`IAPA SEDATION/ ANALGESIA ADVISORY FOR INDIAN CHILDREN

(Statements do not supersede instructions of concerned anaesthesiologist/Sedation Team)

Background

Procedural sedation/analgesia is being practiced in various locations outside operating rooms (*Table 1*). Over a period of years, 'Short Acting Fast Emergence' (SAFE) sedative and hypnotic agents have been administered in these locations, predominantly by non-anaesthesiologists. This is a matter of concern especially since young children have a narrow margin of safety and the administration of these agents, should be only under the supervision of specially trained medical personnel who can recognise and manage adverse events. Furthermore, Rational use of medications and their route of administration should be based upon individual child's needs, urgency and type of procedure.

In 1986, there were published reports of deaths related to dental sedation. Subsequently, the National Institute of Health (NIH) and the American Academy of Pediatrics (AAP) laid down guidelines for pediatric dental sedation and the terms conscious sedation, deep sedation, and general anesthesia were defined. However, it was realized that it was practically difficult to clearly maintain these three levels of sedation and children inadvertently progressed from one level of sedation to a deeper level. An amendment to these guidelines was published, the sedation spectrum was described with terms such as, minimal sedation, moderate sedation, deep sedation and general anaesthesia. Simultaneously, other specialty societies across the world also published guidelines for procedural sedation and analgesia. The United States Joint Commission released standards for pain management, sedation and anesthesia care in 2001. The Commission stated '*The sedation provider must have skills to manage compromised airway and rescue patients from inadvertent general anaesthesia.'* **Emphasis was also placed upon the need for institution specific protocols for procedural sedation.**

With the advances in technology and the complexity of diagnostic and therapeutic interventional procedures in remote locations and to cope up with these

challenges, the need for uniform guidelines across all remote locations has been realized. In 2018, international organizations functioning in these areas along with American Society of Anesthesiologists Task Force on Moderate Procedural Sedation and Analgesia, have jointly drafted Practice Guidelines for Moderate Procedural Sedation and Analgesia. However, western guidelines may not be applicable uniformly across our Indian setting. There is scarcity of published Indian audits and randomized trials on sedation outside operating room and therefore, it is difficult to formulate indigenous guidelines. In addition, it is a debatable, whether non-anaesthesiologists should be caring for children in these high-risk areas. It may be possible for non-anaesthesiology medical personnel, working in institutes and children's hospitals to do so, provided they are trained in pediatric resuscitation and airway management and adequate facilities for periprocedural care are readily available. Medical personnel providing sedation in these resource limited areas, must have adequate experience to handle adverse events. The other important issue and concern is, which sedative and analgesics drugs should non-anaesthesiologists be permitted to administer and by which route for the safe conduct of these procedures? This concern arises from the fact that some of these agents are intravenous anesthetic agents. Therefore, there is a need for an Indian advisory for providing pediatric sedation and analgesia in remote locations.

The Pediatric Sedation Advisory by the Indian Association of Paediatric Anaesthesiologists is an effort to ensure safety of children during and after procedures performed under sedation and analgesia in non-operating room locations. These guidelines are useful for anaesthesiologists who may be called for rescue purposes when a child has been sedated by a non-anaesthesiologist.

This sedation advisory includes issues related to:

I. Appropriate infrastructure and manpower.

II. Patient evaluation and written informed consent.

III. Premedication, monitoring and peri-procedural care.

IV. Post-procedural assessment and safe discharge from hospital.

V. A back up plan for a child who deteriorates after discharge.

I. Infrastructure

It should be ensured that well-defined areas are available for the following:

- The location where the child and care giver should report on arrival to hospital.
- Where the child can be evaluated and examined prior to the procedure.
- Where the child can be monitored prior to premedication and intravenous access.
- Location of the recovery area following sedation and intervention, where the child can be monitored.

Manpower

Qualified medical personnel dedicated for solely providing sedation and monitoring for the child in a remote location should be available to ensure the safe and prompt execution of services.

This team must be trained in Basic and Pediatric Advanced Life Support guidelines and familiar with these locations. It is desirable that team is not only trained in pediatric resuscitation and airway management, but also have adequate experience to handle adverse events in these resource limited areas. A back-up rescue plan should be available if sedation fails or the child deteriorates during or after the procedure. The set up should have facilities to tackle the worst possible scenario.

II **Pre-Procedural Assessment**

- This requires detailed evaluation of all children, similar to a preoperative assessment. A printed proforma helps ensure a complete evaluation and to minimize omissions due to human error. The importance of knowing the relationship of care-taker to the child and whether he actually resides in the same home as the child must be emphasized. Often a child is accompanied by the father, uncle or family acquaintance who may work in cities away from their home, and may not be aware of medical details. Since most children are discharged home following non-operating room anaesthesia

(NORA), the mode of transportation by which they will be taken home should also be known *e.g.,* if the child has been brought alone piggy back on a two-wheeler or a bicycle, discharge should be planned accordingly, to avoid a fall during the travel home. Children with syndromic manifestations, compromised airways, cardiac anomalies, neurological disorders etc. should be investigated in detail for associated problems and their sequel. The sedation provider should explain the plan for sedation and allay fear and apprehensions about the procedure.

- It is important to identify and document (red flag) high-risk patients who *may not* tolerate or are *likely to* deteriorate during or after the procedure in a remote location.

Which patients are considered unfit for sedation to be provided by a non-anaesthesiologist?

- Conjoint Twins
- Children with craniofacial abnormalities
- Compromised airway
- Acute respiratory distress
- Uncorrected or severe cardiac anomalies
- Serious neuromuscular disorders
- Allergic predisposition
- Children with special needs (mentally challenged)
- Previous failed sedation

All these children should be examined in detail for the associated problems, their sequel and a management strategy should be planned with the help of the referring physician and interventionist. Children with any of the above problems, require a trained anaesthesiologist and a well-equipped setup for providing sedation/anaesthesia. The need for carefully titrated

medications taking into consideration the pros and cons of each agent requires expertise. A child with an anticipated difficult airway requirs the availability of a difficult airway cart and should be intubated and extubated in the operating room setting for any interventional procedure.

Written Informed Consent

A valid informed written consent given by a care taker in the language he/she understands, should be obtained and should include:

- Explanation of the sedation technique and its risks.
- Description of benefits of sedation and other alternatives.
- An offer to answer queries.
- Possibility of refusal by the parent/caretaker

III. Premedication, Monitoring and Peri-procedural care

Pre-Procedural Fasting

- Fasting guidelines of the IAPA should be followed. These recommend; 2 hours of fasting for clear liquids, 4 hours for breast milk and 6 hours for solids.
- Precise fasting status should be confirmed on arrival and the time of last feed documented
- Ensure that the procedure is performed at the scheduled time.
- Avoid undue delays which prolong the fasting period and can increase irritability, uncooperative behaviour and dissatisfaction.
- If delay in the procedure is unavoidable, clear non-aerated fluid or juice may be administered two hours prior to the expected time of the procedure.

- In breast fed babies, if the mother is on any sedative medications, a record should be made about the drug and timing of sedative medications administered to her. Caution is needed because many of these medications are secreted in milk.

Premedication

All children must be re-evaluated on the day of procedure by medical practitioner involved in the childs' care. The psychological behaviour of child needs to be understood and depending on the individual child, the need for sedative premedication ascertained. It may be possible to perform the procedure under appropriate sedative premedication alone.

Sedative premedication can be administered to children from aged 9 months to 5 years, to minimize separation anxiety.

Sedative premedication in children older than 5 years, should be reserved for mentally challenged or uncooperative children. Older children may be counselled regarding the need to lie still for the diagnostic non-painful procedures. If the procedure demands complete immobility and cooperation in older children, pharmacological sedation in appropriate doses, under adequate monitoring is indicated. Parental presence during the procedure is debatable. If the child feels secure in the presence of a parent or caregiver and the location of the intervention permits, one care giver may be allowed to stay with the child.

Equipment

Trained personnel should be present during the entire peri procedural duration to clinically monitor the child. Age appropriate equipment for airway management, resuscitation, emergency drugs and antidotes to drugs used, should be readily available. Certain remote locations like the MRI suite, demands for specialized MRI compatible monitoring and resuscitation equipment. It is desirable that equipment and resuscitation carts and labelled drugs similar to those available in the operating room be available in these locations to

enhance prompt actions in emergency situations. Resuscitation carts should be checked regularly, using a check list (*Table 2*).

Monitoring

The IAPA 2016 monitoring guidelines can be followed. These include continuous monitoring of:

- Oxygenation using pulse oximeter with an audible alarm
- Respiration using capnography (via a facemask or nasal cannula)
- Heart rate, preferably with an ECG monitor
- Intermittent measurement of blood pressure
- Although not mandatory, BIS (Bi-Spectral Index) monitoring if available is useful in titrating dosages of anaesthetic agents to targeted level of sedation in children undergoing interventional procedures.

- **Sedation Assessment**
  - It's important to know the nature of the procedure and associated intensity of pain. Age appropriate pain assessment criteria should be followed. Verbal rating scale either by caregivers or older children can be recorded. Whenever possible VAS being more accurate should be preferred.
  - Level of sedation should be continually monitored to maintain a moderate level of sedation. Clinical assessment requires repeated stimulation and this may not be practical. Different scales have been used *e.g.,* the Ramsay Sedation Scale (*Table 4*), University of Michigan Sedation Scale UMSS, OASS etc. None of these however, ensure complete immobility for children of all age groups. The Ramsay Sedation Scale is easy to follow while UMSS has been found to have better validity for CT scanning.
  - Once the child becomes sedated or drowsy, oxygen supplementation with FiO_2 of 0.24 - 0.40 or higher should be administered to maintain the $SpO_2 > 94\%$. A record of these findings should be made.

Drugs for Sedative Premedication

Medications need to be carefully selected depending upon the age and behaviour of the child, associated morbidities, positioning required, type of procedure, need for immobility *e.g.,*

short duration high-speed diagnostic imaging, requires minimal to moderate sedation with immobility for a brief period. Painful procedures require a deeper level of sedation and analgesia. Various sedatives-hypnotics, analgesics, and/or dissociative agents have been used to relieve anxiety and pain. The most widely used medications are listed in *Table 3*. Though, oral benzodiazepines can be used by non-anaesthesiologists with appropriate monitoring, the use of intravenous (IV) sedatives and analgesics need a cautionary warning of use under supervision of an anaesthesiologist experienced in pediatric airway management and cardiopulmonary resuscitation. Some of the common side effects noted with these drugs are mentioned below:

Benzodiazepines: *e.g.,* Midazolam.

Midazolam causes antegrade amnesia (memory loss) and may cause respiratory depression.

Propofol: Due to its favourable pharmacokinetic properties of rapid onset and recovery, the absence of nausea, vomiting and emergence phenomenon, propofol has been commonly used. Propofol does not have specific analgesic properties, necessitating supplementation with opioids (*e.g.,* fentanyl, morphine) or non-opioid analgesics. This drug should only be administered by anaesthesiologists**.**

Ketamine: A dissociative sedative analgesic, it can be used alone or in combination with propofol ("ketofol"). Ketamine mitigates propofol-induced hypotension and propofol mitigates ketamine-induced vomiting and recovery agitation. 'Ketofol' exhibits synergistic properties of smooth sedation, reduced total dose of propofol and obviates the need for opioid use.

Alpha 2 agonists (clonidine, dexmedetomidine): These drugs provide analgesia besides sedation and reduce the requirement of other anaesthetic agents by 30%. There is reduced bioavailability after oral administration and onset of action is slow compared to benzodiazepines and hypnotic agents. Therefore, the intranasal route has been suggested for better bioavailability and when intravenous access is not present. Since small concentration ampoules are not available dosing calculation should be carefully done. One has to take into consideration, willingness to take these medications because the amount of drug actually delivered to a non-cooperative, fighting child is difficult to predict.

Routes of Administration

Oral route:

For anxious but cooperative children, oral midazolam (0.5 mg/kg; maximum dose 20 mg) may be mixed with juice or paracetamol syrup (15-20 mg/kg). The time to maximal effect of oral midazolam is approximately 15 minutes. Combinations of midazolam and ketamine or midazolam and clonidine has been used for more anxious children. Combination therapy mandates 30-50% reduction in dose of each agent to avoid over sedation.

Intranasal route:

Alpha 2 agonists (clonidine 2-4 μg/kg or dexmedetomidine 1-2 μg/kg) may be used for uncooperative children who refuse oral medications. However, these drugs have maximal effect after 40-45minutes. These drugs are to only be administered by an anaesthesiologistIf

Intravenous route (IV):

If an IV cannula is in place, IV sedative premedication can be administered in reduced doses (one third to one fourth the oral dose).

Intramuscular route (IM):

IM premedication should be avoided unless absolutely necessary. In extreme scenario, a stunning dose of IM ketamine 5mg/kg (Ketamine Dart) may be given.

Non-sedative Premedication

Some children may require use glycolytic agents, local anaesthetics and antibiotic prophylaxis. For children at high risk for aspiration prophylaxis with ranitidine 2mg/kg and metoclopramide 0.2 mg/kg may be required. Anti-epileptics need to be continued in children who are already taking these drugs

Special Scenarios

Imaging procedures in the Radiology and Nuclear Medicine suites

With the advent of newer technology, routine scanning time has been reduced considerably and children need to be quiet for a short period. However, certain three-dimensional reconstruction studies for the airway, lungs or cardiac structures pose unique challenges. In such scenarios, additional help should always be available. Whenever, there is a doubt about

securing the airway, the safest practice is to induce the child in the nearest operating room and then transport the child for the scanning using appropriate monitoring facilities. Certain oral contrast studies demand the procedure to be done within 1-2 hours after in the intake of contrast media. The volume which is administered ranges from 60-300 mL, leading to violation of fasting guidelines. To maintain the accuracy of the evaluation, use of prokinetic agents is not recommended. The risk-benefit ratio needs be established and the search for alternate safe diagnostic tools should be made. If unavoidable, caretakers need to be informed about the possible consequences and appropriate backup ventilatory care should be arranged. Anaesthesiologist also need to ensure that the contrast solution is rendered less harmful by diluting the drug.

The choice of anaesthetic agents and airway devices depends upon the duration and frequency of procedure. These patients need to be fully awake at the time of extubation.

Certain SPECT scan studies demand for administration of radio labelled technetium 99 and more than one exposure to study the pharmacodynamics of the drug. Overall drug dosages need careful titration and per day requirement of anaesthetic agents is kept within recommended dosages by using the combination of agents and target controlled drug delivery devices.

Besides routine monitoring, certain investigations like MRI, radiation oncology, and interventional radiology require intermittent remote video monitoring of the patient. Prompt care is needed to handle the worst possible scenarios and to have a neurologically intact survival.

Dental sedation

Dental procedures are challenging because they are painful procedures which demand for sharing the airway and prosthetic appliances can further complicate the management. Sometimes, children can be distracted but may demonstrate uncooperative behaviour due to acute situational anxiety during the procedure. There is a need for continuous monitoring and facility to handle unexpected emergencies like vomiting, aspiration, local anaesthetic toxicity or latex allergy. A common protocol in collaboration with the dental surgeon should be made to manage complications (*Table 6*)

Patient care after the procedure

At the completion of procedure, all children should be monitored in a well-equipped recovery area, until they are no longer at risk for cardio respiratory depression and their vital signs are stable. The recovery location should have the following basic equipment:

- Suction apparatus
- An oxygen source to provide more than 90% oxygen
- Bag-valve-mask device for positive pressure ventilation
- Monitoring should be continued till the discharge criteria are met;
- Age appropriate pain and recovery scores (*Table 5*) of surgical PACU can be used here.
- Attendants should be provided with a list of warning signs and actions to be taken. (Let the care taker repeat the instructions given to ensure they have understood (closed loop communication)
- Clear documentation should be maintained with regard to the of patients' status, vitals at the time of discharge and the parent or caregivers signature taken at the time of discharge.
- Appropriate instructions should be given to a reliable adult, regarding diet, medication and assessment of activity level in the next 24 hours.
- Children who required repeat doses of medications or reversal agents (*e.g.,* naloxone, flumazenil) should preferably be admitted and monitored overnight in the hospital
- A satisfaction score of services provided can also be taken.

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***Table 1*: Locations outside operating room and procedures where procedural sedation and analgesia is required**

Dental Suite	Dental restorations, extractions
Diagnostic Radiology	CT scan, MRI scan, Nuclear scans
Radiotherapy Unit	Brachytherapy, External Beam Radiation
Gastroenterology Procedures	Upper GI Endoscopy, Colonoscopy
Burn-care Unit	Dressing, wound suturing, Fracture reductions
Radiological Interventions	Embolization/Angioplasty/Thrombolysis/Radio frequency ablation/ Transjugular Intrahepatic Portosystemic Shunt (TIPS)
Cardiac Catheterization	Diagnostic & therapeutic interventions
Pulmonological interventions	Flexible bronchoscopic procedures
Psychiatric treatment	Electro Convulsive Therapy

***Table 2:* Equipment Check List for Remote Locations**

S	**Suction** (functioning suction **a**pparatus with all sizes of suction catheters)
O	**Oxygen** (ensure continuous supply of oxygen, pipeline $\pm$ O_2 cylinders]
A	**Airway Equipment** (oropharyngeal airways, bag-valve-mask device, laryngeal mask airways, laryngoscopes, endotracheal tubes, stylets
P	**Pharmacy** adrenaline, atropine, antihistamine, pheniramine (Avil), steroids, dextrose and flumazenil
M	**Monitoring** (Heart rate, SpO_2, $EtCO_2$, temperature, Blood Pressure, ECG)

E	**Equipment** (Defibrillator with pediatric paddles, emergency light, emergency contact numbers (local institute code blue numbers)

***Table 3*. Sedation Agents for Non-Anesthesiologists**

Drug	**ose**	**s**	**ages**
n; Benzodiazepine Age group: 6 months and older)	0.25 - 0.50 mg/kg/dose Onset: 20-30 minutes.	g, retrograde amnesia ntidote: Flumazenil	Respiratory depression with narcotics No Analgesia
Phencyclidine derivative ed age <2 years)	g/kg/dose Onset: 20-30 minutes	istration, Analgesia, Dissociation	alivation, Nystagmus , IOP, Laryngospasm

***Table 4:* Ramsay Sedation Scale**

Patient anxious, agitated or restless	1
Patient co-operative, oriented and tranquil	2
Patient asleep, responds to commands only	3
Patient asleep, responds to gentle shaking, light glabellar tap or loud auditory stimulus	4
Patient asleep, responds to noxious stimuli such as firm nail bed pressure	**5**

Patient asleep, has no response to firm nail-bed pressure, other noxious stimuli	**6**
Acceptable sedation	**2, 3 or 4**
Excessive sedation	**5 or 6**

***Table 5*: Discharge Criteria: Aldrete Score**

Activity	**Score**
Able to move 4 extremities voluntarily or on command	2
Able to move 2 extremities voluntarily or on command	1
Able to move 0 extremities voluntarily or on command	0

Respiration	
Able to breathe deeply and cough freely	2
Dyspnea or limited breathing	1
Apneic	0
Consciousness	
Fully awake	2
Arousable on calling	1
Not responding	0
Circulation	
B/P ±20% of preanesthetic level	2
B/P ±20% to 50% of preanesthetic level	1
B/P ±50% of preanesthetic level	0
Color	
Normal	2
Pale, dusky, blotchy, jaundiced, other Cyanotic	1
cyanotic	0

***Table 6*: Procedural Sedation Complications**

Pain	Procedural pain
Delayed awakening	Prolonged drug action, hypoxia, hypercarbia, hypovolemia
Agitation	Hypoxia, hypercarbia, full bladder, paradoxical reactions, emergence reactions
Nausea and vomiting	Sedative agents, premature oral feeds
Tachycardia Bradycardia	Pain, hypovolemia Vagal stimulation, opioids and hypoxia
Desaturation, hypoxia	Laryngospasm, airway obstruction, over sedation, aspiration