Bridging the gap between science-led research and evaluation of clinical practice: the role of service innovation audits and case studies

Dear Editors,

Two recent publications in *BMJ Nutrition, Prevention and Health*[1 2] have been subject to mixed reactions from members of both nutrition science and clinical practice communities. As a centre bridging both scientific research and clinical practice, we have heard and considered valid arguments from both schools of thinking.[3]

Nutrition science argues that the publication of research based on clinical audits and in particular, n=1 case studies, lack the scientific rigour to justify any implementation in the clinical setting, partly because of a lack of control over variables including unknown confounders and the presence of bias. Proponents of the latter may argue that clinical audits and novel case studies are crucial in supporting implementation of science into practice via recognition of new trends or outliers in clinical findings and practice patterns. Showcasing n=1 cases may also provide motivation to colleagues, helping them to challenge preconceived ideas and consider the difference between research and clinical practice, then to think through and apply similar approaches to help their own patients—ultimately leading to better practice.[4] However, these views are not dichotomous, but complementary, whereby practice should inform science and science should inform practice.

It can be summarised from the work of Sackett *et al*[5] that without clinical expertise, practice risks becoming tyrannised by evidence, for even excellent research evidence may be inapplicable to or inappropriate for an individual patient. Equally, without current best evidence, practice risks becoming rapidly out of date, to the potential detriment of patients. Evidence-informed medicine therefore requires a bottom-up approach that integrates clinical experience and patient choice with robust research evidence.

This discourse has led us to consider the wider differences between clinical and research ethics.[6] The primary aim of research is to generate generalisable knowledge, and while strict ethical guidance protects participants, researchers may not have the same obligations in terms of 'duty of care' towards the individual patient as a clinician. Researchers must ensure participant safety, but the focus is often on generating knowledge to prove or disprove a hypothesis. Quantitative clinical research, which forms the mainstay of evidence generation, is bound to rigid treatment protocols in order to measure the impact of an intervention in a controlled context. However, despite the reductionist quantitative paradigms often defining the source of clinical evidence, the application of knowledge into practice mostly follows a qualitative process. Clinicians, therefore, aim to enhance patient health and well-being, using evidence-informed practice while tailoring treatment pathways to meet interindividual variability in patient needs. This highlights subtle differences in the application of clinical versus research ethics, despite the common stem of underpinning principles.[6 7]

Of course, it is also worth noting the inherent flaws in trying to fit a square peg in a round hole in the context of nutrition research, in this case, a reliance on randomised control trials (RCTs). Though considered the gold standard in biomedical research, RCTs were not designed for nutrition research, yet the prevailing narrative is that changes to practice require 'absolute' findings from RCTs. The truth is that there are multiple reasons why they are either impractical or inaccurate tests of nutrition hypotheses, as described elsewhere.[8] Additionally, the immeasurable number of variables associated with food choice, dietary patterns and eating behaviour, makes it likely that even the most well-controlled nutrition research may struggle to achieve a high external validity, despite maintaining high internal validity. Clinicians therefore are required to apply these findings in an evidence-informed yet practical way for patients.

Therefore, while there is clear distinction between clinical evidence and scientific proof, both clinicians and researchers must be held to rigorous standards when reporting and therefore interpreting their results. Clinicians cannot present their work with the same certainty as rigorous science designed to be generalisable in its findings, and wider applicability of results from clinical service data should not be assumed. Equally, researchers must appreciate that even the most robust evidence must be applied in a patient-centred fashion with appropriate adjustments for individual patient characteristics, balancing the benefits versus risks of the many preventative and therapeutic interventions available, some with a greater body of evidence than others. In drawing research and clinical practice together, we can consider the concept of 'learning healthcare systems', where knowledge generation processes are embedded in daily practice to produce continuous improvement in care.[9 10]

The Learning Healthcare System model[9 10] can balance the tensions between perceived opposing parties by recognising their synergistic relationship. Even though we cannot directly extrapolate from case studies, this should not mean that they do not hold merit. In fact, these observations could be useful in forming scientific hypotheses, which are then tested to these high standards, in order to prove definitive links and allow for sufficiently evidence-informed practice. Evidence-informed practice is a particularly important and distinct concept from evidence-based practice due to the flexibility that it provides. That said, the strength of n=1 studies can be leveraged through investigation of multiple aspects of a particular individual, while case studies which can be temporally replicated are important for pattern recognition.

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Case studies can be useful where an RCT is not realistic or possible (such as in cases of rare genetic configurations) or perhaps where observations would not yet have been established as important enough to warrant an RCT (in the case of novel service innovation). Case studies can also serve as cautionary clinical tales where erroneous departures from ideal clinical practice are highlighted for training as well as to prevent future clinical errors. We suggest there is a need to consider these multiple aspects together when extrapolating reasonably, as well as designing further primary research studies to fill gaps. Accordingly, the importance of balance between practice informing science and science informing practice becomes clear.

These opposing views might be looked at through the lens of practicality versus perfection, either of which might be considered unacceptable or unattainable from the other viewpoint. It is important to remember our primary goal, which is the common good. This is true in both scientific research or improving efficacy of the healthcare system. Our aim must be to balance this primary goal between the approaches of both sides. In order to achieve this, we suggest that bringing these views together will provide a basis to learn from one and other, which will ultimately improve the quality and relevance of both science and practice.

Shane McAuliffe [1,2] **David Unwin,** [1,3] **James Bradfield** [1,4] **Sumantra Ray** [1,5,6] **Kathy Martyn**[1,7]

[1]NNEdPro Global Centre for Nutrition and Health, St John's Innovation Centre, Cambridge, UK
[2]Liverpool University Hospitals NHS Foundation Trust, Liverpool, UK
[3]Norwood Surgery, Southport, Merseyside, UK
[4]Mid and South Essex NHS Foundation Trust, Essex, UK
[5]School of Biomedical Sciences, Ulster University at Coleraine, Coleraine, Northern Ireland
[6]School of Humanities and Social Sciences, University of Cambridge, Cambridge, UK
[7]School of Health Sciences, University of Brighton, Brighton, UK

Correspondence to Shane McAuliffe, Science Communications, NNEdPro Global Centre for Nutrition and Health, St John's Innovation Centre, Cambridge CB4 0WS, UK; s.mcauliffe@nnedpro.org.uk and Dr Kathy Martyn, School of Health Sciences, University of Brighton, Brighton BN1 9PH, UK; k.j.martyn@brighton.ac.uk

Twitter Shane McAuliffe @ShaneMacZ, David Unwin @lowcarbGP, James Bradfield @braddybradfield and NNEdPro @nnedpro

Contributors SM: conceptualisation of letter and writing of initial draft. DU: conceptualisation, reviewed and commented substantively. JB: reviewed and commented substantively. SR/KM: conceptualisation, overall responsibility for supervision of content, review and input.

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ORCID iDs
Shane McAuliffe http://orcid.org/0000-0002-7166-4299
James Bradfield http://orcid.org/0000-0002-1010-2372
Sumantra Ray http://orcid.org/0000-0003-3295-168X

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