



SENSE ABOUT SCIENCE **MAKING SENSE OF TESTING**

A GUIDE TO WHY SCANS AND HEALTH TESTS FOR WELL
PEOPLE AREN'T ALWAYS A GOOD IDEA

INTRODUCTION

CUTTING THROUGH THE HYPE ABOUT HEALTH TESTING MANY DOCTORS AND SCIENTISTS DON'T AGREE WITH THE INCREASINGLY PROMOTED IDEA THAT WELL PEOPLE NEED TO BE TESTED FOR DISEASES

Full body 'MOTs', well-man and well-woman screening, DIY testing kits from blood sugar and cholesterol to genetics and allergy; they're all now part of the armoury for well people who want to protect their health.

Adverts and media reports say that people with no symptoms, nor reason to suspect they have a disease can find out what they will get in the future, "reverse the disease processes before symptoms appear", or even discover how they will die. People are promised instant results, valuable insights and 'peace of mind'. What many people are getting is a lot of confusion and anxiety, ongoing trips to the doctor and, sometimes, unnecessary medical procedures.

It surprises people to discover that they have only been hearing one, attractive side of the story and that many doctors and scientists feel that few of these tests are used appropriately. For people without symptoms there are only a small number of screening tests that are worthwhile. Furthermore, testing the 'worried-well' has definite potential for harm.

Why is there this gap between expectation and reality? How do doctors and scientists decide whether tests are useful? Sense About Science worked with a group of medical professionals who have been engaged in the day to day work of testing, screening and dealing with patients, to find insights that could be shared to help people understand what testing can and can't do. In brief, they said:

- Most tests are not designed for use by people with no symptoms or elevated risk.
- Most tests on well people won't accurately predict the diseases they will get.
- Some tests on well people will suggest diseases that they will probably never get.
- What a test claims to do for your health or tell you about a disease isn't adequately regulated or fully researched.
- Diagnosis is complex, based on clinical experience and research, signs, symptoms and context. These determine which tests to do and how to understand their results.
- Information from many home testing kits and full body scans is usually not clinically useful.
- There is a growing business selling new genetic tests based on very preliminary research – the evidence is far too flimsy to be accepted by evidence-based medical practice.
- Testing for a disease before symptoms appear can even harm in ways people may not have considered.

Making Sense of Testing, edited and published by the Sense About Science trust, presents a few key understandings and highlights common misconceptions about having health tests and scans.

Along the way, we've also heard how the market in health and well-being tests for at-home use, now worth £99 million a year, is forecast to be a top ten trend of 2008¹; and we've noted serious policy concerns about how tests are evaluated and regulated and about the cost to the NHS of seeing people concerned about 'out of range' results they have been given. We hope that these explanations from the medical frontline will help address those developments too. (¹ Mintel 2007)



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A full list of contributors is on page 15; details of organisations and further information are on page 14.

Need help on this subject? Call Sense About Science on **020 7478 4380**

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Well, healthy, symptomatic, asymptomatic... a word on words

The phrase 'worried-well' is commonly used to describe people who are healthy yet concerned about possible diseases. In this document we use *healthy people* to mean people who are *asymptomatic* (with no symptoms of illness) and who are at low risk of developing a particular disease.

Other useful words, like *biomarker* and *population*, are explained as they come up.

I want to know the worst

Blood test 'which can predict disease' is unveiled

www.metro.co.uk

Cholesterol screening for babies?

1 MOST TESTS WEREN'T DESIGNED FOR WELL PEOPLE

Misconceptions: you can find out whether you have a disease; you can predict whether you'll get a disease; tests give a yes or no answer

In brief: Even for people who have a disease, tests are not straightforward. Tests take measurements of *biomarkers* (genes, proteins or chemicals that can act as signposts for certain diseases) or identify other features in the body that fit with what we know about diseases or healthy functions. If you do not have any symptoms or reasons to suspect that you are at significant risk of a particular disease, then most tests weren't designed for your situation. But the more tests we do, the greater the chance of finding something that appears to be wrong.

It would seem to be common sense that illnesses detected in their early stages will respond better to treatment, so all we need is a simple, accurate test to find out if there is anything wrong. However, for people with no symptoms of disease who just want reassurance that they are 'well', it's much more complicated.

FEATURES IN THE BODY CAN BE MEASURED IN VARIOUS WAYS. THEY INCLUDE

- **Direct questioning**, like getting a family history;
- **Clinical measurements**, like feeling your pulse;
- **Physiology**, such as having an ECG to check heart activity;
- **Pathology measurements**, processed in the laboratory, like blood samples for cholesterol or hormone levels, cervical smears and cheek swab samples for genetic testing;
- **Imaging**, like X-rays, CT, MRI and ultrasound scans;
- **Endoscopy**, where a small, flexible tube with a light and camera lens is used to examine and take biopsies from the stomach and bowel; and
- **Psychological measurements**, such as object recognition to aid diagnosis of Alzheimer's Disease.

Laboratory diagnostic tests look for the presence of a biomarker, such as a particular genetic sequence in an individual's DNA; or the amount of a biomarker, such as the level of cholesterol in blood. Off-the-shelf testing kits do the same thing. Tests that measure biomarkers can only tell you the levels present. They do not tell you the implications this may have for your health. This also applies to full body scans, which look for physical anomalies, such as nodules in the lung. Just because something is present doesn't necessarily mean it is causing you harm.

"Liver health tests can be made abnormal for a whole range of reasons. Or you could have cirrhosis and the test could come back negative. The faecal occult testing for bowel cancer looks for the presence of blood in the faeces, but blood may be in faecal matter for many reasons. This is a health check that cannot give you the all clear."



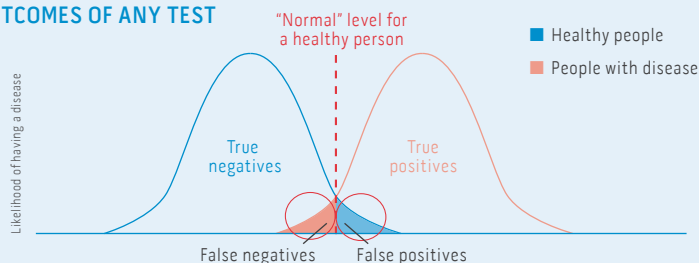
PROFESSOR PETER FURNESS

How is a test assessed?

The first question to be asked of any test is how accurately it can identify the feature it is looking for. This is the **technical performance**.

The test result then needs to be assessed. We need to know how accurately the biomarker levels distinguish between people who are healthy and people who have or will develop disease. This is the **clinical performance**. There are always some healthy people who test positive for a disease (false positive) and some people with a disease who test negative (false negative).

POSSIBLE OUTCOMES OF ANY TEST



There are always some healthy people who test positive for a disease (false positive) and some people with a disease who test negative (false negative).

Testing people with and without symptoms

When doctors choose a test they consider a person's symptoms and match them with the appropriate tests. If a child's symptoms suggest high blood sugar, the doctor will use a blood glucose test to determine whether they have diabetes. The tests chosen will be highly sensitive (so that most of the time it will pick up people with the disease) and also specific (so that it excludes most people who don't have the disease).

When a healthy person takes a test, it is much harder for the test to be sensitive and specific, which means that the accuracy and reliability of the results can be dramatically reduced. Except in

THERE ARE SEVERAL REASONS WHY DOCTORS ORDER TESTS.....

- For **diagnosis**, to determine the likelihood that someone has the disease their symptoms suggest;
- If someone is considered to be at significant risk, but doesn't have the disease, to help **classify the risk and manage it**;
- For **screening**, in order to evaluate risk in a defined group of people with no recognised symptoms;
- When someone does have a disease, to know how it is likely to progress (**prognosis**);
- To determine which **treatment** regime is best;
- To **monitor** a therapy that someone has been put on, to check progress.



Dr Ian Watson

"There is a 1 in 20 chance of a given test result being outside the quoted reference range. In a battery of 20 tests it is very likely one will be 'abnormal'. Spurious abnormalities such as these trigger further unnecessary interventions and worry."



"The word normal should be banned. A 'normal' state that can be applied to everybody does not exist in identifying who is healthy."

SIR MUIR GRAY

"The value of tests can vary with the subject or population being tested, and whether it is connected with a disorder; it must be put into context. For example, the value of a chest X-ray on a 70-year old who is coughing up blood is not the same as one on a wheezing 5-year old. The assay, the chest X-ray, is the same in both cases, but the



value of the test for establishing a correct diagnosis is much higher in the case of the 70 year old than the 5 year old."

DR RON ZIMMERN

the case of screening programmes, **a healthy person is outside of the range of people for which the test was developed.**

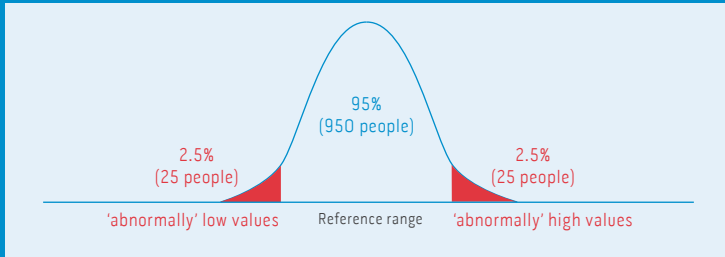
Is the result 'normal'?

Most tests measure things in our bodies that vary from person to person (for example by racial origin, age, weight or sex) and even in the same person from day to day, such as hormone levels. Moreover, as tests become more accurate and pick up tiny changes, it is clear that very few of us are completely normal, and many people if subjected to a CT scan of the brain or endoscopy of the stomach would have 'abnormal' variations even though they are healthy. One of the problems is that, until recently, CT scans have most commonly been done in sick people. But doing these scans in a different population – healthy people – means small deviations from the 'norm' are often seen. These are very difficult to interpret.

'ABNORMAL' RESULTS

A test result is not taken as a number in isolation. It gets compared to a range of values considered 'normal' for a healthy individual. This is called the reference range, and it's what a doctor can use to interpret a set of results for individual patients.

But only 95% of normal people tested would actually fall inside the reference range. So, if a test is performed on 1000 healthy people, 50 would receive abnormal readings. **This is why we say 'reference range' instead of 'normal range'.** (It doesn't apply to imaging tests like CT scans as these are not compared to a reference range.)



DR MIKE HALLWORTH,
LABTESTSONLINE

There are two main misconceptions about test results and reference ranges:

Misconception one: *A result outside the reference range indicates a problem.*

Not necessarily – but it will usually require some further investigation. Many things can give a misleading result. High blood sugar could be related to something recently eaten rather than diabetes.

A cholesterol result could be high because of alcohol consumption the night before.

Misconception two: *A set of results entirely within the reference range means there is nothing wrong.*

There is often a large overlap in the results from healthy people and those from people with diseases.

Just as some healthy people's results fall outside the reference range, lab test results in some people with disease fall within the range. So there is still a chance of an undetected problem.

Screening

National screening is a public health service. Although it may look like it, screening is different from testing healthy individuals because it is directed towards a specified disease and a target **population**. A population refers to people grouped on the basis of a common characteristic, like those who have been to hospital with a particular condition, all women between 50 and 70, or all pregnant women. Screening aims to find people who are at higher risk and detect important health problems before symptoms appear, so that effective early treatment can be offered. This happens by asking a question or offering a test, and then referring them on for more accurate tests (i.e. diagnosis) and treatment if necessary. Even in this case, those who get 'abnormal' results, outside the reference range, are unlikely to be affected by the disease. In other words, there will be false alarms.

A disease must fit stringent criteria to be eligible for a screening programme; its progression must be well understood and **an effective treatment or intervention must already be available**. For example, because prostate cancer commonly grows very slowly, and as it mainly affects older men, its

diagnosis can often have no effect on life expectancy. So if a screening test picked up a prostate tumour there would be a risk of it leading to unpleasant and dangerous treatment, with drugs, radiotherapy or surgery – for a condition that might never affect someone's health. For this reason, the NHS has an explicit policy not to offer screening for prostate cancer, but if a patient presents with symptoms that raise suspicions of a prostate problem, it is routine to do the prostate serum antigen (PSA) test.

"Very few tests identify a specific disease; the majority measure something about you, as a set

of scales might measure your weight. Whether the value obtained is normal depends on what is normal for you – information often not known."



DR ANDREW GREEN

DNA test website raises accuracy fears

In order to avoid inappropriate screening there are several issues that have to be weighed up and that are constantly the subject of review and debate. For example, the number of deaths that could be potentially prevented by the programme must be weighed against the risks of harm from being screened, including over-diagnosis (e.g. finding ‘pseudocancers’ that may be diagnosed as malignant cancers), and over-treatment (because medicines or surgery may be prescribed for an ‘abnormality’ that would never have become problematic).



Professor Mike Baum

“It is said that many more men die **with** prostate cancer rather than **of** prostate cancer. In other words the majority of prostate cancers are not progressive and, therefore, prone to over-diagnosis. The UK Government does not advocate PSA screening and is waiting for the results from

the ProtecT trial. This is the largest study of its kind and should provide unequivocal evidence of the usefulness of the PSA test. Out of nearly 500,000 men from 800 GP practices, half will be offered PSA screening and the others will act as controls. If early prostate cancer is detected by a high PSA and confirmed by ultrasound-guided biopsies, the patients will be randomly allocated to treatment by radical surgery, radiotherapy or active monitoring with full informed consent. This study will find out once and for all whether PSA screening saves lives and at what cost in side effects for the men and cost to the NHS.”

But it's in my genes...

Tests that tell you whether you are likely to get a disease in the future are called **predictive** or susceptibility tests. They are all about likelihood, not certainty. Genetic tests on sale offer to predict your genetic susceptibility to diseases in the future: will you fall victim to heart disease or diabetes? There is very little evidence that these tests help answer those questions.

Some genetic tests are used diagnostically; for example, Huntington's disease is a rare but devastating neurological disorder and if a person has the specific disease-causing sequence of DNA in their genome, a genetic test, done properly, will tell us with near 100% certainty that they will develop symptoms of the disease. Because of the certainty, this is a **truly diagnostic** test. There are no false positives or false negatives – the whole diagnosis can be done by the test. It is very unusual.

Even here, because no test is technically perfect, doctors only use it when there is a family history of the disease, or in people with some of the symptoms. Even then, it is not always appropriate to take the test because of the potential impact of predicting someone will develop an incurable disease.

Most diseases we might develop, such as diabetes and multiple sclerosis, are the complex result of interactions between multiple genes and environmental factors (lifestyle, infections etc.) Advances have now been made in associating genetic sequences with particular diseases. The media and promoters of direct-to-consumer **susceptibility tests** leap from this to conclude that if people test positive for that genotype they are at increased risk of the disease. They might be. But acting on the knowledge of a single (or even a few) gene variants is similar to betting all your money on a poker hand when you've only seen one card. You don't know what hand genetic factors has dealt you, nor what effect your environment will have, and here, instead of 5 cards, there are over 20,000 genes and many thousands of environmental factors! And the effect of one gene may be cancelled out by the effect of lifestyle, family history or by the presence of other, protective genes. Many of us carry faulty genes without them ever causing disease. There is promising research into genetic understanding of disease, but the association between one gene and a particular disease doesn't automatically make useful tests.

“The science that appears to indicate an increased risk associated with a mutation in a gene or genes may be inadequate; or further work may be needed to make any reliable predictions. A result in itself does not provide much of the information needed; it's an incomplete basis for future planning. It does not tell you when or how quickly symptoms will start to show or which aspects of the condition will be most difficult to manage. Knowledge of the family history will help with the former and counselling with the latter. As with other areas of testing in medicine, the print-out from the analytical process is an aid to clinical judgement, not a replacement.”



ALASTAIR KENT



2 MANY TESTS ARE NOT RESEARCHED OR ADEQUATELY REGULATED

Misconceptions: A test is a test is a test; the information from tests must be useful; claims for direct-to-consumer tests must be true

In brief: Some indicators and biomarkers are better understood than others. Healthcare providers already find it hard to assess the benefits and costs of newly designed tests compared with what is currently available. This is because, unlike medicines and national screening programmes, there is no regulation or requirement for research on the effectiveness of testing. With direct-to-consumer tests, anyone can set up a lab and sell testing; the test must measure what it says it will measure but there's absolutely no requirement for them to show the value of that test or whether it benefits anyone.

The NHS and other healthcare providers could also be missing out. Because of the lack of regulation, many providers of new tests put their money into marketing to consumers rather than researching and producing evidence that could help healthcare providers deciding which tests to use with their patients.

What are the regulations?

Testing kits are regulated by the *In vitro* Diagnostic Medical Devices Directive. The government agency, the Medicines and Healthcare Regulatory Agency (MHRA) that regulates medical devices ensures that testing kits are safe and accurately measure what they say they do (for example a cholesterol test must measure cholesterol levels). But whether that measurement helps diagnose or predict a disease is not regulated. Tests will still give false-positive and false-negative results, and no-one has to produce evidence about the overall benefit of the test or how it is best used.

Of course, tests are also used in GPs' surgeries and in hospitals. Here tests play a vital role in diagnosing conditions, monitoring disease and treatment, and prescribing medicines or surgery.

But tests offered by many online and private laboratories do not have to ensure that the quality of investigation is reliable and the provider does not have to be accountable for dealing with the results. There is no responsibility for test providers to make it clear that those evidence-based tests which are privately promoted are nearly always readily available on the NHS in an environment where they can be interpreted by a doctor and accompanied by advice. The effect of this is that GPs spend a lot of time reassuring people about results obtained from testing



Dr Susanne Ludgate

"For general tests the manufacturer self-declares conformity with the relevant essential requirements of the Directive but there is no third-party assessment. For self-test devices, the design and instructions for use must also be checked by a third party, a Notified Body (MHRA in the UK). The

CE mark shows that the product conforms to the requirements of the Directive.

It is solely the test that is regulated, not the service provided on the basis of the test results. For example, there is no regulation to stop a gym selling over-the-counter tests with no supplementary information or follow-up. As for the proliferation of web-based services selling testing kits and tests where a person sends a sample away, this has been found to be a source of the increasing trade in fake or counterfeit medicines and devices. So the quality and safety of internet-marketed products like glucose meters and cholesterol checking kits is unknown."

.....

kits and body scans, and end up repeating them when they are not convinced that the tests are valid or are unable to see the full results. Such tests are being promoted to people who don't like to trouble the doctor, but the results worry them and they end up there anyway!

In contrast to testing, prescription and over-the-counter medications are listed in a directory called the British National Formulary (BNF), published twice a year for doctors and scientists. The BNF lists medications under their generic and commercial names (e.g. ibuprofen and *Nurofen*) and describes circumstances when they are suitable or unsuitable for use. Many doctors and scientists now want a similar directory for new and existing laboratory tests, with evidence of clinical performance where available. Where evidence is missing, this would be stated. They also want to establish an expert body to evaluate the evidence and make recommendations about how tests should be used.



Professor Peter Furness

"There should be an independent, official national assessment process for all health-related tests, covering the circumstances in which their use is valid. Then, companies would have to spend less money on marketing, and more on doing research to

demonstrate that their products actually produce real benefits. Companies offering a genuinely valuable service would prosper. Charlatans offering genetic gobbledegook would go to the wall. The result would be a better service for the public."

THINGS TO KNOW IF YOU DIY...

"Imagine you went to your GP and she took blood from your fingertip for a test – without asking you why you have come, what you are worried about, or how you are, and without considering what to



do with the test results...it just wouldn't happen, but this is effectively what you are getting from a 'DIY test'."

JULIET STEVENS

THE CASE OF A FINGER-PRICK BLOOD TEST TO CHECK LIVER HEALTH - DIY liver health check kits can cost up to £150 on the internet. Here are some points to consider:

GETTING THE BLOOD SAMPLE

Getting finger-prick blood samples is often not as easy as it sounds. People with diabetes do the procedure regularly at home, but are instructed about good technique and have lots of practice. It is difficult to do it for the first time on your own and get an uncontaminated sample with the right volume of blood for testing. Some people bleed profusely. Others do not bleed well – sometimes because the puncture isn't deep enough - and squeezing the finger to get blood out may dilute it with tissue fluid and cause false negative results.

SENDING THE SAMPLE OFF

There are strict statutory Royal Mail regulations about sending blood or body fluid samples by post – all packages have to be marked and comply with them. This is a health and safety measure to protect the public. The biomarker being tested for may also be sensitive to temperature and too unstable to 'survive' the passage to the testing lab intact.

WHERE ARE THE SAMPLES BEING SENT?

The accreditation status of the analytical laboratory may not be known and that signifies standards in how the sample is processed and proper confidentiality of results. There is no way to be assured of the accuracy of the results. NHS laboratories turn round liver function tests in as little as 20 minutes if it is urgent, and routinely within 24 hours. The turnaround time of some tests bought on the internet is ten days.

TESTING WHAT?

Some DIY tests measure two enzymes that are sensitive for certain types of liver damage, like liver cell disease, but are poor at detecting other types of liver damage, like gall stones obstructing bile flow. Someone with very severe liver disease can also have normal results because the liver is making reduced levels of the enzymes. A routine NHS laboratory performs four or five different tests to assess the integrity of the liver. Testing only two enzymes may cause false reassurance when disease is present.

THEN WHAT?

Some internet DIY liver health checks advise you to see your GP with any concerns about the test results, as a normal result does not necessarily mean you are free of liver disease. So if you are worried about your liver – and to be doing this test you must be – you still ought to visit your GP, no matter what the result!

"Most of us have a very dim view of web-based organisations that offer, for example, allergy testing of dubious value. There are also more and more private labs springing up in the UK and abroad offering a range of lab tests at high cost. They are playing to people's anxiety."



JONATHAN MIDDLE

Dr Danielle Freedman

"Diagnostic companies have seen a niche in the market, now worth \$8 billion worldwide. But there is no regulation – anyone could set up shop. If you buy a kit then there are huge implications."





3 TESTS ARE ONLY ONE PART OF DIAGNOSIS

Misconceptions: 'abnormalities' mean something is wrong; I can just buy 'what the doctor would do'

In brief: Tests are most useful when the degree of suspicion is already high. Most tests were devised to help with diagnosis of symptoms or during treatment, or to screen populations who are specifically at risk. They are used in the context of clinical experience and research, assessment of probabilities, signs and symptoms and the circumstances of the individual. For people who are healthy and not at significant risk, there's no such context to guide which tests should be done, let alone to interpret what the results mean.

A test can only tell you the answer to the question asked and can't put it into the overall context of you as an individual. Imagine just having one or two pieces of a jigsaw puzzle from which to guess the overall picture; it's usually impossible.

"For any type of 'testing', the correct interpretation is crucial. Each result has to be interpreted within a lot of parameters and with all the relevant patient information. Also there are many factors that can affect the actual blood sample itself and thus the results. The performance of the method for the test can also be affected by specific factors, and again affect the result of the test."



DR DANIELLE FREEDMAN

Diagnosing a disease, or predicting whether you will have a disease at some point, is not just about the result of one measurement. Diagnosis is a decision-making process. It is a pathway that involves collecting and using information, in order to detect, or exclude, disorders. It is on this basis that decisions about diagnosis and therapy are most safely and effectively made. When doctors request a diagnostic test, they are doing so because the patient's symptoms, signs or preliminary results are concerning. Tests on this type of person are less likely to return false positive results (though they will occur), and proper justification exists for further, more invasive investigations.

"Many things that people think of as diseases, such as high cholesterol or high blood pressure, are not diseases at all, merely factors that influence the progression of normal aging processes, such as the build up of fatty deposits in the arteries."

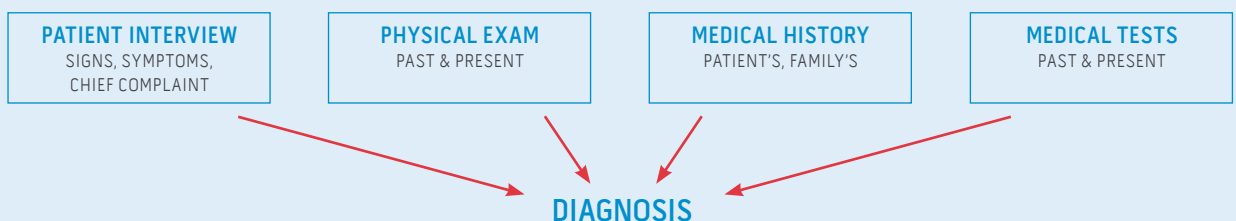


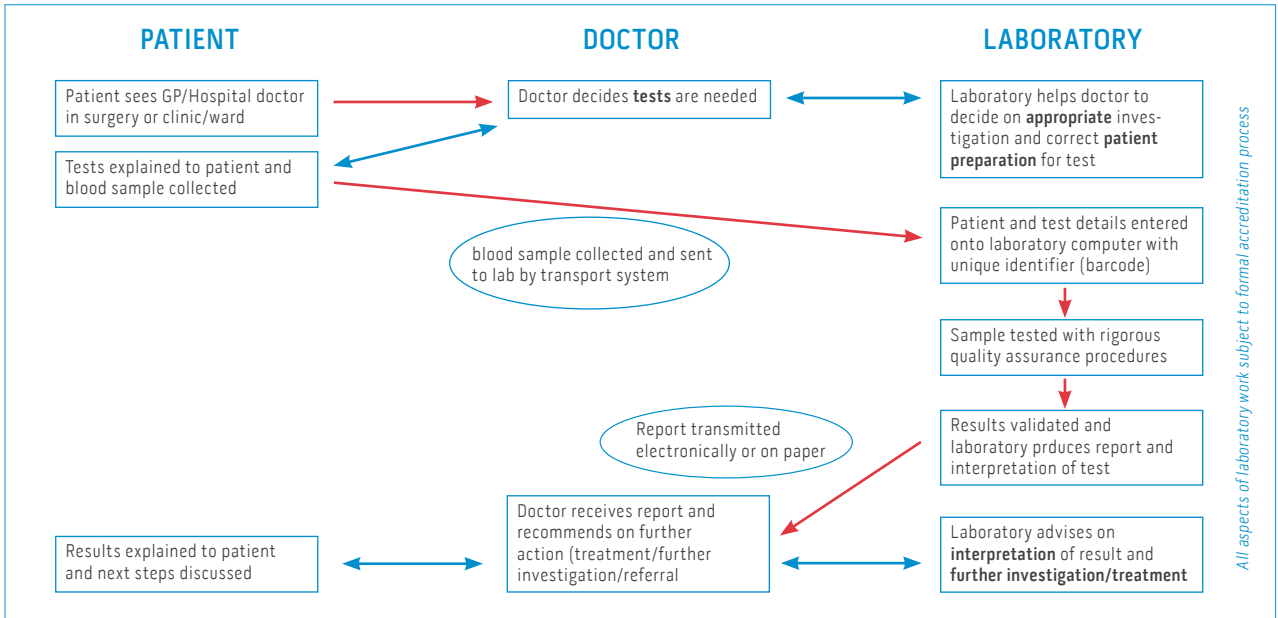
DR ANDREW GREEN

Can a test ever give a yes or no answer?

A test is often just a way of narrowing down possibilities. Where a patient has symptoms, a test can confirm suspicions or make alternative diagnoses less likely. Such tests are most useful when suspicion is already high. Simply taking a measurement of a

THINGS TO TAKE INTO ACCOUNT IN ORDER TO DIAGNOSE DISEASE.....





biomarker does not really mean much unless that is done in the context of a clinical plan, connected to a disorder and in a particular individual. The **triple test for breast cancer** is a gold standard combination of tests that can detect breast cancer in 99.6% of affected people. It combines a thorough clinical history, mammogram and a needle biopsy.

"No test is 100% definite. The final diagnosis can often only be established with absolute certainty after death. Most diagnostic tests, like scans, are only meant to give an indication."



DR RON ZIMMERN

The danger of excluding other diagnoses

A DIY testing kit will give a result but it can't say what that means. Even an apparently simple test such as a routine blood pressure check is usually only meaningful when interpreted in the light of other information such as the patient's lifestyle, family history, cholesterol, weight, age, sex and race. For example, you could have a genetic test for your risk of heart disease, but this would not pick up other illnesses such as kidney disease which will massively increase your risk and invalidate the genetic testing result. Other factors, such as smoking or exercise also need to be considered. And because hardly any tests are 100% reliable – in that they may all show false positive

Dr Margaret McCartney

"It's not just about the answer to a test... it's what to do with the result. The results of diagnostics can only be interpreted and acted on by people able to do it. So your cholesterol is six - what then? What should you do about it - or not? If a test is important enough to do, it's worth doing right. There are two main types: screening tests – which have to be done as part of a proven programme with audited quality controls - or diagnostic tests, in which case, you are narrowing the range of possible diagnoses – which means that you have to be very careful that you are doing the right one."



and false negative findings – the interpretation of a result (whether positive or negative) is not always obvious.

For diagnosis, a dialogue is important so doctors can understand a patient, because no one patient is the same as the other. The relative value of any test must be taken into account. It would be ideal if every test came back from the lab with a clear cut yes or no answer. But we are all individuals, and normality or disease looks different from person to person. Symptoms are important, and these will come to light by speaking to the patient.

DNA kit that reveals how you will die

Warning: scan
cause cancer

"...can give us peace of mind and enable us to take actions to improve our life chances."

'Worried well' at
risk of cancer
from body scans

Scanning craze may do more harm
than good to the wealthy but worried

4 TESTING CAN CAUSE HARM, ESPECIALLY IN WELL PEOPLE

Misconceptions: testing is harmless; they can intervene early and stop me getting a disease; I'll have peace of mind

In brief: Newspaper and magazine articles, adverts in the press, television documentaries and internet sites have all publicised the benefits of health checks for well people. They tell us we will benefit from the opportunity to identify conditions that we didn't know about, and that doing this will provide peace of mind, reassurance, the chance to catch disease early and live longer, healthier lives.

However, some tests carry risks of direct harm, such as infection and exposure to radiation, and some occasionally cause serious injury or death. With all tests there are risks of false positive and false negative results, which lead to unnecessary treatment or false reassurance. The view that discovering a disease early, before symptoms appear, will translate into a better chance of survival is occasionally true but it is commonly overstated.

A negative result does not always mean all clear, so most tests cannot really give you true reassurance. There are tests that have been shown to be worthwhile, but tests that have not been proven to help can actually do more harm than good.

"There is uncertainty in test results – you take a chance every time you have a test done. People know that medicines have side-effects. Tests are different from medicines, because there will be some people who will get the side effects but who do not have the disease."



SIR MUIR GRAY

Peace of Mind?

With DIY tests there are questions about the accuracy of the test itself and the ability of the person using it to administer it effectively. If you get a positive or borderline result from a test, this can be very worrying. Imagine coming to the conclusion that you have serious liver disease, on your own, late one evening.

Dr Margaret Parton

"This is why there is still a strong resistance by the medical profession to view tests supplied direct to the public as advisable. There are three issues that cause major concern: that a false negative could lead to something being 'ruled out' wrongly – which would delay visiting the doctor in a timely fashion. Alternatively a false positive could mean someone being wrongly diagnosed with disease, which means additional tests being carried out at either the surgery or at outpatients thus using more resources than a correctly applied first test within the NHS setting. A positive – false or true – will also cause a third concern, the potential for psychological harm, because a testing kit may, in effect, tell you about a potentially serious disease without appropriate back-up and counselling from a medical practitioner."



"I set breast cancer screening up in 1987 to cover the south of England. After ten years of the screening programme we became more aware

that the information was inadequate for people being invited to come for screening. It is ethically essential that people are provided with information about benefit and harm."

PROFESSOR MICHAEL BAUM

Instant test for
a failing heart

"...you can take control of the situation by
undergoing a preventative examination."
(... and you don't even
have to take your shirt off)

“For many people, a disorder is only detected when the symptoms have been present for a long time. However, the possibility of recovery or stabilising an illness is, in most cases, much greater when the cause of the complaints is detected and subsequently treated at an early stage. A preventative examination will enable you to find out in time or just to get some certainty regarding your health. That alone often gives peace of mind.”

HARM? HOW?

TESTING CAN HARM IN ONE OF FIVE WAYS:

- Firstly, the test itself can cause harm. The radiation from a whole body CT scan is believed to produce a fatal cancer in one in every 2000 people investigated; a colonoscopy will produce a perforated bowel in 1 in every 1000.
- Secondly, testing healthy people can give a false sense of security, causing people to believe wrongly that they will not get a disease, which may reduce the likelihood of them making the lifestyle changes they ought to.
- Thirdly, there is a risk of side effects from unnecessary treatment of a disease that was never going to cause a problem if left alone. Treating slightly raised blood pressure in people with overall low cardiovascular risks can cause significant symptoms (such as erectile dysfunction and tiredness) from the side-effects of medication, without making much of a difference to that person's chance of developing a serious disease.
- Screening can consume large amounts of funds which may reduce the resources available to treat people who actually have the disease. We always have to consider whether more lives would be saved by spending the money devoted to mammography on ensuring that breast cancer patients receive the best possible treatment.
- Finally, the detection of asymptomatic disease turns people into patients, and this itself causes anxiety and leads to increased consultation rates and decreased perceived quality of life.

“There are some screening tests that have been shown to be worthwhile, and the established screening programmes within the NHS are worth following. However it is very important not to have tests done that are not proven to help. You can do yourself more good by eating sensibly, stopping smoking, drinking alcohol in moderation, and getting gentle exercise than you will ever do by having tests performed.”

DR ANDREW GREEN

Professor Peter Furness

“In a PSA test for prostate cancer, lots of false positive results are inevitable. People who pick up a result suggesting that they might have prostate cancer have to go through a battery of further tests including rectal examinations, transrectal ultrasounds and prostate biopsies via six needles inserted into the prostate gland through the rectum. It is very painful and carries the risk of serious infection. But even a negative biopsy might have missed a small tumour, so it has to be repeated at intervals. There is a small mortality rate from prostate biopsy – people die.

You have to balance the risks and benefits very carefully before deciding to have the test. At the moment a large research project is trying to find out whether PSA screening will, on average, actually lengthen life or not. If you decide to have the test, you need to realise that such a basic question has not actually been answered yet.”



The blood test that could spot early signs of cancer

FURTHER INFORMATION

Lab Tests Online www.labtestsonline.org.uk is an internet resource designed to give patients and carers a better understanding of clinical laboratory tests and the laboratory testing process. It is a free service produced by laboratory professionals and funded by professional organisations and the Department of Health. It does not seek to replace a consultation with the GP or hospital doctor, but provides background information on testing to support that consultation and help patients know what questions to ask and how to interpret the answers.

What is pathology? Pathology is the hidden science at the heart of modern medicine, vital for the diagnosis and clinical management of disease. Pathologists are senior scientists, the majority of them medically qualified, who specialise in the laboratory investigation of disease and work in hospital laboratories, universities and industry. They include microbiologists, immunologists, haematologists, clinical biochemists and cellular pathologists. (Despite the common perception, doing post-mortem examinations is only a small part of their work.) **The Royal College of Pathologists** 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, especially in setting professional examinations for pathologists.

What is clinical biochemistry? Clinical biochemistry is used to diagnose, monitor, screen and determine prognoses for diseases that change the chemical make-up of our bodies, like diabetes,

thyroid disease; and those in which biochemical changes occur as a result of a disease, such as renal (kidney) failure. Interpreting this information is the role of the clinical biochemist. They are either medical or science graduates and can train to consultant level.

The Association for Clinical Biochemistry 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 Foundation for Genomics and Population Health www.phgfoundation.org is an international, independent charity that works with partners to achieve better health through the responsible and evidence-based application of biomedical science. It promotes the development of systems and policies for the proper evaluation of new technologies that arise from biomedical research.

Sense About Science 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.

OTHER PUBLICATIONS BY SENSE ABOUT SCIENCE INCLUDE:

Making Sense of Chemical Stories: *A briefing document for the lifestyle sector on misconceptions about chemicals*

Making Sense of the Weather & Climate: *An introduction to forecasts & predictions of weather events & climate change*

I don't know what to believe *A short guide to peer review*

Peer Review and the Acceptance of New Scientific Ideas

Science for Celebrities

Standing up for Science *A guide to the media for early career scientists*

There Goes the Science Bit... *A guide to standing up for science*

All are available as free downloads from www.senseaboutscience.org

USEFUL READING

Testing Treatments: Better Research for Better Healthcare. Evans I, Thornton H and Chalmers I. London: British Library, 2006

This is available from www.jamesindlibrary.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.

CONTRIBUTORS



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Professor Peter Furness is the vice-president of the Royal College of Pathologists. He is a consultant histopathologist, based in Leicester. For several years he has been arguing to establish a national system for the authoritative evaluation of laboratory investigations, much as new drugs are currently evaluated.



Dr Andrew Green has been a GP in the East Yorkshire market town of Hedon for 20 years. He qualified in Sheffield and is a Fellow of the Royal College of General Practitioners.



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Dr Aarathi Prasad is public liaison at Sense About Science. She was a medical writer and completed a PhD and post-doctoral research in cancer genetics at Imperial College London.



Hazel Thornton is an independent advocate for quality in research and healthcare. Her seminal paper in The Lancet in 1992 and her presentation, 'The patient's role in research' in 1994 led to the establishment of the Consumers' Advisory Group for Clinical Trials (CAG-CT), a working group of health professionals and patients.



Dr Caroline Wright is project manager at the Foundation for Genomics and Population Health. She has a PhD in biological chemistry and a background in medical devices and biotechnology.

And

Professor Michael Baum Professor Emeritus of surgery and Chair of the ProtecT Independent Steering Committee for Prostate Cancer; **Sir Colin Berry** Professor Emeritus of pathology, Queen Mary College London; **Dr Michael Fitzpatrick** a London GP; **Sir Muir Gray** Chief Knowledge Officer of the NHS; **Dr Evan Harris MP** a doctor formerly working in public health medicine and the Liberal Democrat Science spokesperson; **Dr Keith Hopcroft** a GP in Basildon and a regular columnist for Doctor magazine and The Times; **Alastair Kent** Patient Advocate and Director of the Genetic Interest Group; **Dr Susanne Ludgate** Clinical Director of Devices at the Medicines & Healthcare products Regulatory Agency; **Dr Anne Mackie** Director of the UK National Screening Committee; **Dr Jonathan Middle** Clinical Biochemist and Deputy Director of UK National External Quality Assessment Service; **Dr Andrew Moore** Head of the Pain Research Unit, Oxford; **Dr Margaret Parton** Chief Executive of the NHS National Technology Adoption Hub; **Dr Ian Watson** Chair of the Association for Clinical Biochemistry; **Dr Ron Zimmern** Director of the Foundation for Genomics and Population Health

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