International Journal of Technology Assessment in Health Care, **17:3** (2001), 316–328.

IMPACT OF HEALTH TECHNOLOGY ASSESSMENT ON PREVENTIVE SCREENING IN BELGIUM

Case Studies of Mammography in Breast Cancer, PSA Screening in Prostate Cancer, and Ultrasound in Normal Pregnancy

Veerle Vermeulen
Katja Coppens
Centre for Health Services and Nursing Research, University of Leuven

Katrien Kesteloot
Centre for Health Services and Nursing Research and University Hospital Leuven

Abstract

Objective: To describe how scientific evidence has influenced healthcare policy making in Belgium in the field of sickness prevention for mammography, PSA testing in prostate cancer screening, and use of ultrasound in pregnancy.
Methods: Review of published and gray literature and interviews with stakeholders and experts.
Results: At the end of 1999, a systematic national/regional screening program had not yet been implemented for any of the three screening strategies. A systematic breast cancer screening program is being prepared for implementation only in Flanders. This limited impact can be attributed to the fragmentation in healthcare policy, the different options among the different regions, fragmentation in healthcare practice, the strong impact of healthcare stakeholders (provider groups and sickness funds) on decision making, and limited attention to scientific evidence in health policy and technology assessment.
Conclusions: Health technology assessment has had very little impact on policy and practice in use of mammography, PSA testing, and ultrasound in pregnancy in Belgium.

Keywords: Preventive services, HTA, Mammography, PSA test, Ultrasound, Belgium

This paper describes how scientific evidence has influenced healthcare policy making in Belgium in the field of sickness prevention, and more specifically, in mammography in breast cancer screening, prostate-specific antigen (PSA) testing in prostate cancer screening and use of ultrasound in pregnancy.

The lack of a systematic approach to prevention policy and practice in Belgium is described for the three cases. Each case study starts with some local epidemiologic data and the rates of use of the specific preventive service in Belgium. The organization and the

context of the screening activity is described, followed by an overview of policy documents, publications, and formal decisions of the service.

Finally, an overview of the new developments and/or the expectations concerning future policies is provided. The paper further discusses the potential reasons for the limited impact of scientific evidence on healthcare policy making.

THE HEALTHCARE SYSTEM

The Belgian picture of healthcare policy making is quite complicated since competence for healthcare policy matters is distributed among both federal and regional health authorities. Fragmentation in healthcare policy matters is inherent to the Belgian state structure. Since the Belgian de-federalization of 1980, some fields of competence in health care, e.g. prevention, were explicitly assigned to the regional policy levels. The national ministries (Public Hlealth and Social Affairs) have retained the largest responsibility, which includes sickness and invalidity insurance, financing, determination of accreditation criteria for hospitals and heavy medical care units, and, in particular, the construction program for new hospitals. The Community Ministries of Health control preventive medicine (e.g., maternity and child health services, including school health but excluding national prevention programs), the application of accreditation standards and planning measures, coordination of home care, and all matters for which the national government is not responsible. Furthermore, the provinces and municipalities have some healthcare responsibilities, e.g., regarding environmental health. This fragmentation hampers the design of consistent, well-coordinated policy measures as well as the consistent implementation of policy decisions. Whenever regional authorities take preventive measures, they have to bear the costs of organizing the activities, but all subsequent savings in curative health care accrue to the federal authorities. Moreover, since financing of health care is a federal responsibility, federal agencies might question the authority of the regional authorities to finance these activities.

Coordination with the federal authorities is furthermore hampered by the fact that the two main regions seem to take divergent options in health policy. The field research revealed, for instance, that in the French community much fewer systematic initiatives for sickness prevention were found than on the Flemish region of the country. Furthermore, it was often difficult to find appropriate authorities for each of the case studies, which reflects the lack of systematic organization. The fact that even a research team has difficulties in finding the door to existing preventive programs illustrates how difficult it must be for patients to have access to systematic screening. As a principle it is believed that matters should be dealt with on the level that most closely encompasses the involved population group (the subsidiarity principle). In Flanders especially, different groups argue in favor of devolving more competence in healthcare policy away from the federal level toward the communities.

Fragmentation in health care practice is another typical characteristic, fueled by the predominance of solo practice for medical doctors and the fragmented healthcare reimbursing systems (budgets are split up according to the type of care provided, or to the type of provider, hospitals are financed separately and through different incentive systems for their nursing and medical activities). Fragmentation in practice is further enhanced by fragmentation in policy making.

Characteristic for the Belgian political situation is the presence of multiple interest organizations, which are often closely linked with political parties. Economic and social pressure groups, organized in well-structured associations, e.g., trade unions and sickness funds, form networks with political parties and collaborate in the decision making. In Belgium, healthcare policy is strongly influenced by healthcare stakeholders such as

providers (strong position of medical doctors), the sickness funds, and the unions and employers' associations (who are responsible for the financial health of the compulsory health insurance). This strong position is illustrated by the fact that medical providers' associations have traditionally opposed the introduction of guidelines and protocols, since they affect their "diagnostic and therapeutic freedom." Consequently, there is little space for scientific evidence to influence decision making.

HEALTH TECHNOLOGY ASSESSMENT IN BELGIUM

Belgium does not yet have any formal national or regional program or institute for health technology assessment (HTA). There is no single institution in which systematic assessments are performed, incorporating all different aspects of HTA. There are some organizations and boards that have the legal authority to give advice on certain health matters, which is a channel through which HTA could find its way into policy making. In practice, however, there is little or no conviction, and sometimes not even the intention, to base the advice on the principles and methods of HTA, as discussed in the previous paragraph.

There are some scattered initiatives whereby certain organizations/councils demonstrate a willingness to work along HTA lines, e.g., the Flemish Health Council attempts to base its reports on the available scientific evidence (but outsiders criticize its "too academic" spirit). The High Health Council plans an HTA unit and some sickness funds attempt to evaluate medical technologies, but all of those initiatives are not coordinated and different organizations interpret HTA in different ways. There is neither consistency nor uniformity in concepts, nor in approach or methods (4).

POLICIES TOWARD PREVENTION AND SCREENING

The case studies illustrate that there is no national systematic policy toward prevention and screening in Belgium. This is because prevention policy is a matter of competence for the regional authorities, and the Flemish and French-speaking regions tend to develop different policy options. At these regional levels, no systematic overall prevention and screening policy has been developed. For the French-speaking part of the country, it turned out to be even more difficult to find information about potential screening and prevention policy initiatives than in the Flemish part of the country.

In Flanders, there was a Flemish Advisory Commission for Cancer Prevention, which was abolished in 1997 and replaced by the Flemish Health Council, which installed a Working Party on Secondary Cancer Prevention to advise the Flemish government on this topic. In these groups, all stakeholders (e.g., radiologists, epidemiologists, oncologists, general practitioners, academia, economists) are present. Furthermore, local health councils (LOGOs) were created in 1998. They are responsible for organizing preventive activities at the local level. Finally, for the first time in 1998, the Flemish Health Minister announced five health targets that the LOGOs should implement. Most of these targets relate to preventive policy (in a broad sense). The targets were announced in the beginning of 1998, and should be achieved by 2002.

RESEARCH ON PREVENTION AND MASS SCREENING IN BELGIUM

In Belgium, there is little research tradition in the area of prevention and mass screening relating to the case studies presented here.

In preparation of the Prevention Conference organized in Flanders in 1997 by the Flemish government, limited resources were available specifically for prevention research

(to prepare papers for presentation at the conference). However, resources were so limited that only some literature reviews could be financed. No new primary research could be set up.

As far as breast cancer screening is concerned, the Flemish community formally requested an evaluation, and the results were published in 1997 (20). This report contains the results of scientific evaluations, performed or commissioned by the Subcommission for Breast Cancer Prevention, and often refers to internal/external evaluations of breast cancer screening. Thus, HTA has had its role in this policy document. Moreover, the study refers explicitly to a number of (inter)national studies as a base for the implementation of a systematic screening program in Flanders (e.g., 1;3;6;8;17;19).

In the French community, the latest policy document about breast cancer prevention concerns a special edition in September 1992 of *Santé et Communauté: Bulletin d'informations épidemiologiques de la Communauté française de Belgique*, an editorial of the French community, targeted toward physicians (24). It contains recommendations for physicians concerning cancer screening, and especially breast cancer screening.

As far as PSA testing in prostate cancer is concerned, one large research project is taking place and a pilot study is planned. Concerning ultrasound, no specific scientific research projects are dealing with the screening issue.

Mammography Screening in Breast Cancer

Local Epidemiologic Data. Table 1 gives the most recent data from the National Cancer Register in Belgium concerning incidence and mortality of breast cancer in the Belgian female population. Since the Belgian National Cancer Register does not register prevalence or survival rates, these data often refer to the cancer patient register of the SouthEast, assuming that the Belgian figures do not deviate much from these. This source reveals a prevalence rate in 1993 of 834 per 100,000 women who have or have had breast cancer since 1970, a 5-year survival rate of 76% from 1987–92, and a 10-year survival rate of 63% from 1980–86 for patients younger than 70 years old and of 55% for patients older than 70 (2;3;4;5;23).

Table 1. Breast Cancer Incidence (1993) and Mortality in Belgium

	Flanders	Wallonia	Brussels	Belgium
Incidence				
Absolute numbers	3,089	1,588	359	5,036
% of all tumors[a]				33.05
Gross incidence (/100,000)				97.74
Cumulative incidence				
0–64 years (%)				4.91
0–74 years (%)				7.11
Mean age of incidence				61 years
Mortality				
Absolute numbers	1,439[b]			2,343
Gross mortality rate (per 100,000)	(1995)			(1992)
	48 (1995)			45.64
				(1992)

Source: National Cancer Register (13) and data from the Health Care Administration of the Flemish Community (1997) and the Mortality Register of the Flemish Community (1996).
[a]Excluding nonmelanoma skin tumors.
[b]5.3% of all female deaths.

Organizational Context

DESCRIPTION OF THE SERVICES

The landscape of mammography screening services is very scattered in Belgium. The communities, which are responsible for prevention, do not have a clear mission for breast cancer screening. In the mid-1980s, when the beneficial effects of mammography screening were published in international studies, separate groups initiated projects for breast cancer screening, incited by the lack of government intervention. These initiatives were limited in scope and tolerated by the government, but without active support. Some of the centers for breast cancer screening created at that time are now well-developed screening centers.

A major part of the actual screening programs is organized by university teams in collaboration with local and/or provincial authorities. The screening programs conform to European quality norms. Experts argue that in an actual situation, where private radiologists play an important role, these norms are not sufficient to guarantee high overall quality (due to large differences in the quality of reading and interpretation of the images). The programs are very different in the way they are organized and financed and in terms of the geographical extent of their activities. In addition to these programs, much opportunistic screening takes place. These are mammograms performed on a nonorganized basis, on the initiative of gynecologists, private radiologists, or general practitioners (GPs).

The Flemish screening landscape for breast cancer consists mainly of five well-organized but mutually independent screening programs. Four of them are organized in an academic environment. Three organizational models can be distinguished (22):

1. A model that works with the local radiologists. The target group receives an invitation letter to visit their GP, who refers patients to a local radiologist.
2. Collaboration between a (semi-)mobile unit and local radiologists. After consultation with their GP, women either go to a local radiologist or to the (semi-)mobile unit, wherein the screening devices as well as the development devices are installed.
3. No collaboration with local radiologists (screening only in the dedicated center).

The first step toward more coordination on the regional level took place in 1993, when a Subcommission for Breast Cancer Prevention within the Flemish Advisory Commission for Cancer Prevention was installed. The objective was to find out which kind of prevention structure would be most favorable for systematic breast cancer screening, following the recommendations of the Committee of Ministers of the European Union for the year 2000. The final conclusions were published in the *Multi-center Study Breast Cancer Screening Vlaanderen* (MCS) in 1997 (20).

A subsequent step toward better coordination and standardization was established through the allocation of subsidies for the (non-) public centers of cancer prevention, on the basis of quality and organizational criteria. The quality criteria require conformity to the European norms, double-reading, and additional education of the radiologists. The organizational criteria relate to involvement of GPs and supra-local and local authorities. Terms include direct invitation without a preceding consultation with a physician, possibility for GPs or gynecologists to encourage participation of individual women, and feedback to the GPs or to the Flemish Community.

In 1998 the Flemish Minister of Health Policy took the initiative to prepare the implementation of a systematic screening program in Flanders, based on the results of the MCS. Through the municipalities, women in the target group would receive an invitation for a mammogram, either via referral to a radiologist, through their GP, or via a direct visit to a central screening unit. All data on the screening efforts would be collected and summarized

through the LOGOs, the local health councils. The second reading of each mammogram must be done by the five accredited regional screening centers. Actual implementation was planned for 1999, but faced strong opposition from the professional organizations of the radiologists, gynecologists, and GPs, who all felt their viewpoints and interests were not sufficiently taken into account. At the end of 1999, no systematic mammography screening program had been implemented yet, despite the announcement of health targets, specifically in this area.

The intervention of the regional Minister of Public Health of the French community in the breast cancer prevention organization, as in other prevention issues, is almost zero. The involvement is limited to the financial support of local initiatives. These latter projects are developed by university teams in collaboration with the local and/or provincial authorities.

Financing. The financing of mammography screening is different for the organizational costs and the screening costs.

The financing of the organizational cost differs for every program. The different communities are the major financiers. For the Flemish community, every screening center formulated its own budget needs and the budgets were allocated independently of the actual number of screening interventions. However, from 1998 on, a more result-oriented financing system was to be implemented, based upon the size of the target group in the region, but this has not yet been realized. Other financiers of the regional programs are the provincial authorities, the Regional Funds for Scientific Research, and/or the European Union with the Europe Against Cancer program.

The screening cost of the mammograms is financed by the National Institute for Illness and Invalidity Insurance (RIZIV/INAMI) in a fee-for-service plan. All interventions are reimbursed, without any frequency restriction. Only one nomenclature number is provided for mammography; hence, no distinction can be made between diagnostic and preventive mammograms. However, reimbursement of mammography is provided only in cases of referral by a GP. In order to obtain sufficient financial resources, this implies that screening centers have to make referral arrangements with GPs.

Accessibility of Procedure and Compliance Rate. The target group in almost all programs consists of women between 50 and 69 years (cf. European Union recommendations). All programs prescribe a screening frequency of at least every 2 years. In the Flemish screening programs, the compliance rate (percentage of women that participated in the first round and continues to participate in the second round) has been evaluated for the different age categories in two different screening situations (Table 2). The study reveals a much higher compliance rate when women are directly invited for mammography. For both screening situations, the compliance rate is highest for the age category of 50 to 59 years. Women between 65 and 69 years participate remarkably less in the second screening round after participation in the first round, and this happens in both screening situations.

Table 2. Compliance Rate

Age of first round	Invitation of consult GP, who refers for screening	Invitation for mammogram without referral
50–54 years	55.1%	76.1%
55–59 years	57.5%	79.9%
60–64 years	56.6%	78.4%
65–69 years	30.0%	57.7%
50–69 years	50.9%	74.0%

Source: Verheyen and Cannoodt (21).

Formal Decisions and Evaluations. Nowadays, policy decisions of the different authorities are still based too much upon advice from the different stakeholders in the field. Since they have different and sometimes conflicting interests, this leads to fragmented policy making.

Only the Flemish community has formally evaluated breast cancer screening activities through the MCS. In the French community, few policy documents are available.

Until now, no legal framework exists for systematic breast cancer screening on the federal or regional level. Influence of the authorities is limited to the allocation of financial resources, which are sometimes restricted, depending on quality and organizational criteria, for example (cf. Flemish community). The proposal for a systematic breast cancer screening program in Flanders, developed by the former Flemish Minister of Health Policy, is not yet implemented, mainly because of the strong opposition by private radiologists, gynecologists, and GPs.

Involvement of Clinicians and the Public. In the Flemish community, clinicians had a substantial influence on the MCS. Radiologists, epidemiologists, oncologists, and GPs were on the advisory committees. Moreover, clinicians are closely involved in organizing the different local programs in Belgium.

The impact of clinicians can be very strong, which was demonstrated in a Brussels breast cancer screening initiative in the early 1990s that was boycotted by the GPs because they felt they were not involved enough in the process. A similar evolution is now taking place in Flanders.

The public was not involved in the policy preparation. However, some sociological studies have examined the attitude of the target group toward different prevention programs (7;12).

Use of the Preventive Services. Precise figures on the amount of preventive mammograms in Belgium are not available, since the RIZIV/INAMI does not distinguish between diagnostic and preventive mammography. The RIZIV/INAMI figures only report the total number of mammograms and expenditures (Table 3). There are data on participation for the Flemish community (21). Also in this study, the researchers were confronted with the fact that the distinction between diagnostic and preventive mammograms could not always be made.

New Technical and Policy Developments. Progress in quality of mammography screening and reading is expected from the evolution toward digital imaging, but the extra cost will probably not be compensated by a much higher effectiveness. For the Flemish Community, the MCS and the former Flemish Health Minister's recent proposals for preventive health care are signs of a new prevention policy, based on scientific evidence, for the future. The fact that the former minister organized a scientific conference on preventive health care in 1997, with the intention to derive solid proposals for policy making, is a clear sign of a move toward more evidence-based policy making. Also, the establishment of LOGOs, which are responsible for organizing and coordinating preventive activities at

Table 3. Mammograms Reimbursed by RIZIV/INAMI

	1994	1996	1998
Number of mammograms	704,716	784,277	882,325
Expenditures in Belgian francs on mammograms	738,368,012	771,099,381	789,389,720

Source: Data from RIZIV/INAMI (1997) and (1999).

Table 4. Prostate Cancer Incidence (1993) and Mortality (1992) in Belgium

	Flanders	Wallonia	Brussels	Belgium
Incidence				
Absolute numbers	2,066	736	156	2,958
% of all tumors[a]				17.73
Gross incidence (per 100,000)				59.98
Cumulative incidence				
0–64 years (%)				1.06
0–74 years (%)				3.93
Mortality				
Absolute numbers				1,713
Gross mortality rate (per 100,000)				34.88

Source: National Cancer Register (13) and data from the Health Care Administration of the Flemish Community (1997).
[a]Excluding nonmelanoma skin tumors.

the local level and for the development of health targets, are signs of a more coordinated regional approach, covering the whole territory of Flanders.

Prostate Cancer (PSA Screening)

Local Epidemiologic Data. The National Cancer Register's most recent data reveal incidence and mortality rates for prostate cancer in the Belgian population (13). These data are comparable with other European countries. The following changes can be observed throughout the European Union: an increase in the number of prostate cancers with age, an increase of the prostate volume with each decade of age, and a yearly absolute decrease of prostate cancer. Above 80 years of age, the risk for men to die *with* prostate cancer is larger than to die *of* prostate cancer.

Organizational Context of PSA Screening

DESCRIPTION OF THE SERVICES

Screening for prostate cancer by PSA is not organized in a systematic way in Belgium. PSA screening activities take place in the physician's office in a more or less arbitrary way. Physicians decide autonomously and for each individual patient whether to perform PSA testing.

There are locally organized experimental screening programs. For instance, in Antwerp a European pilot project named the European Randomized Study of Screening for Prostate Cancer (ERSPC), was started in 1991 in collaboration with Erasmus University of Rotterdam. In September 1997, six centers from six countries participated in the project, with support of Directorate General V. In January 2000, the province of Flemish-Brabant announced a pilot PSA screening program, which raised a great controversy among stakeholders. Opponents argue that the evidence does not support the implementation of a screening campaign. Proponents argue that it is a feasibility study.

Financing. There is no allocation of financial resources specifically for PSA screening. The experimental programs are financed by research funds, local authorities, and foundations. PSA tests are reimbursed by the RIZIV/INAMI only when the patient is over 50 years of age and has manifested specific complaints.

Accessibility of Procedure and Compliance Rate. The ERSPC project's target group consists in principle of men between 55 and 70 years. Quite recently, the Antwerp and

Rotterdam pilot program decided to extend the age limit to 74 years when the population protested against the age 70 limit. The screening frequency is 4 years, but a 3-year screening interval is being discussed. Some stakeholders believe that high-risk persons should be screened monthly. No data are available for compliance.

Formal Decisions and Evaluations

DESCRIPTION OF FORMAL ASSESSMENT

A prospective randomized trial on the benefits of screening for men above 55 years is being conducted with the Antwerp experiment, in the context of the ERSPC project. There is a lot of debate about the predictive value of PSA. The problem of false-positive and false-negative results is a leading topic in this discussion.

RECENT POLICY DOCUMENTS AND PUBLICATIONS

No policy documents on PSA screening have been drafted officially on the federal or regional level in Belgium. A number of scientific publications have emerged from the ERSPC project (18).

DESCRIPTION OF FORMAL DECISIONS

The only formal decision recently made concerning PSA screening was the decision of the Flemish government to stop financing the Antwerp ERSPC project, since it was considered to be a research project. The former Flemish Minister of Health Policy only wants to subsidize the implementation of programs of which the benefits have been proven scientifically. It was argued that (inter)national studies had proven the lack of effectiveness of prostate cancer screening.

Involvement of Clinicians and the Public. In the Flemish Community, clinicians are in principle formally involved in preparing prevention policy currently through the Flemish Health Council and formerly through the Flemish Advisory Commission for Cancer Prevention. However, the representation of these clinicians is often argued.

Global public opinion is not explicitly involved in the discussion on screening. However, in Antwerp the ERSPC team carried out a local sensitization campaign and, due to public pressure, the age limit for PSA screening was raised.

Use of the Preventive Services. The only data concerning the number of PSA screening tests annually performed in Belgium are those of the RIZIV/INAMI. Since the RIZIV/INAMI does not reimburse these tests in all cases, the registered data do not accurately represent the actual number of PSA screening tests (Table 5). Thus, both within and in addition to these reimbursed PSA tests, there is probably an important number of PSA screening tests that can be classified as opportunistic screening. However, the substantial increase in number of PSA tests reimbursed is remarkable.

New Technical and Policy Developments. The different actors in the Belgian healthcare system have different opinions on prostate cancer screening through PSA. Some are rather skeptical about PSA screening and attach more importance to prostate cancer

Table 5. Reimbursed PSA Tests in Belgium

	1995	1996	1998
Number of registered PSA tests	103,921	207,672	232,298
Expenditures (in Belgian francs)	19,362,854	39,229,740	43,612,261

Source: Data from RIZIV/INAMI (1997) and (1999).

treatment than to prevention. Others argue that the Antwerp project should first be finalized (in 2007) before health policy conclusions can be made. Others believe that by integrating PSA screening in a combined test of different screening methods (i.e., multi-test screening), the sensitivity and validity of the screening procedure could be improved.

Routine Use of Ultrasound in Normal Pregnancy

Many Belgian stakeholders question whether ultrasound should be regarded only as a preventive intervention. In almost every pregnancy, ultrasound is used not only as a screening instrument, but also as a means of following the fetal evolution. As is the case for many diagnostic examinations, effectiveness of ultrasound is mainly documented in terms of technical accuracy, but not at all in terms of improved diagnosis or therapy, let alone in terms of superior patient outcomes (20).

Organizational Context

DESCRIPTION OF THE SERVICES

In Belgium no systematic screening program has ever been created for use of ultrasound in pregnancy. Most pregnancies in Belgium are followed through ultrasound by the treating physician. Routine ultrasound has developed into a widespread practice through quality improvement of the devices, increasing experience, better training of physicians, and development of new applications, supported by fee-for-service reimbursement.

The obvious advantages of the use of ultrasound as a routine follow-up instrument are a barrier for an ultrasound prevention study. Nowadays, the advantages of ultrasound are so straightforward to physicians and patients that reducing the use of ultrasound will not be easily accepted. Ultrasound is the first and only imaging method for pregnancy and is, in principle, not harmful. The observation of her unborn child may have a positive psychological and relational impact on the pregnant woman.

Financing. The RIZIV/INAMI reimburses in principle three ultrasound per pregnancy, i.e., one per trimester. This decision was the result of a consensus meeting within the Technical Commission for Medical Care (within RIZIV/INAMI) with members of the academic, hospital, and insurance fields. The idea is that in different pregnancy periods, classified as trimesters, different problems may arise. This rule is applied only in the case of normal pregnancies. In case of special indications mentioned by RIZIV/INAMI, additional ultrasounds can be reimbursed, if preauthorization was obtained. Since no systematic screening program is organized, there are no specific funds for ultrasound as a preventive instrument.

Accessibility of the Procedure. Accessibility to ultrasound is common, since most pregnancies in Belgium are followed up by gynecologists, and they usually have ultrasound in their practice. However, this access is not in the specific context of a screening program.

Formal Decisions and Evaluations. No formal assessments have been made regarding ultrasound in pregnancy, since policy preparation took place in Belgium, although there have been a few academic studies (9;10). Stakeholders base their ultrasound practice mainly on a limited number of European (Scandinavian) studies (2;11;14–16).

The decision to limit reimbursement of ultrasounds to three per pregnancy can be considered as an implicit evaluation of the optimal number of ultrasounds per pregnancy. This number of recommended ultrasound is not binding, however; Belgian physicians performing fewer than three ultrasounds are not liable for negligent conduct. The regional authorities, which are formally authorized for prevention policy, did not take any initiative for a program on elaboration of guidelines regarding ultrasounds screening in pregnancy.

Two organizations, the Flemish Association for Obstetrics and Gynecology (VVOG) and the ultrasound Association of Dutch-Speaking Belgium (VENEB), are developing

Table 6. Rembursed Ultrasound Examinations During Pregnancy in Belgium

	1994	1996	1998
Number of ultrasounds	286,010	279,942	331,528
Expenditure for ultrasounds (in Belgian francs)	211,401,883	213,990,812	272,365,379

Source: Data from RIZIV/INAMI (1997) and (1999).

proposals for an ultrasound policy for the future. However, the implementation of these guidelines remains uncertain, since the professional associations prefer to wait for reforms in hospital financing and because of the fear that the guidelines could be used in liability suits against the physicians.

Involvement of Clinicians and the Public. The only formal decision making, i.e., the number of ultrasound to be reimbursed per pregnancy, did involve clinicians. There is no sign of an attempt to involve the public in the diagnostic ultrasound debate.

Use of Ultrasonography Services in Belgium. Important differences exist in the number of performed ultrasound examinations per pregnancy. There are indications that most physicians perform three ultrasounds per pregnancy, and hence consider the financing decision of the RIZIV/INAMI as an implicit rule. However, there are physicians that provide/prescribe fewer ultrasound (mainly older physicians without adequate equipment, who avoid refering to another physician), and physicians that perform six to nine ultrasound per pregnancy (i.e., not all of them reimbursed by health insurance). Regional differences are said to exist (not documented). Ultrasounds in normal pregnancy are performed for many other reasons than screening for defects, such as comfort and psychological reasons, defensive medical practice, and pecuniary reasons (fee-for-service reimbursement).

Table 6 reports the annual number of ultrasound in pregnancy reimbursed by the RIZIV/INAMI in Belgium between 1994 and 1998, as well as the corresponding expenditures.

New Technical and Policy Developments. An evolution to three-dimensional ultrasound is expected, through which a longitudinal view of the fetus is possible. At the policy level, stakeholders expect the development of guidelines by and for the involved professional groups. Stakeholders mention that a "search and destroy" strategy (i.e., screening for abnormalities), followed by termination of the pregnancy, should be followed very cautiously.

DISCUSSION

HTA has had very little impact on policy and practice in the prevention of breast cancer by mammography, the prevention of prostate cancer by PSA screening, and the routine use of ultrasound during pregnancy in Belgium. This limited impact can be attributed to several factors, including the fragmentation in healthcare policy, different regional healthcare policy options, fragmentation in healthcare practice, the strong impact of healthcare stakeholders (mainly provider groups and sickness funds) on decision making, and, as a consequence, a limited attention to scientific evidence in health policy and technology assessment.

However, there are some signs, especially among the former Flemish government, that there is a growing interest for evidence-based policy making (e.g., initiative by the Flemish Health Minister for a scientific conference on preventive health care). Likewise, at the beginning of 1997, the Flemish Health Council was created to advise the Flemish government on health policy matters. Contrary to many existing advisory committees, this

council is composed of individuals (who do not formally represent their organizations), appointed by the government on the basis of their expertise in certain health (care) matters. It remains to be seen whether the actual Flemish government, in office since last summer, will remain on the same track.

CONCLUSION

A systematic national/regional screening program has not been formally implemented yet for any of the three screening strategies. Formal evidence-based evaluations and uniform strategies are not used in Belgium. Preventive screening programs are most often organized by interested individuals (e.g., by university research teams or in some cases, in collaboration with provincial and local authorities). The limited attempts to implement systematic screening strategies have so far not been successful, mainly due to opposition and lobbying by stakeholders in the field.

REFERENCES

1. Andersson I, Bjurstam N, Fagerberg G, et al. Breast cancer screening with mammography: Overview of Swedish randomized trials. *Lancet*. 1993;341:973-978.
2. Bucher HC, Schmidt JG. Does routine ultrasound improve outcome in pregnancy? Meta-analysis of various outcome measures. *BMJ*. 1993;307:13-17.
3. Buytaert P, De Neubourg F, Leroy Y. Bevolkingsonderzoek naar borstkanker bij vrouwen jonger dan 50: zinvol? *Tijdschrift voor Geneeskunde*. 1995;51:271-279.
4. Cleemput I, Kesteloot K. Health technology assessment in Belgium. *Int J Technol Assess Health Care*. 2000;16:325-346.
5. Coebergh JWW, Janssen-Heynen MLG, Van der Heyden LH. (eds). *Cancer incidence and survival in the Southeast of the Netherlands. A report from the Eindhoven Cancer Registry*. Eindhoven: Integraal Kankercentrum Zuid; 1995.
6. De Koning HJ, Frachebaud J, Boer R, et al. Nation-wide breast cancer screening in the Netherlands: Support for breast cancer mortality reduction. National Evaluation Team for Breast Cancer Screening. *Int J Cancer*. 1995;60:777-780.
7. Eylenbosch WI, Van Hal G, Weyler J. *Niet-participatie aan screening naar baarmoederhalskanker in een telecommunicatiebedrijf in Vlaanderen*. Esoc-publication 13. Antwerpen: UIA; 1988.
8. Kirkpatrick A, Törnberg S, Thijssen MAO. *European guidelines for quality assurance in mammography screening*. Brussels-Luxembourg: Commission of the European Communities, Medicine and Health; 1993.
9. Levi S, Hyjazi Y, Schaaps JP, et al. Sensitivity and specificity of routine antenatal screening for congenital abnormalities by ultrasound: The Belgian multi-center Study. *Ultrasound Obstet Gynecol*. 1991;1:102-110.
10. Levi S, Schaaps JP, De Havay P, et al. End-result of routine ultrasound screening for congenital anomalies: The Belgian multi-center study 1984-1992. *Ultrasound Obstet Gynecol*. 1995;5:366-371.
11. Luck C. Value of routine ultrasound scanning at 19 weeks: A four year study of 8849 deliveries. *BMJ*. 1992;304:1474-1478.
12. Matthijssen M, Van Hal G, Weyler J. Hoe ontvankelijk is the Antwerpse bevolking voor mammografische screening? *Tijdschrift voor Sociale Gezondheidszorg*. 1993;66:11-23.
13. National Cancer Register (Belgisch Werk tegen Kanker). *Breast cancer, prostate cancer.* Brussels: National Cancer Register; 1993.
14. National Institute of Health. Consensus conference: The use of diagnostic ultrasound imaging during pregnancy. *JAMA*. 1984;252:669-672.
15. Saari-Kempainen A, Karjalainen O, Ylostalo P, et al. Ultrasound screening and perinatal mortality: Controlled trial of systematic one-stage screening in pregnancy. The Helsinki ultrasound trial. *Lancet*. 1990;336:387-391.
16. Shapiro S, Strax PH, Venet L. Periodic breast cancer screening in reducing mortality from breast cancer. *JAMA*. 1971;215:1777-1785.

17. Standaert B, Denis L. Vroeg opsporen van prostaatkanker: Hoe oordelen of veroordelen? In *Preventieve Gezondheidszorg, Vlaams Preventiecongres 1997*. Diegem: Kluwer Editorial; 1997:151-161.
18. Tabar L, Fagerberg G, Chen HH, et al. Efficacy of breast cancer screening by age: New results from the Swedish two-county trial. *Cancer*. 1995;75:2507-2517.
19. Vandenberghe K, Van Schoubroeck D. Prenatale diagnose en prenatale screening via echografie. In *Preventieve gezondheidszorg. Vlaams Preventiecongres*. Diegem: Kluwer Editorial; 1997:805-815.
20. Van Hal G, Matthyssen M, Weyler J. Participatie. In J Weyler, J Schrijvers, I Vandermeeren, L Vuylsteke de Laps (eds). *Multicenterstudie borstkankerscreening Vlaanderen, subcommissie borstkankerpreventie*. Brussel: Vlaamse Adviescommissie voor Kankerpreventie; 1997:129-153.
21. Verheyen V, Cannoodt L. Gezondheidseconomische aspecten van de bestaande modellen van georganiseerde borstkankerscreening in Vlaanderen. In J Weyler, J Schrijvers, I Vandermeeren, L Vuylsteke de Laps (eds). *Multicenterstudie borstkankerscreening Vlaanderen, subcommissie borstkankerpreventie*. Brussel: Vlaamse Adviescommissie voor Kankerpreventie; 1997: 293-355.
22. Weyler J, Schrijvers J, Vandermeeren I, Vuylsteke de Laps L. (eds). *Multicenterstudie borstkankerscreening Vlaanderen, subcommissie borstkankerpreventie*. Brussel: Vlaamse Adviescommissie voor Kankerpreventie; 1997.
23. X. Santé et Communauté. *Bulletin d'informations épidemiologiques de la Communauté française de Belgique*. Centres Universitaires Déspistage and of the Société Belge de Cytologie et le Groupement Belge pour la Promotion du Dépistage du Cancer du Sein; September 1992:20.