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## ETHICS AND PUBLIC HEALTH INTERVENTIONS.

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# **ETHICS AND PUBLIC HEALTH INTERVENTIONS**

**Four cases**

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**2008**



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## Preamble

For a specialist in infectious diseases an interest for public health lies not far away. When I studied for my diploma in tropical diseases at the Bernhard Nocht Institute in Hamburg, Germany, I happened to read a book by Alfred Grotjahn, who was professor of social hygiene in Germany.<sup>1</sup> In this book he very condemnably and idealistically writes about the public weal. The German-speaking countries were then really forerunners in considering the health of populations. Acknowledging the context, it is not so surprising to find paternalistic and authoritarian overtones in his text, but what made me wary was Grotjahn's, and more so his disciples<sup>2</sup>, development into professionals, who felt it upon them to discuss who was worthy to live or not in order to improve the health of future generations. The traditional doctor-patient encounter may be fraught with moral complexity, but in its clinical, individual-centred form it is a rather neatly defined and bounded whole. The principles of autonomy, benefits and justice mostly serve to protect patients in the clinical situation. But is there a greater risk for moral failure when public health interventions are at stake and the individuals are seen as anonymous constituents of a population? Is there a need for a special public health ethic? These questions made me join the seminar in medical ethics at Lund University. The encounter between individuals and society brought forward by public health interventions is morally complex, but I do not think there is a need for special ethics for public health, in fact I don't believe there are any fixed and ready-to-use systems of ethics at all. The importance is instead to keep up a continuous dialogue over disciplinary<sup>3</sup> boundaries on what we do, what we ought to do and why, to protect the best becoming an enemy of the good.

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<sup>1</sup> Alfred Grotjahn [1869-1931] was professor of "Soziale Hygiene" in Berlin 1920-1931. He became interested in eugenics, like so many of his contemporaries (Grotjahn A. Erlebtes und Erstrebtes. Erinnerungen eines sozialistischen Arztes. Berlin: F.A. Herbig, 1932). German-speaking universities were leaders in medical science during the last part of the nineteenth century. Many well-meaning scientists' ultimate goal was curing the ill of society. Already by the early 1900s, proponents of eugenics began to offer biological solutions to public health problems not just in Germany but in countries as Sweden, Denmark, Finland, Norway, Switzerland, England, Canada and USA. "It is better for all the world, if instead of waiting to execute degenerate offspring for crime or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind... The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes ....". US Supreme Court Justice Oliver Wendell Holmes, Jr [1841-1935] in *Buck v. Bell* [274 U.S. 200 (1927)]. The Chief Justice relied on an earlier case, [*Jacobson v. Massachusetts*, 197 U.S. 11 (1904)], which upheld a law requiring school children to be vaccinated against smallpox in support of the Court's decision (<http://caselaw.lp.findlaw.com>. Accessed 2006-01-23).

<sup>2</sup> One of the pupils, the social hygienist Hans Harmsen [1899-1989], became an advocate of racial hygiene working within the German protestant, diaconical "Innere Mission". After World War II Harmsen could continue his work based on a "gnadenlosen, consequent mechanistischen Menschenbildes" as "Sachverständiger (Consultant) des Bundesministerium für Familie und Jugend" (Schleiermacher S. Sozialethik im Spannungsfeld von Sozial- und Rassenhygiene. Der Mediziner Hans Harmsen im Centralausschuss für die Innere Mission. Husum: Matthiesen Verlag, 1998).

<sup>3</sup> I here define 'discipline' as "thought domains consisting of problems, theories and methods of investigation." (Aram JD. Concepts of interdisciplinarity: configurations of knowledge and action. *Hum Relat* 2004; 57(4): 379-412).

## Introduction

To retain credibility public health must absorb the changing demands resulting from the dynamics of global, altering societies and face new priorities due to medico-technical developments. Science means acquisition of knowledge and understanding of the world and the things that are in it. Good science seeks to secure useful knowledge about the world. The scientific aspects of medicine consist of cognitive contents concerned with generating knowledge about disease. Medicine is, however, a moral enterprise and a service-oriented professional activity, driven by practical goals, especially so the practice of public health with its particular activities incorporating medicine's cognitive contents along with contributions from other fields of human activities.<sup>4</sup> This particular social practice character distinguishes public health from what is sometimes coined science proper.<sup>5</sup>

With the sceptical advances in the late 1960s the uncritical enthusiasm for technology has abated also among health professionals. The objectivity of science is under attack. Today's well-informed patients are much more preoccupied with risks than before. The various notions of scientific rationality are not agreed upon by all, leading also to different visions of science.<sup>6</sup> These ambiguities inevitably generate variability due to professional backgrounds, and schools of thought – at base, the values.<sup>7</sup> The role that values play in medicine and public health is often not acknowledged, especially when scientific knowledge is venerated as something stable and objective.

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<sup>4</sup> The character of medicine I understand not as a science in the strict sense of the word but as a practical discipline. It serves the practical purpose of helping the sick. "We must always keep in mind that medicine is not a natural science, either pure or applied. Methods of science are used all the time in combating disease, but medicine itself belongs much more to the realm of the social sciences because the goal is social." (Sigerist HE. A History of medicine. New York: Oxford University, 1951; 1: 15). See also Munson R. Why medicine cannot be a science. *J Med Philos* 1981; 6(2):183-208. This claim was comprehensively dealt with by the German doctor Richard Koch [1882-1948] whose 'oeuvre' laid forgotten up to the 1990s due to him being ostracised from Germany 1933-36 (Töpfer F, Wiesing U. The medical theory of Richard Koch I: Theory of science and ethics. *Med, Health Care Philos* 2005; 8: 2007-19). The rest of his life was spent as a spa doctor in Yesentuki, Caucasus. "Was gemeinhin unter wissenschaftlicher Medizin verstanden wird, das mit Kenntnissen und notwendigen Methoden gut Ausgerüstetsein, das Vertrauen auf die Kraft des Verstandes und der Vernunft, habe ich mit keinem Worte angreifen wollen. Aber dass Medizin im Wesen mit Wissenschaft nichts zu tun hat, dass sie schwer dadurch gefährdet ist, wenn man ihre Ziele mit denen der Wissenschaft gleichsetzt, ...". (Koch R. Die ärztliche Diagnose. Beitrag zur Kenntnis des ärztlichen Denkens. Zweite umgearbeitete Auflage. Wiesbaden: J.F. Bergmann, 1920). Koch's way of thinking had an impact outside Germany, which can e.g. be seen in the citation by Sigerist (1951), op. cit., although he is not mentioned by Munson (1981), op.cit. See also Montgomery K. How doctors think. *Clinical judgment and the practice of medicine*. Oxford: University Press, 2006.

<sup>5</sup> The concept 'proper science' here stands for what is ideally meant as the study of facts of structure and behaviour of the physical and natural world that have stood up against falsification tests according to Karl Popper [1902-94] (Popper KR. *Logik der Forschung*. Zweite, erweiterte Auflage. Tübingen: J.C.B. Mohr (Paul Siebeck), 1966. Kap 1. Grundprobleme der Erkenntnislogik).

<sup>6</sup> "One aspect of the standard view of 'rationality' is the assumption that a single method can turn any field of inquiry into 'hard science' like physics. A more balanced view will allow any field of investigation to devise methods to match its problems, so that ...disciplines are all free to go their own ways." (Toulmin S. *Return to Reason*. Cambridge: Harvard University Press, 2001: 83).

<sup>7</sup> See Fleischhauer K, Hermerén G. Goals of medicine in the course of history and today. A study in the history and philosophy of medicine. Stockholm: Kungl. Vitterhets Historie och Antikvitets Akademien, 2006.

As a clinician I am interested in science because it is a tool in helping my individual patient. As a public health practitioner I am interested in science because it is a tool in raising the wellbeing of populations. But both medical practice and public health practice commit their practitioners to particular moral duties. So we have science, social life and the ethical questions to care about if we want to pursue good public health.

Disputes about public health interventions are often couched in the language of science, technology and evidence. 'Evidence' is often taken synonymously with 'science'. If evidence is what public health should rely upon for action, it should, however, comprise more than just science understood as objective facts. Modern technological approaches deny the essential fallibility of medicine and create an expectation of perfection in the population, among administrators and health politicians. The increasing demands for evidence-based practice could also be seen as a way to cope with uncertainty. Public health should be allowed to devise methods to match its problems, which means that the field of inquiry for evidence will have to encompass both so called quantitative and qualitative approaches.<sup>8</sup>

The moral language of autonomy and rights usually serves quite respectably to protect patients in the clinical encounter. They may fail, however, when particular public health interventions are at stake. So many more people and groups of people are involved. Firstly, one has to recognise the fundamental interests all parties have in finding a justification all can accept as reasonable, i.e. the biological and social evidence has to be communicated in an understandable way. Secondly, the weightings that different people give to different moral concerns probably depend on how these fit within the wider moral conceptions people hold. Most individuals have plural goals and values, which also change over time.<sup>9</sup>

Seen from a moral philosophy perspective the methodology in public health ethics involves not only some general theory of values, but also a middle ground between general theories and the details of policy. This condition calls for a weighting of the social and political contexts in which the intervention takes place. In a population intervention there is also of interest to discuss the appropriate limits of the state in regulating, restricting or prohibiting behaviours that might lead to premature morbidity and death.

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<sup>8</sup> Public health interventions are usually more complex than clinical practice. The need for a comprehensive evidence-base to encompass that complexity challenges the usual rather reductionistic view of what is considered to be evidence in clinical medicine (Gupta M. A critical appraisal of evidence-based medicine: some ethical considerations. *J Eval Clin Practice* 2003; 9(2): 111-21; Gupta M. Reconsidering rationality and ethics in the evidence-based medicine debate: a reply to the commentators. *J Eval Clin Practice* 2004; 10(2): 143-46). Dixon-Woods et al argue that "...formal synthesis of both qualitative and quantitative forms of research is essential..." and that "... progress has to be made on the science and methods of including qualitative research in the evidence base of medicine" (Dixon-Woods M, Fitzpatrick R, Roberts K. Including qualitative research in systematic reviews: opportunities and problems. *J Eval Clin Practice* 2001; 7(2): 125-33). Barbour assesses the potential contributions of qualitative findings, examines the ways in which such insights can be utilized and addresses the question as to how qualitative findings can be incorporated in the evidence-base (Barbour RS. The role of qualitative research in broadening the 'evidence-base' for clinical practice. *J Eval Clin Practice* 2000; 6(2): 155-63). Rychetnik et al., from an Australian perspective, suggest an expansion of the criteria that are used in clinical medicine for evaluating public health research but restrict themselves to quantifiable methods (Rychetnik L, Frommer M, Hawe P, Shiell A. Criteria for evaluating evidence on public health interventions. *J Epidemiol Community Health* 2002; 56: 19-27). Hypothesis-driven quantitative research will often oversimplify the complex nature of medicine, especially public health interventions; in the end the nature of the problem must decide what methods are suitable.

<sup>9</sup> Cf. Fleischhauer & Hermerén G (2006), op.cit.: chapter 5, with the discussion of 'essentialism' and the changing goals of medicine.

## Aims

The prefatory aim of this essay is to discuss the need for an epistemic expansion of the evidence-base for public health interventions as a point of departure for ethical deliberations with a principle and virtue approach using a Swedish vaccination programme and screening procedures as cases. The overarching aim is to explore and answer the question whether there is a need for a special public health ethic or not.

The essay is based on four studies presented in four articles, which will be referred to in the text by their roman numbers:

- Article I      Krantz I, Sachs L, Nilstun T. Ethics and vaccination. *Scand J Public Health* 2004; 32(3): 172-8.
- Article II      Krantz I, Sachs L, Ahlberg BM, Nordin P, Nilstun T. Evidens och etik; om värdet av screening med PSA för prostatacancer. [Based on current knowledge the introduction of the PSA screening for prostatic cancer is unethical]. *Läkartidningen* 2005; 102(36): 2498-500. [English summary].\*
- Article III     Krantz I, Löwhagen G-B, Ahlberg BM, Nilstun T. Ethics of screening for asymptomatic Herpes virus type 2 infection. *BMJ* 2004; 329(7466): 618-21.
- Article IV      Krantz I, Eriksson B, Lundquist-Persson C, Ahlberg, BM, Nilstun, T. Screening for postpartum depression with the Edinburgh Postnatal Depression Scale (EPDS): An ethical analysis. *Scand J Public Health* 2008; 36 (2): 211-216.

The specific objectives of the four studies were to

- explore the ethical conflicts in the Swedish childhood measles vaccination programme,
- analyse the ethical conflicts in a hypothetical Swedish population screening procedure for cancer of the prostate,
- analyse the ethical conflicts inherent in clinical screening for Herpes simplex virus type 2 infection,
- analyse the ethical conflicts coming to fore if a self-administered, ready-made questionnaire is used to find depression among mothers to infants in Swedish Child Health Clinics.

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\* This article is not published in an international scientific journal and thus formally not part of the actual thesis.

## Public health

The field of public health is rather eclectic. Definitions of public health will vary, depending on who engages in the practices and interventions, whether governments, community-based organizations, the private sector or charities. Its content, i.e. mission, functions, and services is dependent on how 'health' is conceptualized, ranging from the more utopian conception of the World Health Organization (WHO) of an ideal state of physical and mental health<sup>10</sup> to a more concrete listing of public health practices or interventions.

In the Northern European countries societies have organized efforts to prevent disease on a national level since the latter half of the nineteenth century. The economy grew substantially in the last decades of the nineteenth century up to 1913. Biological solutions became the panacea to social problems common to urbanizing and industrial societies. The notion that the aetiology of many diseases has a social component was systematically pursued for the first time in the German speaking countries at a time when their universities and research centres were leading in medical science.<sup>11</sup> Social factors in the aetiology and prevention of the prevailing infectious diseases were emphasized and bacteriology became but one input to the problems of public health. The target was the health needs of the population as a whole, building on notions that social factors were major contributions to the aetiology of many diseases, that public health would suffer if the gene pool was allowed to degenerate over generations and that health services should be provided by the state.<sup>12</sup> The concern was not with the individual life but with improving the biological quality and thus the strength of the population as a whole.<sup>13</sup>

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<sup>10</sup> "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (WHO. Official Records of the World Health Organization 1947; (2): 100) and entered into force on April, 7th 1948. The definition has not been amended since 1948. Cf. Norman Daniels biomedical account of "health as normal functioning and absence of pathology", which is a more narrow definition and can function as a limit notion in contrast to the WHO one, which expands health to include nearly all of well-being (Daniels N. Equity and population health: toward a broader bioethics agenda. *Hastings Cent Rep* 2006; 36(4): 22-35).

<sup>11</sup> The origin of the term 'Soziale Medizin' in Germany is associated with the work of Rudolf Virchow [1821-1902] and the typhus outbreak in Silesia 1847 (Rosen G. What is social medicine? A genetic analysis of the concept. *Bull Hist Med* 1947; 21: 674-753). The idea of medicine as a social science did not originate with Virchow, however. Industrialization led various investigators to study the influence of such factors as poverty and occupation on the state of health also in France, England and Belgium during the first half of the nineteenth century. (Rosen G. A history of public health. New York: MD publications Inc., 1958).

<sup>12</sup> This was of course also a political strategy to counteract the growing organisation of the labour forces. The population of Germany grew rapidly from some 40 million in 1871 to over 65 million at the beginning of the First World War. During this era, the German colonial empire was expanding as was its navy, while the army was among the most powerful in the world. It was within this context the German chancellor von Bismarck [1815-98] instituted a program of sweeping social reform. Between 1883 and 1889 laws were passed providing for sickness, accident, and old age insurance. Woman and child labour were limited; and maximum working hours established. (Gall L. Bismarck. *Der weisse Revolutionär*. Frankfurt a.M.: Ullstein, 1980).

<sup>13</sup> The Darwinian scientific materialism was not a uniquely German phenomenon. It was also seen in other European states and the USA. I have, however, chosen to restrict myself to follow what happened in Germany, since the German form of

Scientists and physicians in their concern for the collective good and economic productivity invoked Darwinian science and widened their scope to concerns of how inherited characteristics might be encouraged and the worst eliminated to cure the ills of populations. The search by leading Darwinists for a new world view and especially for a new ethical system to replace Christianity and its ethics became more intense around the turn of the 20<sup>th</sup> century together with the notion that biology is destiny.<sup>14</sup> The arguments that knowledge accrued in natural science has important implications for religion, ethics and social thought were ventured vociferously. Opponents were mainly found among neo-Kantian philosophers and liberal theologians, who stressed the radical difference between scientific and social thought.<sup>15</sup>

The concept of social medicine<sup>16</sup>, developed in Germany, had a wide influence on the theoretical development of this field in other countries. Grotjahn was not an isolated phenomenon but he made social medicine part of medical education and practice.<sup>17</sup> The claims for the importance of social medicine were then later on taken over by the fascist movement and used for ends far removed from what many of their initial advocates had envisaged.<sup>18</sup>

Remaining in many countries after the disastrous consequences and World War II was a political will to take responsibility for health of the population and to pursue the ideas on mass aspects of health and disease. The health of the people became a matter of direct social concern. Social and economic conditions were acknowledged as having an important effect on health and disease. The measures involved in actions to promote health and prevent disease had to be social as well as medical.

The cooperative and mutually shared obligation of governments and communities to take responsibility for the health of their populations is emphasized when we, as a society, collectively assure the conditions for people to be healthy.<sup>19</sup> Contemporary definitions of public health also encompass promotion of health and prolongation of life.<sup>20</sup> The broad

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social Darwinism serves as an exceptionally clear illustration of the perils in applications of natural scientific principles to social thought.

<sup>14</sup> Mendelian inheritance was 'rediscovered' 1900. Leading scientists and physicians in late 19th and early 20th century argued that Darwinism did have important implications for religion, ethics and social thought. A new ethical system was searched for to replace that of Christianity (Weikart R. Darwinism and Death: Devaluing Human Life in Germany 1859-1920. *J Hist Ideas* 2002; 63 (2): 323-44).

<sup>15</sup> E.g. philosophers like Wilhem Dilthey [1833-1911] and Wilhelm Windelband [1848-1915]. Dilthey saw a difference between "Naturwissenschaften" (natural sciences) and "Geisteswissenschaften" (human sciences) with their corresponding concepts of "erklären" and "verstehen". Windelband also differentiated between natural sciences and human sciences. The former are concerned with general laws and the latter with what is individual and specific. (Nordin S. *Filosofins historia. Det västerländska förnuftets äventyr från Thales till postmodernism* [The history of philosophy. The adventure of occidental reason from Thales to postmodernism]. Lund: Studentlitteratur, 1995). See also especially the introduction by Collini to Snow CP, Collini S. *The two cultures* (Canto). Cambridge University Press, 1998.

<sup>16</sup> Grotjahn preferred the term 'social hygiene' instead of 'social medicine', which he regarded as being too limited in its connotation (Grotjahn (1932), op.cit.). Besides the physical-biological dimension, a human being has yet another one – the social, which should not be overlooked.

<sup>17</sup> Rosen (1947), op.cit.

<sup>18</sup> Grotjahn, who estimated that one-third of the German population was 'inferior', opposed all forms of killing: war, euthanasia, capital punishment (Weikart (2002), op.cit.).

<sup>19</sup> Public health in US is e.g. defined by Institute of Medicine (IOM) of the National Academies for science-based advice on matters of biomedical science, medicine, and health as "what we, as a society, do collectively to assure the conditions in which people can be healthy." (The US Institute of Medicine. Report on the Future of Public Health, 1988. <http://www.nap.edu>. Accessed 2008-06-16). IOM is a non-profit organization as well as an honorific membership organization, chartered in 1970 as a component of the US National Academy of Sciences.

<sup>20</sup> "Public health is one of the efforts organized by society to protect, promote, and restore the people's health. It is the combination of sciences, skills, and beliefs that is directed to the maintenance and improvement of the health of all the people

determinants of health such as poverty, education, environmental factors, health care and its organization and genetic influences lie within its scope.

Public health is thus nowadays the preferred colloquial term for the study of health in its widest sense.<sup>21</sup> The focus of public health is the health of populations rather than the health of individuals. The centre lies on devising broad strategies to prevent and ameliorate injury and disease and not on clinical interactions between health care professionals and patients. Public health nowadays could be seen as responding both to the developing dynamics of science and technology and to a variety of exogenous factors associated with resource levels, patterns of morbidity and demography. Collective entities such as governments and communities are to take responsibility for health of their populations. According to the so called Acheson Report, public health is considered not just a science but an art.<sup>22</sup>

I will argue that public health could neither be described as a science nor as an art.<sup>23</sup> Like clinical medicine, public health possesses an inherently moral aspect that distinguishes it from science but also from an art in its original sense.

Both disciplines, clinical medicine and public health, have cognitive contents that can be reduced to scientific theories but they cannot be so in themselves. The fact that public health employs methods of science and works to expand knowledge makes it legitimate to talk of 'scientific' public health but not to categorise the activity as a science. The scope is much broader than that and acknowledging this makes it easier to avoid the moral traps not visible in the blinkered field of view of a more reductive scientific approach.

Nor would I consider 'art' as the right epithet for public health. 'Art' somehow implies inspiration, ad-hoc efforts and something that is the concern of an achiever to be consumed by the achieved-for ones, an instrumentality, that does not acknowledge the growing interest in action research and participation in a change for the better. Public health interventions are practical endeavours and have to rely on careful planning, work within existing structures and be based on available evidence to retain credibility. A public health practitioner must expend years of reading and practising to obtain the skill. The good practitioner spends time on rationally deducing conclusions from experience and hard evidence but should not stop there. She or he must also listen to arguments from the public, peers and other colleagues.

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through collective or social actions. The programmes, services, and institutions involved emphasize the prevention of disease and the health needs of the population as a whole. Public health activities change with changing technology and social values, but the goals remain the same: to reduce the amount of disease, premature death, and disease-produced discomfort and disability in the population." (Last LM, Abramson JH, Friedman JH, Porta M, Spasoff RA, Thuriaux M (eds). *A Dictionary of Epidemiology*. Third ed. Oxford University Press, 1995. Referring to Higher Education for Public Health: a report of the Milbank Memorial Fund Commission. New York: 1976).

<sup>21</sup> There have been frequent changes of terminology for the discipline concerned with health and disease as a function of group living. 'Public health medicine' is the term used by the UK Royal Colleges of Physicians and many British academic departments. In Sweden there is a discipline of Social Medicine under the Medical faculties but also departments inside or outside the universities dealing with public health [folkhälsa] both from theoretical and pragmatic positions. There is also an understanding of 'public' as against private in how health care is financed. In this thesis I use 'public health intervention' as a broad term for how society prevents disease, promotes health, organizes health care, controls communicable infections and organizes community efforts for a sound environment without taking any stand in a possible delineation between what in Swedish is called 'folkhälsovetenskap' [public health science] and 'socialmedicin' [social medicine].

<sup>22</sup> "The science and art of preventing disease, prolonging life, and promoting health through organized efforts of society." (Public Health in England; The Report of the Committee of Inquiry into the Future Development of the Public Health Function. Cmnd 289. London: HMSO, 1988. Also called the Acheson report).

<sup>23</sup> Koch (1920), op.cit.; Munson (1981), op.cit. For Kathryn Montgomery - a professor of Medical Humanities - medicine is a practice, neither science nor art (Montgomery (2006), op.cit.).

Successful interventions rely on an intuitive tuning in to the complex systems of the real world.<sup>24</sup>

‘Craft’, as denoting collected skills required for a particular activity, is perhaps a better word than ‘art’.<sup>25</sup> A good public health practitioner could be likened to an artisan when she or he is skilful enough to choose well among large sets of available techniques, is steered by experience and knowledge of limitations and context but also humble enough to see the target population as having a genuine part in the planned endeavour. All this is fundamental for sustainable interventions.

In the end public health is a political matter.<sup>26</sup> The ultimate causes for much illness and suffering lie outside the medical realm as do decisions on societal expenditures and interventions.

Public health has been, and still is, influenced by the prevailing ideology of scientific medicine. Both disciplines share a common attitude about the relationship between health and society. The doctor-patient relationship has a bearing on population health; the institutional settings and policies that mediate population health have to be addressed in the context in which this relationship operates. The medical professionals have not hesitated to be part of regulations of social policy to what they considered would further the health of the nation, however differently they have interpreted the term health.<sup>27</sup> Patient welfare is of course the primary purpose of the clinical encounter. An easily made assumption then is that the patient’s welfare is an objective fact which can be deduced by the physician. But what is medically in the patient’s best interest might not be what she or he considers so. The conviction that public health is ultimately the responsibility of physicians, often means a recourse to compulsory health programmes which do not consider the autonomy of the

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<sup>24</sup> Baruch Spinoza [1632-77] and Henri Bergson [1859-1941] argued that intuition is the highest form of knowledge. (Jacoby E. 50 Klassiker, Philosophen. Hildesheim: Gerstenberg Verl., 2001). This is the situation when the pattern of reality is fully understood not as bits and pieces but as one whole. The experienced chess-player can foresee the party in one vision hundreds of moves ahead and at the same time analyse the consequences of different options. Even a small system in society is more complex than the sixty-four squares and the thirty-two pieces that make up the chess framework (I am grateful to Bo Eriksson for this thought-provoking metaphor). Public health interventions have also been described as complex non-linear systems (Petros P. Non-linearity in clinical practice. *J Eval Clin Practice* 2003; 9(2): 171-8).

<sup>25</sup> The greek word *technē* means know-how. Possession of such a skill enables one to produce something. It is possible to have such know-how on the basis of experience, even if one is ignorant of the general principles. Aristotle [384-322 BC] contrasts it with *epistēmē*, when one knows that something is the case and why (Mautner T (ed). *The Penguin Dictionary of Philosophy*. London: Penguin Books Ltd, 2000). A successful public health practitioner would evidently need both *technē* and *epistēmē*, but also *phronēsis* (prudence).

<sup>26</sup> Cf. Virchow’s famous quotation “die Medizin ist eine sociale Wissenschaft, und die Politik ist weiter nichts, als Medicin im Grossen” [Medicine is a social science and politics nothing but medicine in the broader perspective] (From *Die medicinische Reform 1848*; Nov 1st.). He also in this 1848-9 weekly published periodical maintained that to have an impact medicine must deal with social and political life since diseases were caused by defects in society (Bauer AW. “Die Medizin ist eine sociale Wissenschaft”- Rudolf Virchow (1821-1902) als Pathologe, Politiker und Publizist. *medizin- bibliothek- information* 2005; 5(1): 16-20).

<sup>27</sup> Physicians have not hesitated in taking part in the reasoned choices about appropriate benefits relative to costs and risks in health policies. Virchow was e.g. a Berlin Stadtverordneter [town councillor], a member of the Prussian Landtag [legislative assembly], the Prussian Abgeordnetenhaus [parliament] and the German Reichstag during his life (Bauer (2005) op.cit.); Grotjahn ((1932) op.cit.) was a member of the German Reichstag. In Sweden Axel Höjer [1890-1974] and Karl Grunewald [1921-] are later examples of how politically active physicians can have an impact on health policy (Höjer JA. *En läkares väg: från Visby till Vietnam* [A doctor’s career: from Visby to Vietnam]. Stockholm: Bonniers, 1975; Grunewald K (ed). *The mentally handicapped: towards normal living*. London: Hutchinson & Co Ltd, 1978: 221-39; Grunewald K. *Läkare bortom förståelse och insikt. Sinnesslövdagens framväxt skedde utan läkarnas stöd* [Physicians without understanding and insight. Care for mentally disabled evolved without the support of physicians]. *Läkartidningen*. 2007; 104(13): 1069-72).

citizens.<sup>28</sup> Policies implemented without listening to the people and communities might result in paternalistic control and detrimental procedures launched in the name of common good.

This thesis takes its starting point from two types of public health interventions; programmatic vaccination (I)<sup>29</sup> and screening (II, III, IV)<sup>30</sup>, both actions with the laudable intentions to bring about change for the better, i.e. less ill health in populations. Benevolence and good intentions, however, could pave many a way to hell, so other warrants or limitations that exist in the whole continuum of these public health interventions must be acknowledged for.<sup>31</sup>

The context in Sweden today is quite different from the times when infectious diseases were an everyday sinister threat. Health care is very much seen as a right and preventive health interventions cannot so easily be instigated without listening to the citizens. People want to be informed and take their own stand on issues that concern their health, an escalating trend due to, among other things, the increasing numbers of people getting access to the internet and being part of the information society.

The use of routine vaccination for prophylactic intervention in children has traditionally been justified both on the best interest of the child and public health benefits. It is a true preventive action, since if it is successful; disease will not be the issue. When almost everyone of a population is vaccinated against an air-borne infectious disease, the disease does not spread in the population from person to person, not even to the unvaccinated ones and might in the end be eradicated. The population is said to have satisfactory 'herd immunity' and is then practically immune to the disease (I). Immunity wanes, however, as does the human memory. When the disease has not been visible in the society for some time, the need for a continuous update of the herd immunity by upholding the vaccination programme sometimes get difficult. The risk for side-effects looms larger as the population memory of the disease and its risks blend away.<sup>32</sup> A changing disease panorama also changes the boundaries of what is considered a reasonable price for remaining healthy. Alternative health doctrines and schools

<sup>28</sup> Tuberculosis could serve as a model for how public and preventive health care was organised with beneficial effects but also with not intended consequences such as separation and stigmatisation (For the Swedish context, see e.g. Örnberg S [1925-2007]. *Stilla liv* [Quiet life]. Stockholm: Atlantis, 1981; Jersild PC [1935-]. *Medicinska memoarer* [Medical memoirs]. Uddevalla: Albert Bonniers Förlag, 2006).

<sup>29</sup> Inoculation of a substance (vaccine) into the body for the purpose of producing active immunity against a disease. 'Vaccination' (vacca, *lat.*, cow) was a term used by Edward Jenner [1749-1823] for the process of administering a weakened form of a disease to individuals giving them immunity to a more serious form of the disease. The first vaccine was obtained from the cowpox virus, a relatively benign virus that has the side effect of conferring immunity to smallpox. Louis Pasteur [1822-1895] 1881 suggested 'vaccination' for immunizations against any disease, which is how the term is mainly used nowadays. Vaccination programmes are intended to prevent the transmission of contagious diseases in a population and is considered as a legitimate prophylactic medical procedure by the profession. Bonanni highlights the contribution made by vaccination on population growth in Europe during the eighteenth and nineteenth century and points out the potential reduction of mortality achievable through full implementation of common childhood vaccinations (Bonanni P. Demographic impact of vaccination: a review. *Vaccine* 1999; 17 (suppl 3): 120-5).

<sup>30</sup> Screening is a public health service for "the presumptive identification of unrecognized disease or defect by the application of tests, examinations or other procedures which can be applied rapidly. Screening tests sort out apparently well persons who probably have a disease from those who probably do not. A screening test is not intended to be diagnostic", but identifies those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of a disease or its complications (Wilson JMG, Jungner G. *Principles and practice of screening for disease*. Geneva: WHO, 1968).

<sup>31</sup> Since each potential source of knowledge carries with it a different complement of strengths and weaknesses there is a need for what Pellegrino called a 'reality check', an encounter with reality or a dynamic interplay between praxis and conceptualisation (Pellegrino ED. *The metamorphosis of medical ethics: a 30-year retrospective*. *JAMA* 1993; 269: 1158-62).

<sup>32</sup> Wakefield et al. from the UK have claimed that there is an association between autism, intestinal abnormalities and measles vaccination (Wakefield A, Murch S, Anthony A et al. *Ileal-lymphoid-nodular hyperplasia, non-specific colitis and pervasive developmental disorder in children*. *Lancet* 1998; 351:1327-8). The scientific foundation for their statements is very weak, indeed. Criticisms of the alleged association have been notable. The controversy was reported in Swedish daily media especially during the latter half of the year 2000.

of thinking may also have quite other reasons to follow than what is fostered by the authorities.<sup>33</sup>

It is impossible to state that no children ever will be harmed by a safe and well-tested vaccine. If a large number of people, due to this uncertainty, fail to immunize their own children, clearly, due to diminished herd immunity a much greater number of children – even vaccinated ones<sup>34</sup> - will get the disease, with some of them suffering serious consequences more or less for certain. There is thus an unavoidable conflict between individual and collective interests.

To make a vaccination programme successful and sustainable, authorities need to foster a continuously updated knowledge of the disease to be prevented, its epidemiology and the vaccine and its side-effects but also have skills in the implementation process. In Sweden an expert group for vaccination issues at the National Board of Health and Welfare prepares the foundations for the regulations. The vaccination programme for children, which follows the recommendations issued by The National Board, states that vaccinations are voluntary and that all health professionals have a responsibility to ensure that the vaccine coverage becomes as optimal as possible. Parents should be given all information they need to make decisions of their own and the information should be given with openness and rely on available evidence.<sup>35</sup> This approach must be judged as fairly successful as measured by national vaccination coverage data (I: table 2) although a caveat is the sometimes low vaccination uptake among local immigrant populations.<sup>36</sup>

Contrary to the fairly straightforward notion of a vaccination programme as a true prevention, articles II, III and IV deal with interventions of another character raising other questions.

Clinic-based screening for Herpes virus type 2 infection (III) intends to find people already infected but again without symptoms, now to lessen the spread of the infection in the population. Cure is not available and the premise here is that informed people will act responsibly and not infect others.

Population screening for prostate cancer (II) is a pursuit of early diagnosis in men without symptoms and with the assumption that treatment in an earlier latent phase is better than in a later phase of the cancer disease. In the end this activity should lessen specific mortality in the screened population.<sup>37</sup>

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<sup>33</sup> The anthroposophic school of thought considers measles as a natural part of the development (Swartz J. Är massvaccination mot barnsjukdomar nödvändig? En rapport från mässlingsepidemin i Järna 1994–96. Järna: Vidarkliniken, 1998 [Is mass-vaccination against children's diseases necessary? A report from the measles epidemic in Järna, 1994-96]).

<sup>34</sup> No vaccine is 100% protective.

<sup>35</sup> Socialstyrelsen. Vaccination av barn SOSFS 1996:1 (M). Allmänna råd från Socialstyrelsen [Immunisation of children. General advice from the Swedish Board of Health]. <http://www.sos.se>. Accessed 2003-01-09.

<sup>36</sup> The coverage after publication of article I has been reported to be 88.5% for children born 1999, 90.5% for 2000, 93.5% for 2001, 94.5% for 2002, 95.4% for 2003 and 96.2% for 2004 (Swedish institute for infectious disease control. <http://www.smittskyddsinstitutet.se>. Accessed 2008-06-16). In Stockholm county the overall coverage was 93.6%, but in Rinkeby township the figure was 69.5% 2005 (Årsrapport 2005. Barnhälsovården. Stockholms läns landsting. Juni 2006 [Annual report from the Child Welfare. Stockholm County Council, June, 2006]). The herd immunity level for measles ought to be in the range of 92-96 percent (Anderson RM, May RM. Vaccination and herd immunity of infectious diseases. *Nature* 1985; 318: 323-9).

<sup>37</sup> See Miettinen et al., who in an article originally dealing with the failure of randomized controlled trials to give a valid answer on the utility of cancer screening to save lives, says that screening is not a prevention per se (Miettinen OS, Yankelevitz DF, Henschke CI. Evaluation of screening for cancer: annotated catechism of the Gold Standard Creed. *J Eval Clin Pract* 2003; 9(2): 145-50) and Rose, who state that screening "... is simply the pursuit of earlier diagnosis and it should not be confused with prevention" (Rose G. Mental disorder and the strategies of prevention. *Psychol Med* 1993; 23: 553-5). Cf. Wilson & Jungner (1968), op.cit.: footnote 30.

The Edinburgh Postnatal Depression Scale (EPDS) is a self-administered questionnaire used in child welfare clinics to identify puerperal women at risk of postnatal depression (IV). Again the premise is that that an early diagnosis is better than a late one and that there is therapy available. Vaccination and screening programmes thus have different conceptualisations, which is important to keep in mind when discussing tenets and precepts of evidence and ethics for them.

History gives many examples of injustice as an outcome of the intertwining of medicine and politics that has led to individual tragedies and moral disasters for societies.<sup>38</sup> Political interventions based on pretentious and false biological knowledge exist, although many of them can be explained, if not excused, by the datedness and closeness in how knowledge is created and recreated by the scientific community.<sup>39</sup> Public health interventions have to be judged taking contemporary standards into account – contextualising as that is. Historical knowledge and reflections on past public health experiences are, however, barely not something to be generally interested in, but an endeavour important in planning for new interventions. This is not just building on past experiences, or accumulating scientific evidence, but more of putting one's foot against what has been, in order to foster a critical stance to what one is intending to do.<sup>40</sup>

Another entry-point for a necessary critical stance in public health is cooperation over disciplinary boundaries. Quantitative research misses information that can be gained from naturalistic enquiry – context again – so important for the critical attitude and for understanding that public health solutions are much more complex than controlled trials and modelling can foresee.

Collaboration over disciplinary boundaries is not so easy when the theoretical and methodological horizons differ like for medicine, social sciences and humanities. Shortcomings here might mean implementing tests on epidemiologically non-adequate and not contextualised evidence (IV). Even within medicine, however, there are boundaries and examples of how intra-disciplinary reviews do not take relevant inter-disciplinary knowledge into account. An example is how the development of molecular biology and its commercialisation have meant availability of a vast array of tests unfortunately not paralleled by knowledge in epidemiological thinking as to the effects of applying them to a population (II). In public health both types of boundaries must be dealt with. Public health interventions need a broad inter-disciplinary knowledge base to retain credibility.

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<sup>38</sup> E.g. in footnote 1 and Engwall K. *Asociala och imbecilla. Kvinnorna på Västra Mark 1931-1967*. Örebro, 2000. Diss. [Unsocial and imbecile. Women in Västra Mark Hospital 1931-1967].

<sup>39</sup> According to Thomas Kuhn's [1922-96] theory that each paradigm defines its own puzzles/problems and the scientists try to solve them within the existing norms, i.e. the existing paradigm, which is incommensurable with successive paradigms. (Kuhn T. *Structure of scientific revolutions*. 2<sup>nd</sup> rev. edn. Chicago: Univ. of Chicago Pr., 1970). He is accused of denying the progress of science, although he did not admit to this himself. Kuhn had originally specialised in physics. See also Ludwik Fleck's [1886-1961] theories of how 'thought style' and society have an impact on the growth of knowledge. (Fleck L. *Entstehung und Entwicklung einer wissenschaftlichen Tatsache*. Schäfer L, Schnelle T (eds). Frankfurt a.M.: Suhrkamp, 1980).

<sup>40</sup> "the history of a practice in our time is ... made intelligible in terms of the larger and longer history of the tradition through which the practice in its present form was conveyed to us;" (MacIntyre A. *After virtue, a study in moral theory*. Second ed. London: Duckworth & Co Ltd, 1985).

## Evidence in Public Health

The evidence based approach has become the fashion for today's decision making in clinical care.<sup>41</sup> Obviously there are strong links from medicine to public health policy so the evidence based doctrine has been adopted for public health interventions as well, even if in comparison the latter are so much more complex and context dependent. Terms used to describe these evidence based activities as used for groups of patients or populations vary from one document to another; e.g. evidence based health care, evidence based management, evidence based public health or evidence based policy making.<sup>42</sup>

### *The concept of evidence*

What then is understood under 'evidence'? The concept is for certain not used consistently, which explains a lot of the existent controversies with their stark polarity of opinions.<sup>43</sup> Evidence based medicine (EBM) is a movement or better an ideology; 'evidence' in medicine is information derived from research outcomes based on experiments or observations that are linked analytically to conclusions and beliefs. Health services do not always use the best available methods and some of the methods of diagnosis and treatment could be ineffective. Newer methods are brought into use, even though their benefits and risks never have been critically evaluated. Beneficial methods might also exist that could be used on a broader scale than they actually are, after being scientifically assessed to be effective.<sup>44</sup> EBM thus reflects a particular perception of how medical decisions ought to be made. Institutions concerned with outcome oriented management and EBM are now an integral part of public health in many

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<sup>41</sup> The term 'evidence based medicine' (EBM) appeared around 1990 within the managerial outcomes movement in USA and is explained as a reaction to the escalating health care costs. In its original formulation it promoted the examination of evidence from clinical research for the determination of what works in medical care and what does not. The core of the movement is the application of formal rules of evidence in evaluating clinical research (Tanenbaum SJ. What physicians know. *New Eng J Med* 1993; 329(17): 1268-71; Gyatt G, Cook D, Haynes B. Evidence based medicine has come a long way. *BMJ* 2004; 329: 990-1). In a much-cited editorial Sackett et al. defined evidence based medicine as "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients." This definition explicitly mentions the 'individual patient' but the authors also state that evidence based medicine is "hot topic for public health practitioners". Presumably footing the philosophical origins of the movement in the Enlightenment they extend the origins of evidence based medicine to the mid-19<sup>th</sup> century and earlier (Sackett DL, Rosenberg WMC, Muir Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. *BMJ* 1996; 312: 71-2). For Swedish-speaking persons the Swedish Medical Journal [Läkartidningen] has collected a series of articles on EBM available at <http://www.ltu.se/depts/lib/sociomedicinska/PDF-filer/LakartidningenEBM.PDF>. (Accessed 2008-08-01).

<sup>42</sup> In Sweden the term 'evidensbaserad sjukvård' was suggested to avoid delimiting the area of interest to that of physicians and surgeons only (Nordin-Johansson A, Asplund K. Evidensbaserad sjukvård i praktiken. *Vetenskapliga grunden för kliniskt handlande bättre än sitt rykte* [Evidence-based care in practice; the scientific basis of clinical management fairly satisfactory]. *Läkartidningen* 1999; 96(26-27): 3173-6). In Swedish 'hälso- och sjukvård' means health care in its more overarching sense, also encompassing public health interventions, thus 'evidens-baserad hälso- och sjukvård' would capture interventions for individuals as well as populations.

<sup>43</sup> *Journal of Evaluation in Clinical Practice*, an "International journal of health policy and health services research", has published thematic issues from 1997 to 2007 on EBM. The periodical has published both so-called 'pro-' as well as 'anti-EBM' articles, although the dominant view seems to be a critical one focussing on the EBM movement's lack of theoretical underpinnings. The Editor-in-Chief is Professor Andrew Miles of King's College, University of London, UK.

<sup>44</sup> Concepts around 'effective' are here used in accordance with Cochrane AL. Effectiveness and efficiency. *Random reflections on health services*. London: Nuffield Provincial Hospitals Trust, 1972. *Efficacy*: the extent to which a specific intervention, procedure or service produces a beneficial result under ideal conditions, preferably a randomised controlled trial. *Effectiveness*: the extent to which a specific intervention, procedure or service, when deployed in the field routine circumstances, does what it is intended to do for a specified population. *Efficiency*: the extent to which the resources used to provide a specific intervention, procedure or service of known efficacy and effectiveness, are minimized.

countries with the aim to reduce effects of uninformed decisions and to mandate better accountability by evaluations and reviews of available scientific information.<sup>45</sup>

The EBM movement rests on philosophical assumptions and arguments about the nature of medical knowledge that from the beginning had an explicit preference for empirical evidence.<sup>46</sup> This notion of a general priority for empirical evidence has been seriously challenged and resulted in the EBM proponents talking of integration of non-evidentiary kinds of medical knowledge, although still different in degree rather than different in kind.<sup>47</sup>

### *Evidence and knowledge*

Rationally deduced knowledge is a traditional philosophical model for how we widen our insights. It could be the result of individual efforts or group activities. Since the extent and volume of current scientific evidence on health issues are too great for any person to synthesize on one's own, collecting evidence has to be a cooperative endeavour.<sup>48</sup> EBM has struggled with the integration of other kinds of knowledge but generally priority is given to empirical evidence from increasingly sophisticated meta-analyses of randomised controlled trials (RCT). This evidence construction emanates from an essentialist view of knowledge, where knowledge refers to an objective and universal reality.<sup>49</sup>

Health research is there to fill identified gaps in knowledge and to help diminish the uncertainty in medical decision making.<sup>50</sup> Health care research is the orderly inquiry into phenomena of health care, their nature and especially the occurrence of these phenomena in

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<sup>45</sup> The Swedish Council on Technology Assessment in Health Care (Statens beredning för medicinsk utvärdering, SBU) was established in 1987 by the Swedish Government. In 1992, SBU was commissioned as an "independent public authority for the critical evaluation of methods used to prevent, diagnose, and treat health problems and aims to compile unbiased, scientifically based assessment reports to support decision making in health care" with the mandate of the Swedish Government to comprehensively assess health care technology from medical, economic, ethical, and social standpoints (<http://www.sbu.se>. Accessed 2008-06-19). The Cochrane Collaboration is an international non-profit and independent organisation founded in 1993, which produces and disseminates systematic reviews of health care interventions and promotes the search for evidence in the form of clinical trials and other studies of interventions (<http://www.cochrane.org>. Accessed 2008-06-19).

<sup>46</sup> See The Evidence-Based Medicine Working Group. Evidence-based medicine: a new approach to teaching the practice of medicine. *JAMA* 1992; 268: 2420-5. Cf. Tonelli, who 14 years later proposes a casuistic understanding of clinical decision-making (Tonelli MR. Integrating evidence into clinical practice: an alternative to evidence-based approaches. *J Eval Clin Pract* 2006; 12(3): 248-56).

<sup>47</sup> E.g. a description of an hierarchy from 1996 used for a heart failure guideline, originally based on seven levels but collapsed into three to get a simpler rating system: A. Well-conducted RCTs and cohort studies, B. Well-conducted case-control studies, observational studies and poorly controlled or uncontrolled studies, C. Expert opinion (Hadorn DC, Baker D, Hodges JS, Hicks N. Rating the quality of evidence for clinical practice guidelines. *J Clin Epidemiol* 1996; 49: 749-54). Another example from Gyatt & Rennie 2002 as cited by Tonelli (2006) op.cit.: 1. N-of-1 RCT (a single patient serves as her own control in a double-blinded approach), 2. Systematic review of RCTs, 3. Single RCT, 4. Systematic review of observational studies, 5. Single observational study, 6. Physiologic studies, 7. Unsystematic clinical observation.

<sup>48</sup> See Ross EG, Upshur BA. Seven characteristics of medical evidence. *J Eval Clin Practice* 2000; 6(2): 93-7. Miettinen writes that "the abject inefficiency inherent in the enormous redundancy" of scientific publications makes it impossible for individual clinicians to make personal reviews and meta-analysis (Miettinen OS. Ideas and ideals in medicine: fruits of reason or props of power? *J Eval Clin Pract* 1999; 5(2):107-18).

<sup>49</sup> Modernist theorists argue that knowledge and truth are able to be neutral, objective or universal. Cf. Popper (1966), op.cit. According to his epistemology our hypothesis are easily false, it is impossible ever to be certain that they are right and criticism is the agent of improvement.

<sup>50</sup> As Liberati et al I prefer to distinguish between 'health research' and 'health care research'. The latter has health care rather than health as its object and is largely descriptive fact-finding about the nature and occurrence of various processes of health care (Liberati A, Chatziandreu E, Miettinen OS. Health care research what is it about? *Qual Assur Health Care* 1989; 1(4): 249-57; Miettinen OS. Evidence in medicine: invited commentary. *CMAJ* 1998; 158(2): 215-21). 'Health research' is then often the same as 'medical science'. The strict delineation between the disciplines is of course difficult to uphold and the evidence-base for vaccination and screening programmes will consist of results from both.

relation to their determinants, mainly matters of provider and consumer behaviour.<sup>51</sup> The motivation for health care research is a need to optimize the provision of health care (preventive actions included) for populations according to their needs<sup>52</sup> and an action intended to change the course of health for the better.

We tend to forget the fact that our understanding of being is based on the way we are in the world and relate to entities in it, which may lead to the misguided quest for a definitive theory of everything: a total account, once and for all, of why things are as they are. The EBM movement has not developed a new concept of knowledge.<sup>53</sup> Its major contribution lies in the emphasis it places on epidemiology and health services research on practice. Scientific assessments should identify interventions that offer the greatest benefits for patients or populations while utilizing resources in the most efficient way. EBM has provided a set of procedures to create an incrementally developing, but revisable, body of knowledge. The focus on the hierarchy of evidential reliability with its emphasis on numerical facts in which conclusions related to evidence from controlled experiments are accorded greater credibility than conclusions grounded in other sorts of evidence, might, however, transform into a new fundamentalism devoid of the critical stance so much needed in a world of ‘groupthink’ spin.<sup>54</sup> A belief in the practical superiority of statistical knowledge to other types of knowledge and reliance on rigorous aggregated outcome data – which is still a widespread belief – ignores the fact that knowledge of health care is multifaceted and relies more on deliberation than calculation and is meaningless without context. These complex judgements also involve questions of values.

Technology has become a very strong driving force in society, health being no exception. As for information, the computer hardware development has been enormous over the last 30 years. The software packages of today can do basically everything we can envisage and the skill needed to handle them is minimal. The human mind has not developed accordingly and to some extent got trapped in the technology. A consequence has been a perpetual wish for simplification which also releases us from the responsibility to search for other guidance. One simple regression model e.g. is enough for resource allocation in health care.<sup>55</sup> Evidence, used in that way, counteracts other influences on decisions and ignores the complexity of the decision making process.

The evidence for effectiveness of public health interventions must be sufficiently comprehensive to encompass complexity which means there is actually a need for

<sup>51</sup> Thus not of health; the authors (ibid.) make a distinction between studies of the biomedical premises and the means of effecting the desired care. The former they consider to be science in its narrow sense (See also footnotes 4 and 5 on ‘pure science’), timeless and of global concern. “Concerns about health care phenomena are of here-and-now administrative interest, even though the methodology must conform to scientific standards” (Liberati et al (1989), op.cit.).

<sup>52</sup> “Målet för hälso- och sjukvården är en god hälsa och en vård på lika villkor för hela befolkningen. Den som har det största behovet av hälso- och sjukvård skall ges företräde till vården. [...] aimed at assuring the entire population of good health and of care at equal terms. Care should be provided with respect for the equal dignity of all human beings and for the dignity of the individual.” (Hälso- och sjukvårdslag [The Health and Medical Service Act] 1982:763, 1997:142§2. SFS [Swedish Code of Statutes] (2002: 1028).

<sup>53</sup> Some proponents talk of a paradigm shift, “A new paradigm for medical practice is emerging.” (The Evidence-Based Medicine Working Group (1992), op.cit.), which is not conceptually correct. Cf. footnote 41. EBM, building on reviews and meta-analysis, has a cumulative approach in its critical appraisal of scientific reports. I consider EBM as a practice of handling knowledge.

<sup>54</sup> “One of the most important concepts of groupthink is that it is not something that is engineered – it is simply a process of group dynamics.” (McCormack J, Greenhalgh T. From the authors’ reply to letters on their article “Seeing what you want to see in randomised controlled trials: versions and perversions of UKPDS data”. *BMJ* 2000; 320: 1720-23). UKPDS=United Kingdom Prospective Diabetes Study. See also Fleck (1980), op.cit. and Kuhn (1970), op.cit.

<sup>55</sup> The Swedish health care organisation is financed by taxes and county councils and sections thereof often receive their budgets based on calculations from a regression model incorporating variables that are said to mirror the population’s needs.

methodological pluralism.<sup>56</sup> Some decades ago epidemiological methods were regarded as the only gold standard in public health research. It is increasingly often recognised, though, that population-oriented research cannot be conducted and interpreted in the same way as experimental studies and RCTs.

The methods for creating evidence in public health are likely to be found in other disciplines as well; sociology, psychology, anthropology, pedagogy, geography, economy and a good number of others. An interesting phenomenon is the “multi-level analysis” which has become a fashion word in public health.<sup>57</sup> It is indeed a good thing that it is getting more common to admit to the complexity of the real world but the techniques for and shortcomings of the interpretation of what we see – and omit to see – have been discussed for a long time, for example in educational research.<sup>58</sup>

When performing empirical research in medicine and public health the investigators are faced with a variety of methodological issues most of them usually concerning principles and methods of epidemiology and biostatistics. Evidence is thus usually expressed as quantifiable results, rendered in a statistical language and for some hard-core proponents of EBM the only evidence deemed acceptable in decisions is that derived from RCTs.<sup>59</sup> Most RCTs in the public health domain are not hypothesis testing experiments but epidemiological comparisons of different interventions that measure the effect size of the tested intervention in a sample drawn from a population, a ‘universe’ not always easy to identify.<sup>60</sup>

All empirical research based on experiments is of course context-bound to some extent but in planning RCTs one tries to eliminate context and confounders as much as possible. When a number of RCTs independently of each other demonstrate the beneficial effect of a drug, it appears reasonable to register it for use on the examined indications. For public health interventions this proceeding is usually too simplistic. There is often a lack of possibilities for generalizations once we move away from drugs to manuals and programmatic interventions. The applicability of research data beyond the study population depends on clinical judgement, since the extrapolations of intervention effects are not independent of the specific characteristic of a trial sample. If exact pathology and severity of disease, and concurrent treatment differ, then the intervention effect will differ between the trial sample and the population. ‘Outcomes research’ refers to evaluation of the outcome or effectiveness of

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<sup>56</sup> See Rychetnik et al. (2002), op.cit.; Barbour (2000), op.cit.

<sup>57</sup> Multilevel analysis is a general term referring to statistical methods appropriate for the analysis of data sets comprising several types of hierarchically organized units of analysis. Also known as hierarchical regression, it generalizes ordinary regression modelling to distinguish multiple levels of information in a model. See also Petros (2003)op.cit., and his theories of the non-linearity in clinical practice. Agar discusses from an ethnographer’s perspective how the research process itself mirrors epistemology and representation. Statistics and epidemiological design are applied to make a study predictable and controlled, but what if one looks upon the research problem with a non-linear dynamic lens? Thinking in complex adaptive systems might be a new approach to look upon public health interventions. (Agar M. We have met the other and we’re all nonlinear: ethnography as a nonlinear dynamic system. *Complexity* 2004; 10(2): 16-24.)

<sup>58</sup> See e.g. Paolo Freire [1921-1997], the Brazilian educationalist, when he states that “sectarianism in any quarter is an obstacle to the emancipation of mankind” (Freire P. *Pedagogy of the oppressed*. Rev. ed. Harmondsworth: Penguin Books, 1996, first publ. 1970).

<sup>59</sup> Consideration of unrecognised bias and confounding factors have supported “a hierarchy of evidence, with randomised controlled trials and derivatives at the top, controlled observational studies in the middle and uncontrolled studies and opinion at the bottom. The best evidence to use in decisions is then the evidence highest in the hierarchy” (Barton S. Which clinical studies provide best evidence? The best RCT still trumps the best observational study. *Editorial BMJ* 2000; 321: 255-6). Cf. also footnote 46.

<sup>60</sup> E.g. the comparison of case-fatality between people screened or not screened for prostate cancer. See also Krantz I. Infectious diseases. In Machin D, Day S, Green S (eds). *Textbook of Clinical Trials*. 2nd ed. Chichester; John Wiley & Sons, 2006.

medical intervention in the general population, in everyday clinical settings, as distinct from the highly controlled research context.<sup>61</sup>

Although conventional RCTs are widely recognised as the most reliable method to evaluate pharmacological interventions, scepticism about their role in research on public health interventions remains.<sup>62</sup> The disciplinary and ideological adherence to particular methods seemingly releases us from the responsibility to search for other guidance and could become a mental straitjacket that counteracts the seeking for well informed decisions on public health interventions. Different questions require different methods. It is not rational to regard any method as superior for all purposes.

Critical appraisal is certainly important whatever methodological framework is guiding the search for evidence. Statistical results in clinical studies and their direct clinical application, for example, contain so many assumptions that a great deal of clinical judgement is required in the appropriate use of such information. The same caution is valid for the further step when statistical methods are used for synthesizing available evidence with an aim to reduce bias and statistical imprecision. ‘Meta-analysis’ was coined to refer to the quantitative synthesis of the results of primary studies.<sup>63</sup> Evidence from systematic reviews of good quality RCTs can tell us about efficacy, but is not the same as available evidence on effectiveness.

‘Meta-synthesis’ is the term for an emerging new field of inquiry within the qualitative<sup>64</sup> health research community.<sup>65</sup> It is an attempt to create synoptic claims on the basis of various

<sup>61</sup> The US Congress 1989 created the federal Agency for Health Care Policy and Research (AHCPR), now known as the Agency for Health Care Research and Quality (AHRQ), with the aim to determine what actually works in typical medical care settings in terms of effectiveness, quality and costs (<http://www.ahrq.gov>. Accessed 2008-06-19). The agency sponsors clinical practice guidelines for clinicians and for consumers (sic!).

<sup>62</sup> Speller et al. want systematic review methods of health promotion activities revised to include a broader range of studies and research methods (Speller V, Learmonth A, Harrison D. The search for evidence of effective health promotion. *BMJ* 1997; 315: 361-3). Oakley et al., on the other hand, give three practical examples from U.K. of how informative evaluations have been made of day-care, support to disadvantaged mothers and peer-led sex education just using random allocation (Oakley A, Strange V, Toroyan T, Wiggins M, Roberts I, Stephenson J. Using random allocation to evaluate social interventions: three recent examples. *Ann Am Acad Pol Soc Sci* 2003; 589: 170-89). See also Miettinen et al. (2003), op.cit., of the unsuitability of RCTs to evaluate cancer screening programmes, due to huge expenditures and a prevailing risk for underestimating the effect size.

<sup>63</sup> Again nothing new, social scientists have since at least the 1960s emphasised the importance of making explicit efforts to limit bias in the review of literature (Chalmers I, Hedges L. A brief history of research synthesis. *Eval Health Prof* 2002; 25(1): 12-37). In 1976, Glass, a USA statistician, coined the term ‘meta-analysis’, which refers to the combination of results across studies to yield an overall estimate of effect and to compare effects between studies in order to understand moderating factors. The development of methods for reducing statistical imprecision in meta-analysis antedated the development of methods for controlling bias. (Glass GV. Meta-analysis at 25. Conference Address 1999. Accessed 2008-06-25 at <http://glass.ed.asu.edu/gene/papers/meta25.html>; Glass GV. Primary, secondary and meta-analysis of research. *Educ Researcher* 1976; 5: 3-8). If science is cumulative, scientists have a responsibility to synthesize research and accumulate results systematically and critically.

<sup>64</sup> In order to avoid the problematic terms ‘quantitative’ and ‘qualitative’ I will in the following use ‘nomothetic’ and ‘idiographic’ instead, according to suggestions from Nilstun & Löfmark (2005) going back to Windelband (Windelband W. *Geschichte und Naturwissenschaft. Rede zum Antritt des Rektorats der Kaiser-Wilhelms-Universität. Strassburg. Gehalten am 1. Mai 1984.* 2nd unchanged ed. Strassburg: J.H. Ed. Heitz (Heitz & Mündel), 1900. *Nomothetic* then is about the general, about natural laws and *idiographic* about what is particular and non-recurrent. The contrast does only concern the aim of the inquiry and not the object, which means that the same area can allow for both kinds of theory (Nilstun T, Löfmark R. Hur Semmelweis kombinerade till synes oförenliga idéer. En personlig syn på vetenskapsteori [How Semmelweis combined apparently incompatible ideas. A personal view of theory of science]. *Läkartidningen* 2005; 102(36): 2482-7).

<sup>65</sup> Meta-synthesis studies with more concerted efforts to explicate their methodologies have been conducted since 1994, on e.g. postnatal depression, home-visiting practices of public health nurses and living with HIV. Finfgeld identified 17 studies 2003 and drew inferences regarding key methodological elements and research study integrity (Finfgeld DL. *Metasynthesis: the state of the art – so far.* *Qual Health Res* 2003; 13: 893-904). Synonyms have been meta-interpretation, meta-study, meta-method, meta-theory, grounded formal theory, research integration and also research synthesis. My suggestion is that the latter term is used as collective expression for all the various approaches to knowledge development based on accumulated findings.

analytic and synthetic strategies to bodies of existent idiographic research. The synthesis of idiographic findings is interpretive rather than aggregative as in nomothetic meta-analysis. The intent is to accumulate idiographic knowledge and make it more accessible. Meta-synthesis should reasonably be an indispensable evidence source for public health.<sup>66</sup>

Systematic literature review to locate, appraise and synthesize published evidence is of course the basis for all endeavours; however, the plethora of reports about prevention and treatment often makes the integration of new material with existing evidence as a part in what Chalmers et al. call ‘research synthesis’, to a formidable task in health care research.<sup>67</sup> The digestion and assimilation of already existing studies needs to incorporate history of science aspects, health research and health care research before the final reflection on intervention and its ethics. Seeing the overwhelming numbers of publications one is tempted to ask for a moratorium on proposals for additional primary research until the results of existing research have been used to their full promise.<sup>68</sup>

A research synthesis to its full potential for a public health intervention has thus to consider relevant aspects of a given situation, cover the whole ground of available research with a critical eye to the assumed validity of its underlying assumptions and be aware of the extent of uncertainty that always will prevail in matters of health.<sup>69</sup>

### ***Evidence and vaccination against measles***

The EBM front figures have been criticised for taking upon themselves the authority to define what exactly constitutes evidence and what does not and hence have the care-givers to rely on something considered as a rock of certainty in an uncertain world. This is consistent with the late 19<sup>th</sup> and 20<sup>th</sup> century positivistic<sup>70</sup> model of science, when the views and priorities of doctors dominated health care policies.<sup>71</sup> The medical profession was supposed to deploy progress-producing reason in public interest. In reality it also meant power by means of authority rooted in the profession’s relation to science. Until a few decades ago, doctors know best and paternalism was the rule.<sup>72</sup> Policy decisions around vaccination programmes

<sup>66</sup> In Thome et al. five scholars, who each have a distinctive idiographic meta-synthesis strategy, examine the tensions between comparison and integration, deconstruction and synthesis, reporting and integration within the meta-synthesis endeavour (Thome S, Jensen L, Kearney MH, Noblit G, Sandelowski M. Qualitative metasynthesis: reflections and methodological orientation and ideological agenda. *Qual Health Res* 2004; 14(10) 1342-65).

<sup>67</sup> Chalmers & Hedges (2002), op.cit. have ‘research synthesis’ as an umbrella term covering systematic reviews and meta-analysis. They also agree with Glass (1999), op.cit., “that the future history of research synthesis should be based increasingly on the creation of publicly accessible archives of raw data”. I think the term ‘research synthesis’ functions in the public health context as the said umbrella for systematic reviews, meta-analysis and meta-synthesis.

<sup>68</sup> The idea was brought forward by Bausell 1993 for controlled trials so that more resources could be released for more meta-analytic studies (Bausell BB. After the meta-analytic revolution. *Eval Health Prof* 1993; 16: 3-12).

<sup>69</sup> See e.g. Asplund, who discusses the distinction between clinical praxis and the scientific basis for clinical actions and suggests using moral philosophy as guidance in differing between facts and values. (Asplund K. Den evidensbaserade medicinen är nödvändig men inte tillräcklig. Bör kompletteras inom områden där det vetenskapliga underlaget är svagt [The evidence-based medicine is necessary but not sufficient. Areas with insufficient scientific basis should be completed]. *Läkartidningen* 2001; 98(37): 3898-901) and Fleischhauer & Hermerén (2006), op.cit.

<sup>70</sup> According to positivist theories of knowledge, there cannot be different kinds of knowledge. All genuine inquiry is concerned with the description and explanation of facts. There should in principle therefore be no difference between the methods of the physical and social sciences (Mautner (2000), op.cit.). The only meaningful statements are those that are empirically verifiable.

<sup>71</sup> “Power, .. originates in dependence, and the power of the professions primarily originates in dependence upon their knowledge and competence.” (Starr P. *The social transformation of American medicine*. Basic Books, Inc., New York, 1982).

<sup>72</sup> Patient autonomy is a new development in the history of medicine. There is a special relationship in the power and responsibilities that come with new knowledge and technologies in medicine, including those that bear on extending and terminating life (Daniels N. Equity and population health: toward a broader bioethics agenda. *Hastings Cent Rep* 2006; 36(4):

illustrate how tensions between autonomy and paternalism and differing understandings of what is evidence are enacted.

Vaccinations and vaccination programmes were introduced in an era when there was no questioning of medical authorities. Measles vaccination has been available in Sweden since 1971 and measles vaccine been part of the child vaccination programme since 1982 (I).<sup>73</sup> Measles is highly infectious; before the introduction of the vaccine, practically all children contracted the disease. There is ample evidence for vaccine efficacy and safety in the currently used vaccine preparations.<sup>74</sup> Despite the vision from the 1960s, global eradication remains to be seen and as long as measles continues to circulate in other parts of the world, transmission will always be a risk. Compulsory vaccination programmes based on laws that require children to be vaccinated in order to have the right to start school exist e.g. in the USA and Australia.<sup>75</sup> Coverage in Sweden has always been on a very high level compared to international achievements, despite vaccination being administered on a voluntary basis.<sup>76</sup>

The public uptake of the Wakefield controversies<sup>77</sup> could be considered as a symptom of the shift from paternalism to autonomy. Parents looked for and found information elsewhere than within the child welfare clinics or they followed media reporting. Parents must be free to decide what they think is right, because that is what moral responsibility is about, but their decision should also be informed by trustworthy and clear messages from the health institutions of what are the effects and the side-effects.<sup>78</sup> Health authorities must be transparent in their information; scientific controversies should not be suppressed even if

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22-35). See also Grill & Hansson who discuss how to deal with public health information that is based on less than conclusive scientific evidence: "... openness and truthfulness have better consequences." (Grill K, Hansson SO. Epistemic paternalism in public health. *J Med Ethics* 2005; 31: 648-53).

<sup>73</sup> Measles vaccine was licensed in the US in 1963. Compulsory immunization of school-children followed a severe outbreak in Los Angeles 1977 (CDC/MMWR 1999; 48: 243-8.) Efficacy after two doses, one at 18 months of age with a booster at 12 years is considered very high (>95%) (Linde A, Johansen K. Vaccination mot mässling, påssjuka och röda hund har god skyddseffekt [Vaccination offers good protection against measles, mumps and rubella] *Läkartidningen* 2001; 98(35): 3658-64). WHO envisions eventual eradication of the disease, since man is the only host (Mulholland EK. Measles in the United States, 2006. *New Engl J Med* 2006; 355: 440-3). Total protection against measles, however, might not be achievable when children are confronted with intense exposure to measles virus (Paunio M, Peltola H, Valle M, Davidkin I, Virtanen M, Heinonen OP. Explosive school-based measles outbreak. Intense exposure may have resulted in high risk, even among revaccinees. *Am J Epidem* 1998; 148(11): 1103-10).

<sup>74</sup> See e.g. the extensive report by an expert group representing professional bodies, public sector research establishments, parents and stakeholder bodies, like patient interest groups for autism and Crohn's disease, for a comprehensive account of the knowledge base. Their conclusion is that it is not possible to definitely exclude a link between vaccination against measles, mumps and rubella and autism, because "you can't prove a negative..." Measles vaccine is currently given together with mumps and rubella = MMR (Report of the MMR Expert Group. Scottish Executive Publications Report of the MMR Expert Group. <http://www.scotland.gov.uk/Publications/2002/04/14619/3>. Accessed 2006-10-26).

<sup>75</sup> In 2004, the British Medical Association revised the issue of compulsory vaccination, partly because of decreases in vaccine coverage for MMR that resulted from the widespread concern about associations between the vaccine and autism. The Association supported the 2002 Scottish Executive Report (footnote 74) and concluded that compulsory vaccination runs counter to the core principle that vaccines should be administered on a voluntary basis (Salmon DA, Teret SP, MacIntyre CR, Salisbury D, Burgess MA, Halsey NA. Compulsory vaccination and conscientious or philosophical exemptions: past, present, and future. *Lancet* 2006; 367: 436-42).

<sup>76</sup> Finland also belongs to the very high achievers in coverage for measles vaccination.

<sup>77</sup> Wakefield et al. (1998), op.cit. Zetterström (2001) has given an account of the debate in Sweden 2000-2001 (Zetterström R. Effektiva vaccinationsprogram det bästa sättet att förebygga sjukdom [Effective vaccination programmes are the best prevention for disease] *Läkartidningen* 2001; 98(35): 3648-52). From US there is an overview of the controversies in Maldonado YA. Current controversies in vaccination. Vaccine safety. *JAMA* 2002; 288(24): 3155-8. See also Horton R. MMR. Science and fiction. Exploring the vaccine crisis. London: Granta Books, 2004.

<sup>78</sup> Lindblad E, Krantz I, Sachs L. "Vårt barn kan ju vara en av dom..." – småbarnsföräldrars tankar runt barnvaccinationer ["Our child could be one of them" – how parents think of childhood vaccinations]. *Socialmed Tidskr* 2004; 86: 558-65; Grill & Hansson (2005), op.cit.

compliance will go down. All stakeholders<sup>79</sup> have to understand the dynamic situation and that today's truth might not stand up for tomorrow's scrutiny. Since every disease and therapy is not as easily understood as a broken leg and it's healing by setting a cast, we need to communicate more with our target populations, listen to their concerns and elicit their values.<sup>80</sup> It is indeed a complex task to communicate specialised medical and epidemiological knowledge to non-professionals, since the effectiveness of vaccines in populations must consider both direct and indirect protection.<sup>81</sup>

There are fairly many studies published – both with nomothetic and idiographic approaches – which identify factors affecting the uptake of childhood vaccinations. An interesting attempt to formally synthesize both types of studies using Bayes' theorem<sup>82</sup>, shows how such a secondary analysis might contribute to define the process by which these initial sources of information can be aggregated and complemented, but also contribute to an extended examination of the phenomenon in question, as well as a mutual validation.<sup>83</sup> With either approach alone, important findings of consequences for design of policy and other interventions would have been omitted.

More and innovative health care research is needed to form a broad and useful evidence base of how to deal with the differing meanings stakeholders have of vaccinations and how to uphold the parent motivation in an environment, where measles is not visible anymore and media bristles with competing information.

### *Evidence and screening for prostate cancer*

Screening for prostate cancer has generated considerable debate within the medical community as demonstrated by varying recommendations (II). Much of this debate is fuelled by limited knowledge. The natural course of prostate cancer is poorly understood even though it is the commonest cancer in men in Sweden, considering both morbidity and mortality.<sup>84</sup> Since it is the old man's affliction there are other competing causes for mortality, which complicate follow-up studies. There seems not to be scientific consensus on the value of prostate specific antigen (PSA) screening; despite no evidence so far for survival benefits,

<sup>79</sup> 'stakeholder' I use here according to the constructivist theoretical framework that assumes each stakeholder is able to present his/her construction of reality in a world of multiple realities and therefore should have a say in the matter (Koch T. 'Having a say': negotiation in fourth-generation evaluation. *J Adv Nurs* 2000; 31(1): 117-25).

<sup>80</sup> In a Swedish postal questionnaire study, albeit with only 42% response ratio, and with preformed answering alternatives, reasons for not vaccinating were i.e. that vaccines are harmful and that the diseases are harmless or even beneficial (Alfredsson R, Svensson E, Trollfors B, Borres MP. Why do parents hesitate to vaccinate their children against measles, mumps and rubella? *Acta Paediatr* 2004; 93: 1232-7).

<sup>81</sup> "In all medical consultations the process of communication is not just a matter of transmitting information from one who knows to one who does not. Knowledge created and disseminated in a scientific context is thus recontextualised, first in a clinical situation and then as an interpreted version in people's real lives." (Sachs L. Kommunikativa problem i den evidensbaserade medicinen [Communication problems in evidence-based medicine]. *Läkartidningen* 2002; 99(8): 757-62).

<sup>82</sup> A theorem of probability that in its simplest form says that the probability of A given B is equal to the probability of A multiplied by the probability of B given A (the 'likelihood' of B), divided by the probability of B. Named after the Reverend Thomas Bayes [1702-61] (Mautner (2000), op.cit.).

<sup>83</sup> 32 nomothetic and 11 idiographic studies (Roberts KA, Dixon-Woods M, Fitzpatrick R, Abrams KR, Jones DR. Factors identifying uptake of childhood immunisation: a Bayesian synthesis of qualitative and quantitative evidence. *Lancet* 2002; 360: 1596-9). There are still many methodological issues to be solved but the study is an interesting sign of non-conventional thinking. See also Taube A, Malmquist. Räkna med vad du tror. Bayes – inte P-värdet – mäter tilltron [Count on your beliefs. Bayes – not the P-value – measures credence]. *Läkartidningen* 2001; 98: 3208-11.

<sup>84</sup> In contrast to other solid tumours there is a large disparity between the microscopic prevalence of prostate cancer and its clinical incidence, a fact already noted 1934. Incidence rates and prostate cancer mortality are thus driven by intensity of surveillance procedures, e.g. screening. (Rich AR. On the frequency of occurrence of occult carcinoma of the prostate. *J Urol* 1935; 33(3): 215-23. Reprinted in *Int J Epidemiol* 2007; 36: 274-7, with Commentaries i.a. by Martin RM. Prostate cancer is omnipresent, but should we screen for it? *Int J Epidemiol* 2007; 36: 278-80).

population screening is still promoted in various disguises by some professionals, and lay lobby groups argue for an introduction.<sup>85</sup>

Available evidence is summarised in a Cochrane review<sup>86</sup> from 2006 based on two RCTs out of 99 potentially relevant articles and the authors conclude that due to

*“... the high risk of bias of both trials, there is insufficient evidence to either support or refute the routine use of mass, selective or opportunistic screening compared to no screening for prostate cancer mortality”.*

Neither study assessed the effect of prostate cancer screening on quality of life, harms of screening, all-cause mortality or effectiveness. RTCs give measures of efficacy. Whether the two ongoing large scale multicentre RCTs<sup>87</sup> will constitute enough evidence for wise and acceptable decisions regarding prostate cancer screening in the future remains to be seen.<sup>88</sup>

One hurdle so far is a dearth of discriminatory tests. PSA has a low predictive capacity<sup>89</sup> when it is used for screening of a whole population. The consequences in terms of misclassifications will result in an over-diagnosis of clinically non significant cancers and an under-diagnosis of potentially mortal ones. In a mass-screening situation the numbers in these two categories are daunting (II, table 2)<sup>90</sup>. This complex epidemiological message is difficult to convey to a public in need of definitive answers, especially when policy has a tendency to listen to therapeutic optimists instead of available evidence.

Screening has somehow distorted public belief in that it has become considered a way of ruling-out cancer. Common misconceptions are that all cancers progress, that screening reduces the incidence of cancer and that early detection is always a benefit and implies reduced mortality. Screening is often sold as simple, effective, and inexpensive. Instead, it is often complex, of limited effectiveness, and can be expensive.<sup>91</sup> Screening programmes are

<sup>85</sup> Yamey & Wilkes narration of how they “.. stepped on the toes of a very wealthy and powerful pro-screening lobby..” tells about the wide-spread belief in America that every man should know his PSA (Yamey G, Wilkes M. The PSA storm. Questioning cancer screening can be a risky business in America. *BMJ* 2002; 324: 431; Oottamasathien S, Crawford ED. Should routine screening for prostate-specific antigen be recommended? *Arch Intern Med* 2003; 163(6): 661-2. Mitka refers to the controversy around PSA screening in USA (Mitka M. Is PSA testing still useful? *JAMA* 2004; 292(19): 2326-7). Cf. also how, according to MacKenzie et al., “Australian men are exposed to unbalanced and often non-evidence appeals to seek PSA-testing.” (MacKenzie R, Chapman S, Holding S, McGeechan K. ‘A matter of faith, not science’: analysis of media coverage of prostate cancer screening in Australian news media 2003-06. *J Royal Soc Med* 2007; 100: 513-21).

<sup>86</sup> Ilic D, O’Connor D, Green S, Wilt T. Screening for prostate cancer. *Cochrane Database Syst Rev* 2006; 3: CD004720.

<sup>87</sup> For the European multicenter study see Schröder FH, Denis LJ, Roobol M, et al. ERSPC. The story of the European randomized study of screening for prostate cancer. *BJU Int* 2003; 92 (Suppl 2): S1-13, and for the US one, see Andriole G, Levin D, Crawford D et al. Prostate cancer screening in the prostate, lung, colorectal and ovarian (PLCO) cancer screening trial: Findings from the initial screening round of a randomized controlled trial. *J Nat Cancer Inst* 2005; 97: 433-8.

<sup>88</sup> Cf. Miettinen & Henschke: “The realistically hoped-for consequence of cancer screening on cause-specific death risk is substantially a function of time since the start of continuing screening, and, therefore, the need to study this temporal pattern, especially the asymptote of the mortality-density ratio, which in screening compared with no-screening trials requires screening of long duration” (Miettinen OS, Henschke C. in Authors reply (*Lancet* 2002; 360: 720-1) to correspondence on their original article, Miettinen OS, Henschke CI, Pasmantier MW, Smith JP, Libby DM, Yankelevitz DF. Mammographic screening: no reliable evidence? *Lancet* 2002; 359: 404-6.

<sup>89</sup> I.e. the probability of disease given a positive test and the probability of non-disease given a negative test. Another screening tool, digital rectal examination, also suffers from this weakness.

<sup>90</sup> See also the calculations by Frankel at al. with provenance from social medicine and oncology in the UK: “..exposing men older than 50 years to a process, where, of 1 million men, about 110 000 with raised PSAs will face anxiety over possible cancer, about 90 000 will undergo biopsy, and 20 000 will be diagnosed with cancer. If 10 000 of these men underwent surgery, about ten would die of the operation, 300 will develop severe urinary incontinence, and even in the best hands 4 000 will become impotent.” (Frankel S, Davey Smith G, Donovan J, Neal D. Screening for prostate cancer. *Lancet* 2003; 361: 1122-8). Frankel and Davey Smith belong to a department of social medicine and Neal is an oncologist in the UK.

<sup>91</sup> Cf. Raffle AE. New tests in cervical screening. *Lancet* 1998; 351: 297. Frankel et al (2003), op.cit., calls routine prostate cancer screening outside an experimental framework “a striking instance of therapeutic optimism”.

notoriously difficult to evaluate<sup>92</sup> and here is really a need for approaches of research synthesis calibre.

The ongoing two big RCTs of the benefits of screening for prostate cancer will take time before they can be evaluated. In the end the huge resources in efforts and time might have been used more effectively given that the evaluation of the outcome will have problems with the low predictability of the PSA test. The core problem is easily demonstrated by an ‘epidemiological’ fourfold table as table 2 in article II. The evidence-base needed for ethical deliberations on screening of prostate cancer could start there – with the epidemiology of the screening test – and need not wait for the efficacy outcome of the screening procedure RCT. For public health there is a need for knowledge about effectiveness<sup>93</sup>, at the root of which in this case lies the quality of the PSA test. We really do not need to await the results from the RCTs to have credible evidence as a ground for ethical reflections on the usefulness of population screening for prostate cancer.

### ***Evidence and screening for asymptomatic infection of Herpes virus type 2***

Cancer screening programmes have their own special characteristics. In a sense they are not prophylactic interventions; their task is to lengthen survival time and to find the cancer earlier than if it manifested itself by symptoms. By so doing the assumption is that this will lessen the specific mortality. In clinical screening of Herpes virus type 2 (HSV-2), an infection, the aim is to find infected but asymptomatic individuals to reduce viral transmission.

The majority of HSV-2 infections go without symptoms. It is a sexually transmitted disease, which could also be transmitted from mother to child during delivery (III). The only practical way to identify infected people with otherwise unrecognised genital herpes is by serological tests. The occurrence of the infection, as measured by serological markers, differs between groups of people, geographical areas and over time (III, table 1).<sup>94</sup> Once infected, one remains a carrier of the infection for a very long time, probably for a life-time. The level of contagiousness fluctuates and seems to decline with time. Currently there is no treatment available except the provision of information, counselling, psychosocial support, and antiviral suppressive therapy. The benefits of suppressive therapy on asymptomatic infections are not well known. There are indications that treatment lessens the risk for transmission.

Neonatal herpes is a serious consequence of genital herpes virus infection. The risk of transmission in and around delivery is less than one percent in women with long-standing infection, but it is said to be substantially higher, if the maternal infection is acquired during

<sup>92</sup> The confusion around mammographic screening is an ample evidence of this. Cf. e.g. Olsen O, Gøtzsche PC. Cochrane review of screening for breast cancer with mammography. (Lancet 2001; 358: 1340-2) and the ensuing correspondence, Screening mammography: setting the record straight (Lancet 2002; 359: 439-42). See also Miettinen, Henschke, Pasmantier et al (2002), op.cit., the ensuing correspondence (Lancet 2002; 359: 706 and 360; 720-1) and Horton R. Screening mammography – an overview revisited. Lancet 2001; 358: 1284-5.

<sup>93</sup> See Knox, who discussed the difference between what is efficacy and effectiveness of a screening process: “...of practical concern is that mortality reduction achieved by “true life” screening is less than predicted by randomized controlled trials.” (Knox EG. Case-control studies of screening procedures. Public Health 1991; 105: 55-61).

<sup>94</sup> In the general population of the UK, as indicated by two serological studies from the 1990s, the occurrence should be less than ten percent. The estimated seroprevalence in Sweden was 15-20 percent 1990-91 (Jonsson MK, Levi M, Rudén U, Wahren B. Minimal change in HSV-2 seroreactivity: a cross-sectional Swedish population study. Scand J Infect Dis 2006; 38(5): 357-65). Pebody et al. , representing the European HSV Study Group in a study sponsored by Glaxo-Wellcome, presented comparative seroprevalence data of HSV-2 from Europe using standardised testing and serum sampling: Bulgaria 24%, Germany 14%, Finland 13%, Belgium 11%, Netherlands 9%, Czech Republic 6%, England and Wales 4% (Pebody RG, N Andrews N, Brown D et al. The seroepidemiology of herpes simplex virus type 1 and 2 in Europe. Sex Transm Infect 2004; 80: 185-91).

late pregnancy. Untreated herpes infection has among the highest mortality of any infection in the neonatal period and neurological afflictions are common among the survivors. The serological status of the mother is not a reliable indicator of whether neonatal herpes is going to occur or not. Agreed policies exist in Sweden for how to care for pregnant women with symptomatic genital herpes and their offspring.<sup>95</sup>

Routine screening of pregnant women has been recommended, especially from the USA.<sup>96</sup> Voices have also been raised for the detection of persons with uncomplicated infections so that treatment can be given to prevent complications and inhibit transmission.<sup>97</sup>

Commercial serology tests in kit forms have become available in the past few years for HSV-2 infection. They are fairly simple technically. Precision will depend on who is performing the test; spread on too many hands, the precision will probably be lower than when examinations are centralised. Validation is difficult since no real gold standard exists in the form of a reliable diagnostic test of whether a person carries virus or not. A simple, safe, precise and validated screening test does not exist.<sup>98</sup>

The wide variation in sero-prevalence of HSV-2 makes infection prevalence important for the application of a test, even if its sensitivity and specificity are on an accepted level. In low-prevalence populations 30-40 percent of the tested individuals will wrongly be diagnosed as being infected; even in high-prevalence groups like attendants in a clinic for sexually transmitted infections, around ten percent are at risk of getting a false diagnosis. Likewise, a proportion will wrongly be labelled as non-infected, which especially does not help when one is dealing with neonatal herpes.

Screening of asymptomatic pregnant women and their partners is thus fraught with interpretation problems and complicated by deliberations on probabilities for something to occur, on which the scientific community is in no way unanimous.

The knowledge base for the HSV-2 infection and its prevention is patchy and very often comes from selected populations. Various population groups' perceptions of genital herpes

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<sup>95</sup> E.g. Kunskapscenter för infektioner under graviditet (INFPREG) is an interactive, non-commercial internet database containing the most current multidisciplinary information concerning infectious diseases during pregnancy started in 1999 at Huddinge University Hospital, Stockholm, Sweden. The site is available both to medical personnel and to the public in general (<http://www.medscinet.se/infpreg>. Accessed 2008-06-25).

<sup>96</sup> Cf. Brown, a US gynaecologist from Seattle, who maintained that HSV-2 specific serology should be offered routinely to antenatal patients, a period of time when "...women are generally motivated and compliant." (Brown ZA. HSV-2 specific serology should be offered routinely to antenatal patients. *Rev Med Virol* 2000; 10: 141-4). Cf. the conclusion from a well performed cost-effectiveness analysis also from USA: "... the available data, considered both within the specific context of our decision analysis and in the larger context of screening in general, do not support initiating a program of HSV antibody screening to prevent neonatal HSV infection." (Rouse DW, Stringer JSA. An appraisal of screening for maternal type-specific herpes simplex virus antibodies to prevent neonatal herpes. *Am J Obstet Gynecol* 2000; 183(2): 400-5).

<sup>97</sup> Kinghorn from the UK broadens the HSV-2 screening agenda in discussing the whole complex of sexually transmitted infections albeit with a slightly paternalistic touch: "The high prevalence ...; their costly physical, psychological, and relationship sequelae; and their association with ...HIV necessitate the introduction of screening programs, especially those that encourage opportunistic screening in diverse health care and community settings." (Kinghorn GR. Screening for sexually transmitted infections. *Dermatol Clin* 1998; 16(4): 663-7). Brugha et al, from London School of Tropical Medicine and Hygiene, in a review article do not believe in screening as a prevention on public health level: "...case-finding will not be the basis of an effective population control programme" (Brugha R, Keersmaekers K, Meheus A. Genital herpes infection: a review. *Int J Epidemiol* 1997; 26(4): 698-709).

<sup>98</sup> Type specific commercial tests generally have values of sensitivity and specificity ranging around 95%. Sensitivity of the commercial tests is usually more variable across kits than is specificity. The more commonly used tests could be verified by an assay with maximal specificity, e.g. western blot. The western blot assay is expensive, labour intensive and unlikely to become widely available. Since the distribution of the infection is not known in the general population suitable cut-off levels for the serological tests could not be defined and agreed upon.

infections need to be better known. Control of sexually transmitted infections provides important benefits for public health and individuals, and should unquestionably be provided and promoted for this reason. From a public health point of view we sorely need a research synthesis of the effectiveness of various interventions against transmission of not just HSV-2 but all sexually transmitted infections.<sup>99</sup>

In the end prevention by an effective vaccine would of course be the best option for public health action, although not always a straightforward way to go, since the issue tends to be dominated by advocacy rather than scientific evidence in today's context of constrained budgets and needs for prioritization.<sup>100</sup>

A cost effective primary prevention for HSV-2 infection could ideally be by vaccination of the population before child-bearing age. As yet no such vaccine exists for public use, the only recourse is health promotion. Sexual education of young people could be likened to vaccinations; for effectiveness it has to be delivered in a proper way to each birth cohort with almost 100 percent coverage, followed by close in time repeated booster doses.

Strategies for managing genital herpes infection at a population level need to be tailored to local context and take into consideration the complex dynamics of a sexually transmitted disease.<sup>101</sup> Basically, however, universal serological screening and opportunistic screening would be inappropriate in Sweden for the same epidemiological reasons brought forward in discussing screening of prostate cancer, i.e. existent tests have low predictive capacity and there is insufficient knowledge of the natural course of the disease.

### ***Evidence and screening for postnatal depression***<sup>102</sup>

Various emotional changes can happen to a woman after she gives birth. For a majority of women, these feelings are transient and not associated with any serious morbidity. The most important psychological process is the development of the relationship with the newborn child. From a public health point of view it is important to prevent disturbances in this process.

The psychiatric concept 'postpartum depression'<sup>103</sup> is said to have emerged after a USA physician in the 1950s drew attention to the occurrence of emotional disorders of child-

<sup>99</sup> Marston & King have made one of the first, if not the first, systematic review to identify key themes of importance for policymakers when developing sexual health programmes. Altogether 246 journal articles and 22 books were analysed out of 5 452 reports identified. They concluded that "considerable overlap exists between current studies, which indicates the need to broaden the scope of future work" (Marston C, King E. Factors that shape young people's sexual behaviour: a systematic review. *Lancet* 2006; 368: 1581-6).

<sup>100</sup> See e.g. the comprehensive summary of vaccination against papillomavirus infection in Sweden (Dillner J, Andrae B, Westermark B. Svensk konsensus om vaccination mot cervixcancer. Vaccinprogram bör införas i grundskolan med sikte på att utrota HPV16/18 [Swedish consensus on vaccination for cancer of the cervix]. *Läkartidningen* 2006; 103: 3377-9):

<sup>101</sup> Evidence have also to be viewed with the tangled mix of commercial and power bias in mind. A prominent HSV-2 researcher, Corey from Seattle, USA, has been funded by GlaxoSmithKline (Corey L, Handsfield HH. Genital herpes and public health. Addressing a global problem. *JAMA* 2000; 283(6): 791-4). The latter pharmaceutical company together with Novartis Pharma AG, Merck & Co, Starpharma and Menarini International sponsor the periodical HERPES, the Journal of the International Herpes Management Forum (IHMF) which is a review journal published three times a year, indexed in Medline, Index Medicus and Excerpta Medica (EMBASE). See also Corey L. Raising the consciousness for identifying and controlling viral STDs: fears and frustrations. *Thomas Parran Award Lecture. STD* 1998; 25(2): 58-69.

<sup>102</sup> I have chosen to present this case in more detail due to the difficulties we at first experienced in getting the article published. The journal's referees didn't agree. One difficulty seemed to be our reasoning from a 'critical epidemiology' perspective. For the discussion on validity of psychometric tests, I am much indebted to Bo Eriksson. Many of these considerations were approached in the first versions of article IV.

<sup>103</sup> 'Postnatal' is the term preferably used in British and 'postpartum' in US writings.

bearing.<sup>104</sup> The range of postnatal mood disorders is wide and the commonly used classification of them in the literature in three psychiatric categories - maternity blues, postnatal depression (PND) and puerperal psychosis - is a simplification.<sup>105</sup> Historically, these disorders have been defined in a variety of ways. Postnatal psychosis is a serious and well defined state affecting less than 0.5 percent. PND is a less well defined diagnostic entity, a fact which cited prevalence data unmask: prevalence figures between 20 and 3.5 percent can be found in the Northern hemisphere.<sup>106</sup> Maternity blues is said to be milder, shorter-lasting and not requiring treatment.<sup>107</sup> The similarities between symptoms of depression and the normal sequelae of childbirth make categorization and delimitation difficult. There are also difficulties inherent in obtaining consistency in diagnoses that are valid both for purposes of therapy and research. The precision with which the category PND is used varies between scientific reports and textbooks, something that renders occurrence data extremely complicated to evaluate and compare.

Based on traditional psychiatric diagnostic assessments PND refers to a non-psychotic depressive episode that begins or extends into the postnatal period. As a diagnostic concept it lacks an epidemiological association, indicating the presence of specific causal factors, since there is little scientific evidence of the postnatal period being a period with increased risk of non-psychotic depression.<sup>108</sup> Longitudinal, comparative studies have not been able to find differences in prevalence of Major depression between postnatal and non-postnatal women.<sup>109</sup>

<sup>104</sup> An information often given with a reference to Gordon RE. Emotional disorders of pregnancy and child-bearing. *J Med Soc NJ* 1957; 54: 16-23. Gordon in his article, though, mainly reviews the literature on foremost psychotic symptoms. He initially, just in passing, mentions personal observations of 17 typical and 35 related cases. Since there is a common thread between them, he writes that the symptoms may be grouped together as a "maternity syndrome". The occurrence is that "one pregnant woman in 400 will develop a puerperal psychosis, and five times that many will develop psychoneuroses or other emotional or personality disorders". In another article the same author, now with his nurse and wife, use the concept 'maternity psychiatric syndrome' (Gordon RE, Gordon KK. Some social-psychiatric aspects of pregnancy and child-bearing. *J Med Soc NJ* 1957; 54: 569-72). In Sweden Jacobson et al. made "A retrospective investigation of postpartum disorders...." by "a 49-item questionnaire" already 1965 (Jacobson L, Kaij L, Nilsson Å. Postpartum mental disorders in an unselected sample: Frequency of symptoms and predisposing factors. *BMJ* 1965; 1: 1640-3). In 1968 Pitt from the UK writes "...the months following childbirth are frequently characterised by psychiatric disorder, and that at least 10-15% of mothers experience a marked depressive illness at this time". (Pitt B. 'Atypical' depression following childbirth. *Br J Psychiatry* 1968; 114: 1325-35). In the 1980s the diagnostic concept seemed established enough to merit more targeted efforts in delimitations and standardisation (Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. Development of the 10-item Edinburgh postnatal depression scale. *Br J Psychiatry* 1987; 150: 782-6).

<sup>105</sup> According to a review of postnatal psychiatric disorders by a UK psychiatrist there are different "post partum mood disorders" with their own variations in symptoms and seriousness (Brockington I. Postpartum psychiatric disorders. *Lancet* 2004; 363: 303-10).

<sup>106</sup> As noted e.g. in: Paykel ES, Emms EM, Fletcher J, Rassaby ES. Life events and social support in puerperal depression. *Br J Psychiatry* 1980; 136: 339-46. Cox JL, Murray D, Chapman G. A controlled study of the onset, duration, and prevalence of postnatal depression. *Br J Psychiatry* 1993; 163: 27-31. O'Hara MW, Swain AM. Rates and risk of postpartum depression - a meta-analysis. *Int Rev Psychiatry* 1996; 8: 37-54. Wickberg B, Hwang CP. Screening for postnatal depression in a population-based Swedish sample. *Acta Psychiatr Scand* 1997; 95: 62-6. Bågedahl-Strindlund M, Monsen Börjesson K. Postnatal depression: a hidden illness. *Acta Psychiatr Scand* 1998; 98(4): 272-5. Nielsen Forman D, Videbech P, Hedegaard M, Dalby Selvig J, Secher NJ. Postpartum depression. *Br J Obstet Gynaecol* 2000; 107: 1210-7. Eberhard-Gran M, Eskild A, Tambs K, Opjordsmoen S, Samuelsen SO. Review of validation studies of the Edinburgh Postnatal Depression Scale. *Acta Psychiatr Scand* 2001a; 104: 243-49. Berle JO, Aarre TF, Mykletun A, Dahl AA, Holsten F. Screening for postnatal depression. Validation of the Norwegian version of the Edinburgh Postnatal Depression Scale, and assessment of risk factors for postnatal depression. *J Affect Disord* 2003; 76: 151-56.

<sup>107</sup> See Brockington (2004), op.cit.: "...does not cover mild disorders that require no treatment (such as the maternity blues)".

<sup>108</sup> Cooper PJ, Campbell EA, Day A, Kennerley H, Bond A. Non-psychotic psychiatric disorder after childbirth. *Br J Psychiatry* 1988; 152: 799-806; Cox JL, Murray D, Chapman G (1993), op.cit.; Najman JM, Andersen MJ, Bor W, O'Callaghan MJ, Williams GM. Postnatal depression - a myth and reality: maternal depression before and after the birth of a child. *Soc Psychiatry Psychiatr Epidemiol* 2000; 35: 19-27; van Bussel JHC, Spitz B, Demyttenaere K. Women's mental health before, during and after pregnancy: a population based controlled cohort study. *Birth* 2006; 33: 297-302. A caveat here is the methodological confusion brought forward by authors often not being clear to what purpose a difference is looked for, whether for etiological or just general occurrence reasons. Cf. also the Danish linked register-based cohort study of primipareous mothers that shows an increased risk for serious mental disorders (as measured by psychiatric hospital admission) for 3 months after childbirth with the highest risk occurring 10 to 19 days postnatally. An observation time of at least 5 months

Lately, the suggestion has been to use PND for all depressive disorders without psychotic symptoms during the first year post partum.<sup>110</sup>

Questionnaires are used for many purposes, e.g. to assess ill-health and the quality of life. The typical outcome of such an exercise is one or more scores, numbers for each of the studied persons. An important distinction for the use of questionnaires or scales is between a survey, where the objective is to estimate the prevalence of a certain phenomenon in a population, and a screening, where the aim is to identify individuals who can be offered help and assistance. The questionnaire format is also used to systematize diagnostic criteria for a clinical diagnosis, especially in psychiatry, but the techniques of standardized interviews that would ensure more uniform diagnostic information and reduce the amount of other, potentially confusing, information, were originally addressed by researchers. Knowledge is produced through data gathering and surveillance and in that way human subjects are appropriated as objects of study in the vein of empirical research. The intention is to arrive at a clinical classification that provides a nomenclature, which furnishes a basis for description, therapy and prediction.<sup>111</sup> Some method of classifying the psychiatric ills is clearly essential to guide treatment options, even if one keeps an open mind for the arguments in the dispute on the reality of mental illness.<sup>112</sup> Important to remember, though, is that PND still is an essentially unscientific label as it lacks a clear definition, aetiology and treatment. The evidence for hormonal mechanisms, which are often said to produce it, is weak.<sup>113</sup>

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was necessary for studying unipolar depression only (Munk-Olsen T, Munk Laursen T, Bøcker Pedersen C, Mors O, Mortensen PB. New parents and mental disorders. A population-based register study. *JAMA* 2006; 296(21): 2582-9).

<sup>109</sup> van Bussel et al (2006), op.cit., from Belgium, concluded from a comparative study on 648 women that there was no difference in mental health problems as measured by the General Health Questionnaire (GHQ-12, not originally designed to identify a specific psychiatric disorder in the postnatal period) between pregnant or postnatal women and those who were not pregnant or had not delivered. The correct conclusion, however, should be that they couldn't repudiate the null hypothesis. The authors have not made a power calculation. The Cox et al (1993), op.cit., study based on scales measuring depression and a cross-sectional comparative study with five months recall on 232 matched pairs from North Staffordshire, UK, is reported to have found "that the prevalence of depression in postnatal women is similar to that found in the general population of women." A Norwegian population-based cross-sectional questionnaire study on 2 730 women (416 post partum) resulted in a higher prevalence of depression in the general population of women than among the postnatal ones. When controlling for various risk-factors of depression the odds ratio for depression became 1.6 [95% confidence interval 1.0; 2.6] (Eberhard-Granh M, Eskild A, Tambs K, Samuelsen SO, Opjordsmoen S. Depression in postnatal and non-postnatal women: prevalence and risk factors. *Acta Psychiatr Scand* 2002; 106: 426-33).

<sup>110</sup> "At present, researchers and others interested in postnatal disorders have a major problem: there is no official way of recording the disorder" (Paykel ES. Mood disorders: Review of current diagnostic systems. *Psychopathology* 2002; 35: 94-9). Paykel recommends a coded postnatal specifier not only for mood disorders but for all disorders in future editions of official classification and coding systems. A workshop attended by main researchers suggested "Postpartum/postnatal (3months), Late postpartum/postnatal (more than 3 months until 12 months after childbirth)" (Elliott S. Report on the Sätra Bruk Workshop on classification of postnatal mental disorders on November 7-10, 1999, convened by Birgitta Wickberg, Philip Hwang and John Cox with the support of Allmänna Barnhuset represented by Maria Grönros. *Arch Womens Ment Health* 2000; (3): 27-33). Paykel was also present at this workshop.

<sup>111</sup> See e.g. Jones criteria for the diagnosis of rheumatic fever first published in 1944 (Jones TD. The diagnosis of rheumatic fever. *JAMA*. 1944; 126:481-4). A psychiatric systematic classification (DSM-I) was introduced 1952.

<sup>112</sup> Cf. the psychiatrist and libertarian Thomas Szasz [1920-] known for his view that mental illness is a convenient myth (Szasz T. Mental illness: psychiatry's phlogiston. *J Med Ethics* 2001; 27: 297-301). He wants psychiatry to be a science of human behaviour and to recognize that 'mental illness' does not exist because "erroneous explanations of the material world..." can "...lead to physical catastrophes, false explanations of the human condition, to moral catastrophes." The dispute about the reality of mental illness is dominated by the likeness argument; whether the conditions are sufficiently or insufficiently like some other condition everyone agrees is a disease, as is the case for e.g. pneumococcal pneumonia (Pickering N. The likeness argument and the reality of mental illness. *Philos Psychiatr Psychol* 2003; 10 (3): 243-54).

<sup>113</sup> See Oakley A. *The Ann Oakley Reader. Gender, women and social science.* Bristol: The Policy Press, 2005: 120-1. One experimental study from USA has, however, shown that women with a history of at least one past episode of a more precisely defined condition - Major postnatal depression according to a standardized classification - are differentially sensitive to the mood-destabilizing effects of gonadal steroids. 16 women enrolled by an advertisement formed two groups; 8 women with at least one past episode of Major depression within 4 weeks postnatal and no history of non-puerperal depression according to DSM-IV criteria (women who had had suicidal ideation or psychosis were excluded) and 8 women with no history of past psychiatric illness. They were then exposed to changing levels of estradiol and progesterone in a blinded fashion, acting as

A classification system identifies the category to which an individual belongs on the basis of his or her characteristics, in our case, observed or self-rated ones. When the characteristics are a number of numerical measurements these can be combined to scores which can have discriminatory function. Ideally, this ends up in two distinct groups, one of cases and one of non-cases. The organizing theory then rests on a world-view that believes in the existence of a 'naturally' determined classification and the possibility to reveal its structure independent of observer effects. Against this stands an epistemology where interactions between social interests and nature's behaviour shape the classification.<sup>114</sup> The functioning of mentally ill patients is varied and complex and patients are often in between diagnostic categories. Nature seldom shows true dichotomies; usually a continuous distribution unites sick and healthy in the whole population.<sup>115</sup>

Psychiatry's diagnostic system has mainly evolved around two classifications, the American Psychiatric Association's Diagnostic and Statistical Manuals (DSM) and the World Health Organization's International Classifications of Disease Manual (ICD).<sup>116</sup> Standardized diagnostic 'instruments' are available in abundance to help in classification.<sup>117</sup> Depression can be diagnosed based on the number and severity of symptoms endorsed in questionnaires such as Beck's Depression Inventory (BDI) from the 1960s<sup>118</sup> and Montgomery-Åsberg Depression Rating Scale (MADRS) from the 1980s<sup>119</sup> just to name a few. Facing this multitude, researchers and clinicians need to be aware of the differential sensitivity and specificity of the mood rating instruments and that they, while supposedly measuring the same construct, are focused on different components of this mood disorder. PND is not

their own placebo controls (Bloch M, Schmidt PJ, Danaceau M, Murphy J, Nieman L, Rubinow DR. Effects of gonadal steroids in women with a history of postnatal depression. *Am J Psychiatr* 2000; 157: 924-30).

<sup>114</sup> See Sadler for a comprehensive account of science and psychiatric nosology (Sadler JZ. *Values and psychiatric diagnosis*. Oxford: Oxford University Press, 2005).

<sup>115</sup> E.g. Rubertsson C et al.'s figure 1 shows a distribution of a depression score that is a good illustration of this (Rubertsson C, Waldenström U, Wickberg B. Depressive mood in early pregnancy: prevalence and women at risk in a national Swedish sample. *J Reprod Infant Psychol* 2003; 21(2): 113-23). "Throughout medicine the understanding of prevention has been hindered by the tacit belief that disease and normality are separate entities" (Rose (1993), op.cit.). See also Rose & Day, who from a reanalysis of the Intersalt study suggested that the "inevitable relationship of tail and distribution ...//... may well apply to many physical and mental attributes." (Rose G, Day S. The population mean predicts the number of deviant individuals. *BMJ* 1990; 301: 1031-4).

<sup>116</sup> Diagnostic and statistical manuals of mental disorders (DSM) exist in several editions (e.g. DSM-III 1980, DSM-III-R(revised) 1987 and DSM-IV 1994) and is published by the American Psychiatric Association. Washington DC: American Psychiatric Press. The International Statistical Classification of Diseases and Related Health Problems (ICD) has origins in the 1850s and provides codes to classify diseases. It is nowadays published by the WHO, established world-wide for morbidity and mortality statistics and designed to promote international comparability. ICD-10 is used in the member states since 1994 (<http://www.who.int/classifications>. Accessed 2006-11-20).

<sup>117</sup> The acronyms flourish: ZUNG, a self-rating depression scale used by Cox et al as one of the starting points for EPDS (Cox et al (1987) op.cit.; Zung WW. A self-rating depression scale. *Arch Gen Psychiatry* 1965; 12: 63-70.), CIDI, the composite international diagnostic interview, which is also available in a computerized version (WHO. Composite International Diagnostic Interview - Version 1.1. Geneva: WHO, 1993). Other examples are HADS (Zigmond AS, Snaitch RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983; 67: 361-70), MINI (Lecrubier Y, Sheehan DV, Weiller E et al. The Mini International Neuropsychiatric Interview (MINI). A short diagnostic structured interview: reliability and validity according to CIDI. *Eur Psychiatry* 1997; 12: 224-31), SPI Standardised Psychiatric Interview, a semistructured interview designed for use in the community (Goldberg DP, Cooper B, Eastwood MR, Kedward HB, Shepherd M. A standardised psychiatric interview for use in community surveys. *Br J Prev Soc Med* 1970; 24: 18-23).

<sup>118</sup> Beck AT, Ward CH, Mendelson M, Mock J, Erbaugh J. An inventory for measuring depression. *Arch Gen Psychiatr* 1961; 4: 53-63. This inventory was developed "to provide a quantitative assessment of the intensity of depression". By systematic observations of depressed patients during psychoanalytic psychotherapy the senior author constructed an inventory of 21 categories of symptoms and attitudes consistent with descriptions of depression contained in the psychiatric literature.

<sup>119</sup> MADRS is an observer rating scale composed of 10 items, each graded from 0 to 6. It is designed to measure symptoms of depressive illness, including apparent and reported sadness, inner tension, impairment of concentration, reduced sleep and appetite, lassitude, inhibition of feelings, anhedonia, pessimism, and suicidal ideation. (Montgomery SA, Åsberg M. A new depression scale designed to be sensitive to change. *Br J Psychiatr* 1984; 144: 35-47).

recognized by manuals like DSM-IV and ICD-10 as being diagnostically distinct from its non-*puerperal* counterpart (table 1).<sup>120</sup>

	Main Symptoms DSM-IV	Other	Typical symptoms ICD-10	Other
Depressed mood	*		*	
Loss of enjoyment	*		*	
Less energy		*	*	
Less concentration		*		*
Less self-esteem				*
Guilt/unworthiness		*		*
Pessimism				*
Ideas/acts of self-harm		*		*
Disturbed sleep		*		*
Disturbed appetite				*
Weight loss/gain		*		
Restlessness/agitation		*		

**Table 1.** Internationally agreed symptoms of depression according to DSM-IV and ICD-10. For a DSM-IV major depressive episode a person must have experienced at least five of the nine symptoms for the same two weeks or more, for most of the time almost every day, and this is a change from his/her prior level of functioning. One of the symptoms must be either depressed mood, or loss of enjoyment

Classifications are only valuable if they can release new or confirm old information about the classified object. The vision is a development of objective, measurable and verifiable criteria for a diagnosis based on objectively measurable manifestations. Such a nosology would provide a common language allowing the exchange of knowledge. The creation of categories sets out to bring structure to mental disorders that in themselves, however, are complicated and unique conditions and not stable natural objects. Diagnostic classifications of necessity reduce this complexity. Psychiatric phenomena, whether features (symptoms) or entities (diseases), are not categorical but represent a continuum. The dualism created is too reductive and fails to recognize the plurality of difference that exists in the social world. A psychiatric nosology is not a systematic ordering of categories found in nature but constitutes a map and charter of a social world.<sup>121</sup>

According to Cox et al (1987), the 1980s had provided substantial confirmation of earlier findings that

*“the months following childbirth are frequently characterised by psychiatric disorder and that at least 10-15% of mothers experience a marked depressive illness at this time”.*<sup>122</sup>

<sup>120</sup> Major depressive disorder – a type of mood disorder characterized by one or more major depressive episodes - defined by DSM-III as a major depressive episode of at least 2 weeks during which an individual experiences daily disturbance in mood (intense feelings of sadness or loss of interest in activities that are usually pleasurable) and at least four of eight symptoms: (1) too much or too little sleep, (2) appetite or weight disturbance, (3) psychomotor agitation or retardation, (4) loss of energy, (5) feelings of worthlessness or excessive guilt, (6) problems with concentration or indecisiveness, (7) loss of interest in sex, and (8) recurrent suicidal thoughts or attempts. DSM-IV changed these criteria to the following: (1) symptoms must be present most of the day and nearly every day during the episode, (2) clinically significant distress or impairment in functioning must be present, (3) the syndrome must not be the result of the direct physiologic effects of a substance or a general medical condition, (4) major depressive disorder is still diagnosed after an acute grief reaction if the syndrome lasts for more than 2 months. The DSM-IV allows the addition of a postnatal-onset specifier for patients with an onset within four weeks of delivery; thus, the DSM-IV criteria for diagnosing Major depression apply to the diagnosis of postnatal major depression as well. In ICD-10 ‘puerperal’ is allowed (F53), when symptoms starts within six weeks post partum. There is, however, no scientific basis for these time limits. See also Paykel (2002) op.cit., Elliott (2000) op.cit.

<sup>121</sup> See Kirmeyer L.J. Culture, context and experience in psychiatric diagnosis. *Psychopathol* 2005; 38: 192-6. Berrios - a consultant neuropsychiatrist - outlines the evolution of psychiatric classifications from the perspective of conceptual history assuming that all psychiatric classifications are cultural products and discusses whether classificatory models imported from the natural sciences can be applied to man-made constructs such as mental illnesses. His approach is an interesting endeavour to look at psychiatric classifications from outside the episteme (Berrios GE. Classifications in psychiatry: a conceptual history. *Aust N Z J Psychiatry* 1999; 32(2): 145-60). Cf. also Szasz (2001), op.cit., Rose (1993) op.cit.

<sup>122</sup> Citation from Cox et al (1987), op.cit., who refers especially to Pitt B. “Atypical” depression following childbirth. *B J Psychiatr* 1968; 114: 1325-35. Both studies are based on UK urban populations; Cox’s from Edingburgh and Pitt’s from

Since only few of them were recognised by the Scottish health visitors, a 10-item self-report questionnaire was created to screen for postnatal depression in the community, the Edinburgh Postnatal Depression Scale (EPDS).<sup>123</sup> The growing interest in postnatal mood disorders has since then very much evolved around the validation and application of EPDS in many countries all over the world; it is also the test most frequently advocated as a screening test for PND.<sup>124</sup> Once the theories on PND gained wide acceptance, they have exercised a powerful influence on the scientific communities and become an integral part of how the world is understood. New observations are seen through the lens of prevailing theories.<sup>125</sup>

Validity in a traditional nomothetic understanding is defined as the absence of systematic errors. Behind any statement of validity there is an assumption that something is repeated; repeated measurements, repeated estimations and repeated conclusions. In each of these steps we may commit errors. An error which is constant, i.e. has a certain direction and a certain size, is called systematic. In contrast, random errors have unpredictable size and directions.<sup>126</sup>

The validity of measurements such as responses in structured interviews is crucial for the validity of estimates, the validity of conclusions and finally for the rationality of actions taken based on the evidence. A valid measurement is one that measures what it is intended to measure, in our case the occurrence of PND. A questionnaire can be valid against a particular definition as long as it is used in a specific way and under defined conditions. Yet it might not work in the same way under other conditions. In situations when the correct value cannot be defined, as in many psycho-social studies, it is not meaningful to talk about a valid measurement in the sense of being true or not. The questionnaire has to be judged against other criteria and most often this is another rating instrument<sup>127</sup> used for classification according to DSM or ICD. Thus, validation of measurements is not only a matter of applying standard techniques but also of reflection and discussion about validity itself in any particular situation. Valid conclusions are those that follow from the evidence at hand. The evidence

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London. The inferences drawn from these articles and their earlier validation followers are dubious, since they are biased in their sampling methods. Harris et al e.g. used a population studied for postnatal thyroid dysfunction (Harris B, Huckle P, Thomas R, Johns S, Fung H. The use of rating-scales to identify post-natal depression. *Br J Psychiatr* 1989; 154: 813-7).

<sup>123</sup> Cox validated EPDS in a material consisting of 84 postnatal women, who were selected by health care workers as already suspected of having a depression plus 12 women without symptoms. A structured clinical interview was made based on the DSM-III-R and Goldberg's SPI (Goldberg et al (1970), op.cit.; Cox et al (1987), op.cit.). As gold standard for depressive illness, research diagnostic criteria of Spitzer were used (Spitzer R, Endicott J, Robins E. Research diagnostic criteria. Instrument No. 58. New York: New York State Psychiatric Institute, 1975. Sensitivity was said to be 86%, specificity 78% and positive predictive value 73% [95% confidence interval 59;87, according to my own calculations, although it is dubious to calculate predictive value due to the various bias].

<sup>124</sup> E.g. France: Tesseidre F, Chabrol H. Detecting women at risk for postnatal depression using the Edingburgh Postnatal Depression Scale at 2 to 3 days postpartum. *Can J Psychiatr* 2004; 49(1): 51-4. Denmark: Nielsen Forman D, Videbech P, Hedegaard M, Dalby Salvig J, Secher NJ. Postnatal depression: identification of women at risk. *Br J Obstet Gynaecol* 2000; 107:1210-17. The Netherlands: Pop VJ, Komproe IH, van Son MJ. Characteristics of the Edingburgh Postnatal Depression Scale in the Netherlands. *J Affect Disord* 1992; 26:105-10. USA: Chaudron LH, Szilagyi PG, Kitzman HJ, Wadkins HIM, Conwell Y. Detection of postnatal depressive symptoms by screening at well-child visits. *Pediatrics* 2004; 113(3): 551-8. The Cox & Holden guide contains EPDS in Arabic, Chinese (Mandarin), Czech, Dutch, French, German, Greek, Hebrew, Hindi, Icelandic, Japanese, Maltese, Norwegian, Portuguese, Punjabi, Slovenian, Spanish, Swedish, Urdu and Vietnamese. (Cox J, Holden J. *Perinatal Mental Health. A guide to the Edinburgh Postnatal Depression Scale*. Glasgow: Gaskell, Bell & Bain Ltd, 2005).

<sup>125</sup> See Fleck (1980) op.cit. and Kuhn (1970) op.cit.. Fleck's treatise on 'thought style' [Denkstil] and 'thought collective' [Denkkollektiv] was originally published in Germany 1935. He used syphilis and the Wassermann-reaction to highlight relations between medicine, socio-economic conditions and politics. Fleck was a medical doctor specialised in microbiology.

<sup>126</sup> A valid estimate is an observation of a function of measurements, e.g. a proportion or mean value, which has no bias, i.e. the average over hypothetically repeated applications of the estimation process does not deviate from the 'truth' of the target population. Valid measurements are needed to obtain valid estimates but do not guarantee this.

<sup>127</sup> E.g. SPI (Goldberg et al (1970), op.cit. and footnote 117; BDI (Beck et al (1961), op.cit. and footnote 118.

that the existence of PND is something more than a social label and a unique entity that not just denotes the syndrome but also explains it, depends on whether we can find properties of PND that are independent of the properties we use to define and identify the person with PND, i.e. we have to establish the concept PND as valid.

Validity has different meanings in different epistemological contexts. Even within a predominantly nomothetic discipline like epidemiology it is discussed in different ways. The dictionary for the International Epidemiological Association (I.E.A.) lists three types of validity: construct, content and criterion validity.<sup>128</sup>

A concept is said to have construct validity if it can be logically derived from accepted knowledge and theory. A construct is something postulated to correspond with something in the world. A diagnostic category may be constructed as in patho-physiological medicine with relatively rigid boundaries for inclusion and exclusion. The PND diagnosis means grouping of co-occurring symptoms of various sorts. Grouping made by EPDS questionnaires and the like rests on decisions on which particular properties belong together. It is resolved through the combination of theory, the historical traditions that led to that particular theory and the set of observations of clinical or other features that in fact vary along a continuum.

This means that a validated questionnaire should be able to detect changes and differences between groups, expected from theory. To date we have no theory or evidence that supports PND being a distinct entity, which makes predictions difficult, if not impossible. To conclude that a questionnaire shows differences between groups is, however, not enough to support construct validity. The differences could in fact be the result of lack of such validity.<sup>129</sup>

A particular type of conclusion often seen is that a questionnaire is “suitable as a screening tool”.<sup>130</sup> If that really is the case, the decision should be based on a conviction that the questionnaire returns valid measurements; that sensitivity, specificity and predictive values have been assessed with unbiased estimates and that estimates of correlation supports the conclusion that the outcome of the screening instrument and its ‘gold standard’ are covering the same thing. The conclusion that  $x$  (the screening instrument) measures the same as  $y$  (the old standard) based only on a correlation coefficient might, however, very well be invalid (IV).<sup>131</sup>

<sup>128</sup> Last et al (1995), op.cit. ‘Construct validity’ should be logically derived from accepted knowledge and theory. ‘Content validity’ means that the phenomenon of interest is covered sufficiently well. ‘Criterion validity’ compares the results with an accepted standard. Cronbach & Meehl, referring back to technical recommendations for psychological tests and diagnostic techniques from American Psychological Association, mention four categories for validity studies: predictive, concurrent, content and construct validity, where the first two can be seen as criterion-oriented (Cronbach LJ, Meehl PE. Construct validity in psychological tests. *Psychol Bull* 1955; 52: 281-302). ‘Face validity’, which is also seen, means simply that the questions appear reasonable to a number of competent persons.

<sup>129</sup> A frequent example is a study with a certain amount of non-response where all measurements can be valid but the estimate becomes biased due to selection. This is not uncommon among PND studies.

<sup>130</sup> “. . . and assist to identify postnatal depression in mothers thought by their health worker to be at risk.” (Cox (1987) op.cit., “. . .indicates that the scale is a useful screening instrument.”)(Wickberg B, Hwang CP. The Edinburgh Postnatal Depression Scale: validation on a Swedish community sample *Acta Psychiatr Scand* 1996a; 94: 181-4), “. . . confirms that the EPDS is a valid clinical screening instrument . . .” (Eberhard-Grahn M, Eskild A, Tambs K, Schei B, Opjordsmoen S. The Edinburgh postnatal depression scale: Validation in a Norwegian community sample. *Nord J Psychiatr* 2001b; 55(2): 113-7).

<sup>131</sup> Sometimes it is useful to repeat the tenets behind statistical applications: The Pearson and the Spearman correlation coefficients are often used to measure the correspondence between two scores, obtained from questionnaires and calculated from the answers given by a number of persons. The first is calculated using the raw scores whereas the latter uses the ranks of the scores within each of the two series. Otherwise the calculation is the same and both coefficients can take values from  $-1$  to  $+1$ . For the Pearson version, the extremes mean that one score  $y$ , is given from the other  $x$ , by the linear relation  $y=a+bx$ . Normally, though, there is a random error  $e$  in the model that will then read  $y=a+bx+e$ . The correlation coefficient is symmetric with respect to  $x$  and  $y$  but in the validation application it is useful to think of  $y$  as the test score and  $x$  as the gold standard score. The key interest is the relation between the variation of  $e$  and the variation of  $y$ . For the perfect fit,  $e$  is zero

Systematic and random errors, and hence validity, are dependent on the context where a study is performed. Questions might be differently perceived in different populations or segments of populations. Table 2 shows an example of the huge variation in context when validation is at issue; usually translation of the ten EPDS questions and urban-rural differences are mentioned but very seldom the deeper layers of meaning are discussed in a trans-cultural approach.<sup>132</sup> The validation studies have been made on different populations, with subjects recruited differently and EPDS delivered in different ways. The distribution of EPDS scores in a population is most probably not clearly bimodal with a clear cut-off between cases and non-cases.<sup>133</sup> Whether EPDS is a valid instrument for cross-cultural comparisons still remains an open question.

**Table 2.** Examples of different contexts and procedures from the Northern hemisphere in validation studies of EPDS.

Study	Country	Site	EPDS
Cox et al (1987)	Scotland	Edinburgh, Livingston	EPDS presented and filled in before an interview in the women's homes (or in some cases at a local Health Clinic) by two of the authors, RS and JC. At what time post-partum is not clearly stated, but probably around week 7.
Murray & Carothers (1990)	England	Cambridge	Posted questionnaire to women presenting on the hospital postnatal wards and asked to take part. Six weeks post partum the EPDS was sent by post to be returned in a stamped envelope.
Zelkowitz & Milet (1995)	Canada	Quebec, Montreal?	Telephone interview 6 weeks post partum with women identified through two community centres.
Wickberg & Hwang (1996a)	Sweden	Göteborg, Mölndal	The women filled in EPDS during routine visits to Child Health Clinics 2 and 3 months post partum.
Nielsen-Forman et al (2000)	Denmark	Aarhus	Four months after delivery EPDS was sent by post.
Eberhard-Grahn et al (2001b)	Norway	Two municipalities, approximately 60 km north-east of Oslo	The women got the EPDS when attending routine postnatal visits, 6-12 weeks post partum, completed them at home and returned them by mail.
Berle et al (2003)	Norway	Bergen, Nyland	"Women attending routine postnatal visits were screened using the EPDS."
Börjesson (2005)	Sweden	Southern Stockholm region	Women visiting 9 Child Health Clinics completed an EPDS questionnaire 3 months post partum.
Jardri et al (2006)	France	Lille	The women filled in EPDS + a general information questionnaire between day 3 and 5 after delivery in the postnatal department.

for all persons. If  $b$  is zero, which implies that the correlation coefficient is zero, the variation of  $y$  is the same as the variation of  $e$ . Even when the correlation coefficient is as high as 0.9, the error standard deviation is almost half (44%) of the total standard deviation of  $y$ . The conclusion is that in order for  $x$  to be a good predictor of  $y$ , the correlation coefficient must be very high. The statistical significance of a correlation coefficient depends on the size of the correlation coefficient and the number of observations in a study. Hence the argument that a correlation is statistically significant does not necessarily imply it is large and important. Statistical significance evaluates only the influence of random errors. The Spearman coefficient measures how well the rankings of individuals match for the two scores. If the coefficient is one, the rankings are identical. The Spearman coefficient normally yields smaller values than Pearson. The latter can be high also as an effect of extreme outliers or multimodality of the distributions. As most scales in health research are ordinal, the Spearman coefficient is the appropriate tool for the assessment of criterion validity.

<sup>132</sup> Beck has made a meta-synthesis of 18 ideographic studies of postnatal depression and notes how cultural context can influence expectations and experiences of motherhood (Beck CT. Postnatal depression: a metasynthesis. *Qual Health Res* 2002; 12(4):453-72). There is also the organizational level to take into account; child health care is organized in different ways in different countries.

<sup>133</sup> Rubertsson et al (2003), op.cit., have data from Sweden based on 3 011 pregnant women, and present a figure of the distribution of EPDS scores, with a mean score of 6.6, median 6-7, mode 3 and a range between 0 to 29. Evans et al studied a cohort of 9 028 pregnant women in England using EPDS during pregnancy, at 18 and 32 weeks of the pregnancy and 8 weeks and 8 months postpartum. The mean scores were 6.62, 6.72, 5.84 and 5.25, respectively with standard deviations 4.66, 4.94, 4.65 and 4.61, respectively (Evans J, Heron J, Francomb H, Oke S, Golding J. Cohort study of depressed mood during pregnancy and after childbirth. *BMJ* 2001; 323: 257-60). In Norway the mean EPDS score was 4.3 for postnatal and 4.8 for non-postnatal women with standard deviations 3.7 and 4.5, respectively (Eberhard-Gran et al (2002), op.cit.).

Content validity<sup>134</sup> implies that the content of a questionnaire is in some sense relevant for the objectives used. The questions asked shall cover the phenomenon intended to be studied, in this case depression, and there should be no irrelevant questions. Different approaches are used for the assessment of the content validity. Cronbach's alpha<sup>135</sup> is often used in the PND articles to judge the homogeneity between questions for a certain dimension in the various 'instruments'. The issue then becomes reduced to a psychometric exertion, before one has grappled with the basic classificatory problems, e.g. does PND really exist as an entity of its own and which particular symptoms supposed to belong to the class 'Depression unique for the postpartum period' do or do not belong to the DSM-IV Major depression category. This difficulty is mirrored by the various selections of questionnaires and variants of diagnostic instruments seen in the PND literature.

Since routine screening is the issue here, the content validity of EPDS must be evaluated with the screening goal in mind; can the questionnaire find women at risk of getting or already having a 'DSM-IV Major depression' in a better way than an existing routine? The useful outcome of the exercise is of course not whether one has found more or less women by the various approaches. The helpful outcome is related to success of possible treatments for the identified women, children and families. Only limited research has been conducted demonstrating that screening improves such outcomes.<sup>136</sup> Well-designed controlled trials with sufficient follow up are not existent and further research is warranted to establish a much needed evidence base.

Another way of assessing validity of a measurement process is to compare the results with an accepted standard, observed simultaneously or in the future, most often an empirical study on a number of potential subjects.<sup>137</sup> Typically the results of applying the questionnaire are related to the results of a 'gold standard' for the construct under study. Such a standard is often difficult to find because the construct, as for PND, cannot be precisely defined. Validation can then become a matter of comparing different 'instruments' where one has been used and tested more extensively than the other (table 3).<sup>138</sup> Many of the self-report questionnaire-based scales (e.g. Zung<sup>116</sup>, HADS<sup>116</sup>, MADRS<sup>118</sup>) do not correspond to the DSM-IV or ICD-10 criteria (table 3).<sup>139</sup>

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<sup>134</sup> According to Cronbach & Meehl (1955), *op.cit.*, content validity is established by showing that the test items are a sample of a universe in which the investigators is interested.

<sup>135</sup> A synonym could be 'consistency within an instrument'. Cronbach's alpha is computed as the ratio of the true variation to the total variation (Cronbach LJ. Coefficient alpha and the internal structure of tests. *Psychometrika* 1951; 16: 297-335).

<sup>136</sup> Wickberg & Hwang, after a complicated recruitment process, made a comparative study in Swedish routine Child Health Clinics: 20 women were exposed to extra counselling by especially trained nurses and 21 to routine care. The women were assessed one week after the trial. 12/15 women with Major depression in the treatment group showed no evidence of having Major depression after receiving 6 counselling sessions. The corresponding figure for the controls was 4/16 (Wickberg B, Hwang CP. Counselling of postnatal depression: A controlled study on a population based Swedish sample. *J Affect Disord* 1996b; 39: 209-16). Dennis reviewed over 30 studies with a broad range of approaches. Methodological limitations such as inadequate sample size, lack of randomization and differences between exposed and non-exposed eligible women render intervention efficacy difficult to assess (Dennis C-L. Detection, prevention, and treatment of postpartum depression. In Stewart DE, Robertson E, Dennis C-L, Grace SL, Wallington T. Postpartum depression: Literature review of risk factors and interventions. Faculty of Nursing, University of Toronto, 2003).

<sup>137</sup> I.e. criterion validity according to Last et al (1995), *op.cit.*, or predictive and concurrent validity according to Cronbach & Meehl (1955), *op.cit.*

<sup>138</sup> This validation procedure is very common in serology studies where they are applied with the same epistemological naïveté as often seen in psychiatry.

<sup>139</sup> Najman et al (2000), *op.cit.*, mention that "... despite considerable differences between various scales, correlations between them are generally good, in the range of 0.6-0.8." But not even a correlation coefficient close to 1 indicates in itself validity.

**Table 3.** Examples of gold standards for EPDS and other classificatory instruments in postnatal women.

Study	Screening instrument	Instrument for classification (standardized interview or observation)	Classification manual (gold standard)
Cox et al (1987)	EPDS	SPI <sup>116</sup>	RDC*, minor, major depression
Murray et al (1990)	EPDS	SPI	RDC, minor, major depression
Zelkowitz & Milet (1995)	EPDS	SCID**	DSM-III-R <sup>115</sup>
Wickberg & Hwang (1996)	EPDS	MADRS <sup>118</sup> extended to cover the key points of the DSM-III-R criteria for major depression.	DSM-III-R, major depression
Eberhard-Grahn et al (2000)	EPDS, SCL-25***	PRIME-MD****, MADRS	DSM-IV <sup>115</sup> , major depression
Berle et al (2003)	EPDS, BDI <sup>110</sup> , HADS <sup>109</sup>	MINI-V4.4 <sup>116</sup> , MADRS	DSM-IV, minor and major depression
Jadri et al (2006)	EPDS, "a general information questionnaire"	MINI-V5.0 by telephone (French version)	DSM-IV, minor and major depression

\* RDC = Research diagnostic criteria, a classification system mainly for researchers, developed in USA and based on clinically observable, phenomenological features (Spitzer RL, Endicott J, Robins E. Research diagnostic criteria (RDC). New York: New York State Psychiatric Institute, 1975 as cited by Sadler JZ (2005) op.cit.)

\*\* SCID (Structured Clinical Interview for DSM-III-R). A semistructured interview using a decision tree approach which guides the clinician in testing diagnostic hypothesis as the interview is conducted (Spitzer RL, Williams JB, Gibbon M, First MB. The structured clinical interview for DSM-III-R (SCID). I: History, rationale and description. Arch Gen Psychiatry 1992; 49(8): 624-9).

\*\*\* SCL-25 = Hopkins Symptom Check List 25-item version. (Parloff MB, Kelman HC, Frank JD. Comfort, effectiveness, and self-awareness as criteria for improvement in psychotherapy. Am J Psychiatry. 1954; 3: 343-51).

\*\*\*\* PRIME-MD = Primary Care Evaluation of Mental Disorders. (Spitzer RL, Williams JB, Kroenke K, Linzer M, et al. Utility of a new procedure for diagnosing mental disorders in primary care. The PRIME-MD 1000 study. JAMA 1994; 272: 1749-56).

Judging from published articles, the most common problems and misunderstandings concerning criterion validation seem to be that a high, or even moderate, correlation coefficient implies criterion validity. Particularly the concept of statistical significance is sometimes not well understood, high sensitivity and specificity are taken to always imply usefulness as a screening instrument, predictive values are not handled conceptually right and statistical methods are often not correctly used.<sup>140</sup>

<sup>140</sup> The examples are many, a recent one is Jadri et al (2006) who considers EPDS "... a simple, quick-to-use tool for early screening of postnatal depression..." but do not comment on the consequences of their own calculated positive predictive value of 42.8%. They have calculated the 95% confidence interval, though, [39.1;46.5]. (Jadri R, Pelta J, Maron M, Thomas P, Delion P, Codaccioni X, Goudemand M. Predictive validation study of the Edinburgh Postnatal Depression Scale in the first week after delivery and risk analysis for postnatal depression. J Affect Disord 2006; 93: 169-76). In the Swedish study by Wickberg and Hwang (1996a) op.cit., the DSM-III-R criteria for major depression was used. To "validate" the EPDS among women having delivered a child, the EPDS was completed twice, at 2 and 3 month post partum. The total number of women was 1 874 but only 1 655 completed the questionnaire twice. A cut-off point of 11.5 was used and 91 women were considered as scoring positive for depression on EPDS. A small number, 37 women below 11.5, were randomly selected from the large group of women scoring below 11.5. These 91+37=128 women were checked with the DSM-III-R. The authors now claim that sensitivity is 54/56: 96%. However, only a small fraction of the women with EPDS below 11.5 were included resulting in a strange selection of women. Out of the 37 women < 11.5, two were diagnosed by DSM-III-R. In the whole group of women below 11.5 one would expect several more and a much lower sensitivity. The sensitivity appeared high since the authors selected only few persons with EPDS below 11.5. The issue is important since the authors talk about "validity of EPDS as a screening instrument".

Much effort has been devoted to the demonstration of content validity. Often the importance of this is questionable. When criterion validity is correctly assessed as high we might even ask why new instruments are needed. If there is already one, considered as rendering the ‘truth’, the justification could of course be that we need a questionnaire better adapted to a certain situation, an argument that was originally made for the creation of EPDS.<sup>141</sup>

Diagnosis and classification of mental disorders remain challenging and controversial and this complicates the evaluation of accrued evidence. Some of the disputes in mental health care cannot be settled by the exclusive accumulation of empirical data, since they rest fundamentally upon what conceptual frameworks and theoretical models for mental disorders we as professionals and researchers entertain. Diagnostic categories can be legitimately thought as hypothetical constructs, but most of the times they are simply taken for granted in empirical studies.<sup>142</sup> The outcome of this lack of theory of science approach is an abundance of repetitive research, which probably cements false premises and does not give much evidence to rely on for action.

Thus, there is so far no evidence for the usefulness of EPDS as a screening instrument, whatever maintained. And as if the above aspects were not enough, there is another difficulty that has not been considered carefully, despite the multitude of published studies; the side-effects in terms of misclassifications (table 4). The numbers of misclassified women could well reach 20 000 in our hypothetical example; the question is how an already overburdened health care should handle them.

**Table 4.** A hypothetical EPDS routine screening of a one year cohort of 100 000 postnatal women in Sweden. Sensitivity is set to 86%, specificity 78% (Cox et al (1987), op.cit.) and prevalence to 8% (Rubertsson et al (2003), op.cit.; Evans et al (2001), op.cit.).

EPDS	“Truly” depressed	Not “truly” depressed	Total
- indicates PND	6 880	20 240	27 120
- indicates not PND	1 120	71 760	
<b>Total</b>	8 000	92 000	<b>100 000</b>

Because screening has repeatedly failed to predict psychological vulnerability, other health measures should be emphasized, such as increased access to health care, elimination of the stigma associated with treatment for psychological conditions and raised professional knowledge and awareness.<sup>143</sup> This should not address just postnatal women, but the population as a whole. The patients should be understood in her and his unique, personal situation. Psychiatric disorders are human processes and since a major aspect of being human is our subjectivity, professionals need to pay attention to subjective phenomena, which means meeting and talking to the patient face-to-face. The management and EBM movements are sometimes bed-fellows. Minimalistic purchasing under a cover of science could lead to

<sup>141</sup> Cox et al (1987), op.cit., criticized the existing screening scales for depression (Anxiety and Depression Scale (SAD), Goldbergs 30-item General Health Questionnaire, BDI, RDC, Zung) for emphasising somatic symptoms of the psychiatric disorders, which may be caused by normal physiological changes associated with childbearing, “...recognised the need to modify existing scales of depression for use in new specific clinical situations..”, “..simple to complete, and not require the health worker to have any specialist knowledge of psychiatry.”

<sup>142</sup> Banzato CEM, Mezzich JE, Berganza CE. Introduction chapter to Philosophical and methodological foundations of psychiatric diagnosis. *Psychopathol* 2005; 38(4): 159-61.

<sup>143</sup> In the Swedish context with an almost full coverage of antenatal and postnatal care, the immediate issues are continuous education of staff and well-staffed clinics. In the USA context, where ca. 40 million people do not have health insurance, the priorities should perhaps be ranked otherwise.

rationing and non-purchase of a care which clinical judgement finds important and useful. The use of self administered questionnaires is one way of categorising patients that could easily be misused as a tool for saving staff time, when what is needed is an eye-to eye contact with a professional fellow creature. The goals for the interview during the routine visits to Mother and Child Health Clinics should be to establish rapport and, if needed, a therapeutic relationship.

Few would disown the stated assumption of the EBM movement that providing interventions based on credible evidence will generally result in better outcomes than providing non-evidence based interventions. Idiographic research is also often nowadays acknowledged and accepted as having the potential to augment the evidence base of both health care policy and practice. Evidence-based public health interventions, however, have to consider not only the various indications of needs of the population but also the values of that population. This requires reflexivity<sup>144</sup> with a self-conscious account of how knowledge is being produced.<sup>145</sup>

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<sup>144</sup> 'Reflexivity' here might be understood as a methodological virtue, but what I am after is what Lynch calls an 'ethnomethodological' conception of reflexivity, i.e. a reflexivity that does not privilege a theoretical or methodological standpoint by contrasting it to an unreflexive counterpart (Lynch M. Against reflexivity as an academic virtue and source of privileged knowledge. *Theory Cult Soc* 2000; 17(3): 26-54).

<sup>145</sup> See Malterud K. Reflexivity and metapositions: strategies for appraisal of clinical evidence. *J Eval Clin Pract* 2002; 8(2): 121-6. She discusses clinical interactions but her views are also applicable for interactions with populations such as discussed here.

## Ethics and public health interventions

Ethical deliberations concerning public health interventions should be informed by the best evidence available both from health science and health care science. In addition, all public health actions require an ethical basis. Does this, however, mean that there is a need for a special public health ethic?<sup>146</sup> Is there perchance a different risk for ethical pitfalls in public health interventions since the individuals are anonymous constituents of a population?

Like in all public undertakings people have differing perceptions as to what makes up the justification of a particular public health action. First of all there are different opinions on what makes up biomedical evidence, as exemplified by my four cases (I-IV). Then ethical issues often arise as a result of a conflict among competing sets of values, such as in the field of public health, the conflict between the rights of individuals to do what they want and the needs of communities to protect themselves.

The disagreements are sometimes complicated by how the words ‘ethical’ and ‘moral’ are used and understood.<sup>147</sup> Both could – as well as the words ‘ethics’ and ‘morality’ – be used in a descriptive and normative sense. Used descriptively they aim at describing opinion without taking side. In the latter sense they are sometimes used to recommend the opinions expressed.

Health care ethics<sup>148</sup> is an academic discipline which studies moral actions, phenomena, ideas and theories. *Descriptive ethics* deals with people’s values and actions and gives us knowledge about prevailing moral thinking. *Normative ethics* often examines what is right or good, i.e. gives us our belief about how to act according to moral rules and principles. *Meta-ethics* consists of reflections of what characterizes ethical concepts and theories.<sup>149</sup> Ethics could thus be regarded as the critical and systematic reflection upon what can be considered right or wrong, good or bad, just or unjust. In this thesis I use descriptions of four public health interventions (I-IV) as cases for critical reflections; normative only in the sense that they highlight the need for a critical stance towards scientific knowledge and a preparedness for communicative action in decisions on how to proceed.

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<sup>146</sup> Cf. Charlton, who in an editorial suggests that there is “a sharp difference between the ethics which govern public health compared with those appropriate for clinical specialities”, related to the ‘clinical imperative’, i.e. something must be done in response to the patient’s needs. Public health has little place for uncritical zeal, that may usefully promote the placebo effect in clinical encounters, but can seriously distort the scientific evidence and distract attention from individual disadvantages (Charlton BG. Public health medicine – a different kind of ethics? *J Royal Soc Med* 1993; 86: 194-5).

<sup>147</sup> The two words ‘ethics’ and ‘morality’ have several meanings. The word ‘morality’ could mean how one person thinks about what is right and wrong, good or bad, just or unjust. In this sense it is called ‘individual morality’. But the word could also mean the current opinion in society about what is right or wrong, good or bad, just or unjust. In this sense it is called ‘social morality’. The word ‘ethics’ have at least three different meanings. It could mean the same as the word ‘morality’. In this sense the two words ‘morality’ and ‘ethics’ are synonymous. Today the word ‘ethics’ is often used to denote the opinion of a professional group about what is right or wrong, good or bad, just or unjust. In this sense it is often called ‘professional ethics’. Many philosophers, however, recommend that the word ‘ethics’ should be reserved for a *system* about what is right or wrong, good or bad, just or unjust. Examples of such systems are catholic ethics and utilitarianism. I will in principle follow the latter recommendation in my text.

<sup>148</sup> ‘Medical ethics’ [‘medicinsk etik’] is a common term in Sweden. The term ‘bioethics’ is mainly used in the USA and Canada. I prefer ‘health care ethics’ [‘hälso- och sjukvårdsetik’] as a broad term covering ethical issues in how society prevents disease, promotes health, organizes health care, controls communicable infections and organizes community efforts for a sound environment. See also footnotes 19, 20 for definitions of ‘public health’. Cf. Nordin-Johansson & Asplund (1999), op.cit., who discuss the concept EBM in a Swedish context and there prefer the more inclusive ‘evidence based health care’. Campbell recommends ‘health care ethics’ or “... (more pedantically but also more accurately) ‘the analysis of moral issues in health care’ is perhaps preferable.” (Campbell AV. Mere words? Problems of definition in medical ethics. In Doxiadis S (ed). *Ethical dilemmas in health promotion*. Chichester: John Wiley & Sons, 1987: 17-18).

<sup>149</sup> The separation in three distinct types of how life can be examined and understood from an ethical point of view is of course difficult to uphold and just a concession to an orderly mind.

Health care ethics richly informs practice and policy in clinical medicine, perhaps not so much in public health, however, especially when the thinking is restricted to biomedical actions and the perspective limited to what is effective on group level without considerations for sociological and individual aspects. Ethics for public health interventions should not only concern the ethical dimensions of the public health enterprise itself, but also the character of the professional people, who must be ready for decision-making and imaginary thinking beyond group level in creating and implementing a sustainable public health policy. As members of a democratic society we all have an obligation to protect and defend the community against threats to health, safety, and security. This diffuse general obligation will be more precisely defined for the people chosen to take decisions on behalf of us, in this particular case, public health officials, health professionals and politicians. A zest for decisions to be based on practical reason and critical thinking seems thus to be an important virtue for this special breed of public servants to counteract the risk for bureaucratic rigidity and state paternalism.

Public health ethics has sometimes been divided in three overlapping areas: professional, applied and advocacy ethics. *Professional ethics* deals with the values that help public health professionals to act in a defensible way. *Applied ethics* concerns the values involved in problems of public health policy and practice, *advocacy ethics* with the overarching political values of population health and social justice. The public health interventions dealt with in this essay evidently touches all three of them. The starting ground, however, lies in applied ethics, with citizens being objects of public health actions e.g. in the form of safe and effective vaccination and adequate screening programmes.

### ***The four cases***

The four cases in this essay – the measles vaccination programme (I) and the three screening procedures (II, III, IV) expose problems around the principles of autonomy, beneficence, non-maleficence and justice as solidarity but also on questions of professional knowledge and honesty.

The population based ethical perspective of public health is different from the patient-centred ethical perspective of curative medicine in that final decisions on actions of necessity are taken on policy levels, by officials or politicians in a kind of surrogate decisions. The measles vaccination programme, where the parents are requested to make a decision for their offspring in her/his best interests, and to take a position to society's quest for solidarity and the beneficence of the population, is yet another example (I). Here the ethical issue revolves on the question of autonomy and respect for individual choices. The interests of individuals can be honoured, since neither measles nor, as in the other 'infectious' case, HSV-2 infection (III) will immediately and seriously endanger public health.<sup>150</sup> The officials at the policy level have to invoke solidarity and considerations for fellow citizens by credible information communicated in an understandable way for lay-persons.

There is also the issue of rights to be examined for a potentially lethal disease like cancer (II). On the individual level this is a matter of agreement between the patient and the doctor turning on the principle of autonomy and professional knowledge. For screening of groups of

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<sup>150</sup> A statement made in the safe context of Swedish health care and certainly not valid e.g. for a measles epidemic in an unvaccinated population in a country with poor health care infrastructure.

people, someone has to take responsibility not just for those who might have an immediate benefit, but also for them who have to pay the price for the endeavour, i.e. the ones with missed or wrong diagnosis (II, III, IV). This often results in limit-setting decisions that are difficult to understand for the population, if the reasons are not made publicly accessible in a credible way (II).

What then are the appropriate limits for public health officials in influencing the preferences of citizens and in protecting them from commercial influences that may perhaps have an impact on patterns of illness? Again a difficult question, this time revolving around the principles of autonomy and beneficence but also around professional knowledge and honesty.

What is the ethical standing that should be attached to the common good? What is the maximum level of personal autonomy that will still ensure the success of the community programme? Under what circumstances should individual interests yield to achieve a collective benefit for the population? These are not easy questions to answer and there are surely no fixed alternatives for action. A process of community discernment in which individuals reflect on issues within their actual social context with the aim of reaching mutual agreement as how to proceed, is one way to handle ethical predicaments. If this shared deliberation is guided by two general principles, respect for persons and egalitarian reciprocity<sup>151</sup>, it could give significance to the particular ethical context without abandoning biomedical and epidemiological aspects of public health.

### *Codified values and principles*

If public health is what society does collectively to assure the conditions for their people to retain health<sup>152</sup>, then public health ethics seen as applied ethics should deal with values and principles that help guide actions designed to promote health and prevent injury and disease in the population. The central ethical problem for public health actions is the conflict between rights of the individual and the responsibilities of society<sup>153</sup> for all its members. Individual and community needs are of necessity not always concordant.

The encounter between individuals and society brought forward by public health interventions is always complex and takes place in forever shifting contexts, which makes fixed and ready-to-use systems of ethics less useful in concrete situations. Standard approaches are often inscribed in an ethical theory referred to as e.g. utilitarian, Kantian and virtue ethics.<sup>154</sup> Sometimes ethics is presented as a system of rules and regulations to make possible that life in a society runs smoothly. Problems start when people espouse different and closed systems, where the norms are absolute and forever fixed. Those who investigate ethical problems often

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<sup>151</sup> Seyla Benhabib [1950-], discussing the ideals of universal respect and egalitarian reciprocity, describes communicative ethics or discourse ethics as “the processual generation of reasonable agreement about moral principles via an open-ended moral conversation.” Only those norms can claim to be valid that meet (or could meet) with the approval of all affected in their capacity as participants in a practical discourse. (Benhabib S. *Situating the self. Gender, community and postmodernism in contemporary ethics*. New York: Routledge, 1992). See also Lynch (2000), *op.cit*.

<sup>152</sup> See footnote 10 for comments on the concept ‘health’. Fleischhauer & Hermerén (2006), *op.cit.*, write about how different medical, social and economical values have determined - and still do - goals in public health and how values change with time and geographical/cultural/ contexts. Neither values nor goals are constant, but the conflict between rights of the individual and responsibilities of the society is essential and universal.

<sup>153</sup> With ‘society’ here is meant something else than just a group of individuals.

<sup>154</sup> According to Martha Nussbaum [1947-] ‘virtue ethics’ cannot be a separate approach contrasted with utilitarianism and Kantianism. She concludes “. we would be better off characterizing the substantive views of each thinker – and then figuring out what we ourselves want to say.” Both utilitarianism and Kantianism contain treatments of virtue. (Nussbaum MC. *Virtue ethics: a misleading category?* J Ethics 1999; 3: 163-201).

use invented examples and the ensuing recommendations for moral action are found within their chosen ethical theory and their derived rules and regulations. This is not so helpful in real life, when solutions are looked for in contexts where diverse meanings are at play, like in public health actions that have to be organized in pursuit of what we as a society value. Values are plural and difficult to organize.

Ethics concerns choice and action as well as the agent. Aristotle's comprehensive philosophical system encompasses ethical theories of which much remains in contemporary ethical thinking adapted and recreated to specific contexts.<sup>155</sup> In many ways ethics in the North-Western hemisphere has been formed by Jewish and Christian theology as a mainly demanding ethic. Law, duty and 'ought to' e.g. have one origin in the Jewish Torah.<sup>156</sup> The more secular philosophical ethics of today has kept many of these concepts, but parted from the theological premises they lose their meaning and importance for many people.<sup>157</sup> For some persons it is reason, whether inborn or acquired, which decides what is right or wrong. Some consider themselves as pure deontologists, some as utilitarians and others prefer a more middle ground.<sup>158</sup> We must acknowledge that value bases differ, but understand how they differ, if we want to keep up the dialogue necessary for consensus and credible action in public health.

Nineteenth century utilitarian ethical theories were the driving force behind the sanitary reforms. In many ways utilitarianism still compels the whole medical project, especially if supremacy to the needs of the community is justified (often in economical terms) in the belief that this will benefit most individuals. Cost-benefit analyses e.g. go back to classical utilitarianism.<sup>159</sup> The determinants for the principles of utility, pleasure or pain, happiness or unhappiness are nowadays usually comprehended as 'welfare of individuals' and the ethical theory called consequentialism.<sup>160</sup>

<sup>155</sup> Contemporary examples are e.g. Alasdair MacIntyre [1929-] and Martha Nussbaum. Silfverberg [1946-] reasons around professional virtues and home based care in Sweden (Silfverberg G. Att vara god eller göra rätt: en studie i yrkesetik och praktik [To do good or make right: a study in professional ethics and praxis] (Diss). Nora: Nya Doxa, 1996).

<sup>156</sup> The Hebrew word 'Torah' means 'teaching', 'instruction', 'scribe', or 'law'.

<sup>157</sup> The process gained momentum with the Enlightenment in the 18<sup>th</sup> century and the separation can be illustrated by words from the widely read Arthur Schopenhauer [1788-1860]: "Aechte Moral und Moralität ist von keiner Religion abhängig; wiewohl jede sie sanktionirt und ihr dadurch eine Stütze gewährt" (Schopenhauer A. Parerga and Paralipomena II: XV, §181 Rationalismus. 1851. Available at <http://home.rhein-zeitung.de>). Elizabeth Anscombe [1919-2001] maintains in her essay from 1958 the same, without discussing Schopenhauer, though. He is mentioned as the source by Backström & Torrkulla in their introductory chapter to Backström J, Torrkulla G (eds). *Moralfilosofiska essäer [Essays in moral philosophy]*. Stockholm: Thales, 2001, in which Anscombe's essay is reprinted (Anscombe E. *Modern moralfilosofi [Modern moral philosophy]*. *Philosophy* 1958; 33: 1-19). According to Backström & Torrkulla it was also in the said essay that the concept consequentialism was mentioned for the first time.

<sup>158</sup> Cf. the opinion by Gustav Mayer [1871-1948] with a Jewish background but considering himself as not religious: "Ich suche nicht in biologischer Dunkelheit nach der Wurzel der sittlichen Kräfte die in mir lebendig sind. Alles Bewusste in mir ist das Ergebnis abendländischer Kulturentwicklung und morgenländischer nur insofern, als die abendländische Kultur dies Gut von ihr übernahm." (Mayer G. *Erinnerungen. Vom Journalisten zum Historiker der deutschen Arbeiterbewegung*. Nachdruck der Ausgabe Zürich und München 1949. Hildesheim: Georg Olms Verlag, 1993). Cf. also Callahan, a communitarian philosopher from Hasting Center (a USA research institute founded in 1969), who calls attention to that trained philosophers nowadays have no knowledge of religious traditions, and that physicians sometimes dismiss as too abstract and too little shaped by clinical experience what philosophy might contribute to their moral thinking (Callahan D. *Principlism and communitarianism*. *J Med Ethics* 2003; 29: 287-91).

<sup>159</sup> Utilitarianism is an ethical theory according to which an action is right if and only if it conforms to the principle of utility. Jeremy Bentham [1748-1832] formulated the principle in his "Introduction to the Principles of Morals and Legislation" 1789. According to him the rightness of an action depends entirely on the value of its consequences, which is why the term consequentialism is used, especially since the 1960s. (Mautner (2000), op.cit.). See also footnote 157 on Anscombe.

<sup>160</sup> Consequentialism bases our obligations on consequences. Our acts should give a net balance of pleasure over pain in the universe (hedonism). Two important consequentialist views are classical utilitarianism and rule utilitarianism. Bentham and Henry Sidgwick [1838-1900] are representatives of the former where all morally relevant factors are reduced to consequences. Sidgwick means that we are committed to accepting conflicting basic principles; a conflict we can only hope will not happen in practice, but we can never be sure. Classical utilitarianism might appear simple but it is actually a complex

After World War II the Nürnberg Code was established, which commands that the rights of individuals to autonomy and self-determination must come before authority of the state, science, or medicine. The Code explicitly rejects the argument that the creation of benefits for many justifies the sacrifice of the few.<sup>161</sup> The Nürnberg Code was followed by the Helsinki Declaration by the World Medical Association 1964. Like the Code, the Helsinki Declaration emphasizes the human right to voluntary, informed consent to participation in medical research that may or may not benefit the individual patient, science or humanity.<sup>162</sup> The Council for International Organizations of Medical Sciences (CIOMS) is an international, non-governmental, non-profit organization established jointly by WHO and UNESCO in 1949. The particular contribution of CIOMS has been the issuance of international guidelines for the application of ethical principles in various key areas of which one is on health policy, ethics and human values.<sup>163</sup>

The progress of biomedical sciences, especially during the last decades, confronts our societies with new ethical dilemmas not just in research but also in traditional medical practice and public health interventions. The confrontation between basic values seems inevitable.

The principlist<sup>164</sup> model developed by Beauchamp and Childress has, since its first appearance in 1979, grown to be rather dominant in the discourse of medical ethics in the North-Western hemisphere.<sup>165</sup> The Belmont report from the same year identified basic

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combination of many distinct claims about the moral rightness of acts. Richard Mervyn Hare [1919-2002] means that actions are right if they maximize the satisfaction of preferences or desires, no matter what the preferences may be for (Mautner (2000), op.cit.). Peter Singer's [1946-] consequentialist approach has led to controversies on the ethical superiority of human beings and sanctity of human life (Singer P. Peter Singer "tells it like it is". *Freethought Today* 2005; 22(4). Accessed 2007-08-31 at <http://ffrf.org/ftoday>). In Sweden, Torbjörn Tännsjö [1946-] has maintained a consequentialist view when discussing health care issues (Tännsjö T. *Vårdetik, 3:e reviderade upplagan*, Falun: Thales, 1998; Tännsjö T. *Hedonistic Utilitarianism*. Edinburg: Edinburg University Press, 1998). Rule utilitarianism specifies an underlying value of a particular rule. The rule resulting in the best overall consequences is the best rule and the right action is the one which conforms to the best rule. Rule utilitarianism is said to have been developed to make the implications of utilitarianism less shocking to ordinary moral consciousness.

<sup>161</sup> The judgment by the war crimes tribunal at Nürnberg 1947 laid down 10 standards to which physicians must conform when carrying out experiments on human subjects. The first standard is about voluntary consent and the second says "The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature". The code concerns research and nothing is stated about routine interventions (<http://www.hhs.gov/ohrp/references/nurcode.htm>. Accessed 2007-02-05).

<sup>162</sup> The World Medical Association (WMA) Declaration of Helsinki with ethical principles for medical research involving human subjects was adopted by the 18th WMA General Assembly Helsinki 1964 and revised in Tokyo 1975, Venice 1983, Hong Kong 1989, South Africa 1996, and Edinburgh 2000. A new revision is under way since 2007 (Accessed 2008-17-10 from <http://www.wma.net/e/policy/b3.htm>).

<sup>163</sup> CIOMS programme originated at an international conference in Athens 1984 where the topics covered included equity, social justice, community participation, and the dignity of individuals in sickness and health in the context of health policy-making (Bankowski Z, Bryant JH (eds). *Health Policy, Ethics and Human Values: European and North American Perspectives*. Geneva: CIOMS, 1988). See also 1991 CIOMS International guidelines for ethical review of epidemiological studies (currently under revision) intended for investigators, health policy-makers, members of ethical review committees, and others who have to deal with ethical issues that arise in epidemiological research and also CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects from 2002, which like the earlier ones from 1982 and 1993, relate mainly to ethical justification and scientific validity of research. Their scope reflects the changes, the advances and the controversies that have characterized biomedical research ethics in the last two decades. (<http://www.cioms.ch>. Accessed 2008-01-16).

<sup>164</sup> I am using 'principlist' instead of the longer 'the four principles' just for practical reasons. 'Principlist' has nowadays lost its from the beginning somewhat pejorative touch and is also used by Beauchamp & Childress themselves.

<sup>165</sup> 'The Principles of Biomedical Ethics' is a classic in the field of medical ethics. The first edition was published 1979 in the USA. The four principles (respect for autonomy, beneficence, non-maleficence, justice) soon became popular in the medical ethical discourse. Available now is the 5<sup>th</sup> edition, which is rewritten and restructured. The conclusions and core arguments are, however, the same, but the authors state much more clearly what they mean with 'common morality' which is defined as

principles that would guide the regulation of research involving human subjects.<sup>166</sup> Four<sup>167</sup> basic principles have come to be privileged; respect for autonomy, beneficence, non-maleficence and justice. The principlist model has evolved and been shaped mainly from a patient perspective.

The principles developed during the last part of the 20<sup>th</sup> century have been variously codified on national levels. Bioethics as a USA phenomenon has tended to foster the value of autonomy and place individual rights above communal well-being.<sup>168</sup> In Sweden there is legislation with the stated goals for health care to aim for good health and care on equal conditions for the whole population and that the care should be given with respect for the equal value of all people. Prevention is an obligation for the health care.<sup>169</sup> The principle of autonomy is evidently foremost, but nothing is said about how to balance individual against group interests. The Swedish Communicable Diseases Act, with its aim to protect the population against spread of infectious diseases<sup>170</sup>, explicitly states that disease control shall honour respect for the equal value of all people.<sup>171</sup> Autonomy, expressed as respect for persons, and equity, are thus established ethical principles in the Swedish health care context.

The population based perspective of public health is different from the patient-centred perspective of curative medicine. Public health ethics is not merely the aggregation of individual interests in a population. The interests of individuals must never be neglected but can sometimes be overridden by competing ethical considerations such as when our choices endanger public health which might be the case for some contagious diseases. Beauchamp's

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".. the set of norms that all morally serious persons share" (Beauchamp TL, Childress JF. Principles of biomedical ethics. Fifth ed. Oxford: Oxford University Press, 2001: 3). Tom Beauchamp [?], philosopher, is professor of Philosophy at Georgetown university, USA and James Childress [1940-], philosopher and theologian, is professor of Ethics at University of Virginia, USA. See also Pellegrino (1993), op.cit. for a background and ".. the view of a physician, not a philosopher, but a physician disposed to critical reflection on medical matters." Edmund Pellegrino [1920-] is a USA professor emeritus of Medicine and Medical Ethics, influential on the policy level.

<sup>166</sup> The Belmont Report, created 1979 by the former US Department of Health after four years work and named after a conference centre in Maryland, USA, talks about respect for persons, beneficence and justice and incorporates two distinct ethical convictions: "individuals should be treated as autonomous agents" and "persons with diminished autonomy are entitled to protection" (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>. Accessed 2007-01-31). Tom Beauchamp took part in the writings of the Belmont Report.

<sup>167</sup> Also referred to as 'three' when considering beneficence and non-maleficence together. It is useful, though, to retain them as two separate principles for instances in which we acknowledge no obligation of beneficence for people that we still think we have obligations to not harm.

<sup>168</sup> USA bioethics has been accused of being too obsessed with autonomy and eschewing concerns over relationship and responsibility in favour of concerns over choices and freedom to act. Cf. Callahan (2003), op.cit., who writes that autonomy *de facto* is given a place of honour because of the thrust of individualism, whether it is from the egalitarian left or the market oriented right, to give people maximum liberty in devising their own lives and values. Raanan Gillon [1941-], a principlist from the UK, regards the respect for autonomy as "the first among equals". (Gillon R. Ethics need principles – four can encompass the rest – and respect for autonomy should be the first among equals. *J Med Ethics* 2003; 29: 307-12). Beauchamp & Childress (2001), op.cit.: 57, "firmly deny" .. "that the principle of respect for autonomy overrides all other moral considerations."

<sup>169</sup> "1 §. Med hälso- och sjukvård avses i denna lag åtgärder för att medicinskt förebygga, utreda och behandla sjukdomar och skador [.. measures for the medical prevention, investigation and treatment of disease and injury]. 2 §. Målet för hälso- och sjukvården är en god hälsa och en vård på lika villkor för hela befolkningen. Vården skall ges med respekt för alla människors lika värde och för den enskilda människans värdighet [.. aimed at assuring the entire population of good health and of care at equal terms. Care should be provided with respect for the equal dignity of all human beings and for the dignity of the individual.]" (Hälso- och sjukvårdslag [The Health and Medical Service Act] 1982:763, 1997:142. SFS [Swedish Code of Statutes] (2002: 1028).

<sup>170</sup> "1 §. Samhällets smittskydd skall tillgodose befolkningens behov av skydd mot spridning av smittsamma sjukdomar [.. is primarily to protect the population against communicable diseases ..]" (Smittskyddslag [The Communicable Diseases Act] (2004:168)). According to the Act, measles is a notifiable disease.

<sup>171</sup> "4 §. .... får inte vara mer långtgående än vad som är försvarligt med hänsyn till faran för människors hälsa [.. communicable disease control must not extend beyond the limits necessary to protect people's health..]. Åtgärderna skall vidtas med respekt för alla människors lika värde och enskildas integritet [.. is based on the equal value of all people and the integrity of the individual.]" (ibid.).

and Childress's four principles hardly constitute a general ethical theory but they provide a framework for identifying and reflecting on ethical problems. Appropriate decisions for concrete public health problems need a kind of ethic which unites principles and prudence with the communicative dimensions of these particular situations.

An ethical theory that guides public health actions could not be universal and fixed once and for all given the dynamics in the field.<sup>172</sup> Public health interventions must be the result of communication and dialogue with attention to values of partnership, citizenship, and community.<sup>173</sup> A common factor which could unite value judgements in the field of health care ethics is a sense of responsibility to something external to our selves; a sense considered as one of the universally shared insights<sup>174</sup>, out of which ethical theories are constructed. The morality also rests on values other than those represented by the four principles, e.g. demands for virtues or certain character traits. The goods that human pursue are plural and qualitatively heterogeneous. For action they need to be harmonized with one another. Using reason we should deliberate about means to ends and the ends themselves and not evade life's complexities. Medical ethics could neither be a normative, regulative discipline nor a system of rules that save us from

“...some of the agony of thinking and all the torment of feeling that is actually involved in reasoned deliberation.”<sup>175</sup>

## Virtues

The basic unit for ethical evaluation by utilitarians and pure deontologists is individual actions or types of actions. The unit of evaluation in virtue-based ethics is the person, which is an entity persisting over time. Virtues are dispositions involving the faculties of choice, judgements, desire, emotion and action and they can be manifested in a great variety of ways, depending on circumstances.<sup>176</sup>

Aristotle distinguished between moral and intellectual excellence, the one being attained by habituation, the other by learning. We acquire virtues much in the way we acquire skills and the goals of ethical excellence enlarge as ethical development advances.<sup>177</sup> A successful public health practitioner should have both *technē* and *epistēmē*, but also *phronēsis*, if we

<sup>172</sup> Göran Hermerén [1938-], in reflecting on European values, points at how difficult and multi-layered the concept value is. If there is a distinctive approach to ethics “it has to do with the ranking order of the values” and different ranking orders could exist “not only in different cultures but also relative to what the problem under discussion is” (Hermerén G. European values, ethics and law. Present policies and future challenges. *Jahr Wiss Ethik* 2006; 11: 5-40).

<sup>173</sup> See Benhabib (1992), op.cit., on universal respect and egalitarian reciprocity.

<sup>174</sup> See Rosenberg G. *Plikten, profiten och konsten att vara människa*. Stockholm: Albert Bonniers Förlag, 2004 [Duty, Profit and the Art of Being Human]. See also Beauchamp for a discussion of the distinction between the universality of common morality and non-universality of ‘particular moralities’ (Beauchamp TL. A defense of the common morality. *Kennedy Inst Ethics J* 2003; 13(3): 259-74). I will not go further into that discussion here except to state my conviction of the existence of a common morality in the Swedish society, understood as a core set of values rational and reflecting inhabitants could agree upon, and which are codified in laws and public regulations. See also Hermerén (2006), op.cit. and Nilstun T. Moral reasoning. A study in the moral philosophy of S.E. Tuolmin. Diss. Lund; Studentlitteratur, 1979: chapter 4.

<sup>175</sup> Wiggins D. Deliberation and practical reason. *Proceedings of the Aristotelian Society* 1975-76; 76: 29-51.

<sup>176</sup> Cf. Hunt L. *Character and culture*. New York: Rowman and Littlefield, 1997, as cited by Benkler & Nissenbaum in their essay on how the technical infrastructure of the Internet has brought forward a socio-economic system of production that offers an opportunity for people to engage in practices that permit them to exhibit and experience virtuous behaviour (Benkler Y, Nissenbaum H. Commons-based peer production and virtue. *J Polit Philos* 2006; 14(4): 394-419).

<sup>177</sup> “Virtue, then, being of two kinds, intellectual and moral, intellectual virtue in the main owes both its birth and its growth to teaching (for which reason it requires experience and time), while moral virtue comes about as a result of habit, whence also its name (ethike) is one that is formed by a slight variation from the word ethos (habit). From this it is also plain that none of the moral virtues arises in us by nature; for nothing that exists by nature can form a habit contrary to its nature.” (Aristotle. *Nicomachean Ethics*. Transl. Ross WD. Oxford: Clarendon Press, 1908).

follow Aristotle's train of thought. Some writers in health care ethics even maintain that persons of moral discernment afford greater protection against ethical wrongdoing in medicine than do rules, regulations and principles.<sup>178</sup> There should be space and resources set aside for a continuous address of health care ethics for students, staff, in their training and their educational faculties. Life is too complicated for people to be guided just by simple rules of ethical behaviour.

Raising the question of virtues, however, may boost legitimate concerns. What and whose virtues are we talking about? Are there particular religious or cultural assumptions behind the talk about virtues? What role has virtues vis á vis the codified norms – and what behaviour would we agree are not compatible with a virtuous life in every-day life?

Ethic grounded in principles emphasizes action; virtue ethic emphasizes the agent who performs the action. For people involved in decisions on contemporary public health with the emphasis on evidence based action, one of the cardinal virtues seems especially apt: prudence.<sup>179</sup> The Swedish Communicable Diseases Act explicitly states that the procedures should be built on science and tested experience.<sup>180</sup> The Health Act talks more generally about "good care" and "good quality".<sup>181</sup> Prudence would call for a thorough, broad, transparent review, open for critique of what is the evidence-base, before a public health action is undertaken, but also for a humble attitude to what is considered as today's scientific truths.

Rationality means making the best choice between approximations to the truth.<sup>182</sup> Science advances by refuting hypothesis and solving problems, not by confirming what is already considered as 'truth'. Nobody can alone know all the implications of suggested programmes and researchers and planners seldom criticise sufficiently searchingly their own ideas. Here the professions are ethically responsive, be it on the policy, administrative or operational level. Conclusions, decisions, programmes and every intervention must be questioned and discussed in a never-ending process including authorities of all kinds and the general public. Criticism is important and it need not always be constructive. Sometimes destructive criticism can be more constructive in the long run than suggesting minor amendments to a

<sup>178</sup> E.g Gardiner, a general practitioner from the UK, who discusses how virtue ethics "explores how moral agents can learn by habitual practice to develop good characteristics that will enable us to act well" (Gardiner P. A virtue ethics approach to moral dilemmas in medicine. *J Med Ethics* 2003; 29: 297-302). Virtue ethics and what makes its possessor and his/her work good has had a great influence on Christian tradition, particularly through Thomas Aquinas [ca 1225-1274]. Christian ethics based on theological presuppositions provide both motivation and rationality for ethical enquiries of health care problems often ending up as tragic dilemmas though, due to acolytes following absolute rules.

<sup>179</sup> The four cardinal virtues are prudence, temperance, courage and justice. They are usually listed together with the theological virtues faith, hope and charity. According to Aristotle (1908 transl.), op.cit.: 6v, 6vii, prudence entails a capacity to bring diverse kinds of information to bear on a decision to act. Drawing on MacIntyre, Knud E. Løgstrup [1905-81] and Thomas Aquinas, Sigurdson discusses how prudence helps mediating between theory and practice (Sigurdson O. *De prudentia. Om principer och personer i etiken* [De prudentia. About principles and persons in ethics]. Stockholm/Stehag: Brutus Östlings Bokförlag Symposion, 2001).

<sup>180</sup> "4 §. Smittskyddsåtgärder skall bygga på vetenskap och beprövad erfarenhet och får inte vara mer långtgående än vad som är försvarligt med hänsyn till faran för människors hälsa." (Smittskyddslag [The Communicable Diseases Act] (2004:168)). A renewed Act was accepted 2004, which enables public authorities to take measures to protect the population from communicable diseases while protecting the individual from unnecessarily intrusive intervention.

<sup>181</sup> "2 §. Hälso- och sjukvården skall bedrivas så att den uppfyller kraven på en god vård [Health and medical services shall be conducted so as to meet the requirements for good care.] // Detta innebär att den skall särskilt vara av god kvalitet...[In particular this means .. be of good quality ...] (Hälso- och sjukvårdslag [The Health and Medical Service Act] 1982:763, 1997:142 and SFS [Swedish Code of Statutes] (2002: 1028).

<sup>182</sup> Popper means that the case for democracy and science made by acknowledging the fallacy of induction and concentrating your efforts on solution of problems will destroy authoritarianism and elitism (Popper KR. *Alle Menschen sind Philosophen*. München: Piper Verlag GmbH, 2004).

fundamentally unsound scheme.<sup>183</sup> Technological progress can easily become an ideal in itself as exemplified by what sometimes happen when new diagnostic tests are used indiscriminately (II, III). An ethically responsive profession is an indispensable safeguard against a morality of too consequentialistic policies. To set limits for public health so that it doesn't arrive in the 1930's mess, however, means an expansion of possibilities for critique with a participation of all citizens, not just the professions.

### *The principles model*

The principles model for identification and analysis of the ethical conflicts in I-IV is not the only existing one. It was found useful in our cases, since it incorporates values found in Swedish health care. The model contains two different dimensions; the relevant ethical principles and the affected persons, i.e. the stakeholders. The model's principles should not be seen as action guides that stem from an integrated philosophical theory such as e.g. the duty ethic by Kant.<sup>184</sup> The principles are most certainly grounded in ethical theories and medical codes from throughout history, but none of them is *a priori* privileged; they are *prima facie* rather than absolute.<sup>185</sup> Good use of principlism requires that we pay attention to the uniqueness of each moral situation, take a reflective step back and try to find what values might apply in the specific case.

### **Autonomy**

Autonomy<sup>186</sup> refers to the capacity of a rational individual to make informed, uncoerced decisions. The principle is central in medical ethics and as such incorporates two fundamental ethical ideas; those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination and persons who are dependent or vulnerable should be afforded security against harm or abuse. Patient autonomy is a relatively new development in the history of medicine; until a few decades ago, paternalism was the rule. The Nürnberg trials actualised the principle as 'respect for persons' and the need for 'informed consent' from research subjects. In time it has been applied to the physician-patient relationship as well, but for long doctors knew best. With knowledge and new technologies in medicine, including those that bear on life and death, came power and responsibility that easily translate into paternalism; in public health as a state paternalism seen in the first half of the 20<sup>th</sup> century and driven by strong medical men.

In contemporary Swedish health care, emphasis is placed on values of self-determination and the rights of patients. In epidemiology and preventive thinking, individuals are usually seen as anonymous constituents of populations; health policies will thus reflect reasoned choices about benefits relative to risks and costs on a population level.

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<sup>183</sup> The importance of criticism follows from Popper's solution of the problem of induction (James R. Return to reason: Poppers thought in public life. Ilminster: Open Books Publishing Ltd, 1980. Reprinted with corrections, 1998). James has been general practitioner and served as a city councillor in the UK.

<sup>184</sup> For Immanuel Kant [1724-1804] consequences were not morally important. We should act from respect for the universal moral law defined by the Categorical imperative which comes from reason: „Handle nur nach derjenigen Maxime, durch die du zugleich wollen kannst, dass sie ein allgemeines Gesetz werde.“ [Act only according to that maxim whereby you can at the same time will that it should become a universal law.] (Jacoby (2001), op.cit.).

<sup>185</sup> See Beauchamp & Childress (2001), op.cit., especially chapter 9. *Prima facie*, lat.: At first appearance, prior to closer inspection.

<sup>186</sup> Autonomy, *nomos*, gr.: 'law', an individual gives herself her own law. Sometimes also written as 'respect for persons'. Upto the 17<sup>th</sup> century mostly used politically; the right for a state to pursue its own business. Cf. Gillon (2003), op.cit., for whom the principle of respect for autonomy is "first among equals", because it is a necessary component of aspects of the other three principles.

Populations, however, are usually not homogenous, variation has to be acknowledged. We have to accept that there are other communities of meaning, as e.g. the positions taken by the anthroposophist movement towards childhood vaccinations (I). Enforced public health interventions are often ill-advised and may even be contra-productive. Sufficient vaccination coverage is ultimately dependent on trust for and acceptance of what authorities recommend.

Respect for autonomy is, however, not simply an individual issue. The impact of individual choices and actions on others are for example especially visible in how HSV-2 infection may have consequences for partners and offspring – some of them serious and even lethal (III).

The autonomy principle becomes of special interest when public health actions are designed to limit the threat of infectious diseases, like contact tracing of sexually transmitted infections and vaccination programmes (III, I). If coercion is not an issue, respect for autonomy means enabling individuals to comprehend and appreciate risks and benefits, which could be a formidable task. Intuitively, even for many health professionals, screening is deemed valuable and much lobbying takes place without insight into how the often unacceptably low predictive values work (II).

Based on facts supplied by the health care staff, individuals have to consent (or not to consent) to vaccination and screening. The ideal is that they should base their choice on relevant facts available and be so situated to be able to exercise free power of choice (informed consent). Scientific validity is not, on the other hand, so easy to understand.<sup>187</sup> The capacity to comprehend varies between individuals, which also goes for professional persons. Informed consent becomes very much a matter of communication but communication is more than just transmitting information.<sup>188</sup> It is not farfetched to contend that complicated epidemiological issues such as herd immunity and predictive values in reality render many adults unable to make an informed judgment.

The way out of this epistemic quandary is not to regulate or prohibit but to influence the preferences and desires of all its citizens in an open, transparent, respectful and credible process and thereby also protect citizens from undue commercial influences.

### **Beneficence and non-maleficence**

Beneficence as an obligation in health care is an ancient idea.<sup>189</sup> The principle of beneficence states the ethical obligation to maximise possible benefits and to minimise possible harms. This means that all men have a moral obligation not to harm anybody, to prevent suffering, to remove suffering and, if practically possible, to promote wellbeing. To harm can only be justified when the aim is to make a greater good – first and foremost for the one being exposed to any risks.

Beneficence proscribes the deliberate infliction of harm on persons; this aspect of beneficence is sometimes expressed as a separate principle, non-maleficence; sometimes the two of them

<sup>187</sup> See e.g. Chapple A, Ziebland S, Hewitson P, McPherson A. Why men in the United Kingdom still want the prostate specific antigen test. *Qual Health Res* 2008; 18 (1): 56-64.

<sup>188</sup> Information is always interpreted and evaluated from a particular perspective in a specific context. "That information can be neutral is thus a myth." (Sachs (2002), op.cit.).

<sup>189</sup> The idea is usually referred back to texts related to Hippocrates [ca.460 – ca. 370 BC] and his school. "The physician must be able to tell the antecedents, know the present, and foretell the future - must mediate these things, and have two special objects in view with regard to disease, namely, to do good or to do no harm" (The Hippocratic Corpus. Of the epidemics. Book 1, Section 2. Second constitution: 5. Translated by Francis Adams. <http://classics.mit.edu/Hippocrates/epidemics.html>). Utilitarianism is systematically arranged on the principle of beneficence.

are collected under the umbrella of the caring principle. The classic utilitarian principle of utility determines the overall balance of obligations as an absolute and preeminent principle. Beauchamp and Childress consider the utility principle as one among the *prima facie* principles and limited by the balancing of benefits and harms to produce the best overall results.<sup>190</sup> Beneficence said to provide a rationale for health care and public health is thus basically utilitarian, often giving interventions a paternalistic overtone.

Vaccination and contact tracing programmes sometimes intentionally override known preferences or actions by subjects, when the interventions are justified by the goal of benefiting or avoiding harm to the society. An act of government paternalism may thus override the value of a citizen's autonomous choice on grounds of utility. To choose a paternalistic public health intervention would certainly depend on a delicate balancing of harms, benefits and autonomy. In the end it is a political question who should be the agent deciding upon this trade off between individual and public health interests. In Sweden the National Board for Health and Welfare decides on the risk management strategy concerning vaccination programme issues. The available information texts implicitly evoke the logic of utilitarianism in a broad sense.<sup>191</sup>

Different stakeholders take different views about what constitutes a benefit and harm. Public health professionals' understanding of benefits and harms of a screening programme is often not congruent with the view of clinicians and those working in direct contact with patients. The latter's understanding of a benefit depends on consideration for their patients and the possibility of instigating treatment on the basis of a diagnosis. Predictive values are easily overlooked, when screening instruments are introduced without proper consideration for the whole epidemiological picture (II, IV).

The caring principle carries an inbuilt contradiction; beneficence and non-maleficence are usually not two sides of the same coin. There is a risk that the ethical analysis gets too simplified if this state of things is not acknowledged. The fourfold table used for an in-depth analysis of what happens in a population screened for prostate cancer with PSA illustrates how the target group disperses into four categories with a need for balancing values within and between these categories (II: table 1 and 2).

## Justice

The justice principle obliges us to pursue fairness in the right to preventive health care and refers to the ethical obligation to treat each person in accordance with what is ethically right and to give each person what is due to her or him. A single conception of justice which supports existing public health policies does not exist and no concept of justice is independent of other principles such as beneficence or non-maleficence. Terms like fairness, desert and entitlement have been used to explicate justice.<sup>192</sup>

'Distributive justice' requires equitable distribution of benefits and burdens such as the just allocation of society's limited resources for public health. Differences are justifiable only if

<sup>190</sup> David Ross [1877-1971] makes a distinction between *prima facie* and *actual* obligations. A *prima facie* obligation must be fulfilled unless it conflicts on a particular occasion with an equal or stronger obligation (Ross WD. *The right and the good*. Oxford: Clarendon Press, 1930: 19-36). Every *prima facie* duty has exceptions. *Prima facie* duties guide us to choose our *actual* duty. See also Beauchamp & Childress (2001), op.cit.: 14-5. When *prima facie* obligations conflict with one another, the weightiest is your *actual* obligation.

<sup>191</sup> Socialstyrelsen. Vaccination av barn SOSFS 1996:1 (M) Allmänna råd från Socialstyrelsen. <http://www.sos.se> 2003-01-09. [Immunisation of children. General advice from the Swedish Board of Health].

<sup>192</sup> 'Fairness' (John Rawls [1921-2002]), 'desert' (Alasdair MacIntyre [1929-]), 'entitlement' (Robert Nozick [1938-2002]).

they are based on ethically relevant distinctions between individuals, e.g. vulnerability.<sup>193</sup> Equality and solidarity are other aspects of justice often focused upon.

Today utilitarianism appears to be the dominant view of justice in public health policy.<sup>194</sup> Utilitarian allocations aim at maximising an outcome over the population and as thus should seem very adequate for public health actions. In reality this approach seems to favour policies that will allocate resources to immediate needs over future needs, which often postpones preventive actions. Hence arguments for just allocations to public health actions of preventive character above all need good quality evidence to be heard and acknowledged in priority discussions. For public health policies and actions to be just, the descriptions of the situations they aim to address should be accurate. The justifications must reflect what reasonable people would find right.<sup>195</sup> Lay-persons can only fully accept the choices that representatives have made for them if they understand the courses of action, recognise the underlying values and accept them. It is difficult, however, to achieve justice in public health policy, because justice is not one simple formula or an ideal homogenous principle.

In a vaccination programme, where the goal is eradication of measles by sufficient herd immunity, the staffs have to resort to an appeal for solidarity in the dialogue with parents (I). Sufficient herd immunity benefits both vaccinated, unvaccinated children and the society at large. To be vaccinated against measles seems to be a fair burden to carry for the public good in a just society.

Screening for prostate cancer is sometimes discussed as a question of equality<sup>196</sup> among sexes: since women are screened for breast cancer, men should be entitled to screening for prostate cancer (II). The concept of simple equality, here meaning that everyone is entitled to certain services, has undoubtedly rhetorical power in the applied context. Using equality as an argument without proper rendering of the evidence base is, however, not tenable and highly unethical. The uncertainty of outcome still makes it neither just nor unjust whether a man is screened for prostate cancer with PSA or not.

From a societal point of view it cannot be considered just to set aside resources for PSA-screening. Priority setting and rationing is also a requirement of justice; a population screening like this would most probably require resources needed for more direct and immediate needs of health care.

There are no justice costs for individuals if they, in a proper context like a clinic for sexually transmitted diseases, are offered a screening procedure and are informed in a way that respects the individual variation in understanding and preparedness to internalize and act on the information (III). Within a high risk population appeals to solidarity as a requirement for diminishing the transmission and thereby the suffering would be a possible strategy. The partners have to carry an unjust burden of the disease, if infected, but also – like the index

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<sup>193</sup> This is ‘the difference principle’, which applies to the main public principles and policies that regulate social and economical inequalities but not specifically health (Rawls J. *A theory of justice*. Revised edition. Oxford: Oxford University Press, 1999). Norman Daniels has pursued the implications of Rawl’s theory of justice for health policy (Daniels N. *Equity and population health: toward a broader bioethics agenda*. *Hastings Cent Rep* 2006; 36(4): 22-35).

<sup>194</sup> E.g. policies that rely upon quality adjusted life years (QUALYs) and disability adjusted life years (DALYs).

<sup>195</sup> “For .. public health policies to be just, the description of the situations they aim to address must be accurate and the reasons behind them must be the ones that reasonable people would find most compelling and most appropriate.” (Rhodes R. *Justice in medicine and public health*. *Camb Q Healthc Ethics* 2005; 14: 13-26).

<sup>196</sup> The term equality implies similarity but not ‘sameness’; to say that human beings are equal is not to say that they are identical.

case - if they are falsely labelled as having the disease. The predicament of false-positives and false-negatives is unavoidable, when people are classified as in the screening procedures in II, III and IV. To neglect this fact violates all of the four principles.

Screening Swedish pregnant mothers for HPV-2 for the benefit of their unborn children does not seem to merit priority and does not fit into the justice as solidarity category. The risk for a newborn child to get herpes infection is extremely small, especially in the fairly low-prevalence Swedish population of today (III).

### *Cases and principles as a base for reflections and discussions*

A moral discourse cannot stand independently of a value base; we are all carrying metaphysical luggage, which partly defines what we consider good or bad.<sup>197</sup> My own value base commits me to what might be called dialectic ethics, beginning with a description of a case or a problem, its knowledge base and ethical quandary. The choice of principles and a stakeholder model then give ethical meaning to the otherwise factual circumstances.<sup>198</sup>

A universal ethic cannot be taken for granted in today's world, neither on the theoretical nor on the practical level. A medical ethic for a pluralistic society should probably begin by being rather 'thin'<sup>199</sup>, if one wants to find a common denominator between different ethical views that encompass more particular conceptions of human nature and what constitutes a good life and a good society. The cluster of principles in the four cases (I-IV) are chosen because they are codified in laws and norms situated in contemporary Swedish society, but they are admittedly 'thin' or general, and as such they can only serve as a basis for reflection, not as a decision model. As ethical reasoning progresses towards a justification of actions there should be room for compromise, negotiations and appeals to virtues, analogies and various 'thick' descriptions. Considered judgements for actions thus rely on knowledge of particular facts and appreciation of cultural diversity. Reductive ethic is just as dangerous as reductive knowledge, because neither respects the qualitative distinctions in the richness of human existence. Life is always an untidy affair; reduction and strict modelling can only have their place in laboratories. Having the virtue of prudence means having options to decide how

<sup>197</sup> Cf. Beauchamp & Childress (2001), op.cit., on common morality with which they mean that all morally serious humans have a pre-theoretical awareness of certain norms. "... the set of norms that all morally serious persons share ...". Tom Beauchamp makes a distinction between the universal common morality and non-universal particular moralities (Beauchamp TL. A defense of the common morality. *Kennedy Inst Ethics J* 2003; 13(3): 259-74). Here I do not fully agree. All norms are created and recreated in the society and determined by up-bringing, schooling, religious denominations etc. Human understanding is embedded in historical and social contexts. See also Hermerén (2006), op.cit. Cf. Sigurdson (2001), op.cit.: 103-6, on Hans-Georg Gadamer [1900-2002] and how to apply Aristotle's *phronēsis* in our time. In ethics it means continuous negotiations between concrete cases and the general principles we have gained by ourselves or from others.

<sup>198</sup> Cf. Beauchamp's & Childress' (2001), op.cit.: chapter 9, integrated model: moral justification proceeds from an expansive coherentist framework of norms that originate at all levels of moral reasoning, be it comprehensive theories, principles, rules or case judgments. "These norms can emerge from institutions, individuals, and cultures, and no norm is immune to revision." Their notion of a 'common morality' is that it is a pre-theoretic moral point of view that transcends local customs and attitudes and is needed for the justification of moral actions.

<sup>199</sup> 'Thin' is here borrowed from social anthropology, indicating that the ensuing discussions by stakeholders have to search for meaning and shared webs of significance but also understand that as adherents they will and can continuously enrich meaning in their structuring practice (Geertz C: *Thick Description. Toward an Interpretive Theory of Culture*. In Geertz C (ed). *The Interpretation of Cultures*. New York: Basic Books, 1973). He originally borrowed the concepts 'thin' and 'thick' from the philosopher Gilbert Ryle [1900-76]. Rawls (1999), op.cit.: 384, mentions "thin theory" as something restricted to bare essentials. The political philosopher Michael Walzer [1935-] is a proponent of 'thin ethics' in multicultural societies (Sigurdson (2001), op.cit.). Our fourfold tables with positive and negative predictive values of screening procedures could perhaps be seen as bare essentials.

certain principles mirroring societal norms should be applied in a specific case. As such it is learnt in a social context and dependent of tradition.<sup>200</sup>

There certainly exist different ways of beginning and structuring a dialogue; for the four cases here a weighing of the principles, autonomy, beneficence, non-maleficence and justice against the interests of stakeholders was deemed appropriate. This has proved to be fruitful for applied research and practice, but might not be the best way to proceed for more global ethical questions, when e.g. ethics of stem-cell research and the like are on the agenda.<sup>201</sup>

The four studies/cases are public health-oriented, situated in a Swedish context and could as such be something for the branch of ethical reasoning called casuistry.<sup>202</sup> Casuistry is a traditional method with pedigree from middle ages of interpreting and resolving moral problems. It focuses on the circumstances of particular cases rather than on the direct application of ethical theories. Circumstances here apparently means an analysis of what is the scientific evidence - in its broadest sense - for or against an intervention.

The model used in studies I-IV for identification and analysis of the ethical conflicts in the exemplified public health interventions is certainly not the only existing one. It serves as a matrix (figure 1) for reflections on issues within their actual social context and with the aim of reaching agreement as how to proceed. The deliberations we have made were guided by the principles, chosen to give significance to the ethical contexts and their particularity, so as not to leave out the individual aspects.<sup>203</sup>

	<b>Ethical principles</b>			
<b>Stakeholders</b>	Autonomy	Beneficence	Non-maleficence	Justice
.....				

**Figure 1.** A two-dimensional model for ethical deliberation.

The suggested model should only be seen as an instrument to identify and analyse the multiplicity of ethical problems. As said before, it is not a decision model. The application of the model to a problematic situation requires, besides the fact of the case, an identification of stakeholders involved, a formulation of relevant ethical principles, an assessment of ethical benefits and costs and then finally a weighing of these benefits and costs. A specification like this offers the possibility for a discussion to take place in a structured and orderly manner.

The circumstances may suggest modifications of the principles that specify them into what Jonsen and Toulmin termed 'maxims'. They realised that when the principles function within cases and are shaped and fitted to the topics of a case, they may take the form of specified norms or maxims.<sup>204</sup> This phenomenon will also occur in public health ethics even if one here

<sup>200</sup> See MacIntyre (1985), op.cit, especially chapter 19: "... normative concepts, maxims ... - are nowhere to be found except as embodied in the historical lives of particular social groups..".

<sup>201</sup> See Hermerén (2006) op.cit. Intercultural differences mean that values differ and principles do often not have the same meaning over national boundaries.

<sup>202</sup> Casuists do not say too much about the nature or definition of a 'case' (Jonsen AR. Strong on specification. *J Med Philos* 2000; 25: 348-60). I here consider a specific public health intervention as a 'case'.

<sup>203</sup> See Nilstun T. *Forskningsetik i vård och medicin. [Research ethics in care and medicine]*. 2<sup>nd</sup> ed. Lund: Studentlitteratur, 1994. Francoeur RT. *Biomedical ethics. A guide to decision making*. Canada: John Wiley & Sons Inc, 1983. Cf. Hermerén G. Screening for prostate cancer – ethical aspects. *Int J Cancer* 1996; Suppl 9: 66-8.

<sup>204</sup> An example of a maxim would be: When x is diagnosed with a leukemia and a treatment offers a significant chance of prolonging life, treat him except when the risks and adverse effects are felt to be so burdensome as to outweigh the benefit of prolonged life. (Jonsen AR, Tuolmin S. *The abuse of casuistry*. Berkeley VA: University of California Press, 1988). This maxim can be seen as a specified form of the more general principle of beneficence.

is operating at a group level. There is a relation between circumstances, principles and theory in the decision-making. Some of us will want to call attention to the details of the case, others do not want to get too far away from the background of theory. Some will call similar cases to witness. In the end shared deliberation and mutual agreement should be prominent parts of decisions on how to proceed, irrespective of our various placements along the deductive – inductive continuum.<sup>205</sup> In our four cases the deliberations are hypothetical; we have tried to represent the interests of the various stakeholders by listing them in the left hand column of the matrix (figure 1). The ideal would of course have been to start with descriptive ethics. What do people and the stakeholders really think about the issue at hand? The public interest is often defined by the perception of public and legislative agencies, and it is not always obvious which groups among the public are thereby represented.

What could be the appropriate structure in which such deliberations might take place? It requires the management of complexity in a public space configured by state, market, media, patient groups, citizens etc. in different configurations creating an inclusive process. Measles vaccination and screening for prostate cancer have very much been media issues (I, II). Screening for HSV-2, like EPDS, has been more of an internal professional affair (III, IV). Evidently there are many possibilities for where to discuss and deliberate.<sup>206</sup> Even a more confined issue like screening for HSV-2 in a specialised clinic (III) gets of general interest when there e.g. is a need for prioritization and resources are restricted.

Decisions in public health will almost always be of the surrogate character; for everyone to have a say is not feasible. This makes enforcing bad. In the end everyone should have the right to vote by the feet (I). It is surely proper to argue that a thoroughly ethical position require the communication of the evidence-base to the public. It is also important to think twice of what are meant by a stakeholder in this particular context - the imaginary professionals, lay-persons and users, patients, citizens, in short people we take to be part of the society to whom we all belong. Like all interventions a public health action should be carefully evaluated for its dimensions on who will benefit, how many are likely to be harmed and whether they belong to groups in society who cannot make their voices so easily heard.<sup>207</sup>

Side-effects are usually only talked about in pharmacological contexts; when pharmaceuticals are introduced, we all agree that several requirements have to be satisfied. They have to be tested both in the laboratory and in real life to determine efficacy, side-effects and efficiency. For stated zero side-effects in efficacy studies a confidence interval could be calculated, which admittedly is not very often done. A pharmaceutical agent has the responsibility to document both effects and side-effects. Due to the side-effects usually not being so common, post-marketing surveillance has to be made to evaluate the effectiveness, i.e. performance in routine health care.<sup>208</sup> Side-effects have been an important issue for measles vaccination

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<sup>205</sup> Richardson, as a philosopher philosophically attracted to principlism, has suggested that specification or specified principlism, could remedy the defects of principlism and casuistry alike. His critique of casuistry is that there is a risk for undisciplined intuitionism. Specification starts from a recognition of how norms can be revised; “the initial norms are in some way brought to bear on concrete cases by means of more specific norms” (Richardson HS. Specifying norms as a way to resolve concrete ethical problems. *Philos Public Aff* 1990; 19(4): 279-310). Beauchamp & Childress (2001), op.cit.: 397, put forward an integrated model, that they label ‘coherence theory’: “Principles need to be made specific for cases, and case analysis needs illumination from general principles.”. See also footnote 197.

<sup>206</sup> Cf. Benkler & Nissenbaum (2006), op.cit., who point at how commons-based peer production – an emerging system in the digitally networked environment – generates new venues facilitating collaborative engagement for a wide variety of reasons and motives.

<sup>207</sup> An instructive illustration of the various groups exposed and the potential harms is showed by the right upper and left lower hand cells in the fourfold table used to calculate sensitivity and specificity in table 4.

<sup>208</sup> Cochrane (1972), op.cit.

programmes (I), but the same could not be said for the screening procedures in II, III and IV. The lack of transparency and credible evidence for the latter type of intervention becomes evident when an analogy from codified and generally accepted procedures for introducing pharmacological treatment is used (IV). Analogy is an indispensable tool in casuistry to produce discussions about concrete ethical issues.

### ***Possible ranking of values***

There are several strategies for reconciling ethical conflicts, e.g. single-principle theories, such as pure deontology and utilitarianism, balancing judgements, specification, lexical ordering and codes of conducts.<sup>209</sup> Beauchamp and Childress maintains that rational members of the society share a common morality, from which principles and rules are constructed through considered judgements, where coherence is aimed at by a process of reflective equilibrium<sup>210</sup>. Coherence will require judgements on how to balance competing principles.<sup>211</sup>

According to principlist theories, balancing should rely on adequate reasons but intuitive and subjective weightings are unavoidable, which leaves ways open for arbitrariness.<sup>212</sup> Specification or specified principlism is said to remedy this defect.<sup>213</sup> Circumstances, however, are the essence of a case and for situations where decisions and actions are immanent, the more natural entry-point is casuistic analysis. Casuistry and specified principlism can complement each other as moves in ethical reasoning. Casuistic analysis provides a method for arriving at justifiable resolutions of specific cases in which principles conflict.<sup>214</sup>

Shared values is said to form a moral identity of a particular society and as such can provide the basis when a trade off between different values has to be made. Societies, however, is usually encompassing people with various cultural backgrounds. Concepts are used to categorize activities and make distinctions. The conceptualisation is affected by norms and values shared in given cultures. Different cultures may have different values and these differences have normative consequences.<sup>215</sup> Public health interventions on a national level thus require careful discussion and informed judgement on the part of administrators, health-care practitioners, policy-makers and community representatives. Evidential clarification is an

<sup>209</sup> Veatch RM. Resolving conflicts among principles: ranking, balancing, and specifying. *Kennedy Inst Ethics J* 1995; 5(3): 199-218. Since principlism has never embraced some system of lexical ordering, it is in a poor position to deal with conflict among the principles. Veatch in the 1980s argued that existing medical codes were not philosophies but a series of unsystematic, unreflective and physician-centred traditions. Agreement must be reached among professionals, patients and society on the basic philosophical principles before any medical ethics can be established. (Veatch RM. *A theory of medical ethics*. New York: Basic Books, 1981). Cf. the belief of Beauchamp & Childress (2001), op.cit., in the existence of a common morality. Cf. Hermerén in Fleischhauer & Hermerén (2006), op.cit.: chapter 5, who discusses the need for moral criteria and the ends of medicine and the underlying reasons for arguments that there is “an essential kernel of medical goals, ..., which has remained constant over time”.

<sup>210</sup> Beauchamp & Childress (2001), op.cit.: 397-401. By referring to Rawls they write “.. justification as a reflective testing of our moral beliefs, moral principles, theoretical postulates, and other relevant moral beliefs in order to make them as coherent as possible.” Reflective equilibrium means to “match, prune and adjust considered judgements” to render them coherent with the premises of our most general commitments. The equilibrium is never stable; the matching etc. is a continuous process.

<sup>211</sup> ‘Balancing’ means deliberation and judgment about the relative weight and strength of principles, rules and rights (ibid.)

<sup>212</sup> Cf. Tomlinson: Despite Beauchamp’s and Childress’s “arguments to the contrary, balancing judgements are the product of unreasoned intuitions” (Tomlinson T. *Balancing Principles* in Beauchamp and Childress. Paper given at the Twentieth World Congress of Philosophy, Boston, 1998. (Accessed 2008-02-20 at <http://www.bu.edu/wcp/MainBioe.htm>).

<sup>213</sup> According to Richardson (1990), op.cit., will specification give greater determinacy to general moral norms by adding qualifying clauses to them that respect the intent of the original norm and also bring it closer to concrete cases.

<sup>214</sup> Jonsen (2000) op.cit., argues that specification and casuistic analysis need each other to get close to a case. A moral case is like a painting: the circumstances of the case are the foreground, the relevant maxims and principles are in the midground and ethical theory is in the background. (Jonsen’s choice of painting was *Las Meninas* from 1656 by Diego Velázquez).

<sup>215</sup> Fleischhauer & Hermerén (2006) op.cit.: 348-51.

ancillary to a good solution but it is not the solution itself. In the end one cannot jump the need for a ranking of values.<sup>216</sup> There will be values both of what is considered good evidence and good ethical practice.

Fundamental insights gained from our own personal perceptions, feelings and thoughts are likely to be of more value to us than insights gained in any other way. Here philosophy can be of help in that we can see how great thinkers say and look at reality. Philosophy is mostly about different possible ways of looking at things: its purpose is the achievement not so much of knowledge, as of understanding.<sup>217</sup> Prudence builds on experience and knowledge and is reached through relations to other persons.<sup>218</sup> In the end, we cannot get away from the importance of virtuousness, because individuals are involved in public health interventions and decisions of policy. It is individuals who make differences in framing issues, interpreting contexts and creating processes that are inclusive.

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<sup>216</sup> Cf. Hermerén, who discusses how already the various goals of public health (medical, psychological, economic) are likely to clash and how one has to clarify the underlying values and how they are ranked relatively to one another (Fleischhauer, Hermerén (2006), op.cit.). The need for clarification of values and ranking we in our model try to meet by the matrix and the weighing procedure for each specified problem (I-IV).

<sup>217</sup> See Bryan Magee [1930-] discussing the philosophy of Schopenhauer (Magee B. Confessions of a philosopher. London; Weidenfeld and Nicholson, 1997: 424). "Is reality illuminated for me if I look at it in the light of X's explanation of it?"

<sup>218</sup> An ability for moral judgment is not fostered as an individual project but cultivated among friends (Sigurdson (2001) op.cit.: 116, on Aristotle and the virtue of prudence).

## Epilogue

In this essay I am playing out an ethical standing between principles and persons within specific and concrete problems. In each of the cases my colleges and I have stated our opinion. But still I cannot end up with general recommendations and a set of decision procedures. What I would like to underscore, however, is a need for professional virtue, a respect for diversity and the need for a sustained ethical discourse.

Good evidence is fundamental for trustworthiness in public health actions. Every public health intervention also merits its own ethical analysis, which will be meaningless if that foundation is incomplete or non-existent. Three of my four cases illustrate how imperfect that foundation can be, when inspected more closely. One of them illustrate how a gap between what is known and understood by professionals and lay-persons can distort the picture and jeopardize well-founded interventions. The responsibility for the upkeep and revision of the evidence base is incumbent upon professionals within public health. How knowledge is communicated to stakeholders is the province of both professionals and policy makers. As a citizen of Sweden – especially if I am a stakeholder – I have to decide how to act based on what I can find out and what makes meaning in my life and context. All the way through this process, questions of values abound.

One of my initial questions was whether we need a special public health ethics. My answer to that is now as before, no; no, we do not need *special* ethics for public health, but we certainly need ethics. The conflict between rights of the individual and the responsibilities of society for all its members is central in public health interventions. It is universal and unavoidable. Values vary with time, place and persons and, usually, several moral obligations are possible. Deliberations should end at a minimal set of shared values, which could guide action. Sometimes particular circumstances render values irreconcilable, making it essential for any just society that there is room for critical reflection on values and their consequences before interventions are made or postponed.

I have used the principles autonomy, beneficence, non-maleficence and justice to identify and structure the ethical problems of four specified public health interventions. My assumption is that the values reflected upon in my discussions of the vaccination and screening procedures are accepted in the Swedish context. The principles are admittedly general and sometimes ambiguous. There will always be a need for specification, if the intention is to provide practical assistance in decisions how to act. On the other hand, if one starts with specific but not too typified cases, as I have done here, it avoids mechanisation of the ethical analysis and too much reliance on theoretical reasoning.

History can serve as a mirror for reflection and further enrich ethical deliberations. The road to present-day understanding of what public health interventions are intended for was paved by good intentions, not seldom, however, the outcome has been disastrous. Individuals easily become anonymous constituents of a population. Respect for autonomy thus ought to be an important part in deliberations before public health interventions.

Principlism with its liberal, individualistic outlook is relatively simple in its application and thus an attractive model for decision making, but is not enough. We need to reach beyond disciplinary boundaries to understand the embedded quality of public health interventions and make them credible and sustainable. Knowledge of moral traditions, theories, and arguments

is needed for understanding the tension between individual freedom and considerations for the public good that is part of the modern welfare state. The world and its ethical problems are too complicated for mechanical reasoning. The reality cannot be explained by just one person. Moral knowledge is better understood and explained in dialogues where views and opinions confront one another.

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## English Summary

Two types of public health interventions, programmatic vaccination and screening – both actions with intentions to prevent ill health in populations – are the reasons for this thesis. The practice of public health incorporating medicine's cognitive contents along with contributions from other fields of human activities is basically a moral enterprise. It is important that limitations from the whole continuum of these interventions are recognized to retain credibility. The changing demands resulting from the dynamics of global altering societies, as well as new priorities due to medico-technical developments, must also be acknowledged.

An epistemic expansion of the evidence-base for public health actions is argued for. 'Nomothetic' and 'idiographic' are suggested as more neutral concepts instead of 'quantitative' and 'qualitative' for characterizing the methodological approach. Assumptions about the nature of medical knowledge have from the beginning had an explicit preference for empirical evidence. Natural science is often taken as congruent with medical science, a thought style challenged in the history of public health and from outside the discipline. An integration of nomothetic and idiographic kinds of knowledge, i.e. a true research synthesis, is relevant as evidence-base for public health actions and also needed for a valid ethical analysis in context.

In each of the presented four cases, the measles vaccination programme, a hypothetical mass screening for prostate cancer with prostate-specific antigen, a hypothetical risk group screening for Herpes virus type 2 and screening for postpartum depression, the evidence-base is discussed in its Swedish context and with a critical eye to the assumed validity of underlying assumptions. The role of history, collaboration over disciplinary boundaries and virtues, especially prudence, is highlighted as important for attaining a critical distance to what is described as facts. The casuistic approach is necessary to visualize the complexity and the inherent and sometimes hidden ethical problems of the specific interventions. The principles autonomy, beneficence, non-maleficence, justice and the choice of affected persons then give ethical meaning to the otherwise factual circumstances.

The suggested framework for analysis does not involve a general theory of values but is enacted in the middle ground between theories and the details of policy and practice. It is one of many possible ways to structure ethical deliberations. The casuistic approach begins with a description of the evidence-base and context; it then proceeds with ethical deliberations using principles chosen to mirror values codified in Swedish law and statutes. Each principle is problematized for the identified stakeholder groups in a two-dimensional matrix, assessing the ethical benefits and costs. Finally, these benefits and costs are weighted for their possible impact in a proposed action.

The conclusions thus arrived at are that measles vaccination must remain voluntary to vouchsafe autonomy and credibility; that screening for prostate cancer and Herpes virus type 2 with available tests come with non-acceptable side-effects especially invoking the principles of beneficence, non-maleficence and justice as solidarity. The EPDS screening for postpartum depression at Swedish Child Health Clinics is questionable. The ethical reservations mainly concern the principles of autonomy and beneficence but also how professional knowledge is inundated by values unwittingly having an impact on a weak evidence-base. An analogy approach is used as a complement to illustrate how demands differ, when new methods or technologies are introduced in health care.

The encounter between individuals and society brought forward by public health interventions is morally complex. There is no ready-to-use system of ethics for public health. A universal ethic cannot be taken for granted in today's world, neither on the theoretical nor on the practical level. Instead we have to recourse to dialectic ethics, i.e. a continuous and publicly open dialogue of what we do, what we ought to do and why.

## **Deutsche Zusammenfassung**

Ausgangslage dieser Habilitationsschrift sind zwei Arten von Interventionen im Bereich der Öffentlichen Gesundheit, nämlich Impfungen nach einem festgelegten Impfkalender und Reihenuntersuchungen bei definierten Bevölkerungsgruppen - beides Maßnahmen um Individuen vor möglicherweise gravierenden Krankheiten zu schützen. Diese Praxis der Öffentlichen Gesundheit, die sich auf Erkenntnissen der medizinischen Wissenschaft und anderen Gebieten menschlicher Aktivitäten basiert, ist im Grunde ein moralisches Unterfangen. Es ist wichtig, die Grenzen der Interventionen im Bereich der Öffentlichen Gesundheit zu bestimmen, um die Glaubwürdigkeit von Präventivmaßnahmen nicht aufs Spiel zu setzen. Die Herausforderungen, die aus dem globalen dynamischen Wandel unserer Gesellschaft resultieren, sowie die Festsetzung neuer Prioritäten aufgrund medizinisch-technischer Fortschritte, müssen ebenfalls in eine kritische Beurteilung von Interventionsmaßnahmen einbezogen werden.

In dieser Schrift werden Argumente vorgebracht, die eine Erweiterung von Evidenz-basiertem Wissen stützen. ‚Nomothetisch‘ und ‚idiographisch‘ werden als mehr neutrale begriffliche Konzepte vorgeschlagen anstelle der Termini ‚quantitativ‘ und ‚qualitativ‘, um den gewählten methodologischen Ansatz zu charakterisieren. Annahmen über die Natur von medizinischem Wissen hatten von Beginn an eine eindeutige Präferenz für empirisch gewonnene Daten. Unter wissenschaftstheoretischen Gesichtspunkten werden die Naturwissenschaften häufig als deckungsgleich mit der Medizin betrachtet, ein Denkansatz, der bereits früher in der Öffentlichen Gesundheit selbst, aber auch von außerhalb in Frage gestellt wurde. Eine Integration nomothetisches und idiographisches Wissen, das heißt, eine wirkliche wissenschaftliche Synthese, ist die Voraussetzung, um die Evidenz von Maßnahmen in der Öffentlichen Gesundheit zu beurteilen und wird auch für eine kontextuelle, valide ethische Analyse von Präventivmaßnahmen benötigt.

An Hand von vier paradigmatischen Beispielen - dem Impfprogramm gegen Masern, einer hypothetischen Massenuntersuchung auf Prostatakrebs mit Hilfe des Prostata-spezifischen Antigens, einem hypothetischen Risikogruppenscreening für Herpes-Simplex-Virus Typ 2 und ein Screening für post-partum Depressionen - wird die Evidenzbasis für die Verhältnisse in Schweden diskutiert; mit kritischem Augenmerk in Bezug auf die Validität der zu Grunde liegenden Annahmen. Die Bedeutung historischer Faktoren für die Implementierung dieser Interventionsmaßnahmen, die Zusammenarbeit von Wissenschaftlern aus dem Bereich der Öffentlichen Gesundheit mit anderen Fachdisziplinen und weitere Merkmale, besonders Umsichtigkeit [?] bei der Umsetzung von Maßnahmen, werden analysiert, um eine kritische Distanz zu Aussagen herzustellen, die typischerweise als Fakten dargestellt werden. Ein solcher Fall-spezifischer Ansatz ist notwendig, um die Komplexität und die inhärenten - manchmal verborgenen - ethischen Probleme von spezifischen Interventionen offen zulegen. Die Prinzipien der Selbstbestimmung, des Nutzens, des Nicht-Schaden-Anrichtens, der Gerechtigkeit und der Wahlfreiheit der von Interventionsmaßnahmen betroffenen Personen geben dann den realen Gegebenheiten eine ethische Relevanz.

Der vorgeschlagene Analysenrahmen beinhaltet keine generelle Wertetheorie, aber ist in der Mitte zwischen Theorie einerseits und praxisorientierter Gesundheitspolitik und deren Umsetzung andererseits verankert. Es ist einer von zahlreichen möglichen Wegen, um ethische Überlegungen zu strukturieren. Der Fallansatz beginnt mit einer Beschreibung der jeweiligen Evidenzbasis und ihres Kontextes; im nächsten Schritt werden ethische Überlegungen unter Zuhilfenahme von Beispielen analysiert, die mit schwedischen Gesetzen und Verordnungen verknüpft sind. In jedem Fallbeispiel wird eine zweidimensionale Matrix genutzt, in der die ethischen Prinzipien die betroffenen Menschen gegenübergestellt werden. Schließlich werden die ethischen Kosten der betreffenden Interventionsmaßnahme bewertet.

Diese Untersuchung kommt zu folgenden Schlussfolgerungen: 1) Die Masernimpfung muss ein freiwilliges Unterfangen bleiben, um Wahlfreiheit der betroffenen Individuen und Glaubwürdigkeit der Präventivmaßnahme nicht in Frage zu stellen. 2) Screening-Maßnahmen für Prostatakrebs und Herpes-Simplex-Virus Typ 2, mit Hilfe der derzeit verfügbaren Testverfahren, sind mit inakzeptablen Nebenwirkungen belastet, wenn man die Prinzipien Benefiziens, Non-Malefiziens, Gerechtigkeit und Solidarität zu Grunde legt. 3) Das Screeningverfahren für post-partum Depressionen, wie es derzeit in schwedischen Kinderpflegezentralen [Barnavårdscentraler] durchgeführt wird, ist fragwürdig. Hier betreffen die ethischen Bedenken im wesentlichen die Prinzipien Autonomie und Benefiziens, aber auch die Tatsache, dass professionelles Wissen unabsichtlich mit Werten überflutet wird, was wiederum einen Effekt auf die geringe Evidenzbasis hat. In einem analogen Ansatz wurde gezeigt, wie sich Nachfragen nach Interventionsmaßnahmen ändern, wenn neue Methoden oder Techniken im Gesundheitssektor eingeführt werden.

Das Zusammentreffen zwischen Individuen und Gesellschaft, das durch Maßnahmen der öffentlichen Gesundheit bewirkt wird, ist moralisch komplex. Es gibt kein einfaches ethisches System für Maßnahmen der Öffentlichen Gesundheit. Und es ist auch nicht anzunehmen, dass in der heutigen Welt eine universelle Ethik vorhanden ist, weder auf theoretischem, noch auf praktischem Niveau. Wir müssen dialektische Ethik zu Hilfe nehmen, das heißt, in aller Öffentlichkeit einen kontinuierlich und freien Dialog durchführen, über das was wir tun, was wir tun sollen und warum.

## **Svensk sammanfattning**

Utgångspunkten för denna avhandling är två slags folkhälsointerventioner, allmänna vaccinationsprogram och screening, båda insatser för att förebygga sjukdom i befolkningen. I grunden är disciplinen folkhälsa med sina speciella aktiviteter, som också innefattar medicinens kunskapsinnehåll och bidrag från andra vetenskapsområden, ett moraliskt företag. Det är viktigt att man erkänner insatsernas begränsningar i alla skeden för att man skall behålla trovärdigheten i vad som görs. Ändrade krav, orsakade av en föränderlig och globaliserad omvärld, liksom nya prioriteringar på grund av den medicinsk-tekniska utvecklingen måste också tas med i beräkningen.

Evidensgrunden för folkhälsoaktiviteter måste vara bred och innefatta såväl nomotetisk som ideografisk kunskap. Begreppen nomotetisk och ideografisk förordas i stället för de vanligare kvantitativ och kvalitativ, som en möjlighet att undvika de inte alltför ovanliga motsättningarna mellan kunskapsfälten. Antaganden om den medicinska kunskapens natur har från början baserats på ett empiriskt synsätt. Naturvetenskap ses ofta som likvärdigt med medicinsk vetenskap, ett tankesätt som problematiseras med exempel från folkhälsans historia. En integration av nomotetisk och ideografisk kunskap – dvs. en sann

forskningssyntes – är relevant som evidensbas för folkhälsoinsatser och också nödvändig för en trovärdig etisk analys, som måste ta hänsyn till det aktuella sammanhanget.

I vart och ett av de fyra fallen, mässlingsvaccinationsprogrammet för barn, en hypotetisk mass-screening av prostatacancer med PSA, en hypotetisk riskgruppscreening för Herpes virus typ 2 och den införda screeningen för post partum depression med EPDS, diskuteras evidensbasen i ett svenskt sammanhang med en kritisk hållning gentemot värdet av underliggande antaganden. Genom en redogörelse av historiska exempel, behovet av samarbete över ämnesgränser och dygdetiken visas på möjligheter att få kritisk distans till vad som beskrivs som fakta.

Metodansatsen är kasuistisk och börjar med en beskrivning av den vetenskapliga evidensen samt sammanhanget för att sedan gå vidare med etisk reflektion över principer, som är valda för att de speglar värden kodifierade i svenska lagar och förordningar och rimligen anses som viktiga i det svenska samhället. De etiska vinsterna och förlusterna diskuteras sedan var för sig för de aktuella intressegrupperna för att till sist vägas samman som grund för en insats. Denna ansats visar på ett sätt av flera möjliga sätt att strukturera en dialog om etiska frågeställningar och är användbar under förutsättning att man inte betraktar modellen som för allom given. I andra sammanhang kan andra principer, andra värden och andra intressegrupper bli aktuella.

Våra slutsatser i studierna är att mässlingsvaccination för barn måste vara frivillig för att man skall behålla trovärdigheten. Screening för prostatacancer och Herpes virus typ 2 med tillgängliga test och i dagens kunskapsläge om sjukdomsförloppen ger oacceptabla biverkningar, vilket först blir riktigt påtagligt, när man synliggör de grupper, som kommer att kategoriseras fel i screeningförfarandet. Det är tveksamt att screena för post partum depression med EPDS. Här blir det tydligt hur professionell kunskap omedvetet kan påverkas av olika värderingar, som får ett relativt fritt spelrum, när evidensbasen är svag.

Mötet mellan individer och samhälle, som äger rum i folkhälsoarbete, är ofta komplicerat ur etisk synpunkt. Folkhälsoarbetet kan inte använda sig av ett färdigt etiskt system. Man kan inte räkna med en universell etik i dagens värld, varken på ett teoretiskt eller praktiskt plan. Vi får i stället ta vår tillflykt till dialektisk etik, dvs. en kontinuerlig och för alla öppen dialog om vad vi gör, vad vi bör göra och varför.

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Ingela Krantz

