

HEALTH TECHNOLOGY ASSESSMENT OF THREE SCREENING METHODS IN SWITZERLAND*

Karin Faisst
Julian Schilling

University of Zurich

Pedro Koch

Swiss Federal Office of Social Security

Abstract

Objective: To describe the level of health technology assessments for three screening methods in Switzerland.

Methods: Analysis of documents and expert opinions on mammography screening, ultrasound examinations during normal pregnancy, and screening for prostate-specific antigen (PSA) with a focus on services provided, recommendations, formal regulations, national papers, projects, and formal assessments.

Results: Preventive services are explicitly recommended by the Swiss federal law on health insurance. Two routine ultrasound examinations during normal pregnancy as well as PSA analysis for men over 40 years of age on medical indication are covered by basic health insurance. Mammography screening every 2 years has been covered since 1997 for women over 50 years. A systematic screening program for mammography exists in the western part of Switzerland, and a nationwide program is planned. However, a national program may not come into being until a quality assurance program for evaluation is established, and a nationwide fee for reimbursement—to include all costs of such a program—is accepted by providers and insurers.

Conclusion: According to the Swiss health insurance law, the effectiveness of mammography screening and ultrasound examinations during normal pregnancy have to be proven. Systematic evaluation of these screening methods is in preparation. PSA is not part of current evaluation. It can be concluded that health technology assessment in Switzerland is now required by law for several medical services. However, limited financial and personnel resources as well as the lack of disease registers may hamper progress in the near future.

Keywords: Health technology assessment, Screening, Mammography, Ultrasound in pregnancy, PSA

In Switzerland, health technology assessment (HTA) has become of major importance to decision makers in light of increasing healthcare costs, tight budgets, and fast developments

The authors wish to acknowledge the Federal Office of Social Security for its support, Dr. Richard Cranovsky, MPH, for his contributions, and Caroline Müller for editing this report.

*This article was submitted for publication in January 2000 and has not been updated to reflect new evidence that has been published since that time.

of new technologies. HTA has a long tradition in Switzerland. Projects and activities that have taken place so far have focused on different aspects of social security, policy, patient needs, and public health (e.g., reimbursement of selected services and technologies). This paper provides detailed information about the level of health technology assessments in Switzerland for preventive services by examining three screening methods: mammography screening, ultrasound screening during normal pregnancy, and screening for prostate-specific antigen (PSA).

The first part of the report gives a short description of the Swiss healthcare system, HTA, policies toward prevention and screening, and research on prevention and mass screening in Switzerland. The case studies describe HTA for three screening methods in detail. The data presented are based on review information from published sources, expert opinions, and a workshop focusing on HTA of preventive technologies, which took place in Zurich in December 1997.

THE HEALTHCARE SYSTEM

The Swiss healthcare system is complex, consisting of a mix of public (mainly hospitals) and private (mainly doctors' offices) providers, with jurisdiction divided between the 26 cantons and the confederation. The cantons bear primary responsibility in health and social welfare. Thus, although the organization of healthcare provision occurs at the cantonal level, individual cantons are involved to highly varying degrees in the actual structure and delivery of preventive, curative, and rehabilitative services. The Swiss federal government is responsible for:

- infectious disease control;
- food safety control;
- toxic substance control;
- illicit substance control;
- radiation;
- work safety (accidents and work-related illnesses);
- regulation of federal examinations for medical doctors, pharmacists, veterinarians, and dentists; and
- supervision of social insurance, including health insurance.

The federal government is empowered to act on several important health issues, to finance programs, and to authorize sanctions against illegal activities in several fields. However, since the execution and implementation of laws lie at the cantonal level, the 26 cantons have their own laws on health care, hygiene, hospitals, and social welfare.

The social welfare program in Switzerland covers four major areas: a) provision for old age, widowed spouses and dependents, and the disabled; b) sickness or accident coverage; c) unemployment insurance; and d) family benefits. Health insurance is financed by individual premiums paid by the insured. Federal authorities and the cantons participate to a greater or lesser degree in the financing of social security (old age, disability, health insurance).

One of the major changes in health care was the introduction of a new Swiss Federal Law on Health Insurance in 1996. Two main factors distinguish the new law on health insurance: solidarity between the insured and a series of measures intended to limit health costs. To achieve the principle of solidarity, the entire Swiss population is subject to mandatory healthcare insurance, and insurance premiums are uniform per insurer and region. Insured people in lower income categories have the right to reduced premiums, cofunded by federal or cantonal subsidies. Mandatory health insurance ensures that, in case of illness, everyone

has access to a wide range of basic healthcare services (ambulatory and hospital services) at reasonable costs. The list of services includes both traditionally established services and new technologies, procedures, analyses, and drugs. It also includes some preventive services (e.g., mammography screening for women aged 50 years or older and two ultrasound examinations during normal pregnancy). Complementary insurance schemes are optional. These provide more comfortable hospital conditions and additional benefits (e.g., some plastic surgery procedures).

HEALTH TECHNOLOGY ASSESSMENT

In Switzerland the Federal Commission for General Health Insurance Benefits (ELK) examines the effectiveness, appropriateness, and efficiency of controversial medical procedures and submits its comments to the Federal Department of Home Affairs (3). For new or emerging technologies, a specific standardized system is required. All proposals that advocate coverage under the health insurance scheme should be structured around three parts: a) medical documentation (a scientific presentation of the issue); b) economic documentation (a cost calculation for the service in question); and c) the discussion and justification of the application (so-called plea in favor of the new technology) in view of the effectiveness, appropriateness, and efficiency of a method.

The term *effectiveness* is used to describe the clinical value of a medical procedure in practical use. Clinical effectiveness refers to the extent objectives are reached under particular conditions in clinical practice, taking indications and contraindications into account. Appropriateness reflects an assessment comparing the relative medical value of a procedure to the patient and the risks associated with it. Procedures are considered to be appropriate when the benefit is greater than the risks of the procedure itself and outweigh the risks attached to other alternative procedures or approaches. Efficiency reflects an assessment comparing the use of resources for the procedure with the value of the outcome. The documentation is followed by a formal application, including a proposal for the terms of entry in the procedures ordinance. The ELK then decides on reimbursement. A procedure may be approved for reimbursement without limitations, only for specific indications, only at centers designated with a binding obligation to assess the result of the service performed, or with a binding obligation to participate in multicenter evaluation studies.

In recent years, a pragmatic approach to technology assessment in health care has been taken by setting up a Swiss Network on Health Technology Assessment (SNHTA). All government agencies, all university institutes dealing with technology assessment, as well as the Swiss Medical Association are SNHTA members. The purpose of the SNHTA is to help improve effectiveness, cost-effectiveness, and societal accountability of health care in Switzerland. To achieve this ultimate goal the SNHTA aims:

- To promote health technology assessment projects in Switzerland;
- To promote a forum for the identification and pursuit of common interests among the concerned institutions;
- To exchange and disseminate HTA findings and promote their application in practice; and
- To collaborate in European and international HTA networks and projects.

POLICIES ON PREVENTION AND SCREENING

Until the early 1980s, public health activities focused on traditional tasks such as clean water, food safety, and prevention of infectious diseases. A uniform strategy or priority setting did not exist at the national level due to the fact that the cantons were mainly responsible for

health policies. An attempt to promote prevention by a new federal law in 1983 failed. In 1983 and 1986, the Swiss Society of Social and Preventive Medicine initiated new structures that improved the situation for nationally organized and controlled prevention programs.

In recent years, preventive services have become more important. This is reflected by the coverage of some preventive services in the new Health Insurance Law of 1996. The process of setting priorities and including preventive services in health benefits is under way. An interdisciplinary committee set up by the Swiss Federal Office of Social Security has prepared criteria for insurance coverage of preventive technologies including screening and immunization programs. But implementation of the law will take another 2 to 3 years and will be limited to selected screening programs.

Screening for specific conditions is mainly performed by health professionals in an unsystematic way. However, systematic approaches do exist, such as screening newborns for phenylketonuria (PKU) and blood donors for HIV.

Research on Prevention and Mass Screening

To date, research on prevention and mass screening in Switzerland has not been performed on a national level in a systematic manner. However, certain initiatives have been introduced in mammography screening and ultrasound screening during normal pregnancy, but they are part of the systematic evaluation of health technology for health insurance coverage.

THE CASE STUDIES

Mammography

The incidence of breast cancer in Switzerland is among the highest in the world. About 3,500 cases of breast cancer are diagnosed annually, and 1,600 women die of breast cancer every year, which represents 22% of all women who die of cancer (15). Breast cancer is the leading cause of death in women between 30 and 60 years of age.

The prospects of women with a breast cancer diagnosis have improved thanks to better treatment modalities: 70% are still alive 5 years after diagnosis (with the exclusion of other causes of death in the same group). However, every second breast cancer detected in Switzerland is larger than 2 cm at the time of diagnosis, which decreases the efficacy of curative treatment. Although age is the main risk factor, the mortality due to breast cancer in women over 65 years has increased only slightly over the last 40 years. The mortality rate has been stable since 1980 and has even decreased in younger women. However, the incidence has increased.

The Service of Mammography Screening. The systematic early detection of breast cancer through mammography is not yet routine practice in Switzerland. Mammograms are offered by physicians with mammography devices either in hospitals or in private practices. However, many early detection mammograms are performed as diagnostic mammography, without assurance of quality. According to the Swiss Health Survey of 1992–93, one-third of women over age 20 have had at least one mammography in their lifetime (16). This proportion increases to 50% in women aged 50–59 years. These numbers may be inflated because of the inclusion of diagnostic mammograms. Within Switzerland, a higher proportion of women has had a mammography in the west, namely in Geneva, Vaud, and Basel. The interval between the two exams often exceeded 6 years when more than one mammography had been performed.

National Recommendations. The Federal Office of Public Health and the Swiss Cancer League have clearly recommended mammography screening according to specific quality criteria for women over 50 years (7;15).

Formal Regulations. The first version of the health insurance law from 1996 included up to one mammography screening per year as part of the basic health insurance scheme for women who had first-line family members with breast cancer only.

Since July 1997, mammography screening has been part of the basic health insurance scheme for all women over 50 years every 2 years with specific requirements (paragraph 12, KLV, 4.7.97). Before the first mammography, extensive counseling is required and has to be documented. First and second evaluation of the mammography must be done by a specially trained physician. The safety standards of the mammographs must fulfill the requirements of the 1993 European Guidelines of Quality Assurance in Mammography Screening (this paragraph is valid until December 31, 2007).

This regulation has been valid since January 1, 1998 and applies to centers that already fulfill the requirements mentioned and have a contract to that effect from a local, regional, or cantonal authority. At that time, apart from the project for mammography screening in Vaud canton, no institutions in other cantons fulfilled the requirements or had formulated contracts.

A nationwide contract for quality assurance should have been prepared by January 1999. For this purpose a working group of the Swiss Medical Association formulated criteria to be included in such a contract. Since the negotiations between providers and payers have failed, the Federal Office of Social Security formulated requirements in June 1999. However, at the time of writing, providers and payers have not yet agreed on an acceptable nationwide fee for reimbursement of all costs (e.g., technical equipment, evaluation, etc.)

Policy Papers. In 1996 the Federal Office of Public Health and the Swiss Cancer League formulated a national policy on the prevention of cancer. As a first step, an ongoing action plan for breast cancer control was drafted and is still under revision. The main goals stated in the action plan are:

1. To reduce breast cancer mortality by 5% in the general female population after 10 years of implementation;
2. To improve the quality of life among breast cancer patients and their relatives; and
3. To reduce the incidence of breast cancer in the long term.

The action plan includes aims, visions, strategies, key messages for women, possible partners for executing the plans, and activities in the following areas: health promotion, prevention, early detection of breast cancer, diagnosis, treatment and after-care for breast cancer. Early detection through a mammography screening program is an essential part of the project. The authors state: "Without such a screening program, mortality reduction, one of the main goals of the program, will not be achieved" and postulate that the "majority of women aged 50–69 years participate regularly in systematic breast cancer screening of very high quality." Furthermore, the action plan states objectives in those areas where systematic breast cancer screening takes place, strategies, tasks to be executed at federal and cantonal levels, activities at federal and cantonal levels for implementing mammography screening, monitoring, and evaluation as well as the budget. National, cantonal, and local partners may be involved in the implementation of the action plan.

Mammography Screening Projects. In 1993 a mammography screening project was initiated in Vaud canton by the *Fondation pour le dépistage du cancer du sein* (Foundation for early detection of breast cancer) supported by the *Service de la santé publique du canton de Vaud* (Department of Public Health of the Canton of Vaud), according to the European Guidelines for Quality Assurance in Mammography Screening (4;13). Three regions—Aigle, Aubonne, and Morges—took part in the project. Mammography screening was offered to all women between 50 and 69 years of age who lived in the regions, and

screening could be repeated after 2 years. The main objectives were to assess the quality of the devices and the data obtained, to analyze the attitude and behavior of nonparticipants, to analyze feelings of anxiety caused by mammography screening, and to improve the attitudes of physicians. The evaluation program indicated that the devices showed neither dysfunction nor need for intervention and produced good data. Two scientific reports on the evaluation of nonparticipants and the negative psychological consequences seen in participants were published (10;11). Based on these experiences, the project was expanded to the entire canton in early 1999.

In Geneva, the Department of Public Health started to plan a project to offer every woman aged 50–70 a mammography screening every other year in 1993. Even though a detailed project plan had been worked out, this project was not carried out due to political reasons and a lack of financial resources (2). However, due to the health insurance law and based on this previous work, the screening program has launched in 1999. Under similar conditions, another screening program was started in Wallis canton in the same year. In German-speaking Switzerland, a project was planned in 1991 but not carried out due to a lack of financial resources. Nevertheless, preparations are currently under way to initiate a systematic screening program in the German- and Italian-speaking parts of Switzerland.

Formal Assessment. There is no official data on the density of devices or who is using which devices. Besides the evaluation of mammography screening programs in the western part of Switzerland, no coordinated quality control program exists yet. Nevertheless, a new foundation for the early detection of cancer was founded in 1999 on the initiative of the Swiss Cancer League. One of the aims of this foundation is the organization and coordination of breast cancer screening. Part of their activities will be the coordination of the evaluation of mammography screening programs on a national level.

Conclusion. Since mammography screening has been accepted as part of basic health insurance activities since 1997, efforts to fulfill quality assurance required by law are continuing. The efficacy of mammography screening has to be proven by the year 2007. However, program evaluation is only possible if mammography screening is performed in a systematic manner. At the time of writing, systematic mammography screening programs have been performed in the western part of Switzerland. Several other activities for systematic mammography screening in the German- and Italian-speaking parts of Switzerland are in preparation now. Ongoing activities concentrate on the introduction and organization of mammography screening programs. The consequent evaluation of the programs may be of value in determining its efficacy.

Routine Use of Ultrasound in Pregnancy

Diagnostic ultrasound examinations may be employed in certain situations during pregnancy such as after clinical complications (e.g., bleeding), or where the fetus is perceived to be at particularly high risk of malformation or inappropriate growth (12). Because adverse outcomes may also occur in pregnancies without clear risk factors, it has been posited that routine use of ultrasound in all pregnancies would prove beneficial. Such screening examinations may be planned for early pregnancy, late gestation, or both combined. In 1995, about 280,000 ultrasound examinations were performed in pregnancy in Switzerland. This number is based on an estimated 30,000 examinations performed in connection with abortions, and the assumption that an average of three exams were performed for each of 83,000 pregnancies ending in birth (21).

The Service of Ultrasound Screening in Normal Pregnancy. In Switzerland, routine ultrasound screening is currently offered to all pregnant women at 10 and 20 weeks of gestation, with the costs covered by their health insurance. The main goals of the initial

ultrasound exam are dating and detection of multiple pregnancies. The 20-week ultrasound is a detailed screening for malformations, placenta previa, and other pathologies. Ultrasound is performed by doctors in private practice, in regional public or private clinics, and in tertiary referral university hospitals.

Formal Regulations. Before 1996, the costs of up to three ultrasound examinations in the course of a normal pregnancy were covered by the obligatory health insurance: in early pregnancy, between the 16th and 20th week, and between the 32nd and 36th week at the price of US \$50 per scan. This changed with the 1995 list of services with compulsory health insurance coverage, which included ultrasound examinations for high-risk pregnancies only.

Following that decision, an unprecedented campaign was launched by consumers (pregnant women), interested providers of care, and the mass media (6). In light of the massive reaction, the Federal Office for Home Affairs agreed to include ultrasound screening under mandatory health insurance coverage. In normal pregnancies, control exams are recommended for the 10th to 12th week with a second exam between the 20th and 23rd week. However, this is a provisional regulation introduced in April 1996 and valid for 5 years. During this time, ultrasound examinations in pregnancy are approved with a binding obligation to assess the results.

CERTIFICATION OF SONOGRAPHERS

In response to the conditions set for the coverage of ultrasound examinations in normal pregnancy, the Swiss Specialty Society of Ultrasound in Medicine and Biology formulated a list of requirements for the physicians who perform sonograms (1). These were accepted by the Board of the Swiss Medical Association in July 1997 (18).

Certification for ultrasound examinations in pregnancy allows the certified physician to receive payment for ultrasound exams performed in pregnancy from health insurance under explicit conditions. The certificate provided is valid for 5 years and may be extended. Along with the "certificate of competence," a commission of gynecologists and obstetricians prepared regulations for equipment, performance protocols, and documentation for routine and specially indicated obstetric ultrasound in the summer of 1997. The document also included information for pregnant women explaining possibilities and limitations of ultrasound screening techniques. The document was implemented by the Swiss Society of Obstetrics and Gynecology along with the certificate at the beginning of 1998 (18).

Ultrasound Screening in Pregnancy Projects. The effect of routine ultrasound on the outcome of pregnancy depends on the equipment (technical standards), skills (experience, certificate), aim of the exam (standards), diagnosis (periodic quality control), therapy (intention to treat), outcome (epidemiologic register), and the patient (21). There is no formal nationwide evaluation of ultrasound in normal pregnancy. However, some studies were initiated concerning several aspects of HTA.

Equipment. A representative poll including questions on the nature of equipment used was carried out in 1996 to obtain information from all 721 registered members of the Swiss Society of Obstetrics and Gynecology (21). Ninety-four percent of the respondents were equipped with an ultrasound scanner, which allowed imaging of the fetus in all three trimesters, and 94% had a transvaginal probe, which facilitated imaging in the first trimester. The scanners were relatively new: 90% of the scanners were bought in or after 1988, and the average was around 1992. The price was about 70,000 Swiss francs. Approximately 90% of the scanners were produced by one of four companies.

Training and Experience of Sonographers. The level of training and experience of the physicians performing ultrasounds was elicited in the same poll mentioned above (21). The average length of experience with ultrasound varied between 0 to 15 years. The most

frequently listed source of experience was during hospital training (residency), followed by courses, conferences, and independent study.

Periodic Quality Control. In a questionnaire-based retrospective study, the impact of prenatal screening tests (ultrasound, biochemical screening) on the detection of fetal anomalies and the comparison between sonographically detected fetal malformations and neonatal findings were evaluated (19). Nine Swiss clinics for gynecology and obstetrics were sent a questionnaire on the prenatal detection of malformations in 1995. The preliminary results showed that 89% of prenatally detected malformations were found in the course of a screening exam, that 70% of the cases had been referred to the clinics by physicians in private practice, and that no misdiagnoses were found in cases of abortion. Sonographic diagnosis matched with the clinical examination or autopsy findings in 82% of the cases. There was general agreement in a further 18% of the cases, whereby some additional clinical findings of little importance were first diagnosed after the abortion. Based on these findings, a variety of prospective studies was planned in 1998.

In 5,456 sonograms performed at the Ultrasound Unit of Basel University Hospital in 1996, about 4% of the cases with abnormal ultrasound findings in the fetus ($n = 86$) or mother ($n = 131$) were identified (17). The primary diagnosis of 74% fetal malformations was achieved before 26 weeks of gestation.

Another project is based on the assumption that a defect of the fetal abdominal wall (gastroschisis) should be detectable by routine ultrasound. This pathological finding has been chosen as an indicator to evaluate the sensitivity and specificity of detection of gross fetal abnormalities by routine ultrasound. Work on this project is being supported by the Department of Obstetrics and Gynecology of the University of Zurich. Preliminary results indicate that over 90% of all cases with gastroschisis were diagnosed prenatally.

Additional Studies. A prospective study to evaluate the psychosocial effects of ultrasound was initiated in 1998 in the form of an interdisciplinary project, with particular emphasis on the level of certainty or uncertainty indicated, and the effects of ultrasonic evidence of fetal pathology on pregnant women. A prospective randomized study to detect growth abnormalities in the third trimester of pregnancy was planned for 1998, following a retrospective pilot study to calculate normal growth curves. A study that investigated the causes of maternal mortality in Switzerland from 1985 to 1994 found no record of placenta previa being listed as cause of death in that period, indicating an excellent detection rate for this life-threatening complication (9).

Formal Assessment. A national register with mandatory reporting of birth deformities does not exist. Important standard obstetric data (e.g., gestation age at time of birth) are also missing. However, the Federal Office of Statistics intends to collect additional information on mothers and infants (e.g., gestation age, congenital malformation, etc.).

Some information on congenital malformation is provided by the Federal Disability Insurance (AI). Most infants with serious birth defects are thus registered with the AI at birth (or time of diagnosis). Nevertheless, only limited data from the AI are accessible to the public. Besides, Switzerland has participated in the European Registry of Congenital Anomalies and Twins (EUROCAT), which is a malformation registry, since 1987. The registry is located in Lausanne. Participation grew progressively, so that since 1991, over 85% of births have been registered by EUROCAT. However, participation and coverage vary quite strongly from one canton to another, depending on the type of population (e.g., rural or urban), the organization of the registry, and the source of funding (14).

Most university hospitals have registers of congenital anomalies, which include those detected prenatally. For example, at the University of Zurich, a tertiary referral center, malformations were diagnosed prenatally in 175 gestations in 1995 (5).

Conclusion. With the introduction of requirements and standards for sonographers and their equipment by medical specialists' associations, as well as the planning and implementation of various projects for periodical quality assessment, the first steps toward establishing and evaluating the effectiveness of ultrasound as a screening tool have been taken. Nevertheless, further efforts are needed, particularly with regard to therapeutic recommendations. In comparison with other European countries, further action has to be taken in Switzerland in perinatal care, such as additions to update standard obstetric data and the introduction of a national registry for birth deformities.

Prostate Cancer

Cancer of the prostate accounts for almost 1,500 deaths per year in Switzerland. Rates remain stable for all ages (21.9/100,000) but have declined from 7.3 to 6.6/100,000 for men between 35 and 64 years. This suggests that the long-term increases in certified mortality from prostate cancer in elderly Swiss men has also tended to level off (8).

Approximately 2,700 new cases of prostatic cancer are diagnosed each year in Switzerland, that is, about 80 new cases per 100,000 men per year, whereby three-quarters of these are diagnosed in men over the age of 70. The actual number of cases is much higher, however, since only a small proportion of the latent prostatic malignancies is ever diagnosed, and death by other causes is frequent. Autopsy results have shown that 40% of all men between 70 and 79 years and 70% of those over 80 years have cancer of the prostate.

The Service of PSA Screening. There is no systematic screening program for malignancies of the prostate in men of any particular age group in Switzerland. In practice, many family physicians and urologists offer screening exams in the form of digital rectal examination and determination of the tumor marker PSA. The target group for these preventive measures consists mainly of men under the age of 70. Family practitioners refer men with abnormal digital rectal findings, and even those with elevated PSA levels in the absence of rectal findings, to a urologist (private or clinic) for further investigation. Health insurance providers cover the cost of PSA assays.

Recommendations. The Swiss Cancer League publishes an information leaflet about the causes, symptoms, diagnosis, treatment, and recovery for prostate cancer. In this leaflet, it is recommended that family practitioners perform screening examinations on asymptomatic men over the age of 50 every 2 years. This includes a digital rectal exam and the determination of PSA levels.

PSA Screening Projects. In a prospective study at the University of Zurich among 206 men, the specificity of the combination of total PSA with free-to-total PSA in detecting prostate cancer was evaluated. The authors concluded that 39.7% (25/63) of unnecessary biopsies could be avoided. In the absence of an international PSA standard, it may be important to use an assay-specific "normal value" and PSA-ratio cut-off (20). Studies on the implications of using free PSA and the free PSA/total PSA quotient as a screening method in a predetermined group of men were carried out at the regional level. The interpretation of borderline PSA results in terms of their predictive value for prostatic malignancies in men between the age of 50 and 70 may provide more information in the future.

Formal Regulation. In Switzerland, the measurement of PSA levels is on the Federal List of Laboratory Analysis. Therefore, the cost of the test is covered by the health insurance if ordered by a physician.

Formal Assessment. There are no statistics available on the usage of the PSA. No assessments of efficacy, effectiveness, or cost-effectiveness have been carried out so far.

Conclusion. In contrast to mammography screening and ultrasound screening during normal pregnancy, PSA screening does not need to be evaluated by formal requirements of the health insurance law for health policy purposes. This is because it is a laboratory test that is only reimbursed on medical indication. No population-based PSA screening is performed. To introduce a population-based screening, a formal application to the ELK would be necessary, and then the procedure might be approved for reimbursement with a binding obligation to participate in evaluation studies. So far, there are no efforts to evaluate the efficacy of this screening method.

DISCUSSION

Factors influencing screening in clinical practice may include treatment possibilities, attitudes of clinicians and patients, and costs of the procedure. In 1999 all three screening services were covered by basic health insurance, which means that the costs of the services are free for the client. However, in Switzerland everyone who claims medical procedures has to cover a fixed amount of the costs themselves each year (except services during pregnancy). Thus, if screening is the only medical procedure performed in a year, the person might have to pay for it. Financial burden for preventive services might decrease the participation rate.

However, the effectiveness of any screening procedure is linked to high participation by the target group. This applies mainly to mammography screening, which figures in discussions about the revision of the health insurance law.

The three screening procedures presented in this paper clearly indicate that the requirements on effectiveness, appropriateness, and efficiency vary for different procedures, techniques, and test methods. Comparing mammography, ultrasound during normal pregnancy, and PSA screening in terms of diffusion, regulations, and frequency of data available, PSA may be at the low end of the scale. HTA of three screening procedures are strongly linked to the requirements for quality assurance formulated in the health insurance law. One prerequisite for a systematic evaluation of effectiveness, appropriateness, and efficiency of screening procedures is screening programs. Such programs for mammography screening exist only in the western part of Switzerland to date. This might be because activities in the field started in the early 1990s, even before the health insurance law was formulated. These data indicate that there is cultural influence on attitudes toward establishing systematic screening programs, with a greater effort in the western part compared with the German-speaking part of Switzerland. The study results also show that financial and personnel resources as well as the lack of a Swiss national register limit the progress of health technology in that field.

The fact that recommendations for the diffusion of a procedure are formulated by medical societies who are interested in the procedure, such as training guidelines for providers of mammography screening and obstetrical ultrasound in pregnancy, may improve the quality of the results. On the other hand, the exclusion of care providers may raise prices for screening in the long term.

CONCLUSIONS

The analysis of the data indicates that the requirements for quality assurance formulated in the health insurance law for the three screening methods correlate with the efforts of HTA performed in Switzerland so far. The lack of personnel and financial resources as well as registers hinders fast results. Future decisions on coverage are supposed to be based on the

results of assessment of screening procedures. However, even without consolidated data on effectiveness, appropriateness, and efficiency, the wishes of the population cannot be ignored, as showed with the example of ultrasound screening during normal pregnancy.

REFERENCES

1. Biedermann K. Ultrasound during pregnancy in the new health insurance law. *Arch Gynecol Obstet.* 1996;259(suppl 1):128-136.
2. Bouchardy C, Raymond L. Breast cancer screening program in Geneva: Estimation of costs and benefits on health [translated]. In J Haefliger, W Weber (eds). *Breast cancer screening*. Berne: Swiss League against Cancer; 1995:207-227.
3. Bundesamt für Sozialversicherung. *Manual for the standardization of clinical and economical evaluation of medical technology*. 1998.
4. De Landtsheer JP, Hessler C, Levi F, et al. Status of breast cancer screening program in the canton of Vaud [in English]. *Medizin and Hygiene.* 1996;54:301-305.
5. DeLozier-Blanchet C, Wissler J. Prenatal diagnosis in Switzerland. *Eur J Hum Genet.* 1997;5(suppl 1):77-83.
6. Glinz F. *No heart for pregnant women* [in English]. Blick, 1996.
7. Haefliger J, Weber W (eds). *Breast cancer screening* (in English). Bern: Swiss League Against Cancer; 1995.
8. Levi F. Cancer mortality in Switzerland. *Sozial- und Präventivmedizin.* 1997;42:37-54.
9. Meili G. *Maternal death in Switzerland 1985-1994* (in English). Zurich: University of Zurich; 1996.
10. Meystre-Agustoni G, Dubois-Arber F, De Landtsheer JP, Paccaud F. Exploring the reasons for non-participation of women in a breast cancer screening campaign. *Eur J Public Health.* 1998;8:143-145.
11. Meystre-Agustoni G, Jeannin A, Dubois-Arber F, Paccaud F. *Breast cancer screening with mammography: Development of negative psychological consequences for participants* (in English). Lausanne: Raison de Santé 9;1997.
12. Neilson JP. *Routine ultrasound in early pregnancy*. The Cochrane Database of Systematic Reviews. 1998;3.
13. Paccaud F. Mammographic screening for breast cancer: Background of a pilot program in the Canton of Vaud. *Präventivmedizin.* 1993;38:288-293.
14. Pexieder T, Bloch D. Congenital anomalies in Switzerland: Problems and solutions in data collection and their European integration experience by EUROCAT. *Sozial- und Präventivmedizin.* 1994;39:43-46.
15. Rajower I, Sasco AJ, Kleihues P. (eds). *Breast cancer facts and need for action: National program to combat cancer* (in English). Bern: Swiss Federal Office for Health Care and Swiss League Against Cancer; 1996.
16. Raymond L, Bouchardy C, Wanner P. Participation rate of mammography screening according to the health survey of 1992-1993. In J Haefliger W, Weber (eds). *Breast cancer screening* (in English). Berne: Swiss League Against Cancer; 1995:73-93.
17. Schaub AF, Tercantli S, Hodel M, Miny P, Hozgreve W. *Value of ultrasound screening in obstetrics for diagnosing fetal malformation* (abstract; in English). Lausanne: Swiss Society for Gynecology and Obstetrics; 1997.
18. Skill program "Ultrasound during pregnancy" (in English). *Schweizerische Ärztezeitung,* 1997,78,1352-53.
19. Stiller R, Zimmermann R, Huch R, Huch A. *Multi-centre register of sonographically determined malformation: First results* (abstract; in English). Lausanne: Swiss Society for Gynecology and Obstetrics; 1997.
20. Trinkler FB, Schmid DM, Hauri D, Pei P, Maly F, Sulser T. *Freetotal prostate-specific antigen ratio can prevent unnecessary prostate biopsies.* *Urology.*1998;52:479-486.
21. Zimmermann R, Vial Y. Experience with ultrasound screening and equipment of Swiss gynaecologists. *Arch Gynecol Obstet.* 1996;259:111-117.