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Protection or paternalism: risk, responsibility, and choice in research ethics

In healthcare settings, routine enquiry about experiences of trauma is good practice [<https://www.nice.org.uk/guidance/ph50/chapter/4-Considerations>]. Yet in research studies, whether and how to address trauma 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 should decide where that line is drawn? This question matters; it is one reason 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 which could help to improve healthcare [2]. While the ethical review process has since become more efficient, Nicholl's paper highlights a still relevant tension: how to balance maximising research's benefit to society with minimising risk of harm to the individuals taking part?

With the onset of the 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 machine sped up [3]. Being recognised as a COVID priority became a passport to streamlined permissions, including expedited ethical reviews. However, this change in pace also contributed to a fall in lived experience involvement. Pre-pandemic, patients and the public were involved in 80% of the research reviewed by the UK Health Research Agency. In March 2020, this was 22% [<https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/public-involvement-pandemic-lessons-uk-covid-19-public-involvement-matching-service/>]. A related impact was a pause on research on certain topics: both research asking probability samples of the general population about experience of domestic violence or self-harm, and research focused specifically on affected individuals [1].

While university and other ethics committees sat more regularly and processed applications more swiftly than before the pandemic, this came with increased risk aversion. Researchers - ourselves' included - avoided asking for approaches it was anticipated could cause delay. Committee members were understandably concerned about approving research on sensitive topics, given 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 significant consequences for the evidence base in England and elsewhere, serving to hide the scale of harm, and preventing people in need, including victims/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, may 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 deemed too vulnerable - or too difficult - to ask may also be excluded on the basis of what

others consider to be in their best interests. Even where participants can be informed what a study is about, that questions can be skipped, and that they may 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 victimization intersect with inequalities related to ethnicity, gender, sexual identity and age. Women have historically been left out of research [4], as have children [5] and older people. Bayer's study of agism in research found that of '155 studies that were of relevance 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, while surveying all household members about domestic violence could alert a potential offender that a disclosure has occurred, we reduce this risk this 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 may 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].

What and whom we cannot ask, we also cannot count, represent or ultimately serve or support: who are we protecting when such research isn't allowed, and who should get to choose?

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References

- [1] Chandan, J. S., Taylor, J., Bradbury-Jones, C., Nirantharakumar, K., Kane, E., & Bandyopadhyay, S. (2020). COVID-19: a public health approach to manage domestic violence is needed. *The Lancet Public Health*, 5(6), e309.
[https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667\(20\)30112-2/fulltext](https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667(20)30112-2/fulltext)
- [2] Nicholl J. The ethics of research ethics committees. *Bmj*. 2000 Apr 29;320(7243):1217.
<https://pubmed.ncbi.nlm.nih.gov/10784570/>
- [3] Murphy E, Tierney E, Ní Shé É et al. COVID-19: Public and patient involvement, now more than ever. *HRB Open Research* 2020, 3:35 <https://doi.org/10.12688/hrbopenres.13067.1>
- [4] Howard, L. M., Ehrlich, A. M., Gamlen, F., & Oram, S. (2017). Gender-neutral mental health research is sex and gender biased. *The Lancet Psychiatry*, 4(1), 9-11.
[https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366\(16\)30209-7/fulltext](https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(16)30209-7/fulltext)
- [5] Morris, A., Hegarty, K. & Humphreys, C. (2012). Ethical and safe: Research with children about domestic violence. *Research Ethics*. 8(2): 122-139.
<https://doi.org/10.1177/1747016112445420>
- [6] Bayer A, Tadd W. Unjustified exclusion of elderly people from studies submitted to research ethics committee for approval: descriptive study. *BMJ*. 2000 Oct 21;321(7267):992-3.
https://www.researchgate.net/publication/12284425_Unjustified_exclusion_of_elderly_people_from_studies_submitted_to_research_ethics_committee_for_approval_Descriptive_study
- [7] Heggarty, K. (2004). Ethics Creep: Governing Social Science Research in the Name of Ethics. *Quality Sociology*, 27: 391-414. <https://doi.org/10.1023/B:QUAS.0000049239.15922.a3>
- [8] Ellsberg, M., & Heise, L. (2002). Bearing witness: ethics in domestic violence research. *The lancet*, 359(9317), 1599-1604.
<https://www.sciencedirect.com/science/article/abs/pii/S0140673602085215>
- [9] Dazzi, T., Gribble, R., Wessely, S., & Fear, N. T. (2014). Does asking about suicide and related behaviours induce suicidal ideation? What is the evidence?. *Psychological medicine*, 44(16), 3361-3363.
- [10] Draucker, C. B., Martsof, D. S., & Poole, C. (2009). Developing distress protocols for research on sensitive topics. *Archives of psychiatric nursing*, 23(5), 343-350.