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Ethics committee costs and time delays are a barrier to research: Its time for solutions!

Ethics committees have a vital role in research in participant protection and in ensuring research conducted causes minimum risk to participant well being. The purpose of the ethics committee is to ensure that research being conducted is in the best interests of society and individuals, and to ensure that research is conducted with high moral standards and humane practices (*National Statement on Ethical Conduct in Research Involving Humans*, 1999). The structure and composition of the ethics committee has been designed to include a broad range of adjudicators including lay people, religious and cultural representatives in addition to medical and legal representatives.

Over the past century, the function and process of ethics committees has been influenced by the increase of legal and bureaucratic changes and privacy policy developments. Ethics committees in Australia now seem to be overburdened with paperwork and guidelines which result in time delays and higher costs. A nation wide cancer study in Australia required 60 ethics applications, 550 copies of their research proposal, costing over \$7000 for printing and 40,000 sheets of paper, in addition to costs of labour and time (Whiteman, Webb, Purdie, & Green, 2003). However this is not a problem unique to Australia. A review of applications to a UK based ethics committee found that median time from application to conditional approval was 64 days, and time from conditional approval to final approval (and thus commencement of research) was a further 62 days on average, therefore a total of 4 months on average from submission to approval (Boyce, 2002). Similar results were found elsewhere in Europe (al-Shahi & Warlow, 1999; Dal-Re, Espada, & Ortega, 1999) with one study weighing its applications (29.6 kg for one trial) as there were too many pages to count (al-Shahi & Warlow, 1999). However, a survey sent to 40 research teams in New Zealand found that although half of the participants responded favourably on most aspects of ethics committee functioning, half also reported occasions where they felt ethics committees had unnecessarily impeded research (Paul, 2000). These time delays and costs directly affect the feasibility of small trials of less than 12 months duration, student research and multi-centre research. As shown in these examples, even larger scale research projects with longer timeframes and bigger budgets are hindered by ethics committee delays and costs.

Multi-centre Research Trials

In many cases it is important to conduct research at more than one health facility or clinical location to ensure there is no health facility or practitioner based bias, or simply in the interests of adequate sample size. A West Australian state-wide investigation into prostate cancer patients required application to 29 ethics committees, despite state government Department of Health approval (Jamrozik & Kolybaba, 1999). Currently most multi-centre trials require applications to the ethics committees of all sites where the research will be conducted. In some research designs,

this can mean applications at multiple health care facilities, and often on application forms unique to each health facility (Alberti, 1995), requiring repetitive documentation and sometimes resulting in clashes between ethics committees' approval conditions. It is understandable that each health facility needs to assess potential research projects for suitability of the protocols for the location, and determine if the resources are available to support each proposal. However, these are not ethical issues, they are resource issues and do not need to be dealt with through an ethics committee.

The federal guidelines released in 1999 (*National Statement on Ethical Conduct in Research Involving Humans*, 1999) state that the ethical and scientific assessment of one committee should be accepted at other sites. However, this is rarely the case in most ethics committees in Australia (Breen & Hacker, 2002) or overseas (Lux, Edwards, & Osborne, 2000) even when adequate provisions are in place. In the UK, a multi-centre ethics committee has been formed, which provides approval to multi-centre trials, which are then sent on to an executive subcommittee of the proposed locations of research (Tully, Ninis, Booy, & Viner, 2000). The executive subcommittee has a minimum quorum of 2 members and meets more frequently than the full ethics committee, and provides expedited approval wherever possible. Although this system is still in its infancy and has some flaws (Alberti, 2000), it is a move toward minimising the cost and time delays in multi-centre research. Future multi-centre ethics applications in Australia could be assessed by a national ethics body- or at least on a nationally recognised form, where all participating research locations could accept the standard application format, saving the researcher valuable time and resources re-formatting the same application. Approval on a logistics and resources level can then be negotiated with each health facility as required.

Other demands of ethics committees

In addition to the varied application forms required for ethics committee applications, each committee has its own additional requirements to gain approval. Many applications now charge an application fee just to apply (Roberts, Bowyer, Homer, & Brown, 2004). Although in most cases the fee is below \$100 before GST (Roberts et al., 2004), in multi-centre trials this can add up to a prohibitive amount (Crooks, Colman, & Campbell, 1996; Dunn, Arscott, & Mann, 2000). Student research is also often limited by funding, and costs of multiple ethics committee applications can be a barrier to good methodological design. Some other reported ethics committee requirements are attendance at ethics meetings, informed consent forms, explanatory statements, use of health facility letterhead, full written research protocols, literature search strategies and literature review, proposed budget, curriculum vitae of researchers, signed approval from hospital officials such as the directors of nursing, medicine and finance. In many cases these requirements cause undue delay and provide little benefit to the ethics committee, health facility, or the research.

Solutions

Possible solutions to reduce the workload and paper chase for ethics committees could involve expedited approval of small scale trials, non drug trials and research in healthy volunteer populations. Trials with research grant funding for less than 12 months and student research could also be assessed in different manner to the large scale medical intervention trials, thereby reducing the workload for both researchers and ethics committees.

Medical research that requires access to patient medical records only could also be expedited, as these are retrospective in nature and do not require the manipulation of any variables. These studies are essentially examining the effectiveness and outcomes from existing practices- which is essential for the development of evidence based medicine. These studies do not require contact with the participants and can yield large amounts of information effectively. Privacy is an important issue; however the de-identification of records can effectively deal with this in most medical record review cases.

The process of ethics approval for multi-centre research could be expedited through mutual approval procedures. Although the current legislation allows approval from one ethics committee to be accepted by another, this does not occur in most cases. This demonstrates the need for more precise guidelines for a multi-centre review process. Recent developments between Monash University and Southern Health in Victoria have seen the start of a mutual approval system, where approval at one committee is granted on behalf of both bodies.

Whether the time delays and application costs are created by the demands of the ethics committees, approval processes, administration or legal requirements, it is clear that something needs to change in the process of applying for ethics approval for research. This is particularly important to support small research projects, student research and ease the financial and administrative burden of ethics committee approval on larger multi-centre trials.

References

- Alberti, K. G. (1995). Local research ethics committees: Time to grab several bulls by the horns. *British Medical Journal*, 311(7006), 639-640.
- Alberti, K. G. (2000). Multicentre research ethics committees: has the cure been worse than the disease? No, but idiosyncracies and obstructions to good research must be removed. *British Medical Journal*, 320(7243), 1157-1158.
- al-Shahi, R., & Warlow, C. P. (1999). Ethical review of a multicentre study in Scotland: a weighty problem. *Journal of the Royal College of Physicians of London*, 33(6), 549-552.
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Over the past century, the function and processes of ethics committees have been influenced by the increase of legal and bureaucratic ~~changes and developments, especially~~ privacy especially privacy policy developments. Ethics committees in Australia now seem to be overburdened with paperwork and guidelines which result in time delays and higher costs. An Australian nation wide cancer study ~~in Australia~~ required ~~sixty~~ 60 ethics applications, 550 copies of their research proposal, costing over \$7000 for printing and 40,000 sheets of paper, in addition to costs of labour and time (Whiteman, Webb, Purdie, & Green, 2003). However this is not ~~a problem~~ unique to Australia. A review of applications to a UK-based ethics ~~committee~~ found that median time from application to conditional approval was 64 days, and time from conditional approval to final approval (and thus commencement of research) was a further 62 days on average, therefore typically requiring a total of ~~four~~ 4 months on average from submission to approval (Boyce, 2002). Similar results were found elsewhere in Europe (al-Shahi & Warlow, 1999; Dal-Re, Espada, & Ortega, 1999) with one study weighing its applications (29.6 kg for one trial) as there were too many pages to count (al-Shahi & Warlow, 1999). ~~However, A~~ survey sent to ~~40~~ forty research teams in New Zealand found that although half of the participants responded favourably on most aspects of ethics committee functioning, half also reported occasions where they felt ethics committees had unnecessarily impeded ~~research~~.

~~These Ethics approval associated~~ time delays and costs directly affect the feasibility of small trials (~~of less than~~ twelve ~~12~~ months duration), student research and multi-centre research. As shown in these examples, even larger scale research projects with longer timeframes and bigger budgets ~~can be~~ are hindered by ethics committee delays and costs.

Multi-centre Research Trials

Comment [t1]: 'Conducted' used several times in this paragraph – have offered alternatives where appropriate

Comment [t2]: You could consider emphasising the change of the committee structure from medical professionals to inclusion of laypersons and legal and religious experts. Could also consider moving this to after comment number 3 to improve flow of argument.

Comment [t3]: You could emphasise the change of ethics committee role from treatment ethics to research ethics

Comment [t4]: General convention is to spell out numbers that can be written in one word.

Comment [t5]: Could provide the reader with increased clarity if you noted here whether this was a hospital or university ethics committee – will allow better reader comparison with their own situation

Comment [A6]: Is this a mean?

Comment [A7]: Was it sent to 40 or did 40 respond?

Comment [t8]: You could expand on this point to validate your argument. Researchers have said the reasons for delays were 'unnecessary' did they detail the reasons? Can you offer the reader some evidence that they were in fact unreasonable?

In many cases it is important to conduct research at more than one health facility or clinical location to ensure there is ~~no~~ minimal health facility or practitioner based bias, or simply in the interests of recruiting an adequate sample size. A West Australian state-wide investigation into prostate cancer ~~patients necessitated~~ required application to 29 ethics committees, despite state government Department of Health approval (Jamrozik & Kolybaba, 1999). Currently most multi-centre trials require applications to the ethics committees of all sites where the research will be conducted. In some research designs, this can mean applications at multiple health care facilities, and often on application forms unique to each health facility (Alberti, 1995), requiring repetitive documentation and sometimes resulting in clashes between ethics committees' approval conditions. It is understandable that each health facility needs to assess potential research projects for suitability of the protocols for the location, and determine if ~~the~~ resources are available to support each proposal. However, these are not ethical issues, they are resource issues and ~~do~~ may not need to be dealt with through an ethics committee.

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Solutions

Comment [t9]: Is this Australian data? Provide geographical context to add clarity

Comment [t10]: Consider removing – otherwise define Goods and Services Tax

Comment [A11]: What would be the objection to these? Consider inserting 'individualised' or 'reformatted' before consent forms and explanatory statements as it seems to suggest that these are unreasonable additional demands.

Possible solutions to reduce the workload and paper chase for ethics committees could involve expedited approval of small scale trials, non drug trials and research in healthy volunteer populations. Trials ~~with which have~~ research grant funding for less than ~~12~~ twelve months, and student research, could also be assessed in different manner to the large scale medical intervention trials, thereby reducing the workload for both researchers and ethics committees.

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Comment [A12]: You could comment here on what a reasonable timeframe for approval may be to provide context.

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Throughout the Paper: Examiner/Peer Reviewer's Perspective

Paper summary:

This paper examines the role of ethics committees and their impact on the progress of the conduct of research. This paper reviews the current situation regarding ethics approval for research projects in Australia, comparing it to international processes to demonstrate system based inefficiencies and suggest potential solutions to reduce time and cost delays.

Feedback from Readers Perspective:

- This paper could be improved with some basic statistics to provide the reader with some idea of the size and importance of this issue. The NHMRC website and the National Ethics Committee have publicly available statistics on the number of Ethics Committees in Australia, and the number of applications made to Australian Ethics Committees and the average length of delay, as well as the number of applications rejected.
- The paper fails to acknowledge the positive effects of the ethics committee processes and the importance of ethics approval. These could be briefly stated in the introductory paragraph to provide more balance to the argument, and also to clarify that the author's argument is with the system issues, rather than the principles of conducting ethical research.
- The only subheading is multi-centre research – you also discuss student research and medical records review as specific problem areas. For improved flow of argument, suggest either rearrange under these subheadings, or remove multi-centre subheading.
- The conclusion is also quite weak and too brief; suggest re-emphasis of the importance of the outcome and the potential for improvement in the process.
- The section on multi-centre research trials is 11 point font – suggest change to 12 point font for consistency
- There was some confusion between a research site and an ethics committee in the multi-centre research section – take care to ensure this is consistent in the final submission
- You interchangeably use 'multi-centre' and 'multi centre' and 'multicentre'. Suggest you select your preferred term and conduct a find and replace for consistency
- You interchangeably use 'trials' and 'projects' and 'research'. Suggest you select your preferred term and conduct a find and replace for consistency

References used to guide the copyediting of this document

This document has been copyedited in accordance with the national guidelines on copyediting of PhD theses in Australia [1-3]. All changes suggested are for the author to consider, and at their supervisor's discretion. Literary rules have been guided by National editing standards [4].

1. Council of Australian Society of Editors, *Australian Standards for Editing Practice*, CASE Standards Working Group, Editor. 2001, Council of Australian Society of Editors: Melbourne.
2. Council of Australian Societies of Editors and Deans and Directors of Graduate Studies, *CASE Editing Standards: National policy on editing theses*, Institute of Professional Editors, Editor. 2004, Institute of Professional Editors: Melbourne.
3. Denholm, C., Evans, T and Evans, T., *Supervising Doctorates Downunder*. 2007: Australian Council for Educational Research.
4. Snooks, L., et al., *Style Manual for Authors, Editors and Printers*. 2002, Milton, Queensland: John Wiley and Sons Australia.