

EDITORIAL

Diverse research designs are needed for population health: Lessons from Maslow

1 | THE CHALLENGE

It has been repeatedly shown that randomized controlled trials (RCTs) do not represent real-world patient populations; a recent systematic review showed that more than 70% of trials are not broadly representative, limiting external validity.¹ Consequently, RCT-based conclusions can be true (high internal validity) but many are irrelevant for the real-world setting due to low external validity and generalizability. Evidence-based medicine has given pre-eminence to RCTs, and meta-analyses of RCTs graded as the highest evidence in medicine. Although RCTs are superior in certain situations, mainly for pharmacological intervention aiming to treat a single disease in an otherwise healthy patient population, their inherent reductionist setting can miss much of what is valuable in health—things that can only be captured in a more patient-centred approach.² This over-reliance on a familiar tool, known as the law of the instrument or ‘Maslow’s hammer’, has already been described in 1966: ‘I suppose it is tempting, if the only tool you have is a hammer, to treat everything as if it were a nail.’³ RCTs should consequently be used appropriately, as necessary evidence before acquiring real-world evidence in pharmacological interventions.⁴

2 | A WAY FORWARD

As we realize that societal determinants and individual lifestyle choices—which are not easily evaluated in RCTs—will be the major determinants of health and well-being in the future, over-reliance on the RCT instrument holds the danger of limiting medical progress through ‘by design’ prioritization of pharmacological interventions. Virtual group consultations, able to utilise limited resources (health professionals) maximally and deliver efficient care⁵, are an example of an innovative intervention that cannot be evaluated in a classic RCT. But observational designs have well-recognised limitations, so modern intervention and trial types now available to us should be more widely used and further developed. These include stepped wedge designs, just-in-time adaptive interventions (JITAs, sometimes referred to as ‘jedis’), (sequential) multi-randomisation trials, and ‘small data’ approaches.^{5–7} As innovative interventions spread at scale, we believe

embedded evaluation should be prioritized through novel health technology assessment (HTA) or health service funding schemes, as they and other complex interventions are best studied in real-world conditions, despite a paucity of RCT data.⁹ New—and preferably collaborative to address global inequality—funding streams are needed like the recent initiative from the United Kingdom’s National Institute for Health Research (NIHR) for varied research approaches in diverse populations.¹⁰ Only then can true variety be delivered to facilitate the robust healthcare system changes the syndemic has demonstrated we need.

We suggest therefore that HTA bodies and other stakeholders work actively towards an expansion of their instruments and funding pathways. In this discussion, a ‘value-flower with 12 petals’ to broaden the view of what constitutes value in healthcare has been suggested¹¹ adding to the well-established factors of quality-adjusted life-years, net costs, productivity, and adherence-improving factors, eight new assessments: reduction in uncertainty, fear of contagion, insurance value, severity of disease, value of hope, real option value, equity, and scientific spillovers. Above and beyond these suggestions, we believe that we should aim towards a holistic model, drawing from both the hierarchy of needs by Maslow¹² and the biopsychosocial model by Engel.¹³ Clearly, patient involvement, as we elaborated in an editorial on education in the previous issue,⁹ is critical here too and the quintuple aim of healthcare: good outcomes, patient and clinician satisfaction, cost-effectiveness, and educational value are also criteria through which to judge research. Taken together, these models remind us that we have a long road ahead of us, but there is strength and resilience in diversity and inclusivity, which is probably why NIHR is recommending the same approach for their own reasons.¹⁰

3 | CONCLUSION

Maslow has been an influential thinker in psychology. In 1943, he described the Hierarchy of Needs¹² and in 1966, ‘Maslow’s hammer’³. We should explicitly take inspiration from Maslow and learn from the past to prepare for the future by using more diverse research designs and making them holistic.

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