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ANALYSIS

Acting on incidental findings in research imaging

Incidental findings of imaging research studies can turn healthy individuals into anxious patients, while putting an extra burden on primary care. **J M Wardlaw and colleagues** argue that doctors should ensure that the personal, ethical, healthcare, and cost implications of these common findings are managed proportionately, sensitively, and economically

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Medical imaging is commonly used in research and can lead to major medical advances. However, it can also detect incidental findings of "potential health importance, unknown to the participant, unrelated to the purpose, and beyond the aims of the research."[1 2] Detecting incidental findings may be lifesaving or may cause distress and uncertainty and affect livelihood. Incidental findings increase the already high workloads of general practitioners and hospital specialists.[3 4] They have immediate and emotive impact: participants know that the researcher sees the images during scanning, so they expect that incidental findings will be acted on, even when told otherwise.[5]

Researchers' knowledge of incidental findings varies hugely.[6 7] Little advice is available on what to do, despite calls for clarity and for national frameworks.[8-13] Efforts to establish guidance on incidental findings by UK imaging researchers, the UK Biobank Ethics and Governance Council, the Wellcome Trust, the Medical Research Council, and the Health Research Authority put the United Kingdom ahead of other countries,[14-16] but gaps in our knowledge remain (box 1).

On average, 3% of healthy participants who undergo brain imaging have incidental findings with health implications, rising to nearer 30% over age 70 or with more sensitive imaging.[17-24] Incidental findings in the chest or abdomen are found in 14% to 50% of patients[23 25] and 29% to 94% of volunteers,[26 27] particularly with cardiac and colon imaging.[28-30] Physiological anomalies and artefacts may be misidentified as disease by researchers without specialist medical training.

Major research initiatives in the UK (such the UK Biobank Imaging study, with up to 100 000 participants), the United States (the BRAIN Initiative),[31] and many European countries will soon scan several hundred thousand healthy participants, generating many thousands of incidental findings. These will have a huge impact on primary care and hospital services and will bring research imaging into disrepute if the duty of care to participants goes unrecognised.[1]

Here we discuss the wide ranging personal, ethical, healthcare, and cost implications of incidental findings and suggest the path forward to avoid turning healthy individuals into anxious patients and burdening healthcare systems with even more overdiagnoses.

Huge practical implications

Recognising potential abnormalities requires specific medical expertise, but at least 40% of research imaging is undertaken

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Box 1: Knowledge gaps

Epidemiology of incidental findings with health consequences—Frequency, natural course, lifetime health, psychological and financial consequences of incidental findings, including those that are age and gender specific

How to manage costs—Cost effectiveness of different management strategies

How research participants think about incidental findings—Attitudes of a wider cross section of research participants about management

Better ways to inform research participants about medical and non-medical implications—Methods to improve participant understanding that further investigation and treatment may lead to substantial harm, not just benefit

How to improve engagement with healthcare providers—Hospital and primary care services should understand the practical and resource implications and join the discussion on management

Non-medical implications—Psychological, emotional, and personal financial effects of different management strategies

by non-medically trained scientists, potentially leading to incorrect diagnoses and costs to the participant, researchers, and the NHS.[6-8 10 31-34] Without clearly established management pathways, the burden is likely to fall disproportionately on primary care.

Delays adversely affect participants' quality of life, insurance, and work. Some incidental findings require medical intervention and some trigger further investigations, both of which increase cost, risk, and anxiety.[35 36] For example, a volunteer with an unsuspected ascending aortic aneurysm (but family history of sudden death before age 40) benefited from intensive management of cardiovascular risk factors (fig 1⇓). Other examples include a young volunteer with unsuspected multiple sclerosis who benefited from early prescription of disease modifying therapy (fig 2⇓) and a volunteer with a liver lesion, probably benign, who is now having annual liver magnetic resonance imaging (MRI) to avoid biopsy (fig 3⇓). Another volunteer with a third ventricular colloid cyst was given advice in case symptoms developed (fig 4⇓). In another case a volunteer had major restrictions placed on his pilot's licence after imaging detected an asymptomatic brainstem lesion, probably developmental perivascular spaces (fig 5⇓).

What do participants expect?

Data from potential participants indicate that most want to be informed of incidental findings with health relevance in person, by an expert who knows what to do.[5 37 38] In one study of 133 volunteers 41% said they would participate only if they received feedback about all potential problems.[39] In another study 79% of 1105 respondents thought that the advantages of feedback outweighed the disadvantages, regardless of curability, 71% thought that feedback should be included in the consent process, 60-70% recognised inaccurate findings or loss of insurance as among the main disadvantages, and most thought that it was acceptable to override refusal to receive feedback if the condition was potentially life threatening.[5]

The attitudes of those who have participated in research vary. When 1672 participants in UK Biobank were told that planned additional brain and body imaging would not be a health check, would be stored for future research, and would not be reviewed routinely, but that their doctor would be notified if a potentially serious abnormality was noticed during scanning, 1572 of them (92%) agreed to participate.[40] In a longitudinal study of atheroma only 0.02% of 4500 participants aged 40-54 asked not to receive feedback.[41] We need more data on participants' understanding and experiences of research imaging.

Natural course is unknown

Predicting prognosis of incidental findings would be more accurate if our knowledge of prevalence by age, natural course, and medical implications had progressed at the same pace as the sensitivity of imaging technologies. But for many incidental findings the benefit versus risk of early diagnosis and treatment is unknown. Only five studies provide data on long term natural course of incidental findings detected during research imaging.

In a retrospective analysis of 1000 healthy participants aged 3-83 years who had brain MRI, 180 had incidental findings, 18 of whom went for routine assessment and 11 for urgent medical assessment—but the outcomes are unknown.[42] In another study 32% of 750 volunteers aged 71-74 had an abnormal brain scan, 2% went for further assessment, and none received treatment.[18] Incidental findings on body imaging are investigated and treated more often than those on brain imaging. Twenty four of 124 (18%) incidental findings in 132 healthy doctors on whole body MRI were investigated: five were tumours, of which two were malignant.[27] Fifteen of 101 (15%) incidental findings in 254 volunteers on coronary magnetic resonance angiography were referred for further imaging.[29] In a study of 2500 community participants who had whole body MRI, 1052 incidental findings were confirmed and fed back to the participants, 62 of which (6%) were malignant, 383 (36%) were benign, 607 (58%) were unclear, and only 9 (0.7%) were treated.[22]

Legal precedents are unclear

How the medical profession responds to research detected incidental findings is important. In the absence of a legal "test case" in the UK, courts will take common practice and relevant professional bodies' views into account, enabling the profession to influence legal precedent.[43 44] Although doctors and other healthcare professions have a well established duty of care to tell patients about clinically relevant findings, its scope is less well defined for research or for findings of unknown relevance.[4 44 45] Some duty of care in research undoubtedly exists—what constitutes a reasonable standard of care depends on what responsible peers consider acceptable. It may be informed by the researcher's professional status, experience, and potential to prevent harm.

Reasonable care in research is likely to include informing participants of treatable incidental findings and enabling them to benefit from earlier, perhaps more effective, treatment.[44] Many would argue that the absence of a clear, ethically sound, transparent policy on incidental findings is irresponsible. What if a lesion that could precipitate epilepsy was seen in a commercial driver who had refused feedback? The response should be measured, proportionate to risks (including risks to research), based on actual rather than perceived risks, and should avoid increasing the administration and cost of research and overdiagnoses.

Who pays?

UK primary care currently carries the major burden of referring and counselling the worried, previously healthy participant who

has become a patient based on incidental findings. Total costs and cost effectiveness of managing incidental findings are unknown.[28 46 47] The Wellcome Trust and MRC have agreed to support the costs of providing feedback on incidental findings in research that they fund, but identification is only the first step and much imaging research is funded by bodies who have not made such a commitment.[48-50]

Countries where private healthcare predominates may inadvertently be fostering "research tourism." Worried individuals might participate in imaging research for the "free scan," not knowing that the imaging may be inappropriate, that the researchers may not be competent to interpret the findings, or the cost implications of any additional management of incidental findings.

What now?

We must acknowledge the existence of research detected incidental findings and implement pragmatic and proportionate ways of dealing with them. The expectations of participants should be managed to avoid research imaging being seen as a "health check" and to prevent false reassurance if no feedback is received.[44 51] They should understand the potential for anxiety, health, and personal financial risks.[4 10]

Radiologist review of incidental findings is impractical owing to the high rates of research imaging, insufficient radiologists with already large clinical demands, and expense.[7] Remote review of images via a network of trained individuals who provide quick advice on findings has worked in some places but needs organisation and incurs cost.[52] No alternatives are in widespread use.[53-56] Perhaps non-expert researchers could benefit from a list of common incidental findings with their health implications. But such a list needs developing, validating, and testing for legal implications, with the associated costs, and requires more knowledge of natural course.

A workshop of UK researchers, professional organisations, ethicists, and funders of imaging research in 2011 developed six working principles to aid planning around research detected incidental findings (box 2).[14] We may need mechanisms for handling new health implications of former research findings—for example, features subsequently found to be treatable with new interventions—which raises questions of dynamic consent and re-identification mechanisms.[57]

Further discussion on management of incidental findings must include NHS representatives (and relevant representatives from other countries) who, with a few exceptions, have largely been omitted from the debate.[14] Incidental findings should be part of good clinical practice training. New research imaging centres should plan for medical input to research imaging.[7]

We depend on the public for participants in research; they should understand the implications of sensitive imaging technologies so they can interact with them in an informed way. Participants should understand that all research, while potentially conferring major societal benefits, carries risks, and that detailed feedback can have a negative impact on both research and health services. Responsible use of powerful research technologies now demands national foresight and proactive informed debate to promote trust in research, and the results, without unduly encumbering the scientific process.[1]

Contributors and sources: JMW, AJ, ADW, and TCB are neuroradiologists; DJL is a general radiologist; HD advises the Health Research Authority on ethics and developed advice for research ethics committees; GL is a lawyer specialising in technologies and chaired the UK Biobank Ethics and Governance Council; AC is a neurologist; CF is a psychiatrist; K Kessler is a neuroscientist; MOL is a medical physicist; and FC is a research radiographer. JMW, AJ, TCB, AC, CF, MOL, ADW, DJL, KK, and FC have extensive experience of using imaging in research. JMW and AJ contributed equally to this work. JMW, AJ, TCB, and ADW designed the workplan, collected background data, and organised discussion among experts. CF, AC, ADW, and MOL chaired discussions. DL, HD, KK, and FC provided important background information. JMW, AJ, TCB, HD, and GL drafted the paper. All authors revised the paper and approved the final version for publication. JMW and AJ are guarantors.

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Box 2: Reasonable principles for management of incidental findings in research

Transparency—Acknowledge the frequency and type of incidental findings likely to be encountered in the research and explain in protocols and to ethics committees the procedures for identifying, managing, and informing participants about such findings. Study information sheets and consent procedures should be clear on risk of, and procedures for managing, incidental findings

Expectations—Participants should know what to expect regarding frequency, type, identification, disclosure, further medical management, and personal implications of incidental findings. Participant input to study design, information sheets, and consent processes is important

Duty of care—The legal parameters of researcher duty of care remain under debate and untested in the UK. In the meantime, imaging research centres should have a clear policy on management of incidental findings and should communicate this to research participants at the time of recruitment, not only at the scanner. Researchers should avoid feeding back unverified results without an action plan, as this may increase anxiety

Resources—Resources are finite, so funders, ethics committees, research administrators, and healthcare providers should all be aware of staff and financial constraints

Flexibility—Relevant management will vary with research question, participant characteristics, researcher background, and integration with clinical services

Evolving field—Imaging technologies are increasingly sophisticated; medical knowledge advances rapidly; ambitious population imaging studies, expectations and rights of the individual, and access to medical information, all contribute to changing detection and implications of research incidental findings

Key messages

The burden of managing incidental findings detected by research imaging falls heavily on primary care (referral, counselling, treatment, etc)

Little advice is available on how to manage incidental findings, and legal precedents are yet to be established

We need more data on their natural course, the cost effectiveness of management strategies, and the attitudes of a cross section of research participants

Research participants should be supported to develop realistic expectations on the likelihood of detection and potential implications of incidental findings as part of the consent process

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Figures

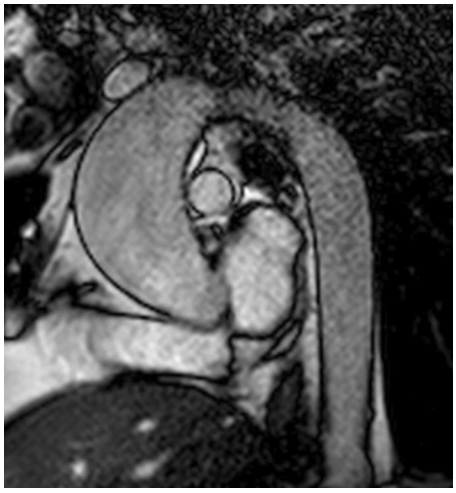

Fig 1 Unsuspected ascending aortic aneurysm detected in volunteer. All the first degree male relatives had died suddenly before the age of 40, and intensive cardiovascular management was started

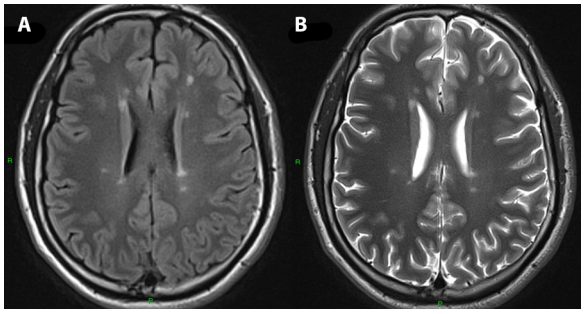

Fig 2 Axial FLAIR (left) and T2 (right) brain MRI show multiple lesions consistent with multiple sclerosis in a young health technologist, who benefited from early treatment

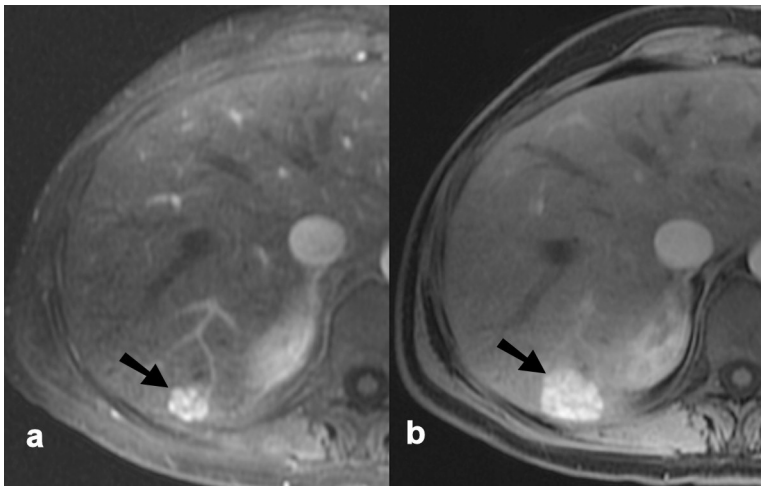

Fig 3 Uncertain liver mass in volunteer required annual follow-up. A 40 year old volunteer had a solid liver lesion found during a renal research MRI examination. A diagnostic MRI (left) suggested either focal nodular hyperplasia or adenoma. Annual follow-up examination at two years (right) showed lesion growth and atypical features. A biopsy to exclude adenoma (which carries a small risk of malignant change and spontaneous haemorrhage) was declined. The volunteer continues with annual follow-up MRI examinations

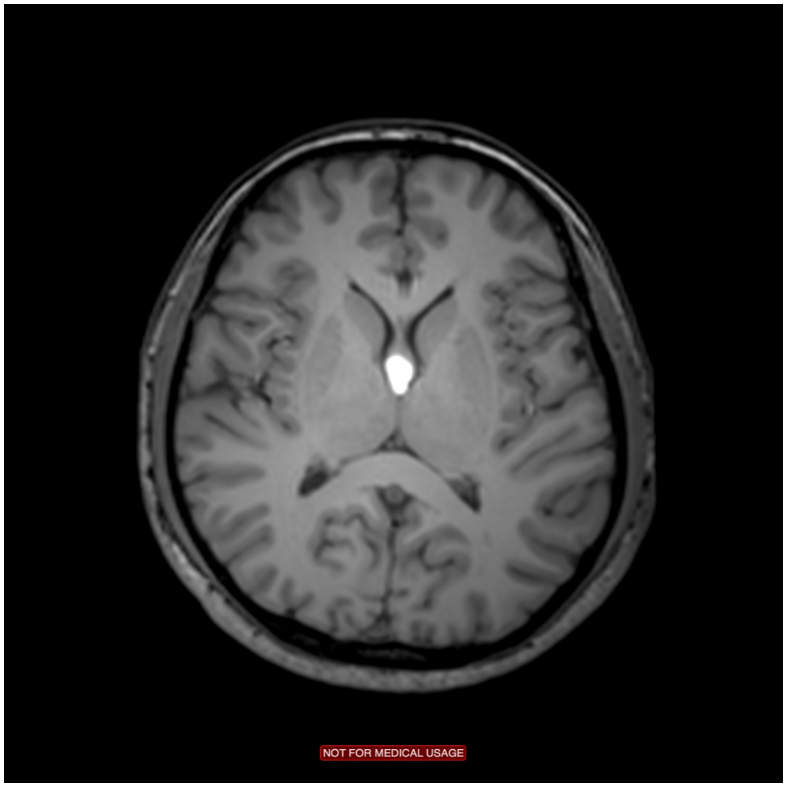

Fig 4 Third ventricular colloid cyst detected in research volunteer enabled advice to be given on how to respond to symptoms

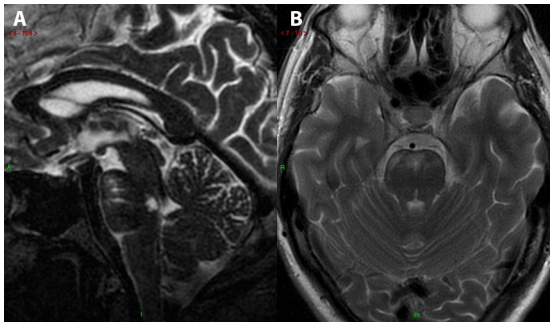

Fig 5 Adverse effect on employment for research volunteer. MRI showed a cluster of prominent perivascular spaces in the pons, initially interpreted as an ischaemic stroke despite absence of symptoms. This led to major restrictions on his pilot's licence