

Historical background, current definitions and criteria

Complete freedom from disease is almost incompatible with the process of living.*

Introduction

The practice of screening in healthcare – that is, actively seeking to identify a disease or pre-disease condition in people who are presumed and presume themselves to be healthy – is one that grew rapidly during the twentieth century and now has wide acceptance in our society. In looking back over the years since our previous book on screening was published,¹ it is perhaps surprising how little appears to have changed in the provision of screening services or in the knowledge base of screening in the UK. Organisation and audit of existing programmes have undoubtedly improved and, importantly, there is now a UK National Screening Committee which acts as a central reference point for screening throughout the country. With the exception of genetic screening, where the possibilities have multiplied exponentially – although, as we shall show, there are major ethical and implementation issues in this area – we still have broadly the same programmes and services. What has changed, however, is the public perception and expectations of screening, the focus of media attention on health in general and screening in particular, and an increasing recognition, especially among health professionals, that screening can be harmful as well as helpful.

In this chapter we shall look at the historical background to screening, including the establishment of the National Screening Committee, restate acceptable definitions of the process, revisit the criteria that must be fulfilled before screening is introduced and consider briefly some political issues and public perceptions.

Historical background

The benefits of screening were first demonstrated by the use of mass miniature radiography (MMR) for the identification of individuals with tuberculosis. With the introduction of effective treatment for this condition after the end of the Second World War, the use of MMR became widespread in many western countries, particularly the USA and the UK.

In the late 1950s and early 1960s, special campaigns of mass radiography were used to good effect in Scotland – first in Glasgow and then throughout the country – to try and find the unknown and infectious sufferers from tuberculosis.² Andrew Semple, Medical Officer of Health in Liverpool from 1953 to 1974,

* Dubos R (1960) *Mirage of Health*. George Allen and Unwin, London.

set up a very successful MMR campaign in that city during which more than 80% of the adult population were screened. In 1953 he had noted that tuberculosis remained an intractable problem, with Liverpool having the highest rates in the country apart from Glasgow. By 1960, Semple was able to report a large reduction in cases, resulting from the campaign, and by 1966 it was possible to close the Central Chest Clinic.³

Other Medical Officers of Health, such as Robert Parry and Robert Wofinden with the William Budd Centre in Bristol, had developed the imaginative new concept of the health centre.⁴ These centres were intended to provide 'lifetime' preventive care and to develop screening services. Integrated care and screening for pregnant women from the antenatal period through birth in hospital or at home to care in the postnatal period were beginning in a few places, as were more co-ordinated care and surveillance for the elderly, the chronic sick and the mentally ill.

With the reduction in the burden of tuberculosis, the concept of screening began to be considered equally applicable to the control of other chronic diseases. This was shown in particular in the USA, where a law on the control of chronic diseases was passed in the late 1950s. A major review of screening in chronic disease was published in the *Journal of Chronic Disease* in 1955.⁵ One of the review's editors, Lester Breslow – Head of the Division of Chronic Disease in the California State Health Department at the time – was a keen advocate of screening in this context. The Commission on Chronic Illness was founded in 1957 and started to publish copiously.⁶

In 1961, Thorner and Remein of the United States Public Health Service published the first comprehensive review of the principles of screening. Its evaluation still remains relevant.⁷

The initial push for screening was particularly evident in North America. One of the first examples of this was the enthusiastic introduction of screening for cancer of the cervix in British Columbia and California. This was reviewed critically by Ahluwalia and Doll,⁸ who did not consider that screening was justified on the basis of this experience.

One of the most ardent advocates of screening at this time was Morris Collen, Medical Director of the Kaiser Permanente Health Maintenance Organisation, who was interviewed 20 years later in connection with a history of the programme.⁹

Collen considered that regular screening of adults for a variety of conditions could reduce the costs and utilisation of medical services. As a result, regular screening – or preventive medical examination as it was described – was introduced as a component of subscribing to the Kaiser Permanente HMO, despite the inability to demonstrate clear benefits.

In the UK, possibly because of fewer financial resources for health, screening lagged behind. However, Sir George Godber, the Chief Medical Officer from 1960 to 1973, quickly recognised that screening was an important possible method of delivering preventive healthcare.¹⁰ He therefore despatched Dr JMG Wilson, a senior medical officer in the Ministry of Health, to North America to review and learn about the possibilities and problems. Wilson developed his views and these were later written up with Jungner, a Swedish biochemist, and published as a World Health Organization monograph. This remains a landmark contribution to the field of screening.¹¹

The 'women's movement' was also growing at this time, with a particular focus on women's health. As a result of the North American experience and the hope that cervical cytology could prevent cancer of the cervix, demand for a national screening programme began to make itself felt. With the development of family planning and women's health services, cervical smears began to be taken increasingly. The ease of performing these smears meant that they were very popular, and there was little concern at this stage about the effectiveness of the procedure or the need for it. Pathology services, particularly cytology, became overwhelmed with the large number of smears needing examination. At that time, most specimen reporting was carried out by medically qualified pathologists. As a result, other aspects of pathology work, such as post-mortems, were neglected. It has been suggested that the demand for cervical cytology in the 1960s was responsible for the great diminution in the number of post-mortem investigations, which had hitherto been more or less routine.

Stimulated by Wilson, the Ministry of Health and various other groups began to consider the implications of screening as a part of healthcare. The Nuffield Provincial Hospitals Trust, for example, convened a Working Party under the chairmanship of Professor T McKeown, which published its findings in 1968.¹²

That group reached two main conclusions. First, evaluation of ten screening procedures showed that, in six of these, evidence was severely deficient with regard to one or more of the following elements: the natural history of the disease; methods of diagnosis and treatment; operational problems; assessment of benefits and costs.

Secondly, examination of screening procedures in Britain suggested that the existing research and administrative framework for screening should be strengthened. Developments appeared to be needed in three main areas:

- 1 sharper definition of the requirements of screening and of the state of evidence concerning current programmes
- 2 promotion of those types of research (large-scale, prolonged, applied and economic) that were not readily accommodated within the present framework
- 3 meticulous attention to the introduction and development of screening programmes to ensure that they were reliable and co-ordinated within the whole range of health services.

Screening was now at the forefront of the health agenda.

That same year the Ministry of Health had created a Joint Standing Subcommittee on Screening in Medical Care with the remit of reviewing the evidence for any screening programme and making recommendations on what needed to be done before a programme could be introduced into the National Health Service – the lessons of the problems created by the unmanaged introduction of cervical screening seemed to have been learned. This committee was a subcommittee of the Standing Medical Advisory Committee (SMAC) and thus its authority was limited. Its terms of reference were as follows:

- 1 to review the field of diagnostic screening of the population for disease
- 2 to identify areas of needed research (co-operating where indicated with other Departmental Advisory Committees)
- 3 to consider the implications for resources
- 4 to advise the Standing Medical Advisory Committees of the Secretary of State

for Social Services and the Secretary of State for Scotland (Scottish Health Services Planning Council) on the justification for and operation of screening services.

The first meeting was held in January 1969 and the sub-committee continued until September 1980, when no further meeting was scheduled 'pending SMAC's consideration of the future of the Sub-Committee.'

The National Screening Committee

There was then a planning gap on screening until the United Kingdom National Screening Committee (NSC) was established in 1996 and an effective mechanism was set up – covering the four countries of the UK – both to influence the implementation of effective programmes and to identify areas for further research.

The remit and terms of reference of the NSC are as follows.

- 1 The UK National Screening Committee will advise Ministers, the devolved national assemblies and the Scottish Parliament on:
 - the case for implementing new population screening programmes not presently purchased by the NHS within each of the countries of the UK
 - screening technologies that are 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 that have been inadequately evaluated or which are of doubtful effectiveness, quality or value.
- 2 The NSC will call on sound evidence to inform its advice and recommendations. In particular this will involve:
 - calling on the advice of the Standing Group on Health Technologies Diagnostic Technologies Panel (formerly the Population Screening Panel), and in turn informing the setting of NHS Research and Development priorities
 - calling on the Department of Health Policy Research Programme and defining research needs for screening
 - calling on other 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.

Thus the NSC has a much more defined role and, by reporting to Ministers, has greater authority than its predecessor, the Joint Standing Sub-Committee. It is responsible for introducing proven screening programmes and for evaluating them, and is thus not merely an advisory body. It also represents an important central reference point for all considerations of screening in the UK although, since screening is a devolved matter, it is theoretically open to each of the four countries to make their own interpretation of the NSC's advice.

Changing definitions and perceptions of screening

In 1968, McKeown¹² defined screening as a ‘medical investigation which does not arise from a patient’s request for advice for a specific complaint.’ Screening thus defined may have one or more of three main aims, and the requirements for its acceptance may be quite different in each case. First, it may be the subject of research – for example, in the validation of a procedure before it is introduced more widely. Secondly, it can be used for the protection of public health (sometimes compulsorily) to identify a source of infection – for example, in the search for the source of an outbreak of food poisoning. Thirdly, screening can have as its main aim a direct contribution to the health of individuals.

There have been various definitions of screening over the years, and a number of the most prominent ones are summarised in Table 1.1.

These definitions do not differ greatly in meaning, although the most recent one from the NSC is hedged round with some rather heavy circumlocution,

Table 1.1 Summary of definitions of screening

<i>Source</i>	<i>Definition</i>
US Commission on Chronic Illness (1957) ⁶	Screening is the presumptive identification of unrecognised disease or defect by the application of tests, examinations or other procedures, which can be applied rapidly. Screening tests sort out apparently well persons who apparently have a disease from those who probably do not
McKeown (1968) ¹²	Screening is a medical investigation which does not arise from a patient’s request for advice for a specific complaint
Wilson and Jungner (1968) ¹¹	Mass screening is the large-scale screening of whole population groups. Selective screening is the screening of certain high-risk groups in the population. Multiphasic screening is the administration of two or more screening tests to large groups of people. Surveillance is long-term observation of individual populations. Case finding is the screening of patients who are already in contact with the health services to detect disease and start treatment. Early disease detection refers to all types of screening
National Screening Committee – <i>First Report</i> (1998) ¹³	Screening is the systematic application of test or inquiry to identify individuals at sufficient risk of a specific disorder to warrant further investigation or direct preventive action among persons who have not sought medical attention on account of symptoms of that disorder
National Screening Committee – <i>Second Report</i> (2000) ¹⁴	Screening is a public health service in which members of a defined population, who do not necessarily perceive that 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

presumably to minimise the possibility of consequences arising from the growing climate of complaint or litigation. Wald¹⁵ describes it as ‘unwieldy and unclear,’ and suggests that the Committee would have done better to stay with its original definition.

Put simply, what we are talking about when referring to screening, as indicated at the start of this chapter, is actively seeking to identify a disease or pre-disease condition in people who are presumed and who presume themselves to be healthy. However, it is important also to acknowledge the difference between *population screening* (where groups of people who are thought to be at risk are invited to attend for screening – as in the national programmes for cancer of the breast and cervix) and *opportunistic screening for prevention or case finding* (where individuals have sought medical contact for some reason and the opportunity is taken to suggest various other tests, such as the measurement of blood pressure or cholesterol, appropriate to their age and sex). As Getz and colleagues have pointed out, it may be timely to look critically at the whole question of opportunistic screening in the modern context:¹⁶

Medical resources are increasingly shifting from making patients better to preventing them from becoming ill. Genetic testing is likely to extend the list of conditions that can be screened for – is it time to stop and consider whom we screen and how we approach it?

Criteria for screening

The basic criteria to be fulfilled before screening for a condition is introduced have been well rehearsed over the years.^{1,11, 17–19} They are absolutely fundamental to the integrity of the screening process, and we make no apology for repeating them here.

Appendix C of the NSC’s *Second Report*¹⁴ summarises the criteria as follows, taking account of the ‘recent more rigorous standards of evidence required to improve effectiveness and the greater concern about the possible adverse effects of healthcare.’ The information is also available on the NSC’s website.²⁰

The condition

- The condition should be an important health problem.
- 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.
- All of the cost-effective primary prevention interventions should have been implemented as far as is practicable.

The test

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

- The test should be acceptable to the population.
- 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

- 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.
- There should be agreed evidence-based policies covering which individuals should be offered treatment and the appropriate treatment to be offered.
- Clinical management of the condition and patient outcomes should be optimised by all healthcare providers prior to participation in a screening programme.
- 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 or cystic fibrosis carrier screening), there must be evidence from high-quality trials that the test measures risk accurately. The information that is provided about the test and its outcome must be of value and readily understood by the individual who is being screened.
- There should be evidence that the complete screening programme (test, diagnostic procedures and treatment/intervention) is clinically, socially and ethically acceptable to healthcare professionals and the public.
- The benefit from the screening programme should outweigh the physical and psychological harm (caused by the test, diagnostic procedures and treatment).
- 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).
- There must be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards.
- Adequate staffing and facilities for testing, diagnosis, treatment and programme management should be made available prior to the commencement of the screening programme.
- 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.
- Evidence-based information that explains the consequences of testing, investigation and treatment should be made available to potential participants to assist them in making an informed choice.
- 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.

In less elaborate language, the principles can be grouped into four categories as summarised in Table 1.2.¹

Table 1.2 Summary of criteria for screening

<i>Category</i>	<i>Criteria</i>
Condition	The condition sought should be an important health problem whose natural history, including development from latent to declared disease, is adequately understood. The condition should have a recognisable latent or early symptomatic stage
Diagnosis	There should be a suitable diagnostic test that is available, safe and acceptable to the population concerned. There should be an agreed policy, based on respectable test findings and national standards, as to whom to regard as patients, and the whole process should be a continuing one
Treatment	There should be an accepted and established treatment or intervention for individuals identified as having the disease or pre-disease condition, and facilities for treatment should be available
Cost	The cost of case finding (including diagnosis and treatment) should be economically balanced in relation to possible expenditure on medical care as a whole

Evaluation of screening

As well as restating the principles that must underlie any reputable screening programme, it is important to emphasise the necessity for scientific evaluation and effective quality control, which we will look at in greater detail in Chapter 3. In the early days of screening, the natural history of the conditions being sought – such as tuberculosis and syphilis – was well understood and lines of treatment were clear. However, with diseases such as HIV/AIDS and a growing emphasis on

Table 1.3 Summary of criteria for evaluation of screening

<i>Factor</i>	<i>Criteria</i>
Simplicity	The test should be simple to perform, easy to interpret and, where possible, capable of use by paramedical and other personnel
Acceptability	Since participation in screening is voluntary, the test must be acceptable to those undergoing it
Accuracy	The test must give a true measurement of the condition or symptom under investigation
Cost	The expense of the test must be considered in relation to the benefits of early detection of the disease
Repeatability	The test should give consistent results in repeated trials
Sensitivity	The test should be capable of giving a positive finding when the individual being screened has the condition being sought
Specificity	The test should be capable of giving a negative finding when the individual being screened does not have the condition being sought

chronic diseases that can take many years to develop and where aetiologies and current treatments may be less certain, the situation is altogether more complex. In 1971, Cochrane and Holland suggested seven criteria for evaluation. These have stood the test of time (*see* Table 1.3).¹⁷

Political issues and public perceptions

In recent years screening has taken on a far higher profile than was previously the case, and has become a politically sensitive issue. There are a number of forces at work here.

First, people have become increasingly knowledgeable about health matters as a result of media focus and the wide availability of health-related information, of whatever quality, on the Internet. There is thus a popular demand for more effective healthcare and the firm belief, among many, that early diagnosis provided by screening will inevitably lead to a better outcome. This demand is being fuelled by charities such as those concerned with cancer, who believe that screening can only be beneficial. Private clinics and healthcare providers advertise general screening programmes for men and women – a human version of the MOT.† Pressure and lay groups, together with the media, may excite a public demand for screening for a particular condition on the basis of a specific case, unsupported by scientific evidence with regard to its efficacy. There is also the possibility of well-intentioned doctors, patients and pressure groups leading a virtual crusade against a particular disease or group of diseases and persuading governments to provide a screening programme before a proper assessment of benefit is available.

Secondly, screening has become a commercial enterprise – not only in terms of the promotion and performance of the procedures, but also in terms of the supply of equipment and reagents. Thus part of the process is driven by financial interests. Examples of this include private mobile units sited in supermarket car parks providing some appropriate tests, such as screening for cancers of the breast and cervix. However, many other tests that are offered do not conform to accepted criteria and are not linked to a system that monitors the results and identifies individuals at greatest risk.

Thirdly, governments are willing to invest in screening services even at high cost and with relatively small benefits (e.g. screening for cancer of the breast) in order to demonstrate that they are concerned with the provision of services that improve health in general and prevention in particular. The NSC's remit and terms of reference include the statement that it will advise on 'the case for continuing, modifying or withdrawing existing population programmes.' Despite this, one politician did actually suggest to us that any government would be most unlikely to halt an existing screening service even if there was good scientific evidence that there was no benefit (personal communication, 2002).

Finally, despite the increased demand for screening, there has been a drop in public confidence. In the past decade there has been at least one annual 'scandal' because of deficiencies in the provision of screening services, mainly those for cervical cancer. Because of the large numbers of smears examined, errors are

† The MOT is an annual test of roadworthiness required in the UK for any car over three years old.

bound to occur in this and in any screening programme. The concepts of false positives and false negatives are difficult to understand, and the media are not slow to highlight – and, indeed, to dramatise – problems of inadequate staffing and training or lapses in administrative efficiency, as well as incompetence by a few professionals. Screening in itself is not a guarantee of diagnosis and cure, but rather it is one tool in the prevention of disease.

As the *Second Report* of the NSC points out, ‘errors occur in all branches of medicine and are inevitable.’¹⁴ In the clinical care of individual patients, adverse events come to the attention of the public and the media in a sporadic way, spread across many clinical specialties. In a national screening programme involving large numbers of women and subject to stringent quality control, such as that for cervical cancer, errors and problems quickly become public knowledge. Steps have to be taken to restore public confidence in screening and to better inform the public and the media of the nature of screening and its merits and limitations.

Increased political involvement and interest in screening are exemplified by a conference on parliaments and screening, with particular reference to ethical and social problems arising from testing and screening for HIV and AIDS, held in 1995 in the European Parliament.²¹

In a PhD thesis entitled ‘The Politics of Breast Cancer Screening,’ published in 1996, Hann took a feminist viewpoint in which she criticised the Forrest Report that recommended the introduction of a national programme in the UK.²² She suggested that the members of the Working Party which produced the Report had been chosen for their views on the benefits of the scheme without sufficient balance from an alternative standpoint.

The Council of Europe has also commented on the need to develop screening services on the basis of clear principles and criteria in a recommendation to the Committee of Ministers on screening as a tool in preventive medicine.²³ This document also emphasises the possible adverse effects of screening, which can include:

- stigmatisation and/or discrimination of (non-)participants
- social pressure to participate in the screening and undergo the intended treatment/intervention
- psychological distress in cases where there is no cure for the disease or where the treatment and/or intervention is morally unacceptable to the individual concerned
- exposure to physical and psychological risks with limited health gains
- creation of expectations which probably cannot be fulfilled
- individuals who are positively screened possibly experiencing difficulties such as access to insurance, employment, etc.
- severe side-effects of invasive clinical diagnosis of false positives
- delay in diagnosing false negatives
- the unfavourable cost–benefit relationship of a screening programme.

This paper also raises important legal and ethical issues. For example, it stresses that although effectiveness is a necessary prerequisite for the screening to be ethical, screening can be effective and still unethical. We shall look more closely at the ethics of screening in Chapter 3.

The involvement of the state in screening is also well illustrated in China, where a premarital examination for hereditary illnesses and psychiatric problems

which could jeopardise parenting abilities is mandatory.²⁴ This is the most extreme form of screening that we have encountered. Although some of the conditions identified (e.g. sexually transmitted diseases, tuberculosis and phimosis) might be treatable, the ethical implications of such a mandatory examination are enormous and, of course, of particular consequence with the development of genetic screening.

Benefit or bane?

Views on the value of screening continue to vary. Screening still has its evangelists and its agnostics, and there is little doubt that the latter group has grown – at least among healthcare professionals – in recent years.

In 1988, Skrabanek restated his view that ‘screening healthy people without informing them about the magnitude of inherent risks of screening is ethically unjustifiable.’²⁵ Screening differs from traditional medical practice in that it aims to detect disease at a very early stage, either before or very soon after symptoms present, and sometimes before an individual decides to seek medical advice. It therefore carries very considerable ethical responsibilities, as it has the potential to transform individuals from a state of supposing themselves to be healthy to a state of having some disorder or potential disorder. Screening should not be used to identify conditions that are either insignificant or untreatable, since at either end of that spectrum lie anxiety and anguish. As Wald and Cuckle stated in 1989,²⁶ ‘Screening must be principally concerned with the prevention of disease and the recognition that it is only worthwhile screening for disorders which lend themselves to effective intervention.’ This is well worth re-emphasising today.

An editorial in the *British Medical Journal* in 2003 examined the modern screening industry.²⁷ With the advent of whole-body scans, the marketing of health has intensified. The sales pitch is simple and on the surface beguiling. You may have some disease or abnormality lurking in your system. Either the scan will show it and allow early treatment, or it will give you the all-clear and you can then celebrate.

In the same issue of the *British Medical Journal*, Swensen describes his experience of using computed tomography to screen for lung cancer within the context of a major clinical trial.²⁸ His research team found 700 ancillary findings within its cohort, but most were false positives which led to adversely affected quality of life and unnecessary diagnostic and interventional procedures. And Raffle and colleagues, in a study of screening for cervical cancer, showed that 1000 women have to be screened for 35 years to prevent one death from the disease.²⁹

The editorial concluded:²⁷

Simple-minded enthusiasm for screening – combined with industrial opportunity to make fat profits – may mean that soon none of us will be normal. . . . It’s always hard to put the case for ‘not knowing,’ but economists . . . have a wonderful notion of ‘rational ignorance.’ It simply isn’t sensible to try to know everything. Ignorance can be bliss.

Another issue that deserves attention was raised by Muir Gray,³⁰ who argued that screening is a programme, not a test. This is one of the problems that the health

service has with private sector screening, where an individual may be offered a test for a specific condition but the investigation and reassurance for those who test positive are then passed to the National Health Service even though the condition tested for did not meet the NHS screening criteria (e.g. ovarian or prostate cancer).

There is a need for balance in the screening debate, and that must surely lie between the extremes of enthusiasm and doubt in a cautious and rigorous consideration of all screening practices and proposals. As Russell³¹ has described, there is a growing body of research indicating that the chronic degenerative diseases of middle or old age can often be prevented or at least delayed, and new vaccines can also offer better protection against infectious diseases. Such developments offer the prospect of better ways to maintain health and prolong life, and have led to a new surge of interest in preventive activities such as screening. The question that must be asked of any preventive measure, or indeed of any investment in health, is whether the gains in health are a reasonable return for the risks and costs involved.

Sackett³² calls time on the arrogance of preventive medicine and emphasises that the 'fundamental promise we make when we actively solicit individuals and exhort them to accept preventive interventions must be that, on average, they will be the better for it.' He cites the example of the Women's Health Initiative randomised controlled trial of hormone replacement therapy, which was stopped when it became clear that the participating women's risk of cardiovascular disease increased rather than decreased on active therapy:³³ 'Without evidence from randomised trials (and, better still, systematic reviews of randomised trials) we cannot justify soliciting the well to accept any personal health intervention.'

Twenty years ago, Chamberlain³⁴ summarised the benefits and disadvantages of screening, and her analysis remains valid today (*see* Table 1.4).

The benefits are straightforward. Early accurate diagnosis and intervention will lead to an improved prognosis in some patients. At this stage treatment may need to be less radical. Scarce health services resources will be conserved by treating diseases before they progress, and patients with true negative test results can be reassured.

Table 1.4 Benefits and disadvantages of screening

<i>Benefits</i>	<i>Disadvantages</i>
Improved prognosis for some cases detected	Longer morbidity for cases whose prognosis is unaltered
Less radical treatment which cures some early cases	Overtreatment of questionable abnormalities
Resource savings	Resource costs
Reassurance for those with negative test results	False reassurance for those with false-negative results
	Anxiety and sometimes morbidity for those with false-positive results
	Hazard of screening test itself

Source: Chamberlain.³⁴ Reproduced by kind permission of the author and the publisher.

The disadvantages are more complicated. There will be longer periods of morbidity for patients whose prognosis is unchanged, and there may be over-treatment of non-serious conditions or abnormalities identified and individuals may become anxious. Haynes and colleagues found an increase in absenteeism from work in steelworkers with raised diastolic pressure after they had been given the diagnosis:³⁵ 'The increase in illness absenteeism bears a striking relationship to the employee's awareness of the diagnosis, but appears unaffected by the institution of antihypertensive therapy or the degree of success in reducing blood pressure.'

Work by Marteau and colleagues³⁶⁻³⁹ and Austoker⁴⁰ has confirmed the problems of anxiety induced by screening, and these will be discussed more fully later in the book in terms both of antenatal and adult screening.

There are also resource costs involved in finding more illness, in terms of the tests themselves, the personnel costs and the subsequent management of whatever is found. There is the unpalatable certainty that some individuals with false-negative results will be given unfounded reassurance and that those with false-positive results will experience at the very least unnecessary anxiety and at the worst inappropriate treatment. Finally there is the possibility, however remote, of hazard from the screening test itself.

Austoker quotes from one of the conclusions of a report on cervical screening in Bristol: 'by offering screening to 250 000 we have helped a few, harmed thousands, disappointed many, used £1.5million each year, and kept a few lawyers in work.'⁴⁰ She emphasises the importance of obtaining truly informed consent for screening and of respecting the patient's autonomy, including their right to decide not to undergo a screening procedure.

The present monograph

Our plan for this book has been to devote Chapters 1, 2 and 3 to a general overview of screening and its history and some of the key issues that it involves. In subsequent chapters we follow a life-cycle approach in four screening segments as summarised in Table 1.5. Chapter 8 contains a brief account of screening practices in Europe, and the final chapter provides an overview and looks cautiously into the future.

When we began to plan the writing we expected to find that many changes had occurred since the publication of the first edition in 1990. However, the general principles and criteria have stood the test of time, and although much knowledge

Table 1.5 Life-cycle screening segments

<i>Segment</i>	<i>Stage of life</i>	<i>Age range (years)</i>
I	Antenatal, neonatal, infancy	< 1
II	Childhood Adolescence and early adulthood	1-11 12-24
III	Adulthood	25-64
IV	The elderly	≥ 65

and experience have accumulated, particularly in the field of human genetics, few dramatic new issues have emerged.

The main changes have been first in emphasis and secondly in increased politicisation.

Fifteen years ago there was great enthusiasm for screening among many healthcare professionals. That has been largely replaced by a more cautious approach and a more open acknowledgement that screening can also cause harm.

Politicians meanwhile – perhaps reflecting popular opinion – have become far more convinced of the need for screening services, but have also on occasion been over-ready to attribute blame for the inevitable mistakes and shortcomings to those providing the service. Screening must not become a political tool that is used to convince the public of action in an increasingly beleaguered health service.

The establishment of the National Screening Committee has provided a very valuable focus and point of reference for screening activities, and the NSC is now able to advise Ministers on screening for various conditions on the basis of sound evidence. It has also highlighted two themes that will underpin its working over the next decade – those of *informed choice* and *risk reduction* – so that people can make their own decisions as to whether or not to participate in a particular programme within the context of a clear understanding of what screening can and cannot offer.

The book is not intended as a comprehensive review of screening for specialists in a particular branch of medicine. Rather, we have tried to take a general look at screening, to discuss some of the important ethical, economic and quality issues involved, to review current practice in screening at the various stages of life, and finally to suggest some constructive ways forward.

We hope that the book will be of interest and value to healthcare professionals across the field – from medicine to management – to medical, nursing and other health-related students and to anyone seeking to understand what screening is really about.

Screening covers the entire lifespan, from before conception to old age. It can never be perfect but, used wisely, it can be a potent force for health improvement in the twenty-first century.

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