Local research ethics committees' approval in a national population study

ABSTRACT — ***Background:*** **Epidemiological research using patient records faces considerable uncertainty regarding requirements for local ethical review, confidentiality of data and patient permission.**

■ ***Setting and design:*** **We report the experiences of the national study of clustering and geographical variation in anophthalmos and microphthalmos, which, from 1994, has been compiling a register of affected children born in England since 1988. The information is obtained from clinicians and local health authority records without any direct contact with patients or their families.**

■ ***Results:*** **Of 110 district health authorities, 47 required ethical approval. Only one committee accepted the approval of any other committee. Procedures and application forms varied widely. Fewer than one-fifth of the forms completed asked about compliance with the Data Protection Act, yet confidentiality safeguards must be the foremost ethical issue faced by the study. Two committees required that the study inform GPs and two committees required that the study obtain parental permission.**

■ ***Discussion:*** **While new mechanisms including regional committees are being established, there is an urgent need for a standard application form to save time and resources for research. Continuing lack of consistency about the need for subject (parental) permission impedes the proper design and costing of research.**

In the UK, epidemiological research, notably that based on the establishment of disease registers or geographically widespread data collection, is impeded by uncertainty regarding the type of study needing ethics committee approval, the long and costly process of obtaining approval from multiple committees[1–7], and uncertainties regarding the need for consent.

The National Study of Clustering and Geographical Variation in Anophthalmia and Microphthalmia was established in early 1994 with funding from the Department of Health to address public concern about alleged clusters of affected children[8–13]. A register has been established of all children born in England since 1988 with anophthalmia or microphthalmia, based on access to health authority and clinician records. The study is distinct from others experiencing ethics committees delays[1–6] in that it involves no direct contact with patients or their families.

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We report here our experience of the procedure for obtaining approval from local research ethics committees for the establishment of a national disease register, and the manner in which committees are addressing issues of confidentiality and patient consent. We assess the implications of the current situation for the optimal design and budgeting of research and for achieving the aims of data protection.

Methods

The register of anophthalmia/microphthalmia is based on multiple sources of case ascertainment which include health authority databases, regional and district health authority registers and records of malformed children, district disability, special needs and child health surveillance, and other specialised sources.

Personal identifying details are required to prevent duplication of notifications, full addresses are required to make follow-up possible and full postcodes are required for geographical statistical analysis. There is no direct contact with patients or their families. Personal information is not entered onto the computerised database, and is held separately from clinical information.

The study obtained ethics approval from the ethics committee of the London School of Hygiene and Tropical Medicine, where the researchers are based. Thereafter every request for notification to local district health authority sources has included an offer to obtain local ethics committee approval should this be deemed necessary by the district contact.

Results

Districts requiring local ethics approval

We approached 110 district health authorities, of whom five have yet to respond. Forty-seven districts required local ethics approval (Fig 1). Since some of these districts have more than one local ethics committee (eg one for each hospital Trust) the study was put before 59 committees.

So far no individual clinicians have required ethics approval to provide details of their own patients to the study. Ethics approval has been requested only by clinicians/managers in charge of district information systems, who are passing on details about patients not under their personal care.

Application process

Of the 59 committees approached, 27 required a full application form to be filled in. The remaining 32 committees

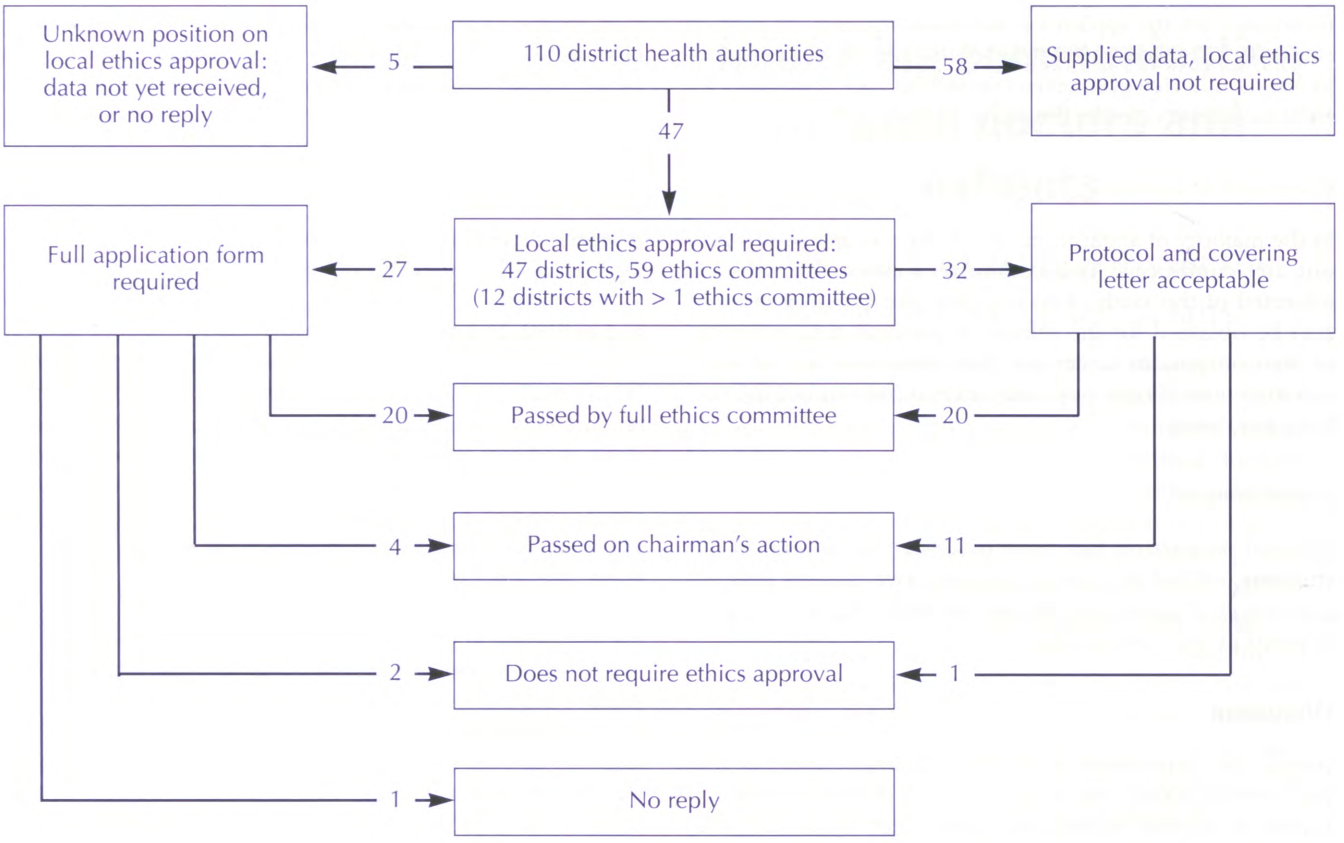

Fig 1. Approaching local research ethics committees.

accepted a protocol and covering letter in application. Although several asked for a representative to be present at the meeting, all of them accepted that this was difficult and time-consuming for a national study, and approved the study in the absence of a representative.

Fifty-five committees have so far approved the study: three decided that formal approval was not required and the decision of one committee has not yet been received. Fifteen approvals were obtained by chairman's action. In the remainder the study was considered by the full committee. One ethics committee accepted the full application documentation and ethics approval from the sister committee within the same district health authority, and passed the study from this documentation on chairman's action. Three committees specifically stated on enquiry that they would not accept or take into consideration the decision of a sister committee within the district. Ethics committees required between 1 and 17 copies of the completed application form.

Application form

In only one or two cases were the application forms for multiple committees within the same district authority in the same format. Forty-two different pieces of information were required by the 27 application forms completed. Of these, only 18 (43%) are common to at least half of the application forms, even when wording differences are ignored. Even questions regarding common information items could not be answered in a standard way. For example, one form asked for the aims, purpose and study design, while another asked for a summary only and another asked for an abstract, objectives, design and a summary of the protocol. Some forms asked an open question concerning procedures involving patients, others asked separately about procedures, tests, taking of samples and drug administration, or provided a checklist of possible tests or procedures.

The majority of the application forms were clearly designed for research involving medical intervention. In only three cases was there a separate application form or a form adapted to take account of non-clinical research or research not involving direct patient involvement. Only 5 of the 27 application forms completed asked whether the study was registered under the Data Protection Act.

Time and resources needed for applications procedures

We estimate that the administration of applications to ethics committees took at least six person-weeks.

Of the 49 committees to whom we made direct applications

(in another ten the application was made through the district contacts), 37 replied within two months, and 18 of these within one month. However, seven committees took from three to eight months to consider the study.

Conditions of approval

In the majority of applications the study was approved without any conditions. Two committees asked that GPs be informed of the study. Two required that parental permission be obtained for the release of personal data, referring to their obligations under the Data Protection Act (at least one more would have required parental consent but did not have any cases).

Patient consent

Parental permission has been requested for a total of 89 children notified by various sources. Two parents refused permission, 51 gave consent and 36 (40%) did not reply to requests or were untraceable.

Discussion

Despite the Department of Health guidelines current at the time which stated that enquiries and surveys involving access to patient records only need not necessarily be submitted to ethics committees[14], almost half the districts required ethics approval to notify cases to our register. Current proposals from the Department of Health are more restrictive, with all research being required to obtain local research ethics committee (REC) approval[15]. The Royal College of Physicians guidelines for RECs suggest that even research not involving patients directly (eg using personal medical records) requires approval of an REC though not necessarily patient consent[16]. A working party set up by the same College concluded that reference to an REC was not always necessary, and this was also the conclusion of the recent WHO/ISEE International Workshop on Ethical and Philosophical Issues in Environmental Epidemiology[17,18]. It seems unlikely, therefore, that the position today will be any clearer for district committees.

Applications to multiple ethics committees involved our study in considerable delay and cost, both to administer the applications and to wait for approval. The 1991 Department of Health guidelines suggested that multicentre research could be approved by one local committee, the decision of which would then be accepted by other committees. Our experience and that of other multicentre research projects[19] shows that this guideline has not been followed. There is a consensus in the literature that a central ethics committee, at a regional or national level, would solve the problem of multilocation research projects[1–3,6,16,20–23]. Regional committees are now being implemented and local committees will address only local issues.

Meanwhile, we believe that a considerable improvement could be quickly made simply by standardising the application forms as recommended by the Royal College of Physicians in their guidelines[16], and by starting to make better use of electronic media. To our knowledge, three regions (South West, Wales and Northern Region) are now using a standard application form. A standard form could be developed to reflect properly the different ethical issues and standards of best practice applying to different types of research. The form could eventually also be used for a regional research (or central) ethics committee.

Our finding of inconsistent responses from local RECs and individual data providers regarding the need for patient consent reflects the inconsistencies in legal requirements. Whereas the Royal College of Physicians working party[17] recommended that no consent was required, the Department of Health took an intermediate position by requiring the public good to be weighed against the principle of individual consent in consideration of each research project. The Data Protection Act, however, made it a legal requirement that any personal information held on computer databases may not be released except with the consent of the individual to whom it relates[24]. Official guidelines relating to ethics committees and medical research do not provide any clear recommendations on the interpretation of the Act. However, the Data Protection Act will need to be in line with the new European Directive which comes into force in October 1998, and which has also been revised to allow access to records for medical or research purposes[25,26].

We have found that patient (or in our case, parental) refusal is not a significant problem. The main disadvantage of any requirement for parental consent is the difficulty of tracing and obtaining a response from parents (we obtained only a 60% response), especially for retrospective data collection. By the nature of the parental consent requirement, the research project team cannot itself contact parents for permission (and send reminders) as it does not know their details. The onus is on the database manager, whose work priorities lie elsewhere, to obtain a high response rate. Clarity is needed as to the current requirement for parental consent (and the position when the European Directive comes into force), so that it can be properly budgeted for, and so that the potential implications for the research of non-response can be taken into account in its design. Moreover, ethics committees need to be aware that the desirability of patient permission should be balanced against the potential detriment to the quality of the research due to the operational difficulties imposed.

Whatever the legal position regarding patient consent, the issue of confidentiality remains an extremely important ethical issue. The Data Protection Principles contained in the 1984 Data Protection Act largely address the proper mechanism for maintaining confidentiality[27], eg limiting the ability to link the individual to the data, making data inaccessible to non-researchers and having explicit standards for data quality, security and accountability. When confidentiality and data protection must be seen as the major ethical issues for projects such as ours not involving contacts with patients, it is surprising that so few ethics

committee application forms ask whether the project is registered under the Data Protection Act, whether the researcher is aware of the principles, and how the principles are to be put into effect.

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