qualitative research elicits a wealth of data from participants. In return, researchers have a responsibility to ensure that the expectations of patients are realistic and that data are managed responsibly to avoid patients being continually frustrated by media hype over supposed cures.

Issues around consent are paramount and particularly difficult in conditions such as dementia. The Mental Capacity Bill should provide clearer guidelines on research on people with dementia, and past wishes and advance directives will need to be included. In practice I would argue that there is less of an imbalance in power in dementia as doctors are effectively powerless because they can do little to treat it. Carers of such patients are often well informed "experts" and are acknowledged by some as being better able to judge moral issues relating to their relative than professionals.

Despite the attention given to ethical research, sadly, no evidence exists of anyone having moral or ethical concerns about low standards of care for tens of

thousands of patients in care homes. Lack of activities and stimulation in care settings, staff shortages, high staff turnover, and lack of funding contribute to poor quality of life for all parties. The impact on patients and their carers should always be considered when deciding on the level of ethical scrutiny of research, audit, medical practice, and social care.

Although SN works in a voluntary capacity for the Alzheimer's Society and serve as a member of the MRC Advisory Group on Public Involvement, I have written this article giving a personal perspective following my experiences of 16 years as a carer. It is not necessarily representative of the Alzheimer's Society, although they read and approved the draft of my original version.

Competing interests: None declared.

- 1 Wade D. Ethics, audit, and research: all shades of grey. *BMJ* 2005;330:468-71.
- 2 Baldwin C, Hughes J, Hope T, Jacoby R, Zieband S. Ethics and dementia: the experience of family carers. *Prog Neurol Psychiatry* 2004;8(5). <http://www.escriber.com/Progress/Features.asp?ID=170&Action=View> (accessed 7 Feb 2004).

Commentary: Research ethics committees deserve support

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I agree with Wade that audit and certain kinds of research have similarities in purpose, structure, and ethics and that audit is not reviewed within the same strict ethical guidelines.¹ However, this does not indicate that "research and audit cannot be distinguished." The definitions and differences have been published.^{2,3} Audit and research surveys raise similar issues regarding validity, confidentiality, inconvenience, and the revelation of unacceptable practice, but the potential ethical problems are less than for, say, trials of medicines. Both audit and surveys merit a thorough but possibly truncated review.

Who should decide?

Wade says that the decision of an ethics committee should not be accepted without question because the decisions of committees may vary. A research ethics committee is formed of medical, paramedical, and lay representatives, including pharmacists and statisticians, men and women. It considers the conflicting ethical interests of, say, the goal of the research, the risks and potential benefits, the autonomy of participants, and the duty of care owed to participants. Different

committees may weight these factors differently, but provided that consideration is thorough, the review is valid. Unfavourable opinions are not given for minor reasons. Committee members who have a vested interest are excluded. This cannot be said of the researcher and not always of a third party. A journal editor, for example, has an interest in publishing controversial or newsworthy articles that will be quoted.

Placing ethical responsibility with journals is dangerous. If journals consider the moral aspects by obtaining their own review or asking the author to discuss the ethical dilemmas within the paper instead of accepting the opinion of an ethics committee, unethical actions may have already taken place by the time of publication. Unacceptable risks may have been taken, autonomy compromised, or participants recruited with inadequate or biased information.

Investigators cannot be relied on

Informed consent receives scant mention except that it should be proportionate—that is, the investigator should decide how much the participant should be told. This view has led to scandals and eroded trust.⁴ Participants being given inadequate or misleading information is the most frequent cause of concern to research ethics committees. Guidance, based on law and ethics, for providing information is published with the research ethics application form, but few investigators meet the standard. Information leaflets should be understood by all for whom they are intended. The imposition of conditions and interventions greater than those presumed from the information causes rancour.⁵ Physical risk is not the only determinant. The undisclosed retention of superfluous biopsy tissue, or organs from dead people, which holds no risk for the owner, has been shown to be unacceptable to the public.

If investigators are to take more responsibility for the ethical concerns of research and audit, they will

need to be trained in the same way as research ethics committees. They can avail themselves of training by serving on these committees. The trusts, or their patients, stand to gain from research. They should encourage attendance.

Competing interests: JA has reviewed nearly 4000 research proposals.

- 1 Wade DT. Ethics, audit, and research: all shades of grey. *BMJ* 2005;330:468-71.
- 2 National Institute for Clinical Excellence. *Clinical audit*. www.nice.org.uk/page.aspx?o=may2004content.ourguidance.otheniceguidance.clinaudit (accessed 27 Jan 2005).
- 3 United Bristol Healthcare NHS Trust Clinical Audit. *How to tell the difference between audit and research*. Bristol: UBHT, 2000.
- 4 Laurence J. Parents were misled over hospital trials that killed premature babies. *Independent* 2000 May 8.
- 5 Stone TJ. Rationality, informed consent and patient decision making for clinical trials. [PhD thesis]. Bristol: University of Bristol, 2004.

Commentary: ethical review and ethical behaviour

John McMillan, Mark Sheehan

Wade's main concern is that the distinction between audit and research is arbitrary and often means that attention is not paid to what is really ethically important in many aspects of medicine.¹ We agree that the distinction between audit and research is difficult to sustain. He is right to insist that the features specific to proposed research or audit are what determine its ethical importance and whether it should be scrutinised. Whether a proposal is audit or research does not and cannot affect its ethical importance.

That said, the intuitive distinction between audit and research often tracks the burdens and risks that Wade points to. So, by and large, audit involves gentler burdens and risks than (clinical) research. Although this is not always the case, audit and studies that do not require ethical scrutiny are likely to roughly correspond. (Confidentiality and consent are likely to remain important in audit-type studies.)

Part of Wade's response to the problems with the distinction between audit and research will place even greater onus on researchers to recognise ethical concerns. But if researchers were always of good character, the distinction between audit and research would not matter—part of their good character would include the recognition that this was so. The distinction has come to matter precisely because some lead investigators either cannot recognise and appreciate ethically important features or because they are unwilling to do so.

Does ethical review ensure ethical behaviour?

In one way it seems odd to question the success of ethical review in ensuring that studies are conducted ethically. However, although we think that ethical review is important, it can encourage the view that ethics is simply a matter of gaining approval from a research ethics committee. Given that ethical approval is a major hurdle for researchers, it would be surprising if many of them didn't consider approval as the beginning and end of their obligation to consider ethics. So, ethical review itself might be accused of encouraging a bureaucratic approach to ethics. It might not be the best way to ensure that people are moral, especially given that Wade suggests that ethics is concerned with the moral character of individuals, as shown by their actions.

This view of ethics is one that we find plausible, but it's one that requires more than ethical review. The moral character of individuals requires a particular kind of sensitivity to the ethically relevant aspects of research, audit, or clinical practice. This sensitivity is primarily obtained by reflection on, and education about, the content and structure of ethics. The practical upshot of this, in line with Wade's recommendations, is that the focus of ethical training should be as much on lead researchers as on ethics committees.

Competing interests: MS and the Centre for Professional Ethics provide training for research ethics committees

- 1 Wade D. Ethics, audit, and research: all shades of grey. *BMJ* 2005;330:468-71.

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Corrections and clarifications

Perinatal asphyxia and inadvertent neonatal intoxication from local anaesthetics given to the mother during labour

Two errors, both involving units of measurement, slipped through during the editorial stage of this Lesson of the Week by Maria Serenella Pignotti and colleagues (*BMJ* 2005;330:34-5, 1 Jan). In figure 2 the y axis (for the blood concentration of mepivacaine) should have been labelled mg/l (not g/l), and in the second paragraph of the Discussion the toxic effects should have given as micrograms per millilitre.

Developing primary palliative care

A crucial negative went missing in the title of one of the letters in this cluster about palliative care. The title of Colin I Guthrie's letter should be "Changed role of general practitioners has not been taken into account" (*BMJ* 2005;330:42, 1 Jan). We also wrongly transcribed the correspondent's email address; the correct address is grey_tricker@hotmail.com.

Clash over public access rights and patient confidentiality sparks trial

Owing to an editorial oversight, readers were left in the dark over the disorder mentioned in the third paragraph of this News article by Caroline White (*BMJ* 2005;330:273, 5 Feb). The two researchers referred to wanted the legal right to gain access to years of confidential data about patients with attention-deficit/hyperactivity disorder.