Campaigning for Safety

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Presented at the Perfusion Downunder Winter Meeting 2011, Hayman Island, Australia, August 4–6, 2011.

Abstract: There are four challenges to practicing evidence-based medicine: obtaining the evidence; evaluating the evidence; promulgating the evidence; and persuading practitioners to adopt the evidence and practice according to the evidence. The Perfusion Down Under (PDU) Collaboration addresses the first three. The fourth is more difficult, and it typically takes many years for new evidence to be adopted into widespread practice. In the case of innovations related to patient safety, evidence from randomized controlled trials is often very expensive to obtain. Other methods of evaluation may be more appropriate, but these do need to be robust and to take account of the constructs underlying the innovations and the context in which they are to be implemented. In the United States, The Institute for Healthcare Improvement (IHI) aims (among other things) to promote the adoption of best practices and effective innovations. The IHI has articulated a useful framework for doing this. Measurement is fundamental to quality improvement, and sustainable change is likely to be more readily achieved if claims are supported by credible, measurable, and clinically relevant outcome data. The PDU is well placed to support quality improvement in perfusion by providing such data. Keywords: evidence-based medicine, patient safety, perfusion, quality improvement.

THE CHALLENGES OF IMPROVING PATIENT SAFETY

The Perfusion Down Under Collaboration (PDU) “provides research infrastructure and support to the Australian and New Zealand perfusion community, with the objective of determining best practices and producing relevant research publications” (1). In effect, PDU aims to provide the evidence for evidence-based cardiac surgical practice. Evidence-based medicine does not mean that every practice needs to be supported by a randomized clinical trial (RCT) (2), and criticisms on that basis may at times be a little disingenuous, albeit that the point is worthy of emphasis (3); in fact, it is more than 15 years since Sackett provided the following clear and practical definition of evidence-based medicine: “Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research” (4).

The challenges of evidence-based medicine seem to be four: 1) obtaining the evidence; 2) evaluating the evidence; 3) promulgating the evidence; and 4) persuading practitioners to adopt the evidence and practice according to the evidence.

The PDU stated aims address the first two, and through its meetings (and the proceedings thereof), it addresses the third. In this way, the PDU has made, and will continue to make, a valuable contribution to the science and practice of perfusion medicine. However, frustratingly, there is already much evidence that has been collected, promulgated, and evaluated as sound and important but which is not implemented. It typically takes many years for new evidence to be adopted into widespread practice. In a general sense, this problem is well known and has been reviewed elsewhere (5,6). In relation to patient safety, specifically, however, there are some intriguing nuances, and it is these that are addressed in the present article.

The Institute of Medicine brought the problem of iatrogenic harm in health care into sharp public focus a decade ago (7,8) and called for national efforts in the United States to make health care safe. Five years later, little demonstrable improvement in patient safety could be discerned (9). Today, it still seems that improvement has been slow (10); part of the problem, however, is that it is
difficult to measure changes in patient safety, even within specific areas of health care (11); it is difficult enough to show reductions in rates of error and provide convincing evidence that these can be attributed to any particular initiative. Demonstrating that lives have been saved thereby is even harder (12).

It is therefore understandable and appropriate that various practices have been adopted in the name of patient safety for which evidence is in fact indirect or scant. Pulse oximetry is a good example. According to a Cochrane review conducted in 2002, there is inadequate evidence to support its use (13). To me (and I believe to many practitioners) this conclusion seems to fly in the face of common sense. Furthermore, it has been argued that it is based on an inadequate consideration of the available evidence (14). For example, all of over 50 national societies of anesthesia surveyed that actually have guidelines mandate the use of pulse oximetry during anesthesia within those guidelines (15), and pulse oximetry is mandated in the recently published “International Standards for a Safe Practice of Anaesthesia” (16) endorsed by the World Federation of Societies of Anaesthesiologists (17). There does not seem to be serious dispute that any attempt to remove pulse oximetry from health care (to save money, perhaps) would be dangerous and counterproductive. Although the evidence to support pulse oximetry is indirect (14), any reasonable evaluation of the risk-to-benefit ratio of this technology is sufficiently convincing that an attempt to demonstrate its value through more definitive research today (e.g., through a RCT) would be a poor use of resources.

At the heart of the debate lies the reality that much of what we do in health care is, today, relatively safe, and it is not easy to improve patient outcomes substantially enough for an affordable RCT or even a credible longitudinal study to demonstrate improvement. At the same time, the pressure to reduce escalating costs in health care is increasing in many countries. Common sense is needed, and initiatives to improve patient safety should not be held up by unreasonable demands for evidence (3,18). The nuance here is that there are risks in innovation, including the possibility of unintended consequences (19) and the potential for opportunity costs in constrained healthcare environments (6).

**MOTIVATING AND BUILDING THE WILL FOR CHANGE**

Information on its own does not seem, typically, to lead to widespread changes in practice. The Institute for Healthcare Improvement (IHI) is now established as a world leader in effectively promoting change and advancing the cause of patient safety in health care. On its web site, it provides the following explanation of who it is and what it does: “An independent not-for-profit-organization based in Cambridge, Massachusetts, IHI focuses on motivating and building the will for change; identifying and testing new models of care in partnership with both patients and health care professionals; and ensuring the broadest possible adoption of best practices and effective innovations” (http://www.ihi.org/about/pages/default.aspx).

In New Zealand and Australia, governments have recently invested in commissions (http://www.safetyandquality.gov.au/ and http://www.hqsc.govt.nz/) to promote the quality and safety of health care (safety being one of the elements of quality) (6). Many of the tools and concepts promoted by the IHI are widely used. For example, the Health Quality and Safety Commission in New Zealand has recently adopted a modification of the Triple Aim developed by the IHI (20).

The IHI has run two major campaigns to motivate best practice in a number of defined, evidence-based initiatives. The first of these was the “100,000 Lives Campaign” (21). This has been followed by the “5 Million Lives Campaign.”

The practices promoted by these campaigns (Table 1) are sound, important, and worthy of promotion. Indeed, their promotion should be a priority for every institution involved with health care.

Similarly, the framework for the campaigns (Table 2) is sensible, well-construed, and likely to be effective. However, the third element, the concept of lives saved, is perhaps more open to debate. McCannon provides the following explanation of this important primary outcome for the campaign: “The campaign defines a life saved as a patient who survived a hospital stay who would have died

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**Table 1.** The interventions promoted in the 100,000 Lives Campaign (21).

- Deploy rapid response teams to patients at risk of cardiac or respiratory arrest
- Deliver reliable, evidence-based care for acute myocardial infarction
- Prevent adverse drug events through drug reconciliation (reliable documentation of changes in drug orders)
- Prevent central line infections
- Prevent surgical site infections
- Prevent ventilator-associated pneumonia

**Table 2.** Essential components identified by the Institute for Healthcare Improvement for spreading a healthcare initiative (21).

- Ensuring leadership commitment
- Setting clear aims (including changes to be spread, target level of performance, target population, and timeframe)
- Identifying and packaging proved ideas and practices
- Developing and executing a plan to communicate and implement the ideas
- Creating a system for measuring progress
- Establishing a process for refining the plan in response to learning during implementation

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had he or she received that hospital’s pre-campaign (2004) level of care. It calculates lives saved by comparing a hospital’s mortality data for each month during the campaign with mortality data for the corresponding month in 2004. The monthly lives saved are aggregated across all months and all participating hospitals with an adjustment to account for changes in national risk of patient mortality between 2004 and the campaign period” (21).

The Institute of Medicine also used the concept of lives lost through preventable harm to galvanize the healthcare community into action, claiming, on the basis of the Harvard Medical Practice Study, that up 98,000 people died every year in the United States from this cause and arguing that this makes it one of the more important public health problems faced by most developed nations (7). This view may be overstated. Hayward et al. (22) repeated the methodology of the Harvard Medical Practice Study and found similarly high levels of preventable acute-care patient deaths but also showed that “after considering 3-month prognosis and adjusting for the variability and skewness of reviewers’ ratings, clinicians estimated that only 0.5% (95% CI = 0.3–0.7%) of patients who died would have lived 3 months or more in good cognitive health if care had been optimal, representing roughly 1 patient per 10,000 admissions to the study hospitals.” This message aligns with those who advocate the use of measures such as quality-adjusted life-years to evaluate the impact of interventions on the health of populations (6), albeit that there is some controversy over this approach as well. Hayward et al. conclude by restating the central message that medical errors are a major concern but argue that overstating the problem may be unhelpful to the credibility of efforts to address them over a sustained period of time.

McCannon and others acknowledged in 2007 that “a summative study providing a comprehensive, definitive understanding of the campaign’s impact” has not yet been produced. The IHI claim in relation to 100,000 lives has been evaluated by Wachter and Pronovost, who concluded: “Although the 100,000 Lives Campaign succeeded in catalyzing efforts to improve safety and quality in American hospitals, the promotion of rapid response teams as a national standard is problematic, and methodologic concerns regarding the “lives saved” calculations make it difficult to interpret the campaign’s true accomplishments” (23). Berwick and Hackbarth have responded (24); one important element of their response is that they have always acknowledged the limitations of their approach, and Berwick’s point (made previously) that the campaign would be a success even if the number of lives saved was substantially smaller than 100,000 is obviously true (25). Indeed, Wachter and Pronovost make it clear that they believe the campaign achieved much of value.

Sound methodology in measuring the impact of interventions to improve patient safety does seem warranted (26–28); after all, that is what evidence-based medicine demands. Even from the perspective of those who believe the end justifies the means, context is important. The campaign framework outlined in Table 2 is applicable without the need for implausible targets.

The PDU should perhaps consider adopting the central learnings of the IHI campaigns to promote key opportunities for improvement in perfusion practice identified from their database. In doing so, however, it may be judicious to set targets based on end points that are more readily measurable and defensible than national estimates of “lives saved.” The PDU is well placed to support quality improvement in perfusion by providing data on end points that are credible, measurable, and clinically relevant.

REFERENCES


