to inform couples of the drastic consequences of unhealthy options. This information must form part of their normal competences and obligations, in order to obtain informed consent for interventions and for the agreement of couples to therapy.

Secondly, each citizen has the constitutional duty to *defend* their own health [26]. I am well aware that this norm cannot be understood in such a way as to eliminate the liberty and private autonomy which underpins the practice of informed consent and extends even to legitimize the refusal of treatment [27]. But I suppose that it is no longer considered eccentric to affirm that individual responsibility involves reasonable behaviours that limit costs to health systems and which permit relocating resources to sectors where there is risk of death due to the lack of rapid and thorough assistance [28]. It does not appear to be sustainable to me that there should be a kind of bohemian citizenship which incessantly extends fundamental rights, and which complies with irresponsibility and accepts one-way solidarity [29]. If this constitutional norm has any significance, it can only reside in the obligation of each one of us to do all in our power [30] to reduce factors of risk that affect one's general heath condition. It does not seem to me at all exaggerated that doctors should establish the condition of altering couples' habits, since, in doing so, they do nothing more than stress that this is the opportune moment for the woman, or the couple, to fulfil their constitutional duty.

In addition, each citizen has the constitutional duty to *promote* their own health, which could also mean the duty to choose the options which improve their general health.

It could be said — conciliating these assertions with liberty and private autonomy — that a justified choice should be expected of citizens whenever the choice is for illness. In other words, each citizen has the right to choose illness, or to make choices which differ from the average person and which might delay a cure; but I believe that what should be demanded are choices which are truly justified and aware — a true exercising of liberty, of autonomy and responsible citizenship — instead of mere neglect and indifference, which only burden in

[26] Constitution of the Republic, art. 64, No. 1: "Everyone has the right to protection of health and the obligation to defend and promote it".

[27] João Loureiro, *Constituição e Biomedicina*, dact., vol II, Coimbra, 2003, p. 798-801.

[28] Cfr. Jorge de Figueiredo Dias, *Na era da tecnologia genética: que caminhos para o direito penal médico?* «Revista Portuguesa de Ciência Criminal», Year 14, No. 1 and 2, 2004, p. 247ff

[29] Solidarity — the sense of living *in solidum*, as part of a whole– implies that everyone is responsible for each person, but also that each person is responsible for everyone. In the end this is the sense of the famous speech by John Kennedy which everyone likes to cite … and then forget.

[30] And not the abstract diligence that might be demanded of a "good family father".

some way all other citizens, if only through lack of consideration and disinterest.

Thirdly, within the specific sphere of reproductive medicine, the law [31] was particularly clear and incisive in imposing duties of collaboration upon the couple, with the aim of achieving the success of medical interventions; and to impose a singular consideration regarding the health of the child [32]. Indeed, article 13.º, n.º 1, b) obliges the beneficiaries to "rigorously observe all the orders of the medical team, both during the phase of diagnosis and during the different stages of the process of medically assisted procreation; and orders regarding "life style", insofar as they have known influence [33], either in reducing risk or increasing success, must be considered as "orders of the medical team" in terms of this norm. Article 12.º, a), in turn, reveals concerns regarding the health of the mother and the child. These rules appear to support a certain way of viewing all participants as responsible for the defence and promotion of health .

Fourthly, it seems more evident today than ever before — bearing in mind the high cost of services, and the scarcity of resources within the National Health System — that it is unreasonable for users to systematically consume resources, compromising the work of health providers merely due to a lack of consideration, without consequences. In truth, within a system whose resources are always finite, excessive and unjustifiable consumption within one sector will always lead to lamentable shortages in other services, which aggravates the health of others or kills.

In spite of everything, establishing these conditions signifies great innovation and should be approached with caution.

Firstly, I consider it indispensable that public health services provide ways of helping couples who experience most difficulty in altering their "life style". I am thinking, of course, in referal for psychological help and social services, as well as for consultations regarding nutrition, tobaccoism and alcoholism, integrated within a programme of accompanied rehabilitation [34].

Secondly, knowing that progress can be slow and that women turn late to reproductive medicine services, the result of a delayed programme of change could mean women are beyond the age of fertility, and of the age in which they can have recourse to public services [35]. Such an outcome would clearly be unjust and inadequate.

Thirdly, it does not appear possible, at least within the sphere of the National Health System, to totally refuse access to women who have been unable to achieve reductions in their weight, or in their consumption of tobacco or alcohol; in fact, alteration of habits can be difficult and delayed. Nor should we overlook the difficulty resulting from

[31] Law No. 32 of 2006, of 26th of July.

[32] See, however, the text below, in cc).

[33] This is one of those cases which confirms the nexus of causality between behaviour and lack of health cfr. João Loureiro, *Constituição e Biomedicina*, cit., p. 801.

[34] In private practices, such care can only take the form of simple recommendations, since isolated private doctors, or private clinics, lack the necessary facilities, integrated within a general health system.

[35] Cfr. the normative circular No. 18 of 2011, of 22 of July, from the central Administration of the health service (ACSS), which establishes upper age-limits consonant with recommended techniques.

consumption habits which are long held, and fed by an absent family and by socially irresponsible advertising, in other words, by other forms of lack of social solidarity of which they themselves have been victims [36].

It is true that article 11, No. 2, of Law No. 32 of 2006, gives doctors the power not to collaborate with medically assisted procreation techniques, if they have medical reasons for refusal. I believe, however, that the refusal to intervene is only justified if it were against the *leges artis*, in such a way that it could be said to harm the woman; that is to say, the refusal only seems conceivable when the clinical profile suggests that the intervention would result, finally, in medical *malpractice*. In other words, there are no juridical instruments that would permit doctors to make decisions beyond their technical abilities, in the application of *leges artis*; in addition to these technical rules, doctors who refuse intervention would have to make a judgement about nonfulfilment of the legal obligation of collaboration and would have to qualify the nonfulfilment as guilty; all of this outside of any legal framework, legal professional intervention and without proper guarantees of a contentious solution.

I believe, therefore, that there are reasons which legitimize the insistence of doctors upon the effective collaboration of women and couples for the success of treatment and to guarantee the health of the child, in accordance with law No. 32 of 2006. And I understand that it is just and oppportune to promote a balance between liberty and individual autonomy and the solidarity which each one of us owes to everyone, in the sense of being responsible for increased costs and for delays in the rendering of care.

cc) Emergent risks of parental incompetence

When one thinks of the systems to protect childhood, the norm is to proceed in the best interests of the child, although the system still resists in issuing an operative definition, which might be understandable as not even worth trying, as each case is unique.

What is not the norm is to try to defend the best interests of a child which has not been born yet or which is not even conceived [37]; the chances of the law intervening to protect *concepturi* are few [38]. This consideration of offspring not yet conceived is also found within the sphere of reproductive medicine [39], where doctors can predict the risks for the

[36] João Loureiro, *Constituição e Biomedicina*, cit., p. 801.

[37] Legal protection of the conceived unborn is already relatively frequent. After all, the question over abortion arises from the search for a level of protection of the fetus which can be accepted by the community; the question of indemnification for harm suffered during pregnancy, normally due to unexpected effects of drugs, is another familiar issue; moreover it is common to add a small set of favourable inherited effects for the fetus, such as passive succession capacity, that is, the capacity to be called to succeed even prior to birth; lastly, it is known that the general rule is that parents represent the children, "even when unborn",… art. 1878.º, No. 1, CCiv.

Perhaps this is the moment to begin a discussion parallel to that which is taking place regarding the protection of future generations.

[38] I mention only passive succession capacity in testamentary and contractual succession, and the protection dispensed towards the goods, of children that a determinate person might have (art. 2033.º, n.º 2, and 2240.º, n.º 1, CCiv); and also the extension of the inhibition of parental responsibility towards children that the inhibited parents might have, when the inhibition falls upon all the children and the court does not give a contrary judgement (art. 1915.º, n.º 3 CCiv).

[39] The deontological code of doctors in Portugal recommends "… the consideration not just of the desire of the candidate parents, but above all of the interests of the future human being that may come to be conceived" (art. 62)

children and refuse access to treatment to couples who reveal serious parental incompetence.

As far as I know, this topic has been largely ignored by jurists, although the first great affirmation of the defense of the welfare of the child not yet conceived can be found in the law about Human Fertilisation and Embriology in the United Kingdom, from 1990. Actually, the law determines that "no woman should receive treatment unless the welfare of the child to be born as a result of such treatment has been guaranteed (…) [40]. In addition, the law determines that the regulating authority issues a code of conduct which helps health units to assess the welfare of the unborn child [41].

After confirming appearances through inquiries and routine interiews, it was established as a practice to refuse access to treatment for couples who reveal absence of child-rearing ability and who put at risk the welfare of the new born child [42]. The typical situations which lead to the presumption of the inability to take care of the child are pyschological instability of the couple, psychiatric disorders, drug abuse, a record of sexual abuse, domestic violence, and removal of parental responsiblity regarding the other children. [43]. And one could add extreme ignorance of all the acts of childrearing which would be indispensable in the event of having a child, or the couple's extreme poverty, which would not guarantee basic care to the future child.

The main reason which justifies this attitude of doctors is the feeling of being resonsible for the birth [44]. Doctors do not want to bear responsibility for an expected and serious risk that the newborn baby is likely to run. And when they are made aware that many newborn babies conceived without medical assistance run the same risks, doctors state that they do not intervene in such births, they are not accountable or responsible for those children; in the present cases they intervene, and therefore feel responsible [45].

However, despite such understanding of how doctors wish to prevent the newborn from suffering, this exclusion of couples based upon their parental incompetence is surprising from the legal point of view.

In fact, this exclusion of access leads to total restriction of a variety of fundamental rights — the right to personality development, to procreation, to forming a family. There is no doubt that fundamental rights allow restrictions, but they have to be enforced by a diploma that carries the force of law, which foresees the restrictions in a necessary, adequate and proportional way.

[40] "Par. 13. (5) A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth".

[41] Par. 25, (1) and (2). The code of conduct was updated in 2013 — cfr. http://www.hfea.gov.uk/402.htm

[42] Apparently, the cases are widely known in Europe and The United States of America, where the scientific communities seek a common orientation — cfr. ASRM, *Child-rearing ability and the provision of fertility services: a committee opinion, , in* «Fertility and Sterility» vol. 100, nº 1, July 2013, p. 50-53*;* ESHRE Task Force on Ethics and Law 13: *The welfare of the child in medically assisted reproduction, 2007*

[43] Art. cit., p. 50-51.

[44] ASRM, *Child-rearing ability…, cit.,* p. 52.

[45] There are also doctors who manage to reduce their responsibility to technical aspects of birth, leaving the consideration of emotional and social risks to others. The ethics committee of the ASRM, however, in spite of considering this position legitimate, does not fail to add the limits of tolerance, measured in terms of serious risk to the newly born — cfr. ASRM, *Child-rearing ability…,* p. 52.

It must be recognised that cases susceptible to restriction by medical services have never been defined, nor are there criteria for their predicted identification, despite all the recent efforts of scientific bodies [46].

It should be added that doctors, when proceeding in this way of protecting the future child due to parents' inability, put themselves outside the universal legitimacy which is recognised of them, outside their typical interventions which are confined to the practice of the technical rules of their profession, to the *leges artis* of medicine.

On the other hand, the protection of children and young people, despite being the object of updated regulation, has never taken this problem into consideration, let alone confer upon health services and their doctors the necessary legitimacy and competence to restrict the access of couples to parentage. There are organs which have the competence to intervene, their intervention being regulated and, if doctors are considered "an entity with competence in childhood and youth", (art. 7.º da Lei n.º 147/99), their practice should never contradict the will of the family in question.

Also the system of protection refers only to children who are in danger under the conditions foreseen in art. 3 of the respective law [47]. Based on these norms, the consequence is that specifically protective intervention cannot be aimed at a specific *concepturus*, not even to an already *conceptus* unborn baby [48].

On the other hand, it has to be said that denying access to parentage can be accused of violating the fundamental right to equality (art. 13.º CRep) and of being therefore discriminatory. In fact, no couple is prevented from procreation without medical assistance; neither does law try to do so — also because that would be unviable — nor does it penalize the one who procreates, despite the existence of the worst conditions of life, in all respects, that surround pregnancy and birth [49]. This being the case, the restriction of access to incapable couples who seek assistance for procreation places them in a situation of inequality relative to equally incapable couples who do not require medical services. Perhaps it could be argued that the response of law against those incompetent couples who procreate without assistance — the inhibition of parental responsibilities and the search for an alternative family — is a worse solution than that which would be convenient: being prohibited from procreating. If this were the case, then it could be said that within the sphere of assisted procreation it is possible to obtain a better solution — the absence of birth — and this new technical possibility creates not only an enormous difference relative to the earlier reality but also legitimizes a different legal treatment, which is therefore not discriminatory. However, even

[46] Cfr. the documents cited in the American Society of Reproductive Medicine (ASRM) and the European Society of Human Reproduction and Embriology (ESHRE).

[47] Law No. 147of 1999 of 1st of September, in Portugal.

[48] In practice, the protection of a pregnancy and of the fetus can only arise reflexively from the protection developed relative to other children of the pregnant woman.

[49] A response which differs from prohibition or penalization is the immediate protection of the child, through inhibition of parental responsibilities and through seeking an alternative family.

though all this is open to discussion, the problem is precisely this: it is open to discussion within the sphere of law, and, in spite of this, restrictions of access are being practiced.

In other words, this practice of European and North American reproductive medicine services develops outside of the legal system [(50)] and of traditional doctrines regarding the respect for, and realisation of, fundamental rights.

Having said that, some observations can be added that can be relevant to this discussion.

Firstly, the difference between private medicine and the public health system carries some weight. In spite of the limits that are imposed by the principle of equality and the struggle against discrimination, it is acceptable for each private medicine unit to make some choice in terms of their clients; such an option appears less justifiable in the public services, paid for by all contributors, including couples who may be rejected.

Secondly, there is a known principle and process by which the newly born are removed from biological parents who place them at risk from birth, with the typical consequence that they are given up for adoption. It could be asked why a course analogous with the issue at stake is not followed, in other words, rendering medical assistance and promoting the birth of the child, with the high probability of this child being sent to an alternative family. This clearly presupposes that reproductive medicine doctors easily accept adoption as an alternative family.

Thirdly, given that doctors assume the responsibility of denying birth when the couple reveal parental incompetence, it can always be asked whether they would be equally responsible to have issued a bad judgement about the progenitors' competence, in the hypothetical event of having rendered assistance to a birth when they should not have done so. Would the children, or other carers of these children, be able to seek damages for harm caused by birth in a situation of danger that had not been properly assessed?

Fourthly, it should be noted that protecting the welfare of future chidren and excluding birth in cases of poor prognosis leads to the concrete idea that it is better not to be born that to be born to such poor parents. This consideration already has a difficult history, in the similar cases of *wrongful life*.

It remains to take into consideration the possibility of invoking 'conscientious objection'. This recourse in extreme situations is expressly foreseen, in general, in the Constitution of the Portuguese Republic (art. 41, No. 6) and is traditionally applied to medical activity. Since 2009, this has the power of Regulation which approved the Deontological Code of Doctors foreseen by the Statute of the Council of Doctors and issued by the competent bodies. In addition to this, Law No. 32 of 2006 guarantees that doctors "cannot be obliged to collaborate in the realization of any medically assisted procreation techniques if, for ethical reasons, they believe they should not do so"; and also states that "the refusal of the professional should specify the clinical or other reasons which motivated the refusal, namely conscientious objection".

[(50)] Unlike in the UK, where the law foresees a framework for such decisions, which is considered sufficient.

Thus, if in cases of futile intervention or based on consideration of risks/benefits respect for *leges artis* can be sufficient to evaluate the lawfulness of abstaining from treatment, in these other cases, of alleged grave parental incompetence, invoking conscientious objection can be justified. It should be added, however, that this recourse should not be trivialised, nor should it diminish the constitutional rights of others. It cannot become a common reponse when faced with couples whose predictable parental behaviour is below common levels. In truth, this evaluation is not supported by objective and known criteria, which raises the possibility that a refusal comes close to being merely subjective arbitrariness. On the other hand, exercising conscientious objection cannot impede the exercising of fundamental rights, for which there cannot be generalised objections, which makes the rendering of medical assistance impossible; and it is for this reason that the deontological code does not permit the exercising of conscientious objection in cases where the patient cannot benefit from "assistance by an equally qualified doctor" (art. 41). In other words, in order for a doctor to invoke conscientious objection, it is necessary to confirm that there is an extreme case of grave parental incompetence, likely to cause evident and inevitable risk for the future child; it will be necessary to report the circumstances foreseen in art. 37, No. 2 of the deontological code; and the assistance of an available doctor must be guaranteed (No. 3).

Supposing that the practice of restricting access due to parental inability is not legitimate (except for cases of conscientious objection) — and previous to a juridical discussion that radically broadens the legitimacy and instruments to protect *concepturi* — it is my belief that doctors should not exclude couples alleging parental incompetence [51].

In spite of these statements, the following cannot be denied: there is a problem of protecting the child to be born; reproductive medicine doctors might know better than other services the real dimension of the risks; and there are cases in which law already restricts parental responsibilities regarding unborn children with the clear intent of protecting them. All this leads to predicting that, sooner or later, law has to intervene to control restrictions of access to parentage in reproductive medicine.

In the meantime, it is worth noting that, from a juridical point of view, the practice is strange and it is a paradox to avoid birth in order to protect... a patient that as yet does not exist.

[51] It seems opportune to suggest that "entities with competence in the area of infancy and youth" and committees for the protetion of children and youths at risk are expressly given powers to intervene in the cases of pregnant women which have been noted by the reproductive medical services, with the aim of advising mothers-to-be, preventing harm, or promoting the search for an alternative family in the event of having found evidence of poor prognosis. This extension of the committees' competence to the time before birth should not alter the nature of the intervention, that is to say, it should always be based on the consent of the interested parties. In other words, the ability to accompany the pregnancy should never involve sending the case to court, in the event of disagreement.

THE LEGAL GUARDIAN'S POWERS IN THE SITUATION OF "VOLUNTARY" COMMITMENT ACCORDING TO PORTUGUESE LAW

Geraldo Rocha Ribeiro [1]

I. Introduction

The present study intends to be a preliminary approach to the legal vacuum that we face within Portuguese private law, concerning the determination of the scope of powers granted to the legal guardian of the legally declared incompetent. Confronting the Portuguese Civil Code's norms with the incompetent's interests, underlying the protective measure given by a judicial sentence (interdiction or inabilitation), we cannot determine, immediately, the limits of the autonomous proceedings of the legal guardian.

Regarding the private sphere of the incompetent we can only find one norm which regulates the representation institute, as far as the function of the incompetent's estate is concerned, Article 145 of the Civil Code.

Therefore, we propose to do an essay about the current legal framework and the consideration of the private sphere as the fundamental basis of what the powers of the legal guardian and its practice should be.

II. The Legal statute of the person legally declared incompetent: of the interdict in particular

The person legally declared incompetent is still a holder of its fundamental rights, namely the right to life, to physical and mental integrity and the right to self-determination and freedom.

Regardless of the rights and duties that someone has, or is responsible for, or potentially might be, the truth is that personality is a quality or a condition of Man — of his own and intrinsic human dignity —, being the concept of legal capacity that the system recognizes, that gives him the ability to be the holder of a, more or less, restricted circle of legal relations [2]. Recognizing that all men have equal legal personality has no link to the verification or absence of the natural capability of wanting or acting. The absence of someone's *de facto* capacity reverberates, essentially, on the effects of the legal

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[2] Carlos Mota Pinto, *Teoria Geral do Direito Civil*, 4.ª Edição por António Pinto Monteiro e Paulo Mota Pinto (Coimbra: Coimbra Editora, 2005), p. 194.

capacity of acting and in the right of the person's self-determination within legal capacity [3].

The universal recognition of legal personality, as an innate and transcendent quality of the human being is not, thus, subject of any doubts. In the words of Carlos Mota Pinto: "the individual's personality is therefore a legal quality or a status where human dignity lies directly — and not only a mask with which some actors move around in the socio-legal life's stage" [4].

To talk about legal personality is to talk about an innate quality that belongs to every human person as is; it is equivalent to a supra-positive legal principle, fundamental in the Portuguese legal system: the recognition of the human person. Every human being is an end in itself, being this one of the basic principles of our Democratic Rule of Law (Article 1 of the Portuguese Constitution). Undelayability, nonexpropriability, unavailability and illimitability integrate the essence of the human personality [5] [6].

Through a judicial sentence that institutes a legal incapacity, a care based legal relationship is established, anchored on the existence of a situation of vulnerability and dependence, in which a certain a person finds itself, which carries the risk of non-governance of his interests as well as the risk of his instrumentalization by others or even by the State itself. Therefore, to talk about the fitness and qualities of being the bearer of rights and duties is not enough when a person, due to its recognized and imposed dignity, has the competence to assure the full materialization, in its juridical sphere, of the subjective dimension of a certain *highly personal* right to act in a free, individual and responsible manner. The impossibility of self-determination means that the person does not have, at that given moment, the necessary *natural* quality to assert his right, to make use of his legal rights, but by imposition of the principle of human dignity the protection of the objective dimension of his fundamental rights remains untouched. Hence, the legal order has to ensure legal mechanisms for the reintegration of the person as a full subject within the legal system.

We can now say that the concept of legal capacity and the capacity to negotiate, according to the traditional sense, are useless as far as the *incompetent's* exercising of personal rights is concerned. These highly personal rights correspond to the affirmation of freedom, in more specific terms, to self-determination. To these rights, the attempt to dissociate the legal capacity from the capacity to act turns out to be pure fiction. The issue ends up subsuming to the availability of protected legal rights by personal rights and its due juridical construction, that is, the affirmation of the right of freedom acknowledged to the person. As an example, we can look at the required assumptions for affiliation capacity, matrimonial capacity, testamentary capacity and consent capacity (for instance, the provision of

[3] Manuel de Andrade, *Teoria Geral da Relação Jurídica (Sujeitos e Objecto)*, Vol. I (Coimbra: Almedina, 1997), p. 34.

[4] Carlos Mota Pinto, *Teoria Geral do Direito Civil*, 4.ª Edição por António Pinto Monteiro e Paulo Mota Pinto (Coimbra: Coimbra Editora, 2005), p. 100.

[5] Castanheira Neves, "Justiça e Direito", in *Digesta: Escritos acerca do Direito, do Pensamento Jurídico, da sua Metodologia e Outros*, Vol. I (Coimbra: Coimbra Editora, 1995, p. 278.

[6] Orlando de Carvalho, *Os direitos do Homem no Direito Civil* (Coimbra: Vértice, 1973), pp. 20-23; from the same author, *Teoria Geral do Direito Civil* (Coimbra: Centelha, 1981), p. 160.

informed consent for medical care), as well as for the exercise of parental responsibilities.

A different situation occurs as far as the equally personal rights are concerned, whose content and legal goods result directly from the human condition, without the need of self-determination by the man, in order to affirm them and get legal recognition.

The restriction of a person's rights requires special considerations and pondering judgments, that is, the conducting of proportionality tests in order to safeguard the respect for formal law restrictions. We can say that the expanding force of human essence, either in its static or dynamic aspect, requires legal recognition of the person's natural, concrete and circumstantial capacity to act: he can act personal and autonomously, except if there's a strict legal restriction by judicial ruling.

The verification of a person's incapacity means that "the legal acts that matter to the incompetent will not cease to be practiced due to the fact that he cannot do it himself or just by him. His capacity of exercising his rights will not be left unpracticed because of that." [(7)]. However, more than capacity of rights, we should claim that the protection of legal interests, in particular the incompetent's personal ones, will continue being assured through the imposition of its protection and promotion which come from the objective sphere of his fundamental rights.

The mentally ill patient, or anyone with a mental illness and weakness of spirit, besides its natural incompetence for self-determination, does not stop being a person with its full dignity and value. Indeed, we can recognize the idea of self-determination that comes from his human condition. It is due to the human dignity principle, consecrated on Article 1 of the Portuguese Constitution, that the protection and recognition of a full, universal and equal human personality is demanded. The axiological dimension that transcends human essence, regardless of the existence of a *de facto* competence for the person to be self-determined, prevents its objectification. Thus, for every human being should be ensured the competence to define and shape his own life, reserving for himself, even in legal incapacity, the potential for realization of a full personality, which the State must ensure and guarantee, due to the objective dimension of fundamental rights.

Since the object of our work is confined to the assessment of the limits of the powers of the legal guardian, we will only address the scope of the incapacity of the interdict stated from Article 138 forth of the Portuguese Civil Code (from here forth it will be designated CC).

Concerning the interdicts, Article 139 (CC) states that they are equivalent to minors. The apparent simplicity with which the legislator determines the incapacity of interdict adults, brings forth some perplexities due to the impossibility of absolute equivalence between the scope of the incapacity by interdiction and by nonage.

In contrast with minors, its usual to say that what is at stake in interdiction is a fixed incapability, once it does not give the judge the ability to shape or adequate the incapacity's scope to the incompetent person's qualities, except in regards to

[(7)] Manuel de Andrade, *Teoria Geral da Relação Jurídica (Sujeitos e Objecto)*, Vol. I (Coimbra: Almedina, 1997), p. 33.

the appreciation of the circumstances and requirements of Article 138 (CC), in order to decide about an eventual judicial decree of interdiction. Therefore it is said that the incapacity by interdiction is rigid and legally pre-determined, generically affecting the interdict's capacity to act.

Despite this difference, Article 139 (CC) equates the interdict to the minor, once, in either case, general incapacities to act are at stake, applying to the first one "with the necessary adjustments, the provisions that regulate the incapacity by nonage and fix the means to suppress the parental power". It results *ex vi* from this Article the implementation of Articles 123 forth and 1921 forth of the CC, with the due adjustments.

Being set before the characteristics of both incapacities, we believe that the interdiction — a rigid incapacity and, at first hand, immutable, which comes from a full absence of capacity of the interdict to manage his interests —, as opposed to nonage — which is based on the gradual process of maturity to the upcoming full age —, which presents itself as a tendentiously broader incapacity [8]. We refer to is as tending due to evolving nature that characterizes nonage: in the first years of life there will be an overlap between the scope of the incapacity of minors and that of the interdicts, while at the final stage of nonage (between the age of 16 and 18 years of age) the range of the incapacity is reduced to its minimum, while that of the interdict remains unaltered.

The acquisition of a progressive autonomy leads to the fact that a power or personal and financial emancipation can be declared, and consequently the recognition of a legal capacity to act, when the minor has powers of discernment; on the other hand, the interdiction results from an inverse judgment, because an incapacity of self-administration of the interdict's interests is noted, without the foreseeing of any personal empowerment. There is a negative prognosis judgment about the interdict's capacity, which is embedded in a constitutive decision which verifies a lingering state of incompetence and, because of that, tendentiously permanent of the person's incapacity to manage his interests.

Therefore, we can say that directing Article 123 of the CC to the interdict, *ex vi* Article 139 of the CC, is only possible, basically, as far as the second part of the Article is concerned, because there will only be a few special norms which, recognizing the competence and autonomy of the minor to act within legal transactions could be considered applicable to the interdict, by presupposing his status as a judgment of absolute incompetence to manage his personal and financial interests. This statement intends to highlight the subsidiary nature of the interdiction as a legal measure set to protect the person, to be assumed as a last resort mechanism. Hence, it cannot be accepted that a person can be declared interdicted when he has a minimal and residual *natural ability of discernment* to deal with occasional and day-to-day life issues. For these cases the appropriate and proportional measure will be the inabilitation adapted to the person's specific interests.

However, traditionally, it is assumed that Articles 123 to 128 of the CC and especially Article 128 can

[8] Manuel de Andrade, *Teoria geral da Relação Jurídica (Facto Jurídico, em especial Negócio Jurídico)*, 7.ª Reimpressão (Coimbra: Almedina, 1992), pp. 82-83.

be applied to interdicts [9]. The way we see it, it will be hard to admit a subsidiary enforcement of this last norm, due to the nature of interdiction as a last resort (which corresponds to an idea of subsidiarity), which comes from the absolute absence of capability and fitness of the interdict to self-administrate his personal and financial interests, and it will be hardly compatible with the true existence of exceptions to the general incapacity to act, due to the lack of his natural capacity, for instance, to celebrate contracts that are inherent to the day-to-day routine [10]. Nevertheless, we can always admit a possible relevance in mobilizing those norms for the situations in which a person that carries an enduring mental disorder has moments of lucidity.

The scope of Article 127 of the CC, with respect to the interdicts, implies a necessary case assessment of the situation set forth in its three points of the article, in order to determine its applicability. However, given the condition which is an assumption of the interdiction, the only provision that is considered to be relevant is that of subsection b) of paragraph 1 of Article 127 of the CC. This subsection states that the minor's everyday life legal transactions will be considered valid if, within the reach of his natural ability, he will only entail costs or provisions of goods of minor importance.

The natural capacity of the person is not at stake here, but his legal recognition (being clear that the capacity to act is not necessarily the natural *de facto* capacity). The law demands, because of that, two criteria to legally recognize the natural *de facto* capacity of the incompetent person: acts of ordinary and usual transactions (everyday life transactions), which entail a reduced risk to the financial interests of the incompetent. Therefore, reference should be made to an individual assessment either in gauging the natural capacity of the person, or in the determination of what are everyday life transactions and financial risks. Thus, it must be in favor of the recognition of self-determination to the incompetent, correcting the tendentiously absolute and castrating effect of the legal freedom to act of the interdicted person. The legal capacity to self-determine the scope of his financial interests is not recognized to the interdict, suffering the transactions celebrated by him of an annulability vice (Article 148 of the CC), regardless of the verification of the capacity to discern at the date of the transaction. The interdiction status puts the person in a defined juridical situation as far as his financial sphere is concerned, even if the *de facto* negotiating capacity is not assessed considering the date of the act or of the legal transaction [11]. The main consequence of interdiction is to achieve the *validity* of legal acts without considering the general rules about the absence or defects of will and *de facto* capacity.

For purposes of legal liability towards the acts put into practice, a person is considered incompe-

[9] Pires de Lima e Antunes Varela, *Código Civil Anotado (artigos 1.º a 761.º)*, Vol. I (Coimbra: Coimbra Editora, 1987), p. 148; Heinrich Ewald Hörster, *A Parte Geral do Código Civil Português — Teoria Geral do Direito Civil* (Coimbra: Coimbra Editora, 1992), pp. 340-341; Luís A. Carvalho Fernandes, *Teoria Geral Do Direito Civil, Introdução, Pressupostos da Relação Jurídica*, 3.ª Edição Revista e Actualizada, Vol. I (Lisboa: Universidade Católica, 2001), p. 332.

[10] António Pais de Sousa e Carlos Frias de Oliveira Matias, *Da Incapacidade Jurídica dos Menores, Interditos e Inabilitados*, 2.ª Edição (Coimbra: Almedina, 1983), p. 241.

[11] Werner Flume, *Allgemeiner Teil des Bürgerlichen Rechts: Das Rechtsgeschäft*, 3. Auflage, Vol. 2, n.º 1 (Berlin: Springer, 1979), pp. 183-184.

tent as far as the negotiating effects are concerned due to the annulment of the legal transaction. When we consider the personal sphere, we cannot recognize any general and automatic effects in the (in)capacity to act of the interdict. The personal nature and, in some cases, the highly personal nature of some rights and obligations, depends on the human nature and condition, on the real and actual verification of the person's incompetence to be self-determined. The interdiction does not imply a general incapacity to act, nor a specific incapacity, due to the fact that the unavailable personal dimension of the essence of human dignity that stands out, imposes the recognition of incapacity when we are before actual fact incapacity. It is not constitutionally permissible to provide a status that constrains, without express statutory provision, the expression of human essence in the exercise of someone's personal and highly personal rights and obligations [(12)].

The provision of someone's personal integrity and his personality rights depends on the distinct notion of a strict negotiating capacity to act, regulated in Articles 123 and 127 of the CC. The requirements of safety and protection of the legal trade will be much lower when the interests in question are of a personal sphere. In this lies the need to safeguard the essential and intrinsic value of human nature — the person's dignity and the right to fully develop his personality. Any restriction must result as a natural and declarative consequence of the *de facto* incapacity and of the protection against the instrumentalization of the person, their objectification.

The constituent sentence of an interdiction only modifies the status of the interdict for protection needs, safeguarding for himself spaces of autonomy in acts of everyday life and of little value. The extent of the incapacity to act, despite its general nature, is limited to the financial dimension, being the presumption of Article 123 of the CC reversed *ex vi* Article 139 of the CC. The outcome of the constitutive sentence of the interdiction is the judicial evidence of a certain natural incapacity, but we cannot draw general effects from it, concerning the exercise of rights of personality that are maintained to the interdict's monopoly of self-determination. The capacity to consent, inherent to the exercise of personal rights, presents itself with distinct qualities and characteristics from the strict negotiating capacity to act.

The evaluation of the capacity to act, in its premises and effects, is different according to the nature of the acts to be undertaken. Hans Lauter differentiates the premises of contractual and personal capacity, in the judgment of *finality* and *certainty* to the contractual capacity. The capacity to act will be situational, according to the verification of some flexible assumptions [(13)].

To understand the concept of the capacity to act in contract terms, as extensive to the whole human dimension of the juridical acting, represents an arbitrary treatment of the competencies and human qualities to freely exercise freedom and self-determination.

[(12)] Gaspare Lisella, *Interdizione "giudiziale" e tutela della persona: Gli effetti dell'incapacità legale* (Napoli: Edizione Scientifiche Italiane, 1984), pp. 106-107.

[(13)] Hans Lauter, "Assessment and Evaluation of Competence to Consent", em *Informed Consent in Psychiatry (European Perspectives of Ethics, Law and Clinical Practice)* (Baden-Baden: Nomos, 1996), p. 313.

The capacity to self-determine interests as well as the personal sphere results from the concrete and contemporary situation of decision-making and acting. Human dignity prevents someone from being denied a full exercise of his highly personal legal rights, through a sentence, if he has full capacity to be self-determined. Any attempt to instrumentalize an individual for legal certainty reasons is prohibited, whenever the legal interests in question relate to the exercise and implementation of legal personality.

Besides the person's legal status, the capacity to act by himself is recognized to everyone as far as his personality rights are concerned, if at the time of the action the person has qualities and intellectual and volitional competencies to be responsibly self-determined.

III. The mentally ill patient: Specificities

Mentally ill patients, besides this autonomy, do not integrate a category or legal status different from incapacity. The diagnosis of a psychiatric disease (or a neurological disease, namely degenerative, vascular or even toxic) does not imply an automatic legal status of incapacity, nor does it justify the automatic establishment of a provisionary measure of care or, for instance, the initiation of incapacity legal proceedings. Therefore the analogous legal provisions to Article 420 of the Italian Civil Code, revoked by Law N. 189/1978, are not permitted, which foresaw the designation of a provisional tutor for a patient committed to a psychiatric hospital and the initiation of incapacity legal proceedings [14].

The mentally ill patient is just part of a group of people whom, by their clinical and associated therapeutics (in particular, psychopharmacology) show increased difficulties in the assessment of the capacity to consent and in the justification of the legal care. Mental illness, as a cause of a mental disorder, is not enough to justify an incapacity to act, nor is the enactment of a legal incapacity, unless it shows a lasting state. The revolution of psychopharmacology [15] ended the myth of incurable psychiatric diseases, allowing the control and clearing of the patient's psychiatric condition, as well as the prevention or reduction of the effects of degenerative and chronic diseases [16]. The psychiatric patient will only be considered incompetent if the disease is associated to the inability to responsibly be self-determined in his circle of interests, for which the diagnosis of the disease is not enough.

The mentally ill patient, despite his clinical state, being of legal age, maintains the legal status of full capacity. The general rules on the capacity to consent apply here, being the capacity to discern enough. Not falling under a protective measure, the psychiatric patient has no one invested with the power of legal guardianship and subsequent representation. But the peculiarities of mental illness, associated with the specificities of care and contraindications, place the patient in a vulnerable position. From the patient's condition may result

[14] Gilda Ferrando, "Il beneficiario," em *L'amministrazione di sostegno* (Milano: Giuffrè, 2005), p. 29.

[15] Phil Fennell, *Treatment without Consent (Law, psychiatry and the treatment of mentally disordered people since 1845)*, Reprinted (London-New York: Routledge, 2001), p. 151 ss.

[16] David Copolov e Philip Mitchell, "Biological Therapies", em *Foundations od Clinical Psychiatry*, ed. Sidney Bloch e Bruce S. Singh (Melbourne: Melbourne University Press, 2007), p. 553.

a risk of a paternalistic intervention that may also jeopardize the self-determination of the patient.

Medical intervention is only valid with the informed consent of the patient able to discern (except in situations of compulsory treatment), in which the consent may be revoked at any time [17]. The consent given does not have to be *present*, because, and due to the particularities of the disease, the person may authorize a certain type of treatment prospectively — for issuance of advance directives -, thus the power to decide over their own personal sphere must be respected, holding the power to be freely revocable, if in a moment of lucidity the patient gets sufficient capacity for discernment [18].

The affirmation of the power of self-determination about the treatment must take into account variations of the clinical status and the patient's current competence. Consent, as a dynamic process of communication, must adapt to the demands and risks of psychiatric treatment. Therefore, a duty of surveillance over the patient's condition must prevail, in order to ensure the verification of factual circumstances for the competent affirmation of self-determination [19].

The particularities of the mentally ill patient are also felt as far as the legal possibility of compulsory detention and treatment are concerned, according to the Mental Health Law (MHL) [20]. The acknowledgment of the person's power of self-determination, whether or not the person is a mentally ill patient, it implies the assurance of treatments according to the expressed will by means of consent. Only in a very exceptional manner, and upon a proportional verification of the relevance of the content of the decision and the personal or supra-individual or third party interests, it the compulsive medical intervention is undertaken [21].

Article 12, paragraph 1 of the MHL allows the compulsory treatment of a person capable of discerning, who has a serious mental disorder and who is in a situation where his state creates a dangerous situation for his own or someone else's legal interests of significant value, of a personal or financial nature, and who refuses to submit himself to the required medical treatment, driving the person to be admitted to the appropriate institution.

Paragraph 2 of the above stated Article foresees the possibility of commitment of the incompetent, when the absence of treatment may seriously deteriorate his status. In the first case we are before a commitment due to *danger* and the second a *tutelary commitment* [22].

[17] Erwin Deutsch e Andreas Spickhoff, *Medizinrecht — Arztrecht, Arzneimittelrecht, Medizinprodukterecht und Transfusionsrecht*, 6. Auflage (Heidelberg: Springer, 2008), pp. 522-523.

[18] Erwin Deutsch e Andreas Spickhoff, *Medizinrecht — Arztrecht, Arzneimittelrecht, Medizinprodukterecht und Transfusionsrecht*, 6. Auflage (Heidelberg: Springer, 2008), p. 524.

[19] Erwin Deutsch e Andreas Spickhoff, *Medizinrecht — Arztrecht, Arzneimittelrecht, Medizinprodukterecht und Transfusionsrecht*, 6. Auflage (Heidelberg: Springer, 2008), p. 526.

[20] Pedro Soares Albergaria, "Internamento Compulsivo", *Sub Judice*, n.º 14 (1999), p. 22; André Gonçalo Dias Pereira, *O Consentimento Informado na Relação Médico-Paciente (Estudo de Direito Civil)* (Coimbra: Coimbra Editora, 2004), p. 587.

[21] Erwin Deutsch e Andreas Spickhoff, *Medizinrecht — Arztrecht, Arzneimittelrecht, Medizinprodukterecht und Transfusionsrecht*, 6. Auflage (Heidelberg: Springer, 2008), p. 540.

[22] José Carlos Vieira de Andrade, "O internamento compulsivo de portadores de anomalia psíquica na perspectiva dos direitos fundamentais" in *A Lei de Saúde Mental e o Internamento Compulsivo* (Coimbra: Coimbra Editora, 2000), p. 83. See also J. C. Dias Cordeiro, *Psiquiatria Forense (A Pessoa como sujeito ético em medicina e em direito)* (Lisboa: Fundação Calouste Gulbenkian, 2003), pp. 204-205

The prediction of an intervention on someone's personal sphere, in a coercive manner, which is able to consent to his medical treatment, is the utter limit of the restriction of the person's power of self-determination. The qualified judgment of proportionality that is here required is observed not only in the verification of the legal requirements for the application of the measure, but also in its execution. The verification of the necessity and appropriateness of compulsory treatment must be contemporary to the interests of the patient and the danger generated by his clinical condition. The commitment is only justifiable as a last resort, when compared to the non-removal of the present danger Article 8, paragraph 3 of the MHL.

The need to refrain as much as possible the restriction of the patient's fundamental rights results in the full affirmation of his rights and the exceptional nature of this restriction. The special power relationship that comes from the compulsory intervention cannot jeopardize the full legal capacity of the assertion of self-determination of the patient, except for the minimal necessary restrictions, for the well functioning of the institution or group he is inserted in, or for the removal of the danger that justified the application of the measure. Articles 8 (paragraph 4), 11 and 18 of the MHL are very clear about the identification and limitation of the restrictive effects of the patient's status, in particular the hospitalized one [(23)].

Regarding the tutelary commitment, there shall exist reinforced caution in the verification of its assumptions. As Helder Roque states, "if the actual injury of legal goods of a personal nature is not always subordinated, regardless of the will of the victim, the compulsory commitment of a citizen that bears a mental illness does not seem justifiable, where there is a mere danger of injury of such goods" [(24)]. The proportionality principle, therefore, requires a close correlation between the coercive imposition of a commitment due to the existence of a serious danger to life or personal integrity of the incapable patient. The patient's incapacity does not legitimize the hetero-determination of his sphere of interest, without a clear justification. In the case of the need to provide for the incompetent's treatment, it should occur in a privileged manner under civil protection measures.

In both types of compulsory interventions, the requirement and extent of the treatment or commitment are the basis that justifies its compulsive nature as far as the mentally ill patient is concerned. Thus, only the mental illness that serves as the basis of the measure can be processed and for all the other pathological conditions are mobilized the general rules (in this sense, Article 7 of the CDBH [(25)]. The breach of self-determination also implies that the medical intervention to be limited to the removal of the danger by resorting to treatments according

[(23)] José Carlos Vieira de Andrade, "O internamento compulsivo de portadores de anomalia psíquica na perspectiva dos direitos fundamentais", in *A Lei de Saúde Mental e o Internamento Compulsivo* (Coimbra: Coimbra Editora, 2000), pp. 89-90.

[(24)] Hélder Roque, "Uma reflexão sobre a nova Lei de Saúde Mental", in *A Lei de Saúde Mental e o Internamento Compulsivo* (Coimbra: Coimbra Editora, 2000), p. 128.

[(25)] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine

to the *legis artis* pelleted and accepted within the medical practice.

IV. The definition of "voluntary" commitment

Once the range of the interdict's general incapacity is determined, one must undergo his efforts to define "voluntary" treatment for the present research. Voluntary commitment is a measure that deprives the interdict from his freedom in a health facility in order to safeguard his interests, either promoting or protecting them. Hence commitment, as a measure which deprives the interdict of his liberty, without his consent, must be marked and validated by the principles of proportionality and subsidiarity, as instruments of protection of the incompetent, especially concerning his dignity and freedom.

The issue of voluntary commitment only arises if the interdict has no ability to decide autonomously about the admission or not. As for the interdicts that have the capacity to consent, that decision is his and not his legal guardian's. It is the interdict that has the power to autonomously self-conform his personal sphere — see Article 1881, paragraph 1 of the CC *in fine, ex vi* Article 1935, paragraph 1 of the CC.

If the legal guardian opposes to the consent or dissent decision, he may only demonstrate in court the need for commitment. In this case the commitment may only be legitimized according to the procedure stated in the Mental Health Law. Thus, strictly personal acts, for which the interdict demonstrates sufficient natural capacity to act independently and freely, are excluded from the scope of the powers of the legal guardian.

V. The legal issue: the legal guardian's range of powers

Therefore, the problem resides on the interdicts with no *de facto* capacity to consent in their commitment. We must then determine the powers that are given to the legal guardian.

The enactment of the interdiction implies, in the same sense as legal incapacity, the establishment of legal representation of the interdict: tutorship, by force of the remission stated on Article 139 of the CC. Tutorship is considered by the Portuguese Civil Code as a means to meet parental responsibilities and is regulated in Articles 1927 forth of the CC. The application of the system of tutorship for the minor implies, necessarily, as analyzed above, the due adaptations to the situation of the interdict.

The tutor is responsible for enacting the executive duties that fall under the tutorship's scope, including representation powers within the general legal sphere of the interdict, including the administration of his estate [(26)]. But the range of functional powers conferred to the tutor are not restricted to representation and we can already anticipate that a set of functionalized powers and duties similar to those which correspond to parents will fall upon the interdict's tutor, as it results from Article 1935, paragraph 1 of the CC.

The parental responsibilities are defined as a "set of powers and duties which are conferred or

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[(26)] Pires de Lima e Antunes Varela, *Código Civil Anotado (artigos 1796.º a 2023.º)*, Vol. V (Coimbra: Coimbra Editora, 1995), p. 456; Carlos Mota Pinto, *Teoria Geral do Direito Civil*, 4.ª Edição por António Pinto Monteiro e Paulo Mota Pinto (Coimbra: Coimbra Editora, 2005), p. 233.

imposed to the parents to take care of the person and estate of the underage children" [27][28], resulting from its content, considering Article 1878, paragraph 1 of the CC, a functional power that falls upon the parents of, in the interest of their children, to ensure their safety and health, as well as provide their livelihood, directing their education, representing them and administrating their estate. The outcome is that the holder of the parental responsibilities undertakes functions of representation and suppression of the incapacity that comes with nonage, but it does not limit itself in these, there is still de duty to secure and protect a healthy and balanced development of the minor, exercising his duties in the minor's interest.

However, the essential content of parental responsibilities does not reside in the allocation of powers for the exercise of representational functions, but rather in the relationship based on the daily care of health, safety and education of the child, with the purpose of its intellectual emotional and development [28]. A personalistic perspective is adopted within the parent/child relationship, in which they child must be understood as a person with feelings, needs and emotions, with recognized autonomy and self-determination, which is greater the higher the extent of its maturity [29].

When we are set before the concept of parental responsibility thus defined, we can conclude it results from an idea of care, which corresponds to the set of powers and duties assigned and implemented in the exercise of the interdict's tutor's functions, because parental responsibilities constitute the common nucleus to all forms of incapacity suppression [30]. It is in consideration of the care powered by emotional bonds that the exercise of guardianship exclusively towards the person of the interdict (Article 1933, paragraph 2 of the CC *ex vi* 139 of the CC), of the inabilitated due to profligacy, insolvents, the inhibited or suspended of their parental functions or removed from tutorship is allowed, excluding the administration of estate.

Pires de Lima and Antunes Varela refer that what is intended, as an objective, is "enjoy the precious capital of the emotional relationship that can connect the tutor to his pupil, without plunging over the minor's estate the shadow of the natural incapacity that falls upon him, which could only bring damage to the incompetent" [31]. These authors summarize the content of the tutorship in three fundamental aspects: the care for the person, legal representation and administration of the estate [32]. The differences of regime between parental responsibilities and tutorship result from interests of an exclusively financial character: prohibited acts and acts dependent of the court's permission (Articles

[27] Francisco Pereira Coelho e Guilherme de Oliveira, *Curso de Direito da Família: Introdução, Direito Matrimonial*, 4.ª edição, Vol. I (Coimbra: Coimbra Editora, 2008), pp. 45-46.

[28] Maria Clara Sottomayor, *Regulação do Exercício do Poder Paternal nos Casos de Divórcio*, 4.ª Edição (Coimbra: Almedina, 2004), p. 19.

[29] Guilherme de Oliveira, "O acesso dos menores aos cuidados de saúde " in *Temas de Direito da Medicina* (Coimbra: Coimbra Editora, 2005), p. 240; e Maria Clara Sottomayor, *Regulação do Exercício do Poder Paternal nos Casos de Divórcio*, 4.ª Edição (Coimbra: Almedina, 2004), pp. 13-14.

[30] Pires de Lima e Antunes Varela, *Código Civil Anotado (artigos 1796.º a 2023.º)*, Vol. V (Coimbra: Coimbra Editora, 1995), p. 340.

[31] Pires de Lima e Antunes Varela, *Código Civil Anotado (artigos 1796.º a 2023.º)*, Vol. V (Coimbra: Coimbra Editora, 1995), p. 453.

[32] Pires de Lima e Antunes Varela, *Código Civil Anotado (artigos 1796.º a 2023.º)*, Vol. V (Coimbra: Coimbra Editora, 1995), p. 460.

1937 and 1938 of the CC), sanctions arising from its violation (Articles 1939 and 1940 of the CC), the obligation to present a record of the minor's estate and accountability (Articles 1943, 1944 and 1947 of the CC), responsibilities and duties of the tutor (Articles 1945 and 1946 of the CC), unavailability of the pupil's income for whatever is not intended to provide for his sustenance, education and administration of his estate (Article 1936 of the CC).

The only provision about the duties of the tutor towards the person of the minor (the interdict) determines that the tutorship should be pursued with the diligence of a good *paterfamilias* (Article 1935, paragraph 2 CC). This provision reflects the nature of the bond that comes from the tutorship and the fears linked to it by virtue of the absence of a "strong" as the biological tie as that of the affiliation, imposing a criteria guide for the tutor's action, something that the legislator did not consider to be necessary for the parental responsibility, due to the implied relationship. Thus, the objective criterion in evaluating the performance of the tutor is enhanced, imposing itself even if the tutor's activity is not remunerated [(33)].

Despite the near coincidence of content between parental responsibility and tutorship, legal constitution of the tutorships aims to fill in the void, for the minors, left by the absence or inability to exercise parental responsibilities, without, however, intending to replace parenthood (as it occurs in the phenomenon of full adoption), and as such, linked to the absence of strong biological and social ties, the relationship between a pupil and his tutor is, in its essence, unidirectional because the tutorship is established exclusively in the interests of the pupil, being assumed as an altruistic institute in almost its full extent. We say almost because the tutor is entitled to remuneration, as it results from paragraph 1 of Article 1942 of the CC, although it is always dependent on the existence of net income from the minor's estate.

But the positivization of the right to remuneration does not arise as necessary for the acceptance of the duties and its exercise by the chosen person [(34)]. That is why Article 1936 of the CC does not allow the use of the pupil's income by the tutor to fulfill his own needs (as we can see in parental responsibilities in paragraph 1 of Article 1896 of the CC). This provision is, therefore, a result of the one-sidedness of the relationship, as opposed to the relationship of mutual understanding and interdependence that is set on parental responsibilities, and founded the imposition of reciprocal aid, assistance and respect duties between parents and children (Article 1874 of the CC). Of course when, as far as the interdicts are concerned, the aim is not to attenuate the absence or inability to exercise parental responsibilities, but it will certainly relate to the need to address the needs of the interdict in promoting his care and administration of his estate. Including, in the first place, the duty to ensure the sustenance of the interdict and to assume the expenses related to his safety, health and education

[(33)] Cfr. Pires de Lima e Antunes Varela, *Código Civil Anotado (artigos 1796.º a 2023.º)*, Vol. V (Coimbra: Coimbra Editora, 1995), pp. 456-457).

[(34)] Pires de Lima e Antunes Varela, *Código Civil Anotado (artigos 1796.º a 2023.º)*, Vol. V (Coimbra: Coimbra Editora, 1995), p. 466).

(Article 1879 of the CC *ex vi* Articles 139 and 1935, paragraph 1 of the CC). The tutor's responsibility will be greater in accordance to the interdict's needs, regarding, of course, the interdict's economic resources and the tutor's possibilities [35].

The tutor will act in the interdict's interest and name according to the criteria of a *bonus pater familias*, under the penalty of being liable for the damages caused with *mens rea* or negligence Article 1945, paragraph 1 of the CC). Besides its executive nature, which runs from the functional powers that are assigned to the tutor, we still characterize him as a singular body that can only be set upon a natural person. The powers of the tutor are characterized as being irrevocable, non-transferable and of functionalized exercise due to the interdict's interests [36]. The family council and, eventually, the protutor are also bodies of the tutorship.

The family council, an organ that works occasionally (Article 1957, paragraph 1 of the CC), is consisted of two members, chosen in accordance with Article 1952 of the CC and chaired by the Public Prosecutor (PP) (Article 1951 of the CC). The PP's presence and the role that he plays are highlighted, as a reflex of the public character of the State's intervention in the tutorship institute [37]. For the choice of the two subsidiary members, the degree of proximity, friendships, skills, age, place of residency and the interdict's interests are not indifferent, as it results from paragraph 1 of Article 1952of the CC. To this body are given the necessary and adequate functional powers to undertake the surveillance and supervision of the tutor's actions (Article 1954 of the CC), as well as a consulting function (see Articles 1931, paragraph 1; 1938, paragraph 2; 1942, paragraph 2; 1949 of the CC).

As a third member we have the protutor, of a singular character, to whom are granted enough powers to permanently monitor the tutor's activities, in the terms stated in paragraph of Article 1955 of the 1 CC. In addition to this, the protutor is assumed as a true auxiliary body to the tutorship because of the grant of cooperation powers, replacement of the tutor and the representation of the interdict's on the verge of a conflict of interests with the tutor (Article 1956 of the CC). The person who performs the functions of protutor is one of the members of the family council, elected by it, and should, whenever possible, represent a line of kinship different from the tutor, to counterbalance it, in accordance to Article 1955 of the CC.

The exercise of the functions of member of the family council and protutor is free, pursuant to Article 1959 of the, as opposed to the right that the tutor has to be paid (Paragraph 1 of Article 1942 of the CC). The teleology behind Article 1959 of the CC is settles on the prevention of eventual abuses and "on the thought that it does not repulse to demand a minimum of altruism in the activities of those who the law must call upon to collaborate" for the care of the interdict on behalf of family

[35] J. P. Remédio Marques, *Algumas notas sobre alimentos (devidos a menores) «versus» o dever de assistência dos pais para com os filhos (em especial filhos menores)*, 2.ª Edição (Coimbra: Coimbra Editoras, 2007), p. 204 ss.

[36] Francisco Pereira Coelho e Guilherme de Oliveira, *Curso de Direito da Família: Introdução, Direito Matrimonial*, 4.ª edição, Vol. I (Coimbra: Coimbra Editora, 2008), p. 153.

[37] Res de Lima e Antunes Varela, *Código Civil Anotado (artigos 1.º a 761.º)*, Vol. I (Coimbra: Coimbra Editora, 1987), p. 479.

solidarity [38][40]. However, this right will depend on the net proceeds of the interdict, it being understood that in no way it affects the obligation of acceptance and the exercise of tutorship duties.

Tutorship ends as soon as the cause of the interdiction ceases, after the judicial decision that results in the lifting of the interdiction, in the terms stated on Article 151 of the CC.

One of the ways to achieve the care is to recourse to legal representation. The powers given to the legal guardian come directly from the law or from a court order under the constitution of an underlying relationship of care, unlike what happens in voluntary representation, where the assumed relationship stems from the business or contractual intent of the one who is represented.

Despite this difference, in both forms of representation the guardian acts on behalf of the represented, where the representative effects end up being identical when legal representation is understood as a legitimizing assumption of the negotiating activity of the guardian. Thus, the legal affairs conducted by the guardian produce legal effects upon the sphere of the one who is represented (Article 258 of the CC).

Like voluntary representation, the performance of the guardian will be undertaken according to the will (even if assumed) and in the interest of the represented.

Whether in voluntary representation, whether in the legal, self-determination of the person represented is affirmed, which shapes his area of freedom [39]. A representação voluntária corresponde ao exercício do direito de autodeterminação, enquanto meio de realização dos interesses do representado. As Carlos Mota Pinto stated "the duty of the empowered guardian is to consistently develop private autonomy, since his powers are based on a manifestation of the will of the one who is represented" [40].

In turn, legal representation does not bring forth a conflict with the right to self-determination or personal autonomy. Minors, interdicts and some inabilitated are not, in the legal system's perspective, able to defend their interests and therefore do not have full capacity to manage their interests on their own. It is due to the need for care that the establishment of a legal guardian is vindicated. In this sense, the legal system provides a substitute — through the legal guardian — of the capacity to exercise rights, non-existent in the case of the legally incompetent [41].

Legal representation aims to reinstate the represented in his legal life [42], by allowing the exercise of the rights of the incompetent. The need to overcome a person's natural incapacity justifies the existence of legal representation out of respect for his self-determination, even if mediated by the legal

[38] Pires de Lima e Antunes Varela, *Código Civil Anotado (artigos 1.º a 761.º)*, Vol. I (Coimbra: Coimbra Editora, 1987), p. 490)

[39] WERNER FLUME, *Allgemeiner Teil des Bürgerlichen Rechts: Das Rechtsgeschäft*, 4. Auflage, Vol. 1, n.º 2 (Berlin — Heidelberg: Springer, 1992), pp. 753-755).

[40] Carlos Mota Pinto, *Teoria Geral do Direito Civil*, 4.ª Edição por António Pinto Monteiro e Paulo Mota Pinto (Coimbra: Coimbra Editora, 2005), pp. 539-540.

[41] Carlos Mota Pinto, *Teoria Geral do Direito Civil*, 4.ª Edição por António Pinto Monteiro e Paulo Mota Pinto (Coimbra: Coimbra Editora, 2005), p. 540.

[42] Uwe John, *Die Organisierte Rechtsperson. System und Probleme der Personifikation im Zivilrecht* (Berlin: Duncker und Humblot, 1977), pp. 78, 231; Hans-Martin Pawlowski, *Allgemeiner Teil des BGB. Grundlehren des bürgerlichen Rechts* (Heidelberg: C. F. Müller Verlag, 1998), p. 129 ss.

guardian [43]. This design fits the legal incapacities system present in the Portuguese Civil Code, that is, it assumes the extent of the powers of the guardian to the precise level of the incapacity of the represented.

The legal representation powers may include the financial as well as the personal sphere. The representation thus relates to all legal acts for which the represented is not able to perform autonomously and by himself, which includes the provision of consent, with particular emphasis on medical care. Article 1881, paragraph 1 of the CC provides the legal criteria on the extent and content of the legal guardian's representation powers.

The performance of the guardian, even if is enacted according to the objective criterion of the *bonus pater familias* (Article 1935, paragraph 2 of the CC), must be compliant with the real or presumed will of the represented and guided by his interests, whether manifested in the prosecution of the right of participation or as a result of the existing framework of values [prevailing the interpretive criteria foreseen in Article 340, paragraph 3, (presumed consent) and 465, subsection. *a)* (business management), both from the CC]. This is to customize the powers of legal representation as a means to affirm the legal personality of the incapable, which invariably requires competency in fact, the power to self conform their lives and interests.

It should also be noted that the difference between legal and voluntary representation does not the result from the function inherent to each of them. In both cases, what is at stake is the materialization of the right to self-determination, by providing legal instruments for the affirmation of the represented within the legal trade. In the context of legal representation, the powers conferred to the guardian are vessels to achieve the interests and will of the represented incompetent, such as, legal instruments to suppress his inability to act. It may differ on the content and criteria for the guardian's activities. However, in an abstract manner representation does not harm, nor offend the person's right to self-determination [44]. The same function can be performed by voluntary representation, particularly in the context of the advance health care directives, because the suppression of incapacity is not exclusive to legal representation.

The component of care requires effective protection of the person's interest, which are not limited to financial affairs. At hand is not the incapacity to act in legal transactions, but the need for protection of the person to be present in legal transactions and, above all, to have quality of life. The judgment of incapacity must be expressed and proportional, and can be only as effective as a protective measure, meaning, as a necessary and appropriate means of care. Not complying with the proportionality test, the person's potential capacity for its self-determination should be reserved. The possibility of a parallel

[43] Werner Flume, *Allgemeiner Teil des Bürgerlichen Rechts: Das Rechtsgeschäft*, 4.Auflage, Vol. 1, n.º 2 (Berlin — Heidelberg: Springer, 1992), p. 754; Karl Larenz e Manfred Wolf, *Allgemeiner Teil des Bürgerlichen Rechts* (Frankfurt am Main: Verlag C. H. Beck, 2004), p. 833.

[44] Werner Flume enquadra a representação legal no âmbito da teoria do negócio jurídico (cfr. *Allgemeiner Teil des Bürgerlichen Rechts: Das Rechtsgeschäft*, 4. Auflage, Vol. 1, n.º 2 (Berlin — Heidelberg: Springer, 1992), p. 754).

approach, in itself, does not require additional risks to the security and interests of the incompetent besides the assertion of the right of freely develop the personality.

VI. Proposed solution: the powers of the legal guardian in the decision of commitment

Once here, we must now figure out when the guardian has powers to decide about the commitment of the interdict. Usually, the tutor has the power to decide whether or not to commit the interdict. Only the inherent limits to the prosecution of the tutorship's functional rights will be applicable, in a first glance — to act according to the best interest of the interdict.

Therefore, the commitment decision will have
146 to meet the real or presumed will of the interdict (Article 1878, paragraph 2 of the CC *in fine* and in particular Article 6, paragraph 3 *in fine* CDHB, Article 12, paragraph 4 of the CDPD). The decision-making process of the tutor becomes bound to the will and values framework of the interdict, and once those are not clear, he shall determine the exercise of his powers to the prosecution of the interdict's best interests. To what has been stated, the principle of proportionality has full application in its three tests: suitability, necessity and proportionality in its strict sense.

The court decreed incompetence wants to ensure the realization of self-determination of the incompetent, here mediated by the institute of legal representation (guardianship), and it cannot serve as an instrument of hetero-determination by third parties on the affairs and interests of the incompetent.

At first we would say that once demonstrated, in particular, the necessity and appropriateness of commitment the legal guardian's decision would be legitimized. However, proportionality is not limited to the control of the merit and timeliness of the decision, but also to the control of decision-making process itself. The lack of capacity for the interdict to self-determination remains objectively guaranteed by law, conforming and linking the actions of a third-party in due representation.

Respect for human dignity and freedom of the interdict — integrated into the framework of his rights, freedom and guarantees - requires in its objective dimension, an interpretation of the rules on tutorship in order to restrict the guardian's discretionarily individual acting.

Therefore a restrictive understanding of the legal representation must prevail, being the constitutional consequences valued in their full extent, with a direct and immediate linkage to rights and freedoms — Article 18, paragraph 2 of the Portuguese Constitution (CRP) — here in a corrective sense as far as the interpretation of the institute of tutorship is concerned. Therefore it is necessary to define the role of commitment in the ends it seeks to justify, because it will depend on the *iter* that determines the validity and effect of the decision of voluntary commitment.

The commitment may be justified due to the performing of a medical procedure. That is, commitment is presented as a means to achieve the necessary medical procedure, whether it is therapeutic or diagnostic. But it may happen that the commitment reveals to be necessary as an end in itself, as a measure meant to ensure the welfare and health

of the incompetent. These are cases in which commitment is necessary because it is the only measure that can protect the interdict against risky behaviors against his life and physical integrity.

Once verified the need for commitment, as a means, or as an end to protect the interdict, an evaluation must be made in order to assess the subsequent assumptions to declare the validity of the decision of the guardian or not. One of the first assumptions is to know whether the commitment implies or not a change of residence. Residence here should be understood as the effective and stable center of the interdict's personal life, in which he has his address (home of fact) and where his circle of friends and family or support sphere are at. A change of residence requires first the *de facto* change in the center of the life of the interdict, either because the commitment does not have a defined term, or because the facts show that the return to the original residence and/or the end of the custodial measure is not expected.

A residential change will also occur whenever the commitment will presuppose a long lasting change (though not permanent), for example, the establishment of the length of stay for a minimum period (without fixing its term) or when the end is predictable but the period of stay would be long enough to be seen as not a temporary but a long lasting residential change. Thus, as opposed to what has been stated, a change of residence will not occur if the internment has a predetermined term (thus ensuring the purely transitory character of the measure) and it is short.

In an inversely proportional rationale to the time of commitment, reside the powers of the legal guardian. The longer the commitment, the smaller will be the independent power of decision of the legal guardian. Monitoring the legal guardian's performance in accordance with the principle of proportionality will trespass the legitimacy of his decision, because the functional right that he pursues will collide with the right to freedom of the incompetent, since it is not only at stake the fixation of the interdict's residence, but also a severe limitation of his freedom.

Short term commitments and with previously established deadlines will, in principle, justify the legal guardian's decision-making. However, it will not be an individual decision, but a "shared" one with the tutorship body — The Family Council. The unnecessary need for judicial justification is due to the fact that the level of intervention in the right of freedom of the incompetent is smaller and, therefore, less intense, once the decision is validated by the principle of proportionality. Once verified this assumption, the legal guardian doesn't need a previous court order under the principle of subsidiarity. Even if it is an indirect judicial intervention, because the PP is present in the Family Council. However, the role of the PP will always be one of supervision because the decision remains with the tutorship bodies.

Given the interference in the legal interests of freedom, and the duties of the Family Council, the decision is assumed to be of particular importance. So, regarding the duties and powers of the tutorship bodies, Article 1902 *ex vi* 1935 of the CC is applicable with the necessary modifications in commitment cases. Thus, because when parental responsibilities are considered a shared decision of responsibility for issues of particular importance is

also required, *a fortiori*, it is also obligatory in the tutorship, where there is a sole body that is accountable and depends on the Family Council and the protutor.

The reason for it to be this way is justifiable by the role that the Family Council plays in giving opinions on most relevant issues, such as the creation, exercise, modification and extinction of tutorship (among others, see Articles 143, paragraph 2; 1931; 1938, paragraph 2; 1940, paragraph 1; 1941, 1942, paragraph 2; 1949; 1954; 1956, subsections a) and c) all of the CC). Hence, we believe that the nature of the advisory and supervisory powers, regarding the structure of the tutorship, impose, in these cases, the previous obtaining, by the tutor, of a favorable opinion of the Family Council, either as a preventive or succeeding measure of control, given the requirement of a qualified decision of the tutor. Thus, by referring to Article 1935 of the CC.

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In conclusion, *in cases where the commitment will not imply a change of residence*, the decision of the guardian will depend on the previous obtaining of a favorable opinion of the Family Council — true integrator of the decision of the guardian — which will be subject to the means of inspection recognized for tutorship (PP (statutory), Family Council and Protutor). Not only is it the duty of the tutor, due to the importance of the decision, to inform about the situation of need for commitment, as well as of the assent of the Family Council, from which will depend the perfection and consequent effectiveness of the decision.

Therefore, the commitment will only be possible without the need of a judicial authorization, provided that it is temporary, and even in this case there are means of control as far as the proportionality and subsidiarity of the measure are concerned, first of all through the need to obtain a favorable opinion from the Family Council. If the guardian does not get the mentioned favorable opinion, he will have to get a court order, because a conflict of interests exists concerning what is considered to be the incompetent's best interest.

If the commitment does not imply a change of residence, then, in principle, there will be no need for an intervention that lacks a previous court order (except in the case of absence of opinion or when there is an unfavorable opinion of the Family Council), being enough a medical indication and the validation of the commitment, by the principle of proportionality in the strict sense.

In the opposite sense, we find the decision that implies a change of residence.

Here is a serious and severe interference in the legal sphere of the incompetent, by virtue of its durability, which will affect fundamental rights: the dignity and freedom of the adult. The durability of the treatment is a strong indication of the harsh effects, being considered *prima facie* as a restriction on rights, freedoms and guarantees. To this type of decisions we set together the ones in which the commitment *is presented as an end* (and not as a means), in the sense discussed above. The protection sought with the commitment, to work upon the interdict's behavior, even if does not involve a change of residence, is embodied as a serious and severe intervention in the rights of incompetent.

In both cases, the recognition of the powers of legal representation and the decision-making pro-

cess referred above are not enough. Something else becomes necessary, given the impact of the measure on the personal legal sphere of the incompetent. Even so, we have to distinguish between commitment as a means and commitment as an end.

In the case of commitment as a means, it will depend on an express court order at the request of the legal guardian. The analogical argument concerning acts of financial disposition will be valuable, which will follow similar civil proceedings. If for relevant financial actions the guardian's decision is not enough, for relevant personal actions, a court order will also be necessary. In the case, it will belong to the PP according to Article 2, paragraph 1, subsection a) of Decree-Law 272/2001, due to Articles 4 and 14 of the CRPD and Articles 18, paragraph 1 and 27, paragraph 1, joined with subsection h), of paragraph 3 or Article 27 of the Portuguese Constitution.

As far as the commitment as an end is concerned the reservations are much broader, particularly after the approval of CRPD — Articles 4, 14, 25 and 26.

Here we find the first problem because there is no enabling act to validate such a decision, only the Mental Health Law. In these cases, by an *a fortiori* argument, if the compulsory commitment against the will of the mentally ill is allowed, it will also be allowed for the incompetent. It is according to this understanding of the legal regime that we integrate the commitment as an end, once the rights and due legal interests have the same dignity and relevance in its objective dimension, and the absence of autonomy and capacity will not justify a diverse understanding of the maximum scope of protection and guarantees accorded to those who are capable. If it is true that when we use the interpretation technique we speak of the *a fortiori* argument, in substance we must speak of the scope of protection of fundamental rights in its objective dimension and the principle of material equality (in particular see Articles 5 and 14 of the CRPD).

The self-harmful behavior always leads to the conflict of the rights to self-determination and the protection of physical/mental inviolability. Even in the absence of a conflict of individual rights, the objective law requires that the decision must be proportionally justifiable, and that the minimum guarantees of the right to dignity and freedom and legally permissible forms of its restriction must be respected. Here we reaffirm the urgent situations in which the commitment does not involve a change of residence. Nevertheless, the validation of the decision will always be required from the moment it is possible to recourse to the courts.

VII. Poster

The adults with sufficient capacity to consent to the commitment have the power to decide for themselves, regardless of their legal guardians, and to settle their personal sphere autonomously
Respect for human dignity and freedom of the adult with incapacity – considered as a fundamental right, liberty or guarantee – requires, in its objective dimension, an interpretation of the rules on guardianship in order to reduce the magnitude of the powers of the guardian. A restrictive understanding of the guardian's powers must prevail.
Voluntary commitment corresponds to a measure that deprives the incapable of his freedom in a health unit in order to safeguard his interests, either by protecting or by promoting them
The problem of voluntary commitment only arises if an adult with incapacity determined by judicial decree does not have the ability to decide autonomously about the commitment. The problem lies therefore with the cases of adults without capacity to consent to the commitment.
The commitment can be justified by virtue of performing a medical procedure. This means that the commitment is seen as a mean to achieve a necessary medical procedure, whether of therapeutic or of diagnostic nature
Concept of residence: effective and stable centre where the adult established his personal life, in which he has his address (domicile of fact), his circle of friends and family or sphere of support. The change of residence requires first a *de facto* change of the life's centre of the adult either because circumstances demonstrate he is not expected to return to his original residence or it is not certain for how long will he be committed.
The legal guardian has, in principle, the power to decide the commitment for a short term. However, the decision needs to be "shared" with the other guardianship's organ – the Family's Council. It's not necessary to obtain prior judicial authorization by the court.
Once confirmed the need for commitment it will be necessary to verify the requirements necessary to ascertain the validity of the decision of the legal guardian.
First requirements: does the commitment implies or not a change of residence?
Commitment as a mean, it will depend upon an express judicial authorisation at the request of the legal guardian. This **competence is up to prosecutors** according to Article 2, No. 1 al a) DL 272/2001
decisions that imply the **change the residence** of the adult
But it may happen that commitment is necessary as an end in itself, i.e. as to ensure the welfare and health of the adult. Those will be the cases where commitment is necessary to protect the adult against the risk of endangering his own life and physical integrity
In this cases it's **necessary to obtain prior judicial authorisation**
Commitment as an end is only possible in the terms of Mental Health Act

VIII. Conclusion

Given the path we have pursued (which, in many parts, corresponds to a revisiting of our dissertation [45] we can see that there are some perplexities that we have tried to overcome. For it, we have assumed a restrictive interpretation of the powers of the legal guardian, highlighting the importance of the tutorship bodies. The legitimacy of the powers of the guardian will always depend on the respect for the rights of the interdict, not being enough a performance according to the presumed will or best interests of the interdict. There will be cases in which the decision of the tutor will depend on judicial (court order) or para-administrative (the functioning of the tutorship bodies) control. Thus the guarantees of protection and promotion of the rights of the interdict are enhanced, and the *apparent* loopholes in the powers of legal guardian and the role of the tutorship bodies are reinforced. Any relevant decision concerning the legal sphere of the interdict depends on the realization of a shared decision-making process, the only available warranty to asseverate that the interdiction will not violate the interdict's dignity.

[45] Geraldo Rocha Ribeiro, *A protecção do incapaz adulto no direito português,* Coimbra: Coimbra Editora, 2010.

TEAMWORK AND PATIENT SAFETY: IS THE SURGEON THE CAPTAIN OF THE SHIP?

Sónia Fidalgo [1]

Abstract: *§ 1. The complexity of the medical activity, division of labour and risk increase; § 2. The captain of the ship doctrine; § 3. The principle of trust; § 4. The principle of trust and the principle of division of labour; 4.1. The horizontal division of labour; 4.2. The vertical division of labour; § 5. Conclusion.*

§ 1. The complexity of the medical activity, division of labour and risk increase

1. Health care institutions are presented today as complex organizations where the delivery of health care is predominantly developed in the context of multidisciplinary teams. The practice of medicine is, therefore, based on the principle of division of labour.

According to this principle, there is an appropriate distribution of tasks between several people who cooperate in order to reach a common goal — the role to be carried out individually by each team member is set out, and the contribution of each person throughout the task, and its accomplishment, as a team, is to be defined [2]. The distribution of the tasks and, consequently, of the duties each member has to perform will, for that reason, enable the delimitation of responsibilities each player will have on every medical intervention.

In abstract, it is impossible to determine which duties will be assigned to each member of a medical team that acts according to the principle of division of labour [3]. Only taking into consideration the specificities of a particular case (type and emergency of the intervention, training and experience of the different collaborators, technical means available) will it be possible to determine which duties should be handed over to each team member. Nevertheless, it is indisputable that the distribution of the tasks and, consequently, of the duties each member has to perform must ensure both the effectiveness of the division of labour itself and, for the most part, patient safety [4].

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[2] See Wilhelm, Dorothee, *Verantwortung und Vertrauen bei Arbeitsteilung in der Medizin. Zu den rechtlichen Grenzen ärztlicher Sorgfalt*, Stuttgard: Ferdinand Enke, 1984, p. 3.

[3] In the same sense, Wilhelm, Dorothee, *Verantwortung und Vertrauen..., op. cit.*, p. 127.

[4] About patient safety and reporting of adverse events, see, in Portugal, Bruno, Paula, *Registo de incidentes adversos e eventos adversos: implicações jurídicas da implementação em Portugal*, Coimbra: Coimbra Editora, 2010, p. 84 and f.,

The sense of the principle of division of labour in medicine (the true genesis of the principle) is to give every team member the opportunity to dedicate themselves exclusively to the tasks that were assigned to them, thus ensuring a better assistance quality and a higher protection of the patient [5]. Researchers and medical professionals agree that patient treatment and safety are improved through interdisciplinary teamwork — actually, patient safety depends on teamwork [6].

2. Paradoxically, teamwork plays an important role either in the prevention or in the causation of adverse events [7]. Given the interdisciplinary nature of the work and the necessity of cooperation among the workers who perform it, teamwork is a risk source [8]. According to the literature, such dangers can be expressed in a number of ways [9]. First of all, there can be a *qualification failure* when one or more team members are not sufficiently qualified to perform the tasks that were assigned to them. On the other hand, *communication failures* can happen when one of the team members does not give an instruction in a way that is sufficiently clear or when, in any case, the collaborator does not understand correctly the instruction given to him. Finally, some *coordination failures* may also occur, which could translate into an insufficient harmonization between the different diagnostic and therapeutic measures, an undue repetition of these measures or an absence of these necessary measures.

3. What must be done to reduce these failures, enhancing the patient safety? There are two possible paths: 1) to follow what is known as the *captain of the ship doctrine*, which states that the team leader has the duty of ongoing control over his collaborators; or 2) to implement the principle of trust.

§ 2. The captain of the ship doctrine

1. *The captain of the ship doctrine* is a principle of medical malpractice tort law that emerged in the USA, in 1949, and grew in popularity through the 1950s [10]. *The captain of the ship doctrine* was a special case of the borrowed servant doctrine that applied in operating rooms. In the operating room, the surgeon, as the *captain of the ship*, picked the "crew" and gave all the orders. The surgeon was charged with supervising all members of the operat-

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and Oliveira, Guilherme, «O sistema nacional de notificação de incidentes e de eventos adversos (SNNIEA)», *Lex Medicinae — Revista Portuguesa de Direito da Saúde*, 18 (2012), p. 5 and f.

[5] In the same sense, Asin Cardiel, Enrique, «La responsabilidad del trabajo in equipo», *in*: *Responsabilidad del personal sanitario*, Madrid: Mateu Cromo S.A., 1995, p. 359, and Jorge Barreiro, Agustín, *La imprudencia punible en la actividad médico-quirúrgica*, Madrid: Editorial Tecnos, 1995, p. 116.

[6] Salas, E. / Sims, E. D. / Klein, C., «Can Teamwork Enhance Patient Safety?», *Risk Management Foundation — Harvard Medical Institutions*, 2003 (*in*: http://www.rmf.harvard.edu/Clinician-Resources/Article/2003/Can-Teamwork-Enhance-Patient-Safety), p. 5.

[7] Manser, T., «Teamwork and patient safety in dynamic domains of healthcare: a review of the literature», *Acta Anaesthesiologica Scandinavica*, 53 (2009), p. 143.

[8] See Baker, D. P. / Day, R., / Salas, E., «Teamwork as an Essential Component of High-Reliability Organizations», *Health Service Research*, 2006 (in: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1955345/?report=classic), p. 1579.

[9] See Stratenwerth, Günter, «Arbeitsteilung und ärztliche Sorgfaltspflicht», *in*: *Festschrift für Eb. Schmidt*, Göttigen: Vandenhoeck und Ruprecht, 1961, p. 393 and f., Carstensen, G., «Arbeitsteilung und Verantwortung aus der Sicht der Chirurgie», *Langenbecks Archiv für Chirurgie*, 335 (1981), p. 572, and Jorge Barreiro, Agustín, *La imprudencia punible…*, *op. cit.*, p. 116.

[10] Murphy, Ek., «"Captain of the ship" doctrine continues to take on water», *AORN J.*, 74, 2001 (*in*: http://www.ncbi.nlm.nih.gov/pubmed/11665386), p. 525.

ing room team [11]. According to the *captain of the ship doctrine*, the surgeon must control and direct the actions of those in assistance, therefore, he could be held liable for the actions of subordinates (*e.g.*, nurses, technicians) [12].

According to Murphy, "the major reason for this doctrine's popularity was that injured patients were precluded from suing hospitals under the then applicable charitable immunity doctrine. Charitable immunity declined in the 1960s, and by the 1970s, so too was the captain of the ship doctrine in decline. Pennsylvania, which first used the picturesque phrase in 1949, rejected the doctrine in 1974. In the meantime, it has come under much criticism, even among states that adopted it"[13].

2. The captain of the ship doctrine made some sense in the early days of surgery when the surgeon was usually the only physician in the room, and the entire surgical team consisted of a nurse to assist and a nurse to give anaesthesia. In a modern operating room, with a physician giving anaesthesia and a team of highly trained nurses with independent responsibilities to the hospital, the idea that the surgeon controls all the activity in the room has become untenable [14]. Despite this decline of the captain of the ship doctrine, "the felicity of the phrase has kept it alive in some states and in many operating rooms, even in states that have expressly rejected the doctrine. Even more than 20 years after its first rejection, however, courts [in the USA] still are being asked to adopt the doctrine" [15].

3. This doctrine grew as a principle of medical-malpractice tort law (which means, a principle of private law). However, even in criminal law there is literature that advocates a duty of ongoing control by the team leader [16]. Nevertheless, in my opinion, this is not the best way of improving patient safety.

From my point of view, we should abandon *the captain of the ship doctrine* in favour of independently determining the liability of each person caring for the patient. And when the team's medical intervention is careless and the patient ends up suffering an offense — negligent bodily harm or negligent manslaughter — one should determine

[11] See «Hospital Litigation», *Medical Risk Management: Preventive Legal Strategies for Health Care Providers* (*The Medical and Public Health Law Site, in:* http://biotech.law.lsu.edu/books/aspen/Aspen-HOSPITAL.html), p. 1.

[12] According to «Captain of the Ship in Medical Malpractice» (*in*: http://wiki.cns.org/wiki/index.php/Captain_of_the_Ship_in_Medical_Malpractice), "in 1949, Pennsylvania became the first state to address this issue when the Pennsylvania Supreme Court decided the case of McConnell v. Williams. In this case the court determined that Dr. Williams could be held liable for damages sustained by an infant he had just delivered even though the damage was not directly caused by him but rather by an intern assisting him (the intern applied silver nitrate to the infant's eyes while Dr. Williams attended to the haemorrhaging of the infant's mother). The court reasoned that "in the course of an operation (…) and until the surgeon leaves that room at the conclusion of the operation (…) he is in the same complete charge of those who are present and assisting him as is the *captain of a ship* over all on board, and that such supreme control is indeed essential in view of the high degree of protection to which an anaesthetized and unconscious patient is entitled" (McConnell v. Williams 361 Pa. 355; 65 A2d 243). With this decision, physicians who had the right or responsibility to control the actions of the 'agents' or 'employees' assisting them became subject to liability for negligent acts committed by those individuals".

[13] Murphy, Ek., «"Captain of the ship"…», *op. cit.*, p. 525.

[14] See «Hospital Litigation», *Medical Risk Management…, op. cit.,* p. 1.

[15] Murphy, Ek., «"Captain of the ship"…», *op. cit.*, p. 525.

[16] See Umbreit, Hans-Werner, *Die Verantwortlichkeit des Arztes für fahlässiges Verhalten anderer Medizinalpersonen*, Frankfurt am Main: Peter Lang, 1992, p. 118 and f., p. 150 and f., p. 172 and f.; Ambrosetti, Fabio / Piccinelli, Marco / Piccinelli, Renato, *La responsabilità nel lavoro medico d'équipe. Profili penali e civili*, Torino: Utet, 2003, p. 756, and Bilancetti, Mauro, *La responsabilità penale e civile del medico*, 5.ª ed, Milano: CEDAM, 2003, p. 756.

each member's liability as far as the delimitation of individual duties of care is concerned. The principles that should be considered to determine the duties of care are the principle of division of labour and the principle of trust [17]: in the course of the team practice of medicine, given the division of labour, each team player can rely on other team players for suitable standard care.

§ 3. The principle of trust

1. In order to be charged with negligent bodily harm or negligent manslaughter, a health worker must have breached the mandatory duty of care in a specific case. Therefore, it is necessary to determine the criteria related to the objective duty of care in those particular circumstances — in the specific case, which duty of care was the health worker obliged to have carried out.

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2. While practising medicine, professionals must respect, from the start, a set of legal rules of demeanour that regulate their activity. For instance, the Chartered Association of Physicians (Estatuto da Ordem dos Médicos) [18], the Physician's Status (Estatuto do Médico) [19], the legal framework of clinical trials on medicinal products for human use [20], the rules of medically assisted procreation [21], among other acts, establish a set of duties that doctors have to observe in the course of their work.

And, in addition to the legal rules, one must comply with the rules established by the healthcare professionals themselves (the so-called *leges artis*), through self-regulatory mechanisms. The Code of Medical Ethics for Physicians (Código Deontológico da Ordem dos Médicos) [22], the declarations of principles formulated by national and international organizations, the guidelines resulting from protocols for action [23] and other codes of conduct which exist in several medical setups are manifestations of this self-regulation.

Nevertheless, not all *leges artis* take the form of written rules. For the most part, the rules in health care are unwritten rules. Frequently, in order to fulfil the duty of care in a particular case, it is thus necessary to turn to professional habits which are common to every cautious professional [24].

And sometimes — when it is not possible to use the legal rules of behaviour or the *leges artis* (written or not) — professionals must turn to the "pattern of behaviour" ("Massfigur", in German) [25], that is, they have to use as a criterion for the breach of the duty of care "the non correspondence between the

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[17] See, in Portugal, Dias, Jorge de Figueiredo, *Direito Penal. Parte Geral I*, 2.nd ed., Coimbra: Coimbra Editora, 2007, Ch. 35, § 32; in Germany, Stratenwerth, Günter, «Arbeitsteilung...», *op. cit.*, p. 383 and f.; in Spain, Jorge Barreiro, Agustín, *La imprudencia punible…*, *op. cit.*, p. 115 and f.

[18] Decree-Law 282/77, 5 of July 1977 (changed by the Decree-Law 217/94, 20 of August 1994).

[19] Decree-Law 373/79, 8 of September 1979.

[20] Law 46/2004, 19 of August 2004 (changed by the Decree-Law 176/2006, 30 of August 2006.)

[21] Law 32/2006, 26 of July 2006 (changed by Law 59/2007, 4 of September 2007).

[22] Statute 14/2009, 13 of January 2009.

[23] In Portugal, the Directorate-General of Health is nowadays the competent entity for the issuance of clinical guidelines (see Pinho, Rita Roque, «The powerful tool of knowledge», *in*: *Fourth European Conference on Health Law — Book of Abstracts*, 9-11 October 2013, p. 102).

[24] See Dias, Jorge de Figueiredo, *Direito Penal…*, *op. cit.*, Ch. 35, § 19.

[25] Burgstaller, Manfred, «Kommentierung zu § 6 StGB», *in*: *Wiener Kommentar zum Strafgesetzbuch*, Wien: Manzsche Verlags — und Universitätsbuchhandlung, 1979, § 6, n. 38.

behaviour and the one that, in an identical situation, a man [a doctor] who is true to the protected values, prudent and conscientious would have" [26].

All these elements (legal and non legal, written and unwritten rules) constitute the criteria that materialize the duty of care which healthcare professionals have to fulfil in the course of their work.

3. For the materialization of the duty of care in the practice of medicine in a team, in addition to the rules referred to, it is also necessary to take into consideration the principle of trust. Nowadays, the principle of trust is regarded as a delimitation principle of the negligent conduct — it is a principle that delimits the duty of care. In that sense, whoever acts under the principle of trust does not breach the duty of care, therefore, his demeanour is not considered to be criminal negligence.

According to the principle of trust, in intergroup relations, each person must be able to trust that others behave according to the rule of care, "unless he has *soundly*-based reasons to think or might think otherwise" [27].

The principle of trust was first stated by the German case-law and doctrine in the context of road traffic. The principle of trust arose as a response to the question of knowing if the driver that was on the major road should have, or not, the duty to expect careless demeanours from drivers on secondary roads [28]. Later on, the principle of trust was transposed to other areas, namely to the labour division in medical teams. For that reason, with regard to the division of labour in a medical team, "any member (...) must be able to count on others to act according to the rule of care" [29], whether their intervention is previous, simultaneous or subsequent to the behaviour under analysis [30].

4. The principle of trust is based on the principle of self-responsibility [31] — it is the responsibility of every agent that justifies and demands a reduction in the scope of responsibility of the others. According to Figueiredo Dias, "other people are also responsible beings; if they behave carelessly, this will only affect, in principle, their own responsibility. In other words: as a general rule, we are not responsible for other people's carelessness; on the contrary, the law allows us to trust that others will fulfil their duties of care" [32].

Nevertheless, to say that the principle of trust is rooted on the principle of self-responsibility does not imply that the principle of trust and the prin-

[26] Dias, Jorge de Figueiredo, *Direito Penal…*, *op. cit.*, Ch. 35, §§ 19 e 23.

[27] Dias, Jorge de Figueiredo, *Direito Penal…*, *op. cit.*, Ch. 35, § 28; see also, Costa, José de Faria, *O perigo em direito penal (contributo para a sua fundamentação e compreensão dogmáticas)*, Coimbra: Coimbra Editora, 2000, p. 466.

[28] See Mantovani, Marco, *Il principio di affidamento nella teoria del reato colposo*, Milano: Giuffrè, 1997, p. 11 e ss.

[29] Dias, Jorge de Figueiredo, *Direito Penal…*, *op. cit.*, Ch. 35, § 32.

[30] See Jakobs, Günther, «Imputación objetiva, especialmente en el ámbito de las instituciones jurídico-penales del "riesgo permitido", la "prohibición de regreso" y el "principio de confianza"», *in*: *Estudios de Derecho Penal*, Madrid: Editorial Civitas, S.A., 1997, p. 219.

[31] In the same sense, in Portugal, Dias, Figueiredo, *Direito Penal…*, *op. cit.*, Ch. 35, § 29; in Germany, Stratenwerth, Günter, «Arbeitsteilung...», *op. cit.*, p. 292; in Italy, Fiandaca / Musco, *Diritto Penale. Parte Generale*, 3rd ed., Bologna: Zanichelli Editore, 1995, p. 499; in Spain, Feijóo Sánchez, Bernardo, «El principio de confianza como criterio normativo de imputación en el derecho penal: fundamento y consecuencias dogmáticas», *Derecho Penal y Criminología,* 69 (2000), p. 48 and f.

[32] Dias, Jorge de Figueiredo, *Direito Penal…*, *op. cit.,* Ch. 35, § 29.

ciple of self-responsibility are two principles with coincident action areas. There are cases where the others are responsible beings and yet the principle of trust does not apply — these are precisely the situations where the *soundly-based reasons* [33] make the agent not trust in the other's behaviour. The principle of trust has limits. If, in the particular case, the third party is not (or will not) behave in a responsible way and the person with whom he will have contact knows about it, it would be unacceptable — it would be contradictory — if he could use the principle of trust in the other's action in order to delimit his duty of care and, therefore, his own scope of responsibility.

5. The principle of trust responds to the protection of legal interests. And, in the practice of medicine in a team, the principle of trust clearly contributes to patient safety. In a medical team, the fact that every player can act without having to take into consideration the possibility that others may, at any time, breach their duties of care will allow them to concentrate on their own duties of care, thus reaching a greater protection of the legal interests in question (for instance, life and physical integrity) [34].

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From another perspective, also the idea of protecting the legal interests will not be strange to the limits of the principle of trust. Criminal law protects legal interests and therefore when he realizes (or should realize) that the other person is not fulfilling (or will not fulfil) his duty of care, the agent should adapt his demeanour in order to avoid a possible infringement of the interests legally protected.

To be precise, maybe Kuhlen is right when he states that the basis of the principle of trust is a "balance of interests, which, in addition to the protection of legal interests, must take into consideration the third party's self-responsibility and the freedom of action of those who must fulfil the duty of care" [35].

§ 4. The principle of trust and the principle of division of labour

In a healthcare services team a complex web of relationships is established among different professionals and the scope of the principle of trust depends on the position each professional has on the team. Taking into consideration the traditional distinction between horizontal and vertical labour division, the literature considers that the scope of the principle of trust is not the same for both types of relationships: the principle of trust will have a more restrict field of action in vertical relationships than in horizontal relationships.

[33] *Idem*, Ch. 35, § 17.

[34] See Jakobs, Günther, *La imputación objetiva en Derecho Penal,* Madrid: Editorial Civitas, S.A., 1996, p. 105, and Mantovani, Ferrando, «Il principio di affidamento nel diritto penale», *in*: *Estudos em Homenagem ao Prof. Doutor Jorge de Figueiredo Dias*, I, Coimbra: Coimbra Editora, 2009, p. 429.

[35] Kuhlen, Lothar, *Fragen einer strafrechtlichen Produkthaftung*, Heidelberg: C. F. Müller Verlag, 1989, p. 133; see also Dias, Jorge de Figueiredo, *Direito Penal...*, *op. cit.*, Ch. 35, § 30, Roxin, Claus, *Strafrecht. Allgemainer Teil. Band I. Grundlagen. Aufbau der Verbrechenslehre*, 4. Auf., München: Verlag C. H. Beck, 2006, § 24, n. 22, and Fidalgo, Sónia, *Responsabilidade penal por negligência no exercício da medicina em equipa*, Coimbra: Coimbra Editora, 2008, p. 107 and f.

4.1. The horizontal division of labour

1. The horizontal division of labour happens among professionals who, taking into account their training and competences, are on a level-playing field. The horizontal division of labour happens in every relationship between doctors of different or same specialities, as long as in this case, none of them has a leadership role. This working relationship can happen regarding a patient, either on simultaneous or on successive actions by different professionals.

2. In the context of horizontal relationships, the doctrine and the jurisprudence focus more in the interaction between surgeons and anaesthesiologists [36].

A few decades ago, the surgeon was considered the *dominus* of operating theatres — he was responsible for everything that happened during the medical intervention and as a consequence of it. But, mainly as from the seventies, anaesthesiology has established itself as an area of expertise alongside surgery [37], and anaesthesiologists are no longer in a situation of dependence regarding the surgeon. Both the surgeon and the anaesthesiologist act with complete autonomy: the anaesthesiologist's role is different from the surgeon's one; the former does not depend on the latter (neither technically nor scientifically) and is not subject to any degree in the hierarchy [38].

In view of the fact that the relationship between the surgeon and the anaesthesiologist is non-hierarchical, the principle of trust is at its prime. Each specialist, as a rule, can trust in the correct performance of functions from the other party — neither controls the activity of the other — not being responsible for the actions of his colleague. Each specialist will only be responsible for controlling the dangers that, on his specific scope of competences, may become an offense to the patient.

3. Nevertheless, we should consider not only the formal delimitation of competences but also the material delimitation of competences [39]. In the specific case, one collaborator can take on a competence of a third party, assuming in fact and voluntarily functions that belong to a colleague, besides his own functions. In this case, the person who has taken on duties which were not up to him to have taken on in the first place cannot call upon the principles of division of labour and of trust to dismiss his responsibility.

[36] See Carstensen, G., «Arbeitsteilung…», *op. cit.*, p. 572, Marinucci, Giorgio / Marrubini, Gilberto, «Profili penalistici del lavoro medico-chirurgico in équipe», *Temi*, (1968), p. 230 and f., and Jorge Barreiro, Agustín, *La imprudencia punible…*, *op. cit.*, p. 136 and f.

[37] In Portugal, the specialty of anesthesiology has been recognized by the Medical Association in 1950 (Sociedade Portuguesa de Anestesiologia, «História da Anestesiologia em Portugal. Apontamentos», *Boletim Informativo da Sociedade Portuguesa de Anestesiologia,* 1 (2004), p. 5).

[38] In the same sense, Nunes, J. Martins, «Da responsabilidade dos médicos anestesiologistas. Dos diversos tipos de responsabilidade, formas de apuramento e instâncias decisórias. Consentimento informado», *Revista da Sociedade Portuguesa de Anestesiologia*, 15 (2006), p. 30, and Caseiro, José Manuel, «A equipa médico-cirúrgica», *Revista da Sociedade Portuguesa de Anestesiologia*, 15 (2006), p. 11.

[39] See Villacampa Estiarte, Carolina, *Responsabilidad penal del personal sanitario. Atribución de responsabilidad penal en tratamientos médicos efectuados por diversos profesionales sanitarios*, Navarra: Editorial Aranzadi S.A., 2003, p. 199.

4. Besides these situations of broadening, in fact, the scope of competences, in horizontal working relationships the principle of trust can only be dismissed in cases of major breach of the duty of care by one of the professionals. But, in these cases, the accountability of the professional who unduly trusts in his colleague's conduct must be regarded with special care, mainly if doctors with different specialties are involved. Often, when one specialist realizes another specialist's mistake, the only thing he can do is to draw his colleague's attention to that circumstance because, as it is a problem related to a different area of expertise, he cannot do anything to correct his colleague's mistake.

4.2. The vertical division of labour

160 1. The vertical division of labour takes place when there is a hierarchical relationship where one person receives orders and is controlled by another person standing in a superior level, thus establishing a relation of top to bottom order. The traditional example of this kind of division of labour is the relationship between the surgeon (team leader) and the nurses who collaborate with him in the surgery. However, the vertical division of labour can also be found among doctors with the same area of expertise, provided that one of them is in a situation of superiority because he is in a leading position in a medical team (for example, the chief surgeon in relation to the assisting surgeons) [40].

2. Traditionally, in hierarchical relationships, the team leader undertook the whole realization of the therapeutic process — each of his subordinates' actions was only a delegated part of the activity undertook by the team leader [41]. The team leader had a set of duties which included not only the responsibility of selecting his collaborators and verifying their technical and personal qualifications, but also the duties of informing, teaching and constant supervising their performance, in order to avoid possible errors [42]. The rule was, therefore, the principle of distrust [43] — which was revealed, in the USA, through the already mentioned *captain of ship doctrine*.

Nevertheless, this position has been subject to well founded criticism. Actually, even in the scope of vertical relationships, the division of the labour principle only makes sense if every participant can trust others to performance according to the rules.

3. Anyway, within the framework of the vertical division of labour, the hierarchical superiority relation determines, for the leader, the duties of organisation and coordination of the team's performance. And everyone agrees that, in some situations, the team leader has also duties of observation and teaching during the team's activity — in one word, in certain circumstances, the leader has to control the performance of his subordinates.

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[40] In the same sense, Wilhelm, Dorothee, «Strafrechtliche Fahrlässigkeit bei Arbeitsteilung in der Medizin», *Jura*, 4 (1985), p. 184, e Feijóo Sánchez, Bernardo, «El principio de confianza…», *op. cit.*, p. 54.

[41] Cf. Gómez Rivero, M. Cármen, *La responsabilidad penal del médico*, Valencia: Tirant lo Blanch, 2003, p. 428.

[42] See Ulsenheimer, Klaus, *Arztstrafrecht in der praxis*, 3. Auf., Heidelberg: C. F. Müller Verlag, 2003, I, § 1, n. 174.

[43] See Crespi, Alberto, *La responsabilità penale nel trattamento medico-chirurgico con esito infausto*, Palermo: G. Priulla Editore, 1955, p. 155-6.

As we have already seen, the division of labour which the practice of medicine in a team is based on is an important source of dangers. During the intervention, qualification, communication and coordination problems might arise. The team leader's duty of control aims at avoiding that these dangers become attacks upon the life and physical integrity of the patients.

4. But in which terms can this duty of control be asserted? The principle of trust and the duty of control mutually limit each other: the higher the reach of the duty of control, the lower the extent of the principle of trust will be and, conversely, the lower the reach of the duty of control, the higher the extent of the principle of trust will be.

In the German doctrine, Umbreit widens the leader's duty of control of his subordinates' performance in such a way that he ends up denying the validity of the principle of trust with general character in vertical relationships [(44)].

In the Italian doctrine many also argue that one should not use the principle of trust within the framework of the hierarchical relations because it would be incompatible with the leader's duty of control [(45)].

In my opinion, the principle of trust has also a general validity in vertical relationships. The team leader will not breach his duty of care when he trusts that his collaborators will adequately fulfil the duties for which they are officially prepared. When there are no reasons to doubt the collaborators' preparation and capacities, the principle of trust is completely valid [(46)].

5. If the duty of permanent vigilance of the collaborator's activity was in place, the risks associated with healthcare services would be greater: someone who is permanently controlling others cannot focus on his own task [(47)]. Besides, current literature demonstrates that mutual trust reduces the negative effects of hierarchy– mutual trust often makes it easier for medical teams to achieve a better level of coordination and cohesiveness [(48)]. On the other hand, with the implementation of the duty of ongoing control, there would be a risk of emptying the distribution of tasks from its contents. It makes no sense making the leader supervise the performance of his collaborators (even if these collaborators are no physicians) when they perform tasks that are precisely of their competence and speciality. For instance, if the task of a nurse is to administer the therapy prescribed by him, the doctor can, as a rule, trust on the proper accomplishment of the task. If the doctor adequately prescribes a drug and the posology, and the nurse switches the drug or administers it in a higher dosage than the recommended one, it is the nurse who is responsible for possible injuries and not the doctor.

[(44)] Umbreit, Hans-Werner, *Die Verantwortlichkeit des Arztes..., op. cit.,* p. 118 and f., p. 150 and f., p. 172 and f.

[(45)] See Ambrosetti, Fabio / Piccinelli, Marco / Piccinelli, Renato, *La responsabilità..., op. cit.*, p. 173, and Bilancetti, Mauro, *La responsabilità penale..., op. cit.*, p. 756.

[(46)] In the same sense, Wilhelm, Dorothee, «Probleme der medizinischen Arbeitsteilung aus strafrechtlicher Sicht», *Medizinrecht*, 2 (1983), p. 51.

[(47)] See Jakobs, Günther, *La imputación objetiva…, op. cit.*, p. 105

[(48)] See Baker, D. P. / Day, R., / Salas, E., «Teamwork as an Essential…», *op. cit.*, p. 1587 and f.

6. The duty of controlling his collaborators' activities is, for the team leader, a *secondary duty of care* [49]. That is, the leader can trust the adequate performance of his subordinates except if there are special circumstances in the particular case that make (or should make) him query their capability of carrying out tasks in question and, consequently, make (or should make) him expect an incorrect conduct from them.

First of all, this will happen in circumstances where the team leader realises (or should realise) mistakes from his collaborators. Also in cases where a team member, in spite of having enough qualifications, is still inexperienced on the task in question, the leader has, besides the prior duty of informing and teaching at the beginning of the intervention, to supervise the activity of the inexperienced collaborator. It may also well be that an experienced and normally competent collaborator, although he has not made any mistake, does not feel physically and/or psychologically well during the intervention, namely because of exhaustion due to overwork. Also in this case the principle of trust must give way to a (secondary) duty of control of the team leader over his collaborator's performance.

But, besides these exceptional situations, the team leader can rely on the performance of his collaborators, according to the duty of care [50].

7. In the vertical labour relationship, the professional in a leading position gives the instructions and the subordinates have the duty of following the instructions provided and carrying out the given tasks. And if the person in a superior position can trust that his instructions will be followed, those who are in an inferior position can trust that those instructions are correct [51]. When the doctor prescribes a drug he can, as a rule, trust that the nurse will administer it properly; in return, the nurse can, as a rule, trust that the medical prescription is appropriate to the therapeutic process of the patient in question. In principle, if the doctor is wrong about the type of drug or the posology, only he, and not the nurse, will be held responsible for it.

The subordinates do not have, in principle, any duty of controlling their superior's actions [52] — it would be a contradiction to impose on the subordinates, who frequently are less experienced professionals and, sometimes, less qualified than their superior, the duty of controlling his activity. On the other hand, patient safety would be questioned if the orders given by the team leader did not have a certain imperative character [53] — it would be damaging to the patient if the decisions could only be taken after all team members had agreed on

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[49] Stratenwerth, Günter, «Arbeitsteilung…», *op. cit.*, p. 392; Stratenwerth / Kuhlen, *Strafrecht. Allgemeiner Teil I. Die Straftat*, 5. Auf., Köln: Carl Heymanns, 2004, § 15, n. 69.

[50] What has been just said is only valid where fully trained healthcare professionals are concerned. In the relationship between the training supervisor and the medical intern there is no principle of trust: the supervisor has the duty of constantly overseeing the trainee doctor's performance. The breach of this control duty is, in itself, a negligent conduct (see, Fidalgo, Sónia, «Responsabilidade penal do médico interno e do orientador de formação», *in*: *Direito penal. Fundamentos dogmáticos e político-criminais. Homenagem ao Prof. Peter Hünerfeld*, Coimbra: Coimbra Editora, 2013, p. 987 and f.).

[51] In the same sense, Jorge Barreiro, Agustín, *La imprudencia punible…*, *op. cit.*, p. 155.

[52] In the same sense,Wilhelm, Dorothee, «Probleme der medizinischen Arbeitsteilung...», *op. cit.*, p. 51.

[53] See Iadecola, Gianfranco, *Il medico e la legge penale*, Padova: CEDAM, 1993, p. 81.

them [54]. As a consequence, subordinates do not have the general right to criticize or resist orders given by the team leader — subordinates can, as a rule, trust corrected orders are given by their superior, and also have the duty to fulfil such orders.

Nevertheless, the trust in the correction of decision-making and instructions on behalf of the superior cannot be blind [55]. Even if there is no right to criticize and resist orders given by the leader, these orders are not absolutely binding to the subordinate — in spite of acting within the framework of a team, each collaborator continues to have professional autonomy. Thus, in situations where he considers that following his superior's orders can hurt the patient, the subordinate has the duty to refuse to follow those orders — the subordinate must abstain from taking action, otherwise he can be held responsible (together with his superior) for the injuries the patient might suffer [56].

§ 5. Conclusion

The increase of risk, associated with medical complexity and aggressiveness, should be tackled by way of implementing the principle of trust in relationships which occur amongst several health professionals. A *captain of the ship* doctrine does not contribute to patient safety. If the team leader has the duty of control the other members of the team, he cannot dedicate the necessary attention to his specific medical tasks. The implementation, as a rule, of the principle of trust in both horizontal and vertical relationships allows professionals to focus on the tasks that were assigned to them. Simultaneously, it is possible do limit the scope of responsibility of each individual, and it becomes clear that patient safety is everyone´s responsibility.

[54] See Landro, Andrea Rocco di, «Vecchie e nuove linee ricostruttive in tema di responsabilità penale nel lavoro medico d'*équipe*», *Rivista Trimestrale di Diritto Penale dell'Economia*, 1-2 (2005), p. 233.

[55] In the same sense, Wilhelm, Dorothee, «Probleme der medizinischen Arbeitsteilung...», *op. cit.*, p. 51.

[56] In the same sense, Wilhelm, Dorothee, «Probleme der medizinischen Arbeitsteilung...», *op. cit.*, p. 51, Marinucci, Giorgio / Marrubini, Gilberto, «Profili penalistici...», *op. cit.*, p. 229-230, Gómez Rivero, M. Cármen, *La responsabilidad...*, *op. cit.*, p. 437.

Chapter 2: Reaction against malpractice/Patients Compensation

LETHAL MEDICINE: THE SAFETY OF MEDICAL PRODUCTS AND CRIMINAL LIABILITY [1]

Susana Aires de Sousa [2]

Summary: 1. Introduction; 2. The case studies; 2.1. The thalidomide tragedy; 2.2. The Baxter Althane disaster; 2.3. The NECC and the meningitis outbreak; 3. The portuguese law; 3.1 The protected interests; 3.2. The administrative sanctions and the *Statute of medicine products* (Decreto-Lei n. 176/2006); 3.3. The portuguese criminal law; 4. The Medicrime Convention

1. Introduction

In this presentation we propose to point out the circumstances in which the use of inadequate and unsafe drugs or medical equipment can support criminal liability. In order to clarify the criminal relevance of these actions, several cases judged by criminal courts will be referred to. We henceforth present and discuss the legal protection offered by the Portuguese Penal Code in the case of such offenses. Finally we will consider whether this regulation is sufficient in order to fulfill the international obligations assumed by Portugal, in particularly those expressed in the *Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health*, opened for signature in Moscow on 28 October 2011.

2. The case studies

2.1. The thalidomide tragedy

One of the most famous cases of lethal medicine was associated to thalidomide. This drug was developed in 1954 in West Germany by a company named Grünenthal and was released into the market in 1957 under the label Contergan [3]. Thalidomide was primarily prescribed as a sedative or hypnotic, but was also claimed to alleviate the morning sickness of pregnant women. The drug became a huge success since it could be bought without medical prescription. Shortly after the drug commercialization had begun, several unusual cases of phocomelia (infants born with malformation of the limbs) were reported. In 1961 the drug was removed from the

[1] This text corresponds, with slight modifications, to the oral presentation given on the 11th October 2013 in the *IV EAHL Conference in European Health Law and Patient Safety* (Coimbra, 9-13 October 2013).

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[3] Mendoza Calderón, Silvia, *La Responsabilidad Penal por Medicamentos Defectuosos*, Valencia, Tirant lo blanch, 2005, p. 112; see also Sousa, Susana Aires de, «Medicamentos e responsabilidade criminal: problemas jurídico-criminais suscitados a partir de uma análise casuística», *Lex Medicinae*, ano 5 (2008), n.º 9, p. 81 and ff.

market. In the period 1958-1962 alone, about 845 cases of phococomelia appear in west Germany. However, very few (if any) cases are registered in countries where the approval of this drug was refused or restricted, such as the USA, where thalidomide was not allowed due to insufficient investigation.

One of the most important questions posed by this case to the criminal court was that relating to the criterion needed to establish a causal connection between the injuries and thalidomide, since this was a new medicine and the studies about its consequences were few. However, the court did affirm the causality between the drug and the injuries suffered by the children based on the personal belief of the judge regarding this causal relation. This decision was therefore much criticized [4].

2.2. The Baxter Althane disaster

In the Autumn 2001 occured an outbreak of deaths in patients with renal disease who routinely performed haemodialysis [5]. Fifty three sudden deaths of patients were reported in Spain, Croatia, Italy, Germany, Taiwan, Colombia and the USA. All had received hospital treatment with Althane hemodialysis equipment, a product manufactured and commercialized by Baxter International, USA.

In Barcelona four people died in four days. The investigation of the spanish Public Prosecutor led to the hemodialysis equipment used by those patients. In other countries the official investigations initially found no link between the cases. However, the investigation conducted simultaneously by Baxter and the FDA (Food and Drug Administration) identified in some dialysers the unusual presence of a liquid substance used to detectet leaks during the manufacturing process of the equipment [6]. For unclear reasons, this test fluid was not removed adequately. In contact with the blood of the patient during the process of dialysis, this liquid created micro bubbles which caused hypoxemia with fatal consequences.

Baxter also announced the discontinuation and permanent recall of all Althane equipment. The families of most non-US victims were compensated by Baxter voluntarily, while US plaintiffs settled an agreement with the company. Until this moment no criminal condemn was decided, to the best of our knowledge.

The importance of this case stems from the fact that the danger to life came from a medical equipment and not from a medical substance. It clearly states that the safety of patients is also dependent on the safety of the medical equipment.

2.3. The NECC and the meningitis outbreak

In October 2012 an outbreak of fungal meningitis was reported in the USA. The fungal contamina-

[4] With further developments, Sousa, Susana Aires de, *A Responsabilidade Criminal e o Topos Causal em Direito Penal*, Doctoral Dissertation, Coimbra, 2012, p. 14 and ff.

[5] Cf. Ramos González, Sonia, *Responsabilidad Civil por Medicamento. Defectos de Fabricación, de diseño y en las Advertencias o Instruciones*, Madrid: Thomson/Civitas, 2004, p. 36 and f.; also Sousa, Susana Aires de, «Medicamentos e responsabilidade criminal: problemas jurídico-criminais suscitados a partir de uma análise casuística», *Lex Medicinae*, ano 5 (2008), n.º 9, p. 84 and f.

[6] Canaud, Bernar, «Performance liquid test as cause for sudden deaths of dialysis patients: perfluorohydrocarbon, a previously unrecognized hazard for dialysis patients», *Nephrol Dial Transplant* (2002), p. 547.

tion originated in three lots of medication used for epidural steroid injections for back pain [7]. The medication was packaged and marketed by the New England Compounding Center (NECC), a compounding pharmacy (pharmacies which combine, mix or alter ingredients to create specific formulations of drugs in order to meet the specific needs of individual patients, and only in response to individual prescriptions) in Massachusetts. Doses from these three lots were distributed to seventy five medical facilities in twenty three states, and doses were administered to approximately 14,000 patients after May 21 and before September 24, 2012. Patients began reporting symptoms in late August, but due to the unusual nature of the infection clinicians did not realize that the cases had a common cause until late September. Infections other than meningitis were also associated with this outbreak, which spanned 19 states in the USA. The company was accused of "unsafe manufacturing practices" that led to 61 deaths and more than 749 injuries in patients infected with a fungus responsible for a rare but deadly form of meningitis. Presently, the latest news indicated that the top executives of the New England Compounding Center are likely to be criminally prosecuted on federal charges that carry possible prison sentences [8].

3. The portuguese law

3.1. The protected interests

The production and commercialization of medicine products are particularly connected to both individual and collective interests: life, individual health, patrimonial interests of the consumer, public safety and public health. These interests are protected by civil, administrative and criminal law.

However, criminal law should be the *ultima ratio* of this protection. Its sanctions are the most serious and heavy foreseen in the law. Thus they should be convoked to face the most serious attacks to legal goods and interests. If the protection of these interests can be fully and sufficiently reassured by other means, then criminal law is not required.

Nevertheless, the presence of an offence of these legal interests through the use, production and commercialization of medicine products can and must raise, in serious cases, the question of criminal liability. A defective product causing major injuries can, under specific requirements of the criminal dogmatic, demand and justify a criminal responsibility.

Although the portuguese law has a long history with respect to the protection from the damages caused by defective products (e. g, the penal Code of 1852 punished in its article 249 the apothecary that sold or applied damaged medicine products) [9], the present criminal rules are minimal and are not fully adequate for the protection of these interests.

[7] Cf. http://www.cdc.gov/hai/outbreaks/currentsituation/ (accessed in September 2013).

[8] Cf. http://www.tennessean.com/article/20130518/NEWS07/305170134/Meningitis-outbreak-criminal-probe-still-ongoing (accessed in September 2013).

[9] With further developments about this matter, Sousa, Susana Aires de, *Reponsabilidade Criminal pelo Produto…, op. cit.*, p. 516 and ff.

Portugal thus fails to accomplish its international obligations in this domain, in particular those assumed in 2011 with the signature of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health.

Which are then the consequences of the production or commercialization of a defective medical product under portuguese legislation? How would the cases presented be treated under portuguese law?

3.2. The administrative sanctions and the *Statute of medicine products* (Decreto-Lei n. 176/2006)

As previously stated, criminal law is the *ultima ratio* of the legal order. If the protection of these interests can be fully and sufficiently reassured by other means, then criminal law is not required.

This idea is particularly obvious on the portuguese law of pharmacy and medicine products (Decreto-Lei n. 176/2006, 30-08). The violation of the rules regarding quality and safety on the production and commercialization of medicine products is sanctioned essentially by administrative law. Article 181 of this Act establishes that:

"without prejudice of the criminal, civil and disciplinary liability or administrative measures that may be applicable, the violation of the duties previewed in the present act, which are supervised by the INFARMED [National Authority of Medicines and Health Products], constitutes an administrative illicit punishable under the terms of the present section".

Decreto-Lei n. 176/2006 sanctions with penalty from € 2000 to € 3740,98, in case of an individual person, or up to € 44 891,81 in case of a collective person, situations such as, among others:

- The production, commercialization, distribution, exportation, importation, selling to the public, use of experimental medicine products without requesting the necessary authorization or using an invalid authorization.
- The production and distribution of medicine products or experimental medicine without the necessary technical authorization.
- The violation of the required information about the medicine product.
- The violation of the required conditions to produce the medicine products (previewed in articles 59, 61 and 62, 63, 65 to 72).
- The modifications to the authorization made in disconformity with the law;
- The violation of the control obligation by a supervisory entity.

In the Portuguese legal system, the infractions related to bad practices in the production or commercialization of medicine products are primarily dealt by administrative sanctions. Criminal law has a very restricted intervention in the protection of these interests.

3.3. The portuguese criminal law

In Portugal the most relevant crimes concerning to medicine products are established in the Criminal Code.

a) When medical malpractice or defective medicine are connected with the death or with an health injury of a patient, a possible criminal liability emanates from the offence of homicide or physical injuries.

However, the criminal liability can not be founded in a simple co-relation between the death of the patient and the consumption of the medicine products. A first requisite is the need of a causal link between the medicine and the event. This is one of the most problematic issues concerning product criminal liability which was well illustrated by the thalidomide case. When the medicine is new, it is extremely difficult to establish a causal connection. The belief of the judge about that causal connection is not sufficient to affirm that the drug was the cause of harm. This causal link must be supported in scientific knowledge: the judge can not ignore the science and he can not formulate scientific judgments.

This causal link was proved in the Althane case. However, there is no notice of a condemnation for imprudent or involuntary homicide.

b) Another important disposition is the article 282 of the Criminal Code: Corruption of food or medical substances.

The conduct of adulteration of a food substance or of a medical substance in the several possible moments of production and commercialization, with danger to life or health of the consumer, is punished with imprisonment from 1 to 8 years.

This norm also requires that the life or health of a person to be put in a concrete and specific danger, which is likely to be difficult to prove in the circumstances of massive consumption.

The case of the NECC meningitis outbreak would be a clear example of criminal liability by corruption of a medical substance, concerning the people whose life was put in danger by the use of the contaminated drug.

These are the principal criminal dispositions concerning dangerous medicine products in the portuguese legal system. As we have pointed out, portuguese criminal dispositions are minimal and reduced to the protection of individual interests such as life or individual health. Portugal has kept the protection of other interests related to medicine substances, such as public health, outside the criminal range. In fact, the protection of public health has no autonomy in the portuguese criminal code from the protection of individual interests such as life or physical integrity. For example, the counterfeiting of medical products only has criminal relevance if the life or physical integrity of a specific person is put in danger. The conduct itself has no criminal value.

This is currently an important question because Portugal has signed the Council of Europe Convention (MediCrime) on the counterfeiting of medical products and similar crimes involving threats to public health.

4. The Medicrime Convention

The Convention will enter into force when ratified by five states, including three Council of Europe Member States. Until March 2014, 20 countries had signed the Convention and it had been ratified by three states (Spain, Ukraine and Hungary).

The object and purpose of this convention are the prevention and combat to threats to public health by:

— Providing for the criminalisation of certain acts, namely counterfeiting of medical products;
— protecting the rights of victims of the offences established under this Convention;
— promoting national and international co-operation.

One of the main obligations of the parties of this convention is to undertake the necessary legislative and other measures to establish the intentional manufacturing of counterfeit medical products (both medicinal products and medical devices), active substances, excipients, parts, materials and accessories, as an offence under its domestic law. That offence is independent of any individual and concrete danger to the life or health of a particular person. The convention also establishes, among others, the criminalization of the intentional supplying, offering to supply, and trafficking of counterfeit medical products, active substances, excipients, parts, materials, and accessories — which is also not foreseen in the Portuguese criminal law.

This Convention deals with the rights of the patients as well. In fact, patients and other users of medical products are given strong protection by the MEDICRIME Convention. A victim of crimes under the Convention is defined very broadly as 'any natural person suffering adverse physical or psychological effects as a result of having used a counterfeit medical product or a medical product manufactured, supplied or placed on the market without authorization or without being in compliance with the conformity requirements as described in Article 8' (*Article 4, k*).

The rights and interests of victims are protected in particular by ensuring that victims have access to information relevant to their case and which is necessary for the protection of their health; also by assisting victims in their physical, psychological and social recovery; finally, by providing in domestic law the right of victims to compensation from the perpetrators (*Article 19*). Parties to the Convention must also take the necessary legislative and other measures to protect the rights and interests of victims at all stages of criminal investigations and proceedings, including providing full access to information regarding those proceedings, access to proper legal representation (and legal aid if necessary), and protection against intimidation (*Article 20*).

As a conclusive note we see that there still is a long way in what concerns the criminal protection of the patient in the Portuguese legal system. This path has now been more emphasized by the Medicrime Convention.

Chapter 2: Reaction against malpractice/Patients Compensation

PATIENT SAFETY IN THE DIGITAL AGE

Paula Moura Francesconi de Lemos Pereira [1]

Abstract: *The advent of new technologies, the improvement of the communication and greater prominence in the huge movement of data through electronic networks, with constant use of the internet in various areas of knowledge, led to the emergence of new legal situations. In health, the biotechnological advances provide several ways to doctors to better serve their patients. The use of Internet related to medical services can occur in several ways, such as: i) source of information about diseases, treatment, online research (medical websites); ii) the practice of medicine and online therapy, remote medical consultations (telemedicine); iii) sending exams and medical records electronically; iv) purchase and sale of healthcare products and services online; v) medical advertising, and vi) procedure simulations. All of these forms cause great impact on the doctor-patient relationship transforming its traditional view. However, the information technology, although considered indispensable today, may entail various risks and damages to patients and their safety can be jeopardized. The law operators have to study the necessary means to ensure greater protection and safety of patients, not only regarding the quality of the information circulated on the Internet but the reliability of the transmission, and also the guard of the sensitive information provided by patients, ensuring their privacy. Nevertheless, there are neither legal nor ethical norms, uniform or specific standards, in the Brazilian or European legal systems, regulating such medical services by Internet.*

Keywords: *Health Services. Internet. Information. Telemedicine. Personal Data. Patient Safety. Privacy. Dignity. Standards. Ethics.*

Introduction

The emergence of new technologies, improved communication and greater prominence in the huge flow of data through electronic networks, with constant use of the internet in various areas of knowledge, led to the appearance of new legal situations.

In health, the technological advances provide doctors several ways to better attend to their patients, since the use of telephone, fax, videoconference, Internet, etc., such as the existence of new treatments, new equipment, which facilitates both, medical professionals and patients, removing all geographical barriers.

The Internet use related to medical services can occur in several ways, such as: i) source of information on diseases, treatment, online research, medical website use; ii) the practice of medicine and online therapy, remote medical consultations (telemedicine); iii) scans, images and medical records sent electroni-

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cally; iv) purchase and sale of healthcare products and services online; v) medical advertising, and vi) procedure simulation. However, the approach is restricted, the first three hypotheses.

All these forms cause great impact on the doctor-patient relationship, bringing changes to the traditional view, based on the physical interaction and examination, direct contact between practitioner and patient, with greater patient participation.

However, these technologies of information, although considered indispensable nowadays, may entail various risks and harm to patients.

For these reasons, it is due to the law professionals study the necessary tools to ensure greater protection and safety to patients. It is not only the quality of the information published on the Internet, but the reliability in transmitting and storing the information provided, such as the protection of privacy, ensuring secrecy, confidentiality of the sensitive personal data of the patient, and the indispensability of informed consent. All in order to avoid the pecuniary or non-pecuniary damages.

Although there is no specifical law or ethical standards concerning digital medical service in Brazil and even in the European Union.

In Brazil, the federal government seeking for the establishment of a standard regulation for the Internet, under civil, sent to the Congress on August 24, 2011, known as the Bill of Marco Civil Internet, which has been recently approved by the House of Representatives and Senate and sanctioned by President Dilma on april 23rd, 2014, by federal law nr. 12.965/2014, it will be made affective sixty (60) days after its officil publication (on april 23rd, 2014). It establishes principles, guarantees, rights and duties for the use of the Internet in the country, with emphasis to the provisions on custody record connection and access to Internet applications, which although not directly address medical services, but may assist (e.g. article 3, II, III, VII, 7, I, II, III, VIII, 10, 11).

Despite these efforts and recognizing the need for regulation of the matter, currently, interpreters of the law in Brazil makes use of the existing legal and ethical rules in Brazil, especially the Constitution, the Civil Code, the Code of Medical Ethics and Federal and Regional Medicine Council Resolutions, among other laws.

In Europe, without entering into a specific legal system, we find examples of rules that deal with the treatment of personal data protection in the European Union for better understanding the issue (conventions, directives). It is mentioned, for example, the Convention for Human Rights Protection and Fundamental Freedoms — ECHR (article 8); the Charter of Fundamental Rights of the European Union (articles 3, 7, 8); the Convention of the Council of Europe for the protection of individuals with regard to automatic processing of personal data, and the Directives of the European Parliament and of the Council. Among them we can mention Directive nr. 2011/24/EU on the application of patient`s rights, in cross-border healthcare (art. 3d); Directive nr. 2000/31/EU on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce), Directive nr. 95/46/EU on the protection of personal data and on the free movement of these; Directive nr. 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communica-

tions sector (Directive on privacy and electronic communications). And the Communication from the Commission to the European Parliament on the Telemedicine for the benefit of patients, healthcare systems and society — COM (2008) 689.

It is important to mention that the Directive nr. 95/46/EU was the subject of a comprehensive reform proposal, by the European Commission, in January 2012, in order to strengthen online privacy rights, boost new digital technologies and prevent disharmonies between national laws, regarding personal data processing and their free movement — COM 2012, 11 final (General Data Protection Regulation).

The breach of the duty of care and protection may lead to the liability of all participants of this new legal relationship, including physicians, health care institutions, and Internet service providers, among others. The goal is to call the attention of the participants in these new relations and legal scholars of law to this new reality, in order to safeguard the life, health, psychophysical integrity of the patient, their human dignity in this new digital age, which is a challenge contemporarily.

I. The use of internet as a source of health information

The internet has often been used as a vehicle for information about issues related to health, sites which allow people to store and manage personal medical information, such as personal and family history, clinical data in the network as a kind of electronic record, allowing customized searches in health in pages considered reliable.

The increase of the search for health information through the Internet has been done by both medical professionals seeking to update their knowledge, improving themselves, and by patients seeking further information about a particular situation or illness. The curiosity of patients ranging from issues relating to nutrition, food problems, exercise for weight loss, alternative treatment, medical insurance, medical products and health information on prescription drugs, to subjects of sensitive diseases they would not like to talk about.

Among the advantages of the Internet use, it is outstood: i) anonymous (although the problem of cookies, storing information about the preferences of a user based on the navigated pages), the right of access to sites with no identification, no monitoring of content, and the search for medical specialists or hospitals, and ii) easy and fast availability of information contributing to disease prevention and health promotion, encouraging the patient to the appropriated treatment, allowing a greater awareness, improving the dialogue between the doctor and the patient.

However, it has been being subject of concern among medical professionals, especially the more paternalistic, due to its substitution for a source of information on health issues on electronic resources available on the Internet. It may affect the doctor-patient relationship [(2)].

The disadvantages may arise several factors, including: i) lack of Internet access by the population,

[(2)] Cardoso, José Eduardo Dias; Coelho, Augusto Quaresma; Coelho, Elisa Quaresma. Informações médicas na internet afetam a relação médico-paciente? Revista Bioética, v. 21, n. 1, 2013, p. 142-9.

behold, it is still a small portion of society who can use this media in public spots and with speed; iii) the difficulty of selecting the most appropriate sources of information, lack of education, health and digital user culture, the place of origin, the diversity of sources, the difficulty of verifying the quality; iv) the degree of control and review the information is submitted to, ultimately restrict users — patients, committing their freedom of choice; v) lack of standards, guidelines, uniform criteria in international placement of information; vi) quality of health information; vii) uncertainty about the credibility [3][4] of the source (regarding the provider ID in ecommerce deserves mention the articles 45A and 45B of the Bill of User Code updating nr. 281/2011, regulation the e-commerce), and viii) self-medication, adopting methods of treatment without proper guidance, where may occur misinterpretation of information and symptoms, etc.

The quality of information includes its credibility, reliability and accuracy related to the seriousness of the authors and websites, besides the availability embodied in the ease of searching and browsing as well as the way they are presented to the public. There is serious difficulty or even impossibility of controlling sites, due to the lack of uniform international legal standards.

Health information should be based on good quality documentation as well as on relevant and accurate bibliography. It can`t be used as an economic and financial mechanism, as it often occurs for the misuse of large laboratories which take advantage of the internet for information on patients, either providing new treatments or manipulating data. This fact raises ethical questions about internet use in the collection of health information and it requests a multidisciplinary analysis.

But what would be the solution to these issues? Some studies have been suggesting as a way to be tracked, a closer cooperation among the medical societies, in order to better qualify scientific information in the Internet. The creation of ethical codes of conduct for suppliers of information and browsers, becomes prior, despite the problem of not having a universal code of ethics and the lack of universal legal bases to regularize health information disseminated in the websites.

Gema Revuella and Cristina Aced [5] advocate the use of the accreditation systems, with the creation of quality standards, web pages accredited, committed to ethical principles, ensuring thereby the strictest reliability, despite the problems of reputation purchase.

According to a study conducted by Lydia Maria Nunes Ferreira [6] there are already some initiatives to implement quality criteria for websites that deliver health information which aims to unify and standardize the quality of health information available

[3] Internationally, one can cite the Directive nr. 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures, and aiming at security and trust in electronic communications, in ecommerce.

[4] Pacios, Marilena; Campos, Carlos José Reis de; Martha, Amilton Souza; BARRA, Paulo Sérgio. Os sites da medicina e saúde frente aos princípios éticos da *Health on the Net Foundation — HON*. *Revista Bioética*, 2010, vol. 18, nº 2, p. 483-496

[5] Revuella, Gema; ACED, Cristina. *Conflictos éticos de la comunicaciòn médica en internet*. In: *Dilemas y acuerdos éticos en la comunicación médica.* Espanha: Thomson Reuters, 2010, p. 71-83.

[6] Ferreira, Lídia Maria Nunes Ferreira. *A internet como fonte de informação sobre saúde um levantamento de percepções dos médicos portugueses*. Dissertação submetida como requisito parcial para obtenção de grau de Mestre em Gestão dos Serviços de Saúde Orientador Prof. Doutor Paulo Moreira, 2006.

on the internet, as well as guide the user or health care professional on reliable health information, with emphasis on: i) HON Foundation [7], founded in 1995 in Switzerland, which created in 1996 a code of conduct called Foundation health on the Net Code of Conduct (HON code); ii) Netscoring; iii) URAC (2006); iv) DISCERN established between 1996 and 1997 by the British Library and the NHS Executive Anglia Oxford Research and Development Program, together with the Division Public Health and Primary Care, University of Oxford; v) the Healthcare Coalition, non-profit organization (1997), having created the eHealth code of Ethics, code of Conduct for websites and health services in the Internet, in 2000, in Washington DC, USA, which was adopted by the Internet Healthcare Coalition; vi) the MIC, instrument based on "a structured system of self — certification with external reference"; vii) eEurope 2002 HSWG (1998), Internet Quality Information Checklist (QUICK) (2000), an instrument supported by the Health Development Agency and Centre for Health Information Quality UK ; viii) Organising Medical Networked Information (OMNI), founded in 1995 to provide a searchable database of filtered and accredited information; ix) guidelines for the American Medical Association (AMA) Websites, which aims to promote the improvement of medicine and public health in the United State of America, and in February 2000 adopted guidelines for medical and health information from the Internet and established four principles of quality standards for content, advertising, sponsorship, privacy and electronic commerce.

Thus, it becomes of great importance from the part of suppliers, responsible for serving the health information on the Internet, and that should have commitment to the final user, the consumer. They must observe the highest ethical and legal transparency, honesty, good faith and privacy.

Failure to comply with these principles and assumptions of good conduct may lead to liability of individuals or entities that deliver information, such as content providers, service providers, and network providers. It is considered as content providers authors, publishers or other copyright holders who introduce their work on the net and are subject to protection, together with software companies, the rules concerning copyright; service providers, identified with both ISPs, who hire and provide the means to access the Internet, as well as service providers and content offering in the Internet environment contents to be accessed or services to be vehiculated through the Internet or from this, developing and concluding the service outside the computer network, offering product or service fulfillment. Finally, network provider, those who provide the physical infrastructure access, ie, the lines of communication which allow connection to the Internet, such as telephone companies or cable company services [8].

Once the matter involves the medical science, it will be due to the Federal and Regional Medical

[7] Barra, Paulo Sérgio Calvacante; Martha, Amilton Souza; Campos, Carlos José Reis de; Pacios, Marilena. Os sites de medicina e saúde frente aos princípios éticos da *Health on Net Foundation* — HON. *Revista Bioética*, v. 18, n. 2, 2010, p. 483-496.

[8] Miragem, Bruno. Responsabilidade por danos na sociedade de informação e proteção do consumidor: desafios atuais da regulação jurídica da Internet. Revista do Direito do Consumidor, ano 18, n. 70, abr.-jun., 2009, p. 49.

Martins, Guilherme Magalhães. *Responsabilidade civil por acidentes de consumo na internet.* São Paulo: Revista dos Tribunais, 2008, p. 359.

Councils, based upon the Law nr. 3.268/57 and Act nr. 44.045/58, the role of defending the own medicine and its ethical exercise by professional ruling norms.

In Brazil, the Regional Council of Medicine of São Paulo (CREMESP) was concerned with the issue of health information transmitted on the Internet and edited the Resolution nr. 97, from March 9th, 2001, which established the Ethics Handbook for sites of medicine and health in the Internet.

Recently, in 2009, they altered, by the Resolution nr. 206 by CREMESP, the Resolution nr. 175/2008 by CREMESP, which rules information security policy and access to resources for information technology, through user registration mechanisms, use of personal passwords and non-transferable, encrypted, use of electronic signatures, record accesses performed by users, among other measurements.

According to the Resolution nr. 97 /2001 by CREMESP the internet user, concerning online health services or products have the right to require the organizations and those responsible for the websites: i) transparency of the information provided on the site, with the identification of those responsible, and direct and indirect sponsors of the site; ii) honesty, not hiding the economic and financial interests, it should be clear when the educational content has disclosed or scientific purpose of advertising, promotion and sales, interest from sponsors, companies products, equipment, pharmaceuticals; iii) quality of information, which must be accurate, up to date, easy to understand language objectively and scientifically grounded; iv) express informed consent of users to file, use or disclosure of any personal data, they should know the potential risks to information privacy; v) personal health privacy; vi) medical ethics, compliance with ethical professional practice regulatory standards, and vii) legal and ethical responsibility for the information, Medicine and Health products and services related to the web (article 1).

The inobservance of ethical and juridical principles of transparency, honesty, good faith, privacy, among others, which meet constitutional and infraconstitutional prediction (articles 5th, X, XIV, by Federal Constitution/88, articles 4th, 6th, 8th, unique paragraph, 9th, 10th, 30th, 31st, 36th, 46th, 51st, IV, 52nd, 54th, paragraph 4th, all by Consumer Defense Code — CDC, article 21st, 113th, 422nd by Civil Code) and good behavior purposes may cause the civil liability of individuals or corporations that vehiculate the information such as the providers. [9] (articles 186th, 187th, 927th by CC and articles 12th, 14th by CDC) [10].

On the other hand, users should seek the accredited sites which observe the quality standards for content, advertising, sponsorship, privacy and electronic commerce.

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[9] Directive nr. 85/374/CEE by Council, from July 25th, 1985, concerning the approach of the legal, regulatory and administrative dispositions of Member-states, in matter of liability upon deffective products.

[10] "Although the backbone, access, content, hosting and e-mail providing services are interlinked among them (in such a way that activities as the electronic mail service or content provision are supposed to provide access to the internet, which is due to the access provider), each of them responding for the damage attributed to their own activity, having as parameter not only the duties expressively assumed in the contract, but also the lateral duties, annexes or instruments of behaviour, based upon the principle of objective good Faith (Civil Code, articles 113th, 421st), which may state the good accomplishment of the duty" Martins, Guilherme Magalães. *Responsabilidade civil por acidentes de consumo na internet.* São Paulo: Revista dos Tribunais, 2008, p. 359.

II. Online medical practice and therapy (telemedicine)

The telecommunications united to computers gave rise to telematics, which in health is characterized by the joint application of these two media to health activities, overcoming barriers of geographical distances to promotion, prevention and cure individual or collective that allows the exchange among health professionals and between their patients and them. Telematics was divided into two groups: telehealth and telemedicine [(11)].

The telehealth comprises all the actions of remote medicine, aimed at the community concerning public health policies and dissemination of knowledge and covers education and data collection of certain groups and populations isolated by distance as well as the improvement of health professionals that can stay in touch with new techniques, diagnosis and innovative treatments for better targeting of preventive medicine. Besides that, frequent updating statistical data and national and regional health policies as well as epidemic control. The most commonly used procedures for telehealth networks are telededidatics; social telephony; communities, virtual libraries and videoconferences.

Telemedicine [(12)], which will be the subject of this study, encompasses the entire distance medical practice focused on the treatment and diagnosis of individual patients (identified or identifiable), using conventional telephony and the Internet, enabling professionals to discuss health issues, publish scientific articles, video conferencing, access to virtual libraries, treat patients, send scans for analysis by other professionals, exchange information with other physicians, provider vocational training [(13)].

The procedures of telemedicine can be classified into various types, such as: i) teleconsultation; ii) the telecare; iii) the teleservice; iv) telepathology; v) to teleradiology; vi) telemonitoring (homecare); vii) telediagnosis; viii) the teleconference; ix) telesurgery, and x) teletherapy.

Several benefits brought by medicine: i) the reduction of time and transportation costs of patients, shortening distances; ii) the interaction among professionals, making it possible to have expertise accessible to any patient without limitations of space or time; iii) the dehospitalization (discharge of patients from hospitals); iv) management of health resources; v) decentralization of health assistance; vi) meeting in remote locations; vii) the opportunity of access to medical specialists; viii) the transmission of images and test results to evaluate the distance, especially in the radiology, pathology, cardiology, neurology areas, and ix) greater possibility of technical developments for the healthcare provider that leverages available equipment, information, and ease of obtaining a second opinion

(11) Schaefer, Fernanda. *Proteção de dados de saúde na sociedade de informação*: a busca pelo equilíbrio entre privacidade e interesse social. Curitiba: Juruá, 2010, p. 82-83.

(12) Based upon Communication from the Commission to the European Parliament about on telemedicine for the benefit of patients, healthcare systems and society COM (2008) 689, telemedicine is "the provision of healthcare services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients."

(13) França, Genival Veloso de. Telemedicina: breves considerações ético-legais. *Revista Bioética*. Vol. 8, n. 1, p. 107-125.

in cases of emergency (equipment, communication infrastructure).

On the other hand, telemedicine is the subject of several debates and has been guided by some instruments such as the Declaration of Tel Aviv on Accountability and Ethical Standards in the use of telemedicine, signed in 1999 by the General Assembly of the World Medical Association, featuring on the principles of doctor-patient relationship in telemedicine; the good Practice Guide for publishing medical services on the Internet of the Committee of European Doctors and Recommendations of the German Society for medical Law relating to legal aspects of telemedicine.

Among the disadvantages, we can mention: i) the difficulty in getting a correct diagnosis; ii) virtual relation doctor-patient; iii) poor communication which may influence in the accuracy of the diagnosis; iv) attendance by non-qualified people or false doctors; v) technology high cost; vi) The secrecy of electronic information; vii) difficulty in encrypted data; viii) access of medical health care for unauthorized people, and ix) higher interpretation mistakes of data and image.

In Brazil, telemedicine is governed by rules of an ethical nature issued by the Federal Council of Medicine (CFM), with normative force, although not considered law, in the strict sense.

The remote medical consultation performed through any kind of media, including the Internet, with the use of e-mails, web interactivity forms [14], blogs, according to the interpretation of article 37 and 114, both by Medical Ethic Code (CEM) [15] and article 1st, item IV, Act nr. 4.113 of February 14th, 1942, are forbidden, except in some hypothesis, should telemedicine or any other method be ruled by the Federal Medicine Council.

The use of telemedicine concerning patient assistance is met, in Brazil, nowadays, ruled by Resolution nr. 1.643/2002 of the Federal Council of Medicine — CFM, and the use of teleradiology by Resolution nr. 1.890/2009 CFM, which disciplines electronic transmission of radiological images in order to query or report.

In European Union there is not any specific Directive about telemedicine, but can be considered: the COM (2008) 689, the Directive nr. 2011/24/EU (article 3d), on the application of patient`s right, in cross-border healthcare; the Directive nr. 2000/31/EU, on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce), and the Directive nr. 95/46/EU on the protection of individuals with regard to the processing of personal data and on the free movement of such data — COM 2012/11.

The telemedicine finds limited application and should only occur in cases of real need such as: i)

[14] It is usual the existence of sites where people relate their health cases and doctors answer the questions. The Federal Medicine Council had already had the opportunity of pronouncing about, considering such practices illegal, in accordance with Consulting-lawsuit nr 4.722/2000 by CFM, NPC/CFM/Nº 38/2002.

[15] The doctos is forbidden to: Article 37. Prescribe treatment or other procedures without direct exam of the patient, except in urgency or emergency cases and impossibility of accomplishing it, making it prior to due it just after the impediment. Unique paragraph: The remote medical attendance, according to telemedicine or any other method, must be held under the regulation of Federal Medicine Council.

when the physician needs the opinion or advice of another colleague; ii) you have permission from the patient; iii) occur for any queries, and for that there might be a prior relationship between the doctor and the patient, or the doctor has an adequate, clear and justified knowledge about the presented issue, and iv) situations where the physician cannot be physically present in reasonable time and safe, or in emergency cases and urgent. The restriction is justified because the information are generally insufficient compromising the diagnosis and treatment.

Other health professionals, besides doctors, also make use of communication technology means and information such as computer mediations with Internet access, television sets, telephone sets, conjugated or hybrid, or any other mean of interaction as the psychologists, who perform remote services.

Recently, the Federal Psychology Council published the Resolution nr. 011/2012, which rules psychological services accomplished by remote communication technological means, the psychotherapeutic attendance, experimentally.

The Federal Nutrition Council (CFN) prohibited expressively in the Ethical Code (Resolution nr. 334/2004, chapter VII, and article 7th, XVII), the accomplishment of consults and nutrition diagnosis, and diet prescription through the Internet or any other communication means.

The remote medical consultations conducted by any means of communication, which includes the Internet, using e- mails, forms of interactivity to websites, blogs, according to the interpretation of Article 37 and 114, both from the Medical Ethics — CEM and article 1st, item IV of Decree — Law nr. 4,113 of February 14, 1942, are prohibited, except in some cases, and the telemedicine or other methods must be regulated by the Federal Council of Medicine.

The use of the Internet for these services require authorization by the patient, through informed consent (article 22 of the CEM) [16] for the electronic transmission of images and clinical data, which accompany the exams, fitting to professionals custody confidentiality, privacy and confidentiality of patient data, must have strict safety standards to ensure the patient's rights

And it can lead to joint and severe liability of the patient's medical expert who carried out the examination and issued the report.

The practice of telemedicine should occur safely, using appropriate technological infrastructure, following the rules of guardianship, handling, data transmission, directly related to the protection of the rights of the patient, answering the patient's doctor and others involved in solidarity.

III. Exams and medical records forwarded and circulated through the Internet

Information about patients' clinical data can move through the various internet forms, sometimes through access to medical records, sending medical examinations, such as images, X-ray, blood and urine exam results, to aware patients or other health professionals, either for storage of such information, among others.

[16] The doctos is forbidden to: Article 22. Not obtaining the patient or their legal representative informed consent after clarifying about the procedure to be done, except in case of imminent risk of death.

This practice is not forbidden, but it must be carried out with caution, in order to avoid the breach of secrecy and privacy of such information. For that, some rules must be followed as data guidance with high technical caution. Concerning the access to secret areas, which may contain personal data, it is important to use passwords, login, cryptographic mechanisms, electronic signature, service providers who strain the access by others, and in a third phase, the use of biometrical data.

With advances in information technology, new methods of data storage and transmission emerged, including patient data, medical records, allowing the latter to be drawn through electronic medical records.

In Brazil, the medical records are defined by the Resolution nr. 1.638/2002 as "a unique document formed by a set of information, recorded images and signs, coming from facts, happenings and situations about the patient health and the due assistance, of legal, secret and scientific nature, which may allow the communication among the members of the multiprofessional team involved and the continuity of the individual assistance."

The electronic medical records are ruled by Resolution nr. 1638/2002 by CFM and Resolution nr. 1.821/2007 by CFM, concerning the use of scanning and computerized systems for the storage and handling of documents from patient charts.

The data contained in the medical records are those belonging to the patient, who must have full access of the clinical data (article 88th by CEM [17]) as well as the rectification (article 5th, LXXII and Law nr. 9.507/97 — *habeas data* [18], articles 43th e 44th by CDC), being restricted forms of disclosure and access to others. And even if the records are in paper form or in electronic media are ensured concerning the confidentiality and patient privacy.

The patient has the right to their medical records are treated confidentially, with complete secrecy about their conditions, their personal data deemed sensitive, alternative treatment, which does not cease even if the fact is public knowledge or after his death.

Alongside this right to confidentiality, has the doctor and companies providing medical care, the duty of secrecy about the facts of which had science due to their professional activity, the personal data of the patient, the results of tests performed with therapeutic purpose, diagnostic or prognostic information in the medical record, file or medical record, the duty to refrain from abuses. All due to the fact that doctor-patient relationship is founded on trust, mutual respect, discretion and reserve.

Similarly, it is important to outstand that the patients who access their clinical records through the Internet, must be careful about the handling of data by non-authorized people.

[17] The doctos is forbidden to: Article 89. Release copies of medical records under their guard, except when authorized, by written, by the patient, in order to attend to judicial order or their own defence. Paragraph 1st: When legally requested, the medical records will be available to the doctor surveyor named by the judge. Paragraph 2nd When the register is presented in their own defence, the doctor may request that the professional secrecy be observed.

[18] The protection of the person facing the treatment of their informatisized personal data, as well stated by J. J. Gomes Canotilho and Vital Moreira when commenting the article 35th of Portuguese Republic Constitution, comprehends not only the individualization, fixing and data collection, but also their connection broadcasting, utilization and publication. Moreira, Vital; Canotilho, J.J. Gomes. *Constituição da República Portuguesa Anotada*: arts. 1º a 107º. V. 1, 4 ed. rev. Coimbra: Coimbra Editora, 2007, p. 550-558.

In Brazil, the Code of Medical Ethics (CEM) is expressed by requiring that professional secrecy is the medical record, being forbidden to reveal the fact that the doctor has knowledge in the exercise of their profession (articles 73-76), access to medical records by persons not required to confidentiality (article 85) especially in the case of insurance companies in the event of circumstances surrounding the death of patient under their care (article 77).

For these reasons, the medical professional is forbidden to release copies of records that are under their care, unless: i) authorized in writing by the patient or his legal representative; ii) to attend court order; iii) to his own defense; iv) the legal duty or cause; v) if the approval of the Regional Council of Medicine of jurisdiction. All in accordance with article 89 of CEM and Resolution nr. 1605/2002 of CFM.

The inobservance of the professional duty of secrecy is so important that is considered a crime of secrecy inviolability, according to the Brazilian Penal Code (CPB), article 154 (articles 153 and 325), except in the cases of Compulsory diseases, considered crime when not released (article 269 CPB, article 66 Act nr. 3.688/1944).

This right of protection of the medical data circulating in the web, derives from the principle of human dignity, the foundation of the Federative Republic of Brazil (article 1, III, of the Constitution), the protection of honor, image and privacy giving the patient the fundamental right to privacy, article 5, section X of the Federal Constitution, art. 21 of the Civil Code. And, worldwidely, it is assured by the Convention for Human Rights and Fundamental Liberty, the Charter of Fundamental Rights of European Union, the Convention of Human Rights and Biomedicine, the Directive nr. 95/46/EU, on the protection of individuals with regard to the processing of personal data and on the free movement of such data — COM 2012/11, as well as the Directive nr. 2002/58/EC of the European Parliament and of the Council of 12 July 2002, concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications).

Thus, must the stakeholders of this new doctor-patient relationship assure that the use of Internet for exams sending, medical prescriptions, access to electronic medical records occur in a safe way and with the patient`s informed consent under the penalty of exposing intimacy of the patient, affecting his privacy and violating the medical secrecy.

Conclusion

The Cybernetic Revolution in the health area, instantaneity of communication through the web made feasible a different interaction among people, which has been changing gradually the physical presence for the virtual. It reflects the social relationships, affecting even the doctor-patient relation, and the way they may be ruled, in order to better safeguard human person.

The use of Internet demand responses that the Civil Law and the legislative technique by themselves are not capable to regulate. The specificity of the matter overdoes the juridical knowledge, thus the need to search for some answers in several sciences, in specialized areas such as Medicine, Informatics and compared Law.

The medical services provided by the Internet amplifies the health knowledge, allowing professional improvements, development of new techniques, treatments, wider access to healing mechanisms and extending life. Furthermore, it reduces the geographical barriers, which eases the exchange of information among specialized professionals and increases patient awareness. In another hand, it may jeopardized the intimacy, the secrecy of sensitive data of patients, which circulate in the web without appropriate protection.

The web consumption relations have some peculiarities due to the lack of contact between the medical professional and the patient, making it difficult the investigation of aptness, product honesty, service provider and vice-versa. Moreover, the existence of great difficulty in controlling some information in the computers, once it increases the possibility of inappropriate information of patient clinical data, there is the possibility of the weakest segment being manipulated by demining interests, privileged groups, which imposes more protection to consumer user.

In order to avoid damages, irreparable to web`s patient and civil liability, it is necessary a greater care from the part of health care professionals and health institutions, the providers, who must guarantee: i) the veracity of the vehiculated information, data safety; ii) transparency; iii) reliability; iv) good faith; v) loyalty; vi) obtainment of free consent from patients, which translates their right to self-determination, and legitimates the act; vii) protection of data using certified sites, and viii) use of password control mechanisms and access.

The main task of the law applicators, facing this legislative lack, is to extract from the axiological constitution framework, from deontological rules and International Conventions and Treaties, the protection in physical and electronic clinical data of the patient`s, preserving their right of free development and dignity.

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MEDICAL MALPRACTICES AND THE COMPLEXITY OF HEALTHCARE LITIGATION: IS THERE A CASE FOR NO-FAULT COMPENSATION REGIME IN ENGLAND AND WALES?

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Abstract: *Although Health Care Law (HCL) [2] has attained the status of a discrete field of law during the past four decades, yet malpractice litigation is heavily based upon the traditional requirements of tort law which is largely entangled with its complexities in establishing medical liability. This conundrum is exacerbated by the perceived excessive deference to medical paternalism in English and Welsh courts. Whether or not medical malpractice litigation should be exempted from strictures of the traditional paradigm of the common law in establishing liability for negligence remains contested. In this paper, I argue that due to the practical difficulties entailed in pursuing healthcare malpractice grievances via the courts system particularly the uphill task of proving clinical negligence, lawmakers should revisit the possibility of adopting a no-fault compensation scheme for all cases that can properly be categorized as medical malpractice.*

1. Introduction

There is no doubt that HCL has come of age as a field of law and a discrete academic discipline in England and Wales with readily identifiable indicators since 1980. Increasingly, patients aggrieved by their clinical experiences have sought redress in courts. Doctors have also resorted to the courts for declarations as to the legality of proposed procedures that are ethically sensitive. The burgeoning litigation in healthcare has not only generated an avalanche of case law for academic study, it has also exposed the inadequacy of the common law in resolving the specific bioethical and legal challenges raised by healthcare. Specific legislation was enacted for the first time to address issues raised by medical advances. Even in areas where no direct solution could be provided for in the statutes due to a lack of compromise in amorally pluralistic society, bodies such as the HEFA have been established by the law to provide a forum for debating contentious ethical issues and guidance to medical professionals [3].

Despite the emergence of a discrete body of HCL in England and Wales, a pursuit of compensation for injuries arising from medical malpractices is still heavily steeped in the traditional tort law requirements; particularly negligence [4]. This makes the burden of a victim of a medical injury always a

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[2] I use health care law to include medical law.

[3] J. Montgomery, 'Rights, Restraints and Pragmatism: The Human Fertilisation and Embryology Act 1990' (1991) 54 *Modern Law Review* 524, 525.

[4] In this paper medical malpractice does not necessarily include professional conduct or ethics.

huge one. The law readily recognises the existence of a duty of care imposed on the doctor towards his or her patient. However, proving the breach of that duty of care is a herculean task which claimants do not often succeed in proving. To sustain a negligence cause of action, the claimant must be able to prove that the injury he or she suffered under a medical procedure was actually caused by the doctor in failing to meet the standard of care expected of him or her. The legal test used in assessing the conduct of the defendant doctor is what has become popularly known as the Bolam test; propounded originally in 1957 and has been reinterpreted and elaborated upon in subsequent cases [5]. The Bolam test simply requires that the claimant must be able to prove that the conduct of the defendant in causing the medical injury must have fallen below what his or her colleague medical professionals would have done in a similar situation [6]. The Bolam test and its application in plethora of clinical negligence cases have generated various debates in the literature [7]. Thus 'for defendants in medical malpractice claims, and for health professionals generally, Bolam may be viewed as no more than simple justice requiring that they, like other professionals, be judged by their peers [8].' Many scholars and bodies campaigning for victims of medical injuries look at the Bolam test very differently [9]. In their view, Bolam has been used by the courts to abdicate responsibility for defining and enforcing patients' rights [10]. The application of the Bolam test by the courts increasingly suggest that there is excessive judicial deference towards the medical profession in determining whether an injury sustained during medical procedure can be blamed on the doctor so as to entitle the affected patient to compensation. In this paper I explore first, the practical difficulties inherent in the fault based tort system; next the need to shift completely towards non-fault based system and finally assess the adequacy of the attempts made towards this shift and lessons that can be drawn from other jurisdiction.

2. The conundrum of establishing medical liability in a fault based tort compensation system

The debate concerning the tort system as a means for providing compensation for personal injuries whether from medical error or from other human activities is not new in academic and policymakers circles [11]. Nevertheless, it has become necessary to explore the issue again due to the latest rejection by England and Wales of a complete no-fault compensation system for medical injuries and also the latest efforts by Scotland to consider its

[5] *Bolam v Friern HMC* [1957] 1 WLR 582; *Rance v Mid-Downs AHA* [1991] 1 All ER 801.

[6] *Bolam v Friern HMC* [1957] 1 WLR 582.

[7] M. Brazier, The case for a no-fault compensation scheme for medical accidents in S.A.M. McLean (ed) *Compensation for Damage: An International Perspective. (*Aldershot: Dartmouth, 1993) pp. 51-74; W.J. Gaine, 'No-fault compensation systems', (2003) *British Medical Journal,* 326, 997-98; C. Hodges, 'Compensation for injury — a reappraisal: discussion paper', (1992) *Journal of the Royal Society of Medicine,* 85, 92-95.

[8] M. Brazier and J. Miola, 'Bye-bye Bolam: a medical litigation revolution?' 8 Medical law review 85.

[9] Ibid.

[10] Ibid.

[11] Ken Oliphant, 'Defining Medical Misadventure Lessons from New Zealand' 4 Med L Rev 1; Marie Bismark and Ron Paterson, 'No-fault compensation in New Zealand: harmonizing injury compensation, provider accountability, and patient safety' 25 Health Affairs 278.

introduction. It is therefore imperative that a reappraisal of the difficulties inherent in the present fault based tort system, which makes it ineffective mechanism for providing medical injuries compensation, is undertaken. This reappraisal is one of the burdens of this paper. The fundamental goal of fault liability 'is to compensate victims of accidental loss shown have been caused by the defendant's negligence [12].' The effect of fault liability is that it discriminates between victims of accidental injury 'not according to their deserts but according to the culpability of the defendant' so that 'the legal fault does not entirely coincide with the moral fault [13].' A patient injured during medical procedure has two potential causes of action against the healthcare professional or his hospital: an action in trespass to the person or battery and an action in the tort of negligence.

Battery arises when a health professional 'carries out any medical procedure which requires bodily contact with the patient and it is done without the patient's consent or without lawful justification [14].' Seabourne has noted that modern medical battery suits may fall into the following different categories:

(a) Surgical operations performed without consent-

  (i) involving removal of part of the body,
  (ii) involving introduction of a substance to the body
  (iii) resting purely on the temporary disruption of bodily integrity

(b) Surgical operations performed without sufficient consent -

  (i) where the surgeon goes further than is warranted by the consent given by the patient, doing something in addition to that which was agreed,
  (ii) where the surgeon operates on the wrong part of the body,
  (iii) where the surgeon performing the operation is not the surgeon to whom the patient gave his consent to be operate upon.

(c) Other medical intervention which involves touching -

  (i) physical examination of a patient by a doctor,
  (ii) treatment which may lead to touching of the patient by another.

(d) More abstract violations of "rights" of others [15].

Despite the variety of potential battery suits, the courts are reluctant to entertain battery actions against doctors except in clear cases. Indeed, the law of battery is applicable in relation to consent to treatment but in practice its deployment as a litigation pad is limited. To avoid liability in battery in *Chatterson v Gerson* [16] Bristow J held that

[12] J. Healy, *Medical Negligence: Common Law Perspectives* (London: Sweet & Maxwell, 1999), p. 231.

[13] James and Dickinson, *Accident Proneness and Accident Law*, (1950) 63 Harvard Law Review, 769, 778.

[14] A. Grubb, 'A Survey of Medical Malpractice Law in England: Crisis? What Crisis? (1985) *Journal of Contemporary Health Law & Policy*, 75, 80.

[15] J. V. McHale, 'Medical Malpractice in England — Current Trends' 2003 *European Journal of Health Law,* 135, 138.

[16] [1981] 1 ALL ER 257

> "In my judgment once the patient is informed in broad terms of the nature of the procedure which is intended, and gives her consent, that consent is real, and the cause of the action on which to base a claim for failure to go into risks and implications is negligence, not trespass."

The willingness to limit liability in battery can be seen in terms of judicial policy limiting the expansion of battery due to the manner in which the civil law action is related to its criminal law counterparts of assault and battery.Three possible reasons may be assigned to justify the apparently unsupportive attitude of the courts towards a resort to battery action by patients. First, battery is an intentional tort usually reserved for hostile action but doctor-patient relationship is not primarily intended to result in hostile action against the patient. Secondly, battery action makes the quest by aggrieved patient for compensation relatively easier and straightforward since the burden of proof immediately shifts to the healthcare professional to prove consent, once the plaintiff has succeeded in showing touching by the doctor as a result of a medical procedure [17]. As it will be seen soon, in negligence action the burden never shifts from the patient. Another justification for discouraging the use of battery action is that there is no need to establish causation unlike a negligence suit [18]. In view of the posture of the courts towards battery action, majority of patients seeking compensation for medical injuries via court system must mount a negligence suit.

A patient bringing a negligence action must prove three elements in order to succeed. First of all, the patient has to establish that the doctor owed him a duty of car. Indeed, Lord Wilberforce underscored this more poignantly when he remarked:

> [f]irst, it is necessary, in order to establish liability of, and to obtain an award of compensation against, a doctor or a hospital that there has been negligence in law. There is in this field no liability without proof of fault.' [19]

Secondly, that a breach of the duty has occurred and thirdly that a breach of that duty caused him damage in the form of personal injury [20]. The existence of a duty of care in the context of the health care or the clinical doctor-patient relationship is generally presumed or taken for granted [21]. Thus, the duty of a doctor towards the patient will be to exercise reasonable care and skill in diagnosis, advice and treatment. Due to the non-contentious nature of the duty of care of the doctor, it is not necessary for the purpose of the present paper to explore it further [22].

Having established the existence of duty of care, a claimant in medical negligence action must prove that the doctor breach that duty of care. This is also dependent upon having a standard of care against

[17] A. Grubb, 'A Survey of Medical Malpractice Law in England: Crisis? What Crisis? (1985) *Journal of Contemporary Health Law & Policy*, 75, 83.

[18] Ibid.

[19] *Whitehouse v. Jordan* [1981] 1 All ER 267 at 270

[20] M. Brazier, *Medicine, Patients and the Law* (London: Penguin, 1987), p. 69.

[21] E. Jackson, *Medical Law — Text, Cases and Materials* (Oxford: Oxford University Press, 2013), p. 106.

[22] For broader interest, see J. Montgomery *Health Care Law (*2nd ed Oxford: OUP 2002) chapters 7 and 8 and J.K. Mason, R.A. McCall Smith and G. Laurie, *Law and Medical Ethics* (6th edn, London: Butterworths (2002) chapter 9, **1.** Kennedy and A. Grubb Medical Law (London: Butterworths chapter 4.

the court can measure the alleged negligent conduct of the doctor. In a general tort of negligence, it is a trite knowledge that the courts approach this exercise by using the notional reasonable [23] man's standard [24]. However, applying this approach to medical negligence cases is problematic since reasonable doctors within the same area of expertise may disagree about how best to treat an individual patient [25]. The inevitability of differences in opinion between equally competent medical professionals necessitate that the court should have a way of preferring one to the other. Nevertheless, in 1957 the leading case of *Bolam v Friern Hospital Management Committee* propounded a test that a doctor will not be held responsible if his practice conformed to that of a responsible body of medical practitioners [26]. Mr Justice McNair, in his classic direction to the jury, said:

> [a doctor] is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a responsible body of medical men skilled in that particular art …Putting it the other way round, a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion who would take a contrary view [27].

The locus classicus status of *Bolam* regarding the standard of care in medical negligence case was not realised until over two decades later in the House of Lords decision in *Whitehouse v. Jordan* [28]. The claimant was born with severe brain damage allegedly caused by the negligence of the defendant, the senior registrar in charge of the delivery. The mother's pregnancy had been difficult and she had been in labour for a about 22 hours when the defendant took charge of the delivery. He sought to perform a "trial of forceps delivery"- a delicate and potentially risky procedure performed with a view to establishing whether delivery per vaginam (rather than by Caesarian section) is viable. The defendant pulled on the baby six times with the forceps but when there was no movement on the fifth and sixth pulls he decided to abandon that procedure in favour of a caesarian section. Shortly after the birth the claimant was found to be suffering from severe brain damage, which the trial judge found as having been sustained in the course of the trial of forceps delivery. The trial judge took the view that the decision to perform a trial of forceps delivery, rather than to proceed immediately to caesarian section, was a reasonable one in the circumstances. However, he concluded that the defendant had been negligent in pulling too long and too hard with the forceps so that the claimant's head had become wedged or stuck thereby leading to asphyxia. The plaintiff was eventually awarded damages of £100,000. The Court of Appeal reversed the decision rejecting any negligence on the part of the defendant [29].

[23] The "reasonable man" is often described as "the man on the Clapham omnibus", Hall v. Brook lands Auto-Racing Club, [1933] 1 K.B. 205, 224.

[24] For detail discussion of the law see Markesinis, BS and Deakin,SF , (4th ed) Tort Law (Oxford, Clarendon Press:1998); Rogers WVH, Winfield and Jolowicz On Tort (18th ed, London, Sweet and Maxwell:2010); I. M. Kennedy, 'The Fiduciary Relationship-Doctors and Patients' in P. Birks (ed.), Wrongs and Remedies in the Twenty-First Century (Clarendon Press 1996) at 116

[25] I.M. Kennedy, 'The Fiduciary Relationship-Doctors and Patients' in P. Birks (ed.), Wrongs and Remedies in the Twenty-First Century (Clarendon Press 1996) at p. 113.

[26] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582.

[27] Ibid.

[28] [1981] 1 All ER 267.

[29] [1980] 1 All ER 650.

Further appeal to the House of Lords was dismissed. The Lords found that the doctor's standard of care did not fall below that of a reasonable doctor in the circumstances and so the baby was awarded no compensation. The House of Lords per the Judgment of Edmund-Davies approved the Bolam test which was acknowledged as being seminal on the subject [30]. The decision in Jordan was heavily detrimental to victims of medical injury especially those who suffered birth or delivery injuries as the boy in Jordan. An aspect of the decision in Jordan which is pretty disturbing is the deliberate judicial policy to discourage medical injuries litigants from pursuing their claims. For example Denning J in the Court of Appeal stated:

> Every one of us every day gives a judgment which is afterwards found to be wrong. It may be an error of judgment but it is not negligent. So also with a barrister who advises that there is a good cause of action and it afterwards fails. Is it to be said on that account that he was negligent? Likewise with medical men. If they are to be found liable whenever they do not effect a cure, or whenever anything untoward happens, it would do a great disservice to the profession itself. Not only to the profession but to society at large. Take heed of what has happened in the United States. ‹Medical malpractice› cases there are very worrying, especially as they are tried by juries who have sympathy for the patient and none for the doctor, who is insured. The damages are colossal. The doctors insure but the premiums become very high: and these have to be passed on in fees to the patients. Experienced practitioners are known to have refused to treat patients for fear of being accused of negligence. Young men are even deterred from entering the profession because of the risks involved. In the interests of all, we must avoid such consequences in England. Not only must we avoid excessive damages. We must say, and say firmly, that, in a professional man, an error of judgment is not negligent [31].

Although the House of Lords rejected Denning LJ's dictum to the effect that an error of judgment by a medical professional cannot be negligence, it is significant to note that the other concerns he expressed were not contradicted by the Lords. Indeed, in barely four years after Whitehouse, the Bolam test was applied even in determining breach of duty in information disclosure. Thus in *Sidaway*, a case concerning the level of information that should have been disclosed to a patient, Lord Bridge in the House of Lords stated that: "Whether non-disclosure in a particular case should be condemned as a breach of the doctor's duty of care is an issue to be decided primarily on the basis of expert medical evidence, applying the Bolam test [32]."

However, a little over two decades of virtually unquestioned authority of the Bolam test as reaffirmed in *Sidaway*, the House of Lords in *Bolitho v City of Hackney Health Authority* [33] made certain dicta which was interpreted at the time by commentators to suggest that there is a manifestation of greater judicial willingness to subject the opinion expressed by the body of professional practice to rigorous scrutiny like how the court ordinarily evaluate evidence in adjudication. The factual matrix was basically that a two year old child was being treated for breathing difficulties and suffered two instances

[30] *Whitehouse v. Jordan* [1981] 1 All ER 267 at 261.

[31] *Whitehouse v Jordan* and another — [1980] 1 All ER 650 at 658.

[32] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] 1 All ER 643.

[33] *Bolitho v City and Hackney Health Authority* [1997] 4 All ER 771.

of acute shortness of breath and became white on one day [34]. On both occasions the ward sister on duty sent for a doctor, but no doctor attended [35]. Later that day he suffered respiratory and cardiac arrest and while he was resuscitated he suffered severe brain damage as a result of the cardiac arrest. The defendant health authority accepted that the doctor on duty who failed to attend to the patient had acted in breach of her duty of care to him but contended that the cardiac arrest would not have been avoided if the doctor or some other suitable deputy had attended earlier than 2.30 pm. It was accepted at the trial that intubation so as to provide an airway would have ensured that respiratory failure did not lead to cardiac arrest and that such intubation would have had to have been carried out before the final episode. The judge found that the views of the claimant's expert witness and that of expert witness for the defendants, though diametrically opposed, both represented a responsible body of professional opinion espoused by distinguished and truthful experts. He therefore held that the doctor, if she had attended and not intubated, would have come up to a proper level of skill and competence according to the standard represented by views of the defendants' expert witness and that it had not been proved that the admitted breach of duty by the defendants had caused the injury which occurred to the patient [36]. The Court of Appeal dismissed an appeal by the deceased patient's mother and she appealed to the House of Lords. The House of Lords were concerned to address the issues as to whether the Bolam test was applicable in relation to causation. Ordinarily speaking, the causation test would not have been linked to *Bolam* but the problem in *Bolitho* related to an omission to act. Even if the doctor had attended the result would not have been intubation. Thus in such a situation the Bolam test was relevant to ascertain whether the doctor on attending should have made the decision to intubate this child [37].

The second issue before the court was the extent to which they could scrutinise the medical evidence provided. The House of Lords held that the courts did have the power to scrutinise such medical evidence for its logical consistency. Lord Browne Wilkinson stated that

> "In particular where there are questions of assessment of the relative risks and benefits of adopting a particular medical practice, a reasonable view necessarily presupposes that the relative risks and benefits have been weighed by the experts in forming their opinions. But if in a rare case, it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible. I emphasis that in my view it will be very seldom right for a judge to reach the conclusion that views genuinely held by a competent medical expert are unreasonable [38]."

The chief criticism of the *Bolam* test is that it fails to distinguish between "what is done" and

[34] Ibid, 772.
[35] Ibid.
[36] Ibid.
[37] J.V. McHale, 'Medical Malpractice in England — Current Trends' 2003 *European Journal of Health Law,* 135, 138.
[38] *Bolitho v City and Hackney Health Authority* [1997] 4 All ER 771, 780

"what ought to be done [39]." Thus, the existence or absence of a negligent action is to be judged against a standard of what ought to be done. The obvious inference here is that something which is done, even if by most people, could still be negligent if it falls below the standard of what ought to be done. Practically, then this allows medical practitioners to set for themselves the legal standard by eliciting the support of a responsible body of medical men. The multi-dollar question is whether this should be allowed in medicine when this is clearly not the case in other areas of professional liability, where the expected standard of the defendant is a matter that is set by the court [40]? The exploration of this particular question is beyond the present purpose of this paper as others have spilt much ink on it [41]. Nevertheless it is worth noting that Bolitho provoked profound remarks from some commentators at the time. For example, Jones stated that

> "The importance of Bolitho lies in the now explicit requirement to undertake a logical analysis of that evidence before characterising it as responsible, rather than relying upon the eminence or the number of the experts expressing the particular view. But the qualifying comments of Lord Browne-Wilkinson and the actual decision on the facts of Bolitho would depend upon how the lower courts and in particular the trial judge, responded to the shift in emphasis that it appeared to herald [42]."

Similarly, Brazier and Miola contended that the true effect of *Bolitho* was to restore English law to the original limits of the judgment of McNair J in *Bolam*. They noted that:

> "While the medical experts are to be required, in rare cases to justify their opinions on logical grounds, there still appears to be a prima facie presumption that non-doctors will not be able fully to comprehend the evidence. This leads inexorably to a conclusion that the evidence cannot after all be critically evaluated by a judge [43]."

Thus, after Bolitho the position of the law as far as standard of care is concerned has become what Jackson called "*Bolam+Bolitho*." [44] This is a two staged exercise. The first leg requires that the court must ask whether the doctor acted in accordance with responsible medical opinion- which might be established using expert medical testimony [45]. The failure of the doctor to follow such a body of opinion is indicative of negligence under Bolam approach. The second leg, which is another opportunity for the claimant if the doctor was not negligent under Bolam, requires that the claimant establishes that the body of medical opinion complied with by the doctor, is not capable of withstanding logical analysis.

The search for better deal for patient claimants in medical malpractice litigation made a huge leap forward in the *Chester v Ashfar* [46]. A patient claim-

[39] A. Samanta, J. Samanta, 'Legal standard of care: a shift from the traditional Bolam test' (2003) 3 *Clinical Medicine*, 443, 444.

[40] Ibid.

[41] For example see, M. Brazier, J. Miola,' Bye-bye Bolam: a medical litigation revolution?' (2000) 8 *Medical Law Review* 85; 'J. Harrington Understanding Medicine and the Common Law- Art or Science? ' (2001) 9 Health Law Journal, 129.

[42] M. Jones 'The illogical expert' (1999) *Professional Negligence* 117.

[43] M. Brazier and J. Miola "Bye Bye Bolam: A Medical Negligence Revolution?" (2000) *Medical Law Review* 85, 100.

[44] E. Jackson, Medical Law: Text, Cases and Materials (Oxford: Oxford University Press, 2013), p.116.

[45] Ibid.

[46] [2004] UKHL 41.

ant, Ms Carole Chester was left partially paralysed after surgery for lumbar disc protrusion. The defendant, Dr Afshar had failed to warn Ms Chester that this was a foreseeable (1–2%) but unavoidable risk of the surgery. The House of Lords concluded that, though the failure to warn was not a direct cause of injury, it did result in negligence on grounds of policy and corrective justice. In particular, Lord Bingham stated:

> A surgeon owes a general duty to a patient to warn him or her in general terms of possible serious risks involved in the procedure. The only qualification is that there may be wholly exceptional cases where objectively in the best interests of the patient the surgeon may be excused from giving a warning…In modern law medical paternalism no longer rules and a patient has a prima facie right to be informed by a surgeon of a small, but well-established, risk of serious injury as a result of surgery [(47)].

Significantly, the House of Lords despite conceding that the traditional but for test of factual causation could not be established by the claimant, the case was one in which the overriding importance of patient's autonomy and dignity made it imperative for the court to attribute the patient's injury to failure of the defendant doctor to warn the patient about the slight risk pre-operatively. Indeed, their Lordships agreed with the counsel for the patient "that policy and corrective justice pull powerfully in favour of vindicating the patient's right to know' [(48)]

The burden of patient claimants remains unmitigated until and unless the courts fully embrace the reasoning in *Chester v Ashfar* as the paradigm for proving causation in medical malpractice suit. Regrettably, this total embrace has not yet occurred and therefore it is apposite to explore if panacea to the extant regime of malpractice litigation lies in no fault model. It is to this exploration that I now turn.

3. Is there a need for shifting towards a no--fault based system of compensating medical injuries?

The complexity and other layers of conundrum inherent in the traditional clinical negligence action make it imperative for a model for compensation other than fault based to be explored. Many different points can be canvassed to buttress the case for a transition to a no-fault based system. In the first place, if it is accepted that patients as vulnerable stakeholders in healthcare have rights and the nature of the clinical interaction is such that establishing the causal link between grievance from their clinical experience with the conduct of doctors is most of the times difficult, then the need to have remediation system that obviates the complexity is apposite. Indeed, *ubi jus ibi remedium* [where there is a right there is a remedy]. The seeming aberration of the law on causation in Chester v Afshar appears to have been tacitly based upon this. Thus, in so far as the majority of the court recognised that the patient had legitimate interest in forewarned about 1-2% risk, it was necessary to vindicate that right even where the strictures of the traditional causation could not be satisfied.

Secondly, a no-fault scheme can promote a better, as well as less defensive, relationships between

[(47)] [2004] UKHL 41, para. 16.
[(48)] Ibid, para. 22.

patients and health practitioners when medical injury has occurred. This will naturally enhance the scope for collection of data on, as well as learning from medical error with a view to enhancing patient safety. This virtue of a no fault based system was re-echoed by Kennedy's Commission when it recommended the abolition of the traditional clinical negligence system. The report stated:

> Ultimately, we take the view that it will not be possible to achieve an environment of full, open reporting within the NHS when, outside it, there exists a litigation system the incentives of which press in the opposite direction. We believe that the way forward lies in the abolition of clinical negligence litigation, taking clinical error out of the courts and the tort system. It should be replaced by effective systems for identifying, analysing, learning from and preventing errors along with all other sentinel events. There must also be a new approach to compensating those patients harmed through such events. The abolition of recourse to clinical negligence litigation would be a major step in changing the climate and the incentive for reporting when things go wrong and, we believe, encourage the openness essential for improving safety [49].

Undoubtedly, a remediation system for medical injuries not predicated upon fault will facilitate a better and a less defensive, relationships between patients and health practitioners when medical injury has occurred. A related dividend is that such a non-fault based system will significantly ease pressure on health practitioners with regard to escalating insurance premiums, the availability of liability and the threat of litigation. This positive aspect of a no fault regime is even more enhanced as it also results in the either a reduction or elimination of the right to take legal action in the courts for medical injury [50]. This ultimately lessens the cost and administrative burden on the courts and interested parties, as well as reducing distress and tension between injured patients and health practitioners/health institutions.

Thirdly, in a no fault regime, there will be an expanded eligibility criteria for cover that facilitates greater access to justice for patients who suffered medical injury than would be the case in relation to clinical negligence claims brought under tort-based systems.[51] Injured patients from clinical encounter that would have gone without compensation not only due to inability to succeed in overcoming the complexity of proving breach of duty of care and causation but also impeded by lack of financial ability can easily access remedy. A corollary of this is greater efficiency in terms of both time and costs than would be the case in relation to the management of clinical negligence claims brought under tort-based systems. Fourthly, a no fault system ensures that rehabilitation can be sought quite early without the need of having to wait until legal action in court is disposed of. This is particularly important for serious medical injuries that need urgent treatment in order to avert exacerbation.

Despite the obvious attractions of a no fault compensation scheme for medical injuries, there are

[49] *Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995* (Cm 5297, 2001) available at http://webarchive.nationalarchives.gov.uk/20090811143745/http://www.bristol-inquiry.org.uk/final_report/index.htm (accessed: 15/02/2014)

[50] No Fault Compensation Schemes for Medical Injury- A Review, http://www.scotland.gov.uk/Resource/0039/00394407.pdf (accessed: 15/02/2014)

[51] Ibid.

certain challenges associated with it. To begin with, there is the issue of lack of affordability, particularly in the context of large national populations and in England, the government since 1970s have consistently rejected the adoption of a no-fault based scheme. It is my submission that the issue of lack of affordability by the state should be separated from embracing the no fault model as better and fairer system for redressing medical injuries. Once the virtue of a no-fault model has been accepted in principle, a broad based dialogue in the form of public consultation could be undertaken to explore ways of operationalising the no fault model within the constraint of available limited resources.

Another criticism often levelled against no fault compensation regime is that the removal of the threat of litigation which provides an incentive for health practitioners and health institutions to avoid unsafe practices in relation to medical treatment provided to patients [(52)]. A related demerit is that it fails to promote institutional and professional accountability particularly in relation to preventable or avoidable medical injury. It is submitted that this objection is equally not compelling sufficiently to deny society of the numerous blessings of a no-fault compensation model in so far as a culture of openness and transparency is established in the healthcare system for candid confession and admission of errors within a framework for lessons learning for greater safety in the future.

4. How adequate are the recent efforts to improve medical injuries compensation claims?

Since the latter part of the 20th century, there has been a tacit recognition by the British Government that the no fault compensation scheme is not appropriate and fair mechanism for remedying medical injuries. Consequently, there have been various efforts to introduce reforms that will ameliorate the predicament of patients that have suffered medical injuries. It is submitted that the efforts towards reforms have not gone deep enough as there is still no no-fault model or its equivalent in place that generate the advantages associated with such schemes, as was explored above. In order to demonstrate the plausibility of this submission, I proceed to explore and assess efforts made since 2000 to revamp the medical compensation scheme.

To begin with, there have been measures to simply improve the fault based system for injured patients. In 1995, for example, the National Health Service Litigation Authority (NHSLA) was set up with the view of encouraging earlier admission of liability, and the provision of explanations and apologies. This initiative yielded some positive dividends. It has been noted that it led to significant reductions in the time taken to settle claims by injured patients. The NHS has reported that new cases now take an average of one and half years to settle compared to the situation before 2000 when it took an average of five and half years to settle such cases [(53)]. Despite the benefits of the NHLSA to the

[(52)] http://www.scotland.gov.uk/Resource/0039/00394407.pdf (accessed: 15/02/2014)

[(53)] NHSLA Annual Report 2011-12, available at www.nhsla.com (accessed: 1/02/2014)

government, it is still not a panacea to the nightmare of injured patients that may not be lucky to have their claims conceded by the Authority. It can reasonably be conjectured that since the NHSLA is more focussed on making savings for the NHS, it is more likely to concede only obvious cases in which their lawyers are convinced that the NHS does not have good chance in putting up a successful defence. Thus, patients whose claims have been rejected will need to face the uphill task of proving breach and causation through the prism of Bolam+ Bolitho test and perhaps, if the patient is fortunate to put the courts in the mood of overriding conventional principles for the sake of policy and corrective justice as in *Chester v Ashfar*, then so better for the patient.

Another equally discernible effort made by the government towards rectification of bottlenecks in the litigation system for patient claimants is the Lord Woolf's report *Access to Justice*. In his comprehensive investigation into the operation of the system of civil justice, Lord Woolf singled out clinical negligence as an area for special consideration and his rationale was that it was in respect of clinical negligence claims that civil justice was "failing most conspicuously [(54)]." One prominent factor explaining the dissatisfaction of the then extant system was an unacceptable delay in the resolution of cases and a success rate which was comparatively lower than that in other personal injury litigation. Consequently under the Lord Woolf's reforms, parties to medical malpractices suit have a built in incentives to quickly settle the action. It is a requirement that patients initiate the process by sending letters of claim, which identify the alleged negligence, and the injuries and losses suffered as a result. The defendant (usually the NHS or sometimes other private defendant) is required to respond to the patient's letter of claim within three months. This response may either be admission or denial as well as specific answers to the allegations made by the patient. In situations where a case does go to court, the court is given a more proactive role during pre-trial sessions to inquire from the parties what exactly they will mutually invite the judge to decide. Undoubtedly, this is an improvement over the old clinical negligence litigation system. Nevertheless, it is submitted that the complexity inherent in the malpractice litigation has not disappeared in so far as the patient claimant will still need to prove breach and causation through the lenses of Bolam/ Bolitho.

Moreover, in 2003, the Chief Medical Officer (CMO) for England published his recommendations for clinical negligence reform in the *Making Amends* report [(55)]. In the report, the CMO considered the option of establishing a comprehensive no-fault compensation scheme in England. This option was ultimately rejected primarily on four main grounds: one, a proper no-fault system would be significantly more expensive than the current approach; two, payments to patients would have to be substantially lower than at present to keep costs within manageable boundaries; three, problems in differentiating

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[(54)] *Access to Justice: Final Report to the Lord Chancellor on the Civil Justice System in England and Wales* (1996), para.15.2.; Also see K. Mason, G. Laurie, *Mason and McCall Smith's Law and Medical Ethics* (Oxford: Oxford University Press, 2013)

[(55)] *Making Amends* report (CMO 2003).

between harm caused by sub-standard care and that occasioned by natural progression of disease would be considerable as has been witnessed in New Zealand and finally, such a scheme does not address broader systemic problems, such as learning from sub-standard practices [56]. Nevertheless, recommendations were made for an NHS redress scheme to be established which would include: (1) care and compensation in the case of birth- related neurological injury (inspired and adapted from the schemes operating in Virginia and Florida); a redress package (including financial compensation) for low- value claims [57]. Mason and Laurie have rightly criticised the recommendation of the CMO as just same old argument about cost and also for its failure to address the conundrum of causation [58].

Furthermore, as a compromise between discontinuation of the traditional clinical negligence litigation system and refusal to embrace a no-fault compensation regime, the *Compensation Act 2006* and the *National Health Service Redress Act, 2006* were passed, although it is yet to be implemented. These two statutes are worth exploring as they can illuminate the extent to which statutory reforms in response to the CMO's report provide panacea to the complexity inherent in medical malpractice litigation. To start with the *Compensation Act 2006* was introduced in response to concerns about a growing compensation culture [59] but conversely to ensure that the public received dependable service from claims management companies. In introducing the Bill, Baroness Ashton said that it was intended "to tackle perceptions that can lead to a disproportionate fear of litigation and risk averse behaviour; to find ways to discourage and resist bad claims; and to improve the system for those with a valid claim for compensation [60]." Consequently, the Act makes it clear that an apology, in itself, will not be taken as an admission of negligence or liability. In the same 2006 the government subsequently adopted the concept of a redress scheme for low value claims (£20,000 or less) the parameters of which were set out in the *NHS Redress Act 2006*. Despite calls for the adoption of alternative tests for eligibility (e.g., avoidability), the government preferred to retain established tort law principles as the basis for determining eligibility [61]. It did not adopt the *Making Amends* recommendation regarding the establishment of a no-fault scheme for birth-related neurological injury. To date, the redress scheme has not been implemented in England, although it seems set to be introduced in Wales in the near future.

In spite of its seeming appeal, one argument against the scheme if implemented is that it is unlikely to bring about greater access to justice for

[56] Ibid.

[57] CMO 2003: 119-21

[58] K. Mason, G. Laurie, *Mason and McCall Smith's Law and Medical Ethics* (Oxford: Oxford University Press, 2013), p. 135.

[59] According to V. Harpwood, "It seems that there is no generally accepted definition of the term 'compensation culture'. In terms of popular understanding, it can be seen as a state in a society in which it is acceptable for anyone who has suffered an injury to seek compensation by means of litigation from some person or organisation connected with the injury, even if the injury is trivial or has a tenuous connection with the alleged wrong." See V. Harpwood, *Medicine, Malpractice and Misapprehension* (Oxford: Routledge-Cavendish, 2007),p.83

[60] http://webarchive.nationalarchives.gov.uk/+/http://www.dca.gov.uk/legist/compensation_wms_lords.pdf (15/2/2014)

[61] A, Farrel, S. Devaney et al *No Fault Compensation Schemes for Medical Injury- A Review.* Available at http://www.scotland.gov.uk/Resource/0039/00394407.pdf (accessed 28/1/2014)

injured patients; "it lacks sufficient independence from the NHS in terms of investigating what went wrong; and it fails to provide for accountability on the part of healthcare professionals. In the circumstances, it is unlikely to address issues of longstanding concern to injured patients and would therefore be unlikely to inspire patient confidence in the scheme [(62)]."

Conclusion

The exploration undertaken in this paper has canvassed many points that may contribute to the broader context for re-opening debate on the recurrent issue of no fault compensation scheme for medical injuries in England and Wales. Undoubtedly, the emergence and maturation of healthcare law as a discrete legal field during the past three decades have projected patient empowerment as the fulcrum around which healthcare discourse revolves. Nevertheless, compensation for medical injuries is a conspicuous site in this area of the law where there remains significant dissatisfaction from patient and the general public [(63)]. Patients that are victims of medical injuries still have to prove their claim on basis of legal standards of care , *Bolam*, that have increasingly been demonstrated by outcome of cases to be unfair towards patients particularly due to desire by health professionals who are being challenged to resist allegation of fault and preserve professional image. The worst of all the complexities saddled with a claimant for compensation for medical injuries through litigation route is the virtually impossible task of proving causation. The modest effort made by the courts to ameliorate the predicament of patient claimant in the *Chester v Afshar* by bending traditional principles in order to advance patient's rights and corrective justice did not have snowball effect in clinical negligence litigation as Courts still follow Bolam with the occasional gloss from *Bolitho*.

Some efforts have been made to improve medical compensation claims for patients. Lord Woolf reforms promoted mediation but the problem of proving causation on basis of traditional tort law still lingered on especially in absence of agreement between the parties. The recent introduction of out of court resolution of compensation claim not exceeding a stated amount through *NHS Redress Act 2006* and *Compensation Act 2006* are laudable but not ultimate panacea to the complexity of medical compensation claims that we have been waiting for since patients still have to prove causation along the lines of fault based tort. Consequently, it will be worthwhile for the government to take a cue from developments in Scotland and re-open the debate on no fault compensation through a broader consultation with the public.

[(62)] ibid.

[(63)] V. Harpwood, *Medicine, Malpractice and Misapprehension (Oxford: Routledge-Cavendish, 2007),*

Chapter 2: Reaction against malpractice/Patients Compensation

PATIENT SAFETY AND CONTRIBUTORY NEGLIGENCE — THE CASE OF TEMPORARILY OR PERMANENTLY MENTALLY DISTURBED PATIENTS

Maria Inês Viana de Oliveira Martins [1]

Contents: §1. Introduction. §2. The relevant case law. 2.1. *The case law*. 2.2. *Appraisal.* §3. Contributory negligence: alternative framings. 3.1. *"Mirror image theory" (Gleichbehandlungs- or Spiegelbildthese)*. 3.2. *Causation conceptions of contributory negligence (Differenzierungsthesen).* 3.3. *Appeal to the self-responsibility of the victim*. 3.4. *Theory of risk spheres.* §4. Concluding remarks

§1. Introduction

Patient safety is used as a broad term. The World Health Organisation defines patient safety as "the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum" [2].

Thus defined, patient safety can be affected by the actions of several entities, ranging from the caretaking institution and its staff to pharmaceutical companies and other suppliers of medical equipment and also to the patient himself.

This presentation will focus on how the safety of the patient can be affected by the interaction of the patient's conduct and the caretaker's conduct. In legal terms, it shall amount to analysing the interplay between the liability of the caretaker and the contributory negligence of the victim/patient. In view of case law that shall be examined, we will circumscribe our analysis to cases where there exists a contractual relationship between the caretaker — who can be either a doctor or a clinic [3] — and the patient.

On the one hand, the caretaker's premises and therapeutic activities create specific dangers for the personal integrity of the (in-)patients. These dangers give rise to duties aimed at assuring the safety of those patients — that is, to duties of protection of the interest on the integrity of the person and goods of the patient. The non-compliance with these duties can cause damage to the person of the patient. On the other hand, it is sometimes the danger that the patient poses to himself that determines his hospitalization (for instance, in the cases of psychiatric disturbances).

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[2] Organização Mundial de Saúde, Conceptual framework for the international classification for patient safety, 2009, available in http://www.who.int/patientsafety/implementation/taxonomy/icps_technical_report_en.pdf (consulted on 04.10.2013), p. 15.

[3] See Carlos Ferreira de Almeida, "Os contratos civis de prestação de serviço médico", *in Direito da saúde e bioética* (ed.), AAFDL, Lisboa, 1996, pp. 75-120, pp. 85 and ff. on the different forms that this relation of medical care can assume.

In some cases — especially in the last ones, regarding psychiatric patients — the duty to protect the integrity of the patient is part of the (main) obligations of performance in charge of the caretaker — the parties agree to take out the contract so that the caretaker will protect the patient from certain harms stemming from the disease or from its treatment. When this duty does not constitute one of the (main) obligations in the contract, it would *primo conspectu* deserve the qualification of protective duty (*Schutzpflicht*) *stricto sensu*, serving the protection of the creditor-patient's interest in his own personal integrity [4]. However, in the context of a medical contract, where the typical duty of treatment serves the protection and beneficiation of the health of the patient, the protection of the health of the patient from the dangers that the treatment can entail can be said to be material to the compliance with the main duties of the caretaker. The duty of the caretaker to guarantee the safety of the medical facilities and of the execution of the therapeutic activity can thus be deemed as being more than a mere protective duty: it is a duty directly connected with the (main) obligations of performance. The duty to protect the integrity of the patient from those risks thus *shows a double nature*, since here *the interest in performance comprehends an interest in the protection of the integrity* [5]. Moreover, when this risk to the integrity stems from the sphere of the other contractual party, then the duty of protection is fundamentally identical to a duty of care (*Verkehrssicherungspflicht*) [6] — however, in this case, the duty of care arises from the risk created by the special proximity that the contract creates between the persons and/or goods of the parties.

Within the medical treatment contract, given the instrumental character of the protection of the interest in integrity in what regards the satisfaction of the interest in performance itself, the *duty to*

[4] We are thus referring to protective duties (*Schutzpflichten*; we follow the translation endorsed by Basil S. Markesinis/Hannes Unberath/Angus Johnston, *The German law of contract, A comparative treatise*, Hart, Oxford/Portland(Oregon), 2006, pp. 126-127) in the restrictive sense that Stoll gave the expression; that is, as duties aiming at defending the parties of all the harmful interferences in their person and goods that the reciprocal contact during the life cycle of the relationship facilitates. See Manuel Carneiro da Frada, *Contrato e deveres de protecção, Suplemento XXXVIII ao BFDUC*, Coimbra, 1994, pp. 191-192.

[5] Thus, Manuel Carneiro da Frada, *Contrato e deveres...* cit., p. 205, referring exactly to the medical treatment contract. Gregor Bachmann/Günther H. Roth, "BGB § 241 Pflichten aus dem Schuldverhältnis, III. Neben- und Schutzpflichten (Abs. 2) ", *Münchener Kommentar zum BGB, 2*, Wolfgang Krüger (ed.), Munique, 2012, available in http://beck-online.beck.de (consulted on 16.12.2013), Rdn. 53, also give interesting examples of duties displaying a double nature of protection of the interest in the integrity of the other party and protection of the interest in the performance. The qualification of this duty of protection of the integrity of the patient as a duty immediately connected with the obligation of performance directly brings the regime of its non-performance to the field of contract liability, dispensing with the debate regarding the regime of liability that should be applied to protective duties — whether the regime of liability in contract, whether the regime of tort. However, as the rule here at stake — art. 570.º of the PCC — is applicable to both of those species of liability, this debate would loose practical meaning for the purposes of the present analysis. On this subject, in general terms, see Manuel Carneiro da Frada, *Contrato e deveres...* cit., *passim*. In the field of the duty to protect the safety and health of the employee, which bears an interesting analogy with our subject, see Milena Silva Rouxinol, *A obrigação de segurança e saúde do empregador*, Coimbra Editora, Coimbra, 2008, pp. 138 and ff.

[6] We follow the translation endorsed by Basil S. Markesinis/Hannes Unberath, *The German law of torts, A comparative treatise*, Hart, Oxford/Portland(Oregon), 2002, pp. 87 and ff. According to the authors, "[t]he term *Verkehrssicherungspflicht* is not easy to translate. But its meaning could be summarized by saying that whoever by his activity or through his property establishes in everyday life a source of potential danger which is likely to affect the interests and rights of others, is obliged to ensure their protection against the risks thus created by him.". The text above follows the conclusions presented by Manuel Carneiro da Frada, *Contrato e deveres...* cit., pp. 308 e ss., who considers that there is no qualitative difference between protective duties and duties of care, but only differences determined by their projection on different fields — respectively, on contract law and on tort law.

guarantee the safety in the execution of the medical treatment results either *directly from the declarations of intention of the parties or from their teleological interpretation* considering the aim of the performance. In any case, the exact content of this duty of protection is influenced by the circumstances of the patient and may therefore vary while the contract is in force. The same happens besides with the obligation of treatment of the caretaker [(7)-(8)].

Against this background, *this paper shall focus on cases that discuss the non-compliance by the caretaker of certain duties of protection of the patient's safety when the intervention of contributory negligence of the patient can also be at stake*.

§2. The relevant case law

2.1. The case law

The Portuguese case law has not, so far, to our knowledge, approached the specific issue of contributory negligence in the context of patient safety [(9)]. We can find, though, interesting German case law on the matter. Due to the proximity between the Portuguese and the German understanding of contributory negligence and of the duties that compose the complex relationship of obligation arising from the contract, the analysis of that case law can give us an insight on the problems that will possibly have to be handled by the Portuguese courts. From this set of case law, we chose to handle two cases that have in common the fact of summoning the theory of the scope of protection of the (patient's) "duty" in order to determine the existence of contributory negligence [(10)-(11)]. This case law will allow us to

[(7)] See Carlos Ferreira de Almeida, "Os contratos civis ...", cit., pp. 107-109, who states that the doctor's obligation of treatment is generic, undetermined and imprecise and that its content — comprising activities of observation, diagnose, therapy, surveillance — can only be determined during the execution of the contract, with regard to its aim of treating the patient.

[(8)] This does not mean that the institution has the duty to assure a permanent surveillance of the patient, since that would be contrary to the dignity of the patient and the success of the treatment and could go beyond what can reasonably be asked from the caretaker. These ideas are often invoked in the case law regarding psychiatric patients — see the case law quoted in the present text and the summary by Gerald Spindler, "§ 823", *Beck'scher Online-Kommentar*, Heinz Georg Bamberger/Herbert Roth (ed.), Beck, Munique, 2013, available in http://beck-online.beck.de/?vpath=bibdata/komm/BeckOK_ZivR_27/cont/BeckOK.ZivR%2Ehtm (consulted on 08.08.2013), Rn. 742 and ff.

[(9)] The thorough survey performed by Ana Mafalda Castanheira Neves de Miranda Barbosa, "A jurisprudência portuguesa em matéria de responsabilidade civil médica: o estado da arte", *Cadernos de Direito Privado*, 38, 2012, pp. 14-27 contains, symptomatically, no reference to this issue.

[(10)] We can find other decisions of the German higher courts regarding the question of the "duty" of self-protection in cases of medical liability — see the case law quoted on Erwin Deutsch/Andreas Spickhoff, *Medizinrecht, Arztrecht, Arzneimittelrecht, Medizinprodukterecht und Transfusionsrecht*, Springer, Berlim/Heidelberga, 2008, pp. 137-138. Thus, for instance, the decision of the BGH of the 20th June 2000 (VI ZR 377/99, available in http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&nr=23584&pos=0&anz=1), which concerned the case of a psychotic patient who attempted suicide during hospitalization by jumping from a balcony of the waiting room and then sued the institution for damages on the basis of fault of the organization, alleging that the waiting room could have been made safe and the accident could have been prevented without great expense to the defendant. That is also the case of the decision of the OLG of Koblenz, of the 30th April 1997 (its short version is available in *MedR*, n.º 9, 1998, pp. 421-422) regarding a patient who had been taken in after an accident, and, following an episode of delirium caused by withdrawal symptoms relating to alcohol addiction (addiction that the patient had omitted from the institution), managed to free himself from the means of physical constriction which had been applied and jumped from a window, having subsequently sued the institution for damages. In these cases, however, the court does not resort to the theory of the scope of protection in order to determine the attribution of responsibility: the court simply concludes that the caretaker did not infringe his duties of care — as in the decision of 2000 — or that he did not infringe his duties, regardless of their contractual or tortious nature — as in the decision of 1997 — and is therefore not liable. The court thus stays one step before the analysis of the scope of protection either of the caretaker's duties, or of the patient's self-protection charges.

[(11)] As we shall see, most of the scholarship rejects the existence of an actual obligation regarding the care towards oneself, since it would collide with personal freedom, and sustains that it consists of a mere charge (*Obliegenheit*/

question the methodology of the application of the theory of the scope of protection to these cases; and it will further allows us to question the different doctrinal constructions of contributory negligence in Portugal and in Germany.

The BGH jurisprudence that matters most to our analysis regards cases where patients with psychiatric problems or under the effects of mind-disturbing medicines cause harm to themselves. The decision of the 8th October 1985, VI ZR 114/84, concerned a patient with psychotic reactions, who during different hospitalizations in the same institution had for two times attempted suicide, from which resulted damage for the patient. The patient's mutuality then sued the hospital in order to recover the expenses had with the treatments made necessary by the suicide attempts. The decision of the 8th of April 2003 of the BGH (VI ZR 265/02) concerned a patient who had been sedated in order to be subject to an endoscopy. In spite of having been warned by the doctor not to drive home after being discharged and having stated that he would go home by taxi, the patient, after the intervention and while still heavily sedated, left the premises without having been discharged and drove his own car home. This led him to suffer a fatal accident. The doctor in charge was then sued by the persons entitled to receive alimony from the deceased.

In *both of the cases*, the BGH considers that the caretaker has *duties of protection towards the patient*; in the *decision of 2003*, the BGH expressly handles this duty under the *doctrine of the duties of care* (*Verkehrssicherungspflichten*), stating that not only the patient himself, but also the caretaker is a source of danger for the patient [12]; thus, the caretaker has duties of care towards the patient. The BGH re-affirms his previous case law that states that contributory negligence can intervene in cases of non-compliance with these duties of care [13]. However, *contributory negligence is never applied to these cases*.

The court's reasoning rests mainly on the doctrine of the protective scope of the duty: the court concludes that (a) either the damage caused is *within the scope of the duty of surveillance* of the caretaker *and thus out of the scope of the "duty" of self-protection of the patient*; or (b) the damage is *beyond the scope of the caretaker's duties and, therefore, there has not been any non-compliance on his part* [14]. The court considers that *when the caretaker was in charge of the duty to prevent that damaging result, then the patient was not in charge of the self-protecting "duty" to avoid*

ónus). For the sake of simplicity, we shall refer to it simply as a duty, duly placed between inverted comas.

[12] See also p. 5 of the decision of 2000, quoted in note 9, referring the tortious nature of these duties. In the case of the sedated patient, the caretaker is deemed to be the (sole) source of danger (see decision of the 8th of April 2003, pp. 7-9: the BGH concluded that in case a patient becomes, during an ambulatory treatment, so heavily sedated that his aptitude for road traffic becomes relevantly compromised for a long period of time, this can give rise to a duty imposed on the doctor to make sure, through adequate measures, that the patient does not move away after the treatment without being noticed.). Differently, in the decision of 1985, the court stresses the contractual nature of the duty to prevent the danger and seems to place it in the centre of the contract.

[13] See all the case law quoted in the decision of the 8th October 1985, p. 775, part II.1.; see also the decision of the 8th of April 2003, p. 10.

[14] The court adopts this reasoning in the decision of the 8th October 1985, p. 776, part II.2.c). The court states that when the psychiatric in-patient, in the course of therapy, *overcomes the danger of self-harming him/herself that determined his/her hospitalization but, nonetheless, for normal-psychological reasons or other considerations, decides to put an end to his/her life*, *the caretaker can not be held responsible for this result,* since *it did not have the duty to protect the patient from this specific danger*.

it [15]. Hence, the conclusion regarding the scope of protection of the "duty" of the patient does not stem from an analysis of his sphere: it is a *mere corollary of concluding that the caretaker had the duty to prevent a determined result*.

This case law is generalized by jurisprudence and scholarship in the following standard: *contributory negligence is excluded when the prevention of the damage at stake was exclusively a duty of the defendant*. That is, the *damage should be attributed solely to the non-compliance with the duty of the defendant when this duty was aimed at hindering the conduct of the victim that could be considered contributory negligence* [16].

2.2. Appraisal

Without further examining the question of the qualification of the caretaker's duty — which, as seen above, shows the double nature of a duty of performance corresponding to a protective duty –, we shall focus on the reasoning that underlies the attribution of responsibility by the court.

In the cases where the caretaker is convicted, the patient is attributed *full compensation under the doctrine of the scope of protection*. But does the court's reasoning under this theory provide the best frame for similar cases? Actually, put like this, the *rule seems too broad*.

In fact, approximately the same *could be said of non-compliance with any protective duty*, since, on the one hand, they are all *intended at avoiding the production of damage on the sphere of the other party*, and, on the other hand, may of the *risks enhanced by the proximity created by the contract require the intervention of the affected party in order to cause damage*. The therapeutic activity is besides, illustrative of how frequently the actions of the patient/plaintiff determine that the risk stemming from the sphere of the caretaker becomes an actual source of damage. It would then seem that non-compliance with protective duties could not, in most of the cases, be weighed with the contributory negligence of the person at risk; but that conclusion is, with good reason, refused by case law and scholarship [17].

[15] Very clearly so, the decision of the 8 October 1985, pp. 775-776; for the decision of the 8th of April 2003, see p. 11.

[16] See the decision of the 8th of April 2003, p. 11; in terms of scholarship, see, for instance, Gottfried Schiemann, "§ 254", *in J. von Staudingers Kommentar zum Bürgerlichen Gesetzbuch, Staudinger BGB, Buch 2, Recht der Schuldverhältnisse, §§ 249-254 (Schadensersatzrecht)*, Staudinger (ed.), Sellier — de Gruyter, 2004, pp. 298-362, pp. 314-315. Jörg Fedtke/Ulrich Magnus, "Contributory negligence under German law ", *in Unification of tort law: contributory negligence*, Ulrich Magnus/Miquel Martín-Casals (ed.), Kluwer Law International, Haia, 2004, pp. 75-98, pp. 82-83, go one step further and state that the harm is outside the scope of protection of the *Obliegenheit* of (self)-care when "the tortfeasor is specifically required to prevent the damaged party from causing harm by acting against its own interests". By saying this, the authors (who quote the 1985 decision of the BGH) seem to narrow the standard to the cases where the tortfeasor has the duty to prevent the victim from taking a "deliberate" action against his own interests. However, in these situations, either we are before an actual free, informed and thus deliberate act of the victim — who is then acting at his/her own risk, for which the tortfeasor should not be exclusively responsible –, or we are before an act which is only apparently deliberate, but does not rest upon the free and informed will of the victim. Only in the latter cases the damage should be borne exclusively by the defendant — although the standard would also cover the previous ones.

[17] See, for instance, Hartmut Oetker, "§ 254 Mitverschulden", *Münchener Kommentar zum Bürgferlichen Gesetzuch, 2*, Wolfgang Krüger (ed.), C. H. Beck, Munique, 2012, available in http://beck-online.beck.de (consulted on 27.12.2013), nm. 46-48, who gives examples of how contributory negligence and non-compliance with duties of care (that, as we saw, are of the same nature of protective duties) can combine in the same case. The author highlights that contributory negligence can be applied even in cases where the plaintiff did not have any indication that the defendant was in non-compliance with a duty of care, as long as the plaintiff has exposed him/herself, *without need*, to a determinate danger.

A further ground for questioning the mentioned standard can be extracted from Labour Law — specifically, from the norms of the Law of the Accidents at Work (Law n.º 98/2009, of the 4th of September). This Law frames the duty of the employer to protect the health and safety of the workers, which bears strong analogy to the caretaker's duties here at stake. It should be remembered that the duty of the employer to protect the safety and health of the employee is considered by the Portuguese scholarship more than a mere collateral duty in the labour contract: it is considered a duty that is material to the main performance obligations [18]. It results from the Law of the Accidents at Work that the liability of the employer, be it strict or based upon fault, can concur with the contributory negligence of the employee [19].

It is beyond the scope of this paper to take a position towards the criterion that should be followed regarding the objective imputation of the result to the conduct [20]. Criticism of the broadness of the mentioned standard is not dependent on accepting or rejecting the theory of the scope of protection of the duty. Applied to the question of contributory negligence, this theory amounts to the following: can the damage be imputed to the non-compliance with that "duty" of self-protection? That is, is the "duty" of self-protection imposed upon the plaintiff aimed at protecting him from that damaging result? [21] However, as we could see, this ques-

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[18] João Nuno Calvão da Silva, "Segurança e saúde no trabalho, Responsabilidade civil do empregador por actos próprios em caso de acidente de trabalho", *ROA*, 1, 2008, available in http://www.oa.pt/Conteudos/Artigos/detalhe_artigo.aspx?idc=1&idsc=71981&ida=72375 (consulted on 08.08.2013), point 1.2.

[19] From arts. 14.º, n.º 1, a) and b), *a contrario*, it follows that contributory negligence can concur with the liability of the employer (strict or based upon fault), unless when the accident was exclusively caused by the worker with intent or gross negligence. This opinion, held for instance by João Nuno Calvão da Silva, "Segurança e saúde...", cit., point 2.2, ddd, and by Milena Silva Rouxinol, *A obrigação de segurança...* cit., pp. 197-198, with regard to the former law, can be transferred to the present law.

[20] In Portugal, though the leading criterion to determine objective imputation continues to be the theory of adequate causation, the theory of the scope of protection has received broad acceptance in some areas of liability law, as a complement of the theory of adequate causation — mainly in the area of what is defined in Germany and Portugal as the second form of unlawfulness (see Jorge Ferreira Sinde Monteiro, *Responsabilidade por conselhos, recomendações ou informações*, Almedina, Coimbra, 1989, especially pp. 271 and ff.). The theory of adequate causation has known many different formulations, ranging from the distinction between its positive — there should be imputation when the harm/damage is a normal or typical consequence of the fact of the defendant — and its negative — there should be imputation when the fact of the defendant was not totally indifferent to the occurrence of the harm/damage — formulations, to the different perspectives on the cognitive standard pertaining to this assessment — regarding, for instance, whether the result should be typical/not at all unlikely from the perspective of an experienced observer or of an optimal observer (see Jorge Ferreira Sinde Monteiro, *Relatório sobre o programa, conteúdo e métodos de uma disciplina de responsablidade civil (Curso de mestrado)*, s. ed., Coimbra, 2001, pp. 41-42 and Ana Mafalda Castanheira Neves de Miranda Barbosa, *Do nexo de causalidade ao nexo de imputação: contributo para a compreensão da natureza binária e personalística do requisito causal ao nível da responsabilidade civil extracontratual, I*, Principia, Cascais, 2013 , pp. 102 and ff.). José Carlos Brandão Proença, *A conduta do lesado como pressuposto e critério de imputação do dano extracontratual*, Almedina, Coimbra, 2007, pp. 444-445, who supports the application of this criterion to the assessment of the imputation of the result to the conduct of the plaintiff in cases of contributory negligence, sustains that it should apply in the positive version. The author configures objective imputation in these cases as an objective judgement of probability, under which it should be questioned whether, according to the rules of experience, the ordinary course of events and the circumstances known by the plaintiff or that would be recognized by an experienced observer, and considering the condition created by the defendant, the conduct of the plaintiff favoured the occurrence of a damage of that kind — that is, if a damage of the kind of the one that occurred was a likely or typical effect of the plaintiff's conduct.

[21] See, for instance, Erwin Deutsch, *Allgemeines Haftungsrecht*, Carl Heymanns Verlag, Colónia/Berlim/Bona/Munique, 1996, pp. 362-36 and Gottfried Schiemann, "§ 254", cit., p. 314, Rn. 35. It should be added that the work of Dieter Medicus, "Zum Schutzzweck schadensabwehrender Pflichten oder Obliegenheiten", *in Festschrift für Hubert Niederländer zum siebzigsten Geburtstag am 10. Februar 1991*, Erik Jayme/Adolf Laus/Karlheinz Misera/Gert Reinhart/Rolf Serick (ed.), Carl Winter Universitätsverlag, Heidelberga 1991, has been decisive in the application of the scope of protection theory to cases of contributory negligence. This article performs a critical appraisal of case law of the BGH. In the cases dealt with, the "fault" of the plaintiff "triggers" the professional intervention of a determinate entity — on the first case, the wounded co-responsible victim of

tion has not been posed in the mentioned case law. In fact, the standard proposed by this case law *fails to give any attention to the sphere interplaying with that of the caretaker: the patient's sphere*. This hinders, in our opinion, the ability of this standard to fulfil its role. Should it be said, in fact, that the caretaker is in charge of preventing each and every damage that those under his care may cause themselves, even when consciously and deliberately exposing themselves to risk?

It should moreover be kept in mind that all these cases regard patients who are under a temporary or permanent mental disturbance. Could it and should it be then said, instead of appealing to this interpretation of the theory of the scope of protection of the norms that, when full compensation is given to the patients, that is so because they caused the damage in a state of incapacity for fault?

Even though the result achieved by the referred German case law seems correct — full responsibility of the caretaker –, the argumentative *iter* behind it should be discussed. Against this background, we intend to discuss possible alternative framings for these cases, summoning contributions by legal scholarship.

§3. Contributory negligence: alternative framings

We shall now proceed to the framing of the mentioned case law under the more relevant theories on contributory negligence in the Portuguese doctrinal context, which shall demand a (necessarily) brief outline of these theories [(22)]. We shall be interested only in the answer that these constructions provide for the cases where the defendant's liability is based on fault, since thus is the case law under analysis. It should furthermore be noted that the last two theses that shall be described are thought for the cases of liability in tort. The specific framing that they provide for the cases of lack of capacity for fault of the plaintiff is nonetheless useful for the present study.

3.1. "Mirror image theory" (*Gleichbehandlungs- or Spiegelbildthese*)

The more traditional approach is based on the principle of equal treatment, consisting of a "mirror image theory" (*Gleichbehandlungs-* or *Spiegelbildthese*). In its purest versions, it sustains that

an accident goes to a doctor and on the second a person looses a valuable object at a service station and that object is afterwards found by the highway officers, who are also in charge of the custody of lost objects –, who then, due to fault in the accomplishment of its professional duties, causes damage to the plaintiff — that is, respectively the doctor causes damage to the patient due to medical malpractice and the highway officers loose the object that was under their custody. Medicus claims that the infringement of a "duty" by the plaintiff can only interfere with the responsibility of those entities for the faults they make in their activity *when that infringement increases the risk of their activity*; *it is not enough that the infringement by the plaintiff "triggers" their intervention*. More specifically, in the case of the patient, the infringement of "duties" by the patient would only be contributorily relevant *when it increased the danger of occurrence of medical errors or of aggravation of the effects of those errors*; the same is applied to the case of the valuable object, where the author states that the *faulty loss of the valuable object does not create an increased danger that the object is lost by the competent custodian authorities* (see especially pp. 338-340 in this regard).

[(22)] See, on this matter, José Carlos Brandão Proença, *A conduta...* cit., pp. 401 and ff. and Helmut Koziol, "Die Mitverantwortlichkeit des Geschädigten: Spiegelbild- oder Differenzierungsthese", *in Medizin und Haftung, Festschrift für Erwin Deutsch zum 80. Geburtstag*, Hans-Jürgen Ahrens/Christian von Bar/Gerfried Fischer/Andreas Spickhoff/Jochen Taupitz (ed.), Springer, Berlim/Heidelberga, 2009, pp. 781-794, pp. 781-784; for an English version of the opinions of the author, see Helmut Koziol, *Basic questions of tort law from a Germanic perspective*, Jan Sramek Verlag, Viena, 2012, pp. 256 and ff.

the fact of the plaintiff makes him responsible for his own damage under the same assumptions that condition the defendant's liability (action/omission, unlawfulness, causation, fault, damage).

A construction that rested upon these bases would however imply that a careless or even intentionally harmful conduct towards oneself *should be deemed contrary to the law* — in order to fulfil the condition of unlawfulness — and *deserving of a legal reproach* — in order to fulfil the condition of fault. This would yet counter the fundamental and ordinary norms of the legal system that protect the personal freedom of the individuals regarding their person and property. Therefore, the mitigated versions of this approach exclude either the reference to unlawfulness — stressing that the victim is under a mere "charge" (*Obliegenheit/ónus*) to care for his/her physical and psychological integrity or for his/her property, and not under an actual obligation to do so —, or the reference to fault in technical sense — referring to a conduct merely analogous to a faulty one, since the law does not reproach the subjects for not taking good care of their person and property —, or even the reference to both of them. Most of the recent approaches thus set apart from a rigorously mirroring approach [23]-[24]. They can be said, however, to grow from this branch, since, although they reject the application to the plaintiff of one or some of the conditions of liability of the defendant, they not only require a subjective imputation of the result to the plaintiff, as they generally base the whole construction on the idea of a replication of the conditions of liability of the defendant. This subjective imputation is consequently built upon the bases of fault, which determines that the *subjective imputation of the result to the victim requires capacity for fault* [25].

Applying this understanding to the cases referred above, we would come to the conclusion that, when

[23] In Portugal, contributory negligence is constructed by reference to the conditions of liability of the defendant, for instance, by Luís Manuel Teles de Menezes Leitão, *Direito das obrigações, I*, Almedina, Coimbra, 2009, pp. 331-333 (clearly mentioning fault *proprio sensu* of the plaintiff); Mário Júlio de Almeida Costa, *Direito das obrigações*, Almedina, Coimbra, 2009, pp. 782-783; Jorge Leite Areias Ribeiro de Faria, *Direito das obrigações, I*, s.ed., Porto, 1987, pp. 523-525, denying that the conduct of the plaintiff may be unlawful, but affirming it may be faulty; João de Matos Antunes Varela, *Das obrigações em geral, I*, Almedina, Coimbra, 2000, pp. 917-918, stating that although there is no fault *proprio sensu* from the plaintiff, his conduct must be reproachable; Nuno Manuel Pinto Oliveira, *Princípios de direito dos contratos*, Coimbra Editora, Coimbra, 2011, pp. 726-731, sustaining that there is a mere charge to care for oneself — therefore rejecting the pertinence of unlawfulness — and that the non compliance with this onus can entail fault, yet fault of a different nature from that of the defendant, since the conduct of the victim only affects his/her own interests. See also Sara Geraldes, "A culpa do lesado", *O Direito*, 141, 2009, pp. 339-375, pp. 356-361 and p. 373, denying the idea of a duty to care for oneself and therefore the existence of "fault" *proprio sensu* from the plaintiff and sustaining first that the plaintiff should act with a degree of care analogous to the one demanded from the defendant and in the end, sustaining that a voluntary fact of the plaintiff is enough to determine the imputation.

[24] See the previous note and, in terms of comparative law, see Ulrich Magnus/Miquel Martín-Casals, "Comparative conclusions", *in Unification of tort law: contributory negligence*, Ulrich Magnus/Miquel Martín-Casals (ed.), Kluwer Law International, Haia, 2004, pp. 259-291, pp. 260-261, stating that among the countries that formulate contributory negligence by reference to the claimant's own fault it is more or less common ground "that fault is not to be understood in a strict technical sense, since no one is under a formal legal obligation not to cause damage in the own sphere"; it should be noted that Germany is ranked among this group (see also Jörg Fedtke/Ulrich Magnus, "Contributory...", cit., pp. 80 and 84); also Miquel Martín-Casals, ""Através del espejo": concurrencia de "culpa" de la víctima y culpa del causante del daño", *in Estudios jurídicos en homenaje al Profesor Luis Díez-Picazo, II, Derecho civil, Derecho de obligaciones*, Antonio Cabanillas Sánchez/Jorge Cafarena Laporta/José María Miquel González/Vicente L. Montés Penadés/Antonio Manuel Morales Moreno/Fernando Pantaleón Prieto (ed.), Thomson Civitas, Madrid, 2003, pp. 2471-2490, p. 2478 and Hartmut Oetker, *§ 254 Mitverschulden*, cit., especially Rdn. 29-31 and 34-35..

[25] See the scholarship quoted in the previous notes and also Dieter Medicus/Stephan Lorenz, *Schuldrecht I, Allgemeiner Teil*, C. H. Beck, Munique, 2010, p. 348.

the breach of the duty of the caretaker caused damage to the patient, that damage should be borne by caretaker alone, since the patient was not capable of fault.

3.2. Causation conceptions of contributory negligence (*Differenzierungsthesen*)

On the other extreme of the spectre we find the objective conceptions of contributory negligence (*Differenzierungsthese*), which start from the principle *casum sensit dominus* and rely in pure causation. Thus, in the allocation of damage between the defendant and the plaintiff, the plaintiff bears (*a fortiori*) all the damage that is attributable to his/her actions in terms of causation, as he/she would bear the consequences of any fortuitous event [26]. Contributory negligence is therefore merely a question of objective imputation of the result to the conduct of the plaintiff.

Purely causation theories are minority both in the Portuguese and in the German legal thought. It is symptomatic that the project of European law of torts (art. 8:101) does not rely on them. They show in fact logical frailties — since we are in situations where it is the combination of the fact of the agent and the fact of the victim that gives rise to a determinate (unitary) damage (actual concurrence of causes), the allocation of quotas of liability for causation may often prove difficult or even arbitrary [27]. Moreover, very commonly a fact proceeding from the victim will have contributed to the fact, as a *condictio sine qua non* or even as an adequate (co-) cause, which leads to an over-extension of the cases where contributory negligence is applied [28] — which becomes clearer when we think that, since this imputation is done in strictly causal terms, it will be established even when the contribution of the victim consisted of an involuntary fact. Very few would then be the cases where the victim would

[26] This understanding is supported in Portugal by Fernando Pessoa Jorge, *Ensaio sobre os pressupostos da responsabilidade civil*, Almedina, Coimbra, 1995, *maxime* p. 360; António Menezes Cordeiro, *Da boa fé no Direito civil*, Almedina, Coimbra, 1997, p. 768, n. 457, and p. 841; more recently, António Menezes Cordeiro, *Tratado de Direito civil português, II, Direito das obrigações, III, Gestão de negócios, enriquecimento sem causa, responsabilidade civil* Almedina, Coimbra, 2010, pp. 731-732. Eduardo Santos Júnior, ""Mitigation of damages", redução de danos pela parte lesada e "culpa do lesado"", *in Prof. Doutor Inocêncio Galvão Telles: 90 anos, Homenagem da Faculdade de Direito de Lisboa*, António Menezes Cordeiro/Luís Manuel Teles de Menezes Leitão/Januário da Costa Gomes (ed.), Almedina, Coimbra, 2007, pp. 349-367, pp. 362-365, also places himself among those who understand contributory negligence as a question of objective imputation. However, the author considers for that purpose that the criterion for objective imputation should incorporate the assessment of the reasonableness of the plaintiff's conduct in regard of the purpose of preventing the damage from occurring. Thus, objective imputation becomes additionally conditional on the reasonableness of the conduct of the victim in the face of the circumstances. The author seems therefore to come to a sort of fusion between the criterion of objective imputation and the criterion of subjective imputation according to an objective standard of care, instead of keeping to his original purpose.

[27] The understanding that we are handling with an actual concurrence of causes (encompassing what can be said co-causation, cumulative causation and alternative causation — see Francisco Manuel Pereira Coelho, *O problema da causa virtual na responsabilidade civil*, Almedina, Coimbra, 1998, pp. 24-25) is of the highest importance for the clarification of the actual role of the *casum sensit domunis* principle. In fact, we are not before hypotheses where the agent has caused part of the damage and the victim has caused another (severable) part of the damage. These are, on the contrary, hypotheses were a single indivisible damage is caused by the interaction between the agent's and the victim's actions. A pure causation criterion is therefore not suited to determine the quota of damage to be borne by each of the interveners — the attribution of percentages of causation would be purely arbitrary in these situations where the damage is unitary. Thus, José Carlos Brandão Proença, *A conduta...* cit., pp. 425 and ff. See also, Ana Mafalda Castanheira Neves de Miranda Barbosa, *Do nexo de causalidade ao nexo de imputação: contributo para a compreensão da natureza binária e personalística do requisito causal ao nível da responsabilidade civil extracontratual, II*, Principia, Cascais, 2013, p. 803, note 1763, stating that what the strictly causal approach seems to ignore is the indivisibility of the process that leads to the occurrence of damage.

[28] See Helmut Koziol, "Die Mitverantwortlichkeit... ", cit., p. 784.

not have to bear part of the damage. This approach would, in sum, lead to unfair results.

These theories appear though in mitigated versions. That is the case of the constructions that rely on the theory of the scope of protection conceiving it as reliant, up to some extent, in subjective elements. We shall see an example of one of these conceptions below, in point 3.4.

The results reached under this framing depend on the causation theory endorsed. Under *condictio sine qua non* or adequate cause theories, the patient's action would be considered to at least co-determined the result in terms of causation. The damage would then either be divided between patient and caretaker — if the conclusion was that there should be objective imputation to both –, or be attributed exclusively to the patient — if the conclusion was that his/her interference in bringing about the damage had interrupted the causal chain that could link that damage to the conduct of the caretaker. Differently, the results attained under the scope of protection theory would depend on the contour of the "duty" of self-protection that would be considered to be impending upon the patient. The outlining of this "duty" of self-protection having regard to the permanent or temporary mental disturbance of the patient would endow this construction with a certain subjective slant.

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3.3. Appeal to the self-responsibility of the victim

This thesis, defended by Brandão Proença, can be said somewhat akin to the mentioned theses that require both objective and subjective imputation of the result to the plaintiff. However, the author gives contributory negligence its own grounds, instead of relying in the mirroring of the conditions for the liability of the defendant. The author considers that the purpose of contributory negligence is to reach a fair distribution of the harmful consequences between the plaintiff and the defendant, based on the idea of attribution to a subject of the economic consequences of his/her decisions that were freely taken but proved unfavourable to his/her own interests, due to their self-harming potential. Thus contributory negligence relies on an act of self-responsibility, which can only exist when that act can be subjectively attributed to the victim [(29)]. Subjective imputation serves as a limit to the results of objective imputation, determined according to the positive version of adequate causation (there is imputation when the conduct of the plaintiff favored the likelihood of that result). Thus, contributory negligence is not conceived as a problem of objective imputation of a result to a conduct, but as a question of allocation of damages.

The non-taking care of one's own interests is not to be reproached — there is usually no unlawfulness underlying contributory negligence [(30)] and there is no fault in technical sense. Nonetheless, if the plaintiff acts towards his/her own interests without fulfilling the required standard of care, that should interfere in the allocation of the damage caused by the combination between a act of the defendant and

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[(29)] See José Carlos Brandão Proença, *A conduta...* cit., especially pp. 407 and 414 and ff.

[(30)] Except, according to the author, when there is a norm imposing a determinate duty of self-protection, such as the duty to wear a helmet — see José Carlos Brandão Proença, *A conduta...* cit., p. 523.

a act of the plaintiff. According to the same author, in order to recognize an act of self-responsibility from the plaintiff, there should be a free and voluntary human conduct, conscious of the dangers and of the damage that are to be avoided and yet contrary to the required standard of care [31]. Self-responsibility is thus generically excluded in what regards persons non capable of fault.

Consequently, even when causation is affirmed, the patient should only bear the consequences of his actions when he acts freely and voluntarily, with conscience of the harmful potential of the conduct. This reasoning would imply, when applied to the case law here at stake, that the damage would be borne by the caretaker alone [32].

3.4. Theory of risk spheres

The approach of Mafalda Miranda Barbosa can be placed among the theses that conceive contributory negligence as a question of objective imputation of the result to the conduct. This objective imputation is determined by the analysis of the spheres of risk that may interfere with the production of the result [33] — that is, that of the tortfeasor, that of the victim, that of other third parties that may interfere with the sphere of the victim and that of the ordinary risks of life (*allgemeines Lebensrisiko*). When the defendant masters a determinate sphere of risks he/she is aware of, he/she is in principle liable for the results whose risk he/she increases by his action; in other cases, the defendant becomes liable for a determinate sphere of risks when he infringes a duty of care that impended upon him. This should be put side by side with the sphere of risk of the plaintiff.

The self-responsibility of the person can only come into play, however, when it is based upon his/her *free conduct*. This freedom may be excluded by the lack or the diminution of the capacities of the plaintiff [34]. If it is the case, in cases such as the ones under scrutiny, the result should be attributed to the caretaker-defendant alone.

§4. Concluding remarks

This paper has analysed a standard developed by German case law regarding cases of contributory negligence of a patient-victim. According to this

[31] See José Carlos Brandão Proença, *A conduta...* cit., pp. 530 and ff., especially pp. 540 and ff., and also 418.

[32] It should be noted, however, that, in this point, we are beyond the author's opinion. In fact, the author himself tends to temper the pure functioning of adequate causation theory through the consideration of a number of material standards — see José Carlos Brandão Proença, *A conduta...* cit., pp. 446-450. Against this background, the author denies the objective imputation of the result to the victim *in the cases where the duty to avoid the damage at stake is among the duties of care of the defendant* — the author refers as examples the cases where the defendant is in charge of controlling the access to the course of a railway or where the defendant is in charge of controlling the access to a determinate public transport. According to the author, if the defendant allows the plaintiff to access the railway or the transport at stake and the plaintiff suffers damage following this access — due to the passage of a train or to the transport being beyond its capacity –, then the damage should be exclusively attributed to the defendant in terms of causation. Once again, however, we find the mentioned standard too broad — should the damage be exclusively attributed to the defendant even when the plaintiff was fully conscious of the danger he was exposing himself to and nonetheless insisted on being allowed to access the railroad or the transport in cause?

[33] See Ana Mafalda Castanheira Neves de Miranda Barbosa, *Do nexo…II*, cit., *maxime* pp. 900 and ff., 967 and ff., and 1456-1459.

[34] Ana Mafalda Castanheira Neves de Miranda Barbosa, *Do nexo… II*, cit., pp. 996 and ff., pp. 800-802 and 1458-1459. Although the author does not categorically define a position for the cases of lack of capacity for fault, this idea seems to stem from her words on the quoted pages, especially on notes 2135 and 1760.

standard, contributory negligence is excluded when the prevention of the damage at stake was exclusively an obligation of the defendant. We have concluded that the standard is formulated too broadly, in a way that would give cover to unreasonable solutions and even counter some of the norms in force. A critical remark that can be made in general terms is that this standard is only concerned with the sphere of the defendant, thus disregarding the sphere of the plaintiff, that also interferes in bringing about the damage.

Since the relevant case law refers to victims who do not have capacity for fault, the search of a more sustainable solution should be sought through an inquiry on how different approaches to contributory negligence assimilate the lack of capacity for fault of the plaintiff. This has lead this paper to a brief outline of different dogmatic approaches to contributory negligence and thus to the framing of the referred case law under each of these approaches.

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DEFENSIVE MEDICINE IN THE CZECH REPUBLIC — AN UNDERESTIMATED CONSEQUENCE OF THE FEAR OF MEDICAL LIABILITY

Helena Peterková [1]

1. Introduction

Defensive medicine could be defined in general as those treatment measures undertaken to avoid liability rather than to benefit the patient, i.e. medical decisions based not on professional judgement of what is best for the patient but on what is legally the safest action for the doctor [2].

Sometimes it is argued that the preventive strategy intrinsic to defensive medicine has not been proven to be an evidence-based matter, or that it actually has the potential to establish some good practices, such as a better medical report policy, more consistent courtesy towards patients, etc. [3] Nevertheless, defensive medicine is observed as a reality in most western countries [4] and is strongly criticised[5] because of the fact that it is equally as wrong to over-treat the patient (i.e. to treat the patient too much or too intensively) as to under-treat the patient. This is especially true if the purpose of the doctor to provide the patient with additional examinations or treatment is rather for his own future legal protection and not due to his genuine belief in any benefit to the patient.

Apart from all the notoriously known health hazards such as exposing the patient to an unnecessary quantity of radiation, increasing the risk of the patient becoming resistant to most antibiotics, performing general anaesthesia during medically non-indicated Caesarean sections, etc., as well as the recent increasingly emphasised question of the costs of defensive medicine, the unwanted side effects of defensive medicine are also to be found in the less obvious form of a breach of the personal rights of the patient and next of kin, as has been suggested by some recent experiences in the Czech Republic.

Unlike in some other countries, where defensive medicine has been studied for decades [6], in

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[2] Brazier, M., Cave, E.: Medicine, Patients and the Law. 4th ed., LexisNexis and Penguin, 2007, p. 204.

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the Czech Republic it has not yet been regarded as worthy of much attention. In fact, open public debate about the causes and unfortunate side effects of defensive medicine has just started in some segments of the healthcare system, typically in those providing palliative and hospice care. Unlike in some other countries where defensive medicine is practised because of the increasing number of lawsuits [(7)], in the Czech Republic defensive medicine is more likely a negative consequence of the criminalisation of the health care provider.

2. Defensive medicine in Czech clinical practice

2.1. Case Study I.

An ambulance was called to an 89-year-old polymorbid patient who was obese, somnolent, near death, with a wrist fracture, suffering from serious cardiac disease, breast cancer, dementia, Parkinson disease, renal insufficiency and incontinence. After examination of the patient, the doctor diagnosed irreversible heart failure. Because of the fact that the daughter of the patient, who was a guardian of the patient and care-giver, introduced herself as a medical doctor as well, the attending doctor allowed himself to reveal honestly to the daughter the infaust prognosis of the patient who was near death.

The attending doctor therefore recommended that the patient should not be treated any further, because of the fact that any causal treatment was futile in that situation and because transporting the patient would only increase her stress and confusion.

The prognosis of the patient and the recommended procedure was not accepted by the daughter at all. The attending doctor was forced by the daughter to admit the patient to hospital under the threat that, if not done, she was going to report the doctor as an offender to the police. Within a few hours, the greatly stressed and totally confused patient died in hospital due to the untreatable heart failure [(8)].

Because of the inner conviction of the daughter that her mother had died due to malpractice by the attending doctors, she filed a disciplinary complaint not only against the doctor who had been reluctant to transport the patient to the hospital, but also against the doctors who had treated the patient after admission to hospital.

The defensive strategy of the attending doctor, i.e. to provide the patient with non-indicated (possibly even contraindicated) transport and further hospital care at the daughter's demand, fulfilled its goals in a questionable way. Although the putative crime was not reported, the daughter finally complained to another authority (which, according to all the evidence, considered the original decision by the doctor not to transport the patient in a terminal state to the hospital as appropriate and *lege artis* [(9)]).

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[(7)] Kenedy, P.: Is it the way we want to go? J.P.I. Law 2005, 2, 117-128. Quick, O.: Patient safety and the problem and potential of law. P.N. 2012, 28 (2), 78-99. Korobkin, R.: Comparative effectiveness research as choice architecture: The behavioral law and economics solution to the health care cost crisis. 112 Mich. L. Rev. 2014, p. 523- 524.

[(8)] Complaint No. 11/74-001,002/0715 heard by the disciplinary bodies of the Czech Medical Chamber.

[(9)] A withdrawal and/or withholding of a futile treatment was explicitly acknowledged by guidelines both published by professional medical societies and the Czech Medical Chamber. Further, according to the Ethical Code and Dis-

By contrast, the transport enforced by the daughter clearly led to the degrading treatment of the patient who died in extreme stress, which had been evitable.

2.2. Legal liability of a doctor in the Czech Republic

In the Czech Republic, a doctor, as an employee, whilst providing health care could be personally held liable for breach of the Criminal Law, Disciplinary Law or Labour Law. As far as the cases of medical malpractice or administrative offence are concerned, it is the healthcare provider (the subject entitled to provide health care, the legal person, the employer of a doctor) [10] who will be found responsible for breaching the law and who will pay damages and/or compensation; a legal person cannot be held criminally liable for offences against life and health [11].

In all branches of the law, the basic human rights (the patient's right to life, health, health care, dignity) are to be protected. Although Criminal Law is explicitly recognised as *ultima ratio* and criminal liability shall only be imposed subsidiarily in only the most serious cases when sanction according to the other branches of the law is not satisfactory, in reality the concerned person very often prefers to report his/her case to the police rather than to bring a lawsuit. This phenomenon could be explained by the fact that in the criminal procedure (just as in the disciplinary procedure) there is no further action expected from the patient or the next of kin. This is because the procedure is ruled by the principle of material truth and by the principle of legality, and the injured person is not required either to pay any fee or to carry the burden of proof.

From the historical point of view, providing health care has been constructed as a state service for more than 40 years, regulated mainly by Public Law [12]. Even though the private nature of the patient-doctor/healthcare provider relationship has been repeatedly confirmed by the highest courts of the Czech Republic [13], it was not until the new Civil Code came into effect in 2014 when the relationship between the patient and the doctor or healthcare provider was statutorily declared to be a contract under the provision of Private Law [14].

Because of all the above-mentioned facts, it is a matter of convenience (and perhaps also of moral satisfaction) for the injured person to start his/her legal battle by engaging the police or prosecution, even if the case could be more adequately dealt with by other authorities.

There have been no significant studies carried out in the Czech Republic. However, it can be estimated that the most crucial reasons for practising defensive medicine are the gradual criminalisation

ciplinary Order of the Czech Medical Chamber, it shall not be the goal of the doctor to prolong the dying process at all costs.

[10] As regards a single-member private practice, the doctor himself/herself is the healthcare provider.

[11] Act No. 418/2011 Coll., On the Criminal Liability of the Legal Persons.

[12] Act No. 20/1966 Coll., On the Care of Health of the People.

[13] Among all others the Judgement of the Constitutional Court of the Czech Republic Pl. ÚS 36/11.

[14] S. 2636 ff. of the Act No. 89/2012 Coll., Civil Code. In this context, it is not surprising that, after 1989, Medical Law was taught at the biggest Czech Law Faculty at Charles University in Prague as a part of Criminal Law. Comp. the textbook on Criminal Law and Health Care: Císařová, D., Sovová, O.: Trestní právo a zdravotnictví, 2nd ed., Praha: Orac; 2004.

of the area of providing medical care and particularly doctors' fear of criminal sanction, including imprisonment or a ban on their future medical activities [15].

2.2.1. The conflict of duties

The main duty of a doctor is to provide the patient with health care on an appropriate level, which, under S. 4 para. 5 of the new Act on Healthcare Services, means providing health care according to the science and acknowledged medical guidelines, with respect to the individuality of the patient, with regards to concrete conditions and objective possibilities.

On the one hand, patients and their next of kin very often expect not only the best available treatment, but sometimes automatically consider unsuccessful efforts to revive the patient as a failure of the doctor to provide the proper care. In this context, it is clear that the assumption of medicine as being triumphant can substantially mislead the expectation of patients. Furthermore, during recent decades, a prominent shift from the paternalistic doctor — patient relationship has occurred in the Czech Republic. Nowadays, the patient is much more self-confident with regard to patient rights and much more inclined to fight for access to proper treatment, both in advance and a posteriori.

On the other hand, in the clinical reality, doctors are facing great pressure because of the obvious limits of curative medicine — maybe even more so, due to the strengthening impact of scarce resources in the system of the provision of health care. To further complicate the Czech reality, attempts to save money were explicitly introduced for the first time by the Czech authorities some years ago in order to deal with the financial unsustainability of the Czech public healthcare system based on health insurance. These attempts have been explicitly admitted on the macro-level, but implicitly enforced on the micro-level. In addition, the determination of mistrustful patients to fight for their rights of access to health care has substantially increased. The legal battle very often takes place a posteriori, by suing a doctor, filing a claim, reporting the (alleged) crime, while actions against the authorities occur only in exceptional cases [16].

In this context, Czech doctors very often point out that, according to the law, doctors only have duties to patients, employers, health insurance schemes, but they themselves have no rights at all. Such a statement should not be accepted as fully legitimate — the new Act on Health Services [17] has made some progress in this area, as from 1.4.2012 it recognises the right of a medical staff member not to provide health care in case of danger (S.50 para. 1), the right to conscience clause (S.50 para. 2) and therapeutic privilege (S.32 para. 2).

Nevertheless, the legal position of Czech doctors is unsatisfactory: they very often find themselves

[15] Mach, J.: Lékař a právo. Praktická příručka pro lékaře a zdravotníky. Grada Publishing, a.s., 2010, p. 17-21.

[16] Dostál, O., Dostálová, M.: Liability for Rationing Decisions: Health Care Insurance Fund as a Medical Malpractice Defendant? Book of Abstracts. Fourth European Conference on Health Law. Patient Safety. AEHL 2013, p. 91-93.

[17] Act No. 372/2011 Coll.

in the middle of conflicting duties and the correct legal solution is not often convincingly obvious to them. All this, naturally, has some unfortunate consequences. Because of doctors' sense of legal uncertainty, they very often consider a situation to be even more legally problematic than it really is, while it is merely their attempts to minimalize any subsequent conflict or harm which actually (secondarily) cause the real problem.

2.2.2. Case Study II.

A complaint was brought before the Czech Medical Chamber regarding a patient suffering from advanced heart failure, as an irreversible result of cardiomyopathy, arterial hypertension and ischaemic cardiac disease, complicated by diabetes mellitus. At the time of admission to hospital, the patient was in a terminal state. Despite the maximum therapy, the patient was developing subsequent respiratory failure. Therefore, after consultation with an anaesthetist, the DNR decision was reached.

Cardiac arrest occurred that same evening. The fact that the family had not been informed about the prognosis and DNR strategy was explained by the attending doctor as being due to mutual communication from the very outset. The family did not trust the doctors, so the doctors had not wanted to "provoke" the family by telling them that the life of the patient would not be prolonged at all costs. As the family stated afterwards, it was not the DNR decision itself, but the fact that they had not been informed about the prognosis and withholding of resuscitation that they were blaming the doctors for, because they had not had the chance to say 'goodbye' [(18)].

Although there is no legal provision imposing the duty on doctors to proactively — i.e. without being asked — inform relatives about the health condition of a dying patient, withholding the information about the prognosis could be interpreted as a breach of the rights of private and family life and is to be considered at least unethical, if not illegal.

3. Conclusion

It can be concluded that the excessive threat of a doctor being found liable whilst providing medical health care not only does not offer any safeguards to the patient and next of kin, but leads to the practice of defensive medicine which is to be regarded as an undesirable phenomenon. As recent Czech experiences demonstrate, it is not only the health risk connected with overdiagnosis and overtreatment or the extra financial burden which are at stake, but also the other side effects of defensive medicine, such as breaching the dignity, private and family life of the patient and/or next of kin.

[(18)] Complaint No. 11/23-001/0070.

Chapter 3: Learning with errors

PATIENT SAFETY IN CHEMOTHERAPY ADMINISTRATION

Isabel Fernandes [1] / *Maria Céu Rueff* [2] / *João Borges-Costa* [3]

Abstract: *Patient safety is a growing concern in healthcare management and essential for healthcare quality.*

Evolution of patient-doctor relationship from medical paternalism to a growing patient autonomy lead to a higher respect for patients' rights and to inform consent. Patient's autonomy includes the right of not knowing since they have the right to make decisions based on their own self-determination. However, true telling is not achieved, especially when the outcome is adverse. Moreover, physicians use the therapeutic privilege in specific cases for afraid to be more harmful to cancer patients than benefic.

In oncology, there are several steps in which errors can occur during the process for chemotherapy administration with different degrees of severity and detection.

The main objectives of our work were the detection of potentially avoidable errors in the administration of chemotherapy using the model of breast cancer which is one of the most frequent pathologies in oncology. FMEA (Failure Mode and Effect Analysis) *was used for analysis of the potentially avoidable errors in breast cancer.*

The researchers were unable to calculate the different risk indices since data concerning occurrence, severity and detection of errors is not available. The main reason for the paucity of data is the absence of a culture of systematic reporting of errors in Portuguese hospitals.

Errors notification are essential to identify the occurrence and severity of mistakes. A culture of trust and reporting is important to improve patient safety. However, systematic reporting is not a reality maybe because medical responsibility in Portuguese law is subjective and systematic reporting can lead to self-incrimination (Oliveira, 2008). To accomplish the goal of a good notification system in Portugal, it is necessary a more consistent disciplinary responsibility, a civil responsibility without blame or necessity for repair. The penal responsibility should therefore be reserved only for the extreme cases.

Patient safety, a growing issue

Patient safety has become a major concern in modern healthcare systems. The majority of health systems consider the improvement of patient safety as seeking quality in healthcare organizations. For instance, the costs of incidents are higher due to litigation and consequent treatments (Sousa, 2006)

Patient safety is also a growing concern in healthcare management and it is necessary to increase publications about errors and to act in order to minimize its occurrence (Miasso, 2000).

"Medicines can do a lot of good but they also have the potential to cause harm. Medication errors are one of the most common causes of patient harm and prescribing accounts for a large proportion of medication errors." (The health foundation, 2012, pg. 4)

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"A medication error is a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient" (Aronson, 2009). This kind of errors are nearly 1 of every 5 doses in the typical hospital and skilled nursing facility with a rated percentage of potentially harmful errors of 7% (Barker, 2002).

Medication errors are among the most common medical mistakes, harming at least 1.5 million people every year and there are 44.000–98.000 deaths per year from medical mistakes (watcher, 2004). 400.000 preventable drug-related injuries occur each year in hospitals and 800.000 in long-term care settings, and roughly 530.000 among Medicare recipients in outpatient clinics. (The National Academy of science, 2006) This cannot be ignored in a time when quality and efficiency are the aim of health organizations. However, new technologies and pharmaceuticals are emerging, costs can became higher than what governments can pay and quality can be compromised (Watcher, 2004).

Healthcare organizations must abandon the aim of requiring error free performance from individuals. Instead, organizations should admit the inevitability of error and design systems that "proactively seeks to identify latent treats" (Nieva, 2003, pg. 17).

Most experienced professionals prefer to hide the errors fearing that the revelation could compromise their professional competence and will lead to punishment. Moreover, the lawsuits and monetary compensations are feared by health professionals which reduce the reporting and lead to a defensive medicine. This will rise cancer costs if a proper risk management are not applied.

If patient safety is a dimension of quality, risk management is dependent of quality management. The management of clinical risk should be perceived as crucial for safety and quality in oncology and the organizations leaders should integrate this in the strategic aims of the institution.

The definition for quality adopted by Joint Commission on Accreditation of Healthcare Organizations (JCAHO) consider quality "the manner in which health services, with the current level of knowledge, increase the possibility of obtaining the desired results and reduce the possibility of obtaining results unwanted" (Batalden, 1993 cited in Sousa, 2006, pg. 310)

The Institute of Medicine (IOM) report, *To Err Is Human*, raised the issue that the majority of medical errors result from faulty systems and processes, proposed some solutions for a safer system and defined the six goals of health care: effective, safe, patient-centered, timely, efficient, and equitable (Kohn, 2000).

The problem is that doctors are pressured by organizations, law and society to have an error-free practice during diagnosis and treatments. Moreover, for damage compensation, in Portuguese civil code, it is obligatory the imputation of blame and the decisions which can be different if the responsibility is contractual (private medicine) or extra contractual (public medicine). In the cases where there was violation of *legis artis*, with real blame, disciplinary and penal procedures can be taken (Fragata, 2011). This creates an environment where mistakes are not discussed and, if possible, adverse events are not registered. Therefore this reduces the possibility of learning with errors and diminishes patient safety.

The Agency for Healthcare Research and Quality (AHRQ) has been doing an effort to reduce medical errors and improve patient safety. For instance, this agency created a high reliability network to allow the identification of new ways to reduce errors by the leaders of health organizations (Alonso, 2006).

The World Health Organization (WHO) that together with Joint Commission also promoted the world alliance for patient safety. This program lead to the international goal of safety in healthcare and as a result it was published in 2009 the international classification for patient safety. This classification consider the continuous improvement based on learning which means that it is focused in risk identification, detection, prevention and reduction, recovering from incidents and system resistance (Fragata, 2011, pg. 256). It also wants the uniformization of concepts, methodologies and definitions in order to reduce the risk in healthcare (Fragata, 2011).

The Swiss cheese model, also called cumulative act effect, is an accident causation model used in risk analysis and risk management. It is used not only for healthcare but also for aviation and engineering and it likens human systems to multiple slices of Swiss cheese, stacked side by side (Reason, 2000). Indeed, healthcare has been compared with commercial aviation. But, although this field has also been focused on safety and teamwork, the diversity and complexity in healthcare is higher, increasing the possibility of errors (Wachter, 2004).

Reason defined error as "any situation in which a sequence of planned physical or mental activities does not reach the intended purpose and when the failure cannot be attributed to chance and implies the existence of a plane gesture." (Reason, 1990; as quoted in Ballard, 2003).

It is possible to typify medical errors. Accordingly with the institute of medicine (IOM) (Konh, 2000), errors of implementation are a failure to execute a previously intended and planned action and errors of planning are the use of a wrong plan to achieve a particular end.

The adverse events (AE) are an injury caused to a patient due to medical intervention itself and not the underlying medical condition of the patient.

A non-preventable adverse event is an AE unexpected, in the absence of any error (*hypersensitivity reactions* during chemotherapy administration are a typical example).

A preventable adverse event is an AE due to an error (e.g. Prescription of a drug in a patient with known hypersensitivity to that drug).

A negligent adverse event is defined as a subgroup AE that occurs when the standard of care is not followed (e.g. prescription of trabectidine in a patient with levels of transaminases higher than 2.5 times the normal range).

Finally, the "near misses" are errors that do not induce any adverse effect on the patient (Carneiro, 2010; Kohn, 2000).

Several studies have estimated that around 4% to 17% of patients have an adverse event, and that up to half of these events could have been prevented (Sousa, 2006).

Errors that result in serious injury or any process variation for which a recurrence would carry a significant chance of a serious adverse outcome are considered "sentinel events" (Joint Commission on Accreditation of Healthcare Organizations, 2013).

In this cases it is necessary an immediate response, analysis to identify all factors contributing to the error, and reporting to the appropriate individuals and organizations (Reason, 2000).

As referred by Pepper "an individual is rarely the sole cause of an error…" (Pepper, 1995) and errors should be considered as system failures, instead of individual flaws" (Cassiani 2000, pg. 24). In fact, "errors can be committed either due to lack to standardize procedures" and failure to comply with the rules established" (Van Castle et al. 2004, p. 611).

Several system factors are related with errors in healthcare organizations: The latent factors are the organization, the managerial policies, the hierarchy, the work environment, the workload, the equipment, the physical agents and the fatigue; the active factors are the ones more implicated in lawsuits such as the mistakes, the negligence and the incompetence (Kalra, 2013).

Errors can be avoided using a well-designed interdisciplinary application and alert system that allow health professionals to be aware of the data that can influence decisions. (Van Castle, 2004).

It is necessary to gather the causes which contribute to the error, the most frequent types of errors and the implications that will arise from it and what actions were taken. (Pepper, 1995)

Several mistakes were already described in literature in the prescribing, transcribing or dispensing stages such as wrong doses, wrong routes, wrong patient, wrong drugs, wrong frequency, illegible or ambiguous prescriptions and prescriptions of one drug in a patient with a known allergy.

Human error has been implicated in nearly 80 percent of adverse events that occur in complex healthcare systems. The vast majority of medical errors result from faulty systems and poorly designed processes versus poor practices or incompetent practitioners (Palmieri, 2008).

The human factors are a well-known cause of error and the solutions to avoid them include five approaches (The Health Foundation, 2012):

1) Training the health professionals to prepare them for the work;
2) Selecting individuals for each specific job;
3) Improve work conditions;
4) Improve the working tools and automation;
5) Rearrangement of tasks between workers and automatic processes

It is fundamental to establish a strategy with priorities and hierarchy's interventions which could represent a global framework and allow the organizations to engage all stakeholders who are involved in patient care (Sousa, 2006).

Healthcare organizations should create measures to improve quality and patient safety and for that it is necessary to have a culture of safety and to consider the management of clinical risk (Benner, 2005).

Healthcare will always involve risk but the risk can be lower with notification, the analysis of incidents and a strategy to help organizations promoting a culture of fairness (Sousa, 2006).

In the departments of oncology, as already mentioned by Cook about the general healthcare, to create safety, anticipate hazards and battle against intrinsic inefficiencies are all important issues to improve the quality (Cook, 2000).

Oncological drug therapy regimens have become increasingly complex which increasing the risk of injury (Cohen, 1996) since new drugs are released every year on the field and health professionals are frequently not trained in their management.

Given the interdisciplinary nature of oncology and the necessity of collaboration among the different professionals, teamwork is even more important than in other areas of medicine to improve patient safety but it should be based in mutual respect and trust.

Drug error prevention is a main goal in oncology since antineoplastic agents have a lower safety margin. Moreover, the type of medication, intervals between administrations, doses and associations are different in function of tumor type and stage of disease. It is therefore essential to develop and implement a structured error-avoidance plan and to be assertive in the request of resources for prescribing, processing, dispensing and administration of medication. It is also necessary the creation of a safety environment with double checking procedures, reduced noise levels, minimal distractions, adequate light, with the continuous improvement of drug storage, automation, technology and protocols (Dwight, 2010).

Evolution of patient-doctor relation

The relationship between doctors and their patients has received philosophical, sociological, and literary attention since Hippocrates, and is the subject of some 8.000 articles, monographs, chapters, and books in the modern medical literature (Goold, 1999).

Hippocrates brought the notion to medical practice that diseases have a natural cause and that there are means to fight the diseases (Rueff, 2009, p. 56). Moreover, Hippocratic texts mentioned that physicians should not damage patients, be fraudulent, abuse or treat patients differently depending on their legal-political connection or social condition (Rueff, 2009, p. 47).

The Hippocratic spirit defended that "all human beings are equal because they all represent nature in its multiple, rich and very small variety" (Rueff, 2009, p. 117).

At the time of Hippocrates, doctors were paternalistic and were considered the mediators of a divinity because they not only decided on what to do (without any interference of the patient) but also were considered to have the power over life and death (Rueff, 2009, pg. 121).

During centuries paternalism was the main position for the majority of doctors and was taught in medical schools. Only recently, with the development of bioethics and medical ethics, occurred a shift on the paradigm with an increase in patients' autonomy (Rueff, 2009).

Hippocrates defended secrecy and confidentiality in medical practice (Rueff, 2009, p. 60). This condition allows to establish a relationship of trust with more effective diagnoses and treatments. A good relationship between the patients and their doctors will allow physicians to establish with more accuracy causal factors and patients will be more prompt to do the proposed treatments.

However, many of the Hippocratic writings ended with patients' death which is similar with what happens in medical oncology. Hippocrates

believed that if doctors "do what must to be done" they should not be upset with a bad result (Rueff, 2009, p. 52).

A robust science of the doctor–patient encounter and relationship should guide decision making in health care plans for oncology, especially for prescription of chemotherapy (Goold, 1999).

The omission of facts contributes to deteriorate the relationship of trust that should be present between doctors and patients. However, when a fault occurs is difficult for physicians to handle and admit an error because of the fear of being considered individual blamed with consequent conviction (hierarchical, institutional and public disclosure). Therefore, medical responsibility should be objective and systematic reporting should not lead to incrimination as observed in countries such as Portugal.

Another problem in patient-doctor relationship is that physicians not always respect the wishes of competent patients to know about their diagnosis and prognosis even in countries with a high value on patient autonomy (Elger, 2002). The growing number of oncological cases puts also pressure on the time that every doctor can spend with the patient. It is important to allow enough time for the patient to speak out his doubts and fears, otherwise a doctor-patient relation that is benefical for the patient will not be obtained.

1. The growing patient autonomy

In the presence of an error is always necessary to consider the patient (victim), the clinicians and the patient's family (Fragata and Martins, 2005). So, "the patient is entitled to be encouraged and obtain from physicians and other direct care providers, timely and understandable information regarding the diagnosis, treatment and prognosis" (Thompson, 2004, p. 404).

The patients have the right to the truth about their diagnosis, treatment and prognosis (article 340 — civil Portuguese code; article 156 — Portuguese criminal code)[1, 2]. If a mistake was practiced upon a patient, accordingly with ethical principle of justice, he has right to have knowledge of it and to be physically repaired and compensated for damages (Law nº 67/2007, 31st September)[3] considering extra-contractual/ delictual responsibility (art. 483rd Portuguese civil code). The Convention of Oviedo mentioned that "any intervention in the health field may only be carried after the person concerned has given his consent in a free and enlightened manner" (Convention on Human rights and biomedicine, 1997).

In order to ensure a high quality health service, it is essential to observe the patient's rights and meet their needs and expectations, as well as offering the best service possible (Erer, 2008). It is important to ensure basic rights of the individual through various legal regulations in order to ensure a high quality in oncology. Patient rights as an extension of human rights in oncology have to allow equity, access, privacy, respect and constant health services. Full information and truth-telling are considered sensitive subjects in diseases such as cancer (Erer, 2008). However, when we are thinking in potential harmful treatments it is essential that patients can make decisions freely with the best possible information.

The preponderance opinion is that "Disclosure is the right thing to do" however, if medical errors

result in patient injury, disclosure often does not occur (Mizrahi, 1984; Allman, 1998; Blendon, 2002; Lamb, 2003).

Patient consent disclosure is related with the provision of relevant information by healthcare professionals and with patients understanding of that information (Etchells, 1996).

Disclosure promotes a reflective participation of the patient and a relationship based on trust between patients and doctors (Etchells, 1996). Taking the example of a patient with cancer that has indication for chemotherapy, the description of the treatment and its expected effects (e.g. adverse events, pre-medication needed, duration of the administration, expected time to recovery, restrictions on daily activities); information about alternative drugs and their expected advantages, disadvantages and relevant risks and an explanation of the consequences of declining or delaying treatment (diminished time until disease progression).

The disclosure of information should be adapted to each one of the patients, allowing for the opportunity for the patients to ask questions and time for the clinician to respond to all the questions or requests (Etchells, 1996).

Patient autonomy is a growing concern in health care and medical ethics and the idea that patients should take up an autonomous position in the decision-making process is generally appreciated (van Kleffens, 2004). But what is meant by patient autonomy and which factors influence patient autonomy? Uncertainty continues to surround the concept of autonomy (Schermer, 2001) and there are different concepts of autonomy (Beauchamp & Childress, 2001; Ten Have, 2000; Schermer, 2001). However, we can say that patient autonomy is the right to make decisions using their own self-determination, without the doctor trying to influence the decision. This does not allow the health care provider to make the decision for the patient, even knowing that cancer treatment is an asymmetrical process (van Kleffens, 2004).

Concepts like patient autonomy and informed consent have been used to balance physicians' dominance in medical decision making. Informed consent is an autonomous authorization form the patient to do a certain treatment after disclosure of medical information (Beauchamp & Childress, 2001). Especially when physicians are proposing aggressive treatments, the disclosure should be as complete as possible in order to ensure an independent judgment during the process of decision making (van Kleffens, 2004). Therefore, when a patient gives informed consent for oncological treatments it is supposed that he will be informed of everything that could happen (Thompson, 2004). This fiduciary responsibility means that anyone entrusted to oncological care, should voluntarily surrender to them and trust. (Thompson, 2004, p. 80).

The "break of duty is a target for judicial process" (Thompson, 2004, p. 110). Likewise, in oncological treatments the risk of dead is a reality and informed consent is essential (Article 340 of the Portuguese Civil Code and Article 156 of the Portuguese Criminal Code) [1, 2]. It is important to realize that consent forms should not replace detailed information about the situation and/or procedure to be performed. An explanation about the treatments is better for a shared decision-making, reconciliation and collaboration between doctor and patient (van Oosten, 1993).

Therefore, the accuracy of the information and the promotion of conditions for the effective exercise of patient autonomy have become key issues in current medical practice (Rueff, 2009) particularly for oncology.

In Portugal, interventions or treatments without patient consent can be punished with imprisonment up to three years or a fine and the patients can accept or refuse the treatment that is offered to them (Law on Health, Base XIV)[4].

A study performed in 2004 analyzed the concept of patient autonomy in a practical view on oncological patients. The researchers found that patient autonomy is a multi-layered modality in which values of freedom, independence, trust, and responsibility reveal to be important with regard to oncological patient autonomy (van Kleffens, 2004).
228 Unexpectedly, the results show that patients who refuse an oncological treatment do not so much rely on the medical information they receive but also in patients' experience of having the freedom to choice. Accordingly with this research, an oncological patient who does not experience a possibility to choose, can still have the idea of being free to make a decision. However, medical information influence patients' experiences of being free and/or of having a choice and the extent of pressure physicians will exert to persuade the patient to be treated as recommended depends on factors such as treatment goal (curative vs. palliative) (van Kleffens, 2004).

Doctors have ethical and technical autonomy (4th and 125th — medical professional code)[5,6] even when they are in public functions (Law 58/2008, 9th September) but physician-patient relationship is changing from the paternalistic classic model, where patient involvement is limited to providing consent and the doctor exert control over information and treatment (Tariman, 2013).

The shared decision-making (SDM) model has challenged the paternalistic approach during the past several decades (Brock & Wartman, 1990). This was mainly due to the different treatment options for one particular disease with different types of trade-offs between benefits and risks, as seen in patients with cancer (Charles, et al., 1999; Gilbar & Gilbar, 2009; Tariman, 2013).

New models emerged but we can identify four patterns of decision-making, which include physician-controlled, patient-controlled, jointly-controlled and family-controlled decision making (Tariman, 2013). In fact, sometimes patients transfer decision for their family or they do not want to know their prognosis.

It is now recognized a right of not-knowing which is a dimension of the principle of autonomy of the human person, the right to private life , in right to free development of personality , integrity and self-determination of the patient (Oliveira, 2006).

2. Right of not knowing

There was a change in doctor-patient relationship from the old paternalism where the clinicians were allowed not to tell the truth to the patient, to an attitude focused in patient's autonomy in the last decades. The main point of view was the patient's rights to be informed about treatments benefits, risks and prognosis and to give consent to any kind of intervention (Andorno, 2004). Therefore, the ethical

and legal principle "the right to know" has become fundamental in clinical practice.

The need for an informed consent before any medical intervention is a well-known rule of biomedical ethics (Andorno, 2005). The patient should give his freely consent after knowing the nature, risks and consequences of oncological treatments. The free consent became important after the world discovery about the research on concentration camp prisoners with Nazis and the Nuremberg code in 1947[7] was the first step in the development of measures to avoid medical atrocities (Andorno, 2005). Nowadays, based on both UNESCO declaration and WHO guidelines it is necessary for patients to express their wishes if they do not want health professionals to disclose information about diagnosis, treatment and/or prognostic (Andorno, 2005).

However, published studies have indicated that 6% to 18% of patients prefer not to know about the risks of treatment (Bunker, 1983; Farnill, 1993; Dawes, 1994). Moreover, the "Declaration on the Rights of the Patient" revised on October 2005, "the patient has the right not to be informed on his/her explicit request, unless required for the protection of another person's life" (World Medical Association, 2005).

The no disclosure puts patients in a state of ignorance, depriving them of choice therefore, the right of not knowing is largely criticized. It is the opposite of patients' autonomy considering that the autonomy depends on the capacity to understand the relevant information (Andorno, 2004).

Cancer patients are in a situation of fear and anxiety which led some patients to express the desire of not knowing their prognosis. If we consider autonomy as an individual's self-determination, we can say the right of not knowing is part of a bioethical principle of self-determination and should be as respected as the decision to know (Andorno, 2004). Oviedo Convention also mentioned the right of not knowing as an exception when it says that "…the wishes of individuals not to be informed shall be observed." [8]

This convention was the "first multilateral binding instrument devoted to biomedical law and the countries who ratified it are obliged to introduce implementing legislation to bring their national laws into conformity with its principles". It also aspires to cover the whole domain of bioethics and addresses the linkage between human rights and biomedicine. This instrument aims to set up a framework of principles to prevent practices that would most seriously infringe on human rights and human dignity (Andorno, 2005).

3. Therapeutic privilege in oncology — how far it is feasible?

The term "Therapeutic privilege" refers to the withholding of information by the clinician during the consent process in the belief that disclosure of this information would lead to the harm or suffering of the patient.[6]

A legitimate question that arises is whether it is permissible to inform all cancer patients about the risks of treatment and prognosis. For example, if the patient is depressed, can this information have negative effects that become detrimental to the patient? This question arises incidentally contemplated in paragraph 1 "in fine" Article 157 of the Criminal

Code that allows the non-disclosure of information to the patient "if it involves the communication of circumstances, to be known by the patient , would endanger his life or would be likely to cause serious harm to health, physical or mental". Doctrine calls the faculty that assists the physician to withhold information when there are life threatening or serious injuries as "therapeutic privilege" or as therapeutic exception (article 157 — Portuguese criminal code) [9].

The non-discloser of information is an exception to informed consent but does not apply when disclosure will merely lead to refusal of care that the physician thinks advantageous. In trial court it should be ensured that the decision of the physician to withhold information was based on specific considerations in the individual patient's case and those considerations should be identified.

Some data mentioned the probability that therapeutic privilege has been "vastly overused as excuse for not informing patients of acts they are entitled to know" (President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1982; van den Heever, 2005).

Disclosure should be viewed as a process and normally several encounters are needed between the doctor and the patient before complete disclosure (Etchells, 1996). This will allow the patient to interiorize the information and to do some mental adaptation to a complex and/or dramatic situation such as cancer. An effective communication is critical in order the patient can be encouraged to provide personal information such as his or her values, goals and fears (Etchells, 1996).

In oncology, cultural or religious considerations are particularly important. For instance if a patient is a Jehovah's Witnesses and completely refuse transfusions it is very important to inform that certain oncological drugs can cause severe anemia with an high likelihood of needing transfusions. In this case the patient has to have the best possible information to decide if he or she wants to do the indicated treatments or not. In fact, understanding and compliance of oncological patients is fundamental to have an efficient treatment. The main problem is that a large number of cancer patients have a poor prognosis and for that reason most of healthcare professionals do not favor the total disclosure of information about prognosis (Elger, 2002)

Most of patients with cancer have indication for aggressive treatments therefore, it is necessary to be careful about the non-disclosure of information. It is necessary to have an exceptional circumstance such as a real treat to patient's physical and mental health or when a patient is unable to do a rational decision based on that decision. Moreover, "the legal, ethical and moral principles relating to the medical practitioner's therapeutic privilege should protect patient autonomy without unduly restricting medical judgment, with the object of achieving the best medical result for the patient" (Van den Heever, 2005, pg. 421).

Chemotherapy, hazards and specific risks

The administration of chemotherapy is a process with different stages in which errors can happen. Strategies to minimize the occurrence of errors should be implemented and published. The errors

in oncology can lead to morbidity, mortality and resources consuming. Therefore, they should be identified, analyzed and controlled (Carneiro, 2010).

A medical error can be defined as a preventable adverse effect that can be or not evident or harmful to the patient.

In a study published by Ghandi and colleagues, 10.112 medication orders were reviewed in 1606 patients and the researchers found an error rate of 3% with 2% potential harmful. However 45% of errors were detected and avoided by nurses and pharmacists (Ghandi, 2005).

The gaps in knowledge are the systemic causes and are often related with dosages of medications to administer (Leape, 1991) and in the case of chemotherapy; a serious medication error can lead to patient death. Antineoplastic agents are frequently given in combination with an increase of efficacy but at the same time with a higher toxicity and complexity. In addition, the increasing number of new drugs in the different oncological pathologies can lead to unavailability of protocols with these new treatments.

We can take the example of cetuximab and panitumumab which are monoclonal antibodies approved in colon cancer. This drugs can be administered in patients with *ras* wild type in monotherapy or, preferably, with 5-FU based chemotherapy. However, the time until inclusion of these alternative treatments in the existing protocols is not homogeneous between hospitals. Thus, not only there are a problem of equity but the potential for the occurrence of mistakes is increased since the way of prescribing the new drugs is not well known by physicians and it is necessary some expertise to do it well.

Nowadays, the majority of oncological medication is provided in the ambulatory setting and there are several potential causes for chemotherapy medication errors such as miscommunication verbal orders; wrong doses; the use of trade names instead of generic names; lack of procedures and warning labels to prevent inadvertent intrathecal administration of drugs such as doxorrubicin and vincristine; use outdated laboratory values; the existence of different doses and regimes for the same disease in the same stage; the use of abbreviations; similar sounding names; long distances between the pharmacy and the administration area; excessive interruptions during prescriptions and drug preparation; lack of a proper copy or use of fax copy which may be illegible (Dwight, 2010, page 12)

The detection of answers to several mistakes in chemotherapy administration can be done by several means such as clinical files review, trigger tools, quality indicators systems (the *Agency for Healthcare Research and Quality* in EUA has one of the best lists) and audits. Likewise, it is necessary to accept the limits to system performance, optimize security strategies and, if possible, to simplify rules and procedures (Carneiro, 2010).

Health professionals organize their work more or less methodical with a systematic routine that seek to address the particular needs of each individual. Accordingly, in Portuguese law damage resulting from the commission of errors are evaluated in the light of culpability of an individual, as if this is found isolated from the environment in which the error occurred (Fragata and Martins, 2005). This attitude does not prevent errors in the case of chemotherapy because preventing one individual error

does not change the trajectory of potential mistakes, as explained by Reason in the Swiss cheese model (Reason, 2000).

The possibility of error is higher in oncology since patients invariably use more drugs and more complex combinations of drug therapies. Indeed, patients with cancer are subject to treatments and spend much more time in the hospital than the regular patient. These kinds of patients (that remain longer times in the hospital) have higher probability to suffer damage as a result of errors (Fragata and Martins, 2005, p.32).

Several measures has been proposed to reduce drug errors such as the introduction of computerized prescribing systems (Bates, 2000), pharmacist participation in drug root (Leape, 1999), double checks in the several steps until drug administration, standardization of the prescribing language, avoidance of abbreviated words, avoid putting a trailing zero, set up a multidisciplinary team to review the prescriptions, education about chemotherapy drugs for health care providers, patients and their families (Cohen, 1996).

However it is necessary to consider that computerized systems sometimes have technical problems and in case of electronic failure, prescription can turn to be impossible during a certain period of time with consequences for patients and for all the organization. This knowledge turns in a necessity the existence of manual alternatives and the double checks in the process of chemotherapy administration.

In Portugal there are just a few statistics about the size of the error in health organizations (Weingart, 2000). As far as we know patients with more serious conditions, such as the ones in chemotherapy, are more subject to damage as a result of errors (Fragata and Martins, 2005, p.32). Indeed, the risk of occurrence of an error is higher in the more complex, invasive and random situations as already mentioned above. The reliability of the professional organizations is also important for the occurrence of errors. We can understand this reality taking the example of errors that can occur until and during chemotherapy administration considering breast cancer.

Safety in the administration of chemotherapy — a practical application in breast cancer

In one of the main Portuguese hospitals, 63 clinical files from female patients with breast cancer (one of the most frequent pathologies in oncology), with necessity for intravenous chemotherapy, were reviewed.

We did a transversal study with review of clinical files in which the first visit was between January and April 2012. The inclusion criteria were female patients with breast cancer with necessity for intravenous chemotherapy.

A FMEA (Failure Mode and Effect Analysis) was used for analysis of the potentially avoidable errors in breast cancer treatment (see figure 1 — appendix 1). This is an instrument whose purpose is, through the research of potential failures at each stage of illness trajectory and proposing actions to improve, enhance security and reliability of a product or procedure.

We did not found, so far as was possible in the literature search, FMEA designed for the trajectory

of chemotherapy administration in breast cancer so, the authors adapted the existing health care[10].

The severity index ranges between 1 (minimum) and 10 (very high) and the rate of detection from 1 (definitely will be detected) and 10 (certainly not be detected).

We create a visual map of the process and identify possible failure modes (see figure 1). However, we did not found literature data on the occurrence of failure, which prevents the calculation of risk indicators.

The study used a frame of qualitative methodology from the type exploratory and descriptive.

We also analyzed peer review articles which allowed the evaluation of the causes of errors in chemotherapy extravasation and some of the recommended actions.

Results revealed that failures occurred in different stages of chemotherapy probably with different degrees of severity and detection. However, occurrence, severity and detection of errors were not available so, it was impossible to calculate risk indices (absence of a culture of systematic reporting). Mainly, we can consider seven different steps from the moment the patient is informed that he has to do chemotherapy until treatment administration.

The first step is when the patient is informed by his oncologist that he has to do treatments with cytotoxic and/or biologic drugs. This kind of information is supposed to be understood by the patient and the items related with adverse events should be perceived. In fact, a good communication between doctor and patient, with a valid informed consent can avoid errors.

In order to allow an adequate decision, staging should be done in a proper way, especially if the patient has to do treatments with severe adverse events such as chemotherapy (e.g. alkylating agents, taxanes and/or anthracyclines) or biologics (e.g. trastuzumab, cetuximab, panitumumab, bevacizumab, everolimus and several others).

Multidisciplinary teams are essential for choosing the best available treatment and electronic prescription with specific protocols and electronic records will be important to minimize errors such as misreading of drugs names and failures in dose calculation.

Teams with a common goal and integrated in a culture where transparency (among caregivers, between caregivers and patients, between organizations and with the public) reduce the probability of mistakes (Leape, 2013).

Teams should be effective and therefore it is necessary to examine the environmental conditions, give specific training to develop individual level competencies, afford team members to practice the learned skills and give feedback of that same work (Baker, 2006).

It is necessary cooperation between oncologists, surgeons, radiologists, radiotherapist, pathologists, pharmacists, nurses and other health professionals because the management of cancer patients involves the administration of complex treatment protocols with necessity to monitor the effects of treatment (Hammond, 1994).

Electronic prescription with specific protocols and electronic records will be important to minimize errors such as misreading of drugs names and failures in dose calculation. The electronic prescription leads to a reduction of the transcription errors and the individual method of work assumes extreme

importance in the increase of patient safety. A computer with electronic prescription also eliminates the problem of deciphering prescriptions and allows providing decision support (Van de Castle, 2004; Weingart, 2001). However, it has been difficult to start electronic prescription in the department mentioned above because several informatics errors were detected in the program and there have been delays in solving them. It is therefore important to guarantee that a measure to prevent mistakes does not lead to another kind of potential harmful events.

In the study mentioned above, the researchers identified four cases of extravasation from chemotherapy in one year and one of the patients had the necessity to be evaluated by plastic surgeon. Other errors were not reported by clinicians in the clinical files.

As observed in the study mentioned above, errors in chemotherapy administration occur during the process and/or in the prescription and can lead to morbidity and mortality which should be avoided (Oliveira, 2008). Indeed, the toxicity of many oncological treatments turn all decisions potential harmful and there are benefits of combining different approaches (formal and informal) to analyze and represent safety (Hammond, 1994).

Ethical and professional guidelines emphasize the responsibility to disclose medical errors based on disciplinary responsibility (American Medical association Council on ethical and judicial affairs, 2000; Mazor, 2013). Moreover, medical accidents are intolerable (political and financial) due to their consequences and costs (Carneiro, 2010) and the break of duty is a target for judicial process.

Measures to prevent errors must be applied to cancer chemotherapy (Cohen, 1996) and notification is essential in order to identify their occurrence and severity. Moreover, a culture of trust and reporting inside the departments of oncology is important to improve patient safety.

Notification of errors, approaches in different countries and opportunities for improving patient safety

Healthcare organizations have a growing interest in changing the culture based on personal blaming to one in which errors are treated not as personal failures, but as opportunities to improve patient's safety (Nieva, 2003). In punitive cultures there are chronic underreporting problems and analytical methods such as root cause analysis (RCA) and failure mode effects analyses (FMEA) will not succeed in uncovering latent sources of error if health professionals do not break the "code of silence" and start to expose the weaknesses of processes (Nieva, 2003).

A culture of risk and safety in health organizations accepts that accidents happen as a result of complex trajectory errors or failures mostly of which can be avoidable (Fragata and Martins, 2005). Moreover, the systematic approach allows us to evaluate what happened in a pragmatic manner without serving to justify mistakes (Fragata and Martins, 2005). The identification of missing circuits and the promotion of mechanisms to improve security will make others less likely to make mistakes and, if errors occur, it will allow a minimal harm to the patient (Fragata and Martins, 2005, p. 41).

Notification is probably reduced or even absent in European health systems since error notification can lead to incrimination. Since health professionals fear of legal prosecution or financial penalties, they tend to respond corporately, which obscures understanding (Carneiro, 2010). So, a systemic approach of the errors facilitate error notification by the person who commits them (Fragata and Martins, 2005).

There are several models with voluntary notification in which the reporting is much lower. For another side, in structures with quality control and that intend to have international accreditation, notification is obligatory (Casabona in: Rueff, 2013).

"Failures threaten patient safety" (Carneiro, 2010, pg. 6) so, it is necessary to gather the causes which contribute to the error, the most frequent types of errors and the implications that will arise from it and what actions were taken (Pepper, 1995).

An adverse drug event prevention study analyzed 4031 adult admissions in USA hospitals during 6 months and reported that 49% of errors occurred in prescription (wrong dose, wrong frequency, known allergy and wrong choice), 11% in transcription, 14% in dispensing and 26% in administration (Bates, 1995; Leape, 1995).

In countries such as the United States it is essential to report medical errors as a condition to be paid by some insurances (Pear, 2012) but most of the errors are not reported because the fear from health professionals and the lack of knowledge regarding which events are reportable and recommended (Office of Inspector General, Department of Health and Human Services released January, 2012).

The healthcare *reporting systems* should function in an anonymous way, confidential, and also follow a normative regulation and allow a retrospective analysis of errors in order to achieve greater confidence of health professionals. The goal of reporting medical errors is to transform it in safety (Kalra, 2013). Moreover, it should increment transparency and legal security (Casabona in: Rueff, 2013).

In Portugal, it was created the SNNIEA ("Sistema de notificação de incidentes e de eventos adversos) which is a new platform of adverse events for voluntary notification from health professionals and that is able to do the causal analysis of errors. This platform is anonymous, confidential and non-punitive. It will do the management of incidents and adverse events that occurred in the care units of the National Health System[11].

In Portuguese law, such as in other European countries, errors notification can lead to incrimination so, reporting is therefore reduced or even absent and damage resulting from the accumulation of errors are evaluated in the light of culpability of an individual (Fragata and Martins, 2005).

The real problem is the identification of health professionals in the process that lead to a certain mistake. The predominant option in comparative law is anonymisation of data regarding the identity of the subject (Casabona in: Rueff, 2013).

To accomplish the goal of a good notification system it is necessary a consistent disciplinary and civil responsibility (Oliveira, 2005; Fragata and Martins, 2008) with completely anonymous systems of notification.

Conclusions and problems remaining to be solved

Patient safety is a serious problem in health and it is important to define a strategy in order to reduce the probability of errors. Oncologists should try to identify the different areas for chemotherapy administration, establish priorities and select indicators to evaluate the efficacy and effectiveness of the processes.

However, blame is still a mainstay solution and most healthcare organizations do not recognize that safety should be a precondition, not a priority.

An evaluation of errors in the system without complaining the individual people could be beneficial (Reason, 1997). It is unlikely that errors occur due to a single act of a health professional and individual blaming is not a form of preventing the repetition of the error and do not address risk factors underlying. The problem of patient safety among institutional health is not the bad professionals, but the bad systems, which also need to become safer (ICN, 2005).

An approach based on transparency and proactive communication, not blaming the individual worker, and incorporating measures covering the human factors and system in harmful situations can prevent errors in cancer chemotherapy administration (Cohen, 1996).

The importance of patient-doctor relation cannot be forgotten, among all the innovation and technology in healthcare. Allowing more time for the medical appointment permits also to avoid potential mistakes, such as overlooking drug allergies.

There is also necessity for simplification of rules and professional procedures (simplification of the system), to eliminate regulations that are counterproductive and to return more autonomy to professionals (Carneiro, 2010).

Centers delivering chemotherapy must have systems to prevent errors which should be continuously revised. Cooperation between different health professionals with multidisciplinary teams can help to establish effective and practical strategies to improve patient safety and to create in the hospitals a culture of error reporting. It should avoid blaming the individual and be more focuses in the processes.

Medical interdisciplinary, evidence based medicine, notification systems with legal protection for health professionals are essential for patient safety in chemotherapy administration.

The constant innovation in oncology lead to adverse effects not yet known due to new drugs so, a constant need for updating and identification of errors is needed. If it is not created a new notification system of errors with guarantee of legal protection for professionals, defensive medicine will be overspread with increased costs and without beneficial to patients.

Excellency in oncology is based in teamwork, a culture of trust, transparency and evidence based medicine.

More studies should be done to explored chemotherapy safety and errors in order to find possible solutions to improve patient safety in oncology.

Oncological departments are dynamic, give rise to greater reliance on teams and have an increasing complexity. It is therefore a necessity to be aware of the consequences of errors in order to turn its occurrence extremely low. Only that way we can

have high reliability organizations for cancer patients with an increase of efficiency as well as safety.

Endnotes

[1] **Article 340 — Portuguese civil code** (Consent of the victim)

1- "The act adversely affecting the rights of others is lawful, provided that it has consented to the injury."

[2] **Article 156 — Portuguese Criminal Code**

(Arbitrary interventions and medical and surgical treatments)

1 — "The people mentioned in Article 150, in view of the purposes indicated that conduct interventions or treatments without patient consent shall be punished with imprisonment up to 3 years or a fine."

[3] Law No. 67/2007, 31st September

(Approves Scheme of Liability Extracontractual State and Other Public Entities)

Article 1

1 — "Noncontractual liability of the State and other public law for damages resulting from the exercise of legislative, judicial and administrative function persons is governed by the provisions of this law , in all matters not provided for by special law."
2 — ..."correspond to the exercise of administrative function actions and omissions taken in the exercise of public power or regulated by provisions or principles of administrative law.

3 — ... also regulates the liability of holders of bodies , public servants for damages arising from acts or omissions taken in performance of administrative and judicial functions and because of this exercise."

4 — "The provisions of this law are still applicable to the liability of other workers in the service covered entities, considering these extensive references to holders of bodies, employees and agents."

5 — "The provisions in this law governing the liability of legal persons in public law , as well as members of its bodies , employees and agents , for damages resulting from the exercise of administrative function , are also applicable to the liability of legal persons private and their employees , corporate officers , legal representatives or assistants , by acts or omissions which they adopt in the exercise of public authority or which are regulated by provisions or principles of administrative law right."

Article 3

1 — "Who is obliged to repair damage, according to the provisions of this law, must reconstruct the situation that would exist if the event had not occurred requiring repair"...

Article 5 — "The right to compensation for non-contractual liability of the State, other legal persons governed by public law, the holders of the respective agencies, officials and employees as well as the right of return"...

Article 6

1 — "The right of return, where this is provided for in this law, shall be binding, subject to disciplinary action that may arise."

[4] **Law on Health, XIV Base**

(Statute of users)

1. Users are entitled:

b) "To accept or refuse the provision of care that is proposed to them, unless specifically provided otherwise by law"…

[5] **Article 4th — Portuguese medical professional code**

(Independence of Physicians)

1. "The Doctor, in the exercise of his profession, is technically and ethically independent and responsible for their actions, not may be subject to technical and ethical orientation of strangers to the medical profession in the exercise of clinical functions."
2. "The preceding paragraph does not contradict the existence of legally or contractually established institutional hierarchies techniques can not in any case be constrained to a Physician Medical practice acts against their will."

[6] **Article 125 — Portuguese medical profissional code**

(Freedom of choice in diagnosis and treatment)

1. "The freedom to choose the doctor in diagnosis and treatment cannot be limited by statutory, contractual or regulation or enforcement authority to provide medical care."

2. "The preceding paragraph shall not prevent the committal hierarchical medical doctor which, if any, shall be held always in the interest of the patient."

[7] The Nuremberg Code (1947) In: Mitscherlich A, Mielke F. Doctors of infamy: the story of the Nazi medical crimes. New York: Schuman, 1949: xxiii-xxv

[8] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Oviedo.

Article 10. Private life and right to information. 1 — "Everyone has the right to respect for his private life in relation to information relating to your health." 2 — "Any person has the right to know any information collected about your health. However, the wishes of individuals not to be informed shall be observed."

[9] **Article 157 — Portuguese criminal code**

(Duty of clarification)

"For purposes of the preceding Article , the consent is effective only when the patient has been properly informed about the diagnosis and character , reach, scope and possible consequences of the intervention or treatment" (...)

[10] HFMEA. Veteran's health administration national center for patient safety. Healthcare failure mode and effect analysis course materials. [Accessed 2013 November 27]. Disponível em www.patientsafety.gov.

[11] Norma nº 008/2013 de 15/05/2013 — Direcção-Geral da Saúde. www.dgs.pt/directrizes-da.../norma-n-0082013-de-15052013-jpg.aspx

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Appendix 1

STEP	FAILURES	EFFECT	CAUSE	POSSIBLE DETECTORS	RECOMENDED ACTION	RESPONSIBLES FOR CORRECTION
Information	communication	Wrong perception	incomplete Information	Patient/ Nurse	Confirm information; informed consent	Doctor/ nurse
Staging	Incomplete staging	Treatment delay	Quantity of work/ Inexperience	Doctor	Verify all the exams	Doctor
Treatment decision	Wrong choice	Inefficacy / loss of efficacy	Inexperience	Doctor/ Pharmaceu tic	Electronic prescription; multidisciplinarity	Doctors (Team)
Dose calculation	Wrong doses	Toxicity/ loss of efficacy	Quantity of work/ inexperience	Doctor/ Pharmaceu tic	Double verification: electronic prescription	Doctor/ Pharmaceutic
Blood tests	No results	Treatment delay	forgotten	Doctor/ Nurse	Programming the collection for the previous day	Doctor
Venous catheterization	Difficulties in catheterization	Treatment delay	Wrong evaluation	Nurse	Central catheterization	Doctor
Treatment administration	Extravasation	Tissues lesion	Damaged veins; inexperience	Nurse/ Patient	Emergency KIT	Nurse

Figure 1 — FMEA (*Failure Mode and Effect Analysis*) for chemotherapy administration in breast cancer

Chapter 3: Learning with errors

PHARMACEUTICAL RESEARCH ON CHILDREN IN GERMANY

Bernd-Rüdiger Kern [1]

I. Introduction

Medical research on minors raises ethical as well as legal problems. The legal debate is based on the fact that medical interventions for children are only permitted if they are indicated. The indication is not at least necessary to protect our youngest patients from dangerous medical trials.

Normally, parents or other custodians are not allowed to agree to non-indicated medical interventions. On the other hand, pediatricians stress the need to research on minors to improve the safety of drugs and pharmaceutical products for the simple reason that children cannot simply be seen as "little adults" because their bodies differ from those of adults. As a matter of fact, about 80% of children's treatments are off-label-use, because there are not enough evidence-based studies with children. So we need to pay attention to ensure the safety for all children.

In addition to a non-negligible economical aspect, in Germany the main problem is, that there is no statutory rule or regulation that states that the medical treatment of an individual person takes precedence over every kind of medical research using pharmaceutical drugs. Nevertheless, this lecture wants to emphasize the necessary priority of medical attendance.

Therefore this lecture attempts to classify this subject in its legal sphere. Based on the statutory regulations of the German Medicinal Products Act (German: "Arzneimittelgesetz", hereafter AMG), the conditions of pharmaceutical research on persons who are — on grounds of age — incapable of giving consent will be presented, including the existing problems. Thereby we will also consider the basic decisions and evaluations that the legislator has to take; for example, the chances of research using medications have to be higher than its risks, especially if it does not serve the own personal health of the test person. Besides the specific therapeutic indication and the question of how to compensate this condition if it is missing, information and consent with the medical treatment are — similar to every curative treatment — of particular importance to support the intention of the lecturer. Unfortunately, the AMG is not very clear in its structure.

II. The basic decisions of the German Medicinal Products Act

1. The balance between benefits and risks

§§ 40 and 41 of the AMG provide the conditions for research on all human beings. The

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admissibility of this kind of research depends on two main factors: a medical one and a voluntative one. Although therapeutic indication is not strictly required, according to § 40 sec. 1 s. 3 nr. 2 of the AMG clinical trials "of a medicinal product may only be conducted on human beings if and as long as the foreseeable risks and inconveniences are medically justifiable, compared with the benefit for the person on whom the clinical trial is to be conducted (person concerned), and the anticipated significance of the medicinal product for medical science" and if the person concerned agrees. The balance between benefits and risks depends not least on the benefits to the concerned person. The problem at the research of concerned children is, who may agree instead of them.

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2. Groups of cases

Concerning this subject, §§ 40 and 41 of the AMG also determine different cases — some of which are really difficult to understand:

a) healthy minors capable of giving consent and if the medical product is intended to diagnose or to prevent diseases in minors and if the use of the medical product is indicated for the purpose of diagnosing or preventing disease in the minor himself (§ 40 sec. 4 nr. 1 nr. 3 s. 4 AMG),

b) healthy minors incapable of giving consent and if the medical product is intended to diagnose or to prevent diseases in minors and if the use of the medical product is indicated for the purpose of diagnosing or preventing disease in the minor himself (§ 40 sec. 4 nr. 1 nr. 3 s. 3 AMG),

c) diseased minors capable of giving consent who themselves do benefit from the use of the investigated medical product (§§ 41 sec. 2 s. 1 nr. 1, 40 sec. 4 nr. 3 s. 4 AMG),

d) diseased minors incapable of giving consent who themselves do benefit from the use of the investigated medical product (§§ 41 sec. 2 s. 1 nr. 1, 40 sec. 4 nr. 3 s. 3 AMG),

e) diseased minors capable of giving consent and who do not benefit themselves from the use of the investigational medical product, but where the clinical trail has some benefit to the group of patients suffering from the same disease as the person concerned (§§ 41 sec. 2 s. 1 nr. 2a, 40 sec. 4 nr. 3 s. 4 AMG),

f) diseased minors incapable of giving consent who do not benefit themselves from the use of the investigational medical product, but where the clinical trail has some benefit to the group of patients suffering from the same disease as the person concerned (§§ 41 sec. 2 s. 1 nr. 2a, 40 sec. 4 nr. 3 s. 3 AMG),

g) diseased minors who are unable to give consent also in majority age due to illness or disability and not because of age-related incapability (§ 41 sec 2 s. 2 sec. 3 AMG).

At any rate, medically indicated interventions are acceptable because they are necessary for the minors. If the child is not able to consent, their parents or other custodial persons have to do so.

If no approved medical treatment is available, the participation in a course of studies with the

medicinal product may be necessary. The same applies where the participation promises a significant advantage over the standard treatment for the condition.

III. Research on minors

1. Objective conditions

a) Indicated medical treatment (§ 41 sec. 2 s. 1 nr. 1 AMG)

In order to allow the participation in a medical trial of a minor who suffers from a disease in the treatment of which the investigational medicinal product is to be used, "the use of the investigational medicinal product must be indicated according to the findings of medical science and in order to save the life of the person concerned. The use of the investigational medicinal product has to restore the health or to alleviate suffering of the test person". The treatment is indicated if it helps the purposes aforementioned and if it does not contain excessive risks.

The main problems with this regulation are that minors normally are not allowed to participate in placebo-controlled trials without an individual therapeutically benefit and that they are not allowed to take part in a so-called "Phase I study".

b) Relative indicated medical treatment (§ 40 sec. 4 AMG)

According to § 40 sec. 4 nr. 1 AMG the possibility of minors to participate in clinical trials if there is no indication is very limited. Studies of new methods of treatment are strictly prohibited. There are only two possibilities: The medicinal product must be intended either to diagnose or prevent diseases in minors. To interpret the provision, it is only allowed to test diagnostic products and products that are intended to prevent and avoid illnesses. In practice, the rule mainly covers medical vaccination studies.

Hence, the experimentation on minors is only permitted if there is a personal individual benefit for the subject's health. However, the relationship between this regulation and the provisions of "the benefit to the study group as a whole" in § 41 sec. 2 s. 1 nr. 2 AMG is at least doubtful.

Moreover, there are further restrictions, for example the principle of subsidiarity, which only allows clinical trials if the performance "on adults cannot be expected to produce satisfactory test results according to medical knowledge" (§ 40 sec.4 nr. 2 AMG). Medical reasons for research on minors will usually imply that there are no suitable results of research on adults.

Furthermore, "with the exception of adequate compensation, no advantages may be granted" (§ 40 sec. 4 nr. 5 AMG). Finally, "the clinical trial may only be conducted if it subjects the person concerned to as little burden and other foreseeable risks as possible; both the degree of burden and the risk threshold must be defined specifically in the trial protocol and monitored constantly by the investigator" (§ 40 sec. 4 nr. 4 AMG). Minimal risk means a merely marginal and temporary interference: a small discomfort for the minor.

c) Non-indicated treatments: benefit to the group of patients (§ 41 sec. 2 s. 1 nr. 2 AMG)

Alternatively, minors can participate in a clinical study supposing a benefit not for the minor him/herself, but to the study group as a whole. According to § 41 sec. 2 s. 1 nr. 2a AMG "the clinical trial must be of direct benefit to the group of patients suffering from the same disease as the person concerned". The group does not only cover simply all minors, but all age groups, such as — for example — babies, infants and adolescents. It is really difficult — maybe impossible — to define the special "benefit to the group of patients". So currently, the group benefit is more or less a benefit of someone else in disguise.

246 In order for a minor to take part in such a medical trial, some more conditions have to be fulfilled. According to § 41 sec. 2 s. 1 nr. 2b AMG "the research must be absolutely necessary in order to confirm data obtained in clinical trials on other persons or by means of other research methods". Moreover the "research must relate to a clinical condition from which the minor concerned is suffering", § 41 sec. 2 s. 1 nr. 2c AMG. Therefore, this does not necessarily require an indication, but physical symptoms which need to be medically treated. Finally, "the research may cause only minimal risk and minimal burden to the person concerned; research bears a minimal risk only when it is to be expected, owing to the nature and scope of the intervention, that it will result, at the most, in a very slight and temporary impairment of the health of the person concerned; it causes a minimal burden only when it is to be expected that the discomfort will be, at the most, temporary and very slight for the person concerned" (§ 41 sec. 2 s. 1 nr. 2d AMG). A very slight but lasting impairment is not permitted. Compliance with this condition has to be controlled. However, the Central Ethics Committee just started some attempts to relax the requirement.

2. Medical information and consent

a) Consent

According to § 40 sec. 4 s. 1 nr. 3 AMG, "the consent is granted by the legal representative". Legal representatives are the custodians, normally both parents. If they are both legal representatives, they both have to consent and to sign. Exceptionally, only one parent is entitled to custody. Moreover, legal guardians or curators can be able to consent, but there are no carers for minors, § 1896 German Civil Code.

The law distinguishes between minors who are able to consent and those who are not. "If the minor is in a position to comprehend the nature, significance and implications of the clinical trial and to form a rational intention in the light of these facts — [so that he/she is able to consent] — then his/her consent shall also be required" (§ 40 sec. 4 nr. 3 s. 4 AMG) — in addition to the consent of the patient´s parents. It is also called "co-consent". At the age of 12 to 14, the capability to consent normally can be assumed. The dispute whether parents are entitled to consent next to their child — him/herself able to consent — was solved by the statute in cases of participation in medical trials.

The legal status of minors who are not able to consent it much more difficult: "Should the minor declare or express in any other way that he/she does not wish to take part in the clinical trial, this must be respected." (§ 40 sec. 4 nr. 3 s. 3 AMG). This word shows that the requirements for the patient to express his/her own will are not very high. Rather, it is possible to express the will not to participate in a medical study in every imaginable nonverbal way — although it is (at least in practice) questionable if babies and infants can do so. For example, disagreement can be expressed by fear or signs of anxiety. Practically, that would normally mean that blood samples would be inadmissible. Therefore a negative will needs to be expressed for a longer time. The behaviour of the infant should be lasting and unmistakable.

That the children's wish "must be respected" can mean various "ways". Most likely, it implies the minors right of veto. This means that the underage person is not able to consent to the participation on his/her own, but he/she can prevent it on her/his own. If the legal representatives and the young person disagree about the participation, the minor's will is more important. As a consequence of the power of veto being part of the self-determination, the minor has to be be informed about it.

According to § 40 sec. 4 nr. 3 AMG, the consent given by the legal representatives "must correspond to the minor´s presumed will where such a will can be ascertained".

b) Medical information

"The person concerned shall be informed by an investigator who is a physician [...] or by a member of the investigating team who is a doctor [...] about the nature, significance, risks and implications of the clinical trial as well as about his/her right to withdraw from the clinical trial at any time" (§ 40 sec. 2 s. 1 AMG). In cases minors will take part in medical studies their legal representatives have to be informed like this, § 40 sec. 4 nr. 3 s. 1 AMG. That is a matter of course, because the one who is entitled to consent therefore needs the necessary knowledge (informed consent). The medical information aims to close all knowledge gaps and is thus a compulsory part of the consent. After that, the importance of a "counselling session", which is provided additionally by § 40 sec. 4 nr. 3 AMG, is questionable.

The minor has to be informed by a physician in the same way if he/she is able to consent. Errors or omissions in the medical information may have legal and liability consequences.

Even if a child is not able to consent, "the minor shall be informed, by an investigator who is experienced in dealing with minors who is a doctor or [...] an adequately experienced member of the investigating team [...] about the trial, the risks and benefits, in so far as this is possible taking into account the minor's age and mental maturity" (§ 40 sec. 4 nr. 3 s. 3 AMG), and by these means ensure their understanding. That could mean that an investigator has to instruct a special qualified physician with this task.

IV. Conclusion

Basically, there are concerns about the participation of minors in clinical studies, especially if the minor is an infant who is not able to consent. According to general medical law, the infants' legal representatives are not allowed to do so if there is no indication. Therefore, the Medicinal Products Act (AMG) provides the only possibility for an underage person without the mental maturity to consent to take part in research on minors. At least the AMG allows this treatment. Without this regulation, it would be forbidden completely.

The requirements must be strictly observed. Furthermore, the relationship between these rules and the individual's self-determination, guaranteed by the German constitution, is at least questionable. One solution could be a commitment to the child's well-being, determined in § 1627 German Civil Code, but this would lead to a prohibition. Another way might be the development of a special authority to control the research on minors, which currently does not exist in Germany.

Chapter 3: Learning with errors

"FROM THE ERROR (IN MEDICINE) TO THE ACCIDENT (IN HEALTH): STATE OF ART AND CHANGING CULTURE IN PORTUGAL"

Maria do Céu Rueff [1]

Abstract: *I will explain the evolution of literature about error and liability both in medicine and law authors and also examine the diversity of implications of medical/clinical practice in the Portuguese legal system (notably, in the Penal Code, the Civil Code and the new law on State's Extra-Contractual Civil Liability of 2007).*

In order to better understand the issue, I will use the trans-disciplinary method of medical law (Eser, 2004) to approach the "health language" of error and accidents in clinical settings, namely: adverse incident, accident, near miss, error by negligence, human error and system error.

These deficiencies are caused by many factors that must be all of them taken into account, above all those of systemic nature which predispose to failure. If risks are inherent in clinical procedures, then we have a duty to acknowledge, identify and take reasonable steps to prevent the repetition of adverse effects. Instead of putting our attention on a "culture of guilt", we should rather focus on the factors and consequences of poor performance, first of all on the ability to report, in voluntary terms, in order to know exactly what happened, in this way cutting the "fear's cycle" (Fragata, 2006). I agree with Merry and McCall Smith (2004) when they stress that when an "accident" has happened the situation was a matter of fact that nobody can blame; on the contrary, the term "negligence" has always something to do with the assumption of agent's culpability.

I will notice also the recent (2012) introduction in Portugal of "Sistema Nacional de Notificação de Incidentes e de Eventos Adversos (SNNIEA)", which allows the anonymous report of adverse incidents. This is an important step in our changing culture but maybe not the last to achieve a culture of safety.

Medical Practice as "a social construction"

Two autonomies, ie, the patient's and the physician's autonomy, have faced in the medical relationship, but the universe has expanded to other actors who have also populated the field. Though invisible, administrators, legislators, politicians, employees of insurers, ethicists are now also present. I agree with Antunes (2012: 46) who says that nowadays "medical practice is largely a social construct". Team work, new forms of organization of health systems, technological innovations and biological discoveries led to what this author call "New Medicine", where the challenges are many, and most often in tension with mental frames and regulations in force because inherent to previous paradigms.

All of this occurs when medical information exponentially increases. The issue of the access to information becomes crucial because it can be a facilitator of the decision, taking the perspective of both the professional and the patient.

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However, the most important question is not so much the increase of information as the question of the existence of multiple schemes of interaction between human activity and the systems, established by it, that have altered the reality [(2)]. As J. Reason (2009: 148) highlights:

> Errors are […] the inevitable and usually acceptable price human beings have to pay for their remarkable ability to cope with very difficult informational tasks quickly and, more often than not, effectively. […] the centralised supervisory control of complex, hazardous, opaque, tightly-coupled and incompletely understood technologies can, on occasions, transform these normally adaptive properties into dangerous liabilities.

Information and choices depend on the medical knowledge but detection of errors became also an important issue. Indeed, "Error detection processes form an integral part of the multilevel mechanisms that direct and coordinate human action", J. Reason (2009: 148) stresses. Perhaps for this reason medical doctor Antunes (2012: 39) argues that medical error was born within the profession itself, and its recognition is no longer one of the worst-kept secrets of the medical corporation. This statement raises some questions:

Has medical error ever belonged to the matter of confidentiality?

Has medical confidentiality — which is essentially connected with the medical method and the creation of trust in the therapeutic alliance (Rueff, 2009) — brought somewhere advantage for the institution of medicine itself?

What happens when the medical practice becomes a "social construction" and the way to access knowledge changes?

Knowing that the human factor comes integrated alongside other systemic factors of health organizations that have become complex and multidisciplinary, what is the role of human contribution to systems disasters?

What is the weighing that should be given to the error or adverse event in this kind of multi-complex systems?

According to Merry and McCall Smith (2004: 11),

> What is required is an enhanced understanding of the underlying causes of iatrogenic harm. This necessitates a more sophisticated appreciation of how things go wrong. It is also important to distinguish between notions of best practice and the reality of how medical practice is actually carried out in the face of pressing need and limited resources. Finally, the ways in which the standard of care is assessed are themselves subject to a number of limitations: for example, expert evidence may be a very poor indicator of what should reasonably be expected in a particular case [(3)]."

[(2)] As Merry and McCall Smith (2004: 41) pointed out: "It is our human cognitive ability that has given us our highly organised and technologically sophisticated societies, with all their advantages and disadvantages. Yet it is precisely this cognitive process that also make human beings prone to error. To this risk must be added the fact that the technology and complexity which characterise modern life, and which have resulted from our ability to think, have created an environment in which the opportunities for error are numerous […] Error, then, should be viewed not as an unfortunate frailty on the part of human beings but rather as an inevitable concomitant of the powerful cognitive processes that have permitted us to extend the limits of human achievement."

[(3)] To address this issue was recently published a work entitled: *Malpractice and Medical Liability — European State of the Art and Guidelines*, by editor Ferrara and co-editors Boscolo-Berto and Viel (2013). I quote from the Foreword: "…In the nineteenth century, forensic medicine became a special discipline at European Universities. […] Accountability for medical error can be assigned to individual physicians but also to a group of professionals cooperating in a complex health care system. In every malpractice claim, it has to be proved that the provider failed to observe the relevant standard of care resulting in an injury with consecutive damage in pecuniary or emotional respect. […] On this broad basis, a panel of

That is to say, we have a duty to acknowledge, identify and take reasonable steps to prevent the repetition of adverse effects. All deficiencies must be taken into account, above all those of systemic nature that predispose to failure.

Human and systemic errors

In a chapter called "Latent errors and systems disasters" J. Reason (2009: 173-216) makes the distinction between Human errors and those errors imputable to the organization. Cause of error can be either the person acting on the end of the system (*active errors*, ex. the surgeon or the pilot); or the system/organization (*latent errors*) with its defences and its conditioned design. Errors can be committed by people — good or bad — , but these act within systems with design defects, which are the truly responsible.

According to the determinant cause when errors occur, there are individuals' and system's errors. What is important to stress here is that the single person associated with the performance of the "front-line" operators in a system ceases to be the sole feeling guilty, and the focus shifts to the responsibility of the system. The author further explains that the systems have become more complex, dangerous, opaque and this opacity means some times ones not knowing what is happening or not understanding what the system can do.

The possibility of this kind of inevitable errors in complex organisations is also stressed by Perrow (*apud* Merry and McCall Smith, 2004: 48) in the title of his book: *Normal Accidents: Living with High-Risk Technologies.* In order to reduce the consequences of human errors' Perrow defends the need to consider all the factors of the system in question according to the acronym DEPOSE: design, equipment, procedures, operator, supplies and environment. Merry and McCall Smith (2004: 51) add that not only is it too limited to focus on the operator, but this is the part most difficult to make-error free, because operators are human.

Systemic approach, Swiss cheese model and health risk

According to this systemic approach, there are safe/unsafe systems, reliable / unreliable organizations [4]. Errors and accidents don't necessarily mean

renowned jurist and medico-legal experts worked out a document in a consensus process with the objective to introduce uniform standards for the medico-legal assessment in cases of suspected malpractice. The ultimate goal of this proposal for European guidelines is a harmonization of methods and evaluation criteria similar to the already existing Recommendation on the Harmonization of Medico-Legal Autopsy Rules. It is to be hoped that the guidelines proposed by the authors will help to bring about common principles of medical assessment in the context of malpractice claims."

I have many doubts about the goodness of this solution. Above all, I am persuaded — based on J. Reason (2009: 209) — that the control of safe operations, like the control of production, is a continuous process and that "The prerequisites for adequate safety control are: (a) a sensitive multichannel feedback system, and (b) the ability to respond rapidly and effectively to actual or anticipated changes in the safety realm." More then "naming and blaming" practices, to use the terminology of Merry and McCall Smith (2004).

[4] J. Reason (2000) clarifies: "High reliability organisations are the prime examples of the system approach. They anticipate the worst and equip themselves to deal with it at all levels of the organisation. (…) Individuals may forget to be afraid, but the culture of a high reliability organisation provides them with both the reminders and the tools to help them remember. For these organisations, the pursuit of safety is not so much about preventing isolated failures, either human or technical, as about making the system as robust as is practicable in the face of its human and operational hazards. High reliability organisations are not immune to adverse events, but they have learnt the knack of converting these occasional setbacks into enhanced resilience of the system."

evolutionary stages of a single process: most errors don't cause accidents, but when an accident occurs, this normally happens due to a series of unfortunate mistakes: a series of "security holes" have to align in a certain moment (Fragata, 2006: 193).

J. Reason (2009: 207) speaks of the limited window of accident opportunity; commenting on the diagram that represents the trajectory of the accident, Reason (2009: 208) explains that this "results from a complex interaction between latent failures and a variety of local triggering events", and observes that the chances of such a trajectory of opportunity finding loopholes in all of the defences at any one time is very small.

In fact, an accident has multifactorial causes: active/passive failures and defence faults create "security holes" that are always changing in positions; if they align in a linear trajectory, an accident will occur, because all holes are crossed without any inhibitive defence. This model became known as the Swiss Cheese and tries "to capture some of the stochastic features involved in the unlike coincidence of an unsafe act and a breach in the system's defences" (J. Reason, 2009: 209) [5].

In order to avoid accidents, it is necessary to act on all causes: beginning with the system, continuing with the team, and ending with the individual actions or the human factor (Fragata, 2006: 194). That is to say, the human error does not explain every accident: there can be no accidents (near miss) although the circuit has errors [6].

However, in this matter of medical responsibility, the whole attention is focused on the health professional, "the visible face of the problem" — what corresponds to the culture of "name, blame and claim", despite of the fact that most accidents occur due to uncontrollable reasons, ie., latent causes that are situated upstream: at the structural/organizational level. Accordingly, the present tendency is to shift from fault liability focused on the single person to the core responsibility of the health care institution (Cascão, 2004: 101).

In fact, the prevention and compensation for iatrogenic damage is complicated by the restriction of medical civil responsibility only to unlawful and culpable acts. Therefore, instead of focusing on "medical negligence", the problem has to be re-centred on the notion of "health risk": on the systemic causes — the structure and organization of the health care institution (Cascão, 2004: 101, n. 15).

As Wienke (2013: 2) also emphasizes, a totally perfect and error-free treatment will never occur but

[5] J. Reason (2009: 216) explains potential measures to reduce the human error risk, but states as concluding remarks: "Given the ease with which the contributing human failures can subsequently be identified, such scapegoats are not hard to find. But before we rush to judgement, there are some important points to be kept in mind. First, most of the people involved in serious accidents are neither stupid nor reckless, though they may well have been blind to the consequences of their actions. Second, we must beware of falling prey to the fundamental attribution error (i.e., blaming people and ignoring situational factors). As Perrow (1984) argued, it is in the nature of complex, tightly-coupled systems to suffer unforeseeable sociotechnical breakdowns."

[6] Merry and McCall Smith (2004: 57) stress: "In any analysis of the ways in which human cognitive processes can go astray, the question of context is very important. Exactly the same external events may represent the endpoints of completely different cognitive processes, and actions cannot be evaluated adequately in isolation. As human beings extend the boundaries of possibility by means of increasingly sophisticated systems of organisation and technology, hitherto unattainable standards are achieved. Unfortunately, as we have already noted, one result of this is to create expectations amongst the population of near-infallibility. Infrequently, but inevitably these systems fail. They do so because their design and operation depend on human beings."

this fact leads to the obligation to do everything possible to reduce the risk to an absolute minimum.

Following the systemic approach, the Dutch Civil Code states that the (public or private) hospital is always civilly responsible towards the patient. So well as highlight Merry and McCall Smith (2004: 34):

> The emphasis is on identifying the truth rather than on attributing blame. This is shown by the way in which inquiries of this sort will seek to encourage maximum disclosure by focusing on the information itself rather than by seeking to establish authorship and responsibility. This also recognizes that the individual operator is only one component of the complex system, and often the least important one.

We should focus on the factors and consequences of poor performance and also on the ability to report, in voluntary terms, in order to know exactly what happened, instead of putting our attention on a "culture of guilt", in this way cutting the "fear's cycle" (Fragata, 2006).

Some definitions

J. Reason (2009: 9), in his approach to working definitions of error and its principal types, defines error as following:

> …a generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot be attributed to the intervention of some agency.

Referring to this definition Merry and MacCall Smith (2004: 73) claim that it has nothing to do with blame and suggest other definition for the same topic but bearing in mind their purposes:

> An error is an unintentional failure in the formulation of a plan by which it is intended to achieve a goal, or an unintentional departure of a sequence of mental or physical activities from the sequence planned, except when such departure is due to a chance intervention.

The same authors also distinguish this concept from that of *violation*, particularly important in Law:

> To qualify as an error, this failure in planning or acting must be unintentional. If the act or decision knowingly falls short of a reasonably expected standard, we would classify the act in question as a *violation*, even though there may be no intent to cause harm or to jeopardise a particular goal. (Merry and MacCall Smith, 2004: 73)

As J. Reason soon explains, there is, however, no universally agreed classification of errors [(7)], and a

[(7)] Fragata/Martins (2004: 311-324) distinguish among the following categories: *Incident*: unexpected event that can, or cannot, cause damages; if it causes damages, these don't affect the whole.

Accident: unexpected and unintended event causing general damages that change the outcome of the action and jeopardize the whole.

Error: unintended failure in the performance of the planned action and whenever such failure is not due to random. Error's premises are: (1) plan; (2) no intentionality in its infringement; (3) deviation of the sequence of the foreseen actions; (4) incapacity of reaching the proposed target; (5) identified causality (excluding random). In this sense, error cannot be completely abolished or avoided. Errors may result from unintended actions: the plan failed for distraction, misapplication of rules or bad decision (*honest errors,* fruit of human nature: *errare humanum est*). But they may also result from the transgression or disregarding of the *Leges Artis* (*dishonest errors*, ie, violations committed by recklessness, risk behavior or disobedience to the established or good rules).

Near Miss: any situation or event that could have ended in an accident but that just did not end so, because corrective measures were timely implemented and prevented the accident. This concept is especially important in the taxinomy

taxonomy is normally made for a particular purpose, so that no specific scheme would satisfy all goals.

In my view, the taxonomy of Vaz Carneiro (2010) is particularly accurate, because it is directly related to patient safety and gives some examples of medical practice:

> *Error:* a failure of implementation of a pre-planned and intended action (error of execution), as well as the use of a wrong plan for the achievement of a certain aim (error of planning);
>
> *Adverse event (AE):* an injury caused to a patient due to the medical intervention itself (and not to the underlying medical condition), ex. esophageal rupture during endoscopy);
>
> *Non-preventable adverse event:* unexpected AE, in the absence of any error (ex.: surgical complications, drug allergy, etc..);
>
> *Preventable adverse event:* Adverse event due to an error (ex.: arterial puncture in anticoagulated patients);
>
> *Negligent adverse event:* subset of preventable adverse event, due to care that did not follow the care standards expected of a physician averagely qualified to treat the given patient (eg, perinatal hypoxia due to too long labor parturition);
>
> *"Near misses":* errors that do not induce any adverse effects on the patient.

Summing up, Vaz Carneiro (2010: 4) claims that the approach to error by identifying and blaming a few "bad apples" acting within the system — and we should never underestimate the culture of infallibility within which doctors are trained — is not correct. Although negligence exists in all systems, the problem of safety has more to do with competent and dedicated professionals, working in absolutely chaotic and disorganized systems without any awareness of the issue of patient safety, than with individual failures of those professionals.

In 2002, the World Health Organization (WHO) sensitized all countries to the problem of patient safety and in 2004 created the World Alliance for Patient Safety. This Joint Commission published in 2009 the Conceptual Framework from The International Classification for Patient Safety — Final Technical Report (WHO/Patient Safety — A World Alliance for safer Health Care) that promote continuous improvement based in identification of risks, prevention and recovering from incidents and resistance of the system. The "Executiv Summary" of the document (p. 3) states:

> The purpose of the International Classification for Patient Safety is to enable categorization of patient safety information using standardized sets of concepts with agreed definitions, preferred terms and the relationships between them being based on an explicit domain ontology (e.g., patient safety). The ICPS is designed to be a genuine convergence of international perceptions of the main issues related to patient safety and to facilitate the description, comparison, measurement, monitoring, analysis and interpretation of information to improve patient care. It is important to note that the ICPS is not yet a complete classification. It is a conceptual framework for an international classification which aims to provide a

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of errors, because only errors causing accidents are known for the damage they cause and the personal and social impact they determine. However, the accident is only the visible damage of a trajectory of errors, and many of these do not cause accidents, ie, do not get enough alignment failures, or are avoided by the system or its defenses.

Adverse Event: any (unwanted) negative event occurring as a result of treatment, but not of disease or associated states (incidents, accidents or near miss).

Among the *errors*, defined as deviations from a pre-conceived plan — deviations that are involuntary and do not result from random –, Fragata (2006: 194-197) distinguishes between: *human errors* (so-called *honest errors*: errors by negligence, committed by humans acting at the "sharp end" of the system, ex. surgeon's errors), and *systemic errors* (those imputable to a bad organizational design, although involving human action: their real causes reside in the system).

> reasonable understanding of the world of patient safety and patient concepts to which existing regional and national classifications can relate. (International Classification for Patient Safety Statement of Purpose — http://www.who.int/patientsafety/taxonomy/ICPS_Statement_of_Purpose.pdf). [8]

Prevention of accidents (in Health) and risk management

Some authors speak of "risk as a concept" (Samantha & Samantha, 2011: 53) stressing that risk management places emphasis on improving the quality of care through a process of minimizing the risks.

The methodology of accident prevention consists in a series of steps, including the development of procedures to prevent accidents, but begins with the identification of the own and frequent mistakes, which will be then made known by statement or report.

Although it is known that blaming individuals is more satisfying than targeting institutions, from the viewpoint of emotions, it is also known that we cannot change human beings but we can change the conditions under which they work (J. Reason, 2000). This is exactly the objective of the system approach as J. Reason puts the question:

> A central idea is that of system defences. All hazardous technologies possess barriers and safeguards. When an adverse event occurs, the important issue is not who blundered, but how and why the defences failed. (J. Reason, 2000).

Vaz Carneiro (2010: 6) wonders about the barriers that rise against the construction of a secure hospital system, and refers to R. Amalberti (2005), who enounces five barriers that must be overcome to achieve this objective. The following measures are among them: acceptance of limits on system performance, reduced professional autonomy, or transition from artisan mentality to "equivalent actor" mentality (Vaz Carneiro, 2010: 7).

One of the major obstacles to access to the information is the punitive nature of the guilty-based liability that underpins many of the sanctioning systems of errors/accidents in medicine (Fragata/Martins, 2004; Fragata, 2006; Cascão, 2004; Oliveira, 2005). Beyond being wholly unable to prevent/stop the error, such systems make the collaboration of health professionals in the discovery of truth impossible, precisely because the fear of self-incrimination (Cascão, 2004: 103). [9]

Dekker (2007) wonders about who draws the line in criminalization's medical error and states that simply charging practitioners excludes beneficial effects, produces excessive stress and leads to defensive medicine.

[8] The General Directorate of Health from Portugal under the national strategy for quality provided in 2011 the Portuguese translation of this document that can be found at the department's microsite quality on health (www.dgs.pt).

[9] Even in relation to United Kingdom where several measures have been taken, Reckless et all. (2013: 8) assert: "Despite the publication of *An Organisation with a Memory*, the NHS still shows symptoms of an unhealthy blame culture. The report pointed out the difficulty faced by individuals who draw attention to problems in their working environment. Its authors recommended that the NHS should foster a more open culture in which errors can be admitted without fear of discrimination or reprisal (though individuals still need to be held accountable for their actions)."

State of Art in Portugal

This is exactly the case in Portugal, where medical professionals can essentially be charged at three levels: criminal law, civil law and disciplinary statutes (based on code of medical ethics).

The criminal liability concerns the greatest offenses against the constitutionally protected rights and can impose a sentence of imprisonment. It requires a typical offense expressly foreseen in the Criminal Law and presupposes: action, result, causal relation between the act and the result, guilty of the agent (negligence or malice).

The civil liability occurs when the patient seeks compensation for damage resulting from an act of malpractice, and comprises two modes: tortious liability (art. 483 ff of Civil Code) and contractual liability (art. 798 ff of Civil Code). The requisites are the same in both modes: liability chargeable event (art. 483/798 of Civil Code); illegal fact (not fulfilling contractual obligation / violation of absolute right, ex. personality right); imputation of guilt (arts art. 487 / 488 of Civil Code); existence of damage (art. 496 of Civil Code), a causal link between the fact and the damage (adequate causation, art. 563 of Civil Code).

Our medical liability system remains based on the guilt of the agent in the cases both of civil and criminal liability. Then we can say that medical responsibility in Portugal is always a subjective one.

Even in health care provided by NHS, where doctors work as public servants in a public hospital, medical liability system remains based on the guilt of the agent. The relationship between the public institution and the patient is here at stake. The doctor is a public-sector servant who performs (material) acts of public management.

In fact, when the doctor is a state administrative agent, the doctrine tends to consider that the acts of care provided by the NHS are (materials) acts of public administration, and not acts of private management. Theories of the institutional framework and of the public interest prevail against the theories of the material nature of the activity and power of authority (Amaral, 1991; Correia, 1996; Sousa, 1996).

In this situation acts of public administration (and not privately managed), integrated into a patient/physician relationship that is external to a contract, can lead to extra-contractual liability. The action may be brought exclusively against the State, or against the medical doctor and the State, or both, under the Public statute of Extra-contractual Liability of the State — Law No. 67/2007, Dec. 31 (Administrative Law) (Gomes, 2008; Cadilha, 2008).

Despite the fact that this Regime of Extra-contractual Liability concerning the State and other public entities has progressed to a systemic approach, there is not yet a real shift in this direction as we will see (Gomes, 2008).

When the doctor is a public-sector servant, he/she responds directly before the patient in case of intentional misconduct (grievous fault or malice) (art. 8, No. 1 of Law No. 67/2007, Dec. 31). The State responds, in solidarity with the doctors, for the damage caused by these acts (joint liability), either when they practice them intentionally, or when their diligence and zeal were manifestly inferior to those to be required (art. 8, No. 1/2). The State has the

right of subrogation against the doctor, beyond any disciplinary procedure (art. 8, No. 3 of Law No. 67/2007).

The sole responsibility of the State (exclusively) is only allowed in the case of ordinary fault (art. 7, No. 1, of Law No. 67/2007), and when damages do not result from a determined performance of a particular person or if it is not possible to prove the personal authorship of the act or omission, being these attributed to an abnormal functioning of the service (art. 7, No. 3). (Gomes, 2008, Cadilha, 2008). There is abnormal functioning of the service when — given the circumstances and average patterns — a performance avoiding the produced damages would be reasonably required (art. 7, No. 4, of Law No. 67/2007).

The existence of ordinary fault in the practice of unlawful acts (art. 10, No.2, of Law No. 67/2007) is presumed, leading to the exclusivity of the State's responsibility (Article 7, 1). In the case of breach of due diligence (art. 10, No. 3 of Law No. 67/2007), the same regime is followed, by applying the general principles of liability. In the case of a plurality of respondents (art. 10, No. 4) each respondent has a right of subrogation according to the respective guilt (by assuming that this is equal), unless the intentionality or severe negligence of the agent is proved. (art. 497, Civil Code).

The European Union, The National System of Notification of Incidents and Adverse Events — SNNIEA and Changing culture in Portugal

The European Union assumed that the need for security in the care provided by hospitals and other services, such as safety of drugs, implantable medical devices and harvest of human tissues and blood, has yet to be recognized.

Recommendation Rec (2006) 7 of the Committee of Ministers to Member States on Management of Patient Safety and Prevention of Adverse Events in Health Care recognized that safety is a fundamental principle to be applied to primary, secondary and tertiary care.

This instrument recommended the promotion of the system of reporting incidents and adverse events, stressing that it should be:

(a) not punitive;
(b) independent of other regulatory processes;
(c) designed in order to motivate health professionals to notify in safety.

Annexes to the Recommendation state that patient safety depends on many factors, such as adequate resources, equipment and medicines of high quality, setting standards of clinical practice guidelines, appropriate information systems, effective communication and motivation of staff.

Annexes to the Recommendation also state the need for a culture of safety and stress that this is essentially a culture according to which everyone is aware of their role and contribution to the organization and that is a fair and open culture where professionals can learn from the mistakes and fix them.

The General Directorate of Health of Portugal followed these recommendations, having enacted the National System of Notification of Incidents and Adverse Events — SNNIEA (DGS Guidance 025/2012, Dec. 19).

SNNIEA is characterized by being an anonymous, confidential and non-punitive platform, as it carries out an analysis of the root causes of adverse events in order to introduce corrections/improvements in the system (Norm 008/2013, Dec. 15) [10].

How to articulate SNNIEA and traditional ethical and legal frameworks, notably privacy, medical confidentiality and data protection?

How to combine this goal with the Law of Personal Data Protection and the Law on Health Information (Laws No.: 67/98, Oct. 26, and 12/2005, Jan. 26)?

Casabona (2013: 101) stresses:

> Every system not directed to a mere collection of data for statistical purposes involve the practice of Root Cause Analysis (RCA), process under which it will describe the professional conduct of each of the subjects involved in the adverse event. Only in a second stage, once performed RCA and implemented an action plan in order to avoid repetition of the adverse event, one will proceed to the anonymisation of data [11].

In my view, the Portuguese legal system is not yet ready for all goals targeted by SNNIEA; some adjustments remain to be made.

Furthermore, I ask: is a new concept of confidentiality emerging, which consists in the protection of the team's truth in order to allow the RCA? There will be a kind of internal confidentiality that would permit not using disclosed data for the purpose of RCA? How should this kind of confidentiality be protected?

We need also to understand how to conjugate the SNNIEA with the mechanisms of socialization of risk that might be also adopted (R. Faria, 2013: 69; Cascão, 2005), and the mechanisms of extra-judicial interests' composition (ex. mediation in health and arbitration; see Casabona, 2013: 95, and Merry and McCall Smith, 2004: 204-241).

All this in order to make the system more efficient and to enable the achievement of the real *transition from a culture based on guilt to a culture based on transparency and safety.*

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[10] Samantha & Samantha (2011: 57) explains: "Root cause analysis involves the comprehensive dissection of an error to expose all relevant facts while searching for the underlying cause. The concept of route cause analysis can be misleading since it implies that errors have a single root cause, whereas in reality causation is likely to be multifactorial. Root cause investigations are often only a preliminary step in the investigative process and further deliberations are necessary to expose any inadequacies within the host environment. Proactive prevention of error requires that weaknesses within the system are corrected to avoid repetition of the index event and systems analysis needs to be balanced with organisational factors as well as individual and team accountability."

[11] Merry and McCall Smith (2004: 34) defend similar position: "Typically, in a hospital using this system, a report will be submitted by the doctor concerned with the incident. This may be anonymous, although in practice it may be difficult to conceal the identity of the reporting. The vital requirement is for the doctor not only to explain the facts but also to offer his or her opinion about what went wrong. In this situation, the right to silence is being set aside."

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Chapter 3: Learning with errors

PATIENT SAFETY WITHIN MEDICINAL PRODUCTS — MEDICATION ERRORS AND OFF-LABEL USE

Margarida Brito da Cruz [1]

Abstract: *Patient safety is one of the most important aspects of health care, comprising both medication errors and off-label use. These two topics are not sufficiently dealt with within patient safety and the information available is somehow disperse. Therefore, and following the new pharmacovigilance legislation of 2010 and its implementation process, I decided to gather these topics and explore their relevance and importance in order to create a safer medical care. The main goal of this article is to demonstrate how the legislative changes regarding both medication errors and off-label use have contributed to patient safety, through a better prevention of medication errors, on one hand, and through a more adequate use of medicinal products off-label for the patient's benefit, on the other hand. The main conclusion is that we are just halfway and many developments can be expected over the next few years.*

Introductory Note

Patient Safety is of major importance for the quality of health care. Nowadays, there is a great focus on patient safety, and yet there is still a lot to be improved. There are two specific issues among patient safety which were paid more attention to by the new pharmacovigilance legislation of 2010: medication errors and off-label use.

Medication errors are now part of the Directive 2001/83/EC [2]. Therefore, their actual place within the directive is somehow uncertain, and the main question is how the directive aims to include them. Off-label use is even more ambiguous, for it is not even explicitly mentioned in Directive 2001/83/EC — so what are the real developments brought by the pharmacovigilance legislation?

This article aims to scrutinize what has been done so far and which gaps need to be filled regarding both medication errors and off-label use at European Union level.

From the Start: Patient Safety

Council Recommendation of June 2009 [3] provided that "*poor patient safety represents both a severe public health problem and a high economic burden on limited health resources*" [4], therefore recognizing a need to create a framework to stimulate policy development and future actions between Member States

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[2] Directive 2001/83/EC, November 2001, OJ L311, 67-128, on *the Community code relating to medicinal products for human use*, as amended.

[3] Council Recommendation, June 2009, OJ C-151/01, *on patient safety including the prevention and control of healthcare associated infections*.

[4] Ibid, Recital 4.

to address the key patient safety issues confronting the European Union (EU). Since November 2012, several actions were taken at Member State level regarding patient safety, including more information about adverse events through reporting and learning systems [5]. In fact, Council Recommendation of June 2009 supported the establishment of national policies and programmes on patient safety by "*including a specific approach to promote safe practices to prevent the most commonly occurring adverse events such as medication-related events, healthcare associated infections and complications during or after surgical intervention.*" [6] The specific reference to adverse medication-related events in the recommendation represented a call for attention regarding events resulting from medication errors, which are associated with adverse drug events. Directive 2001/83/EC would be the next step.

Medication Errors: Legal Developments

In 2003, the Council of Europe Committee of Experts on Pharmaceutical Questions established the Council of Europe Expert Group on Safe Medication Practices to review medication safety and to prepare recommendations to specifically prevent adverse events caused by medication errors in European health care. According to the Expert Group, "*Medication Errors are the most common single preventable cause of adverse events*" [7], therefore a specific strategy to promote medication safety was established as part of the Council of Europe Recommendation Rec(2006)7 on management of patient safety and prevention of adverse events in healthcare.

Under the terms of Recommendation Rec(2006)7, medication safety comprises both adverse drug reactions and medication errors. Consequently, a clear distinction must be made between the two concepts: while adverse drug reactions are mostly connected with product safety, medication errors concern the safety of health care services [8]. The distinction was clearly assumed by the World Health Organization (WHO) Resolution WAH55.18 and adopted by WHO's 55th World Health Assembly in May 2002 and its associated report of (4 December) 2003.

There is no official definition of "medication error" in the EU — the lack of an universal and single definition of medication errors, as well as a common terminology concerning harm to patients caused by medication, complicates the analysis of medication errors and their causes, for most definitions of medication errors are circular and focus on the preventability aspect.

The most relevant definition is, perhaps, the one established by the Guideline on Good Pharmacovigilance Practices (GVP), in module VI, where medication error is referred as *"any unintentional error in the prescribing, dispensing, or administration*

[5] European Commission, *Report from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation (2009/C 151/01) on patient safety, including the prevention and control of healthcare associated infections*, Brussels, November 2009, pages 4-5.

[6] Council Recommendation, June 2009, OJ C-151/01, page 3.

[7] Council of Europe, Expert Group on Safe Medication Practices, *Creation of a better medication safety culture in Europe: building up safe medication practices*, 2006, page 9.

[8] Council of Europe, Recommendation Rec(2006)7*, on management of patient safety and prevention of adverse events in healthcare*, 2006, Appendix, paragraph E 2.

of a medicinal product while in the control of the healthcare professional, patient or consumer." [9]

Even though the new EU Pharmacovigilance legislation does not specifically define medication errors, great progress was made. Since July 2012, the new legislation explicitly includes medication errors in the definition of reportable adverse drug reaction[10] referring that *"the definition of the term 'adverse reaction' should be amended to ensure that it covers noxious and unintended effects resulting not only from the authorized use of a medicinal product at normal doses, but also from medication errors (…)"* [11].

Also, the Expert Group on Safe Medication Practices created a glossary in order to allow the use of terms having the same signification, to avoid less mistakes and confusions, taking into consideration all the different available definitions of terms related to medication errors. The proposed definition of "medication error" by the Expert Group is:

> *"any deviation from ordinary standards of care appropriate for the time of the medicine therapy of a patient. A medication error is a non intentional omission or failed activity related to the medication use system, which can be the cause of a risk or of an adverse event reaching the patient. By definition, a medication error is preventable because it evidences what should have been done and what was not during the medicine therapy of a patient. A medication error can concern one or several stages of the medication use system, such as: formulary selection, prescription, dispensing, orders validation, preparation, storage, delivery, administration, therapeutic monitoring, and information; but also its interfaces, such as communications and transcriptions."* [12]

During the medication errors' workshop organized by the European Medicines Agency (EMA) in February 2013, Ms. Elizabeth Swain, in representation of the European Federation of Pharmaceutical Industries and Associations (EFPIA), provided an industry perspective regarding the evaluation, classification and management of medication errors during the different stages of product development, and recommended various initiatives to improve the way medication errors could be defined, detected and reported. The initiatives included namely, the agreement on a clear definition of what constitutes a medication error and the improvement of the granularity of the Medical Dictionary for Drug Regulatory Activities (MedDRA) terminology used for coding reports of medication errors [13].

The creation of an EU official definition of medication errors is an important prevention tool, since it would facilitate the identification of medication errors, and allow a more efficient reaction towards them. Moreover, if medication errors were defined in Directive 2001/83/EC there would be a greater certainty that the directive also aims to regulate them.

[9] European Medicines Agency, *Guideline on Good Pharmacovigilance Practices (GVP) — Module VI — management and reporting of adverse reactions to medicinal products*, June 2012 (EMA/873138/2011), page 16.

[10] Article 1(11) of Directive 2001/83/EC defines adverse reaction as "*a response to a medicinal product which is noxious and unintended."*

[11] Recital 5 of Directive 2010/84/EU, December 2010, OJ L348, 74-99, *amending as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use*.

[12] Council of Europe, Expert Group on Safe Medication Practices, *Creation of a better medication safety culture in Europe: building up safe medication practices*, 2006, page 195.

[13] European Medicines Agency, *Medication Errors Workshop Report*, 2013, (EMA/144458/2013), page 6.

Analyzing Medication Errors

Even though the awareness regarding medication errors has increased through the years, it is doubtful whether this issue is truly taken seriously or if, on the contrary, medication errors are somehow still underestimated.

Most medication errors cause a large number of Adverse Drug Reactions (ADR's) each year. They represent a great public health burden, representing 18.7 — 56% of all adverse drug events among hospital patients and have serious impacts on patient safety, especially in more risk-prone populations such as older people and children [(14)]. According to the Expert Group on Safe Medication Practices Report [(15)], risks arising from medication errors are poorly managed in Europe, and safe medication practices are not properly developed and implemented in most EU countries. The Report recommended several actions to be taken by the European health care organizations and other stakeholders in order to promote patient safety, such as, the establishment of medication errors reporting systems, the use of a common terminology concerning harm to patients caused by medication, the creation of a culture of safety and the creation of a nationally recognized focal point for safe medication practices [(16)].

In order to tackle the issue of medication errors and adopt an adequate prevention strategy, it is important to understand the types of medication errors which may occur. The most common medication errors are errors concerning naming, labelling and packaging of medicinal products, due to the existence of sound-alike or look-alike names, similarities in the lay-out of the packaging, or whenever the packaging or labelling of medicinal products are unclear, ambiguous or incomplete. For example, concerning medication errors related to name confusion in particular, they occur whenever there are look or sound-alike invented names, trademarks of medicines with different non-proprietary names or with similar non-proprietary names, or in case there are umbrella names for different presentations of medicinal products. The Expert Group on Safe Medication Practices recommended European health authorities to take several actions to tackle this type of medication errors, specifically, the use of international non-proprietary names (INN's), instead of invented names, to reduce the likelihood of name confusion and the use of different design features for packaging and labelling, such as large front sizes, the use of Braille on medicine's packaging and clear descriptions for the strength of a medicinal product to minimize errors in dosage, a prominent positioning of the INN, appropriate use of the colour and design to minimize errors caused by mis-selection and a clear presentation of "essential information" on at least three surfaces of the medicine pack, among others [(17)]. Prescribing, dispensing and administration errors are also quite common. Prescribing errors may relate to the choice of the medicine, dosage,

[(14)] European Medicines Agency, *Medication Errors Workshop Report*, 2013, page 2.

[(15)] Council of Europe, Expert Group on Safe Medication Practices, *Creation of a better medication safety culture in Europe: building up safe medication practices,* 2006, page 15.

[(16)] Ibid, page 9.

[(17)] Ibid, page 69-70.

concentration, posology, pharmaceutical form, route of administration, duration of treatment and instructions of use, but may also be related with the failure to prescribe a medicine needed to treat or to prevent a certain pathology or to prevent the adverse effects of other medicines [18]. The dispensing of the wrong medicine, strength, form or quantity or labelling medication with incorrect instructions for use are the most frequent dispensing errors, depending on the study setting, dispensing system research method and operation definitions. Administration errors relate mostly to time errors and also the incorrect administration of dosage [19]. Medication errors may also occur due to inappropriate patient behaviour, for instance, a poor compliance by the patient of the prescribed medication regime and, in some cases, the lack of information of the patient regarding the treatment, and may also occur due to inappropriate monitoring and reporting [20].

It is important to emphasize these aspects of the medicinal product life cycle — naming, labelling, packaging, prescribing and dispensing of medicinal products — since they are supposed to have a preventive role when it comes to medication errors, and ultimately, contribute to patient safety. Therefore, it is necessary to strengthen the legislation regarding these aspects and make rules regarding naming, labelling, packaging, prescribing and dispensing of medicinal products more medication errors-oriented.

Reporting of medication errors constitutes an essential preventive mechanism. The new pharmacovigilance legislation brought new changes regarding the reporting of medication errors, by broadening the definition of Adverse Drug Reaction (ADR), which now specifically provides that pharmacovigilance systems capture new safety information, including data resulting in harm, stating that *"Member States should ensure that reporting and processing of personal data related to suspected adverse reactions, including those associated with medication errors (…)"* [21]. The reporting of adverse reactions is provided in two different articles of Directive 2001/83/EC. Article 101 of the directive respects to adverse reactions arising from the use of the medicinal product within the terms of the marketing authorization, as well as from use outside the terms of the marketing authorization. The outside terms of the marketing authorization include overdose, misuse, abuse and medication errors[22]. In addition, the directive provides that Member States shall ensure that reports received of suspected adverse reactions arising from an error associated with the use of a medicinal product should be made available to Eudravigilance database and any other authorities, bodies, organizations or institutions of that Member State which are responsible for patient safety. Directive 2001/83/EC specifically uses the expression *"error*

[18] Ibid, page 108.

[19] Council of Europe, European Directorate for the Quality of Medicines & Healthcare, *Pharmaceutical Care — Policies for a safer, more responsible and cost-effective health system*, Strasbourg, 2012, page 23-25.

[20] Ibid, page 20-28.

[21] Recital (5) of Directive 2010/84/EU, December 2010, OJ L348, 74-99.

[22] Recital (17) of Directive 2010/84/EU, December 2010, OJ L348, 74-99.

associated with the use of a medicinal product" which obviously relates to medication errors [23].

There are several medication errors reporting systems (MERS) in Europe and outside Europe, even though not all European countries have MERS. MERS are an essential mechanism for incident report analysis and to understand potential or actual health damages caused by medicinal products. When it comes to medication errors in particular, MERS may have an important role since medication errors are part of errors occurring during the medical treatment, contributing to patient injury through preventable adverse drug events. However, despite the benefits arising from MERS, the existing difficulties in defining an appropriate terminology and taxonomy, create several obstacles within the cooperation between MERS at European level [24]. Moreover, national reporting systems such as MERS may be complex due to the involvement of many different organizations in the collection of ADR's and medication errors reports — the work between all these entities should make medication use systems safer for patients.

There are many other challenges associated with reporting, which were called to attention during EMA's medication error workshop in 2013. For instance, the analysis of the procedures and practices related to the medication-use system should be performed by experts in order to fully understand the reports and develop adequate solutions. During EMA's medication error workshop, Ms Kaisa Immonen-Charalambous, Senior Policy Adviser at the European Patient's Forum, reinforced the need to stimulate reporting within patients and consumers, which has been limited at EU and national level so far. Patient involvement in the reporting would contribute to a major clarity on what to report and how, a better accessibility of the reporting system and public awareness through the media and ensure that information aimed at patients tailors their needs and health literacy levels. Health professionals' role is also extremely important within reporting, however, even though Directive 2001/83/EC provides the essential framework for reporting medication errors, there are no provisions regarding liability of health care professionals, which does not constitute an encouragement for them to report within a system which should be non-punitive, voluntary and confidential. Finally, the lack of an operational definition of a medication error and the failure in the coding terminologies to capture medication errors lead to difficulties in identifying them and separate them from spontaneous reported suspected ADR's reports[25].

Even though the new pharmacovigilance legislation brought important developments on the issue of reporting, still not quite enough was done regarding this matter. EU rules should clearly differentiate medication errors from adverse drug reactions upon reporting — national pharmacovigilance systems should be better prepared to receive reports of

[23] Article 107a (5) of Directive 2001/83/EC, November 2001, OJ L311, 67-128.

[24] Council of Europe, Expert Group on Safe Medication Practices, *Creation of a better medication safety culture in Europe: building up safe medication practices,* 2006, page 29-30.

[25] European Medicines Agency, *Medication Errors Workshop Report*, 2013, page 7-9.

adverse reactions resulting from medication errors — differentiate information is the first step to solve the error — therefore knowing that a certain report purports to a medication error is the way to prevent it.

Medication Errors: The Way Forward

EMA's workshop on medication errors intended to raise awareness for the new pharmacovigilance legal provisions amongst stakeholders involved in the reporting, evaluation and prevention of medication errors. The workshop was concluded with the adoption of six key recommendations. The first recommendation was the harmonization and further development of terminologies and definitions at EU and international level, through a common operational definition of medication error in a way to improve reporting, classification analysis and prevention activities within existing patient safety and pharmacovigilance systems. The development and alignment of MedDRA with International Classification for Patient Safety (ICPS) and WHO Adverse Reactions Terminology (WHO-Art) standards and a better guidance for regulators, patient safety authorities and industry in the use of terminologies for coding and analysis of medication errors' was also suggested as a contribution for the mentioned action. The second recommendation was the establishment of collaborative relationships between national patient safety authorities, national regulators, EMA and the European Commission. During the workshop it was considered that this action could be achieved through an awareness campaign of the new legal requirements brought by pharmacovigilance legislation — the reporting of adverse reactions resulting from medication errors [(26)], aimed at Member States and the industry. The establishment of standardized criteria for data sharing agreements and operational rules between national patient safety authorities and national pharmacovigilance centres, as well as, a collaborative work between these entities and EMA, was also suggested. The way the information on medication errors not resulting in harm (near misses) could be voluntarily collected, collated and made available (e.g. through EudraVigilance) at EU level, for the benefit of public health, was considered of major importance, as well as, the development of the best practice guidance for anonymisation of patient and health care practitioner data and the compliance with EU data protection laws in reporting systems. Moreover, the need to encourage reporting at health care professional and patient level, by communicating to stakeholders how the data is used to minimize medication errors, was emphasized. The measure at stake could be more efficient if the format, content and accessibility of ADR reporting forms were revised, in order to introduce medication errors in pharmacovigilance reporting systems on a daily basis. Another key recommendation was the development of new methods to identify medication errors from a patient safety and pharmacovigilance perspective through data pooling and analysis. This action entails the review of new ways to improve the identification of medication errors in pharmacovigilance and patient safety reporting systems, the development of a standard MedDRA query to support the detection of medication errors resulting in

[(26)] The reporting includes Eudravigilance.

harm, as well as, a mechanism for an early detection of adverse reactions that could be preventable (which is the case of those resulting in medication errors) on the basis of EudraVigilance data analysis. Regarding this recommendation, suggestions were made as to consider medication errors part of the Agency's transparency measures implemented with the new pharmacovigilance legislation and to develop guidance for the industry on how to follow-up reports of medication errors. Another recommendation was to engage in a systematic assessment and prevention of the risk of medication errors during the product life cycle, which includes the period before the granting of the marketing authorization through the EU risk-management planning process. The proposed measures to fulfil this recommendation were, essentially, the provision of the key findings of the industry regarding the prevention of medication errors' risk to patient safety authorities and regulators and the review of EMA's existing guideline on product name review to reduce name-confusion situations. In addition to this, it is necessary to take into account EMA's safety considerations on labelling, packaging, product design, devices' design and health care professional information. According to EMA, the prevention of risk can also be achieved through the inclusion of data concerning the risk of medication errors in a pre- and post-authorization situation, regarding medicinal products and other devices, seeking feedback from patient safety organizations and other stakeholders, in respect to the effectiveness of risk minimization tools for medication errors, and the improvement of safe medication practices and the inclusion of new technologies in prescribing and dispensing systems. Moreover, an active engagement and capacity building with patient consumer groups and health care professionals to improve safe medication practices were recommended. The adopted strategy would be a better communication of risks and risk-management strategies to health care providers, patients and caregivers, the improvement of the education and training of healthcare professionals, as well as patients and caregivers with respect to medication errors' reporting and prevention and, in particular, learning how medication errors are captured and how the reporting is conducted at national level, through the creation of a survey for that purpose. As a final recommendation, EMA encouraged the support to research into safe medication practices, namely into safe naming, packaging, labelling and medication practices, the effectiveness of medication error prevention and the introduction of new technologies [27].

The Medication Errors' Workshop Report further added that all six recommendations would be carefully considered by both EMA and the European Commission, envisaging their implementation plan to be made public in Q4 2013. Even though the implementation plan has still not been made public, the six recommendations already constitute a great step towards tackling medication errors.

Off-Label Use

Within patient safety, off-label use is, perhaps, one of the most controversial topics, which has been in the backstage of the pharmaceutical legislation for

[27] European Medicines Agency, *Medication Errors Workshop Report*, 2013, page 15-16.

a long time. Off-label use, similarly to medication errors, was also included in the recent legal developments brought by the new pharmacovigilance legislation of 2010.

As previously mentioned in the present article [28], medication errors do not have an official EU definition yet. The same situation applies to off-label use, and therefore the same obstacles are encountered, when attempting to regulate it. The definition of off-label use is essential and there is a great urge for harmonization, since a common EU definition of off-label use can also provide further guidance to national jurisdictions. There is no available definition of off-label use in Directive 2001/83/EC, however, Directive 2001/82/EC relating to veterinary medicinal products defines off-label use as "*the use of a veterinary medicinal product that is not in accordance with the summary of the product characteristics, including the misuse and serious abuse of the product*" [29]. The use which is not in accordance with the summary of the product's characteristics (SmPC) as referred in the definition, may include the use of a medicine for a different therapeutic indication or a therapeutic indication unrelated to the therapeutic indication for which the product is approved or the use within an approved indication but for a different patient group or under different conditions [30]. There are also other references to off-label use in the mentioned directive; Recital 30 of the Directive provides that the *"(…) collection of information on adverse reactions due to off-label use, investigations of the validity of the withdrawal period and on potential environmental problems may contribute to improve regular monitoring of good usage of veterinary medicines"*. Article 73 of the mentioned directive, referring to the implementation of a veterinary pharmacovigilance system used to collect useful information in the surveillance of veterinary medicinal products, with particular reference to adverse reactions in animals, explicitly includes off-label use information as part of the pharmacovigilance system [31]. Moreover, in Annex I of the Guideline on Good Pharmacovigilance Practices of EMA, off-label use is defined as *"situations where a medicinal product is intentionally used for a medical purpose not in accordance with the authorized product information"*, stating clearly that off-label use includes use in non-authorized paediatric age categories and that, unless specifically requested, it does not include use outside the EU in an indication authorized in that territory which is not authorized in the EU [32]. However, there is neither a definition of off-label use in Directive 2001/83/EC, nor an express reference to this concept. Why is off-label use not included in Directive 2001/83/EC? Both Recitals (5) and (17) of Directive 2010/84/EU [33] clearly use the expression *"uses outside the terms of the marketing authorization"*; even though off-label use is never clearly mentioned,

[28] Vide page 2.

[29] Article 1 (16) of Directive 2001/82/EC, November 2001, OJ L311, 1-66, *on the Community code relating to veterinary medicinal products*.

[30] P. Bogaert & A. Schwabl in *Cost Considerations should not drive off-label drug use in the EU*, Script Regulatory Affairs, June 2012, page 7.

[31] Article 73 of Directive 2001/82/EC states *"this system also takes into account any available information related to the lack of expected efficacy, off-label use, investigations of the validity of the withdrawal period and on potential environmental problems, arising from the use of the Product (…)"*.

[32] European Medicines Agency, *Guideline on Good Pharmacovigilance Practices (GVP) — Annex I (Rev 2)*, 2013, (EMA/876333/2011), page 15.

[33] Which amends Directive 2001/83/EC in what regards pharmacovigilance.

one can consider off-label use to be a use outside the terms of the marketing authorization [34]. It is however curious to realize how off-label use is specifically defined in the veterinary medicines directive but not in the medicinal products' directive — the lack of specific marketing authorizations for medicinal products used within the veterinary medicine may explain the need to resort to off-label use and, consequently, specifically regulate it in Directive 2001/82/EC.

Off-label use is frequently identified as a borderline situation with unauthorized use of medicinal products and unlicensed use of medicinal products, so, for this reason, a distinction between these concepts is of the utmost importance. Unauthorized use of medicinal products pertains to medicinal products which do not have a valid marketing authorization in the EU Member State where they are used and unlicensed use of medicinal products refers to the use of a medicinal product for which an authorization has been granted, but in a different pharmaceutical form (the therapeutic indication is the same, and the variation lies exclusively in the pharmaceutical form) [35].

Legality and Liability within Off-Label Use

EU pharmaceutical law does not expressly regulate off-label use of medicinal products and consequently, its borders and limitations are also not clearly defined. The new pharmacovilange legislation was a big step towards the inclusion of off-label use within EU rules, even though indirectly. As previously mentioned, Recitals (5) and (17) of Directive 2010/84/EU both refer to off-label use indirectly. The fact that Recital (5) establishes *"the definition of the term 'adverse reaction' should be amended to ensure that it covers noxious and unintended effects resulting not only from the authorized use of a medicinal product at normal doses, but also from medication errors and uses outside the terms of the marketing authorization, including the misuse and abuse of the medicinal product"* can only mean that the 'adverse reaction' definition should be interpreted in a way to include off-label use, despite the fact that the directive only mentions "misuse and abuse of the medicinal product" as examples of uses outside the terms of the marketing authorization. Another evident reference to off-label use arises from Recital (12) of Directive 2010/84/EC, when it establishes the obligation of the marketing authorization holder to provide all the available information, including any information related to the use of medicinal products outside the terms of the marketing authorization.

EMA has already given its views on off-label use on several occasions. On 20 of May of 2011, EMA published a document with questions and answers on the potential off-label use of celecoxib in patients with familial adenomatous polyposis. Celecoxib, whose commercial name is Onsenal, received an EU-wide marketing authorization in October 2003, for the reduction in the number of polyps in patients with FAP (genetic disease that causes 'adenomatous intestinal polyps). However, in March 2011, Pfizer Limited, Onsenal's company, voluntarily withdrew

[34] In line with the definitions of off-label-use analyzed herein.

[35] P. L'Ecluse, C. Longeval & K. T'Syen, *Off-label use of Medicinal Products and Product Liability*, Multi-Jurisdictional Guide 2013 Life Sciences, Practical Law Company, 2013, page 1.

its marketing authorization in the EU because it was unable to provide the required confirmatory data on the benefits of the medicine. The European Commission, concerned with a possible off-label use of celecoxib, asked EMA's Committee for Medicinal Products for Human Use (CHMP) to issue an opinion of the benefit-risk balance of using celecoxib for the reduction in the number of polyps in patients with FAP. The CHMP concluded that *"in view of the dose-related risks, the currently available evidence of efficacy is insufficient to support a recommendation for use of celecoxib in FAP patients"* [36]. Also, on 27 November 2012, EMA published a presentation regarding off-label use and patients' needs within rare diseases. The presentation concerned an online survey conducted during 2 months, between May and July of 2012, and whose main target were people with rare diseases who had used off-label medicinal products in the past. The main objectives of the survey were learning patients' experience with off-label use and which information patients receive, the creation of a database on off-label uses within rare diseases, knowing how patients handle adverse reactions resulting from off-label use and defining future actions on off-label use within rare diseases. The survey revealed that, in most cases, it was explicitly discussed with the patients that the medicinal product at stake was being used off-label, and the large majority of the respondents considered that there should have been more explanations about the risks and benefits of the off-label use. When asked if an informed consent form should be required for off-label use, the majority of the respondents answered affirmatively. Nevertheless, most of the respondents did not experience an adverse event during the off-label treatment and overall, they were very satisfied with the off-label use experience [37].

One of the core principles of EU pharmaceutical law is to guarantee the highest possible level of public health, therefore off-label use must be in line with the interests of public health and the medical needs of the patient. It is important to take into account that off-label use constitutes an "off the record" treatment, and it must remain exceptional and must not be promoted. This is due to two main factors: Directive 2001/83/EC provides, in article 6 that *"no medicinal product may be placed on the market of a Member State unless a marketing authorization has been issued by the competent authorities of that Member State"*. In general, a medicinal product can only be placed on the market when it benefits from a marketing authorization, and the marketing authorization includes the SmPC, where the therapeutic indication is described, as well as the posology and the method of administration, thus off-label use cannot be considered to be within the marketing authorization. The second factor has to do with the promotion of the medicinal product [38]. Article 87 of Directive 2001/83/EC prohibits the advertising of medicinal products for which a marketing authori-

[36] European Medicines Agency, *Questions and answers on the potential off-label use of celecoxib in patients with familial adenomatous polyposis*, May 2010, (EMA/CHMP/376406/2011).

[37] R. Camp & R. West, *Understanding off-label use and the information needs of patients: a pilot Eurordis survey in rare diseases*, European Medicines Agency, September 2012.

[38] P. Bogaert & A. Schwabl, *Cost Considerations should not drive off-label drug use in the EU*, Script Regulatory Affairs, June 2012, page 7-8.

zation has not been granted [39]. In this respect, the Court of Justice of the European Union (CJEU) has previously stated that the rules regarding advertising of medicinal products are not only applicable to pharmaceutical companies which advertise the medicinal product, but also to all persons, providing that *"even where it is carried out by an independent third party outside any commercial or industrial activity, advertising of medicinal products is liable to harm public health (…)"* [40]. There are some exceptions regarding the marketing authorization requirement, such as medicinal products prepared in a pharmacy in accordance with a medical prescription for an individual patient (magistral formula) and medicinal products prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia, to be supplied directly to the patients served by the pharmacy in question (official formula), which are not under the scope of application of Directive 2001/83/EC [41]. Article 5 of the Directive also provides an exemption for named patient sales stating that *"a Member State may, in accordance with legislation in force and to fulfil special needs, exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorized health care professional and for use by his individual patients on his direct personal responsibility"*, placing liability on the health care professional. This is confirmed in the judgment Commission v. Poland [42], where the CJEU states *"It is apparent from the conditions as a whole set out in Article 5(1) of Directive 2001/83, read in the light of the fundamental objectives of that directive, and in particular the objective seeking to safeguard public health, that the derogation provided for in that provision can only concern situations in which the doctor considers that the state of health of his individual patients requires that a medicinal product be administered for which there is no authorized equivalent on the national market or which is unavailable on that market."*. Similarly to the wording of Article 5(1) of Directive 2001/83/EC, the exceptionality of the administration of a medicinal product for which an authorization has not been granted or for which there is no authorized equivalent or which is unavailable in the market is clear, as well as the role of the doctor in deciding if the use of the medicinal products under those circumstances is justified.

Another very important aspect of off-label use is the informed consent of the patient. Even though Directive 2001/83/EC does not explicitly require the patient's informed consent, it is now considered an European right and essential within off-label use of medicinal products. The Council of Europe's Convention on the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, mostly known as the Oviedo Convention, provides, as a general rule, that an intervention in the health field may only be carried out if the patient has given free and informed consent to it. The Convention further adds that the

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[39] Article 87 of Directive 2001/83/EC states specifically *"Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorization has not been granted in accordance with Community law."*

[40] Case C-421/107, *Vestre Landsret (Denmark) v Frede Damgaard*, [2009] ECR I-2629, paragraphs 22 and 29.

[41] Article 3 of Directive 2001/83/EC, November 2001, OJ L311, 67-128.

[42] Case C-185/10, *Commission v. Poland*, [2012], paragraph 36.

patient shall *"beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks"* and he "*may freely withdraw consent at any time"* [43]. The general rule concerning informed consent established by the Oviedo Convention is applicable to all situations where medical treatment is involved.

Moreover, the Charter of Fundamental Rights of the European Union (European Charter), also refers explicitly to informed consent, providing *"the free and informed consent of the person concerned, according to the procedures laid down by law"* as one of the specific rights of the person to be respected in the fields of medicine and biology[44]. The fact that informed consent is explicitly provided for in these two international diplomas emphasizes its importance, especially due to the fact that it constitutes a fundamental right of the patient. Therefore, if a patient receives a medical treatment where a medicinal product is used outside the therapeutic indication for which it has been approved, the prior informed consent is even more justified, particularly because the margin of risk is bigger. When it comes to off-label use specifically, the informed consent must contain information regarding all the available treatments, and this includes medical treatments using medicinal products on-label, as well as off-label and the risks and benefits of each treatment [45]. Furthermore, there is another important aspect to take into account, which is the health care professional role. The health care professional is the entity responsible for deciding whether a specific patient shall be treated off-label, and, as a result, it is crucial that the patient is fully and adequately informed, so that he can validate the treatment through an informed consent and create a greater balance within the prescribing doctor's liability. The prescribing doctor can still be held liable even if there was an informed consent, however, if there was no prior informed consent when starting a medical treatment off-label there might be a breach of the duty of medical care [46].

Informed consent leads us to another aspect of off-label use: liability. Once again, Directive 2001/83/EC is silent regarding the liability of health care professionals when a certain medicinal product is used off-label. There is only one reference to liability in the directive, within very special circumstances. Article 5 of the directive establishes that "*Member States shall lay down provisions in order to ensure that marketing authorization holders, manufacturers and health professionals are not subject to civil or administrative liability for any consequences resulting from the use of a medicinal product otherwise than for the authorized indications or from the use of an unauthorized medicinal product, when such use is recommended or required by a competent authority in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm"* [47], without

[43] Article 5 of *Convention on the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, Oviedo, 4.IV. 1997.

[44] *Charter of Fundamental Rights of the European Union*, OJ 2000/C 364/01, 1-22.

[45] C. García Molyneux & P. Bogaert, *The Need for Informed Consent in Off-Label Use in the EU*, Script Regulatory Affairs, November 2010, page 14.

[46] Ibid, page 14.

[47] Article 5 (3) of Directive 2001/83/EC, November 2001, OJ L311, 67-128.

prejudice of paragraph 1 of the same article, which provides the possibility of a pre-launch use of a medicinal product to fulfil special needs and under the responsibility of an authorized health care professional, as previously analyzed [48]. Article 5(3) of Directive 2001/83/EC confirms the exceptionality of off-label use and it is the closest provision related to liability regarding off-label use, for it specifically mentions *"use of a medicinal product otherwise than for the authorized indications"* — however it does not, by any means, provide enough clarifications as to whether there would be civil or administrative liability in case there was a use of a medicinal product outside the authorized indications in circumstances other than those described in the provision.

Very recently, the Court of Justice of the EU issued a decision where off-label use and the liability of the health care professional were approached [49]. The judgment concerned a request for a preliminary ruling regarding the interpretation of Article 3(1) of Regulation (EC) No 726/2004 [50], which provides the conditions according to which a medicinal product may be granted a marketing authorization. The request was made in proceedings between Novartis Pharma GmbH ('Novartis') and Apozyt GmbH ('Apozyt') discussing whether Apozyt could produce, distribute and promote ready-to-use syringes intended for the treatment of eye disease and contain doses of the medicinal products Lucentis and Avastin, whose marketing authorization holders are Novartis and Roche Pharma AG, respectively [51]. Novartis brought proceedings before the CJEU seeking an order that Apozyt cease commercial activities of this kind, due to the fact that they amounted to acts of unfair competition, for the activity of filling ready-to-use syringes with doses of the unmodified medicinal product also requires a marketing authorization. Apozyt argued that a marketing authorization was not required for the procedures it carrie out, since the process of producing the medicinal product has already been completed at the time when it repackages it, then distributes it in the form of ready-to-use syringes containing lower doses than those contained in the original medicinal products that are the subject of a marketing authorization[52]. The CJEU considered that *"the processes in question do not result in any modification of the medicinal product and that they are carried out solely on the basis of individual prescriptions making provision for them, there is no ground for considering that the activity thus carried out can be equated with a new placing on the market of a medicinal product"*. It was further questioned in the judgment whether Apozyt's activities were covered by the derogation established by Article 5(1) of Directive 2001/83/EC. The CJEU considered that the derogation established by Article 5(1) was not applicable *"on with regard to the use of a medicinal product such as Lucentis since those circumstances do not entail prescription of a medicinal product different from the product which already has a marketing autho-*

[48] Vide page 8.

[49] Case C-535/11, *Novartis Pharma GmbH v. Apozyt GmbH*, 11 [2013].

[50] Regulation (EC) 726/2004, *laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency*, OJ 2004 L 136, 1-33.

[51] Case C-535/11, *Novartis Pharma GmbH v. Apozyt GmbH*, [2013], paragraphs 3, 18 and 21.

[52] Ibid, paragraphs 24-26.

rization; the injection volumes used are no different from those provided for in the marketing authorization and nor is the product used for a therapeutic indication not covered by the marketing authorization"[53]. However, the CJEU did not exclude "the *making available of an authorized medicinal product, such as Avastin, for therapeutic indications not covered by the marketing authorization, where such a formulation is in accordance with the specifications of an authorized practitioner and is for use by an individual patient under his direct personal responsibility"*. According to the CJEU, the active ingredients of Avastin and Lucentis are different, therefore, a doctor facing a particular condition and taking into consideration specific therapeutics aimed at his patients may come to the conclusion that a treatment *"not covered by the marketing authorization, in accordance with the pharmaceutical form and the dosage which he considers appropriate and using Avastin which has a Community marketing authorization, is preferable to treatment with Lucentis",* notwithstanding, however, the fact that the doctor is obliged not to prescribe a medicinal product, if it is not appropriate for the therapeutic treatment of his patient[54]. This judgment provides further clarifications in respect to the doctor's conduct when prescribing his patients a medicinal product for therapeutic indications not covered by the marketing authorization, which should be under his direct and personal responsibility and, at the same time, the duty not to prescribe such medicinal product, whenever he considers it inappropriate for treating his patient. All in all, the CJEU expressly admits the possibility of treatment resorting to off-label use medicinal products, as well as a possible liability of the prescribing doctor.

Conclusions

Throughout this article we have analyzed and discussed new legal developments which have occurred within medication errors and off-label use, two important areas of patient safety which shall not be ignored. A lot of progress has been done, and a lot of progress can still be done.

First of all, it is extremely important to create an EU common definition of medication errors. The lack of an official definition in EU pharmaceutical law creates greater difficulties in identifying and reporting medication errors, and consequently, reacting accordingly. Furthermore, it is necessary to strengthen the legislation within certain aspects of the medicinal product life cycle: for instance, making rules regarding naming, labelling, packaging, prescribing and dispensing of medicinal products more medication errors-oriented. It is important to take into consideration that health care professionals and the industry are in a better position to tackle medication errors than the patient itself, because they are the information providers — therefore new legal provisions aimed at reducing medication errors should be essentially addressed to them. Even though the new pharmacovigilance legislation brought important developments on the issue of reporting, still not quite enough was done regarding this matter. EU rules should clearly differentiate medication errors from adverse drug reactions upon

[53] Ibid, paragraph 47.
[54] Ibid, paragraphs 48-49.

reporting and national pharmacovigilance systems should be better prepared to receive reports of adverse reactions resulting from medication errors.

Off-label use is also not officially defined or regulated in EU legislation, even though it is now somehow included in Directive 2001/83/EC, due to the new pharmacoviligance legislation. Despite being a common practice in some medical areas, such as paediatrics, off-label use still entails several risks, and for that reason, the benefits of off-label use should clearly outweigh the potential risks of using a medicinal product for a specific therapeutic indication for which it was not approved. This places an enormous responsibility on the prescribing doctor, because the liability lies on him, and not the product itself.

Since off-label use is not expressly regulated, neither the liability resulting from its use, the informed consent acquires an extremely relevant role. The fact that the patient is aware that he is using a medicinal product for a therapeutic indication which is not approved, and consents to it, might be a way to reduce the liability that lies on the health care professional.

We hope that the new developments brought by EU legislation will be an incentive to further regulation which can better address both medication errors and off-label use.

Chapter 3: Learning with errors

REPORTING INCIDENTS AND ADVERSE EVENTS: TO LEGISLATE OR NOT?

Paula Bruno [1]

Abstract: *Patient Safety is a major problem for the world Public Health and a vast economic burden for the health resources available. The Patient Safety movement emerged on a international context after several studies have reported that between 8% to 12% of the hospital patients are affected by adverse events, i.e., patient harm that results from healthcare and not from their condition. The international organizations, which play an important role on patient safety (WHO and EU), recommend the state members to change healthcare institutions safety culture. They also recommend the implementation of confidential and non-punitive reporting systems as an essential learning tool for risk management and to prevent and reduce patient harm. However, these systems are not efficient if they are not confidential and non punitive; otherwise, the practitioners will fear the consequences and will not be willing to report incidents. In Portugal, with the legal system in place, practitioners are not guaranteed total confidentiality and lack of punishment and this will only change by evidencing new laws certifying such protection. Legislating reporting systems will raise a confrontation between citizen's rights and personal interests. This paper has been developed based on this conflict (public health/citizen's rights), including an approach to the international expertise and to the comparative law about confidentiality in reporting systems, as well as an assessment of the current national background and a presentation of the juridical and constitutional aspects of an eventual law that may consecrate a Portuguese Adverse Events and Incidents Reporting System.*

I. Introduction

Patient safety has been the main focus over the last 15 years in international public context and it has been the concern for international scientific organizations, both governmental and non-governmental.

In Portugal, this subject has been gaining visibility in society for the last decade, especially due to the media work with some cases of "medical errors" in hospitals. It has also gained more visibility due to the papers target on Error in Medicine and Clinical Risk and to the accreditation procedures and risk management, as well as the World Health Organization and European Union recommendations about patient safety.

The Patient Safety movement rises in the international context with a great emphasis after the IOM [2] reported high rates for medical errors. This

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[2] Kohn, T. Linda; Corrigan, M. Janet; Molla, S. Donaldson — To err is human: building a safer health system. Institute of Medicine. Washington, DC: National Academy Press, 2000.

report accounts for 44 to 98 million people dying every year due to medical errors which are the eighth leading cause of death and raised attention due to the high costs that these errors involve, which are estimated to be between 17 and 29 billions of dollars. The same report appeals to a change in the healthcare system to redesign the procedures according to a new patient safety culture involving all the individuals.

Patient safety was also a subject of research in other countries, like United Kingdom (*An Organization With a Memory,* 2000) [3], Canada (*Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Healthcare*, 2002) [4], Australia (*Australian Safety and Quality Goals for Healthcare,* 2011) [5], Spain (*Observatorio para la Seguridad del Paciente — Plan de Calidad para el Sistema Nacional de Salud*, 2006) [6], and many other countries in which it was initiated a research to achieve higher patterns of safety.

The international studies published, establish adverse events rates around 3% (USA), 16% (Australia), 7% (Canada), 11% (United Kingdom), 12% (New Zealand), 9% (Denmark) and 9% (Spain). Most of these studies concluded that at least half of the events were preventable.

Portugal has an incidence rate of adverse events of 11%, of which, 50% could be preventable. The study led us to the conclusion that in the majority of cases, neither the patient nor the family knew of the adverse event. [7]

In the European Union it is estimated that between 8 and 12% of hospital patients are victims of adverse events whilst receiving healthcare and not from the disease, from which 25% are hospital-acquired infections. The remaining percentage is related to medication errors, surgery and diagnostic errors [8].

The ECDC (*European Center for Disease Prevention and Control*) reported a rate of 5% of the patients being victims of hospital-acquired infections, which corresponds to 4,1 million of people per year in the UE. It also reports an occurrence of 37.000 deaths per year due to hospital-acquired infections.

Facing the evidence of high prevalence rates of incidents and adverse events, and the underlying costs to property damage and personal injuries that occur in healthcare, along with the awareness of how much can be done to reduce them, it comes across the civilized world a movement around Patient Safety.

It is important to make clear two concepts commonly used in the patient safety language and part of the WHO International Classification: a patient

[3] UK. DEPARTMENT OF HEALTH — An organization with memory : report of an expert group on learning from adverse events in the NHS. London : Department of Health, 2000. ISBN 011 322441 9.

[4] CANADA. NATIONAL STEERING COMMITTEE ON PATIENT SAFETY — Building a safer system : a national integrated strategy for improving patient safety in Canadian healthcare. Ottawa, ON : National Steering Committee on Patient Safety, 2002. ISBN 0-9692155-3-3.

[5] AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTHCARE — Australian safety and quality goals for healthcare: consultation paper. Sydney: Australian Commission on Safety and Quality in Healthcare, 2011.

[6] ESPAÑA. MINISTÉRIO DE SANIDAD Y CONSUMO — Plan de Calidad para el Sistema Nacional de Salud. Madrid : Ministerio de Sanidad y Consumo, 2006.

[7] Sousa P, et al., Escola Nacional Saúde , 1.ª Edição. Maio. 2011.

[8] RAND, 2008; SAÚDE UE. http://ec.europa.eu/health/patient_safety/policy/index_en.htm

safety *incident* is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient and an *adverse event* is an incident which resulted in harm to a patient [9].

The scientific community recognizes that healthcare organizations are considered very complex environments and systems where too many variables coexist, like the disease, the staff, the equipment, the organizational politics and procedures [10] and the inevitability of human error in present in such a complex environment.

A remarkable psychologist and researcher [11] who studied error and human fallibility showed that the highlight should not be the person liability but the system's. This researcher has driven the attention to the organizations safety culture and to the importance of having (i) a system that collects, analyses and spreads incident information; (ii) a culture of reporting; (iii) a culture of trust where the practitioners are encouraged to provide information related to safety; (iv) flexibility and ability to change the organizational structure; (v) ability to draw conclusions from the safety system; (vi) implement changes when needed. This is the emblematic author of the analogy between latent failures and the existence of holes in a Swiss cheese (the Swiss cheese model) and that spread the message that healthcare organizations should act on the system (in order to reduce the cheese holes and create protective barriers to prevent the alignment of these holes) and multiple organizational factors contribute to the production of events, the so called active failures.

Patient safety is an important dimension of Healthcare Quality, as efficiency (maximizing resources and minimizing waste) and effectiveness (healthcare management according to evidence of best results), availability (healthcare provided in time), equitability (healthcare regardless the gender, ethnicity, geographical location and socioeconomic level) and patient centeredness (responding to the preferences of users) [12]. Patient safety is also a serious public health issue and represents a high economic and social burden, specially facing the limited resources that characterize the current context of economic and financial crisis, with severe budget constraints. The search for solutions to this public health issue justifies the effort of national and international scientific organizations and healthcare institutions to follow procedures that showed evidence to prevent and reduce incidents and adverse events. This procedures should be taken not only to protect patient's life but also because of the additional costs of the consequences of those events, as it is shown in the literature mentioned above as well as other studies that have analyzed the cost-efficient correlation for patient safety interventions [13]-[14].

[9] WHO. The Conceptual Framework for the International Classification for Patient Safety, 2009.

[10] Kalra, J. Medical errors: an introduction to concepts. (2004) Clinical Biochemistry 37 1043-1051.

[11] Reason J., 1997, Managing the Risks of Organizational Accidents (Aldershot: Ashgate).

[12] WHO. Quality of care: a process for making strategic choices in health systems. World Health Organization, 2006.

[13] Etchells. E. et. al. -The economics of patient safety in acute care. Technical Report. Consulta no site CPSI. ICSP-Canadian Patient Safety Institute

[14] COM(2012)658 final, Bruxelas 13.11.2012. pag. 14.

II. International environmentworld health organization

The World Alliance for Patient Safety was created by the World Health Organization (WHO) in 2004, which since than has being researching, promoting and recommending programs/campaigns/procedures and online training in areas that matters, namely: World Challenges to Patient Safety (for example "*Clean Care is Safer Care*" and "*Safe Surgeries Saves Lives"*; Patients for Patient Safety; Research in Patient Safety; International Classification for Patient Safety (one example is the launching, in 2009, of the *"The Conceptual Framework for the International Classification for Patient Safety"*); Reporting and Learning (with the release of an important study on reporting systems[15]); Patient Safety Solutions; Patient Safety Technology; Education and Training, among several other acting and investigation areas that this organization promotes to the Member States.

This paper highlights very briefly the WHO's ten recommendations for Member States:

1. Adverse event reporting and learning systems should have as their main objective the improvement of patient safety through the identification of errors and hazards which may warrant further analysis and investigation in order to identify underlying systems factors.
2. When designing adverse event reporting and learning systems, the responsible parties should clearly set out:
   the objectives of the system who should report what gets reported mechanisms for receiving reports and managing the data sources of expertise for analysis the response to reports methods for classifying and making sense of reported events ways to disseminate findings technical infrastructure and data security.
3. Health-care workers and organizations should be encouraged to report a wide range of safety information and events.
4. Health-care workers who report adverse events, near misses and other safety concerns should not be punished as a result of reporting.
5. Reporting systems should be independent of any authority with power to punish the reporter.
6. The identities of reporters should not normally be disclosed to third parties.
7. Reported events should be analyzed in a timely way.
8. Reported events should be analyzed by experts who understand the clinical circumstances and care processes involved and who are trained to recognize underlying systems causes.
9. The entity that receives reports should be capable of making and disseminating recommendations. Participating organizations should agree to implement recommendations wherever possible.

[15] WHO. Draft guidelines for adverse event reporting and learning systems. World Health Organization, 2005.

10. Recommendations for preventative strategies should be rapidly disseminated, especially when serious hazards are identified.

European Union

The European Union has an important mission and high skills in public health [16] and coordinates and complements the Member States actions concerning the health policies and the healthcare organization and practice. In the last eight years the European Union has promoted several actions for patient safety in the European Union.

After the release, in 2005, of the Luxembourg Declaration "Patient Safety — making it happen!" [17], the issue of patient safety in Europe raised a strategic priority, shared by all Member States.

In 2006, the European Council[18], after a discussion with he ministers from all Member States, released several endorsements for patient safety management and healthcare adverse events prevention. This recommendation reflects not only the need for an enhanced harmony between Member States through best practices in health, but also the need of understanding errors and their prevention. This document also highlights some guidelines about reporting systems (topic D), in a very similar way to the WHO recommendations for reporting systems, stressing the need for a legal structure (topic J) to those systems.

This paper will review some of the recommendations to the Member States in order to have a legal approach to patient safety policies, national and local mechanisms which allow an analysis of the adverse events; define the reporting system characteristics and structure; create data protection rules to ensure the confidentiality of reporting and garanty the legal protection for the reporting practitioners. The EU work on patient safety issues is evident in the following years, either at the European Commission level (COM (2008) 836 e 837), or at the European Union Council level and it concludes with the publishing of the Council Recommendation of 9 June 2099 about *"Patient Safety, including prevention and control of healthcare associated infections"* [19]. This document has a great importance to Patient Safety at European level and this importance is highlighted by the demands on Directive 2011/24/EU [20], of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

The 2009 Recommendation allowed the Member States to clarify the acting areas for patient safety improvement and invited the European countries to adopt several measures to minimize patient harm, such as:

— Establish and develop national policies and programs on Patient safety

[16] Art. 6.º, al. *a)* e 168.º Tratado sobre o Funcionamento da União Europeia

[17] EUROPEAN COMMISSION — Health and Consumer Protection. Luxembourg Declaration on Patient Safety. Patient Safety — Making it Happen! 2005. Luxembourg.

[18] RECOMENDATION REC (2006) 7.

[19] JOUE, (2009/C151/01).

[20] JOUE 88 de 4.4.2011.

— Empower and inform citizens and Patient
— Support the establishment or strengthen blame-free reporting and learning systems on adverse events
— Promote at the appropriate level, education and training of healthcare workers on Patient Safety
— Classify and measure Patient Safety at community level, by working with each other and with the Commission
— Share knowledge, experience and best practice by working with each other and with the Commission and relevant European and international bodies
— Develop and promote research on Patient Safety

282 Those measures have the purpose of developing national policies and programs for patient safety; the citizen liability and the release of information; the creation of non punitive reporting systems; the practitioners training in Patient Safety; the classification and measure of Patient Safety at community level; the knowledge, practices and expertise sharing; and, at least, the development and promotion of research in the patient safety domain.

The second chapter of this Recommendation is dedicated to the healthcare-acquired infections prevention and control and invites the Member States to adopt preventing and control strategies at a national level, surveillance systems, training for practitioners, research and information release for patients.

Member States were asked to communicate to the European Commission the policies implemented, contributing to the Council Report in November 2012 [(21)]. In light of the obtained results, the European Commission decided to extend for another two years the monitoring of the Recommendation enforcement due to the recent character of the actions in some of the Member States, resulting in different maturity and application levels between the UE countries (page 4 of the above mentioned report).

III. Incidents and adverse events reporting systems

The incident and adverse events reporting systems have risen from the high-risk industries like aviation and nuclear technology. It has allowed us to identify and therefore make a qualitative and quantitative incidents' analysis, and thus build a learning organization [(22)].

A reporting system enhances the possibility to learn from the healthcare systems failures. They also allow the dissemination of information and the implementation of safer practices, changes and system solutions [(23)].

In highly complex organizations, as healthcare institutions, the implementation of an incident and adverse events reporting system allows important results which lead to preventing and reducing patient harm, making easier to the organization to learn and to assure an continuous improvement of

[(21)] COM(2012)658 final, Bruxelas 13.11.2012.

[(22)] Barach; Small. -Reporting and preventing medical mishaps: lessons and safety in clinical medicine. *BMJ*. 320. 2000.

[(23)] World Alliance for Patient Safety — WHO Draft Guidelines for Adverse Event Reporting and Learning Systems. 2005.

healthcare quality and Patient Safety. This consists of a learning process regarding errors, incidents and adverse events having as its consequence the spread of knowledge about the occurrence and the underlying factors. The success of the reporting systems depends on the learning process, which must rely on strong and regular activities, like having a good reporting system, systematically reports analyzes, failures identification, main contributive factors analyzes, constant feedback and information about the implementation of the improvement measures and, above it all, having a non punitive reporting system [(24)].

The main goal is to create a safety culture for all the organization, involving all staff, based on valuable procedures and risk management tools, as reporting systems, clinical auditing, procedures reviews, safety indicators, surveys, risk evaluations (risk scores that allows the comparison of the obtained values with the expected values), Failure Modes and Effects Analysis (FMEA), Root Causes Analysis (RCA). These tools already began to be in place, Lage (2010) says, *"none of the tools created and adapted for this purpose should be considered as superfluous and dispensable in clinical practice*", because they aim to benefit the patient and avoid harm as a result of healthcare [(25)].

Reporting systems are recommended as an essential criteria to risk management in accreditation programs, such as Joint Commission International (USA), Caspe Healthcare Knowledge Systems (UK), Accreditation Canada, and lastly, in Portugal, the National Accreditation Program.

The benefits of these reporting systems contrast with the ineffectiveness of the same, which is due, in large measure, to reporting barriers, as revealed by various international studies on the investigation of the phenomenon of underreporting.

Based on the literature review, we sought to identify the barriers to reporting incidents and adverse events, in a generic and brief way, but consensus on the major causes, as seen in table 1:

Table 1 — Barriers to Incidents and Adverse Events Reporting

Uncertainty in the reporting object/the events definition [(26)] [(27)] [(28)] [(29)] [(30)] [(31)]
Fear (guilt, shame) of lawsuits [(32)] [(33)] [(34)] [(35)] [(36)] [(37)] [(38)] [(39)] [(40)] [(41)]
Lack of feedback [(42)] [(43)] [(44)]

[(24)] Mahajan R.P. Critical Incident Reporting an Learning. British Journal of Anaesthesia. 105(1): 69-75. 2010.

[(25)] Lage, Maria João — Segurança do Doente: da teoria à prática clínica. Rev. Port. Saúde Publica. 2010;Vol Temático (10). 11-16.

[(26)] Rosenthal, Jill *et al.* — How States Report Medical Errors to the Public: Issus and Barriers. Washington, DC: National Academy for State Health Policy, October 2003.

[(27)] Kaveh G. Shojania, *et al.* — Understanding medical error and improving patient safety in the inpatient setting. Medical Clinics of North America. 86. 2002. 847-867.

[(28)] Bhatia R., *et al.* — Developing a departmental culture for reporting adverse incidents. International Journal for Quality in Health Care. 16 : 3. 2003. 154-156.

[(29)] Evans S.M., *et al.* — Attitudes and barriers to incident reporting: a collaborative hospital study. Quality and Safety in Health Care. 15. 2006. 39-43.

[(30)] Uribe C.L., *et al.* — Perceived barriers to medical error reporting: an exploratory investigation. Journal of Health Management. 47. 2002. 263-80.

[(31)] Edmondson. A. — Learning from failure in health care: frequente opportunities, persistent barriers. Qual. Saf. Health Care. 13. 2004. 3-9

[(32)] Kohn T. Linda *et al* — To err is human: building a safer health system. Institute of Medicine. Washington, DC : National Academy Press, 2000.

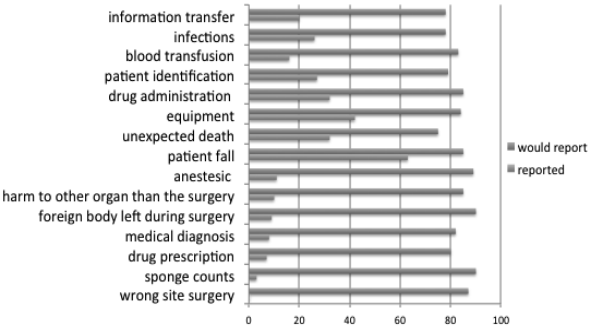
[(33)] Barach P.; Small S.D. — Reporting and preventing medical mishaps: lessons and safety in clinical medicine. BMJ. 320. 2000. 759-763.

The literature presents strong reasons for the occurrence of underreporting like shame, fear of lawsuits and disciplinary procedures, and the weak culture of reporting.

There is strong international literature that reveals that health professionals report few incidents, or none, and physicians report less than nurses.

In a study from Bruno (2010) with 200 respondents (doctors and nurses) of four Portuguese hospitals, was found that 50% had not reported in the last 12 months and the other half of the professionals reported few incidents[45]. In another study on the Safety Culture Assessment in seven Portuguese hospitals [46], it was found that 73% of the health professionals had not reported in the last 12 months.

In the same study it was found that the existence of laws that guarantee confidentiality to the staff who report, would have a positive effect and would increase reporting. Bruno (2010) found that in specific cases (like error in the surgery, strange body retained in surgery or diagnostic error) there are few or no reports due to the lack of legislation but that, if there were adequate legislation, these cases would be reported.



Graph 1 — Percentage of notification/events that would have been reported (Bruno, 2010)

Bruno (2010) found that there is a strong and direct correlation between fear of lawsuit and reporting. Staff also fears that reporting could be used against them either in court or in a disciplinary process.

[34] Annas G.J.. The patient's right to safety-improving the quality of care through litigation againts hospitals. New Engl. Journal Medicine 354. 2006. 2063-6.

[35] Benn J., *et al.* — Feedback from incident reporting information and action to improve patient safety. Quality and Safety in Health Care. 18. 2009. 11-21.

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[37] Berlinger N. — After Harm: Medical error and the ethics of forgiveness. Johns Hopkins University Press. Baltimore.

[38] Hartnell N. *et al.* — Identifying, understanding and overcoming barriers to medication error reporting in hospitals: a focus group study. BMJ. Qual. Saf. 21. 2012. 361-368.

[39] Waring J.J. — Beyong blame: cultural barriers to medical incidente reporting. Soc.SCi Med. 60. 1927-35. 2005.

[40] Osborne J. *et al.*. Nurses' perceptions: when is it a medication error? J. Nurs Adm. 29. 1999, 33-8.

[41] Zane, R.W, Ronda G.H. Patient Safety and Quality: An Evidence--Based Handbook for Nurses. Agency for Healthcare Research an Quality. 2008. Cap. 35. Pag. 18.

[42] Livingston E.. Solution for improving patient safety. JAMA. 303. 2010. 159-61.

[43] Firth-Cozens J. — Confronting errors in patient care: the experiences of doctors and nurses. Clinical Risk. 10. 2004. 184-90.

[44] Wallace, Louise M. *et al.* — Improving patient safety incident reporting systems by focus group on feedback — lessons from English and Welsh trusts. Health Services Management Research. 22 (2009) 129-35.

[45] Bruno, Paula. Registo de Incidentes e Eventos Adversos: Implicações Jurídicas da Implementação em Portugal (20), Wolters Kluwer/Coimbra Editora, 2010.

[46] DGS, Avaliação da Cultura de Segurança do Doente nos Hospitais Portugueses — Estudo piloto, 2012.

Several international studies, regardless the cause (fear, liability, shame) show a strong and direct correlation with the fear of lawsuit; i.e. with practitioners aware that their actions can be reviewed in court or in disciplinary actions within their organizations, and that the report can be used against them.

Although it is not our main purpose, we will make some brief considerations on disclosure of errors to patients. This is an ethical issue related to the Bioethics principles, like the non-maleficence, beneficence, justice, autonomy of patients, and rules of confidentiality, fidelity and veracity [(47)], and ethical obligations that rule the exercise of medical professions.

We aim to demonstrate that the issue of disclosing/revealing the errors to patients is distinct to adverse event reporting, it is in fact the disclosure of harm to the patient, i.e. to explain what happened, apologize if necessary, in order to maintain the trust between doctor and patient and eventually reduce the probability of lawsuit. [(48)]

The literature shows that, although the practitioners have this liability and honesty values, many of them do not disclose the errors to the patients because of fear, shame, guilty or fear of lawsuits. The chapter 35 of Zane R. and Ronda G.'s study is particularly enlightening of this reality [(49)] because it presents several international studies that prove the weak rates of disclosure. Also the article of Lage[24] presents the barriers and advantages to the error disclosure and the fear of lawsuit as the main cause of disclosure omission.

We are aware that, at this level, Portugal is not far from the international reality. Some countries like the USA or Canada have been creating disclosure policies and strategies encouraging the so called *"apology law"* as a way to encourage the practitioners, including the approval of specific laws to control this issue. Some authors believe that disclosure reduces lawsuits, others believe otherwise. However, it is not known any credible and conclusive study that had established the cause-effect correlation between disclosure and lawsuits [(50)].

Regardless the international community thoughts about this subject (reporting vs. disclosure), in our opinion it hasn't the adequate focus in Portugal. We highlight that these are two different realities, on one hand the reporting based upon professional scripts and on the other hand disclosure based on the patients needs and rights. As a result of this difference, we believe that healthcare organizations should adopt adequate policies and procedures towards an new approach on Patient Safety issues.

IV. Guarantees of confidentiality and non punishment for incident and adverse events reporting in portugal

The legal aspects regarding confidentiality and not punishment were early concern in many coun-

[(47)] Beauchamp TL, Childress JF. Principles of biomedical ethics. New York. Oxford University, 1989.

[(48)] Flowers L. Does "sorry" work for errors? OR Mang. 2005

[(49)] Zane, R.W, Ronda G.H. Patient Safety and Quality: An Evidence-Based Handbook for Nurses.

[(50)] McDonnell Willian, Guenther Elisabeth — Narrative Review: Do State Laws Make it Easier to Say "I'm Sorry?". Ann. Internal Medicine. 149. 2008. 811-815.

tries. This concern was the topic under the name of protection of reporting systems of legal knowledge, since the first major publication *To err is Human*[1].

From a legal perspective, the confidentiality and non punishment assurance does not exist in Portugal. As to the question whether the report of an incident or an adverse event, may be used as proof (documentary in a civil or criminal lawsuit) the answer is YES!

There is also the possibility of using a report against the health professional in a disciplinary proceeding by the institution. This is one of the major concerns of the current system!

So, in fact, health professionals do not want to cooperate with the current system because of the legal consequences it could bring about. This conclusion is invariably shown by international studies.

Another aspect of great importance is the possibility of health professionals being called to court proceedings as witnesses.

The members of any Committee of Quality and Patient Safety, who have the task of analyzing and investigating all reports may effectively be called to testify in Court (civil or criminal), as well as in a disciplinary inquiry. This is a delicate matter and of concern to Portuguese health professionals!

It's important to know if, in a situation as described above, these two situations are in conflict: That is, on one hand, the obligation to *cooperate with the justice*, and on the other hand, the *duty of confidentiality*. Which should prevail?

According to the principle of prevalence of overriding interest, it prevails the vital public interest underlying the duty to cooperate with the administration of justice?

We understand that it makes sense to call into Court other interest, hence the *Public Health*, in order to promote and safeguard the reporting systems as they were created with such purpose, in other words, tackle a public health problem.

V. Legal-constitucional context: the (possible) legal system for the national incident and adverse events reports in Portugal

This work aims to contribute to the knowledge of the issue of Patient Safety and to clarify the legal aspects related to reporting systems, strongly motivated by the weaknesses that these systems have at local and national levels, but also by the need to regulate these systems in Portugal.

We consider necessary and useful an analysis, on the legal point of view, to a possible legal framework for reporting systems. This framework must be rigorous, ethically balanced and scientific, because on one side we have to consider public health interests an on the other side we have the fundamental individual rights, both protected by the Portuguese Constitution.

The Portuguese Constitution [51] and the Health Law [52] established that the state must ensure and guarantee all citizens access to healthcare through the use of the National Health Service.

Rights, guarantees and interests in confrontation

Create Portuguese laws for Incident and Adverse Events Reporting Systems sets in confrontation

[51] Art. 64.º, n.º. 2 e 3, da CRP.
[52] Lei 48/90, de 24/08.

rights and guarantees of citizens with different interests, such as public health.

Consider, then, the **rights included in the Constitution** and included in the *Rights, Freedoms and Warranties* (Title II), in Chapter I, dedicated to the ***Rights, Freedoms and Personal guarantees.***

We want to highlight the right to life[53], the right to personal integrity (physical and moral)[54], the right to privacy[55] and the right of all citizens to access data concerning themselves, the right to be informed without hindrance or discrimination[56]. To every citizen is also guaranteed access to the law and the courts to defend their rights and to be legally protected[57] and the right to information and of access to administrative records and files, since it is the governments' responsibility to respect and legally protect the citizens rights and interests, including providing them information and giving them the right of access to files and administrative records [58].

On the other hand, in Chapter II, devoted to ***Social Rights and Duties***, we highlight the **right to health protection** [59], which implementation depends on the intervention of the legislator [60], because, facing the developments in modern societies operated from time to time, it is necessary to create legislative interventions to promote and ensure the health of Portuguese citizens.

Rights and Personal Guarantees are also included in several other Portuguese legislation, including the right of access to data [61]-[62]-[63], the right to be informed about their clinical situation[64], the duty of clarification health professionals and obtain the patient's informed consent for the practice of medical procedures [65]-[66], the ethical/legal obligations (duty of confidentiality, duty of explanation, duty of documentation in the medical record), in addition to other civil and criminal procedural rights, which we were able to analyze with the purpose of confidential reporting systems. In the face of all this rights, we conclude that legislate reporting systems in Portugal deserves a serious and comprehensive legal/factual reflection.

Restrictive Law

To legislate the reporting systems undermines, affects and restricts fundamental individual rights and guarantees, and constitutional law expressly provides that conditions may be developed and approved these restrictive laws. Let us, then, briefly name the **requirements of restrictive laws**, in the teaching of the remarkable Constitutionalist Jorge Miranda [67] and the letter of our Constitution:

[53] Art. 24.º Constituição da República Portuguesa (CRP).
[54] Art. 25.º CRP.
[55] Art. 26.º CRP.
[56] Art. 37.º CRP.
[57] Art. 37.º CRP.
[58] Art. 268.º CRP.
[59] Art. 64.º CRP.
[60] Lopes, Almeida J. J. Constituição da República Portuguesa, 6.º. Revisão Anotada, Almedina, 2005, pag. 410.
[61] Art. 11.º da Lei 67/98, de 26/10 (Proteção de Dados Pessoais)
[62] Art. 5.º, 11.º da Lei 46/2007 de 24/08 (Acesso aos Documentos da Administração).
[63] Art. 3.º da Lei 12/2005, de 26/01 (Informação genética pessoal e informação de saúde).
[64] Base XIV da Lei 48/90, de 24/08 (Lei de Bases da Saúde).
[65] Art. 156.º do Código Penal.
[66] Art. 5.º da Convenção de Oviedo.
[67] Miranda, Jorge. Manual de Direito Constitucional, Tomo IV, 5.ª. Edição, Coimbra Editora, 2010.

"*The law may only restrict the rights, freedoms and guarantees in cases expressly provided in the Constitution; restrictions shall be limited to what it is necessary to safeguard other constitutionally protected rights or interests*". [68]

Thus we have: requirement of formal law [69]; requirement of generality and abstraction of restrictive law; requirement of non-retroactivity of the restrictive law; principle of proportionality, also known as prohibition of excess, and the principle of safeguarding the essential core [70].

Without disregarding the other statements, we will devote some attention to the **principle of proportionality**, applicable to legal and constitutional rights restrictions. This will require a complex assessment with a view to making the decision to legislate or not the reporting systems, especially regarding the characteristics of confidentiality and not punishment before mentioned, which may sacrifice some of the rights referred above [71]. The **principle of proportionality** includes three sub-principles, which are:

(i) ***the principle of suitability or fitness*** — the restrictive norm of individual rights and guarantees should be appropriate for its purpose — to promote patient safety (public health);

(ii) ***the principle of need*** — among the possible hypotheses, we believe that assigning the aforesaid confidentiality to reports is the one that meets better the intended purpose (Public health). Another possibility would be to adopt an anonymous system, with no laws, in which players would not be identified and therefore the report could not be used against them. However, the systems do not recognize such benefits in terms of efficiency, especially *in situ* (institution), where it is essential to investigate thoroughly following the incident — a Root Cause Analysis (ACR), what happened? with whom? when? why? how?, in order to identify its contributing factors so that later, based on the knowledge obtained, it is possible to implement preventive measures to prevent the repetition of that incident. Furthermore, even if in a reporting system that is, at the outset, anonymous, their players are easily identifiable, not only through the recorded data (service, day, type of incident, etc.), but also by the reports produced as a result of this investigation which will aggregate all available information about the incident and/or adverse event, answering questions from the RCA. Even in the absence of documentary evidence (report), there would always be testimonial evidence (the testimony of the professionals from the practice, that investigated the incident and know it in detail), and, given the reasons described, an anonymous system without legal protection does not give any guarantee to the professionals that report.

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[68] N.º. 2 do art. 18.º da CRP.
[69] Art. 168/1, 2, 3, 4 e art. 115.º/2.
[70] Art. 18.º, n.º 3, in fine da CRP.
[71] Miranda, Jorge. Manual de Direito Constitucional, Tomo IV, 5.ª. Edição, Coimbra Editora, 2010.

(iii) ***principle of rationality or proportionality*** — the legislature must assess whether the restrictive rules are not beyond or below or if they are the right measure for the intended purpose, under penalty of violation of the principle of proportionality by excess, which can lead to over protection (disproportionately positive) or a lack of protection (disproportionately negative). Given that the implementation of systems for reporting incidents and adverse events is essential and urgent in the Portuguese health system in order to detect, analyze and prevent errors, incidents and harming to patients, it seems fair to legislate these systems and regulate them with characteristics that confer efficacy, which, in our view, will be reached through a system that addresses the confidentiality and non-punishment of the professionals that report these incidents because the sacrifice that may be required constitutional rights will be compensated with health gains.

We think that, with the consecration of a voluntary system, it will reach this fair measure imposed by the principle in question, as the option of a mandatory system would not be proportionate; to compel health professionals to notify incidents and adverse events generates distrust, and the government would necessarily require the creation of supervision and sanctions mechanisms for non-compliance.

It is justified, therefore, a legislative intervention to safeguard assets of great legal and constitutional relevance: public health (patient safety), access to healthcare quality, and the physical and moral integrity and life of patients.

Obviously that a legislative procedure having as object this matter does not involve only the mentioned subjects and it is certainly much more complex and, if implemented, will necessarily lead to deserved reflection on these matters. We should recall that a legislative process begins with the phase of the initiative, followed by assessment/consultation, deliberation/discussion, vote and, finally, the promulgation and control [(72)] of the legislative act.

VI. Comparative Law

The problem of underreporting is not strictly limited to our country, as other countries felt the need to legislate on patient safety and reporting systems.

We will make a short analysis to have a better understanding of the models of comparative law.

In Denmark, in December 2001, was created the **Danish Society for Patient Safety (DSFPA)**, and in June 2003 it was approved the Law on Patient Safety in the National Health System — **Act on Patient Safety in the Danish Healthcare System — Act No. 429** of 10/06/2003 — which came into force in January 2004. This law implemented a national system for mandatory reporting of adverse events, in which the reports are confidential and can not be disclosed, neither the professional who

[(72)] Miranda, Jorge. Manual de Direito Constitucional, Tomo V, 4.ª. Edição, Coimbra Editora, 2010.

notifies may be subject to disciplinary measures or sanctions by the courts.

In Australia it was created the **Australian Patient Safety Foundation**, a non-governmental organization, which in 1993 created the Australian Incident Monitoring System, a voluntary and confidential reporting system that protects all information about individuals, disallowing its disclosure. Was defined by law, the **Health Insurance Act 1973, Part VC — Quality Assurance Confidentiality**, and the data provided by the reporting systems are part of a formal activity for quality assurance, so the disclosure deserves legal protection; the development or dissemination of personal information resulting from the activities of safety and quality is an offense punishable by two years of imprisonment. It was also consecrated the law that establishes that health professionals that report events, as well as members of committees, do have legal protection.

In the **United States of America** there is not a national reporting system, but different systems of registration of incidents coexist, most of which are mandatory in several sentinel events, and more and more states are implementing voluntary reporting systems [73] aiming to learn and prevent future errors and adverse events. The United Sates have the **Patient Safety and Quality Improvement Act — Public Law 109-41, July 29th, 2005,** which shows clearly the purpose of ensuring the confidentiality of "Patient Safety Work Product", including data, information, records, analysis (RCA), oral and written statements related to the report of adverse events, as well as legal protection to those who notify adverse events — the so-called "Reporter protection", as in Part-C Patient Safety Improvement, Section 921E of 922 Patient Safety and Quality Improvement Act (Public Law, 2005). This Act provides not only protection of documents (reports), but also the witnesses, expressly forbidding civil, criminal, administrative or disciplinary, local, state or federal prosecutions based on the records mentioned.

VII. Conclusion

Poor Patient Safety represents both a severe public health problem and a high economic burden on limited health resources.

We believe that the adoption of legislation that guaranty the confidentiality and non punitive reporting, assuring that all reports are not used as proofs and all professionals will not be considered as witness, will reveal as great contribution to the reporting systems success.

In our view, the real factuality and legal regime of liability (based on fault) are insufficient grounds to be taken to set up a legislative choice in the Portuguese health reporting systems, defining their goals and features and ensuring legal certainty to the information of all the players, expressly providing for the confidentiality of the information reported and guarantee to the health professionals no punishment related to the reports. Legislate this matter is also legislate on constitutional rights (Rights and Personal Guarantees), so in our opinion this will be the exclusive competence of the Assembly of the Republic.

[73] Rosenthal. J., Takach. M — Guide to State Adverse Event Reporting Systems 2007. State Health Policy Survey Report. 1. 2007.

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