

CORRESPONDENCE

Rethinking Evidence-Based Medicine in the perioperative safety scenario

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Editor—We read with great interest the recent Editorial by Webster¹ in which he invites one to think beyond the traditional randomised controlled trial (RCT) in patient safety studies. We work on patient safety in the perioperative setting and have some additional comments regarding Evidence-Based Medicine (EBM). Scientific output and evidence in the field of patient safety has increased dramatically in recent years. Research on the efficacy of the interventions to decrease unnecessary risks related with patient safety has some particularities, clarified by Brown and colleagues²: First, patient safety interventions are often complex interventions that require carefully planned evaluation and development. Sometimes interventions and outcome evaluations are difficult to blind. Second, patient safety interventions are often delivered to and implemented with groups of subjects (or clusters i.e. surgical patients, hospitals, certain populations) rather than at an individual level, in an equally complex environment, such as health organisations. Third, patient safety interventions are often expected to do more good than harm, implying that professional equipoise may be absent. Therefore, traditional study designs such as a parallel RCT may not be ethically acceptable.³ Finally, if patient safety research refers to interventions to prevent harm, countable outcomes are rare events and in many times difficult to assess. They require large multicentre studies and collaboration with increased cost and logistics.

Prospective RCTs are considered the research design of choice to evaluate the efficacy of health interventions providing the most robust evidence.⁴ Nevertheless, interventions in patient safety are not suitable to be studied using only this approach. In patient safety, studies on interventions (using randomisation) are less common than large observational population studies of the incidence and causes of medical errors, and the number of RCTs and systematic reviews of randomised trials published in specialised journals are scarce.⁵ At a first glance, this could be interpreted as a lack of strong evidence, but as Leape and colleagues⁶ suggest in

agreement with the editorial by Webster,¹ this lack of evidence means that 'the traditional evidence-based approach cannot be the sole source of information for advancing patient safety'.

From its origins in the 1990s, EBM was a movement supporting the use of evidence from high-quality RCTs and observational studies, in combination with clinical expertise and the needs and wishes of patients.⁷ EBM quickly became a core topic in an intellectual community committed to making clinical practice more scientifically and empirically grounded and thereby achieving safer, more consistent, and more cost-effective healthcare. Taking into account that not all situations in healthcare require nor enable an RCT, nobody denies the advantages of this movement and its successes.⁸ Finally, EBM must be understood as a combination of scientific tools developed to improve patient care, and therefore it should not be about 'evidence', but about responding to patient problems, as much as possible, with evidence. In that sense, EBM principles must be integrated with and adapted to the patient safety scenario. As in other areas, patient safety can be refined by using high-quality evidence, but considering its particularities and differences.

Observational data are highly relevant in patient safety research and sometimes considered enough to implement policies, and common sense interventions. It is unrealistic to wait for randomised controlled studies for all interventions in patient safety.

A great approach to integrate EBM principles in patient safety was clearly described by Shojania and colleagues⁹ and Leape and colleagues⁶: 'the best approach for ensuring patient safety will be one in which the general insistence on evidence does not prevent implementation of practical, low-risk, but understudied, interventions that rationally seem likely to work'. EBM thinking should always include critical thinking.

In quality and patient safety, improvement initiatives could be practical (aimed at producing change) and scientific (aimed at producing new knowledge). These initiatives include: more methodological and study designs and approaches such as

variants of trial designs; stepped wedge trial designs; quasi-experimental designs; before-after studies; program, process, or both evaluations; qualitative studies; and economic analysis.¹⁰

Declaration of interest

The authors declare that they have no conflicts of interest.

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doi: [10.1016/j.bja.2019.04.050](https://doi.org/10.1016/j.bja.2019.04.050)