

# Standardizing care and monitoring for anesthesia or procedural sedation delivered outside the operating room

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## Purpose of review

The purpose of this review is to summarize recommendations for the safe and efficient conductance of sedation and anesthesia at remote locations; and to define safety standards, monitoring techniques, quality of care and procedural eligibility.

## Recent findings

Anesthesia outside of the operating room is rapidly increasing in numbers, which has seen a growth of older and sicker patients. These circumstances have created a need for guidelines, for both specialist anesthesia providers and nonanesthesia-trained practitioners, that define patient selection, minimum monitoring (hemodynamics and respiration), facility design and equipment, policy framework, recovery facilities and policies. The patient's safety throughout all stages of sedation and/or anesthesia is the most pertinent goal. Recent data emphasize the importance of monitoring pulse oximetry and end-tidal carbon dioxide for any sedating or anesthetic procedure. Substandard monitoring combined with oversedation and subsequent respiratory depression are implicated as the main reasons for catastrophic sedation and anesthetic outcomes at remote locations.

## Summary

Patient selection, procedure appropriateness and location appropriateness are the key elements defining the provision of safe anesthesia care outside the operating room. Titratable, short-acting intravenous drugs are preferred such as propofol and remifentanyl.

## Keywords

anesthesia at remote location, monitoring, safety, sedation, standards

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## Introduction

The delivery of anesthetic care outside the operating room in remote locations has become commonplace. Pino [1] observed that by 2007 12.4% of all anesthetic care in the United States was delivered outside the operating room environment, mostly by nonanesthesiologists. Some estimate that up to 55% of all ambulatory procedures in the USA are currently performed as 'office-based anesthesia' [2]. The reasons are manifold, though the economic pressure to cut health costs is of overwhelming importance. The request to move beyond the comfort of the operating room is confronted with a population of patients that is increasingly older and sicker. The spectrum of care delivered in these circumstances ranges from light sedation ('conscious sedation') to general anesthesia; depths of sedation short of a general anesthetic are often referred to as 'monitored anesthesia care', particularly in the USA, though the terminology continues to expand and diversify. Deeper levels of sedation and general anesthesia are essential if patient immobility is the requirement.

Although cost may be a key driver, medications that have shorter durations of action and wider safety margins have enhanced the potential to deliver safe anesthetic care and, perhaps, by a broader array of healthcare providers. These facts together with different National Regulatory Frameworks have promoted position statements by various national anesthesia organizations focused on the performance of sedation by nonanesthetists [3,4].

Major advances in diagnostic and interventional techniques and the decreasing willingness of patients to tolerate pain and discomfort have raised the expectations that these providers are confronted with. The patient population, on the opposite, is tending to the extremes of life: the very young and the very old.

Key factors to be considered when evaluating remote locations to perform sedation or anesthesia under adequate safety conditions are:

- (1) adequate monitoring;

- (2) policies regarding staffing, equipment, emergency response, and so on;
- (3) sufficient anesthesia support, including specialized rapid response in case of emergency;
- (4) adequacy of procedure and recovery facilities;
- (5) piping of medical gases, meeting air exchange and electrical safety standards, and other engineering issues.

In anesthesia the safety standards have improved considerably over the past two decades, not only by defining the environment of care but also by ensuring appropriate training and certification of those who deliver sedation or anesthesia. Safety and quality is of exceptional importance. Remote locations are usually characterized by a high degree of specialization in treatment (i.e. angio suite, MRI), but often lack equipment for appropriate monitoring and delivery of anesthesia. Quality management and standardizing care have to ensure that conditions in these environments are equivalent to those within the operating room.

This review provides an overview of the monitoring techniques that may be used and the sophistication of anesthesia care that is recommended. It is crucial that all involved in the planning and performing of these procedures understand the requirements imposed by healthcare organizations, specialty societies and National Regulatory Frameworks. General anesthesia should only be administered by qualified, adequately trained and certified providers. To accommodate the increasing demands for anesthesia related services outside the operating room it is perceived that more and more non-anesthesiologists will enter this practice domain. National Societies of Anesthesiology and National Regulatory Frameworks must meet the imperative of ensuring that patient safety is not compromised.

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### Standardized monitoring

Monitoring of vital organ function is mandatory irrespective of the depth of the sedation or anesthesia. Monitoring at remote locations should be equivalent to the operating room standard. Prerequisites in the provision of safe care are the monitoring of hemodynamics and respiration. The monitoring devices should be consistent with American Society of Anesthesiologists (ASA) Standards [5] for Basic Anesthesia Monitoring. The monitoring devices must give an audible signal when their alarm thresholds are exceeded. It is the care providers' accountability to adjust the alarms within reasonable limits.

### Hemodynamic monitoring

Basic hemodynamic monitoring includes an ECG and noninvasive blood pressure (NiBP) measurement.

### ECG

In the absence of a history of cardiac events or cardiac risk factors a three-lead ECG appears reasonable. The five-lead ECG is recommended for patients with a history of ischemic heart disease, chronic heart failure or severe hypertension. The ST-segment analysis of the monitor should be enabled each time a patient is monitored during care.

### Noninvasive blood pressure measurement

Every patient receiving deep sedation or anesthesia shall have arterial blood pressure (BP) determined and evaluated at least every 5 minutes. The same standard can be adapted to any sedating episode. Modern, automatic noninvasive machines employ a detection system based on an oscillometric principle. The shortcomings of the NiBP technique are those of any cuff measurement technique and usually involve patients with obese arms, uncooperative moving patients, and those with very high or very low BP. Even with these limitations, automatic machines are more accurate, precise, and reliable than auscultation techniques [6].

### Invasive blood pressure

An increasing number of potentially invasive procedures are done in remote locations under sedation, such as transjugular portocaval shunt, endovascular stents, or pacemaker/defibrillator insertion. The procedural risk and/or the hemodynamic instability of these often multimorbid patients dictate the need for invasive monitoring of arterial blood pressure.

### Monitoring of respiration

Respiratory depression is a particular concern in patients undergoing procedural sedation or anesthesia. Unrecognized hypoxia and hypercarbia demand close respiratory monitoring. Clinically, respiration may be monitored by chest excursion and auscultation of breath sounds. These methods are imprecise and require supplementation with technologies that monitor the oxygenation and ventilation of the patient.

### Oxygenation

The inspiratory oxygen concentration has to be measured with a low oxygen concentration limit alarm activated. Hemoglobin oxygen saturation (SpO<sub>2</sub>) is monitored by pulse oximetry. Limitations to the value of pulse oximetry exist with vasoconstriction (e.g. shock, hypothermia), excessive movement, synthetic fingernails, and nail polish, severe anemia and abnormal hemoglobins (e.g. methemoglobinemia or carboxyhemoglobinemia). The variable pitch pulse tone and the low threshold alarm must be audible to the care provider.

Desaturation is more likely to occur in patients with reduced functional residual capacity, such as with infants,

obese patients or pregnant women. The administration of oxygen during procedural sedation is a double-edged sword in that oxygen saturations may remain normal, even in the face of apnea for some time. Downs [7] reported that supplemental oxygen during sedation masks the early detection of apnea. On the contrary, an increased fraction of inspired oxygen can prevent alveolar hypoxia caused by the increase of alveolar carbon dioxide concentration during hypoventilation. Nevertheless it is generally accepted that the delivery of supplemental oxygen is the standard of care for procedural sedation and anesthesia.

#### Ventilation

End-tidal carbon dioxide (EtCO<sub>2</sub>) monitoring aids in the detection of apnea in cases where oxygen administration fails to reveal it [8,9]. Continuous monitoring of EtCO<sub>2</sub> will detect clinically occult hypoventilation and is indispensable in patients undergoing deep sedation or general anesthesia. For patients with preexisting pulmonary or cardiac diseases EtCO<sub>2</sub> should be monitored even for light sedation [10].

In spontaneously breathing patients, as opposed to intubated patients, a sampling line for EtCO<sub>2</sub> can be housed together with nasal prongs. However with this technique only breathing activity rate is displayed, although hypoventilation, as indicated by rising EtCO<sub>2</sub>, slowing or cessation of respiratory rate, becomes apparent early to prompt immediate corrective intervention, for example stimulation of breathing, bag-mask ventilation, or sedating agent reversal. During mechanical ventilation, disconnection from the ventilator has to be monitored continuously.

#### Temperature

Operating rooms and remote procedural locations are typically air-conditioned for comfort and to avoid overheating of technical equipment. Both sedation and anesthesia may compromise physiologic thermal homeostatic mechanisms, which put patients who are exposed to cool ambient temperatures at risk for hypothermia. Even moderate hypothermia may be harmful, causing coagulopathy, shivering and patient discomfort. Patients undergoing prolonged anesthesia or sedation should routinely be monitored for temperature, ideally with a continuous temperature probe in the oropharynx or integrated into a Foley catheter [5]. The use of active warming devices for prolonged cases should be considered irrespective of the location.

This basic monitoring should be the minimal standard for safe procedural sedation and anesthesia inside or outside the operating room. However the ASA acknowledges that 'compliance with these guidelines cannot guarantee any specific outcome' [3]. This implies a clear-cut pathophy-

siologic rationale making it impossible to defend a case of patient harm if these basic requirements were not met. In other words, the standard of care does not vary with the location.

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### The here and now: a view on the state of remote sedation and anesthesia care

A recent analysis of the American Society of Anesthesiologists Closed Claims database, from anesthesia claim files throughout the USA, showed a significant risk of adverse effects if anesthesia and sedation were delivered in remote locations [11••]. They found that injuries occurring in remote locations were more severe than those associated with operating rooms. Inadequate oxygenation/ventilation was the most common claim, associated with oversedation and inadequate monitoring. The anesthetic care was judged as substandard in 86% of claims and errors to be preventable by better monitoring in 62% of claims. Many of the claims were associated with 'monitored anesthesia care' (MAC), which is a procedural sedation ranging from light sedation to light general anesthesia. EtCO<sub>2</sub> monitoring was used in only 15% of these cases and is probably the key preventive measure for improving the quality and safety of anesthesia care at locations outside the operating room. In a nationwide survey in the Netherlands the addition of capnography to standard monitoring reduced hypoxia and provided advance warning for all hypoxic events in adults receiving sedation induced by propofol [12]. Improvement in monitoring is the most effective way to decrease the anesthesia complication rate in procedures outside the operating room [13].

In an analysis of 24 claims from incidents during anesthesia by Robbertze *et al.* [14] a greater proportion of claims for death and more substandard care were associated with remote locations than with operating room claims [14]. Inadequate breathing related to oversedation and a lack of adequate monitoring of SpO<sub>2</sub> and EtCO<sub>2</sub> were frequent contributors. Cravero *et al.* [15] supported these findings, observing respiratory complications in approximately one in 400 procedures, mostly associated with anesthesia outside the operating room. The majority of adverse events related to injuries are respiratory in operating rooms, but the proportion of respiratory to total events at remote locations was doubled outside operating rooms (44 vs. 20%), and the proportion of respiratory complications with fatal outcome was also higher (54 vs. 29% inside the operating room) [11••]. One can conclude that procedures at remote locations are more often performed under inferior conditions than those in the operating room. Complications or even fatal outcomes arising from inadequately diagnosed hypoventilation are preventable and need to be taken seriously.

Other potential problems occurring outside the operating room are listed by Melloni [16], including death, hypothermia, airway difficulties, anaphylaxis, postoperative nausea and vomiting and procedure related complications. Kurrek and Twersky [17•] published data collected by the College of Physicians and Surgeons of Alberta of adverse incidents and deaths in registered out-of-hospital facilities. They found a rate of 0.05% for reportable adverse events (243 events for 474 166 procedures) and a death rate of 0.0017% (eight deaths for 474 166 procedures, all unrelated to the anesthetic) from 2002 to 2007. Although the data on mortality and morbidity that are presently available are limited, death and major complications in remote locations seem to occur very rarely.

### **A safe and standardized way of sedation and anesthesia care and monitoring at remote locations: key concepts**

Advances in technology, the diversification of particularly invasive techniques, and the ability to safely provide anesthesia and procedural sedation facilitate a growing number of procedures to be performed outside an operating room environment. This might be an expression of 'what is possible', perhaps at the expense of 'what is best'!

The ongoing improvements in monitoring and medications have embellished the notion that procedural sedation and anesthesia can be performed in a variety of remote locations as safely as in the operating room. However, this is only true if the factors defining that cocoon of safety are also replicated: sophisticated, experienced, adequately trained and certified personnel and advanced, modern, up-to-date monitoring meeting safety standards, appropriate patient selection and the ability to prevent and treat predictable and unpredictable events.

Although perceived economic advantages and physician and patient conveniences continue to drive this development, it must be emphasized that it is the care provider's responsibility to provide safe care to each patient at any time. The establishment of guidelines by national specialty societies reflect the patient safety imperative [18], and are of the utmost importance when care is provided at remote locations, particularly if the care provider is a nonanesthesiologist.

#### **Patient, procedure and location selection**

Several factors prohibit procedures to be safely undertaken outside the operating room:

- (1) significant risk of major blood loss;
- (2) extended duration of surgery (>6 h);
- (3) critically ill patients;

- (4) the need for sophisticated, and at times subspecialized anesthetic or surgical expertise or equipment (cardio-pulmonary bypass, thoracic or intracranial surgery);
- (5) supply and support functions or resources are in limited supply or not immediately available;
- (6) limited provision for postprocedural care;
- (7) the physical plant is inappropriate or fails to meet regulatory standards.

Patient selection is of the utmost importance [19]. It is anticipated that ASA class III or IV patients have a higher rate of complications, rendering many of these patients inappropriate for a nonoperating room setting. However, some procedures are mandated in locations outside the operating room such as cardiologic, endoscopic or radiologic interventions, and the patients receiving those are typically ASA III or IV patients [20]. Under these circumstances it is difficult to determine a standard for patient selection. It seems reasonable to primarily select patients of ASA class I and II [21], and carefully select ASA III and IV patients, depending on the location specificity, the depth of sedation contemplated, the proximity of operating room and ICU facilities and the availability of emergency trained staff. Another special patient population is pediatric patients for a variety of investigations (e.g. MRI, endoscopy, bronchoscopy). Pediatric patients are mostly without comorbidities and data on pediatric sedation/anesthesia outside the operating room show that they are at relatively low risk of adverse events (four aspirations, two cardiac arrests, no deaths among 50 000 sedations) [15].

The responsibility for care begins with preprocedural assessment. Care providers must have detailed knowledge about the planned procedure, complete a thorough evaluation of the patient and get informed consent. The documentation of this assessment must include: assignment of ASA physical status, airway assessment, previous anesthetic history, allergies, fasting status and a medical history and physical examination. Specifically, the suitability of patients with an anticipated or documented difficult airway, morbid obesity, moderate or severe sleep apnea or chronic obstructive pulmonary disease, any end-stage organ failure, including myocardial or cerebral infarction in the last 6 months, uncontrolled diabetes or hypertension, or a history of previous adverse experience with anesthesia and surgery ought to be questioned. If the procedure cannot be performed in the operating room environment for technical reasons, it has to be assured that specialized anesthesia care and support are available to the same extent as in the operating room.

The patient assessment should be done in advance of the scheduled procedure with sufficient time to arrange for additional consultations and investigations as needed. A

patient-specific plan of care is formulated based on patient assessment and the anticipation of potential problems in the unique setting. An open communication between anesthesiologists and physicians working in the nonoperating room environment is the key to efficient and timely provision of anesthesia care to these patients [22\*].

#### Equipment, personnel and safety aspects

An evaluation of the remote procedure location has to be performed prior to providing anesthesia care. The safety of the patient and the care team, such as radiation or electrical/fire hazards and equipment malfunction, has to be taken into account. The evaluation team should take reasonable steps to ensure that established policies regarding fire, safety, drugs, emergencies, staffing, training, and unanticipated patient transfers are in place. The minimum in monitoring equipment as identified above needs to be equipped with a backup power source. Formal arrangements for technical maintenance of the equipment shall be determined.

It may be suitable for anesthesia departments to have mobile anesthesia care units that hold all the needed equipment, such as a mobile ventilator, airway management equipment, comprehensive monitoring and a complete drug cart including emergency drugs. These units can be used in various locations as needed and decrease the capital costs of equipping rarely used locations.

In agreement with consulting services the policies for fasting, preprocedural evaluation and laboratory work, minimal personnel requirements, postprocedure recovery facilities and plans for adequate pain relief, discharge criteria and postprocedural follow-up should be determined [23\*].

Postprocedure, the care provider must provide continuous care for the patient in a properly equipped recovery location until predetermined discharge criteria are fulfilled [24,25]. To be discharged, the patient must have stable vital signs, be fully oriented, and ambulate without dizziness and with minimal pain, nausea, vomiting, or bleeding. The patient should receive specific written instructions, including management of pain, relevant postoperative complications, and routine and emergency follow-up.

Alternatively, postsedation care can be provided by the institution's regular postanesthesia care unit (PACU), if safe transport of the patient from the procedural site to the PACU is guaranteed.

All perioperative care (preprocedure, intraoperative and postprocedure) shall be documented. Accurate documentation facilitates comprehensive patient care, pro-

vides information for review and research, and establishes a medical-legal record.

#### Anesthetic agent and technique

The patient's and proceduralist's expectations need to be integrated into the sedation/anesthesia plan and reconciled beforehand with what is best for the patient, within the capabilities of the facility and consistent with the skills and abilities of the individual performing the sedation or anesthesia. Patient factors such as their physiologic reserve and capacity for pain or stress tolerance; procedure-specific factors such as the intensity of the stimulation anticipated and its duration; and the skill of the proceduralist all come into play. Ultimately, it must be agreed as to the desired patient state for the procedure on the consciousness continuum:

- (1) no sedation or analgesia;
- (2) light sedation and/or analgesia ('conscious sedation');
- (3) moderate sedation and/or analgesia;
- (4) deep sedation;
- (5) general anesthesia.

Generally speaking, 'titratable' drugs are safer and preferred for intravenous titration to the desired stage of sedation and analgesia (e.g. remifentanyl, sufentanyl, propofol). Propofol is often the preferred sedative hypnotic agent for most procedures outside the operating room. Short-acting opioids can be added to establish an acceptable level of analgesia. The absence of an anesthetic gas scavenger system may mandate the use of total intravenous techniques.

Prevention of postoperative nausea and vomiting (PONV) is of great importance to the quality of care. Therefore it has been recommended that opioid-free propofol sedation whenever possible should be employed and that prophylactic antiemetic medication is administered for patients at risk for PONV [26]. Most common antiemetic medications are similarly effective (dexamethasone, scopolamine, 5-hydroxytryptamine 3 antagonists) and can be used according to preference and the numbers of risk factors posed by the patient.

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#### Conclusion

Major advances in procedural and anesthetic techniques, reduced costs for 'ectopic anesthesia' as opposed to the costs of an operating room combined with a high degree of patient and surgeon convenience are the key drivers for a rapidly increasing proportion of procedures performed at remote locations.

The minimum in monitoring is independent from the depth of the sedation or anesthesia and includes: pulse oximetry, continuous ECG (including five-lead

capability), BP, end-tidal carbon dioxide and temperature monitoring.

Anesthesia care outside the operating room can be done safely provided recommended standards and guidelines are followed. Patient and location selection, coupled with equipment, personnel and periprocedural policies, will determine which cases can be done safely in remote locations.

## References and recommended reading

Papers of particular interest, published within the annual period of review, have been highlighted as:

- of special interest
- of outstanding interest

Additional references related to this topic can also be found in the Current World Literature section in this issue (p. 537).

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