



National Screening Committee

*First Report of the National
Screening Committee*

**Health Departments of the United Kingdom
April 1998**

This Department of Health report has been produced in partnership with all the Health Departments in the United Kingdom - England, Scotland, Wales and Northern Ireland.

A version of this report is also available on the Department of Health website:-
<http://www.open.gov.uk/doh/nsc/nsch.htm>

Foreword

We are pleased to introduce the first report of the National Screening Committee.

Events in recent months in the breast and cervical screening programmes have rightly highlighted the high expectations we have of our national screening programmes and how public confidence can be quickly undermined when questions are raised about quality, effectiveness and reliability.

Quality is a concern across the UK and that is why firm action has been taken by all UK health departments to introduce a range of improvements to address and assure quality in our screening services and to monitor progress closely.

After a piecemeal start, national quality standards were introduced for cervical screening in 1988 and have helped improve the quality of many local services across the UK. But plainly the local monitoring arrangements in Kent & Canterbury were not adequate to meet all eventualities. We must learn lessons from these unfortunate failures promptly and effectively. We must also ensure that our collective experience informs our consideration and implementation of other potential national screening programmes, such as neonatal, ante-natal and child health surveillance.

This is all part of a broader Government commitment, which was set out in recent White Papers, to ensure that quality is at the heart of the NHS. This applies as much to those who deliver the service as to the experience of people who receive screening services. Clearly quality cannot be taken for granted and a continued robust approach to assuring quality in existing programmes must remain a high priority.

Quality is dependent on a range of influences and needs to be addressed in a number of ways. We need to be sure that the new technologies for screening are effective; that they will not cause more harm than good; that the health needs of people determine the necessity to screen; that false hope is not raised by screening for conditions where an effective cure or treatment is unavailable, and that people's experience informs the continued improvement of screening services.

Early identification of a disease is important to the patient. As new technologies are discovered so people's interest is raised in the possibilities for new programmes. However, the promise of new screening technologies must be looked at carefully if the major undertaking and investment of a new programme is to meet all our expectations. It is therefore vital that before proceeding there is careful development and discussion with the service, the professions that would provide the screening service and the potential users of the service and consideration of whether this is the best use of resources.

This report is a reminder of how much has been achieved in a very short space of time. However, the report is one important stepping stone in a long line of steps that will need to address difficult issues such as, what should or should not be screened for, where improvements in quality could be gained, where new research is needed on the effectiveness of new technologies, and where the case exists to modify existing programmes. The role of the National Screening Committee is becoming ever more important in providing essential advice to health Ministers across the UK.

Chief Medical Officers

Sir Kenneth Calman, England Sir David Carter, Scotland

Dr Ruth Hall, Wales

Dr Henrietta Campbell, Northern Ireland

Preface

Throughout our lives, from conception to old age, screening programmes will have an impact. Perhaps some of us take for granted the important contribution that screening has made and continues to make in improving our Nation's health.

However, it is important to understand the limitations of population screening as well as the obvious benefits. A screening test is not a diagnostic test. Screening is applied to apparently healthy people in order that a small number with the potential to develop disease might then be diagnosed and receive effective treatment. Screening tests do sometimes wrongly identify some people as suffering from a disease or condition when they are in fact healthy (false positives), and, conversely, may give a falsely reassuring result to some others who do in fact have the disease or condition (false negatives). In these cases good quality assurance mechanisms and sensitive handling by clinicians can help ensure that potential distress to individuals is minimised.

Any national screening programme is, however, designed to confer more benefit than harm to the population in terms of lives saved or suffering avoided. One often hears of new screening technologies which claim to revolutionize the approach to particular diseases, but in practice it is difficult to achieve the benefits observed in a small research project for a whole population. It is, therefore, vitally important to manage the policy on what is and what is not screened, and also to manage the practice of screening to the highest quality. In its first year the National Screening Committee has made an excellent start in addressing this potentially vast area.

Our first year aim was to review the whole of screening and to identify key issues such as ethical issues or the criteria that should be used to assess whether a new programme should be introduced. The most significant single event was the Committee's decision to advise the Secretary of State and his Ministerial colleagues that a national screening programme for prostatic cancer, with current techniques, was of no benefit and could cause considerable harm. This decision has saved the male population from unnecessary, unpleasant and ineffective testing and treatment.

The Committee also completed the first national inventory of screening, identifying over 300 screening programmes. Many of these are still in the research stage, whilst many others have been introduced by Health Authorities to meet a variety of local needs each with their own arrangements and protocols. Yet until now there has not been the means to ensure that the technologies being used are effective for their purpose, that the appropriate populations are being screened and that wherever you live, there is a consistent and reliable approach to ensuring the quality of the screening service. The Committee now has the formidable task of assessing which programmes meet its stringent criteria on evidence for effectiveness and quality.

Vigilance to maintain quality of delivery continues to be crucial for screening programmes. Even those programmes - breast and cervical screening, and neonatal bloodspot screening for PKU and hypothyroidism - which meet the stringent criteria for both evidence of effectiveness and quality have illustrated recently in two cases that maintaining quality assurance each and every day continues to be of paramount importance.

The Committee will now bring the lessons learned on quality assurance to bear on the development of all existing and future national screening programmes. On the basis of its first year of work the National Screening Committee is now drawing up a challenging three year plan to maximise the benefit and minimise the risks and costs of screening. We now look forward to meeting the challenges that our future work programme holds.

Dr Muir Gray Dr Pat Troop

Joint National Screening Committee Programme Directors

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First Report of the National Screening Committee

Introduction

This is the first report of the National Screening Committee (NSC) which advises the Secretary of State for Health and his Ministerial colleagues within The Department of Health of England and in the health departments of Wales, Scotland and Northern Ireland. The report is a look back on what has been achieved over the previous twelve months. The report also highlights the key directions to be taken in the NSC's future work programmes.

The NSC is not solely a high level committee that advises Ministers on UK screening policies, it also has a key role in building its advice from the foundation stones of patient experience, and clinical and managerial "shop floor" views from within the NHS throughout the UK. Increasingly much of the advice is being formulated through workshops which take on local community and public health perspectives.

Screening has a number of important ethical differences from clinical practice. It is generally understood that the patient seeks help from the health service for a problem that is causing distress or anxiety and that, that person seeks help on the understanding that the clinician will do their best to help even where a cure cannot be guaranteed. The clinician and the health service have an important responsibility to do the best possible for the patient; this contract between patient and the service is vital. When, on the other hand, the health service seeks out a healthy person and invites them to come for screening, the contract is different.

One of the first tasks of the National Screening Committee in its first year was to develop a framework for screening; this framework has been divided into two parts. The first part is concerned with the definition and classification of population screening programmes (*Chapter 2*) and includes the introduction of the first edition of *The NSC Handbook (Chapter 6)*; the second part, on the otherhand, deals with the ethical and social issues (*Chapter 3*) involved with screening. Part 2 of this framework provides an important foundation for the work of the Committee; the origin of which can be traced back to a speech made by the Chief Medical Officer at the launch of *The Journal of Medical Screening* in 1994 (1). In that speech it was emphasised that, not only the important ethical difference from the rest of clinical practice but that screening was a large and growing type of health care, and time had come to manage it more effectively. Only in a structured way can these broad range of screening issues be considered. The NSC has therefore developed a Framework for Screening within which work of this last year and work intended for the future fit together as key components of the NHS strategy to continually improve our screening services.

Chapter 1.

The UK National Screening Committee

The main role of the UK National Screening Committee is to advise on:-

- (i) the case for implementing new population screening programmes not presently purchased by the NHS;
- (ii) implementing screening technologies of proven effectiveness but which require controlled and well-managed introduction;
- (iii) the case for continuing, modifying or withdrawing existing population screening programmes: in particular, programmes inadequately evaluated or of doubtful effectiveness, quality, or value.

The NSC seeks clinical evidence from a variety of research programmes and expert advisory groups from within and outside the NHS, both from the UK and overseas. It involves healthcare professionals, research experts and organisations, the media, as well as voluntary and consumer groups in its decision making, after all one of the critical success factors of any screening programme depends upon the co-operation of all of these team players. The NSC is also responsible for ensuring that practical mechanisms, essential guidelines and quality standards exist, prior to the introduction of new programmes or the modification of existing programmes. On some occasions this may mean that some programmes will have to be validated by the use of pilots.

The NSC also requires that systems exist to monitor continually the effectiveness, quality assurance and the management of the overall performance of all screening programmes. The full remit, terms of reference and membership of the UK National Screening Committee can be found in *Appendix A*.

The introduction of the NSC Handbook for population screening programmes is the Committee's first attempt at specifying the most important issues for defining and managing any screening programme; it is expected that this report will be updated on at least an annual basis. The Committee has already planned for the next edition to contain standards for specific programmes and, in particular, work is already in progress on defining standards for both antenatal, neonatal and child health surveillance screening programmes.

This report together with the NSC Handbook is also available on the Department of Health website (<http://www.open.gov.uk/doh/nsc/nsch.htm>) and your comments are invited on, all or any part, of this *The First Report of the National Screening Committee*. You can do this by choosing one of the options shown at the back of this report.

Whilst this report summarises both the work of the first year of the NSC and its forward programme (see Chapters 4.1, 4.2, 5.1, 5.2, 6.1, 6.4, & 6.5), it is also intended as a source of reference for all Healthcare professionals:-

Health Authority Chief Executives
NHS Trust Chief Executives
Trust Medical Directors
Trust Directors of Nursing
District Directors of Public Health
Regional Directors
Regional Directors of Public Health
Regional Directors of Research and Development
Regional Directors of Nursing
Regional Directors of Performance Management
CHC Chief Officers
General Practitioner Fund Holders

in all of the Health Departments in the United Kingdom - England, Scotland, Wales and Northern Ireland, as well as:-

Patient and Consumer Groups
The Royal Colleges
Professional Organisations

who are either interested in or involved in decision making with regard to population screening programmes. It is also written in a format that can be readily understood by the media and general public who may be involved with, or have an active interest in, population or opportunistic screening programmes.

Health Authorities and all healthcare professionals responsible for the provision of population screening programmes are to be reminded that "The NHS Executive accepts and supports the recommendation of the National Screening Committee that new screening programmes should not be introduced or expanded until reviewed, evaluated and proven effective": an extract from Executive Letter EL(96)110 on Improving the effectiveness of clinical services.

Chapter 2.

A Framework for Screening - Part 1

Definitions and classification of population screening programmes

2.1 *Defining screening*

'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'

Screening can be undertaken **pro-actively** or **opportunistically**.

In **pro-active screening** members of a target population are invited to attend for testing in a systematic programme which will cover the whole of that population over a defined period of time. For example, in the National Breast Cancer Screening Programme women in a defined population between the ages of 50 and 65 are invited for screening over a three year period so that by the end of the three year period every woman whose address is accurately known to the health authority receives an invitation.

Opportunistic screening is the term given to the offer of a test for an unsuspected disorder at a time when a person presents to the doctor for another reason. For example, most people have blood pressure screening, to reduce the risk of stroke, by having their blood pressure taken during the course of a consultation initiated by the patient for some reason other than concern about blood pressure or a stroke.

2.2 *Programmes and not tests*

Much attention is focused on screening tests, for example the cervical smear test or blood pressure measurement, but it is inappropriate to think of screening as simply a test. A screening programme consists of all those activities from the identification of the population likely to benefit right through to definitive diagnosis and treatment.

Some individual in each primary care team or Trust needs to be given clear responsibility for managing each screening programme, to national standards where these are available. The responsibility of the health authority, on the other hand, is to ensure that screening programmes which are proven as effective are appropriately provided to meet their population needs. Furthermore there is a continued responsibility to manage actively, matters of quality and new technology and to take the necessary actions when programmes fail to meet the required standards. For example, a health authority's population may be covered by two cervical screening programmes, each focused on a different cytology laboratory, but with one individual within each programme responsible for ensuring that all the relevant activities are co-ordinated to create an effective and efficient programme within the national framework.

The first task of the National Screening Committee was to identify how many programmes were actually being offered to the UK population, and to identify programmes that were being proposed for introduction. Nearly 300 actual and proposed programmes have been identified and the National Screening Committee has started to develop an inventory of screening programmes. A summary of this inventory is shown in *The NSC Handbook*, see Chapter 6.5; other programmes will be added to this inventory when evidence becomes available.

2.3 *Classifying programmes*

In an ideal world all the programmes that were being offered to a population would:-

be based on good quality evidence that they did more good than harm at reasonable cost;

a set of criteria against which programmes can be appraised has been developed based on the Wilson & Jungner Criteria is shown in *The NSC Handbook*, see Chapter 6.2;

be delivered within the context of an effective quality assurance programme;

These criteria are not met in any developed country, but the National Screening Committee has the potential to achieve this situation within the UK.

We have, however, inherited a wide range of different programmes and some of the programmes currently being offered to the population are not supported by evidence of the quality that would be required today were a new proposal to be made that they should be introduced. Furthermore, not all of the programmes have a quality assurance system that would allow quality failures to be anticipated, identified and dealt with. For example, the National Breast Cancer Screening Programme has a quality assurance system based on the model developed by Japanese industry in which every individual feels responsible for some aspect of quality but with three essential elements:

explicit quality standards;

an information system that allows performance to be compared with standards;

managerial authority to take action if quality is failing or declining or is not improving fast enough.

Problems in breast cancer screening revealed by the quality assurance process may mandate that local issues need to be addressed, or that national action is necessary, or even that the quality assurance system itself is in need of further strengthening. This has been demonstrated recently in the action taken in both breast and cervical screening programmes following the indication of weaknesses in management of the quality assurance function.

Chapter 3

A Framework for Screening - Part 2

Ethical and social dimensions

3.1 Introduction

'The systematic application of a test or enquiry, 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'

3.1.1 Screening is different from most other forms of health care. For most health care, the patient comes to the clinician, who will offer the treatment available on current knowledge. This may be limited, and it is legitimate for the clinician to say this. In screening, the health service is saying to apparently healthy people, 'come to us, go through this procedure, and there will be a subsequent benefit'. Under those circumstances, it is imperative that the service is able to demonstrate that benefit will follow, and that the collective benefit will outweigh the side effects or the harm from the screening programme.

3.1.2 There are clear criteria for assessing individual screening programmes (see *The NSC Handbook, see Chapter 6.2*), but the nature of screening raises a number of wider ethical and social questions, which this paper addresses.

3.2 Screening in context

3.2.1 Screening should not be seen in isolation, but in the overall context of the health problem to be tackled. The benefits and harm need to be assessed in relation to other ways of approaching the problem. The pressure to introduce a programme may be because the problem is a major one, and the intuitive assumption that '*prevention is better than cure*'. It may also be driven by technology, the ability to carry out the screening, or the development of new treatment techniques or drugs.

3.2.2 There may also be a lack of evidence on the potential for primary prevention, or where there is evidence, a perception that the behavioural changes needed may be difficult to achieve. An overall assessment of the health problem is needed if the response is not to be driven by the technology. The costs of screening, which can be substantial, need to be assessed against the alternative approaches to the problem, such as programmes of primary prevention.

3.2.3 When screening appears to be the appropriate response, it is unknown to find a programme that gives 100% benefit and no harm. In most circumstances, a judgement has to be made about the relative importance of the benefits and side effects. These judgements will inevitably be affected by the values of those making them. In some circumstances, the situation is made more difficult by the incomplete evidence.

3.3 *The purpose of screening*

- 3.3.1** The purpose of the programme needs to be defined. This could be to enable individuals to make better informed decisions about their own health, for example to change their lifestyle or accept treatment. This implies that each individual who attends screening will benefit, and accepts the 'human rights' approach of giving people information about themselves, enabling them to make decisions .
- 3.3.2** The outcome of the programme might also be seen in population terms. It may be to reduce the prevalence of the disease in the community, for the benefit of the community as a whole. For example, this could be by reducing the risk of others contracting the disease, or by reducing the economic burden of caring for those with the problem. The individual may still benefit, but if the benefits of screening have been assessed, for example, in terms of a reduced mortality in the screened population, it may not be clear in advance which individuals will benefit.
- 3.3.3** Whether the programme is defined in this 'human rights' approach, or the 'utilitarian' approach will influence the way a programme is offered and its success measured. In the latter, the success measures might be in terms of uptake and mortality reduction in the screened population. In the former, they might be in terms of the number enabled to make choices, although not all individuals have the same opportunity to make choices, for example in their lifestyle.

3.4 *The nature of the health problem or disease*

- 3.4.1** One of the criteria for assessing screening programmes is that the natural history of the disease should be understood, otherwise apparent benefits could be artefact. For example, an apparent longer survival after screening may be because the disease is identified earlier rather than the prolongation of life. There could still be benefit, in that the treatment needed may be less, and therefore the quality of life may be better. On the other hand, the patient may just be aware they have the disease for longer, which can create anxiety, and sometimes confer other disadvantages.
- 3.4.2** The progression of disease may not be uniform. For example, in cervical cancer, the early changes may regress and not progress onto the disease itself. Therefore, without this understanding, individuals might be subjected to unnecessary treatment. Long term studies are often needed to determine these factors, which may be difficult to balance with the need to respond to pressure to introduce screening.

- 3.4.3** The nature of the disease itself can also cause problems. Some diseases carry stigma, which can create social problems, and if they are associated with the potential for reduced survival, may affect the individual's ability to obtain life assurance and a mortgage. For diseases which are non-fatal, the benefits may be more difficult to define and therefore evaluate.
- 3.4.4** Some screening detects risk factors for a disease, rather than the disease itself. Knowing the 'potential' for the disease can, on the one hand confer benefit, as the individual may be able to take preventive action. On the other hand, it can create anxieties and affect behaviour in a negative way, such as an individual believing they are sick and behaving accordingly.

3.5 *The treatment*

- 3.5.1** One of the criteria for screening is that there should be effective, acceptable and available treatment. This raises its own dilemmas, as most treatment is effective 'to a degree', and may vary amongst different individuals. The long term evaluation of screening is usually in terms of the impact of the disease through treatment, not just the uptake of screening. Therefore, there is an implicit assumption in programmes that those found positive will move on to treatment. Explanations about the risks and benefits are essential, and should recognise psychological and social outcomes as well as clinical ones.
- 3.5.2** Currently, there is the technical ability to carry out some genetic screening, but the potential for treatment is very limited. Individuals may argue that they wish to know if they have the potential for disease, but as there is also the potential for harm, one could question the ethics of offering screening on a population basis.
- 3.5.3** The potential for treatment poses particular problems in antenatal screening. In these programmes, the screening may be to detect a problem in the mother or the foetus. Screening for maternal problems is usually to prevent the problem affecting the child, although it may also affect her own health. For example, screening for rhesus factors enables treatment of the baby, and so avoids major illness in the child. It may also avoid potential problems later for the mother.
- 3.5.4** However, some maternal screening is aimed at identifying 'abnormalities' in the foetus. For many of these problems, there is little 'treatment' to be offered, and certainly not before birth. Therefore, the aim is to let the mother know that there is a potential or actual 'abnormality' in her foetus. She can then choose whether or not to request a termination. This is one of the conditions under the Abortion Act.
- 3.5.5** This is always a difficult decision for the mother. As treatment for hitherto untreatable conditions becomes better, possibly even in utero, the question as to what constitutes an abnormality may be more difficult.

3.6 *The test*

- 3.6.1** Any test will find true and false positives, and true and false negatives. An ideal test only finds true positives and true negatives. In practice, this is rarely possible, and there is a trade off between not missing real cases (sensitivity) and not finding false cases (specificity). It is because screening is rarely precise that much of the potential for harm may come.
- 3.6.2** For the people who are ‘true positive’ there may be treatment benefits, but there may be stigma associated with the disease. The people who are ‘false positive’ may go through unnecessary further investigations, and even treatment, which may carry side effects, none of which will confer benefit.
- 3.6.3** For the people who are ‘true negative’, there is the potential benefit of reassurance. However, this could have the disadvantage of giving them a false sense of security. For example, in breast screening, the test only shows that the disease is not detectable at the time of the test. It does not, as some may think, mean that the disease cannot develop, which may prevent some from seeking help at an early stage with symptoms. A negative test can also leave the individual with the belief that their current ‘health’ behaviour is not harmful, which again may not be true.
- 3.6.4** For people who are ‘false negative’, there are a number of potential problems. As symptoms of the disease develop, the individual may ignore them as they have been reassured they do not have the disease. This may result in treatment being offered at a late stage, with the attendant difficulties. If the test is to identify risk factors for disease, the individual may again continue with poor health behaviour.

3.7 *Delivering the programme*

- 3.7.1** Screening is more than applying a screening test. It is a programme, which needs clear management, monitoring and quality assurance. Those offered screening must be able to make informed choices, and have their decisions respected. It must not be assumed that once an individual has entered a programme, they must automatically move onto to the next stage, for example for a more definitive diagnosis or treatment. If the purpose of the screening is for a benefit to the community, it should not be at the expense of the respect for the individual.

3.8 *Conclusion*

- 3.8.1** The problems in assessing screening come mainly from the incomplete knowledge of disease and treatment, and the imprecise nature of screening. Those offering screening must be able to draw up a table of benefit and harm, and demonstrate that the benefits to the population or individuals outweighs the harm. However, benefit and harm are not absolute values, and their perception may depend on individual, cultural and religious beliefs, and they may change over time. In deciding on a screening programme, these ethical issues must sit alongside the scientific evidence.

Chapter 4

The Research Base of Screening

The NHS has an R&D Programme which has been set up to produce the knowledge that decision-makers need for evidence-based decision-making. One important part of this R&D is the Health Technology Assessment Programme, which is chaired by Professor Sir Miles Irving, and one of its working groups is the Population Screening Panel. Work of this Panel, which is currently in progress, is shown in *Chapter 4.1*, complements the well established and high quality work programmes of the Medical Research Council (MRC). The current MRC research programme into screening is shown in *Chapter 4.2*.

In addition to the work commissioned through the Population Screening Panel and work funded by the MRC there is a considerable amount of research evidence that is forthcoming from other funding organisations in the UK and abroad. To keep abreast of new developments the NSC monitors the research literature and responds to significant new findings from any recognised research establishment or country. Crucial to this role is the horizon scanning work of the NHS Managing Clinical Innovations Group which highlights to the NSC where new technologies are likely to make an impact on the screening services.

Whatever the new or modified technology, the NSC will require that the introduction of, or modification to, screening programme should satisfy all the conditions identified in The NSC Handbook, see Chapter 6, namely the Criteria, Format and the Strategic Framework for Quality Assurance.

4.1 The Health Technology Assessment Programme

The Health Technology Assessment Programme was established by the Department of Health in 1993. It is one of the largest elements of the NHS's Research and Development Strategy and makes an important contribution to the development of a knowledge-based NHS.

The programme aims to ensure that high quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most economical way for those who use, manage and work in the NHS.

Potential questions are prioritised by six panels of experts who advise on acute care, population screening, primary and community care, diagnostics and imaging, pharmaceuticals and methodology of health assessment. By mid 1997, some 240 important research questions had been identified and more than 110 research projects had been commissioned to help answer these.

Health technology assessment seeks to meet the information needs of those who make decisions and policy. Close links have been established between the Population Screening Panel of the HTA and the National Screening Committee.

The following screening reports have already been published (or are expected to be published by the end of 1997) in the HTA monograph series. Executive summaries of these reports and further information about the programme can be found at our website on www.soton.ac.uk/~wi/hta.

Published papers

Selley S, Donovan J, Faulkner A, Coast J, Gillatt D. Diagnosis, management and screening of early localised prostate cancer. *Health Technol Assess* 1997; 1 (2).

Chamberlain J, Melia J, Moss S, Brown J. The diagnosis, management, treatment and costs of prostate cancer in England and Wales. *Health Technol Assess* 1997; 1 (3).

Murray J, Cuckle H, Taylor G, Hewison J. Screening for Fragile X syndrome: information needed for health planners. *Health Technol Assess* 1997; 1 (4).

Snowdon S, Stewart-Brown S. Preschool vision screening: results of a systematic review. *Health Technol Assess* 1997; 1

Pollitt R, Green A, MacAbe C, Booth A, Cooper N, Leonard J, Nicholl J, Nicholson P, Tunaley J, Viridi N. Neonatal metabolic screening: cost, yield and effects on outcome. *Health Technol Assess* 1997; 1

Davis A, Bamford J, Wilson I, Ramkalawan T, Forshaw M, Wright S. A critical review of the role of neonatal screening in the detection of congenital hearing impairment. *Health Technol Assess* 1997; 1.

Wald N, Kennard A, Hackshaw A, McGuire A. Antenatal screening for Down's syndrome. *Health Technol Assess* 1997; 1.

Thomason M, Lord J, Chalmers R, Littlejohns P, Seymour C, Bain M, Addison G, Wilcox A, Cockburn F. Newborn screening for inborn errors of metabolism. *Health Technol Assess* 1997; 1.

NHS Centre for Reviews and Dissemination. Screening for ovarian cancer: a systematic review. *Health Technol Assess* 1997; 1.

Research projects commissioned by the HTA programme

The following research projects have been commissioned by the HTA programme and are currently ongoing:

Title	Design	Aims of Study
An assessment of screening for the fragile X syndrome.	SR	A critical review in order to inform an assessment of what screening approach, if any, would be more effective than the current genetic service for families.
Information Needs for Health Planners: screening for cystic fibrosis.	SR	Will include (1) genetic screening to identify high risk couples, and (2) biochemical screening of neonates. A decision analysis will be prepared for planners to compare options.
A policy for the drug treatment of high blood pressure.	SR	A systematic review of scientific evidence of methods of improving the detection and management of high blood pressure will be conducted.
Screening for stroke.	SR	To summarise the benefits of lowering blood pressure (in ten-year age groups and in strata of "cut-off" levels of systolic and diastolic blood pressure).
Child Health surveillance: an evaluation of screening for language delay.	SR	An evaluation of screening for language delay.
Cost analysis of child health surveillance	SR	The aims of this project are: (i) to estimate the total cost of the Child Health Surveillance programme and to investigate the impact of differences in organisation on total cost and (ii) to provide an estimate of the costs of each component in the programme.
Universal antenatal HIV testing: acceptability, costs and benefits	PR	A randomised multi-intervention trial assessing different approaches to testing, compared with a control group.
Screening for haemoglobinopathies in the UK: review and economic analysis.	SR	A systematic review will be carried out of current models of preconceptional, antenatal and neonatal screening practice for haemoglobinopathies in the NHS.
Haemoglobinopathy: Information needed for health planners.	SR	To undertake a systematic review of the current evidence relating to screening for the haemoglobinopathies. This will encompass costs, benefits and outcomes, as well as acceptability and uptake.
Informed decision making in health care.	SR	A structured search and review of the literature of comparative studies of informed decision making interventions in health care.
SURUSS (serum, urine and ultrasound screening study).	PR	A national, observational study of first and second trimester Down's syndrome to assess the individual and combined performance of serum, urine and ultrasound markers in the first trimester of pregnancy.
Acceptability, benefit and costs of early screening for hearing disability.	PR	Pilot to inform a randomised controlled trial on the early provision of hearing aids for the over 60s, evaluating various screening methods.
Cross cutting issues, the implication of false negatives.	SR	Systematic review of research into the implications (medical, psychological, economic) of receiving a false negative in a screening programme.

PR = Primary research

SR = Systematic review

4.2 The Medical Research Council

The Medical Research Council has supported research into screening technologies for many years. This has been done in close partnership with the Health Departments, through the arrangements described in the MRC/HDs Concordat. For some screening research, MRC has been co-funding with other bodies, most notably with the Cancer Research Campaign and the Imperial Cancer Research Fund for the breast screening trials conducted under the auspices of the United Kingdom Coordinating Committee on Cancer Research (UKCCCR).

Suggestions for research on screening come from the academic community (in response- mode), from the Council's own strategic discussions, or from discussions with the Health Departments and the NHS R&D Programme. Applications for funding are considered by one of the Council's Research Boards in competition with other requests for support across the whole of the Council's remit. Decisions are taken by Council itself.

In addition to supporting research on specific screening methods and programmes, the MRC also supports a large body of underpinning research (e.g. on disease causation and biological markers) which may inform the development of future screening technologies.

The following research projects in the field of screening have received Council support over the past five years.

Title	Design	Aims of study	Status at Aug 1997
Assessment and management of elderly people in the community - a multi-centre controlled trial	PR	To establish the effectiveness and cost-effectiveness of different approaches to screening people over 75 in the community and to the subsequent assessment and management of cases as being in need of follow-up.	O
A multi-centre RCT of the relative values of yearly versus three-yearly screening by mammography (UKCCCR)	PR	To establish the cost-effectiveness of screening at yearly intervals, instead of three-yearly as at present.	O
A trial to study the effect on breast cancer mortality of annual mammographic screening starting at age 40 (UKCCCR)	PR	To establish the cost-effectiveness of starting screening at age 40 instead of at age 50 as at present.	O
A multi-centre trial of 1- and 2-view mammography in breast cancer screening (UKCCCR)	PR	To establish the cost-effectiveness of screening with two views (oblique and craniocaudal), instead of with one view only (oblique).	P(i)
Effect of hormone replacement therapy on the efficacy of mammographic screening	PR	To provide a reliable estimate of the effect of HRT use on the sensitivity and specificity of mammography and of its contribution to the interval cancer rate in the NHS breast screening programme.	O
National multi-centre study of magnetic resonance imaging	PR	To compare the sensitivity and specificity of contrast-enhanced MRI	O

screening in women at genetic risk of breast cancer		with double view X-ray mammography in women below the age of 50 at high genetic risk of breast cancer.	
An RCT of faecal occult blood screening for colorectal cancer	PR	To determine whether Haemoccult faecal occult blood screening test, when offered to the population aged 50-75 reduces the mortality of colorectal cancer.	P(ii)
Multi-centre RCT of 'once-only' flexible sigmoidoscopy screening in prevention of bowel cancer morbidity and mortality	PR	To quantify the reduction in incidence and mortality from colorectal cancer resulting from a single sigmoidoscopy screen at age 55-64 years with colonoscopy surveillance for those found to have high-risk polyps.	O
Multi-centre aneurysm screening study	PR	To assess the effect of a single screening episode by ultrasonography for abdominal aortic aneurysm in men aged 65-74 on (i) mortality from, and incidence of, ruptured AAA, (ii) NHS costs, (iii) quality of life, (iv) surgical workload.	O
Ultrasound imaging in the management of clinical neonatal hip instability - an RCT	PR	To assess the clinical effectiveness of a policy of ultrasound imaging to guide the decision about whether to initiate treatment for clinical hip instability in neonates.	O
Cost-effectiveness analysis of screening for congenital hip dislocation to help prioritise and plan a clinical trial	PR	To undertake a cost-effectiveness analysis of screening for CDH in early infancy, with particular reference to the current UK policy of universal clinical screening, and to identify key areas of uncertainty to be addressed in further primary research.	O
Evaluation of two interventions to improve explanation to patients of a routine prenatal screening test	PR	To evaluate the effects of two brief training interventions to improve obstetricians' and midwives' information - giving and communication skills in the presentation to patients of a routine prenatal test for Down's Syndrome and spina bifida.	P(iii)
Effects upon parents of false negative results on prenatal serum screening for Down's Syndrome	PR	To determine whether there is a need for pre- or post-natal interventions to prevent or ameliorate any adverse effects for parents of receiving false negative results on prenatal screening for Down's Syndrome.	O
Carrier screening for cystic	PR	To compare the delivery and	P(iv)

fibrosis in couples		acceptability of "couple screening" for CF carrier status with those of "two-step screening", in antenatal clinics.	
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PR = Primary Research

P = Published

O = Ongoing

i) BMJ (1995) 311: 1169-93

ii) Lancet (1996) 348: 1472-77

iii) Prenatal Diagnosis (1995) 15: 317-24

iv) BMJ (1994) 308: 1459-62

Chapter 5

Developing Policy and Improving Quality

Having developed a framework for screening, the future work of the National Screening Committee will be focused on two key areas - developing policy and improving quality.

5.1 *Developing policy*

The National Screening Committee advice to Ministers and the Executive Boards of the NHS across the UK on screening policy has been a key step toward having a clear and open position on what screening services ought to be provided through the NHS.

There are principally four policy options that can be considered when the Committee is satisfied that it has available a synthesis of the best evidence available:

the proposed programme should not be introduced;

the proposed programme should be introduced, provided that the resources, both financial and human, are available to ensure adequate quality standards;

the programme that is currently being offered to the population should be stopped;

the policy for a programme currently being offered to the population should continue unchanged or be revised.

When recommendations are made concerning proactive screening programmes careful thought is given to assess whether or not the advice should extend to opportunistic screening. It is foreseeable that programmes may be introduced on a national basis or where local health needs determine, but care is needed to ensure that localised approaches to screening services do not lead to inadmissible variations or inequalities.

In the year to 31 March 1997 the National Screening Committee considered evidence about the effect of screening on the health problems listed below:

breast cancer,
colorectal cancer,
hepatitis B in pregnancy
prostate cancer.

The Committee recommended to Ministers:

- accepted the NSC recommendation that prostate cancer screening should not be introduced until further evidence showed there to be a reliable test for screening purposes .
- accepted the NSC's recommendation to introduce universal screening for Hepatitis B in pregnancy; the submission to Ministers in Scotland is currently being finalised. The NHS Executive Board have accepted the proposal that health authorities be asked to implement this programme from their available resources by a proposed target date of April 2000

Work continues on colorectal cancer and in further refinements to the breast cancer screening programme. In the forthcoming year, the Committee will have to consider evidence about the benefits, risks and costs of screening for conditions currently being investigated by research workers commissioned by the Health Technology Assessment Programme (see *Chapter 4.1*).

5.2 *Improving quality*

The three prerequisites for effective quality assurance i.e. that of having explicit quality standards, an information system that allows performance to be compared with standards and managerial authority to take action if quality is failing or declining or is not improving fast enough, are set out in Chapter 2.3. The National Screening Committee's policy will be to oversee the development of effective quality assurance for all the screening programmes that are currently offered the population. At present the effectiveness of quality assurance varies from programme to programme and the Committee heard in its first year's work reports from those programmes in which there are comprehensive QA systems in place, namely:

the Neonatal PKU (phenylketonuria) Screening Programme,
the Neonatal Hypothyroidism Screening Programme,
the Breast Cancer Screening Programme,
the Cervical Cancer Screening Programme.

In the course of 1997/8 the Breast and Cervical Screening programme's quality assurance arrangements have been the subject of further in depth review, following incidents in Exeter (breast) and Kent and Canterbury (cervical). These have led to extensive revision of the management arrangements for quality assurance in both programmes.

Using these as models the National Screening Committee will be promoting the development of quality assurance in all of the screening programmes currently on offer to the public and as part of this process will be identifying and strengthening the different contributions of the clinicians, managers, commissioners and the public involved in screening. The Committee is also currently reviewing the quality assurance arrangements for a number of other programmes and in particular a strategic framework for quality assurance of population screening programmes can be found in the *NSC Handbook* at *Chapter 6.4*.

References

1. Calman K. Developing Screening in the NHS.
Journal of Medical Screening (1994); 1: 101-105
2. CANADIAN MEDICAL ASSOCIATION (1994)
Canadian Guide to Clinical Preventive Health Care
Minister of Supply and Services Canada
ISBN 0-660-15732-2
3. US PREVENTIVE SERVICES TASK FORCE (1996)
Guide to Clinical Preventive Services
Williams & Wilkins, Baltimore. ISBN 0-683-00237-6

Chapter 6

The NSC Handbook of Population Screening Programmes - First Edition

6.1 Introduction

The introduction of the NSC Handbook for population screening programmes is the Committee's first attempt at specifying the most important issues for defining and managing any screening programme; it is expected that this handbook will be updated on at least an annual basis. The Committee has already planned for the next edition to contain standards for specific programmes and, in particular, work is already in progress on defining UK standards for both antenatal, neonatal and child health surveillance screening programmes. Whilst the main sections of the present handbook are concerned with the Criteria, Format and the Strategic Framework for Quality Assurance it must not be forgotten that the major components of any screening programme have to fall within the Framework for Screening as outlined in Chapters 2 & 3 of this report, particularly with respect to the ethical considerations.

6.2 *The Criteria*

The 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 (2) and the United States (3).

Ideally all the following criteria should be met before screening for a condition is initiated:

The condition

- 6.2.1 The condition should be an important health problem.
- 6.2.2 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.

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

The test

- 6.2.4** There should be a simple, safe, precise and validated screening test.
- 6.2.5** The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed.
- 6.2.6** The test should be acceptable to the population.
- 6.2.7** 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

- 6.2.8** 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.
- 6.2.9** There should be agreed evidence based policies covering which individuals should be offered treatment and the appropriate treatment to be offered.
- 6.2.10** 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

- 6.2.11** There should be evidence from high quality Randomised Controlled Trials that the screening programme is effective in reducing mortality or morbidity.
- 6.2.12** 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.
- 6.2.13** The benefit from the screening programme should outweigh the physical and psychological harm (caused by the test, diagnostic procedures and treatment).
- 6.2.14** The opportunity cost of the screening programme (including testing, diagnosis and treatment) should be economically balanced in relation to expenditure on medical care as a whole.
- 6.2.15** There should be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards.
- 6.2.16** Adequate staffing and facilities for testing, diagnosis, treatment and programme management should be available prior to the commencement of the screening programme.
- 6.2.17** All other options for managing the condition should have been considered (e.g. improving treatment, providing other services).

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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.

6.3 *The Format*

A recommended format for systematic reviews

The National Screening Committee has now identified the questions that it requires answered when considering a screening programme, whether that programme is already being offered to the population or proposed for introduction. These questions are designed to help the National Screening Committee prepare and formalise the criteria of a screening programme, which can then be compared to the criteria (*see Chapter 6.2*) that they have developed. This will then enable an objective assessment to be made on the balance of benefit to harm to cost for any particular programme.

- 6.3.1** Executive summary.
(set out under the criteria for appraising screening programmes)

Introduction

- 6.3.2** Purpose of the proposed screening programme - "Why screen for this disease?"
(a single paragraph)

- 6.3.3** Systematic review method:-

- i.* What question did the review address?
- ii.* Which populations were included/ excluded?
- iii.* Which bibliographic databases were searched?
- iv.* Review strategy (e.g. keywords/ MeSH searched).
- v.* Reference list follow up, personal contacts.
- vi.* Search for unpublished/ ongoing/ Non-English language studies.
- vii.* What inclusion/ exclusion criteria were used for the studies?
- viii.* How was the quality of the studies assessed?
- ix.* What was the overall quality of the studies?
- x.* Were the results from the studies combined? How was this done?

The health problem

- 6.3.4** Natural history of the disease.
(including pathways of disease transmission, early symptomatic stage, recognisable latent period, disease markers)

- 6.3.5** Epidemiology of the disease:-

- i.* Incidence, prevalence and projected trends.
- ii.* Mortality, morbidity and burden of disease by age/sex.
- iii.* "Is this an important health problem in comparison to other diseases?"

- 6.3.6** Primary prevention of the disease:-

- i.* What are the opportunities/ interventions for the primary prevention of the disease?
- ii.* How effective are these primary prevention interventions and what is the quality of the evidence?

Current policy and practice

6.3.7 What is the current UK policy on screening for the disease?

6.3.8 Describe the current UK service (if any).

The screening test

6.3.9 The screening test:-

- i.* Describe the main screening tests and what they involve? What alternative tests are under consideration?
- ii.* For each test, what is the distribution of test values in the target population? What is a suitable cut-off point and has this cut off point been defined and agreed? Is there agreement on what constitutes a normal/abnormal/borderline test result?
- iii.* For each test, what is the sensitivity, specificity, likelihood ratios for continuous test results and what is the quality of the evidence?
- iv.* What are the side effects/ harmful effects of each test?
- v.* What is the acceptability of each screening test and what is the quality of the evidence?

The diagnostic process

6.3.10 Diagnostic procedures:-

- i.* What is the sequence of events for those who are positive/ borderline on testing? (describe the diagnostic process for positive/ borderline individuals and the choices available to those individuals). Is there an agreed policy on this sequence of events?
- ii.* What are the diagnostic procedures and what do they involve?
- iii.* What are the side effects/ harmful effects of each diagnostic procedure?
- iv.* What is the acceptability of each diagnostic procedure and what is the quality of the evidence?

6.3.11 Is there an agreed policy as to which individuals should be offered treatment? State the policy.

The treatment

- 6.3.12** What are the treatments/interventions and what do they involve?
- i.* What is the effectiveness of each intervention and what is the quality of the evidence? Is there evidence that the treatment of patients identified through early detection leads to better outcomes than late treatment?
 - ii.* What are the side effects/ harmful effects of each intervention?
 - iii.* What is the acceptability of each intervention and what is the quality of the evidence?
 - iv.* Is the quality of treatment and patient outcomes consistently high in all health care providers or is there evidence of variation in quality of care/ patient outcomes?

The screening programme

- 6.3.13** What is the target population to whom screening will be offered?
- i.* What proportion of potential cases are in the target population?
 - ii.* What will be the positive rate at first screening?
 - iii.* How best can the population be identified and targeted?
- 6.3.14** What is the proposed screening interval? (frequency with which the test is to be repeated).
- i.* Describe the evidence on interval disease progression and the rationale behind the proposed screening interval.
- 6.3.15** What level of patient uptake is required? (based on available evidence).
- 6.3.16** Present a decision analysis diagram of the pathway through the screening programme (from test to diagnosis to treatment/ recall).

Beneficial effects

- 6.3.17** What are the benefits of screening for the disease?
- i.* What is the relative risk for the screened population compared to the control population? (for all cause and disease specific mortality/morbidity).
 - ii.* What is the absolute risk reduction? (for all cause and disease specific mortality/morbidity).
 - iii.* How does the benefit as a result of screening compare to that achieved in other screening programmes?

Adverse effects

6.3.18 What is the harm caused by the screening programme? (including consequences of false positive, false negative, borderline results).

- i.* The physical harm.
- ii.* The psychological harm.

Absolute considerations

6.3.19 For every 100,000 individuals screened:-

- i.* How many cases will be missed? (under-detection).
- ii.* How many will be treated? How does this compare to the number who would actually develop significant disease in a control group who were not offered screening? (over-detection).
- iii.* How many of the treated individuals will actually be helped? (i.e. In what proportion of screen-detected cases is an outcome improved?).
- iv.* How many individuals will be classified as borderline cases and what will happen to them?

6.3.20 Numbers needed to screen:-

- i.* How many people have to be screened in order to find one treatable case?
- ii.* How many people have to be screened in order for one person to benefit?
- iii.* How many people are made anxious for each treatable case found? (false positives and untreatable true positives).
- iv.* How many people are made anxious for one person to benefit?
- v.* How many people are physically harmed for each treatable case found?
- vi.* How many people are physically harmed for one person to benefit?
- vii.* How many people are made anxious per 1000 persons screened?
- viii.* How many people are physically harmed per 1000 persons screened?
- ix.* How broad are the confidence intervals around the estimated size of the beneficial effect, and what are, at each end of the confidence intervals:-

The number needed to screen.
The number adversely affected.

Economic considerations

6.3.21 The costs of the screening programme:-

- i.* State the anticipated costs of the following if the screening programme was set up for a standard UK total population of 10 million:
 - a.* Set up costs.
 - b.* Staff training.
 - c.* The call up procedure.
 - d.* The counselling.
 - e.* The tests (and repeat tests).
 - f.* The diagnostic procedures.
 - g.* The intervention and follow up.
 - h.* The total set up and annual revenue/ capital costs in order to deliver the programme for a standard UK population of 10 million.
- ii.* What is the cost of finding one treatable case?
- iii.* What is the cost in order for one person to benefit?

6.3.22 What are the potential savings which might result from the screening programme?

6.3.23 What is the cost-effectiveness of the screening programme (and on what evidence is this based?).

6.3.24 Cost-benefit/-utility analysis and sensitivity analysis of screening for the disease.

- i.* What is the cost per QALY gained as a result screening?
(The £ per QALY).

6.3.25 What implications does the screening programme have for other services?

Staffing and facilities

6.3.26 What are the clinical staffing implications of the screening programme? What will be the staffing requirements in order to introduce the screening programme for a standard UK total population of 10 million? Are sufficient numbers of clinical staff currently available or will further recruitment/training be required?

6.3.27 What facilities will be required in order to introduce the screening programme for a standard UK total population of 10 million?

Alternative options

- 6.3.28** What are the alternative policy options to screening?
- i.* What are the other ways of managing this health problem? (e.g. improving the treatment, providing other services).
 - ii.* How does the level of benefit as a result of screening compare to the benefit which could be achieved by improving treatment alone?

Quality management

- 6.3.29** Who should manage the screening programme?
- 6.3.30** Quality assurance:-
- i.* How should quality assurance be managed and monitored?
 - ii.* What quality assurance standards should be recommended?
- 6.3.31** Describe an outline of the proposed service (equipment, siting, training, information needs of patients).
- 6.3.32** What are the critical success factors for the successful implementation of the screening programme?

Research

- 6.3.33** What relevant research is currently in progress?
- 6.3.34** Identify key areas for further research.

Conclusions

- 6.3.35** Conclusions:-
- i.* General conclusions.
 - ii.* Conclusions on each of the criteria for appraising screening programmes (see *The NSC Handbook: see Chapter 6.2*).
 - iii.* The grade of the overall evidence for the screening programme is:-
 - A:** Robust evidence that benefit outweighs harm.
 - B:** Evidence that benefit outweighs harm.
 - C:** Evidence of both benefit and harm.
 - D:** Evidence that harm outweighs benefit.
 - E:** Robust evidence that harm outweighs benefit.
 - F:** Insufficient or inadequate evidence about benefit and harm.

6.4 A Strategic Framework for Quality Assurance

Screening programmes can only be effective if there is a coherent, coordinated, and consistent approach to Quality Assurance (QA). Recent events at Exeter, Kent and Canterbury, and elsewhere have illustrated that quality is not an aspect of the screening services that can be taken for granted. Robust approaches are necessary to ensure that quality assurance methodologies are in place and are being used. Furthermore flexibility is required to allow development to best fit local circumstances but which ensures a consistent and acceptable standard of service.

The NSC has acted promptly on two fronts. It has responded to the recent concerns over quality in breast cancer and cervical cancer screening and through the Cancer Screening Action Group agreed specific measures for addressing issues in and around the two national cancer screening programmes. In addition, over the forthcoming months the NSC will be developing a strategic framework for evaluating QA arrangements for population screening programmes. An initial version of this is set out below, subject to revision as the development work continues. The details of individual QA systems need to be considered on a programme by programme basis and will encompass lessons learned from the existing cancer programmes.

6.4.1 A quick response to concerns over QA in the Cancer Screening Programmes

In response to the failures in the cancer screening programmes at Kent and Canterbury and at Exeter, the Secretary of State ordered wide ranging action to strengthen quality assurance in the cancer screening programmes. In particular:

- * a review of all breast and cervical screening programmes and action plans by end February 1998 to address any weaknesses;
- * responsibility and resources for quality assurance to be removed from lead purchasers and restored to regional offices.

The action was set out in Executive Letter (97)67 and progress is being checked regularly.

In the light of subsequent events at Rugby, Ministers agreed an action plan to further strengthen the cervical cancer screening programme. In particular all laboratories undertaking cervical screening must apply for accreditation within the next six months. This further action was set out in Executive Letter (97)83 and is being monitored by a high level Action Team.

Given:

- * the problems which occurred, and are now being addressed, in the cervical and breast screening services; and
- * a perception that the quality assurance arrangements for other screening programmes may need to be strengthened,

the National Screening Committee has made proposals for a Quality Assurance Framework to cover all population screening programmes.

6.4.2 National criteria for QA systems

The NSC's criteria against which screening programmes are appraised include the stipulation that there should be a plan for managing and monitoring each programme and an agreed set of quality assurance standards.

Key Criteria

The key criteria for QA systems for screening programmes should be the existence of:

- * explicit quality standards;
- * monitoring systems to allow performance to be compared with those standards;
- * clear lines of managerial authority to take action if quality is failing, declining or not improving fast enough.

EL(96)110 (Improving the effectiveness of clinical services, 18/12/96) endorsed the recommendation of the NSC that "new screening programmes should not be introduced or expanded until reviewed, evaluated and proven effective". In addition, under the strategic framework for QA:

- * no screening programme should be set up in the NHS unless it includes a QA system which meets the criteria set out above
- * all national screening programmes should be aiming to meet these minimum criteria;
- * Health Authorities should ensure that local QA systems for existing non-national screening programmes meet these criteria.

Additional criteria

All existing and planned national screening programmes should be working towards QA systems which also meet the following additional criteria, now adopted for breast and cervical cancer screening:

- * any UK screening programme must operate to UK standards;
- * lines of accountability and funding flows should be aligned;
- * clear accountability should be established at all (national, regional and local) levels and that this should be supported by information flows to allow effective performance management at each level;
- * the advisory and management functions in QA should be clearly distinguished.

6.4.3 Further development work

Further work to develop the strategic framework will cover the following aspects of QA:

- * performance indicators (working within the *Performance Development Framework* - now out to consultation);

- * national standards; (working with the proposed **National Institute for Clinical Excellence** as set out in the White Paper *The New NHS- Modern -Dependable*)
- * management systems;
- * information systems;
- * quality promotion.

6.5 An Inventory of Screening Programmes

SCREENING PROGRAMMES	UK POLICY
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PROGRAMMES WHERE CURRENT GUIDANCE EXISTS

Breast cancer	all women aged 50-64 invited once every 3 years; women over 65 on request.
Cervical cancer	all women aged 20-64 invited once every 5 years.
Phenylketonuria	all neonates.
Congenital hypothyroidism	all neonates.
Physical examination	all neonates.
Child health screening	GMS Regulations.
Cardiovascular risk factor screening	GMS Regulations: newly registered patients and patients not seen within 3 years.
Elderly - general assessment	GMS Regulations: patients aged 75 years and over assessed every 12 months.
Bladder cancer	occupational exposure.
HIV antibody	PL/CO(92)5: all women receiving antenatal care.

EXPLICIT POLICY NOT TO OFFER

Prostate cancer	Executive Letter (97)12 which appears as Appendix B.
Neuroblastoma	

UNDER CURRENT REVIEW OR PLANNED FOR REVIEW WHEN EVIDENCE IS AVAILABLE

Aortic aneurysm Chlamydia trachomatis Colorectal cancer Hepatitis B in pregnancy	Awaiting outcomes from other research programmes
Cystic fibrosis Down's syndrome Diabetic retinopathy Fragile X syndrome Haemoglobinopathies Inborn Errors of Metabolism Ovarian cancer	Awaiting outcomes from systematic reviews from the HTA programme; see Chapter 4.1 for additional details, the expected timescales range from the present time until 2001.

Note: *Whilst it is recognised that many health authorities have taken the decision to introduce screening programmes for diseases, other than those listed above, for the benefit of their local populations, at present no UK national policy exists for these programmes. Many are currently either under review or exist as part of research programmes. However, no further screening programmes should be introduced except where high quality research is used to demonstrate clinical effectiveness.*

Appendix A

National Screening Committee:

The Remit and Terms of Reference of the NSC

The remit and terms of reference of the National Screening Committee are:

- (i) The UK National Screening Committee 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 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.
- (ii) 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 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.
- (iii) 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.
- (iv) 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.

National Screening Committee:

Membership

Chairman:

Sir Kenneth Calman

Chief Medical Officer

Secretary:

Dr Timothy Riley

NHS Executive, Head of Outcomes and Effectiveness, NHS Public Health and Development Unit including lead on National Screening Policy.

Programme Directors:

Dr Muir Gray

Regional Director of Research and Development - NHS Executive (Anglia and Oxford). Links with the Faculty of Public Health Medicine and FPHM screening groups.

Dr Pat Troop

Regional Director of Public Health Medicine - NHS Executive (Anglia and Oxford). Public Health expertise.

Members:

Dr J Gordon Paterson

Director Public Health and Health Development - Grampian Health Board (Scotland) - Chairman of Ministerial Advisory Committee on breast screening.

Dr Susanna Lawrence

General Practitioner and member of Leeds Health Authority. Primary Care expertise.

Mr Robin Simpson

Deputy Director National Consumer Council. Service user input and expertise.

Mr Colin Reeves

Director of Finance and Performance (NHS Executive) Link with NHS Executive Board and resource allocation.

Mr Clive Smee

Chief Economic Adviser, Department of Health - Economic and Operational Research Division (NHS Executive). Link with economic consideration.

Ms Polly Toynbee **Journalist. Ethics interests and links with the public domain.**

Ms Pippa Gough

Assistant Director/Nursing in the Department of Nursing. The Royal College of Nursing.

Professor Sir John **Member of Medical Research Council and based at The**
Grimley Evans **Radcliffe Infirmary, Oxford (Department of Geriatric Medicine).**
Chairman of Population Screening Panel on Standing Group on
Health Technology Assessment Programme.

Sir David Carter **Chief Medical Officer - Scottish Office.**

Dame Deirdre J Hine **Chief Medical Officer - Welsh Office.**

Dr Henrietta Campbell **Chief Medical Officer - Northern Ireland Office.**

Dr Philip Milner **Director of Public Health - Wiltshire Health Authority.**

Observers:

Dr Tony Peatfield **Secretary to the Health Services and Public Health Research Board, The**
Medical Research Council.

Professor Newell Johnson **Head of RCS Department of Dental Sciences, King's College Dental School.**
Primary Dental Care expertise.

Miss Lesley Best **Researcher to the Population Screening Panel, Wessex Institute for**
Health Research and Development, NHS R&D national Co-
ordinating Centre for Health Technology Assessment.

Secretariat:

Dr Robert Sherriff **Senior Registrar, Public Health Medicine, NHS Executive (Anglia and**
Oxford).

Mrs Ann Dixon-Brown **Committee Secretary to the National Screening Committee, NHS**
Executive (Anglia and Oxford).

Executive Letter on Population Screening for Prostate Cancer

To: Health Authority Chief Executives
NHS Trust Chief Executives

Copy: Trust Medical Directors
Trust Directors of Nursing
District Directors of Public Health
Regional Directors
Regional Directors of Public Health
Regional Directors of Research and Development
Regional Directors of Nursing
Regional Directors of Performance Management
CHC Chief Officers
Patient and professional contacts
General Practitioner Fund Holders

EL(97)12

June 1997

Dear Colleague

Population Screening for Prostate Cancer

Summary

1. Population screening for prostate cancer, including the use of prostate specific antigen (PSA) as a screening test, should not be provided by the NHS or offered to the public until there is new evidence of an effective screening technology for prostate cancer. Screening, for the purposes of this Executive Letter, is defined as the application of a test or inquiry to identify individuals at sufficient risk of a specific disorder to warrant investigation or direct preventive action, amongst persons who have not sought medical attention on account of symptoms of that disorder.¹

Background

2. Two systematic reviews commissioned by the NHS Research and Development Health Technology Assessment Programme^{2&3} have concluded that current evidence does not support a national screening programme for prostate cancer in the United Kingdom.
3. Current screening technologies (including the PSA test) have a limited accuracy that could lead to a positive result for those without the disease. Follow up procedures could thus cause unnecessary harm to healthy individuals. The introduction of a prostatic cancer screening programme at present carries an unacceptable risk of more harm resulting than good.
4. The National Screening Committee has considered the evidence for introducing screening for prostate cancer and concluded that at this time and with current technology, there is no evidence of benefit resulting from population screening. This recommendation has been accepted by Department of Health Ministers.

5. Health Authority and General Practitioner Fund Holders are asked not to introduce or plan the purchase of population screening for prostate cancer until the National Screening Committee recommends an effective and reliable procedure.
6. This Executive Letter does not affect the clinical management of men presenting with symptoms of prostatic disease.

**DR GRAHAM WINYARD
DIRECTOR OF HEALTH SERVICES
NHS EXECUTIVE**

References

1. Adapted from: Wald NJ. Guidance on terminology. *Journal of Medical Screening* 1994;**1**:76.
2. Selley S, Donovan J, Faulkner A, Coast J, Gillatt D. Diagnosis, management and screening of early localised prostate cancer. *Health Technology Assessment* 1997;**1** (2).
3. Chamberlain J, Melia J, Moss S, Brown J. The diagnosis, management, treatment and costs of prostate cancer in England and Wales. *Health Technology Assessment* 1997; **1** (3).

This letter will be cancelled on 30 June 1999.

Additional copies of this letter are available from:

The NHS **Responseline**
Telephone: 0541 555 455

For further information about this Executive Letter contact Dr Robert Sherriff, NHS Executive, Anglia and Oxford Regional Office, 6-12 Capital Drive, Linford Wood, Milton Keynes MK14 6QP. Tel: 01908 844526.

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Contact Points for further information or for comments on this report:-

Further information about this report and updates on the work of the National Screening Committee can be found on the Department of Health website:- <http://www.open.gov.uk/doh/nsc/nsch.htm>

For further information about disease specific programmes contact Mrs Ann Dixon-Brown,

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