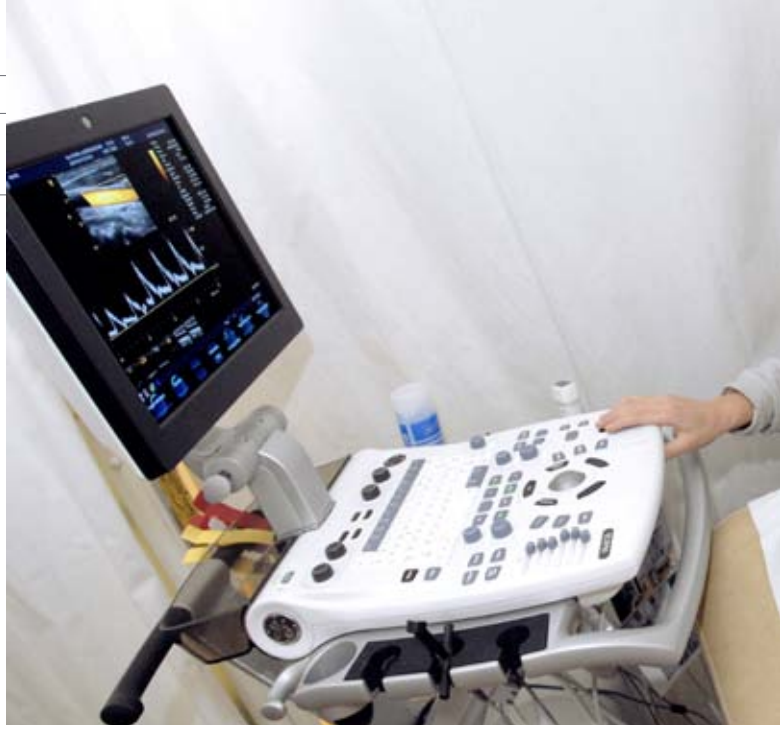
What companies don't tell you about screening

Margaret McCartney questions whether customers of private screening companies are given information to really understand what they are undertaking



The full page advertisements in the weekend press are hard to ignore. "Your quick and easy way to help prevent a stroke," goes the headline, with "Did you know that strokes are the third most common cause of death in the UK?" underneath. Two customers support the company offering the tests, Life Line Screening: "No matter how healthy you might think you are, it could save your life," and "I had very significant narrowing of both coronary arteries . . . I can't thank you enough for virtually saving my life."

Life Line Screening doesn't just advertise in newspapers; it also sends personal looking letters to people; one that I received started, "Did you know that cardiovascular disease is the #1 killer of men and women in the UK—and a leading cause of permanent disability?" Followed by, "Did you know that the majority of strokes can be prevented?"

Life Line's business model is to send letters to people in an area before setting up ultrasound scanners and electrocardiography machines in church halls or leisure centres. For around £100-£200 (€120-€240; $160-$320) it will perform Doppler ultrasound examinations of the carotid arteries and abdomen, testing for peripheral artery disease, and electrocardiography. It also has extra packages offering ultrasound assessment of risk of osteoporosis and a "10 year heart disease risk assessment [that] includes a cholesterol and preventable diabetes glucose test."

"Why doesn't your GP order these screenings?" asks the company's letter. "The answer is that typically such preventative screenings are not available on the NHS for people without symptoms or family history."

Life Line Screening is one of many companies offering testing to asymptomatic people; this is a competitive field. Lifescan, which operates from 19 UK venues, ran a television advertisement stating, "There are lots of ways to keep your health in check. Like eating well, taking regular exercise, getting plenty of sleep, and visiting Lifescan. Our highly advanced CT [computed tomography] health checks could help detect signs of serious illness before symptoms appear, including heart disease, strokes, lung or colon cancer, and aneurysms . . . So if you're 40 or over, keep your health in check with Lifescan."[1] Other companies offer health checks such as a "head to toe clinical exam," spirometry, faecal occult blood testing, CT calcium score of the heart, mammography, lung CT, and magnetic resonance imaging of the brain.[2]

Benefits and harms

It is completely legal for the companies to offer these screening services. But their promotion of these services contrasts with the stance of the NHS, which introduces screening programmes only after a robust review of the evidence against internationally recognised criteria by the UK National Screening Committee (UK NSC). NHS screening programmes are subject to rigorous controls and quality assurance to ensure they maximise the ratio of benefit to harm, and there is a clear pledge in the NHS constitution to "provide screening as recommended by the UK NSC."

The committee's director of programmes, Dr Anne Mackie, says: "Screening tests should be offered only when there is evidence that their use in asymptomatic populations will produce more benefit than harm." The UK NSC has a database listing all of its policies and stating whether screening for a particular condition is recommended. When no good quality research evidence is available, or research has found that screening for a particular condition causes more harm than good, the UK NSC will recommend that routine screening should not take place.

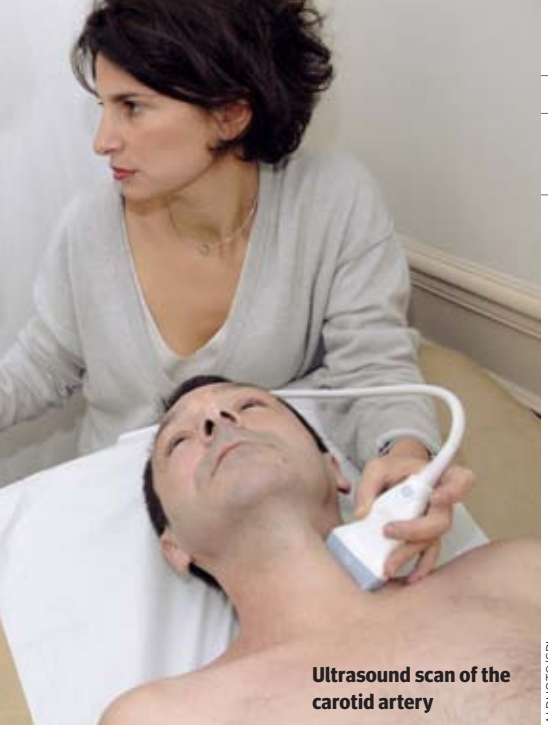
Mackie says that "The UK NSC upholds the right of people to buy these services, but offering screening without explaining fully the risks relating to false positives, which can lead to raised anxiety and further unnecessary diagnostic tests, and false negatives, which provide false reassurance, is unethical." Although Life Line and other providers may give full information to their customers at screening, the letters sent to my home address and the recent full page advertisements do not state the risk of false positive results.

Mackie would like providers of screening tests to be obliged to plainly state the risks of having these tests in their advertisements.

"Screening is not a one way street, and benefit is not inevitable. There must be mention of the risks." She would like to see "providers of screening tests produce good unbiased information up front that outlines whether the test is recommended or not by the UK NSC, that they are explicit that screening is not a foolproof process, and that there is always a risk that screening will falsely identify people as having or not having a condition."

This has also been noted by the independent, not-for-profit consumer organisation Which? The organisation has recently investigated screening companies. A spokesman for Which? explains: "We were concerned about the quality of information given to people making important decisions about whether or not to use them." In particular, Which? wanted to see if the 12th report of the Committee on Medical Aspects of Radiation in the Enviroment (COMARE),[3] published in 2007, had changed the way screening tests were offered. This report recommended regulation of private screening clinics, stating that customers should be given "comprehensive information" including rates of false positive and false negative findings, and that CT screening of the whole body or lung should not be offered.

Other organisations also have concerns about the information given to potential customers. The chairman of the BMA, Hamish Meldrum, and Neil Douglas, chair of the Academy of Medical Royal Colleges, wrote to Andrew Lansley in 2010 to ask

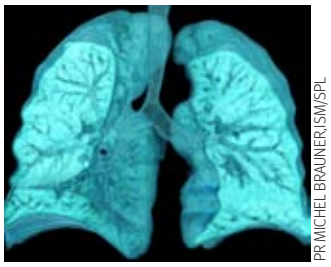


Ultrasound scan of the carotid artery

A/PHOTO/SPL

for improvements in the information on, among other things, false positive and negative results, risks, and limitations of screening tests from private clinics. No legislation has followed.

In the *Which?* investigation, a researcher posing as a potential customer telephoned five companies requesting information about screening tests and what they could achieve. Analysis of the transcripts—which I helped with—found that three companies (Prescan, the European Scanning Centre, and Lifescan) did not mention false positives or negative results and one company, Vital Imaging, only partially covered the risks.



PR MICHEL BRAUNER,ISM/SPL

"Screening is not a one way street, and benefit is not inevitable. There must be mention of the risks"

Which? says "We found that companies were still using CT scans without properly explaining the risks or the further risks about false positives and negatives, even when specifically asked. As well, one company was offering 'peace of mind,' which these scans can't offer and shouldn't be marketed as such. Our experts were very concerned at the complete lack of information given at the point of booking, even when prompted, and that lung scans were being offered to a healthy person with no risk factors." Although the clinics may have given better information to people at the point of being tested, *Which?* says, "We believe that the information given to consumers before they decide to buy should be comprehensive on all risks as well as benefits, allowing them to make an informed choice. It's unrealistic to expect someone to cancel or change their decision on the day."

John Giles, is a consultant radiologist and clinical director of Lifescan, which has scanned 65 000 people since 2003. Lifescan's website says it is "providing awareness, providing peace of mind." I asked whether he thought that offering peace of mind is fair? "Yes," he replied, "we only offer to help provide peace of mind—and only for those illnesses for which the use of CT scans for screening is supported by clinical evidence." Although there has been research into the use of CT of the coronary arteries in cardiovascular risk assessment, as well as CT screening of the lungs and colon, these uses have not been approved by the National Screening Committee. Lifescan's website says that lung scanning is the "ideal check for those who have either smoked in the past, or been exposed to secondary smoke at home or work, have worked with asbestos and hazardous chemicals, or for those with a family history of lung cancer."

Giles said that "we do not offer CT chest scans; however, we do offer low dose CT lung scans, which as you know are very different. The COMARE report published in 2007 was superceded by the US trial for lung cancer, which supported the use of low dose CT lung scans in high risk individuals." This study, however, was of people with a 30 pack-year history of smoking, not passive smokers.[4]

Regulatory confusion

Most screening clinics are registered with the Care Quality Commission (CQC), which has an interest in "treating people with respect and involving them with their care" as well as staffing and management issues. The commission also enforces the Ionising Radiation (Medical Exposure) Regulations, which are intended to "ensure the benefits outweigh the risk in every case."[5] In a statement, the CQC said that "The essential standards of quality and safety (based on the Health and Social Care Act 2008) state that patients are given appropriate information and supported in relation to their care or treatment choices, that they understand those choices available to them and are able to express their views [about] the care or treatment they are receiving. We would expect to see any service that we regulate have policies and procedures in place to make sure that this happens and would look for evidence of that when we inspect." However, it does not assess the literature supplied by each clinic.

The medical director of Life Line Screening, Dr John Coltart, passed my inquiries to the marketing director, Peter Blencowe. Does the company think that its media campaigns are fair? "I feel that our communications fairly and accurately describe the services that we offer," he says. "We focus on an appropriate age group and typically our customers have risk factors such as high blood pressure, high cholesterol, and a family history of vascular disease." However the advertising letters Life Line sends out can be to people at ordinary risk or who are already being managed by their GP for higher risk.

So who is responsible for regulating the standard of information given to people and ensuring that advertising is balanced? Earlier this year, I and several colleagues complained to the General Medical Council about lack of adequate information in advertising for screening. The GMC dismissed this, saying that "We are unable to investigate a matter of this nature unless the complainant(s) have evidence that the doctors in question did not fully explain the risk/benefits of the procedures." In other words, potentially misleading advertising from clinics, even if the company is part owned or directed by doctors, is not something that the GMC will investigate.

So who does protect customers? The Advertising Standards Authority has been investigating a complaint about Life Line Screening since August 2011. It also upheld complaints about the biased nature of Lifescan's advertising in 2008 and 2010.[6 7] However, the authority's impact is limited because adverts can continue running until complaints are upheld: persistent offenders can be referred to the Office of Fair Trading, but this is uncommon.

Dennis Ager, lead officer for health at the Trading Standards Institute, shares concerns about the overlapping responsibilities of agencies in this area. He says that spurious or inaccurate advertisements can be acted on and tend to be treated more seriously when there is evidence of harm or injury to people. "Anyone making such claims must be able to provide evidence to demonstrate that claims are accurate and that they do not mislead consumers." Enforcement action is the ultimate sanction.

This hasn't yet happened to private screening clinics. In June 2011 a revision was made to existing radiation protection legislation to include protection for "any exposure of an asymptomatic individual."[8] The Department of Health has subsequently asked the Royal Colleges of Radiologists and Physicians to produce guidelines on the use of radiation by private clinics offering health checks. There is currently no publication date set. Meanwhile, the adverts promising peace of mind and "quick and easy" non-evidence based and costly screening tests pull people in, with the NHS being left to sort the fallout.

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Competing interests: MMcC is a GP who often has to deal with the results emerging from such private clinics.

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References are in the version on bmj.com.

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● PERSONAL VIEW, p 34; FROM THE FRONTLINE, p 51

BMJ Group Improving Health Awards In association with MDDUS

Joined-up working: introducing the best teams of the year

Anne Gulland reveals the shortlist for the Working in Partnership award

Working with different agencies is not always easy, but it is vital for patients whose conditions do not fit into neat treatment silos. The shortlisted candidates for the 2012 Working in Partnership award are testaments to how team working across many different sectors can yield great outcomes.

North Tyneside Falls Prevention Service (1)
The falls prevention service began with the premise that falls are not an inevitable part of ageing. The service screens all patients over the age of 60 at participating general practices and those identified at risk of a fall attend a review where they have a range of tests.

Steve Parry, consultant geriatrician at Newcastle Hospitals NHS Foundation Trust, believes the service is unique because it seeks out people at risk of a fall: it saw 2554 patients in its first two years.

"We have seen this astonishing number of people who never darken the doors of specialist services, people who have had falls or blackouts. Older people are stoic—they feel that falls are their lot in life," he says.

The success has been striking—in 2010-11 rates of fracture of the neck of the femur rose in neighbouring Newcastle by 11.42%, whereas in North Tyneside they rose by just 2.46%, says Parry. And rates were lower among patients from practices taking part in the pilot.

The partners are the foundation trust, the university, private primary care provider Norprime, North of Tyne Primary Care Trust, North Tyneside social services, North East Ambulance Services, and the charity Age UK.

"If it wasn't for the partnership, there wouldn't be this falls service," says Parry.

Scottish Care Information—Diabetes Collaboration (SCI-DC) (2)
The idea that knowledge is power drives the largest collaboration on the shortlist, covering all 14 Scottish health boards. The SCI-DC provides what it says is the "most comprehensive and highest quality population-based data on people with diabetes anywhere in the world."

The collaboration began in 2000 and has evolved to cover the whole of Scotland, turning data captured from all 1050 general practices, hospitals, screening services, and laboratories into clinically useful tools for the care of diabetic patients.

The annual Scottish Diabetes Survey shows both an increasing prevalence of diabetes and an improvement in the recording of the data. For example, more than 90% of diabetic patients have their blood pressure, haemoglobin A_{1c}, and cholesterol checked annually. Between 2003 and 2010 there has been a 40% reduction in lower limb amputations and sight threatening retinopathy throughout Scotland.

Scott Cunningham, technical consultant for the collaboration, says that good use of information technology has been vital to the success of the project.

"All that information captured in previous consultations is available to the next member of the healthcare team, not relying on a paper trail of letters going from clinics to doctors. People can access that in real time," he says.

Family Drug and Alcohol Court Intervention Team (3)
Michael Shaw, child and adolescent psychiatrist at the Tavistock and Portman NHS Foundation Trust in London, uses a musical analogy to describe the work his team does with parents with drug and alcohol problems who are going through the family courts. The psychiatrists are like the conductors of an orchestra, getting all the different agencies to play their parts in harmony.

The team is a joint venture between the mental health trust and the charity Coram, alongside judges, lawyers, social workers, drug and alcohol workers, housing workers, and researchers. Team members meet parents on their first day in court and design a "trial for change" to test whether parents can overcome their drug and alcohol problems and look after their children properly. Parents must abstain from drugs and alcohol and begin to deal with the causes of their substance misuse.

A small study of 41 families that had gone through the process and 19 comparison families found that the model resulted in higher rates of children being reunited with their families (39% versus 21%). Nearly half of mothers (48%) stopped substance misuse compared with 39% in the comparison families.

Shaw describes the joint working as the "holy grail for policy makers."

"We save money and improve outcomes for children and families," he says.

Fit for Work Team
Leicestershire's Fit for Work Team was one of six pilots launched by the government in 2008 to reduce sickness absence and improve health at work. However, Rob Hampton (4), GP principal and clinical director of the Fit for Work pilot, says that his team has a unique make- up, comprising two primary care trusts, two local authorities, and Jobcentre Plus.

In Leicestershire GPs refer patients on long term sickness absence to a fit for work team made up of occupational health nurses and case managers. The team provides access to services such as musculoskeletal therapies, counselling, and legal and debt advice.

In the first 20 months the team had over 1000 referrals, and 77% of patients returned to or stayed at work. Last July the Fit for Work pilot set itself up as a social enterprise so that it could offer its services commercially. Stress related illness is behind many of the diagnoses, says Hampton.

He acknowledges that bringing people together who had never worked outside their own sphere was difficult.

"We had a common purpose, but how do we work together? It took a while for us to bond as a team. But we have a team day every week and we have lunch—I try to make sure it's fun," he says.

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For more information about the BMJ Group Improving Health Awards 2012 go to http://groupawards.bmj.com.

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BMJ BLOGS **Marge Berer**

Another anti-abortion missionary

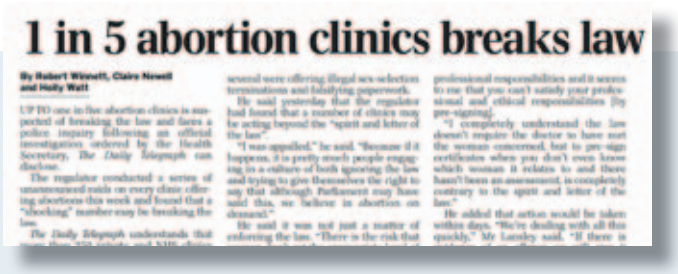
Punch drunk on power after his success at sticking up two fingers to the entire health profession at the passage of the Health and Social Care bill in parliament last week, Andrew Lansley has apparently found a new mission—to harass doctors and clinics who provide abortions, both in the private sector, which he otherwise seems to love so much, and in the NHS, whose death knell he has just sounded.

His first target was abortion counselling. Despite parliament's outright rejection of an attempt by Nadine Dorries MP to change abortion counselling regulations, the Department of Health went fishing for evidence of wrongdoing by non-NHS abortion clinics. It has sought (ironically) to problematise counselling by independent service providers as being linked to profit. After a great deal of fuss, and no evidence of wrongdoing emerging, a consultation on the future of abortion counselling was announced. We await the questions with bated breath, now that the next phase of what is beginning to look like a longer term campaign against abortion providers has begun to emerge.

The next media splurge, thanks to the *Daily Telegraph*, centred on several extremely short, ambiguous video clips, purporting to show two young doctors authorising illegal abortions on grounds of sex selection. These were obtained clandestinely and in violation of key aspects of the ethical code of practice of the Press Complaints Commission, violations that one might have expected a secretary of state for health to be appalled about. He was not. Instead, he seemed to be waiting and ready to use the "full force of the law" (his words) against anyone found violating the Abortion Act.

The lack of understanding of the terms of the 1967 Abortion Act that emerged from this—of what was and was not an illegal abortion under the Act—was breathtaking. And please note, in case you missed my last blog, that so-called sex selective abortion as such is neither legal nor illegal under the Act. Yet the General Medical Council moved with unseemly speed to suspend three of the accused doctors, pending investigation as to whether in fact they had committed any crime.

Then, on Thursday morning, there



1 in 5 abortion clinics breaks law

By Robert Winnett, Claire Newell and Holly Watt

UP TO one in five abortion clinics is suspected of breaking the law and faces a police inquiry following an official investigation ordered by the Health Secretary, *The Daily Telegraph* can disclose.

The regulator conducted a series of unannounced raids on every clinic offering abortions this week and found that a "shocking" number may be breaking the law.

The Daily Telegraph understands that several were offering illegal sex-selection terminations and falsifying paperwork.

He said yesterday that the regulators had found that a number of clinics may be acting beyond the "spirit and letter of the law".

"I was appalled," he said. "Because if it happens, it is pretty much people engaging in a culture of both ignoring the law and trying to give themselves the right to say that although Parliament may have said this, we believe in abortion on demand."

He said it was not just a matter of enforcing the law. "There is the risk that professional responsibilities and it seems to me that you can't satisfy your professional and ethical responsibilities [by pre-signing].

"I completely understand the law doesn't require the doctor to have met the woman concerned, but to pre-sign certificates when you don't even know which woman it relates to and there hasn't been an assessment, is completely contrary to the spirit and letter of the law."

He added that action would be taken within days. "We're dealing with all this quickly," Mr Lansley said. "If there is

was an unannounced raid by the Care Quality Commission on over 250 abortion clinics, again seeking evidence of so-called criminal activity, this time in relation to the forms that doctors are required to fill in authorising every abortion they approve. What these officials seem to have been looking for this time was poor paperwork: evidence of any forms that were signed in advance of consultations, or that had missing or incomplete information on the legal grounds for abortion as per the Abortion Act. Has the CQC really not got anything more serious to worry about? One wonders how much this raid cost the taxpayer, from a health secretary whose government claims we have no money for essential NHS and social welfare services.

To top it off, it seems he just happened to have a press statement ready, which was published on Friday on the front page of—you guessed it—the *Daily Telegraph*, about the evidence collected during these raids. How the CQC managed to collate, analyse, and double-check the evidence from 250 clinics in less than a day is a mystery that may never be solved. However, in the *Telegraph*, it said: "more than 250 private and NHS clinics were visited and more than 50 were 'not in compliance' with the law or regulations. Doctors were regularly falsifying consent forms and patients were not receiving acceptable levels of advice and counselling in many clinics, the Care Quality Commission (CQC) discovered…The main problem identified by the CQC was that doctors were 'pre-signing' consent forms." Oh my goodness. Does that mean they were agreeing to abortion on demand? Not shown, if you ask me, not in the least. Here was his real point: maybe the Abortion Act is not fit for purpose. I smell a full scale anti-abortion campaign coming on.

Marge Berer is the editor of *Reproductive Health Matters*

Read this blog in full and other blogs at bmj.com/blogs

BMJ readers raise almost £34 000 for Lifebox

The final tally from the *BMJ's* winter appeal for the Lifebox Foundation is now available: in just a few short months, readers have donated an astonishing £33 792.03. Thanks to your generosity, Lifebox is sending out more than 211 pulse oximeters to operating theatres in countries from Cambodia to Sierra Leone.

"The generosity of *BMJ* readers around the world will help safeguard thousands of lives that are currently at risk from unsafe surgery," said Lifebox chair and surgeon, Atul Gawande. "It has been a privilege to introduce you to our work over the last few months, and to hear from so many of you about ways we can work together to improve the quality and safety of surgery in low-resource settings. Thank you from all of us."

Atul Gawande: "The generosity of *BMJ* readers will help safeguard thousands of lives"

Online at bmj.com this week (doi:10.1136/bmj.e807), Tony Falconer, president of the Royal College of Obstetricians and Gynaecologists, explains how pulse oximetry makes a major contribution to safer obstetric care.

"Caesarean section is not a luxury. It's the only safe way to give birth in many cases. In addition, pulse oximetry can help doctors in low income countries manage critically ill mothers with obstetric problems such as haemorrhage, high blood pressure and sepsis."

Building on the success of the *BMJ* appeal, Lifebox is now going global. Next week the charity is launching the Make It Zero campaign to eliminate the global pulse oximetry gap, beginning with a two year initiative to provide 5000 pulse oximeters to operating rooms across Africa, Asia, Eastern Europe, and Latin America. Please visit www.lifebox.org/makeitzero for more information. And thank you again.

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lifebox
Saving lives through safer surgery