U.K. ACADEMY OF MEDICAL ROYAL COLLEGES AND THEIR FACULTIES

Implementing and ensuring

Safe Sedation Practice

for healthcare procedures in adults

Report of an Intercollegiate Working Party chaired by the

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I: Executive summary

Sedation techniques may make unpleasant healthcare procedures more acceptable to patients, but have the potential to cause life-threatening complications. The Working Party, having reviewed existing guidelines, concluded that these documents provide advice which should prevent such complications. However, the recent literature provides disturbing evidence that the recommendations have not been implemented fully and that, as a result, patients are exposed to unnecessary risk. In this report the established principles of managing patients undergoing healthcare procedures (section IVA), and current guidance on the safe use of sedative drugs (Table) are drawn together and supported strongly. However, it is recognised that more specific advice is required if the barriers to changes in practice are to be overcome. It is further recommended that

− Royal Colleges and associated organisations should define safe sedation techniques (including the human and equipment resources required) for each specialty. It is emphasised that this report is a generic document produced to provide specialist groups with a basis for developing more specific guidance.

− Organisations and individuals responsible for postgraduate training should define what formal instruction is required, and ensure that all users of sedation have received it. Revalidation procedures should check that both knowledge and skills are maintained after initial training.

− There should be audit of the process and outcome of procedures performed under sedation, particularly the incidence of major complications (e.g. cardiopulmonary arrest, unexpected admission to intensive care and delayed hospital discharge).

− The clinical governance framework should enable implementation of these recommendations on training and audit by delivering a patient centred approach, improved safety and ever-improving quality in an open and questioning environment.

− Each hospital should appoint two consultants (one an anaesthetist and the other a user of sedation from another specialty) to lead and support implementation of these recommendations at hospital level.

− Those responsible for commissioning healthcare in the primary and private sectors should ensure that similar processes are in place to ensure a safe standard of sedation practice.
II: Introduction
Concerns about the safety of the sedation techniques used for healthcare procedures that do not require the services of an anaesthetist have been expressed for over a decade. As a result there has been no shortage of authoritative publications making recommendations on safe, effective sedation practice. Of these the most definitive were, arguably, the ‘Poswillo’ report of 1990 relating specifically to dental practice [1], the recommendations on standards for gastro-intestinal endoscopy published in 1991 [2], and the 1993 multi-disciplinary report from the Royal College of Surgeons of England [3].

Each of these documents drew attention to the need to follow defined indications for the use of sedation, and described the various components of safe practice. Since then a number of other organisations have published specialty-specific guidelines [4], all of which have drawn on the evidence and conclusions of these earlier documents. However, concerns have persisted that sedative drugs are, in some circumstances, being used unnecessarily, inappropriately, or without adherence to some of the key components of published recommendations.

Thus the U.K. Academy of Medical Royal Colleges and their Faculties asked the Royal College of Anaesthetists to establish a multi-disciplinary Working Party. Its remit was to review the evidence on the safe provision of sedation services and produce recommendations applicable to the full range of training and practice. Because the Scottish Intercollegiate Guideline Network was, at the same time, developing recommendations for paediatric practice, the Working Party agreed that this document would limit its scope to adult patients.
III: Problem Statement

After reviewing the literature and discussing the current position, the Working Party concluded that the guidance already available to clinicians is, in general terms, appropriate. The problem is that, all too often, the advice is not followed. It was agreed that the main strategy for improving standards should be presentation of a review confirming that sedation practice is not always acceptable, exploring why this is so, and making recommendations on how the position can be changed. The Working Party believes that the answers to a series of linked questions will support its aim:

1. What are the current standards of care?
   All the published guidelines draw attention to the need for each stage of the procedure to be managed in a controlled fashion, recognising that any drug which depresses the central nervous system has the potential to impair respiration, circulation or both, particularly in the presence of disease or old age. The details of the various guidelines vary according to the needs and problems of individual specialties, but there is considerable agreement on the broad principles (Table).

2. Are the existing guidelines followed?
   There is good evidence that this is not the case in all areas of practice. Many of the original concerns about the safety of sedation developed over a decade ago in relation to endoscopy [5,6]. It might be assumed that practice would have improved subsequently, but worrying exceptions to the availability of adequate monitoring and resuscitation training for bronchoscopy were demonstrated in U.K. respiratory units in 1997 [7]. Since then, a survey of sedation for transoesophageal echocardiography in the UK has shown significant failures in the level of sedation produced, the monitoring devices used and the availability of tipping trolleys [8]. Oxygen was not immediately available in a few centres, and some did not secure venous access routinely. Given these findings it is not surprising that the majority of practitioners had not received any training in sedation, and some were unaware of published guidelines.

Table: Précis of existing guidelines on safe sedation practice
Patient assessment

In advance of the procedure the patient, preferably assisted by attendant staff, should complete a ‘check-list’ to identify any risk factors. The level of detail, and the need for further clinical examination or investigations, will depend on the procedure and the patient’s general condition. Protocols must be in place for dealing with any intercurrent disease etc. In the case of outpatients or day-cases, instructions on activities before and after the procedure are provided for the patient at an early stage.

Target state: Conscious Sedation

This has been defined [25] 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 to provide conscious sedation….should carry a margin of safety wide enough to render loss of consciousness unlikely.”

Some workers, particularly in North America, have described a state referred to as “deep sedation”. No matter how this is defined, it is inherent that the patient does not respond to verbal or simple physical stimuli, and may not maintain a clear airway. In terms of the procedures that can be performed this state may not equate to general anaesthesia, but there is a consensus that its supervision requires the same level of training and skill [32].

Drug administration

Sedative drugs are usually administered by the oral, intravenous or inhalational routes. The specific technique used should be one defined by a relevant specialty organisation, and drug doses should be adjusted to individual patient requirements. When the intravenous route is used, secure venous access is mandatory, and specific antagonist drugs, if available, must be to hand. Combinations of drugs, especially sedatives and opioids, should be employed with particular caution. The opioid should be given first and allowed time to become maximally effective before any sedative is added.
Monitoring
A suitably trained individual, present throughout the procedure, must have a defined responsibility for monitoring patient safety and making a written record. A pulse oximeter should be attached to the patient until discharge from the unit is contemplated. Monitoring of blood pressure and the ECG may not be necessary in young healthy patients, but can be essential in older patients, especially if there are any cardiovascular problems.

Oxygen therapy
Oxygen, and devices for administering it by the nasal and facial routes, must be available. It should be administered if there is any concern that the oxygen saturation might decrease below the resting figure, remembering that a reading below 90% is dangerous and requires immediate intervention.

General facilities
The above requirements imply considerable human and physical resources, which must be available in both treatment and recovery areas. All patient trolleys should be capable of being tipped head down, and appropriate resuscitation equipment must be immediately available, with all staff being familiar with its use. An appropriate level of clinical and instrumental monitoring should be continued until discharge criteria are met, at which time instructions on aftercare are reinforced to the accompanying person.
Most recently a survey of nearly 9000 patients undergoing colonoscopy has been performed [9]. It has also shown variation in sedation technique, and failure to secure venous access or use supplementary oxygen when appropriate [10]. This is very disappointing, gastro-enterologists having been pro-active in promulgating improved standards in sedation. Continuing reports that patients suffer complications of sedation (see below) provide further evidence that guidelines are not followed. Given that the majority of users of sedation, other than in dentistry, never attend formal courses of instruction [11], this is not surprising.

3. Are patients harmed as a result?
Surveys of endoscopic practice published over the last ten years have identified clearly that both morbidity and mortality are produced by the methods of analgesia and sedation used. In a survey of over 14,000 procedures Quine and colleagues reported a procedure-related, 30-day mortality of 1 in 2000, primarily due to cardiovascular and respiratory factors [12]. Not all of the problems reported may have been due to the sedation: topical local anaesthesia of the upper airway, for instance, might contribute to tracheo-bronchial aspiration. However, the evidence presented in the study generated a coherent argument for the use of better monitoring and supplementary oxygen therapy [13].

There has not been a similarly large scale survey of morbidity published since, but anecdotal reports of death after sedation continue to appear [14], and most intensive care units have to deal with occasional patients who have suffered cardio-respiratory complications during or soon after sedation [15]. Unfortunately, there is no formal documentation or audit of these admissions nationally, although changes in the reporting system may allow this information to be obtained in future [15].

Although there is limited epidemiological evidence of harm, the anecdotal evidence is worrying. The reports of failure to follow existing guidelines indicate that the risks of major complications are ever present because there is good evidence that adverse changes in cardio-respiratory physiology occur quite frequently during procedures performed under
sedation. Electrocardiographic evidence of myocardial ischaemia (S-T segment and T wave abnormalities) has been ascribed to both hypoxaemia and tachycardia [16,17].

Hypoxaemia seems to be particularly prevalent and a number of risk factors – old age, obesity, hepatic cirrhosis, low resting oxygen saturation, emergency endoscopy – all increase its severity [18]. Hypoxaemia and adverse circulatory changes also occur during upper gastro-intestinal endoscopy undertaken without sedation [19,20], but this only emphasises the need for better patient supervision no matter what method is used. The diversity of procedures performed across a range of specialties perhaps obscures the underlying potential for complications.

4. Why are the guidelines not followed?
This is a difficult question, but the answer, to a great degree, may simply be because of a lack of knowledge or resources. Postgraduate training programmes for specialties that use sedation techniques do not include any requirement for specific instruction and so, as has been noted already, many practitioners never receive formal training in sedation methods [11]. With the number of guideline documents published it might be expected that practitioners would become aware of the relevant standards without the need for formal training, but there are problems.

Little, if any, of the guidance on safe sedation practice is based on randomised controlled studies, so it does not meet modern requirements for ‘evidence based medicine’ [21]. The existing guidelines are consensus documents based on a mix of first principle analysis, expert opinion and anecdote, although (crucially) with a firm foundation in a number of high quality audit projects [7-9, 12, 22]. It would be impossible to mount a comparison of ‘good’ with ‘bad’ practice, but the nature of the evidence does not help overcome the multiple barriers that have been identified as obstructing valid changes in practice [23].

5. If sedation causes complications, why use it?
Recent reviews and reports confirm that it is possible to perform many procedures for which sedation is often thought essential, without any systemic medication. This applies to interventions as different as upper G-I endoscopy [11], bronchoscopy [24], transoesophageal echocardiography [8], interventional radiology [25] and the vast majority of dental procedures [26]. It is particularly noteworthy that there are marked variations in
practice in different countries [17], a parallel with the past use of general anaesthesia for routine dentistry in the UK, something which was unnecessary and occasionally caused serious harm [27]. In Germany and Sweden only a minority of patients receive sedation for upper G-I endoscopy [11], and sedation was used routinely in only 1 of 15 centres returning data to a multi-centre survey of the safety of transoesophageal echocardiography [22].

Cultural and individual patient factors, as well as the clinical skill of the individual doctor or dentist, play a part in the need for sedation. However, the fact that a procedure can be performed without systemic medication increases the pressure to use sedation safely. Therefore, there is a challenge to clinicians to optimise their skills in patient management (particularly the control of pain, and discomfort such as gagging), in order to minimise the need for sedation, because all drug (especially sedative) administration carries some risk. Careful explanation, indicating the reasons for the discomfort that may be experienced, reduces the need for sedation. Nevertheless, there are few, if any, absolute contra-indications to sedation properly administered in the right setting by an appropriately trained individual.

Sedation does increase the resources needed, and many techniques produce significant disruption to the patient’s normal routine, but many of the procedures for which it is used are inherently very unpleasant. In Germany, where sedation is not used widely for endoscopy, anxiety about the procedure has been shown to cause a significant proportion of patients to delay its performance for as long as possible [28]. This is not a desirable outcome. Thus conscious sedation, with effective pain control, can contribute much for both patient and operator [25], and its proper use should help minimise the adverse cardiovascular effects of endoscopy seen in cardiac patients [20].

In the UK, there are contradictory reports on patient attitudes to sedation for bronchoscopy, with some finding that placebo was as acceptable as midazolam, but superior (in terms of patient satisfaction) to the combination of phenoperidine with droperidol [29]. Factors which might have contributed to these findings include the nature of the intervention, the quality of patient management, the efficacy of pain control, and the effects of different sedative agents. While a number of generic issues are vital to safe sedation practice, each specialty has to evaluate those factors which influence effectiveness and patient satisfaction, but the benefits must outweigh the risks in every case.
6. Are the methods used correct?

Sedatives and anxiolytics such as the benzodiazepines have no analgesic properties when conventional doses are given systemically, and attempts to use them to control pain will result in significant overdose. **Pain control requires the administration of a specific analgesic agent.**

Local anaesthetics, given by topical application, local infiltration or minor nerve block, form the cornerstone of dental work and could, within published dose limits [30], be used much more effectively for medical procedures. If systemic analgesia is required the opioids produce a degree of sedation as well, and are widely used, but they have respiratory depressant and other adverse effects. In addition, there may be potentially dangerous synergistic effects when they are used in combination with sedatives. For instance, fentanyl adds significantly to the depression of airway reflexes produced by propofol [31].

Inhalational sedation has an established role in dental practice and could be used more frequently in other settings. Nitrous oxide has both sedative and analgesic actions, can be titrated rapidly to effect, has an equally rapid recovery time and few side effects. It must be given mixed with oxygen, but this can only be an additional benefit. The efficacy and safety of nitrous oxide/oxygen mixtures are shown by its longstanding use in childbirth (50% fixed concentration for analgesia) and dentistry (titrated concentration for sedation). It is also used widely in the Accident & Emergency Department [32], and preliminary work has shown that it can be used effectively for flexible sigmoidoscopy [33].

In general, only one sedative drug (administered by the oral, inhalational or intravenous route) will be necessary for the vast majority of patients. Combinations of drugs (polypharmacy) may occasionally be necessary, but they are often synergistic and the safety margin between ‘conscious sedation’ and ‘anaesthesia’ can be reduced significantly [34]. An associated cause for concern is the use, for sedation and by untrained staff, of drugs introduced primarily as intravenous anaesthetics (e.g. propofol and ketamine). Although these drugs have some excellent properties for use in sedation [35], very specialised knowledge, skills and equipment are needed. Certainly, these drugs cannot, at the present level of knowledge, be considered as safe for use by the ‘operator-sedationist’ [36].

Alternative methods of administration (e.g. nasal midazolam, patient-controlled propofol) have been tried recently in attempts to improve utility or convenience [37], but
most of these methods have, as yet, poorly defined profiles for either efficacy or safety. For the same reasons (but primarily simplicity of administration), the oral use of much larger doses of sedatives than are given for the relief of anxiety, looks very attractive. However, the use of such larger doses for conscious sedation, as opposed to the lower doses used for relief of anxiety, requires exactly the same standards as any other method. It is the endpoint achieved which dictates the level of care required, not the route of administration.

Virtually all the guideline documents published in the past advise the use of a single sedative agent given by a traditional route in a restricted maximum dose whenever possible. If this approach is insufficient, the advice, and often the assistance, of an anaesthetist or other expert in sedation should be sought. This is not to suggest that the techniques currently available are perfect because there is considerable room for development of many aspects [38]. However, such development must be carried out in formal, collaborative research projects, not by uncontrolled variations in day to day practice.

The key point is that safety will be optimised only if practitioners use defined methods of sedation for which they have received formal training.

7. Summary

Many healthcare procedures are unpleasant. Sedation, as an adjunct to good pain relief and sympathetic patient management, can improve both patient tolerance and acceptance, and increase the technical success of the procedure, but patient safety must be preserved. Unfortunately there is ongoing evidence that many users of sedation have received no formal training and that they do not follow existing guidelines - often because they are not even aware of them. As a result patients are being exposed to unnecessary risk. Thus the real requirement is for an improvement in both the awareness and implementation of information that is already widely available. The Working Party’s recommendations follow.
IV: Recommendations

Little short of a change in culture is needed in some areas. The established principles of managing patients undergoing healthcare procedures, and current guidance on the safe use of sedative drugs, must be followed.

A) General Principles

The Working Party reminds users of sedation of the following important general principles:

1. Sympathetic patient management is the foundation of all clinical care. Explanation at each and every stage of any procedure is essential, particularly where sudden manoeuvres may disturb the patient acutely.

2. Anxiety, discomfort and pain may still occur. They are inter-related, and each may increase the others. As a result, the procedure will become more difficult for all parties, but any drug treatment must be targeted specifically to each symptom.

3. Often, anxiety can be alleviated by careful explanation, a sympathetic attitude and expert clinical management. Drug sedation should not be used for operator convenience, but as a supplement to behavioural management.

4. The nature and site of potentially painful components of the procedure should be identified in advance so that local anaesthetic or systemic analgesic drugs can be administered to prevent that pain whenever possible.

5. If pain is variable or unpredictable the patient should be made aware of this, and the operator should have in place a safe strategy for dealing with any pain that occurs during the course of the procedure.

6. In many situations, good analgesia and expert management suffice. The need for additional sedation should be related to the individual patient’s psychological and medical status because both affect the response to, and the need for, sedation.

7. When conscious sedation is employed, the agents and doses chosen must be adjusted to the patient’s requirements and ensure that verbal contact is possible at all times.

If verbal responsiveness is lost the patient requires a level of care identical to that needed for general anaesthesia.
8. Interactions between drugs of different types (especially opioids and sedatives) are often synergistic so that both the degree of effect and its rate of onset are increased significantly. Drug combinations must be used with particular care.

9. The resources needed to support a particular drug sequence should relate to the clinical status of the typical patient, the clinical setting in which it is normally used, and the number and type of drugs administered.

10. Clinical and instrumental monitoring, to a degree relevant to the patient’s medical status and the sedation method, should be used. In addition, one member of the care team must have a defined responsibility for patient observation and record keeping.

B) New Measures

It is clear that additional measures are needed to ensure that the above recommendations are followed. The current climate requiring greater individual responsibility for practice, and the focus on clinical governance and revalidation, will do much to support implementation, but change is not achieved easily. To overcome the barriers a multi-faceted approach is required. This must be resourced adequately, involve people with appropriate knowledge and skills, include monitoring and evaluation processes, and have local as well as national elements [23]. The Working Party recommends that:

1. Royal Colleges, in association with the relevant sub-specialty organisations, should develop guidelines [e.g. 4] on sedation methods appropriate to clinical practice in their sphere of influence.

2. Royal Colleges and their Faculties should incorporate the necessary instruction [e.g. 39] and assessment into training and revalidation programmes of those specialties that use sedation techniques.

3. The clinical governance framework should deliver safe sedation practice at hospital level by enabling a patient centred culture in which:
   a) multidisciplinary team training ensures that all staff understand their roles;
   b) those who actually administer sedative drugs are aware of the possible adverse consequences and are able to deal with these; and
c) audit [e.g. 40] of adverse incidents, complications (particularly severe ones such as admission to intensive care) and adherence to agreed national and local protocols promotes continuous quality improvement.

4. NHS Trusts should apply to sedation techniques the standard of the Clinical Negligence Scheme which requires that all medical and dental staff in training be, on appointment, competent in the technical skills and specified tasks expected of them [41].

5. Each hospital should nominate two consultants, one an anaesthetist and the other a user of sedation, to collaborate in the local implementation of guidelines and the provision of a specialist service for patients with particular problems.

6. Those responsible for commissioning and providing healthcare in the primary and private sectors should ensure that similar processes are in place to ensure a high standard of sedation practice.
V: Further Reading


VI: References


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