

PREVENTIVE SCREENING: PROVIDING PEACE OF MIND OR LOOKING FOR TROUBLE?

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Introduction

Most of us will have direct or indirect experience of ultrasound, computerised (or computed) tomography (CT) or magnetic resonance imaging (MRI) scans. The former being commonly used to check foetal development during pregnancy and the latter two are often used to detect abnormalities or disease such as cancer or degenerative bone disease. However, recent years have seen two significant developments in the use of these forms of scans. First, with the use of scanning technology in preventive screening programmes and second, with such scans being marketed directly to the public as an integral part of health checks offered by commercial health care companies.

In this article I focus upon the recent roll-out of the National Abdominal Aortic Aneurysm (AAA) Screening Programme in England, which uses ultrasound scanning to detect AAA disease,¹ and on the use of ultrasound, CT and MRI scans by private companies offering their customers check-ups to test for possible signs of health problems or disease. The latter development has recently been examined by the Nuffield Council on Bioethics in their report, *Medical profiling and online medicine: the ethics of 'personalised healthcare' in a consumer age*.² Finally, I consider some of the practical, ethical and legal implications in relation to the use of scanning in these contexts.

In Part I, I briefly explain what ultrasound, CT and MRI scans involve and their principal risks. In Part II, I examine the National AAA Screening Programme, and the use of scanning technologies in health checks offered by commercial companies, and consider some of the practical and ethical issues and difficulties in relation to these uses of scans. In Part III, I consider possible legal implications in relation to the conduct of scans.

I. Technology Commonly Used in Preventive Screening: Uses and Risks

The National AAA Screening Programme uses ultrasound scanning³ whilst commercial health care companies offer a variety of checks that make use of

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¹ UK National Screening Committee (NSC), *NHS Abdominal Aortic Aneurysm (AAA) Screening Programme*, available at: <http://aaa.screening.nhs.uk/screeningresults> (13 December 2010).

² Nuffield Council in Bioethics, 'Direct-to-consumer body imaging' in, *Medical profiling and online medicine: the ethics of 'personalised healthcare' in a consumer age* in London: Nuffield Press 2010, Available at: <http://www.nuffieldbioethics.org/personalised-healthcare/personalised-healthcare-body-imaging> (13 December 2010).

³ See Part II, *post*.

ultrasound, CT and MRI technologies.⁴ It is therefore helpful to begin by considering in simple terms what these methods of scanning do and what the principal risks involved in each form of technology are, before moving on to a more detailed consideration of the practical, ethical and legal implications involved in preventive scanning.⁵

1.1 Ultrasound Scanning

Ultrasonography, also known as ultrasound scanning, uses high-frequency ultrasound (sound which is of a frequency above 20,000 hertz) to produce pictures of structures within the body, e.g.: organs such as the liver, pancreas and gall bladder; lymph nodes, and the vascular system.⁶ Since it does not use X-rays, it does not carry the radiation risks associated with CT scanning. Furthermore it is regarded as being safe for use during pregnancy, when it is commonly used to provide images of the developing foetus. Among its many uses are the confirmation of pregnancy, the assessment of gestational age and the detection of foetal abnormality.⁷ Ultrasonography may produce less satisfactory images in obese patients, because the clarity of the image produced decreases with the depth of tissue which has to be penetrated by the ultrasound.⁸ In such patients, CT scans are likely to provide more satisfactory images.⁹

1.2 CT Scanning

CT scanning involves using a computerised X-ray scanner (a CT scanner) to take X-rays of 'slices' of the body and then using a computer to create cross-sectional images, which may be displayed in two or three dimensions.¹⁰ CT scans have many uses, including the assessment of brain injury and the staging of cancer (assessing the size of a tumour and the extent of any metastases).¹¹ CT scanning has advantages over ultrasound scanning in that it provides better defined images in many circumstances, but, since it uses X-rays, it is not suitable to use during pregnancy, and it may expose the patient to quite a high

⁴ See Table 1, Part II, *post*.

⁵ Definitions are provided in the Nuffield Council on Bioethics Report, *supra* note 2, p.167. For a more detailed consideration of health screening see: A. Raffle and M. Gray, *Screening: Evidence and Practice*, Oxford: Oxford University Press, 2007.

⁶ *Oxford Concise Medical Dictionary*, Oxford: Oxford University Press, 1994, p.685; D. Venes (ed.), *Taber's Cyclopedic Medical Dictionary*, Philadelphia: F.A. Davis Co., pp.2399-2400; D. Provan (ed.) *Oxford Handbook of Clinical and Laboratory Investigation*, 3rd Edn., Oxford: Oxford University Press, 2010, pp.751-752.

⁷ Provan, *supra* note 6, pp.753-754.

⁸ *Ibid.*, p.751.

⁹ L. Kreel & H.B. Meire, *The diagnostic process: a comparison of scanning techniques*, *BMJ* 1977-2 pp. 809, 810.

¹⁰ *Ibid.*; *Oxford Concise Medical Dictionary*, *supra*, note 6, p.143; Venes, *supra*, note 6, p.2331; Provan, *supra*, note 6, pp.756-759.

¹¹ *Oxford, ibid.*; Provan, *ibid.*, p.757. See e.g.: J.E. Husband, 'Role of the CT scanner in the management of cancer', *BMJ* 1985- 290, p.527; S.M. Nazim, M.H. Ather, K. Hafeez and B. Salam, 'Accuracy of multidetector CT scans in staging of renal carcinoma', *International Journal of Surgery* 2011-9, p.86.

dose of radiation, which may increase their risk of developing radiation-induced cancer. For example, it has been estimated that a CT of the abdomen may expose a patient to a dose of radiation of 8.0 mSv, which is equivalent to 400 chest X-ray examinations or 1217 days of average exposure to natural background radiation.¹² There is approximately a one in three lifetime risk of a person in the United Kingdom developing cancer.¹³ However, data indicates that exposure to radiation via CT scans increases this risk of developing cancer and that the risk further increases with repeat scanning which exposes the patient to higher doses of radiation.¹⁴ It has been estimated that exposure to ionising radiation via medical radiological examinations may lead to an additional number of cases of solid tumours amounting to 800 men and 1300 women per year in the United Kingdom,¹⁵ and that one in 270 women aged 40 who undergo CT coronary angiography will develop cancer as a result of their exposure to radiation during the procedure.¹⁶

I.3 MRI Scanning

MRI scanning techniques use a magnetic field to produce images of the body. The powerful magnets within an MRI scanner cause the protons within the nucleus of the hydrogen atoms in the water molecules in the body to align in the same direction. These magnetic nuclei are then subjected to radiofrequency pulses, which causes them to absorb energy and, when the radiofrequency source is switched off, to emit signals in the form of radio waves. Computer analysis is then used “to ‘map out’ the variation in tissue signals in any plane and to produce images of the tissue.”¹⁷ It has many uses, particularly to provide images of the brain, spine, limbs and joints and pelvis.¹⁸ It is contraindicated for patients who have implants or devices that are either susceptible to magnetic field, or would cause serious harm if they were removed or disabled, e.g. internally implanted defibrillators or heart pacemakers, metal heart valves, or certain types of clip used to repair brain aneurysms.¹⁹

¹² H.E. Davies, C.G. Wathen, F.V. Gleeson, ‘Risks of exposure to radiological imaging and how to minimise them’, *BMJ* 2011-342, p.589, 590. C.f.: Committee on Medical Aspects of Radiation in the Environment (COMARE), 12th Report, *The impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals*, 2007, available at: <http://www.comare.org.uk/documents/COMARE12thReport.pdf> (13 December 2010), para. 2.16 ; Z. Kmietowicz, ‘Better safe than sorry?’, *BMJ* 2007-335, 1182, p.1183. C.f. Nuffield, *supra*, note 2, para. 10.10.

¹³ Davies, *supra* note 12, p.591.

¹⁴ *Idem*, p.590.

¹⁵ *Ibid.* C.f. COMARE, *supra*, note 12.

¹⁶ R. Smith-Bindman, R. Marcus, K.P. Kim, M. Mahesh, R. Gould, A. Berrington de González and D. Migliovetti, ‘Radiation Dose Associated With Common Computed Tomography Examinations and the Associated Lifetime Attributable Risk of Cancer’, *Archives Internal Medicine* 2009-169, 2078, p.2079.

¹⁷ *Oxford Concise Medical Dictionary*, *supra*, note 6, p.387; Nuffield, *supra*, note 2, para. 10.1; A. Berger, ‘How does it work? Magnetic Resonance Imaging’, *BMJ* 2002-324, 35.

¹⁸ Provan, *supra* note 6, p.762.

¹⁹ *Ibid.*; NHS Choices, *MRI Scan – Who can use it*,

<http://www.nhs.uk/Conditions/MRI-scan/Pages/Who-can-use-it.aspx> (27 April 2011).

II. Recent Developments in Preventive Screening: Practical and Ethical Implications

As indicated in the introduction, in recent years we have seen two notable developments in the use of scanning technology in preventive screening programmes. First, with the use of ultrasonography in the national AAA screening programme and second, with the direct-to-the-public marketing of scans by commercial health care companies offering private health checks. In this part, I turn to consider the use of scanning technology in this context and to examine possible practical and ethical implications.

II.1 Abdominal aortic aneurysm screening

In 2009 phased implementation of a national abdominal aortic aneurysm (AAA) screening programme was started in England, with the aim of achieving nationwide coverage by 2013.²⁰ Under the scheme, men will be automatically offered an initial NHS ultrasound screening of their abdomen in order to measure the diameter of their aorta in the year that they turn 65.²¹

An AAA occurs when the wall of the aorta, the main artery supplying blood to the body, becomes weakened and a dilation of the blood vessel occurs in the abdominal region.²² AAAs occur most commonly in the elderly and are six to eight times more common in men.²³ Once they form, they tend gradually to become larger, but many with an AAA may experience no symptoms, or merely mild back or abdominal pain. The main health concern is that the AAA may rupture without warning, causing sudden and massive internal bleeding which may lead to the patient dying before he can even be admitted to hospital.²⁴

²⁰ NSC, *supra* note 1.

²¹ NSC, (2010) *NHS Abdominal Aortic Aneurysm (AAA) Screening Programme: Information for Health Professionals*, available at: http://aaa.screening.nhs.uk/information_for_healthcare_professionals.

²² See e.g. <http://aaa.screening.nhs.uk/aaa> ; <http://www.patient.co.uk> : (2008) *Abdominal Aortic Aneurysm*.

²³ J.J. Earnshaw, 'Ultrasound imaging in the National Health Service Abdominal Aortic Aneurysm Screening Programme' *Ultrasound* 2010-18 p. 167. 95 percent of ruptured AAAs occur in men over 65: NSC, *supra* note 19 . C.f. A.R. Sparks, P.L. Johnson & M.C. Meyer, 'Imaging of Aortic Aneurysms', *American Family Physician* 2002-65, p. 1565.

²⁴ See e.g. P.E. Norman, J.B. Semmens, M.M.D. Lawrence-Brown, C. D'Arcy an J. Holman, 'Long term relative survival after surgery for abdominal aortic aneurysm in Western Australia: population based study', *BMJ* 1998-317, p.855, where it is suggested that 80% of men with ruptured AAAs die either before being admitted to hospital or within 30 days of surgery. C.f. J.B. Semmens, P.E. Norman, M.M.D. Lawrence-Brown, A.J. Bass & C.D.J. Holman, 'A population based record linkage study: the incidence of abdominal aortic aneurysms in Western Australia for 1985-94', *British Journal of Surgery* 1998-85 648; the UK National Vascular Database Report 2009, available at: www.vascularsociety.org.uk/library/vascular-society-pub (13 December 2010), which gives a total mortality rate of 38.3 percent. C.f. M.J. Bown, A.J. Sutton, P.R.F. Bell & R.D. Sayers, 'A meta-analysis of 50 years of ruptured abdominal aortic aneurysm repairs', *British Journal of Surgery* 2002-89 where it is suggested (p. 714) that rates vary from 15 to 90 percent with a usual rate of 45 percent.

About 6,000 men in England and Wales die from ruptured AAAs each year;²⁵ Earnshaw *et al.* suggest that death rates for ruptured AAAs are in the region of 50 percent.²⁶ The aim of the screening programme is to identify AAAs early so that they may be monitored or treated, either by open surgery or endovascular (EVAR) stent-grafts.²⁷ If the patient's aorta is found not to be enlarged, they will not be invited for further AAA screening.²⁸ Patients with small aneurysms will be offered regular surveillance scans,²⁹ whilst those with aneurysms of 5.5cm or above will be referred to a consultant vascular surgeon for possible surgical treatment.³⁰ It has been estimated that this screening programme will prevent up to 50 percent of deaths from AAA,³¹ potentially offering considerable health benefits to men over 65 who participate. It will enable patients to have what might otherwise have remained an undetected condition monitored and, if necessary, to receive surgical intervention to prevent the potential catastrophic consequences of a rupture.³²

However, if an AAA which requires surgery is detected, the repair operation is not without risk: in 2009, the UK National Vascular Database Report, indicated that elective open surgical repair carried a mortality rate of 4.6 percent whilst EVAR repair has a mortality rate of 1.5 percent.³³ Surgery also carries the risk of

²⁵ R. Brownsword & J. Earnshaw, 'The ethics of screening for abdominal aortic aneurysm in men', *Journal of Medical Ethics* 2010-38 p. 828, although the authors state that: "figures taken from national statistics on the cause of death are notoriously inaccurate in this group", *ibid.*

²⁶ J.J. Earnshaw, E. Shaw, M.R. Whyman, K.R. Poskitt & B.P. Heather, 'Screening for abdominal aortic aneurysms in men', *BMJ* 2004-328, p. 1122; *C.f.* Bown, *supra* note 24.

²⁷ Keyhole surgery to repair an AAA which uses a metal tube (stent) covered with fabric mesh (graft). The stent-graft is inserted into a blood vessel at the top of the leg and moved to the point of the aneurysm, where it is used to strengthen the aorta and stop it from rupturing; for more information see: <http://www.nice.org.uk/nicemedia/live/12129/43292/43292.pdf> (13 December 2010). The National Institute for Clinical Excellence (NICE) has recommended endovascular stent-grafts as a possible treatment for people with abdominal aortic aneurysms provided that the repair is carried out in a specialist centre by staff with relevant experience; surgery is appropriate; the aneurysm is below the kidney, has not ruptured and the patient and specialist have discussed the risks and benefits of available procedures and concluded that endovascular stent-grafts are appropriate: see NICE (2009) *Endovascular Stent-Grafts for the Treatment of Abdominal Aortic Aneurysm*, available at: <http://www.nice.org.uk/nicemedia/live/12129/43289/43289.pdf> (13 December 2010).

²⁸ NSC, (2010) *Abdominal Aortic Aneurysm (AAA) Screening: A simple scan that could save your life*, <http://aaa.screening.nhs.uk/leaflet-text> (27 April 2011).

²⁹ Patients whose aortic diameter measures between 3-4.4cm will be offered annual re-scans, whilst those with an aortic diameter of 4.5-5.4cm are to be offered three monthly surveillance: NSC, *supra* note 1.

³⁰ *Ibid.*

³¹ NSC, *supra* note 1; Earnshaw, *supra* note 26; Brownsword, *supra* note 25; S.G. Thompson, H.A. Ashton, L. Gao & R.A.P. Scott, 'Screening men for abdominal aortic aneurysm: 10 year mortality and cost effectiveness results from the randomised Multicentre Aneurysm Screening Study', *BMJ* 2009-338 p. 2307. *C.f.* R.A.P. Scott, 'The place of screening in the management of abdominal aortic aneurysm', *Scandinavian Journal of Surgery* 2008-97 p. 136, which suggests a 58 percent reduction in mortality.

³² See *e.g.* H. Hafez, 'Abdominal aortic aneurysm disease: health risks, management and screening', *Clinical Risk* 2008-14, p. 208.

³³ Available at: www.vascularsociety.org.uk/library/vascular-society-pub (13 December 2010), at p.43. Brownsword, *supra* note 25, p.827, refers to a mortality rate of 1-7 percent, citing the UK National Vascular Database. It appears that the lowest mortality and morbidity rates for AAA repair are achieved by specialist vascular surgeons who perform the highest numbers of such repairs in hospitals in which the largest volume of such operations are conducted: P.J. Holt, J.D. Poloniecki,

complications, including haemorrhage, heart attack, limb ischemia, impaired renal function and infection³⁴ and, even if these do not materialise, the procedure must be regarded as major surgery, from which the patient will take weeks to recover.³⁵

Given the mortality and morbidity rates for repair surgery, as Brownsword and Earnshaw have presciently observed, the AAA screening programme has the “potential to result in the death of an otherwise well individual... If AAA screening is not to be condemned as unnecessarily killing healthy people, it must be scientifically justified and ethically sound.”³⁶ Whilst scientific justification may be found in the anticipated significant decrease in deaths from AAA rupture outlined above, there remain significant ethical implications, particularly in relation to informed consent, considered in more depth below.

II.2 Private Health Care Screening

In the last few years a number of commercial private health care providers have begun to market directly to the public a variety of health checks, including scans. These checks may be offered as individual tests or as packages, with the structure and cost of the package varying from company to company, as may be seen from the examples provided in the table below.

Table 1

Company ³⁷	Examples of Packages/Tests Offered	Advertised Cost ³⁸
iHealth ³⁹	Platinum Package ⁴⁰ Includes an abdominal ultrasound (aorta, liver, gallbladder, kidney), carotid Doppler ultrasound to assess stroke risk, CT heart scan, CT colonoscopy, spirometry to test lung function, plus a wide variety of other tests and assessments.	£2450
Life Line Screening ⁴¹	Vascular, Heart Rhythm, Osteoporosis and 10 year Risk score ...includes the four key tests reviewing	£199

I.M. Loftus, J.A. Micheals & M.M. Thompson, ‘Epidemiological study of the relationship between volume and outcome after abdominal aortic aneurysm surgery in the UK from 2000 to 2005’, *British Journal of Surgery* 2007-94 p. 441; R. Rosenthal, O. von Kanel, T. Eugster, P. Stierli & L. Gurke, ‘Does specialization improve outcome in abdominal aortic aneurysm surgery?’, *Vascular* 2005-13, p. 107. Nice has issued guidance stating *inter alia* that EVAR stent-graft surgery “should be performed by a multidisciplinary team with access to facilities for cardiothoracic surgery and cardiopulmonary bypass”: <http://guidance.nice.org.uk/IPG127/Guidance/pdf/English> (13 December 2010).

³⁴ National Vascular Database Report 2009, *supra* note 30, p.48.

³⁵ Brownsword and Earnshaw suggest that “quality of life returns to normal within 6-12 weeks of surgery” *supra* note 25, p.827.

³⁶ *Ibid.*

³⁷ A similar table is set out in the Nuffield Council on Bioethics Report, *supra* note 2, p.168.

³⁸ As of 13.12.2010 when the websites from which these figures were taken were accessed.

³⁹ <http://www.ihealthttd.com/individualpackages.html> (13 December 2010).

⁴⁰ *Ibid.*

⁴¹ <http://lifelinescreening.co.uk/health-screening-service/> (13 December 2010).

	stroke, aneurysm and cardiovascular risk. It also features an ultrasound scan for osteoporosis risk. You will receive additional checks to calculate your 10 year heart risks based on the internationally recognised Framingham score. ⁴²	
Company	Examples of Packages/Tests Offered	Advertised Cost
Life Scan ⁴³	Lifescan Enhanced Check Plus Described as a 'CT health check', this includes a heart scan, a 'low dose CT' lung scan, an abdomen scan and a bone mineral density scan: "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" ⁴⁴	£790
European Scanning Centre ⁴⁵	Offers a variety of CT scans including CT coronary angiogram, virtual colonoscopy, and brain, lung, abdominal or pelvic scans. "...we use the world's most advanced CT scanner - the Aquilion ONE 640 slice CT scanner - to scan patients for the very earliest signs of disease, including cardiovascular disease and many cancers. Most of us accept that early detection leads to better health outcomes, and that more focus on preventive health is beneficial." ⁴⁶	£1250 ⁴⁷ (CT coronary angiogram) £1125 ⁴⁸ (virtual colonoscopy) £650 (brain ⁴⁹ , lung ⁵⁰ , abdominal or pelvic scan ⁵¹ - each)
Prescan ⁵²	Total Body Scan ⁵³ "The Total Body Scan provides a complete picture of your whole body. During this examination the vital organs and blood vessels are examined." ⁵⁴ "During the Total Body Scan use is made of the MRI-scanner and, if deemed necessary the CT-scanner." ⁵⁵	£1290 ⁵⁶

⁴² *Ibid.*

⁴³ <http://www.lifescanuk.org/healthchecks/services/lifescan-enhanced-check-plus/> (13 December 2010).

⁴⁴ *Ibid.*

⁴⁵ <http://www.europeanscanning.com/our-scans.html> (13 December 2010).

⁴⁶ <http://www.europeanscanning.com/home.html>.

⁴⁷ <http://www.europeanscanning.com/coronary-angiogram.html> (13 December 2010).

⁴⁸ <http://www.europeanscanning.com/virtual-colonoscopy-scan.html> (13 December 2010).

⁴⁹ <http://www.europeanscanning.com/brain-scan.html> (13 December 2010).

⁵⁰ <http://www.europeanscanning.com/lung-scan.html> (13 December 2010).

⁵¹ <http://www.europeanscanning.com/abdominal-pelvic-scan.html> (13 December 2010).

⁵² <http://www.prescan.co.uk> (13 December 2010).

⁵³ <http://www.prescan.co.uk/examinations/total-body-scan> (13 December 2010).

⁵⁴ *Ibid.*

⁵⁵ *Ibid.*

⁵⁶ *Ibid.* Stated to be a 'winter discount', for bookings made before 31 December 2010. Full price quoted at £1640.

Company	Examples of Packages/Tests Offered	Advertised Cost
Preventicum ⁵⁷	Ultimate Plus Check-Up ⁵⁸ “Designed specifically for key people, the Ultimate Check-up gives a thorough assessment of current health and risk factors together with the highest level of reassurance and peace of mind.” ⁵⁹ This check-up involves a number of medical tests, including ultrasound examinations of “Carotid arteries, liver, gallbladder, biliary tree, pancreas, kidneys, spleen, uterus, ovaries, urinary bladder, prostate” ⁶⁰ and MRI scans of the “brain, heart structure and function and arterial system” ⁶¹ and an MRI colonoscopy. Advised for those aged 40+. ⁶²	£3,400 ⁶³
Vitalimaging ⁶⁴	Male Health Check ⁶⁵ “...a comprehensive evaluation designed to screen against the most prevalent diseases that affect men.” ⁶⁶ Includes heart and colon scans, ECG and ultrasound scans of the testes and abdominal aorta. Female Health Check ⁶⁷ “...a comprehensive evaluation designed to screen against the most prevalent diseases that affect women.” ⁶⁸ Includes heart and colon scans, ECG, a bone density scan and an ovarian ultrasound scan.	£1375 £1375

An examination of the websites of these companies suggests that they are targeting as customers those who might be regarded as the ‘worried well’, those in middle or late middle age who are currently symptom-less, but are seeking ‘peace of mind’ about possible major health problems.⁶⁹ Some of these sites mention that, if detected early, the health problems are easily treatable,⁷⁰ and/or suggest periodic repeat scanning.⁷¹

⁵⁷ <http://www.preventicum.co.uk/ultimate-plus-check-up.asp> (13 December 2010).

⁵⁸ *Ibid.*

⁵⁹ *Ibid.*

⁶⁰ *Ibid.*

⁶¹ *Ibid.*

⁶² *Ibid.*

⁶³ *Ibid.*

⁶⁴ <http://www.vitalimaging.co.uk> (13 December 2010).

⁶⁵ <http://www.vitalimaging.co.uk/mha.htm> (13 December 2010).

⁶⁶ *Ibid.*

⁶⁷ <http://www.vitalimaging.co.uk/fha.htm> (13 December 2010).

⁶⁸ *Ibid.*

⁶⁹ See *e.g.* the Prescan website (*supra* note 52), which contains a testimonial from Duncan Bannatyne: “My trip to Presvan gave me peace of mind”; Preventicum Website (*supra* note 57), “...the highest level of reassurance and peace of mind.”

⁷⁰ See *e.g.* European Scanning Centre website (*supra*, n.45): “Most of us accept that early detection leads to better health outcomes, and that more focus on preventive health is beneficial”; Vitalimaging (<http://www.vitalimaging.co.uk/>) (13 December 2010): “In the early development stage,

The Nuffield Council on Bioethics, in its recent report *Medical profiling and online medicine*,⁷² examines the possible benefits and harms and the ethical implications of the types of scanning which these companies offer directly to the patient.⁷³ These tests and check-ups are not without their potential benefits: they may be seen as providing reassurance, promoting health awareness and patient responsibility for their own health; there may be health benefits if a significant health problem is spotted and can be treated at an early stage, and, if the testing and any subsequent treatment are conducted within the private health care system, there may be a saving of NHS resources.⁷⁴

However, as the Nuffield Council identifies, there is potential for CT scans exposing patients to unnecessary and potentially harmful levels of radiation, which may lead to future health problems such as radiation-induced cancer.⁷⁵ It makes specific recommendations on warning patients about health risks, including radiation risks, in relation to imaging procedures.⁷⁶ There is also the possibility that scans conducted during these private health checks will disclose

many life-threatening diseases can be prevented with quick and simple treatment. Vital Imaging can detect many diseases, including heart, lung and colon conditions before they become serious or untreatable"; iHealth

<http://www.ihealthltd.com/ourbeliefs.html> (13 December 2010): "Most healthcare systems of today are effectively sick care systems where meaningful care often only begins once an individual is symptomatic, often with conditions that could have been prevented. Prevention can help identify risk factors and pick up abnormalities early, leading to enhanced outcomes. For all key killer diseases, preventive diagnostics can help with early identification and risk assessment."

⁷¹ Prescan offers a 'Repeat Total Body Scan': All you have to do is notify us that you would like to have periodic examinations, and we will do the rest. You will receive an invitation informing you of the time and date of your periodical check-up. Your personal profile will be re-examined each year and will be tailored to suit your needs. As a loyal Prescan customer you will receive a discount. <http://www.prescan.co.uk/examinations/regular-examination> (13 December 2010).

⁷² Nuffield, *supra*, n.2.

⁷³ *Ibid.*, Ch. 10, *Direct-to-consumer body imaging*. As the Nuffield Council notes in its report (p.167, fn.521), it appears that private health care companies are also approaching general practitioners (GPs) offering private screening to NHS patients. The NSC has provided advice for GPs approached in such a manner at: <http://www.screening.nhs.uk/getdata.php?id=9618> (13 December 2010).

⁷⁴ Nuffield, *supra* note 2, p.50, Table 3.1; p.169, para.10.4.

⁷⁵ *Ibid.*, paras.10.10-10.12. See: Davies, *supra*, note 12; COMARE, *supra*, note 12; Kmietowicz, *supra* note 12; D.J. Brenner & E.J. Hall, 'Computed tomography – an increasing source of radiation exposure', *New England Journal of Medicine* 2007- 357 p. 2277, and S. Birnbaum, 'CT scanning: too much of a good thing?', *BMJ* 2007-334, p. 1006: "A spiral scan of the abdomen of pelvis exposes a patient to about 10 nSv of radiation...in young patients, five of these studies exposes a patient to the amount of radiation that produced carcinogenic effects in the atom bomb survivors of Hiroshima and Nagasaki." C.f. D.J. Brenner, C.D. Elliston, E.J. Hall & W.E. Berdon, 'Estimated risks of radiation-induced fatal cancer from pediatric CT', *American Journal of Roentgenology* 2001-176, p. 289.

⁷⁶ Nuffield, *supra*, note 2, para.10.33, where it is recommended that information should be "prominently available in law language" of "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)." It is recommended that the commercial provision of CT scans "sold as a 'health check' to asymptomatic individuals" be prohibited on the basis that "Any benefits for asymptomatic people do not justify the potential for harms caused as a consequence" (para.10.26). It is also recommended that publicly-funded health service websites should include information about commercial body imaging services, including "the potential risks and benefits, including the possibility of further inventions being recommended and their implications": see para.10.31.

what are called ‘incidentalomas’,⁷⁷ asymptomatic abnormalities which may be detected—particularly during the course of MRI scans. Studies of those undergoing MRI scans suggest that the finding of incidentalomas as a result of such scans is fairly common. For example, Hoggard *et al.*⁷⁸ found a high rate of incidentalomas amongst volunteers participating in brain MRI studies: out of 525 individuals scanned, 46 (8.8 percent) had “definite significant abnormalities”,⁷⁹ including 4 with tumours and 24 with forms of white matter disease.⁸⁰

There is, of course, the possibility that patients will be pleased to have discovered that they have a health abnormality and welcome the chance to be able to obtain treatment before symptoms develop,⁸¹ but the concern is that learning of an incidentalomas will cause stress and upset, perhaps leading to a more serious psychological condition.⁸² The diagnosis may reveal a condition which cannot be treated, so that the patient is left with the knowledge that they have a serious health condition, but that nothing can be done about it.⁸³ It may also lead to a ‘false positive’ result, identifying as harmful a benign condition or an abnormality which would never in fact cause health problems, leading the patient to undergo unnecessary further tests and/or treatment.⁸⁴

Alternatively, where conditions or diseases are difficult to identify, scans may lead to ‘false negative’ results, which leave the patient with the impression that

⁷⁷ Nuffield, *supra* note 2, para.10.13. R. Al-Shahi Salman, W.N. Whiteley & C. Warlow, ‘Screening using whole-body magnetic resonance imaging scanning: who wants an incidentaloma?’ *Journal of Medical Screening* 2007-14, p. 2.

⁷⁸ N. Hoggard, G. Darwent, D. Capener *et al.*, ‘The high incidence and bioethics of findings on magnetic resonance brain imaging of normal volunteers for neuroscience research’, *Journal of Medical Ethics* 2009-35, p. 194. Morris *et al.*, in a systemic review and meta-analysis of studies of people without neurological symptoms who underwent MRI brain scans, found that incidentalomas (*e.g.* benign & malignant tumours, structural vascular abnormalities and inflammatory lesions) were common, and that they were more likely in older people and with high resolution MRI sequences: Z. Morris, W.N. Whiteley, W.T. Longstreth, F. Weber, Y.C. Lee, Y. Tsushima, H. Alphs, S.C. Ladd, C. Warlow, J.M. Wardlaw & R. Al-Shahi Salman, ‘Incidental findings on brain magnetic resonance imaging: systemic review and meta-analysis’, *BMJ* 2009-339, b3016.

⁷⁹ *Idem*, p.194.

⁸⁰ *Idem*, p.197, Table 2.

⁸¹ See *e.g.* the reported experience of the well-known businesswoman, Karren Brady, who discovered following a full-body MRI scan that she had a symptomless brain aneurysm. She describes the fear, panic and shock that she experienced on hearing of this, and her terror that she would ‘have a stroke at any minute.’ However, following ‘coil’ surgery to prevent rupture, and in spite of the need to have brain scans for the rest of her life, she described feeling “incredibly glad” to have had the MRI scan and stated that she felt that “my mortality is back in my own hands”: L. Atkins, ‘I was terrified that I would die at any minute’, (2006) *The Guardian*, April 20, p.24. *C.f.* Al-Shahi Salman *et al.*, *supra* note 78, p.3, who cast a rather more critical gaze upon this case: “...the case report clearly illustrates not only the potential adverse consequences of indiscriminate screening in general but also the specific dangers of inappropriate brain MRI.”

⁸² Nuffield, *supra* note 2, para. 10.13; C. Shaw, K. Abrams & T.M. Marteau, ‘Psychological impact of predicting individuals’ risks of illness: a systematic review’, *Social Science & Medicine* 1999-49, p. 1571.

⁸³ Nuffield, *ibid.*, Al-Shahi Salman, *supra* note 78, p.4.

⁸⁴ Nuffield, *ibid.*; I.M. Burger & N.E. Kass, ‘Screening in the dark: ethical considerations of providing screening tests to individuals when evidence is insufficient to support screening populations’, *American Journal of Bioethics* 2009-9, p.3.

all is well when, in fact, a significant health problem remains, and the erroneous reassurance which this may provide may lead to future symptoms being ignored.⁸⁵ Apart from the cost of private body scans or health check-ups and any subsequent private treatment, there may be additional future financial implications for the patient: for example it may affect their insurability, the level of their premiums or, if they fail to disclose such tests or the results, the validity of any insurance claim subsequently made.⁸⁶

II.3 Ethical Implications

Both the rolling out of the National AAA Screening Programme and the provision of body scans by commercial companies directly to the public present ethical difficulties. First, there is the issue of whether the preventive screening procedure involved causes harm to the patient. The principle of non-maleficence, enshrined in the maxim, “Above all, do no harm”,⁸⁷ is a key concept in medical ethics and imposes on medical practitioners an obligation not merely not to inflict harm on their patients, but also not to expose them to unjustified risks of harm.⁸⁸ In relation to whole-body CT scans for asymptomatic patients a strong case may be made that, because of the high radiation risks involved in these scans it is ethically permissible to prohibit them because of their potential to cause serious physical harm. The potential harms which such scans may cause by exposing patients to relatively high doses of radiation appear to outweigh any health benefits to such an extent that state action to prohibit such scans may be justified to prevent individual harm and wider public harm such as the imposition of the costs of radiation-induced cancer treatment upon public health care systems.⁸⁹ Such an approach conflicts with individual autonomy, but as Burger has observed, the potential risks of full-body CT scans are such that interference with a patient’s right to pursue their interests in the way that they see fit may be ethically justified, even in the case of patients who could be fully informed of the health implications:

Even if the individual requesting the whole-body CT had a good understanding of the uncertainties of the test and believed he would derive great psychological benefit from screening, these potential psychological benefits are inadequate ...to outweigh the potential medical risks, including radiation exposure, false-positive results leading to invasive, risky and costly follow-up procedures, false negatives and the detection of pseudo-disease...⁹⁰

⁸⁵ Nuffield, *ibid.*

⁸⁶ Nuffield, *supra* note 2, para. 10.15. The Council recommend that both private providers of direct-to-consumer body imaging and publicly funded health service websites provide information to the public about whether it may be necessary to inform mortgage or insurance companies of tests: paras. 10.31, 10.33.

⁸⁷ *Primum non nocere*. T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics*, 6th edition, Oxford: Oxford University Press 2008, p.149.

⁸⁸ *Idem*, pp.152-153.

⁸⁹ Nuffield, *supra*, note 2, paras.3.9, 10.10-10.12.

⁹⁰ Burger, *supra* note 84, p.8.

The Nuffield Council on Bioethics has accepted such an approach in concluding that coercive state powers should be used to prohibit this type of imaging.⁹¹

In relation to the NHS AAA screening programme and other forms of scanning, a pressing ethical consideration is whether the informed consent of the patient is being obtained in relation to the procedure. In the case of the state-funded NHS AAA screening programme, as Brownsword and Earnshaw have observed, the responsibility “to ensure that invited participants have a sufficient understanding of both the risks and the benefits”⁹² falls not merely upon those treating the patient, but upon the State and its agents.⁹³ They suggest that the programme is ethically justified so long as best endeavours are made to ensure that people invited to participate in the programme are making free and informed decisions,⁹⁴ including making it “unequivocally clear from the outset that submission to AAA screening is entirely at the option of the man.”⁹⁵ However, as they recognise, the obtaining of informed consent in this context is “far from a formality.”⁹⁶

Some of the main difficulties are highlighted in an American study of patients by Berman *et al.*,⁹⁷ which investigated communication between surgeons and patients and the issue of informed consent in relation to AAA repair. This study found that patients who had been informed that they had AAA disease tended to see surgery as their only option, lacking a balanced appreciation of the likely progression of their condition, the risks and causes of rupture and the risks of surgery. The poor understanding of the risks involved was reflected in the comments made by participants in the study. For example, one patient mistakenly believed that her everyday activities might lead to an AAA rupture: “I felt like all of a sudden I was going to bump into something, I’m just going to bleed out like a stuck pig, and it was terrifying”,⁹⁸ whilst another felt that he had to have surgery because he felt as if he was ‘walking on eggshells for fear the thing would burst’.⁹⁹ As O’Neill has emphasised, merely providing the patient with additional information does not necessarily make them better

⁹¹ Nuffield, *supra* note 2, paras.10.24-10.26. As the Council noted, commercial companies do not currently appear to be offering whole-body CT scans: para.10.25. *C.f.* COMARE’s recommendation, “that services offering whole-body CT scanning of asymptomatic individuals should stop doing so immediately”: COMARE, *supra*, note 12, p.52.

⁹² Brownsword, *supra* note 23, p.829.

⁹³ *Ibid.*

⁹⁴ *Idem*, p. 830.

⁹⁵ *Ibid.*

⁹⁶ *Ibid.*

⁹⁷ L. Berman, L. Curry, R. Gusberg, A. Dardik & L. Fraenkel, ‘Informed consent for abdominal aortic aneurysm repair: the patient’s perspective’, *Journal of Vascular Surgery* 2008-48, p. 296. *C.f.* H.A. Vohra, J. Ledsham, H. Vohra & R.L. Patel, ‘Issues concerning consent in patients undergoing cardiac surgery – the need for patient-directed improvements: a UK perspective’, *Cardiovascular Surgery* 2003-11, p. 64. See also the study by A.M. Knops, D.T. Ubbink, D.A. Legemate, J.C.J.M. de Haes & A. Goossens, *European Journal of Vascular & Endovascular Surgery* 2010-39, p. 708, which concluded that patients with AAA tended to be informed inconsistently about their disorder and treatment options and, more worryingly, that the information provided frequently did not meet legal requirements.

⁹⁸ Berman, *idem*, p. 299.

⁹⁹ *Ibid.*

informed about their options,¹⁰⁰ and care needs to be taken to try to ensure that patients are making free and informed decisions. One way to do this might be to make more use of interactive aids to support decision-making: following a recent pilot study, Berman *et al.* have suggested that the use of an evidence-based personalised interactive computer-based decision support tool might help patients to become better informed about the relative risks and benefits involved in treatment options.¹⁰¹

In relation to private preventive scanning, concerns also arise regarding the level of information being provided to patients and whether they are being adequately advised as to the benefits and risks of the testing techniques being used, particularly as commercial providers are not required to provide the same level of information as the NHS in relation to screening tests: "...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."¹⁰² However, this information is not required for screening tests offered outside the NHS."¹⁰³

The Nuffield Council was unhappy with the information being given to patients by the providers of commercial health checks and concerned about whether sufficient impartial information was being conveyed to enable the patient to make informed choices.¹⁰⁴ In an attempt to ensure that ethical requirements in relation to patients making informed decisions about their health care are met, they have recommended that companies providing direct-to-consumer body imaging to asymptomatic customers be regulated. They are also required to provide specific information about the risks and benefits of their services and of possible outcomes before the customer commits to purchase a service,¹⁰⁵ and to recommend that independent information about such services be provided on publicly-funded health service websites.¹⁰⁶ Such information could perhaps be made available on the current NHS *Choices* website, which already provides accessible patient information on a variety of health topics, including private cosmetic surgery both in the UK and abroad.¹⁰⁷

III. Legal Implications

As the Nuffield Council noted, there is currently no overarching regulatory framework which applies to commercial providers of preventive body scanning

¹⁰⁰ O. O'Neill, 'Some limits of informed consent', *Journal of Medical Ethics* 2003-29, p.6. See also: N.C. Manson & O. O'Neill, *Rethinking informed consent in bioethics*, Cambridge: Cambridge University Press, 2007.

¹⁰¹ L. Berman, L. Curry, C. Goldberg, R. Gusberg & L. Fraenkel, 'Pilot testing of a decision support tool for patients with abdominal aortic aneurysms', *Journal of Vascular Surgery* 2011-53, p.285..

¹⁰² *E.g.* see <http://aaa.screening.nhs.uk> (13 December 2010).

¹⁰³ Nuffield, *supra*, note 2, para.10.19.

¹⁰⁴ *Ibid.*, paras.10.19, 10.24 & 10.32.

¹⁰⁵ *Ibid.*, paras.10.33-10.35.

¹⁰⁶ *Ibid.*, paras.10.30-10.31.

¹⁰⁷ <http://www.nhs.uk/Livewell/Cosmeticsurgery/Pages/Cosmeticsurgeryhome.aspx> (13 December 2010).

services in the UK.¹⁰⁸ As we shall see below, the provision of CT scans is subject to the regulatory framework governing the use of ionising radiation but, of course, both NHS and private providers of healthcare scanning services are subject to the ordinary law of negligence. Commercial health care companies will additionally have a contractual arrangement with those purchasing scanning services, and these contracts will contain at least an implied term that the scan will be conducted with reasonable care and skill,¹⁰⁹ although in practical terms this appears to be “indistinguishable from the duty to take reasonable care in the tort of negligence”.¹¹⁰ In this part I also consider some of the circumstances in which civil liability might arise.

III.1 Regulatory Framework

There are clear legal implications in relation to the use of CT scans because they use ionising radiation. Under the Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R),¹¹¹ which apply to private companies conducting such scans,¹¹² providers of such scans are required *inter alia* to “ensure that doses are kept as low as reasonably practicable consistent with the intended purpose”,¹¹³ that exposures to ionising radiation are individually planned¹¹⁴, authorised by a medical practitioner¹¹⁵, and that medical exposures are justified as “showing sufficient net benefit”¹¹⁶ giving appropriate weight to:

- (a) the specific objectives of the exposure and the characteristics of the individual involved;
- (b) the total potential diagnostic or therapeutic benefits, including the direct health benefits to the individual and the benefits to society, of the exposure;
- (c) the individual detriment that the exposure may cause; and
- (d) the efficacy, benefits and risk of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.¹¹⁷

¹⁰⁸ Nuffield Council on Bioethics, *supra* note 67, para.10.20.

¹⁰⁹ *Thake v. Maurice* [1986] QB 644.

¹¹⁰ E. Jackson, *Medical Law: Text, Cases and Materials*, 2010, 2nd edition, Oxford: Oxford University Press. P.102.

¹¹¹ SI 2000/1059. These regulations are amended by the Justification of Practices Involving Ionising Radiation Regulations 2004: SI 2004/1769, which implements Arts. 6(1), 6(2) and part of Art. 6(5) of Council Directive 96/29/Euratom (OJ No.L159, 29.6.96. p.1), “laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation” (Explanatory Note), and by the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006, SI 2006/2523. This regulatory regime is considered by the Nuffield Council on Bioethics, *supra* note 67 at paras.10.21-10.22.

¹¹² See SI 2000/1059, Reg. 3; Department of Health, *The Ionising Exposure (Medical Exposure) Regulations 2000 (together with notes on good practice)*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_064707.pdf (13 December 2010).

¹¹³ SI 2000/1059, Reg 7.

¹¹⁴ *Ibid.*

¹¹⁵ *Ibid.*, Reg 6.

¹¹⁶ *Ibid.*

¹¹⁷ *Ibid.*

A breach of these Regulations by a commercial provider would amount to a criminal offence.¹¹⁸ The Care Quality Commission, the organisation currently responsible for the enforcement of IR(ME)R,¹¹⁹ has indicated that it proposes to make the inspection of organisations that provide CT scanning services to asymptomatic patients a priority in 2011/2012.¹²⁰ It remains to be seen whether the Care Quality Commission acts upon this statement of intent.

The Nuffield Council expressed concern that commercial companies selling imaging services directly to consumers were not subject to any regulatory provisions other than IR(ME)R and recommended that these companies should be subject to regulation by an appropriate regulator, such as the Care Quality Commission.¹²¹ Under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010,¹²² from the 1st October 2010 organisations that provide “diagnostic and screening procedures involving the use of X-Rays and other methods in order to examine the body by the use of radiation, ultrasound or magnetic resonance imaging”¹²³ will, unless they fall within one of the exemptions provided for in the regulations,¹²⁴ have to register with the Care Quality Commission.¹²⁵ The regulations impose a number of requirements intended to safeguard the health, safety and welfare of service users, including

¹¹⁸ SI 2000/1059, Reg.12 provides that these Regulations are to be enforced as if they were health and safety regulations. It appears that these offences are ones of strict liability, since Reg. 13 makes provision for a due diligence defence: “In any proceedings against any person for an offence consisting of the contravention of these Regulations it shall be a defence for that person to show that he took all reasonable steps and exercised all due diligence to avoid committing the offence.”

¹¹⁹ Care Quality Commission website:

<http://www.cqc.org.uk/guidanceforallhealthcarestaff/managingrisk/useofionisingradiation/radiationregulations.cfm> (13 December 2010)

¹²⁰ Care Quality Commission, *IR(ME)R: A Report on Regulatory Activity in 2010, 2011*, http://www.cqc.org.uk/db/documents/20110329_IRMER_annual_report_FINAL.pdf (27 April 2011).

¹²¹ Nuffield, *supra*, note 2, paras. 10.34-10.35. Diagnostic facilities where ultrasound and/or MRI were used did not need to be registered with the Care Quality Commission under the Care Standards Act: Care Quality Commission, *A New System of Registration: Existing providers registered under the Care Standards Act 2000 who also provide services that were exempt from registration, 2010*, http://www.cqc.org.uk/db/documents/RP_PoC2A_100800_20100518_v1_00_Guidance_for_providers_on_CSA_registered_providers_also_with_NinS_services_FOR_EXTERNAL_PUBLICATION.pdf, p.2 (29.4.2011).

¹²² SI 2010/781

¹²³ Schedule 1, para. 8.

¹²⁴ Schedule 1, para. 8(3) and (4). National cancer screening programmes are excluded, and minor procedures such as the use of ultrasound by physiotherapists and the use of X-rays by chiropractors.

¹²⁵ Care Quality Commission, *A New System of Registration: The Scope of Registration, 2010*, [http://www.cqc.org.uk/db/documents/8798-CQC-The_Scope_of_registration_\(revised\).pdf](http://www.cqc.org.uk/db/documents/8798-CQC-The_Scope_of_registration_(revised).pdf) (29.4.2011), pp.31-33. The legal entity that provides the service must register and the service provider must have a registered manager if they are a non-NHS body, the manager being the person in day-to-day charge of the service provider’s activity in the particular location: Care Quality Commission (Registration) Regulations 2009, SI 2009/3112, regs. 4 and 5. This registered manager must be of ‘good character’, possess the necessary qualifications, skills and experience to carry on the regulated activity and the 2010 regulations impose requirements in relation to the provision of suitable training: SI2010/781, regs. 5-7.

requirements in relation to the safety of equipment,¹²⁶ the obtaining of consent from patients,¹²⁷ and accurate record keeping.¹²⁸ Breach of these requirements is a criminal offence.¹²⁹ These regulations will help to ensure that appropriate standards of quality and safety are met by the private providers of scanning services, although their effectiveness is likely to depend on how effectively they are policed by the Care Quality Commission.

III.2 Claims in Relation to Diagnosis Following Scans

Litigation may arise when diagnostic errors are made. There have been well-documented cases in which failures by medical practitioners to detect the signs of a disease on time or at all during the course of screening or scanning programmes have led to actions in negligence. For example, the notorious Gisborne cervical smear scandal¹³⁰ in New Zealand, which subsequently led to the litigation in *A v. Bottrill*,¹³¹ arose out of the widespread misreading of cervical smear tests: a subsequent investigation into the work of the pathologist, Dr. Bottrill, disclosed that he had a false negative reporting rate of 50 percent or higher.¹³² Litigation also arose out of the negligent failure to identify potentially cancerous cell changes in cervical smears in *Penney v. East Kent Health Authority*.¹³³ In relation to ultrasound scanning, successful reported claims have arisen in the context of negligent failures to detect prenatal abnormalities, most notably in the cases of *Pithers v. Leeds Teaching Hospitals NHS Trust*,¹³⁴ and *Lillywhite v. University College London Hospitals' NHS Trust*,¹³⁵ both of which are considered in more detail below.

¹²⁶ SI 2010/781, Reg. 16. Equipment must be *inter alia* properly maintained, suitable for its purpose and maintained correctly.

¹²⁷ SI 2011/781, Reg. 18: "The registered person must have suitable arrangements in place for obtaining, and acting in accordance with, the consent of service users in relation to the care and treatment provided for them."

¹²⁸ SI 2011/781, Reg. 20.

¹²⁹ SI 2011/781, Reg. 27. Criminal liability is imposed in respect of breaches under regs. 9-24. The maximum punishment is a £50,000 fine: Reg. 27(3). A due diligence defence is provided for the registered person: Reg.27(4).

¹³⁰ See: A.P. Duffy, D.K. Barrett & M.A. Duggan, *Gisborne Cervical Screening Inquiry Report*, 2001. Available at: http://www.csi.org.nz/report/table_of_contents.htm (13 December 2010).

¹³¹ [2001] 3 NZLR 622 (NZCA); [2002] UKPC 44, [2003] 1 AC 449 (PC). For discussion of this case see: J. Manning: 'Exemplary damages in negligence: The story of a screening programme', *Torts Law Journal* 2001-9, p. 229; "'Never Say Never': exemplary damages in negligence: case comment", *Law Quarterly Review*, 2003-24; A. Phang & P-W Lee, 'Case Comment: Exemplary damages- two Commonwealth cases', *Cambridge Law Journal* 2003-32. See also the Irish case of *Philp v. Ryan* [2004] IESC 105, in which a negligent failure to diagnose prostate cancer meant that the patient suffered shortened life expectancy.

¹³² A.P. Duffy Q.C., D.K. Barratt & M.A. Duggan, *Report of the Ministerial Inquiry into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region* (2001) available at: <http://www.csi.org.nz/report/> (13 December 2010).

¹³³ [2000] PNLR 323. See also: *Thurman v. Wiltshire & Bath HA* (1997), (unreported), QB, Hedley J. In *BM v. Norfolk, Suffolk and Cambridge HA* a settlement of £75,000 was made in respect of the reporting of two borderline cervical smears as normal, which delayed a diagnosis of cancer: *Clinical Risk* 2003-9, p. 121.

¹³⁴ [2004] EWHC 1392 (QB).

¹³⁵ [2005] EWCA Civ 1466. *C.f.* *CC v. Blackpool, Flyde and Wyre Hospitals NHS Trust* [2009] EWHC 1791 (QB); *Morris v. University Hospital Birmingham NHS Foundation Trust*, 2009, 27th January

Somewhat ironically, since they are aimed at the early detection of abnormalities and the prevention of severe patient morbidity or mortality, screening programmes for breast and cervical cancer appear to have led to an increase in litigation.¹³⁶ It has been suggested that this may be due to a failure by the patient to appreciate the limitations of screening,¹³⁷ or because patients and their families may have unrealistic and/or erroneous expectations of what scanning can achieve, believing either that scanning prevents, rather than detects, cancer, or that cancers which arise in between scans must have been negligently 'missed' by the scanner.¹³⁸

Whether such a pattern will be repeated in relation to the AAA screening programme remains to be seen, but even before the introduction of the national screening programme in 2009, complaints in relation to vascular surgery were a source of litigation within the NHS. For example, a study by Markides *et al.*¹³⁹ on legal claims made in respect of vascular surgery, identified 395 claims being made to the National Health Service Litigation Authority (NHSLA)¹⁴⁰ between 1995 and 2007. Of these, 160 claims were successful, with claimants receiving compensation (ranging from minimal damages to in excess of £650,000). Of the successful cases, 10 (less than one case per year) involved AAA surgery, but failure or delay in relation to diagnosis and/or treatment, which led to serious complications, was the subject of complaint in seven of the successful cases.¹⁴¹ In relation to screening for AAA, I suggest that fears that the introduction of the national scanning programme will lead to an increase in the number of elderly men being diagnosed with an AAA and thus to an increase in the number of elective surgical AAA repairs that are likely to follow such diagnoses, are not without foundation.

In relation to the standard of care required from those conducting scans, English law requires that a doctor exercises the ordinary skill of their specialty: a doctor "is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in

(Birmingham County Court), Westlaw transcript, where claims in negligence failed- both cases are considered in more detail below.

¹³⁶ R.M. Wilson, 'Screening for breast and cervical cancer as a common cause for litigation', *BMJ* 2000-320, p. 1352. *C.f.* J.R. Benson, A.D. Purushotham, R. Warren, 'Screening and Litigation', *BMJ* 2000-321, p. 760. *C.f.* J.F. Dick, T.H. Gallagher, R. J. Brenner, J.P. Li, L.M. Reisch, D.L. Miglioretti, P.A. Carney, G.R. Cutter and J.G. Elmore, 'Predictors of Radiologists' Perceived Risk of Malpractice Lawsuits in Breast Imaging', *American Journal of Roentgenology* 2009-192, p.327.

¹³⁷ Benson, *ibid.*

¹³⁸ Wilson, *supra* note 136.

¹³⁹ G. Markides G, D. Subar & H. Al-Khaffaf, 'Litigation claims in vascular surgery in the United Kingdom's NHS', *European Journal of Endovascular Surgery* 2008-36, p. 452. I have previously considered the potential legal implications of AAA scanning: T. Elliott, 'Screening for abdominal aortic aneurysm: some legal implications', *Clinical Risk* 2008-14, p.211.

¹⁴⁰ The NHSLA 'handles negligence claims and works to improve risk management practices in the NHS', <http://www.nhsla.com/home.htm> (13 December 2010).

¹⁴¹ Markides, *supra* note 139.

that particular art.”¹⁴² This is an established and well-known legal principle known as the *Bolam* test. In the context of routine ultrasound, MRI or CT scanning, the standard is that of a reasonably competent sonologist or radiologist exercising reasonable care at the time when the scan was being conducted. For example, in *B v South Tyneside Health Care NHS Trust*,¹⁴³ the claimant failed to establish a breach of duty because, from the evidence in the case, it was unlikely that the abnormality in question would have been observable at the time of the scan and, even if it had been visible, a sonographer exercising reasonable care could have failed to see an apparent abnormality.

A similar outcome arose in *Morris v. University Hospital Birmingham NHS Foundation Trust*,¹⁴⁴ where it was held that the defendant’s radiologist had not been negligent in failing to detect an abnormally swollen lachrymal gland (which contained a tumour) in a CT brain scan conducted to exclude the possibility that the claimant was suffering from a sub-arachnoid haemorrhage. In reaching the conclusion that the radiologist had not fallen below the standard of care accepted as reasonable by a body of competent professional and responsible opinion in his specialty, the judge placed emphasis on the fact that the claimant’s condition was very rare and that it was “understandable that it might not be picked up,”¹⁴⁵ and on the evidence of the defendant’s expert that five consultant radiologists shown the scan had also failed to detect the lachrymal tumour.¹⁴⁶

However, the task of a court considering a clinical negligence claim goes beyond merely relying on the *Bolam* test. First, following the decision of the House of Lords in *Bolitho v. City and Hackney Health Authority*,¹⁴⁷ if a judge considering expert evidence as to whether the practice of a medical practitioner acted in accordance with responsible professional practice concludes that “...in a rare case,¹⁴⁸ it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible”¹⁴⁹ and to reject it.

¹⁴² *Bolam v. Friern Hospital Management Committee* [1957] WLR 582, McNair J., p.587. This test was subsequently approved by the House of Lords: *Whitehouse v. Jordan* [1981] 1 WLR 246; *Maynard v. West Midlands RHA* [1984] 1 WLR 634.

¹⁴³ [2004] EWHC 1169 (QB). See also: *CC and GC v. Blackpool, Fylde and Wyre Hospitals NHS Trust* [2009] EWHC 1791 (QB). *C.f. Sidaway v. Governors of Bethlem Royal Hospital* [1984] 1 WLR 634, Lord Scarman, p.648.

¹⁴⁴ (2009) January 27, Birmingham County Court, Case No. 7BM08785, HHJ Worster, (transcript available via Westlaw).

¹⁴⁵ [2004] EWHC 1169 (QB), at para.[40].

¹⁴⁶ [2004] EWHC 1169 (QB), at paras.[41]-[42].

¹⁴⁷ [1998] AC 232. *C.f. Hucks v. Cole* [1993] 4 Med LR 393 (decided in 1968).

¹⁴⁸ *C.f. R. Mulheron*, ‘Trumping *Bolam*: a critical legal analysis of *Bolitho*’s ‘gloss’, *Cambridge Law Journal* 2010-69, p. 609, which discusses more than 20 decisions in which *Bolitho* has been invoked and suggests this number is “not quite so low as to be labelled ‘rare’” (at p.610).

¹⁴⁹ *Bolitho v. City and Hackney HA* [1998] AC 232, Lord Browne-Wilkinson, 243. For more detailed analysis of the decision in *Bolitho*, see *e.g.*: M. Brazier and J. Miola, ‘Bye-Bye Bolam: A medical litigation revolution?’, *Medical Law Review* 2000-8, 85; A. Maclean, ‘Beyond *Bolam* and *Bolitho*’,

Second, it is clear from the Court of Appeal decision of *Penney v. East Kent Health Authority*¹⁵⁰ concerning the negligent classification of cervical smear tests as negative, that a judge must distinguish between matters of professional judgment, to which the *Bolam* test applies, and issues of fact, to which it does not and are for the judge to determine.¹⁵¹ In *Penney*, the question of what could be seen on the slides was regarded as a matter of fact by the Court of Appeal.¹⁵² Following *Penney*, it appears that, in the event of a claim being made in respect of an alleged failure to spot an AAA during a scan, the question of what was apparent from the scan would be a question of fact for the judge who, having determined the answer to that issue, would then have to go on to consider:

- i. whether a sonographer exercising reasonable care could have failed to see what was on the ultrasound scan; and
- ii. whether a reasonably competent sonographer, aware of what a sonographer exercising reasonable care would observe on the scan, has treated the appearance of the scan as normal.¹⁵³

Medical Law International 2002-5, p. 205; R. Heywood, 'The Logic of *Bolitho*', *Professional Negligence* 2006-22, p. 225; Mulheron, *supra* note 148. Professor Mulheron, in a detailed examination of the case law which has considered *Bolitho*, has provided helpful guidance as to "the factors that have indicated...that the requisite logical basis for a defendant doctor's expert medical opinion was absent" (at 610). She suggests *inter alia* that the case law discloses that *Bolitho* is likely to be applied and a doctor's conduct is likely to be found to be negligent even if it is supported by a responsible body of medical opinion if he fails to take "a clear precaution", which is "obvious as a matter of common sense, invoking no particular medical knowledge." *C.f. French v. Thames Valley Strategic HA* [2005] EWHC 459 (QB), Beatson J, [112]; *Marriott v. West Midlands HA* [1999] Lloyd's Law Reports: Medical 23, pp.26-27.

¹⁵⁰ *Penney & Ors v. East Kent HA* [2000] PNLR 323 (CA).

¹⁵¹ *Ibid.*, at 330-331. For discussion of this case, see. S. Elliston, 'Medico-legal aspects of cervical screening', *Journal of Cytopathology* 2006-17 (Suppl.1), p. 5; M. Jones, *Medical Negligence*, 4th edition, London: Sweet & Maxwell, 2008, para. 3-051.

¹⁵² *Penney*, *supra* note 150, p.331. See also *Conway v. Cardiff & Vale NHS Trust* [2004] EWHC 1841 (QB), where a similar approach was adopted in relation to what could be seen on slides created from amniotic fluid for the purpose of chromosome analysis.

¹⁵³ *Ibid.*, Lord Woolf MR, 331. This was the approach adopted by Simon J. in *B v. South Tyneside Health Care NHS Trust* when considering whether the defendant's sonologist had negligently failed to notice a partial sacral agenesis (under-development of the sacral spine) during an ultrasound scan conducted at 19 weeks' gestation: [2004] EWHC 1169, para. [13]. *C.f.* the Singapore case of *Khoo v. Gunapathy d/o Muniandy* [2003] 1 LRC 239, in which the Singapore Court of Appeal overturned the trial judge's finding of negligence. The judge had decided that the question of whether a lesion was scar tissue or a tumour was a question of fact, and having concluded that, as a matter of fact the lesion was scar tissue, went on to find that no responsible practitioner would have recommended radiotherapy for a non-existent tumour. The CA found this reasoning to be wrong, stating that: [71] "The salient point in *Penney* was that the trial judge's finding of fact as to the correct diagnosis was not the touchstone of liability. The crucial question was what the medical practitioner, and not the judge, would have diagnosed under the circumstances. It does not follow then that the doctor would be negligent simply because his conclusion was different from that of the judge. This observation is crucial as it breaks the back of the judge's reasoning in the court below. Having found the nodule to be a scar, the judge went on to discredit all the experts who disagreed with him. We found ourselves unable to agree with this method of reasoning. To follow it would be to surreptitiously import into *Bolam* by the back door a practice of adjudicating between medical experts on a balance of probabilities. We do not think *Bolam* should be thus emasculated in content

Furthermore, it has been made clear by the Court of Appeal in *Lillywhite v. University College London Hospitals' NHS Trust*¹⁵⁴, a case involving antenatal ultrasound scanning, that the context in which the treatment takes place may be relevant to the determination of the standard of care and skill required: a higher standard of care may be required where a patient is referred to a specialist centre.¹⁵⁵ Following a routine abnormality scan of Mrs Lillywhite, during which the radiographer had been unable to see the normal anatomy in the front part of the foetal brain, she had been referred to a distinguished consultant at the respondent hospital, who conducted a further scan and concluded after a long examination that the brain of the foetus was normal. However, in due course, Mrs Lillywhite gave birth to a severely disabled daughter who suffered from holoprosencephaly, a severe malformation of the brain which is caused by the brain failing to separate into two cerebral hemispheres.¹⁵⁶

Mr and Mrs Lillywhite subsequently brought an action in negligence against the respondent Trust, claiming that their consultant had, when conducting the scan, negligently failed to appreciate that it showed foetal brain abnormalities indicative of holoprosencephaly. The trial judge dismissed the claim, concluding that negligence had not been established. However, the majority of the Court of Appeal disagreed and concluded that, given that this was a scan in a tertiary referral centre by a consultant sonologist following a referral because an initial scan had failed to detect normal foetal brain structures, this was a 'scan with a focus',¹⁵⁷ and that the duty of care owed by the respondent's consultant 'demanded a high standard of care and skill'.¹⁵⁸ Although this was not a case in which the principle *res ipsa loquitur* applied, given that the consultant concerned had 'purported to identify structures which were simply not

and application. The judge's finding of fact should accordingly have had little direct influence on the question of medical standards."

¹⁵⁴ [2005] EWCA Civ 1466.

¹⁵⁵ See Jones, *supra* note 151, para. 4-032. For further discussion of the case see: D. Harris, 'Medical misdiagnosis: a shifting of the burden of proof', *Melbourne Journal of International Law* 2008-14, p. 8.

¹⁵⁶ The condition is described at [2005] EWCA Civ 1466, para. [3].

¹⁵⁷ This term is taken from the first instance decision in *Pithers v. Leeds Teaching Hospitals NHS Trust* [2004] EWHC 1392 (QB), Holland J, para. [14], a decision which was endorsed and followed by the majority of the Court of Appeal in *Lillywhite*: at paras. [30]-[33]. In *Pithers*, a pregnant mother had been referred to the defendant's hospital because the initial sonographer had been unable to see a bladder and suspected an omphalocele (or exomphalos), a defect of the anterior abdominal wall which presents as a sac protruding from the wall which may contain abdominal contents. Subsequent scans at the defendant's hospital identified an exomphalos, but failed to identify the severe cloacal extrophy (which involved an exomphalos with the extrusion of the bladder and bowel and deformity of the male genitalia), from which the claimant's son was found to be suffering when he was born. Holland J found the defendants negligent on the basis that this was a referral to a tertiary centre of a suspected abnormality and the scan was therefore a 'scan with a focus' (para.14) and a high standard of skill and care was required.

¹⁵⁸ [2005] EWCA Civ 1466, Latham LJ, para.[31].

there',¹⁵⁹ he was 'under a heavy burden... to reconcile his incorrect conclusions with the exercise of all reasonable care and skill'.¹⁶⁰

Since the House of Lords refused leave to appeal, the approach of the Court of Appeal in *Lillywhite* appears to be authoritative on this point in this jurisdiction, although the scope and effect of the ruling may be further developed by the courts in subsequent cases. The significance of the decision so far as AAA and other forms of body scanning are concerned, is that a higher standard of care is required from consultant sonologists or radiologists dealing with referrals at tertiary centres than from sonologists or radiologists conducting routine scans. If a claim is brought in respect of a 'scan with a focus' at a tertiary centre, where relevant structures have been misidentified, it is likely that the defendant will need to provide 'a plausible explanation' for the misidentification, if the judge is not to conclude that the sonologist failed to act with reasonable care and skill.

III.3 Failure to Obtain Informed Consent and Civil Claims

I have discussed above some of the difficulties in relation to the obtaining of informed consent both in relation to AAA scanning and in relation to the provision of other scans by commercial health care providers. In particular, there are concerns and problems with regard to providing the patient with adequate information about their options and the risks involved so they may make informed choices about their treatment options. As suggested above, if patients are not properly informed about the risks and benefits of scans, they may fail to appreciate the limitations of screening techniques, leading both them and their families to have unrealistic expectations as to what scanning will achieve. In due course this may lead to complaints or litigation if expectations are not met. For example, in the case of patients who are scanned for AAA disease, they may incorrectly assume that they are 'safe', and if, prior to the next scheduled scan, an aneurysm grows unexpectedly quickly and ruptures with fatal results, their family may leap to the conclusion that the death was caused by a failure of diagnosis. Alternatively, patients faced with a diagnosis of AAA and their families may focus on the benefits of scanning and early treatment, without comprehending the very real risks of surgery. If the patient then dies during surgery, their family may conclude that 'something must have gone wrong' and blame the surgeon.¹⁶¹

So far as the law of negligence is concerned, a doctor is under a duty to advise his patient about his options and the significant risks involved in treatment,¹⁶² and to take "reasonable and appropriate steps to satisfy themselves that the

¹⁵⁹ [2005] EWCA Civ 1466, para. [32].

¹⁶⁰ [2005] EWCA Civ 1466, para. [34].

¹⁶¹ See Wilson, *supra* note 136.

¹⁶² *Pearce v. United Bristol Healthcare NHS Trust* [1999] PIQR P53, Lord Woolf MR, p.59; *Chester v. Afshar* [2005] 1 AC 134, Lord Steyn, paras. [15]-[16].

patient has understood the information which has been provided”,¹⁶³ although he is not under any obligation to make sure that the patient understands this information.¹⁶⁴ Given that the risk-benefit assessment in relation to most scanning techniques is not straightforward, care needs to be taken to ensure that patients are properly informed about their condition and its treatment, if *Chester v. Afshar*-type claims, made on the basis that there was a failure to warn the patient of significant risks and that, had he been properly informed, he would not have undergone that treatment, are to be avoided. I would suggest that it would be prudent to extend care in relation to the provision of information to patients not merely to the aftermath of scanning, but to the scan itself.

Scanning is generally seen (by patients, at least) as a beneficial, or at least a benign process and studies indicate that patients tend to overestimate the benefits of screening tests and to underestimate the risks.¹⁶⁵ It appears that some of the commercial providers of preventive scans do not take sufficient steps to emphasis the possible risks of scans: the Nuffield Council noted that the information provided by some of the companies gave “the impression that only useful information can be gained from taking these tests.”¹⁶⁶ However, as I have already indicated, this may not always be the case. For example a scan may show that a patient has an untreatable but nevertheless potentially fatal condition. In such a case, the patient is placed in the unenviable position of knowing that they have a condition which might suddenly cause their death and that it cannot be treated. In the event that they had not been warned that this was a possible outcome and if, faced with this bleak outcome, they were to develop clinical depression, one might envisage them seeking to bring a claim on the basis that, had they been informed that the scan might reveal a potentially fatal, but untreatable condition they would have decided not to have the scan and would have preferred to remain in blissful ignorance.¹⁶⁷

Conclusion

An examination of the practical, ethical and legal implications in relation to preventive screening leads one to the conclusion that the use of scanning technologies on asymptomatic patients is not necessarily the unalloyed boon that many lay people may assume it to be. Preventive screening may provide benefits to patients by affording them with an opportunity for a significant health problem to be detected and treated at an early stage, providing them with reassurance, and promoting individual health awareness and responsibility for their own health. However, it is not without its risks and potential harms. CT

¹⁶³ *Al-Hamwi v. Johnston* [2005] EWHC 206 (QB), Simon J, para. [69]. For fuller discussion of this case, see: J. Miola, ‘Autonomy rued ok?’ *Medical Law Review* 2006-14, p. 108.

¹⁶⁴ *Ibid.*

¹⁶⁵ See e.g. Burger, *supra* note 84, p.7.

¹⁶⁶ Nuffield, *supra* note 2, para. 10.32.

¹⁶⁷ Following the House of Lords’ decision in *Johnston v. NEI Combustion Ltd.* [2008] 1 AC 1, claims based upon a mere ‘fear of the future’ are not tenable in English law, at least where there is no physical damage and the only basis for the claim is a fear of developing an illness in the future.

scans pose particular health risks because they expose patients to additional radiation which increases the risk of them developing iatrogenic cancer. Even though ultrasound and MRI scanning techniques do not carry such risks, they cannot be regarded as being 'risk free', since they may disclose 'incidentalomas', which may require extensive further treatment, or may even be untreatable, leaving the patient with the knowledge that, although they have a serious health condition, they can do nothing about it. Scans may also provide 'false positive' results, which lead to unnecessary treatment, or 'false negative' results, which may cause a patient to ignore future symptoms because they mistakenly believe that all is well.

There are particular ethical considerations in relation to CT scanning because of its potential to expose patients to unjustifiable risks of harm, which, it is submitted, justify the more specific regulation of this technology under the IR(ME)R regulations, which aims to ensure that medical exposures to ionising radiation are justified. In the case of whole-body CT scans, whilst it appears that in practice they are not a cause for concern in the United Kingdom, because they are not being performed by NHS or private providers, the health risks involved outweigh any potential benefits to such an extent that state action to prohibit such harm may be justified and it was appropriate for the Nuffield Council on Bioethics to recommend that such a course be taken.

Most of the pressing ethical and legal concerns in relation to preventive screening relate to the provision of information to patients about the risks and benefits of screening and the obtaining of informed consent. These concerns are not without foundation: the Nuffield Council was particularly concerned about the level of information provided by private companies providing preventive screening, suggesting that it did not meet the level of information provided by NHS screening programmes and questioning whether sufficient information was always provided for patients to make informed choices about their health. However, state-provided preventive screening programmes also raise significant concerns about the provision of information to patients: it has been suggested that information provided to patients about the risks and benefits of scanning and its possible outcomes may not always be sufficient or sufficiently accessible, particularly in the case of AAA screening, as the risk-benefit analysis may be particularly complex and difficult for patients to comprehend.

The recommendations made by the Nuffield Council in relation to the provision in an accessible form to patients of proper information about the risks and benefits of screening both by the health care provider, and by the state, via publicly-funded health service websites, will, if followed, address many of these concerns. However, some more general concerns remain, particularly in relation to the regulation of commercial providers who provide direct-to-consumer body imaging to asymptomatic individuals. The recent requirements imposed by the Health and Social Care Act (Regulated Activities) Regulations 2010 on private companies providing ultrasound and MRI scans in relation to

registration with the Care Quality Commission and the meeting of appropriate standards of quality and safety, are likely to help to protect patients undergoing preventive scanning tests, and should be welcomed. Ultimately, however, the effectiveness of such regulation is likely to depend on the extent to which the regulator takes steps to ensure that these standards are met.