

Can research that is not intended or unlikely to be published be considered ethical?

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Background

For research to be ethically acceptable, the potential benefits must justify any risks involved for participants. Dissemination of research findings through publication is one way of creating benefit, but not all researchers intend to publish their research. Other factors, such as lack of size or representativeness, generalisability or innovativeness, or negative findings mean the research is unlikely to be published in a peer-reviewed medical journal.

Objectives

This paper discusses ethical considerations in research where peer-reviewed publication is not intended or unlikely.

Discussion

Proposing research that is not intended or unlikely to be published in a peer-reviewed journal does not preclude it from being considered ethical. Additional benefits of such projects may include professional development of investigators, pilot data collection leading to more definitive studies, or developing collaborations with research users that increase relevance and improve utility of findings.

The *National statement on ethical conduct in human research*¹ (National Statement) describes research as investigations undertaken to gain knowledge and understanding, or to train researchers. Human research is conducted with or about people, or their data or tissue. Research ethics in Australia is underpinned by the National Statement that has at its core four principles: merit and integrity, justice, beneficence and respect. The design, review and conduct of research must reflect each of these values.² The National Statement provides broad guidance on how research should meet these four principles, and we have previously described this in the context of ethical review of primary care research.³

From the perspective of an ethics committee, the outcomes of the research and dissemination of findings are core to the assessment of research merit and integrity. Research conducted with integrity includes a commitment to 'disseminating and communicating results, whether favourable or unfavourable, in ways that permit scrutiny and contribute to public knowledge and understanding'.¹

A question that arises from this is whether research that investigators do not intend to publish, or is unlikely to be accepted by a peer-reviewed publication, can be considered ethically acceptable. We explore this in the context of submitting ethics applications to The Royal

Australian College of General Practitioners' (RACGP's) National Research Ethics and Evaluation Committee (Committee), and provide advice on how the Committee approaches assessment of applications in relation to merit and integrity.

The case for publication

For research to be considered ethical, the likely benefits must justify any risks of harm or discomfort to participants.⁴ Traditionally, publication in a paper-based journal following a process of peer review has been regarded as the gold standard for the dissemination of research findings, and an important milestone in achieving impact and maximising potential benefits. Pre-publication peer review can be expected to eliminate findings from the scientific record that have problems with the science, integrity, quality of reasoning and application of scientific principles.⁴ Pre-publication peer review remains a necessary way to identify scientific manuscripts that are worthy of publication and improve the quality of reporting in those that are published.⁴

Timely dissemination of findings assists patients and physicians to make clinical decisions based on the best, up-to-date scientific evidence.⁵ This is an important ethical issue, especially in the context of clinical trials, where participants have exposed themselves to risks in order for society to benefit from the knowledge

gained. Clinical trials that should be published (ie adequately powered, well conducted), but are not, are particularly problematic as the data may show decreased efficacy or increased risk of an intervention or drug. Given the recognised difficulties in publishing negative results, unpublished clinical trials are likely to be those showing negative findings.⁶

This publication bias exaggerates the relative weight of positive findings, and the risk that ineffective treatments may be wrongly believed to be useful in the absence of published results is very real. For instance, the antidepressant reboxetine was ultimately discovered to have been ineffective and potentially harmful, compared with the placebo, when unpublished data were included in a systematic review and meta-analysis published in 2010, more than a decade after it was approved for sale.⁷

Other factors to consider when assessing the benefit profile of a study

Beyond the possibility that research findings will be disseminated through publication in a peer-reviewed journal, there are other factors an ethics committee will consider when assessing the benefits profile of a study, including purpose, context and intended outcomes of the research. These factors include the potential for professional development and capacity building of the researcher or research team, and the intended audience and opportunities for alternative forms of dissemination, such as knowledge exchange.

We advocate a communitarian, rather than a principlist approach to human research ethics. The principlist approach implicitly promotes community dialogue and knowledge exchange as important considerations in determining research merit and integrity.⁸ It is also consistent with a broader social justice view of ethical research – that research findings or products should benefit the communities in which the research takes place.⁹

For instance, a small preliminary study may be necessary to pilot test key aspects

of a research protocol while not being suitable for peer-reviewed publication (Case 1). Indeed, pilot data are seen as an advantage in gaining funding to enable the conduct of larger, definitive studies. In itself, this pilot study may provide information that is valuable in a local context, for example, to guide healthcare improvements within a single community or practice.

A single-site study, such as that described in Case 2, is a further example of useful research in the local context, but this is often a major reason why papers do not get published in peer-reviewed journals. Here, the methodology is sound and the study meets a local need or the researchers' training requirements. However, other factors such as size, and lack of representativeness, generalisability or innovativeness of the study may mean that publication is unlikely. In this context, the merit of the study relates to training and local relevance rather than peer-reviewed publication.

The opportunity to build the knowledge and experience of researchers is also an important consideration. Within the primary care community, conducting research is a powerful form of professional development. There is a compelling case for healthcare providers and trainees/students to be involved in and/or initiate research,^{10,11} even if it is unlikely to gain publication. Completing studies of sufficient scale to ensure statistical power and broad generalisability, or to ensure qualitative findings are robust (eg through the saturation of themes in a thematic analysis) can be difficult with limited resources and/or within the short time frames and competing demands of the academic year or graduate training program. These factors may limit the opportunity to publish, particularly in higher impact academic journals. Rather, the benefits to the community lie in developing the knowledge and skill of the researcher and creating capacity for high-quality future research. In the context of low-risk research, these benefits outweigh risk to participants.

While papers that are peer reviewed gain respectability and acceptance, and

are considered relevant contributions to the field,¹² the process is not faultless.¹²⁻¹⁴ There is criticism that potential end users of research may never read the relevant papers, especially if they lack commercial access to academic journals. The translation of research into practice is also important in realising the benefits of research and justifying risk. This relies on findings reaching the appropriate audience in ways that can be effectively implemented, and may warrant alternative or additional forms of dissemination to traditional peer-reviewed publication.

The use of diverse communication formats can be effective in engaging different knowledge users.¹⁵ These multifactorial influences are the focus of knowledge exchange as a philosophy for the design and conduct of research and dissemination of findings. Here, research users work together with researchers to produce knowledge that is relevant for the setting in which it is to be applied,¹⁶ and confidence in findings is increased, allowing research knowledge to be more effectively translated into policy and practice. In this context, research that is needed or valued by the community is favoured over unnecessary or unwanted research, enhancing the ethical value of the research, as unnecessary research, or research that is not generalisable to the social or cultural contexts of users is not undertaken. Some other form of peer review, such as from a scientific advisory group, is valuable in this situation to provide confidence to end users that the findings and any recommendations are scientifically sound.

Conclusion

Broadly speaking, research is ethically acceptable only when its potential benefits justify any risks involved. The National Statement provides some guidance as to what those benefits may be, and these include gains in skill or expertise of individual researchers, teams or institutions, as well as achievements in knowledge, and the wellbeing of individuals and communities. Proposing

research that is not intended or likely to be published in traditional ways, such as through peer-reviewed journals, does not preclude research from being considered ethical if there are other benefits that are likely to arise from the project, and where benefits outweigh risk of harm to study participants. In the case of research that is methodologically weak (but not flawed), which affects the likelihood of publication, this may still be the case, although ethics committees will carefully consider risks and benefits.

When writing an application for ethics approval, investigators should consider how their findings will be disseminated, including through non-traditional and interactive means. Readers are encouraged to take a knowledge exchange perspective in order to maximise uptake and use of findings, and realise optimal benefit. This information should be incorporated into the ethics application so it can be considered in conjunction with other aspects of the proposed study by the relevant ethics committee as part of the process of review and assessment of research merit and integrity.

Case 1. Is it ethical to conduct research to generate pilot data that are not intended to be published?

An academic general practitioner seeks ethics approval for an honours student under his supervision to conduct a pilot study that aims to explore the acceptability and feasibility of data collection from within a new mobile health app he is developing. Pilot-testing patient recruitment and the inbuilt survey technology to show feasibility would benefit a future grant application, and the student will write her thesis from the results. You question whether the study is ethical given it will only generate data to support a future grant application and an honours thesis, and would not benefit patients or lead to a publication.

Case 2. Is it ethical to conduct research when it is unlikely to lead to a peer-reviewed publication because of size or lack of representativeness, generalisability or innovativeness of the study?

As a general practice registrar, you have been intrigued by a patient who came with an unusual complaint, and would like to conduct research on this topic in your practice population. You make contact with an academic supervisor who is conducting research in this area. You describe your plan for a single-site study, but the academic supervisor questions whether this will lead to a publishable outcome. She suggests a more expansive study, but you do not feel you could conduct this research, given your clinical load and inexperience. You question whether it is ethical to continue with your planned smaller study if it is unlikely to lead to a publication.

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