other problems faced in all services—namely, the lack of trust and the futile and wasteful attempt to monitor every practice.[20] The solution is to return to the better aspects of professional practice. Professional lead investigators could take responsibility for research and audit.[21] Their professional responsibilities would include upholding good ethical practice (already integral to professional standards for many professional groups).

Ethics committees could then exist to answer specific ethical concerns. They would not need to distinguish between audit and research, or indeed other areas of clinical practice. They would consider the ethical aspects of any study or situation needing it and help the investigator or clinician reach a reasonable decision. They would be expected to explain and justify their reasoning and decision, but this would be tailored to the question concerned.

Responsibility for the more bureaucratic aspects of current work of ethics committees, such as ensuring clear communication with patients and documenting participant agreement, would remain with the principal investigator (with appropriate guidance and standards). This approach should reduce the burden on ethics committees by removing the bulk of minor research projects with little ethical challenge and leaving more time to review more challenging proposals, both research and audit.

Contributors: DTW is a member of the BMJ ethics committee and edits a clinical journal (which does not have an ethics committee). He is involved in many research projects and advises other researchers. Information was sought from searching Medline and EMBASE using words such as audit, research, and ethics but it was not a systematic search. The ideas came from discussions held with many people, including the BMJ ethics committee. Liz Wager gave some specific advice and Peter Halligan stimulated some changes.

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Summary points

Distinctions between audit and research may affect a study's funding, insurance, and need for external review

Audit and research cannot be distinguished in a reliable or valid way

Ethical (moral) aspects should be considered for every action within health systems

Any direct patient contact is the responsibility of the clinician involved; other ethical aspects should be the responsibility of a named investigator

External ethical review should be sought according to the nature and extent of moral conflict

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Commentary: patients may be less risk averse than committees

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Ethical considerations should apply to all medical practice and interventions that affect patients. This should include social caregiving, which at present is not seen as being in need of moral or ethical consideration. And if audit is potentially more likely to lead to change than research, as Wade claims,[1] clearly it should be given equal consideration and outcomes followed up.

Sometimes, however, it feels as though ethics committees are putting up barriers to much needed research. As a former carer for my husband, a general practitioner who developed Alzheimer's disease in his 50s, I know that some people with dementia and their carers perceive acceptable risk differently from ethics committees and are more willing to take risks, feeling there is little to lose. Indeed, research has shown that carers and people with dementia are particularly altruistic in their desire to be included in research.[2]

Affected patients should be given a voice on what constitutes "adverse effects" in ethical decisions on research and treatment interventions. Being included in a clinical research project has considerable placebo effect on the wellbeing of both patient (and carer), and

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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.

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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