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Editorial

Health promotion practice, research ethics and publishing in the *Health Promotion Journal of Australia*

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This special issue of the HPJA focuses on ethics in the context of health promotion practice. This editorial takes a narrower focus: the issue of Human Research Ethics Committee (HREC) approval for health promotion research, evaluation and quality assurance (QA). We will focus on three papers in the special issue: each argue that those working in health promotion should consider ethics from the very beginning of their research, evaluation and/or QA activities.

The first paper, by Ainsley Newson and Wendy Lipworth, is entitled 'Why should ethics approval be required before publication of health promotion research?' In it they argue that 'journals should not, in general, publish articles with no ethics approval', even if the findings are interesting or apparently important.[1] The second paper, by Peter Sainsbury, is entitled 'Development and oversight of ethical health promotion quality assurance and evaluation activities involving human participants'. In it he argues that the boundaries between research, evaluation and QA are not clear, and that all of these activities should be underpinned by research ethics principles and focus on the central issue of potential risk to participants.[2] The final paper, a commentary by Judy Allen, reflects on the ethical dimensions of health promotion research and evaluation from the inside of an HREC.[3]

What are Human Research Ethics Committees, what do they do, and when should I apply to one?

Human Research Ethics Committees (HRECs) are the main mechanism for ethical oversight of research involving humans in Australia. There are more than 200 HRECs registered with the National Health and Medical Research Council (NHMRC), Australia's leading expert body on healthcare and research ethics, most located in universities or hospitals.[4] In addition, some organisations, particularly outside the health sector, have their own systems of ethical review of research. HRECs registered with the NHMRC must be 'properly constituted', as defined in the National Statement on Ethical Conduct in Human Research[5] and the Australian Code for the Responsible Conduct of Research.[6] A properly constituted HREC, at minimum, must have an experienced chair without relevant conflicts of interest, and seven additional members including two lay people, one person involved in patient care and another in pastoral care, a lawyer and two researchers.[5] HRECs review proposals for research projects involving humans (before the research commences) to determine whether the projects are methodologically and ethically justifiable. They make this assessment based on the standards set out in the National Statement and their own best judgement and deliberation. Many other countries have similar systems for overseeing research activities.

The importance of the National Statement on Ethical Conduct in Human Research cannot be overstated. As all of our featured authors argue, this document should be used to guide practice at all stages of activity, not simply to achieve approval from a HREC. The National Statement contains sections including:

> Section 1: Values and principles of ethical conduct: (to paraphrase) respecting participants, designing good quality research and carrying it out well, paying attention to justice (e.g. ensuring that the benefits and burdens of research are fairly distributed) and ensuring that potential benefits outweigh potential harms.
> Section 2: How to evaluate risk, benefit and consent
> Section 3: Ethical considerations for particular research methods (e.g. qualitative methods, intervention research)
> Section 4: Ethical considerations specific to participants (e.g. pregnant women, children, people in unequal relationships, Aboriginal and Torres Strait Islander people)
> Section 5: This section sets out the processes for research governance and ethical review.

The NHMRC has also made an additional short statement on Ethical Considerations in Quality Assurance and Evaluation Activities,[7] which is highly relevant to authors who publish in the HPJA. We will discuss this further below.

The National Statement does not distinguish between research, evaluation and quality assurance, other than to indicate that any activity that generates new knowledge should receive some kind of ethical oversight. Instead, the National Statement distinguishes

between negligible risk, low risk and more-than-low risk research, with a more stringent oversight required as the level of risk increases. Any work that is more-than-low risk must be considered in the normal ethics committee processes. Low and negligible risk research are not exempt from HREC review, but can in some circumstances be considered under a modified ethics review process.

But HREC approval is only for research: this is health promotion!

It is common for health promotion practitioners to believe that their activities do not need HREC oversight: as editors we hear this regularly. In table 1 of his paper, Sainsbury provides a list of 'Myths about why health promotion quality assurance and evaluation do not need ethics committee approval'.[2] These are familiar to us, and include: 'This isn't research, it's just good practice', 'It would have taken so long to get ethics approval that we would have lost the opportunity to do the project' or 'We don't have access to an HREC'. The most common objection, however, is that 'The benefits will be immense', or to paraphrase, 'This is very important information for health promotion, so you shouldn't stop publication just because the work didn't have ethics approval'.

Practitioners also commonly believe that HREC approval is only for research, not for evaluation or QA. This is sometimes because HRECs have advised practitioners that ethics approval is not required for any QA activities, which is confusing. However, as all of our featured authors argue, the boundaries between research, evaluation and quality assurance are blurry. Sainsbury lists the NHMRC's 'seven triggers' for ethical review, including infringing privacy, using data that were collected for a different purpose, or doing something – including collecting information – that would not ordinarily have been done in regular service provision. He notes that many of these are common in health promotion QA and evaluation, not just research.[2] All three papers show that the ethical issues in research, QA and evaluation are similar. To quote Allen:

> Research, quality improvement or evaluation – whatever you call it, it raises the same fundamental ethical issue. The essence of the activity is that of using people for ends of your own, not for their benefit. The overall objective may be a public benefit and people may well choose to participate in it for altruistic reasons, however, when you are using people in this way great care must be taken. Categorising the activity is unimportant. What is important is careful thought about the ethical responsibilities.[3]

Sainsbury makes a similar argument, but focuses on the ethical significance of risk. What matters, he argues, is not whether we call something research, evaluation or QA, but 'what being a participant in the research, quality assurance or evaluation involves and the risks to which s/he may be exposed by participating.'[2]

In the past, the HPJA has published papers reporting on research that has not had ethics approval. We have not consistently adhered to internationally agreed standards such as those of the Committee on Publication Ethics (COPE)[8] or the International Committee for Medical Journal Editors (ICMJE).[9] We are now putting processes in place to make our own practices more consistent. Authors will now be required to indicate, during submission, whether their work involved human participants and, if so, whether they had ethics approval, or if not, why not. This will create a formal flag for Editors to automatically integrate questions about research ethics approval into HPJA decision making.

Newson and Lipworth discuss the benefits available to practitioners who apply for and receive formal HREC approval. Participating in the HREC approval process encourages greater reflection on plans for a project; this can lead to real improvements and, thus, benefits. It can improve the intervention being tested. It can reduce risk of harm. It is a way of demonstrating respect for the participants in a study. And, importantly, it can make health promotion research – both individual projects and the enterprise in general – more publicly legitimate.[1] This latter point is important. An official HREC 'stamp of approval' can provide assurance that research-like activity in health promotion, and the knowledge it generates, are more likely to be trustworthy. But the systematic process required to obtain HREC approval is just as important as the approval itself. This process is designed to maximise the quality and ethical justifiability of research and evaluation. It also encourages ethical reflection on issues such as the possibility of unintended harms, and whether a plan for data collection or intervention shows sufficient respect to participants.

Making the system better for health promotion

There is no doubt that there can be problems with seeking HREC approval. The processes can be bamboozling, bureaucratic and inefficient; HRECs rarely include members who are expert in health promotion; and health promotion workers often do not have access to training or support in research ethics. In addition, health promotion activities have a tendency to mutate from one kind of activity (for example, simple record keeping of attendances) into another (evaluation of an entire program), making it difficult to predict that new knowledge is being generated and, therefore, that HREC approval is required. However, these are not arguments for exempting health promotion projects from approval processes. They are arguments for making the approval processes simpler to navigate for low risk activities and putting supports in place to assist health promotion workers to participate in them. We must also ensure that robust systems are in place within organisations to facilitate early consideration of the longer term ethical implications of their data-collection activities. Whose responsibility these improvements should be is an open question, but they are conceivably the domain of professional associations, training institutions such as universities, bodies overseeing standards of practice and employers such as health services. It is important that all of these institutions cooperate to solve the problem, rather than simply pushing it back onto individual practitioners or small health promotion units.

As a profession, health promotion could establish infrastructure to support health promotion workers participating in the HREC process. One possibility would be to form Community Ethics Research Offices to assist community practitioners who undertake research, QA and evaluation, by providing ready access and support for obtaining ethics approval. A model for a Community Ethics Research Office has been established in Canada and since 2011 it has provided ethical review and protocols for community workers for a nominal fee ($100.00), as well as consultation on ethical processes and practical workshops on ethics.[10]

Conclusion

Much of the research, evaluation and QA work done in health promotion is of negligible or low risk; but this does not mean that research ethics becomes irrelevant. Any activity that generates new knowledge requires careful consideration of ethical issues, including the quality of the methods used, justice, respect for participants, and paying attention to benefits, potential harms and the balance between them. The very minimum that authors should do is to seek advice as to whether ethical approval is required, and consider for themselves the ethical dimensions of what they are planning to do. These papers together provide a resource for that reflection. Sainsbury's table 2 provides a practical checklist to support health promotion workers to engage in the HREC process.[2] And Allen's paper is shaped around a set of helpful questions responsive to the health promotion context, informed by her extensive experience on ethics committees.[3] To quote verbatim from Allen's paper:

1. Do you need help with your HREC application?
2. Have you thought about the skills you will need to conduct the evaluation?
3. Do you have a conflict of interest?
4. Has anyone already collected the information you need?
5. How do you demonstrate respect?
6. Have you separated consent for the intervention from consent for the evaluation of the program?
7. When can you use government-held information?
8. Have you thought about how to maximise privacy?
9. Have you thought about security – storage, transport and archiving?

Editors have ethical responsibilities too. We need to satisfy ourselves that the ethical dimensions of a project have been taken seriously and thought through. As Newson and Lipworth argue, if journal editors continue to make exceptions to the need for HREC approval, we communicate that research ethics is not important, and we provide no reason for authors to take research ethics seriously.[1] So editors need to consistently require authors to demonstrate how they have considered and addressed the ethical issues in their activities.

Consistent with the three papers we have featured in this editorial, the editors of the HPJA will take the following position from 2016. It applies to all papers reporting on research-like activities, whether they are called research, evaluation or quality assurance. This includes any paper that reports on analysis of data from or about people, whether generated using surveys, observations, interviews, focus groups, from routinely-collected data or by other means. All of these papers should report approval for the project from a properly constituted HREC (or an appropriate formal institutional process for oversight of low or negligible risk research, consistent with the National Statement[5]). Exceptions to this rule should be rare and made for convincing reasons. Such papers should be accompanied by an editorial that draws attention to the lack of ethical approval, explains why an exception was made and lays out the grounds for such an unusual decision. This will bring the HPJA in line with the generally held views and international standards for journal publishing.

This editorial is endorsed by the HPJA Editor-in-Chief Dr Jonine Jancey and the HPJA Associate Editors (in alphabetical order): Dr Lisa Barnett, Professor Colin Binns, Associate Professor Stacy Carter, Professor Peter Howat and Associate Professor James Smith.

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