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MAMMOGRAPHY, ROUTINE ULTRASONOGRAPHY IN PREGNANCY, AND PSA SCREENINGS IN ITALY

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Abstract

Objective: To present current scientific statements and practice on mammography, ultrasonography in pregnancy, and PSA within the Italian National Health Service (NHS).
Methods: Information on the three screenings was found in several position papers prepared by working groups at national and regional levels.
Results: For mammography the adjusted mortality rate for breast cancer increased in the last four decades and decreased in the last few years. Only 4.9% of women aged 50–70 years are covered by screening. In 1996 a consensus paper stated that biennial examination for women aged 50–69 years should be offered to reduce breast cancer mortality. A national program for breast cancer screening was launched under the responsibility of regional governments, but data about its implementation are not yet available. Regarding PSA screening, the results show that prostate cancer is the fourth most frequent neoplasm in males. A formal evaluation of prostate cancer screening was done in 1995 by the National Research Council and the Italian Association for Cancer Research; they did not recommend the NHS implement this service. In the National Health Plan 1998–2000, prostate cancer screening is not mentioned. So far, an organized and standardized screening program, based on routine PSA testing, does not exist in Italy. Nevertheless, a lot of PSA tests are performed at the clinical level to detect early prostate cancers. The results with regard to routine ultrasonography in pregnancy show that in 1996 the birth rate was 9.30 per 1,000 inhabitants, with 536,740 live births. In the period from 1992–94, the percentage of babies with a birth weight less than 2,500 gm and less than 1,500 gm were 5.85% and 0.91%, respectively. A formal screening program for detecting fetal growth retardation, based on the routine ultrasonography in the third trimester of the normal pregnancy, doesn't exist in Italy, but this test is widely performed. It is paid for under NHS coverage.
Conclusion: In 1998 the National Health Plan 1998–2000 stated that the NHS should offer only evidence-based preventive and diagnostic interventions and stressed the importance of appropriate use of health technology.

Keywords: Mammographic screening, Ultrasonographic screening in pregnancy, PSA screening

The aim of this paper is to present current scientific statements and actual policy of the Italian National Health Service (NHS) on three screenings discussed in this European overview. In addition, we would like to give a picture of the Italian NHS and its major reforms and show the practical role of health technology assessment (HTA) in a country where specific agencies dedicated to HTA only do not exist, but a great deal of HTA analyses has been carried out, and the impact of these analyses on policy making is increasing both at the national and regional levels.

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Information included in this paper gives an interesting overview of three preventive medicine strategies in comparison to healthcare policy in the same fields in other European countries.

THE ITALIAN HEALTHCARE SYSTEM

The Constitution of the Italian Republic states in Article 32 that health is a right for all Italian citizen, and health protection is a primary benefit not only for individuals but also for society and a prerequisite for the development of social progress and common welfare.

In Italy, the healthcare system is dominated by the NHS, which was established in 1978, even though in recent years the private sector has become more assertive. The NHS underwent two major reforms in 1992 and 1999 and is changing in several institutional mechanisms, with an increasing role for regional governments (which will become fully responsible for funding in the next 3 years), the diffusion of a directive management instead of that based on consensus, and a clearer accountability of different levels. The mandate of the NHS is broad, encompassing activities of disease prevention, treatment, rehabilitation, environmental and occupational health, and health promotion.

The last reform, approved in June 1999 and now under implementation, states in Article 1, entitled "Defense of health as a right, health planning and definition of essential and uniform levels of health care":

- The defense of health as a right . . . is guaranteed by the NHS . . .;
- The definition of essential and uniform levels of care is based on dignity of human being, health needs, equity of access to health care, quality of care, appropriateness, and economic evaluation;
- The NHS will pay health care packages based on scientific evidence, with high probability to produce health gain both for individuals and community, and cost-effectiveness; and
- The NHS will not pay healthcare services and procedures that are not effective and appropriate.

This is the first time that a utilitarian approach is introduced in Italian legislation, overcoming the tradition of the humanitarian approach. This is a cultural shift that will probably create some problems in the short term for politicians and doctors. Anyway, some experiences carried out in the last decade will probably help the diffusion of HTA in the day-by-day activity of the NHS.

HTA IN ITALY

Even though specific national or regional bodies, specifically dedicated to HTA only, do not exist in Italy, several important experiences were carried out and are ongoing. The most important national experience is called TRiPSS, an acronym corresponding to the English GRIP (getting research into practice).

This program was initiated in 1995 and was coordinated by the Centre for Health Services Research of the Mario Negri Institute in Milan. Twenty local health units and hospital trusts in northern and central Italy were involved. The aim was to introduce principles and methods of HTA in decision-making processes both at managerial and clinical levels. The idea was to link the separate worlds of clinicians and managers. Many activities were carried out and specific projects were activated.

The coordinating center produced a database, including about 400 clinical guidelines in different fields, thoroughly examined by a panel of experts and classified by quality of production and affordability. The same center organized several continuing education programs to increase knowledge, skills, and attitudes of a group of key persons working

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at managerial and clinical level in the 20 participating organizations. Four specific projects have been carried out by groups of organizations: preoperative examinations, heart failure, pregnancy, and breast cancer.

Several managerial tools have been identified to support the transfer of scientific knowledge to practice: continuing education, appropriate use of financial incentives, coherent investment policy, budgeting system, auditing and monitoring of clinical practice, and patient education.

Other experiences have been carried out in Italy: two national consensus conferences on head trauma and breast cancer follow-up. Italian groups took part in European Union (EU) projects. Several HTA services or centers were set up at the local or regional level in the Veneto region, Bergamo, and Modena.

In the Veneto region, several initiatives have been carried out, including implementation in the decision-making process, time trends in distribution and utilization of cardiac catheterization facilities in Italy during the years of 1983–93 (13), appropriateness of use of coronary angiography (1), appropriateness of use of hospital, appropriateness of use of blood, appropriateness of use of echocardiography (involving general practitioners), utilization of hospital-based services by the elderly, utilization of percutaneous transluminal coronary angioplasty (PTCA) (17), use of contrast media in radiology, assessment of hospital preventive medicine examinations, perceptions of waiting lists by the elderly (16), clinical guidelines (within the TRiPSS project) (12;23), hospitalized patients' falls, and urinary catheterization management.

Bergamo has studied the appropriate use of intensive care units, vascular surgery, contrast media in radiology, and computerized bone densitometry. In addition, the Hospital Trust is giving particular attention to innovative technology. Bergamo has a relevant impact on other hospitals in the Lombardia region, which is one of the most important in the country because of the size of the population (about 10 million inhabitants) and the socioeconomic level.

Modena is acting as scientific leader of an extended national program, coordinated by the autonomous region of Valle d'Aosta and financed by the Ministry of Health and 12 regions, which is focused on the identification and application of tools to implement clinical guidelines in the NHS.

At the national level, following the mandate of the last reform of the NHS, the Agency for Regional Services, based in Rome, will probably be more and more involved in systematic technology assessment activities.

At the scientific level, the Italian Society for Quality in Health Care established a specific interest group on technology assessment within its Scientific Committee, aiming to have systematic contributions on the subject in its *Journal*, to hold specific sessions during the national and regional meetings, and to stimulate multicentric activities.

POLICIES TOWARD PREVENTION AND SCREENING

The mandate of the NHS is broad, including health protection and promotion, disease prevention, and preventive medicine. Compulsory vaccinations against poliomyelitis, hepatitis B, tetanus, and diphtheria are carried out regularly. In addition, recommended vaccination campaigns are offered against measles, rubella, mumps, influenza, pertussis, and *Haemophilus influenzae* b.

Health education campaigns have been launched addressing smoking habits, nutrition, healthy lifestyles, and drug and alcohol addiction. Specific healthcare services are provided for drug and alcohol addicts. Screening is very much unevenly distributed across the country. Pap tests and mammography are offered as systematic screening in selected areas in northern

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and central Italy. Nationwide the procedures are widely carried out on an individual basis and inappropriate use rates are probably high.

THE CASE STUDIES

Mammography

Epidemiology. In Italy breast cancer is the most frequent cancer among females, comprising 26.8% of all cancers in 1992. As a consequence of breast cancer, 10,889 females died in 1992, with an annual crude mortality rate of 37.28 per 100,000 females and an annual age-adjusted mortality rate of 28.49 per 100,000 females (7) (adjustment on European standard population). The trend of annual mortality rates for breast cancer has been increasing in the last four decades (adjustment on the world standard population); nevertheless, in the last few years the trend of mortality is decreasing (8;10;27).

Incidence data on breast cancer at the national level have been estimated using a mathematical model, based on survival data and specific mortality rates for the period from 1970–87; a crude rate of 111.1 per 100,000 women (20–84 years) has been estimated in 1987. Decreasing age-standardized incidence rates from North to South Italy have been shown (18).

In 1990 to 1994, the Venetian Tumor Registry estimated in the Veneto region an annual crude incidence rate of 127.8 per 100,000 females and an incidence rate of 102.0 per 100,000 females (adjustment on European standard population). Data of this registry are based on hospital discharges, histologic records, and death certificates (28).

Formal Assessments of Screening. In June 1996 a document entitled Consensus on Screenings in Oncology: Suggestions for Research and Recommendations for the National Health Service was published by the National Research Council (CNR) and the Italian Association for Cancer Research (AIRC), a nonprofit organization (5). This document reports the results of a workshop organized in 1995 by the CNR, the AIRC, and the National Oncological Committee of the Ministry of Health. Leading specialists on early diagnosis of cancer took part in this workshop.

Six cancers were considered, including breast, cervical, colorectal, endometrial, ovarian, and prostate cancers. This report describes principles of screenings, available tests, effectiveness and feasibility, and recommendations for the NHS.

The conclusions about screening for breast cancer were the following:

- *Efficacy*: On the basis of published studies, it is possible to state that screening for breast cancer carried out by inviting women for periodic mammographic examination, followed by diagnosis and treatment when necessary, leads to a significant reduction of breast cancer mortality;
- *Target population*: Women aged 50–69 years;
- *Frequency of test*: Biennial;
- *Implementation*: A standardized program for breast cancer screening in each Italian region, led by a regional steering committee, is recommended; the extension of programs to the whole population must follow a pilot feasibility study;
- *Cost-effectiveness*: If a national standardized screening program were implemented in the next 30 years (with a screening compliance of 70%), a mortality reduction of 1,650 death for year should be expected. The net cost of the program (screening tests, diagnostic investigations, and treatment of detected cancers) has been estimated between 50 million and 70 million Euro per year, the cost of one saved life is estimated between 31,300 and 44,000 Euro, and the cost of 1 year of saved life is estimated between 3,450 and 4,850 Euro; and
- *Other targets*: As far as the effect of screening in women under 50 years of age is still uncertain, a mammographic screening is not justified, and any screening for these women should only be

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performed as a part of a properly controlled research program; women over 69 years have not been invited in the screening program because of cost/effectiveness considerations.

The level of scientific evidence is the first level with regard to the references of this document, examined by an expert committee: randomized controlled trials, meta-analysis, non-randomized controlled trials, and case-control studies are mentioned.

Accessibility of Procedure and Compliance Rate. In 1990 the Italian Group for Planning and Evaluating Mammographic Screening (GISMa) was created, and in 1994 a questionnaire was sent to participants in 15 ongoing mammographic screening programs. These programs involved 4.9% of women aged 50 to 70 years who reside in Italy. Most screening projects are currently undergoing the second or third round, except the Florence province program (which has already performed 5 to 10 rounds) (14).

An attendance rate of 50% has been reported by almost all centers with ongoing screening programs, but only six have reached the desired standard (70% of eligible women). Attendance rate depends on age (it is higher in younger women) (3;11), whereas an association with socioeconomic status, educational level, and health behavior is questioned.

The most common reasons for lack of response are that the screening is useless, fears of discovering breast cancer, laziness, and a tendency to postpone the screening. Although there is a high proportion of women who undergo breast examinations and mammographies annually (24), a remarkable number of women have never had a mammography nor a breast examination in absence of symptoms (26).

Recent Policy Reports and Papers on the Subject. In June 1996, within the framework of the National Health Plan for the years 1994–96, guidelines for the organization of prevention and care in oncology (20) were produced by the National Oncological Committee. This document deals with primary prevention of lung cancer and early diagnosis of cervical cancer and breast cancer. For breast cancer, these guidelines agree with recommendations of the consensus document published by the CNR and AIRC (5). Following the guidelines, regions and local health units established a technical committee, and regional guidelines and recommendations have been given for the local implementation of the national screening strategy. For example, the Ministry of Health of the Veneto region funded several local programs.

The National Health Plan 1998–2000 (22), published in May 1998, has the target of reducing the breast cancer mortality of 10%. The mammographic screening should be extended throughout the country, and a national guideline on breast cancer care will be adopted in the next months.

Description of Formal Decision. The national program will be offered every 2 years to women aged 50–69 years. The guidelines detailed recommendations about the structure and management of screening programs, information to the population, the role of the general practitioners (GPs), quality assurance, education of health personnel, and counseling protocols.

Involvement of GPs, who have a very important role both in persuading women to undergo the screening and to avoid inappropriate use of mammography, is considered particularly important in screening programs.

Since a high attendance rate is a fundamental requisite for the success of the screening program, national guidelines recommend developing local advertising campaigns to adequately inform the population about the benefits of the screening. Moreover, communication of the results of the mammography must be done with special attention to avoid anxiety.

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Prostate-specific Antigen Screening

Epidemiology. In Italy prostate cancer is the fourth most frequent cancer among males: in 1992 there were 6,232 males who died from prostate cancer, with an annual crude mortality rate of 22.61 per 100,000 males and a mortality rate of 19.31 per 100,000 males (age adjusted on European standard population) (7). Trends of annual mortality rates for prostate cancer in the four last decades (age adjusted on the world standard population) have been increasing (8;10;27).

National incidence rates for prostate cancer are not available; the Venetian Tumor Registry estimated in 1990–1994 in the Veneto region an annual crude incidence rate of 55.9 per 100,000 males and an annual incidence rate of 51.2 per 100,000 males (age adjusted on European standard population) (7). These data are based on hospital discharges, histologic records, and death certificates of inhabitants of the Veneto region (28).

Formal Assessments of Screening. In 1994 a paper entitled Comparing Two Modalities of Screening for Prostate Cancer: Digital Rectal Examination (DRE) and Transrectal Ultrasonography (TRUS) vs. Prostate-Specific Antigen (PSA) was published by Ciatto et al. (2). The study compared the performance of screening by TRUS with the screening by PSA and was carried out by the Centro per lo Studio e la Prevenzione Oncologica of Florence.

Two consecutive studies on two comparable populations were performed: a) in 1992 a total of 4,228 subjects were invited and 1,425 (33.7%) were examined with DRE–TRUS; and b) during 1993 a total of 1,965 subjects were invited and 1,314 (66.9%) were examined with PSA.The paper's conclusions were the following:

> PSA screening is undoubtedly more acceptable than DRE or TRUS, as shown by the difference in attendance rates observed in two cohorts. The results of the present study did not show any effectiveness of prostate cancer screening. Prostate cancer screening is feasible and able to detect early cancer. The benefit of this anticipation on health outcomes is under scrutiny and requires other studies. The possible harmful aspects of prostate cancer screening are so much that, at present, any suggestions for introducing screening in the current prevention procedures do not exist.

The level of the scientific evidence of this document is the seventh level: noncontrolled clinical series.

The guidelines published by the CNR and AIRC in 1996 (5) contained the following conclusions about prostate cancer screening:

- With reference to effectiveness of screening tests, "at the moment, there is no scientific evidence of effectiveness of the screening, with one or more of the available tests; it is possible that screening is harmful"; and
- The authors of the document recommend to the National Health Service that "without further clarification of the role of available tests, it is neither lawful nor ethical to plan prostate cancer screening; particularly the prescription of the PSA in subjects without a suspicion of prostate cancer must be discouraged and not financed with public money."

The level of the scientific evidence of this document is the seventh level: expert committee, descriptive studies.

Accessibility of Procedure and Compliance Rate. At the moment, an organized and standardized screening program for detecting early prostate cancer, based on routine PSA dosage, doesn't exist in Italy. Nevertheless, a lot of PSA tests are prescribed by physicians with the generic aim of detecting early prostate cancers.

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Behavior of physicians and their clients varies greatly. As demonstrated by Ciatto et al. (2), the PSA test is more acceptable than DRE or TRUS, and with this test the compliance to an organized and standardized screening program could be higher.

Recent Policy Reports and Papers on the Subject. The guidelines for the organization of prevention and care in oncology (21), produced by the National Oncological Committee in 1996, do not take into consideration an organized screening program on prostate cancer and recommend "the necessity of planning controlled studies for determining the effectiveness of new screening procedures for early diagnosis." In July 1996 the Ministry of Health of the Veneto region gave instructions for organizing other screening programs in oncology, but prostate cancer screening was not mentioned. Even in the National Health Plan 1998–2000 (22) prostate cancer screening is not mentioned.

Routine Ultrasonography in Pregnancy

Epidemiology. In 1996 the Italian live birth rate was 9.30 × 1,000 inhabitants and 536,740 babies were born. In the last 5 years there was a slight drop in the birth rate. In the period from 1992–94, babies with a birth weight less than 2,500 gm and less than 1,500 gm were 5.85% and 0.91%, respectively (15).

Formal Assessments of Screening. In 1996 a proposal of guidelines for care in physiological pregnancy was published by the Ministry of Health of the Umbria region (4). These guidelines have been produced by a multidisciplinary panel of 14 regional experts in collaboration with the Italian Cochrane Centre. The recommendations of this document result from formal integration between opinions of the panel experts and evidence of the scientific literature. As a consequence, each recommendation has been rated on the basis of its strength of recommendations. For this task, the researchers of the Italian Cochrane Centre adopted the classification of the U.S. Preventive Task Force.

The recommendation about the use of ultrasonography in the third trimester of normal pregnancy is as follows:

> In the third trimester of the gestation, the ultrasonography evaluation allows an improvement in perinatal mortality rates and a reduction in the number of babies with a low Apgar score; therefore, the panel urges this examination around the 32nd week.

In this paper cost-effectiveness analysis is not considered.

The strength of this recommendation is level A for the scientific evidence (good evidence to support the recommendation that the condition be specifically considered in a periodic examination), but references supporting these guidelines are not mentioned in the paper.

In 1994 a paper entitled Guidelines for Care in Physiological Pregnancy was published by Regalia and Terzian for the Review of the Centre of Studies for a Natural Birth (25). The paper is the result of a collaboration among several midwives and gynecologists who analyzed their practice and suggested a reduced diagnostic protocol for care in normal pregnancy.

The recommendation on ultrasonography in the third trimester of normal pregnancy is:

> The ultrasonography screening in the third trimester for detecting the intrauterine growth retardations is an unjustified procedure in the physiological pregnancy, because in this case the probability to find a growth retardation is very low.

The recommendations of the abovementioned paper are based on: Chalmers I, Enkin M, and Keirse M. *Effective care in pregnancy and childbirth*. Oxford: Oxford University Press; 1989. A paper entitled *Guidelines for monitoring physiological pregnancy* was edited by a

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working group of the local health unit of Treviglio (Lombardia region) (6); the compilation date is not indicated in this document.

The recommendations on ultrasonography in normal pregnancy is the following:

> In light of the present scientific evidences, routine ultrasonography seems an unjustified procedure in every period of the pregnancy. Nevertheless, as the discussion is still open and this examination is very widespread, two routine ultrasonographies at 8–12 and 20–22 weeks of gestation are suggested.

The level of scientific evidence is the first level: in the references of this document, examined by an expert committee, randomized controlled trials, meta-analysis, and noncontrolled clinical series are mentioned.

Accessibility of Procedures and Compliance Rate. Health care during pregnancy is offered free of charge by the NHS. Analysis of the birth certificates in the Toscana region in 1991–94 showed that 2% to 3% of pregnant mothers received no health care and that more than 50% of women during their pregnancy received four or more ultrasonographies.

Even though a formal screening program for detecting fetal growth retardation, based on the routine ultrasonography in the third trimester of the normal pregnancy, does not exist in Italy, this test is widely performed. In addition, a number of women turn to private care (9). This is probably due to the fact that normal pregnancy has mostly lost the characteristic of a physiological event: during pregnancy a lot of medical examinations are prescribed by physicians (defensive attitude) and required by women (anxiolytic attitude).

Recent Policy Reports and Papers on the Subject. In 1995 a first decree dealing with pregnancy was issued by the National Ministry of Health (19) with the list of examinations that can be offered free of charge by the NHS during pregnancy. The decree is not a real diagnostic protocol but a simple administrative deed regulating access to health care. The decree reports a list of free examinations that can be offered during pregnancy by the NHS: an ultrasonography between the 36th and 40th week is quoted with the generic indication "for monitoring pregnancy."

In the decree, scientific references supporting the examination list are not mentioned. A second decree was issued by the same ministry in 1998 with a new list of free examinations during pregnancy. An ultrasonography is offered between the 28th and 32nd week (21).

DISCUSSION

Mammography

The development of a national program for breast cancer in Italy is an example of the importance of HTA. In the last few years some local screening programs were performed in Italy without a definite national strategy. As a consequence, only 4.9% of women aged 50–70 years are covered. In 1995–98 two important scientific documents supported the new National Health Plan 1998–2000, which established a national strategy for breast cancer screening.

In spite of these formal statements, implementation of the screening programs across the country is very difficult because:

- Present mammographic services are planned for diagnostic activities and not for screening;
- A number of mammographies are prescribed without appropriate clinical indication;
- Women are not educated to have screening mammographies (biennial tests between 50 and 69 years of age);
- Physicians did not yet develop systematic counseling for women to have mammographic screening; and

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- For implementing breast cancer screening throughout the country, further financial resources will be necessary.

PSA Screening

Assessments performed in Italy on prostate cancer screening are coherent. There is no evidence that PSA dosage is effective in reducing prostate cancer mortality. The paper published by the National Research Council and the Italian Association for Cancer Research is very clear: "The prescription of the PSA in subjects without a suspicion of prostate cancer must be discouraged and not financed with public money." Nevertheless, this statement has not spread among clinicians and the public, and so many PSA tests are performed in the NHS with the generic aim of detecting early prostate cancer.

The National Health Plan 1998–2000 stressed the importance for the NHS to adopt only evidence-based interventions and particularly cost-effective screening. Guidelines of the National Oncological Committee indicated that further studies have to be planned for evaluating the effectiveness of single methods or their combinations for early diagnosis of prostate cancer. On the contrary, the paper published by the CNR and the AIRC states that "it is not opportune to carry out other studies on efficacy," because two international randomized studies on the effectiveness of prostate cancer screening are in progress and their size is adequate to assure good statistical power.

In short, we observe a paradox: policy and scientific papers are in agreement against prostate cancer screening, but in routine clinical practice, the PSA test is prescribed.

Routine Ultrasonography in Pregnancy

Routine ultrasonography in the third trimester of normal pregnancy is a test widely performed in Italy. Even though there are many international statements against it (as the assessment performed by the U.S. Preventive Services Task Force), the Ministry of Health included this procedure in the list of examinations that can be offered free of charge by the NHS during pregnancy. This is probably due to the fact that the few explicit assessments carried out in Italy are not unanimous. In particular, the proposal of guidelines for care in physiological pregnancy of the Umbria region urges an ultrasonography around the 32nd week. In the opinion of the regional experts, the strength of this recommendation is level A (good evidence to support the recommendation that the condition be specifically considered in a periodic examination). This statement clashes with the opinion of the U.S Preventive Task Force, which in 1996 did not recommend routine ultrasound examination in the third trimester of gestation (recommendation of level D: fair evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination).

The matter is under scrutiny because there is awareness that ultrasonography in the third trimester absorbs many resources of both the NHS and private care. If this procedure were considered inappropriate, a lot of resources could become free. It is impossible to estimate these resources, because the total number of ultrasonographies in pregnancy performed by the NHS is registered without a separation between procedures carried out in normal and at-risk pregnancies and without distinction of the trimester in which these tests are performed. Since ultrasonography in the third trimester is considered a routine procedure, it is necessary to involve women, public and private physicians, and the media for spreading a new evidence-based attitude.

At the moment the contradiction between the abovementioned decrees and the National Health Plan 1998–2000, which stresses the importance of evidence-based medicine in policy decisions, is very strong and can be considered an obstacle in changing attitudes. As far as the decrees mainly deal with administrative and financial aspects, we hope that in the near future a more coherent approach will be followed by the NHS.

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In several hospital trusts and local health units, a few multi-professional working groups have been developing local guidelines for normal pregnancy monitoring consistent with the current scientific evidence. Since many women turn to private care during their pregnancy, an involvement of private gynecologists in these working groups is probably required.

The new National Health Plan strengthens the need for guidelines for physiological pregnancy care, which will be adopted in the next months.

CONCLUSION

HTA is increasingly seen as an important bridge between science and health policy.

The examples of mammography and PSA screening show the coherence between results of HTA analysis and policy decisions at the macrolevel, but they also show the difficulty of having an impact at the microlevel (or clinical level). Both tests are reimbursed by the NHS and can be prescribed by GPs on an individual clinical basis. Mammography is completely free when included in a screening program and requires a partial fee for service payment in a clinical context. PSA is only prescribed in a clinical context with a partial fee for service payment. Both tests are probably overused with a high rate of inappropriateness.

The National Health Plan stresses the importance of mammographic screening for women aged 50–69, and several regional governments are specifically funding the initiative with the aim to increase the coverage, which is very low from a national perspective.

The example of ultrasonography in pregnancy is more difficult to understand. Several official statements and some administrative and financial regulations are not consistent with scientific findings and the National Health Plan. In the near future there is a need to change the healthcare package in this field.

Even though no specific agencies of HTA are officially set up in Italy, a great deal of HTA analysis has been carried out and is ongoing. The National Health Plan, the last reform of the NHS, and the regional legislations that are now under discussion will probably help to close the loop where assessment is linked to action at the macro-, meso-, and microlevels of the healthcare system.

HTA seems to be more and more an essential tool for planning and evaluating healthcare services, because it increases the role of scientific evidence in decision making, integrates different disciplines (i.e., medicine, epidemiology, economics, engineering, sociology, ethics, etc.), emphasizes the role of systematic reviews, and requires effective communication strategies for getting research into practice.

The abovementioned TRiPSS project had the role of demonstrating that it is possible to introduce principles, methods, and practice of HTA at the mesolevel and microlevel of the healthcare system. The ongoing national project, sponsored by the Ministry of Health and including 12 regions, will probably have a major impact on the diffusion of HTA at all levels of the Italian NHS.

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