Differentiating between audit and research: postal survey of health authorities' views

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Access to patients and their records for non-clinical purposes has recently come under scrutiny.[1] Research ethics committees control access for research purposes, but audit is explicitly excluded from their remit.[2] Although there is consensus that locally organised audits do not need ethical approval, the status of larger scale audits designed to influence broader practice remains unclear; some journals do not publish papers based on clinical audit data if they do not have ethical approval.[3] Guidelines published by the Royal College of Physicians suggest submission to a research ethics committee if doubt exists about whether a project is audit or research.[4]

Subjects, methods, and results

We recently completed a national audit of screening for diabetic retinopathy. The aim of the audit was to identify factors associated with screening coverage and to provide baseline data for local audit cycles. The study involved collecting data from every health authority in England and Wales on how they organised screening and then sampling 25 districts representing different types of provision. In the districts selected, a random sample of general practices was invited to take part. Participation involved allowing scrutiny of a random sample of records from the diabetes register, to identify where, when, and by whom patients had retinopathy screening examinations within the previous four years. Data extraction was usually done by members of the local primary care audit group, but in some cases an external researcher was recruited. When a patient had no record of being screened, practices were asked to write to the patient to check whether tests may have been done elsewhere, for example in the private sector.

We sent our protocol to the directors of public health in the districts sampled, asking whether we should submit the proposal to the local research ethics committee. Four of the 25 directors (or their deputies) replied that they conceived the project as audit, and so ethical approval would not be required. No reasons were given. In the remaining 21 districts, our letter was passed to the local research ethics committee or we were advised to approach the committee directly. Our proposal was sent to 28 committees, as several authorities required submission to more than one committee in their district. In five cases the director gave reasons why he or she believed that approval was necessary: use of a patient questionnaire (2 directors); "access to NHS patients requires ethical committee approval"; "study is answering a research question"; and "an outsider is extracting data."

Of the 28 local research ethics committees we approached, two replied that the study was audit and therefore outside their remit.

Comment

Our experience shows that consensus is lacking on the definition of research and audit. An accepted distinction is that "research is finding out what you ought to be doing; audit is whether you are doing what you ought to be doing."[4] However, this is difficult to reconcile with the Medical Research Council's definition of health services research, which includes "investigation of the effectiveness and efficiency of services."[5] Perhaps the most helpful distinction is about motivation and the objectives of the project: audit has the objective of directly improving services against a standard; research may include the objective of defining best practice. This distinction seems more helpful than the views expressed by some of our respondents, who focused on the method of data collection—for example, use of a questionnaire—or whether data were collected by service providers or "outsiders." Even so, some studies, such as ours, although conceived as audit, may also contribute knowledge on the effectiveness and efficiency of services and permit new standards to be set. One reason that investigators are advised to submit borderline cases for ethical approval may be the lack of a mechanism to ensure that audit studies are ethical. Recent developments in clinical governance may help to address this problem.

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4 Royal College of Physicians of London. *Guidelines on the practice of ethics committees in medical research involving human subjects.* 3rd ed. London: RCP, 1996.
5 Medical Research Council. *The Medical Research Council scientific strategy.* London: MRC, 1993.

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Endpiece

On ageing: the best things

I love everything that's old—old friends, old times, old manners, old books, old wine … and old friends are best!

She Stoops to Conquer, Oliver Goldsmith, 1728-74

Submitted by Fred Charatan, retired geriatric psychiatrist, Florida