



**SENSE ABOUT SCIENCE  
MAKING SENSE OF SCREENING**

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## INTRODUCTION

Public expectations about screening don't match what screening programmes can deliver. High profile cases, such as Kylie Minogue's treatment for breast cancer and Jade Goody's death from cervical cancer, have made screening an emotive and politicised subject. They have led to demands (and political promises) that more sections of the population should be included in screening programmes, for longer and more frequently. Magazines and online discussions carry many personal stories of people saved, especially by cancer screening, and of people who died because of a lack of screening. Letters to newspapers complain that screening programmes are dictated purely by financial calculations. Confusingly, another group of stories protest about the failure of screening to detect a friend's or a relative's disease. Amidst all this, the specific benefits of screening programmes and the sensitive calculation of these against possible harm have been largely lost from public view.

To complicate it further, the benefits and harms of some screening programmes are in dispute among scientists and policy makers. The statistics about who benefits and who is harmed by breast cancer screening, for example, are being actively debated. But for most people, it's surprising just to learn that there are limitations as well as potential downsides to screening. It is important to know about this, both to be properly informed about screening you might take part in and to understand why screening programmes are offered to some parts of the population and not others.

We have drawn up this guide: first we asked specialists (clinicians and researchers) how screening programmes are evaluated and we investigated what people say about screening in day-to-day life. We then worked with the clinicians and researchers to pick out where discussions about screening are going wrong. We also liaised with some helpful members of the public, who explained back to us what the responses meant and whether they were useful or surprising. The following points helped most to make sense of it all:

- Screening can identify some of the people who have a disease but it cannot prevent disease.
- Screening may cause harm, which needs to be balanced with the benefits.
- Some false positives and false negatives are the unavoidable cost of screening groups of people who have no symptoms of disease.
- Screening rarely benefits all sections of the population so it needs to be targeted at those most likely to benefit.

Whether you are a professional, or want to know for yourself, we hope that the discussion in the following pages helps you to make sense of screening too.

**Síle Lane, Joe O'Meara, Hedley Glencross**



# CONTRIBUTORS



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Screening is a programme designed to reduce the risk of disease in the whole population. Screening programmes identify some of the people most at risk of a disease so that they can be offered early treatment. They are based on careful calculation, including who will benefit, the scope for treatment and the level of accuracy.

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The side effect of screening programmes is that some people will get false results and some of those will receive unnecessary treatment. When choosing who to screen and for which conditions, the benefits for people with early stage disease are weighed against these harms to others. Widening the population to be screened can reduce the benefits of screening.

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clear sinister symptoms. Many people on this site have again reiterated that their's or their loved one's cancer was found too late because of this reluctance. Screening may not be perfect but screening seems a greater evil.

I feel so strongly about this. I had my first abnormal smear at the age of twenty five. It took only six months for abnormal cells to go from CIN 1 (mild pre-cancerous cells) to CIN 3 (Severe pre-cancerous cells).

The removal of tissue from the cervix also increases the risk of a later premature birth, especially for younger women.

These are valid arguments but we think we must take any chance of saving more women

"I could be dead by now if I hadn't gone for that smear."

'Jade is thrilled by this campaign. If one young life can be saved that's a result'

Screening could prevent bowel cancer

She booked a test last October and says: "Thank God I did because ten weeks later the results showed abnormal cells. My GP told me not to worry but to go for a biopsy and colposcopy to find out more."

"I still can't believe I took a chance with my health knowing if or when they would have become pre-cancerous."

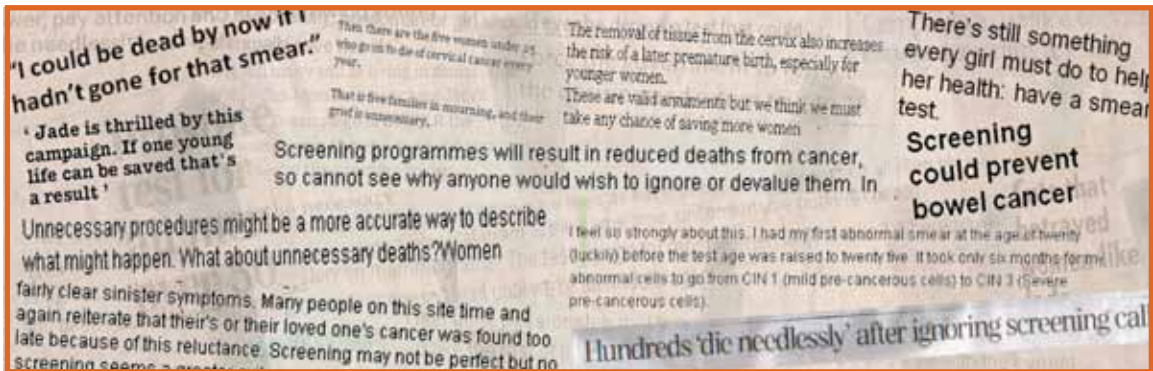
Hormone clue could lead to screening for autism

I know the issue is that women are more likely to be young and so needlessly worry, but I would have found to be fine than not have a smear to begin with anything.

Prostate test for all men over 50

But still many will be living in denial - this is why Sun Woman is launching Jade's Legacy: To campaign to LOWER the screening age in England to 20 and to raise awareness of the screening process.

Force the government to retract the decision and return to it to 18



## 01. Screening 'populations'

Screening is a public health programme, a series of events designed to reduce the risk of the disease in the *whole population*. In this sense, it is different from the individual diagnostic tests used on people who have symptoms and who are suspected of having a disease. Screening programmes aim to identify the people who are at risk and have otherwise undetectable health problems so that early treatment can be offered before symptoms appear.

Some examples of screening programmes in the UK include breast cancer, cervical cancer, weighing and measuring babies and checking the hearing of newborns<sup>1</sup>. Each screening programme is directed towards a specified disease or condition and a target **population** (people without symptoms but who are in a group where the disease is known to be more common). For example, people with diabetes are screened for diabetic eye damage (retinopathy) and women over 50 are screened for breast cancer.

There are a lot of misconceptions about screening. Some politicians and commentators have described it as preventing disease. In fact what it aims to do is detect people with signs that a disease might develop, so that it can be prevented from progressing to a further stage when treatment is more unpleasant or less likely to succeed, when damage may be permanent or symptoms distressing. Because they're looking for the people with early signs that a disease might develop, screening programmes will not help the majority of people who take part in them, who wouldn't have developed the disease looked for, and some people who do develop the disease won't be picked up by screening.



**Hedley Glencross:**

*If someone goes to the doctor showing symptoms of particular disease and they are referred for a test, this is not screening. For example*

*there have been media stories of women visiting their doctors after having intermenstrual bleeding, which can be a symptom of cervical cancer. If the women are offered 'smear' tests, this would be part of a diagnosis process and not cervical screening.*

**A population refers to people grouped on the basis of a common characteristic, such as those who have been to hospital with a particular condition, all women aged between 50 and 70, or all pregnant women.**

**The main events in a screening programme are usually:**

1. Initial selection of a group of people (population).
2. This is followed by a screening test.
3. Those apparently more at risk (e.g. showing heightened levels of an indicator, known as a **marker**, for the disease) are then referred for diagnostic tests.
4. Treatment if necessary.

<sup>1</sup> See [www.screening.nhs.uk](http://www.screening.nhs.uk) for more information and a full list of existing programmes.

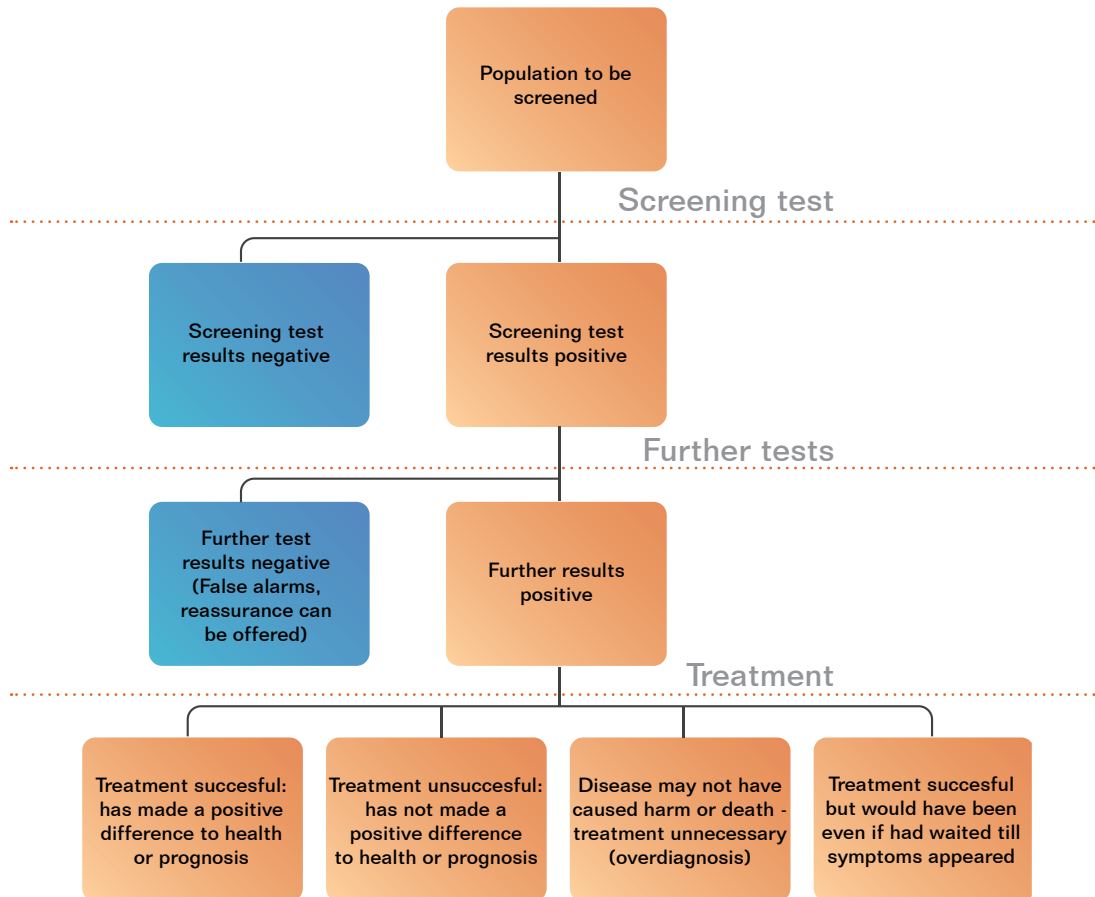


**Angela Raffle:**

The screening process is like passing people through a sieve. The holes in the screening sieve are a certain size that will catch some people and allow others to pass through. A screening test is designed to catch people who are at risk of a disease (it must be very sensitive) and allow those not at risk to pass through (it must be very specific).

Sometimes people will get stuck in the sieve who will turn out not to be at risk i.e. false alarms. Others will pass through the sieve despite being at risk i.e. missed cases. Everyone picked up in the sieve will go on for more testing to determine if they have the disease and need treatment.

**What happens to people who go through the screening process?**



**Possible outcomes**

**Screening for breast cancer**

A screening test for breast cancer, mammography, uses x-rays to check for areas of high density tissue in women's breasts, which sometimes indicate a cancerous growth. Women whose screening tests are positive for this are then referred for further investigation combining a thorough clinical history, repeat mammography and removing a sample of the breast tissue.

## Criteria that need to be considered when setting up a screening programme:

**The disease** should be relatively common and cause death or chronic illness. The early stages of the disease must be known and recognisable, to identify people before they develop symptoms. The proportion of people in the population who have it, suffer from it and die from the disease should be known prior to the screening programme starting in order to help judge whether it is effective.

**The screening test** must be readily available, inexpensive, safe and agreeable to the people it will be used on. There should be an agreed policy, based on good evidence, about which people (i.e. which kinds of results) to refer from the screening programme for diagnostic testing.

**The risk marker** (the evidence being looked for) should be a reliable indicator that a disease will develop in the majority of cases. It should also be able to distinguish, in the majority of cases, between those who have (or will get) a disease and those who do not have (and will not get) that disease.

**The treatment** should be well established, effective and available.

**The cost** of screening and of potential treatments should be considered against the possible expenditure on treating the disease in the population if there was no screening programme.

**The evaluation** must be ongoing. The available evidence will be constantly revised: a better test may come into existence or new evidence may arise about the benefits and risks of harm from screening.

## Who should be screened?

In short, the aim is that it should be those people most likely to benefit. Clearly, there are some diseases that only affect men (such as prostate cancer) or women (such as cervical cancer). Some diseases are only likely to affect people in a particular age group (such as dementia) or those with certain environments or exposures (such as smokers). Some population groups might be unlikely to benefit from the available treatment: for example it would be unlikely that chemotherapy would be suitable for the frail elderly. Or it might be that the 'risk marker' (the indicator of possible disease being looked for) does not distinguish between normal and abnormal in some populations. For example, women aged 20 often experience changes in the cervix which do not indicate that cervical cancer will develop.

## Weighing up the benefits

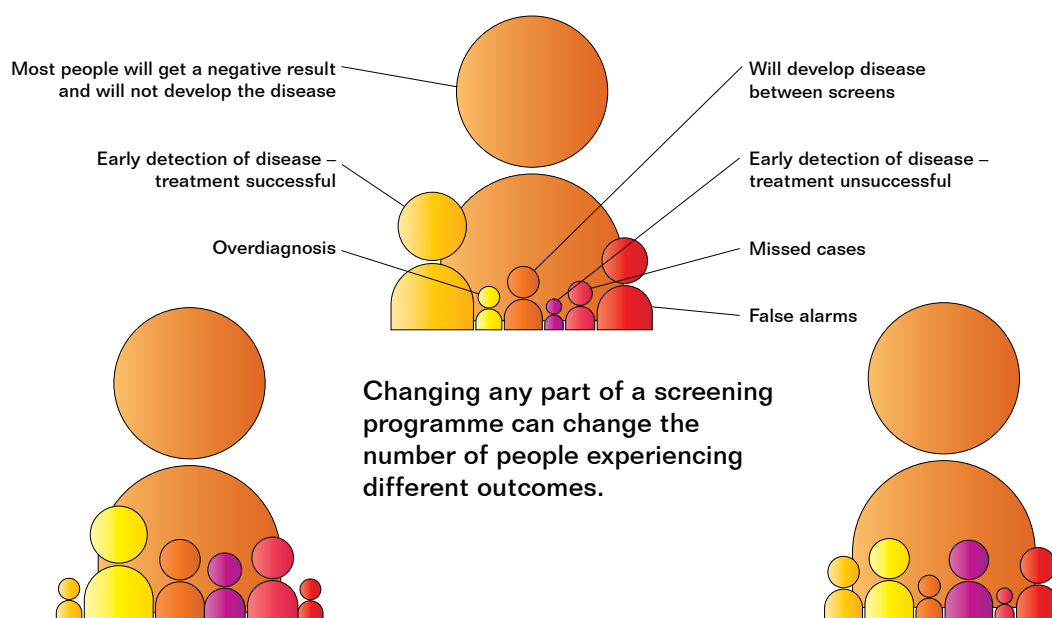
Screening can also cause harm, and this has to be considered too. Some people may be made very anxious or they may experience side effects from tests, false alarms, unnecessary treatment or false reassurance. These potential harms need to be weighed against the possible benefits from detecting a disease in its early stages. The assessment of whether to implement a screening programme also takes into account the potential benefits of other ways to improve the detection and treatment of the disease, such as a campaign to raise awareness of early symptoms among GPs and rapid referral to specialists.

Decisions about the use of screening don't end when a programme is introduced. It is also important that medical researchers and policy makers continue to review the balance of benefits and risks after a screening programme has been implemented, when more evidence starts to become available about its actual effects. It may be some time before there is sufficient or clear evidence for everyone to agree on what the benefits and risks are, and sometimes there are big debates about these.

An example of a screening programme that was stopped because it caused more harm than good was the Japanese programme for the childhood cancer neuroblastoma. New evidence from randomised controlled trials found that screening wasn't reducing the number of children dying from the disease; instead it was identifying children with tumours which would have never produced symptoms or which would have regressed. These children were undergoing unnecessary operations and chemotherapy, with all the suffering and risks attached.

## Making choices

When changing parts of a screening programme, such as who is invited for screening or the test that is used, the overall calculation of the benefits versus the risks has to be made again. A change in the one part of the screening programme can affect the balance between the people who benefit from screening and those who don't:



NB. These diagrams do not represent real data.

The death of UK television personality Jade Goody from cervical cancer has led to demands for England to lower the age at which women are screened from 25 to 20. However, this could lead to thousands of women being given the early treatment for cervical cancer, with no certainty that this would be saving any lives. This is because women closer to puberty are more likely than older women to have changes in the cervix, so a higher rate of so-called abnormalities is detected by the screening. Cervical cancer is very rare in 20-25 year olds, but the abnormalities detected through screening would lead to investigation and possibly treatment. This is known as over-diagnosis. Treatment risks damaging the cervix, leading to higher risk of future miscarriage or premature labour. So the decision to offer screening only from the age of 25 is not simply about cost: it is about the balance of benefit and harm.

**Who decides what to screen for?** In the UK, screening programmes are overseen by the NHS National Screening Committee. Most countries have a similar body connected to their health service. The NHS National Screening Committee:

- assesses the evidence and makes recommendations to ministers and the NHS on which new screening programmes to implement and how they should be managed.
- evaluates existing programmes for effectiveness, quality and value. Changes in society and medicine can affect the usefulness of a screening programme, including accumulating evidence for harms of a test, advances in treatment and changes in people's expectations and awareness of screening programmes.



## 02. What does screening actually tell you?

The idea that having a quick test can let you know whether there is anything wrong is appealing. However, getting a 'yes' or 'no' answer from screening is not clear cut. The tests used are not able to give answers with complete certainty. In order to understand why this is, it is helpful to know a bit about the selection of the test and what the test is actually able to identify.

**What is a screening test?** A test used in a screening programme is different from a diagnostic test:

- A **diagnostic test** is designed for an individual *with symptoms of a disease* to confirm they have it or to follow its progress.
- A **screening test** is designed for populations of individuals who don't necessarily have any symptoms of the condition tested for. It identifies those *with a risk marker* for the condition and divides them into high and low risk.

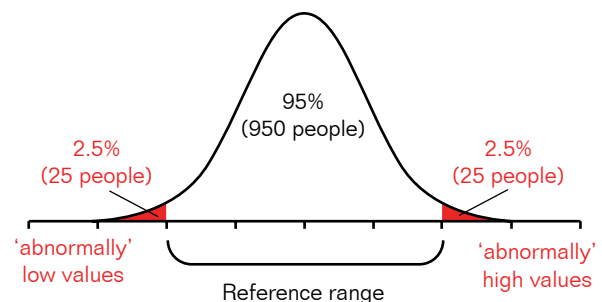
Screening for hepatitis B in pregnancy is an exception to this as the diagnostic test is the same as the screening test.

A risk marker is something that can be measured to indicate whether someone is at risk of developing a disease. Measuring risk markers could be testing someone's hearing, weighing them, performing a scan or looking at a biomarker (such as the level of a hormone in the blood or a particular genetic sequence in the DNA).

### So will a screening test mean someone will know if they have the disease or not?

As tests become more accurate and pick up tiny aberrations, it is clear that very few of us are completely normal. Even though they are healthy, many people have 'abnormal' variations if subjected to a CT scan of the brain or endoscopy of the stomach.

To deal with this, for some kinds of tests, the person's result is compared to a *range* of results considered 'normal' for a healthy individual. If we performed a test on 1000 healthy people, 950 (95%) would have results that fall inside the reference range and 50 (5%) would receive abnormal readings.



While an 'abnormal' result outside the reference range doesn't necessarily indicate a problem, a 'normal' result doesn't always mean there is nothing wrong. Just as some healthy people's results fall outside the reference range, results in some people with or at risk of getting a disease fall within the reference range so there is still a chance of an undetected problem.

Even with screening tests that don't refer to a reference range, the test might (accurately) identify an abnormality that will not cause further symptoms during a person's lifetime. For example, screening can pick up potentially 'pre-malignant' conditions like bowel polyps and abnormalities in breast tissue or cervical cells that may never progress to cancerous cells or cause significant illness.

### The 'all clear'?

Just because someone has been screened and is not identified as being at risk at that point in time, it doesn't mean they won't go on to develop the disease. This may be because the test is not accurate enough and inevitably there will be missed cases (false negatives). You also may still develop the disease in the time between screening appointments (interval diseases).



**Margaret McCartney:** *The problem with a negative test is knowing what it means – or doesn't. It can only guide a path and you need to encompass other important bits of knowledge, like symptoms and examination findings, to know when to stop or what to do with a negative test.*

**Angela Raffle:** *Even in a high quality programme, with everybody trained and no errors, the screening test will pick up only a proportion of those who are destined to go on and develop the condition that you are trying to reduce the risk of. For example, not everybody who will die of a stroke has high blood pressure when they are screened and not everyone who will die of cervical cancer has abnormal cells in their sample.*

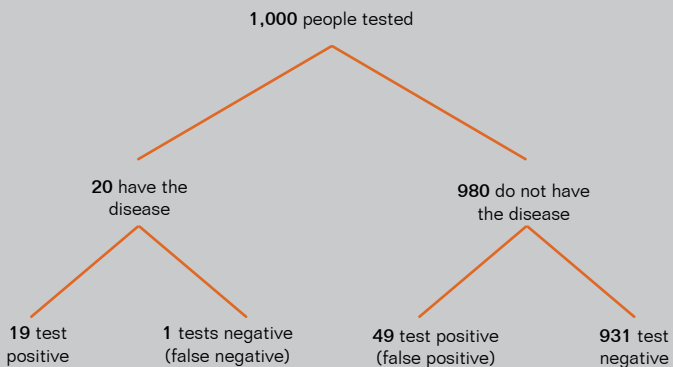


**Danielle Freedman:** *Most screening tests are designed to have a low rate of false negatives (to avoid missing real cases), but the downside of this approach is that false positives are more common. Consequently, a larger number of people will have to be invited for further investigation before being told the disease is not present.*

### If you have a positive result what is the chance you actually have the disease?

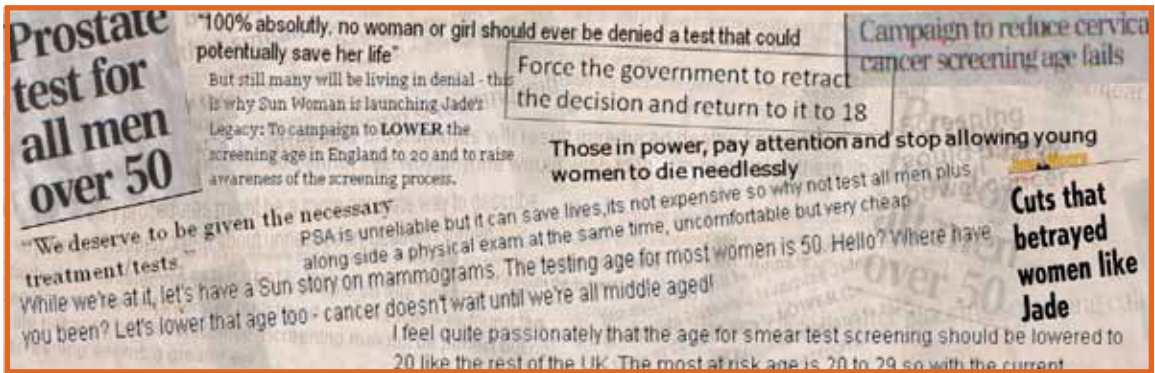
**Caroline Wright:** If a test is 95% accurate, 5% will get the wrong results either as false positive or false negative. It might seem logical to think that there is a 95% chance you have the disease if you are given a positive test result. But the chance of you actually have the disease following a positive screening result is actually much lower.

For a disease with a prevalence of 2% using a screening test with 95% accuracy



Total number of 'positive' results = 68 but only 19 of these are correct so the chance you have the disease if you have received a positive result is actually only 28%

A 28% chance is higher than the 2% chance you had before taking the test but for most diseases this isn't enough to start treatment and further investigation would be needed.



## 03. Why don't we screen more people, more often, for more conditions?

It seems sensible that we should screen as many people as we can for as many diseases as we can. However, only certain diseases are suitable to be screened for and increasing the population screened can end up adding to the harm and doing little to the benefits.

### Are all tests suitable for screening programmes?

There are often stories in the media about researchers discovering a new cause or risk factor for disease, such as a genetic susceptibility to Alzheimer's disease. So will these discoveries lead to new screening programmes?

The accuracy of any potential test needs to be evaluated, along with considerations such as potential costs, potential harms and whether it is only accurate in a very specific group of people. Any of these may make it unsuitable to be rolled out in a population wide screening programme. For example, the Checklist for Autism in Toddlers or CHAT test is used in children who show signs of developmental delay. On evaluation, it was found not to be effective for screening for autism in all children between 18-24 months, as there were high rates of missed cases (these recommendations are summarised in the National Autism Plan for Children, [www.nas.org.uk/content/1/c4/34/54/NIASARep.pdf](http://www.nas.org.uk/content/1/c4/34/54/NIASARep.pdf)).

There also needs to be a suitable intervention for the disease. There is currently no cure for Alzheimer's disease, so even if we had a good test that we could use to screen for risk of developing the condition, it would be hard to advise people at higher risk on what to do next.



**Caroline Wright:** *To be clinically useful, a test must be able to distinguish between those who have (or will get) a disease from those who do not have (and will not get) that disease. Because numerous common genetic and environmental factors are important in most diseases, each of which only has a small effect, a test for one or even a few of these may not be able to make this distinction accurately enough, particularly for predicting the risk of future disease – it's a bit like trying to guess an entire poker hand when you can only see one card!*

## Not all diseases are suitable for screening

It seems intuitive that the earlier you find out about having, or being at risk of, a disease the sooner you can act on it and the less likely you are to die of the disease. So should we screen for all diseases?

Diseases, such as fast growing cancers, which progress rapidly are unlikely to be suitable for screening. The individual is likely to become symptomatic between screening tests and seek medical attention.



### Michael Fitzpatrick:

*The diagnosis of a disease, such as prostate cancer, for which no treatment has been shown to increase life expectancy, may*

*result in treatments that impair the quality of life (causing impotence and incontinence) without extending its duration.*

Despite some demands by commentators, prostate cancer screening with a PSA test is not offered as a screening programme in the UK. Most men with an elevated PSA test result turn out *not* to have cancer because of a high number of false positives from the test.



### Peter Furness:

*About two-thirds of men with raised PSA levels turn out not to have prostate cancer; but they have to go through a battery of further*

*tests including rectal examinations, transrectal ultrasounds and prostate biopsies, which involves inserting a large needle into the prostate via the rectum, typically 12 times. The biopsy is painful and carries a small risk of serious infection.*

Even if a man is identified as having prostate cancer, it may not cause him harm. Prostate cancer is quite common amongst men but in the majority of cases it will not cause any clinical symptom or require treatment. Hence it is often said that many men die *with* prostate cancer, not *of* it. The PSA test can't distinguish between the benign or harmful forms so there would be a lot of over-diagnosis.

## Is it fair to leave out some groups from screening programmes?

There are often calls to widen existing screening programmes to avoid missing people who may have the disease, but there is a downside. If screening was simply offered to everyone, for example all age groups rather than those where the disease is more common, the proportion of the people screened who actually have the disease would be smaller in these groups. The benefits would therefore be smaller (sometimes non-existent).

### So why does it matter if the benefits are smaller, if a few more lives might be saved?

Unfortunately it isn't as simple as this because screening programmes can have negative effects:

- Further investigations can cause harm. For example, a colonoscopy used in diagnosis of colon cancer causes a perforated bowel in 1 in every 1000 tests, so there need to be good grounds for believing a person might have colon cancer before sending them for this test.
- There is a potential for psychological harm from worry if the screening test gives a positive result. The harm from anxiety is often underestimated. It can have a profound impact on people's life choices and relationships, or itself lead to being ill.
- People with abnormal results that will never develop into the disease are likely to still undergo treatment which may be unnecessary. Doctors are unable to know which individuals are over-diagnosed so that person will undergo treatment which may have been unnecessary.
- Negative results can lead to false reassurance. An apparently 'clean bill of health' can discourage people from seeking advice about symptoms they experience. This is likely to be a very small group of people but it has to be considered when designing a screening programme.
- A screening test itself may carry a small risk of harm. National screening programmes would not select tests that were likely to cause harm but some types of screening tests may become harmful if used more frequently, for example repeated exposure to x-rays is known to cause cancer in rare cases. This is part of the calculation, alongside cost, benefit and inconvenience to participants, about how often to screen.

## Personal stories are not a reliable way to make sense of screening

We often read about someone whose disease was caught by screening and who is certain that they would have died had it not been discovered. Some of these may be people who have been over-diagnosed and had unnecessary treatment but still feel their life was saved by the treatment. So the greater the over-diagnosis and over-treatment in a screening programme, the more people there are who believe they 'owe' their life to it.

### The debate about breast cancer screening

Even in well-established screening programmes such as mammography for breast cancer over-diagnosis is a problem but the question is how much. Currently there is a debate in the scientific community over how often it occurs. Studies estimate that between two and ten women will have unnecessary treatment for every one life saved by mammography screening but there is no consensus on the figure. These debates have proved to be emotive with some regarding them as an attack on screening while others have criticised the NHS for overplaying the benefits of mammography and downplaying the potential for harm. All are agreed that mammography will help some women but hurt others. Until more data are available to help resolve this scientific debate, there is agreement that women should be given better information about the potential for benefits and harms when deciding whether to attend for screening. In an editorial in the British Medical Journal (*BMJ* 2009;339:b1425), H Gilbert Welch discusses the current debate in more detail and provides references to scientific reviews.



**Hazel Thornton:** *People invited for screening should be provided with all the necessary information to be able to make a decision on whether they wish to attend. It is the responsibility of all those who provide information about screening programmes to tell people about potential harms and potential benefits, as well as its limitations and possible consequences.*

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## Screening is one tool for reducing disease



**Susan Bewley:** *Check-ups or screening don't stop you getting disease. There is easy advice doctors can give to people worried about cancer - stop smoking. For some people this is probably much better than all the check-ups you might buy or be offered.*

Screening plays an important role in reducing the impact of disease on the population, leading to improved treatment and aftercare overall. But it can consume large amounts of public health funds, reducing the resources available to treat people who are diagnosed with the disease. It is important to remember that screening is just one tool for managing disease and, as this guide has discussed, it is only appropriate for some tests, for a limited number of diseases and in particular populations. This is why good screening programmes arise from careful and continuous assessment of where it can be of most benefit, rather than from emotive stories or political demands.

# 04. Further information and useful reading

## Further information

**The Association for Clinical Biochemistry** ([www.acb.org.uk](http://www.acb.org.uk)) is a professional body dedicated to the practice and promotion of clinical science. It has medical and non-medical members in all major UK healthcare laboratories, in many university departments and in several commercial companies, and a fruitful relationship with the clinical diagnostics industry. The Association liaises with national and international organisations on issues relating to clinical biochemistry.

**The Institute of Biomedical Science** ([www.ibms.org](http://www.ibms.org)) is the professional body for biomedical scientists and is involved with the quality, promotion and practice of biomedical science. The Institute does this through a number of activities including: degree accreditation, the setting of professional standards, awarding professional qualifications and through its research grant programme. The Institute has a world-wide membership, advising national and international organisations on biomedical science and related matters.

**The NHS UK National Screening Programme** ([www.screening.nhs.uk/about](http://www.screening.nhs.uk/about)) advises Ministers and the NHS about all aspects of screening policy. The UK NSC regularly reviews policy on screening for different conditions in the light of new research evidence becoming available. Assessing programmes in this way is intended to ensure that they do more good than harm at a reasonable cost.

**The Royal College of Pathologists** ([www.rcpath.org](http://www.rcpath.org)) is the professional organisation for pathologists, established by its Royal Charter to strive to improve the quality of pathology services for the public. The College is principally responsible for setting standards and professional examinations for pathologists.

**Sense About Science** ([www.senseaboutscience.org](http://www.senseaboutscience.org)) is an independent charitable trust. We respond to the misrepresentation of science and scientific evidence on issues that matter to society and work with scientists and civic groups to share the tools and insights of scientific reasoning.

## Useful reading

**Making Sense of Testing:** A guide to why scans and health tests for well people aren't always a good idea. Sense About Science.

**Testing Treatments: Better Research for Better Healthcare.** Evans I, Thornton H and Chalmers I. London: British Library, 2006. This is available from [www.jameslindlibrary.org/testing-treatments.html](http://www.jameslindlibrary.org/testing-treatments.html). Written by a medical journalist, a critical patient, and a well known scientist, this book is for non-scientists who want to understand and critically appraise health care.

**Screening, evidence and practice.** Raffle A and Gray M. Oxford: Oxford University Press, 2007. A non-technical, introductory guide covering all levels and aspects of screening.

**Should I be tested for cancer, maybe not and here's why.** Welch, HG. California: University of California Press, 2004. A comprehensive overview of current challenges in cancer screening, drawing from published literature, case histories, and the author's own medical practice experience.

**It is not wrong to say no.** Heath I. *BMJ* 2009;338:b2529. Observations by a GP on the benefits and harms of breast cancer screening.

**Effectiveness of cervical screening with age: population based case-control study of prospectively recorded data.** Sasieni et al. *BMJ* 2009;339:b2968. Research paper describing how the effectiveness of cervical screening varies with age groups.

**Prostate cancer screening: the controversy continues.** Stark et al. *BMJ* 2009;339:b3601. An analysis of the benefits and harms of prostate screening.



## CONTACT A SCIENTIST

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