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COMMENTARY

Developing Guidance on Ethics for Patient Groups Collecting and Reporting Patient Information for Health Technology Assessments

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Agencies around the world are seeking to include patient and carer perspectives in health technology assessments (HTAs) [1–3], as this may enable a more accurate assessment of a health technology [2] and lead to more appropriate decisions for patients [4]. In a 2010 survey of International Network of Agencies for Health Technology Assessment (INAHTA) members, 22 agencies reported involving consumers (defined to include patients) in their HTA processes [1], and the Health Technology Assessment International's (HTAi's) Interest Group for Patient and Citizen Involvement (PCIG) has published summaries of the patient involvement processes of 11 HTA agencies [5]. In addition to these perspectives being gained through literature reviews and primary research [6], patient perspectives are sought through patient submissions, which usually take the form of responses to questions designed to elicit information not found in the published literature, such as patients' and caregivers' needs, preferences and experiences [7–11]. To create these submissions, some patient groups collaborate with researchers, but others gather the information from their members themselves using tools such as call logs, social media, surveys, interviews and focus groups. Because this entails engaging with people and collecting their personal information, patient groups need to consider the ethical and legal issues and implications. As no guidance on these issues could be located, the PCIG began developing its own specifically for patient groups involved in this work.

1 Working Towards HTAs Informed by Patient Knowledge

HTAs provide evidence-based advice to healthcare policy makers as to whether a health technology should be funded. They typically focus on systematic evaluations of the clinical and cost effectiveness and safety of a health technology, but may also consider broader consequences of a health technology, such as its social and ethical impact [2]. Unlike clinical-effectiveness evidence, which draws on quantitative studies such as randomised control trials, patient submissions are drawn from the unique knowledge patients and caregivers gain from the lived experience of a condition or illness. Submissions can include information about the impact of a condition on daily life, the burden of current treatments, tolerable and intolerable side effects, what is valued most in a treatment, information about how a treatment works outside of clinical trials, and the specific needs of particular sub-groups of patients (e.g. those with co-morbidities or living in remote areas).

The PCIG develops and promotes the use of robust methodologies to incorporate patients' perspectives in HTAs, and shares best practice in patient and citizen involvement in the HTA process [12]. As time, resources and knowledge about methods present a barrier to agencies considering incorporating patient input [3], the PCIG seeks to develop tools to assist agencies to appropriately involve patients and public in HTA.

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Thus, in 2014, the PCIG launched standard submission templates for HTAs following a major project by Dr. Karen Facey involving a review of a wide variety of patient group submission processes used around the world and international consultation on the proposed documents [7, 8]. The aim was to ensure patient group submissions captured information that is most useful to HTA decision making. The intention was that HTA agencies should adapt the submission templates to suit their processes. Following the release of the templates, agencies such as the Canadian Agency for Drugs and Technologies in Health [11], Scottish Medicines Consortium [9] and National Institute for Health and Care Excellence [8] reviewed their patient group submission forms, while countries such as Australia, Germany, Finland and Taiwan have translated and/or adapted the templates for trial (personal communication, Karen Facey, 17 September 2015).

While the PCIG encourages patient groups to work with qualified researchers—such as statisticians, social scientists, bioethicists and other health researchers—to help design, conduct and analyse evidence for submissions, it recognises that some patient groups may prepare submissions independently and some may lack the knowledge and skills such activities demand. To help address this issue, the PCIG published guidance for patient groups on how to collect information using surveys and interviews, and how to summarise the information in a way that is most helpful for an HTA [13]. The guidance was an adaptation of a pan-Canadian Oncology Drug Review (pCODR) guide [14] and was prepared by the PCIG in consultation with pCODR. During its development, questions arose about the expectations placed on patient groups invited to prepare submissions for HTAs. In particular, members were concerned that patient groups may be unaware of the ethical requirements around collecting information from patients and their caregivers. In October 2014, the PCIG agreed that some ethical guidance was needed for these patient groups. When suitable guidance could not be located, the PCIG formed a working group and collaborated with the HTAi Ethics Interest Group (EIG) to develop its own guidance for patient groups.

2 Is It Research?

When considering the guidance, the question arose as to whether patient groups should be complying with research ethics and applying for formal ethics approval from relevant committees. This question highlighted differences of opinion among the members of the interest groups, which included university researchers, agency and industry staff, patient group representatives and patient advocates. Some suggested that patient groups lack the time and resources to conduct research and apply for research approval. Others suggested that information gathering and reporting could not be considered research as patient group staff seldom had the formal, academic training, such as a masters or PhD, required for research; while others felt that patient groups' activities meet some definitions of research, such as that used by the National Health and Medical Research Council (NHMRC) in *The Australian Code for Responsible Conduct of Research*: "The meaning of 'research'… is original investigation undertaken to gain knowledge, understanding and insight" [15].

As agreement on a definition of research was not possible, and was a diversion from the remit of the PCIG, it was decided to set aside this question and focus on the nature of the work that is being conducted by patient groups and the needs arising. Members of the PCIG and the EIG agreed that while patient groups often do not have the time, resources or training to undertake rigorous, systematic investigations, most patient groups do have a network of patients and caregivers that they can collect valuable information from. Collecting this information involves engaging with people and handling their personal information, including health information. As a result, there is a requirement for this activity to be conducted in accordance with principles of ethics even if it does not require formal ethics approval. Patient groups thus require guidance so that when they conduct these activities with the aim of improving the lives and outcomes of their members, they also protect the "personal safety, dignity, rights and well-being" [16] of their members.

3 Key Ethical Issues

Members of the PCIG and the EIG identified the following ethical issues as most pertinent to the work of the patient groups:

- Need for activity.
- Informed consent.
- Inclusivity.
- Anonymity and confidentiality.
- Data protection.

"Need for activity" considers the need to balance giving patients the right to share their knowledge and have a say with not overburdening patients with requests for information. For example, patient groups may be able to consider re-using information they have previously collected for an HTA submission, or structuring their information gathering activities such that one activity provides information for multiple HTA submissions.

It is essential that volunteers, staff and others gathering information understand that although the activity is important to the patient group and HTA agency, the needs

of the patients always come first. This is achieved by using an informed consent process where those invited to take part are told the reasons why they are being asked for information and the ways in which this information will be used and shared; are helped to understand that they can refuse to participate or can stop participating at any point; and are given realistic expectations about how patient group submissions are used in an HTA.

During discussions about competency to consent and vulnerable populations, a further area for consideration was identified: inclusivity. It was felt that it was important to include the issue for two reasons. First, patient involvement activities seek to include input from a broader population than those usually included in clinical trials. Second, while encouraging patient groups to take account of individual competencies, the guidance wishes to encourage patient groups to appropriately reach out to people such as children, the cognitively impaired, the homeless or the imprisoned when gathering information.

"Anonymity and confidentiality" were identified as key issues because the privacy of medical information is subject to legal protections and patients and caregivers often require the certainty of confidentiality before sharing very personal stories. Finally, it is important that patient groups are aware of the existence of data protection laws in their area or country and act in accordance with them and the policies of their organisations.

4 Creating Guidance that is Fit for Purpose

The project provided several challenges for the PCIG and EIG. First, there was the need to balance the inclusion of all the key issues against not making the guidance so complicated or lengthy that it would discourage patient groups from attempting an activity that may be of value to them, their members and assessment agencies. The authors had to particularly consider the needs of small patient groups that often lack resources, but may be the only voice for patients who are not well-represented in the literature, such as those with rare or contested conditions. The second challenge was the breadth of the audience for the guidance. Patient groups exist within different cultures and legal jurisdictions, and have very different skills, resources, knowledge and experience. Any guidance given had to be sufficiently broad to take account of these differences, but also sufficiently plain in its language and meaning to reduce the chances of being misunderstood when adapted or translated.

The ethical guidance is presented as two complementary documents published on the HTAi website, http://www.HTAi.org; one a short summary of questions to consider and the other a longer document for patient groups seeking a better understanding of the issues. To create guidance that is fit for purpose, broad consultation is being undertaken which includes PCIG members directly approaching patient groups, seeking their views about the content, language, format and the title of the document. The initial versions of the documents will then be trialled and revisions will be informed by feedback sought from HTA agencies, patient groups active in HTA and researchers with an interest in patient involvement in HTA. The intention is to add links to the website, showing useful examples of how others deal with the ethical issues.

5 Conclusion

This important project highlights the need to consider the potential of patient involvement activities to influence the nature of the work of patient groups and their relationship to members. Just as we encourage patient groups to tell us what matters most to their members, we focus patient groups towards what matters most to HTA decisions by asking them to collect particular types of information in our submission forms. We also encourage robust methodology to collect and report information, thus building knowledge and skills, but also influencing working practices. And by advising on ethics, we are encouraging them to work in certain ways. Such activities should not be undertaken lightly. They require consultation, reflection and a consideration of the ethics behind patient group involvement. For the PCIG, this may mean monitoring its own activities against the *Values and Quality Standards* [17] it promotes for patient involvement.

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Compliance with Ethical Standards

Conflict of interest Single A. N. V. and Wale J. declare that they have no conflict of interest. During the preparation of this paper, Scott A. M. was employed by the NHMRC Clinical Trials Centre, which is contracted by Medical Services Advisory Committee (MSAC) to perform systematic reviews as part of its HTA process.

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