#### PREOPERATIVE EVALUATION (BJ SWEITZER, SECTION EDITOR)



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#### Abstract

**Purpose of Review** The purpose of this review is to provide a summary of the recent literature addressing the aims, content, outcomes and quality metrics for presedution evaluation.

**Recent Findings** There is a trend towards multidisciplinary development of minimum standards for sedation practice, including presedation assessment. A risk-based paradigm underpins presedation assessment. Improved and validated risk scores are required, especially to predict airway difficulty. There is an increasing focus on skillsets rather than roles. Clinicians should explain the intended depth of sedation, how that may be experienced by patients and how patient preferences for sedation can be incorporated into decision-making.

**Summary** High-quality presedution evaluation will improve the value of sedution care by aligning appropriate resources (including sedution provider), based on patient risk, and also by improving communication and decision-making.

Keywords Presedation assessment · Preprocedural assessment · Sedation risk management · Shared decision-making

# Introduction

Sedation and general anaesthesia exist on a continuum. Clinicians who provide sedation are required to manage risks specifically associated with sedation and also risks associated with the facilitated procedure. Preprocedure evaluation prior to an episode of sedation serves the same purpose as evaluation prior to general anaesthesia, that is, to identify baseline comorbidities that will lead to modification of perioperative care [1]. Preprocedure evaluation prior to sedation is part of the process of clinical risk management and includes

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information gathering, optimization of the patient's health status, discussion and development of a mutually acceptable sedation plan. The aim of the sedation management delivered according to the plan and informed by the preprocedure evaluation is to reduce the likelihood of adverse events, optimize peri-procedure outcomes and enhance the patient's experience and satisfaction with care.

# A Risk-Based Paradigm

Increasingly in anaesthesia practice, the binary concept of fitness/unfitness for anaesthesia or surgery has been replaced with a more nuanced risk management approach to preprocedure assessment [2, 3]. For sedation practice, preprocedure assessment and evaluation include risk identification, risk stratification, risk modification (where possible) and residual risk communication, expressed as an appropriate risk management plan. Importantly, planning for an episode of sedation includes identifying and securing the appropriate resources, based on risk, and therefore appropriately aligned with patient need. Where, by whom and under what circumstances (or if at all) sedation is provided should be informed by explicit and agreed criteria and aligned with patient risk.



#### **Guidelines and Standards**

Provision of procedural sedation inside and outside the operating theatre and administered by a range of clinicians, including anaesthesiologists, is described in a wide range of contexts worldwide [4••]. Guidelines and policies for sedation provision have historically been developed according to expert opinion, often led by, or with input from anaesthesiologists and/or other critical care physicians, as the acknowledged experts in the sedation-anaesthesia continuum. Guidelines for sedation provision in emergency departments and dentistry (commonly described for paediatric patients) are the most frequently quoted guidelines available in the published literature, along with guidelines for sedation in cardiology, radiology and gastroenterology procedures.

Horeczko et al. describe the mindset in the paediatric sedation setting, which is essential to developing a sedation plan and note that "communication is the key to a successful sedation." [5•] These authors also note the plethora of siloed guidelines, position statements and policies, developed separately by different professional societies, together with the lack of consensus between clinical specialties as to what constitutes mutually accepted minimum standards of knowledge, skills, equipment, agreed targeted sedation levels or agreed definitions of adverse events.

Almost all recently published guidelines refer to a process of preprocedure assessment, usually based on risk [6••, 7–12, 13•, 14••, 15, 16••, 17, 18]. Increasingly, guidelines addressing sedation are being developed jointly among professional groups, including anaesthesiology, and describe common standards of care including preprocedure assessment. Guidelines which omit presedation evaluation appear to be the exception.

In almost all published guidelines where presedation assessment is described, a process of risk-based assessment and subsequent triage to the most appropriate provider is outlined. Triage is most commonly based on an alignment of patient risk with provider skillset (rather than mandating referral to a specific clinical group). Provider skills (such as the ability to monitor and manage airway obstruction and/or to provide bag-mask ventilation) are increasingly explicitly described. However, most guidelines state explicitly that referral to, or consultation with, a medical anaesthesiologist is appropriate for the highest-risk patients needing procedural sedation. Some guidelines indicate that these triage and referral arrangements are best decided and organized locally, based on available skills of the trained workforce [11••].

It has been recognized for some years that patient/ consumer involvement is an important component in the development of high-quality clinical practice guidelines, and frameworks for patient involvement have been proposed [19, 20]. However, there appears to be little evidence of patient input into clinical guideline development generally, nor into sedation guidelines in particular [21]. Patient input into the development of clinical guidelines for sedation practice may result in improved decision-making regarding need for sedation and an improved focus on communication.

# Shared Decision-Making: Is Sedation Required?

One initial question which should always be considered as part of presedation evaluation is: Is there a need for pharmacological sedation? Or can the patient be managed without sedation? Whether or not to include sedation for some procedures appears to be preference-sensitive and is subject to wide variation in clinical practice, both within and between countries [22, 23]. Particularly when decisions are preference sensitive, patient decision aids to support shared decision-making have been shown to improve decisional quality and may also reduce the likelihood of unwarranted variation [24].

Chittle et al. studied outpatients presenting for venous access device placement under local anaesthesia and found that there was significant variation in patient preference for sedation levels. Chittle suggests that the role of shared decision-making regarding the need for sedation, or level of sedation, enhances patient satisfaction and may also have economic benefits [25].

For dental sedation, Coulthard et al. describe the development of the Index of Sedation Need (IOSN) tool, which includes measures of dental anxiety, co-morbidity and likely dental treatment complexity and which correlates with need for subsequent sedation or for complex sedation [26]. The IOSN tool has also been found to be useful in paediatric dental practice [27]. Shokouhi et al. have described how the tool can be further modified and potentially include a "traffic-light" indicator for green (no sedation needed), amber (potential need for sedation) and red (clear need for sedation). Use of this tool may help to predict dental patients who are more likely to fail simple or non-anaesthesiologist sedation and require more specialized referral. A lower score correlates with lower (or no) need for sedation [28•]. However further research is required to confirm the utility of this tool for such an indication.

Rates of unsedated colonoscopy appear to show significant variation among countries [29]. In Australia, colonoscopy is commonly associated with the use of intravenous sedation, although the preferences of providers appear to be better understood than those of patients [30, 31]. Lai has established risk predictors for pain during colonoscopy, which may be inferred to predict need for sedation in the cohort of Chinese patients studied [32]. For upper gastrointestinal endoscopy screening, Gupta demonstrated in North America that most patients surveyed preferred unsedated techniques [33].

Some patient groups whose need for sedation is particularly difficult to predict include those who experience chronic pain and who may present for pain-related or other procedures. Simopoulas et al. evaluated a group of such patients who underwent interventional pain management procedures and found that although most patients in their study had no need for sedation, the group was heterogenous and predictors of high sedation need were not easily identified [34].

Music has been described as a non-invasive, safe and inexpensive intervention which may substitute for medications, including sedation [35]. In their systematic review, Hole et al. suggest that music can reduce pain, analgesia use and anxiety in conscious patients undergoing procedures and also appears to increase patient satisfaction. Bashiri et al. suggest that music can reduce sedation requirements and enhance patient satisfaction during colonoscopy [36]. A more recent study by Graff et al. found music to be non-inferior to mid-azolam in reducing patient anxiety prior to peripheral nerve block, but that midazolam use was associated with better patient satisfaction [37].

# Informed Consent: What Needs to Be Communicated and Discussed?

Having agreed a need for sedation, a risk-based discussion is likely to be helpful to underpin informed consent. In order to appropriately prepare a patient for a procedure involving sedation, the preprocedure evaluation should result in a plan for sedation which is realistic and which the patient understands and accepts and reflects the risks involved [38]. A shared understanding among sedation providers, proceduralists and patients of the targeted depth of sedation, and how different depths of sedation are likely to be experienced by the patient, are also necessary in order to obtain informed consent for sedation [39].

Many patients do not understand the meaning of sedation, and clinicians may use terms such as "asleep" without specifying the intended depth of sedation and how this might be appreciated from the perspective of patients. For paediatric sedation, Tobias stresses that preprocedure evaluation is an opportunity to "educate and inform.... the goals of sedation" [40]. Furniss et al. describe the use of a template, initially described in the National Audit Project (NAP5), which outlines, from the perspective of patients, how no sedation, minimal/moderate/deep sedation and general anaesthesia differ and what the relative risks are for each level of sedation/ anaesthesia [41, 42•] (see Table 1).

In the UK, the NAP5 examined the issue of unintended awareness associated with anaesthesia [43]. Surprisingly, approximately 20% of all cases of unintended awareness reported were associated with intended sedation (rather than general anaesthesia). Mashour et al. noted as controversial that

"undesired awareness with explicit recall of procedures performed under sedation is a clinical problem" [44•]. Kent has reported that a significant number of patients who report unexpected awareness during intended sedation also report feelings of distress, nightmares and flashbacks, similar to patients who experience awareness associated with general anaesthesia [45]. The NAP5 authors attribute these reports and associated episodes with failures of communication and suggest that the solution to prevent patient distress is better communication and "better management of expectations and consent processes." In a qualitative survey, Saxon et al. reported that when high-risk patients who underwent bronchoscopy under conscious sedation reported recall of the procedure (in approximately 50% of their survey patients), it was likely to be a significant event and associated with distress [46]. Conway has commented that clinicians who administer conscious sedation should ensure that their patients understand that this technique will not guarantee lack of recall of the procedure, although how information should best be presented and delivered is unclear [47•]. Other researchers have also noted that those patients who are appropriately informed of the likelihood of awareness associated with procedural sedation are less likely to report apprehension regarding this outcome [48].

#### **Risk Identification and Stratification**

Having identified a need for sedation, further risk assessment is required, in order to develop an appropriate sedation plan and manage resources. Many sedation guidelines reference the American Society of Anesthesiologists (ASA) physical status classification system as a basis for risk stratification [7–10, 12, 14••, 17]. The ASA score was never intended as a risk predictor, and while it can be a useful descriptor, there is increasing evidence that scoring using the ASA classification within and between disciplines can be inconsistent [49-52]. The ASA descriptors were initially written for adult patients, and on inspection do not appear appropriate for paediatric patients (e.g. ASA I healthy, non-smoking, no or minimal alcohol use). The consistency of ASA scores between clinicians in paediatric practice also appears poor [53, 54]. For these reasons, the ASA status, although widely used, is likely to be of limited use as a valid risk discriminator on which to base sedation triage decisions. Better sedation-appropriate risk-based descriptors are needed.

Extremes of age are commonly referenced in sedation triage criteria, and guidelines are again inconsistent. Higher-risk age groups include both paediatric patients and also frail elderly patients. NICE guidelines refer to paediatric patients of ASA grade 3 and above and infants (including neonates) as constituting greater risk and therefore necessitate specialist advice, although the guidelines do not indicate the precise pathway intended [17]. The ASA taskforce document refers

	What will this feel like?	What will I remember?	What's the risk related to the sedation drugs?
Not sedated; awake	I am awake, possibly anxious. There may be some mild discomfort, depending on what I am having done	Everything	Nearly zero
Minimal sedation	I am awake and calm. There may be some mild or brief discomfort	Probably everything	Very low risk
Moderate sedation	I am sleepy and calm but remain in control. I may feel some mild discomfort	I might remember some things	Low risk
Deep sedation	I am asleep. I will not be in control	Probably very little	Higher risk. My breathing may slow when I am asleep, and I may need help to breathe; a tube might be inserted into my nose, mouth or (rarely) windpipe. I will need oxygen and special monitoring
Anaesthesia	I am deeply "asleep" and unable to respond	Very unlikely to remember anything	Higher risk (but the presence of an anaesthetist increases safety). My breathing may slow or stop and my blood pressure and heart rate may fall. I will need a specialist doctor to look after my breathing and support my blood pressure and heart rate. I will need oxygen and special monitoring and equipment

 Table 1
 Patient perception/experience of sedation

(Reproduced here with the permission of the Royal College of Anaesthetists, but the RCoA has not reviewed this article as a whole. Originally published in the Report and Findings of the 5th National Audit Project: Accidental Awareness During General Anaesthesia, 2014)

to extremes of age but is no more specific [6••]. ANZCA PS09 refers to children under 2 years, elderly patients and ASA grades 4 and above as constituting increased risk. They state that for these patients, an anaesthetist "or other trained and credentialed medical practitioner working within his/her scope of practice" should be present to care for the patient [14••].

Rather than age or ASA status, some guidelines use red flags (e.g., for increased risk of failed sedation, or for other adverse outcomes) as a prompt for clinicians to consider referral to different providers [11...]. The most common risk indicators are those for airway obstruction, or the risk of failure to provide effective manual ventilation in the context of over sedation. Few guidelines refer to Mallampati or STOP-BANG scores [9, 11...]. The American Academy of Pediatrics does not use a score but does give detailed and practical flowcharts for treatment of airway obstruction, laryngospasm and apnea [10]. Of note, the Cardiac Society of Australia and New Zealand refers to obstructive sleep apnea (OSA) as a relative contraindication for cardiology-directed sedation and in some units as "an absolute contraindication." [13•] The Australian document of the NSW Agency for Clinical Innovation gives a tool which enables more detailed airway assessment [11...].

## **Presedation Testing**

In order to further delineate sedation and procedural risks accurately, there may be a need to gather extra information (based on pre procedure testing and/or referral to specialist colleagues). On occasion there may be a need to optimize a patient's preprocedure medical condition. Historically, most procedures performed with sedation (rather than general anaesthesia) have been considered low risk. However, there has been an enormous growth of vascular and interventional radiology procedures and a move to care for these patients out of the operating theatre and in the interventional environment. Although better outcomes for patients are assumed, data is lacking, and guidelines suitable for pre anaesthesia and surgery testing may not necessarily be appropriate for less invasive interventional procedures.

Even for surgical procedures performed in operating theatres, improvement in operative techniques may reduce the universal requirement for general anaesthesia and result in increasing use of local or regional anaesthesia, with or without sedation. Cataract surgery is a good example, with increasingly available phacoemulsification and reduced requirements for general anaesthesia. There is good evidence that routine preprocedure testing does not increase the safety of cataract surgery [55]. NICE guidelines recommend against routine preoperative testing for low-risk procedures and for most patients [56]. Other authors have noted the lack of high-quality evidence underpinning most recommendations for (or against) preoperative testing and reliance on expert opinion [57]. How this advice should be interpreted for minimally invasive procedures undertaken with sedation is unclear, but aligned with a risk-based paradigm, a testing regimen based on the likelihood of conversion to major surgery (or assuming the same risk as for major surgery) may be prudent and may also need to incorporate local factors.

## Presedation Preparation: Fasting and Medication Management

Other significant risks include the need to mitigate against pulmonary aspiration of gastric contents. Coté et al. nominate similar fasting guidelines for elective sedation in children as for general anaesthesia and describes the process of balancing risks and benefits in the emergency context of proceeding despite a likely gastric aspiration risk [10].

Medication management also aligns with the process of risk management, with the aim of maintaining normal physiology and avoiding sedation-related harms. Particularly with increasing evidence that even brief periods of perioperative hypotension are likely to be harmful, increasing consideration is given to preprocedure avoidance of medications such as angiotensin-converting enzyme inhibitors (ACE-I) and angiotensin receptor blockers (ARB) which appear to contribute to procedural hypotension [58]. Withholding these medications prior to major noncardiac procedures may be associated with reduced peri-procedural mortality and vascular events, and similar management for procedures performed with sedation may also be beneficial, although evidence is lacking [59].

# Intraprocedure Risk Management: Airway Management

The most critical sedation-related risk is failure to maintain a patent airway and the need to support or assist inadequate spontaneous ventilation, particularly when there is inadvertent transition towards deeper sedation and unconsciousness. From the Academy of Royal Medical Colleges: "Sedating practitioners should always ask themselves beforehand *Will I be able to ventilate this patient, if necessary?*" [16••] The incidence of difficult bag mask ventilation (BMV) is estimated to be approximately 1–2:100 [60••].

A recently published multicentre prospective observational study from Germany examining adverse outcomes in more than 310,000 cases of gastrointestinal endoscopy performed with sedation found that of 1000 minor complications (including the need for mask ventilation due to desaturation), more than 40% were ventilatory (including respiratory depression, aspiration and laryngospasm) [61]. Sedation-related mortality was quoted as 0.004%, and intubation was required in 0.008% of cases.

It is reasonable to expect that clinical guidelines for sedation practice, and specifically presedation evaluation, should therefore focus on specific ways to predict airway and breathing-related risks. However, few available guidelines provide detailed and prescriptive advice. Rosenburg discusses at length predictors for difficult BMV, which is noted as "the primary and most important airway rescue technique" for patients undergoing moderate or deep sedation [62]. Rosenburg also notes that in contrast to numerous publications and risk scoring systems designed to predict difficult intubation, there are very few guides available to predict difficult BMV.

One often-quoted study found that 5 factors were associated with difficulty in BMV age > 55, BMI > 26, beard, lack of teeth and history of snoring [63]. Cattano notes that there is no single, simple predictive test and that difficult BMV is common, occurring in up to 9% of a sample in a US trauma centre [64]. Leoni et al. found that in obese patients, difficult BMV is more common than in non-obese patients and predictors include reduced mandibular protrusion, higher Mallampati score and greater neck circumference [65]. More recently, Lundstrøm et al. have described the DIFFMASK score, using ten independent criteria, to predict difficult facemask ventilation during general anaesthesia [66]. Although the score has some predictive value, a clear distinction between scores which are associated with easy versus potentially difficult facemask ventilation was unclear, and further validation is required.

It is expected that airway assessment will be more accurately completed via direct examination than via distance screening. Whether examination must be directly face-toface (rather than via videoconference or similar) is uncertain.

## Models of Care: Who Should Perform Presedation Assessment? How Is it best Done?

Gooden has described the options for preprocedure evaluation for anaesthesia, not confined to sedation. These options include facility visit before the procedure, office visit, telephone interview, review of a health survey, screening associated with face to face visit on the day of the procedure and computerassisted collection of health information [67].

Preprocedure evaluation for sedation, as for general anaesthesia, can potentially be initially carried out via screening questionnaires, delivered face-to-face or remotely and can be recorded via hard copy or electronically. Furniss notes that evaluation and appropriateness for sedation (under the model of care in question) should occur prior to the day of the procedure, and this assessment is distinct from the evaluation and assessment for the procedure itself [41]. Furniss reports excellent outcomes and experiences of care associated with nursebased evaluation and sedation services for cardiology procedures.

There is some evidence supporting the effectiveness of non-clinician-delivered screening before general anaesthesia, to assess the need for anaesthesiology evaluation before the day of surgery [68]. Grant et al. noted airway assessment to be the most frequent error or omission in computer screened patients. The same authors note however that clues to potentially difficult airway identification can be gleaned from the presence of other co-morbidities, particularly a history of obstructive sleep apnea and obesity. These factors are likely to also apply to presedation screening and evaluation.

# Evaluation and Risk Management for Postprocedure Monitoring

Planning for recovery and discharge is part of the presedution evaluation. Despite a lack of robust outcome data, most guidelines recommend a process of recovery and discharge under supervision and with instructions [6••, 7, 8, 10, 11••, 13•, 14••, 16••, 17].

In a large series of children receiving sedation for magnetic resonance imaging (MRI), Trost et al. identified a rate of overnight respiratory events in 10% of patients [69]. Risk factors included prior anaesthesia complications, higher apnea/ hypopnea indices and home non-invasive positive pressure ventilation. Of note, the depth of sedation is not recorded. Over one third of patients required a supraglottic airway during the procedure, and 33% received sevoflurane for sedation. So the implications of this study are unclear for patients receiving conscious or moderate sedation.

### **Quality Assurance and Quality Improvement**

The quality of presedation evaluation can be assessed using metrics such as those described by the Committee for the Advancement of Procedural Sedation [4..]. The TROOPS tool described by Roback et al. examines unplanned interventions or outcomes which are either immediate or sentinel events and, importantly, also includes patient and provider experience measures such as dissatisfaction with sedation. These measures may adequately describe the safety, effectiveness and patient-centredness of presedation evaluation, especially where patient risk is appropriately aligned with a skilled sedation provider. In the future, there may also be measures which reflect the timeliness, equity, efficiency and value of presedation evaluation. Efficient and high value presedation evaluation will occur when low-risk patients are aligned with appropriately skilled providers, and more complex patients tasks are matched with more highly skilled providers.

# Conclusion

Patient evaluation before an episode of procedural sedation is an integral part of high-quality sedation practice. Preprocedure evaluation is increasingly an important feature of multidisciplinary, interprofessional standards of care for sedation practice and is reflected in clinical guidelines and minimum standards. Careful evaluation, based on patient and procedural risk, will result in the development of an individualized and agreed upon sedation plan negotiated between patient and clinician. This serves to ensure that appropriate resources (including trained and skilled sedation providers) are aligned with patient-specific risk. Gaps in knowledge and priorities for research include the development of validated risk scores to predict sedation-related complications (especially related to airway compromise), evidence to inform the need for presedation testing and tools to assist with shared decisionmaking for sedation choices to enhance patient satisfaction and experience with procedural sedation.

#### **Compliance with Ethical Standards**

**Conflict of Interest** Joanna R. Sutherland served as Chair of the working party that developed the Minimum Standards for safe procedural sedation, NSW Agency for Clinical Innovation, which is quoted within this article.

Aaron Conway declares that he has no conflict of interest.

Erica L. Sanderson declares that she has no conflict of interest.

Human and Animal Rights All reported studies or experiments with human or animal subjects performed by the authors have been previously published and complied with all applicable ethical standards (including the Helsinki declaration and its amendments, institutional/national research committee standards and international/national/institutional guidelines.

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