

What does 'following the guidance' mean in an era of increasingly pluralistic guidance for the development, evaluation and implementation of interventions?

Graham Moore, Rhiannon Evans, Jemma Hawkins, Yulia Shenderovich, Honor Young.

DECIPHer, School of Social Sciences, Cardiff University

Guidance for intervention research in public health, health services and beyond, has evolved rapidly since the turn of the century. To take UK Medical Research Council (MRC) guidance for developing and evaluating complex interventions as an example, this began in 2000 (1) with guidance for randomised controlled trials (RCTs) of complex interventions. This guidance followed a linear sequence from intervention theory toward a goal of demonstrating whether an intervention 'worked', and then, whether and how to implement more widely. An updated version, published in 2008 (2) reflected a number of shifts in thinking. The RCT was still considered the most robust evaluation design in many cases, but the new guidance recognised that for many important interventions, RCTs are infeasible. It introduced a focus on process evaluation, recognising that while estimating effects is important, it is of limited value if we do not also know what was implemented (i.e. what the intervention actually was, not just what it was 'supposed' to be according to the manual), or what contextual issues need to be considered where using an intervention elsewhere. The following years saw emergence of a diverse range of guidance, including MRC guidance for natural experiments (3) and process evaluations (4), and researcher-led guidance on intervention development (5-7) and adaptation of interventions to new contexts (8). In 2018, the MRC-NIHR commissioned a further update to overarching guidance for the development and evaluation of complex interventions, published in 2021 (9). This moved toward further pluralism in method, emphasising a role for studies focused on efficacy, effectiveness, theories of change, complex systems, or in many cases, combinations of these. It identified six issues for teams to consider throughout the development-evaluation-implementation process. These were i) consider context, ii) develop, refine and test programme theories, iii) engage stakeholders, iv) identify and focus on key uncertainties, v) refine the intervention and vi) consider economic issues. The guidance reflected more comprehensively the growing influence of traditions such as realist(ic) evaluation (10) and complex systems perspectives (11), which were advocated by some prior to the 2008 MRC guidance, but had yet to be well integrated into mainstream ways of doing intervention science.

Increasingly, as this family of guidance evolves, we have noticed through roles as peer reviewers or on funding committees that guidance is commonly cited within journal articles, and by applicants for research funding, who simply state that their study 'followed the guidance/framework'. In some cases, authors cite a number of different guidance documents, without articulating how these have been synthesised, and tensions between them reconciled. Like clinical guidelines, applying several of these uncritically is likely to lead to contradictions, gaps and redundancies (12). Using guidance is not a passive process, but involves active interpretation and application to a specific problem in a specific context. Guidance cannot, and should not, automate the process of developing and evaluating interventions, and is not a substitute for skill, experience and judgment (13). Differences in perspectives, and human judgement, will mean that two teams could legitimately claim to have used the same guidance, while ending up having designed and undertaken very different studies. Rather than an end to the conversation on how to do intervention science, new guidance is often a starting point to help those involved in the development, evaluation and implementation of interventions to frame their thinking and innovate. It can however also have unintended consequences. It can simply become a heuristic tool which anchors practice in thinking about the right way of doing research at a particular point in time, and hence limits movement from that point. Arguably, one of the most influential features of earlier MRC guidance for example was a strong

emphasis on rigorous feasibility testing prior to a full-scale evaluation. The key point that we should not rush into large scale evaluations without having first considered whether they are feasible is important. However, interpretation of this recommendation by researchers and funders has arguably given rise to an industry in highly expensive feasibility studies which test and test again things that the literature already shows to be feasible (14). While the increased pluralism in recent guidance is welcome, one risk of this pluralism is that almost any study could now make a legitimate claim to consistency with some aspect of one or more of the guidance documents described above. Hence, there is a risk of guidance being applied selectively as a justification for what researchers were planning to do anyway, rather than acting as a starting point for innovation to move the field forward.

Understanding the consequences and impacts of guidance for the practices of those using it – good and bad, intended and unintended – is necessary for guidance to be revised and updated by others in the future. This will always remain challenging if journal articles, reports and research funding applications simply state that authors ‘followed the guidance’ without clear articulation of the human decision making processes involved. How did the team select which guidance to use, interpret that guidance, and apply it to their situation? How did they select which aspects are (or are not) relevant for a given intervention in a given context? Were deliberate decisions made to thoughtfully ignore aspects of the guidance or to augment, with other guidance and local knowledge, to build upon its recommendations? We have written previously about the tendency for behavioural theories to be picked off the shelf and applied without consideration of whether they are appropriate to the context (15). Many of the same risks also apply to uncritical use of ‘off the shelf’ guidance. That two teams may use the same guidance yet develop a different evaluation isn’t necessarily a problem. There is much to be learned from understanding how different groups interpret and use the same guidance. However, understanding how and why divergence occurs, and what may be learned from it, requires greater transparency over the *process* of using guidance to shape intervention science.

In summary, we have argued that more critical consideration of how and why particular guidance documents are used for a given research study, is important in designing and reporting intervention research studies. Where research decisions align with guidance, for example, due to the fact that guidance reflects recognised ‘good practices’ which experienced teams were doing anyway, it may be useful to highlight this consistency. However, where a team's decision-making was not actually influenced by guidance, we would argue that it is not good practice to attribute decisions to it. Claims to have ‘followed the guidance’ because of a perception that a funder or journal expects it are problematic. Greater detail on how guidance has been interpreted and applied within journal articles and funding bids is not always possible within given word limits, just as it is not always possible to document every micro-level decision made within a statistical or qualitative analysis. However, questions of ‘Why did you choose this guidance? How did you follow this guidance? In what specific ways is this study different to what you’d have done had you never read this guidance?’ should be asked by critical journal editors, reviewers and research funding committees. Just as research teams would be expected to transparently answer questions on exactly how they undertook their analysis beyond the details provided in a published article, they should also have coherent responses to questions on how guidance documents cited were selected, interpreted and applied to their research.

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