REVIEW

The shifting sands of research ethics and governance: effect on research in paediatrics

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Basic principles governing the ethical conduct of research have not changed but recent years have seen the burgeoning of bureaucracy to support and monitor research ethics and governance. More changes are planned, and the effect of the proposed changes on paediatric research are examined and broadly welcomed.

received research ethics committee (REC) approval as a substantial amendment to the equivalent study in adults.

EFFECT OF RECOMMENDED CHANGES

The first recommendation of the NPSA Ad Hoc Advisory Group is that the remit of National Health Service (NHS) RECs should not include surveys or other non-research activity if they present no material ethical issues for human participants. COREC should develop guidelines to aid researchers in deciding what is appropriate or inappropriate for submission to an RECs.

Our paediatric study, in common with the study in adult patients, is non-interventional and involves return of questionnaires and (where available) results of lung function tests. It does not touch on sensitive issues such as mental or sexual health. As such, it could be deemed to constitute a survey and not require submission to an REC. The proposed triage system, however, calls for mandatory review at an REC meeting of any research involving vulnerable groups. Although children constitute a vulnerable group, a study that would not require submission to an REC for adult patients would need submission if children were involved, as is the case in our example. This could lead to situations where paediatric populations are excluded from research to avoid the necessity for submission to an REC.

The second recommendation relates to scientific review, which is outside the remit of RECs. It states that in the unusual situation of an REC having reservations about the quality of the science proposed, they should be able to refer to COREC for guidance. No issues specific to paediatric research exist relating to this recommendation, except in cases where the scientific validity of a non-interventional paediatric study is in question, whereas a parallel study in adults, which did not require an REC review, would not face such a situation.

Recommendation 3 states that responsibility for site-specific assessment (SSA) should be transferred to NHS hosts as soon as acceptable mechanisms for quality assurance are in place. Recommendation 4 calls for improvement in the application form and process. We welcome these suggestions, which do not have special implications for paediatrics.

Abbreviations: COREC, Central Office for Research Ethics Committee; NHS, National Health Service; NPSA, National Patient Safety Agency; REC, research ethics committee

The past decade has witnessed massive changes in the organisation and implementation of research ethics and governance. Although the basic principles governing ethical conduct in research have not changed, the associated bureaucracy has burgeoned. The establishment of the Central Office for Research Ethics Committee (COREC), a single online application form, and a single ethical review and decision, has brought a welcome degree of order and consistency to a previously haphazard procedure. The price for this has been a form that many have found daunting and complex.¹

The need to consult pages of guidance to complete the form, and the perception that some of what is asked is irrelevant and unnecessary for ethical review has led to frustration. This is compounded by the nature of the computerised form, which is difficult to navigate and has unfamiliar features such as the requirement to lock the form before submission and a print button that does not do what it says. The irritation provoked by the form will reduce as established researchers become familiar with it and the generation of new research-active colleagues develops without having known anything different.

The National Patient Safety Agency (NPSA) launched a consultation document on the future of research ethics committee services.² This commentary looks at the effect of the proposed changes on paediatric research by examining the effect they would have on a specific, ongoing project.

The aim of this project is to investigate the range and frequency of tests of respiratory function in paediatric patients with respiratory problems who undertake air travel, and the nature of problems (if any) they encounter. There are no interventions in this study, which requires a short questionnaire to be completed by a consultant paediatrician and returned to the coordinating centre along with results of any lung function tests. A separate questionnaire is sent to the family involved, who then return it by post after completion. This study

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Recommendation 5 is described by the ad hoc committee as the most pressing of their recommendations, and is a strong encouragement to NHS research hosts to adopt common national systems. Although this is not a matter of research ethics, it relates to research guidance. We would strongly support this recommendation on the basis of our own experience. We monitored the time taken to gain local research and development (R&D) approval at each participating centre. After an REC approval and granting of sponsorship, the process of gaining local R&D approval for each participating centre was time consuming and arduous. The time taken to grant local R&D approval, from the time of first approach, ranged from 6 to 15 weeks. This shows not only a considerable delay but also that the process required many hours of time spent by the research nurse coordinating the project. The process required the equivalent of three working days per participating centre to gain approval, which constitutes an additional financial burden to the running of the project. The centres that were most time consuming to deal with were those that had individual requirements in addition to, or in place of, the national R&D form. In one case, 3 weeks elapsed while the local R&D office considered which headed paper should be used for information sheets. Any step that minimises this part of the procedure is to be welcomed.

Recommendation 6 is for a smaller number of RECs working more intensively than at present with payment of an REC members either directly or by compensation to their employers. This would not have specific implications for paediatrics, but the definition of paediatric expertise could make it difficult to recruit people with this background. Where the definition is restricted to a consultant paediatrician or a qualified paediatric nurse (as is sometimes the case), it might be difficult to find people willing to make the necessary time commitment or employers willing to release them. Many studies involving children, and infants would not require such specialised experience, and other professional or lay members who were used to working with children would be equally valuable when paediatric studies were being considered. We would recommend that each an REC has at least one member with experience in dealing with children and, in case this member has no medical or nursing expertise, specialist advice be sought when needed. The use of trained support staff (such as "scientific officers" as recommended by the Ad Hoc Advisory Group) would be helpful in identifying when advice from a consultant paediatrician or nurse was required. The inclusion of individual members who, although not being consultant paediatricians or nurses, had experience in dealing with children and were familiar with the ethics of research involving

children, could also help to achieve recommendation 7, which is that RECs must represent the public interest as well as patient perspectives on research, meaning that membership needs to be drawn from a wider mix of society. We would also suggest that RECs actively seek to include members in their late teens or early 20s, who may be better placed to represent children than their older counterparts, although we recognise that the level of training required by a young person may be considerable and that the period of time spent on committee might be relatively short as they move into higher education or into the workplace.

Recommendation 8 relates to reducing excessive inconsistency by provision of training, sharing good practice and quality assurance by peer review. We welcome this recommendation, which would benefit paediatric and non-paediatric studies equally. Similarly, recommendation 9, which proposes the creation of "scientific officers" in COREC to support the work of committees, is something that we would welcome. Although the term "scientific officer" may not be ideal, the proposal that trained members should support RECs is reasonable. We would envisage the training of such members to include a strong element relating to paediatrics and to encourage its development in consultation with the Royal College of Paediatrics and Child Health.

In conclusion, we broadly welcome the recommendation of the NPSA Ad Hoc Advisory Committee, which would streamline the process for obtaining an REC approval. The ongoing requirement for studies involving children to have a mandatory an REC opinion implies that some non-interventional studies, such as surveys that pose no ethical issues, would be handled differently for adults and children. Although we acknowledge that children will always be a "special case" owing to their vulnerability, we suggest that the development of the role of scientific officer would obviate the need for this apparent anomaly.

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