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GUIDELINE

Practical guide for safe sedation

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Abstract

This practical guide has been developed to ensure safe and effective sedation performed in adult patients outside of the operating room, for instance in intensive care units and dental treatment rooms and in the field of palliative care. Sedation levels are classified based on level of consciousness, airway reflex, spontaneous ventilation, and cardiovascular function. Deep sedation induces loss of consciousness and protective reflexes, and can cause respiratory depression and pulmonary aspiration. Invasive medical procedures necessitating deep sedation include cardiac ablation, endoscopic submucosal dissection, and internal radiation therapy. Appropriate analgesia is necessary for procedures that require deep sedation. The sedationist should evaluate the risks of the planned procedure, explain the sedation process to the patient, and obtain the patient's informed consent. Major parameters to be evaluated preoperatively are the patient's airway and general condition. Equipment, instruments, and drugs necessary for emergency situations should be defined and routinely maintained. To prevent aspiration, patients scheduled for moderate or deep sedation should fast preoperatively. In both inpatients and outpatients, biological monitoring should be continued until the discharge criteria are met. Anesthesiologists should be involved in management systems that ensure safe and effective sedation even if they do not personally perform all sedation procedures.

Keywords Sedation · Patient safety · Practice guideline · Non-anesthesiologists

Basic principles and overview

This practical guide has been developed to ensure safe and effective sedation performed in adult patients outside of the operating room, for instance in intensive care units and dental treatment rooms and in the palliative care field. In a wide variety of clinical settings, sedation is performed to alleviate discomfort and pain associated with invasive surgical and

Practical guide for safe sedation were published in Japanese in November 2021. We share these guidelines in English with healthcare professionals and the general public around the world to improve medical practice and patient outcomes.

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diagnostic procedures. The target level or depth of sedation depends on clinical needs. The term "sedation" may be used to refer to different states of consciousness in patients under treatment, ranging from fully conscious (minimal sedation) to totally unconscious (deep sedation). Because medical practitioners understand and use the term according to their own experiences, miscommunications regarding sedation may occur unnoticed during multidisciplinary medical consultations and other discussions involving multiple medical personnel.

In this practical guide, we describe different levels of sedation, build common understanding of the levels of sedation required in major clinical settings, and provide criteria for safe sedation. Since monitoring the effects of sedation should be performed by a team of physicians, nurses, clinical engineers, and other experts, this practical guide will help them develop a shared understanding about safe sedation.

Various sedative drugs are used worldwide. In Japan, however, only a few sedative drugs have been approved for clinical use. This situation needs to be improved. Moreover, effective monitoring and emergency response systems need to be established to secure the safety of patients undergoing sedation, particularly deep sedation. To this end, national health policies should be strengthened to improve the safety, quality, and accessibility of sedation services.

In this guide, the quality of evidence and the strengths of various recommendations were determined based on the *Minds Handbook for Clinical Practice Guideline Development 2014* and the *GRADE System for Clinical Practice Guideline: Therapeutic Intervention Study.* Recommendation strengths were classified into the following categories:

A: Mandatory.

B: Strongly recommended.

C: Desirable.

These symbols are shown in bold italic type and enclosed in brackets at the end of relevant recommendations. Symbols are presented immediately following a heading or title if all recommendations in that section belong to the same category.

Classification and definition of sedation

Sedation is completely different from natural sleep. Individuals in natural sleep awaken if their ventilatory or circulatory system begins to fail. Snoring does not cause airway obstruction, respiratory arrest, or cardiac arrest. While drug sedation superficially resembles natural sleep, it involves a completely different physiological state. Sedatives, even in small doses, can cause upper airway obstruction. There is also a risk of respiratory or cardiac arrest depending on the patient's condition.

1. Sedation occurs in a series of stages

The figure depicts the following. Drug doses are shown on the x-axis, physiologic states are shown on the y-axis, and the range of monitored anesthesia care (MAC) is shown by an ellipse (Fig. 1). The consciousness level gradually decreases from the wakeful state as the drug dose is incrementally increased. Then, at a certain dose, consciousness is lost and there is a progressive loss of protective reflexes. The boundaries between levels of minimal sedation, moderate sedation, deep sedation, and general anesthesia are ambiguous, and care should be taken.

2. Classification and definition of sedation and general anesthesia

Table 1 shows that grades of sedation and general anesthesia are classified by responsiveness (consciousness level), airway status, spontaneous ventilation, and cardiovascular function.

- Minimal sedation is a drug-induced state during which patients respond normally to verbal stimulation. Airway status, ventilation, and cardiovascular functions are unaffected.
- Moderate sedation is a drug-induced depression of consciousness in which patients respond purposefully to verbal commands (either alone or accompanied by light tactile stimulation), no interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
- Deep sedation suppresses consciousness and protective reflexes, but patients readily respond purposefully following repeated or painful stimulation. Patients may require assistance in maintaining a patent airway, and

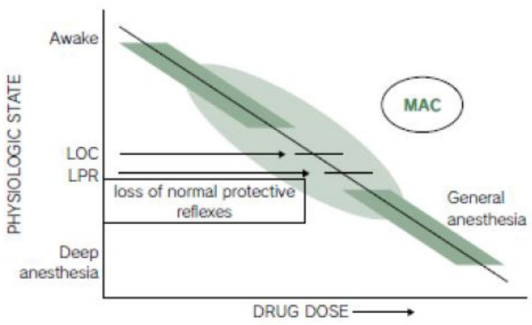

Fig. 1 A conceptual representation of the physiologic state of a patient under sedative or anesthetic treatment [14]. The shaded elliptic area represents monitored anesthesia care (MAC) in which anesthesiologists provide or direct specific diagnostic or therapeutic services. *LOC* loss of consciousness, *LPR* loss of protective reflex

Table 1 Classification and definitions of sedation and general anesthesia

	Minimal sedation	Moderate sedation	Deep sedation	General anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful response to verbal or tactile stimulation	Purposeful response after repeated or painful stimulation	Unarousable, even with painful stimuli
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

Moderate sedation and deep sedation are very different, as indicated by the parameters discussed above. It should be emphasized that the distinction between these two classifications is important when considering safety (green line in the center of the table). The degree of sedation should always be considered in conjunction with other factors, including the stress of invasive procedures, the level of responsiveness, and the level of action associated with each sedative used. Even if a drug usually causes minimal sedation, moderate sedation can easily be reached depending on the dose. Deep sedation is achieved by finding the correct balance between the invasiveness of the procedure and the degree of sedation resulting from analgesics.

Deep sedation and anesthesia

1. Deep sedation

Deep sedation is different from minimal and moderate sedation, as it is defined by loss of consciousness and suppression of protective reflexes. It is used in the context of highly invasive and painful procedures such as surgery. When some analgesics and sedatives exceed the proper dose, the patient loses their protective reflex and develops respiratory depression.

Since deep sedation and general anesthesia overlap, deep sedation requires the same careful management as general anesthesia. There is no relationship between drug type and safety, it affects the airway, ventilation, and circulation.

The primary complications of deep sedation are respiratory depression and aspiration. Medical safety management system is always the most important consideration, not what sedatives or analgesics are used.

2. Deep sedation and intravenous anesthesia

Anesthetics are classified according to their route of administration. Intravenous anesthetics reach the central nervous system is intravenous anesthesia and general anesthesia. The level of sedation may be minimal, moderate, or deep depending on the administration rate and dose of the anesthetic and differences between patients, and general anesthesia is also possible.

Again, the boundaries between deep sedation and general anesthesia with intravenous anesthetics are ambiguous. As such, sedationists aiming for deep sedation must also be able to manage general anesthesia.

3. Indications for deep sedation with intravenous anesthesia

Invasive medical procedures that require deep sedation include cardiac ablation, endoscopic submucosal dissection, and internal radiation therapy or brachytherapy. Dislocation reduction is an indication for intravenous anesthesia. If long-term immobilization is required, a muscle relaxant is needed and general anesthesia is indicated.

Sedation and analgesia

Sedatives and analgesics have different clinical purposes. While sedatives are used to relieve anxiety and induce sleep, analgesics aim to relieve pain. Highly invasive procedures that require deep sedation also require appropriate use of analgesics. Like hypoxemia, hypoglycemia, and hypotension, pain is a major cause of agitation and contributes to failed sedation. Adequate analgesia is often emphasized before sedation [1] ("analgesia-first" sedation). This approach helps prevent complications resulting from sedative overdose. The combination of sedatives and analgesics also improves patient satisfaction [2].

1. Significance of concomitant analgesics

The following points should be considered regarding concomitant use of analgesics:

- Highly invasive procedures are very painful.
- Sedatives show less potent pain-relieving effects than analgesics.
- Adequate analgesia helps reduce sedative doses.
- Appropriate analgesia helps prevent complications of sedative overdose.

2. Typical sedatives

a. Midazolam

Midazolam is used for the following purposes: pre-anesthetic medication, induction and maintenance of general anesthesia, sedation in mechanically ventilated intensive care unit (ICU) patients, sedation during local anesthesia, and seizure treatment.

For sedation during local or regional anesthesia, midazolam should preferably be administered under the supervision of an anesthesiologist. The following points should be noted:

- The usual adult dose of midazolam is 0.02–0.03 mg/kg. The drug should be infused slowly via an intravenous line.
- When necessary, administer an additional dose that is equal to or half of the initial dose.
- Patients may require doses higher than those specified above. In such cases, attention should be paid to avoid oversedation and respiratory and cardiovascular depression.
- Apnea, respiratory depression, and glossoptosis may develop. These conditions should be treated by securing airway patency, and through ventilation and other appropriate means.
- If necessary, midazolam sedation may be reversed with the benzodiazepine antagonist flumazenil.

b. Dexmedetomidine hydrochloride

Dexmedetomidine hydrochloride is used for the purposes listed below.

An infusion pump is used for continuous intravenous administration of dexmedetomidine. Attention should be paid to hemodynamic changes when administering the drug. The recommended maintenance infusion rate is 0.2–0.7 μg/kg/h. Higher rates may sometimes be required to reach the desired level of sedation.

3. Common analgesics

a. Fentanyl

- Sedation in mechanically ventilated ICU patients and in patients weaned off of mechanical ventilation. This drug can be administered long term.
- Sedation and analgesia in non-intubated ICU patients. Examples include patients with acute aortic dissection undergoing conservative treatment, patients requiring bed rest after trauma or surgery, and pediatric patients.
- Adjunct to general anesthesia (off-label use). Dexmedetomidine helps reduce the dose of anesthetics needed, stabilize the cardiovascular system, prevent shivering in waking patients, and suppress postoperative delirium.
- Sedation of non-intubated Patients prior to or during medical procedures such as awake craniotomy, epidural anesthesia, and spinal subarachnoid anesthesia, as well as endoscopic tracheal intubation (off-label use).
- Sedation during diagnostic examinations. Dexmedetomidine is effective for alleviating anxiety in pediatric and adult patients undergoing computed tomography, magnetic resonance imaging, electroencephalography, and other scans.

Fentanyl citrate is used for the following purposes: analgesic supplement in general anesthesia, analgesic adjuvant to local or regional anesthesia, and alleviation of severe pain (e.g., acute postoperative or cancer).

Fentanyl is typically used as a supplement in general anesthesia. Previously, fentanyl citrate was commonly used in combination with the neuroleptic droperidol for neuroleptanalgesia. More recently, fentanyl citrate has increasingly been used (i) to prevent rises in blood pressure and cardiac output associated tracheal intubation, (ii) for anesthetic induction with intravenous anesthetics, (iii) in combination with inhaled general anesthetics, and (iv) as an analgesic in general anesthesia with intravenous propofol. To induce sedation, 0.5–2 μg/kg of fentanyl is administered intravenously, and bolus 25–50 μg doses may be added for maintenance.

As an analgesic adjunct to local or regional anesthesia, fentanyl citrate at a dose of 1–3 μg/kg is administered intravenously.

4. Common Intravenous Anesthetics and Sedatives

a. Propofol

Propofol is used for the following purposes: (i) induction and maintenance of general anesthesia (most common indication), (ii) sedation during regional anesthesia or clinical examination, and (iii) ICU sedation of mechanically ventilated patients. It should be noted that Item (ii) has not been approved in Japan.

Propofol may be administered as a bolus or continuous infusion. A target-controlled infusion (TCI) pump (e.g., Diprifusor™) has been developed for continuous dosing of

propofol. The TCI system uses pharmacokinetic modeling to regulate the infusion rate and blood drug concentrations.

For sedation during local or regional anesthesia or diagnostic procedures, an initial dose of 0.5 mg/kg is infused over a period of 3–5 min, followed by maintenance infusion at a rate of 2 mg/kg/h (range: 1.5–4.5). When the Diprifusor™ TCI system is used, the target blood concentration of propofol is preferably set at 1.0–2.0 μg/mL. Given interindividual variation, the target blood concentration should be gradually increased and titrated to achieve a desirable clinical response while closely monitoring cardiorespiratory function. An emergency backup team consisting of a sedationist, anesthesiologist, intensivist, and other healthcare experts should be in place to respond to significant changes in hemodynamic and other parameters that are continuously measured by pulse oximeters and capnometers. Oxygenation should be administered when necessary. Blood pressure should be measured at least once every 5 min to monitor for hypotension.

Prolonged and high-dose infusions of propofol should be avoided in children. Propofol should also be avoided in patients with a known hypersensitivity to propofol and other components of the emulsion formulations (e.g., soybean oil, egg yolk lecithin).

Explanation and consent

Patients have the right to be fully informed of and understand the benefits and risks of the sedation required for their surgical or non-surgical interventions and diagnostic procedures. The sedationist should explain the sedation approach and obtain the patient's informed consent. The consent form must provide details about the sedation procedure, the types of sedation medications, and their complications [3–5]. Any other matters that the sedationist explains and are agreed to by the patient should be documented in the medical chart. Patients may withdraw their consent even after signing the consent form. If consent is withdrawn, the reason should be recorded in the medical chart.

1. Explanation of sedation procedures [*B*]

By the day before the medical procedure, the sedationist will explain the following matters:

- Pre-procedural patient evaluation (for details see Chapter "Patient evaluation")
- Duration of sedation, i.e., the expected duration of the procedure and the time until the patient can go home
- Oral ingestion restrictions (for details see Chapter "Oral intake restrictions")
- Sedation medications
- Hospitalization criteria for outpatients undergoing highly invasive procedures. On the day of the surgical or non-surgical intervention, or diagnostic procedure, the sedationist will explain the following matters:
- Final criteria for withholding the procedure (e.g., in the case of patients with acute airway disease)
- Venous access necessary for deep sedation
- Staff member(s) in charge of patient monitoring and recording
- Management of possible sedation complications (for details see Chapter "Emergency backup")
- Patient monitoring in the recovery room (for details see Chapter "Postsedation care and confirmation of recovery")
- Possible emergent termination of the procedure during sedation and procedure postponement

2. Explanation of the types of sedatives and their complications [*B*]

Regarding the types of sedatives and their complications, the sedationist will explain the following:

- Types of sedatives (e.g., oral, suppository, and intravenous) selected for the patient
- Incidence and management of mild complications
- Incidence and management of severe complications.

Preprocedural patient evaluation [*B*]

The sedationist should evaluate the risks of the planned sedation procedure and determine whether an anesthesiologist or other healthcare professionals with expertise in sedation should be called in for help. Major evaluation parameters relate to the patient's airway and general condition. The risks of sedation-induced airway obstruction and respiratory depression should be assessed. Sedation must be performed with extreme caution if airway management and ventilatory support are challenging (e.g., cases with difficult intubation) [6–12]. Patients with an American Society of Anesthesiologists Physical Status (ASA-PS) score of III or greater and those with anatomic airway abnormalities are at elevated risks of sedation-related complications. For these patients, the sedationist should make careful a decision on the optimal sedation method, consulting an experienced anesthesiologist.

1. Evaluation parameters

a. Patient interview

The physician conducting the medical interview of a patient scheduled to undergo procedural sedation should evaluate the following parameters: age, current medications, allergies, factors relevant to airway obstruction, and underlying medical conditions that may lead to sedation-related complications.

Factors relevant to airway obstruction can be classified as follows:

- Oral: snoring, nocturnal awakening, breathlessness, obesity, and tonsil/adenoid hypertrophy
- Lower airway: tracheal stenosis, tracheomalacia/bronchomalacia, airway foreign bodies, and intratracheal tumors
- Non-airway: neoplastic lesions in the neck and mediastinum, including cervical lymphangioma, and thyroid tumor.

Underlying medical conditions that may lead to sedation-related complications can be categorized as follows:

- Cardiac: congenital heart diseases, congestive heart failure, and arrhythmia
- Respiratory: sleep apnea and bronchial asthma
- Neuromuscular: cerebral palsy, myopathy, epilepsy, and ventricular shunt
- Gastrointestinal: gastroesophageal reflux disease and gastrointestinal tract stenosis
- Preterm and low birth weight infants: chronic lung disease and apnea
- Liver and renal dysfunction

b. Physical examination

Physical examination should include height, weight, vital signs (blood pressure, heart rate, respiratory rate, percutaneous oxygen saturation [SpO2], and body temperature), and airway assessment.

Airway assessment includes the following:

- Acute airway infection and signs of allergy (nasal obstruction, nasal discharge)
- Facial abnormalities, tonsillar hypertrophy, trismus, macroglossia, micrognathia, and cervical extension problems
- Mallampati classification

The Mallampati classification is evaluated based on visualization of the faucial pillars, soft palate, and uvula when the mouth is opened as wide as possible, and classes III and IV suggest difficult intubation. The classes are defined as follows:

- I, faucial pillars, soft palate, and uvula are fully visible
- II, faucial pillars, soft palate, and upper part of the uvula are visible
- III, only the soft palate is visible
- IV, soft palate is not visible at all

c. ASA-physical status

Patients classified as ASA-PS Categories III, IV, V, and VI should be sedated at medical institutions staffed with anesthesiologists, intensivists, and emergency physicians. ASA-PS categories include the following:

- I: normal healthy patients
- II: patients with mild systemic disease (e.g., asthma without exacerbation)
- III: patients with severe systemic disease (e.g., asthma with exacerbation)
- IV: patients with severe systemic disease that is a constant threat to life (e.g., head trauma)
- V: moribund patients who are not expected to survive without the operation (e.g., brain herniation and hemorrhagic shock)
- VI: patients declared brain dead and whose organs are being removed for donor purposes.

The sedationist will assess the overall risk of sedation-related complications based on the results of the patient interview and physical examination.

Emergency backup

Equipment, instruments, and medications necessary for emergency situations should be defined in consultation with the emergency backup team. They should be routinely maintained to ensure that they are immediately available [*B*].

1. Preparation for emergencies

Sedatives may cause serious complications such as airway obstruction and respiratory arrest, and occasionally bradycardia and cardiac arrest. Therefore, when sedation is performed, the equipment and instruments needed for emergencies and resuscitation must be available, and an emergency backup team must be assigned in advance [***A***].

2. Airway and respiratory complications

Deep sedation may cause airway and respiratory complications, such as airway obstruction, hypoventilation, hypercapnia, hypoxemia, and respiratory arrest. These may further

lead to hypotension, bradycardia, and cardiac arrest. Serious anaphylactic reactions are rare but still possible. Appropriate medical staff, equipment, and instruments must be available to immediately respond to these complications and emergencies [*A*].

3. Assignment of a physician or nurse to oversee patient monitoring [13–15]

A physician or nurse must be dedicated to the task of monitoring the patient under sedation [*A*]. This individual must be sufficient trained to appropriately handle medical emergencies. Their tasks include calling for the emergency backup team and conducting basic life support procedures (at least manual ventilation with a bag mask) until the emergency backup team arrives [*A*].

4. Installation and maintenance of equipment in the sedation room

The room where sedation is performed must be equipped with an oxygen supply and vacuum suction pipeline system [*A*]. If no such pipeline system has been installed, a medical oxygen cylinder and suction device must be ready for use [*A*].

5. Emergency backup

Protocols must be developed that specify the details of the backup team, the procedure for calling for their help, and the storage location for emergency equipment and instruments [*A*]. We strongly recommend that medical institutions stipulate the details of emergency backup measures to be carried out during staff shortages, such as during night hours and holidays [*B*]. We also strongly recommend that the emergency backup team include anesthesiologists, emergency physicians, and other medical professionals with experience in medical emergencies [*B*].

6. Provision and maintenance of emergency equipment, instruments, and drugs

Life-saving and resuscitation attempts must be made in cases of medical emergencies [*A*]. Emergency carts and other supply kits must be kept in place to allow for immediate access to equipment, devices (e.g., a defibrillator for cardiopulmonary resuscitation), and medications (for more details, see Table 2) [*A*]. Defibrillators, laryngoscopes, and other instruments must be regularly maintained for future use [*A*]. Emergency equipment and devices such as those used in airway management, suctioning, and venous access should be available. Medication drawers should contain sufficient amounts of necessary resuscitation drugs. We strongly recommend that hospital management consult with the emergency backup team to determine the types and amounts of equipment, devices, and medications to store in crash carts [*B*].

Table 2 Examples of devices and drugs required for the emergency cart

Devices[a]	Medium-density oxygen masks (standard type)
	Face masks (various sizes)
	Bag valve mask
	Nasopharyngeal airway tubes (various sizes)
	Oropharyngeal airway tubes (various sizes)
	Bite blocks
	Laryngoscopes
	Tracheal tubes
	Stylets
	Endotracheal tube holders and devices
	Stethoscope
	Capnometer
	Suction catheters
	Syringes
	Infusion lines
Drugs[b]	Resuscitation drugs (e.g., adrenaline, atropine)
	Vasoactive drugs
	Intravenous fluids
	Physiological saline (for dilution or dissolution)
	Adrenocortical hormone preparations (e.g., methylprednisolone)
	Antihistamines (e.g., chlorpheniramine)

[a]Different sizes should be available to suit the patient's age and size [*A*]

[b]We strongly recommend including weight-based dosing charts for quick emergency reference [*B*]

7. Proposal for a sedation cart

We propose that a dedicated cart be set up to expedite sedation-related emergency responses (Tables 3 and 4). Sedation carts should specifically contain medications and instruments that are not necessarily included in crash carts but are useful for responding to sedation complications. Some drugs need to be locked up to prevent unauthorized access. Security arrangements for storing these drugs should be made in consultation with the department of pharmacy.

Preprocedural preparation

Sedatives inhibit airway reflexes, increasing the risk of pulmonary aspiration. To prevent aspiration, patients scheduled for moderate or deep sedation should be advised to refrain

Table 3 A proposed dedicated sedation cart: comparison with emergency, anesthesia, and difficult airway carts

	Drugs	Devices/instruments	Monitors
Emergency cart	Vasoactive drugs Resuscitation drugs	Face mask Airway SGA Tracheal intubation device BVM	SpO_2 End-tidal CO_2 BP ECG
Anesthesia cart	Sedatives Analgesics Muscle relaxants Vasoactive drugs	Face mask Airway SGA Tracheal intubation device	SpO_2 End-tidal CO_2 BP ECG body temperature EEG
Difficult airway cart	Local anesthetics	Face mask Airway SGA Tracheal intubation device Surgical airway management device	SpO_2 end-tidal CO_2
Sedation cart	Sedatives Analgesics Antagonists of the above Drugs Vasoactive drugs	Face mask Airway SGA Tracheal intubation device BVM	SpO_2 End-tidal CO_2 BP ECG

Because anesthesia carts and difficult airway carts contain a wide range of equipment and medications, carts dedicated to sedation management can be useful at medical institutions where procedural sedation is frequently administered. Tracheal intubation devices include the classical laryngoscope, video laryngoscope, and bronchoscope

SGA supraglottic airway device, *BVM* bag valve mask, SpO_2 percutaneous oxygen saturation, CO_2 carbon dioxide, *BP* blood pressure, *ECG* electrocardiography, *EEG* electroencephalography

Table 4 Examples of sedation cart contents

Drugs	Analgesics
	Sedatives
	Muscle relaxants
	Antagonists of above drugs
	vasoactive drugs
Airway devices	Supraglottic airway tubes (familiar to the team, various sizes)
	Good-fitting face masks (various sizes)
	Special devices to assist with intubation (e.g., video laryngoscope)
	Tracheal tubes (various sizes, especially those with small diameters)

from oral intake for a certain period before starting sedation [13, 15, 16]. If the patient's condition suggests that aspiration may occur, its risk should be evaluated in more depth.

1. Rationale behind oral intake restrictions [*B*]

Sedatives suppress airway reflexes. This elevates the risk of pulmonary aspiration due to regurgitation of gastric contents. To minimize the risk of aspiration, patients should refrain from oral intake before surgical or diagnostic procedures. Restrictions on oral intake should continue until the patient is fully awake.

2. Evaluating the risk of sedation-related aspiration [*B*]

Before administering sedation, the sedationist should explain the risks of aspiration to the patient, ensure their understanding, and obtain consent. Regardless of their dose or route of administration, sedatives are associated with the risk of aspiration. Patients with gastrointestinal stenosis or dysfunction may require more stringent intake restrictions. In addition, aspiration complicates airway management in patients with difficult airways.

3. Restrictions of oral intake before sedation [*B*]

Oral intake restrictions for patients undergoing sedation are the same as those for patients undergoing general anesthesia. Specifically, adults should refrain from ingesting clear fluids and solid materials for at least 2 and 6 h before induction, respectively.

4. Balancing the need for emergency interventions and the risk of sedation-related aspiration

The sedationist must check the times at which the patient last ate and drank [***A***]. Using medical records, physical examination findings, interviews, and other sources, the sedationist should collect data to assess the patient's aspiration risk [***B***]. Patients with gastrointestinal stenosis or dysfunction, trauma, impaired consciousness, and severe obesity require a longer time to excrete gastric contents than those without these conditions. The sedationist should weigh the benefits and urgency of the surgical or diagnostic procedure and the risks of sedation. If the procedure is urgent and the patient has a high risk of aspiration, it is desirable to conduct the procedure under endotracheal intubation and general anesthesia.

Patient monitoring

1. Presedation check-up [*B*]

Before the patient receives sedatives or analgesics, his or her condition should be evaluated using a well-designed checklist (Table 5). This evaluation should be conducted by the physician in charge of sedation and one or more additional medical staff members. The sedationist should have knowledge about the characteristics, contraindications, and possible adverse reactions of the planned sedatives, as well as skills to solve problems associated with the sedation [13].

a. Issues to check on the day of sedation

On the day of sedation, the physician in charge of sedation will ensure that the following matters have been addressed before administering sedation: the last meal time [*A*], symptoms of acute respiratory tract infection [*A*], any contraindications to the planned sedative [A], and vital signs immediately prior to sedation (blood pressure, heart rate, respiratory rate, SpO_2, and temperature) [B].

b. Preparation and confirmation of items necessary for resuscitation [*B*]

All materials and supplies prepared for resuscitation should fit the size of the patient undergoing sedation, and should be free from damage and be ready for use. The contents of the crash cart and other emergency trolleys should be inspected for expiration and defects (see also Chapter "Emergency Backup").

c. Preparing monitors [*B*]

A fully functional pulse oximeter, blood pressure monitor, and electrocardiograph machine should be installed before induction. We strongly recommend ventilation monitoring with an end-tidal carbon dioxide monitor (capnometer) [17].

d. Confirming the emergency backup system [*B*]

Medical institutions providing sedation services should establish an emergency response system and document the procedures for activating it. Table 6 shows a basic example of a safe sedation checklist [18].

2. Patient monitoring from induction to the end of the sedation procedure [*B*]

a. Assignment of medical staff for patient monitoring

One or more physicians or nurses should be dedicated to the task of patient monitoring. From the time of sedation induction until the patient awakes, the patient monitors will watch for any abnormalities the patient may develop and take appropriate remedial actions if necessary.

b. Patient monitor qualifications

The sedationist must have good knowledge and skills pertaining to resuscitation. They must be capable of implementing resuscitative measures such as airway management, manual ventilation, and circulatory support. If a resuscitation attempt is necessary, the emergency backup team should be called in.

c. Patient monitor tasks

Patient SpO2 levels should be continuously checked with a pulse oximeter. Patient monitors should assess changes in blood pressure and electrocardiogram to detect and control hemodynamic instability, arrhythmia, and other risks. Note that SpO2 is not an indicator of alveolar ventilation. SpO2 levels may remain relatively high even when patients develop hypercarbia. For early detection of hypoventilation, it is useful to monitor end-tidal carbon dioxide levels using a capnometer.

Table 5 An example of a presedation checklist

Date of sedation:	_____ (/MM/DD/YYYY)
Drug(s) to be used:	
ASA-PS classification	I II III IV
Mallampati classification	I II III IV
Allergies	□No □Yes
Regular medication	□No □Yes
	If yes, enter drug name:
Any risk factors for airway obstruction	□No □Yes
Any sedation problems in the past	□No □Yes
Contraindication for the planned sedatives	□No □Yes
Signed the sedation consent form	□No □Yes
Presedation checkup completed on the day of scheduled procedure	
Blood pressure	mmHg
Heart rate	/minute
Respiratory rate	/minute
SpO_2	%
Body temperature	°C
Any upper respiratory tract infections	□No □Yes
Last meal time	____ hours _____ minutes
Last drinking time	____ hours _____ minutes
Signatures	
Sedationist:	
Nurse:	

Table 5 (continued) *ASA-PS* American Society of Anesthesiologists Physical Status, SpO_2 percutaneous oxygen saturation

d. Recording of monitored parameters

The sedationist should record vital signs at regular intervals, as a general rule every 5 min. The format for vital sign recording should correspond with that used in anesthetic procedures.

Temporal changes in blood pressure, heart rate, and SpO2 should be recorded during sedation. The respiratory rates should also be documented, if chest movements are visible. Moreover, end-tidal CO2 measured by the capnometer should be reported.

e. Postprocedural monitoring

For details of patient monitoring and recordkeeping requirements after completion of the procedure, please refer to Chapter "Postsedation care and confirmation of recovery."

Postsedation care and confirmation of recovery

The patient remains sedated upon completion of a surgical or diagnostic procedure involving sedation. Sedation is considered to have ended when the patient is fully awake, close to his or her presedation state, and able to return to daily activities [13]. Until the patient has sufficiently recovered consciousness, he or she should be treated in the same manner as during sedation. The patient should only be allowed to return to the ward or home after the sedationist confirms that it is safe to do so. Patient monitoring should be continued for outpatients until home discharge criteria are met, and for inpatients until the criteria are met for both return to the ward and termination of sedation-related recordkeeping.

1. Postsedation measures common to outpatients and inpatients

a. Recovery room [*C*]

The recovery room should be equipped with a pulse oximeter, oxygen supply, suction device, and capnometer. The location of equipment and instruments to be used in emergency situations should be communicated to the sedation staff. Resuscitation kits and other supplies should be readily available when required. A sufficient number of medical staff should be available to respond to medical emergencies. A document that describes emergency response systems and procedures should be established.

b. Patient monitoring staff [*C*]

One or more physicians or nurses should be assigned to detect and respond to the development of abnormal vital signs.

c. Patient monitoring tasks [*C*]

The staff assigned to patient monitoring should continuously monitor SpO2 levels using a pulse oximeter and measure respiratory rates by visual inspection or auscultation. They should also check for changes in blood pressure and electrocardiogram to prevent hemodynamic instability, arrhythmia, and other risks. Note that SpO2 is not an indicator of alveolar ventilation. SpO2 levels may remain relatively high even when patients develop hypercarbia. Monitoring end-tidal carbon dioxide levels is useful for early detection of hypoventilation.

The following variables should be recorded: level of consciousness, blood pressure, heart rate, SpO2, respiratory rate (including respiratory findings such as labored breathing and abnormal breath sounds), temperature, and others (e.g., nausea and vomiting, time of resuming water intake).

d. Actions for abnormalities noted during monitoring [*B*]

If any abnormality occurs during monitoring, the patient's airway and breathing should be quickly examined, and the sedationist or other physicians skilled in respiratory management and resuscitation must be called immediately.

2. Postprocedural management of outpatients

Outpatients will be allowed to return home when they meet specific home discharge criteria [*B*]. Conformity to the criteria should be ultimately confirmed by the physician to whom the sedationist has delegated this responsibility [*B*].

a. Discharge criteria (must include each of the following) [*A*]:

- Normal vital signs (i.e., recovery to presedation levels)
- Recovery of consciousness to the presedation level and the ability to walk without assistance (or with usual aids, if applicable)
- Stable respiratory status with no evidence of labored breathing or abnormal breath sounds
- Ability to drink water without vomiting
- No need for oxygenation, suctioning, or other care

b. Other requirements to check [*B*]

- Presence of a caregiver to monitor patient at home

Table 6 An example of a safe sedation checklist

Before admission to procedure room

□ Patient evaluation

- medical history, findings, and overall assessment
- problems with allergies or airway

□ Informed consent for sedation

□ Confirmation of last meal/drink time

□ Monitoring devices

- end-tidal CO2, SpO2, blood pressure, heart rate, ECG

□ Drugs and oxygen supply

□ Equipment

□ Patient monitoring and recording

□ Identification of sedation manager, sedationist, and monitors

□ Emergency response team

Preprocedural timeout

□ Team member introductions

- chief surgeon/operator, sedationist, patient monitors

□ Major anticipated events shared by all team members

Preprocedural timeout

□ Team member introductions

- chief surgeon/operator, sedationist, patient monitors

□ Major anticipated events shared by all team members

During procedure

□ Respiratory status

- Respiratory rate and patterns

□ Biometric monitoring

- end-tidal CO_2, SpO_2, blood pressure, heart rate, ECG

Table 6 (continued)

- Dose titration
- Vital sign recording: 5-minute intervals
- Need for oxygenation
- Early detection of complications
- Respiratory depression, cardiovascular suppression, aspiration, allergic reactions (acute and delayed), cardiopulmonary arrest
- Medical emergency preparedness

Personnel, materials (drugs, equipment), support system

Postprocedural care

- Patient monitoring by trained staff
- Bedside observation: 30 minutes
- State of consciousness
- Biometric monitoring
  - end-tidal CO_2, SpO_2, blood pressure, heart rate, ECG
- Discharge criteria
  - Aldrete score
  - absence of pain, nausea, and dizziness
  - presence or absence of caregiver
- Adequate specimen storage
- Attending physician responsibilities:
  - future course and plans
  - explanation about possible complications and their treatment
- In case of adverse events
  - patient follow-up
  - reporting to the medical safety office

The hospital management, medical safety office, and anesthesiologists should work together to establish sedation surveillance programs to guarantee patient safety. Adapted with modifications from the *Guidelines for Safe Surgery* published by the World Health Organization, *Practice Guidelines for Sedation and Analgesia* published by the American Society of Anesthesiologists, *Guidelines for Procedural Sedation and Analgesia* jointly published by the European Society of Anesthesiology and European Board of Anesthesiology, and sedation standards published by the Joint Commission International

- Caregiver received explanations and instructions for home discharge
- Caregiver informed about how to contact the medical institution if the patient develops abnormal signs at home
- Understanding the need for prescribed medications and a follow-up appointment
- Prohibition from driving home

c. Discharge guidance for caregivers [*C*]

- Information on possible postsedation events and how to approach them
- Guidance in the form of relevant written materials and a signature to indicate comprehension

The option of an overnight stay or transfer to another medical institution must be considered if the patient has not recovered well enough to leave for home [*B*]. If it is agreed that the patient will be admitted to a ward overnight or transferred to another hospital, the sedationist with similar expertise in sedation should accompany the patient.

3. Postprocedural management of inpatients [*B*]

Inpatients should be allowed to return to their wards only when specific criteria are met. Conformity to the criteria should ultimately be confirmed by the sedationist or by a physician to whom the sedationist has delegated the responsibility.

a. Ward discharge criteria

- Normal vital signs (i.e., recovery to presedation levels)
- Complete or near-complete recovery to the presedation level of consciousness
- Stable respiratory status with no evidence of labored breathing or abnormal breath sounds

b. Other requirements to check

- Continuous pulse oximeter monitoring in the patient's ward room
- Organizational structure for emergency response

c. Prerequisites for terminating monitoring and record-keeping

- Nursing care to assist with the patient's oral liquid intake and ambulation on the ward
- Confirming the safety of both liquid intake and ambulation

4. Scoring system to evaluate recovery [*C*]

Degrees of recovery should be evaluated chronologically. A semiquantitative scoring system to evaluate patient recovery, such as the Modified Aldrete Score [19], can be a useful tool to make objective and consistent judgments across shift changes.

Sedation management and surveillance

1. Management system to ensure safe sedation [*B*]

Given that sedation is similar to general anesthesia in many respects, it is preferable that anesthesiologists provide sedation services. In Japan and many other parts of the world, however, this is not always the case. Patients with various backgrounds undergo procedural sedation involving drugs with the potential to cause airway obstruction and respiratory depression. Although most procedural sedation practices can be conducted safely, anecdotal reports suggest that untoward incidents, either minor or major, may occur any time. It is therefore important that anesthesiologists be involved in a management system to ensure safe sedation even if they do not attend to all patients undergoing sedation [20, 21].

Since the availability of anesthesiologists differs from one hospital to another, we recommend that an organizational management system be tailored to suit the situations of individual institutions, as described below.

2. Establishing a sedation management system based on availability of anesthesiologists [*C*]

At medical institutions in which the availability of anesthesiologists is limited, non- anesthesiologist physicians may provide sedation in their departments, while anesthesiologists should be involved in the sedation management system. In these situations, the sedation management system must ensure the following:

- The chief anesthesiologist oversees and manages all sedation procedures performed at the institution.
- Anesthesiologists are responsible for the maintenance of monitoring equipment and other devices in the areas where sedation is performed.
- When patients with severe conditions undergo surgery, anesthesiologists provide MAC in the operating room.
- The chief anesthesiologist obtains approval for off-label use of sedative medications from the institutional pharmaceutical affairs committee, ethics committee, or other appropriate standing committees of the hospital.
- Appropriate education and training on sedation and resuscitation are provided to sedationists, and their knowledge and skills are evaluated at regular intervals.
- An emergency response structure and flow chart for emergency management are established.
- Regular surveillance of sedation practices is conducted (for details see Section "Surveillance").

Greater availability of anesthesiologist resources will allow for the following considerations:

- Anesthesiologists participate in emergency response activities within their department and in coordination with other departments.
- The department of anesthesiology provides sedation consultation services.
- Anesthesiologists take opportunities to join surgical teams treating patients at high risk of sedation complications [22]. The proportion of high-risk patients attended to by an anesthesiologist will increase with greater availability of anesthesiologist resources.

3. Creating institutional monitoring policies for safe sedation

To ensure safe sedation, it is important that individual medical institutions develop and adhere to a monitoring policy that is appropriate for their sedation practices [*B*]. The Japanese Society of Anesthesiologists has developed the *Monitoring Guidelines for Safe Sedation* as provided below.

Japanese society of anesthesiologists monitoring guidelines for safe sedation *preamble*

Sedation is practiced in a wide range of clinical settings. Importantly, when deep sedation is achieved by sedatives or analgesics, it is accompanied by loss of protective reflexes and loss of consciousness. It therefore can lead to respiratory depression, pulmonary aspiration, and other potentially life-threatening complications. To protect patient safety during sedation, especially deep sedation, we strongly recommend that each medical institution take note of the present guidelines and create their own monitoring policies tailored to their situations.

Monitoring guidelines for deep sedation

- Patients undergoing deep sedation should be attended to by a physician or nurse dedicated to patient observation ("patient monitoring"), who closely watches over their condition.
- The patient monitor checks the patient's skin, mucous membranes, blood color, and other variables to determine if sufficient oxygenation is provided. A pulse oximeter should be installed to monitor and record oxygen saturation levels.
- The patient monitor should check breath sounds and the respiratory movements of the chest to ensure proper ventilation. A hemodynamic assessment device (e.g., capnometer) should be used for ventilation monitoring and recording.
- Pulse wave analysis should be conducted continuously. An electrocardiograph should be used if necessary.
- Blood pressure should be measured every 5 min. Measurements may be made more frequently when necessary.
- Body temperature should be measured in patients receiving prolonged sedation.

4. Surveillance

No guidelines have been published that refer to institutional sedation management systems or their surveillance. Since deep sedation is accompanied by loss of defensive reflexes and loss of consciousness, it can lead to respiratory depression, pulmonary aspiration, and other potentially life-threatening complications. It therefore is important that the head of the medical institution acknowledge the governance framework for procedural sedation, emergency management procedures, and other critical aspects of sedation safety.

To safeguard patient safety, we recommend that patients scheduled for procedural sedation be evaluated for complication risks, and appropriate criteria be established to define the conditions for consultation with anesthesiology specialists. Taking note of available anesthesiologist resources, the head of the medical institution should formulate written protocols that define the levels of sedation that non-anesthesiologist physicians are allowed to administer and the levels of sedation and anesthesia that should be delivered by anesthesiologists. Internal surveillance inspections should be conducted at appropriate intervals to assure compliance with the systems, standards, and other requirements established at the facility.

a. Examples of surveillance checkpoints

- Has an internal monitoring and oversight system been established to ascertain and document safe sedation practices? Does the head of the institution have effective governance of safe sedation?
- Check the departments that provide sedation services, the organization of sedation teams within individual departments, and the annual or monthly numbers of patients receiving sedation.
- Are patient's general and airway conditions assessed in advance to ensure sedation safety? Is an organizational system in place to maximize sedation safety based on the patient's condition?
- Check for proper use of presedation evaluation forms and whether they have been completely filled out and signed by evaluators. Check whether risk-based sedationist appointment criteria have been established and

properly implemented (examples of criteria: non-anesthesiologist physicians may practice minimal or moderate sedation in patients with severe cardiovascular, renal, or hepatic disease; sleep apnea (including suspected cases); body mass index > 40; age > 70; or ASA-PS score of III or IV).

- Are fully functioning monitoring devices in place? Check whether the devices are appropriate for use in their locations.
- Have specific staff members been assigned to the task of vital sign monitoring? Check whether the assigned staff have proper knowledge about drugs and monitoring procedures.
- Have sedation-related records been properly archived? Check for documentation of monitoring, sedation evaluation, medications, and patient conditions.
- Has an emergency response system been established? Check whether sedation staff are qualified (examples of qualifications: all sedationists must have received basic life support training, while patient monitors must also have completed advanced cardiovascular life support or immediate cardiac life support programs). Check whether an emergency response flow chart has been created.
- Have regular sedation training programs been implemented? Has a periodic assessment schedule been in place to evaluate the knowledge and skills of the sedation staff? Check for training textbooks and staff training records.

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