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Risk, responsibility, and choice in research ethics



For more on **enquiring about trauma in health-care settings** see <https://www.nice.org.uk/guidance/ph50/chapter/4-Considerations>

In health-care settings, routine enquiry about experiences of trauma is good practice. Yet in research studies, whether to address trauma and how is contested. Some studies prioritise inclusive samples and questions about people's lived experience. Others avoid potentially retraumatising topics and exclude people considered too vulnerable to participate.

Safeguarding is essential, but when does protection become paternalism, and who gets to decide this? These questions matter and contribute to why we know so little about the extent and nature of domestic violence and of self-harm during the COVID-19 pandemic.¹

In 2000, Jon Nicholl wrote that it was immoral for ethics committees to have become barriers to ethical research that could help to improve health care.² Although the ethical review process has since become more efficient, Nicholl highlights a still relevant tension: how can we balance maximising the benefit of research to society while minimising risk of harm to the individuals taking part?

With the onset of the COVID-19 pandemic, face-to-face survey fieldwork around the world largely ceased (and 18 months later, few surveys have fully resumed). As new data needs emerged, all parts of the research process moved faster.³ Research that was recognised as a priority for the COVID-19 evidence base was given streamlined permissions, including expedited ethical reviews. However, this change in pace also contributed to a fall in lived experience involvement. Before the pandemic, patients and the public were involved in 80% of the research reviewed by the UK Health Research Agency. In March, 2020, public involvement was 22%. A related effect was a pause on research on specific topics, such as research asking probability samples of the general population about experiences of domestic violence or self-harm, and research focused specifically on affected individuals.¹

Although university and other ethics committees convened more regularly and processed applications

more swiftly than before the COVID-19 pandemic, this came with increased risk aversion. Researchers avoided asking for approaches that were anticipated to maybe cause delay. Committee members were understandably concerned about approving research on sensitive topics, given the reduced ability to direct participants to curtailed and remote services or support. Since the start of the pandemic, few general population surveys have been permitted to ask about violence, abuse, or self-harm. This omission continues to have substantial consequences for the evidence base in England, UK, and elsewhere, serving to hide the scale of harm, and preventing people in need, including victims and survivors, from being heard.

As harm to participants is unethical, might exclusion from research also be considered unethical and an epistemic harm? Some standard mechanisms for protection, such as requiring participants to sign quasi-legal documents stating that their consent is full and informed, might serve to protect researchers, data guardians, and institutions more than participants. People who prefer not to sign such declarations are often excluded from research, constituting a hermeneutic injustice in itself. Those participants deemed too vulnerable—or too difficult—to ask might also be excluded on the basis of what others consider to be in their best interests. Even if participants can be informed about a study, that questions can be skipped, and that they might withdraw at any time, decisions about their fitness to be asked are pre-emptively made by a remote external regulatory body.

What assumptions are made about competency and protection when research about domestic violence or self-harm is not approved? We know, for example, that assumptions about vulnerability and victimisation intersect with inequalities related to ethnicity, gender, sexual identity, and age. Women have historically been left out of research,⁴ as have children⁷ and older people. Bayer and Tadd's study of ageism in research found that "of the 155 studies that were of relevance

For more on **public involvement in research** see <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/public-involvement-pandemic-lessons-uk-covid-19-public-involvement-matching-service/>

to elderly people, over half had an upper age limit that was unjustified” with none of these needless exclusions challenged by the ethics committees.⁶ Protection against disclosure is often cited when information on ethnicity and sexual identity are removed from or aggregated in archived datasets, restricting analyses.

Potential harms identified by ethics committees are not fictional.⁷ There are very real, but often surmountable, challenges. Balance is needed.⁵ For example, even though surveying all household members about domestic violence could alert a potential offender that a disclosure has occurred, we reduce this risk by including such questions only on surveys asked of one household member.⁸ Additionally, evidence suggests that rather than increasing risk, acknowledging and talking about suicide in research might reduce suicidal ideation and lead to improvements in mental health in treatment-seeking populations.⁹ Further steps to mitigate risk include training interviewers to manage psychological distress, consistently monitoring participants’ emotional reactions, providing frequent breaks, debriefing, and providing information on available psychological or social services.¹⁰

The topics and people excluded from research cannot be counted or represented, and information on their

experiences are not available to inform policy or services. Who is protected when such research is not allowed?

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Coercion as a response to violence in mental health-care settings

Aggressive and violent behaviour are major public health problems. The association of these behaviours with severe mental illness has been controversial and supported by some but not all research.¹ The display of aggressive or violent behaviour can be a final endpoint of the various underpinning causes of mental illness (eg, distress, frustration, cognitive impairment, substance misuse, low self-control, and high trait anger) relating to intrinsic and distal processes, including the person, the environment, and the person’s social networks. The possible association with mental illness might, in part, drive public negative perceptions and stigmatisation of people with these mental disorders, and the mandated imposition of treatment to avert further risk of interpersonal violence might even exacerbate stigma.

Coercion, defined as “compelling a person who is receiving mental health care... through physical force or threat to accept care or treatment against their will”,¹ is often implicit in the management of aggressive behaviour. A 2017 survey of 2809 mental health-care workers across Europe found that the most commonly used interventions in the management of violent patients were physical restraint, seclusion, and administration of medications, all of which are examples of restrictive interventions.²

Specific population groups, such as people with intellectual and developmental disabilities, are more likely to be subject to such restrictions. National UK data indicate that coercion took place in 13% of inpatients (>10 000 incidents) with intellectual disabilities or autism over a period of 3 months in 2019, although the