Irish College of General Practitioners

Research Ethics Committee

Past Activity and (some) Future Challenges

A discussion paper for members

April 16th 2003

Background

The Irish College of General Practitioners Research Ethics Committee (ICGP REC) was established in 1986. Since then, it has served to offer guidance on potential ethical issues that need to be considered by researchers before initiating programmes of research.

At present, the ICGP REC meets six times each year, at intervals of approximately two months, in Dublin. The committee is multidisciplinary in composition. Researchers are required to submit a proposal outlining their planned research and to complete a standard ICGP REC application form in advance of each meeting. Most proposals are reviewed by the committee, with one of the research team invited to attend committee meetings to clarify any issues identified as potentially problematic by the committee.

The development of guidelines to facilitate ethical research in general practice in Ireland has been identified as a priority by the committee. In addition, individual researchers have requested guidance on the types of research proposal that need to be reviewed in detail by the committee in consultation with a member of the research team, and those that can be reviewed and approved without the investigators attending.

A recent review of factors that need to be considered in facilitating ethical research in primary care has addressed this issue. [1] Recognising that current guidance for ethical research practice is "complex and fragmentary," Rogers and Schwartz highlight four main ethical issues that are central to the process of conducting ethical research in primary care:

- Consent and competence
- Confidentiality
- Power relations
- Procedural issues.

More importantly, they highlight the need to support ethical practice through:

- Education and resources
- Greater clarity of relevant standards
- Financial support
- A greater role for primary care research networks
- Greater public debate.

There is little published data available on the main ethical issues facing those conducting research in primary care or general practice.[1] Furthermore, there is no published data on commonly encountered ethical considerations in general practice-based research in Ireland. To inform debate and discussion by members of the ICGP REC regarding the potential development, publication and dissemination of guidelines for ethical research practice in general practice in Ireland, this report describes the workload of the Research Ethics Committee of the Irish College of General Practitioners since its foundation in 1986, with a detailed review of research proposals considered during a recent two-year period.

Methods

All proposals reviewed by the ICGP REC between 1986 and 2002 inclusive were retrospectively reviewed. Basic information relating to the nature of the applicant for each proposal was recorded for years 1986 to 2000 inclusive. Proposals submitted for years 2001 and 2002 were reviewed in more detail, with information recorded on: nature of applicants, type of research proposed, number of proposals approved with no suggested amendments, the number of amendments suggested per review and the nature of these amendments.

'Amendments' were taken as those recommendations that had been entered into the minutes of the REC at the time each respective proposal was reviewed. They were subjectively classified into one or more of four categories according to whether the problems or concerns related to:

- Deficient background information
- Methodological considerations
- The application process not properly being followed
- Necessary supporting documentation.

Results

Data is presented on 261 proposals reviewed by the REC during the period under study. The number of proposals reviewed ranged from a minimum of two to a maximum of 35 per annum (mean of 15). During the first seven years of the study period, less than ten proposals were reviewed per annum, with this number increasing to a range of 13-19 during the next five years, and increasing further to a range of 22-35 during the most recent five-year period.

Pharmaceutical companies accounted for the majority of proposals reviewed (n=157), followed by GPs (n=55), universities (n=37) and other agencies (n=12). Proposals from institutions other than pharmaceutical companies are accounting for an increasingly large proportion of submissions in recent years (see Tables 1, 2). Universities accounted for slightly less than 33% of submissions during 2002.

The most common type of research proposal reviewed during 2001-2 were clinical drug trials (accounting for 50% of total), followed by cross sectional surveys of patients, other patient cohort studies, surveys of healthcare professionals, complex health services interventions and epidemiological surveys (see Table 3).

A total of 10 proposals (18% of total reviewed) were passed without amendment during 2001-2. Of those proposals where amendments were suggested, the majority required three or four amendments (see Table 4). Proposals submitted by GPs had the highest proportion 'passed without amendment' (50%), followed by universities (25%) and pharmaceutical companies (7%).

The most common category of amendments suggested were: problems with supporting documents, followed by problems with the application process, methodological concerns and insufficient background information. Specifically, the most commonly suggested amendments were: patient information not clear, consent form problems, investigators' CVs not submitted and evidence of Irish Medicines Board approval not provided (see Table 5).

Discussion

The findings of this report should be interpreted with some caution. All data was reviewed retrospectively. In addition, proposals were reviewed by only one reviewer, with detailed consideration being given to only those proposals most recently submitted for consideration by the committee. Nonetheless, the data presented here offers an insight to the work of the ICGP REC, and identifies some important trends and problems.

It is clear the workload of the committee is increasing. There has been almost a five-fold increase in the number of proposals reviewed by the committee since its foundation in 1986. Each proposal is discussed at committee for a minimum of 15 minutes. In addition, each submission generates a considerable amount of unquantifiable work of an administrative nature, both in advance of and after each meeting.

A graph of the number of proposals reviewed each year would indicate the sharpest rise in workload occurred during the periods 1992-3 and 1997-8. While a large rise in the number of proposals submitted by pharmaceutical companies was also observed during these time periods, it is possible that other changes in general practice in Ireland may have contributed to these findings.

For example, the development of the Irish College of General Practitioners during the 1990s, the mandatory completion of research projects as part of specialist training in general practice, the establishment of departments of general practice at each university in Ireland, the holding of an annual research workshop by the ICGP and the appointment of senior registrars in general practice, are all likely to have contributed to the amount of research being conducted in general practice in Ireland, and as a result, to the number of proposals being reviewed by the ICGP REC.

This is to be welcomed. Internationally and in Ireland, the need for more research in primary care or general practice has been recognised. [2] [3] To this end, the recently published Primary Care Strategy has highlighted the need to expand the capacity of primary care to undertake research in Ireland. As new initiatives and supports are put

in place to facilitate this outcome, it is likely the workload of the ICGP REC will continue to rise in the short to medium term.

Less than one-fifth of all proposals were approved by the ICGP REC without any suggested amendments. In addition, multiple amendments were required for the majority. This compares quite poorly with the experience of research ethics committees elsewhere. A review of 100 general practice based research projects submitted to the ethics committee of the Royal College of General Practitioners between 1984 and 1989 found 63 were not approved or required amendments.[4] A review of activity at a local research ethics committee in the Manchester area during 1995-6 found that 44% of proposals were approved at first review.[5] Given the small proportion of proposals approved at first review by the ICGP REC and the high prevalence of multiple amendments, it is clear there is a need to commit all proposed research for detailed ethical review.

This report indicates differential rates of 'approval without amendment' among respective applicants. While all proposals require detailed review, it is clear that those submitted by pharmaceutical companies require special consideration, largely given the nature of research being conducted by these organisations.

Most of the amendments suggested are preventable. While clear guidelines and recommendations / checklists obviously have a key role to play in improving the clarity of patient information leaflets, and in reducing the number of consent forms with errors, the numbers of investigators that do not submit CVs or evidence of approval by the IMB, is it more appropriate to think in broad terms about how best we can facilitate and support ethical research practice in general practice in Ireland?

By adopting this perspective, it is clear interventions such as providing education and additional resources, developing research networks and engaging with all interested parties in active debate on the issue can lead to a more profound and sustained improvement in ethical research practice:

1. Education

It has been suggested further education is crucial for all those involved in primary care research. Members of research ethics committees may need to be educated about the nature of general practice or primary care; researchers may need to be educated about understanding and meeting ethical obligations and overcoming obstacles to best practice and practitioners may need to be educated about their responsibilities to their patients before, during and after research projects. [1]

2. Resources

There is also a need to produce authoritative information about ethical standards in general practice based research and how to meet them. Web-based resources, workshops, part of postgraduate qualifications or continuing medical education have all been suggested as appropriate methods to disseminate such information. [1]

In the United Kingdom, the Department of Health has recently outlined a research governance framework, the purpose of which is to ensure the highest possible ethical standards in the conduct of medical research. This framework has recognised adopting highest possible standards of ethical practice has cost implications. [6] There is a need for the principle funders of research in Ireland to also recognise this fact.

3. The role of general practice research networks

Research networks are now an established part of the primary care research infrastructure in the UK.[7] The establishment of such networks is an important step in improving the quantity and quality of research being conducted. Such networks are also a useful mechanism by which local research ethics committees can promote and support ethical practice in the conduct of research, by providing expert peer review or by troubleshooting proposals prior to submitting to the research ethics committee. [8]

4. Debate

Debate of the important issues is needed at all levels, in particular by the public who fund, participate in and benefit from research. The constant tension between protecting individuals from potentially harmful research and the benefits to be gained to the wider community through research is an example of one issue that would benefit from public. [1]

Conclusion

This paper describes the experience of the ICGP REC; it highlights a considerable increase in workload undertaken by the committee in recent years and describes some of the commonly encountered reasons why proposals fail to be approved. With a sustained increase in the number of proposals for research in primary care likely in the next 5-10 years, it seems there is a need to promote and support ethical research practice. The development and dissemination of clear and authoritative guidelines will form an important part of this process, however more lateral and sustained interventions such as providing education and additional resources for those involved in general practice research, the development of research networks and engaging with all interested parties in active debate may prove more important in the long term.

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Appendix 1. Tables used in text.

Table 1. Nature of applicants to ICGP REC 1986-2000

Year	Pharmaceutical company	GP	University	Health board	Total
1986	5	2	0	0	7
1987	4	1	0	0	5
1988	2	0	1	0	3
1989	1	0	1	0	2
1990	7	2	0	0	9
1991	2	0	0	1	3
1992	2	0	0	0	2
1993	9	4	0	0	13
1994	7	3	1	1	12
1995	11	8	0	0	19
1996	7	5	2	0	14
1997	12	3	0	0	15
1998	22	6	5	0	33
1999	16	5	11	3	35
2000	21	8	4	0	33

Table 2. Nature of applicants to REC (2001-2).

Applicant	2002	2001
Pharmaceutical company	11	18
University	11	1
GP	6	2
Hospital	5	0
Independent agency	1	1
Total	34	22

Table 3. Types of project reviewed by REC (2001-2).

Methodology used	Number of proposals
Clinical drug trials	28
Cross sectional surveys of patients	12
Other patient cohort studies	5
Surveys of healthcare professionals	5
Health services interventions	5
Epidemiological (prevalence / screening)	3

Table 4. Number of amendments suggested by committee for each category of applicant (2001-2).

Applicant	No amendments	1-2 amendments	3-4 amendments	>4 amendments
Pharmaceutical company	2	8	14	5
University	3	8	1	0
GP	4	2	2	0
Hospital	0	1	2	1
Independent agency	1	0	1	0
Total	10	19	20	6

Table 5. Amendments suggested by REC (2001-2).

Category (total number of proposals where amendment suggested)	Amendment type	Problem issue	Frequency
Background (n=11)	Literature	Results from other studies needed	1
	IMB	Approval not submitted	10
Methodology (n=16)	Clinical	Examination or investigations problematic	3
		Female gender	3
		Genetics	2
	Statistics	Sampling deficient	1
	Subject	Selection / definition	2
	Data collection	Proforma not submitted	4
		Proforma changes	1
Application process (n=18)	Application form	Not completed	1
		Incorrect	6
	Investigator details	CV absent	11
Supporting documents (n=67)	Patient information leaflet	Unclear	14
		Not suitable for minors	4
		Payments not explicit	6
		Display in practice	1

	requested	
	Legal rights of patients not explicit	3
	Role of REC incorrect as stated	5
	Potential risks not outlined	4
	Need to communicate information to third party not outlined	1
	Insurance / indemnity not clear	7
Consent form	Investigator signature absent	3
	Witness signature absent	13
	Absent	3
Data Protection Act	Relevance not outlined accurately	3

Appendix 2. References.

1. Rogers W, Schwartz L. Supporting ethical practice in primary care research: strategies for action. *British Journal of General Practice* 2002;52:1007-1011.
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3. Howie J, O Cuinneagain F. Realising the potential: a report on the present position and future needs of the university departments of general practice in the medical schools of Ireland. Dublin: Association of University Departments of General Practice in Ireland, 2002.
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