

Highlighting the ethics of implementation research



The uptake of many health interventions of proven efficacy and effectiveness remains suboptimal. Implementation research focuses on the systematic approach to understanding and addressing barriers to implementation and scale-up of effective and high-quality health interventions, strategies, and policies. As such, implementation research involves multiple trade-offs and complexities, which raise particular ethical issues requiring specific consideration.¹ Importantly, given the real-world context of implementation research, the boundaries between clinical care, quality improvement, and public health might be blurred, as might be the perceptions of the relevant ethical implications.² Furthermore, researchers and research ethics committees might not fully appreciate that implementation research, by its nature, is different from biomedical and clinical research (eg, randomised controlled trials), which often occurs under tight research conditions; therefore, the application of research ethics principles in implementation research might differ.^{1,2}

A 2018 Health Policy manuscript by Sally Theobald and colleagues³ outlined the defining characteristics of implementation research, which include its context specificity, its relevance and responsiveness to local health priorities, its multidisciplinary and multistakeholder nature, its conduct under real-world conditions with real-time adaptability for optimisation, and its focus on processes and outcomes that should lead to sustainable health gains. The authors highlighted many successful examples in which implementation research has contributed to important advances across multiple health systems.³ Success is not universal, however. Implementation research is highly susceptible to the impact of local contextual factors, which could reduce effectiveness of interventions by up to 50%.^{4,5} Theobald and colleagues³ also highlighted important trade-offs inherent to implementation research: rigour versus pragmatism; fidelity versus adaptation; embeddedness versus objectiveness; generalisability versus context specificity; and misalignment of incentives amongst stakeholders.³ Some of these tensions are further illustrated by Doherty and colleagues,⁶ who suggest that the goals, integrity, and independence of implementation research must be clear to all stakeholders upfront, such that competing priorities can be identified and addressed

early. Alonge and colleagues⁷ reviewed the consistency of the conduct of implementation research with its principles and identified that, overall, implementation research is only done under real-world conditions—as it should be—in a minority of cases. Such circumstances might contribute to the suboptimal translation of implementation research findings into real-world practice and the persistence of evidence-implementation gaps.

To support efforts to address these gaps, the Special Programme for Research and Training in Tropical Diseases (TDR) and other agencies have undertaken a range of activities aiming to strengthen implementation research capacity in low-income and middle-income countries. The training tools (such as the Implementation Research Toolkit and the implementation research Massive Open Online Course developed by TDR) and training activities have helped to galvanise interest in and conduct of implementation research, as evidenced by the rapid rise in publications over the past decade.⁴ In addition, the importance of accurate and thorough reporting of all implementation research methodology and contexts, following published guidelines, has been emphasised to optimise efficient and effective interpretation and utilisation of implementation research results in diverse contexts.^{7,8}

The Global Health Ethics Team at WHO, in collaboration with TDR, have identified an important knowledge gap concerning the ethical implications of implementation research, from both the research design and conduct perspective and that of ethical review. International expert consultations were convened to identify the ethical challenges raised in implementation research and to develop frameworks to assist researchers and members of research ethics committees in designing and reviewing implementation research.^{1,9} Particular ethical considerations in implementation research, which might differ from those in clinical research, include: the need for comprehensive stakeholder engagement throughout the implementation research process; upfront commitment to sustainability if the intervention is successful; careful consideration about from whom and how informed consent can or should be obtained; balancing of risks and benefits that could accrue to different groups; the ethics of randomisation when treatment benefits are known (ie, the principle of equipoise might apply differently in

For the Implementation Research Toolkit see <https://www.who.int/tdr/publications/topics/ir-toolkit/en/>

For the Implementation Research Massive Open Online Course see <https://www.who.int/tdr/capacity/strengthening/ir-training/en/>

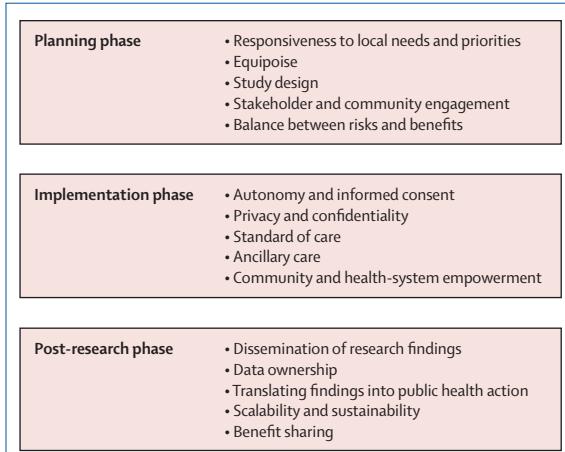


Figure: Ethical considerations throughout the phases of implementation research

Reproduced from Gopichandran and colleagues¹ under the CC BY 4.0 license.

implementation research, in which the question might relate to contextual concerns rather than known efficacy of an intervention); the acceptability of local standards of care; the responsibility of researchers to address ancillary findings, especially where health systems are weak; and appropriate dissemination of results to ensure timely uptake and scale-up of successful interventions (figure).^{1,9–11}

An interactive training tool has been developed highlighting the important ethical considerations in implementation research. The tool comprises six modules, including theory, case examples, tasks, and role plays, which systematically guide the participants through the process of defining, situating, designing, and doing implementation research, through to the post-research phase (figure). Understanding how implementation research differs from basic science, clinical research, epidemiology, and surveillance is key to understanding its ethical implications. The potential overlap of implementation research with quality improvement and public health practice is discussed to identify which activities might require formal research ethics review (ie, an intervention or data-collection activity primarily done for research purposes vs for quality assurance or surveillance), but importantly also to emphasise that many of the ethical concerns raised by implementation research might apply equally to quality improvement and public health interventions. Vigilance and oversight regarding ethical conduct and practice should not be restricted to research.

For the **interactive training tool** see <https://www.who.int/tdr/publications/year/2019/ethics-in-ir-course/en/>

The stakes of implementation research are high given the scale and the importance of the research topics and their notable implications for population health. It is imperative that ethical issues are considered throughout the implementation research process during the design, review, conduct, and post-research phases, such that studies are trusted and valued by communities, risks are minimised, and implementation research outcomes are sustainable and have maximal impact.

Valerie A Luyckx, *Andreas Reis, Dermot Maher, Mahnaz Vahedi

Institute of Biomedical Ethics and the History of Medicine, University of Zurich, Zurich, Switzerland (VAL); Global Health Ethics Team, World Health Organization, 1211 Geneva, Switzerland (AR); and Special Programme for Research and Training in Tropical Diseases, WHO, Geneva, Switzerland (DM, MV) reisa@who.int

We declare no competing interests. We participated in development of the WHO teaching tool. MV, DM, and AR are staff members of WHO. We, alone, are responsible for the views expressed in this Comment, which do not necessarily represent the decisions, policy, or views of WHO. We specifically thank Pascal Launois, Vijayaprasad Gopichandran, and Abha Saxena for seminal contributions. We are grateful to all the collaborators who contributed to the development of the training tool as acknowledged individually in the training tool itself.

© 2019 World Health Organization; licensee Elsevier. This is an Open Access article published under the CC BY 3.0 IGO license which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited. In any use of this article, there should be no suggestion that WHO endorses any specific organisation, products or services. The use of the WHO logo is not permitted. This notice should be preserved along with the article's original URL.

- 1 Gopichandran V, Luyckx VA, Biller-Andorno N, et al. Developing the ethics of implementation research in health. *Implement Sci* 2016; **11**: 161.
- 2 Macklin R. Ethical challenges in implementation research. *Public Health Ethics* 2014; **7**: 86–93.
- 3 Theobald S, Brandes N, Gyapong M, et al. Implementation research: new imperatives and opportunities in global health. *Lancet* 2018; **392**: 2214–28.
- 4 Ridde V. Need for more and better implementation science in global health. *BMJ Glob Health* 2016; **1**: e000115.
- 5 Durlak JA, DuPre EP. Implementation matters: a review of research on the influence of implementation on program outcomes and the factors affecting implementation. *Am J Community Psychol* 2008; **41**: 327–50.
- 6 Doherty T, Lewin S, Kinney M, et al. Addressing the tensions and complexities involved in commissioning and undertaking implementation research in low- and middle-income countries. *BMJ Glob Health* 2018; **3**: e000741.
- 7 Alonge O, Rodriguez DC, Brandes N, Geng E, Reveiz L, Peters DH. How is implementation research applied to advance health in low-income and middle-income countries? *BMJ Glob Health* 2019; **4**: e001257.
- 8 Hales S, Lesher-Trevino A, Ford N, Maher D, Ramsay A, Tran N. Reporting guidelines for implementation and operational research. *Bull World Health Organ* 2016; **94**: 58–64.
- 9 Luyckx VA, Biller-Andorno N, Saxena A, Tran NT. Health policy and systems research: towards a better understanding and review of ethical issues. *BMJ Glob Health* 2017; **2**: e000314.
- 10 Alba S, Mergenthaler C. Lies, damned lies and epidemiology: why global health needs good epidemiological practice guidelines. *BMJ Glob Health* 2018; **3**: e001019.
- 11 Mzombwe M, Desderius B, Kapiga S, Smart L, Peck R. The ethical imperative to treat NCDs during research in Africa. *Lancet Glob Health* 2019; **7**: e406–07.