Facing the Ethical Challenges: Consumer Involvement in COVID-19 Pandemic Research

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Abstract Consumer involvement in clinical research is an essential component of a comprehensive response during emergent health challenges. During the COVID-19 pandemic, the moderation of research policies and regulation to facilitate research may raise ethical issues. Meaningful, diverse consumer involvement can help to identify practical approaches to prioritize, design, and conduct rapidly developed clinical research amid current events. Consumer involvement might also elucidate the acceptability of flexible ethics review approaches that aim to protect participants whilst being sensitive to the challenging context in which research is taking place. This article describes the main ethical challenges arising from pandemic research and how involving consumers and the community could enable resolution of such issues.

Keywords Consumer · Community · Involvement · Ethics · Research · Pandemic

Introduction

Consumer (patients, carers, and people who use healthcare services) and community involvement in research (herein “consumer involvement”) describes the active partnerships between consumers and researchers or research organizations to shape decisions about

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health research priorities, policy, and practice (National Health and Medical Research Council 2018).

Responses to public health emergencies pose challenges to involvement activities, as they are often conducted in conditions that limit effective dialogue and relationship formation—exacerbated further by common structural (e.g., infrastructure) and individual (e.g., attitudes) involvement barriers (Happell et al. 2018). Consequently, in the race for knowledge, rapidly initiated studies can often be slow to involve consumers or in some cases completely forgo involvement, negatively impacting study outcomes. For example, during the Ebola epidemic, researchers acknowledged this power imbalance and that the lack of early consumer involvement hampered both the clinical response and preliminary research efforts (Bedrosian et al. 2016).

The purpose of this article is not to reiterate the case for involving consumers in research in general but rather to explore some of the ethical issues COVID-19 has presented to research and how involving consumers may help address these concerns. It also explores opportunities to further enhance and embed consumer involvement in research going forward.

Consumer Involvement in Pandemic Research: Challenges and Opportunities

Pandemic challenges are often underpinned by time pressures, logistical issues, and social distancing measures, resulting in a limited window of opportunity to gather knowledge. Examples of these are discussed below, including potential opportunities to further enhance and embed consumer involvement in research going forward.

Awareness and Access to Research

During a pandemic, key national agencies will be responsible for the immediate responses needed to protect the health and safety of the population. This might include temporary or permanent changes to health and research policy and regulation to facilitate access to care facilities, treatments, or vaccination (e.g., NHSX 2020, Government of Western Australia 2020). Involving consumers in the decision-making processes around risks (including curtailment of human rights) versus the benefits (public health gains) is necessary to ensure that new policy and regulatory changes do not erode public perception and support for research endeavours in these times (WHO 2016; The University of Auckland 2020).

Unfortunately, there is a recognized inequity in awareness of and access to research (Leiter et al. 2015). Throughout the pandemic it is important that all people are aware of research and how to access it, either to participate in, contribute to, or simply learn about it. Therefore, one of the greatest potential legacies of this outbreak will be increased awareness (understanding of the role, process, and value of research) and improved access opportunities for the broader Australian population. Achievement of such outcomes will be enhanced by deliberate efforts to involve consumers from diverse backgrounds in COVID-19 research, reaffirming the expectation that research and consumer involvement are core business of the health system.

Informed Consent

Consent is central to the ethical principle of respect (National Health and Medical Research Council, Australian Research Council, and Universities Australia 2007/2018), but many factors challenge the ability to obtain traditional informed consent in pandemic research (Nuffield Council on Bioethics 2020). For example, the clinical consequences of COVID-19 can include diminished capacity, in a setting where patients do not have the support of those that care for them due to isolation. Infection control measures and family separation mean the usual practice of written informed consent by a patient or guardian may not be possible. Consequently, the pandemic has expedited the need to review the ethical considerations for consent in emergency settings.

In Australia, the National Health and Medical Research Council and other national bodies recognize these challenges (Department of Health 2020), with solutions such as modifications to pre-existing ethical frameworks for consent, for example the wider use of verbal consent obtained through telehealth. In Western Australia (WA) amendments to guardianship law have aligned consent requirements with other state’s legislation that have established provisions allowing waiver of consent when it is not reasonably practicable to seek the consent of a guardian or “person responsible”—a change advocated for by clinicians and consumers for many years. Yet whilst this allows WA researchers to join COVID-19 research studies, the justification for
modifications that reduce autonomy must be carefully explained. Partnering with consumers can enable this by facilitating effective public communication approaches in order to prevent loss of confidence in the research process. If patients no longer support (and thus benefit from) clinical research due to a loss of trust, this in itself may impact patients’ welfare (Symons et al. 2020).

Consumer involvement at this stage can also have a critical role in giving ethics committees and governing bodies confidence in the acceptability of a revised consent process. As an example, in a pre-COVID-19 trial which involved premature babies requiring oxygen support (Oei et al. 2017), a consumer co-applicant (mother of preterm children) was instrumental in convincing the ethics committee that a traditional consent process would render the trial infeasible. The research team (which included consumers) explained that the risks posed by the loss of autonomy from the use of altered consent processes were less than the risks posed by “unresearched” neonatal care (Tarnow-Mordi et al., 2015).

Appropriateness of Study Design

Consumer involvement provides a direct opportunity in this context to help researchers, clinicians, and multi-stakeholder groups resolve uncertainties about the design of pandemic research and the appropriateness of the risk-benefit balance proposed (Smith et al., 2016). For example, a common contentious issue is the use of health data, yet the need for data to understand and address the pandemic is unprecedented. Initial issues in this context often arise when there is a failure to develop transparent approaches for the sharing of data and biospecimens (e.g., tissue and blood) for research purposes. Further challenges are due to management considerations of biospecimens, such as governing laws and regulations, individual beliefs and values, and a recognition that the resources themselves are depletable. Such factors add an extra level of appraisal complexity for both researchers and consumers to decide not only appropriate use but prioritization of research access.

Solutions to these ethical challenges can however be overcome when consumers are involved in the study design phase, informing the appropriateness of sample (data or tissue) collection or identifying unreasonable burden on participants related to intensive visit schedules. Furthermore, in previous outbreaks, consumers helped co-design recruitment approaches, for example by translating complex research terminology (placebo) and processes (randomization) into plain language, proposing storytelling methods, reducing misinterpretation of research aims, and preventing recruitment delay (National Academies of Sciences, Engineering, and Medicine 2017). Such input improves the chances of successful trial completion through improved recruitment and retention. This is often evidenced in emergency medicine research (Ernst and Fish, 2005) and more recently in development of the Australasian COVID-19 trial (ASCOT), where consumers deliberated the pros and cons for the use of verbal consent, as pens, paper, and devices were not feasible due to infection control protocols, further removing embedding challenges.

Applicability of Research Results

Data to date suggests COVID-19 disproportionately affects the more vulnerable members of our society—older adults, people with underlying health conditions, and certain racial and ethnic groups (Garg et al. 2020). To help understand how the disease behaves in different groups and ensure the results are broadly applicable, effort must be made to recruit diverse participants in research. Acknowledging that such groups may have been partially overlooked in previous pandemic research (Crooks et al., 2020), and recruitment may require considered strategies that are best developed by involving consumers, taking into account cultural and logistical issues posed during this time.

Involving diverse groups in research is not without its complexities (Clark et al. 2018) but is essential for ethical, clinical, and social reasons. Such inclusive approaches will ensure that what matters most (in particular for adversely affected populations) is captured and can be prioritized effectively in the research response. Involving consumers also recognizes that one approach may not fit all, increasing the transparency of the research effort and helping to contextualize it both locally and nationally. Moreover, evidence suggests consumers are empowered and want to be involved in clinical research, even more so during a pandemic (Tizzard 2020), and stakeholders need to be prepared. Gathering an understanding of pandemic practicalities from an end user’s perspective can help the research sector be more informed and organized and plan for future responses.
Achieving Meaningful Involvement

Tokenism (symbolistic involvement lacking meaning) in the context of meaningful consumer involvement is a problem in clinical research (National Health Research Institute 2015). Given the time constraints of planning pandemic research, the risk of limited involvement may be heightened and in some cases only an afterthought to ratify established research proposals. Research practice such as this challenges the core philosophy of co-production with consumers (Ocloo and Matthews 2016). Furthermore, limited access to training for researchers on how to effectively involve consumers may leave consumers feeling unclear about their role, poorly prepared, and misaligned with involvement expectations. Worse still, if researchers feel compelled to involve consumers (e.g., funder requirements), consumer involvement activities may be relegated to a tick-box exercise.

However, contrary to the perception that involving consumers at the design stage of pandemic studies delays time to study initiation, it may well do the opposite (Ennis and Wykes 2013). Consumers can utilize their experiential knowledge (e.g., disease, community, health system, or research experiences) to provide rapid feedback on which study plans and processes are likely to work. Despite current constraints, examples of such meaningful involvement endeavours are evolving in Australia. For example, led by expert advocates, the Telethon Kids Institute utilizing embedded infrastructure was able to rapidly (sometimes in less than twenty-four hours) reach out to consumers who had the necessary skills and knowledge to undertake many activities relevant to the Australian COVID-19 research portfolio, expediting the development and implementation of pandemic research into routine healthcare settings.

The Research Ecosystem: Are we Ready for Consumer Involvement in Pandemic Research?

Whilst there has been a growth in consumer involvement in research over the past decade (e.g., in the United States, Canada, and the United Kingdom), recent data from the United Kingdom demonstrated a decrease in consumer involvement plans to 20 per cent of COVID-19 proposals, compared to nearly 80 per cent in normal research plans received by ethics committees (Hanley and Tarpey 2020). This highlights the importance of not only infrastructure but ongoing national leadership advocating the importance of consumer involvement in research at all times and even more so during a pandemic.

Fortunately, the moral and ethical reasons for consumer involvement in research are increasingly being recognized, with dedicated organizations and expanding infrastructure. Australia continues to foster such growth with emerging exemplars of internationally recognized best practice for consumer involvement in research (Australian Health Research Alliance 2018). Yet attitudes and support for consumer involvement in research still varies, often exacerbated by limited access to involvement training and

Fig. 1: UK Integrated Research Application System Form
resources, pathways to identify consumers, and insufficient funds to comprehensively develop and sustain involvement activities (Scholz et al. 2019).

Embedding the requirement for consumer involvement into research practices (including policy frameworks, grants, and ethics applications) will continue to support such efforts. An example of this has been demonstrated in the U.K. (Integrated Research Application System (IRAS), 2019) national ethics application form (see fig. 1), which includes a mandatory “involvement question.” These partnerships are particularly important in pandemic research, as demonstrated consumer input can help alleviate questions of feasibility and ethics in pandemic research; moreover, they can reduce the potential risk of research waste (Department of Health 2011) by ensuring the intended research outcomes match the desired outcomes of patients and service users.

Conclusion

A pandemic exposes several issues for research, including how to rapidly recruit and involve diverse populations, how to design and conduct research at speed in a way that is cognizant of the needs and concerns of the community, and how to obtain data and biospecimens that will help us learn about the new disease whilst minimizing participant burden and maintaining the trust necessary to support and engage with research. Involving consumers in pandemic research is therefore critical in developing solutions for these issues, but to do this effectively means that the infrastructure, culture, funding, and relationships need to be established and sustainable. Preparation and ongoing leadership remain fundamental to ensure the gains made through consumer involvement in research outside of this health emergency can be realized for pandemic research and beyond.

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