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EVIDENCE-BASED SCREENING IN THE UNITED KINGDOM

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National Screening Committee Program

Abstract

Objective: To review the assessment of screening in the United Kingdom, focusing on three methods: mammography for breast cancer, screening for prostate cancer, and routine use of ultrasound in pregnancy.
Method: To review policy documents and published papers dealing with prevention and screening in the United Kingdom.
Results: Indicate that the United Kingdom has an active policy concerning the assessment of screening methods. Generally speaking, this assessment policy is part of the national program for health technology assessment (HTA). The government has given HTA an important place within health care in the United Kingdom, and prevention and screening is no exception to this general rule. The assessment of screening is now implemented through the National Screening Committee, established in 1997. The three issues reviewed in this paper have all been assessed within the context of the Department of Health. In the case of mammography, the assessment was done more than 10 years ago and was followed by a rational implementation of a national screening program for breast cancer. In the case of prostate cancer screening, two systematic reviews have concluded that screening should not be carried out. In general, this recommendation has been accepted in the United Kingdom. Use of ultrasound in pregnancy has been assessed by the National Screening Committee. This complex technology is difficult to assess, and the screening procedure is deeply embedded in clinical practice in the United Kingdom, so assessment has not had much impact on the frequency of screening.
Conclusion: HTA and the assessment of screening are well established in the United Kingdom. Policy is generally based on the assessments done, and practice generally follows the results of assessment. Assessment of screening is expected to become increasingly important in the United Kingdom during the next years.

Keywords: Preventive services, Health technology assessment, Mammography, PSA test, Ultrasound, United Kingdom

The British National Health Service (NHS) emphasizes prevention in its activities, and screening is an important part of prevention activities. Screening has important differences from clinical practice. In clinical health care, the patient seeks help from the health service for a problem that is causing distress or anxiety. The patient seeks help on the understanding that the clinician will do their best to help even where a cure cannot be guaranteed. When, on the other hand, the health service seeks out a healthy person and invites them to come for screening, the moral duty is different. Therefore, the United Kingdom Department of Health concluded that screening required more rigorous standards of evaluation and quality assurance than clinical practice.

The NHS set up a National Screening Committee with two functions: a) technology appraisal and policy making; and (b) quality assurance.

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THE HEALTHCARE SYSTEM

Over 90% of health care in the United Kingdom is provided by the NHS. The NHS is funded principally by taxation and offered free at the point of care.

The four countries of the United Kingdom each have their own health department, and management arrangements vary slightly from one country to another. In England, with a population of nearly 50 million people, there are eight regions of the Department of Health, and within each region there are health authorities and primary care groups responsible for needs assessment. In addition, there are a number of provider organizations, either hospitals or community health services, which deliver the service. Most clinicians are salaried, but in primary care the income of the general practitioner is made up of a combination of capitation payments and fees for individual services.

HEALTH TECHNOLOGY ASSESSMENT

The future of the House of Lords in the United Kingdom has been discussed for a century or more. The place of an unelected second chamber in a modern democracy is currently receiving close scrutiny and change is under way. It is, however, important to appreciate that the House of Lords has, in addition to serving the traditional function of a second chamber, also been a repository of wisdom and experience. It has initiated a number of significant developments as well as responding to, and seeking to adapt, legislation passed on to it from the House of Commons.

One significant contribution that it has made to health care in the last decade was the proposal that the United Kingdom needed a research and development (R&D) strategy in health care, analogous to the investment in R&D which everyone now accepts as being essential in industry but which the healthcare industry, in many countries, has neglected.

NHS-driven Research

In the absence of an R&D program driven by the health service itself, the agenda and priorities for research are determined either by researchers or by industry, notably the pharmaceutical industry, or by a combination of the two. This inevitably drives research in a certain direction because industry is only interested in funding, quite understandably, research that could lead to a patentable product. As a consequence, research into the effects of new tests or treatments that were not able to be patented (for example, psychological treatments) was relatively ignored, and there was very little interest in health services research into different patterns of service organization and delivery.

Service-driven Research—Necessary but not Sufficient

The recommendations, however, went considerably further than proposing that commissioned research be strengthened at the expense of responsive funding. The Committee of the House of Lords was also concerned about the gap between what we know and what we do and how that gap could be closed more effectively and efficiently than has been the case hitherto. Thus they saw the need to introduce a series of measures that would revolutionize health care as well as revolutionize healthcare research. The functions of the NHS R&D Program are:

- To find the questions that decision makers—patients, clinicians, managers, and policy makers—want answered;
- To ensure that the knowledge required is produced;
- To increase the capacity for R&D in the United Kingdom;

- To ensure that knowledge is easily available; and
- To promote an evaluative culture.

The R&D Program was not given the responsibility of implementing research findings, which some have criticized as a weakness, but it was not possible for the R&D Program to do this. Furthermore, the whole principle of the R&D Program was that the health service should be driven by research. Thus, the mission of the R&D Program was to change the culture of the health service and to change the skills of those who make decisions, whether as managers, clinicians, patients, or purchasers of health care, for this change took place at a time when the United Kingdom introduced the purchaser/provider split into health care, so that these decision makers would be hungrily seeking best current knowledge as a basis for decision making.

Evidence-based Medicine, Evidence-based Health Care, and Evidence-based Screening

Central to the ideas that underpinned the R&D Program was the concept of getting research findings into practice, but this assumed that the only problem was the slowness of diffusion. Evidence-based medicine is a term that was coined in the United States, and articles on evidence-based medicine appeared in the *Journal of the American Medical Association* in the late 1980s. In the United Kingdom a Center for Evidence-Based Medicine was set up in Oxford, funded by the R&D Program.

Evidence-based medicine has been defined as:

> ...the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgement that individual clinicians acquire through clinical experience and clinical practice. (8)

This definition emphasized that evidence-based decision making is, as stated, evidence based, but has to take into account the condition of the individual patient and his or her values.

In the United Kingdom the concept was adapted for collective decision making about groups of patients or populations and called "evidence-based health care" (4). In evidence-based health care, decisions about groups and populations are based on best current knowledge but have to take into account the particular needs of the population, the values of the population, and the resources available, as shown in the Venn diagram in Figure 1.

One of the first areas of health care in which these principles were of evidence-based decision making applied was screening because:

- There was concern about the unplanned drift of new tests into screening practice;
- The population that might benefit from, or be harmed by, a screening program is easy to identify;
- The evidence base on which decisions could be made was strong with both randomized trials and systematic reviews of screening;
- A high value was placed on protecting the public from the harmful effects of screening; and
- Small changes in screening policy could have large resource consequences in a time in which resources were constrained and value for money had to be maximized.

The focus for this work was the new National Screening Committee.

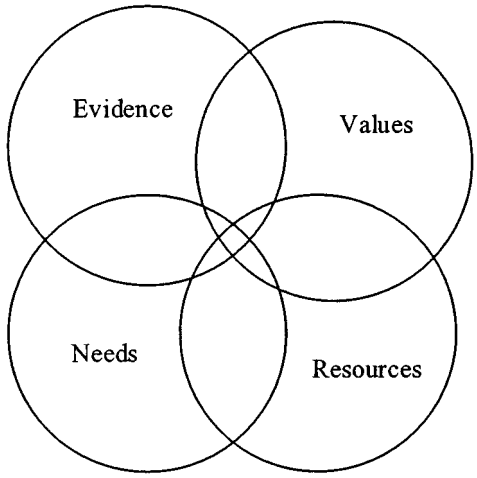

Figure 1. Factors influencing evidence-based healthcare decisions.

POLICIES TOWARD PREVENTION AND TREATMENT

There is a strong commitment to making prevention and screening available uniformly across the whole country as part of a public health service. Screening has been assessed by many investigators and policy-oriented bodies in the past, and many of these assessments have been excellent (1;3;5;7). However, the decisions about screening had generally been made on a piecemeal basis, and it was therefore decided to set up the National Screening Committee.

The National Screening Committee was set up on the basis of a lecture given by the Chief Medical Officer, Sir Kenneth Calman, at the launch of the *Journal of Medical Screening* early in 1994. The remit and terms of reference of the National Screening Committee are outlined below.

The UK National Screening Committee (NSC) will advise ministers and their appropriate NHS Executive boards with responsibility for the NHS in England, Scotland, Wales, and Northern Ireland on:

- The case for implementing new population screening programs not presently purchased by the NHS within each of the countries in the United Kingdom;
- Screening technologies of proven effectiveness but which require controlled and well- managed introduction; and
- The case for continuing, modifying, or withdrawing existing population screening programs, in particular, programs inadequately evaluated or of doubtful effectiveness, quality or value;

The NSC will call on sound evidence to inform its advice and recommendations, in particular:

- Calling on the advice of the Standing Group on Health Technology's Population Screening Panel and in turn inform the setting of NHS R&D priorities;
- Calling on the DH Policy Research Program and defining research needs for screening; and
- Calling on other and appropriate sources of sound evidence from within and outside the NHS.

The NSC will set up practical mechanisms to oversee the introduction of a new program and its implementation in the NHS. It will also monitor effectiveness and quality assurance. The NSC will be informed by reports from the advisory groups for specific programs on the

performance of those programs and issues that arise which would have relevance to general screening policy.

The National Screening Committee has two main tasks: policy making and quality management.

Policy Making

Technology assessment is now a major activity in health care, as is quality management, but one important gap exists between technology assessment and quality management: the process of policy making. In policy making evidence is taken, the values, needs, and resources available are taken into account, and policy decisions are made.

The NSC started by using the famous Wilson and Jungner criteria, which have stood the test of time very well, but were of the opinion that these criteria were not suitable for the late 1990s for three reasons: a) they paid insufficient attention to the adverse effects of screening; b) the opportunity cost of screening was not sufficiently emphasized; and c) the statement that there should be an acceptable treatment was not regarded as being sufficiently robust for an era in which there was increasing sophistication in analyzing the strength of evidence and not merely the presence of absence of evidence about the "acceptability" of a treatment.

Thus the NSC developed its own set of criteria (6) (Table 1).

In policy making the NSC wished to deal with both the technology bypass and the knowledge bypass, identifying all new technology and all new knowledge and ensuring that neither new technology drift into practice nor that new knowledge bypassed the service (Figure 2).

In setting objectives for policy making, three different types of outcomes were identified: a) stopping things starting; b) starting things stopping; and c) starting things starting right. These will be discussed in more detail with examples in the case studies.

Quality Management

One of the first tasks undertaken by the NSC was the development of an inventory of screening programs, identifying all the programs that people wished to introduce as well as those currently being offered. The results of this inventory demonstrated that of the many programs being delivered to the public, only four were both evidence based and had a good quality management system. These four were the breast and cervical cancer screening programs, and the screening programs for PKU and hyperthyroidism, based on the neonatal blood spot.

In addition to policy making, which was intended to control the number of screening programs, the NSC also had the major task of developing quality management systems for all the other screening programs being offered to the public. The jargon of quality assurance

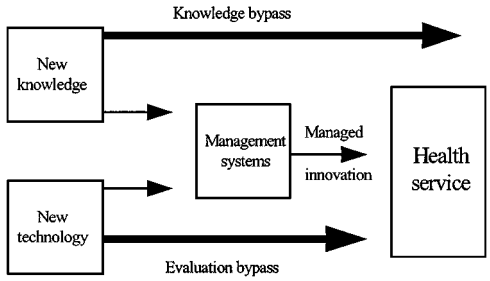

Figure 2. Technology and knowledge bypass.

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Table 1. Criteria Developed by the National Screening Committee

The condition

1. The condition should be an important health problem.
2. The epidemiology and natural history of the condition, including development from latent to declared disease, should be adequately understood, and there should be a detectable risk factor, disease marker, latent period, or early symptomatic stage.
3. All the cost-effective primary prevention interventions should have been implemented as far as practicable. *The test*
4. There should be a simple, safe, precise, and validated screening test.
5. The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed.
6. The test should be acceptable to the population.
7. There should be an agreed policy on the further diagnostic investigation of individuals with a positive test result and on the choices available to those individuals.

The treatment

8. There should be an effective treatment or intervention for patients identified through early detection, with evidence of early treatment leading to better outcomes than late treatment.
9. There should be agreed evidence-based policies covering which individuals should be offered treatment and the appropriate treatment to be offered.
10. Clinical management of the condition and patient outcomes should be optimized by all healthcare providers prior to participation in a screening program.

The screening program

11. There should be evidence from high-quality randomized controlled trials that the screening program is effective in reducing mortality or morbidity.
12. There should be evidence that the complete screening program (test, diagnostic procedures, treatment/intervention) is clinically, socially, and ethically acceptable to health professionals and the public.
13. The benefit from the screening program should outweigh the physical and psychological harm (caused by the test, diagnostic procedures, and treatment).
14. The opportunity cost of the screening program (including testing, diagnosis, and treatment) should be economically balanced in relation to expenditure on medical care as a whole.
15. There should be a plan for managing and monitoring the screening program and an agreed set of quality assurance standards.
16. Adequate staffing and facilities for testing, diagnosis, treatment, and program management should be available prior to the commencement of the screening program.
17. All other options for managing the condition should have been considered (e.g., improving treatment, providing other services).

is complicated and confusing, but four types of activities were identified by the NSC as being relevant:

- Preventing major errors;
- Dealing with errors, and the possible loss of confidence in the screening program when they occurred;
- Promoting continual improvement in performance; and
- Setting and resetting standards regularly.

The prevention and identification of errors may be said to be analogous to the old industrial process of quality control, but the two new elements in quality assurance are to expect continual improvements in performance by all involved in screening, compared with explicit standards. Furthermore—and this is a lesson learned from the Japanese industry, which in turn had learned it from Edwards Deming—standards have to be continually reset to set new and challenging goals for those involved in screening, so just as individuals thought that performance was improving and getting above standard, they or their professional associations reset the standard to give them new and challenging targets for performance improvement.

RESEARCH INFORMATION AND MASS SCREENING

Most of the research on mass screening is carried out by the Health Technology Assessment Program, which is part of the national R&D Program, and information about the program is found on its Web site, www.hta.nhsweb.nhs.uk/.

However, the Medical Research Council is also active in screening research. For example, it funded the randomized controlled trial of screening for colorectal cancer and is currently funding, among other studies, a major randomized controlled trial of aortic aneurysm screening.

CASE STUDIES

Breast Cancer Screening

The results of randomized controlled trials of breast cancer screening in Sweden led the U.K. government to set up a committee to review the evidence and make recommendations about screening. The committee's report, called the Forrest Report after its chairman, Sir Patrick Forrest, recommended screening at 3-year intervals for women aged between 50 and 65.

It was understood that it would be necessary to reproduce standards of screening close to, if not identical with, the standards achieved in the research setting if more good than harm were to be done by the program, and it was therefore decided to manage the introduction of screening with strong national leadership. Resources were invested in the following national systems for breast cancer screening:

- Education and training delivered through for national training centers;
- A single information system for the Breast Screening Program;
- External quality assurance, particularly for mammography and pathology;
- Strong professional networks to ensure that each profession worked in a standard way throughout the United Kingdom;
- Clear responsibility for program management;
- Limitation of the number of assessment centers to ensure that each had sufficient throughput to ensure adequate levels of quality; and
- A major public education and information program.

Furthermore, the money for screening was kept separate from the general healthcare budget until the screening programs were deemed to be sufficiently well established for responsibility for commissioning and monitoring the quality of screening to be allocated to the 100 health authorities that commission healthcare in the United Kingdom.

The program has now been running 10 years and is achieving performance levels close enough to those in the Two Counties Trial to allow it to be concluded that the Breast Screening Program is contributing to mortality reduction. However, the precise size of the contribution is impossible to calculate, because of other innovations that have taken place in the last 10 years (e.g., the introduction of tamoxifen), and because breast cancer screening quality assurance and training systems have contributed not only to the quality of the screening program but also to the quality of the treatment services offered to women with cancer.

Prostate Cancer Screening

The Standing Group on Health Technology Assessment of the R&D Program commissioned two systematic reviews on the management of prostatic cancer that included screening (2;9). These reviews produced consistent results, and the National Screening Committee

considered the conclusions of these systematic reviews and recommended to the Secretary of State that population screening for prostate cancer should not be introduced (6). In an unusual move, but this may be the shape of things to come, the Secretary of State authorized the issue of an executive letter on population screening for prostate cancer.

The reaction to this decision was mixed. One particular journalist stated that the decision had been made by "faceless men in gray suits" primarily for financial reasons, but in general the press accepted the arguments about the need to balance benefit and harm, and the decision was seen to be based on evidence without the issue of resources playing a part in the decision. This decision has been strongly challenged on a number of occasions, but it is still U.K. policy.

However, the NSC recognized that there was a need to keep all its decisions under review and that with decisions in which the evidence was changing quickly, it might prove necessary to revisit decisions on an annual basis; this has proved to be the case with prostatic cancer screening. New evidence has emerged about both the treatment of localized cancer and the use of the PSA test in a way that will increase specificity. On this basis the evidence and guidance were reviewed.

On the review of new evidence, the policy still states that prostatic cancer screening should not be introduced, but a recommendation was made that there should be a randomized controlled trial of prostatic cancer screening illustrating how the active promotion of research can be a policy decision.

Ultrasound Screening in Pregnancy

Ultrasound screening in pregnancy was one of the programs that the NSC inherited. Since there was widespread use of ultrasound in pregnancy, the NSC was asked to make policy recommendations.

One of the first lessons to emerge from an analysis of ultrasound screening in pregnancy is that the analysis of a screening technology aimed at identifying more than one disease is very difficult. The same problem has occurred in the appraisal of tandem mass spectrometry, health visiting, and school nursing. The NSC has come to the conclusion that questions such as "Is ultrasound screening in pregnancy effective?" or "Is school nursing effective?" are unhelpful questions. What is required is to ask what diseases are intended to be prevented through screening with this modality, and then to examine the case for or against screening for each particular disease using the criteria in Table 1. Having decided that four or five diseases can be screened using the particular modality, the question is whether all of these can be carried out in a single intervention. In the United Kingdom this is still the subject of research, and ultrasound screening in pregnancy is classified as a screening service that is yet to be fully evaluated but which should continue.

Of particular interest in ultrasound screening in pregnancy is the ethical issue, which raises another issue that the National Screening Committee perceives as being of increasing importance, namely the issue of informed choice. The question is whether individuals should have to opt in to a screening program for more than one disease or whether it should be assumed that a woman going to an antenatal screening clinic is agreeing that she wishes to have a number of screening tests by virtue of the fact that she is attending, and then requiring the woman to opt out of screening for some particular condition. This issue is unresolved but is seen as an issue of central importance for screening in the 21st century.

It might be that the evidence would suggest that we should start stopping ultrasound screening in pregnancy, but we have to recognize the limits of management. When a practice is so deeply ingrained as the ultrasound examination in pregnancy, it may prove to be impossible to stop it. The pregnant woman may value the ultrasound image of her fetus so

highly that all scientific arguments about effectiveness, cost-effectiveness, and the balance between benefit and harm may be regarded as irrelevant in comparison with the value of seeing an image of the fetus.

DISCUSSION

The NSC has had an influence on both policy making and quality management, but it has found difficulties in stopping long-established screening programs (e.g., in child health screening) and in controlling the drift of screening programs where the cost of the initial test is low (e.g., PSA testing) (6).

For the future, the NSC will focus on the development of the concept of informed choice and will be promoting screening as a means of risk reduction because of the continuing problems that the media have in accepting that every screening program must have a sensitivity and specificity less than 100%.

CONCLUSIONS

The NSC plays a useful function within the Public Health Service. In a world in which there is increasing concern about the adverse effects and costs of health care, it would seem to be unthinkable to reduce the authority of a national body able to stop the drift of technology into practice. There have been problems in the past with the implementation of national screening programs and considerable confusion between policy makers, managers, clinicians, and lay people. Supported by the NSC, good work is being done to develop the National Screening Program. All those involved are sure that the best way to deal with problems associated with screening is to prevent them by starting the right programs systematically, based on careful scientific assessment.

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