Editorial

Extending the WHO ‘Safe Surgery Saves Lives’ project through Global Oximetry

Pulse oximetry is widely accepted as essential during anaesthesia and its use is considered mandatory in the UK, Canada and the USA, Australia and New Zealand, much of Europe and South America, and many other countries around the world. At present, however, there are still places where oximeters are simply not available [1, 2].

At the World Congress of Anaesthesiologists in Paris in 2004, the Quality and Safety of Practice Committee of the World Federation of Societies of Anaesthesiologists (WFSA) identified the provision of pulse oximeters for use on every patient undergoing anaesthesia in the world as a priority for patient safety. From this grew the Global Oximetry (GO) initiative [3, 4]. Pilot projects have been underway in regions of Uganda, Vietnam, the Philippines and India. The World Health Organization (WHO) has now adopted this mission as a significant component of its Second Global Patient Safety Challenge.

This challenge, Safe Surgery Saves Lives (SSSL) [5], launched in 2007, recognised the rising importance of surgery to public health. With increasing urbanisation and longevity, diseases characteristic of industrialised nations are becoming more prevalent even in resource-challenged low income nations and access to safe and effective surgery is increasingly essential for the health of populations worldwide.

In 2008, Weiser et al. estimated the number of operations performed annually around the world as in the order of 230 million – double the number of births [6]. Global distribution is uneven: only 3.5% of surgery is undertaken in the poorest third of the world’s population, and this inadequacy of surgical services in many countries leads to the loss of 164 million disability-adjusted life years annually [7]. Even in industrialised countries, where there is generally good access to surgical services, major complication rates (estimated between 3% and 17%) are unacceptably high. Some of these complications are attributable to anaesthesia; many of them are avoidable. Safe surgery depends on (amongst other things) safe anaesthesia. The WHO SSSL initiative intends to improve safety in surgery and anaesthesia on a global scale.

Anaesthesia today is typically very safe in high-income countries, where mortality solely attributable to anaesthetic complications has fallen to rates between 1 in 50 000 and 1 in 200 000 [8]. Unfortunately, there are still places where the anaesthesia mortality rate is probably 1000 times higher than this [9]; in such areas most anaesthesia providers tend to have little training and appallingly inadequate resources [10]. Furthermore, these colleagues are often very disempowered, and poorly placed to address the serious deficiencies in the services they are asked to provide for the large numbers of patients in need of surgery. If adequate access to surgery is important for a nation’s health, then so is adequate access to anaesthesia. However, surgery (and particularly elective surgery) is only worthwhile at acceptable limits of safety. No surgeon would attempt to provide an elective surgical service without a basic set of sterile instruments and sutures; safe anaesthesia is just as important and, in the same way, safety requires trained anaesthesia providers in adequate numbers with access to essential equipment and drugs.

In the Safe Surgery Saves Lives project [5], the WHO brought together experts in surgery, anaesthesia, perioperative nursing and related disciplines. The task was to develop a strategy for safer surgery globally. The participants met face to face on several occasions during 2007 and 2008, corresponded between meetings, reviewed the relevant evidence, and iteratively developed consensus guidelines, captured in a substantial technical document. A key output was the WHO Surgical Safety Checklist [11]. As part of the development of this work, the International Standards for a Safe Practice of Anaesthesia, developed in the early 1990s, were revised to reflect advances in anaesthesia over the intervening years [12]. A key revision was the recommendation that pulse oximetry should be used in all anaesthesias worldwide.

On the basis of this recommendation, oximetry was included as an essential item on the ‘Sign-In’ of the WHO surgical safety checklist. For some, this endorsement of oximetry by the WHO may seem controversial.

In this era of evidence-based medicine (EBM), the fact is that hard evidence to support the routine use of pulse oximetry is limited. In fact, a 2002 Cochrane review concluded: ‘... we have found no evidence that pulse oximetry affects the outcome of anaesthesia. The conflicting subjective and objective results of the studies, despite an intense, methodical collection of data from a relatively large population, indicate that the value of peri-operative monitoring with pulse oximetry is questionable in relation to improved reliable outcomes, effectiveness and efficiency.’ [13]

It is tempting to ignore this review or, as with the value of parachute use [14], simply to discount it as flying in the face of the obvious. However, a close analysis of this Cochrane review is quite illuminating.

The starting point of such an analysis must be an appreciation that ‘evidence’ does not only come from randomised controlled trials. Sackett has defined EBM as ‘the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of EBM means integrating individual clinical expertise with the best available external clinical evidence from systematic research’ [15]. We think the 2002 Cochrane review of Pedersen et al. fails...
to use all available evidence, and, in particular, totally discounts the overwhelming weight of expert opinion as well as the fact that USA medical liability anaesthesia claims showed a dramatic decrease in number and severity following adoption of routine pulse oximetry.

In this review, the systematic search of the literature identified only six studies of oximetry, two of which were deemed ineligible for inclusion because they lacked a control group, or lacked information on relevant postoperative outcomes. In relation to the remaining four, the authors explain: 'Due to the variety of outcome variables used in the four studies, there are no two groups which could be compared directly by formal meta-analysis.' [13]

Thus, their negative conclusions were not based on the synthesis of a substantial body of comparable data from a number of different studies (which is the fundamental construct on which the Cochrane approach to EBM should surely be based). Instead they are almost entirely based on a single study – the only large RCT in which pulse oximetry has been evaluated, which, incidentally, was conducted by the main authors of the Cochrane review.

This trial of pulse oximetry, published in 1993, involved 20,802 patients [16, 17], and is impressive in size, concept, the detail of the data collected, and the care with which the findings were presented. The study was powered to show a difference in cumulative cardiovascular complications, but the expectation that the occurrence of many of the cardiovascular complications included in this analysis (notably hypertension, hypotension, and hypovolaemia) would be reduced by oximetry would not seem reasonable today. Similar comment could be made about a number of other negative findings, involving various respiratory (atelectasis, infection, postoperative respiratory insufficiency requiring ventilation), neurological and infectious complications, which no-one today would expect to be substantially reduced by oximetry. It is unlikely that these endpoints would be included in a similar study now, because it is not good science to test a hypothesis that has no plausible foundation in physiology – but the benefits of oximetry are clearer now than then. These benefits lie in the early detection of hypoxia, which allows diagnosis and intervention early enough to avert disaster, and thereby reduce the incidence of cardiac arrest, ischaemic injury, and mortality.

Unsurprisingly, mortality was not different between the two groups in the RTC. The authors acknowledged that the trial, large as it was, was substantially underpowered to demonstrate a reduction in mortality (almost 2 million patients would have been needed, given their observed rate of one death partially associated with anaesthesia per 335 patients), or indeed a reduction in myocardial infarction (500,000 patients would have been needed). However the study clearly does confirm the value of oximetry in detecting hypoxaemia – this was increased 19-fold (p < 0.0001). We know that hypoxemia was the most common cause of death in the time before the routine use of oximetry [18, 19], so this is a profound finding. Furthermore, the detection of endobronchial intubation and hypoventilation were also substantially and highly significantly increased. Although the difference in the rate of myocardial infarction was not significant, oximetry did decrease the frequency of myocardial ischaemia (from 0.2 to 0.1%, p = 0.03), and perhaps of cardiac arrest (from 0.1% to 0.04%, p = 0.06, one-tailed, calculated with Fisher’s exact test by us rather than the original investigators). Therefore, in our view, in contrast to that in the Cochrane review, this trial clearly confirms the essential assumptions behind the use of oximetry and provides considerable evidence of its clinical value.

The remaining five randomised trials [20–24] which together included only 1500 patients, also consistently showed that pulse oximetry allows early detection of hypoxemia by anaesthesia providers. Several retrospective reviews also provide indirect evidence for the efficacy of pulse oximetry: an analysis of 2000 anaesthesia-related adverse events showed a reduction in cardiac arrests when pulse oximetry was used [25], and a later review of 4000 ‘incidents’ in Australia and New Zealand revealed no cases of hypoxic brain injury from inappropriate ventilation after the introduction of pulse oximetry and capnography [26]. Closed claims analysis in the USA has not provided traditional statistical evidence (p < 0.05) of benefit attributable to oximetry (or capnography) over time [27], but the situation is not one of equipoise. There is a simple reason why randomised controlled trials to assess the impact of oximetry will not be repeated: anaesthetists are collectively completely convinced that oximetry is essential to safe anaesthesia and would not consider such an investigation ethical (nor would research institutional review boards, who would be highly unlikely to approve a ‘no oximetry’ control group).

Should capnography also have been regarded as essential to anaesthesia care by the WHO? Capnography is also recommended by many anaesthesia societies and colleges. It allows detection of oesophageal intubation and hypoventilation nearly 100% of the time and is the monitoring modality of choice for this purpose [28, 29]. However, in resource-limited settings, the benefits of capnography are less compelling than those of pulse oximetry. In an incident reporting study by Webb et al., pulse oximetry would have detected 82% of the relevant incidents and 60% prior to organ damage whereas capnography alone would have detected only 55% and 43%, respectively [29]. Furthermore, increased alveolar carbon dioxide concentrations from any cause (notably hypoventilation) can be (indirectly) detected early with pulse oximetry if the inspired oxygen concentration is maintained at or close to that in ambient air. By contrast, hypoxia is not readily detected with capnography. Additionally, the cost and maintenance requirements of oximetry are generally lower than capnography. For these reasons, the WHO Anaesthesia Safety Group concluded that pulse oximetry is the preferred monitoring modality in resource-limited settings.
The decision to promote pulse oximetry as a requirement was not made lightly; considerable debate occurred over the question of resources, and over what might reasonably be expected in the poorest regions of the world. However, in the end it was the final category of evidence that carried the day – expert consensus overwhelmingly supports pulse oximetry. A strong belief in the pivotal value of oximetry to patient safety in anaesthesia is reflected in standards from anaesthesia organisations around the world, even in middle- and low-income countries. Moreover, in stark contrast to many other standards or guidelines in healthcare [30], compliance with the requirement for a pulse oximeter during anaesthesia appears to be universal where resources permit (even, as in the Philippines, where the anaesthetists may need to buy the oximeters themselves); it is not only those in anaesthesia organisations but also those who actually practise at the coal face who clearly believe in the value of this technology. In deliberations, this point was articulated most strongly by those who face the reality of working with limited resources in difficult environments; these practitioners were clear that no patient should undergo anaesthesia without oximetry, except to save life or limb in an emergency.

It is one thing to recommend that a pulse oximeter is used on every patient undergoing anaesthesia, anywhere in the world: it is another to make this vision into a reality. The WHO is undertaking a major exercise to specify and procure inexpensive and robust oximeters suitable for use in any environment. Nevertheless, an oximeter will only be of value in the hands of an anaesthesia provider who is present in the operating room, and has the knowledge to interpret the information and sufficient skill and resources to respond effectively to episodes of desaturation. Furthermore, it will not be enough just to deliver oximeters and leave – the goal has to be a sustained change in practice. The need for device maintenance, repair and replacement (in due course) must be addressed, and an appropriate educational package developed to deploy with the oximeters. All this is being done and will be delivered as part of the training of surgical and anaesthesia teams in the use of the WHO Checklist. Many of the tools used in this exercise will be based on those developed by the WFSA/AAGBI Global Oximetry (GO) initiative [3, 4] and on the lessons learnt in the pilot studies in Uganda, Vietnam, the Philippines and India, reported in this issue of Anaesthesia [31].

Herein lies the true power of the WHO strategy: including oximetry on the surgical safety checklist (and all that follows from that) reflects strong support for the technology itself, but also goes much further. It is highly symbolic – and there is huge power in good symbolism. It draws attention to the International Standards as a whole and underpins them, it elevates the importance of anaesthesia in the framework of peri-operative patient care, and it puts properly resourced anaesthesia firmly on the agenda for safe surgery. The WHO initiative to ensure that every patient undergoing anaesthesia has routine, continuous oximetry is bold, innovative and lifesaving. It is unlikely that anyone reading this editorial would volunteer to undergo anaesthesia without oximetry; no patient, anywhere, should have to do so either.

Acknowledgements

The International Standards for A Safe Practice of Anaesthesia were revised by (in alphabetical order) Meena Cherian, Jeff Cooper, John Eichhorn, Alan Merry, Olaitan Soyano, and Iain Wilson. The GO project involved (among others, again in alphabetical order) Alan Merry, Florian Nuevo, Ellen O’Sullivan, Gavin Thoms, David Whitaker and Iain Wilson, and was supported by General Electric Healthcare and the Association of Anaesthetists of Great Britain and Ireland as well as WFSA. Atul Gawande led the WHO Safe Surgery Saves Lives initiative. This editorial has benefited from discussions or correspondence over several years with all of these people, and with others, including Bill Runciman and Charlie Cote, and from much appreciated critical review by Isabeau Walker.

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References

Editorial

Pre-operative coronary revascularisation before non-cardiac surgery: think long and hard before making a pre-operative referral

Many of us use the ‘American College of Cardiology/American Heart Association (ACC/AHA) 2007 Guidelines on Perioperative Cardiovascular Evaluation and Care for Noncardiac Surgery’, to inform our practice [1]. These guidelines are downloadable free from http://circ.ahajournals.org and propose that there are no clear cut indications for coronary revascularisation before non-cardiac surgery. Coronary revascularisation may be useful in patients in whom it would be indicated in the absence of surgery; for example those with stable angina and left main stem disease, stable angina and triple vessel disease (particularly if the left ventricular ejection fraction is < 50%), unstable angina and/or acute ST-elevation myocardial infarction (MI). However, in most cases, coincidental findings suggesting asymptomatic coronary artery disease are probably best left alone.

In this edition of *Anaesthesia*, Biccard and colleague [2] have systematically reviewed randomised controlled trials of pre-operative coronary revascularisation for vascular surgery and conclude that there is no advantage with pre-emptive revascularisation and there may be