Is sedation by non-anaesthetists really safe?

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Sedation is frequently given by non-anaesthetists but is it actually safe? The definition of ‘safe’ is inherently difficult, and depends upon one’s perspective, however, we believe most patients would expect mishaps to be rare (<1:10 000). Anaesthetists themselves may approach sedation with caution as in some circumstances its administration can be as difficult as general anaesthesia, often requiring equal skill. However some patients, and importantly, many of our professional colleagues, view sedation as a lesser and therefore safer procedure than a ‘full’ general anaesthetic, perhaps because an anaesthetist is ‘not needed’. Others believe themselves safer if a fully trained anaesthetist is present when their level of consciousness is to be altered in any way. These factors, together with the markedly varying techniques used and the inconsistent quality of published data, make quantification of risk very difficult, and comparison of risk between different techniques almost impossible.

In 1995, Quine1 published the findings of a prospective audit of upper gastrointestinal endoscopy in 14 149 patients in 36 UK hospitals. A mortality rate of 1:2000 and a morbidity rate of 1:200 were reported and poor sedation practice was identified as a frequent contributory factor. In 2001, the UK Academy of Medical Royal Colleges and Faculties (AoMRC) published cross-specialty recommendations for standards for sedation practice titled ‘Implementing and ensuring safe sedation practice for healthcare procedures in adults’.2 The document reiterated a previous definition of ‘conscious sedation’ as ‘a technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation. The drugs and techniques used should carry a margin of safety wide enough to render loss of consciousness unlikely’. The document goes on to state ‘if verbal responsiveness is lost the patient requires a level of care identical to that needed for general anaesthesia’, clarifying that in the UK, what is termed ‘deep sedation’ by the American Society of Anesthesiologists (ASA),3 is considered outside the remit of non-anaesthetists. The AoMRC also recommended that Royal Colleges and specialist societies should develop specialty-specific guidance and provide appropriate training so that ‘practitioners use defined methods of sedation for which they have received formal training’. Now, >20 yr since Quine’s audit and 10 yr after the AoMRC guidance, progress has been limited. There are a number of difficulties complying with the AoMRC recommendations.

First, the target level of sedation. Conscious sedation is regarded as a safe target level of sedation because airway intervention is not required, ventilation is adequate, and cardiovascular function is maintained.2 However, sedation is a continuum, margins of safety can easily be breached and training to rescue patients from deeper levels of sedation, described by the ASA,4 have not been formally introduced in the UK. Rapid diagnostic and therapeutic developments in many specialties have stretched the boundaries of practice for the non-anaesthetist sedationist. In cardiothoracic centres, cardiac electrophysiology procedures often require patient immobility for several hours during mapping as well as control of severe retrosternal pain during subsequent ablation. Electrical cardioversion or testing of an implantable cardiac defibrillator requires a period of profound unresponsiveness, albeit brief, during which airway support may be required. Interventional bronchoscopic procedures often require cough suppression and may necessitate repeated periods of apnoea. Complex transoesophageal echocardiography studies also require deeper levels of sedation for prolonged periods. Conscious sedation is not sufficient for many of these patients who require deep sedation or general anaesthesia, if not for the whole procedure, for repeated brief periods during it. From our own experience, it appears that non-anaesthetist sedationists, perhaps unaware of the limitations of their practice, frequently target and achieve deep levels of sedation.

In this regard, the waters have been muddied recently by the publication of the National Institute for Health & Clinical Excellence guidance Sedation in children and young people in 2010,5 and the Royal College of Anaesthetists and College of Emergency Medicine guidance Safe Sedation of Adults in the Emergency Department in 2012.6 Both documents refer to the ASA’s definition of deep sedation as an appropriate target level of sedation and therefore acknowledge that a non-anaesthetist may target a state of sedation in which ‘patients...
may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate.\(^3\)

Secondly, the drugs used for sedation. Propofol is now being used commonly as a sedative agent by non-anaesthetists particularly outside the UK. As propofol was developed as an agent for inducing anaesthesia, we contend that it may not be a drug which has ‘a safety margin wide enough to render loss of consciousness unlikely’.\(^2\) The propofol-related death of Michael Jackson in 2009 and subsequent trial of his non-anaesthetist personal physician provided a worldwide public analysis of the drug’s pharmacological properties.\(^1\) However, is propofol really dangerous when used by non-anaesthetists? Not necessarily. Various terms have sprung up to describe this practice including non-anaesthetist administered propofol (NAAP), nurse-administered propofol sedation (NAPS), and endoscopist-directed propofol (EDP). Observational studies of EDP for gastrointestinal endoscopy by non-anaesthetists suggest that it is associated with low morbidity and mortality and significant cost savings when ‘formal training in EDP’ is provided,\(^3\) indeed that it is safer than when benzodiazepines are used.\(^9\) Proposals for training in sedation for gastrointestinal endoscopy have now been put forward by US gastroenterology professional bodies.\(^10\) American gastroenterologists continue to reject monitored anaesthesia care, in which sedation is administered by an anaesthetist, as being unnecessary for gastrointestinal endoscopy provided that the endoscopist and the sedationist are appropriately trained. However, the US Food & Drug Administration upheld the advice of the ASA\(^11\) (issued after Michael Jackson’s death) and denied a petition from gastroenterologists to remove the warning that propofol should only be administered by anaesthetists.\(^12\) Meanwhile in Europe, the original endorsement of NAAP for gastrointestinal endoscopy by the European Society of Anaesthesiology was subsequently withdrawn by its General Assembly in response to criticisms from member national societies.\(^13\) In the UK, guidance from the British Society of Gastroenterology for sedation for endoscopic retrograde cholangiopancreaticography and other complex upper gastrointestinal endoscopic procedures has recommended that propofol should be only administered by an appropriately trained anaesthetist.\(^14\) In cardiothoracic centres, there is increasing interest in the use of NAAP for cardiac electrophysiology procedures in response to emerging published experience, especially from Germany.\(^15\) We have grave concerns about the use of NAAP in cardiac electrophysiology compared with gastrointestinal endoscopy. The procedures last much longer (hours rather than minutes), deep levels of sedation are targeted and sustained, and importantly, propofol is administered by continuous infusion rather than small incremental boluses which have contributed to the impressive safety record of EDP.

Thirdly, specialty-specific guidance and training. In the UK, a number of specialty-specific professional bodies have produced recommendations but only dentistry and anaesthesia have set out comprehensive training programmes.\(^16\)\(^17\) Despite published guidance, poor sedation practice continues to be identified.\(^18\)\(^19\) Without clear requirements for comprehensive programmes for training and assessment, there is no safety net for sedation practice for non-anaesthetists. Currently, it is expected that non-anaesthetic trainees simply ‘pick up’ sedation skills during their specialty training as an aside without formal training or assessment. Meanwhile, there appear to be limited opportunities in the UK for non-anaesthetic consultants to participate in continuing professional development in sedation to meet General Medical Council requirements for appraisal and revalidation.

Lastly, local clinical governance. Clinical governance requirements were set out in the AoMRC guidance including the appointment of lead clinicians to implement local guidelines, the need for multidisciplinary education and training, and participation in monitoring of adverse events. Both authors’ institutions struggle to adhere to all parts of the AoMRC guidance and the national picture of compliance is unknown. It seems that in many institutions an anaesthetist has been placed ‘in charge’ of sedation by non-anaesthetists and these individuals are coming under increasing pressure to sanction the use of deep sedation in an increasing range of unsuitable scenarios. This pressure often stems from publications of underpowered small case series of ‘successful’ sedation techniques. These should be interpreted with caution and readers be aware of the mathematics for determining the risk of a complication that has not yet occurred; the ‘rule of three’\(^20\) This demonstrates that a series of 100 patients without a death can only show with a 95% certainty that the absolute risk of death is \(< n/3\), i.e. 1 in 33. Clearly, very large case series are needed to demonstrate that undesirable outcomes are rare.

So where do we go from here? We need to understand that non-anaesthetists usually have limited interest in sedation per se, only in using ‘procedural sedation’ as a tool to allow them to carry out the primary procedure. Are we right to suggest that sedation by non-anaesthetists is inherently less safe than that administered by anaesthetists, or is it a matter of getting the right training? If so, what skills should be gained, who should deliver the training, what competencies should be targeted and who will pay? Should the combined roles of operator and sedationist be forcibly separated in all circumstances, or are some combinations of procedure and technique demonstrably safe enough to allow the operator/sedationist? Mandating the need for a trained individual solely responsible for administering sedation and patient monitoring for all procedures will have major implications for healthcare staffing and costs. It is hoped that the revised AoMRC guidance on sedation, which is currently in preparation (personal communication), will clarify the situation and alleviate the pressure directed at local anaesthetists who are currently nominally responsible for the actions of non-anaesthetist sedationists in their institutions. Safer sedation may involve increased cost, in training, monitoring, and staffing, which will need to be recognized in the business plans of non-anaesthetic departments.

Declaration of interest
None declared.
References


