

Chapter 10

Direct-to-consumer body
imaging

Chapter 10 – Direct-to-consumer body imaging

Overview

What is new? Body imaging technologies that have been used for some time in healthcare for diagnosis (once a person has presented to their doctor with symptoms) have also in the last few years been used in new services offering body imaging directly to people who do not necessarily have any medical symptoms. These screening services are advertised and sold directly to consumers by commercial companies as a form of ‘health check-up’. They offer the possibility of more personalised healthcare in a number of the senses we identified in Chapter 1, although such an outcome depends heavily on the meaningfulness of the results. They raise ethical issues relating to consumerisation and responsabilisation, given that they can be marketed directly to consumers and that undergoing such screening can be presented as responsible behaviour on the part of individuals who want to look after their health.

Which ethical values come into conflict as a result of this development? Potential conflicts arise between the value of individuals being able to pursue their own interests and those of state action to reduce harm, safeguarding private information, fair and efficient use of public resources, and possibly social solidarity.

What is the existing pattern of interventions like? Given that these services involve activity by medical professionals and some of them carry physical risks, most of the interventions that currently apply to them in the UK involve application of state-specific legal powers. In terms of general governance measures the data protection regime applies, and where health professionals are involved they are bound by their own general professional codes and regulatory requirements. More specifically, the equipment itself is regulated for safety.

What gaps or shortfalls are there in existing interventions? We find that the existing arrangements do not promote the provision of good information to potential consumers about direct-to-consumer body imaging services offered as a form of health check, and do not prevent potentially serious harm from some types of scanning. We think more evidence is needed about the range of potential harms that may result from such testing and scanning.

What types of intervention might possibly fill those gaps or remedy those shortfalls? Possible interventions range from research on the benefits and harms involved, requirements for information, restrictions on what is allowed or how it is provided, to outright bans of some types of imaging services.

What types of intervention do we recommend, and why? Some of our recommendations over direct-to-consumer body imaging are similar to those made in the previous chapter on genetic profiling for disease susceptibility, given that some of the same problems are encountered. We attempt to reconcile the value of individuals being able to pursue their own interests in their own way (namely to have the freedom to take these tests should they wish) with that of reduction of harm by state activity, and we consider that the radiological risk that arises from one type of imaging, namely full-body CT scans, is sufficient to justify the introduction of coercive state powers to prohibit the provision of such services. For other types of imaging, including part-body CT imaging, the risk-benefit ratio is unclear and we recommend measures that we think will improve the quality of the services and give consumers better information. Specifically, we recommend: (i) independent research on the impact and effects on individuals of direct-to-consumer body imaging performed as a health check; (ii) appropriate regulation of services; (iii) better provision of information; and (iv) good professional medical practice in the public healthcare system adapted to the situation where patients have had these tests.

Introduction

- 10.1 Body imaging technologies, including computerised tomography (CT), magnetic resonance imaging (MRI) and ultrasound, have been used for some time in healthcare for diagnostic purposes (see Box 10.1). Specialised equipment is used to obtain image data from different angles to produce detailed cross-sectional images of body tissue and organs in two or three dimensions. Patients usually have scans following a referral from a healthcare professional who has considered their symptoms. For example, pictures of the inside of the body can reveal the size and location of cancerous tumours. Our study here focuses on new services that use these same technologies to offer body imaging directly to people who do not necessarily have any medical symptoms. These screening services are often advertised and sold directly to consumers by commercial companies as a form of ‘health check-up’,⁵²¹ often with the suggestion that this is a form of responsible behaviour by people who want to look after their health for the sake of themselves and their families, and analogous to having regular eye tests or dental check-ups. The provision of such services has been made possible by the development of the technologies on which the tests are based and reductions in the cost of that technology. Hence some of the features of these services are similar to those of genetic profiling tests for disease susceptibility that we investigated in our last chapter.

Box 10.1: Types of body imaging

Computed tomography (CT): A medical radiographic imaging technique that uses a computerised x-ray scanning system to produce a digitally processed sectional anatomic image in either two or three dimensions.⁵²² The radiation dose received may be quite substantial (see Paragraph 10.10).

Magnetic resonance imaging (MRI): A medical imaging technique that uses magnetic fields to produce images of tissues and organs. The magnetic nuclei of a patient are aligned in a uniform magnetic field and then subject to a radiofrequency pulse, causing them to absorb and release energy. The energy is picked up by sensitive detectors and converted into a current which in turn is converted into an image. The energy released varies in intensity depending on the environment (i.e. the characteristics of the body organ or tissue) in which it was generated. Thus, different types of tissue will provide different signals, allowing for imaging differentiation of different parts of the body.⁵²³

Ultrasonography: An ultrasonic medical imaging technique, used to produce images of organs and tissue within the body. Ultrasound is sound in the frequency range of 20,000 to 10 billion cycles per second (hertz). The velocity of ultrasound varies according to the medium through which it travels (such as different types of body tissue). Consequently it can be used to outline the shape of different tissues and organs within the body by recording the echoes as they return from the medium through which they travel.⁵²⁴

- 10.2 Private companies offer body imaging in specialist clinics and using mobile equipment, in local halls or other accessible locations. The services and products are marketed as a tool for people who are, as far as they know, in good health and not necessarily in any specific risk group, to obtain reassurance and better information about their body and health. The services are advertised as screening checks to look for the early signs of cancer and heart disease, for

⁵²¹ We also note that the UK National Screening Committee (NSC) has reported that general practices across England are being approached by companies offering private health screens to their NHS patients. The NSC has produced guidance for general practitioners on private screening. See: UK National Screening Committee (2010) *Advice on private health screening being offered through GP practices*, available at: <http://www.screening.nhs.uk/getdata.php?id=9618>.

⁵²² Venes D (Editor) (2009) *Taber's cyclopedic medical dictionary* (Philadelphia: FA Davis Co), p2331.

⁵²³ Adapted from: Venes D (Editor) (2009) *Taber's cyclopedic medical dictionary* (Philadelphia: FA Davis Company), p1391; Pugh MB (Editor) 2000 *Stedman's medical dictionary 27th Edition* (Maryland: Lippicott Williams & Wilkins), p876.

⁵²⁴ Venes D (Editor) (2009) *Taber's cyclopedic medical dictionary* (Philadelphia: FA Davis Co), pp2399–400.

example, and the potential risk of certain conditions such as stroke. See Table 10.1 for examples of some of the imaging tests that are currently available.

- 10.3 Like genetic profiling, direct-to-consumer body imaging, performed as a health check or a risk assessment, can in principle be conducive to at least three of the four types of personalisation we described in Paragraph 1.18: individualised management tailored to the individual involved (when results are meaningful), services provided as a good or commodity directly to consumers, and healthcare services that encourage individuals to take responsibility for their own health and healthcare. But this development can also place new responsibilities on individuals to interpret complex and ambiguous data and weigh up the risks of further treatment (preventive surgery etc.) on the basis of that data. We return to these themes in Chapter 11.

Table 10.1: Examples of direct-to-consumer body imaging services on offer in the UK

Company	Service	Price	Details
Prescan	Total Body Scan	£1,290	"...provides a complete picture of your whole body" "During the Total Body Scan use is made of the MRI-scanner and, if deemed necessary the CT-scanner." ⁵²⁵
Preventicum	Ultimate Plus Check-up	£3,400 ⁵²⁶	Includes several different tests, such as a full physical and hearing test. Imaging scans provided include ultrasound examination of "carotid arteries, liver, gallbladder, biliary tree, pancreas, kidneys, spleen, uterus, ovaries, urinary bladder [and] prostate" and an MRI scan of brain, heart structure and function, arterial system, as well as an MRI colonoscopy. ⁵²⁷
Lifescan	Lifescan Enhanced Check Plus	£790 ⁵²⁸	"This is the most detailed CT health check service offered by Lifescan. It incorporates all the CT scan elements of the Lifescan Enhanced Check but also includes other health assessment techniques to provide a more complete picture of your health." The scans include heart, lung and virtual colonoscopy. ⁵²⁹
European Scanning Centre	CT coronary angiogram	£1,250	"The coronary CT angiogram (CTA) is a diagnostic scan that is used to determine if any of the coronary arteries supplying blood to the heart are narrowed or becoming blocked." ⁵³⁰
Life Line Screening	Abdominal Aortic Aneurysm ⁵³¹	£60 ⁵³²	Screening takes place at venues across the country, such as community centres. ⁵³³ "Life Line Screening uses ultrasound technology to measure the size of your abdominal aorta. The process is painless... Anyone who has risk factors for abdominal aortic aneurysms should have this screening." ⁵³⁴

⁵²⁵ Prescan (2010) Total body scan, available at: <http://www.prescan.co.uk/examinations/total-body-scan>.

⁵²⁶ Preventicum (2010) Prices, available at: <http://www.preventicum.co.uk/prices.asp>.

⁵²⁷ Preventicum (2010) Ultimate plus check-up, available at: <http://www.preventicum.co.uk/ultimate-plus-check-up.asp>.

⁵²⁸ Lifescan (2010) Special offers, available at: <http://www.lifescanuk.org/healthchecks/services/lifescan-enhanced-check-plus/>.

⁵²⁹ Lifescan (2010) Lifescan enhanced check, available at: <http://www.lifescanuk.org/healthchecks/featuresandprices/lifescanenancedcheck/>.

⁵³⁰ The European Scanning Centre (2010) CT coronary angiogram, available at: <http://www.europeanscanning.com/coronary-angiogram.html>.

⁵³¹ Life Line Screening (2010) Screening for abdominal aortic aneurysm, available at: <http://www.lifelinescreening.co.uk/Services/Pages/abdominal-aortic-aneurysm.aspx>. Abdominal aortic aneurysm screening is now being introduced by the NHS. See: Paragraph 10.6.

⁵³² Life Line Screening (2010) Pricing and discounts, available at: <http://www.lifelinescreening.co.uk/Services/Pages/Pricing-and-discounts.aspx>.

⁵³³ Life Line Screening (2010) Preventive health screening, available at: <http://www.lifelinescreening.co.uk/faqs/preventive-health-screening.aspx>.

⁵³⁴ Life Line Screening (2010) Screening for Abdominal Aortic Aneurysm, available at: <http://www.lifelinescreening.co.uk/health-screening-services/abdominal-aortic-aneurysm.aspx>.

Benefits and harms

10.4 Several potential advantages and disadvantages of direct-to-consumer body imaging were listed in Table 3.1.

Potential advantages

- More information;
- allows early intervention and monitoring (if something of clinical significance is found);
- allows more personal control;
- may provide reassurance; and
- possibility of saving public healthcare resources if testing and treatment conducted privately.

Potential disadvantages

- Costs and harms of obtaining information: a) when tests themselves can be damaging (e.g. through radiation), b) when private testing can undermine equal access to healthcare;
 - costs of consequences of having information: a) for individual when inaccurate or hard to interpret, b) for individual when nothing can be done, c) for individual if inaccurate risk assessments lead to misplaced anxiety (or false reassurance in some cases), d) for individual if results lead to stigma or information abuse (e.g. blackmail) or other effects that may be regretted, given that information once known cannot be un-known (e.g. for insurance declarations), d) for taxpayers when unnecessary follow-up testing and treatment is carried out; and
 - can change perception of wellness and illness through medicalisation of normal variation.
- 10.5 As with taking genetic profiling tests (Chapter 9), having imaging scans has the potential to help people to learn more about their health and thereby take more responsibility for looking after their health and managing their healthcare. In their marketing material, the companies offering scans emphasise this theme, giving the following types of reason for individuals to take up their services:⁵³⁵

“At Lifescan we have helped thousands of people to either gain peace of mind about their health or an essential early warning about serious illnesses.” *Lifescan*

“Most of us accept that early detection leads to better health outcomes, and that more focus on preventive health is beneficial.” *European Scanning Centre*

As with genetic profiling, it may be that simply having body imaging and thinking about health encourages some people to take more interest in their health and live healthier lifestyles than they would otherwise do. But to assess properly any benefits and harms, we need to make some assessment of how useful such tests actually are, which we do in the following section.

Clinical validity

10.6 As mentioned in the previous chapter (Box 9.1), in the UK the National Screening Committee (UK NSC) advises the Government and the National Health Service (NHS) about population screening programmes. It assesses the evidence for introducing screening programmes against a set of criteria covering the condition, the test, the treatment options and the effectiveness and acceptability of the screening programme. Assessing programmes in this way is aimed at ensuring that they “do more good than harm at a reasonable cost”.⁵³⁶ We include a summary of

⁵³⁵ Information correct at the time of writing.

⁵³⁶ NHS Evidence (2010) NHS Evidence – screening, available at: <http://library.nhs.uk/screening/>.

the criteria in Box 9.1. These criteria apply to all screening programmes, whether they are genetic or use imaging. An example of a public health programme that uses imaging is the NHS Abdominal Aortic Aneurysm Screening Programme which uses ultrasound, began in 2009 and is being introduced for all men aged over 65 in England, with the rest of the UK to follow.⁵³⁷ Screening can facilitate early detection of disease allowing earlier, possibly more effective treatment although whether to introduce a programme, and the section of the population that should be targeted, is not without controversy.⁵³⁸

- 10.7 A number of trials involving other types of imaging are being conducted to see whether it can be effective for screening for other conditions.⁵³⁹ There are also studies considering the predictive utility of various scanning modalities. For example, some studies suggest it may be possible to use functional MRI to predict the progression of mild cognitive impairment to Alzheimer's disease.⁵⁴⁰ However, there is currently insufficient evidence to suggest that using CT or MRI as a screening tool reduces disease or mortality.⁵⁴¹ Consequently it has been argued for CT that "four decades after the development of this 'technology', we still do not have experimental evidence for or against the implementation of this screening modality".⁵⁴²
- 10.8 As noted above, the screening programmes provided by the NHS in the UK must meet stated criteria for effectiveness. However, these requirements do not apply to screening tests carried out by private providers, and the value of such tests is contestable. Some doctors and scientists argue that conducting many of the tests available on well people will not accurately predict the diseases they will get; it has been suggested that "the recent increase of direct-to-consumer marketing of screening puts patients at risk of making harmful choices in the absence of adequate guidance and constraints".⁵⁴³ Some authors conclude that, because of the potential harms, MRI scanning (for example) for health check-ups should be used only in research studies.⁵⁴⁴

⁵³⁷ For further information see: NHS (2010) Welcome to the NHS Abdominal Aortic Aneurysm screening programme, available at: <http://aaa.screening.nhs.uk/>. See also: Health Scotland (2010) Abdominal Aortic Aneurysm screening, available at: <http://www.healthscotland.com/topics/health/screening/abdominalaorticaneurysm.aspx>; Public Health Wales (2010) Planning of abdominal aortic aneurysm screening to start, available at: <http://www.wales.nhs.uk/sitesplus/888/news/16431>.

⁵³⁸ Raffle AE and Gray JAM (2007) *Screening: Evidence and practice* (Oxford: Oxford University Press).

⁵³⁹ For example, in 2009, there were seven randomised control trials of low dose CT screening in progress, the largest of which were the US National Lung Cancer Screening Trial and the NELSON trials in Belgium and Denmark. These trials are scheduled to report results in 2012 and 2014, respectively. See: Edey AJ and Hansell DM (2009) CT lung cancer screening in the UK *The British Journal of Radiology* **82**: 529–31; Field JK and Duffy SW (2008) Lung cancer screening: The way forward *British Journal of Cancer* **99**: 557–62; McMahon PM and Christiani DC (2007) Computed tomography screening for lung cancer – results of randomised trials are needed before recommending its adoption *British Medical Journal* **334**: 271.

⁵⁴⁰ Zang B, Li M, Sun ZZ *et al.* (2009) Evaluation of functional MRI markers in mild cognitive impairment *Journal of Clinical Neuroscience* **16**: 635–41; Vemuri P, Wiste HJ and Weigand SD *et al.* (2009) MRI and CSF biomarkers in normal, MCI and AD subjects: Predicting future clinical change *Neurology* **73**: 294–301.

⁵⁴¹ Burger IM, Kass NE, Sunshine JH and Siegelman SS (2008) The use of CT for screening: A national survey of radiologists' activities and attitudes *Radiology* **248**(1): 160–8.

⁵⁴² Field JK and Duffy SW (2009) Lung cancer screening: The way forward *British Journal of Cancer* **99**: 557–62.

⁵⁴³ Burger IM and Kass NE (2009) Screening in the dark: Ethical considerations of providing screening tests to individuals when evidence is insufficient to support screening populations *American Journal of Bioethics* **9**(4): 3–14. See also: Sense About Science (2008) *Making sense of testing: A guide to why scans and health tests for well people aren't always a good idea*, available at: <http://www.senseaboutscience.org.uk/pdf/makingsenseoftesting.pdf>.

⁵⁴⁴ Salman RA-S, Whiteley WN and Warlow C (2007) Screening using whole-body magnetic resonance imaging scanning: Who wants an incidentaloma? *Journal of Medical Screening* **14**(1): 2–4. A parallel issue has been raised by the British Medical Ultrasound Society Council, which has noted that developments in real-time three dimensional ultrasonic imaging have led to some parents asking for souvenir images of fetuses, sometimes at several stages during the pregnancy, without any diagnostic element being involved in scan. The British Medical Ultrasound Society Council notes that little information is currently available on possible subtle biological effects of diagnostic levels of ultrasound on the developing human embryo, but has recommended that ultrasound scans should not be performed solely for producing souvenir images or recordings and has drawn attention to the recommendation of the EFSUMB Clinical Safety Statement for Diagnostic Ultrasound that ultrasound examinations should be performed only by competent personnel who are trained and updated in ultrasound safety matters. See: European Federation of Societies for Ultrasound In Medicine and Biology (2006) *Statement on the use of diagnostic ultrasound for producing souvenir images or recordings in pregnancy*, available at: <http://www.efsumb.org/ecmus/souvenir-scanning-statement.pdf>, approved and endorsed by the British Medical Ultrasound Society Council. See: <http://www.bmus.org/about-ultrasound/au-safetystatement.asp>). Similar guidelines have been issued by American Institute of Ultrasound in Medicine. See: http://www.eurekalert.org/pub_releases/2005-08/aiou-tar081005.php.

Clinical utility

10.9 We have seen some reports sent to patients (and sometimes their general practitioners) following scans that have been carried out by one of the major companies involved. We have a number of concerns about the clinical relevance and meaningfulness of the information provided: (1) the information provided was difficult for a lay person to interpret and advised that they contact their general practitioner without offering any further advice or opportunity for consultation by the company itself; (2) patients without any risks classed as higher than 'moderate' were advised to attend for a repeat annual CT scan without reference to the associated radiological harms (see below); (3) patients were informed of the risk of adverse health problems within the following five years without any advice about how to lessen this risk beyond continuing to live a healthier lifestyle; (4) some of the terms used, such as current risk being 'likely' and the risk of a 'significant' condition, were undefined; and on a slightly different point (5) the qualifications of the people analysing the images was not made clear. We recognise however, that a patient who receives a warning about the risk of a substantial adverse health event may be more likely to take care of their health and live a healthier lifestyle as a result. We make a recommendation aimed at obtaining more evidence about the impact of taking these scans in Paragraph 10.29.

Physical harms of the tests themselves

10.10 One difference between some of the imaging procedures available, specifically CT scans, and the genetic tests considered in the previous chapter is the risk of physical harm resulting from the procedure itself. The radiation dose from a CT scan is clinically significant, and more so for whole-body scans than smaller body sections; evidence suggests that it can lead to an increased risk of radiation-induced fatalities.⁵⁴⁵ A major study in this area by the UK-based Committee on Medical Aspects of Radiation in the Environment (COMARE) reported in 2007 that, if 100,000 people were to undergo a typical whole body CT scan with a dose of 10 mSv,⁵⁴⁶ every five years between the ages of 40 to 70 years, then the estimated impact would be 240 radiation-induced fatalities over this time⁵⁴⁷ – risks that are clearly substantial. However, we note that companies currently do not appear to be offering whole-body CT scans (see Paragraph 10.16). We make a recommendation about warning customers about health risks in Paragraph 10.33. MRI and ultrasound do not use ionising radiation and do not carry physical risks in the way that CT scans do.

10.11 The more of the body that is scanned, and the more frequent the scanning, the higher the risk. The COMARE report concluded: "We recommend ... that services offering whole body CT scanning of asymptomatic individuals should stop doing so immediately. Where scans are offered for a number of discrete anatomical regions within a single scanning procedure, the advertising should clearly state which regions are examined and for which conditions the scan is optimised. In CT scanning it is not possible to optimise exposure parameters for scans of the

⁵⁴⁵ Committee on Medical Aspects of Radiation in the Environment (2007) *Twelfth report – the impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals*, p13, available at <http://www.comare.org.uk/documents/COMARE12thReport.pdf>; Fazel R, Krumholz HM, Wang Y *et al.* (2009) Exposure to low-dose ionizing radiation from medical imaging procedures *New England Journal of Medicine* **361(9)**: 849–57.

⁵⁴⁶ Committee on Medical Aspects of Radiation in the Environment (2007) *Twelfth report – the impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals*, p13, available at <http://www.comare.org.uk/documents/COMARE12thReport.pdf>; Kmietowicz Z (2007) Computed tomography screening – Better safe than sorry? *British Medical Journal* **335**: 1182–4.

⁵⁴⁷ Committee on Medical Aspects of Radiation in the Environment (2007) *Twelfth report – the impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals*, available at <http://www.comare.org.uk/documents/COMARE12thReport.pdf>, p13.

whole of the body.”⁵⁴⁸ The Committee did not judge any benefits of whole body scanning to be worth the exposure to radiation and other potential harms such as those mentioned below.

10.12 In April 2010, the Department of Health in England announced that it had accepted all the recommendations made in the COMARE report. The Department of Health also requested that the Royal College of Radiologists and the Royal College of Physicians develop “guidance for practitioners based on the balance of risk and benefit involved in the CT scanning procedures concerned.”⁵⁴⁹ No further announcement has been made since the new Government entered office in May 2010.

Psychological harms and harms caused by further investigations

10.13 All types of imaging can result in finding ‘incidentalomas’⁵⁵⁰ – abnormalities without clinical signs or symptoms that are picked up incidentally during imaging. MRI scans are particularly likely to result in such discoveries, especially when using high-resolution MRI sequences.⁵⁵¹ It may of course be that some people are pleased to be informed of the possibility that they may have a serious medical condition. But it may also be that such abnormalities will never in fact cause any symptoms or have simply always been present in the individual concerned. Moreover, if there is no treatment or means of prevention available for the possible ills that the scans might indicate, people receiving this news could suffer from considerable anxiety. One study found that “adverse psychological effects are a common immediate consequence of positive test results following [the] risk assessment” of an illness.⁵⁵² Additionally there is the possibility of a false negative result where, for some diseases that are very difficult to identify using imaging, a patient is given the ‘all-clear’ when in fact there is significant pathology present. There is the risk that they may then stop their healthy behaviours or ignore clinical signs and symptoms they experience. Screening tests carried out in the NHS are accompanied by information explaining this problem. Thus it is important that people who have screening tests understand that the information they will be provided with is subject to error, and we return to this point in our recommendation in Paragraph 10.31.

10.14 Some of the most potentially serious harms could result from people being either advised or wanting to undertake further invasive tests and procedures following an initial body scan. This may, for some people, result in the early identification and treatment for a medical condition. However, invasive procedures always carry an associated risk, and in some cases – such as operations and complications arising thereafter – the risk can be potentially serious. If we remember that a person might be exposed to this risk on the basis of imaging that was not optimised for a particular condition or body part (see Paragraph 10.11) and not clinically indicated (i.e. there are no symptoms), the harm caused could be greater than any benefit. It is this type of consideration that the UK NSC takes into account when considering whether to recommend a screening programme in the NHS: the Committee states that it would not recommend a programme that would produce more harm than good or where there was no effective treatment or intervention available.

⁵⁴⁸ Committee on Medical Aspects of Radiation in the Environment (2007) *Twelfth report – the impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals*, available at <http://www.comare.org.uk/documents/COMARE12thReport.pdf>, p52.

⁵⁴⁹ Department of Health (2010) Better protection for patients having ‘MOT’ scans, available at: http://www.dh.gov.uk/en/MediaCentre/Pressreleasesarchive/DH_115243. See also: Department of Health (2010) *Consultation response to the COMARE 12 report: Recommendations on CT scanning of asymptomatic self-referred individuals*, available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_116721.

⁵⁵⁰ Salman RA-S, Whiteley WN and Warlow C (2007) Screening using whole-body magnetic resonance imaging scanning: Who wants an incidentaloma? *Journal of Medical Screening* **14**(1): 2–4.

⁵⁵¹ Morris Z, Whiteley WN, Longstreth WT Jr *et al.* (2009) Incidental findings on brain magnetic resonance imaging: Systematic review and meta-analysis *British Medical Journal* **339**: b3016.

⁵⁵² Shaw C, Abrams K and Marteau TM (1999) Psychological impact of predicting individuals' risks of illness: A systematic review *Social Science and Medicine* **49**: 1571–98.

Impact on insurability

10.15 Some issues relating to insurability following taking screening tests are similar to those related to genetic profiling. As we noted in Chapter 9, we have been informed by the Association of British Insurers (ABI)⁵⁵³ that insurers ask about tests and investigations carried out (or planned) and not specifically how tests or investigations originated. It is for the insurer to decide whether the information provided is relevant and insurers require full and accurate answers to direct questions for a policy to be valid. Different insurers vary as to the time period covered by their questions, and what they ask for and how they treat it will depend on how relevant they think the information could be to the insurance policy concerned. Some media reports have suggested that insurance premiums could rise as a result of undergoing ‘body MOTs’, including medical imaging services.⁵⁵⁴ We conclude that there may be questions as part of applications for various types of insurance that require the applicant to disclose information relating to imaging tests: not answering or hiding the existence of test results would constitute non-disclosure that could affect the validity of an insurance claim. We return to these issues in the recommendations in Paragraphs 10.31 and 10.33.

Extent of use

10.16 It has proved difficult to find out how many of these types of body imaging tests are being carried out. We wrote to all the major companies operating in this business in the UK asking for information about the scale of their operations but received only one response – which said that information about the company’s number of patients was commercially sensitive and therefore could not be disclosed to us. As with UK genetic profiling companies, we examined the information about UK imaging companies held at Companies House.⁵⁵⁵ The major UK body imaging firms were, according to the most recent filings at the time of our inquiries, either small companies or not currently making a profit.⁵⁵⁶ Whole- (or ‘full-’) body CT scanning was previously being offered in the USA but the two main companies involved have stopped offering this service. In the UK, companies offer scans of various body regions and organs but they do not appear to be offering ‘whole-body’ CT scans.

Current system of interventions

10.17 As in our other case studies, we note that medical professionals working in the UK are subject to a system of responsibility and liability which we summarised in Box 4.1. Therefore any medical professionals involved in providing imaging services will be bound by their own professional standards and the laws of the country they are operating in. In addition to those general provisions, there are other types of intervention applying to imaging services that are briefly described below.

⁵⁵³ Information supplied by the Association of British Insurers.

⁵⁵⁴ One report claims such a premium increase took place after a customer declared the presence of gallstones. See: *Which?* (2009) *Which?* checks up on private health MOTs *Which? Magazine* 1 August.

⁵⁵⁵ Companies House performs a variety of functions, one of which is to “examine and store company information”. Information regarding companies established in the UK are available for a fee. See: Companies House (2010) Our main functions, available at: <http://www.companieshouse.gov.uk/about/functionsHistory.shtml> and Companies House (2010) WebCheck, available at: <http://wck2.companieshouse.gov.uk/c221d2b44f40d1871bd8f703b9ae2db7/wcframe?name=accessCompanyInfo>.

⁵⁵⁶ Defined under s382 Companies Act 2006 as meeting two or more of the following requirements: having a turnover of less than £5.6 million, a balance sheet total of less than £2.8 million and fewer than 50 employees.

Data protection

10.18 We have already summarised the data protection regime earlier in this report (see Paragraphs 5.37–40 and 9.23) and the data protection laws described there apply to providers of body imaging services that are based in the UK and Europe, just as they do to other types of personal data.

Provision of information by providers and advertising

10.19 As we said in Chapter 9, NHS screening programmes are required to provide advisory information to people before they take a test, concerning the risks and benefits, the potential for diagnostic errors and the implications of any subsequent investigations or treatment. However, this information is not required for screening tests offered outside the NHS. If companies meet the general requirements of the advertising standards regime as described in Chapter 5 (i.e. that their advertising is not considered to be misleading) they do not have to satisfy any further legal or self-regulatory standards relating to the information provided prior to sale other than those applying in the general tort law described in Chapter 4.

Regulation of services

10.20 There is no general and complete regulatory framework applicable to private providers of body imaging services for asymptomatic individuals in the UK. Some have argued that those providers are not adequately regulated, such that either regulation in the strict sense used in Chapter 4, or a medical screening code of practice, would be valuable.⁵⁵⁷

10.21 CT scanning is subject to the law relating to exposure to ionising radiation. The Ionising Radiations Regulations 1999 are designed to protect people whose work may expose them to ionising radiation. The regulations aim to “establish a framework for ensuring that exposure to ionising radiation arising from work activities is kept as low as reasonably practicable and does not exceed dose limits specified for individuals.”⁵⁵⁸

10.22 As for people having CT scanning, the Ionising Radiation (Medical Exposure) Regulations 2000 outline the basic protections necessary,⁵⁵⁹ which apply to both NHS and private provision.⁵⁶⁰ The regulations are designed to protect patients from unintended, excessive or incorrect exposure to radiation; ensure that the risk from exposure is assessed against the clinical benefit; ensure that patients receive no more exposure than is necessary to achieve the desired benefit within current technical limits; and protect volunteers in research programmes and those undergoing medico-legal exposures.⁵⁶¹ The Justification of Practices Involving Ionising Radiation Regulations 2004⁵⁶² provided a framework in which decisions relating to the

⁵⁵⁷ Committee on Medical Aspects of Radiation in the Environment (2007) *Twelfth report – the impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals*, available at <http://www.comare.org.uk/documents/COMARE12thReport.pdf>, p51; Wald NJ (2007) Screening: A step too far. A matter of concern *Journal of Medical Screening* **14**: 163–4; Sense About Science (2008) *Making sense of testing: A guide to why scans and health tests for well people aren't always a good idea*, available at: <http://www.senseaboutscience.org.uk/pdf/makingsenseofesting.pdf>.

⁵⁵⁸ Health and Safety Executive (2000) *Work with ionising radiation: Ionising Radiation Regulation 1999 – approved code of practice and guidance*, p6, available at: <http://www.hse.gov.uk/pubns/priced/l121.pdf>.

⁵⁵⁹ The Regulations implement Council Directive 97/43/EURATOM on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/446/Euratom [1997] OJ L180/97.

⁵⁶⁰ Department of Health (2007) *The Ionising Exposure (Medical Exposure) Regulations 2000 (together with notes on good practice)*, p1, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_064707.pdf.

⁵⁶¹ Commission for Healthcare Audit and Inspection (2008) *Ionising Radiation (Medical Exposure) Regulations 2000: A report on regulation activity from 1 November 2006 to 31 December 2007*, p4, available at: http://www.carequalitycommission.org.uk/db/documents/IRMER_14month_report.pdf. The 2000 Regulations were amended in 2006 by the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006 which, among other changes, altered some definitions. In 2009, the responsibility for this area passed to Care Quality Commission.

⁵⁶² Which implements elements of Council Directive 96/29/Euratom laying down basic safety standards for the protection of the health of workers and the general public against the danger arising from ionising radiation [1996] OJ L159/96.

justification of exposure to ionising radiation may be made. These decisions involve “weighing the overall benefits of classes or types of practices which might result in the exposure of people to ionising radiation against the harm likely to be caused by the radiation exposure”.⁵⁶³ Against this legal background, CT whole-body scanning of asymptomatic individuals in particular seems hard to justify.⁵⁶⁴ We return to these issues in our recommendations in Paragraphs 10.26 and 10.27.

Softening the ethical dilemmas

- 10.23 The evidence reviewed in this chapter indicates that offering body imaging directly to people who do not have any apparent medical need presents some distinct problems. As we have noted, there are potential benefits, including the possibility of people being better informed about their state of health if they want to be, and of being prompted to make healthier lifestyle choices. Imaging tests will also sometimes reveal information that is valued by, or useful to, the customer and reveals serious conditions that would not otherwise come to light and which can be acted upon. However, when looking at the risks at the population level, we consider the potential for harm to be large, including as it does the radiological risk for CT scans, and the harms associated with false negatives and positives, finding ‘incidentalomas’ that may never cause any clinical symptoms, finding features that are likely to cause clinical symptoms but there being no treatments available, and finding features that lead to people having invasive further testing or procedures that themselves carry risk.
- 10.24 In these circumstances we face several conflicts between the ethical values we set out in Chapter 3. We attempt to reconcile the value of individuals being able to pursue their own interests in their own way (namely to have the freedom to take these tests should they wish) with that of reduction of harm by state activity. We consider that the radiological risk that arises from one type of imaging, namely whole-body CT scans, is sufficient to justify the introduction of coercive state powers to prohibit the provision of such services. For other types of imaging, including part-body CT imaging, the risk-benefit ratio is unclear, and on the basis of our other ethical values we recommend measures that we think will improve the quality of the services and give consumers better information. These measures are: (i) independent research on the impact and effects on individuals of direct-to-consumer body imaging provided as a health check; (ii) appropriate regulation of services; (iii) better provision of information, and (iv) good professional medical practice in the public healthcare system adapted to the situation where patients have had these tests.

Physical harms of CT scanning

- 10.25 As noted above, CT scans carry serious physical risks from the radiation involved, especially when whole-body scans are involved and when carried out on repeated occasions (see Paragraph 10.10). Whole-body CT scans do not appear to be on offer at present from private companies in the UK, and we do not consider the harms to be outweighed by any benefits they might offer. In this case we consider the harm serious enough to justify the use of coercive state powers, according to the proportionality principle discussed in Chapter 4.
- 10.26 **We recommend that the commercial sale of whole-body (full-body) CT imaging sold as a ‘health check’ to asymptomatic individuals should be prohibited. Any benefits for asymptomatic people do not justify the potential for harms caused as a consequence. Although there is a common law negligence framework that applies to harms caused by**

⁵⁶³ Department for Environment, Food and Rural Affairs (2004) *Explanatory memorandum – the justification of practices involving Ionising Radiation Regulations 2004*, available at: http://www.opsi.gov.uk/si/em2004/uksiem_20041769_en.pdf.

⁵⁶⁴ Committee on Medical Aspects of Radiation in the Environment (2007) *Twelfth report – the impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals*, available at <http://www.comare.org.uk/documents/COMARE12thReport.pdf>, p52.

these services as with others, it is difficult to use this legal remedy because a claimant would need to prove that damage had been caused by a particular service. Therefore we think legislation for whole-body CT scans is required and proportionate to potential harm. Any such legislation should also cover attempts to carry out various part-body CT scans on the same day or in close proximity. Legislation would need to be kept under review were the risk-benefit ratio to change.

- 10.27 With regard to part-body CT scans, we recommend to providers that the carrying out of these on asymptomatic people should be governed by the best-interests principle, applied for each customer. We do not consider there is sufficient evidence to prohibit these scans.

Information available to customers

Research and information provided by public healthcare systems

- 10.28 As with genetic profiling (Chapter 9), there is a lack of evidence on the effects on people of undergoing direct-to-consumer body imaging, in terms of either their health behaviour or their psychological health (see also Paragraph 10.13–10.14). We therefore make a similar recommendation to the one in the previous chapter (Paragraph 9.47) based on the fact that, if people are to be able to pursue their own interests in their own way, they need good information about services they might consider purchasing.

- 10.29 **We recommend that independent research on the health benefits, psychological harms and harms resulting from any follow-up procedures of direct-to-consumer body imaging when offered as a health check should be carried out by public healthcare systems. Such research should involve investigation into how many people are purchasing this type of service. The results of this research should be made easily accessible. We recognise this information will need updating periodically if technical or other developments change the level of risks or the potential for finding out useful information. Potential buyers could then better assess the impacts they might expect, whether positive or negative. In the UK the National Institute for Health Research could be best placed to fund and commission this research.**

- 10.30 As mentioned in Paragraph 10.19, the information provided by commercial companies to consumers of body imaging sold as a health check, either in advance of purchase or after the imaging has been done, is not subject to any formal regulation or self-regulatory code, other than through the advertising standards regime and through the general law of tort and delict in the UK and elsewhere. As with genetic profiling for disease susceptibility, we are concerned that it is difficult for people to find out general information about these body imaging services from an independent source (i.e. from somewhere other than the companies themselves). Such general information about other commercial sector services is available from government sources, for example (see Paragraph 9.48). Provision of such information would serve both to enable people to pursue their own interests in their own way and to prevent harm by state activity.

- 10.31 **We recommend that appropriate publicly-funded health service websites should include general information for the public about body imaging services offered by commercial companies directly to the consumer for people without symptoms. This information should include details of:**

- **potential risks and benefits, including the possibility of further interventions being recommended and their implications;**
- **how imaging might not be optimised for analysing all conditions;**
- **the difficulties of interpreting these tests without reference to clinical symptoms;**
- **the possibility of finding out about conditions for which treatment is not available; and**

- whether it could be necessary for consumers to inform life, mortgage or travel insurance companies of the results of any tests, either at the time or in the future.

We further recommend that governments should require details about where to find this information to be included in the advertising and information provided by companies selling body imaging services directly to the consumer as a health check in their countries (see also recommendation in Paragraph 10.33).

Information provided by commercial providers

10.32 As with genetic profiling services (Chapter 9), the information on some body imaging providers' websites and in their promotional information gives the impression that only useful information can be gained from taking these tests. This impression is conveyed particularly in the 'customer testimonials' that are provided. However, we do not find this information comprehensive.⁵⁶⁵ Potential customers would be better able to make informed choices if these companies were to provide better information about the services they offer, indicating both how those services can be useful and what their limitations are. We recommend a two-pronged approach: governments should provide independent general information as set out above, and the providers themselves should make available specific information relating to their services.

10.33 **We recommend that all companies that provide direct-to-consumer body imaging for asymptomatic individuals should make the following information prominently available in lay language to the consumer before they buy:**

- the operator of the services;
- information about the evidence on which interpretations of the test results are based;
- the tests' limitations;
- the price and what the cost covers;
- the specialism of the person analysing and reporting the imaging results;
- the proportion of all those having body imaging who are advised to undergo further imaging;
- the possibility of further interventions being recommended and their implications;
- the average interval recommended between imaging;
- any physical or other harms or risks of the imaging procedure (including relating to the radiological risks of CT scans depending on how much of the body is scanned);
- information about the possibility of finding serious health problems and how 'bad news' will be broken;
- the nature of the risk (absolute or relative) being communicated to the consumer;
- advice about whether it might be necessary for consumers to declare any results they receive as a result of the imaging to mortgage or travel insurance companies;

⁵⁶⁵ See also: Committee on Medical Aspects of Radiation in the Environment (2007) *Twelfth report – the Impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals*, p51, available at: <http://www.comare.org.uk/documents/COMARE12thReport.pdf>.

- which other third parties, if any, have access to the information/data;
- arrangements for data security (including in cases of any changes to the administration of the company); and
- where to find independent information about this type of service on public healthcare service websites (see our recommendation in Paragraph 10.31).

Regulation of imaging services

10.34 In the UK, a number of statutory bodies regulate health services,⁵⁶⁶ whether provided by the NHS, local authorities, private companies or voluntary organisations (see Box 4.1). However, because the imaging scans on which this chapter focuses do not involve interventions or treatment, the services are not currently subject to any regulatory provisions other than those applying to the safety of the ionisation technology. The distinction between being a ‘health’ service or not does not appear relevant when imaging is sold on the basis of being able to provide health information.

10.35 We recommend that commercial companies that sell imaging tests directly to consumers should be regulated by an appropriate legally constituted regulator such as the Care Quality Commission in England, the Scottish Commission for the Regulation of Care, Healthcare Inspectorate Wales and the Northern Ireland Regulation and Quality Improvement Authority, to ensure services are meeting established standards of quality and safety. We further recommend that the regulator should require the companies involved to provide the information that we recommend in Paragraph 10.33.

Impacts for public healthcare system

10.36 We observed in the previous chapter on personal genetic profiling for disease susceptibility that the availability of these services could have implications for publicly-funded healthcare systems. Our consultation respondents informed us that patients who had undergone commercial body imaging as a health check were often also reporting to their general practitioner (GP) for advice and follow-up. A survey of 260 GPs by *Pulse* magazine supports this finding.⁵⁶⁷ We have seen the results from one of the major companies offering imaging in the UK in which the client is encouraged to consult his/her GP. As we explained in the previous chapter, this situation involves a dilemma between our ethical value of solidarity (risk pooling and helping the vulnerable) and that of using public resources fairly and efficiently. We think it would not be appropriate for a public healthcare system to turn away people who were worried about their health as a result of a privately bought body imaging service. If the information provided as a prerequisite to taking the tests were more comprehensive (as we recommended above, see Paragraph 10.33), we would expect the impact on primary care doctors in the public healthcare system to be reduced.

10.37 We recommend that organisations responsible for the training of healthcare professionals and professional standards (such as medical schools, Royal Colleges and the General Medical Council in the UK) should train and advise healthcare professionals about best practice in the areas of giving advice about direct-to-consumer body imaging services offered as a health check: recognising their value as a tool for discussing healthier lifestyles, addressing their limitations, and taking a responsible position with regard to when to refer patients for specialist services.

⁵⁶⁶ The Care Quality Commission in England, the Scottish Commission for the Regulation of Care, Healthcare Inspectorate Wales and the Northern Ireland Regulation and Quality Improvement Authority.

⁵⁶⁷ The survey reports that “Four GPs in five reported seeing patients who have requested treatment for suspected problems uncovered by private screening.” The survey also reported that 46% of the respondents thought that the NHS should pay for the cost of follow-on treatment. See: Anekwe L (2009) Investigation: GPs cope with fallout from private screening explosion *Pulse* 24 June, available at: <http://www.pulsetoday.co.uk/story.asp?storycode=4123069>.

Safeguarding private information

- 10.38 Companies that provide imaging services hold personal information about their consumers. Consistent with the value of safeguarding private information, we think providers of these services should take seriously their responsibilities about transferring and holding private information. Even if a company guaranteed security, if it went into administration or changed hands, there is no guarantee that the data held would be secure.
- 10.39 **Body imaging companies should provide details about what would happen to body imaging data should the company go into administration or change hands in the information available to consumers before they buy (see also our recommendation in Paragraph 10.33). Healthcare regulators, such as the Care Quality Commission in England, should include a requirement to this effect for companies in their regulation requirements (see our recommendation in Paragraph 10.35).**

Future impact

- 10.40 It is difficult to predict how popular direct-to-consumer body imaging services will become given the lack of information about the size of the industry at the moment. But the volume of scientific research on the use of body imaging techniques for screening for diseases suggests that new commercial applications may well become available in the future, and the more commercial applications develop, the more impact we can expect on public healthcare services. More evidence about the way people respond to body imaging could help both to guide interventions relating to commercial applications and to shape the development of state-funded programmes.