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EVALUATION OF PREVENTIVE TECHNOLOGIES IN GERMANY

Case Studies of Mammography, Prostate Cancer Screening, and Fetal Ultrasound

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Abstract

Objective: In this article, three preventive strategies—mammography screening for breast cancer, PSA screening for prostate cancer, and routine ultrasound in normal pregnancy—are discussed in the context of German health care.
Methods: Epidemiologic data and German studies evaluating different aspects of these preventive measures were identified and analyzed.
Results: Only a few studies could be identified that investigate these preventive measures. Despite sufficient evidence, in part derived from a German study, there is not yet a mammography screening program. In contrast, ultrasound in pregnancy is offered routinely, although there are controversies regarding the benefit of this practice. PSA screening is not offered as part of the screening program for prostate cancer. However, PSA tests as well as mammographies are done in large numbers in German ambulatory care—a practice that could be considered wild or opportunistic screening.
Conclusions: These case studies show that preventive programs and practices in Germany are not sufficiently based on sound evidence. The paucity of evaluation activities related to prevention in Germany is probably due to the low threshold to introduce new preventive programs into the German healthcare system in the past.

Keywords: Breast neoplasms, Mammography, Prostatic neoplasms, Prostate-specific antigen, Ultrasonography, prenatal, Mass screening

This article aims at describing the current status of three selected preventive measures (mammography screening for breast cancer, prostate-specific antigen [PSA] screening for prostate cancer, and routine ultrasound in pregnancy) in Germany against the background of the legislative framework and regulation of preventive medicine in the German healthcare system.

This article is based on different sources of information. Epidemiologic data mainly come from the Federal Bureau of Statistics, which maintains mortality statistics and collects data from many other information sources in its newly established health reporting system (25). A literature search was performed that yielded 11 references specific to the topic of this article (3;4;9;12;14;15;20;21;23;27;28). This surprisingly low number of papers probably reflects the previously low threshold of introducing preventive measures into the healthcare system without need of evaluation of the usefulness of these measures.

THE GERMAN HEALTHCARE SYSTEM

The German healthcare system is a statutory health insurance (SHI) system, which currently covers almost 90% of the population. The statutory health insurance system began in the 1880s and initially included only 10% of the population. Over the last 100 years, eligibility has widened and the benefit package has become more and more comprehensive. Financial services such as sickness benefits and continued payment in case of sickness were introduced or increased, and preventive measures and nursing benefits were included (1;8).

In 1999, a comprehensive reform law, the Reform Act of SHI 2000, passed the Parliament and has been in effect since January 2000. Among others, regulations for sectoral budgeting of ambulatory and hospital care are tightened and prolonged indefinitely; the prospective payment system (similar to the U.S. system of diagnosis-related groups) in the hospital sector will be extended to all patients in 2003; and a positive list for pharmaceuticals will be issued (8).

Three main groups are involved in the organization of the system: the federal government, the state governments and the corporate bodies, which comprise the sickness, funds, the physicians' associations, and in addition, but with fewer rights, the hospital organizations. The Federal Ministry of Health sets the legal framework of the healthcare system and supervises federal agencies for licensing of pharmaceuticals, sera, vaccines, and supervision of medical devices. Currently, the following benefits are legally included: prevention of disease, screening for disease, diagnostic procedures, treatment of disease, and transportation. Treatment includes all necessary and state-of-the-art ambulatory medical care, dental care, drugs, nonphysician care, medical devices, inpatient/hospital care, home nursing care, and rehabilitation.

The states (Lànder) are responsible for maintaining the hospital infrastructure by means of fulfilling hospital plans and through paying for investments according to these plans. Other important responsibilities are public health (mainly supervision and monitoring activities of personnel, goods, and diseases), undergraduate medical, dental, and pharmaceutical education, supervision of regional physician chambers, regional associations of sickness fund-affiliated physicians, and sickness funds operating in the state.

Corporate bodies comprise the associations of sickness funds, physicians, and dentists. The latter two corporate institutions have the full obligation to secure the actual provision of all direct and acute healthcare services since they have both the corporate monopoly and mission to secure ambulatory care. The monopoly implies that hospitals, communities, sickness funds, and others do not have the right to offer ambulatory medical care (8).

HEALTH TECHNOLOGY ASSESSMENT IN GERMANY

Compared to the situation in the mid-1990s, health technology assessment (HTA) is now a high-ranking topic among decision makers in health care. Although HTA is not yet established as a routine to the evaluation of new or established medical technologies in

Germany (except for coverage decisions upon new technologies in the ambulatory care sector, see below), a number of initiatives and changes according to the Reform Act of SHI 2000 have resulted in a more systematic approach to HTA in Germany. For example, within the German Institute for Medical Documentation and Information (DIMDI), a federal HTA department has now been established. This institute is closely collaborating with the German Scientific Working Group Technology Assessment for Health Care (5).

The working group carries out the German HTA project funded by the German Ministry of Health with the aim of establishing an information system for the evaluation of health-related technologies. Currently, a major part of this project consists of evaluating a number of diagnostic and therapeutic health technologies. Besides university departments, the German Cochrane Centre, the Federal Medical Review Board of Sickness Funds, Federal Committee of Physicians and Sickness Funds, and DIMDI are working together. The methodologic standard of the HTA reports carried out by the working group are acknowledged and are relied on for coverage decisions in the ambulatory care sector (5).

The mandate for coverage decisions in the ambulatory sector of new technologies by the Federal Committee of Physicians and Sickness Funds has been extended in 1997 to established technologies. According to the Reform Act of SHI 2000, a federal standing committee for hospital care will be created. This new committee will be charged with the evaluation of medical technologies to be introduced into the hospital sector. Both federal committees will be coordinated by a new umbrella committee. It can be expected that the evaluation of health technologies in the hospital sector (up to now this was only the case in the ambulatory care sector) will increase the demand for HTA dramatically during the next years.

PREVENTION IN THE GERMAN HEALTHCARE SYSTEM

Until 1988, sickness funds could voluntarily provide supportive measures such as preventive spa treatments for their members. Decision making took place within the elected self-government of every sickness fund. Since 1989, these benefits have been included in the mandatory benefits' catalog decided upon by the lawmakers through the *Social Code Book Part V* (SGB V) as part of the standardization of the benefits' catalog (with the notable exception of health promotion).

Immunizations covered by the sickness funds are given by physicians in private practice who have the monopoly for delivering ambulatory services. The range of immunizations covered is determined by the sickness funds. Immunization rates have been decreasing in Germany—a fact that in 1996 alerted the physicians. The "physicians' parliament" urged all physicians to increase their immunization activities.

On the other hand, the scope of screening examinations is determined at the federal level through negotiations between the sickness funds and physicians' associations. As for all negotiations concerning the scope of benefits, the Federal Committee of Physicians and Sickness Funds is responsible for this (7;19). This committee has several subcommittees—among them Prevention and Family Planning. The former is responsible for drafting guidelines regulating regular health examinations (according to SGB V §25[1]), cancer screening (§25[2]), and check-ups for children and adolescents (§26). The latter issues, among others, the prenatal care guidelines. The committee negotiates intervals between examinations, services included, and documentation required. For example, in 1995–96, screening for chlamydia was included, in prenatal care and ultrasonographic screening for congenital hip dysplasia was made obligatory within the check-up program for children. In 1999, a routine electrocardiogram was removed from the regular health examinations based on the ground of insufficient scientific evidence. Another joint committee of physicians and

sickness funds determines the number of points attached to each service, which are the basis for reimbursement, as well as the exact definition of the service and the conditions for reimbursement.

CANCER SCREENING PROGRAMS

Coverage for annual cancer screening within the statutory health insurance comprises Pap smears for cervical cancer for women from the age of 20 years, and inspection and palpation of the breasts and skin examination for malignant melanoma for women older than 30 years. From the age of 45, men are offered palpation of the prostate gland for cancer and both sexes are eligible from the age of 45 for colon cancer screening with the guaiac test (SGB V §25[2]).

Motivating people to participate in the screening examinations is mostly done by the sickness funds. They mail a separate voucher for every screening or check-up to all eligible members or family members (in addition to the usual permit, which enables them to receive curative services). After a decrease in attendance in the mid-1980s, participation rates for cancer screening have been increasing. In 1997, 51% of eligible women and 17% of eligible men participated in the western part of Germany, and 49% and 13%, respectively, in the eastern part (6). These rates vary widely between the different types of sickness funds (ranges: 32–67% for women, 5–19% for men in the west, and 28–79% and 5–14%, respectively, in the east) which may indicate the importance of both socioeconomic status and promotion through the funds. The total costs for the cancer screening program in 1995 was 684 million Deutsche Marks (DM), about half of the cost of the entire prevention program (25).

CASE STUDIES

Mammography Screening for Breast Cancer

Mammography has been available in Germany for almost 60 years, but there is no formal national screening program in place. In contrast, instruction for breast self-examination has been included in the breast cancer screening program in 1982 despite doubtful evidence at that time (21). De facto, many physicians offer mammography for screening purposes though this examination is not part of the uniform benefits package for those insured with the sickness funds. The sickness funds reimburse mammography only in cases where a suspicion of cancer exists. This opportunistic screening covers about 40% of all women between 40 to 70 years of age. Unfortunately, there is no German data collected with which to evaluate the effectiveness of this method for detecting breast cancer. For example, little is known about the false-positive and false-negative rates that result from such screening. Moreover, important data about morbidity and mortality due to breast cancer are lacking. Registries have been established recently, but the first nationwide reliable data are not expected to be available within the next few years.

Since 1971, the SHI's cancer screening program has been offering all women over the age of 30 an annual screening examination, which comprises a clinical examination and instruction on how to perform regular self-examinations. Mammography screening is not part of this program.

In Germany, breast cancer (ICD-9 Code 174) is the most common cause of death of women between the ages of 38 and 50. In 1995, a total of 18,674 women or 34 of 100,000 population (standardized to the European standard population) died of breast cancer in Germany. Deaths from breast cancer account for 3.9% of all deaths in Germany. The standardized incidence rate in the early 1990s was 85 per 100,000 women, and an increase

in incidence of about 10% to 20% over the last 20 years was observed. In 1990, the detection rate for breast cancer was 14 per 100,000 women examined (25).

Few formal assessments of mammography screening in Germany have been identified. From 1971 to 1986, the small Hamburg Screening Study (3;10) recruited 14,000 women, which were examined biennially. The study tested a combined approach of clinical and mammography screening. In the course of this study, 176 carcinomas were detected, of which 22 were interval cases. The relative mortality reduction among the screened women was 32% as compared with nonparticipants. Of note, two-thirds of the screened women were below the age of 50 years.

The German Mammography Study, which was funded by the Federal Ministry for Research and Technology, developed training and quality assurance for mammography screening in preparation for incorporating this into the German Cancer Screening Program. This study showed that it is possible to assure standards for breast cancer screening programs in Germany (11;14;27). Over a period of 3 years, 43 office-based physicians included women over the age of 40 in an annual screening program. During the 3-year period, the technical quality as well as the outcome in terms of the detection rate increased considerably from 2.4 to 5 per 1,000 women screened. In total, 33,353 women were screened and the overall detection rate was 3.3 per 1,000. About 30% of all detected carcinomas were of the prognostically favorable intraductal non-infiltrating type. In addition, a cost-effectiveness analysis showed costs of 18,800 to 25,300 DM for each life-year gained (biennial screening interval, women from 50 to 69 years). The estimated decrease in mortality of 11% was two to three times lower than in the United Kingdom and in the Netherlands (4;11). A number of recommendations for the introduction of a mammography screening program in Germany were derived from these results. The German Mammography Study showed that 70% of the participating physicians accepted and agreed to the quality measures taken during the study, and 93% of the screened women would continue to participate in the program, suggesting a high rate of patient satisfaction.

A recent approach to specifically motivate women for participation in a local breast cancer screening program was very successful but associated with considerable organizational effort (14).

Despite these favorable results, mammography screening has not yet been included in the cancer screening program. There are several reasons for the present situation. First, the value of mammography screening is still considered controversial in Germany (22;28). Consequently, there is no guideline or policy statement that advocates a regional, or even a national, screening program. Second, mammography is offered by both radiologists and gynecologists, who are paid on a fee-for-service basis. Due to the requirements for a successful screening program (i.e., number of examinations per year, quality assurance, etc.), of the 1,700 facilities that currently offer mammograms, many of the smaller providers fear they may not qualify to participate in such a program. This was the case in the United States, where small-scale providers found that they did not meet the standards set by the U.S. Food and Drug Administration. Another reason is that the German government traditionally deals with the healthcare sector only on an aggregate level. The details of healthcare provision are delegated to the sickness funds and statutory healthcare physicians. This self-governing, corporate approach to healthcare delivery leaves health goals, such as the reduction of breast cancer mortality, to individual agencies or joint committees (such as the Federal Committee of Physicians and Sickness Funds) involved in health care. Consequently, there are no nationwide health programs initiated and maintained by government. Particularly in times of financial constraint, there seems to be no incentive to establish a costly screening program that might deliver health benefits to society but not necessarily to healthcare and insurance providers. There is also an information deficit regarding the well-established effectiveness of breast cancer screening. As a result, patients and special interest groups may

regard mammography—a radiation-based technology—as the possible cause of additional cancers. Furthermore, current attitudes toward the use of complementary medicine do not favor mammography screening.

However, in 1998 a multi-center trial was initiated to test the feasibility of mammography screening in the German healthcare system. The trial will cover 240,000 women between the ages of 50–69, in three different regions, at a cost of approximately 30 million DM (13). This is in line with the conclusion of a systematic review, conducted by the German Scientific Working Group Technology Assessment for Health Care (12), that the results from mammography screening studies conducted in centrally organized healthcare systems are not directly transferable into the German context.

The standards used are those of the European Union (EU), and the project will be part of the Europe Against Cancer program of the EU (12). The action plan of this European initiative comprises five specific objectives: a) data collection and research; b) information and health education; c) establishment of an annual meeting for Europe Against Cancer; d) early detection and screening; and e) training and quality control. The financial framework for implementation of this plan for the period from 1996 to 2000 is set at ECU 64 million.

With this step, Germany is the last country to sign up with a project within the program. It still has not joined important other initiatives to date (e.g., the International Breast Cancer Screening Network).

Despite conflicting evidence from a recent study (24), the above-mentioned HTA report (12) concludes that the implementation of a national mammography screening program will have several beneficial effects besides mortality reduction. Among these are improvements in quality assurance, enhancing communication between the ambulatory and hospital sectors, and organizing a nationwide cancer registry. The often-voiced argument, however, that the unique circumstances of the German healthcare system prevent the creation of programs similar to those in the United Kingdom or Sweden, is still unproven.

PSA Screening for Prostate Cancer

The incidence of prostate cancer (ICD-9 Code 185) in Germany, as in most Western countries, is increasing. This is probably due to an aging population as well as the result of increased screening efforts. It is estimated that about 25,000 new cases of prostate cancer were diagnosed in 1995 (15;25). Mortality, age-standardized to the European standard population, increased from about 24 in 1973 to 38.5 per 100,000 (11,868 men in absolute terms) in 1995. In total, deaths from prostate cancer account for 11% of all male cancer deaths in Germany. In 1990, the detection rate for prostate cancer was 127 for 100,000 persons examined (25).

The German screening program for prostate cancer as a benefit of the SHI was established in 1971. Men older than 45 years of age are eligible. The program comprises a medical history and a digital rectal examination, but PSA measurement is not part of the program. However, PSA tests are increasingly used in German ambulatory care. The frequency of use of this test almost doubled between 1990 and 1995, from 783,000 to 1,533,400. Remarkably, office-based urologists used this test in 1990 only 22,500 times, but in 1995 more than 460,000 tests were performed in their offices. The remainder of the tests were done by laboratory specialists (data from the frequency statistics of the National Association of Statutory Health Insurance Physicians).

Only one study dealing with the efficacy of PSA screening could be identified. This hospital-based study of 561 men older than 45 years of age who were screened by digital rectal examination showed an increase in the detection rate from 2.85% to 3.2% if PSA is also measured (9). However, this study was biased since only patients admitted to surgery were included in the study.

Another study, based on a questionnaire survey of 876 persons (mainly administrative personnel), investigated the attitudes toward cancer screening of different types of cancer: prostate, rectum, skin, and lungs (23). The results showed that 70% would participate in a skin/lung cancer screening program, but only 51% would participate in a "below-the-belt" screening program for cancer of the prostate and rectum. In the latter case, participants were not comfortable with the interference of the rectal examination with their privacy. Subgroup analysis revealed that this phenomenon was more marked among persons who never took part in a prostate/rectal cancer screening examination. PSA testing was not asked for in this survey.

The systematic review of PSA screening by the German Scientific Working Group Technology Assessment for Health Care (20) came to the conclusion that this technology is still experimental and should not be recommended for inclusion into the prostate cancer screening package.

Routine Ultrasonography in Normal Pregnancy

Routine ultrasound in pregnancy is, in contrast to PSA screening and mammography screening, covered in the benefit package of the German statutory health insurance. According to the prenatal guidelines, three ultrasound examinations have to be provided during a normal pregnancy, specifically between weeks 9 and 12, 19 and 22, and 29 and 32. According to the Uniform Value Scale (which determines reimbursement of services provided in German ambulatory care), a documented ultrasound examination is necessary to obtain the capitation fee for antenatal care (29). Additional examinations need a documented justification. These are higher risk for pregnancy-related complications in the medical history (e.g., earlier miscarriage, age younger than 18 or older than 35 years) or according to findings during antenatal care (e.g., diabetes mellitus, uterine bleeding, pathological presentation of the fetus). These additional examinations are reimbursed on top of the capitation fee. Therefore, on average six to seven ultrasound examinations are de facto performed during pregnancy in Germany. Antenatal care is usually performed by office-based obstetricians (18). The third trimester ultrasound examination has been offered since 1996. According to the guidelines, all ultrasound examinations have to be carefully documented.

According to a collective contract between the National Association of Statutory Health Insurance Physicians and the federal sickness fund associations (16), physicians qualified for performing routine follow-up pregnancies need at least 300 documented ultrasound examinations if they are licensed gynecologists/obstetricians. For other physicians, at least 18 months of clinical experience in the field are required. In addition, they have to acquire a specific qualification in three ultrasound courses (basic, advanced, final level) covering in total 64 hours of training.

Studies specifically related to assessing the benefits of third trimester routine ultrasound could not be identified. However, analysis of data collected for the purpose of quality assurance showed a decrease of perinatal morbidity (in terms of transferring newborns to pediatric hospitals and premature births) as well as of perinatal mortality (i.e., stillbirths and neonatal deaths) between 1983 and 1993 by about 30%. Women having only the minimal recommended number of examinations (including ultrasound) had a 10 times higher rate of stillbirths as compared with those having had more than the standard number of procedures (2;30). Preliminary data of the perinatal quality assurance program from Northrhine-Westphalia show an increase in documented abnormalities. However, whether this has an impact on perinatal morbidity is not yet clear.

Compliance with routine examinations in pregnancy appears to be very high in Germany. In 1992, 73% of all pregnant women were routinely examined at least 10 times during pregnancy, though it is not clear whether ultrasound was performed at each visit

(17). There seems to be no significant difference in follow-up due to socioeconomic status; however, pregnant teenagers are less compliant and show a higher rate of small-for-date infants (26).

CONCLUSION

It can be concluded that the preventive programs and practices in Germany discussed here are not sufficiently based on sound evidence. There are two aspects for consideration. First, preventive measures are introduced without sufficient evidence of their effectiveness. One example discussed in this article is routine ultrasound in uncomplicated third trimester pregnancy, which is paid for in the German health insurance scheme despite unclear evidence of its benefit. It is possible that the low threshold of introducing new preventive measures in the past obviated the need for a thorough evaluation. However, in contrast to the screening programs for breast cancer and prostate cancer, pregnancy care is embedded in a quality assurance program, allowing evaluation of its effectiveness.

Second, despite evidence of their benefit, preventive programs are not introduced. This is the case with mammography screening for breast cancer, for which a mortality reduction has been demonstrated in several studies, including one performed in Germany. The reasons for this are unclear. However, data show that mammography screening is frequently performed as wild screening.

PSA screening for prostate cancer lies in between these two cases: there is evidence of a wild or opportunistic screening practice using PSA as a marker for prostate cancer, but the benefit catalog does not include this test for the specific purpose of screening.

Evaluative research in Germany, especially HTA, has gained importance during the last few years. Especially the production of evidence, (i.e., the conduction of HTA reports [also for preventive technologies], systematic reviews, cost-effectiveness, and other studies) has reached both higher frequency and higher standard. This also includes preventive measures. It can be expected that these developments will lead to a better understanding of the benefits and risks of preventive measures in the German healthcare system.

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