Department of Health, Social Services & Public Safety, Northern Ireland

Cynulliad Cenedlaethol Cymru
The National Assembly for Wales

THE SCOTTISH EXECUTIVE

DH Department of Health

Second Report of the UK National Screening Committee

CHAIRMAN'S FOREWORD

The UK National Screening Committee (NSC) was established in 1996 under the distinguished chairmanship of Sir Kenneth Calman. Strong foundations were built and the profile of the Committee was raised. I felt very privileged to take over the chairmanship of this Committee from Sir Kenneth Calman in December 1998. Since that time we have made progress in consolidating its work and looking at programmes on a systematic basis.

We now have systems in place for ensuring that the gap is bridged between the R&D programme and policy-making. The Committee has provided clear advice to Ministers on issues such as chlamydia screening, colorectal cancer screening and prostate cancer screening. All screening programmes will be based on the best evidence and have in-built quality and information systems, with benchmarks, to monitor standards.

In the past eighteen months we have concentrated on the Antenatal and Child Health programmes as well as making progress on men and women's health. We will be turning next to health in old age, so that in a few years' time there will be clear and evidence-based information on all individual programmes presented with respect to the major population groups. We are recommending that these are: antenatal, child, men, women, and older people.

In this Second Report of the UK National Screening Committee there is an important theme - the need to be absolutely clear and explicit about the risks and limitations of screening. There is a responsibility to ensure that people who accept an invitation do so on the basis of informed choice, and appreciate that in accepting an invitation or participating in a programme to reduce their risk of a disease there is a risk of an adverse outcome.

I am pleased that we have developed a web-site to communicate our progress in these areas. This can be viewed at http://www.nsc.nhs.uk/. I am sure this will be a helpful resource to all those in the UK Public Health field.

Our Committee has representatives from all four UK countries and we have recently had to face the potential challenges brought about by devolution. My view is that devolution offers a UK committee particular opportunities. It is inevitable that Ministers in one country might take a different approach to a particular recommendation or might want to proceed at a different speed. However, this can only enrich our approach to screening and make it all the more important that we provide high quality advice backed by the best evidence.

Dr Henrietta Campbell, CMO NI
Chair of the UK National Screening Committee

SCREENING IN THE FOUR UK COUNTRIES

This section explains the structural context within which the UK National Screening Committee operates and the different arrangements in the four countries.

Screening is a devolved matter. When the NSC offers advice it is then for officials in the four UK countries to advise government on next steps.

The NSC is well aware of the needs to fulfil the Prime Minister's key challenges of partnership, performance, professions, patient care, and prevention and has been working to standards, which embrace these key topics for the last two years.

This will need to be done in the context of clinical governance. Quality is at the core of screening programmes wherever they are delivered. It is vital quality does not take place in isolation.

England & Wales

Screening programmes will be included in the Commission for Health Improvement's (CHI) independent scrutiny of local efforts to improve quality in England and Wales.

As part of its emphasis on quality the NSC will be making closer links with the National Institute for Clinical Excellence (NICE) in England and Wales. These links could occur at two stages: firstly the agenda setting stage in response to horizon scanning, clinical innovation, outputs of the Health Technology Assessment (HTA) programme and related research, proactive consultation and any unsolicited approaches. Secondly, there might also be links to develop suites of tools for clinical and cost effectiveness to support the implementation of national priorities so there is an integrated approach to screening and diagnostic services.

Scotland

The Clinical Standards Board for Scotland (CSBS) will play a role similar to the CHI in England and Wales. The NICE functions of technology assessment and guideline development will be carried out in Scotland by the Scottish Health Technology Assessment Centre (SHTAC) and the Scottish Intercollegiate Guideline Network (SIGN). The CSBS will not have the same clinical governance role as CHI, nor will it have a specific role in clinical competence. It will instead be responsible for ensuring appropriate quality standards are set for each area of service delivery and will monitor services against the set standards.

Northern Ireland

In Northern Ireland work is continuing on developing proposals for a quality framework for the Health and Personal Social Services (HPSS). Subject to Ministerial approval this framework will include arrangements to:

- develop and disseminate clear service standards and guidance for the HPSS;
- support the delivery of services at local level by ensuring there are appropriate mechanisms in place to secure accountability for the quality of services delivered; and
- monitor more effectively the delivery of services.

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CHAPTER 1: SCREENING POLICY-MAKING: GETTING RESEARCH INTO PRACTICE

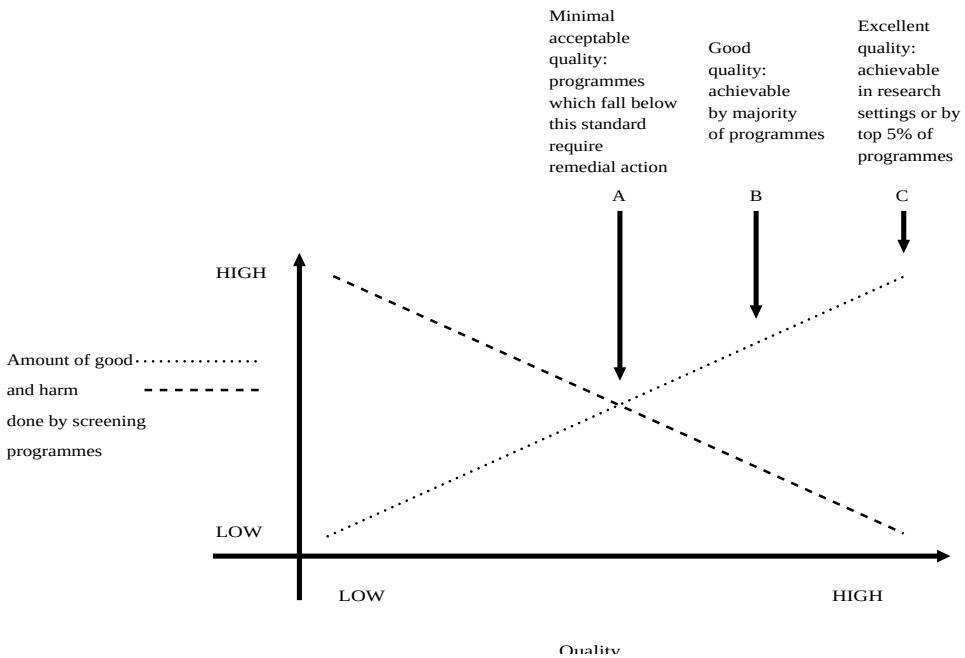
"One of the main functions of the NSC is to advise Government on whether or not a screening programme should be started, continued or stopped."

1. One of the main functions of the UK National Screening Committee (NSC) is to advise Government on whether or not a screening programme should be started, continued or stopped. The basis for the advice is evidence derived from research, usually randomised controlled trials or, preferably, systematic reviews of controlled trials. It is insufficient, however, for the NSC to base its advice simply on the fact that research has demonstrated that a particular screening programme does more good than harm at reasonable cost. The NSC also has to reach a decision about the feasibility of achieving a standard of professional performance which will be, if not as good as that achieved in the research setting, at least sufficient to ensure that the screening programme will do more good than harm when rolled out nationally.

2. Most research on new screening programmes is highly atypical. The research is often led by a highly committed individual, leading a specially chosen team who work with great commitment to a tight protocol with constant checks on service quality. When, for example, the Forrest Committee, the committee chaired by Sir Patrick Forrest, considered the evidence from the Swedish Two Counties Breast Cancer Screening Trial, they had to take into account the fact that the screening in that trial was done by some of the world's leading experts in mammography and that those experts were able to offer a service to about one per cent of the population that would have to be covered were screening to be rolled out in the UK.

3. The results achieved in the Two Counties Trial were in part due to the inherent nature of mammography and the follow-up tests, but they were also determined by the skill of the individual clinicians and the commitment and organisation of the team running the screening programme in the trial. Figure 1 shows that the excellent quality achieved in research, level C, resulted in the population receiving more good than harm.

Figure 1



"The decision to recommend a screening policy is determind not only by the interpretation of research findings but also the judgement that it would be possible to reproduce those findings in everyday practice across the whole country."

4. Those planning the new service worked on the assumption that it would not be possible, at least immediately, to reproduce this quality of service across the whole of the UK, but they were able to define a level of quality which they believed that the majority of screening programmes would be able to achieve, with the right training and support, level B in Figure 1. They were also able to identify a level of quality below which there was a possibility of doing more harm than good or, at best, doing little more good than harm with the screening programme. The advice given to Government was that it would be possible to achieve a level of quality sufficiently good to do more good than harm at reasonable cost, even though

it would not immediately be the same excellent standard as had been achieved in the research setting. Thus the decision to recommend a screening policy is determined not only by the interpretation of research findings but also by the judgement that it would be possible to reproduce those findings in everyday practice across the whole country.

5. For this reason, recommendations to introduce new policy are always accompanied by the recommendation to ensure that the service is managed in such a way that quality can be assured.

Assuring quality in screening programmes

6. The second main function of the NSC is to ensure that the screening programmes being offered to the public have adequate mechanisms to monitor, maintain and improve quality.

7. In part this requires the development of systems which can identify programmes, or individual screeners, who fall below the minimal acceptable standard. However, identifying only the small proportion of programmes which have serious quality problems is by itself an inadequate and insufficient quality assurance system.

8. Experience from industry, particularly the Japanese car industry, has demonstrated that it is necessary to:

- help all screening programmes and screeners continuously improve their performance against explicit quality standards, and
- regularly re-set those standards so that programmes and screeners are continually set new targets for improving their performance.

The benefits of total quality management

9. This approach, called by diverse names such as "total quality management" and "continuous quality improvement", is essential to ensure that the healthy populations offered screening are offered services of a standard more likely to do good than harm. However, this approach has also had adverse effects both for the public and for the professionals involved in screening.

Errors occur in health care

10. Errors occur in medicine. A recent study in two hospitals, which will be regarded by most clinicians as offering the highest quality of care, identified serious or potentially serious medication errors in 6.7 per cent of patients (1). Another study which reviewed 30,000 hospital records in New York State found that adverse events occurred in 3.7 per cent of hospital admissions; one half of these were preventable and 13.6 per cent of them led to death, that is, about one in 400 hospital admissions resulted in death due to an adverse event (2).

11. Adverse events in conventional clinical care come to the attention of patients and the press in a sporadic haphazard fashion. In one hospital an error is experienced by a patient in the orthopaedic service; for the next patient the problem is in general surgery. There has been, until very recently, no systematic approach to the identification of medical errors and adverse events in clinical care, although this is changing with the development of the concept of clinical governance.

12. In contrast, a different approach has been adopted in screening.

- Errors and quality problems are systematically sought across the whole service.
- Errors and problems are identified in every service.
- Quality problems are public knowledge.

"The way the quality assurance system has developed ensures not only that quality is continuousely improved but also that short-comings are identified."

13. Furthermore, the way the quality assurance system has developed ensures not only that quality is continuously improved but also that short-comings are identified.

14. If there were no programmes below the minimal acceptable standard it would not be a cause for congratulation; it would simply indicate that standards had been allowed to slip too low, for standards need to be regularly re-set at higher and higher levels. If all programmes were above minimal acceptable standards year after year this would inevitably lead to complacency.

15. Thus in screening there always should be short-comings identified.

16. Unfortunately because members of the public are not clear about the aims and objectives of quality assurance and do not know that errors occur in all aspects of health care, screening programmes are criticised for their poor quality and for the errors that are identified.

Clinical care is catching up with screening

17. As systems of clinical governance develop, many other quality problems are likely to be revealed and screening will not be the only service systematically measuring quality and identifying problems. Thus screening will not be criticised, as those involved in screening often see it, unfairly for identifying quality problems.

18. However, it would be unwise for those involved in screening to wait for the rest of clinical care to catch up. Steps need to be taken to restore public confidence in screening, and to support professionals who often feel unfairly criticised as a result of participating in quality assurance.

"Screening is a programme to reduce the risk of diseases and not a guarantee of diagnosis and cure."

19. Obviously it is important to try to inform better the public and journalists about the nature of screening and quality assurance, but a programme for public and media information is difficult to organise and can be ineffective. What is needed are interventions that will be immediately obvious to the individuals offered screening and will make the nature of screening, with all its strengths and weaknesses, more immediately apparent to the person being screened, and thus to journalists. The NSC has been considering two measures by which the nature of screening, and therefore the implications of quality problems that are identified, are made apparent to everyone involved in screening, both clinicians and members of the public. These two measures are:

- ensuring that screening is offered and that the individual to whom it is offered is helped to make an informed choice, and
- ensuring that screening is seen for what it is, a programme to reduce the risk of diseases and not a guarantee of diagnosis and cure.

Promoting informed choice

20. The definition of screening used in the NSC's first report (3) is set out below.

> *The systematic application of a test or inquiry, to identify individuals at sufficient risk of a specific disorder to warrant further investigation or direct preventive action, amongst persons who have not sought medical attention on account of symptoms of that disorder.*

21. A new definition is proposed to take into account the importance of informed choice and risk reduction and this is set out below.

> *a public health service in which members of a defined population, who do not necessarily perceive they are at risk of, or are already affected by, a disease or its complications, are asked a question or offered a test to identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of disease or its complications.*

"Screening developed as a public health service to improve the health of populations. "

22. Screening developed as a public health service designed to improve the health of populations. Many individuals benefited while some other individuals suffered adverse effects, but in population terms there was a net health gain. Thus the main focus on screening was to deliver a service to populations and to seek to "cover" as high a percentage of the population as possible with the screening service. Thus the main focus of those providing screening was to emphasise the benefits of screening and to achieve high levels of coverage because the adverse effects were deemed to be insignificant in comparison with the benefits.

"Screening programmes should offer choice to individuals."

"Each individual should appreciate the risks and benefits of the screening programme for them as an individual."

23. As more is known about the psychological consequences resulting from both false positive and false negative tests, and as social attitudes change, this approach is no longer acceptable. The NSC, while holding to the principle that screening benefits populations and is an important public health service, has adopted the principle that screening programmes should offer choice to individuals and that each individual should appreciate the risks and benefits of the screening programme for them as an individual. This approach would not only have important social benefits because it would remove from individuals the feeling that they were being coerced into participation and remove from clinicians the feeling that they were coercing; it would also offer opportunities for increasing value for money, for it would allow general policies for whole populations to be tailored to sub-populations or to individuals based upon the profile of risk for that particular sub-group or, if it is possible to calculate, for the particular individual.

24. Nowhere is this more important than in antenatal screening, and the Antenatal Screening Sub-Group of the NSC has already considered this issue.

Emphasising that screening is risk reduction

25. The identification of individuals or groups who are believed to have had their disease "missed" by screening generates anxiety and anger in the individual, hostile criticism in the press, and loss of morale in screeners or programmes where these quality problems have been identified.

26. Without wishing to evade accountability or to deny the fact that negligence can occur in screening as in any other branch of clinical practice, the nature of screening is that it is a form of risk reduction.

27. All that screening offers is the opportunity to reduce the risk of contracting a disease or suffering its complications.

28. This is made clear in the definition of screening and attempts have been made in the past few years to convey the message to both the public and the press about the nature of screening, emphasising its possible adverse effects and its limitations as well as its benefits. However, it may well be that the term "screening" has too many connotations for such a change in perception to be easily effected. An alternative approach would be to start emphasising, in the titles of screening programmes and in all correspondence and information about screening, that screening is a risk reduction programme; for example:

- the breast screening programme reduces the risk of dying from breast cancer;
- the cervical screening programme reduces the risk of cervical cancer;
- the diabetic retinopathy programme reduces the risk of visual impairment.

"Emphasising risk reduction could reduce psychological impact of issues that individuals sometimes find hard to accept."

29. Emphasising risk reduction could reduce the psychological impact of issues that individuals sometimes find hard to accept, for example:

- the fact that an individual with a negative test may eventually develop the disease or its complications, even when the test has been carried out perfectly, or
- the fact that someone with a positive test will not necessarily be cured as a result of being identified through screening.

30. Thus rather than simply talking about retinopathy screening, those involved in reviewing the evidence and making recommendations about the prevention of diabetic eye disease have chosen to call the programme "preservation of sight in diabetes: a risk reduction programme". Similarly, screening for high blood pressure could be called a "stroke risk reduction programme", and screening for breast cancer and the Breast Screening Programme would "reduce the risk of dying from breast cancer".

CHAPTER 2: ORGANISING SCREENING PROGRAMMES

1. In the United Kingdom we have much to be proud of in the way we organise health care. For example, the strong emphasis on primary care since the inception of the NHS, in particular since the sixties, has provided us with a very firm foundation for a National Health Service. Similarly, the early concepts of primary prevention, secondary prevention, and tertiary prevention of disease have also been useful. Primary prevention stops disease starting; tertiary prevention was the name formerly given to what we would call "treatment and care services", and secondary prevention was usually equated with screening, namely the detection of a disease or its precursors at an early stage.

2. The development of the NSC has formalised the approach to screening by developing common standards and techniques for policy-making and quality management.

The benefits of vertical programming

3. Although we have much to be proud of in our approach to service planning and development, it is important also to appreciate that other approaches have been effective. One of the reasons for emphasising primary care, when the World Health Organisation produced the Declaration of Alma Ata, was because it was aware that unconnected vertical programmes, as they were called – for example the schistosomiasis control programme or the malaria control programme – were not cost-effective unless they were integrated. However, just as those countries that had favoured vertical disease control programmes were moving towards a horizontal organisation of health care into primary, secondary and tertiary care, so it was appreciated in the United Kingdom that there were benefits from this approach, sometimes called "vertical programming". One of the reasons for this was that studies of service delivery in clinical practice showed much wider variation in practice than could be explained by variations in the incidence or prevalence of disease. Thus it was appreciated that it was only by taking specific health issues and tackling them in their entirety that variations in practice could be reduced and research put into practice much more quickly and systematically. In England and Wales, an important manifestation of this approach has been the development of the National Service Frameworks covering topics such as cancer, coronary heart disease and diabetes.

"The screening programme for a particular disease should fit into other methods of disease control, notably primary prevention and treatment."

4. It has always been the policy of the NSC that although the Committee should make recommendations about screening based on principles and standards common to all screening programmes, screening should not be envisaged as a homogeneous entity but the screening programme for a particular disease should fit in to other methods of disease control, notably primary prevention and treatment. Thus in making a plan to pilot screening for colorectal cancer, the NSC also recommended to Government that primary prevention of colorectal cancer through dietary change should also be promoted in linked projects.

5. Thus the work of the NSC fits in to and is part of the work being done by UK Health Departments to develop comprehensive control programmes for health problems.

Tackling specific diseases

6. The main focus of the NSC has been on screening programmes designed to control specific diseases or health problems such as prostate cancer or neonatal deafness. However, by focusing on this type of specific issue, necessary though this approach is, the fact that an individual may have more than one health problem, or that health problems are inter-related, can easily be overlooked. Furthermore, the objective of screening is to help people. Individuals may have risk factors for more than one disease and who do not wish to be treated as a test tube containing a number of disparate and unrelated conditions.

7. For this reason we are planning to integrate all the work of the NSC into five population screening programmes.

The five population screening programmes

8. All of the work being done by the NSC will be integrated into five main programmes based on different stages of the life cycle. These are antenatal, child, men, women and the older person.

9. These programmes will fit into the major health programmes for these populations of the four Health Departments and will not stand in isolation.

10. Because screening programmes involve so many people, the individuals and teams involved in screening need clear information, regularly updated, about the programme and their part within it.

"The UK National Screening Committee's approach is to look increasingly to the Web as a means of providing knowledge and know-how, to clinicians,managers and the public. "

11. Hitherto this has been sent out by paper but as other treatment programmes follow the approach taken by screening, the amount of paper is increasing exponentially, as one important study of guidelines demonstrated (1). In this study the researchers found that every general practitioner had been sent 22.8 kg. of guidelines, 855 guidelines of every shape and hue, spiral bound, ring-bound, paper clipped and printed. It is completely impossible for screening programmes to seek to become more systematic and standardised by adding to this paper mountain and the NSC's approach is to look increasingly to the Web, not only as a means of publicising information on a Web site but as a digital nervous system, a means of providing knowledge and know-how, to clinicians, managers and the public. Using electronic networking, our aim is to manage screening consistently across the four countries of the United Kingdom, immediately able to alert everyone involved when the programme has to be adapted or changed.

12. In England and Wales, the development of the National Electronic Library for Screening, not only as a repository of knowledge and know-how but as a means of managing programmes, will be facilitated by the NHS Information Authority as part of its new strategy Information for Health (2). In future it is hoped that everyone will have their own electronic health record, starting at birth, and this record, in whatever form it takes, will incorporate that individual's screening record and allow the individual to be reminded of invitations for screening when they are due. Development of such technology will be of central importance to the development of screening programmes in the 21st century.

CHAPTER 3: THE NSC'S FORWARD PROGRAMME

1. The Second Report of the NSC highlights the progress that has been made; it is appropriate at this time to complement the report of past progress with a forward look.

2. The work of the NSC is part of a strategic plan. However, there is also flexibility to be responsive to emergent issues. Some of the work can be planned by looking at the work of the HTA Programme (http://www.hta.nhsweb.nhs.uk/). The production of reports commissioned by the Diagnostic Technologies and Screening Panel (formerly the Population Screening Panel) of the R&D Programme provides the single most important and quantitatively largest influence on the work of the NSC. It sits at the end of the R&D conveyor belt picking up the research reports and appraising them to consider their implications and relevance for policy-making and practice.

3. Two major research priorities have been discussed by the NSC – screening for prostate cancer and screening for ovarian cancer – but even if these studies were to be commissioned the results would not appear within the next three years. Time would also be needed to consider the merits of introducing programmes in these areas and, if agreed, a necessary lead in time (possibly years) would be needed to roll out a programme.

Policy-making

4. Most of the major policy-advice decisions in screening came to the NSC before summer 2000. This advice contributed to the development of the NHS Plan in England (for the next three years), Priority will be given to implementation for the next three years.

5. In adult life it is envisaged that there will be continuing issues about screening for cervical cancer but these will be technical issues focusing on the screening tests employed and may not require the NSC to become involved.

6. The publication of the National Service Framework for Coronary Heart Disease for England and Wales (http://www.doh.gov.uk/nsf/coronary.htm) emphasises that the priority in the control of coronary heart disease should be given to people at high risk. It does, however, leave the issue of people who are not at high risk unresolved. One of the things that the NSC will need to do is to develop a policy for people who are not at high risk of coronary heart disease related to the work that is proposed to develop a policy for screening for Type 2 diabetes and screening for diabetic retinopathy.

Quality management

7. Evaluation of the pilots in colorectal cancer and chlamydia screening, designed to assess the feasibility of achieving adequate levels of quality in practice settings, as opposed to research settings, will have to be considered by the NSC during the forthcoming three year period.

8. In addition, there will be a major amount of work concerned with the implementation of the Antenatal and Child Health Screening Programmes.

9. This work will be based on the Quality Management for Screening Report, prepared for, and approved by, the NSC but it will also have to relate to the Commission for Health Improvement and the National Institute for Clinical Excellence in England and Wales and to analogous bodies in Scotland and Northern Ireland. The Quality Management for Screening Report can be found on the website of the Nuffield Institute for Health at http://www.leeds.ac.uk/nuffield/pubs/index.htm

Presentation and communication

10. Once the proposals for Antenatal and Child Health Screening Programmes are agreed, it will be necessary to develop a communication strategy and to set in train a number of steps to implement programmes that are not implemented at present or improve the quality of programmes in which there is wide variation in policy, practice and quality.

11. In the coming years, screening programmes for men's health, women's health and health in old age will also be completed so that there will be clear and evidence-based information on all individual programmes presented with respect to the five major population groups.

Constitutional change

"There will be clear and evidence-based information on all individual programmes presented with respect to the five major population groups."

12. In the next three years it is also important for the NSC to adapt to the changes that have taken place within the United Kingdom, notably:

- the creation of the Scottish Parliament, the National Assembly for Wales and the Assembly for Northern Ireland;
- the establishment of the National Institute of Clinical Excellence in England and Wales and analogous bodies in Scotland and Northern Ireland;
- the establishment of the Commission for Health Improvement for England and Wales, the Clinical Standards Board in Scotland and any similar body which may be established in Northern Ireland.

CHAPTER 4: A PROTOCOL FOR PILOT MANAGEMENT

Introduction

1. The NSC has accepted that pilots are a useful mechanism for testing the feasibility, public acceptability and cost-effectiveness of new screening technologies or programmes in practice. Pilots have been established for colorectal cancer screening and opportunistic chlamydia screening.

2. This paper seeks to clarify the management structure of pilot screening programmes, in particular:

- Setting a framework for a pilot
- Responsibilities before and during the Pilot Phase
- Resolving difficulties
- Identifying tasks and commissioning additional research.

3. Annex A shows the stages and responsibilities in a diagram.

The Purpose of Pilot Studies

4. Policy decisions on screening are based on rigorous assessment of technology, often through randomised controlled trials (RCTs), which show screening for a condition to be effective in reducing mortality and morbidity. However, these studies are often atypical, operating to strict protocols and carried out by dedicated, specially trained teams. The impact of a screening service in ordinary practice may therefore be considerably different, for example, it may be difficult to recruit staff as committed and skilled as those on the research team. This is especially important in those screening programmes where clinical skill largely determines success.

"The purpose of pilot studies is to appraise the potential for translating the positive effects of screening shown in a research setting into the ordinary service setting across a whole nation."

5. The purpose of pilot studies therefore is to appraise the potential for translating the positive effects of screening shown in a research setting into the ordinary service setting across a whole nation (1).

Setting the Framework for a Pilot

6. If the NSC's advice to the Minister about piloting screening programmes is accepted, a policy for the pilot will be drawn up based on research evidence, professional colloquia, cost-benefit analyses and the resources available. The process for site selection may be competitive or the sites may be chosen using other criteria such as location, demographics or capacity to deliver.

7. The policy will be drafted as a pilot specification which will be passed to the project managers and pilot sites. This marks the handover of responsibility from the policy makers to the pilot co-ordinators. The specification will identify the target population and the screening procedures as well as setting the context in which the pilot is operating. Quality standards and structures will also be set.

8. Whilst major policy decisions are reserved to the NSC and therefore remain above the handover line shown at Annex A, the lead responsibility for delivering the objectives of the pilot now passes to the project managers.

The Pilot Phase

9. Three key bodies need to be established to oversee progress, support operational decision-making and advise on significant issues.

The Steering Group

10. This group is comprised of clinical experts nominated by the relevant professional groups and Royal Colleges and of consumer representatives. It provides external scrutiny for the pilot and gives expert consideration to those medical or scientific issues which are beyond the remit of the Executive Group. If the Steering Group cannot reach a consensus, if it recommends a significant change in policy or if extra resource needs are identified, the issue will be referred back to the NSC. Proposals for research projects allied to the Pilot should be addressed to the Steering Group which, in commissioning any research, should consider the effect on the Pilot as a whole whilst also ensuring that there is no duplication of work.

Executive Group

11. An Executive Group should be established to run the pilot. This is comprised of pilot co-ordinators at national level, site clinical and evaluation leads and policy leads where appropriate. It is given operational responsibility for the pilot and is briefed to ensure co-ordination of the pilot at each site, enable communication between the sites and the policy leads and tackle practical difficulties.

12. This work could be broken down into the tasks involved (examples attached at Annex B) and task groups could be established to complete each one. The Project Group may also alter aspects of the specification or Workbook, although policy questions and resource issues should be referred to the Steering Group.

13. It is likely that specialist groups will be set up at each site, under the Executive Group's umbrella. As the pilot phase progresses it is likely that new questions will arise from the sites. The Executive Group should be able to address general queries. However, difficult issues may be referred to the Steering Group.

Evaluation Panel

14. The evaluation of the Pilot should be seen as an independent part of the project, but managed in parallel. Members of the Evaluation Panel should be involved at each stage, liaising closely with the Executive Group and the Steering Group to ensure that the pilot does not become overburdened with additional research.

Products

15. The Evaluation Group's report on the pilot will inform a policy advice report to the NSC (similar to the Forrest Report on which the Breast Screening Programme is based). If the advice is to implement a national programme, this policy report should contain a resource pack giving specifications on commissioning, IT, quality standards and protocols, local resources and recruitment and public information. The Secretariat will present the NSC's advice to Government who will decide whether or not to introduce a national programme.

Progress on the Chlamydia Pilot

What is Chlamydia?

16. Chlamydia is a very common sexually transmitted infection affecting both men and women and it can be passed by a mother to her baby at birth. It is estimated that 1 in 14 young people have chlamydia. Symptoms of chlamydia can include unusual discharge from the vagina or the penis, pain on passing urine or during sex and in women, pain in the pelvis or lower abdomen. Once chlamydia is diagnosed, it can be easily treated with special antibiotics. However, most people, especially women, with chlamydia are not diagnosed because they have no obvious symptoms.

17. While it may not produce any symptoms, if left untreated, chlamydia may cause serious problems. Some women suffer from pelvic inflammatory disease, which can cause severe pain in the lower abdomen. Research shows that one in five women having a single episode of pelvic inflammatory disease may become infertile. Chlamydia can also lead to ectopic pregnancy where the baby develops outside the womb.

18. The aim of screening is to find undiagnosed, asymptomatic cases and thus prevent the long-term sequelae and reduce prevalence of the infection in the population.

Screening for Chlamydia

19. In Scandinavia, screening for chlamydia has been found to reduce the risk of infertility and ectopic pregnancy in the future. After considering advice from the NSC and other expert bodies, the Department of Health established a pilot chlamydia screening programme in Portsmouth and the Wirral. This will provide valuable information on the feasibility and acceptability of chlamydia screening and inform future policy. Full screening began on September 1st 1999 and is due to run for a year.

"After considering advice from the NSC and other expert bodies, the Department of Health established a pilot Chlamydia screening programme in Portsmouth and the Wirral."

20. Women aged 16-24 who have ever been sexually active are being offered screening when they attend selected health care settings such as general practice whatever their original reason for attending. Screening is by a urine test and is available from GPs, young people's clinics, the genitourinary medicine (GUM) clinic and selected hospital clinics. If a woman is found to have chlamydia, she will be referred to the GUM clinic, treated and asked to provide details of her partner(s). Partners are then contacted and treated as necessary.

21. The pilot programme focuses on women because they are more likely to attend health care settings; the consequences of infection are more serious for them than men and

computer modelling has indicated that this is a cost-effective approach. However, young men are offered screening in the GUM and young people's clinics.

Next steps

22. The pilot is being evaluated and the NSC will consider the results and report back to Government. These data will be used to develop policy on any future national screening programme for Chlamydia.

Progress on the Colorectal Pilot

What is bowel / colorectal cancer?

23. Colorectal cancer is the second most common cause of cancer deaths in the UK. It develops in the large bowel, the last part of the digestive system where stool is formed. This has two parts: the colon and the rectum, which lead to the outside of the body through the anus (the back passage).

24. Before some tumours become cancers they can exist for a long time as a polyp on the bowel wall. Polyps are like small spots or cherries on stalks. If these pre-cancerous polyps are removed the risk of colorectal cancer may be reduced. Not all polyps are pre-cancerous. Colorectal cancer starts on the inside wall of the large bowel. The tumour can grow there for several years before spreading to other parts of the body.

25. People with colorectal cancer who are diagnosed before it has spread to other parts of the body have a good survival rate. Many symptoms of colorectal cancer do not start until the tumour has spread, making treatment and cure much more difficult. This is why screening and early detection are so important.

Screening for bowel / colorectal cancer

26. Research in Denmark and Nottingham has shown that screening can reduce mortality and morbidity from bowel cancer by up to 25% if performed to a high standard and if a large proportion of those invited to be screened accept. Screening for colorectal cancer helps to find the disease early but it is not fail-safe.

27. The initial screening test takes a small sample of faeces to test for blood, which is not visible to the naked eye. This is called a faecal occult blood (FOB) test. This can sometimes fail to show blood when it is present (false negative) and can sometimes say that blood is present when it is not (false positive). Colorectal cancers can bleed intermittently, which could lead to a false negative result. Finding an abnormal result in screening tests only means that there is a higher chance of that person having the disease being screened for. Further tests will be needed to make a confirmed diagnosis.

The NSC's Bowel / Colorectal cancer screening pilot

"Based on the NSC's advice, the Government have introduced a bowel / colorectal cancer screening pilot. This is in Coventry and Warwickshire (England) and Tayside, Grampian and Fife (Scotland)."

28. Based on the NSC's advice, the Government have introduced a bowel / colorectal cancer screening pilot. This is in Coventry and Warwickshire (England) and Tayside, Grampian and Fife (Scotland). This pilot will provide valuable information on the effectiveness, feasibility and public acceptability of screening for bowel / colorectal cancer in an ordinary NHS setting rather than a specialised research site. The pilot will run for two years beginning in 2000. The NSC will use the results of the pilot to inform its decision on whether or not to advise Government to introduce a national population screening programme.

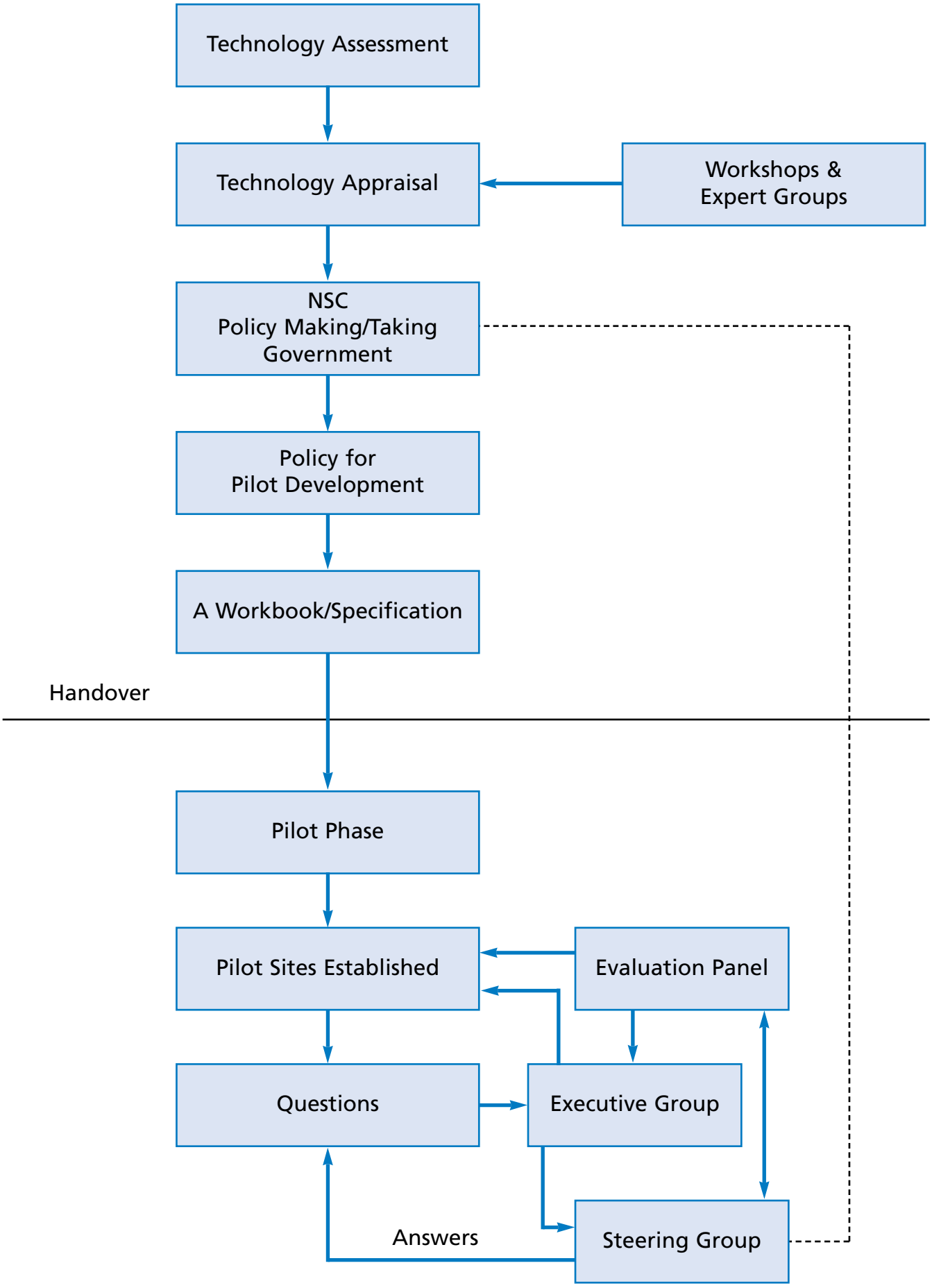
How will the pilot work?

29. Men and women aged 50-69 living in the area of the pilot sites will be sent an FOB test kit to complete in their homes. If this test and a repeat test with dietary restriction are positive, they will be invited to hospital for a colonoscopy.

30. This is an examination of the rectum and colon (bowel). Colonoscopy does not just look for bowel cancer. It can also identify polyps, which are small growths of cells. These polyps can be removed without the need for surgery to give long-term protection from bowel cancer. Following colonoscopy 9 out of 10 people will have been found not to have cancer. The blood detected by the FOB test could have been due to some other cause such as piles or haemhorroids or it could have no obvious cause.

31. When the pilot finishes in 2002, a report will be made to the NSC. The NSC will then advise Government on whether or not to introduce a national screening programme.

ANNEX A: THE PILOT FRAMEWORK



ANNEX B: TASKS TO BE COMPLETED UNDER THE UMBRELLA OF THE EXECUTIVE GROUP

Develop a bespoke IT system

Develop common data sets
- clinical disciplines,
- administration,
- office management

Develop patient pathways and clinical protocols

Primary Care
- Develop information pack
- Visit practices involved in Pilot

Communications
- Information for the public and for patients
- Information for primary care and GPs
- Briefing material for the Press - identify key on-site media contacts
- Information for the Health Departments
- Information for Screening Staff

Training

Development of a website to share information and experiences
- Some sections protected to enable private discussion between those involved in the Pilot.

CHAPTER 5: THE NSC'S RECOMMENDATIONS SINCE 1998

Adult Programmes

Since 1998 the NSC considered evidence about the effect of screening on the health problems listed below:

- Aortic aneurysms
- Diabetic retinopathy
- Vascular disease
- Osteoporosis
- Cardiomyopathy
- Ovarian Cancer
- Prostate Cancer
- Syphilis

1. Abdominal Aortic Aneurysms:

1.1Background

Abdominal aortic aneurysms commonly remain symptomless until they rupture. Aneurysms are a significant cause of sudden death and form a large part of the vascular surgical caseload. The possible screening test would be ultrasound with positive cases treated by open surgical repair of small abdominal aortic aneurysms.

1.2 Progress

A paper in the Lancet (1) in November 1998 reported a trial of active intervention versus watchful waiting of small aneurysms, indicating that watchful waiting did more good and less harm at lower cost. The trial made no comment on the effectiveness or cost-effectiveness of screening, but found that, when an aneurysm is detected, watchful waiting appears to be better than early intervention.

The Medical Research Council is currently funding a randomised controlled trial of abdominal aortic aneurysm screening but is not due to report until 2003.

The Health Technology Assessment Programme is about to commence a trial of surgical treatment of aortic aneurysm compared with the use of stents, small prostheses inserted within the aorta to maintain and open the passageway, but this study will also take between two and three years.

1.3 Current advice

The NSC agreed that there was currently no evidence to introduce screening and that it should not be introduced in a piecemeal fashion. It agreed that it would encourage researchers of existing studies to meet to see how issues interrelate and make a fuller report to the NSC.

2. Diabetic Retinopathy

2.1 Backgound

Diabetic retinopathy is a common complication of diabetes affecting the blood vessels of the retina. It is the largest single cause of blindness amongst working age people in the UK. Early detection of sight threatening retinopathy and treatment by laser therapy has been shown to be effective in preventing the onset of visual impairment. Protection lasts for over 10 years in two-thirds of treated patients. In some cases, the costs of screening and treatment may be less than the costs of the blindness that results without treatment.

2.2 Progress

In April 1999, the NSC commissioned a working group to develop proposals for a national screening programme for diabetic retinopathy. An expert panel selected by Diabetes UK (formerly the British Diabetic Association) has advised this working group. A workshop was held in Glasgow to address controversial questions and to update experts on progress.

Retinopathy screening can be done either by an eye examination by a high street optometrist using indirect slit-lamp ophthalmoscopy, or by taking a photograph of the retina with a digital camera, either in a hospital or in the high street. Although both methods meet sensitivity and specificity criteria, the Glasgow workshop recommended digital photography as the best retinopathy screening tool. This is because photographs of the retina can be stored on a CD-ROM for audit and training purposes. However, it is likely that the widespread use of digital photography would be phased in over time with the optometrist's eye check being used for several years to come. The Glasgow recommendation does not limit the location or professional background of the screener. More detail on these proposals will be placed at http://www.nsc.nhs.uk/otherres-ind.htm

2.3 Current Advice
In March 2000, the NSC approved the working group's final paper on a national programme to reduce the risk of diabetic eye disease. Officials in the four UK health departments will now submit these proposals to their Ministers / Assembly Secretaries. In England, the NSC's recommendations will inform the development of the forthcoming National Service Framework for Diabetes.

3. Vascular Disease

3.1 Background
The disease may affect the large vessels (macrovascular disease) for example coronary heart disease and stroke or disorders of the peripheral arteries, or small vessels (microvascular disease) principally due to diabetes. The screening undertaken is the measurement of blood pressure and the detection of other risk factors e.g. smoking. GPs are recommended to include the measurement of blood pressure in checks of new patients and in periodically arranged health checks.

3.2 Progress
The policy that is evolving for screening is to distinguish between people at high risk from those who have no known risk factor. Those at high risk are likely to have cardiovascular disease already or some other identifiable risk factor. Some of the people who have no known risk factor and who are not known to have vascular disease will be at very high risk through having disorders with a strong genetic basis. Policy is evolving to improve the management of those who have vascular disease or are at very high risk. The NSC will not be covering the management of risk factors in people who are already under surveillance as this is the promotion of good clinical practice. There is a need to define policy for people who are not known to be at high risk. Further work will be undertaken across the four countries to provide policy recommendations to the NSC.

3.3 Current advice
Screening for vascular diseases should continue until the NSC receives new advice.

4. Osteoporosis:

4.1 Background
The 1994 WHO expert group definition of osteoporosis is "a disease characterised by low bone mass and micro-architectural deterioration of bone tissue, leading to enhanced bone fragility and a consequent increase in fracture risk". There does not appear to be a simple, reliable test for osteoporosis that would meet all the criteria for a screening programme.

4.2 Progress
The impact on health services of fractures after minimal trauma from osteoporosis is considerable. The increased numbers of elderly people that will be present in the population in the future means that the numbers of fractures will increase.

The problem of screening to prevent osteoporotic fractures lies in the nature of the bone itself and its variations within the skeleton, together with the fact that fracture rates are not always consistent with a lower bone mineral content (BMC). The size, shape, and orientation of bone influence the bone mineral density (BMD) and BMC measures but do not indicate the internal structure of the bone. The rate of bone loss in postmenopausal women varies and the bone mass at the menopause correlates only moderately with the mass 10-20 years later when fractures occur most. There is thus no value of BMD that discriminates well between patients who get a fracture and those that do not. This is a major drawback in its use as a screening tool.

BMD measurements have a high specificity but a low sensitivity. A negative test (suggesting the absense of osteoporosis) indicates a low risk of fracture but the low sensitivity of 50% means the prediction that half of all osteoporotic fractures will occur in women who were not detected as having osteoporosis.

There is a comprehensive approach for the prevention and treatment of this disease (HRT, diet, exercise, and the use of specific drugs such as bisphosophonates and selective oestrogen receptor modulators) which can be directed towards the general population. This approach has the additional advantage of being helpful to health in a general way and in particular to ischaemic heart disease.

4.3 Current advice
The NSC decided that no screening programme could be justified at present but the various markers of bone health should be regularly reviewed as the numbers of potentially osteoporotic individuals increase.

5. Hypertrophic Cardiomyopathy:

5.1 Background

Hypertrophic Cardiomyopathy (HCM) is the name given to a genetically determined cardiac disease usually with an autosomal dominant pattern of inheritance characterised by left ventricular hypertrophy (LVC) not explained by another cause. Screening could consist of a family and personal history and physical examination by a doctor with a low threshold for proceeding to further investigation either in the general population or among the relatives of people who have developed or died from HCM. The latter activity is not screening as defined by the NSC.

5.2 Progress

The NSC considered a preliminary review of the evidence (2) for screening for hypertrophic cardiomyopathy prepared for the Institute of Child Health at its meeting in June 1999. The Committee accepted the conclusions of the report. This stated that the absolute requirements for a possible screening programme were a clear case definition linked to prognosis, and good evidence that intervention can improve the prognosis of the condition if instituted before cases would have been expected to present without screening. Hypertrophic cardiomyopathy fulfils neither of these criteria. The case definition misses many of those at risk and identifies many others whose life span is likely to be no different from the general population. There is currently little evidence that treatment changes the course of the disease if instituted before the onset of symptoms. Screening of adolescents and young people who intend to engage in competitive sport can similarly not be justified at present. Most people identified by the screening process would be individuals who are destined to live a normal lifespan, most of whom would remain asymptomatic at least until much later in life.

5.3 Current advice

There is no justification to introduce screening for this condition.

6. Ovarian Cancer:

6.1 Background

Ovarian cancer is the fifth most frequent cause of death from cancer in Western Europe, with a 5 year survival rate of only 25%. The two methods of screening are trans-vaginal ultrasound and a blood test for cancer antigen.

6.2 Progress

The HTA systematic review (3) suggested that more evidence was needed before a conclusive recommendation could be made. The relatively low prevalence of ovarian cancer means that the positive predictive value of screening tests is low. Since the consequence of a false positive result is a surgical procedure, consideration of the overall impact of ovarian cancer screening is important. The low prevalence also limits the potential cost-effectiveness of population screening.

Screening women who are at risk because of a strong family history may be more cost-effective but this has not been established.

Results from three control trials should provide an estimate of the impact of screening on mortality but evidence is unlikely to be available before 2003. Assessment of the adverse effects of screening and the relative cost-effectiveness of different strategies would enhance information from the trials. New or modified screening tests should be compared with those being evaluated in current trials.

The UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS), a major new trial sponsored by the Department of Health in England and the Medical Research Council, began recently. This will recruit 200,000 women, half of whom will be screened, 50,000 with the CA125 test and 50,000 by ultrasound. This trial will report in 2010.

Research efforts should be directed towards evaluating both the clinical and cost-effectiveness of screening strategies for patients at high risk. Research is also needed into the impact of genetic testing on health outcomes and the level of demand for such services.

The NSC agreed with the conclusion of the HTA report that further evidence was required before a decision can be made about the introduction of a screening programme. This should be re-evaluated in 2003 when the new studies became available.

6.3 Current Position

Screening should not be offered for this illness.

7. Prostate Cancer:

7.1 Background

There is pressure to introduce screening for prostate cancer but there is no high quality evidence that screening reduces mortality. The prostate specific antigen (PSA) test has a limited accuracy and could lead to a positive result for those without the disease. It should not be used for screening. A further ethical issue surrounds those correctly identified as having prostate cancer. Prostate cancer often develops slowly and, if screening were to be introduced, many men would be subjected to traumatic treatment with unpleasant side-effects of impotence and incontinence who would never have suffered any ill effects from their prostate cancer in their lifetime.

7.2 Progress

On the basis of two systematic reviews (4, 5) on the diagnosis and management of early prostatic cancer published in 1997, the NSC advised the Secretary of State that it was not appropriate to introduce nation-wide screening. The reports emphasised the need to keep prostatic cancer under active review and to consider the need for research in this field.

The Standing Group on Health Technology has funded a study to examine the feasibility of conducting a multi-centre randomised trial of treatment for localised prostatic cancer.

At a workshop held on 13 January 1999 it was agreed that if no action was taken there would be a steady increase in uncoordinated PSA testing, initiated by members of the medical profession working in the NHS, or in private screening clinics, in spite of the policy guidance. There was also agreement that three existing protocols for a trial of prostatic cancer should be integrated. The NSC accepted these views and asked that a bid should be put in for one co-ordinated trial.

In September 2000, the Department of Health in England published a Prostate Cancer Action Plan intended to raise the standards of prostate cancer care in the NHS.

7.3 Current Position

Prostate screening should not be offered. This does not affect the clinical management of men with symptoms of prostate cancer who should be tested and referred for treatment as necessary.

In England, the Minister for Public Health announced that a Prostate Cancer Risk Management Programme is being developed to ensure that people who are anxious about prostate cancer can make an informed choice about whether to take the PSA test. The Risk Management Programme would ensure that they received high quality information, PSA testing and follow-up.

Antenatal Programmes

The Antenatal Screening Sub-Group of the NSC has considered a number of issues over the last eighteen months. Further information will be posted on the NSC's website at http://www.nsc.nhs.uk/

8. Syphilis

8.1 Background

Serological screening is both sensitive and specific, though some confirmatory test results require expert interpretation and final diagnosis requires clinical judgement. Tests are validated by the PHLS reference laboratories.

8.2 Progress

The NSC considered a report from the PHLS Communicable Disease Surveillance Centre (6). The conclusions were:

(i) there was uncertainty over the future epidemiology of syphilis in the UK with a modest rise in incidence being the most likely scenario.

(ii) Abandoning the antenatal syphilis screening programme would result in a small amount of preventable fetal loss, infant mortality and morbidity. The numbers of these depend on the impact of international syphilis epidemics on the UK as well as on levels of indigenous transmission.

(iii) The gain in resource resulting from stopping screening would be small (under £1 a pregnancy).

(iv) Targeted screening, either by locality or risk group (ethnic group or country of birth) would result in even less economic gain, would also probably be ineffective and might be unacceptable.

The NSC decided that antenatal screening was effective and that only a small amount would be saved by withdrawing the service. Standards would be worked up as part of an integrated package with the whole of the antenatal programme.

8.3 Current Position
Screening should continue while standards were prepared.

Child Health Screening Programmes

The Child Health Screening Sub-Group of the NSC has considered a number of issues over the last eighteen months. Further information will be posted on the NSC's website at http://www.nsc.nhs.uk/

REFERENCES

CHAPTER ONE: SCREENING POLICY-MAKING - GETTING RESEARCH INTO PRACTICE

1. Brennan T. A., Leape, L. L., Laird, N. M. et
   Incidence of adverse events and negligence in hospitalized patients.
   New England Journal of Medicine, 1991; 324: 370-376.

2. Leape, L. L., Brennan T. A., Laird, N. M. et al.
   The nature of adverse events in hospitalized patients.
   New England Journal of Medicine, 1991: 324; 377-384.

3. Health Departments of the United Kingdom
   First Report of the NSC
   April 1998

CHAPTER TWO: ORGANISING SCREENING PROGRAMMES

1. Hibble A, Kanka D, Pencheon D, Pooles F
   Guidelines in General Practice: The new Tower of Babel?
   BMJ 1998, 317, 862-863 (26th September)

2. Department of Health, England
   Information for Health: An Information Strategy for the Modern NHS 1998-2005
   http://www.nhsia.nhs.uk/

CHAPTER FOUR: A PROTOCOL FOR PILOT MANAGEMENT

1. Gray, J A M
   Pilots of Screening Services - Aims, Objectives and Evaluation
   NSC Papers 98/21

CHAPTER FIVE: THE NSC'S RECOMMENDATIONS SINCE 1998

1. Powell, J T et al
   Mortality results for randomised controlled trial of early elective surgery or ultrasonographic surveillance for small abdominal aortic aneurysms
   The Lancet, Vol 352, November 21 1998

2. Logan S, Mytton J
   Screening for Hypertrophic Cardiomyopathy: A preliminary review of the evidence
   Systematic Reviews Training Unit, Institute of Child Health, London

3. Bell R, Petticrew M, Luengo S, Sheldon T A,
   Screening for Ovarian Cancer - a systematic review
   HTA 1998, Vol 2, No 2

4. Selley S, Donovan J, Faulkner A, Coast J, Gillat D,
   Diagnosis, Management and Screening of early localised prostate cancer
   HTA 1997, Vol 1, No 2

5. Chamberlain J, Meilia J, Moss S, Brown J
   The diagnosis, management, treatment and costs of prostate cancer in England and Wales
   HTA 1997, Vol 1, No 3

6. STD Section, HIV and STD Division
   Antenatal syphilis screening in the UK: A systematic review and national options appraisal with recommendations
   PHLS Communicable Disease Surveillance Centre, June 1998

APPENDIX A: REMIT AND TERMS OF REFERENCE OF THE UK NATIONAL SCREENING COMMITTEE

The remit and terms of reference of the NSC are:

1. The National Screening Commitee will advise Government 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 programmes not presently purchased by the NHS within each of the countries in the UK;

    - screening technologies of proven effectiveness but which require controlled and well-managed introduction;

    - the case for continuing, modifying or withdrawing existing population screening programmes. In particular, programmes inadequately evaluated or of doubtful effectiveness, quality, or value.

2. The NSC will call on sound evidence to inform its advice and recommendations. In particular:

    (a) calling on the advice of the Standing Group on Health Technologies Diagnostic Technologies and Screening Panel (formerly the Population Screening Panel) and in turn inform the setting of NHS R&D priorities;

    (b) calling on the DH Policy Research Programme and defining research needs for screening;

    (c) calling on other and appropriate sources of sound evidence from within and outside the NHS.

3. The NSC will set up practical mechanisms to oversee the introduction of a new programme and its implementation in the NHS. It will monitor effectiveness and quality assurance.

4. The NSC will be informed by reports from the Advisory Groups for specific programmes on the performance of those programmes and issues that arise which would have relevance to general screening policy.

This information is available on the NSC's website at http://www.nsc.nhs.uk/

APPENDIX B: MEMBERSHIP OF THE UK NATIONAL SCREENING COMMITTEE

Chair:	
Dr Henrietta Campbell CB	Chief Medical Officer - Department of Health, Social Services and Public Safety, Northern Ireland
Members:	
Professor Liam Donaldson	Chief Medical Officer, Department of Health, England
Sir David Carter	Chief Medical Officer - Scottish Executive Represented by **Dr Rosalind Skinner,** Principal Medical Officer
Dr Ruth Hall	Chief Medical Officer, National Assembly for Wales Represented by **Dr John Pritchard,** Chief Scientific Adviser (previously by Dr Kay Richmond)
Dr Margaret Boyle (from December 1999)	Senior Medical Officer, Department of Health, Social Services and Public Safety, Northern Ireland (previously represented by Dr Philip McClements)
Professor Yvonne Carter OBE (from September 1999)	Professor of General Practice and Primary Care, St Bartholomew's & the Royal London School of Medicine and Dentistry, Queen Mary & Westfield College, London
Dr David Elliman (from December 1999)	Chairman of the Child Health Sub-Group Consultant in Community Paediatrics, St George's Hospital
Professor Sir John Grimley Evans	Member of the Medical Research Council. Based at the Radcliffe Infirmary, Oxford (Geriatric Medicine). Chairman, Diagnostic Technologies and Screening Panel (formerly the Population Screening Panel), Health Technology Assessment Programme
Dr Mike Gill (from September 1999)	Regional Director of Public Health, NHS Executive, South East Regional Office
Ms Pippa Gough	Assistant Director/Nursing in the Department of Nursing, The Royal College of Nursing
Dr J A Muir Gray CBE	NSC Programme Director, Institute of Health Sciences, Oxford
Professor Neva Haites (from September 1999)	Professor of Medical Genetics, University of Aberdeen
Dr Hemantha Kumar MBE (from September 1999)	GP, Bharani Health Centre, Slough
Dr Surendra Kumar (from September 1999)	GP, Upton Medical Centre, Widnes
Dr J Gordon Paterson	Public health specialist with particular experience in cancer screening
Mr Colin Reeves CBE	Director of Finance and Performance, NHS Executive HQ

Mr Clive Smee CB	Chief Economic Adviser, Department of Health, England
Ms Polly Toynbee	Journalist. Ethics interests and link with the public domain
Mr Robin Wild	Chief Dental Officer - Department of Health, England
Professor Martin Whittle (from December 1999)	Department of Fetal Medicine, Birmingham Women's Hospital Chairman, Antenatal Screening Sub-Group
Vacancy	Consumer Interest

Members who left the NSC in 1999 and 2000

Professor David Hall (until December 1999)	Chairman of the Child Health Sub-Group Professor of Community Paediatrics, Sheffield President of the Royal College of Paediatrics and Child Health
Dr Tim Riley (until June 2000)	Head of Outcomes and Effectiveness, NHS Executive
Professor Philip Milner (until September 1999)	Director of Public Health, Wiltshire Health Authority
Dr Pat Troop (until September 1999)	Chair of the Antenatal Screening Sub-Group Regional Director of Public Health, NHS Executive Eastern Regional Office (now Deputy CMO in England)

Observers:

Dr Peter Dukes	The Medical Research Council.
Dr Norman Waugh	Diagnostic Technologies Panel of the Health Technology Assessment Programme (previously represented by Dr Julie Parkes and Dr Ruairidh Milne)

Secretariat:

Sir Charles Nightingale	Secretary to the (NSC), Section Head, National Screening Policy, NHS Executive HQ
Mrs Ann Dixon-Brown (until October 2000)	Programme Manager, UK (NSC), NHS Executive, Eastern Regional Office
Mr Steve Pugh	National Screening Policy Manager, NHS Executive HQ
Mrs Beth Micklethwaite	National Screening Policy and Development Officer, NHS Executive HQ

This information is available on the NSC's website at http://www.nsc.nhs.uk/

APPENDIX C: THE UK NATIONAL SCREENING COMMITTEE'S CRITERIA FOR APPRAISING THE VIABILITY, EFFECTIVENESS AND APPROPRIATENESS OF A SCREENING PROGRAMME

The criteria, which are set out below, are based on the classic criteria first promulgated in a WHO Report in 1966 but take into account both the more rigorous standards of evidence required to improve effectiveness and the greater concern about the adverse effects of healthcare; regrettably some people who undergo screening will suffer adverse effects without receiving benefit from the programme.

These criteria have been prepared taking into account international work on the appraisal of screening programmes, particularly that in Canada and the United States. It is recognised that not all of the Criteria and questions raised in the Format will be applicable to every proposed programme, but as many as possible should be answered since this will assist the NSC to make quicker and better evidence based decisions.

All of the following criteria should be met before screening for a condition is initiated:

The condition

1.1. The condition should be an important health problem.

1.2. 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, or disease marker and a latent period or early symptomatic stage.

1.3. All the cost-effective primary prevention interventions should have been implemented as far as practicable.

The test

1.4. There should be a simple, safe, precise and validated screening test.

1.5. The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed.

1.6. The test should be acceptable to the population.

1.7. 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

1.8. 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.

1.9. There should be agreed evidence based policies covering which individuals should be offered treatment and the appropriate treatment to be offered.

1.10. Clinical management of the condition and patient outcomes should be optimised by all health care providers prior to participation in a screening programme.

The screening programme

1.11. There must be evidence from high quality Randomised Controlled Trials that the screening programme is effective in reducing mortality or morbidity.

Where screening is aimed solely at providing information to allow the person being screened to make an "informed choice" (e.g. Down's syndrome, cystic fibrosis carrier screening), there must be evidence from high quality trials that the test accurately measures risk. The information that is provided about the test and its outcome must be of value and readily understood by the individual being screened.

1.12. There should be evidence that the complete screening programme (test, diagnostic procedures, treatment/ intervention) is clinically, socially and ethically acceptable to health professionals and the public.

1.13. The benefit from the screening programme should outweigh the physical and psychological harm (caused by the test, diagnostic procedures and treatment).

1.14. The opportunity cost of the screening programme (including testing, diagnosis, treatment, administration, training and quality assurance) should be economically balanced in relation to expenditure on medical care as a whole (i.e. value for money).

1.15. There must be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards.

1.16. Adequate staffing and facilities for testing, diagnosis, treatment and programme management should be made available prior to the commencement of the screening programme.

1.17. All other options for managing the condition should have been considered (e.g. improving treatment, providing other services), to ensure that no more cost effective intervention could be introduced or current interventions increased within the resources available.

1.18. Evidence-based information, explaining the consequences of testing, investigation and treatment, should be made available to potential participants to assist them in making an informed choice.

1.19. Public pressure for widening the eligibility criteria for reducing the screening interval, and for increasing the sensitivity of the testing process, should be anticipated. Decisions about these parameters should be scientifically justifiable to the public.

This information is available on the NSC's website at http://www.nsc.nhs.uk/

References:

Department of Health. Screening of pregnant women for hepatitis B and immunisation of babies at risk. London: Department of Health, 1998. (Health Service Circular: HSC 1998/127)

Wilson JMG, Jungner G. Principles and practice of screening for disease. Public Health Paper Number 34. Geneva: WHO, 1968.

Cochrane AL. Holland WW. Validation of screening procedures. Br Med Bull. 1971, 27, 3.

Sackett DL, Holland WW. Controversy in the detection of disease. Lancet 1975; 2:357-9.

Wald NJ (Editor). Antenatal and Neonatal screening. Oxford University Press, 1984.

Holland WW, Stewart S. Screening in Healthcare. The Nuffield Provincial Hospitals Trust, 1990.

Gray JAM. Dimensions and definitions of screening. Milton Keynes: NHS Executive Anglia and Oxford, Research and Development Directorate, 1996.

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