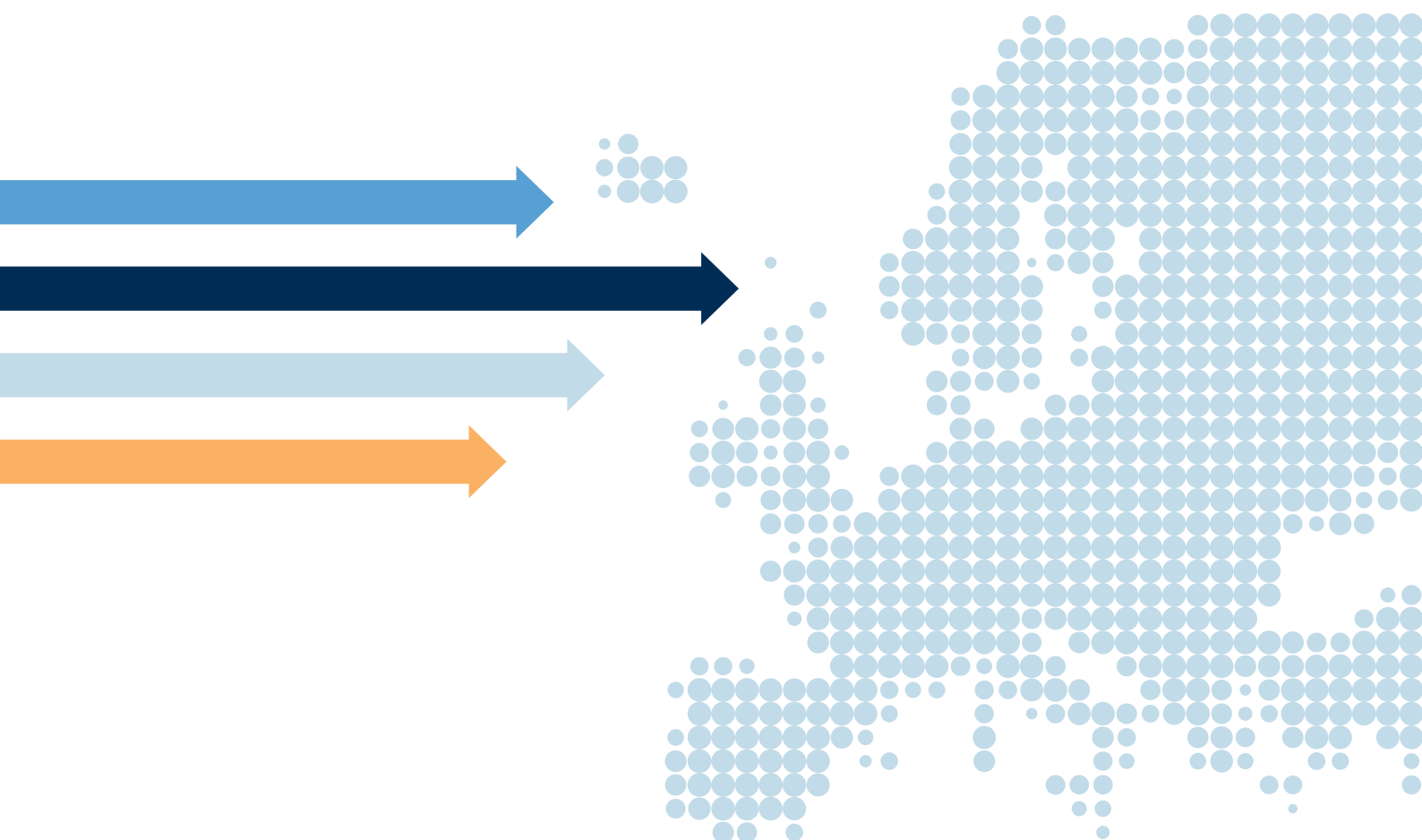


ACCESS TO HIGH-QUALITY ONCOLOGY CARE ACROSS EUROPE



Thomas Hofmarcher, IHE

Bengt Jönsson, Stockholm School of Economics

Nils Wilking, Karolinska Institutet and Skåne University Hospital

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Access to high-quality oncology care across Europe

Thomas Hofmarcher

*IHE – The Swedish Institute for Health Economics,
Lund, Sweden*

Bengt Jönsson

Stockholm School of Economics, Stockholm, Sweden

Nils Wilking

*Karolinska Institutet, Stockholm, Sweden and Skåne
University Hospital, Lund/Malmö, Sweden*

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Box 2127 | Visit: Råbygatan 2
SE-220 02 Lund | Sweden
Phone: +46 46-32 91 00
Fax: +46 46-12 16 04
E-mail: info@ihe.se
www.ihe.se
Org nr 556186-3498
Vat no SE556186349801

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Executive Summary

Cancer is one of the major diseases in Europe. It is the second most common cause of death in the European Union, after cardiovascular diseases, and 2.7 million new cancer cases are diagnosed every year. Cancer also presents an economic challenge for health care systems. The ageing of the population in conjunction with continuous technological improvements renders it difficult for health care systems to constantly provide high-quality oncology care. Additionally, the economic crisis and resulting austerity measures have further highlighted the cost of cancer and threaten the sustainability and continuous improvement of quality in oncology care. Solutions are needed to optimize oncology care and to establish a high and sustainable standard of care across Europe.

This report aims at providing a framework for the development of policies to ensure access to high-quality oncology care. A comprehensive approach has been chosen that encompasses the whole patient pathway from prevention to treatment. The barriers that prevent the provision of effective oncology care are identified and described in the report alongside the determinants of a high-quality standard in care. Special emphasis is placed on access to effective screening programs for cancer prevention as well as on access to innovative treatments in the form of new cancer drugs. The analysis is based on assessments across three common cancer types (colorectal, lung and prostate cancer) and four health systems from the following selected European countries - France, Germany, Poland and Sweden.

Six policy recommendations have been derived from the analysis. Firstly, a cost-effective allocation of resources is pivotal for a more accessible and sustainable oncology care system. For instance, in the area of screening there is room to improve patient outcomes and cost-effectiveness. By optimizing prostate cancer screening and the development of well-designed colorectal cancer screening, improved outcomes and value for patients may be achieved.

Secondly, an adequate level of resources is needed to provide effective cancer care. Lack of funding limits the availability of high-quality treatment facilities, health care professionals and medical technologies used for diagnostics and treatment. This hampers the geographic accessibility of oncology services, results in low treatment standards and patient outcomes, and might discourage patients from seeking care. Further studies on the level and direction of spending on cancer in Europe are needed for the development of a strong evidence base.

Thirdly, to continue to incentivize innovative research, the value of innovation in cancer care has to be rewarded. Inadequately designed reimbursement systems hinder patients from benefiting from innovation and threaten the development of new treatments with better outcomes. The development of new mechanisms of payment for new innovative cancer treatments should be a priority policy.

Fourthly, oncology care is an integrated process and its internal organization is critical for the timely management of cancer patients. Resource inputs, e.g. medical technology and health care professionals, have to be well-balanced, otherwise bottlenecks emerge that result in long waiting times. Clinical guidelines and multidisciplinary teams support the provision of effective cancer care.

Fifthly, complete and up-to-date data on resource use and outcomes of the current care system is fundamental to sustainability and improvement. A comprehensive system of nationwide cancer registries facilitates the monitoring of the quality of care. It also helps to plan the allocation of resources, identify over- and under-consumption, detect regional differences in access to and quality of treatment, monitor the implementation of policy measures and enables the measurement of progress in care over time.

Finally, health policies need to better recognize the importance of quality of life as an outcome measure in cancer care, due to improvements in survival and the occurrence of co-morbidities in elderly cancer patients. The potential benefits and value from high quality cancer care that improves patient quality of life, enables participation in activities of daily living, and maintains or restores work performance must be recognized and supported.

1. Introduction

1.1. Purpose and scope of the report

Rising health care expenditures and the squeeze on national health budgets are putting a heavy strain on health care systems in Europe. These developments underline the need to reform and optimize health care systems for the longer term. The challenge herein is to strike a balance between containing health care expenditures and sustaining access to and quality of health care. Cancer presents a high health-economic burden to society and oncology care forms a key area in response to this challenge [3]. The purpose of this report is therefore (1) to inform policy-makers on the value and importance of ensuring access to high-quality oncology care and (2) to provide evidence-based policy recommendations on how to optimize access to oncology care and how to achieve a high-quality standard that is both achievable and sustainable.

This report is designed to look at the full cancer patient pathway encompassing primary prevention measures, screening efforts, diagnostics and treatment with curative and palliative intent. These are the central elements determining access to high-quality oncology care and are decisive in determining patient outcomes. In order to highlight areas for quality improvement, the report identifies barriers that prevent access to effective oncology care and establishes determinants of a high-quality standard in care. The report puts a special emphasis on access to effective screening programs as well as on access to innovative treatments in the form of new cancer drugs, given the availability of good data in these areas.

For the analysis, this report focuses on three cancer types, viz. colorectal, lung and prostate cancer, and four selected European countries: France, Germany, Poland and Sweden. Alongside breast cancer, colorectal, lung and prostate cancer constitute the most common cancer types in Europe and present a high health-economic burden to society. They were chosen on this basis of and on the grounds of comparatively good availability of data.

Data availability also played a role in the selection of the four countries. France, Germany and Sweden are all characterized by a fairly similar high level of living standards. However, resources are allocated differently and care is organized in a different way across these three health care systems. Poland is the most populous country to have joined the European Union during the last decade and has developed its own health care system with implications for priority setting in the provision of care. All countries are members of the European Union and even though health policy primarily rests with member states, the European Commission plays an increasing role in the sharing and promotion of best practice in health care, including goals and recommendations in the common fight against cancer.

1.2. The EU's role in the fight against cancer

The European Commission has for a long time recognized the burden of cancer and the challenge that it poses to society. In the past, several initiatives were specifically directed towards cancer. Under the Commission's "Europe Against Cancer" programs (1987-2000), a target 15% reduction in cancer mortality in Europe by 2000 was set. Even though this aim was not quite reached, the initiative made inroads in the common fight against cancer [4]. In 2009, the Commission reinforced its efforts to support member states in the fight against cancer by setting up the European Partnership for Action Against Cancer (EPAAC). This initiative brings together the efforts of different stakeholders in a joint response to prevent and control cancer, with the goal of reducing cancer incidence by 15% by 2020 [5, 6].

Progress was also achieved at the political level. In 2003, the Council of the European Union adopted a recommendation on cancer screening for three cancer types; cervical, breast and colorectal cancer [7]. The member states were urged to implement screening programs and to ensure equal access to screening, taking due account of the possible need to target particular socio-economic groups. Since then, the European Commission has issued guidelines for screening programs for breast cancer (latest edition from 2006) [8], for cervical cancer (latest ed. from 2008) [9], and for colorectal cancer (1st ed. from 2010) [10].

In the area of primary prevention, the European Code Against Cancer was issued by the European Commission to reduce risk factors contributing to the development of cancer [11]. It sets out 11 recommendations for citizens to adopt healthier lifestyles (e.g. stop smoking, avoid obesity) and urges them to participate in the above mentioned screening programs as well as vaccination programs against hepatitis B virus infection to prevent liver cancer. In 2008 (and updated in 2012), the European Centre for Disease Prevention and Control has offered guidance to member states for the introduction of vaccinations against human papillomavirus (HPV) for girls/women to mainly prevent cervical cancer, and also considered HPV vaccination for boys/men to prevent HPV-related cancers such as anal, neck and oropharyngeal cancer [12, 13]. The prevention of lung cancer has recently been subject to a new directive on tobacco products that the European Parliament passed in October 2013 which aims at reducing smoking and keeping young adults from starting to smoke [14, 15].

In 2008, the Council of the European Union adopted a set of measures to reduce the burden of cancer [16]. Member states were, among other things, invited to develop and implement comprehensive cancer strategies or plans, to promote the European Code Against Cancer and screening, and to provide the best possible evidence-based treatment for cancer patients, within the context of national health priorities and financial resources. The Commission was, among other things, invited to promote cancer research and to continue to support the networking of cancer registries to provide data at EU level on cancer incidence, mortality, prevalence and survival. Both member states and the Commission were also invited to find ways of working with relevant stakeholders to ensure a steady stream of innovation and development of affordable treatments.

Despite these EU-led cancer initiatives, the economic crisis has led to some direct and indirect consequences for future access to high-quality oncology care. The European Commission has increasingly called for cost-effectiveness of spending in the health policy area and underlined the need for health system reform to achieve greater efficiencies. These recommendations not only form part of targets for bail-out countries, but are also a core element of some of the economic and structural country-specific recommendations (CSRs) adopted for member states [17]. At the same time, the Commission has emphasized the continued need for investment in health care in times of austerity as a contributor to growth and jobs [18]. For member states this means striking a balance between achieving greater efficiency in health spending with guaranteeing access to health care and medical treatment, as enshrined in the Charter of Fundamental Rights of the EU [19].



The prevention of lung cancer has recently been subject to a new directive on tobacco products that the European Parliament passed in October 2013 which aims at reducing smoking and keeping young adults from starting to smoke.

2. The burden of cancer in Europe

Conclusions

- **Cancer represents one of the major diseases in Europe.** In the EU in 2012, the estimated number of newly diagnosed cases of cancer was 2.7 million (1.45 million men, 1.21 million women). Some 1.3 million people died from cancer (715,000 men, 560,000 women). This makes cancer the second most common cause of death after cardiovascular diseases.
- **Age-standardized overall cancer incidence rates decreased slightly in men but increased slightly in women** during the period 2006 – 2012 in the EU. Prevention measures and screening programs might offer some explanation for this trend. **Age-standardized overall cancer mortality rates decreased, but the decrease in men was relatively stronger than in women.** Increasing screening efforts and better treatment have been put forward to explain this trend. However, for some cancer types, such as lung cancer in woman, incidence and mortality increased substantially. Incidence also increased considerably for prostate cancer.
- **The real cancer burden continues to increase.** Recent trends (2008 – 2012) in non-age-standardized rates in the EU reveal that overall cancer incidence increased in both men and women. Mortality rates increased in males and remained stable in females.
- **The demographic change in Europe is the driving factor behind the increasing trend in number of newly diagnosed patients.** Yet, as observed for age-standardized rates, the rise in cancer incidence is decoupled from the slower rise in mortality, which can be indicative of progress in the area of screening and treatment.
- **Cancer corresponds to around 16% of the total health burden of all diseases and illnesses in the EU.** In contrast to most other diseases, the mortality component comprises by far the largest share of the health burden of cancer. However, with improving survival prospects for most cancers, the morbidity component becomes increasingly important as patients live longer with the disease.
- The share of cancer-related direct costs on total health care expenditures in the four countries in this report (France, Germany, Poland and Sweden) ranges from 5% in Poland to 7.3% in Sweden. However, **purchasing power adjusted per-capita spending on cancer is more than three times higher in Sweden, Germany and France than in Poland.** Inadequate funding is one reason for poorer patient outcomes in Poland. Despite fairly similar levels of spending in France, Germany and Sweden, these countries also differ in their achieved outcomes. **This highlights the importance for health policy to set the right priorities in cancer care and that a sole focus on spending is too narrow.**
- **The share of cancer-related indirect costs on total costs is around 60% in the EU.** Overall, productivity loss due to morbidity and premature death is of the same magnitude as the total direct health care expenditures. Thus, a large part of the economic burden of cancer accrues to areas outside the direct scope of the health care system. This should not overshadow the importance of a comprehensive cancer management system. **Effective cancer care has an immediate impact on indirect costs by it preventing premature death, reducing morbidity and cutting early retirement.**
- **Lung cancer accounts for around 15% of the total direct and indirect cost of cancer in the EU, colorectal cancer for 10% and prostate cancer for 7%.** If direct costs alone are considered, both colorectal cancer and prostate cancer account for around 11% of the total direct cost for cancer and lung cancer for 8%. This reflects the high share of indirect costs of lung cancer due to the comparatively high mortality rates in lung cancer patients.

Cancer represents one of the major diseases in Europe. This chapter describes the burden that cancer entails for societies in Europe. First, incidence and mortality rates are presented and compared between countries. Recent trends are analyzed with regards to the impact of the demographic change, advances in treatment, screening programs and primary prevention measures, such as policies to reduce smoking. Second, prevalence rates are studied. Third, the

health burden of cancer is quantified and also contrasted with other diseases. Fourth, the economic burden that cancer imposes on both the health care system and society is studied. These last two sections show that the resources spent on cancer (5.0-7.3% of total health expenditures) are a far cry from the health burden of cancer (16.3% of the total health burden of all diseases and illnesses).

2.1. Incidence and mortality

In 2012, the estimated number of newly diagnosed cases of cancer¹ was 2.7 million (1.45 million men, 1.21 million women) in the EU-28 [2]. Out of the 5.0 million people that died in the EU-28 in 2012 [20], some 1.3 million people

(715,000 men, 560,000 women) died from cancer [2], and similar figures are expected for 2013 [21]. This makes cancer the second most common cause of death in the European Union, after cardiovascular diseases² [22].

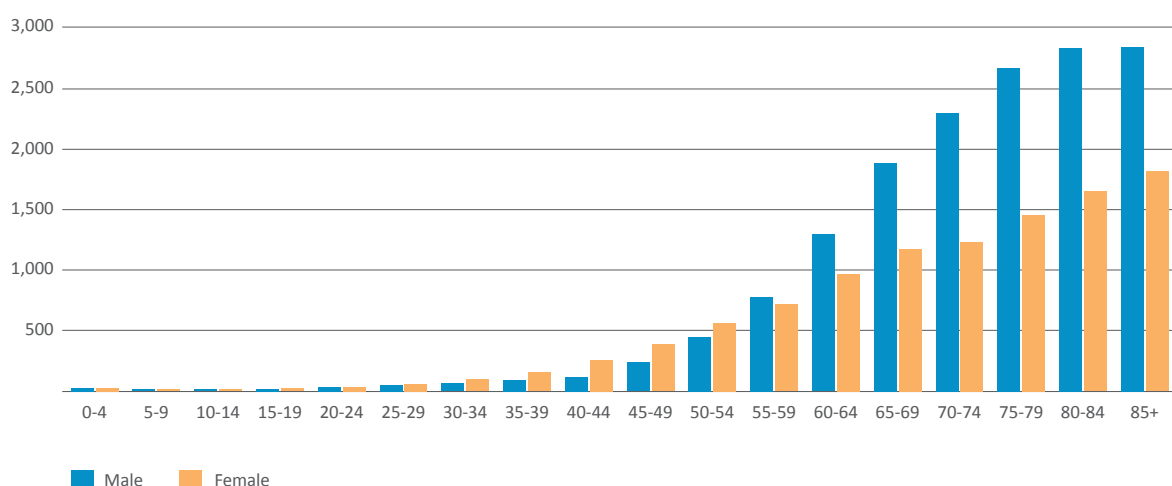


Figure 1: Cancer incidence rates per 100,000 inhabitants by age group and gender in Germany 2009-2010; ICD-10 C00-C97/C44 [23]

Cancer is a disease that troubles people in all ages, yet mainly the elderly. This can be seen in Figure 1 which shows incidence rates by age groups for all cancer types but non-melanoma skin cancer. Differences between the genders are another striking observation. From the age of 30 to 54 years, more new cancer cases are diagnosed in women than in men. In people aged 55 years and older, new cancer cases in men outnumber the female cases by far. An explanation

for this pattern offers the different average age of diagnosis of the most common cancer types in females and males. Breast cancer, the most commonly diagnosed cancer type in females, is typically diagnosed at an earlier age than prostate cancer, the most commonly diagnosed cancer type in males.

1. Cancer refers here to ICD-10 code C00-96/C44, i.e. all cancer types but non-melanoma skin cancer.
 2. Cancer refers here to malignant neoplasms (ICD-10 code C00-C97). Cardiovascular diseases refer to diseases of the circulatory system (I00-I99).

2. The burden of cancer in Europe

Age-standardized rates

Sound international comparisons of cancer incidence (i.e. the number of newly diagnosed cancer cases in a given year) and cancer mortality (i.e. the number of cancer deaths in a given year) require some data standardization. On the one hand, incidence and mortality figures have to be adjusted for total population figures (usually per 100,000 inhabitants). On the other hand, adjustments have to be made to eliminate the effect of different age structures in countries, as incidence and mortality is typically higher in countries with older populations.

Recent estimates of cancer incidence in Europe indicate that age-standardized overall incidence rates increased only slightly for women during the period 2006-2012 and show a slight decrease for men (see Table A1 in the Appendix) [2, 24]. Age-standardized overall mortality rates decreased quite significantly for both men and women during the same period, but the relative decrease for men was almost twice as large as that for women. However, the level of both incidence rates and mortality rates for women are still far below that of men. Figure 2 and 3 show incidence rates and mortality rates, respectively for colorectal, lung and prostate cancer for each country and by gender. It should be noted that taken together colorectal, lung and prostate cancer account for around half of all incidence and mortality cases in men and for around a quarter in women, respectively.

For colorectal cancer³, incidence rates and mortality rates are fairly similar across countries, although the mortality rate in men in Poland is noticeably higher (see Figure 2 and 3). The female rates are around 50 percent lower than the male rates in all countries. Regarding trends between 2006 and 2012, a sharp decrease in incidence and mortality was recorded amongst women in Germany, whereas incidence increased for women in the other countries (see Table A1). Among men with colorectal cancer both incidence and mortality has fallen markedly in Germany and France, but the incidence in Poland showed a strong increase while mortality rates in Poland remained stable.

For lung cancer⁴, the countries exhibit very different levels of incidence and mortality rates, with men in Poland having exceptionally high levels (see Figure 2 and 3). Sweden seems to be a special case. It is the only country where the incidence and mortality rates are almost equal for men and women. This might be explained by an equal gender distribution in smoking rates since the early 1990s in Sweden [25], along with the widespread use of smokeless tobacco ("snus"). Between 2006 and 2012 incidence rates among women in France almost doubled and increased also in all other countries (see Table A1), which is mainly a consequence of increased smoking in women. Lung cancer mortality among women also increased considerably in all countries, apart from Sweden. The incidence and mortality rates of men with lung cancer decreased in all countries, yet at different magnitudes.

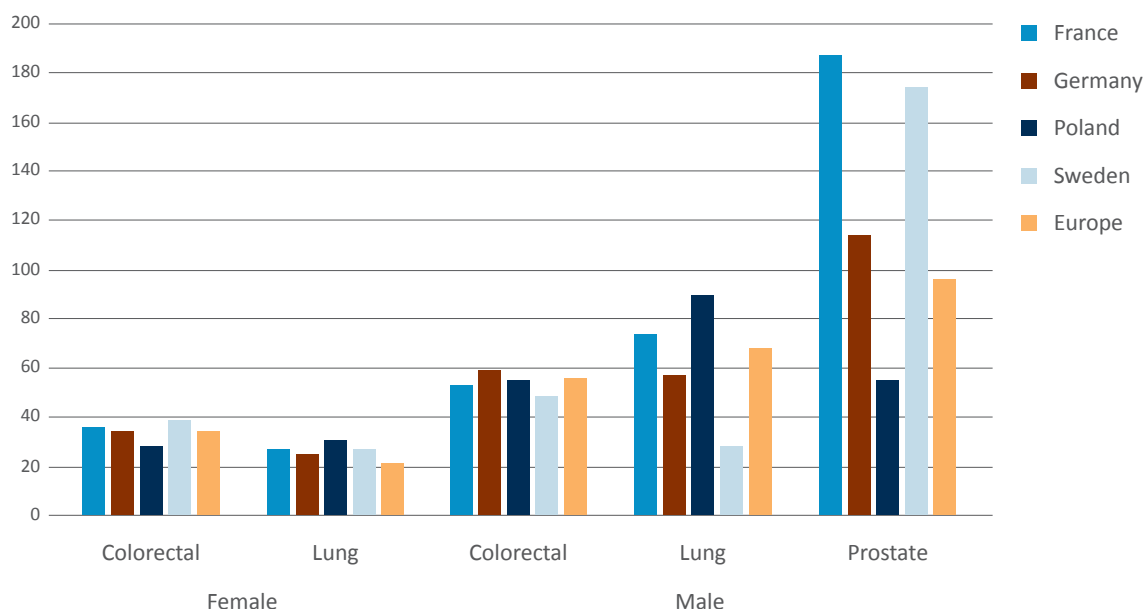


Figure 2: Estimated number of cancer incidence cases per 100,000 inhabitants (age-standardized rates), 2012 [2]

3. Colorectal cancer refers to ICD-10 code C18-21 in this report, if not otherwise stated.

4. Lung cancer refers to ICD-10 code C33-34 in this report, if not otherwise stated.

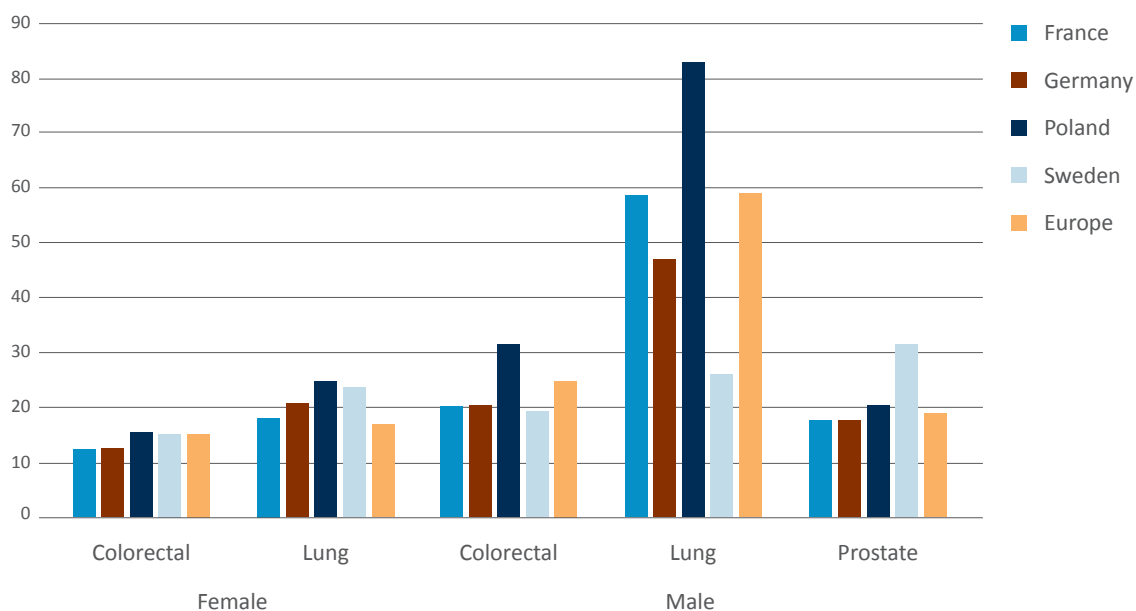


Figure 3: Estimated number of cancer mortality cases per 100,000 inhabitants (age-standardized rates), 2012 [2]

For prostate cancer⁵, a very heterogeneous picture for incidence rates emerges in the different countries (see Figure 2). The incidence rate in Poland is just a bit more than a quarter of the rates in France and Sweden. On the other hand, mortality rates are very similar across countries, except in Sweden where they are about 50 percent higher (see Figure 3). Between 2006 and 2012 incidence rates increased by 40 percent in France, which might be attributable to widespread screening, but remained constant in Germany (see Table A1). Mortality rates decreased in all countries by at least 13 percent.

To sum up, the absolute levels of incidence and mortality rates show distinct differences across countries particularly for lung and prostate cancer. Moreover, there are significant differences in the developments of incidence and mortality across countries, yet a common trend is evident for colorectal and prostate cancer with increasing or stable incidence rates and falling mortality rates. One factor that could explain this common trend is the impact of screening programs for colorectal and prostate cancer that help to detect more cases and thus raise incidence rates [26, 27]. In addition, more cancer cases are detected through screening at an early stage which facilitates curability and thus leads to improved survival and decreasing mortality rates [28]. However, this factor does not really explain the trends for lung cancer. In men with lung cancer, incidence rates have declined by a relatively lower

extent than mortality rates (except for Poland). In women with lung cancer, incidence rates have swelled by a relatively greater extent than mortality rates (except for Poland). This partly reflects changes in smoking patterns, but also advances in treatment of lung cancer cases might have contributed to improved survival. For prostate cancer, both increased screening efforts and better treatment have been put forward to explain the trends of increasing incidence and decreasing mortality rates [27].

At this point it should be emphasized that incidence rates for many cancer types are driven by the development of underlying risk factors in the general population. The effects of smoking on an increased risk for developing lung cancer are well-established [29]. It has been shown for colorectal cancer that an unhealthy diet, lack of physical activity and being overweight increase the number of cancer cases [30]. In general, it has been estimated that only 5 to 10 percent of all cancer cases can be attributed to genetic defects and the remaining 90 to 95 percent to lifestyle and environmental factors. Furthermore, around 25 to 30 percent of all cancer-related deaths are related to tobacco consumption and around 30 to 35 percent are linked to diet [31].

5. Prostate cancer refers to ICD-10 code C61 in this report, if not otherwise stated.

2. The burden of cancer in Europe

Crude rates

Crude rates are non-age standardized rates and indicate the real number of cancer patients. They are less relevant for international comparisons, but very much important for (national) policy makers. An analysis of trends in crude rates of incidence and mortality can be done both for all cancer types together and for specific cancer types. Such an analysis is vital to enable an efficient planning of the resource mix in cancer care.

Comparable data on crude rates in Europe are available for the years 2008 and 2012 and can give an idea on the most recent trends. For this report, crude rates were calculated by taking absolute figures on cancer incidence and mortality from two studies referring to the years 2008 and 2012 [2,

32], and adjusting them for population size with data from Eurostat. Crude rates are presented in number of cases per 100,000 inhabitants. Incidence rates are shown in Figure 4 and mortality rates in Figure 5.

Between 2008 and 2012 colorectal cancer incidence increased in both females and males in all countries but Germany (see Figure 4). In all countries female colorectal cancer incidence rates are below male rates. Lung cancer incidence in females increased in all countries, and also in males with the exception of Poland. However, the female lung cancer incidence rate is still half the male rate. Prostate cancer incidence increased in France and Sweden, but fell in Germany and Poland.

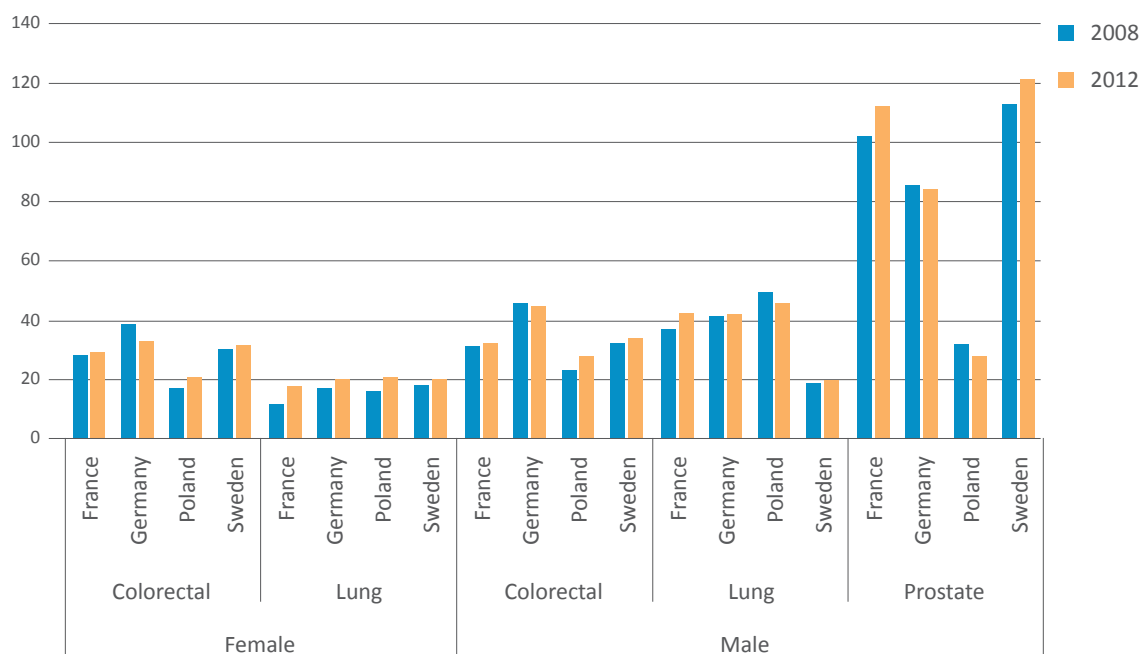


Figure 4: Estimated number of cancer incidence cases per 100,000 inhabitants (crude rates), 2008 - 2012 [2, 32]



Lung cancer incidence in females increased in all countries, and also in males with the exception of Poland. However, the female lung cancer incidence rate is still half the male rate.

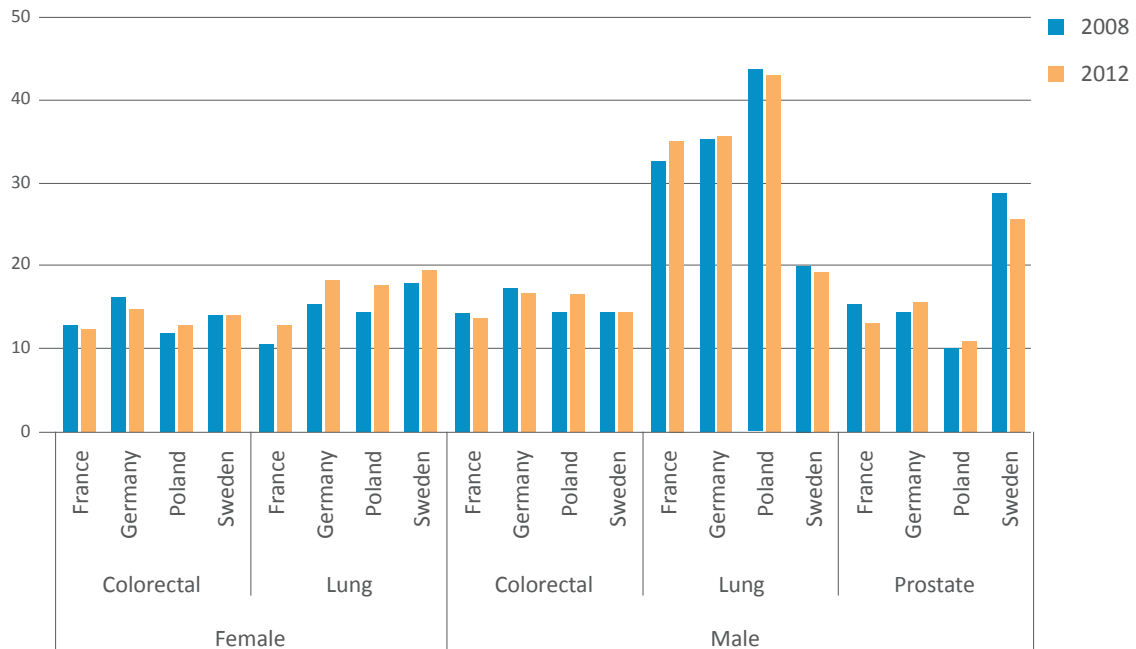


Figure 5: Estimated number of cancer mortality cases per 100,000 inhabitants (crude rates), 2008 - 2012 [2, 32]

The trends in cancer mortality are more mixed between countries (see Figure 5). Colorectal cancer mortality fell in France and Germany in both females and males, remained stable in Sweden, and increased in Poland. Lung cancer mortality in females increased markedly in all countries. Lung cancer mortality in males increased in France and Germany and decreased in Poland and Sweden. Prostate cancer mortality decreased in France and Sweden, but increased in Germany and Poland.

From the perspective of the European Union (28 member states) and considering all cancer types, the overall incidence rate for males increased by 3.4 percent for females by 4.5 percent between 2008 and 2012. The mortality rate increased by 1.8 percent in males and remained stable in females (-0.1

percent) during the same period. In contrast to the previous conclusion on the trends in age-standardized rates, this section on crude rates highlights that the real cancer burden continues to increase. The demographic change in Europe, that entails a growing share of elderly people, manifests itself in increasing incidence rates despite prevention efforts. Yet, as observed for age-standardized rates, the rise in cancer incidence is decoupled from the slower rise in cancer mortality, which can be indicative of progress in the area of screening and treatment.

2. The burden of cancer in Europe

2.2. Prevalence

Cancer prevalence is the number or proportion of the population living with cancer in a given time point or during a specified time period. Data on cancer prevalence are usually provided in the form of 1-year, 3-year and/or 5-year prevalence and describe the number of patients diagnosed with cancer and still alive one/three/five year(s) after the diagnosis in the given population [33]. For instance, 5-year prevalence in 2012 includes all cancer cases diagnosed within the 5 previous years and still alive in 2012.

In the EU-28 with its 505 million inhabitants in 2012, the 1-year, 3-year, and 5-year overall cancer prevalence was around 1.9 million, 4.9 million, and 7.2 million respectively [33]. Patients with colorectal cancer accounted for 14%, 13%, and 13% of the total cases in the respective prevalence group; lung cancer patients accounted for 7%, 6%, and 5% respectively; prostate cancer patients accounted for 18%, 18%, and 19% respectively. The corresponding shares in the four considered countries are quite similar to this EU-aggregate estimate and deviations can be explained by different incidence and survival rates.

For this report, the 1-year, 3-year and 5-year prevalence also has been calculated for each cancer type by country. This was done by using the total number of (male and female) cases from the EUCAN website [33], and adjusting them with population figures from Eurostat to receive crude prevalence rates per 100,000 inhabitants. Figures 6 to 8 present the results separately for each cancer type (see Table A2 in the appendix for the underlying figures). For reasons of comparison even the incidence rate, which has been calculated with the same methodology, is included.

Unfortunately, data are only available for 2012, and so no trends can be presented. Nonetheless, in times of increasing (crude) incidence rates and increasing survival rates (see section 3.2.3), crude prevalence rates should increase too.

In order to interpret Figures 6 to 8 correctly, three points should be kept in mind. Firstly, the shorter the incidence column is the better, because it indicates a lower number of new cancer cases. Secondly, the drop between the incidence column and the 1-year prevalence column should be zero, which would imply that everybody survives⁶. Thirdly, the 3-year prevalence column should be three times the size of the 1-year prevalence column and the 5-year prevalence five times its size respectively, which again would imply that everybody survives⁷.

A comparison of the three cancer types in Figure 6 to 8 shows that there are wide differences between cancer types. For instance, in Germany a similar number of patients had been diagnosed with colorectal cancer (79 people per 100,000 inhabitants), lung cancer (63 people) and prostate cancer (85 people) in 2012. The 5-year prevalence rate that indicates all patients diagnosed during the previous 5 years that are still alive in 2012 was 229 people per 100,000 inhabitants for colorectal cancer, 69 people for lung cancer and 330 people for prostate cancer. These stark differences in prevalence rates stem from differences in survival rates between these cancer types (see section 3.2.3). Also country differences are visible. For instance, in the case of colorectal cancer the relative drop between the incidence rate and the 1-year prevalence rate is highest in Poland among the four countries (see Figure 6). Sweden has about the same colorectal cancer incidence rate and 1-year prevalence rate as the EU-28 average, but the 3-year and even more so the 5-year prevalence rate is distinctly better in Sweden.

6. Theoretically even a situation with non-zero difference might be favorable, because patients that have been diagnosed in different years are being compared here. Since the incidence rates change from year to year, even a drop between the incidence column and the 1-year prevalence column could be indicative of every patient surviving in times of increasing incidence rates.

7. The same principle described in the previous footnote analogously applies here.

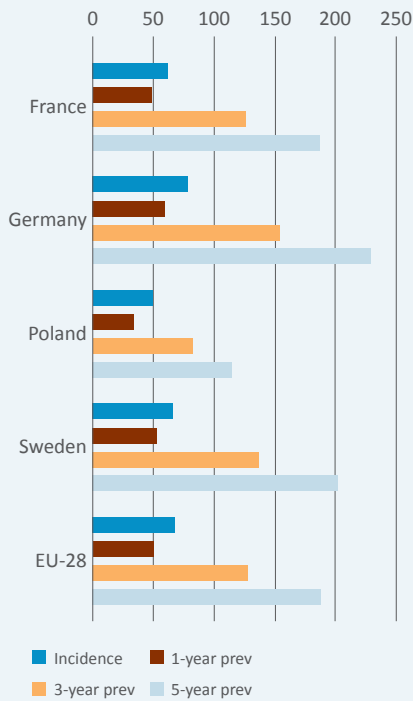


Figure 6: Colorectal cancer - estimated incidence and prevalence rates per 100,000 inhabitants (both sexes), 2012 [33]

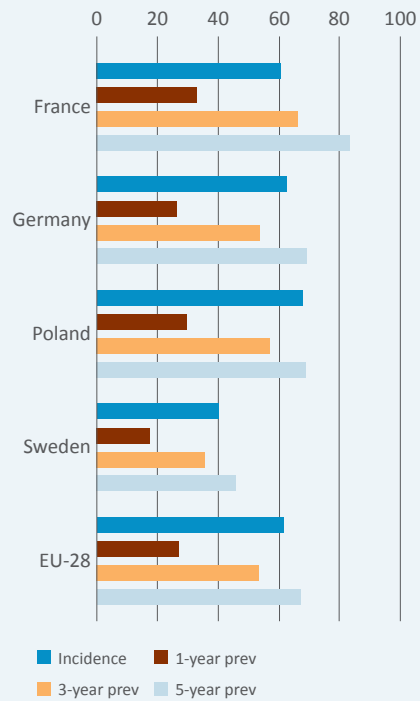


Figure 7: Lung cancer - estimated incidence and prevalence rates per 100,000 inhabitants (both sexes), 2012 [33]

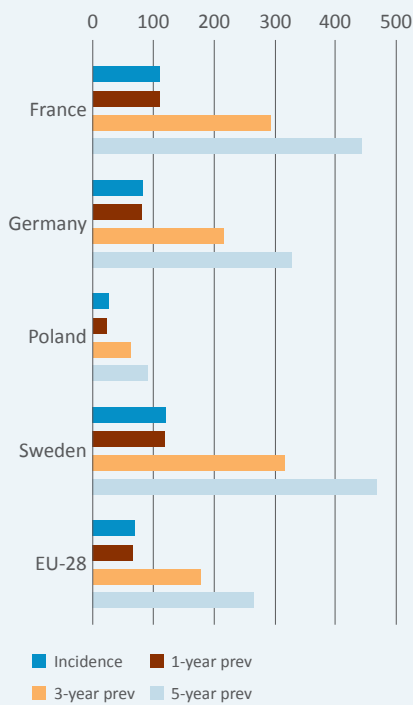


Figure 8: Prostate cancer - estimated incidence and prevalence rates per 100,000 inhabitants, 2012 [33]

2. The burden of cancer in Europe

2.3. Health burden

Cancer is the second most common cause of death in the European Union, after cardiovascular diseases [22]. Some 1.3 million people (715,000 men and 560,000 women) died from cancer in the EU-28 in 2012 [2]. Nonetheless, premature death is only one component of the health burden that cancer presents to society. The other component is the decreased quality of life of patients that have to live with the disease. In the past almost all cancer types were considered to be incurable, which meant that the mortality component constituted the major share of the health burden. In time, with more effective care, survival chances continue to improve and more and more patients live for a longer time with the disease. That means that the morbidity component is growing in importance, as for some cancer types a shift from what once was a deadly disease to a more chronic disease is under way.

A common measure to quantify the health burden of a disease is Disability Adjusted Life Years (DALYs). This measure combines the burden in terms of mortality and morbidity, and has been developed by the World Health Organization (WHO) and the World Bank. DALYs combine Years of Life Lost (YLL) due to premature death and Years Lost due to Disability (YLD) attributable to a certain disease or illness.

One DALY represents one lost year of “healthy” life. The sum of all DALYs across the population represents the burden of a disease. It can be thought of as a measurement of the gap between current health status and an ideal health situation where the entire population lives to an advanced age, free of disease and disability. Consequently, the disease burden can be interpreted as patients’ unmet need for care.

When applied in cross-country comparisons, a lower number of DALYs of a certain disease is equivalent to a lower disease burden. It should be noted though, that a lower burden of a certain disease in a specific country does not necessarily imply that patients’ unmet need for care is lower because of better treatment in this country. In the case of cancer, a lower disease burden in a country might reflect a younger population, healthier dietary habits in the population, lower smoking rates, etc.

The heavy health burden of cancer can be read-off in Table 1. Cancer (i.e. malignant neoplasms) accounts for more than 10 million DALYs lost in the European Union. This corresponds to a share of around 16.3 percent of the total health burden of all diseases and illnesses, but varies from 14.6 percent in Sweden to 18.2 percent in France. If the cancer burden is standardized by the population, then the European average is 21.2 DALYs lost per 1000 inhabitants, and Poland has the highest burden with 23.7 DALYs lost whereas Sweden has the lowest burden with 16.8 DALYs lost.

Table 1: Estimated total DALYs per country (in thousands), 2004 [34]

	All causes of disease or illness	Malignant neoplasms (cancer)	Share of cancer on all causes	DALYs of cancer/1000 inh
EU-28	64,403	10,466	16.3%	21.2
France	7,434	1,355	18.2%	21.8
Germany	10,358	1,747	16.9%	21.2
Poland	5,703	906	15.9%	23.7
Sweden	1,033	151	14.6%	16.8

Notes: Population data were taken from Eurostat.

Table 2 shows that in terms of overall burden of disease, cancer was the third largest disease group in the EU in 2004 after neuropsychiatric conditions and cardiovascular diseases. The proportions of Years of Life Lost (YLL) and Years Lost due to Disability (YLD) of a DALY vary considerably depending on the disease group. For cancer, YLL represent

over 90 percent of DALYs lost in Europe. YLL represent 75-85 percent of DALYs lost for injuries and cardiovascular diseases, whereas for neuropsychiatric conditions YLL represent only 9 percent of DALYs lost. For sense organ diseases, the disease burden is only composed of YLD [34].

Table 2: Top 5 disease groups in terms of burden of disease in the EU-28, 2004 [34]

	Total DALYs lost	DALYs/1000 inh	Share (%)
1. Neuropsychiatric conditions	15,400,700	31.2	23.9
2. Cardiovascular diseases	12,000,000	24.3	18.6
3. Malignant neoplasms	10,466,500	21.2	16.3
4. Injuries	5,221,400	10.6	8.1
5. Sense organ diseases	4,715,500	9.6	7.3
All disease groups	64,402,600	130.5	100.0

The cancer disease burden does not exhibit a uniform pattern across all cancer types. For types with comparatively low survival rates, such as lung cancer, the mortality component weighs heaviest. For types with comparatively high survival rates, such as prostate cancer, also the morbidity component constitutes a significant part of the disease burden [2].

Figure 9 illustrates the disease burden of colorectal, lung and prostate cancer in terms of DALYs and their mortality (YLL)-morbidity (YLD) composition⁸.

8. The corresponding figures can be found in Table A3 in the Appendix.

2. The burden of cancer in Europe

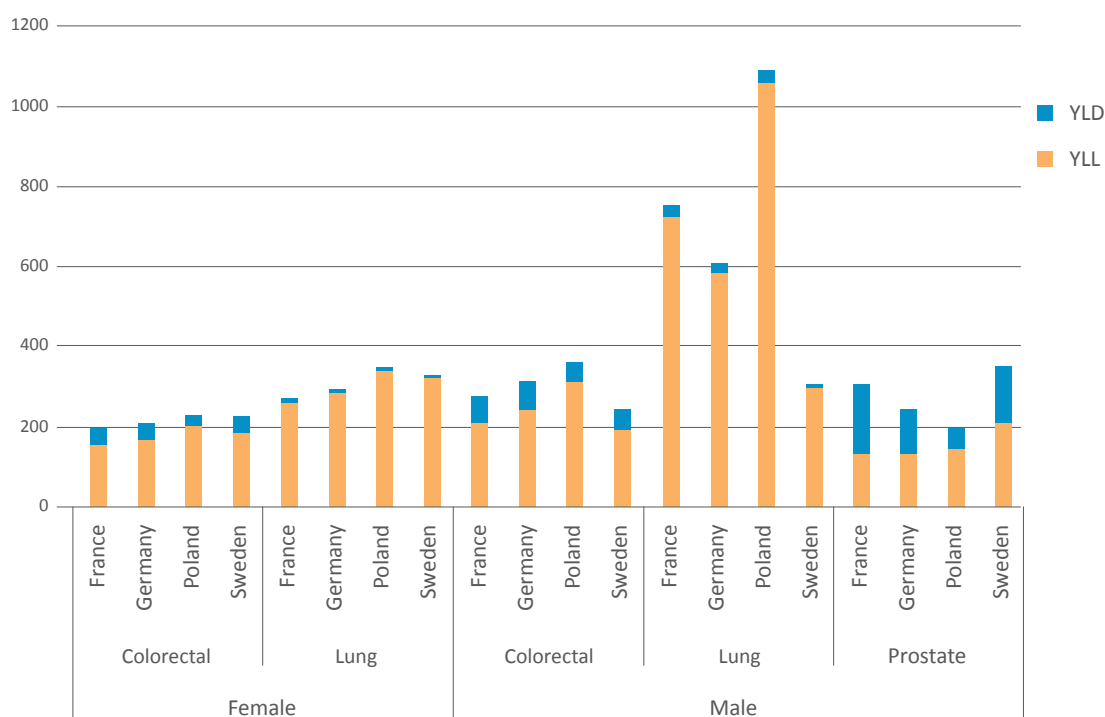


Figure 9: Estimated disability-adjusted life years (DALY), years of life lost (YLL) and years lived with disability (YLD) in age-standardized rates (ASR (W)) per 100,000 inhabitants, 2008 [35]

Figure 9 shows that the disease burden of prostate cancer is highest in Sweden, followed by France, Germany and Poland. Regarding the mortality-morbidity composition it is evident that in Poland the mortality component (YLL) plays a much bigger role than in all other countries. In France, for example, the morbidity component is larger than the mortality component, which indicates that the containment of the deadliness of prostate cancer has progressed far but that patients' quality of life is nevertheless impaired by the condition.

The disease burden of lung cancer is highest in Poland, both for men and women, and higher than that of prostate or colorectal cancer in all countries (see Figure 9). Furthermore, the mortality component of lung cancer is by far the largest component of the disease burden in all countries, reflecting the low survival chances with this type of cancer. An interesting result can be observed for Sweden where the disease burden of women with lung cancer is higher than that of men. In contrast, in Poland and France the male figure is around three times larger than the female one. As pointed out before, the low smoking rates in Sweden among men due to smokeless tobacco use together with the equal gender distribution in smoking rates offer an explanation for this phenomenon.

The disease burden of colorectal cancer is fairly similar across countries, yet men exhibit a higher disease burden in all countries (see Figure 9). In Poland, where the disease burden is highest in both men and women, the mortality component seems to be relatively large in comparison to the other countries. This might reflect the lower survival rates in Poland for this type of cancer (see section 3.2.3).

In conclusion, cancer represents one of the major diseases in Europe. Compared with other major diseases, the mortality component comprises by far the largest share of the disease burden in cancer. However, for cancer types with comparatively high survival rates, such as prostate cancer, the morbidity component also constitutes a significant share of the disease burden. With the survival odds for most cancer types continuing to improve, the morbidity component becomes increasingly important as patients live longer with the disease.

2.4.

Economic burden

The economic burden of cancer is composed of direct costs and indirect costs. Among the direct costs are public and private expenditures on outpatient care, inpatient care, medications, screening programs, primary prevention measures, etc. The indirect costs comprise costs due to productivity loss and informal care costs.

Comparative studies on the economic burden of cancer are still rare. A lack of data on the consumption of cancer care resources and their prices are a major limitation for the preparation of such studies [36]. As a solution, the OECD has suggested the implementation of disease-specific health accounts [37]. This would not only facilitate international comparisons, but most importantly provide (national) policy makers with clear evidence on the amount of resources being spent on different diseases and on how spending evolves over time.

Direct costs

Direct costs comprise a wide range of different cost categories that directly have an impact on the public health care budget and on costs covered by the patient. Direct costs include public and private expenditures on outpatient care, inpatient care including curative and palliative care, medications, screening programs, primary prevention measures, and public grants for cancer research.

Table 3 shows the estimated share of cancer-related direct costs on total health care expenditures. Data on total health care expenditures were obtained from Eurostat. Data on the share of cancer-related expenditures were obtained from national sources or other country-specific publications (see Appendix for the applied methodology). Table 3 illustrates that the share of cancer-related direct costs on total health care expenditures ranges from 5 percent in Poland to 7.3 percent in Sweden. Data for Germany show that this share increased from 5.2 percent in 2002 to 5.8 percent in 2004, but since stabilized to 6.2 percent in 2006 and 6.1 percent in 2008 [38].

Countries also differ in their overall level of spending on health care (see Table 3). As a consequence, per-capita spending on cancer is more than three times higher in Sweden, Germany and France than in Poland after adjusting for purchasing power. The gap in unadjusted per-capita spending on cancer is more than twice as large and ranges from €33 in Poland to €283 in Sweden (see Table A4 in the Appendix). As subsequent chapters of this report will demonstrate, sufficient spending is a prerequisite for ensuring access to oncology care and for establishing a high-quality standard in oncology care, which is in turn necessary to achieve better outcomes. Nonetheless, section 3.2.4 in this report will show that there is evidence of a non-linear relationship between health care spending and outcomes, which means that the health gain from additional spending is decreasing as the absolute level of spending increases.

Table 3: Health care expenditures and estimated direct costs of cancer (adjusted for PPP), 2011

	Health care expenditure (share of GDP)	Health care expenditure (in M€)	Health care expenditure (per capita in €)	Cancer-related share of health care expenditure	Direct cost of cancer (per capita in €)
France	11.6%	208,231	3,196	6.6% (2004) [39]	211
Germany	11.3%	286,230	3,499	6.1% (2008) [38]	213
Poland	6.9%	46,167	1,198	5.0% (2002) [40]	60
Sweden	9.5%	27,788	2,941	7.3% (2004) [41]	215

Notes: PPP = purchasing power parity.

Source for health care expenditure: Eurostat [42].

Source for cancer expenditure: own estimate based on national sources (see Appendix for methodology).

2. The burden of cancer in Europe

The obtained results in Table 3 can be contrasted with the ones from a recent publication which estimates the share of cancer-related direct costs on total health care expenditures for every country of the EU-27 [43]. For the whole EU-27 the estimated share was 4 percent (see last row in Table 4). For Germany, this study estimates a 5 percent share whereas the estimate provided by the German Statistical Office is 6.1 percent as shown in Table 3. The difference is greatest for Sweden, where this recent study estimates a 3 percent share, but Table 3 indicates a share of 7.3 percent. Moreover, the estimated per-capita total direct costs in this study show very different results from the ones in Table 3, since the estimate for Germany is almost 80 percent higher than both the estimates for Sweden and France (see second last row in Table 4). Even though the results in this study are not adjusted for purchasing power differences, this cannot explain the large discrepancies.

For France and Sweden, the composition of direct cancer costs has been estimated for the year 2004 [41, 44]. Direct costs were grouped into five components in both countries, yet different components (see Figure 10). In France, hospital care accounts for 60 percent of the total direct costs and ambulatory care for 31 percent, thus total care accounts for 91 percent. In Sweden, the share of care is 82 percent and the separately calculated share of drugs is 11 percent; taken together this yields a share of 93 percent similar to the French figure. The remaining direct costs in both countries are a result of spending on prevention policies (in France targeted at tobacco, alcohol, food and physical training), screening programs (in France for breast cancer and colorectal cancer) and public funding of cancer research.

The above mentioned study for the EU-27 also considered the composition of health care costs for cancer in 2009 [43]. In this study health care cost were split into five categories; primary care, outpatient care, emergency care, hospital inpatient care, and drugs. As such, this study does not include all relevant direct costs and leaves out spending on health promotion and prevention activities, spending on screening programs and publicly funded cancer research. According to this study, costs for inpatient care account for more than half and drugs for more than a quarter of all health care costs, respectively (see Figure 11). Figure 11 also illustrates that the share of the different cost categories varies considerably between cancer types. For colorectal and lung cancer, expenditures on inpatient care account for more than two thirds of all health care costs and expenditures on outpatient care exceed those for drugs. By contrast, drug costs are the main cost category for prostate cancer. However, the estimates on drug expenditures for specific cancer types should be regarded with caution since their proportions are only based on real data from Germany and the Netherlands in this study.

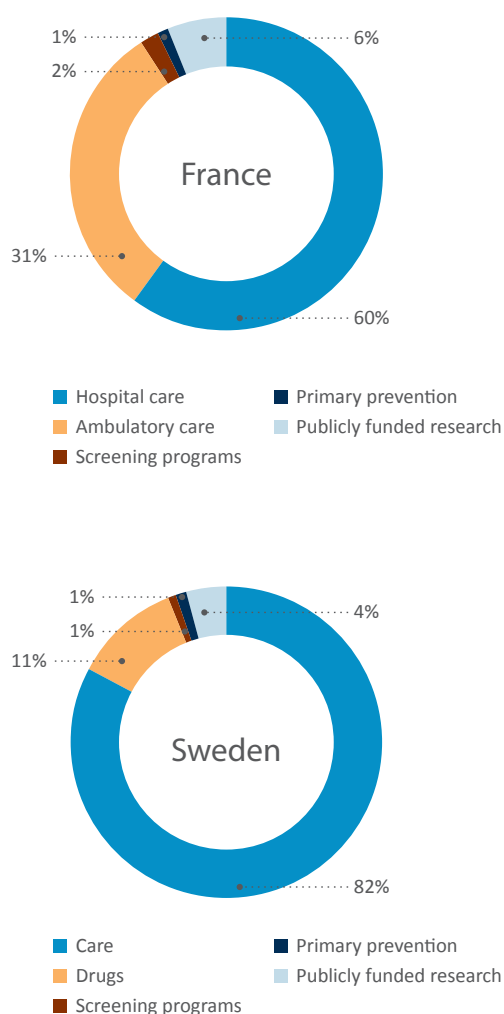


Figure 10: Cancer-related direct costs in France [44] and Sweden [41], 2004

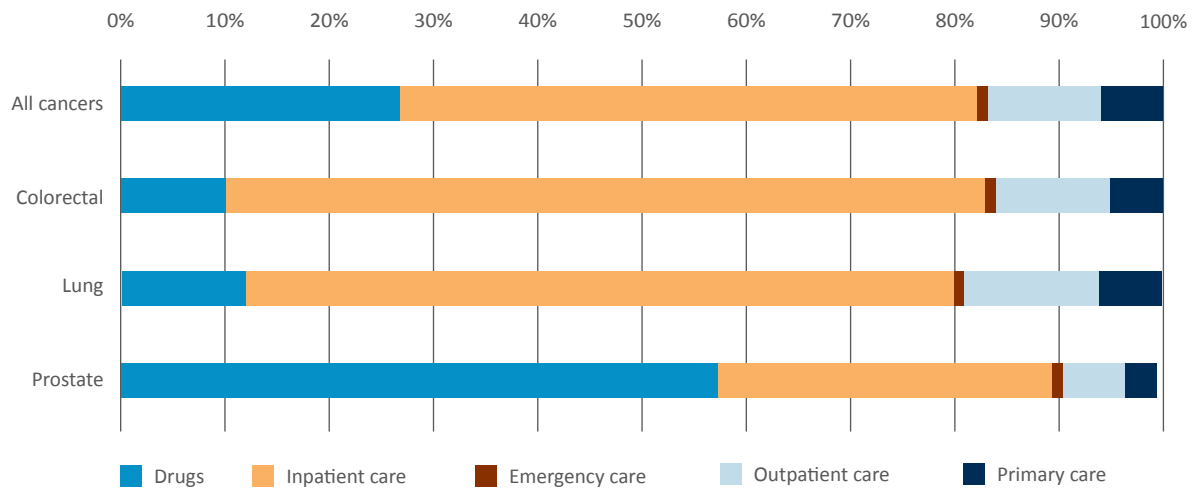


Figure 11: Composition of health care expenditures by cancer type in the EU-27, 2009 [43]

Table 4: Health care expenditures on cancer per capita in euros by country (not adjusted for PPP), 2009 [43]

	France	Germany	Poland	Sweden	EU-27
Primary care	2 (2%)	9 (5%)	3 (8%)	5 (5%)	6 (6%)
Outpatient care	3 (3%)	21 (12%)	10 (27%)	26 (25%)	11 (11%)
A&E	0.3 (0%)	0.4 (0%)	0.4 (1%)	4 (4%)	1 (1%)
Inpatient care	58 (53%)	119 (65%)	16 (43%)	44 (42%)	57 (56%)
Drugs	47 (43%)	33 (18%)	7 (19%)	25 (24%)	27 (27%)
Total health care costs	110 (100%)	182 (100%)	37 (100%)	105 (100%)	102 (100%)
Share of health care costs for cancer on total health expenditures	3%	5%	6%	3%	4%

2. The burden of cancer in Europe

The same study also showed that the composition of health care expenditures on cancer differs significantly across countries (see Table 4). In France, more than 40 percent of expenditures on cancer are allocated to drugs, as compared to 18 percent in Germany and 19 percent in Poland. On the other hand, hospital inpatient care accounts for almost two thirds of the expenditures in Germany. The share of expenditures on outpatient care is comparatively small in France with 3 percent, but quite significant in Poland with 27 percent and Sweden with 25 percent.

Indirect costs

To assess the economic burden of cancer from a societal perspective, indirect costs have to be added to direct costs. Indirect costs stem mainly from four areas. The first one is productivity loss due to foregone earnings attributable to premature death (i.e. mortality) of people of working age. The second one is productivity loss attributable to the morbidity of cancer patients that leads to lost working days due to sick leave. Early retirement due to patient morbidity forms the third area. Finally, informal care for cancer patients gives rise to indirect costs as relatives/friends forgo earnings to provide unpaid care.

Table 5: Direct and indirect costs of cancer by cancer type in the EU-27 (in billion euros), 2009 [43]

	All cancers	Colorectal cancer	Lung cancer	Prostate cancer
Total costs	126.21	13.09	18.78	8.43
% of total costs of all cancers		10%	15%	7%
Direct costs	40%	43%	23%	64%
Indirect costs	60%	57%	77%	36%

As Table 5 indicates, the share of indirect costs on total costs has been estimated as 60 percent for all cancers in the EU-27, but differs greatly between different cancer types. For lung cancer, the share of indirect costs is 77 percent, whereas for prostate cancer indirect costs account for 36 percent of total costs. This pattern is partly attributable to the low survival rates in lung cancer patients and their comparatively young average age, since both of these factors impact the size of productivity losses due mortality. In contrast, many prostate cancer patients are already retired and thus the productivity losses due to mortality are small. At the same time the higher survival rates in prostate cancer patients also cause the possible treatment to last for a longer time which drives up direct costs.

Another observation from Table 5 is that lung cancer accounts for around 15 percent of the total costs of cancer, colorectal cancer for 10 percent and prostate cancer for 7 percent in the EU-27. However, the order changes if only direct costs are considered. In that case, both colorectal cancer and prostate cancer account for around 11 percent of total direct costs and lung cancer for 8 percent [43]. This reflects the high share of indirect costs of lung cancer due to the comparatively high mortality of lung cancer patients.

Figure 12 depicts the composition of indirect costs for each cancer type. For prostate cancer, informal care is the main driver of indirect costs with 63 percent, whereas for lung cancer productivity loss due to mortality is the main driver of indirect costs with 68 percent. For colorectal cancer, informal care costs and productivity loss due to mortality are both important drivers of indirect costs. As explained before, many prostate cancer patients are already retired and thus the productivity losses are small, but their comparatively good survival prospects cause high costs for informal care. The opposite is true for lung cancer patients which are younger and have comparatively poor survival prospects.

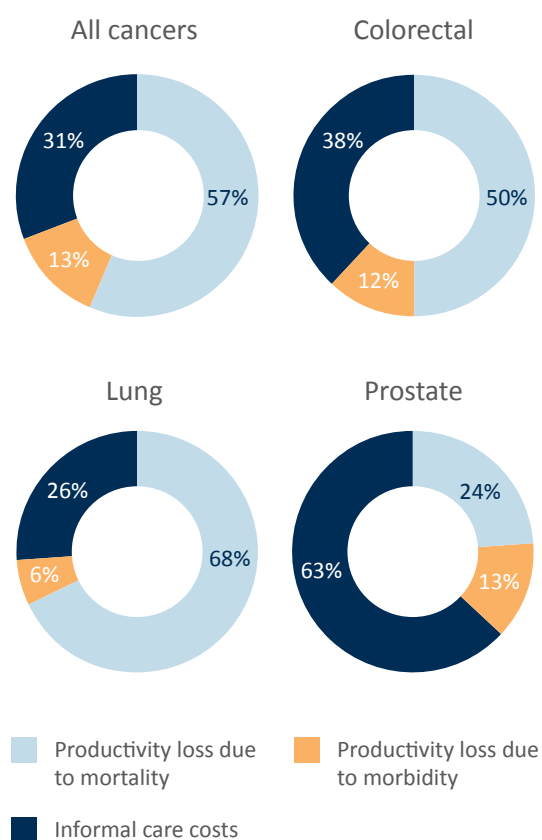


Figure 12: Composition of indirect costs by cancer type in the EU-27, 2009 [43]

Table 6: Direct and indirect costs of cancer by country (in billion euros), 2009 [43]

	France	Germany	Poland	Sweden	EU-27
Total costs	16.88	35.13	3.64	2.77	126.21
Direct costs	42%	42%	38%	35%	40%
Indirect costs	58%	58%	62%	65%	60%
Indirect costs (=100%) of which:					
- Productivity loss due to mortality	51%	57%	58%	51%	57%
- Productivity loss due to morbidity	23%	11%	17%	27%	13%
- Informal care costs	26%	32%	25%	22%	31%

As pointed out before, a recent study estimated the direct costs to account for around 40 percent of the economic burden of cancer in the EU-27, and the indirect costs for the remaining 60 percent (see Table 6). The investigated countries do not deviate too far from this aggregate. Another study for France for the year 2004 yielded very similar results. There,

the direct costs accounted for 41 percent and indirect costs for 59 percent of total costs, although indirect costs did not include informal care costs in this study [44]. By contrast, in a study for Sweden (which also excludes informal care costs) for the year 2004, the share of direct costs was 53 percent and of indirect costs 47 percent [41].

2. The burden of cancer in Europe

CONCLUSION

This section has shown that the share of cancer-related direct costs on total health expenditures ranges from 5 percent in Poland to 7.3 percent in Sweden. Purchasing power adjusted per-capita spending on cancer is more than three times higher in Sweden, Germany and France than in Poland and the country differences are even greater if unadjusted per-capita spending on cancer is considered. Furthermore, indirect costs account for around 60 percent of total costs in all countries, yet this share differs greatly between cancer types. Overall, productivity loss due to morbidity and due to premature death is of the same magnitude as the total direct health care expenditures.

From these observations two important findings can be deduced. Firstly, the largest part of the economic burden of cancer (i.e. indirect costs) accrues to areas that lie outside the direct scope of the health care system. Nonetheless, this fact should not overshadow the importance of a comprehensive cancer management system. Effective care has an immediate impact on indirect costs by it preventing premature death, reducing morbidity and cutting early retirement. The second finding stresses this as well. Despite fairly similar levels of spending in France, Germany and Sweden, these countries differ in their achieved outcomes as measured by survival rates (see section 3.2.3). This highlights the importance for health policy to set the right priorities in cancer care and that a sole focus on spending is too narrow.

To provide a forward-looking statement on the development of the economic burden is difficult. Section 2.1 has shown that the demographic change is still the driving force behind an increasing number of new cancer cases. More incidence cases mean more patients to be taken care of by the health care system, which has implications both for direct costs and indirect costs.

Direct costs are likely to increase, because of the sheer greater number of patients to be treated, but also because screening programs are steadily being extended (e.g. for colorectal cancer) and primary prevention measures (e.g. HPV vaccination) being implemented and enforced. The latter two measures are, however, expected to decrease the cost for care in the long-term. Drugs as the cost-driver behind increasing direct costs for cancer care are a debated

issue. New targeted cancer therapies allow a greater share of patients to be treated but often come at a high price which dramatically increased drug costs in the last decade, yet the increase leveled off in recent years and might be further moderated in the coming years as some widely-used cancer drugs come off patent (see chapter 6). If the shift from intravenous to oral delivery methods of drugs continues, hospital inpatient care costs could be expected to decrease as more patients can be treatment at home.

Indirect costs may also increase simply because of the continuing rise in cancer patients. Productivity loss due to morbidity might therefore increase as a whole, but not necessarily at the individual level if cancer care becomes more effective. The latter could possibly even contribute to a reduction in early retirement. Informal care costs are likely to increase because patients live longer with disease and therefore need care for a longer time. Nonetheless, productivity loss due to mortality might decrease as survival rates continue to increase. Finally, if increased primary prevention efforts succeed in shifting cancer cases away from younger people and/or more deadly cancer types (e.g. lung cancer), a reduction in indirect costs could be expected.



Informal care costs are likely to increase because patients live longer with disease and therefore need care for a longer time.

3. Defining access to high-quality oncology care

3.1.

Defining access to oncology care

Conclusions

- **General determinants of access to health care are the availability of health care services**, which determines whether people “have access” to health care, and **(geographic) accessibility, affordability and acceptability**, which determine whether people can “gain access” to health care.
- Access to health care in terms of (subjectively assessed) unmet needs for medical examination is superior in France and Germany compared to Sweden and Poland.
- **Access to oncology care can be separated into three areas; primary prevention measures, screening, treatment.**
- **Primary prevention measures aim to reduce the incidence of cancer by seeking to impact on lifestyles that increase the risk of developing cancer.**
- **Access to screening services enables the detection of cancers at an early stage** which helps to reduce the disease burden in terms of mortality and morbidity.
- **Several factors affect access to cancer treatment:**
 - The **availability of oncology facilities** is determined by a trade-off between costs and quality, and patient proximity considerations.
 - The spatial concentration of oncology facilities creates a **geographic barrier** that is especially important if repeated treatment sessions are necessary.
 - A **financial barrier** arises if co-payments are required and if access to new costly treatments is restricted by low public financial means.
 - A **social and cultural barrier** arises if patient trust in the quality of the health care system is low and leads to patients being discouraged from seeking help.
 - Access to treatment can be restricted by lengthy internal processes and bottlenecks in the health care system which results in **long waiting times**.

The purpose of this section is to outline a set of factors that determine access to oncology care. This is done in a two-step process. First, general determinants of access to health care

are summarized. Second, additional determinants of access that pertain specifically to the area of oncology care are described.

3. Defining access to high-quality oncology care

3.1.1.

Access to health care

Access to health care is a multi-dimensional concept. In general, two ways of defining access to health care can be distinguished. Firstly, the availability or supply of health care services influences the degree of access and describes whether people “have access” to health care services. Secondly, availability is a prerequisite for people to “gain access” to health care services [45]. Thus, the former describes the potential to utilize health care services, whereas the latter refers to the actual utilization of health care services.

Besides the fundamental determinant of the availability of health care services, there are several barriers that prevent patients from gaining access to health care. These barriers are accessibility, affordability and acceptability.

Determinants of access to health care:

- Availability of health care services
- Accessibility
 - Geographic accessibility
 - Contact accessibility
 - Appointment accessibility
- Affordability
- Acceptability

Accessibility refers to the geographic barrier that patients have to overcome to get from their homes to the health care facility. Geographic accessibility is linked to the availability of a means of transportation, distance, travel time and cost [46]. Two other forms of accessibility are contact accessibility, describing the ease of contacting providers for appointments, and appointment accessibility, indicating the length of time it takes to get an appointment [47]. Waiting lists are a result of appointment inaccessibility, which in turn depends on the demand for and the supply of health care services.

Affordability represents the financial barrier and describes the patient’s ability to pay for health care services taking into account any health insurance scheme that the patient might have signed or is included in [46].

Finally, acceptability of services denotes the social and cultural barrier that stands in between patients and the health care system. Acceptability (or satisfaction) describes the patients’ attitudes with which the health care systems is met [46], and thus indicates patients’ trust in the ability of the system to deliver the help that patients reach out for.

Table 7: Self-reported unmet needs for medical examination or treatment by reasons of barriers of access in 2005 and 2012 (in % of total population), EU-SILC [48]

Year	France		Germany		Poland		Sweden	
	2005	2012	2005	2012	2005	2012	2005	2012
Unmet need:								
- total	3.8	5.5	16.9	5.8	16.2	14.2	15.0	11.5
- men	4.0	5.3	16.2	5.9	14.8	12.9	13.7	10.2
- women	3.6	5.7	17.6	5.8	17.5	15.3	16.4	12.8
- 1st income quintile	6.7	9.3	25.9	9.8	19.0	16.6	17.6	14.2
- 5th income quintile	2.1	3.3	11.6	3.4	15.5	11.2	10.9	10.3
By reason (selected):								
- Waiting list	0.3	0.3	1.6	0.7	2.4	5.0	2.0	0.8
- Too far to travel	0.0	0.1	0.2	0.1	0.4	0.6	0.1	0.1
- Too expensive	1.3	1.9	7.3	0.8	6.8	3.5	0.5	0.4
- Wait and see*	0.8	1.1	4.3	1.3	1.8	1.5	6.6	5.4

Notes: *Wanted to wait and see if problem got better on its own.

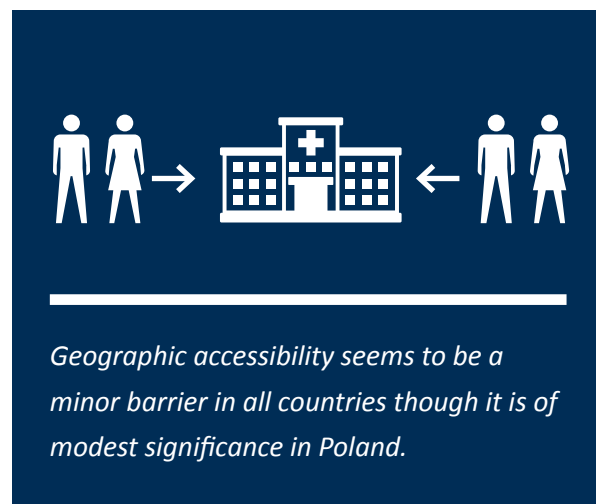
One way of measuring access to health care is to look at the share of the population reporting unmet need for medical examination or treatment as well as the reasons for this. Table 7 displays this share for the four included countries for the years 2005 and 2012. The most remarkable difference between the countries is the lower share of the population in France reporting unmet needs in 2005. With the exception of France, the countries show a similar pattern of decreasing unmet need over time. By 2012, Germany had improved from being the country with the largest unmet need to almost take the top spot from France. Regarding gender breakdown, men and women tend to report a similar level of unmet need in France and Germany, but women in Poland and Sweden report a higher unmet need than men. Not surprisingly, people in the lowest income quintile report higher unmet need than people in the highest quintile. The general decline (increase in France) in unmet need between 2005 and 2012 was, however, equally shared across the income distribution.

In line with the four previously identified determinants of access to health care, Table 7 also highlights four selected barriers that evoked this unmet need for medical care. Firstly, waiting lists are an indicator of whether the available health care facilities can meet the demand for health care. This barrier seems to be greatest in Poland, where it increased in recent years and now explains more than a third of total unmet need for medical care, whereas in the other countries waiting lists are a comparatively small barrier. Secondly, geographic accessibility seems to be a minor barrier in all countries though it is of modest significance in Poland. Thirdly, affordability-related unmet need has declined in all countries but France from 2005 to 2012, where it now explains a third of total unmet need for medical care; in absolute terms the financial barrier is, however, largest in Poland. Fourthly, acceptability of medical services might be approximated by the reported unmet need due peoples' decisions to wanting to wait and see if their medical problems got better on their own. This social and cultural barrier is a significant factor in all countries and highest in Sweden, where it explains almost half of the total unmet need for medical care.

To draw specific policy conclusions from this type of general data in Table 7 is difficult. Medical examination and treatment can include everything from a broken arm to lung cancer. Moreover, the answer to the question of unmet need is subjective and may result from cultural factors and/or express general dissatisfaction with the health care system which renders cross-country comparisons

difficult. Nonetheless, this description can serve as an initial overview of differences between the four countries' health care systems and how well they use it to meet peoples' demands for medical care. It also stresses the need to consider different breakdowns, e.g. by gender and socio-economic status, wherever possible.

Finally, it should be noted that there have been efforts to compare and rank health care systems by their performance. In 2000, the WHO ranked the French health care system as the world's best among 191 member states, whereas the Swedish system was ranked 23rd best, the German system 25th best and the Polish system finished up in 51st place [49]. The Euro Health Consumer Index (EHCI) has been ranking European health care systems since 2005 from a consumer and patient perspective. The 2013 edition of the EHCI used 48 indicators, covering six areas that are essential to health consumers: patients' rights and information, accessibility of treatment (waiting times), medical outcomes, range and reach of services provided, pharmaceuticals and prevention [50]. In 2013⁹, Germany occupied the 7th place (with 796 out of a maximum 1000 points), France the 9th place (777 points), Sweden the 11th place (756 points) and Poland the 32nd place (521 points) among 35 European countries¹⁰.



9. The 2013 edition of the EHCI includes 35 countries, viz. all 28 European Union member states (UK was separated into England and Scotland), Albania, Iceland, FYR Macedonia, Norway, Serbia and Switzerland.
10. The Netherlands were leading the ranking with 870 points.

3. Defining access to high-quality oncology care

3.1.2.

Access to oncology care

To improve patient outcomes and alleviate the burden of cancer, active measures in three main areas can be taken. These areas are primary prevention policies and initiatives, screening programs and treatment. For a comprehensive description of the determinants of access to oncology care, factors in all three areas have to be looked at.

Primary prevention policies and initiatives to reduce the exposure to risk factors are important for influencing the burden of disease, even if they may not be classified as real “access factors”. They often take the form of public campaigns to inform people about lifestyles that are suspected or known to increase the risk of developing cancer. This is for example manifested in the European code against cancer issued by the European Commission [11]. Regarding lung cancer, anti-smoking campaigns are conducted to explain the harms attached to smoking to people. Another example regarding lung cancer is the new directive on tobacco products that the European Parliament passed in October 2013 which aims at curbing smoking and preventing young adults from starting to smoke [14, 15]. Prevention initiatives regarding colorectal cancer promote a healthy diet, regular physical activity and maintenance of a healthy weight as these are all risk factors related to colorectal cancer [30]. However, it should be noted that for certain cancers not all risk factors are amenable to primary prevention policies. In terms of access, the aim of primary prevention measures is to reach the largest possible share of the population segment that the prevention initiative is targeted at.

Screening services aim to detect cancer at an early stage in a certain population group known to have an increased risk for developing a certain type of cancer. Screening programs are sometimes called secondary prevention measures. The benefit of early cancer detection is the improved survival probability as the treatability of cancer is easier at an early stage than at a metastasized stage. Access to screening services thus is of great importance for reducing the disease burden of cancer [51], and a decisive factor that needs to be considered in assessing access to oncology care. Chapter 5 of this report is therefore devoted to the assessment of determinants of access to high-quality screening.

The third area that determines access to oncology care concerns the access to actual treatment at a health care facility. The general determinants of access to health care discussed in the previous section of this chapter have a different importance in light of oncology care. Facilities for oncology treatment are usually located in larger cities as the establishment and maintenance of such facilities involves high economic costs [52]. This leads to a spatial concentration of the supply of highly specialized facilities. Choosing the optimal location thus involves a trade-off between costs and quality, and patient proximity.

The geographic barrier is intuitively larger for oncology care as compared to many other types of health care. However, for common cancer types this barrier will be lower than for rare cancers, whose treatment is only available in a few specialized centers. Geographic distance is of lower importance for a single surgical intervention or a single screening session. In contrast, geographic proximity is of higher importance for radiation therapy or chemotherapy since these treatments require repeated visits to an oncology clinic. In any case, in areas with inadequate supply of oncology care, (long) waiting lists would be an expected consequence.

In Europe, where most people have health insurance, the financial barrier may be of less importance since oncology care is often fully covered by the insurance scheme and no co-payments are requested. However, access to new costly treatments is restricted in countries with low per capita income and low health care expenditures (this will be discussed in more detail in chapter 6). A social and cultural barrier with regards to oncology care might be present in countries where patient satisfaction with the health care system is generally low. Patients facing the prospect of low quality care might feel less inclined to seek treatment.

A special characteristic of oncology care is that the treatment is usually not initiated at the first contact with the health care system. Instead cancer patients have to be referred to specialists, which then run tests and assess the severity and spread of the cancer to derive a comprehensive diagnosis. After the diagnosis a treatment plan has to be set up and agreed upon with the patient before the actual start of treatment. Thus, in terms of access to oncology care not only the first contact with the health system matters, but also the time that passes until initial treatment, i.e. waiting times within the health care system. Figure 13 illustrates

the different steps that cancer patients have to go through between the first symptoms and the start of treatment. In general, a swift treatment start is desirable in order to keep cancer progression as small as possible and to thereby improve the odds of survival. Consequently, to enhance access to treatment, the internal processes in the health care system have to be optimized by identifying possible bottlenecks and other lags.

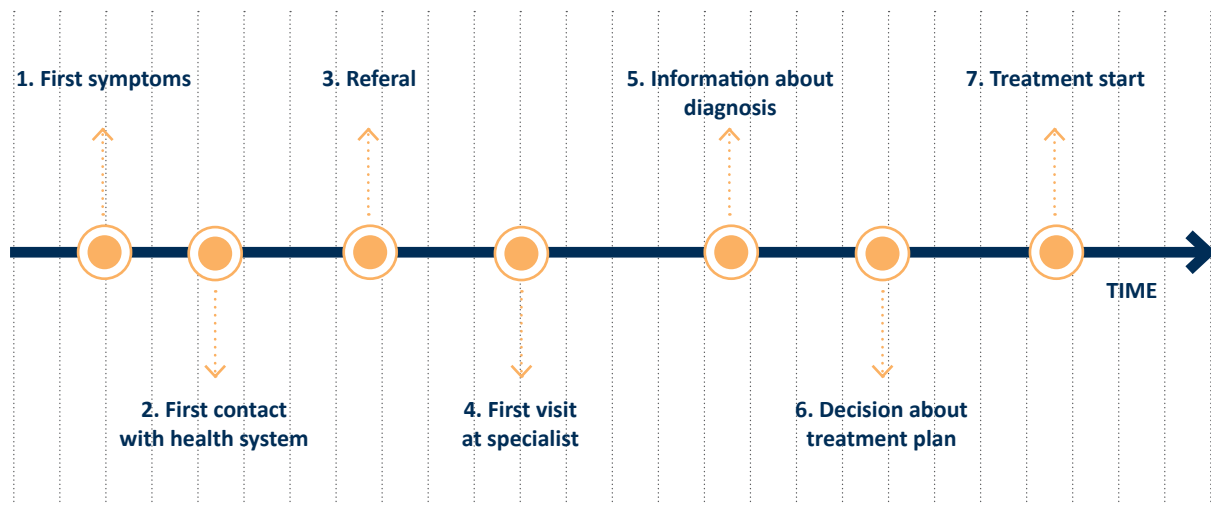


Figure 13: Steps in cancer care before initial treatment; adapted from *The National Board of Health and Welfare - Socialstyrelsen (2012) [53]*

Waiting times within a country can be quite different for different cancer types. The example of Sweden shows that the median waiting time between referral and decision about a treatment plan was 31 days for lung cancer in 2009. By contrast, the median waiting time between referral and treatment start was 42 days for colon cancer, 59 days for rectal cancer, and 141 days for prostate cancer in 2011 [53].

To sum up, access to oncology care is mainly determined by factors from three areas; prevention measures, screening, treatment. Through prevention measures lifestyles that increase the risk of developing cancer should be reduced. In terms of access, the aim of prevention measures is to inform as many people as possible about risk factors. Access to screening services enables the detection of cancers at an early stage which helps to reduce the disease burden. Several factors affect access to actual treatment. The availability of oncology facilities is determined by a trade-off between costs and quality, and patient proximity considerations.

The spatial concentration of oncology facilities creates a geographic barrier that is especially important if repeated treatment sessions are necessary. Despite oncology care services usually being covered by health insurance and no or only small co-payments being required, the financial barrier becomes an issue if access to new costly treatments is restricted by low public financial means. A social and cultural barrier arises if patient trust in the quality of the health care system is low and this leads to patients feeling less inclined to seek help. Lastly, access to treatment can be restricted by lengthy internal processes in the health care system which results in long waiting times.

3. Defining access to high-quality oncology care

3.2.

Defining and measuring quality of care in oncology

Conclusions

- A discussion about access to oncology care as done in section 3.1 is incomplete, unless the kind of care that patients gain access to is included. **The quality aspect of oncology care can be divided into three domains; quality of structure, process quality, and quality of outcome.**
- **Quality of structure comprises material and human resources** needed for diagnostics and treatment of cancer as well as **organizational factors** such as comprehensive cancer centers that propel research and disseminate knowledge on modern approaches to diagnose and treat cancer. **Process quality is determined by the sum of all actions that make up health care.** It is shaped by clinical and health policy guidelines on diagnostics and treatment, it can be monitored through cancer registries and is partly reflected by patient satisfaction. **Quality of outcome can be measured by survival rates and health-related quality of life.**
- **The achievement of the highest possible quality of outcome is the main interest of patients.** A discussion about the quality of oncology care thus must be output-driven. However, causal inferences about the quality of oncology care on the basis of outcome quality factors are difficult due to an inherent lack of up-to-date data.
- **The identification of current and future bottlenecks in cancer care provision is important for improving patient outcomes.** The general lack of data on relevant indicators to properly assess structural and process factors is a major shortcoming and limits the ability of policy makers to take the right measures.
- **At most vague predictions can be made on country performance in terms of overall quality of cancer care.** For instance, the fact that Germany currently has an undersupply of radiation therapy machines can be expected to limit the ability to improve outcomes. Sweden can meet the demand for such machines, but it (and also Germany) has a shortage of cancer health care professionals which can be expected to prolong waiting times. In France, the availability of medical technologies and health care professionals is good and the unmet need for radiation therapy machines small. However, monitoring of the quality of care is insufficient in the absence of a comprehensive nationwide cancer registry. By contrast, Germany is about to introduce such a registry and Sweden has already had it for a longer time. In the case of Poland, a considerable undersupply of medical technologies and health care professionals will probably make it impossible to catch up with France, Germany and Sweden in terms of outcomes in the near future.
- Three important findings can be derived from the analysis: (1) **Countries can attain fairly high survival rates with modest spending on health care.** With increasing per-capita spending, the additional improvements in survival rates start to decrease. (2) The Polish example shows that **without sufficient resource input, the achievement of high outcome quality is not feasible.** (3) Discrepancies in country-specific results on outcomes despite similar levels of spending stress that **the quality of cancer care (i.e. resource-mix, organizational and process-related factors) plays an important role for outcomes.**

The discussion in section 3.1 was merely confined to access to oncology care. However, it did not highlight the kind of oncology care that patients gain access to. Any discussion about access must include the quality aspect of the care that is being provided. Following the Donabedian model, quality of care is composed of three components; quality of structure, process quality, and quality of outcome [54]. Quality of structure can be measured by the availability of material and human resources that are needed for diagnostics and treatment and organizational factors. Process quality is determined by the sum of all actions that make up health care and, among other things, shaped by existing clinical

and health policy guidelines for the actual execution of diagnostics and treatment and is partly reflected by patient satisfaction. Finally, quality of outcome can be assessed in terms of survival, since the overall aim of cancer care is to prolong patient lifetime and enhance patient quality of life.

In the following, the determinants of high-quality oncology care for each of the three domains of the Donabedian model will be discussed. At the end of each section a comparison of the four countries France, Germany, Poland and Sweden regarding their performance on the outlined domain-specific determinants is provided.

3.2.1. Quality of structure

Quality of structure is the first cornerstone that determines quality of cancer care. It can be viewed as the quality of inputs that are being used for diagnostics and treatment of patients. In particular, access to medical technologies used in diagnostics and treatment of cancer (material resources), the availability of qualified health care professionals (human resources) and the organizational factors are important determinants that are discussed in this section. Access to effective cancer drugs that are needed for and used in cancer treatment also belongs to the determinants of quality of structure. This determinant is not reviewed here, but extensively discussed in chapter 6 of this report.

Access to medical technologies

Medical technologies are the material resources needed for diagnostics and treatment of cancer. With diagnostics the aim is to locate the cancer and determine its spread, i.e. to ascertain if it is locally restricted or if it metastasized. The investment costs for scanners to detect cancer tissue are high and thus their availability is restricted by the limited resources of the health care system. General guidelines or benchmarks regarding the ideal number of e.g. CT or MRI scanners per inhabitant do not exist [25]. It is clear though, that an undersupply of scanning units may lead to access problems in terms of geographic proximity and/or waiting times. An oversupply of units may result in an overuse of these expensive diagnostic procedures, with little if any benefits for patients.

Cancer is usually initially treated with surgery or radiation therapy with curative intent and sometimes preceded by neoadjuvant systemic therapy¹¹, and in many cases succeeded by adjuvant systemic therapy. Radiation therapy, as well as cancer drugs and to some extent surgery, is also extensively used in palliative care. In terms of material resources, access to high-quality oncology treatment thus depends on the availability of radiation therapy machines and the availability of effective cancer drugs for systemic therapy.

Availability of health care professionals

Human resources in the form of health care professionals are needed to perform all necessary diagnostics and treatments by making use of medical technologies and equipment. Hence, access to high-quality diagnostics and treatments also depends on the availability of health care professionals.

Oncology care is not the sole domain of medical and radiation oncologists. Surgeons, radiotherapists, pathologists, specialized nurses, psychosocial workers, etc. are necessary for a comprehensive assessment of different factors in

order to result in an effective treatment [55]. This insight has resulted in the establishment of multidisciplinary teams in many countries that bring together health professionals from various specialties. The teams discuss treatment options, develop individualized treatment plans and focus both on the physical and psychological needs of the patient. Studies have shown that there is supporting evidence that multidisciplinary teams improve cancer patient survival in general [56], and specifically for lung cancer [57], prostate cancer [58], and rectal cancer [59].

Comprehensive cancer centers

Comprehensive cancer centers (CCCs) are an organizational factor intended to ensure that high-quality standards in oncology care are being promoted. As centers of knowledge, their tasks include to initiate and/or conduct innovative clinical trials and other forms of research, to disseminate information on advances in cancer treatment to health care professionals as well as to the public. Thus their focus is not only limited to provide patient care but to propel research and to ensure that patients can benefit from advances in research by communicating these advances to the health care professionals that will actually treat patients.

Comprehensive cancer centers do not only operate at the national level. For instance, the Organisation of European Cancer Institutes (OECI) consists of 68 CCCs from all over Europe. The aim of the OECI is to improve communication and to increase collaborative activities among European cancer institutes [60]. In France 7 CCCs are associated with the OECI, 3 in Germany and 1 in both Poland and Sweden.

Country-specific results

Information on the availability of medical technologies and health care professionals in the different countries is summarized in Table 8. Regarding medical technologies, the population-adjusted numbers of CT units in France, Germany and Poland are fairly similar. In contrast, Germany has twice as many MRI units as Poland. It should be noted though, that data on medical technologies outside of hospital are not available for Germany leading to underreporting. In France, Germany and Sweden around 1 PET scanner unit is available per one million inhabitants, while Poland does not reach up to that level. In Sweden nine stationary and two ambulatory PET-CT units had been in use in 2012. Around 80-90 percent of all scans with PET-CT are cancer-related, and every PET-CT unit carries out about 8 to 12 scans per day in Sweden [55].

11. Systemic therapy encompasses chemotherapy, immunotherapy, molecularly targeted therapy and hormonal therapy.

3. Defining access to high-quality oncology care

Table 8: Availability of medical technologies and physicians by medical specialty related to diagnostics and treatment of cancer (per 100,000 inhabitants), 2010

	France	Germany	Poland	Sweden
Medical technologies				
CT scanners [61]	1.2	1.8	1.4	NA
MRI scanners [61]	0.7	1.0	0.5	NA
PET scanners [61]	0.1	0.1	0.0	0.11 [55]
Radiation therapy machines [62]	0.65	0.65	0.28	0.82
Health care professionals [63]				
All physicians or doctors	327.0	407.9	238.4	399.5
Oncologists*	1.0	NA	2.3	4.1
Pathologists	2.3	1.8	1.3	1.6
Radiologists**	14.5	10.5	8.5	13.9

Notes: Data for CT, MRI and PET scanners refer to units in hospitals and providers of ambulatory health care and in Germany only to units in hospitals.

Data for PET scanners include also PET-CT scanners.

Data for PET scanners for Sweden include only PET-CT units in 2012.

Data for radiation therapy machines as of July 2012.

All physicians or doctors are defined as "professionally active physicians or doctors".

Oncologists (physicians with oncology as specialty) include clinical oncology, chemotherapy, pediatric oncology and hemato-oncology.

Pathologists (physicians with pathology as specialty) include pathological anatomy, neuropathology, cytopathology, dermatopathology, hematopathology, histopathology, immunological pathology, forensic pathology, forensic medicine, legal medicine and, pediatric pathology.

Radiologists (physicians with radiology as specialty) include diagnostic radiology, diagnostic radiology of the chest, diagnostic radiology of the nervous system, interventional radiology, neuroradiology, radiotherapy, nuclear medicine and pediatric radiology.

Data for health care professionals in Sweden refer to year 2009.

NA = not available.

* In Sweden oncologists usually include medical and radiation oncologists, whereas in most other countries oncologists only refer to medical oncologists.

**According to Eurostat radiologists include radiation oncologists (who carry out radiotherapy), yet they might have been excluded from the Swedish figure and instead are counted as oncologists.

Radiation therapy machines are primarily used to treat cancer. The availability of these machines differs greatly between countries, with Sweden having almost three times more machines per 100,000 inhabitants than Poland (see Table 8). Germany and France have a similar number of machines per capita, but fewer than Sweden. A recent study estimated the unmet need for radiation therapy machines across Europe [62]. The estimations were based on the number of new cancer cases and an assumption that 62.5 percent of all cancer patients will need radiation therapy treatment or retreatment. Given the maximum treatment capacity of a machine, the required number of machines was calculated. This figure was then contrasted with the actual number of available machines. Figure 14 shows the relative gap between available number of machines and needed number of machines. The undersupply is largest in Poland with 45 percent. Here 107 machines are available but an additional 89 would be required to meet the estimated demand if used at greatest efficiency. An undersupply also exists in Germany and France. Even though both countries have the same number of available machines per 100,000 inhabitants, the unmet need is higher in Germany due to a relatively higher number of cancer patients. For Sweden an oversupply of 22 percent was estimated. This can partly relate to the geography of Sweden where many patients have to travel over long distances to access radiotherapy.

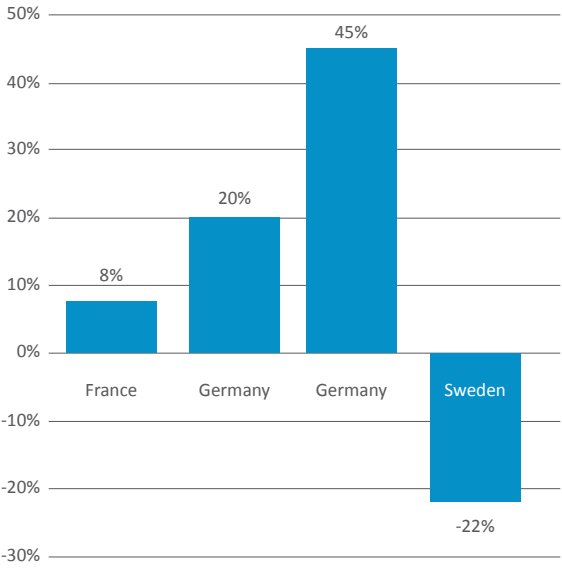


Figure 14: Unmet need for radiation therapy machines, 2012 [62]

Table 8 also presents data on the availability of cancer care professionals. As a benchmark the number of all physicians and doctors is displayed. Germany and Sweden have around 400 physicians and doctors per 100,000 inhabitants, France 327 and Poland 238. Regarding cancer-related specialists, the number of oncologists per 100,000 inhabitants is highest in Sweden, two times lower in Poland and four times lower in France. France commands over the most pathologists and radiologists, whereas Poland has the lowest number these specialists. Note that in Table 8 the definition of radiologists (carry out diagnosis) includes radiation oncologists (carry out treatment, i.e. radiotherapy). Note also that in most countries oncologists only refer to medical oncologists, but in Sweden they include medical and radiation oncologists which might explain the relatively high number of oncologists in Sweden in Table 8.

Over the last years there has been a widening gap between the available versus needed number of cancer care professionals in both Germany and Sweden. Both countries share the same challenges. As a result of the demographic change, the number of new cancer cases is expected to rise. Already now Sweden experiences severe shortages of pathologists and radiologists [64], whereas the German health care system lacks oncologists [65]. Looking at the current age profile of oncology care specialists, the situation will get worse in the coming years, when large retirement waves await both countries. For instance, in Germany around 25 percent of the active oncologists in 2010 will be at least 65 years old in 2020. The future prospect of patient access to cancer care might thus be characterized by long waiting times for diagnostics and treatment due to staff shortages.

3. Defining access to high-quality oncology care

3.2.2.

Process quality

Process quality is the second cornerstone that determines quality of cancer care. All procedures, measures and knowledge used in the treatment of cancer are factors that impact on process quality. Moreover, a supporting system in the form of treatment guidelines issued by national authorities and a national cancer registry to monitor the quality of treatment is needed to ensure that high-quality standards are followed and met on a nationwide basis. From a patient perspective, the satisfaction with the health care services consumed is also a decisive factor of process quality.

Patient satisfaction

Patient satisfaction with cancer care can give a good indication of the quality of care received. However, satisfaction measures are inherently subjective and it has to be remembered that patients can only give indications on the grounds of limited information on the effectiveness of treatment. A pleasant treatment environment might lead to high satisfaction during the treatment itself, but this satisfaction might be short-lived if the received treatment was ineffective and does not lead to an improvement of the health condition. Instead, if one can be certain about the good quality of the treatment received, fears and concerns of a relapse, for instance, will be lower and thus patient satisfaction higher. It should also be noted that cultural norms may influence the subjective ratings of satisfaction with the quality of care which renders cross-country comparisons difficult.

The role of guidelines and registries

The purpose of national or European guidelines is to standardize procedures, processes and quality standards so that cancer patients receive equal treatment irrespective of a health care facility's location. In principal, there are two types of guidelines. Clinical guidelines are mainly based on clinical trials and are not too different across European countries, since the same studies serve as an evidence basis for them. For instance, the European Society for Medical Oncology (ESMO) publishes clinical guidelines for different cancer types, but clinical guidelines are usually also issued by national cancer organizations. Since clinical guidelines are often solely based on clinical trials rather than clinical practice, they inform the efficacy of certain health interventions but not their effectiveness.

On the contrary, health policy guidelines that are adopted at a national level show more differences between countries due to different priority settings. Drawing up and disseminating health policy guidelines takes time and thus it is difficult to keep up with new clinical developments. Consequently, health policies have a tendency to lag behind. However, they are based on established facts and thus tend to inform

interventions for which there is practical evidence on their effectiveness. Since new developments in care may not be picked up on at the same pace across the whole country, the role of health policy guidelines also is to ensure that high-quality treatment is spread across the whole country and available to all patients. For instance, in Sweden it has been noted that there are regional variations in care and treatment of patients for chronic illnesses, despite national policy guidelines being in place [66].

A problem that both clinical and health policy guidelines share is compliance. It has been shown that the sheer existence of guidelines does not imply that they are followed by all health care professionals [67, 68]. In order to monitor, among other things, the quality of care at different places in a country, regional or national registries are needed. Registries facilitate follow-ups on quality and enable cross-checking of quality indicators and use of resources between different oncological centers. Once registries are in place, registry-based analyses can be used to enhance the quality and also the cost-effectiveness of care. In conclusion, clinical and health policy guidelines are needed to establish common quality standards, but at the same time registries are needed to monitor their attainment and compliance.

Country-specific results

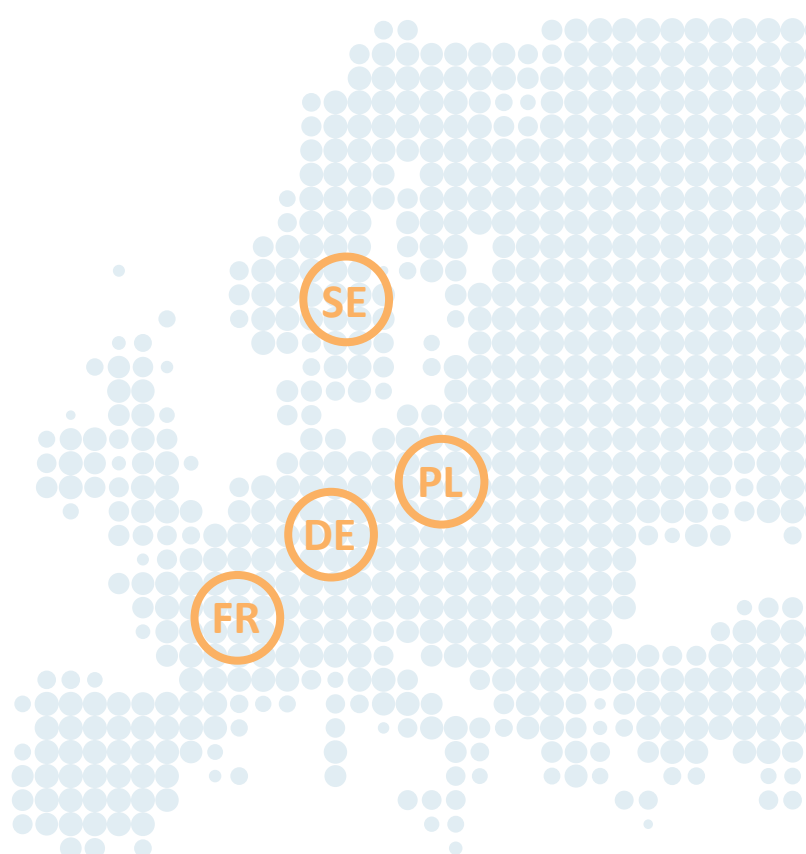
Comparable data on patient satisfaction for colorectal, lung or prostate cancer patients are not readily available¹². Only more general data on patient satisfaction with secondary care services are available. Such data might mirror the satisfaction of cancer patients though. Table 9 shows two indicators of public perceptions of secondary care regarding three different aspects; quality, availability and accessibility, and affordability. In France, the belief in good quality of both hospitals and medical or surgical specialists is high, whereas nearly half of the people think that the affordability of services offered by specialists is not very or not at all affordable. The public opinion about ease of availability and accessibility to hospitals and specialists is highest in Germany and lowest in Sweden. In contrast, only a small proportion of the public in Sweden thinks that affordability poses a difficulty. Finally, people in Poland hold the lowest opinion about the quality of hospitals and medical or surgical specialists among the four countries. However, perceptions about quality might also reflect to a certain degree the way the health care system is structured. As noted before, cultural norms may influence the subjective ratings of satisfaction presented in Table 9.

12. For breast cancer, comparable data on satisfaction are, for instance, collected by the patient organization Europa Donna.

Table 9: Public perceptions about quality of care for hospitals and medical or surgical specialists, 2007 [69]

	France	Germany	Poland	Sweden
Hospitals				
Quality (very good + fairly good)	83%	79%	42%	90%
Availability and accessibility (very easy + fairly easy)	80%	87%	69%	68%
Affordability (not very affordable + not at all affordable)	17%	24%	21%	7%
Medical or surgical specialists				
Quality (very good + fairly good)	87%	77%	57%	71%
Availability and accessibility (very easy + fairly easy)	62%	71%	52%	38%
Affordability (not very affordable + not at all affordable)	48%	28%	31%	7%

The country-specific cancer registries are reviewed in chapter 4 of this report. In general, all countries have cancer registries, but with very different degrees of completeness and scope. Hence, their ability to monitor the quality of care across the whole country and use them as a tool to enhance quality and cost-effectiveness of care varies. Sweden has the most comprehensive system of registries with both general and cancer-specific registries covering the whole country. On the other hand, France poorly monitors its cancer patients with a system of regional registries that only covers around 20 percent of the population. Germany also has a system of regional registries in place that does not cover the whole population, yet a national cancer registry is planned. In Poland a national cancer registry that is based on regional registries which cover the whole country exists.



3. Defining access to high-quality oncology care

3.2.3.

Quality of outcome

Quality of outcome is the third and final cornerstone that determines quality of cancer care. As pointed out before, the burden of cancer is comprised of a mortality component and a morbidity component. The attempt to alleviate the disease burden through care means aiming at both decreasing mortality, i.e. improving chances of survival, and decreasing morbidity, i.e. improving quality of life. Consequently, the performance of cancer care is reflected by the quality of treatment outcomes and can be measured by the survival prospects as well as the quality of life of cancer patients.

Survival rates are the most common outcome measure. The concept is easy to communicate to patients and, at least in theory, comparatively easy to monitor over time within or between countries or health care regions. By contrast, health-related quality of life (HRQoL) is a less common outcome measure in cancer patients. A uniform measurement method is not established. Given it being a multi-dimensional concept, it requires more data collection efforts than is the case for survival rates.

The lack of standardized and (internationally) comparable data on patient quality of life is disadvantageous for informing health policy. Patients suffering from the main cancer types, i.e. breast, colorectal, lung and prostate cancer, are typically aged over 50 years and many of them still in working age at the time of diagnosis. For instance, in the United Kingdom 32 percent of all new cancer cases¹³ are diagnosed in people aged 15-64 years, but almost half (47%) of all new cases are diagnosed in the age group 15-69 years [70]. In order to support labor market participation and to reduce the number of patients forced to retire early, the health state of the older share of the working-age population is critical. Amid plans across European countries to raise the statutory retirement age beyond 65 years [71], a stronger focus on the assessment and improvement of patient quality of life becomes increasingly important.

Survival rates

Survival rates measure the share of people that have been diagnosed with a certain type of cancer in a certain year and are still alive after a certain period of time after the diagnosis. Survival rates are related to the mortality burden of cancer and, as the OECD points out, reflect both how early the cancer was detected and the effectiveness of cancer treatment [37].

One of the biggest difficulties with survival rates as a measure of quality of outcome is the lack of up-to-date data. For instance, survival rates are often measured in terms of 5-year survival rates, i.e. the share of people diagnosed with a certain type of cancer in a distinct year t that is still alive in year $t+5$. That means that data on the 5-year survival rate of cancer patients diagnosed in 2010 can only be evaluated after 2015 with this method called “cohort analysis”. Nonetheless, there are other methods to get around this problem by using so-called “period analysis” or “mixed analysis” [72, 73].

The issue herein is that causal inferences have to be made very carefully, because the quality of treatment that patients receive right now can only be deducted retrospectively in a few years from now, when the survival rates of today’s patients can be evaluated. What is more, the advances in treatment of cancer patients are steadily progressing and thus the outcomes that we know of today reflect a picture from the past. Consequently, the assessment of the real impact of today’s cancer care in a certain country on outcomes cannot be made now. However, what can be done is to look at the changes in cancer care that occurred in the past that have led to the improvements in survival rates that we know of.

Finally, cancer survival rates are usually presented as relative survival rates rather than absolute survival rates. The relative survival rate refers to the ratio of two survival rates: the absolute survival rate of cancer patients divided by the expected survival rate of a group of people with corresponding age structure and gender distribution in the general population of the same country (or region) and calendar year¹⁴ [74]. By doing so, the survival rate is adjusted for the effect of different competing causes of death that could bias cross-country comparisons, because relative survival rates indicate the hypothetical situation in which cancer is the only cause of death [72, 75].

13. All cancers excluding non-melanoma skin cancer (C00-97/C44); average number of new cases per year (2008-2010)

14. Example: Assume that (1) the observed share of cancer patients that are alive 5 years after their diagnosis is 60%, i.e. the absolute survival rate. And assume that (2) the 5-year expected survival rate in the general population (with the same age profile, gender mix, etc.) is 80%. The 5-year relative survival rate is then $60\%/80\% = 75\%$. Thus, of the 40% ($1 - 0.60$) of cancer patients who were to die by 5 years, 25% ($1 - 0.75$) can be expected to die from cancer and the remaining 15% ($0.75 - 0.60$) from other causes.

Country-specific results

The latest available and comparable data on cancer survival rates in Europe (EUROCARE-3 to 5) cover the period from 1990 to 2007 [75-77]. Age-adjusted 5-year relative survival rates served as the outcome measure and were estimated separately for the periods 1990-1994, 1995-1999, 2000-2002 and 2000-2007. Estimates are available for different cancer types and countries. Figures 15 to 17 display the development of 5-year relative survival rates for colorectal, lung and prostate cancer for France, Germany, Poland and Sweden and for a European aggregate. The underlying figures for all graphs can be found in Table A5 in the Appendix.

For colorectal cancer, the 5-year relative survival rates in the period 2000-2007 were around 60 percent in France, Germany and Sweden, but only 46 percent in Poland, which was well

below the European average of 56 percent (see Figure 15). The survival prospects for colorectal cancer patients improved in all countries from 1990 to 2007. Germany started out from a somewhat lower level than France and Sweden but managed to edge up to both countries in 2000-2007. Significant improvements were achieved in Poland, but from a low initial level. A worrisome observation is that survival rates during the two overlapping periods 2000-2002 and 2000-2007 remained more or less stable in all countries. Several factors (e.g. increasing prevalence of obesity) might have contributed to this development and it should be noted that these survival rates cover the last bit of the pre-colorectal cancer screening era.

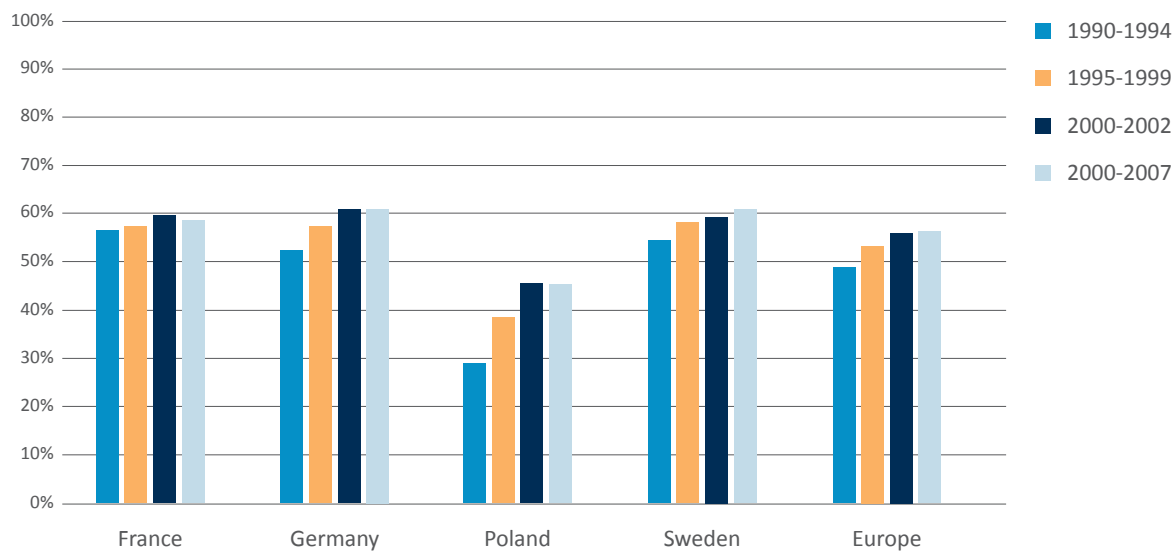


Figure 15: Colorectal cancer - age-adjusted 5-year relative survival rates in patients ≥ 15 years [75-77]

3. Defining access to high-quality oncology care

The 5-year relative survival rates for lung cancer in the period 2000-2007 were around 14-15 percent in all four countries which was above the European average of 13 percent (see Figure 16). Put another way, around 85-86 percent of all lung cancer patients die due to this disease within the first five years after the diagnosis. France was the only country

where survival rates did not improve between 1990-1994 and 2000-2007. However, the improvements observed in the other countries were only minor in absolute terms. In relative terms Poland doubled its 5-year relative survival rates between 1990-1994 and 2000-2007, but yet again from a low initial level.

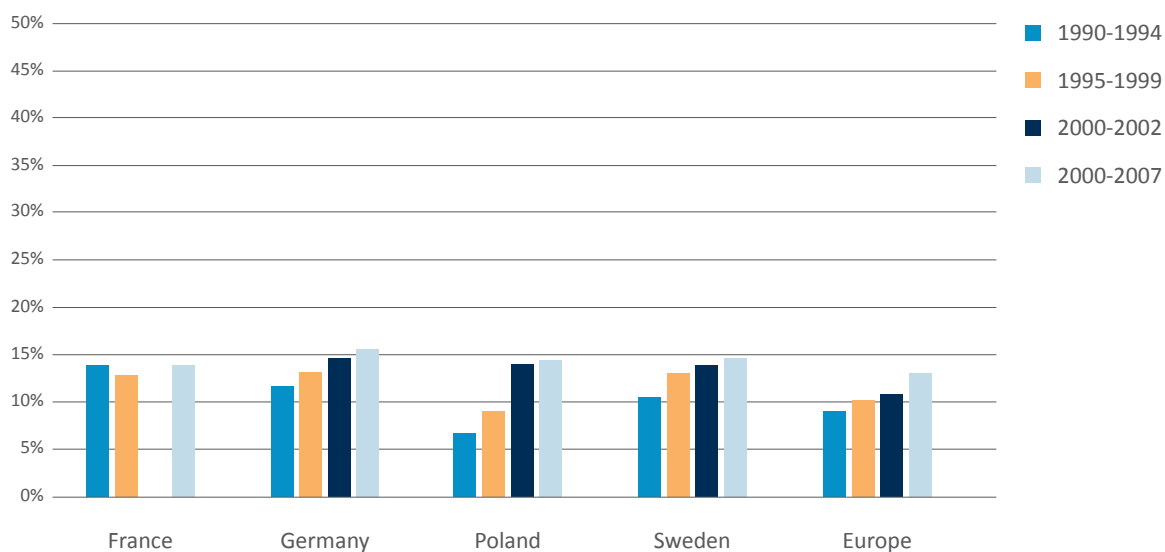


Figure 16: Lung cancer - age-adjusted 5-year relative survival rates in patients ≥ 15 years [75-77]

For prostate cancer, the 5-year relative survival rate in the period 2000-2007 was highest in Germany and France with 89 percent, followed by Sweden with 88 percent (see Figure 17). Poland at 67 percent was below the European average of 83 percent. However, Poland had shown a significant improvement in the 5-year relative survival rates of more

than 30 percentage points between the periods 1990-1994 and 2000-2002, but fell back in the period 2000-2007. Sweden improved quite considerably during the observed period and almost edged up to Germany and France. Starting from an already high level, the improvements in Germany and France were relatively smaller.

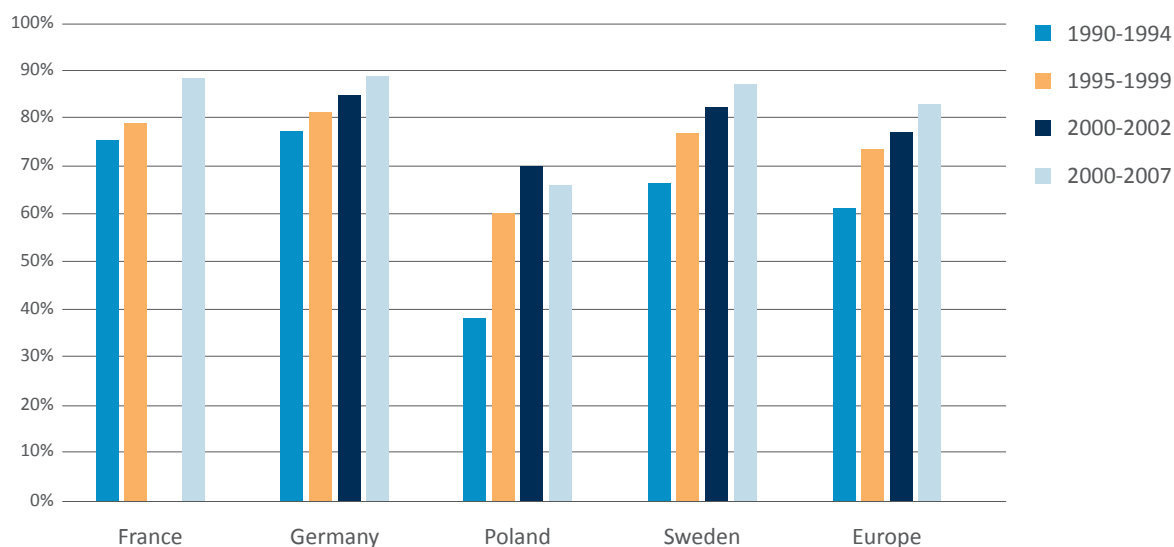


Figure 17: Prostate cancer - age-adjusted 5-year relative survival rates in patients ≥ 15 years [75-77]

Overall, Germany had the highest 5-year relative survival rates for all three cancer types among the investigated countries in the latest period from 2000-2007. France was the best performer in terms of 5-year relative survival rates in the period 1990-1994 for colorectal and lung cancer, but could not quite parallel the German improvements. In the period 1990-1994, the 5-year survival rates for lung and prostate cancer were lower in Sweden than in Germany and France, but already by 2000-2002 Sweden had caught up with these countries. In Poland the 5-year relative survival rates for all cancer types were markedly lower than the European average in 1990-1994. However, significant improvements were achieved for all cancer types, bringing Poland closer to the European average and in the case of lung cancer even beyond it.

Explanation of trends in survival rates

The general trend of increasing relative survival rates during the last decades in Europe has been attributed to advances in cancer management. Country differences have been explained by factors such as differences in accessibility to good care, different stage at diagnosis, different diagnostic intensity and screening approaches, differences in cancer biology, variations in socio-economic conditions, different lifestyles and general health [77].

Nevertheless, the interpretation of trends in cancer survival rates has to be made carefully. The aim is to determine how much of the observed improvements are due to improvements in screening, diagnosis and treatment. Increasing screening efforts and more sensitive diagnostic technologies detect more people with early-stage cancer, including some who would never have become symptomatic from their cancer [78]. Since survival of early-stage cancer patients is better, this can lead to an overall increase in 5-year survival rates. Obviously, countries with a worse stage distribution among patients, e.g. due to diagnostic delay and poorer awareness of symptoms, would have lower survival rates [79]. To take into account this effect of stage at diagnosis, one would need to examine stage-specific survival rates to isolate the impact of treatment. Previous analyses have shown that differences in colorectal cancer survival also exist for each stage of disease in Europe, suggesting unequal access to optimal treatment [79]. Finally, even stage-specific survival analysis comes with a drawback. More sensitive diagnostic technologies improve the accuracy of the classification of clinical stage, resulting in a phenomenon called stage migration. This happens when cancers previously classified as localized are now being classified as non-localized, which will result in improvements in survival in both groups (localized cancers and non-localized cancers) even when there has been no change in survival [80]. By contrast, all-stage survival analysis is not confounded by stage migration.

When discussing trends in survival rates, socio-economic differences in cancer survival are an additional point to consider. In general, it has been found that more affluent patients have better survival rates than deprived patients [81]. Stage at diagnosis seems to be a strong explanatory factor for these differences. It has also been documented that survival in elderly patients is related to them being married or widowed which influences their psychological status, life habits and social relationships [82]. Furthermore, differential treatment between social groups has been cited as a contributing factor to the socio-economic differences [83]. For instance, for metastatic colorectal cancer, it has been demonstrated that patients living alone receive less combination chemotherapy and less secondary surgery resulting in poorer survival [84]. The conclusion is that socio-economic differences affect access to cancer care and that social support needs to be targeted at disadvantaged groups to reduce the socio-economic imbalances in survival rates.



3. Defining access to high-quality oncology care

3.2.4.

CONCLUSION

The main concern of patients diagnosed with cancer is surviving the disease. The achievement of the highest possible quality outcome is therefore in the interest of patients. That means that a discussion about the quality of oncology care must be output-driven. However, a prerequisite for high outcome quality is high process quality and high quality of structure. Hence, all three domains that comprise quality of oncology care have to be considered in the discussion of improving quality of oncology care. This section highlighted that the previous discussion on access to oncology care, which distinguished between patients having access and patients gaining access, is incomplete. The kind of care that is available and that can be accessed is crucial for patient outcomes.

It is difficult to draw country-specific conclusions on the impact of the current quality of cancer care on future patient outcomes. Unfortunately, the impact of the quality of care that patients receive right now can only be deducted retrospectively in a few years from now, when reliable survival rates of today's patients are available. Nonetheless, the analysis has shown that the availability of medical technologies used for diagnostics is comparatively high in Germany and Sweden, somewhat lower in France, but distinctly lower in Poland. In the case radiation therapy machines that are used for treatment, Poland has an undersupply of almost 50 percent. The undersupply of these machines in Germany and in France is modest while Sweden seems to be able to fully meet the demand. A critical factor is, however, that Sweden experiences severe shortages of pathologists and radiologists and Germany lacks oncologists, which all are needed to make use of the available medical technologies. Furthermore, the shortages of these health care professionals are expected to worsen in the future, which will probably lead to long waiting times and thereby restrict patient access.

Identifying current and future bottlenecks in cancer care provision is important for improving patient outcomes. Sweden has a comprehensive system of cancer registries in place that allows monitoring of the quality provided in the whole country. Poland also has a nationwide cancer registry, but one that is less comprehensive than the Swedish one. Germany is about to implement a national cancer registry which should facilitate monitoring efforts of the quality of care. In contrast, France lacks a cancer registry covering the whole country. Despite the different monitoring systems in the four countries, the analysis in this section has shown that there is a general lack of relevant and up-to-date data. The lack of data is a major shortcoming and limits the ability of policy makers to take the right measures.

A recent OECD report examined the relationship between per-capita spending on health care (i.e. a general measure for input) and survival rates (i.e. one possible measure for output). Figure 18 shows that there is a non-linear relationship between input and output factors in the case of colorectal cancer [37]. Three important findings can be derived from this observation. Firstly, it seems that countries can attain fairly high survival rates with modest spending on health care. With increasing per-capita spending, the additional improvements in survival rates start to decrease. Secondly, the Polish example shows that without sufficient resource input, the achievement of high outcome quality is not feasible. Finally, the high variance in country results in Figure 18 underlines that health care spending alone is an insufficient predictor of outcome and that the quality of cancer care, i.e. how resources are spent as well as other organizational and process-related factors, plays an important role in fully explaining this relationship.

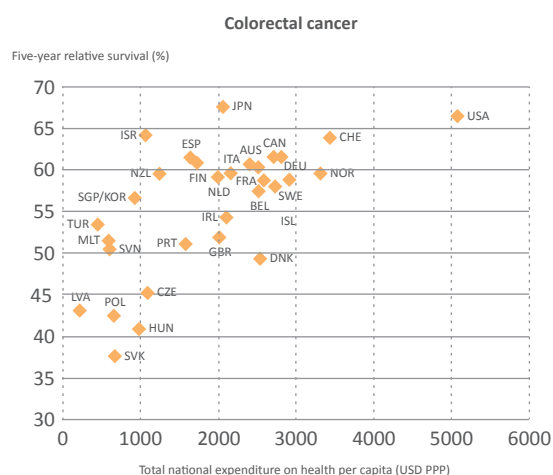


Figure 18: Relationship between survival for colorectal cancer and total health expenditure, OECD [37]

Notes: FRA = France, DEU = Germany, POL = Poland, SWE = Sweden.

4. Organization of oncology care

Conclusions

- All countries adopted a national cancer plan during the last decade. This underscores their determination to address the disease burden of cancer.
- Driven by guidelines from the European Commission, the promotion of cancer prevention through screening occupies a central role in all cancer plans. However, only France has an organized national screening program for colorectal cancer in place, while Germany is planning its implementation.
- At the moment, only Sweden has a comprehensive system of cancer registries. Comprehensive cancer registries covering the whole population are needed to monitor the quality of cancer care and to identify weak points in the system.
- All new drugs that seek reimbursement are subject to a mandatory assessment in all countries. Germany was the last country to implement this policy in 2011. Moreover, a paradigm shift happened in France in October 2013 when economic considerations were explicitly included in the mandatory assessment – as is the case in Poland and Sweden. Germany is now the only country where the therapeutic relevance alone is the main criterion for a positive reimbursement decision.
- The recent changes in reimbursement and pricing policies in France and Germany were carried out in light of containing pharmaceutical expenditures. The extent to which these policies will restrict patient access to new cancer drugs remains to be seen. It is clear though, that patient access to new and effective cancer drugs is a prerequisite for improving patient outcomes. Access restrictions undermine the provision of effective cancer care and lead to lower patient outcomes. The example of Poland, where serious underfunding of the health system restricts patient access to new drugs, is indicative of this case.

This chapter gives a brief overview of the health care system of the four countries considered in this report. It provides information on the organization of oncology care, on national cancer plans and their priorities, as well as on cancer registries. The reimbursement and pricing process

of pharmaceuticals is also described. Each country-specific section contains an information box providing some basic demographic, economic and cancer-related facts¹⁵. Finally, Table 10 presents some key characteristics of the four countries and a summary of key differences is provided.

15. Note that “all types” in the information boxes refers to cancer types C00-96/C44, i.e. all types but non-melanoma skin cancer.

4. Organization of oncology care

4.1.

France

FRANCE 2012 [1,2]		
Population:	65.5 million	
Share of population aged 50-79	31.0%	
GDP (in PPP per capita)	€27,500	
Health expenditure (% of GDP) (2011)	11.6%	
	Female	Male
Cancer incidence (all types), no. of cases	160,360	211,320
Cancer mortality (all types), no. of cases	64,460	90,110
Top 3 cancer types (incidence)	1. Breast 2. Colorectal 3. Lung	1. Prostate 2. Lung 3. Colorectal
Top 3 cancer types (mortality)	1. Breast 2. Lung 3. Colorectal	1. Lung 2. Colorectal 3. Prostate

The French health care system is universal and covers almost 100 percent of the population. Health care is provided by public and private sources. Ambulatory care is mostly in private hands and delivered by self-employed professionals, whereas hospital care is predominantly public or private non-profit. The provision of health care has recently undergone some changes following the 2009 Hospital, Patients, Health and Territories Act. 26 regional health agencies (*Agences Régionales de Santé*, ARS) were established on April 1, 2010 covering both metropolitan France and the overseas departments. The ARS were tasked with ensuring health care provision meets the needs of the population by improving communication between the ambulatory and hospital sector as well as the social care sector. The ARS work within a national framework and the state enforces health policies and oversees their implementation. The national health insurance fund finances public health care. Public health insurance (*assurance maladie obligatoire*) is compulsory and is mainly financed by income-based contributions from employees and employers and also by earmarked taxes. In 2007, around 79 percent of total health expenditures were funded by the national health insurance fund. It is common to have a voluntary private health insurance that supplements the public health insurance and that covers most out-of-pocket payments [85].

Cancer care

Since the first national cancer plan for 2003-2007 regional cancer networks (*Réseaux Régionaux de Cancérologie*, RRC) coordinate cancer care. There are currently 21 RRCs in metropolitan France and 4 RRCs covering the overseas departments. The RRCs are responsible for promoting and improving the quality of oncology care, the dissemination of recommendations for good clinical practice and the collection of data on cancer care and quality assessment. The RRCs are guided by the National Institute for Cancer (*Institut National du Cancer*, INCa), which was set up in 2004 [86]. A second national cancer plan was implemented for the period 2009-2013. As a part of the national cancer plans, large investments have been made in diagnostic and therapeutic equipment in order to increase access [87], and two national screening programs for breast cancer and colorectal cancer have been implemented. Certain innovative drugs are also made available by more accessible reimbursement policies. A new cancer plan is expected to be launched in 2014 [88].

As of June 2010, 881 health facilities were allowed to treat cancer patients following institutional accreditations issued by the responsible ARS [85, 86]. They provided care in the main areas of oncology; chemotherapy, cancer surgery, radiation therapy. There are 20 non-profit private hospitals specializing in cancer treatment, with a broad remit that includes prevention, screening, treatment, teaching and research. They are the main providers in the area of cancer treatment [85].

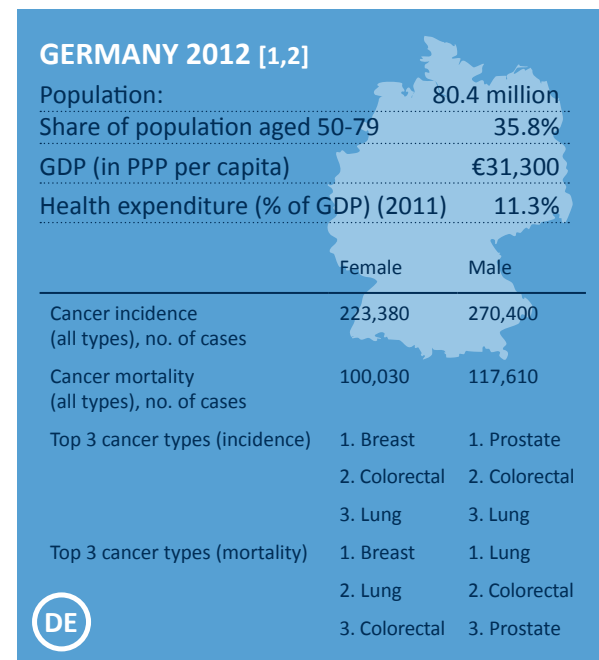
Cancer data in France are managed by three institutions: the French network of cancer registries (FRANCIM), the Epidemiological center on medical causes of death (*CépiDc-Inserm*) and the Institute for Public Health Surveillance (InVS). Only mortality data were collected at a national level in 2010. Most cancer data were collected at local level by 21 cancer registers covering some 20 percent of the population. 13 of the 21 registers are general, collecting data on every type of cancer in a defined area. The remaining eight registers are specialized, collecting data on specific cancer types, e.g. there are three registers for digestive cancers. Two registers are specialized in childhood cancer and collect data nationally. The FRANCIM gathers all registers and runs a database. The InVS ensures the quality of the data by monitoring the data collection process [44].

Reimbursement and pricing of pharmaceuticals

Since its establishment in 2004, the High Authority on Health (*Haute Autorité de Santé*, HAS) is the central HTA body in France. HAS assess all drugs authorized by the EMA or by the national drug agency (*Agence Nationale de Sécurité du Médicament et des Produits de Santé*, ANSM). Within the HAS, the Transparency Committee (*Commission de transparence*) performs the clinical evaluation, which includes two elements. Firstly, the medical benefit (*Service Medical Rendu*, SMR) is assessed and given one of the following five ratings: major, important, moderate, low or insufficient. Secondly, the improvement of the medical benefit (*Amélioration du Service Médical Rendu*, ASMR) is the result of a comparison with an existing treatment options. The ASMR can be major (I), important (II), moderate (III), minor (IV), none (V) or negative (VI) [89].

The assessment of the HAS is then sent to the Economic Committee on Health Care Products (*Comité Économique des Produits de Santé*, CEPS) which belongs to the Department of Health. Based on the SMR and ASMR ratings, the CEPS fixes a price after negotiations with the pharmaceutical manufacturer. The reimbursement decision is made by the National Union of Health Insurance Funds (*Union Nationale des Caisses d'Assurance Maladie*, UNCAM). Four reimbursement rates (100%, 65%, 30% and 15%) are possible, which usually correspond to the SMR rating (insufficient SMR is not reimbursed). Once approved for reimbursement, a drug will be on a positive list for five years after which it will be re-evaluated and its price and reimbursement rate reviewed [90]. In 2008, the HAS established a separate committee responsible for economic evaluation of new drugs (*Commission Évaluation Économique et de Santé Publique*, CEESP), yet health-economic studies were rarely considered. However, in October 2013 a mandatory economic evaluation by the CEESP for new drugs with implications for reimbursement and pricing was introduced [91]. Since 2012, the introduction of the so-called Relative Therapeutic Index (*Index Thérapeutique Relatif*, ITR) to replace the current systems of SMR and ASMR has been discussed with no concrete measures yet taken.

4.2. Germany



The organization of the German health care system is linked to the federal organization of the country. The authorities responsible for public health services are the Bund at national level, the Länder at regional level and the Gemeinden at local level.

The financing of the health care system is based on social health insurance through some 134 Statutory Health Insurance Funds (SHIF) (*Krankenkassen*) covering about 90 percent of the population [92]. The remaining part of the population has private health insurance. Public health insurance is mandatory for people without private health insurance [93]. Since 2009 the SHIFs are financed by the national health fund that in turn is financed by income related contributions¹⁶ by employers and employees. Only 4.8 percent of the total health expenditures are financed centrally by taxes [94]. Ambulatory care and hospital care have traditionally been distinct domains with almost no outpatient care delivered in hospitals. Hospital inpatient care is provided by a mix of public and private providers. Private hospitals are mostly run by non-profit organizations.

16. As of 2011 the uniform contribution rate was set at 15.5 percent of income by the government.

4. Organization of oncology care

Cancer care

Cancer care in Germany is coordinated in a federal government program. In Germany there are about 48 Tumorzentren bringing together specialized cancer care with a regional uptake [95]. These may be organized within a single organization or in a network also involving regional hospitals. A number of regional hospitals also organize cancer treatment themselves. The Tumorzentren are often, but not always attached to university hospitals. In 2013, twelve of these centers are also designated Comprehensive Cancer Centers [96]. Cancer care can also be administered outside of the Tumorzentren in outpatient facilities and private practices.

On April 9, 2013 the “act on early cancer detection and cancer register” (*Krebsfrüherkennungs- und -registergesetz, KFG*) came into force as part of the National Cancer Plan from 2012. A national cancer registry will be established as well as national cancer screening programs implemented. So far only the mammography screening program fulfills the requirements of an organized nationwide screening program. The aim of the National Cancer Plan is to improve the organization of the currently existing non-organized screening programs for cervical and colorectal cancer and to adapt them according to the European Commission’s guidelines [97].

Reimbursement and pricing of pharmaceuticals

The Federal Joint Committee (*Gemeinsamer Bundesausschuss, G-BA*) is the central decision making body concerning drug provision for those with statutory health insurance. The G-BA is comprised of representatives for doctors, dentists, hospitals, the SHIFs and patients. Reimbursement and pricing of new pharmaceuticals to be covered by the SHIFs has recently undergone a major revision with the Act on the Reform of the Market for Medical Products (*Arzneimittelmarktneuordnungsgesetz, AMNOG*) [98]. Since 2011, pharmaceutical companies are for the first time obliged to submit a dossier to the G-BA on product benefit when a new product is launched on the German market or authorized for new indications. The G-BA assesses any additional benefit claimed over the appropriate comparator. The G-BA can delegate the benefit assessment to the Institute for Quality and Efficiency in Health Care (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG*) or third parties [99].

At the end of the assessment a drug receives a score between 1 and 6 depending on the level of added benefit. The score greatly impacts the reimbursement and pricing prospect of the drug. If added benefit is proved (score of 1 to 4), the Federal Association of the SHIFs (*GKV-Spitzenverband*) and the pharmaceutical company negotiate the reimbursement price paid by all SHIFs plus all private health insurance companies. This takes the form of a rebate on the retail price originally set by the company. If no agreement is reached, an arbitration board determines the reimbursement price using European pricing levels as its standard. If the G-BA decides that the new drug does not have any added benefit (score of 5 or 6), it will be included in the reference price system under a non-negotiable price [99]. However, the negotiated price is only valid from the second year after market launch. Within the first year after market launch, i.e. during the assessment by the G-BA and price negotiations, the manufacturer can sell the drug at a freely chosen price [100].

4.3. Poland

POLAND 2012 [1,2]		
Population:	38.5 million	
Share of population aged 50-79	31.6%	
GDP (in PPP per capita)	€16,800	
Health expenditure (% of GDP) (2011)	6.9%	
	Female	Male
Cancer incidence (all types), no. of cases	74,510	77,710
Cancer mortality (all types), no. of cases	41,930	53,030
Top 3 cancer types (incidence)	1. Breast 2. Colorectal 3. Lung	1. Lung 2. Colorectal 3. Prostate
Top 3 cancer types (mortality)	1. Lung 2. Breast 3. Colorectal	1. Lung 2. Colorectal 3. Prostate

Poland's health care system is financed by both public sources (around 70% of total health expenditures) and private sources. Universal and compulsory health insurance (covering 98% of the population) was introduced in 1999 and constitutes the majority of public financing. In 2003, the social insurance system was centralized, with the creation of the National Health Fund (*Narodowy Fundusz Zdrowia*, NFZ) that replaced a system of 17 sickness funds [101]. The NFZ is responsible for providing access to medical services by contracting public and non-public health care providers [102, 103]. The NFZ operates 16 regional branches and also finances selected public-health programs, medicines prescribed in ambulatory care, experimental programs, rehabilitation and spa treatments, as well as long-term care. Central and local governments are responsible for reimbursing the costs of health services for certain uninsured groups, financing specific health programs and emergency and lifesaving services. Local governments fund the every-day operational costs of hospital facilities (gas, electricity, water), the maintenance of buildings, repairs and renovations, and investments in medical equipment [104]. The insured have the right to health services including primary health care provided by GPs. The sickness fund contracts GPs from which the insured can choose freely for primary care. Hospital services are in general subject to referral from a GP [102]. Private health care financing plays a larger role in Poland than

in most other EU member states and comes mainly from out-of-pocket spending (about 22% of total health expenditures in 2009). The role of voluntary health insurance is limited and mostly comes in the form of medical subscription packages offered by employers [103].

Cancer care

Cancer care in Poland is organized in a three-tier system. At the top tier is the Maria Skłodowska-Curie Institute of Oncology in Warsaw which is the leading and most specialized cancer research and treatment center in Poland. The second tier consists of 16 regional Comprehensive Cancer Centers, which provide overall cancer treatment, including chemotherapy, radiotherapy, and surgery, in one institution [105]. The third tier consists of cancer wards and chemotherapy and radiotherapy units in hospitals, many of which are attached to medical faculties at universities. In addition, there are consultation points and outpatient oncologic clinics located in larger cities.

People with cancer have guaranteed access to health care, including prescribed chemotherapy, financed by the NFZ. Oncology services are funded almost entirely out of public sources, i.e. on the one hand from the national budget as sustained by tax revenues (Ministry of Health) and on the other hand from the NFZ as sustained by the obligatory public health insurance contributions. Resource allocation decisions and co-payments rest with the Minister of Health, which covers oncology needs from the central budget, and with the President of the NFZ. Co-payments for oncology services and drugs are very small compared with other health care provisions in Poland [106]. In general, drugs proven to be effective in cancer treatment and which are reimbursed are available to all insured persons free of charge [103].

In 2005, a national cancer plan was adopted for the period 2006–2015. The list of objectives shows a strong focus on early detection, but also on prevention, and enhancing treatment effectiveness as well as monitoring the effectiveness of the fight against cancer. Among other things, population programs for early detection of cervical, breast and colorectal cancer and selected cancer types in children are to be implemented, the procedures for radiation therapy to be standardized and combined treatment methods to be disseminated. For the whole ten year long implementation period PLN 3 billion (ca. €750 million) in funds are made available from the government, which corresponds to around €2 per citizen and year; 10 percent of the funds are earmarked for early cancer detection [106, 107].

The Polish National Cancer Registry in Warsaw collects and processes data from a network of 16 Regional Cancer Registries that cover the whole population [106].

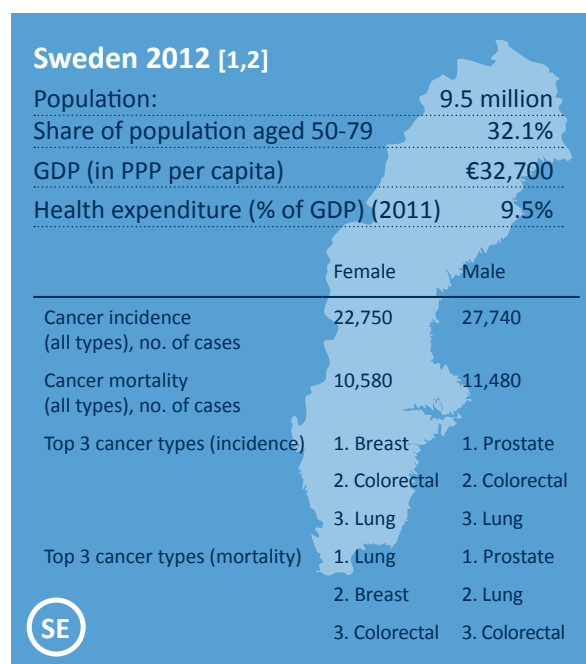
4. Organization of oncology care

Reimbursement and pricing of pharmaceuticals

Reimbursement decisions and prices are set by the Ministry of Health [108]. The Agency for Health Technology Assessment in Poland (*Agencja Oceny Technologii Medycznych*, AOTM) was established in 2005 as an advisory body to the Ministry of Health. Its role is to assess and appraise all medical technologies and services claiming public funding. The AOTM prepares recommendations for the Minister of Health on the financing of health care services from public funds, i.e. drug reimbursement list, therapeutic drugs programs (high-cost, innovative drugs) and hospitals' chemotherapy drugs list, non-drug technologies (medical devices, surgical procedures, etc.), and national and local government health care programs. Recommendations, statements and opinions issued by the AOTM are based on officially published data, expert opinions, manufacturer submissions and NFZ evaluations. For its own evaluations the AOTM draws on the Polish HTA guidelines (first issue 2007; current version from April 2009) [109]. However, only 35 percent of all drug technologies that received a positive HTA recommendation from AOTM during 2007-2009 were eventually reimbursed [110].

Positive reimbursement lists have been in place since the end of 2009 and are issued periodically by the Ministry of Health [103]. Since 2012, the regulated prices for reimbursable drugs are set by the Ministry of Health based on price negotiations between the pharmaceutical manufacturer and the Economic Committee, which is an advisory body of the Ministry [104, 111]. For non-reimbursable pharmaceuticals, the manufacturer/importer sets the price freely ("free pricing") [104].

4.4. Sweden



Financing and provision of health care in Sweden is decentralized to 21 county councils at a regional level, whereas overall health policy is defined at the state level. About 80 percent of all expenditures on health are public expenditures financed mainly through regional taxes supplemented by national taxes. Health services are subject to small point-of-service fees to the patient, and prescribed outpatient pharmaceuticals are co-financed by the individuals up to a fixed ceiling. These private expenditures on health amount to around 17 percent of total health expenditures. Private health insurance plays a marginal role in financing and only 4 percent of the population have a voluntary health insurance [66]. Primary care is given by health centers, while secondary care delivery is dominated by public hospitals owned by the county councils. In addition, the county councils are grouped into six medical care regions for coordination of highly specialized care, mainly provided by the university hospitals in each region. Private providers play a limited but growing role in provision of health care [66].

The National Board of Health and Welfare (*Socialstyrelsen*, SoS) has a supervisory role in monitoring the quality of health care provided by county councils, local authorities and private institutions. The Swedish Council on Health Technology Assessment (*Statens beredning för medicinsk utvärdering*, SBU), founded in 1987, assists the county councils in their decision making by reviewing and evaluating health care technology from medical, economic, ethical and social points of view [66].

Cancer care

Cancer care in Sweden is administered at a regional level. Within each of the six medical care regions there is a cancer center, coordinating its own cancer care resources. The regional cancer centers (RCC) are also responsible for regional cancer registries and the promotion of a series of cancer care and prevention initiatives. In 2011, these six centers have been tasked with ensuring that cancer care becomes more coordinated at a national level, patient-oriented and knowledge-based as part of the national cancer strategy [112].

In 2011, the SoS published recommendations for lung cancer care in the areas of diagnostics, surgery, radiotherapy, drug treatment, care and palliation [113]. Similar recommendations for breast, prostate, and colorectal cancer that also include target levels for some indicators have already been issued in 2007 and updated in 2013 [55].

Since 1958, a national full coverage cancer registry has been in place based on data collected by the regional cancer centers. Since 1996 there is also a specific prostate cancer registry in Sweden with a greater level of detail than the general cancer registry. A specific lung cancer registry has been collecting data since 2002 and a colorectal cancer registry since 2007, even though a rectal cancer register already started in 1995 [114].

Reimbursement and pricing of pharmaceuticals

Since 2002, the Dental and Pharmaceutical Benefits Agency (*Tandvårds- och läkemedelsförmånsverket*, TLV) decides on the reimbursement of drugs and their inclusion in the National Drug Benefit Scheme. In 2010, the mandate of the TLV was augmented to also include the assessment of hospital drugs. The reimbursement decisions are principally based on the cost-effectiveness of a drug. Moreover, value-based pricing is employed for prescription drugs and a societal perspective used in the TLV's assessments of cost-effectiveness and decisions on reimbursement. A time limit of 120 days for decisions on reimbursement and pricing has been set by the Swedish government [66].

The cost of pharmaceuticals in both inpatient and outpatient care are borne by the county councils. However, they receive subsidies for prescription drugs covered by the national reimbursement scheme through designated state grants. Prescription drugs are also co-financed by the patient. Co-payment corresponds to about 25 percent of all expenditures for prescription drugs. Regarding pharmaceuticals for use in inpatient care, decisions are made by hospitals or clinics at hospitals. In most county councils the financial responsibility for drugs is decentralized

to the prescribing physicians. In each county council there is a formulary committee whose responsibility is to make recommendations concerning the use of pharmaceuticals. The recommendations should support physicians in their choice of pharmaceuticals by listing medicines recommended as the first choice of treatment for a range of common diseases. Prescribers are encouraged to follow the recommendations via financial incentives.

Generic substitution has been mandatory for medically equivalent pharmaceuticals reimbursed since 2002. The Medical Products Agency (*Läkemedelsverket*) decides whether drugs are medically equivalent. Patients can, however, choose to pay the extra dividend for a non-generic drug [115]. In 2009, the sales of generics corresponded to 14.4 percent of the total sales value of pharmaceuticals. This was equal to almost 45 percent of the total sales volume in terms of defined daily doses [66].

4. Organization of oncology care

Table 10: Country comparison of selected characteristics of health care, cancer care and reimbursement and pricing of pharmaceuticals

	France	Germany	Poland	Sweden
Health care				
Share of population covered by public health insurance	almost 100%	90%	98%	100%
Cancer care				
Provision	The INCa guides 26 regional cancer networks; 881 health facilities accredited by the 26 regional ARS	48 regional Tumorzentren; outpatient facilities and private practices	Three-tier system: 1. Institute of Oncology 2. 16 regional CCCs 3. Cancer wards and hospitals, consultation points and outpatient oncologic clinics	6 regional cancer centers coordinating care in each region
National cancer plan	1st plan 2003-2007 2nd plan 2009-2013 3rd plan 2014 (expected)	Current plan adopted in 2012	Plan for 2006-2015	"A National Cancer Strategy for the Future" adopted in 2009
Cancer registry	Only mortality data collected at national level; 21 local registries (13 general and 8 specific) covering 20% of the population	National cancer registry is planned; Several regional registries not covering the whole population are in place now	National full coverage registry based on 16 regional registries	National full coverage registry and cancer specific registries
Organized national screening programs	Breast cancer (since 2003) Cervical cancer (opportunistic) Colorectal cancer (2008)	Breast cancer (2005) Cervical cancer (planned) Colorectal cancer (planned)	Breast cancer (2006) Cervical cancer (2006) Colorectal cancer (since 2000 opportunistic)	Breast cancer (1986) Cervical cancer (1976) Colorectal cancer (since 2008 in 1 medical region)
Reimbursement and pricing of pharmaceuticals				
Body responsible for assessment	Transparency Committee within the High Authority on Health (HAS)	Federal Joint Committee (G-BA); possibly also the Institute for Quality and Efficiency in Health Care (IQWiG) or third parties	Agency for Health Technology Assessment (AOTM)	Dental and Pharmaceutical Benefits Agency (TLV)
Body responsible for reimbursement decision	Union of Health Insurance Funds (UNCAM); Ministry of Health decides on listing	G-BA	Ministry of Health	TLV

Main criteria for reimbursement decision	Safety, effectiveness, diseases severity, preventative/curative nature of the disease, interest in terms of public health, economic evaluation	The drug must not belong to one of the categories excluded from reimbursement by the law of the G-BA	Main criteria for positive recommendation by the AOTM: clinical effectiveness, efficacy, safety, cost-effectiveness ratio	Cost-effectiveness; need and solidarity and human value principles
Body responsible for pricing decision	Economic Committee on Health Care Products (CEPS)	Federal Association of the SHIFs (GKV-Spitzenverband) after negotiations with manufacturer	Ministry of Health	TLV for purchase and retail price

Summary of differences between countries

- In all countries but Germany the whole or almost the whole population is covered by public health insurance. People in Germany not covered by public health insurance have a private one.
- The provision of cancer care is steered centrally in France and Poland, and regionally in Germany and Sweden.
- All countries adopted a national cancer plan during the last decade.
- All countries have cancer registries, but with very different degrees of completeness and scope. Sweden has the most comprehensive registries, whereas France monitors its cancer patients poorly.
- A nationally organized screening program for colorectal cancer only exists in France, though Germany is planning its implementation and Sweden is conducting a pilot-study in one county council. For prostate or lung cancer no organized screening programs exist in any country.
- In recent years, significant changes in the regulative procedures for reimbursement and pricing of pharmaceuticals have occurred in all countries but Sweden. In France and especially in Germany, the main reason for these changes was cost containment of pharmaceutical expenditures.
- Germany was the last of the four countries to introduce a mandatory assessment of all new pharmaceuticals claiming public funding in 2011.
- Germany is the only country where the therapeutic relevance of pharmaceuticals is the main criterion used to inform the reimbursement decision. In Poland, Sweden and since October 2013 in France, economic considerations play an important role alongside the therapeutic relevance.
- The influence of national HTA agencies' assessments in reimbursement decisions differs greatly between countries. In Sweden, the HTA agency is itself responsible for reimbursement. The situation in Germany is somewhat similar to that in Sweden. In France, the assessment of the HTA agency is decisive for the reimbursement decision. In Poland the majority of pharmaceuticals with a positive recommendation from the HTA agency are not reimbursed due to budgetary issues.
- Generic substitution is mandatory in Germany and Sweden, and indicative in France and Poland. The main rationale of this policy is to contain pharmaceutical expenditures without compromising health objectives. It is surprising to see that France, despite its aim of cost containment, and Poland, where sufficient funding is a serious problem, have not made generic substitution mandatory yet, even though European Commission staff papers advocate such a step [116].

5. Access to quality in oncology care – Screening

5.1.

Principles for high-quality screening

Conclusions

- **To be accessible and effective, cancer screening programs have to satisfy a number of criteria.** These include the type of organization, public information campaigns, the test method, the target group, the screening interval, the follow-up actions, and a system to monitor the quality of the program at all stages.
- **The success of screening programs, as measured by the realized screening rates, is directly affected by these screening-specific determinants together with the general determinants of access to health care.**
- **Cancer screening programs must be accompanied by a system to follow up the detected cases.** Otherwise the benefits of early detection cannot be reaped.
- **Not all cancer screening programs are beneficial.** The impact of **prostate cancer screening** with PSA testing on mortality is ambiguous and there is evidence that the harms outweigh the benefits. Sufficient evidence on the effectiveness of **lung cancer screening** still has to be established. In contrast, **colorectal cancer screening is an effective method to reduce colorectal cancer induced mortality. Its cost-effectiveness is also better compared with screening for other cancers.**
- **Countries should take some resources used for prostate and/or breast cancer screening and devote it to colorectal cancer screening instead.**
- **France and Germany could attain efficiency gains by spending less on prostate cancer screening and instead investing the savings in the existing program for colorectal cancer screening and/or cancer treatment.**
- **Additional investments are needed both in Poland to modify the current colorectal cancer screening program, and also in Sweden to extend the current regional program to nationwide one.**

Besides prevention initiatives and actual treatment, screening is one of the three main areas where active measures can be taken to affect patient outcomes and to alleviate the burden of cancer. Screening plays therefore a prominent role in the overarching aim of improving access to high-quality oncology care. Population screening aims to detect cancer at an early stage among asymptomatic people. Early detection is important as the curability of cancers at an early stage is easier to achieve than that of cancers at an advanced/metastasized stage. Hence, ensuring access to effective screening helps to reduce the morbidity and mortality from the disease [51]. It should be clear though, that the benefits of screening can only be reaped, if detected cancer cases are followed up and receive the appropriate treatment.

This chapter will first focus on general principles for efficient and high-quality screening. These will be reviewed together with evidence on the benefits of organized screening programs for colorectal, lung and prostate cancer. Secondly, the screening programs that the four countries have in place for the three cancer types are reviewed. The realized screening rates indicate the accessibility of these programs and hence their success. Finally, by contrasting evidence on high-quality screening with the existing programs and their outcomes, recommendations on improvements are derived for each country.

5.1.1

Determining factors

Several factors determine the quality and success of cancer screening programs. The first one is the type of organization. Three organization types of cancer screening programs can be distinguished; organized population-based screening programs, non-organized screening programs or opportunistic case finding [51, 117]. Organized population-based screening programs address a healthy population

Determinants of high-quality screening:

- Type of organization
- Public information campaigns
- Test method
- Target group
- Screening interval
- Follow-up actions
- Quality assurance at all levels

segment eligible for screening and actively urge the whole target population to participate. This means that people receive a personal invitation for screening and a reminder after some time in case they did not show up after the initial invitation. Moreover, a recall at the prescribed intervals for screening is sent out. In contrast, non-organized population-based screening programs define an asymptomatic target population which has a right to receive screenings but these programs lack the active element of personally contacting eligible people. Finally, opportunistic screening occurs when a screening test is offered to an individual without symptoms of cancer when they present to their health care practitioner for unrelated reasons. The WHO emphasizes that only organized screening programs are likely to be fully successful as a means of reaching a high proportion of the at-risk population. Other methods are unlikely to realize the full potential of screening [118].

The second factor for high-quality screening is public information campaigns. They are intended to raise awareness and to inform people about the benefits of screening. Information campaigns have been shown to be a powerful tool to promote and increase the utilization of screening services by lowering peoples' reservations and concerns about it [119-122].

The third factor is the test method used in screening. The method has to be safe and effective. The effectiveness depends on the accuracy of the screening methods. The accuracy is determined by both the frequency of false positive diagnoses (i.e. detection of cancer that does not exist; type I error) and on the frequency of false negative diagnoses (i.e. failure to detect existing cancer; type II error). In medical terms, an effective screening method should be characterized by high sensitivity, i.e. as few as possible with the disease get through undetected, and high specificity, i.e. as few as possible without the disease are subject to further diagnostic tests [118]. Hence, the effectiveness of the screening method influences the number of deaths that can be prevented, and the number of unnecessary treatments that are caused [123].

The fourth factor for high-quality screening is the correct selection of the target group. The target population should be a population segment that has an increased risk of developing a certain cancer type, e.g. all people older than 50 years, or all people older than 50 years that have a history of smoking. The WHO also notes that screening that concentrates solely on a high-risk group is rarely justified, as identified risk groups usually represent only a small proportion of the cancer burden in a country [118]. Thus, the target group should not be defined too narrowly. However, defining the target group too broadly will increase the number of people subject to false positive diagnosis and also negatively impact on the cost-effectiveness of the screening program.

Cost-effectiveness considerations are also important for the fifth factor; the interval between screening sessions. If the interval is too short, it will lead to high screening costs with no additional benefit for the patient. If the interval is too long, the benefit of screening in terms of detecting cancer at an early stage is reduced. The follow-up actions taken after a positive diagnosis form the sixth factor for high-quality screening. That means that mechanisms for referral and treatment of abnormalities have to be defined [118].

The seventh and last factor for high-quality screening is the coordination and quality assurance of activities across the entire pathway. This factor is essential if a screening program is to attain mortality reductions [51]. This includes a quality control system to manage and monitor screening tests and clinical quality as well as an information system that can send out invitations for initial screening, recall individuals for repeated screening, follow those with a positive diagnosis, and monitor and evaluate the program.

5. Access to quality in oncology care – Screening

5.1.2. The impact of screening on survival

As mentioned before, screening efforts aim at detecting cancer cases at an earlier stage which facilitates their treatment and thus enhances chances of survival. However, this does not automatically imply that countries with high screening rates are marked by good survival odds. Whether this holds true depends crucially on the quality of treatment that one receives after the diagnosis. In order to disentangle the effects of screening and cancer treatment on survival, the following has to be considered.

To identify the impact of treatment quality on survival in different countries, one would need to compare the survival rates of patients being diagnosed with cancer at equal stages. By holding cancer stage constant, survival itself depends on the type of care and treatment that is being provided. In contrast, assuming that treatment quality is equal across countries, those countries with higher screening rates should have higher survival rates, because more cancer cases are detected at an early stage where the curability is better.

Nonetheless, in the absence of any treatment, cancer usually leads to death irrespective of whether the cancer was discovered through screening or not. Hence, high-quality screening increases the potential to improve survival, but it is the type and quality of care that determines the survival of patients after the diagnosis.

5.1.3. The EU's stance on cancer screening

Cancer screening efforts have been on the agenda of the European Union since 2003, when the Council of the EU adopted a recommendation on this topic [7]. The recommendation encompassed the implementation of nationwide organized screening tests for three cancer types; cervical, breast and colorectal cancer. The member states were urged to take action and to ensure equal access to screening taking due account of the possible need to target particular socio-economic groups. Since then, the European Commission has issued screening guidelines for breast cancer (latest edition from 2006) [8], for cervical cancer (latest edition from 2008) [9], and for colorectal cancer (see below).

5.1.4. Colorectal cancer screening

In 2010, the 1st edition of the European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis was issued by the European Commission [10]. It contains over 250 recommendations, individually graded according to the strength of the recommendation and the supporting evidence. The recommendations address the entire screening process, including identification and outreach to the target population, diagnosis and management of the disease and appropriate surveillance in people with detected lesions. It was concluded that although none of the currently available screening tests were ideal, the immunochemical fecal occult blood test (iFOBT) and the guaiac fecal occult blood test (gFOBT) for men and women aged 50-74 years fulfill the criteria for screening set out by the Council of the EU. The interval between two negative screening examinations with gFOBT should not exceed two years, whereas the interval for iFOBT screening should not exceed three years. It also was noted that there is evidence showing that iFOBT is superior to gFOBT with respect to detection rates and positive predictive value for adenomas and cancer. Finally, it was acknowledged that there exists some evidence that iFOBT is a cost-effective alternative to gFOBT.

In general, there is broad consensus and well-established evidence that colorectal cancer screening with FOBT reduces mortality [124-126]. Simulations for the United States also indicate that declines in mortality will continue if risk factor modification, screening, and treatment remain at current rates, but that they could be accelerated further with favorable trends in risk factors and higher utilization of screening and optimal treatment [127]. Moreover, a large European survey, spanning 1998 to 2010, showed that the largest declines in colorectal cancer mortality were recorded in those countries where the greatest proportions of the population were screened. It also has been pointed out that the evidence for this impact is stronger than that for breast cancer screening and that screening for colorectal cancer is the most effective screening modality available for making an impact on a major cancer. Regarding cost-effectiveness, colorectal cancer screening is superior to cervical cancer screening which itself is superior to breast and prostate cancer screening [128].

5.1.5.

Lung cancer screening

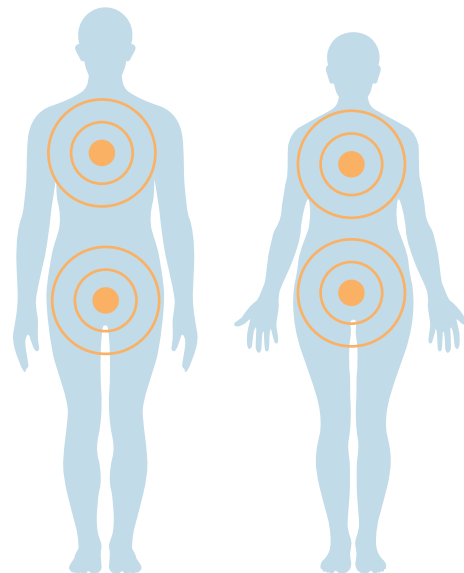
In 2013, the National Comprehensive Cancer Network (NCCN) in the United States recommended CT lung cancer screening for people aged 55-74 years with a 30 pack-a-year or longer history of smoking tobacco, and who are either current smokers or ex-smokers who have quit within the past 15 years [129]. European plans for nationwide lung cancer screening programs have not yet been developed. However, eight European randomized trials have been undertaken to compare lung cancer CT screening with no screening. The results of NELSON (Nederlands-Leuvens Longkanker Screenings Onderzoek), the largest of the European trials, as well as a planned pooling of European randomized controlled trial data to estimate mortality and cost-effectiveness in the European population are expected in 2015-2016 [129].

5.1.6.

Prostate cancer screening

The most common method for prostate cancer screening is the Prostate-Specific Antigen (PSA) test, which is often preceded by digital rectal examination (DRE) of the prostate. The impact of PSA screening on mortality is ambiguous [130], and the evidence for and against prostate cancer screening is highly controversial [131]. PSA-testing had received FDA approval as a screening tool in 1986 and had been widely used in the United States, but in 2011 the U.S. Preventive Services Task Force recommended against its use [132]. The American Cancer Society is also against mass screening with PSA in men aged over 50 years and recommends that the decision to use PSA testing should only be made after getting information about the uncertainties, risks, and potential benefits of prostate cancer screening [133]. Endorsed guidelines from the European Union on prostate cancer screening do not exist.

The main problem with PSA screening is the high risk of a false positive diagnosis [128]. It is not possible to identify which of the prostate tumors detected will be life-threatening to the patient during their lifetime and which will not. Screening for prostate cancer has increased the number of cancers detected generating expense and morbidity from detection and treatment of cancers that pose minimal risk [134]. Hence, the over-diagnosis due to PSA screening results in over-treatment with many men receiving unnecessary radical treatment [135]. The harm of prostate cancer treatment encompasses impotence, incontinence, and other side effects that can severely affect quality of life of patients. Due to the limitations of the test and the likelihood of it causing harm, PSA screening in asymptomatic men is not recommended [135]. However, it is generally accepted that high-risk groups, such as men with a family history of aggressive prostate cancer, can benefit from PSA testing [135]. Finally, in order for prostate cancer screening to be effective, the main challenge is to develop methods that can discriminate minimal-risk from high-risk cases [134].



Screening efforts aim at detecting cancer cases at an earlier stage which facilitates their treatment and thus enhances chances of survival.

5. Access to quality in oncology care – Screening

5.2.

Review of country-specific screening programs and screening rates

Screening programs are an integral part of the measures that can be taken by governments to tackle the disease burden of cancer. France, Germany, Poland and Sweden have all adopted screening programs for different cancer types. However, the countries differ in the cancer types that they have established programs for. They also differ in the configuration of screening programs for the same cancer types. Table 11 tries to summarize the key characteristics of the different

screening programs. For colorectal cancer screening, France is the only country that follows the recommendations of the European Commission, but Germany is about to follow suit. A common feature is lung cancer screening, where none of the countries has any type of screening program in place. Prostate cancer screening is only practiced in France, Germany and Sweden.

Table 11: Overview of screening programs for colorectal, lung and prostate cancer

	Type of organization	Age/target group	Interval	Test method	Year of launch
Colorectal cancer					
France [136]	organized	50-74 years	2 years	gFOBT	2008
Germany [97, 137]	non-organized; (organized is planned)	50-54 years; 55+ years	annually; CS: 10 years gFOBT: 2 years	gFOBT; either CS or gFOBT	NA
Poland [106]	opportunistic	Low risk: 50-65 years High risk: 25-65 years	10 years	CS	2000
Sweden [117, 138]	organized pilot project in 1 medi- cal care region	60-69 years	2 years	gFOBT; since 2012 iFBOT	2008
Lung cancer					
France	None	-	-	-	-
Germany	None	-	-	-	-
Poland	None	-	-	-	-
Sweden	None	-	-	-	-
Prostate cancer					
France [135, 139]	opportunistic	50+ years	NA	PSA	NA
Germany [137]	non-organized	45+ years	annually	DRE	NA
Poland	None	-	-	-	-
Sweden [117]	opportunistic; 1 organized clinical trial in a county council	50-69 years	NA	PSA; PSA + other biomarkers	NA

Notes: gFOBT = guaiac fecal occult blood test.

iFOBT = immunochemical fecal occult blood test.

CS = colonoscopy.

PSA = prostate-specific antigen.

DRE = digital rectal examination.

NA = no information available.

France

Cancer screening policy in France has been shaped by the 2003 national cancer plan. The Ministry of Health decides on the implementation of mass cancer screening programs. The responsibility for implementing the programs is jointly held by the Ministry of Health and the National Cancer Institute (INCa) [85]. Already in 2002, a national pilot population-based screening program for colorectal cancer was set up [140]. The nationwide rollout commenced in 2008 [136]. It targets men and women aged 50-74 years who are invited every 2 years to perform a gFOBT, followed, if positive, by a colonoscopy. All people are invited by mail to go to their GP for free screening. If people do not go to their GP in the following three months, they receive a second letter of invitation. After two letters of invitation, the test material is sent to people's homes expecting that they will do it and mail it back for interpretation [85]. The national cancer plan for 2009-2013 proposed, among other things, measures aimed at tackling inequalities in access and take-up of screening, enhancing participation of GPs in screening programs, and improving and standardizing the screening techniques used across the country [85].

In France, approximately 75 percent of men aged 60 have had a PSA test done within the previous three years despite no national recommendation to promote PSA screening for prostate cancer [135]. Still, it is quite common that GPs recommend a prostate cancer test to men over 50, i.e. opportunistic screening. Screening begins with a digital rectal examination and then a blood test to measure the amount of PSA is conducted [139]. Regarding lung cancer screening, the French intergroup for thoracic oncology group and the French-speaking oncology adopted a positive opinion on it in 2013. They suggested the target population to be subjects aged 55-74 years, who are smokers or have a 30 pack-a-year smoking history and to use low-dose computed tomography (LDCT) for screening [141].

Germany

In Germany no organized population-based screening programs for colorectal, lung or prostate cancer were established as of 2013. Instead, non-organized population-based programs for colorectal cancer and for prostate cancer exist. The screening program for prostate cancer gives the right to all men from the age of 45 years to a yearly digital rectal examination (DRE) [137].

The non-organized screening program for colorectal cancer gives the right to all men and women aged 50 to 54 years to a yearly examination with gFOBT. From the age of 55 years all men and women can choose between two alternatives. The first alternative is a colonoscopy which may be repeated only once after 10 years. The second alternative is a gFBOT carried out every two years [137]. Several shortcomings of this program have been identified. These include insufficient participation rates, inadequate and often incomplete documentation and implementation of the gFOBT without

adequate clarification of abnormal findings, absence of organized personal invitations and recalls, lack of targeted screening for people with a family-history of colorectal cancer, and insufficient accuracy of the gFOBT method. As a consequence, the aim of the National Cancer Plan from 2012 is to improve the organization of the currently non-organized screening program and to adapt it according to the European Commission's guidelines [97]. On April 9, 2013 the "act on early cancer detection and cancer register" (*Krebsfrüherkennungs- und -registergesetz, KFG*) was enacted and will enforce the implementation of an organized population-based screening program for colorectal cancer.

Poland

Opportunistic screening for colorectal cancer was launched in 2000 in Poland. Asymptomatic men and women of low risk aged 50-65 years and men and women with high family risk aged 25-65 years are eligible. Screening consists of a colonoscopy once every 10 years. People are referred by their family physician to centers that can carry out the screening. The national cancer plan for the period 2006-2015 provides funding to promote free colonoscopy screening [106]. Quality control of the equipment and staff engaged in screening is carried out by the Institute of Oncology in Warsaw and the regional Comprehensive Cancer Centers [103]. As far as available information suggests, Poland lacks screening programs for lung cancer and prostate cancer.

Sweden

Sweden has no national screening program for colorectal cancer, lung cancer or prostate cancer. However, in January 2008 a regional population-based screening program for colorectal cancer was initiated in the medical care region Stockholm-Gotland which encompasses around one fifth of the population. The program targets men and women aged 60-69 years. The test method used is gFOBT and the screening interval is two years [117]. Starting in 2012, gFOBT will gradually be replaced by iFOBT as the screening method [138]. Regarding prostate cancer screening, the official recommendation from the National Board of Health and Welfare is not to offer PSA screening to patients [142]. Yet upon patient request, PSA screening is commonly carried out (i.e. opportunistic screening). Karolinska Institutet and Stockholm County Council are currently conducting a study to refine the methods for detecting prostate cancer, where in addition to PSA screening other biomarkers are used. The study commenced in January 2013 and the recruitment of patients (i.e. men between 50-69 years) will continue for approximately two years [117].

5. Access to quality in oncology care – Screening

Screening rates

The success and accessibility of screening programs can be read-off by the realized screening rates. Data on screening rates are only available for colorectal cancer and for certain countries. Figure 19 illustrates these screening rates. Great cross-country differences can be observed. Only 3.5 percent of people aged 50-74 years in Poland have been screened

within the last 2 years, whereas one fifth of the population in France and more than half of the population in Germany has been. The share of people in this age group that indicated to have never had a screening for colorectal cancer is less than 20 percent in Germany, but 70 percent in France and 90 percent in Poland.

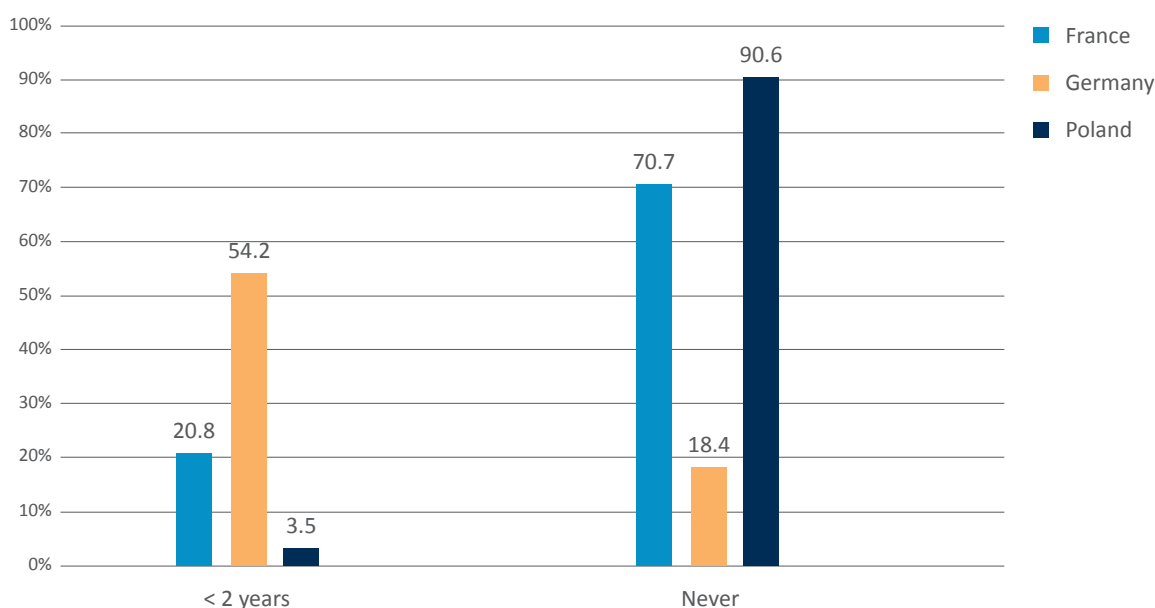


Figure 19: Colorectal cancer screening rates by time of last screening in the age group 50-74 years, 2009 (in % of the total age group), EHIS [143]

Notes: Data for France from 2008.

Eurostat does not provide data on the screening method used.

As stated before, an organized nationwide screening program for colorectal cancer was implemented in France in 2008 and the first results suggest that it has already lifted the screening rates. In fact, in the 46 French districts that conducted a comprehensive screening campaign during 2008-2009 the participation rate in the target group (50-74 years) was

34.3 percent [136]. The low screening rates in Poland are indicative of the ineffectiveness of the program implemented in 2000. No data were available for Sweden. As noted before, an organized pilot program was only implemented in one of the six medical care regions in 2008.

5.3.

How to improve access to and quality of screening

Population-based screening programs aim to detect cancers early among asymptomatic people. Provided that a positive diagnosis is followed by a treatment, early detection is beneficial as it facilitates treatment and curability. Several determinants of high-quality screening programs have been identified. These include the type of organization, public information campaigns, the test method, the target group, the screening interval, the follow-up actions, and a system to monitor the quality of the program at all stages. These determinants together with the general determinants of access to health care (see section 3.1.1) directly affect the success of screening programs as measured by the realized screening rates.

Nonetheless, not all cancer screening programs are beneficial. There has been a long-lasting debate on the benefit of prostate cancer screening with PSA testing. The impact of PSA screening on mortality is ambiguous and there is evidence that the harms outweigh the benefits. In contrast, the evidence on colorectal cancer screening as an effective method to reduce colorectal cancer induced mortality is well-established. The European Commission promotes the introduction of a population-based screening program for colorectal cancer to the member states. Moreover, it has been suggested that in terms of mortality reduction the cost-effectiveness of colorectal cancer screening is better than that of screening for cervical cancer and especially better than screening for breast and prostate cancer [128]. Sufficient evidence on the effectiveness of lung cancer screening still has to be established. Despite this, some organizations in the United States and in France have already promoted lung cancer screening. Given all these considerations, the case has been made that countries should take some resources used for prostate and/or breast cancer screening and devote it to colorectal cancer screening instead [128].

France, Germany, Poland and Sweden all have screening programs for different cancer types in place. However, the exact configuration varies considerably between countries and impacts their accessibility and chances of success. Hence, different country-specific recommendations on how to improve access to and quality of screening can be derived.

- In France, the high proportion of elderly men that have had a PSA-based prostate screening is indicative of a high ineffective use of resources. The savings potential in this area could be used to support the already existing organized population-based program for colorectal cancer or could be used in the treatment of cancer instead.
- In Germany, the non-organized program for prostate cancer screening gives the right to a digital rectal examination (DRE) once every year, despite a lack of evidence on the effectiveness of this method [144, 145]. The costs arising from this practice would be spent in a more efficient way in the funding of the planned organized population-based program for colorectal cancer.
- In Poland, the low screening rates for colorectal cancer are indicative of the ineffectiveness of the current program. To improve the situation, the program should be adapted according to the guidelines of the European Commission. This would involve a modification to an organized program and a change of the screening method from colonoscopy (CS) to FOBT. Both these measures are likely to increase the screening rates, since all people would actively be encouraged to participate and given screening with FOBT is more convenient to patients. As opposed to FOBT, CS cannot be carried out at the local GP and thus people need to travel to a health center that offers CS. Moreover, the non-invasive nature of the FOBT is unlikely to discourage people from using it than the more physically demanding CS. However, modifying the existing program would probably not be achieved with a mere rearrangement of the current resource input but would need additional funding.
- In Sweden, the current population-based screening program for colorectal cancer in the Stockholm-Gotland medical care region should be expanded to a nationwide program. In addition, the relatively small target group should be extended according to the guidelines of the European Commission.

6. Access to quality care in oncology – Treatment

Conclusions

- **The introduction of new cancer drugs has increased in recent years.**
- **Market access is delayed by lengthy pricing and reimbursement decisions at national or regional level.**
- **Inequalities in access to cancer drugs exist across Europe.** France shows the quickest and most substantial market uptake of new cancer drugs. Germany and Sweden have similar uptake levels of established drugs, but Sweden seems to fall behind in market uptake of new cancer drugs. The gap between Poland and the three other countries in terms of market uptake is remarkable. Overall the level in Poland of sold cancer drugs is low and the uptake of some newer cancer drugs effectively zero.
- French and Swedish data show that the **cost for cancer drugs increased dramatically in the last decade. However, the increase has leveled off in recent years and will be further moderated as some widely-used cancer drugs come off patent in the coming years.**
- The “high” cost of (cancer) drugs has already led to substantial changes in reimbursement policy in Germany in 2011 and in France in 2013. However, **the share of pharmaceutical expenditures on total health expenditures did not increase in any of the four countries between 2003 and 2011.** Thus, evidence supporting the notion of pharmaceuticals as the main cost driver of increasing health care expenditures is rather thin.
- The main aim of the new German reimbursement policy is to contain increasing pharmaceuticals expenditures. It can be assumed that patient access to new drugs will be restricted as a consequence, even if some measures are directed more towards price rather than volume.
- **In France, economic evaluations of new drugs have now become mandatory.** In Sweden, such evaluations have been in place since 2002. The Swedish example indicates that **this will probably restrict patient access to new drugs in France.** However, it is still too early to evaluate how the new regulations will be applied.
- **The consequences of restrictions to access of new cancer drugs due to inadequate reimbursement can be exemplified by Poland.** The results show **inappropriate use of ineffective treatments with cheaper drugs or no drug treatments at all. The consequential low quality standards undermine the aim to improve patient outcomes.**
- **Patient access schemes have been developed as a means to improve access to new high-priced cancer drugs in both high and middle income countries.** The pros and cons are numerous, and the (limited) country experiences are mixed. Adequate evaluation of schemes is scarce in most countries. This inhibits the needed discussion on how to design and implement schemes properly and on which schemes work well.

The survival prospects of cancer patients have improved over the last decades (see section 3.2.3). Different factors have contributed to this development. Among these factors are the advances in treatment achieved through the use of more effective cancer drugs. As noted in section 3.2, cancer drugs are part of the material resources which belong to the structural domain of the quality of oncology care model. In addition to increasing survival rates, new cancer drugs have also led to an increase in the quality of life of cancer patients. A shift from intravenous to oral delivery methods has improved process quality. Patients can be treated at home, which reduces time and costs for travel and improves the chances of returning to work. If however treatment at a health care facility cannot be avoided, the use of more effective drugs may decrease the number of treatment sessions, which also benefits patients.

Nevertheless, the development of more effective cancer drugs will not improve outcomes if they do not reach the patients. Several hurdles have to be overcome before a new drug can be accessed by patients. Historically the safety aspect occupied a central role in the process of market approval and marketing authorization of a new drug. Then, in addition, the health aspect in terms of efficacy gained momentum as well as the quality aspect. Since 1995, the European Medicines Agency (EMA) is responsible for the evaluation of safety, efficacy and quality of new drugs and for granting marketing authorization in the European Union. Finally, as health budgets got tighter and tighter in the 1990s the cost aspect was added as a fourth pillar on which new medicines are nowadays assessed. The evaluation of the cost aspect rests with the member states and is usually carried out by a national or regional health technology assessment (HTA) agency. In many member states considerations of the cost-

effectiveness of new drugs are part of a health technology assessment, which is a multidisciplinary approach to policy analysis, studying the medical, social, ethical, and economic implications of development, diffusion, and use of a health technology.

The assessment of safety, efficacy, quality, relative effectiveness and cost-effectiveness carried out at different administrative levels is time consuming and costly. It also means that the regulatory demands to provide sufficient evidence are nowadays higher than ever. As a consequence, extensive clinical trials are required which drive up the costs of new cancer drugs [146]. High prices of drugs restrict their use, which becomes particularly pronounced in periods of austerity and in countries with lower incomes and health care spending. Data on the actual access to and use of new cancer medicines are thus of increasing importance for the design of health policies to improve access, both at the national and European level.

This chapter will first review studies on market access and market uptake of cancer drugs in France, Germany, Poland and Sweden. Secondly, using the example of the cancer drug sunitinib, the different hurdles new cancer drugs have to overcome at the national level before reaching the patient are illustrated for all countries. Lastly, the notion of the “high” cost of new cancer drugs is addressed, given recent policy changes, and patient access schemes are discussed.

6.1. Review and summary of published studies

Patients can only benefit from innovative drugs if they have access to them. There are two major aspects that need to be considered in assessing access to cancer drugs in Europe. The first one is market access, of which one aspect is the time period between drug approval by the EU and access in different markets in terms of first sales. The other is market uptake. This describes the speed and level of uptake, i.e. actual usage, of a given drug after its introduction on the market.

6.1.1. Availability of new cancer drugs

A precondition for patient access to effective cancer drugs is the development and supply of new drugs. The availability of new drugs can give an indication of how dynamic the market for cancer drugs is. Figure 20 shows the number of new cancer drugs that are launched within a period of three years, starting from 1990 to 2013. For the period 1 January 1990 to 31 December 2005, launch is defined as the worldwide date a product or pack is first made available for general release by the manufacturer, i.e. for general prescribing and dispensing. These data were taken from Wilking and Jönsson (2009) [147]. For drugs launched between 1 January 2006 and 31 December 2013, the authorization date provided by the European Medicines Agency (EMA) was used. These data were compiled from EMA’s database [148]. Cancer drugs with ATC code L01, L02A and L02B were included. As Figure 20 displays, the number of new drugs was quite low in the beginning of the 1990s, and first reached a peak around 1998. Until 2010 the number of new drugs remained more or less constant. Between 2011 and 2013 a record number of new cancer drugs had been granted marketing authorization.

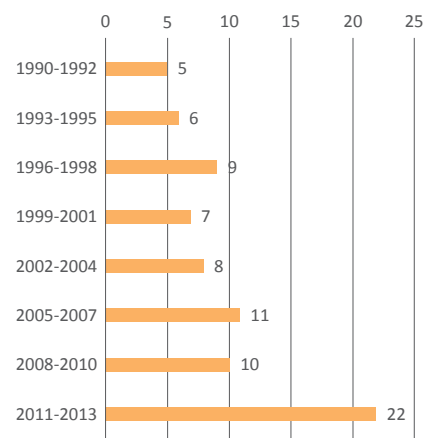


Figure 20: Number of new cancer drugs launched according to date of introduction worldwide [147, 148]
Notes: Drugs with ATC code L01, L02A and L02B introduced between January 1, 1990 and December 31, 2013 are included.

6. Access to quality care in oncology – Treatment

6.1.2.

Market access

There is a centralized procedure for marketing authorization of new drugs in the EU. The procedure is laid down in Regulation (EC) No 726/2004 [149]. The producer submits an application to the regulatory body, the European Medicines Agency (EMA). The Committee for Medicinal Products for Human Use (CHMP) of the EMA evaluates safety, efficacy and quality. It then issues an opinion as to whether to grant marketing authorization. The CHMP also issues opinions for already authorized drugs to be used in new indications. The maximum time limit for the evaluation procedure is 210 days. If the drug constitutes a product of major public health interest, there is the possibility of an accelerated evaluation within 150 days. There are four types of opinions issued by the CHMP; positive, negative, under exceptional circumstances, and conditional. After the CHMP issued its opinion, the European Commission has a maximum of 67 days to confirm this opinion. In the case of a confirmed favorable opinion, marketing authorization for the entire EU is granted.

The member states each decide for themselves the pricing and reimbursement of drugs approved by the EMA. According to Directive 89/105/EEG, the pricing and reimbursement process for medicinal products should not take longer than 180 days [150]. In 2012, the European Commission proposed a revision of this directive. According to the new directive currently under discussion, pricing and reimbursement decisions for new medicines would have to be made within 90/180 days and for generic medicinal products within 30/60 days. Furthermore, the Commission proposed strong enforcement measures in cases where decisions do not comply with the time limits, which are often exceeded by member states. Progress and agreement on this new directive within the legislative process has however been slow, and therefore implementation is not envisaged as originally planned for 2014 with a deadline for transposition by member states in 2015 [151].

Patient access to new drugs is dependent on the pricing and reimbursement decision, as this is a precondition for market access in many countries. Pricing and reimbursement decisions are often subject to a health technology assessment (HTA) conducted by a national or regional HTA agency. The preparation of an HTA report is time consuming and thus compliance with the time limit of 180 days is not always feasible.

Table 12: Average time delays in days between marketing authorization and effective market access (hospital and retail combined) – all products [152]

	No. of products	No. of products accessible to patients	Average time delay between approval and market access	Maximum time delay between approval and market access	Minimum time delay between approval and market access
France	84	47	326	636	69
		Hospitals: 16	299	434	155
		Retail: 31	334	636	69
Germany	80	80	0	0	0
Poland	78	5	214	731	0
Sweden	85	57	169	805	0

Notes: Marketing authorization granted between January 1, 2003 and December 31, 2006. Accessibility as of June 30, 2007.

No comparable data on market access delays specifically for cancer drugs in the EU are available. However, a report from IMS studied the time between EU marketing authorization and patient access to pharmaceuticals in different countries [152]. Patient access was defined as the day post-marketing authorization administrative processes including pricing and reimbursement processes was completed. Drugs that had been granted EU marketing authorization between January 2003 and December 2006 were included in the study. Table 12 indicates that not all drugs approved by the EU during this period were available to patients in mid-2007, except in Germany.

As shown in Table 12, the average time delay was longest in France, amounting to almost a full year. The average time in Poland was 214 days and 169 days in Sweden. Table 12 also highlights that there is a lot of variation in market delays within countries, with some drugs being immediately available to patients while for other drugs patients wait for well over two years. In Germany until 2011 patients did not have to wait, because access to new medicines was allowed upon marketing authorization and no pricing and reimbursement process needed to be completed before new medicines could be prescribed to patients. For France, a distinction could be made for drugs used in hospitals and in ambulatory care (i.e. retail). The average time delay was somewhat shorter for hospital drugs. However, it should be noted that the formal reimbursement process for cancer drugs is not applicable to all countries. In Sweden, for instance, cancer drugs used in hospitals are immediately available once the marketing authorization is granted.

A more recent report from the European Federation of Pharmaceutical Industries and Associations (EFPIA) adopting the same methodology confirmed the results from the previous IMS report [153]. Drugs that had been granted EU marketing authorization between 1 January 2008 and 31 December 2010 were included in this report. Among the four countries, the average time to patient access was longest in France with 316 days¹⁷. Patients in Sweden had to wait 272 days. For reasons explained above, no market access delay was assumed in Germany. Poland was not included in this study, but it has been pointed out that reimbursement decisions take longer than the proposed 180 days limit by the EU [108]. Compared with the previous study-period (authorization between 1 Jan 2007 and 31 Dec 2009) [154], market access delay increased in almost all European countries including France and Sweden.

6.1.3. Market uptake

Conclusions about access to new cancer drugs cannot be drawn on the sole basis of information on availability and first sales. To evaluate the value of the access gained, the actual usage of new drugs has to be investigated, i.e. evaluation of market uptake. Assessing market uptake of new cancer drugs is a delicate task. Two different dimensions have to be considered in order to derive meaningful results. The first one is the level of uptake, which describes the extent of usage at a specific point in time after market introduction. The second one is the speed of uptake and refers to how quickly a drug is used after its market introduction and how its usage evolves over time. Market uptake of cancer drugs in Europe has been the subject of recent studies. The basic methodologies and results of four studies are discussed below and summarized in Table 13.

Firstly, in a report for the Swedish research-based pharmaceutical industry (LIF) the share of sales of “innovative” cancer drugs in the fourth quarter of 2012 was examined based on IMS Health data [155]. The result showed that Poland and Germany have a similar share with 29 and 30 percent, respectively, of sales related to newer drugs, and France and Sweden showing higher proportions with 40 and 41 percent, respectively. However, these results have to be interpreted with caution as an arbitrary choice was made of what constitutes an “innovative” cancer drug. Only a selection of drugs that had been issued between 2001 and 2012 were attributed the label “innovative”. Furthermore, solely looking at the share of sales of new and old drugs conveys limited information about access to drugs. If, for instance, the total amount of drug sales was small, then access to drugs was restricted, but this kind of information was disregarded in the study.

Secondly, in a report by the UK’s national cancer director in 2010, cancer drug usage was assessed through calculating the drug volume sold (in milligrams) per capita [156]. The analysis was based on IMS Health data supplemented with manufacturer data covering sales between April 2008 and March 2009. Cancer drugs were divided into three groups based on time of launch (within the last 5 years, 6-10 years, 10+ years) and a fourth group for hormonal drugs. Countries were ranked according to sold volume per capita. Highest usage was recorded in France followed by Germany and Sweden in each of the three time-of-launch-specific groups (Poland was not included in this study). For hormonal drugs Germany exhibited the highest usage followed by France and Sweden.

17. EFPIA notes that its indicator is - though related - not a measurement of the delay as meant by the EU’s “Transparency” Directive 89/105/EEG.

6. Access to quality care in oncology – Treatment

Thirdly, a report prepared for the Belgian presidency of the Council of the EU in 2010 measured the uptake of “innovative” medicines (i.e. also other than cancer drugs) through sales measured in euros per 100,000 inhabitants in 2009 based on IMS Health data [157]. The report contrasted sales figures with the number of available innovative medicines in each country. The findings showed that the uptake of innovative medicines had no apparent link with availability across EU countries. For instance, in France 44 innovative medicines were available and 43 in Sweden, but French sales figures of some €2.6 million per 100,000 inhabitants were twice as high as the Swedish ones at about €1.2 million. 47 innovative drugs were available in Germany and 33 in Poland; the differences in sales were huge with some €1.5 million per 100,000 inhabitants in Germany and a mere €0.2 million in Poland.

Finally, in an earlier report by Wilking and Jönsson the market uptake of cancer drugs was analyzed during the period 1998-2008 based on IMS Health data [147]. Drugs were grouped into four categories according to their period of launch (earlier than 1999, 1999-2002, 2003-2005 and 2006-2007). Overall, old drugs launched before 1999 constituted around

two thirds of total sales in 2007 in Germany and France, 70 percent in Sweden and around 75 percent in Poland. Level and speed of drug uptake was also investigated for selected drugs that are used in the treatment of colorectal and non-small cell lung cancer (NSCLC). For colorectal cancer drugs, France was by far the best performer both in terms of level and speed of uptake. Germany and Sweden showed similar levels of uptake for well-established drugs, but for more recently released drugs Germany showed higher levels of uptake than Sweden. Poland was worst in terms of level of uptake, with population-standardized sales at best 5 times lower than in France and 3 times lower than in Germany or Sweden for drugs that had been available for a longer time. For recently released drugs Polish sales were effectively non-existent. For NSCLC drugs the same picture emerged. France showed a quick uptake and comparatively high levels of uptake. Germany performed slightly better than Sweden and especially with regards to more recently released drugs. Polish uptake of NSCLC drugs that had been available for a longer time was lower than in Sweden or Germany, whereas for newer drugs the level of uptake was only marginal.

Table 13: Overview of recent studies examining market uptake of cancer drugs

Author	Methodology	Result
Opticom International Research AB (2013) [155]	Share of sales of innovative cancer drugs on total sales in euros in the fourth quarter of 2012; Note: only a selection of drugs that had been issued between 2001 and 2012 were considered “innovative”	Share of innovative cancer drugs: Sweden: 41% France: 40% Germany: 30% Poland: 29%
Richards, M. (2010) [156]	Drug volume sold (in milligrams) per capita between April 2008 and March 2009; Three groups of cancer drugs by time of launch (within the last 5 years, 6-10 years, 10+ years) and a fourth group for hormonal drugs	Ranking according to highest uptake in any of the three groups: 1. France 2. Germany 3. Sweden Ranking for hormonal drugs: 1. Germany 2. France 3. Sweden
Annemans, L., Arickx, F., Belle, O., Boers, K., Bogaert, M., Callens, S., et al. (2010) [157]	Sales of “innovative medicines” (i.e. also other than cancer drugs) in euros per 100,000 inhabitants in 2009; Number of available innovative medicines	France: 44 innovative drugs available; sales of €2.6 million per 100,000 inhabitants Germany: 47 drugs, €1.5 million Sweden: 43 drugs, €1.2 million Poland: 33 drugs, €0.2 million

Author	Methodology	Result
Wilking, N., Jönsson, B., Högberg, D., Justo, N. (2009) [147]	Share of sales of new cancer drugs on total sales in euros in 2007; Four groups of cancer drugs by time of launch (earlier than 1999, 1999-2002, 2003-2005 and 2006-2007) Level and speed of uptake for selected cancer drugs for specific cancer types; Level of uptake in 2007 measured in volume sold per 100,000 inhabitants; Speed of uptake from 1998 or start of launch until 2007	Share of new cancer drugs (launched 1999-2007) ca.: France: 33% Germany: 33% Sweden: 30% Poland: 25% Colorectal cancer: Level of uptake of established drugs: 1. France 2. Germany & Sweden 3. Poland Level of uptake of new drugs: 1. France 2. Germany 3. Sweden 4. Poland Non-small cell lung cancer: Level of uptake of established drugs: 1. France 2. Germany 3. Sweden 4. Poland Level of uptake of new drugs: 1. France 2. Germany 3. Sweden 4. Poland

In conclusion, market uptake of newer drugs varies considerably between the investigated countries. Independent of the applied method, France seems to excel comparatively well in terms of overall market uptake of cancer drugs and is also the leader in uptake of newer cancer drugs. Germany and Sweden exhibit comparatively high and similar uptake, but Sweden seems to lack behind in the uptake of newer drugs. The gap between Poland and the three other countries in terms of market uptake is remarkable. In Poland, the overall level of sold cancer drugs is low and the uptake of some newer cancer drugs is effectively zero. These results underscore the inequality in access to cancer drugs across Europe and confirm the results of previous studies [158-160]. The ability to access new cancer drugs thus depends on where patients live.

Even though the results suggest great cross-country variations in drug usage, numerous factors have been put forward that might help explaining some differences. Among these factors are different survival rates for certain cancer types between countries which may impact on the length of time of drug use; the overall level of health expenditures

and the overall spending on drugs; cost of drugs and levels of generic prescribing; the nature of the health care system including payment mechanisms, reimbursement systems and prescribing incentives; access to cancer specialists and the capacity within the health system for diagnosis, detection and treatment; national disease priorities and specific policies and guidelines (e.g. national cancer plans); clinical and patient confidence in the national health authorities responsible for drug approval; patient confidence in clinicians' prescribing decisions; clinical practice including the impact of practitioner's experience, how they are trained, and the existence of guidelines; clinical and patient attitudes towards the benefit and toxicity of individual treatments; patient safety concerns; cultural attitudes towards the use of newer and more expensive drugs and influence of historical use; and the role of patient representative groups in supporting patients [156].

6. Access to quality care in oncology – Treatment

6.2.

Access to sunitinib – an example

As described before, by means of the EMA the European Commission grants marketing authorization for new drugs. The member states determine pricing and reimbursement themselves. Market access to new drugs thus can only be delayed by lengthy decisions on pricing and reimbursement at the national or regional level. However, patient access is dependent on the outcomes of these decisions. Chapter 4 of this report already showed that the formal pricing and reimbursement mechanisms differ between countries. How these differences impact the assessment of the same pharmaceutical and what implications these differences have for patient access in the four countries will be analyzed in this section and section 6.3. The analysis in this section is exemplified by the cancer drug sunitinib, for which good data from all countries are available.

The European Commission granted a conditional marketing authorization for sunitinib (brand name Sutent®, marketed by Pfizer) on July 19, 2006, before switching to a full marketing authorization on January 11, 2007. Currently, sunitinib is indicated for metastatic renal cell carcinoma (MRCC), as a second line treatment for gastrointestinal stromal tumor (GIST), and for pancreatic neuroendocrine tumors (pNET) [161].

France

In France, the HAS issued an opinion on sunitinib 63 days after EU authorization on September 20, 2006 [162]. As a second line treatment for GIST it received the SMR rating “important” and the ASMR level II. It was noted that there was no treatment alternative. As a second line treatment for MRCC it received the SMR rating “important” and the ASMR level III. It was noted that one treatment alternative (sorafenib) exists. The reimbursement rate was set at 100%. In May 2007, sunitinib was indicated for first line treatment of MRCC and received the SMR rating “important” and the ASMR level II [163]. The existence of alternative treatments was noted and the reimbursement rate set at 65%. Finally in May 2011, sunitinib was indicated for first line treatment of pNET and received the SMR rating “moderate” and the ASMR level V [164]. It was acknowledged that few treatment alternatives exist. The reimbursement rate was set at 100%. In all assessments by the HAS sunitinib was not subject to an economic evaluation.

As explained in chapter 4 of this report, the reimbursement rate usually corresponds to the SMR rating. Only drugs with an SMR rating “major” would thus receive a rate of 100%. Yet, sunitinib received a reimbursement rate of 100% for all but one indication despite receiving “important” or “moderate” SMR ratings. The 100% rate for the treatment of pNET is especially surprising given that the absolute medical benefit (SMR) is only moderate and the relative medical benefit (ASMR) shows no improvement. However, the opinion of the HAS also noted that the estimated yearly number of patients with pNET is a mere 170 in France. The small target group means that the budgetary impact of full coverage would not be dramatic and might offer an explanation for HAS’ decision.

Germany

At the time of approval of sunitinib by the European Commission, the old reimbursement system was still in place in Germany. Most drugs that received approval by the Commission or the German Federal Institute for Drugs and Medical Device were automatically covered by the statutory sickness funds (SHIFs). Pharmaceutical companies were free to set their drug prices. However, inefficient drugs were put onto a negative list and not reimbursed. It also was possible to set a maximum price for patented drugs, if a negative cost-benefit-assessment supported such a decision [165]. Sunitinib was not subject to an economic evaluation though [91].

Poland

In Poland, sunitinib is covered by the reimbursement system for MRCC. In general, the procedure to receive funding for molecularly targeted drugs, such as sunitinib, is rather bureaucratic as an individual application has to be made which requires the approval of an oncology consultant and an official from the regional NFZ branch. Moreover, the treatment of MRCC is run under a program in which only one of several molecularly targeted drugs approved for the indication, sunitinib, is reimbursed. This has resulted in a promotion of sunitinib and a marginalization of other drugs approved for MRCC therapy. Data also show that a considerable number of MRCC patients do not receive any treatment, which cannot be explained by medical ineligibility alone. The restricted access to molecularly targeted drugs in the treatment of MRCC has also resulted in the use of cheaper but less effective immunotherapy [166].

Sweden

In Sweden, sunitinib was approved by the TLV for treatment of GIST and MRCC 124 days after EU authorization on November 20, 2006 [167]. It received reimbursement at the manufacturer's requested price. The approval dossier showed that the incremental cost-effectiveness ratio (ICER) was around SEK 1 million per QALY for patients with GIST and SEK 550,000 per QALY for patients with MRCC, but that these results were uncertain. The ICERs were also well-above a non-established threshold of SEK 500,000 per QALY. Several factors were mentioned in the dossier that might have supported the approval despite the unfavorably high ICERs. These included: the high disease burden of the two cancer types; the end-of-life setting that sunitinib is used in; lack of treatment alternatives; assumed marginal savings in indirect costs due to decreased production loss given the advanced age of patients were not included in the ICERs; and the advocacy of the Pharmaceutical Benefits Group of the County Councils to reimburse sunitinib.

Market uptake of sunitinib

In Figure 21 the market uptake of sunitinib in all four countries is illustrated for the period 2006 Q1 to 2008 Q3. Market uptake is expressed in population-size adjusted sales in volumes, i.e. in milligrams per 100,000 inhabitants. Data were obtained from IMS Health (for more details on the methodology and data see the next section 6.3). Figure 21 shows that uptake of sunitinib was quickest and most substantial in France and Germany. In Sweden, the uptake was slower and the level of uptake was around half of the French and German levels throughout the covered time period. In Poland, the uptake of sunitinib was only marginal until 2008, but even then it was around four to five times lower than in France and Germany.

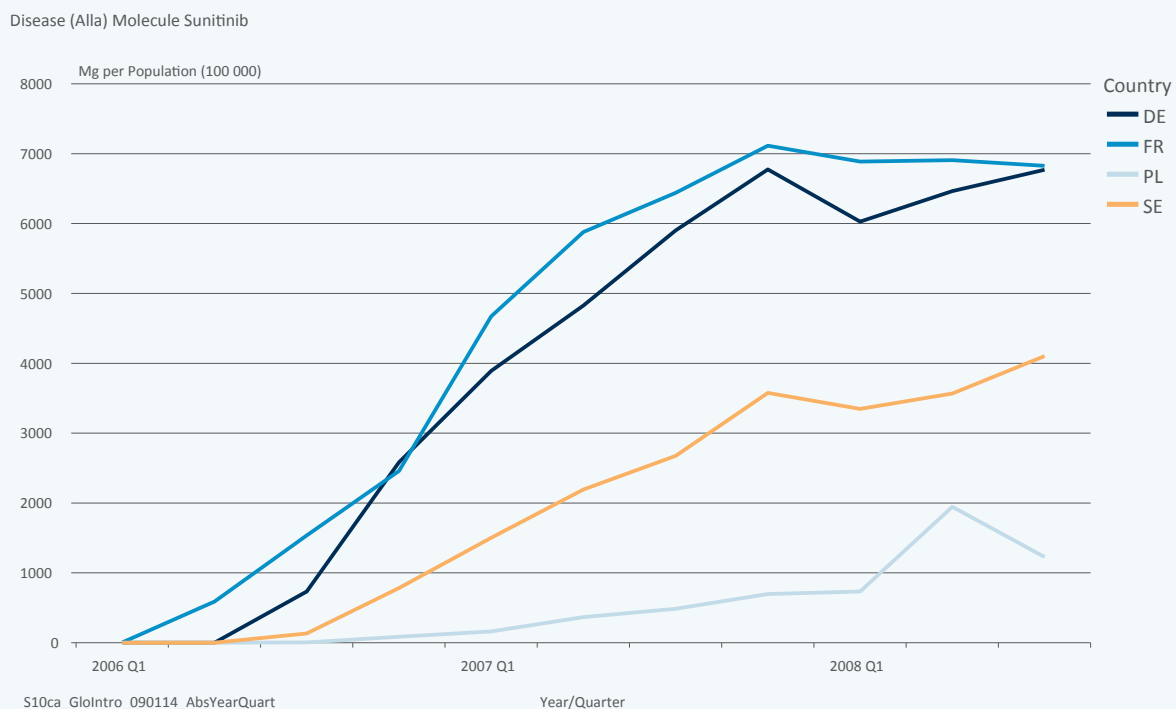


Figure 21: Usage of sunitinib (in mg/100,000 inhabitants)

Notes: DE = Germany, FR = France, PL = Poland, SE = Sweden.

As explained above, an economic assessment of sunitinib was not part of the approval process in France and Germany and the drug received quick reimbursement after EU authorization which resulted in a swift and substantial uptake. In Sweden, sunitinib was also reimbursed but had been subject to an economic assessment which questioned

the cost-effectiveness of sunitinib and might explain the lower uptake levels. In Poland, sunitinib also received reimbursement but the rather bureaucratic individual application to receive the drug and the lack of funding of cancer drugs offer an explanation for the marginal uptake levels.

6. Access to quality care in oncology – Treatment

CONCLUSION

In France, a mandatory economic evaluation of new drugs came into force in October 2013. This means that in addition to the two previous criteria of absolute and relative health benefit, another criterion will affect the reimbursement decision. It is hard to see how the introduction of an additional assessment criterion could facilitate the reimbursement of new drugs. Instead, it can be assumed that it will become more difficult to receive a positive reimbursement decision or a higher reimbursement rate, which will directly feed into lower patient access to new drugs. However, it is still too early to evaluate how the new regulations will be applied.

The Swedish example shows that despite a health-economic decision criterion in place, new and expensive cancer drugs can still receive full coverage even if the health-economic evaluation yields unfavorable results. Both in France and Sweden the decision of the authorities indicated that the high disease burden of cancer, the use of cancer drugs in an end-of-life setting and a small number of patients favor a positive decision. In addition, the absence of treatment alternatives also plays a decisive role for a positive decision, which demonstrates that innovations in treatment are rewarded. However, the Swedish example also shows that the speed and level of uptake of new drugs might decrease in France as a result of the mandatory economic assessment.

The new German reimbursement system introduced in 2011 replaced the old practice of free upfront drug pricing. The public aim of the reform was to contain rising expenditures on pharmaceuticals. The new rules require an assessment of the new drug with the most appropriate comparator. Since the comparator is often a generic drug or a lower-priced drug, new patented drugs have difficulties competing with the comparator in terms of price. Consequently, it can be assumed that patient access to new drugs will become restricted, even if some measures are more directed towards price rather than volume.

The Polish example illustrates what can happen if patient access to new drugs is seriously restricted due to inadequate reimbursement. The consequence is an inappropriate use of ineffective treatments with cheaper drugs or no treatment at all. The resulting low quality standards make it difficult to achieve improvements in patient outcomes.

6.3. Market uptake of new cancer drugs

This section describes the total sales of cancer drugs (ATC code L1, L2A and L2B) in France, Germany, Poland and Sweden and is based on a previous report by Wilking and Jönsson [147]. Quarterly and annual sales statistics in the period 1998 Q1 – 2008 Q3 and 1998 – 2007, respectively, were obtained from IMS Health, IMS MIDAS. These sales statistics were based on the manufacturers' prices in most countries, except in Sweden, where sales were based on trade prices (wholesaler price). Cost of distribution to the pharmacy is not included. This is mainly of importance for low priced drugs prescribed in ambulatory care, where the pharmacy margin is highest. Cancer drugs are mainly used in the hospital setting. Costs of administration of drugs are not included. Sales are presented in nominal prices and have been converted to euros where necessary, using the 2005 market exchange rate. IMS pharmaceutical audits report sales at either manufacturer selling price (wholesale purchase price, trade price, pharmacy purchase price/wholesale price) or public price. IMS audits in Poland and Sweden measure sales to hospitals from wholesalers and directly from manufacturers. In France and Germany hospital usage is established with data from a panel of hospitals, reporting the product issues from pharmacies. These data are then projected to the national level.

Differences in prices may influence the country comparisons made using value terms. International price comparisons are problematic for a number of reasons, and it is difficult to make a precise correction for price effects. In order to avoid differences based on price effects, data based on volume sales in milligrams (mg) are provided. It should also be noted that dosages can differ between countries, which may influence the interpretation of sales data per treated patient.

6.3.1. Sales of new cancer drugs

The total sales of 24 cancer drugs approved during 1995-2004 are shown in Figure 22. The data show that total sales of these drugs in the France, Germany and Sweden were fairly similar in 1998 at around €5,000 to €6,000 per 100,000 inhabitants. Germany and Sweden exhibit an almost identical pattern in sales over the period 1998-2008. In contrast,

France shows a much higher uptake of these drugs and in 2008 the sales were almost twice as high as in Germany and Sweden. In Poland, the sales of these cancer drugs was almost zero in 1998, and increased by 2008 to the level that the other countries had in 1998.

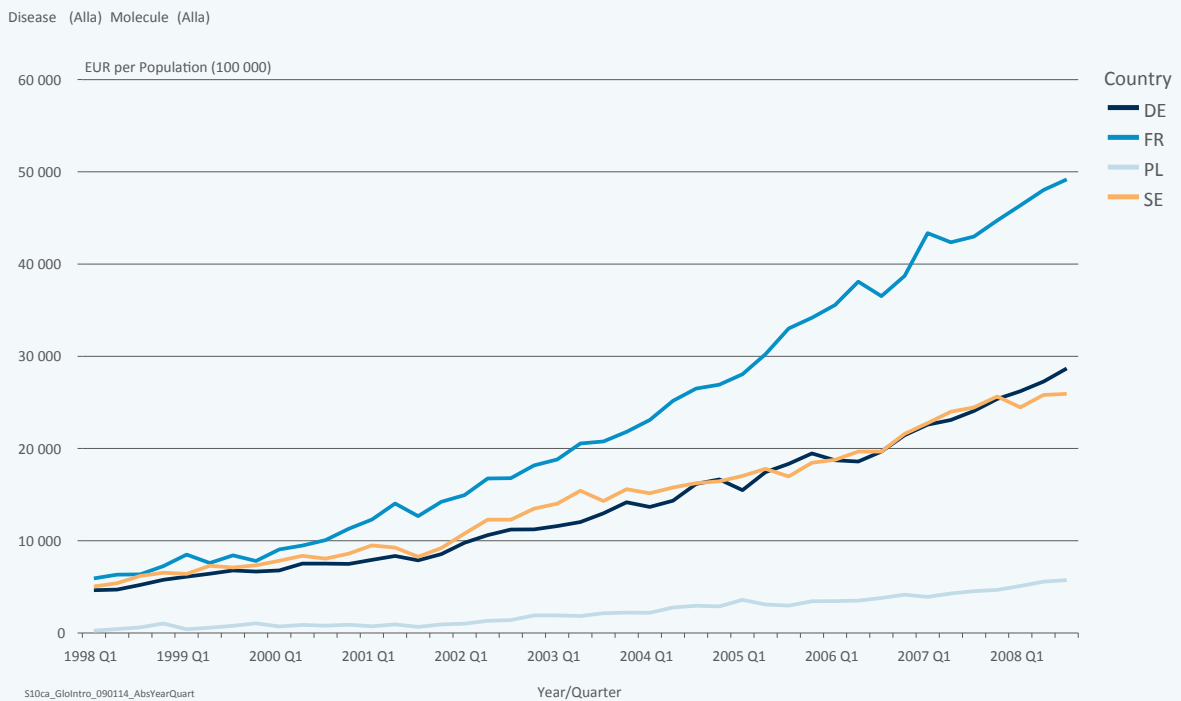


Figure 22: Total sales of 24 cancer drugs approved during 1995-2004. Sales are expressed in euros/100,000 inhabitants
Notes: DE = Germany, FR = France, PL = Poland, SE = Sweden.

6. Access to quality care in oncology – Treatment

6.3.2.

Uptake of selected cancer drugs

In this section, the uptake of a number of cancer drugs for specific cancer types is presented. For each drug, uptake is given as sales (in mg) from the time of local introduction or first sales (a drug could have been sold under special license prior to national authorization). Data are expressed in sales per mortality case of the specific cancer types in the year 2000. This was done to eliminate the effects of variation in mortality rates for the cancer types in the countries studied.

A number of drugs that are used in the treatment of the three cancer types discussed in this report and approved in the period 1995-2004 were selected. These are:

- Colorectal cancer: bevacizumab, cetuximab, irinotecan and oxaliplatin
- Lung cancer: erlotinib, gemcitabine and pemetrexed
- Prostate cancer: docetaxel

Colorectal cancer

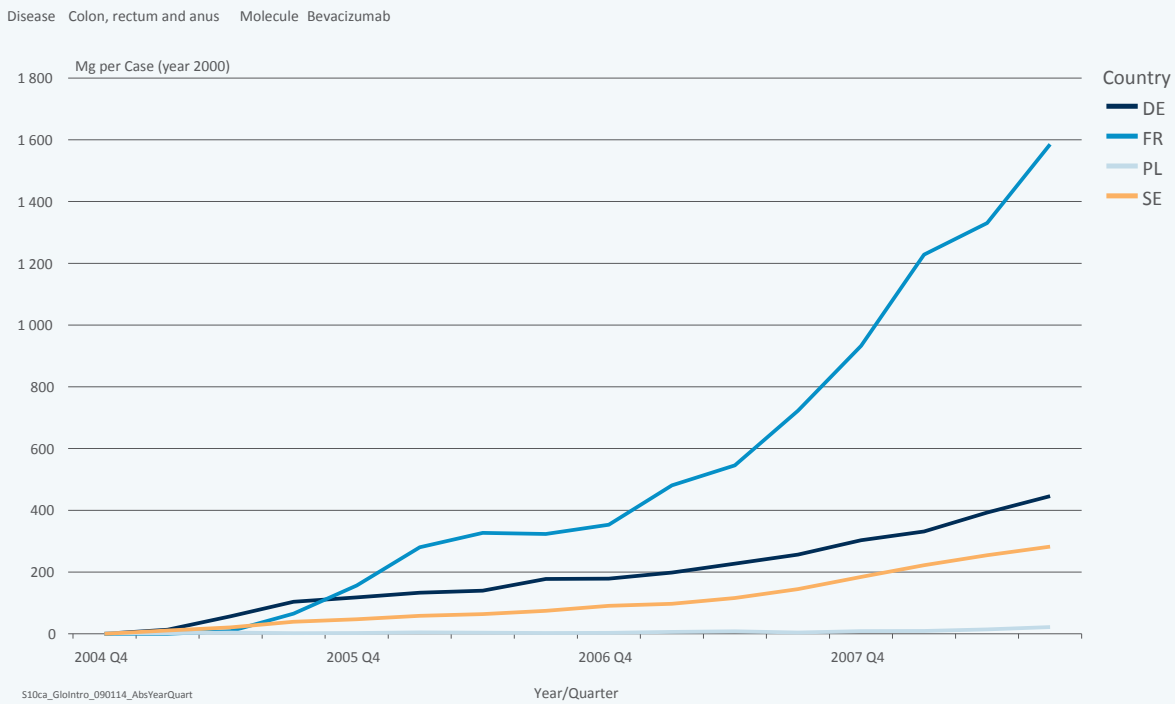


Figure 23: Usage of bevacizumab expressed as mg/case (case = mortality in colorectal cancer in year 2000)

Notes: DE = Germany, FR = France, PL = Poland, SE = Sweden.

Disease Colon, rectum and anus Molecule Cetuximab

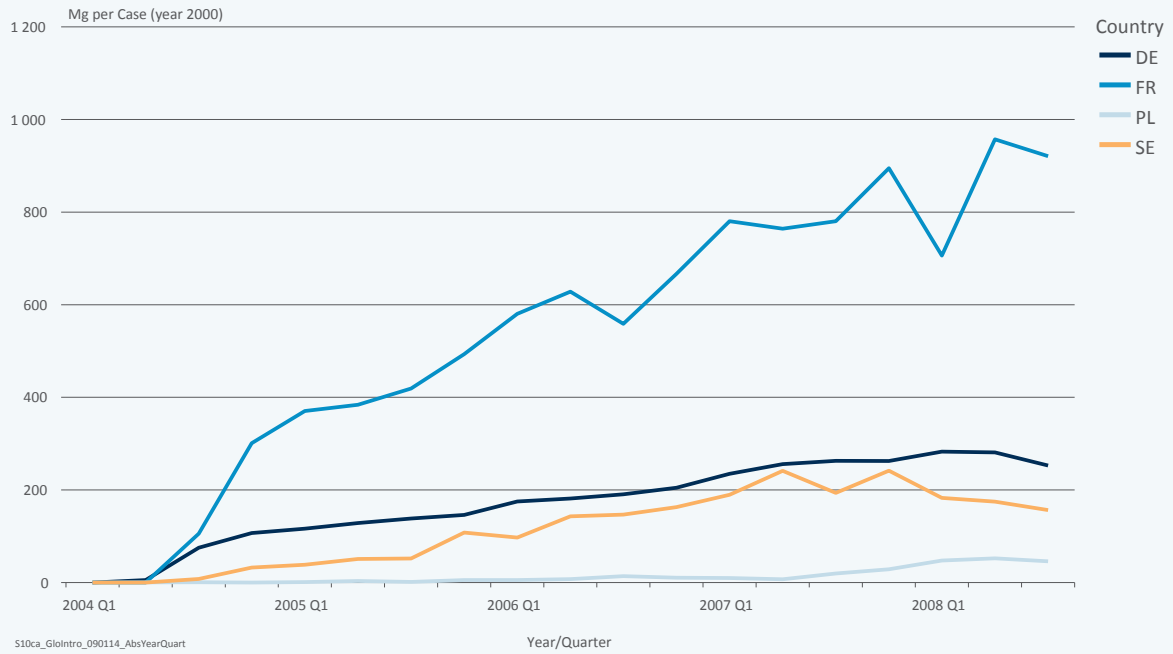


Figure 24: Usage of cetuximab expressed as mg/case (case = mortality in colorectal cancer in year 2000)
Notes: DE = Germany, FR = France, PL = Poland, SE = Sweden.

Disease Colon, rectum and anus Molecule Irinotecan

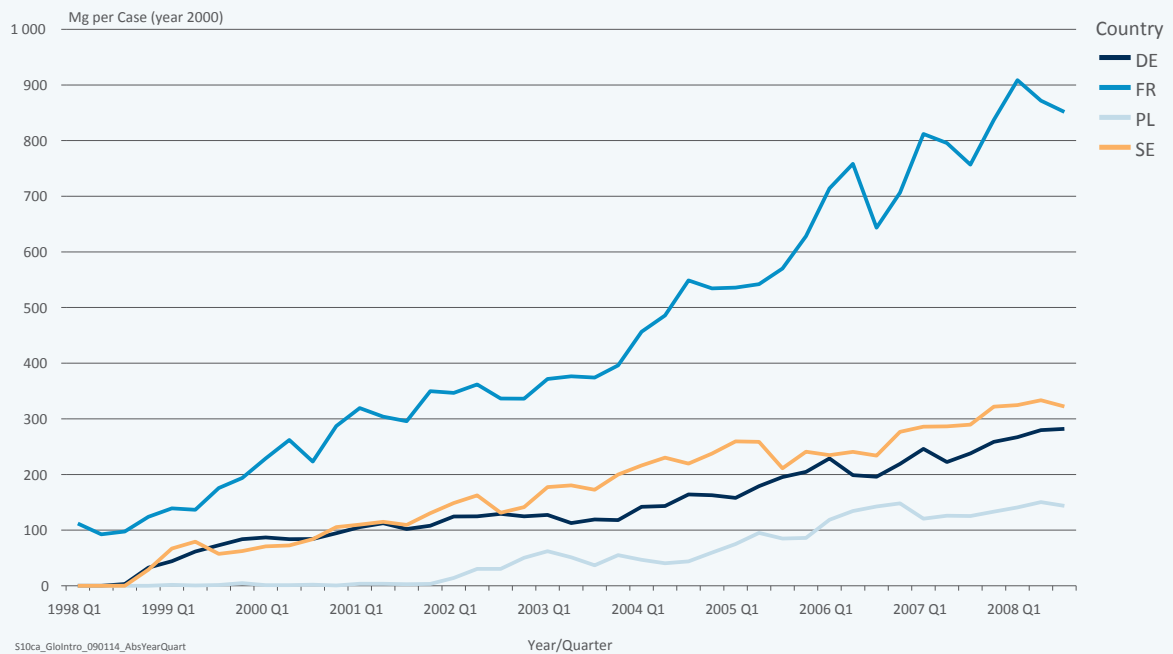


Figure 25: Usage of irinotecan expressed as mg/case (case = mortality in colorectal cancer in year 2000)
Notes: DE = Germany, FR = France, PL = Poland, SE = Sweden.

6. Access to quality care in oncology – Treatment

Disease Colon, rectum and anus Molecule Oxaliplatin

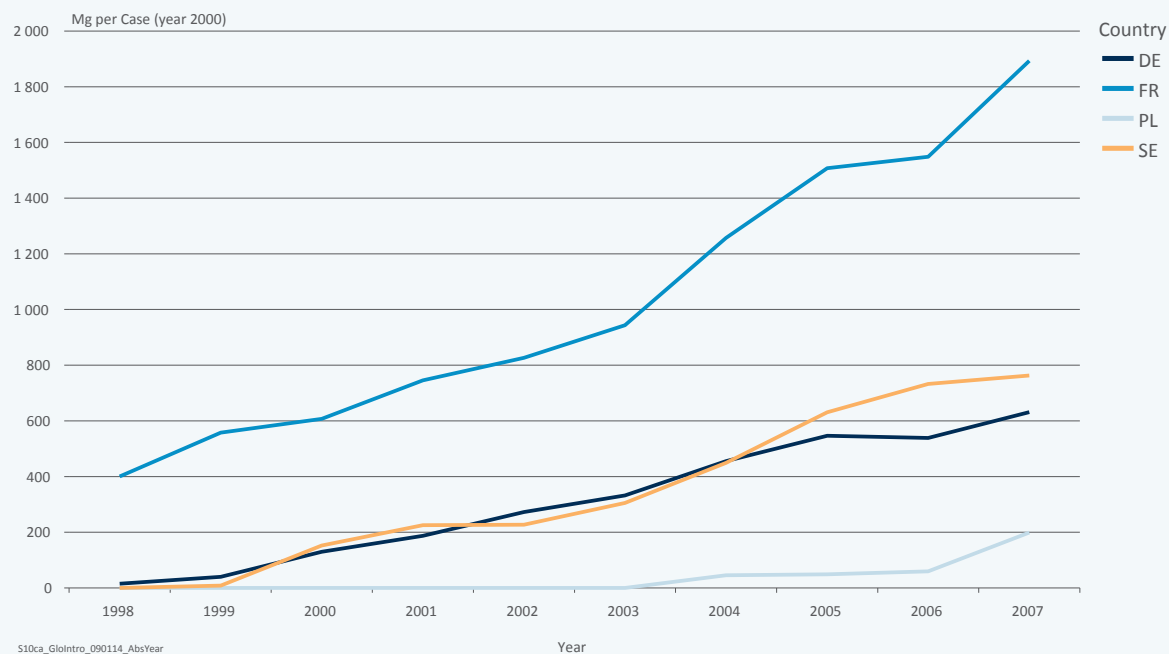


Figure 26: Usage of oxaliplatin expressed as mg/case (case = mortality in colorectal cancer in year 2000)

Notes: DE = Germany, FR = France, PL = Poland, SE = Sweden.

Lung cancer

Disease Lung Molecule Erlotinib

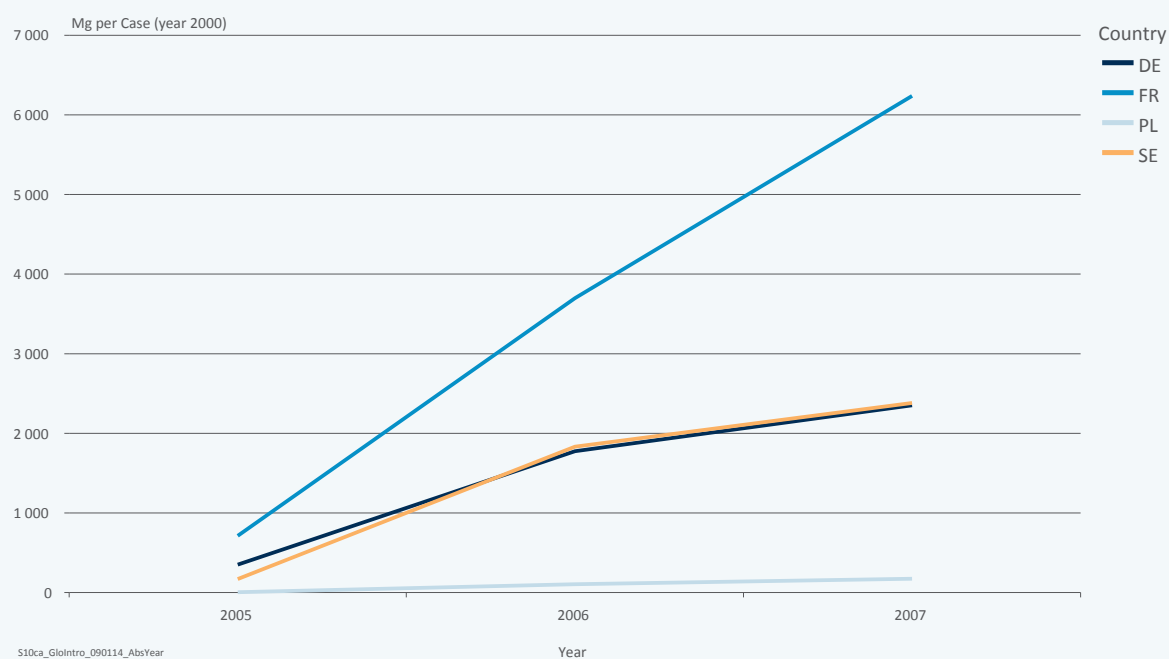


Figure 27: Usage of erlotinib expressed as mg/case (case = mortality in lung cancer in year 2000)

Notes: DE = Germany, FR = France, PL = Poland, SE = Sweden.

Disease Lung Molecule Gemcitabine

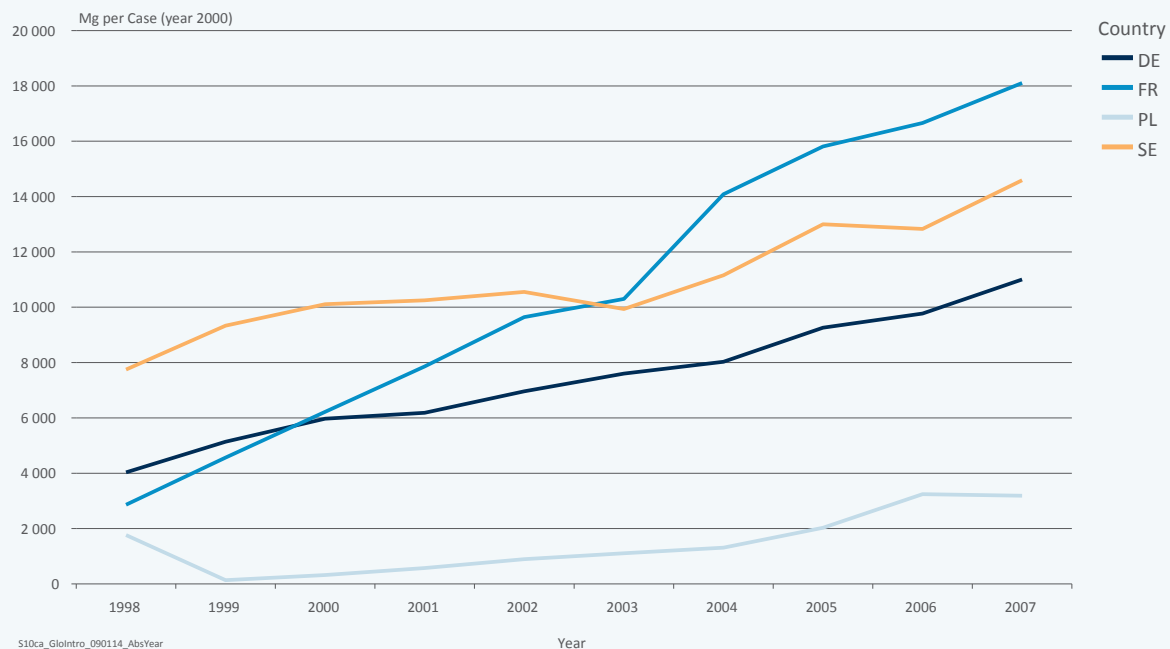


Figure 28: Usage of gemcitabine expressed as mg/case (case = mortality in lung cancer in year 2000)

Notes: DE = Germany, FR = France, PL = Poland, SE = Sweden.

Disease Lung Molecule Pemetrexed

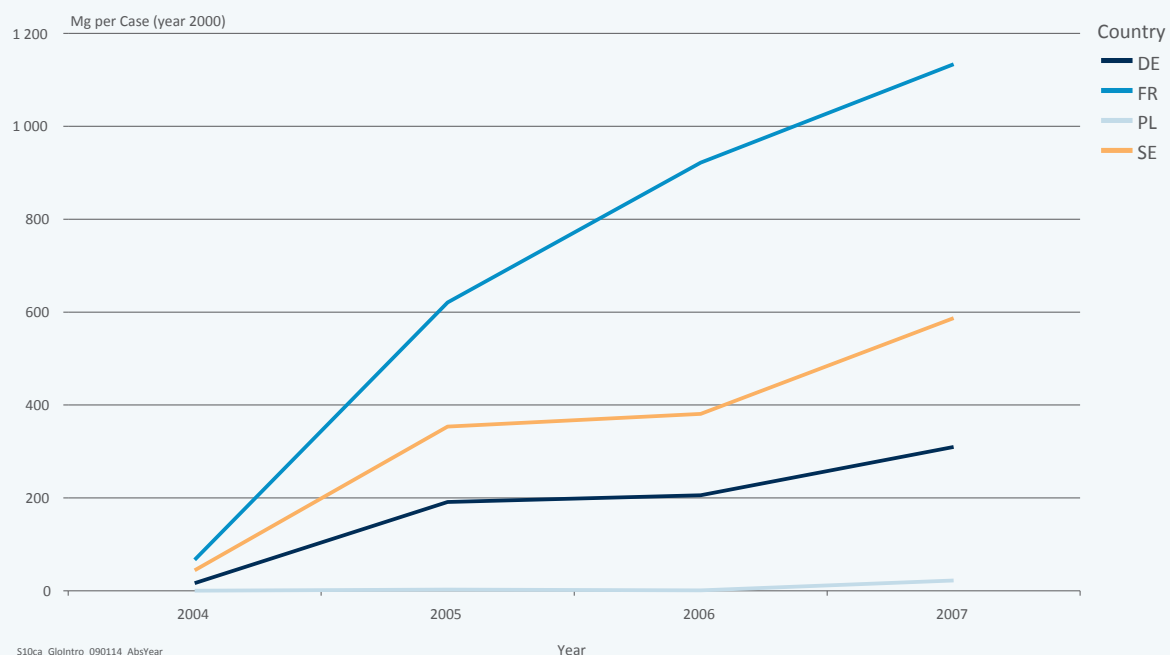


Figure 29: Usage of pemetrexed expressed as mg/case (case = mortality in lung cancer in year 2000)

Notes: DE = Germany, FR = France, PL = Poland, SE = Sweden.

6. Access to quality care in oncology – Treatment

Prostate cancer

The example for prostate cancer is docetaxel. Note that this drug is approved in several indications and mainly used in breast cancer.

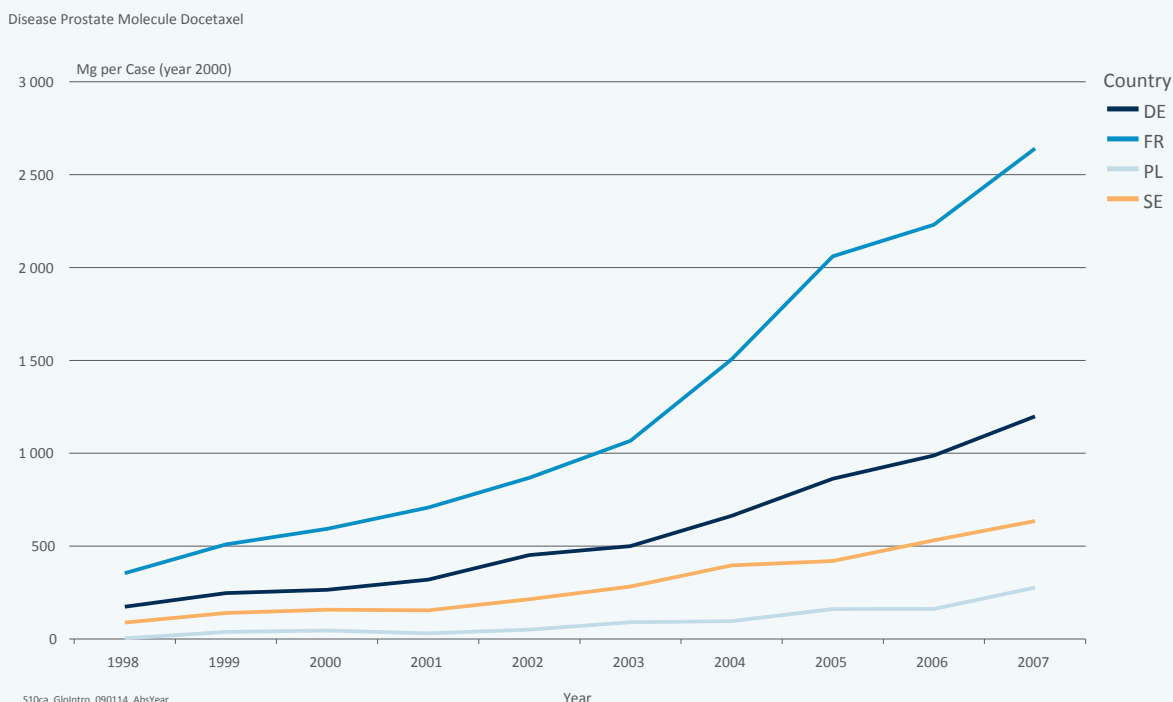


Figure 30: Usage of docetaxel expressed as mg/case (case = mortality in prostate cancer in year 2000)

Notes: DE = Germany, FR = France, PL = Poland, SE = Sweden.

CONCLUSION

Figures 23 to 30 illustrate the market uptake of selected cancer drugs for colorectal, lung and prostate cancer in France, Germany, Poland and Sweden. The first observation is that market uptake of cancer drugs varies considerably between the countries. It also seems that countries with rapid uptake of newer drugs have a high usage of all types of cancer drugs. Independent of the investigated drug, France shows by far the highest levels of market uptake of all investigated cancer drugs and the fastest speed of market uptake of newer cancer drugs. Germany and Sweden exhibit a fairly similar pattern in terms of level of uptake. However, Sweden seems to lack behind in the uptake of newer drugs (e.g. bevacizumab and cetuximab, but not pemetrexed). Sales in Germany may be

subject to some underreporting with respect to hospital drugs, thus the uptake may in reality be higher in Germany compared to Sweden. The gap between Poland and the three other countries in terms of level and speed of market uptake is remarkable. In Poland, the uptake of all newer cancer drugs (bevacizumab, cetuximab, pemetrexed, erlotinib) is effectively zero. The uptake of drugs that had been issued before 1998 is also very low in Poland compared with the other countries. These results underscore the inequality in access to cancer drugs across Europe and confirm the results of the reviewed studies in section 6.1.

6.4.

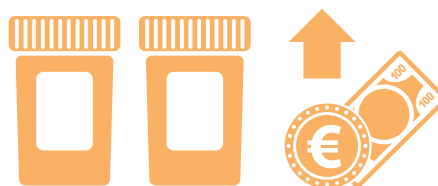
The “high” cost of new cancer drugs

The possibilities for cancer treatment with drugs have changed during the last decade. Chemotherapy was the standard treatment alongside surgery and radiation therapy. Drugs used in chemotherapy utilize the characteristic of cancer cells to rapidly divide and thus try to inhibit the ability of cancer cells to replicate their DNA. However, normal cells in the digestive tract or bone marrow also divide rapidly. As a result, the toxic drugs used in chemotherapy target both cancer cells and normal cells often resulting in severe side effects. Moreover, these side effects might prevent the usage of high doses of drugs to more effectively fight the cancer. Nonetheless, a small revolution was achieved with the development of targeted cancer therapies. Targeted cancer therapies are drugs that utilize another characteristic of cancer cells. Mutations in the genes that are responsible for causing cell growth have been identified in cancer cells. By interfering with specific molecules involved in tumor growth and progression, targeted cancer therapies block the growth and spread of cancer. The benefit of these drugs is that they better target cancer cells and harm fewer normal cells, resulting in the same or better results but with fewer side effects and improved quality of life [168].

Spending on cancer drugs is expected to continue increasing, not only as a result of newer and more expensive drugs but also due to an increasing number of cancer patients and a wider share of patients eligible for drug treatment. However, this conclusion overlooks several issues. Firstly, the introduction of newer and more effective drugs does not necessarily increase the total cancer-related direct costs. More effective drugs may lower medical costs through decreasing demand for other medical services, such as inpatient care [169], and might also lead to a decrease in relapse episodes. Secondly, the cancer-related indirect costs may decrease due to increased survival [158], decreased morbidity and less time needed for informal care. Thirdly, the patents of several widely-used and expensive cancer drugs are due to expire during the next decade [170]. Hence, there is potential to cushion the expected increase in drug costs by the savings derived from the use of generic versions of newer drugs [158]. In the same way but probably to a lower extent, biosimilars (also known as follow-on biologics) present opportunities for savings [170]. Fourthly, as shown in section 6.1.1 of this report, the number of new cancer drugs has increased sharply during the last three years. This increasing competition among suppliers might contain the costs of new drugs in the long term [158].

The introduction of new drugs that come at a high cost is difficult, even if the superiority in terms of health benefit has been proved. For a drug to be granted reimbursement by a national or regional HTA agency, the cost-effectiveness of the drug plays a decisive role. Analysis of cost-effectiveness is based on a comparison of the new drug with a comparator, which is usually an older drug that is the standard treatment option. If the comparator drug has already come off patent then the new drug has essentially to compete with a generic drug. Price reductions for generic drugs can be substantial. For instance, docetaxel and paclitaxel experienced price decreases of 76–87 percent in Australia after the drugs came off patent [171]. In Sweden several of the drugs that have gone off patent including paclitaxel, docetaxel and the aromatase inhibitors used in breast cancer are now available at price levels of 3-10% of premium prices [172]. Hence, proving the superiority in cost-effectiveness of new drugs is complicated if generic drugs serve as comparators.

Research on new ways to fight cancer is expensive. Targeted cancer therapies have brought us one step closer to finding a cure for cancer. Yet the health-economic burden of cancer is still high and the need to find innovative ways to fight cancer remains. To ensure that the incentive to conduct research is maintained, the value of innovative treatments has to be rewarded through adequate reimbursement. Apart from encouraging the private industry to continue to invest in research, this is critical for patient access. Patients can only benefit from new treatments if they have access to them. This underlines the necessity to reimburse innovative cancer drugs, to reduce delays in market access and to propel market uptake by swiftly incorporating these drugs in the current treatment regime.



Spending on cancer drugs is expected to continue increasing, not only as a result of newer and more expensive drugs but also due to an increasing number of cancer patients and a wider share of patients eligible for drug treatment.

6. Access to quality care in oncology – Treatment

Evidence on increasing costs for cancer drugs

Despite the economic crisis and austerity measures taken by governments, total health care expenditures per capita in real terms have been increasing in all countries of the EU-28 during the period from 2000 to 2010 [25]. Increasing

expenditures on pharmaceuticals in general and increasing costs for cancer drugs in particular have been reported as the driving factors behind this development.

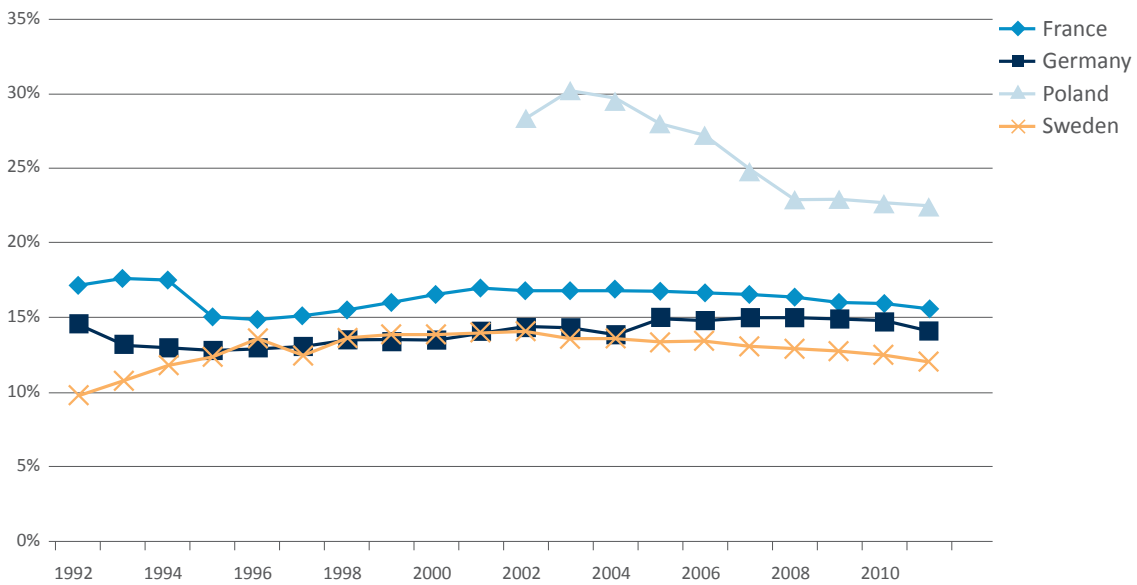


Figure 31: Total expenditure on pharmaceuticals and other medical non-durables as a share of total health expenditure, 1992-2011 [173]

Figure 31 illustrates the development of the share of pharmaceutical expenditures on total health expenditures for the period 1992 to 2011. Since around 1995 France, Germany and Sweden exhibit a fairly stable trend. This means that in these countries pharmaceutical expenditures grew at about equal pace as total health expenditures. In fact, both France and Germany are trending down since 2007 and are approaching values from the late 1990s. Sweden has been trending down since 2002 and in 2011 recorded the lowest value since 1994. In contrast to these recent gradual declines in France, Germany and Sweden, a sharp decline in Poland is noticeable. Data on real annual growth rates reveal, for instance, that total health expenditures increased by 14 percent in Poland between 2007 and 2008, whereas the growth in pharmaceutical expenditures was less than 6 percent [91] (see Table A6 in the Appendix for growth rates). Despite a narrowing trend, the share of pharmaceutical expenditure is distinctly higher in Poland than in the

other countries. A reason for this could be that patented pharmaceuticals have a somewhat “global” price, whereas other health expenditures, such as health care professionals, have a “local” price. Thus, the relatively cheaper human resources and the relatively more expensive drug costs is one explanation for the higher share of pharmaceutical expenditures in middle income countries such as Poland. One reason for Sweden having the lowest share might be the mandatory generic substitution that has been in place since 2002 for medically equivalent pharmaceuticals which are reimbursed. Germany has the same rule in place, whereas generic substitution is only indicative in France and Poland [116].

For France, it has been estimated that the cost of innovative cancer therapies increased from €335 million in 2003 to €714 million in 2006 [158], i.e. more than doubled within four years. Furthermore, drug costs in France constituted around 20 percent of the social security health budget (ca. €28 billion) in 2006. By contrast, innovative cancer drugs accounted for some €0.75 billion, or less than 0.6 percent of the total public health budget [158].

For Sweden, both a retrospective analysis and prospective estimates on the development of cancer drug costs had been made [174]. Between the years 2000 and 2007 cancer drug costs increased from SEK 640 million to SEK 2450 million, corresponding to an average annual growth rate of 21 percent. However, it also has been noted that this enormous increase is not solely attributable to price increases for drugs and the change to new therapies, i.e. new cancer drugs. During 2000 and 2007 both an increase in cancer patients and a wider patient share receiving drug treatment had been observed, which resulted in increased volumes being sold. Based on the sales of SEK 2.45 billion in 2007, drug costs were projected to grow by an average annual rate of 5 percent to SEK 4.8 billion in 2022. The reason for this rather modest increase compared to previous years is that the patents of many expensive and widely-used cancer drugs are due to expire (or already have expired by now), which is expected to result in significant savings [174].

In conclusion, the presented data do not support the notion that pharmaceuticals are the drivers behind increasing health care costs. The expenditures on cancer drugs have been increasing rapidly in the past, but forecasts indicate only modest increases in the next 10 years. Whether increasing expenditures on cancer drugs had been paralleled by an increase or decrease of total health expenditures on cancer, cannot be assessed due to a lack of data in this area. However, the available data suggest that the impact of the increasing use of expensive cancer drugs on the overall level of spending on pharmaceuticals in the investigated countries is at most limited and not the driving force behind increasing health care expenditures. This calls the notion of the “high” cost of new cancer drugs into question.

6.5. Patient access schemes

The reimbursement of drugs has seen changes in recent times. It is no longer a binary decision of either including (and fully reimbursing) or excluding a new drug in a national or regional reimbursement scheme. As explained before, France for instance, routinely applies three different reimbursement rates apart from full or no coverage. This is, however, just the tip of the iceberg. Different payment schemes have been developed that are summarized under the term “patient access schemes”, “risk sharing schemes/mechanisms/agreements” or “managed entry agreements”. They have been defined as agreements between payers and pharmaceutical companies to diminish the impact on the payer’s budget brought about by uncertainty about the value of the drug and/or the need to work within finite budgets [175, 176]. The aim of which is to improve patient access to new drugs.

The definition of patient access schemes reveals the reason for their development. The high prices of new drugs, especially cancer drugs, have been considered overly expensive and/or not cost-effective by payers. In response, pharmaceutical companies have developed payment schemes that allow companies to offer discounts or rebates to reduce the cost of a drug to the payer [177]. Furthermore, the definition stresses the uncertainty aspect of new drugs with regards to their effectiveness (and not clinical efficacy) in clinical practice, as well as the uncertainty about their budgetary impact. These two points on uncertainty are valid for any new drug, but they naturally weigh heavier on the payer’s decision in the case of high-priced drugs.

Taxonomy of patient access schemes

Attempts have been made to classify different patient access schemes [178, 179]. One common way is to make a distinction between non-health-outcomes-based schemes and health-outcomes-based schemes. It should be noted that in reality hybrid examples of the different agreements described below have been observed [178].

Non-health-outcomes-based schemes determine effective prices for a given drug¹⁸ at the population level (i.e. across all patients) or at the patient level [179]. Three types at the population level have been identified:

- (1) Price changes (i.e. rebate/discount) involve the negotiation of a price per unit for the drug between the pharmaceutical company and the payer that differs from the list price.
- (2) Expenditure caps limit the payer’s total expenditure on a treatment without limiting the total quantity of the treatment provided.
- (3) Price-volume agreements link the price paid per unit for a drug to the total number of units purchased, i.e. the unit price decreases as the purchased quantity increases.

18. Patient access schemes are not solely limited to drugs. In principal, reimbursement of any health technology can be subject to a patient access scheme.

6. Access to quality care in oncology – Treatment

At the patient level three types have been described:

(1) Manufacturer funded treatment initiation involves patients receiving a drug for a price that is different from the list price at initiation of treatment, with the price reverting to the list price if the patient remains on the treatment after a fixed number of courses or period of time.

(2) Utilization caps (individual volume agreements) involve the cost of treatment of patients being reduced, following an agreed length of treatment if the patient is judged still to require further treatment.

(3) Fixed cost per patient involves a set price for an entire treatment course irrespective of the number of treatments received.

Health-outcomes-based schemes relate the effective price paid for a drug to some clinically relevant health outcome measure [178, 179]. One can distinguish between the following main types:

(1) Performance-linked reimbursement ties the reimbursement level of a drug to the measure of clinical outcomes. This can take the form of an outcome guarantee, where the payer receives rebates, refunds or price adjustments if the treatment fails to meet the agreed upon outcome targets (i.e. some clinical endpoint or intermediate endpoint). Another form links the reimbursement level to the impact on clinical decision making or practice patterns (e.g. whether or not patients adhere to treatment).

(2) Conditional treatment continuation involves the payer only paying for continued use of a drug in those patients who have achieved a targeted (short-term) clinical effect (e.g. tumor response).

(3) Coverage with evidence development allows access to a new drug but conditions reimbursement upon the collection of additional evidence. This takes either the form of “only in research”, where the drug is only paid for in patients involved in the research, or “only with research”, where all patients are given access to the technology but new evidence is also generated.

Patient access schemes in Europe

Previous studies have shown that patient access schemes (PAS) are used across European countries. Yet some countries use them more frequently than others, and some countries do not use them at all [180]. A recent study investigated the use of PAS by public payers for 10 different cancer drugs¹⁹ at the end of February 2010 in different countries [176]. France and Sweden each used PAS at least for one of the drugs, whereas Germany did not (Poland was not included in this study). This study also showed some evidence that drugs which initially were not recommended for reimbursement (in most cases due to concerns over cost-effectiveness) were subsequently approved with PAS.

Another study conducted in 2010 and supported by the European Commission used an online survey format aimed at government representatives to examine the use of PAS for cancer drugs [180]. France was again among the countries to have had at least one PAS in place. Sweden reported no PAS, which is inconsistent with the result of the study described above. The problem herein (and also with other European countries) was that, for instance, the use of price-volume agreements was not considered a PAS by national authorities. This stresses the importance of a consistent terminology in order to make valid comparative international analyses. Furthermore, Sweden indicated in this study that it does not have any defined plan on the implementation of PAS in the near future [180]. Poland did not have any PAS in place. However, it indicated plans to implement such schemes for cancer drugs in the near future and was supposedly preparing the legal basis for it. Germany did not answer the survey, but it was pointed out that there is at least one example of a scheme for a cancer drug [180].

19. Bevacizumab, bortezomib, cetuximab, erlotinib, imatinib, pemetrexed, rituximab, sorafenib, sunitinib, and trastuzumab.

CONCLUSION

Taken at face value, PAS seem to be a good way of improving access to innovative but expensive drugs. However, no evidence on which scheme or class of schemes work best or well seems to have been collected yet. Little has been published on the results from implemented schemes [178]. It has been noted that many European countries do not have any plan aimed to evaluate the schemes they have in place. Yet evaluations of current schemes would help identify “lessons learned” that could help improve the design of future schemes [180]. In France, for instance, the only evaluation information that the Economic Committee on Health Care Products (CEPS) provided in this regard focuses on the net amount of clawback payments that pharmaceutical companies paid back: €260 million in 2008 and €236 million in 2009. But these numbers do not answer the relevant questions: Did patient access improve? And as a result, did patient outcomes improve? Did the scheme(s) result in overall savings to the public payer? etc.

In general, long lists weighing the pros and cons of PAS have been compiled. The three main arguments in favor of an implementation are (1) to limit budget impact, (2) to address uncertainties regarding clinical effectiveness and cost-effectiveness, (3) to manage utilization to optimize performance [181]. These three arguments are also the main reason that some European countries indicated to introduce PAS in the near future. European countries that already have implemented PAS for cancer drugs also emphasize the following points in favor of PAS: to facilitate quick patient access once the medicine has received EMA approval; an alternative if it is not possible to obtain lower prices for certain medicines; a means to promote the appropriate use of medicines; to avoid excluding some medicines from reimbursement; to improve the health system’s sustainability without denying access to medicines for needed treatment [180].

European countries that are opposed to introducing PAS stress their downsides, e.g. difficulties with the implementation and the associated resources needed to follow up on schemes, belief that the investment probably will not outweigh the benefits. Also countries with experience with PAS indicated some caveats: additional work time, mainly for hospital pharmacists; the need to have a well-designed and easy-to-use computer system, the generation of biased/misleading prices for countries using external reference pricing, the need to ensure that the cumulative burden of schemes is manageable for the health system [180]. The British experience from the National Health Service (NHS) has shown that the administrative consequences of PAS use for cancer drugs had been underestimated. It was concluded that PAS are not working properly in the NHS due to inadequate staffing needed to implement and manage the schemes [177].

Finally, PAS have been discussed as a means to increase patient access to new (cancer) drugs in middle income countries and to improve the quality of health care provision in these countries [182]. Differentiable drug pricing based on an individual country’s ability to pay may also be considered a special form of PAS. However, efforts to increase price transparency across countries might prevent such an approach. It has been suggested that pharmaceutical companies are reluctant to grant lower prices to lower income countries, because they fear that lower prices will undermine the prices they charge in higher income countries [183].

7. Conclusions and policy recommendations

In recent times progress and documented successes in the fight against cancer have been achieved. Over the last decade reductions in age-standardized overall mortality rates have been recorded in Europe, overall age-standardized incidence rates have started to stabilize and survival odds have continuously been improving. Despite these encouraging achievements, cancer is still the second leading cause of death in the EU and responsible for around 1.3 of all 5.0 million deaths per year. In addition, the 2.7 million newly diagnosed cases per year show that the disease burden of cancer is still weighing heavily on societies in the EU. Furthermore, recent trends in non-age-standardized rates reveal that cancer incidence and mortality are still on the rise due to the demographic change. On the other hand, the rise in cancer incidence is decoupled from the slower rise in mortality. The recent achievements indicate that improved quality of care can have an impact on the disease burden and that active measures can make a difference.

Which steps are needed to make a difference? A comprehensive approach is required to effectively tackle the cancer burden. This means that active measures in all three key areas of cancer care – primary prevention, screening, and (curative and palliative) treatment – have to be taken to improve patient outcomes. Most importantly, this report has demonstrated that access to high-quality cancer care is an important driver for improved patient outcomes. It has also highlighted several barriers that prevent patient access to and the provision of high-quality cancer care.

The main question for health policy in the area of oncology is then how to ensure equal access to the best possible care for all cancer patients. At the heart of a conclusive answer is the efficiency in use of resources for improved outcome, and reducing inequalities in access to care both between and within countries in Europe.

Nonetheless, the circumstances are challenging. Despite advances in prevention, the number of new cancer cases continues to increase as a consequence of the increasing share of elderly people in Europe. At the same time, technological improvements in cancer care allow for treatment of a wider share of patients, and increases in survival mean that patients are being treated for a longer period of time, which increases the demand for resources. On top of this, the economic crisis placed a financial strain on the health care systems in Europe.

All of these factors are putting the sustainability of access to high-quality oncology care to the test. The need to optimize oncology care as part of the overall reform of health care systems for the longer term has arisen. Improving outcomes and value, regardless of the level of resources available, is the most critical factor for sustainability. Based on the analysis, this report provides a set of policy recommendations to support priority setting in health policy in order to ensure access to a high standard of care in oncology that is both achievable and sustainable.

Cost-effective spending

A theme that runs like a common thread through the whole report is the emphasis on cost-effective spending. Since budgetary resources for the health care area are limited, payers and providers have to strive for a cost-effective allocation of these resources as part of the overall aim to establish a more accessible and sustainable health care system. The European Commission has also called for cost-effective spending that secures health outcomes, brings savings, reduces inequalities in health and helps to reduce poverty and social exclusion [18]. This is particularly relevant for cancer care, where these policies must be implemented together with measures for introducing new innovative treatments that can improve outcomes.

For countries that have already reached a fairly high quality standard in oncology care (e.g. France, Germany and Sweden), cost-effective spending should be of highest priority to achieve further improvements in patient outcomes at no (or small) additional costs. For countries with an urgent need to enhance the quality of cancer care (e.g. Poland), cost-effective spending is fundamental when planning the introduction new policy measures, as resources can be allocated into areas of care where the greatest health benefit can be achieved per money spent.

This report showed, for instance, that there is great potential for cost-effective measures in the area of screening in order to improve the quality of oncology care. In general, cancer screening programs have to satisfy a number of criteria to be accessible and effective, on top of the general determinants of access to health care. These include the overall organization, public information campaigns, the test method, the target group, the screening interval, follow-up actions, and a system to monitor the quality of the program at all stages. However, not all population-based cancer screening programs are necessarily beneficial and cost-effective. The benefit of PSA-based prostate cancer screening is doubtful, and evidence on the benefit of lung cancer screening remains to be established. Colorectal cancer screening, on the contrary, is an effective and efficient method to reduce mortality. The value of breast cancer screening has decreased due to the increased use of adjuvant therapy, but it is still of value. Continuous follow-up studies, alongside monitoring of resource use and outcomes, are necessary for the development of evidence-based policies for cancer screening programs.

For policy making these findings imply that countries should spend less on prostate cancer screening and instead increase their efforts for colorectal cancer screening. This would result in savings stemming on the one hand from less expenditure on actual screening for prostate cancer and on the other hand from a reduction in unnecessary surgeries and other treatments of prostate cancer patients. France and Germany could especially benefit from such a policy shift and could use the savings from reduced prostate cancer screening to either support existing programs for colorectal cancer screening or re-invest the money in cancer treatment, e.g. purchase of additional radiation therapy machines to reduce the unmet need in this area. Poland and Sweden could also achieve efficiency gains, yet additional investments are needed first to adapt the current screening programs for colorectal cancer to meet the outlined quality criteria. In the short-term this would lead to an increase in costs for screening as well as treatment costs due to a surge in number of detected cases. However, in the medium-term treatment costs would decrease as colon polyps are detected and removed before they become carcinomatous in an increasing number of people, thereby making costly treatment redundant.

Adequate level of resources

Patient access to oncology care presupposes the availability of oncology services. For patients to benefit from the provided care, the quality standard of care is critical. These two basic requirements highlight the need for an adequate level of resources to be spent on cancer care. On the one hand, an adequate level of resources may refer to the relative share of total health care expenditure being allocated to oncology care. On the other hand, the absolute level of spending in terms of per-capita expenditure on oncology care has to be adequate, particularly to enable access to new innovative treatments.

This report has shown that the share of cancer-related direct costs on total health care expenditure ranges from 5% in Poland to 7.3% in Sweden. However, purchasing power adjusted per-capita spending on cancer is around €210 in Sweden, Germany and France and more than three times higher than in Poland at €60. The gap in unadjusted per-capita spending on cancer is more than twice as large and ranges from €33 in Poland to €283 in Sweden.

An inadequate level of resources restricts access to high-quality oncology care in a number of ways. First of all, it restricts the availability of oncology facilities which are determined by a trade-off between costs and quality, and patient proximity considerations. It also creates a geographic barrier due to the concentration of oncology facilities. A financial barrier arises if low public financial means necessitate patient co-payments and if they restrict access to innovative care. Finally, it might also evoke a social and cultural barrier if patients are being discouraged from seeking help, due to an awareness of the low quality of care being provided from inadequate level of resources.

Without adequate funding, entitlements to care exist only on paper in universal health care systems. Real access to care cannot be gained due to a lack of resources. The example of Poland in this report was indicative of this case. Cancer care in Poland is characterized by a considerable undersupply of medical technologies needed for diagnostics and treatment, and health care professionals. Screening programs yield unsatisfactory results and access to new cancer drugs is effectively non-existent. This restricts access to high-quality cancer care, limits the ability to improve patient outcomes and renders it difficult for Poland to catch up with other EU countries. The observations made for Poland are probably also true for other European countries with similar or lower levels of income per capita.

Two issues have to be kept in mind regarding the importance of the level of expenditures for outcome. Firstly, a recent OECD report showed that the relationship between per-capita spending on health care (i.e. a general measure for input) and survival rates (i.e. one possible measure for output) is non-linear in the case of colorectal cancer [37]. The findings suggest that countries can attain fairly high survival rates with modest spending on health care. With increasing per-capita spending, the additional improvements in survival rates start to decrease. Secondly, this report has shown that despite fairly similar per-capita spending on cancer care, France, Germany and Sweden differ in outcomes as measured by survival rates. This finding stresses the importance for health policy to set the right priorities in cancer care. It further emphasizes that an adequate level of resources is vital to improve patient outcomes, as is how resources are spent.

Nonetheless, these observations should not overshadow the seriousness of the huge variations in resource availability for health care in Europe, and in particular the consequences for access to new innovative cancer treatments. Differentiable pricing based on an individual country's ability to pay, should be given careful consideration. Although the WHO and WTO originally intended such a pricing strategy for developing countries [184], it might offer a way to improve access in the middle income countries in Europe and maintain value-based reimbursement (see below).

7. Conclusions and policy recommendations

Maintaining access to innovative care through adequate reimbursement

Reimbursement is essential for access to high quality cancer care. Although cancer care is fully reimbursed in most European countries, out-of-pocket payments still account for a considerable part of health care financing, and austerity measures have worsened this situation, particularly in those European countries with the lowest incomes. The design of reimbursement systems and the criteria for reimbursement must therefore be reconsidered to improve access to effective treatments.

In the area of primary prevention for example, HPV vaccination has offered a new way to decrease the risk of developing cervical cancer and other HPV-related cancers. Yet HPV vaccinations are not fully reimbursed in all countries of the European Union and in some countries parents have to cover the full cost, which effectively restricts access [13]. In the area of screening, cost-effective methods such as colorectal cancer screening with FOBT should be reimbursed to encourage and enhance people's participation. Sufficient evidence on the effectiveness of lung cancer remains to be established, but if it proves to be a cost-effective method to reduce mortality, it also should receive adequate reimbursement. It is worth noting that such health policy actions have a signaling function and also can stimulate the development of more reliable screening methods for other cancer types, e.g. prostate cancer.

The principles and practices for reimbursement will not only affect the effective use of today's resources, but also the kind of methods that will be available in the future. The promotion of access to innovative treatments in general and access to new cancer drugs in particular should be a priority of health policy. The supply of new cancer drugs has increased in recent years. However, market access is delayed by lengthy pricing and reimbursement decisions at national or regional level. More importantly, this report has shown that market uptake of new cancer drugs varies considerably across Europe. The ability to access new cancer drugs thus depends on where patients live.

The total expenditure on cancer drugs increased dramatically over the last decade. This is a result of increasing volumes being used to treat an increasing number and a wider share of patients, and not just the price of new drugs. The cost increase has leveled off in recent years and will be further moderated as some widely-used cancer drugs will come off patent in the coming years. Nonetheless, recent shifts in the reimbursement and pricing policy of new drugs in Germany and France were carried out with a view to containing pharmaceutical expenditures. Even if some measures are more directed towards price than volume, the sustained patient access to new cancer drugs in these countries may be affected. The extent of the impact on patient access remains to be seen; however, the example of Sweden, where patient

access to newer drugs is particularly restricted, might be indicative of the consequences that will result from the latest policy shift in France.

The Polish example shows that considerable underfunding of the health care system leads to inadequate reimbursement of new cancer drugs. Without reimbursement, patient access to these drugs becomes marginalized. In Poland this has led to inappropriate use of ineffective treatments with cheaper cancer drugs or no drug treatments at all. The resulting low quality standard inhibits the provision of effective cancer care, keeps patients from benefiting from innovations and limits improvements in patient outcomes. The development of new mechanisms for the payment of oncoming innovative cancer treatments should therefore be a priority for policy.

Organization and evidence-based provision of oncology care

The quality of oncology care is not only determined by resource inputs (e.g. radiation therapy machines, drugs, etc.) but also by organizational factors that impact on the process of care provision. Firstly, clinical guidelines that establish a certain standard of cancer care have been found to contribute to increased survival (provided that they are complied with) [185]. It has also been shown that guidelines for cancer treatment play a key role in the provision of equal care across a country [186]. The OECD suggests, for instance, that countries should develop national clinical guidelines around the management of the most common cancers [37].

Secondly, there needs to be an integrated chain of care including prevention, early detection, curative treatment as well as palliative treatment. In these processes the focus should be on the multidisciplinary structure of a well-functioning cancer care. Multidisciplinary teams are a key element in this process, where different specialists representing diagnostics (radiology, pathology, cytology), treatment (surgery, radiation and medical oncology) as well as specialized nurses and psychosocial workers are represented. Studies have shown that there is strong evidence proving that multidisciplinary teams improve cancer patient survival in general [56], and specifically for lung cancer [57], prostate cancer [58], and rectal cancer [59].

Once cancer is diagnosed, patients need to be able to access high-quality care in a timely manner. As mentioned above, cancer care is an integrated chain of processes. Since a chain is only as strong as its weakest link, a resource shortage in one link will affect the quality of the whole cancer care process. In other words, the resource inputs in the care process have to be well-balanced, otherwise bottlenecks emerge that result in long waiting times. Sweden, for instance, has an oversupply of radiation therapy machines and access to this treatment modality should not constitute an obstacle. Yet the shortage

of pathologists and radiologists delays access to treatment and leads to long waiting times. Germany faces similar problems with a shortage of oncologists, which is predicted to aggravate until 2020. This emphasizes the importance of long-term planning in the area of human resources, as the education and training of skilled oncology care professionals takes time. On the contrary, shortages in material resources are in principal easier to amend, provided budgetary means allow for it.

Monitoring the quality of care

A prerequisite for taking measures to improve oncology care is to have good data on the current care system. Data are important for the documentation, assessment and communication of quality of care. They help to inform and plan the allocation of cancer resources, identify oversupply and undersupply of resources and detect regional differences in access to and quality of treatment. They are also fundamental to make comparisons over time in order to assess the progress and impact of policy measures within a country. Finally, data on variations between countries in the use of methods for prevention, screening and treatment help to identify best-practice measures to achieve a cost-effective re-allocation of resources that improves patient outcomes.

A comprehensive system of cancer registries that covers the whole population of a country is one tool that can provide this kind of data. Yet registries need to record not only the treatment provided and outcome of the treatment, but also to collect relevant individual patient data on quality of life. Such a system eases the monitoring of the quality of the provided care and helps to uncover weak points and inefficiencies in the care system. France has, for instance, a nationwide cancer registry for children only; adults are only covered in a few regions. In the absence of a comprehensive nationwide system of cancer registries, regional differences in access to and quality of care might remain undetected. Germany was faced with the same problem until recently, but the planned national cancer registry will facilitate the monitoring efforts on the quality of the care system, which should enable further improvements in care provision.

An important finding of this report is that the data availability on cancer care is insufficient in most European countries. Basic data on incidence, mortality and prevalence are available for most European countries solely for the year 2012 through the European Cancer Observatory, which was set up by the International Agency for Research on Cancer and the European Network of Cancer Registries in 2012. However, the most pressing issue is the limited availability of data on survival rates. At the beginning of 2014 comparable data are only available for a bulk of European countries for the 1990s up to 2002 through the EURO-CARE-3 and EURO-CARE-4 projects and for 23 member states²⁰ of the EU

for the period 2000-2007 through the EURO-CARE-5 project. These most recent figures have been published at the end of 2013 which means that there almost is a 6 year lag in between the date of publication and the end of the reference period. Even worse is that these data are not based on cohort analysis but on period analysis that followed patients until the end of 2008. Providing comparable data from a large number of European countries is a major task, but 5 years for analysis and publishing appears to be a rather long time. This lag brings along disadvantages both for policy-makers and patients. Since survival rates are a key factor to measure the outcome of cancer care, it is difficult for health policy to take the right measures based on this outdated evidence. On the other hand, in times of improving survival rates, patients' hopes should not have to hinge on outdated survival rates that portray an unreliable picture of their survival chances.

Apart from the outcome quality domain, the process quality domain is also characterized by a general lack of data for key indicators. There are, for instance, only limited data available on waiting times which would describe the effectiveness of the organizational care structure to handle cancer cases in a timely manner. Data would also be desirable on the degree of involvement by multidisciplinary teams in the care process and the share of cancer cases being reviewed by such teams.

The domain for which comparatively good up-to-date data is available is the structure domain. For instance, data on medical technologies such as CT scanners, radiation therapy machines or number of oncologists is being provided by Eurostat. However, comparable data on the most basic indicator in the structure domain – the amount of health care expenditures dedicated to cancer care – is lacking. This report provided estimates both for the share of cancer-related expenditure on total health care expenditure and for the cancer-related per-capita expenditure for the four investigated countries based on national sources. Yet the national sources did not provide for the most part up-to-date information. To tackle this issue, disease-specific health accounts would be needed. The Statistical Office of Germany, for instance, used to publish such information based on ICD-10 disease classification every other year. Furthermore, a disaggregation of costs into separate categories such as inpatient care, ambulatory care, medications, screening, etc. would be desirable but is not always available. Not knowing how much money is spent on a certain disease and which specific resources the money is used for is obviously a major limitation to informing health policy.

20. The five missing member states are Cyprus, Greece, Hungary, Luxembourg and Romania.

7. Conclusions and policy recommendations

Improving quality of life and functioning to support labor market participation

The health burden of cancer is two-fold. On the one hand cancer leads to premature death. On the other hand cancer patients are faced with a decreased quality of life. In the past, almost all cancer types were considered to be incurable, which meant that the mortality component constituted the major share of the health burden. In time with more effective care, survival chances continue to improve and more and more patients live for a longer time with the disease. That means that the morbidity component is growing in importance, as a shift from what once was a deadly disease to a more chronic disease is under way for some cancer types. For this reason cancer care increasingly fulfills the role of improving patient quality of life (instead of merely preventing death) to enable participation in daily life activities and to foster labor market participation. This point has also recently been emphasized by the OECD [37].

Health policy needs to recognize the increasing importance of quality of life as an outcome measure in cancer care in addition to survival rates. For instance, a shift from intravenous to oral delivery methods of cancer drugs has improved the quality of life of patients and increased their chances to live a normal life. It allows for patients to be treated at home, which reduces time and costs for travel to oncology clinics and improves the likelihood of returning to work. This aspect is also gaining importance in light of plans to raise the statutory retirement age beyond 65 years throughout Europe. Cancer patients suffering from the main cancer types, i.e. breast, colorectal, lung and prostate cancer, are typically aged over 50 years and still working at the time of diagnosis. In order to support labor market participation and to reduce early retirement, the health state of this share of the working-age population is critical. If governments want people in advanced ages to participate in the labor market until the statutory retirement age is reached, measures to enhance the quality of life of cancer patients have to be a priority for health policy.

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Appendix

Table A1: Estimated number of cancer incidences and mortality cases per 100,000 inhabitants in 2012 (age-standardized rates - ASR) and change in ASR between 2006 and 2012 [2, 24]

	Incidence				Mortality			
	Female		Male		Female		Male	
	ASR	Change	ASR	Change	ASR	Change	ASR	Change
All cancer sites								
Europe	306.3	1.1%	429.9	-2.2%	128.8	-4.9%	222.6	-9.1%
Colorectal cancer								
France	36.9	0.3%	53.8	-10.0%	12.9	-2.3%	20.6	-11.2%
Germany	34.8	-22.8%	59.7	-15.0%	13.1	-20.6%	20.7	-22.5%
Poland	28.9	4.3%	55.5	28.8%	15.9	-8.6%	31.8	1.0%
Sweden	39.4	5.3%	48.9	-0.6%	15.4	0.0%	19.6	-5.3%
Europe	34.6	0.0%	55.7	0.5%	15.4	-7.2%	25.2	-7.7%
Lung cancer								
France	27.9	86.0%	74.5	-1.3%	18.4	34.3%	58.7	-2.2%
Germany	25.4	22.1%	57.3	-6.4%	21.1	17.2%	47.0	-12.6%
Poland	31.1	8.7%	89.6	-13.0%	25.3	16.1%	82.9	-9.9%
Sweden	27.5	15.5%	28.8	0.7%	24.1	2.6%	26.4	-11.1%
Europe	21.6	18.0%	68.3	-9.3%	17.2	13.9%	59.1	-8.8%
Prostate cancer								
France			187.5	40.4%			17.7	-25.6%
Germany			114.1	1.0%			17.8	-16.0%
Poland			55.3	8.4%			20.8	-14.4%
Sweden			175.2	11.5%			31.6	-13.4%
Europe			96.0	10.7%			19.3	-13.1%

Table A2: Estimated cancer incidence and prevalence rates per 100,000 inhabitants (both sexes) (crude rates), 2012 [33]

	France	Germany	Poland	Sweden	EU-28
Colorectal cancer					
Incidence	62.3	79.0	50.4	66.8	68.4
1-year prevalence	49.3	60.5	35.1	53.4	51.1
3-year prevalence	126.9	155.0	82.8	137.6	128.8
5-year prevalence	187.6	229.5	115.9	203.1	188.7
Lung cancer					
Incidence	61.2	63.2	68.1	40.9	61.9
1-year prevalence	33.4	26.9	30.1	18.1	27.6
3-year prevalence	66.8	54.2	56.9	36.3	53.9
5-year prevalence	83.7	69.4	69.6	46.2	67.3
Prostate cancer					
Incidence	112.4	84.9	28.6	121.8	71.7
1-year prevalence	109.8	80.4	24.8	118.8	67.3
3-year prevalence	295.3	217.3	63.3	316.5	178.4
5-year prevalence	443.6	329.5	92.8	468.4	265.9

Notes: Underlying population figures were taken from Eurostat.

Table A3: Estimated disability-adjusted life years (DALYs), years of life lost (YLLs) and years lived with disability (YLDs) in age-standardized rates (ASR (W)) per 100,000 inhabitants in 2008 [35]

	DALYs	YLLs	YLDs
France			
Prostate cancer	309	136	173
Lung cancer (female)	271	263	8
Lung cancer (male)	753	726	27
Colorectal cancer (female)	199	156	43
Colorectal cancer (male)	277	214	63
Germany			
Prostate cancer	250	133	117
Lung cancer (female)	295	286	9
Lung cancer (male)	609	586	23
Colorectal cancer (female)	214	167	47
Colorectal cancer (male)	318	241	77
Poland			
Prostate cancer	200	148	52
Lung cancer (female)	350	341	10
Lung cancer (male)	1091	1055	37
Colorectal cancer (female)	232	204	28
Colorectal cancer (male)	359	310	49
Sweden			
Prostate cancer	353	212	142
Lung cancer (female)	332	323	9
Lung cancer (male)	309	298	10
Colorectal cancer (female)	229	184	45
Colorectal cancer (male)	248	193	56

Table A4: Health care expenditures and estimated direct costs of cancer (not adjusted for PPP), 2011

	Health care expenditure (share of GDP)	Health care expenditure (in M€)	Health care expenditure (per capita in €)	Cancer-related share of health care expenditure	Direct cost of cancer (per capita in €)
France	11.6%	232,287	3,592	6.6% (2004) [39]	237
Germany	11.3%	293,801	3,565	6.1% (2008) [38]	217
Poland	6.9%	25,481	661	5.0% (2002) [40]	33
Sweden	9.5%	36,690	3,883	7.3% (2004) [41]	283

Notes: PPP = purchasing power parity.

Source for health care expenditure: Eurostat [42];

Source for cancer expenditure: own estimate based on national sources (see Appendix for methodology).

Table A5: Age-adjusted 5-year relative survival rates in patients ≥ 15 years [75-77]

	France	Germany	Poland	Sweden	Europe*
Colorectal cancer					
1990-1994	56.7	52.4	29.4	54.9	49.3
1995-1999	57.5	57.5	38.8	58.3	53.5
2000-2002	59.9	61.2	46.0	59.8	56.2
2000-2007**	58.8	61.2	45.5	61.0	56.4
Difference	+2.1	+8.8	+16.1	+6.1	+7.1
Lung cancer					
1990-1994	14.0	11.7	6.8	10.6	9.2
1995-1999	12.8	13.2	9.2	13.1	10.2
2000-2002	NA	14.7	14.0	13.9	10.9
2000-2007	13.8	15.6	14.4	14.7	13.0
Difference	-0.2	+3.9	+7.6	+4.1	+3.8
Prostate cancer					
1990-1994	75.8	77.5	38.7	66.9	61.4
1995-1999	79.1	81.6	60.5	77.3	73.9
2000-2002	NA	85.3	70.7	82.5	77.5
2000-2007	88.9	89.4	66.6	87.5	83.4
Difference	+13.1	+11.9	+27.9	+20.6	+22.0

Notes: *Europe = Austria, Czech Republic, Denmark, Finland, France, Germany, Iceland, Italy, Malta, Netherlands, Norway, Poland, Slovenia, Spain, Sweden, Switzerland and UK for the periods 1990-1994 and 1995-1999. Europe for the period 2000-2002 also includes Belgium and Ireland but excludes Denmark. Europe for the period 2000-2007 also includes Belgium, Bulgaria, Croatia, Estonia, Ireland, Latvia, Lithuania, Portugal and Slovakia.

**To ensure comparability to previous periods, the estimate for colorectal cancer in the period 2000-2007 is calculated as the arithmetic average of the two estimates for rectal cancer and colon cancer. Note that these two estimates are very similar in all countries and that in some countries the 95% confidence intervals of the estimates overlap in fact.

Difference = change between 1990-1994 and 2000-2007 or nearest period.

NA = not available.

Table A6: Annual growth rates in real total health expenditures ("growth total expenditures") and real pharmaceutical expenditures ("growth pharmaceuticals") and share of pharmaceutical expenditures on total health expenditures [91] [173]

	2006	2007	2008	2009	2010
France					
Growth total expenditures	1.9%	2.1%	-0.9%	3.3%	1.3%
Growth pharmaceuticals	-0.5%	2.8%	-1.4%	1.6%	0.5%
Share of pharmaceuticals	16.5%	16.5%	16.3%	16.0%	15.9%
Germany					
Growth total expenditures	2.0%	1.7%	3.2%	4.1%	2.6%
Growth pharmaceuticals	0.1%	3.6%	3.1%	3.3%	1.7%
Share of pharmaceuticals	14.7%	15.0%	15.0%	14.9%	14.7%
Poland					
Growth total expenditures	6.0%	9.1%	14.3%	6.5%	0.6%
Growth pharmaceuticals	2.9%	-0.4%	5.7%	6.2%	-0.5%
Share of pharmaceuticals	27.2%	24.8%	23.0%	22.9%	22.7%
Sweden					
Growth total expenditures	3.0%	3.0%	2.9%	2.3%	2.0%
Growth pharmaceuticals	3.3%	0.6%	1.4%	1.1%	1.1%
Share of pharmaceuticals	13.4%	13.1%	12.9%	12.7%	12.5%

Notes: Pharmaceutical expenditures refer to total expenditures on pharmaceuticals and medical non-durables.
Growth rates in year x refer to growth from year $x-1$ to year x .

Methodology for estimating the cancer-related share of total health care expenditures

- France

The National Institute for Cancer (INCa) estimated the direct and indirect costs of cancer in 2004 (original publication in [9], English version available in [44, 158]). Direct costs amounted to €11,923 million. These costs include expenditures for inpatient care (€7,185 million), outpatient care (3,701), screening programs (248), primary prevention (120), and publicly funded research (670). According to Eurostat [42], the total health care expenditures amounted to €181,608 million in 2004 in France. Consequently, the cancer-related share of health care expenditure in France was 6.6% in 2004.

- Germany

The German Statistical Office directly provides the cancer-related share of health care expenditure. The most recent estimate from 2008 was 6.1% [38].

- Poland

The cancer-related share of health care expenditure was estimated to be around 5% in 2002 [40].

- Sweden

The Swedish Cancer Society (Cancerfonden) estimated the direct and indirect costs of cancer in 2004 [41]. Direct costs amounted to SEK 17,570 million. These costs include expenditures for care (SEK 14,465 million), drugs (2,005), screening programs (200), primary prevention (160), and publicly funded research (750). According to Eurostat [42], the total health care expenditures amounted to SEK 241,827 million in 2004 in Sweden. Consequently, the cancer-related share of health care expenditure in Sweden was 7.3% in 2004.

