PPDSI Clinical Practice Guidelines on Non-Hospital Ambulatory Sedation for Dental Procedures in Children



Evidence-Based Guideline developed by the Philippine Pediatric Dental Society, Inc.'s Committee on Clinical Practice Guidelines

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EXECUTIVE SUMMARY OF RECOMMENDATIONS

No.	Recommendation	Strength of Recommen- dation	Quality of Evidence
1	Question: Who are the patients in need of sedation? Recommendation 1: Sedation in a dental clinic may be given to any pediatric patient with urgent need of dental procedures, for any reason as deemed valid by the practitioner. Reasons for sedation include inability to cooperate for whatever reason and is not limited to : dental fear / anxiety, patients who incur dental trauma, patients requiring urgent treatment. Sedation may also be considered when treatment cannot be rendered safely without pharmacologic management	Strong	Low
2	Question 2: What should be the qualifications of those providing dental sedation?Recommendation 1 : All members of the delivery and care team must have undertaken appropriate, validated education and formal training and demonstrated an acceptable level of competence by means of a robust assessment process.Furthermore, all team members should have updated certification on Basic Life Support; and the anesthesiologist must have an updated certification on Pediatric Advanced Life Support.	Strong	Low
	Recommendation 2 : A medical anesthesiologist should be the anesthesia provider for IV sedation procedures.	Strong	Low

No.	Recommendation	Strength of Recommen- dation	Quality of Evidence
3	Question 3: What are the basic facilities and emergency equipment, pre- and post-operative risk assessment procedures that must be undertaken to provide sedation?		
	Recommendation 1: Minimum supporting equipment Minimum supporting equipment for dental sedation in a non-hospital setting should include an emergency kit or cart that is easily accessible.	Strong	Low
	Recommendation 2: Environment/setting The physical environment, supporting facilities and equipment must be appropriate for the delivery of dental care under sedation.	Strong	Low
	Recommendation 3 : Backup/Emergency services First, the clinic setting must have immediate access to back-up emergency.	Strong	Low
	Second, a protocol for immediate access to back-up emergency services and roles of each dental team member should be clearly outlined.		
	Recommendation 4: Pre-assessment Routine request and examination of the patient's recent complete blood count that includes bleeding parameters for invasive dental procedures especially when done under sedation where multiple extractions or invasive procedures are often anticipated.	Strong	Low
	Aside from obtaining a detailed medical and dental history of the patient, recording the patient's vital signs and investigating the patient's airway are also essential.		

No.	Recommendation	Strength of Recommen- dation	Quality of Evidence
3	Recommendation 5: Intra-operative and Post-operative Monitoring A sedationist or another appropriate person who has the capability within his or her scope of practice must monitor the patient throughout and even after the procedure. The assigned appropriate monitor should confirm at regular intervals (every 5 minutes) the patient's vitals signs and that the patient is doing well until the child recovers full consciousness from sedation.	Strong	Low
	Recommendation 6: Informed consent A written informed consent form should be signed, whenever possible, by both parents or legal guardian that all pre- and post-operative instructions were thoroughly discussed, including details of the procedure with full understanding of the consequences and risks involving the treatment and sedation.	Strong	Low
	Recommendation 7: Documentation during treatment The patient's chart shall contain a time-based record that includes the name, route, site, time, dosage/kilogram, patient effect of administered drugs. Before sedation, a "time out" should be performed to confirm the patient's name, procedure to be performed, and tooth number, and possible unexpected complications that may occur during the sedation.	Strong	Low

No.	Recommendation	Strength of Recommen- dation	Quality of Evidence
	Recommendation 8: Documentation after treatment A suitably equipped recovery area with accessibility for continuous monitoring of the patient, such as through a CCTV or glass window panes, is ideal. The time of discharge from the treatment area or facility and condition of the child at discharge shall be documented, together with the child's level of consciousness and oxygen saturation in room air have returned to a state that is safe for discharge by recognized criteria. If a dedicated recovery room is not available, the operatory may function as recovery area provided that the child/patient and the guardians have adequate privacy, can be thermoregulated, necessary monitoring equipment are within premises, and can be monitored closely by a member of the dental team.	Strong	Low
	Recommendation 9 : Fasting A 2-4-6 fasting rule (two hours for clear fluids, four hours for breast milk and six hours for solids) should apply for all children who will undergo sedation.	Strong	Low

No.	Recommendation	Strength of Recommen- dation	Quality of Evidence
4	Question 4: What drugs should be used for sedation among pediatric patients undergoing dental procedures?		
	Recommendation 1 : For minimal sedation, oral midazolam may be used for children undergoing short and simple dental procedures to improve their behavior.	Strong	Low
	Recommendation 2 : The medical anesthesiologist must be the anesthesia provider for moderate sedation. They shall decide on the sedatives as he/she deems appropriate to be used on the child.	Strong	Low
	Recommendation 3 : The maximum duration of moderate sedation, particularly the intramuscular / intravenous route of sedation, should be confined to 2 hours as much as possible when working on pediatric patients or those with special health care needs.	Conditional	Low
	Recommendation 4 Nitrous oxide may be used for children undergoing dental procedures.	Conditional	Moderate
	Recommendation 5 : Chloral hydrate is not recommended as sedative for dental procedures.	Strong	Low

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INTRODUCTION

Dental caries (if left untreated) is a chronic progressive oral disease that is prevalent worldwide. **Early Childhood Caries** (ECC) is defined as the presence of one or more decayed (non-cavitated or cavitated lesions), missing or filled (due to **caries**) surfaces, in any primary tooth of a child under six years of age. There are about 600 million children across the globe with ECC and most of it remain untreated.¹ ECC is a

	Male Female		Overall			
Age	Total Examined	%	Total Examined	%	Total Examined	%
5	314	89.5	272	86.8	586	87.7
12	283	71.0	294	79.9	577	75.6
15 -19	274	80.7	302	80.1	576	80.4
35 - 44	111	90.1	495	96.0	606	94.9
65 - 74	167	99.4	401	98.5	568	98.8
ALL	1149	86.1	1764	88.3	2913	87.4

 Table 1. Prevalence of dental caries among gender and age groups. (NMEDS 2011)

result of poor bottle feeding habits, aggravated by lack of oral hygiene and inadequate brushing dexterity. Unattended dental caries leads to either repeated bouts of pain and infection. Severe infection could affect the supporting alveolar bones. Consequently, the resulting pain and facial swelling leads to frequent school absenteeism and poor nutrition² affecting the child's quality of life and that of the entire family.

Dental management is necessary to relieve pain and infection. This becomes extremely challenging among the young children. Behavior management is difficult in a child in the precooperative stage. Current oral health programs of the Department of Health has not created an impact in decreasing the prevalence of untreated early childhood caries because of the complexity of the disease process. While local government units develop initiatives and implement their own oral health programs, ECC and cases of facial swelling continue to be seen in young children.

The World Health Organization (WHO) has stated that dental caries affects 70% to 95% of school-aged children and the vast majority of adults among the Member States of the Southeast Asia Region. The majority of teeth affected by dental caries remain untreated, particularly in children, due to limited access to and high cost of oral health services.³

The four most prominent non-communicable diseases (NCDs) – cardiovascular diseases, diabetes, cancer, and chronic pulmonary diseases are the leading disease burden worldwide.⁴ Because one of the risk factors of NCD — an unhealthy diet rich in sugar, is also a key risk factor for dental caries, there is a good opportunity for integrating oral disease and NCD prevention and control efforts. A focus on prevention and control of diseases in the early stages of life must be maintained.⁵

According to the Philippine's Department of Health, though dental disease conditions do not directly cause disability or death, these can weaken bodily defenses and serve as portals of entry to other more serious and potentially dangerous systemic diseases and infections.

In a study conducted by the Philippine's National Monitoring and Evaluation Dental Survey (NMEDS 2011) of almost 3,000 Filipinos aged 5 to 74 years of age across the 16 regions of the country, both living in the urban and rural communities, prevalence of caries across the country

was as high as 87%.⁶ To date, there are no published statistics on the prevalence of dental caries among children below 5 years old, a vulnerable age group more susceptible to neglected and rampant prevalence of caries in the primary dentition.

I. Rationale

Young children needing multiple dental procedures involving pulp treatment and/ or extractions, is a behavioral challenge. If treatment necessitates the injection of local anesthesia needed for extensive dental procedures, a chance of experiential trauma from dental treatment ensues even from the most cooperative patient. In order to prevent traumatic dental experiences, pediatric dentistry uses pharmacologic management techniques such as general anesthesia and other pharmacologic means for oral rehabilitation.

Over the years, in order to provide safe and effective treatment, health professionals have resorted to pharmacologic means of behavior management of children, including management of dental diseases where techniques of non-pharmacologic behavior management have failed. This means high cost of treatment as a result of a whole regimen of dental materials, cost of private hospital and clinic facilities and professional fees. This has proven to be a major deterrent for families to proceed with the treatment. Its high cost prohibits a majority of the patients to avail of treatment, making children suffer pain and infection for the rest of their childhood, ultimately creating an adverse impact in their overall health and quality of life.

II. Background

The difficulty in behaviour management and the absolute need for dental treatment necessitates a definitive intervention. Most government hospitals do not have trained pediatric dentists in their dental departments for a more affordable hospital facility and the Department of Health has not included oral rehabilitation in their procedures as part of Philhealth's accredited funding. This leaves the dental profession to resort to a more affordable alternative to provide quality dental care to children in desperate need of treatment.

Ambulatory sedation has allowed safe and economical means in performing oral rehabilitation as an alternative to general anesthesia. Pediatric dentistry training has included pharmacologic management techniques in order to provide the necessary treatment to accomplish a healthy, cavity free oral cavity. As it is a recognized fact that total health begins with an orally healthy individual.

However, it must be clear that sedation is not a substitute for behavior management techniques. The decision to sedate a child is based on a thorough assessment of the oral health needs towards total health and wellness of the child, the skills of the practitioner and their team, and the facility the patient will be treated in.

Ambulatory Sedation in Pediatric Dentistry

The goal of sedation is to eliminate anxiety and render a safe treatment for the dentists to work on an uncooperative child with minimal traumatic experience.

The term conscious sedation is used because the child is awake but calm and his reflexes remain intact. However, the American Academy of Pediatric Dentistry (AAPD) changed "conscious sedation" to "sedation", since a child can pass from a conscious state to a an unconscious state, at any time during the procedure. Hence, <u>conscious sedation is simply termed sedation</u>.

There are 3 classifications of sedation: minimal, moderate and deep. According to the AAPD, minimal sedation (formerly anxiolysis) is a drug-induced state during which patients respond normally to verbal commands; although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are affected. Moderate sedation (formerly conscious sedation) is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands; no intervention is required to maintain a patent airway and cardiovascular function is maintained. Deep sedation is a drug-induced depression of consciousness during which patients are affected verbal or painful stimulation. Cardiovascular function is usually maintained but may be accompanied by partial or complete loss of protective airway reflexes.⁷

The risk of sedation cannot be over emphasized, it is a continuum and may result in a deeper sedation than intended, resulting to respiratory depression and loss of the patient's protective reflexes. According to the AAPD, it is common for children to pass from the intended level of sedation to a deeper, unintended level of sedation. The American Society of Anesthesiologists' (ASA) article *Distinguishing Monitored Anesthesia Care ("MAC") from Moderate Sedation/Analgesia (Conscious Sedation)* recommends that providers of moderate sedation must be qualified to recognize deep sedation, manage its consequences, and adjust the level of sedation to a moderate or lesser level.⁸

In a setting where the dentist is also the one providing the sedation, the risk for medication errors become higher since they are usually in a solo practice, as against dentists who are practicing in hospitals where several doctors are on hand to help out. Dental providers who use sedation and/or general anesthesia in their practice are likely to have greater risk for medication errors and adverse drug events primarily because of the increased frequency with which drugs are being used for patient care.⁹ A medication error is a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient.¹⁰ The United States National Coordinating Council for Medication Error Reporting and Prevention has defined this as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.

The risks in dental sedation are:11,12

- 1. Shared airway between the dentist and the anesthesiologist
- 2. Coexisting medical conditions such as cardiac anomalies, mental instability, and epilepsy
- 3. Chances of arrhythmias during surgery due to trigeminal nerve stimulation
- 4. Enlarged tonsils and adenoids in children, likely to precipitate respiratory obstruction
- 5. Risk of patient losing consciousness, respiratory, and cardiovascular depression
- 6. Vasovagal syncope due to the dependent position of legs in dental chair

Due to the close proximity of the surgical field with the patient's airway, dental treatment in a child is complicated with the flooding of water from the dental handpiece and dental water syringe in the operatory field that can easily flow down the posterior pharynx and potentially obstruct the oro-nasal airway; and the sedative drugs designed to decrease the level of consciousness also relaxes the muscles, including those for respiration, of the patient. Hypoxia, apnea, airway obstruction, largyngospasm, aspiration, and other cardiovascular and respiratory complications can happen quickly and a practitioner should be sufficiently skilled not only to identify these complications, but also be able to perform timely rescue of the patient. Immediate and proper rescue of the patient by the dental team requires adequate training, advanced skills and proper equipment.¹³

It is therefore imperative that patients who will undergo ambulatory sedation, must also undergo risk stratification assessment from a qualified pediatrician in accordance to the parameters set by the American Society of Anesthesiologists. Needless to say, the clinician must carefully assess the risk and rationalize the benefit to the patient when considering ambulatory sedation.

III. Guideline Objectives

To the best knowledge of the PPDSI, there are no written clinical guidelines that exist in the Philippines specific to ambulatory sedation in the dental practice. The need for a written guideline prompted the Clinical Practice Guidelines Committee of the PPDSI to form its first set of recommendations on "Guidelines for Non-Hospital Ambulatory Sedation for Dental Procedures in Children" to promote safe, quality dental service.

The goal is to provide every patient under sedation a certain degree of quality of care. This includes but not limited to: the dentist's additional training to be well versed with the pharmacology and pharmacokinetics of the drugs; and be able to reverse and act in a skillful manner to meet the possible adverse reactions during the course of the treatment. In the Philippines, some hospital-based post graduate specialty training programs provide additional training in general anesthesia and sedation. These specialty training programs have been

accredited and passed required standards set forth by their respective specialty boards, in accordance with global standards.

However, the absence of a guideline has led to sedation practices by some dentists even without the proper training. Thus the need for the creation of this guideline to establish standards for proper patient selection, drug to be administered and minimum equipment needed in a clinic facility to address possible emergency.

Similarly in Japan, some dentists opt to undergo informal training such as apprenticeship with previously trained oral surgeons or medical anesthesiologists who are skilled at sedation management to learn the skills of the technique and eventually apply their own pharmacologic behaviour management. Thus, a written guideline is one of the methods the Japanese Dental Society of Anaesthesiology for Dentists Practicing Sedation in Japan uses to promote safe dental anesthesia management.¹⁴

The UK National Clinical Guidelines in Paediatric Dentistry has described the requirements and acceptable modes of sedation for provision of dental treatments for children through the article *Managing Anxious Children: The use of conscious sedation in paediatric dentistry* released in 2002. The publication is twelfth of the series of clinical guidelines, having circulated their first article in 1997.¹⁵

IV. Use of this guideline

- 1. PPDSI intends this guideline as a reference for the dentists with post graduate training* for a guided decision towards the use of ambulatory sedation.
- 2. Provisions in this guideline are limited to pediatric patients including patients with special health care needs.
- 3. The scope of this guideline is limited to oral sedation and IM/IV sedation outside the hospital setting and does not intend to answer questions or describe clinical situations relating to intranasal/inhalation and rectal route of ambulatory sedation.

Adherence to these guidelines is not a guarantee for specific patient outcomes. It is the hope of the Committee that these guidelines will assist dentists in carefully deciding the best treatment option for the benefit of the patient.

*See definition of terms for dentists with post graduate training.

For the purpose of quick understanding, this article will use the terms <u>mild sedation</u> to pertain to decreased consciousness brought about by an orally administered sedative during which patients can still respond normally to verbal commands. Cognitive function and coordination may be slightly impaired but cardiovascular and respiratory functions are unaffected; <u>moderate</u> <u>sedation</u>, on the other hand, to pertain to depression of consciousness after administration of a cocktail of sedatives given via intramuscular shot and/or intravenous line, and where the patient can respond purposefully to verbal commands. Spontaneous ventilation is still adequate and cardiovascular function is usually maintained.

V. Creation of PPDSI CPG Committee

In 2018, PPDSI has carefully appointed ten of its members to form the CPG Committee. The key role of this committee is to formulate a guideline specific for ambulatory sedation outside hospital settings. These individuals represent the undergraduate and postgraduate level of education, dental clinicians and members of the academe to participate in the creation of this publication.

The CPG committee members received minimal financial compensation from the PPDSI for meetings attended and their participation in development of this clinical practice guideline. The committee members and the representatives of partner stakeholders were asked to disclose potential conflicts of interest. The PPDSI has neither solicited nor accepted any commercial involvement in the development of the content of this publication.

The CPG committee is composed of two sub-committees. The Steering Committee, mainly responsible for identifying and screening proposals of clinical topics of interest for development of guidelines. The second, the Technical Working Committee guided the Steering Committee on the protocols of clinical practice guidelines development.

The duties of the Steering Committee include:

- identify areas of need for a written guideline
- develop oral health policies or best practices
- review and update existing guidelines
- write guidelines based on the systematic review and meta-analysis of the studies collected

The duties of the Technical Working Committee include:

- develop a research protocol
- develop the PICO (Patient, Intervention, Comparison, Outcome) question for each guideline
- select studies for full-text retrieval and extraction, and extract for each study selected
- perform evidence synthesis: meta-analysis or narrative synthesis
- Assist the Steering Committee in grading evidence (based on GRADE criteria)

VI. METHODOLOGY

A. Identifying the guideline questions

Topics of interest for CPG development followed a hierarchy of prioritization. Topic selection and prioritization of CPGs was carefully considered by the committee*. Time shortage, limited financial resources, and mobilization of human resources were some of the limitations the committee faced in deciding which questions to prioritize.¹⁶

*See Appendix 1 for the guide used in the selection of the questions formulated for this document.

ni	cal Questions
	Question 1: Who are the patients in need of sedation?
	Question 2: What are the qualifications of one who will employ sedation?
	Question 3: What are the basic and emergency facilities/equipment and procedures necessary to administe sedation?
	Question 4: What drugs should be used for sedation among pediatric patients undergoing dental procedures?

B. Search and Retrieval of Relevant Articles

Based on the questions formulated by the Steering Committee, a systematic search of literature was conducted by the Technical Committee using electronic databases and other conventional methods. Medline was searched for relevant articles indexed from 1984 until October 2018, using the terms derived from each of the questions.

In addition to the literature search, published guidelines were also used as reference including: American Academy of Pediatrics and American Academy of Pediatric Dentistry's *Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures* in 2019 and the Royal College of Surgeons of Edinburgh, the Royal College of Physicians and Surgeons of Glasgow, the Royal College of Surgeons of England and the Royal College of Anaesthetists' Standards for Conscious Sedation in the Provision of Dental Care in 2015, and the Japanese Dental Society of Anaesthesiology's Practice Guidelines for Intravenous Conscious Sedation in Dentistry in 2017.

There were no restrictions placed on language, age, or year of publication. Metaanalysis or systematic reviews were retrieved and used when available. There were 815 papers found, duplicates were removed and each paper was assessed according to the level of quality of evidence in accordance with the criteria set by GRADE: Grading of Recommendations Assessment, Development and Evaluation; modified from WHO Handbook in Guideline Development, 2014.

For each of the general clinical questions, the same exposure —conscious sedation, and outcomes —based on morbidity and mortality, will be used. It is intended that the same search strategy will be used to identify:

- 1. The population of children who will be needing conscious sedation.
- 2. The procedure for conscious sedation including details on
 - a. The sedative to be used

b. Pre, during and post-procedure risk-assessment, work-up, risk assessment and monitoring

*See Appendix 2 for PECOM details (population, exposure, comparison, outcome, methods), general framework of research questions, and corresponding search terms used.

C. Grading the Quality of the Evidence

The TWC rated the quality of evidence based on the strength of recommendation based on the GRADE methodology (GRADE Working Group, 2004):

Quality level	Definition	
High	We are very confident that the true effect lies close to that of the estimate of the effect.	
Moderate	We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.	
Low	Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of effect.	
Very Low	We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.	

Table 1: Quality of Evidence Rating Using the GRADE Methodology

The quality of evidence is defined as the confidence that the reported estimates of the effect are adequate to support a specific recommendation. The GRADE system classifies the quality of evidence as high, moderate, low and very low. Randomized

control trials are usually given a high quality of evidence rating but this may be downgraded if there are flaws within the publication including risks of bias, inconsistency of results, indirectness of evidence, imprecision and publication bias. While observational studies are considered low-quality, it may be upgraded if the magnitude of treatment effect is very large, evidence indicates dose-response relationship or if plausible biases would underestimate the overall effect.

D. Preparation of the Draft Recommendations

After reviewing the evidences, the TWC drafted the recommendations and presented the same to the CPG Oversight Committee. Based on the evidences presented, the Oversight Committee deliberated and finalized the proposed recommendations. The final recommendations were presented during the Stakeholders meeting.

E. Consensus Development Process

1. Panel's declaration of conflict of interest

The members of the PPDSI CPG Oversight and Steering Committee and the Technical Working Group were asked to declare their conflicts of interests. At the time of the formulation of the questions until the final writing of this guideline no conflicts of interest were declared by the members of the voting panel.

2. Panel of stakeholders

The members of the TWC sent the first evidence-based draft and recommendation statements for review prior to the presentation. Each recommendation was thoroughly discussed and the supporting criteria were considered for the inclusion in the recommendations.

c. Public forum

Presentation of the recommendations together with the supporting evidence were presented to the different stakeholders.

F. Guideline dissemination

This guideline will be published in the PPDSI website and submitted to the different bodies for administrative perusal and as such.

VII. WRITING THIS GUIDELINE

Due to the rigorous process of creating a guideline, one which conforms to the standards set by the DOH and WHO, this final manuscript took a while before it can be put together and published.

The initial search by the TWC consisted of publications until 2018. However, during the final writing of this document, recently published guidelines (after the initial search in 2018) had to be used as additional references in order to keep this document up to date.

VIII. DISCLAIMER

The recommendations presented in this document serve as a guide for healthcare providers. Admittedly, not all cases will present the same and ideal situations are not always present. Best clinical judgment, knowledge, expertise and available resources should still be considered when using the provisions in these recommendations.

IX. DEFINITION OF TERMS

For the purpose of this document, the following definitions shall apply:

1. ASA classification¹⁷

Classification	Definition	Pediatric examples, including but not limited to:
ASA I	Normal, healthy patient	Healthy (no acute or chronic disease), normal BMI percentile for age
ASA II	A patient with mild systemic disease	Asymptomatic congenital cardiac disease, well controlled dysrhythmias, asthma without exacerbation, well controlled epilepsy, non-insulin dependent diabetes mellitus, abnormal BMI percentile for age, mild/moderate OSA, oncologic state in remission, autism with mild limitations
ASA III	A patient with severe systemic disease	Uncorrected stable congenital cardiac abnormality, asthma with exacerbation, poorly controlled epilepsy, insulin dependent diabetes mellitus, morbid obesity, malnutrition, severe OSA, oncologic state, renal failure, muscular dystrophy, cystic fibrosis, history of organ transplantation, brain/spinal cord malformation, symptomatic hydrocephalus, premature infant PCA <60 weeks, autism with severe limitations, metabolic disease, difficult airway, long term parenteral nutrition. Full term infants <6 weeks of age.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Symptomatic congenital cardiac abnormality, congestive heart failure, active sequelae of prematurity, acute hypoxic-ischemic encephalopathy, shock, sepsis, disseminated intravascular coagulation, automatic implantable cardioverter-defibrillator, ventilator dependence, endocrinopathy, severe trauma, severe respiratory distress, advanced oncologic state.
ASA V	A moribund patient who is not expected to survive without the operation	Massive trauma, intracranial hemorrhage with mass effect, patient requiring ECMO, respiratory failure or arrest, malignant hypertension, decompensated congestive heart failure, hepatic encephalopathy, ischemic bowel or multiple organ/system dysfunction.
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes	

**The addition of "E" denotes Emergency surgery: (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)

- 2. Best practices "the best clinical or administrative practice or approach at the moment, given the situation, the consumer's or community's needs and desires, the evidence about what works for this situation/need/desire, and the resources available."¹⁸ Like CPG, best practices are more flexible than standards and originate in an organization with recognized professional expertise and stature. Although they may be unsolicited, they usually are developed following a stated request or perceived need for clinical advice or instruction.¹⁹
- 3. Clinical practice guidelines (CPG) statements that include recommendations intended to optimize patient care. They are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.²⁰
- 4. Dentist / Dental clinician with postgraduate training are licensed Filipino dentists who underwent post-graduate training in Pediatric Dentistry whose curriculum included application of pharmacologic management; with a minimum of 6 months full-time formal training conducted by the PPDSI or a certificate program with a minimum of 2 years, in an institution accredited or recognized by the Philippine Board of Pediatric Dentistry.
- 5. Validated education in pediatric dentistry are the post-graduate programs which includes didactics and clinical training with pharmacologic management; with a minimum of 6months full-time formal training conducted by PPDSI or a certificate program with a minimum of 2 years, in an institution accredited or recognized by the Philippine Board of Pediatric Dentistry.
- 6. Invasive procedures are those procedures requiring local anesthesia administration (e.g. dental extractions, pulp treatment, etc.)
- 7. Urgent dental procedures are those dental procedures which needs immediate care and will have dire consequences if left unattended.
- 8. Morbidity any departure, subjective or objective, from a state of physiological or psychological well-being. In practice, morbidity encompasses disease, injury, and disability.²¹
- 9. Mortality death²²
- 10. 'Multiple' dental procedures may mean treatments needing multiple visits to accomplish.

- 11. Must or shall indicates an imperative need and/or duty; an essential or indispensable item; mandatory.
- 12. Pediatric dental patients includes all patients who are infants, children, and adolescents less than the age of majority of 18 years and 364 days
- 13. Rescue management of adverse events that may occur during the delivery of dental treatment under conscious sedation.²³
- 14. Sedation ²⁴
 - a. Mild sedation (formerly Anxiolysis) a drug induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be slightly impaired, ventilatory and cardiovascular functions are unaffected.
 - b. Moderate sedation (formerly Conscious sedation) a drug induced depression of consciousness during which the patients respond purposefully to verbal commands or after light tactile stimulation. No intervention is required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. However, in the case of procedures that may themselves cause airway obstruction (eg, dental or endoscopic), the practitioner must recognise an obstruction and assist the patient in opening the airway. If the patient is not making spontaneous efforts to open their airway to relieve the obstruction, then the patient should be considered to be deeply sedated.
 - c. Deep sedation a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated verbal or painful stimulation (eg, purposefully pushing away the noxious stimuli). The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. A state of deep sedation may be accompanied by partial or complete loss of protective airway reflexes.
- 15. Sedationist²⁵ a suitably qualified person responsible for conducting or administering the sedation.

X. Clinical Questions, Recommendations and Scientific Evidence

Question 1: Who are the patients in need of sedation?

The following populations were searched. Normal children (2-19 years old) requiring multiple invasive procedures; Uncooperative patients; Patients with dental fear/anxiety; Patients with special health care needs; Patients who incurred dental trauma; Patients requiring urgent treatment

Recommendation 1: Sedation in a dental clinic may be given to any pediatric patient with urgent need of dental procedures, for any reason as deemed valid by the practitioner.

Reasons for sedation include inability to cooperate for whatever reason and is not limited to : dental fear / anxiety, patients who incur dental trauma, patients requiring urgent treatment. Sedation may also be considered when treatment cannot be rendered safely without pharmacologic management. (Low quality of evidence, strong recommendation)

<u>Summary of Evidence:</u> There are no trials among the considered special groups that suggest that the following: 1. Children (2-19 years old) requiring multiple procedures, 2. Uncooperative patients, 3. Patients with dental fear/anxiety, 4. Patients with special health care needs, 5. Patients who incurred dental trauma, 6. Patients requiring urgent treatment will have better outcomes with sedation vs no sedation.

In a systematic review by Klingberg, Broberg in 2007 of 32 papers searched in PubMed base, they estimated that the prevalence for dental fear and anxiety varied from 6-20% in children and adolescents.²⁶ We can only surmise that this figure is higher for the Philippines, since almost half of our 100 million population comprise the 0-15 years old age group. Fear of dental treatment leads to functional impairment in terms of avoiding dental treatment in general or specific parts of it. ²⁷

In a randomized clinical control trial by Antunes, Viana, Costa, Costa, 2015, fifty children under 4 years old were treated under moderate sedation and were followed for 29 months. They concluded that moderate sedation helps improve future behavior in pediatric dental patients.²⁸ Dental anxiety also remains high in adulthood (19%) as they cite fear of dental experience and previous negative dental experience as some of the reasons.²⁹ By the consensus of the PPDSI Committee on CPG and its stakeholders, it is logical that dental fear or anxiety is a barrier to dental treatment. Therefore, sedated patients perceive their procedures more favorably compared to those who have not been sedated. The group is also in agreement that the following patients who are classified under ASA III and IV categories of the American Society of Anesthesiologists' Physical Status Classification System, those with a hyperactive gag reflex, obstructive sleep apnea and obesity, including those who are extremes of age should be considered for treatment in the hospital setting. In a study by Lee, Milgrom, Starks and Burke in 2013 revealed that most deaths (n=21/44) occurred among 2-5 year old children in private dental office settings.³⁰ Therefore, risk stratification of the patient from the child's physician before sedation is imperative.

Explanation:

Untreated early childhood caries causes pain and infection in children, which can have deleterious effects on their overall health and growth. Pain and infection, therefore, drives the urgent need for dental treatment. The immature cognitive development of young children hinders them from fully understanding the need of the dental treatment. Forcing a pre-cooperative child to bear an invasive dental treatment which he/she does not fully comprehend can only result to a childhood trauma which he/she can bring into adulthood, resulting to dental phobia.

Almost all apprehensive patients, whose behavior cannot be managed with traditional behavior management techniques can be sedated. But a thorough assessment of a child is of utmost importance and those who are only deemed fit by their pediatricians may undergo sedation. Airway should be assessed - their tonsillar and Mallampati scores graded and any obstructive sleep apnea investigated— to prevent any potential for airway obstruction. Children may be good candidates for sedation as long as they fall under ASA I and ASA II categories of the American Society of Anesthesiologists Physical Status Classification System, can tolerate NPO instructions and are considered low risk for sedation by their pediatricians.

For those who are not good candidates for sedation in an ambulatory setting but with urgent dental treatment needs, exhaust non-sedation behavior guidance techniques, or consider treatment under general anesthesia. Sedation, when properly carried out, can be a valuable tool in reducing the anxiety and agony of toddlers and preschoolersq during treatment leading to better behavior which they can carry onto adulthood.

Question 2: WHAT should be the qualifications of those providing dental sedation?

Recommendation 1: All members of the delivery and care team must have undertaken appropriate, validated education and formal training with dental sedation within the program, and demonstrated an acceptable level of competency by means of a robust assessment process, with a qualifying certification as deemed fit by a body appointed by the Society. (Low quality of evidence, strong recommendation)

Furthermore, all team members should have updated certification on Basic Life Support; and the anesthesiologist must have an updated certification on Pediatric Advanced Life Support. (Low quality of evidence, strong recommendation)

<u>Summary of evidence</u>. There are no existing trials that demonstrate better outcomes among patients sedated by anesthetists, anesthesiologists or dentists with special training. There are no explicit randomized controlled trials comparing competencies (with or without) of healthcare professionals who are providing dental sedation. But, in a study by Lee, Milgrom, Starks and Burke in 2013, they found that 25 out of 44 deaths occurred when the general/pediatric dentist is the anesthesia provider.³¹

In the UK, all members of the delivery care team should have undergone appropriate validated education and training with an acceptable level of competence. Aside from their advanced and comprehensive education programs, they also have accredited educational courses that provide training which undergo rigorous accreditation with their government and universities; and they also require revalidation of their sedation techniques every 5 years.³² In Japan, all children in need of conscious sedation are referred and treated by pediatric dentistry specialists.³³ In the US, they require that dentists should have completed either a comprehensive training program in moderate sedation in accordance to the requirements of the American Dental Association or an advanced education program accredited by the Commission on Dental Accreditation which includes comprehensive and appropriate training necessary to administer and manage moderate sedation.³⁴

The members of the dental team providing sedation should be qualified by education or training.

<u>Explanation</u>. No evidence can be found among the databases as all the countries searched have training programs and courses on sedation. In the Philippines, training in proficiency in providing sedation in private dental office settings are in the post-graduate training programs accredited by the Philippine Board of Pediatric Dentistry.

The members of the delivery and care team for sedation are the dentist <u>assisted</u> by properly trained dental aides for mild sedation; with an inclusion of a medical anesthesiologist to provide moderate sedation.

The updated report on 2019 of the *Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures,* replaces the "Personnel" section of 2016 guidelines that called for only one trained person to be present during procedures in a dental facility or hospital. According to the new recommendations, sedation must be administered by a qualified anesthesia provider (a medical anesthesiologist, certified registered nurse anesthetist, dentist anesthesiologist or second oral surgeon). In addition, a second person must be present and have the skills to assist in an emergency, with the ability to monitor the patient, manage the airway, establish venous access for the administration of rescue medications and perform resuscitation. The second person must be an independent observer with no other responsibilities. The stronger guidance followed recent deaths of children in the dental setting in which inadequate supervision may have played a role.

For the dentist. A validated education in Pediatric Dentistry with courses in sedation is important to achieve an acceptable level of competence. Knowledge on the unique physiology of children, a know-how in evaluating children for any probable underlying systemic disease, awareness on the pharmacodynamics of the sedatives, drug interactions and anesthesia techniques, a clear understanding of risks and skills in rescue management should all be applied comprehensively in sedating a child. Therefore, the dentist should have undergone didactic courses and supervised clinical practice to gain the experience and proficiency required to execute a safe and successful sedation. Furthermore, the PPDSI Committee on CPG suggests for dentists to undergo continuing education courses on sedation when available. For the dental aides. While there is no need for formal education, at present, to become a dental aide in the Philippines, they should however, have had training within the facility in dental assisting. Further, they should have experience and knowledge of the dental treatment to be performed to carry out their duties in a very efficient manner. They should have specific assignments during dental emergencies, be knowledgeable of emergency protocols and aware of where the emergency drugs and equipment are placed and how they are used. Ideally, they should have updated Basic Life Support training since they have critical roles in supporting the whole dental team in monitoring the patient and assisting in any resuscitation measures.

For the anaesthesiologist. They should be diplomates of the Philippine Society of Anesthesiology, preferably with a profound knowledge and experience in ambulatory sedation, and understanding of the nature of dental procedures. Since we share the same surgical field with the anaesthesiologists, the flooding of the field with water when hand pieces are used and the small particles which may potentially be swallowed are all risks for aspiration and airway obstruction; the length of time needed to complete a dental procedure, and the lack of resources in private dental office settings are all risk factors which an anesthesiologist should be able to effectively manage.

An updated Basic Life Support (BLS) for all members of the dental team, including the dental assistants, and Pediatric Advanced Life Support (PALS) certification for the anesthesiologists are part of the minimal requirements for the dental team. The knowledge and the skills to be able to rescue the patient immediately and the contribution and alertness of each member of the dental team is invaluable as precious time can be lost while waiting for emergency services, which can translate to severe consequences or even death of the patient.

Recommendation 2: A medical anesthesiologist should be the anesthesia provider for moderate sedation procedures. (Low quality of evidence, strong recommendation)

<u>Summary of Evidence</u>. There are no existing trials that demonstrate better outcomes among patients sedated by anesthetists, anesthesiologists or dentists with special training. There are no explicit randomized controlled trials comparing competencies (with or without) of healthcare professionals who are providing dental sedation. But, in a study by Lee, Milgrom, Starks and Burke in 2013, they found that 25 out of 44 deaths occurred when the general/pediatric dentist was the anesthesia provider. ³⁵

Explanation. There is no special training on sedation in the Philippines. As seen in other countries, mortality is higher when the dentist is also the anesthesia provider.

Question 3: WHAT are the basic facilities and emergency equipment, pre- and postoperative risk assessment procedures that must be undertaken to provide sedation?

Recommendation 1: Minimum supporting equipment

Minimum supporting equipment for dental sedation in a non-hospital setting should include an emergency kit or cart that is easily accessible. (Low quality of evidence, strong recommendation)

<u>Summary of evidence</u>. The emergency kit must contain the necessary age and size-appropriate equipment to resuscitate a non-breathing and unconscious child. Additionally, the contents of the kit must allow for the provision of continuous life support while the patient is being transported to a medical/dental facility or to another area within the facility.

The emergency cart must at least include the following:

- Laryngoscope (with age-appropriate blade)
- Endotracheal tube (ET) (cuffed and non-cuffed)
- Automated external defibrillator (AED)
- Patient monitors (i.e. BP, pulse oximeter, cardiac monitor, ECG monitor)
- IV cannulas
- Ambubag (pediatric and adult)
- Oxygen source, oxygen cannula, masks of appropriate sizes
- High-volume Suction
- Drugs (i.e. atropine, epi, naloxone, NSS, flumazenil etc.)

<u>Explanation</u>. All appropriate equipment must be available in working order when sedation is being provided and during recovery. To ensure this, equipment must be maintained in accordance with the schedule described by the manufacturers, and records of the maintenance of equipment must be retained and made available for subsequent formal inspections.

Recommendation 2: Environment/setting

The physical environment, supporting facilities and equipment must be appropriate for

the delivery of dental care under sedation. (Low quality of evidence, strong

recommendation)

All providers of sedation services are responsible for ensuring that the environment in which care is delivered is appropriate for the needs and safety of patients, caregivers and staff.

<u>Summary of evidence.</u> All facilities providing sedation for the delivery of dental care should be assessed by the dental team to ensure that the necessary standards are in place. An appropriate physical setting of the clinic must permit access for the emergency services and trouble-free transfer of the patient to a hospital facility. Below outlines a few requirements regarding the premises where sedation will be conducted:³⁶

- Clinically fit for purpose and fulfill legislative and regulatory requirements (lighting, heating, ventilation, safe access)
- Waiting room, surgery and recovery room of adequate size for management of emergencies
- Adequate access for emergency services
- Separate area for patient recovery and waiting room
- Patient confidentiality and privacy maintained throughout the patient journey

<u>Explanation</u>. Appropriate physical setting of the clinic must permit easy access for patients with special needs (e.g. access of wheelchair), monitoring equipment, emergency services and trouble-free transfer of the patient to a hospital facility.

Recommendation 3 : Back up/Emergency services

First, the clinic setting must have <u>immediate access</u> to back-up emergency. (Low quality of evidence, strong recommendation)

Second, a <u>protocol</u> for immediate access to back-up emergency services and roles of each dental team member should be clearly outlined. (Low quality of evidence, strong recommendation)

<u>Summary of evidence</u>. Sedation of pediatric patients caries potentially serious procedural risks, morbidity and mortality that may be directly attributed to sedation.³⁷ As it is common for children to pass from the intended level of sedation to a deeper, unintended level of sedation, an established protocol for access to back-up emergency services should be clearly identified with an outline of the procedures necessary for immediate use. For non-hospital facilities, a protocol for ready access to ambulance service and immediate activation of the EMS system for life-threatening complications must be established and maintained.³⁸

<u>Explanation</u>. Immediate access includes modalities for prompt activation of EMS system for lifethreatening complications during sedation. This includes a list of emergency numbers, particularly one direct hotline to the emergency response team of the nearest hospital. For non-hospital facilities, a protocol with detailed step-by-step instructions for the immediate activation of the EMS system for life-threatening complications must be established and maintained. Rehearsal sessions of mock emergencies should be planned and practiced annually, especially if there is a new member of the dental team.

Recommendation 4: Pre-assessment

A cardiopulmonary risk stratification and examination of the patient's recent complete blood count that includes bleeding parameters for invasive dental procedures especially when done under sedation where multiple extractions or invasive procedures are often anticipated.

Aside from obtaining a detailed medical and dental history of the patient, recording the patient's vital signs and investigating the patient's airway are also essential. (Low quality of evidence, strong recommendation)

The decision to perform dental treatment under sedation will depend on the risk to benefit ratio for the child.

<u>Summary of evidence</u>. A thorough and detailed history and physical examination are mandated to effect a positive sedation and general anaesthesia outcome. Neglect in ascertaining a detailed history can lead to adverse respiratory events during and after sedation and general anaesthesia, including atelactasis, bronchospasm, hypoxaemia, and respiratory failure.³⁹

<u>Explanation</u>. For all confirmed <u>and</u> suspected medical conditions which may affect the child's cardiovascular and respiratory status during sedation, these should be properly consulted with their respective physicians as well. For patients who are considered by pediatricians as being high risk, performing the procedures in a hospital setting should be highly considered.

Considerations for treatment in the hospital setting:

- Congenital heart defect
- Neurologic conditions (epilepsy, seizures, CP)
- Severe craniofacial deformities
- ASA 3 patients
- Extremes of age (less than 3 years of age)
- Hyperactive gag reflex
- Obesity

All dentists should indicate the contemplated procedure, estimated operative time and other relevant patient information when referring the patients to the pediatrician for an ageappropriate risk assessment that is typically valid for 7 days.

It is prudent to include in the pre-assessment protocol to request for CBC and bleeding parameters (e.g. BT, PT, PTT, INR, thrombin time) for anticipated tooth extraction. While there is no evidence for routine evaluation of such laboratory examinations, it is strongly advised with strong recommendation not for the purpose of improving anesthesia outcome but to screen for possible hematologic concerns even unknown to parents of the child patient. Additional tests/ examinations (i.e. chest xrays, etc.) are requested on a case-to-case basis (i.e. history, physical examination), according to the patient's needs.

Evaluating a patient's medical condition for a possible underlying systemic or medical condition prior to the dental procedure is strongly encouraged. For any suspected medical illness, these should be properly investigated and referred to the proper physician. The dental practitioner or attending physician may require sub-specialty assessment/evaluation to address any underlying condition that may affect the proposed dental procedure.

On the day of the appointment, prior to the procedure, a patient work-up is still essential. This includes confirming the patient's compliance of fasting, verifying the patient's patent airway (no

cough or colds) and obtaining normal vital signs. Failure to meet these criteria will compel the scheduled dental treatment to be deferred.

Recommendation 5: Intra-operative and Post-operative Monitoring

A sedationist⁴⁰ or another appropriate person who has the capability within his or her scope of practice must monitor the patient throughout and even after the procedure. The assigned appropriate monitor should confirm at regular intervals (every 5 minutes) the patient's vitals signs and that the patient is doing well until the child recovers full consciousness from sedation. (Low quality of evidence, strong recommendation)

<u>Summary of evidence</u>. The panel agreed to adopt the 2019 American Academy of Pediatrics and American Academy of Pediatric Dentistry "Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures."

Clinical monitoring and the use of pulse oximetry for ASA I/II children undergoing sedation is required. Clinical monitoring involves checking the level of consciousness/depth of sedation, airway patency, respiration (rate and depth), skin colour, capillary refill, pulse rate, rhythm and volume. Non-invasive blood pressure monitoring, which also records the heart rate, is not necessary for children.⁴¹

All members of the clinical team must be:

1.) Capable of monitoring the condition of the patient.

2.) While the sedationist, who may be a dentist or medical doctor, must be able to manage any complication arising from the sedation itself and from medical emergencies, all members of the dental team (dentist, sedationist and dental nurse) must be competent in life support.⁴²

All members of the clinical team must be:

- 1) capable of monitoring the condition of the patient.
- 2) able to manage any complication arising from the sedation itself
- 3) able to manage medical emergencies

4) competent in life support.⁴³

Adverse events prior to discharge of a patient are not uncommon. A few reported incidents include, but are not limited to, laryngospasm, nausea and/or vomiting.

Laryngospasm is observed with the highest frequency occurring in 35 cases out of approximately 7,041 pediatric cases (0.50%). Over 85% (30 cases) of these occurred in children 6 and below; 8.5% (3 cases) occurred in children 7–12 and 5.7% (2 cases) occurred in the 13–18-year-old age group. This is followed by post-operative nausea or vomiting requiring antiemetic rescue occurring in 28 cases (0.40%).⁴⁴ Thus during recovery, the patient must be supervised by a trained member of the dental team who must be responsible for the patient and monitor the patient throughout the immediate post-operative period. A written copy of post-operative instructions that has been explained verbally and includes the possible risks and complications, and pain control together with the aftercare arrangements and emergency contacts must be given to the guardian.⁴⁵

<u>Explanation</u>. Consciousness, ventilation, oxygenation and circulation are all important to be monitored continuously throughout the sedation procedure. The primary role of the sedationist / <u>anesthesiologist</u> is to keep the patient at the intended level of sedation and monitor the patient's vital signs (pulse rate, respiratory rate, blood oxygen saturation, and/or blood pressure).

If the intended level of sedation is exceeded, the team caring for the patient must have the appropriate skills to manage the situation.

When the dentist is also the sedationist, as in the case of oral sedation, another trained personnel should monitor the patient for the duration of the procedure, including post-op monitoring.

Recommendation 6: Informed consent

A written informed consent form should be signed, whenever possible, by both parents or legal guardian that all pre- and post-operative instructions were thoroughly discussed, including details of the procedure with full understanding of the consequences and risks involving the treatment and sedation. (Low quality of evidence, strong recommendation) <u>Summary of evidence</u>. If the child is deemed not legally competent, consent will need to be obtained from someone with parental responsibility, unless it is an emergency. Families of children under the age of 18 years should be involved in decisions about their care *unless the patient does not have the proper cognition to understand the procedure*.

Information regarding the sedation technique should contain a description of the sedation procedure that has been suggested and recommended as the most appropriate management technique for the individual patient, including its benefits, risks and alternatives.⁴⁶

Clear and easy-to-understand information should be conveyed to the parents / caregivers of the patients. This includes objectives and options of dental management and sedation, the expectations from the procedure, the anticipated changes in behaviour during and after sedation, the step-by-step procedure of sedation and its complications and risks.

Clinical or hospital networks should develop clear, written protocols for consent for clinical photography which can aid the clinician in gaining consent, with a signature required to consent for every possible use of the image.⁴⁷

To avoid miscommunication and failure of understanding, written orders of pre-operative and post-operative instructions and/or prescriptions shall be provided to the patient. To ensure that pre- and post-operative instructions are understood well, it is prudent to ask for the parent/ guardian to sign the the document stating their understanding of the discussion and for their consent.

Recommendation 7: Documentation during treatment

The patient's chart shall contain a time-based record that includes the name, route, site, time, dosage/kilogram, patient effect of administered drugs. Before sedation, a "time out" should be performed to confirm the patient's name, procedure to be performed, and tooth number, and possible unexpected complications that may occur during the sedation. (Low quality of evidence, strong recommendation)

Recommendation 8: Documentation after treatment

A suitably equipped recovery area with accessibility for continuous monitoring of the patient, such as through a CCTV or glass window panes, is ideal. The time of discharge from the treatment area or facility and condition of the child at discharge shall be documented, together with the child's level of consciousness and oxygen saturation in room air have returned to a state that is safe for discharge by recognized criteria. (Low quality of evidence, strong recommendation)

<u>Summary of evidence</u>. A properly equipped recovery area must have a functioning suction apparatus as well as the capacity to deliver more than 90% oxygen and positive-pressure ventilation. The physician/dentist or his designee shall document the name, route, site, time of administration, and dosage of all drugs administered. The initial recording of vital signs should be documented at least every 5 minutes. Once the child begins to awaken, the recording intervals may be increased to 10 to 15 minutes. If the patient is not fully alert, oxygen saturation and heart rate monitoring shall be used continuously until appropriate discharge criteria are met.⁴⁸

Though there are a number of methods to assess discharge readiness, a practical and reasonably objective evaluation tool may be the ability of the infant or child to remain awake for at least 20 minutes during recovery after sedation in children.⁴⁹

Recommended Discharge Criteria:⁵⁰

- 1. Cardiovascular function and airway patency are satisfactory and stable
- 2. The patient is easily arousable, and protective airway reflexes are intact.
- 3. The patient can talk (if age and cognitive development appropriate)
- 4. The patient can sit up unaided (if age appropriate)
- 5. For a young child or a child with disability who is incapable of the usually expected responses, the presedation level of responsiveness or a level as close as possible to the normal level for that child should be achieved
- 6. The state of hydration is adequate.

Special instructions shall be given to the adult responsible for infants and toddlers who will be transported home in a car safety seat regarding the need to carefully observe the child's head position to avoid airway obstruction. Consideration for a longer period of observation shall be

given if the responsible person's ability to observe the child is limited (e.g., only 1 adult who also has to drive). Another indication for prolonged observation would be a child with an anatomic airway problem, an underlying medical condition such as significant obstructive sleep apnea (OSA), or a former preterm infant younger than 60 weeks' post- conceptional age. A 24-hour telephone number for the practitioner or his or her associates shall be provided to all patients and their families. Instructions shall include limitations of activities and appropriate dietary precautions.⁵¹

<u>Explanation</u>. Written post-operative instructions explained and given to the guardian and a standardized discharge criteria must be followed. If a dedicated recovery room is not available, the operatory may function as recovery area provided that the child/patient and the guardians have adequate privacy, can be thermoregulated, necessary monitoring equipment are within premises, and can be monitored closely by a member of the dental team.

Recommendation 9 : Fasting

A 2-4-6 fasting rule (two hours for clear fluids, four hours for breast milk and six hours for solids) should apply for all children who will undergo sedation. (Low quality of evidence, strong recommendation)

<u>Summary of evidence.</u> The Academy of Medical Royal Colleges' publication Safe Sedation Practice for Healthcare Procedures, devotes a section to fasting, which is quoted in full:

'Pre-operative fasting for sedation is controversial and considered unnecessary by some authorities within dentistry and emergency medicine for conscious sedation. Airway reflexes are assumed to be maintained during moderate and minimal sedation, and lost during general anaesthesia. It is not clear where the point of loss of reflexes lies, or if such a point exists. The argument is that using minimal and moderate sedation, airway reflexes are maintained but this does not consider the potential for inadvertent over-sedation and the loss of protective airway reflexes. In the United Kingdom the loss of verbal communication/ deep sedation is deemed to require the same level of care as general anaesthesia, and many practitioners therefore follow accepted fasting guidance.

Guidance from NICE (National Institute for Health and Care Excellence) on sedation of children recommends fasting before sedation unless the sedation is limited to:

- minimal sedation
- sedation with nitrous oxide (in oxygen)
- moderate sedation during which the child or young person will maintain verbal contact with the healthcare professional

For elective procedures using any sedation other than the above (and specifically for deep sedation and moderate sedation during which the child or young person might not maintain verbal contact with the healthcare professional) the 2-4-6 fasting rule applies (that is, two hours for clear fluids, four hours for breast milk and six hours for solids)."⁵²

Question 4: What drugs should be used for sedation among pediatric patients undergoing dental procedures?

Recommendation 1: For minimal sedation, oral midazolam may be used for children undergoing short and simple procedures to improve their behavior. (Low quality of evidence, strong recommendation)

<u>Summary of evidence</u>. A systematic review of all sedatives used for dental procedures by Ashley, Chaudhary, Lourenco-Matharu in the Cochrane Library in 2018 provides a comprehensive discussion of all modalities.⁵³ There were 34 different sedatives used in this review given either orally, by inhalation, intramuscularly, intranasally and/or rectally at varying dosages. Out of the 50 studies, only those of oral midazolam compared to placebo could be explored for a meta-analysis. Six heterogenous trials were included in the meta-analysis using overall behavior as measured by Houpt as an outcome measure. It revealed that there is low certainty but consistent evidence that following the administration of oral midazolam, the patients were more cooperative for dental treatment, with variations in dosage used in all of these trials (SD 1.96, 95% confidence interval). (See Table 1) Dosage at 0.5 mg/kg given orally has been the widely accepted dosage based on a balance of safety and efficacy, but 0.75 mg/ kg has been given with few adverse events. Isik 2008 and Somri in 2012 reported that 0.75 mg/ kg is the optimal dose for effectiveness, acceptability and safety.^{54,55}. However given the small number of studies (n = 6), participants (n =202) and high risk of bias of a couple of these papers, this conclusion must obviously be treated with some caution.

Explanation. Midazolam is a lipid-soluble benzodiazepene with peak plasma concentrations at 60 minutes when given orally; and its onset of action at 20 minutes. Therefore, we can propose that midazolam can be the drug of choice for simple and short procedures, not exceeding 30

minutes. With its rapid onset of action and recovery and its property of anterograde amnesic effect, midazolam has been widely used as a sedative in the dental setting in the Philippines. While it has been seen to improve behavior in children, the effects of oral midazolam can also be unpredictable. With that said, the parents must be made aware of the unpredictability of oral midazolam when used on their children. And the dental team should also be trained to manage these effects.

Table 1. Summary of Findings table for Midazolam compared to placebo

Patient or population: Setting: Office setting Intervention: Midazolam Comparison: placebo		ergoing dental procedu	res		
Outcomes	Anticipated ab	Anticipated absolute effects [*] (95% CI)		№ of participants (studies)	Certainty of Comments the evidence
	Risk with placebo	Risk with Midazolam			(GRADE)
Mean behavioral score assessed with: Houpt Scale from: 1 to 6	s -	-	-	182 (5 RCTs)	⊕⊕⊖O Low ^{a,b}
The risk in the interve and its 95% CI).	ention group (and its	95% confidence interva	al) is based on the a	assumed risk in the co	mparison group and the relative effect of the intervention
CI: Confidence interval; S	MD: Standardised me	an difference			
s substantially different ow certainty: Our conf	very confident that the are moderately confi idence in the effect es	true effect lies close to dent in the effect estim timate is limited: The to	ate: The true effect rue effect may be s	is likely to be close to ubstantially different f	o the estimate of the effect, but there is a possibility that it rom the estimate of the effect tially different from the estimate of effect

a. Five studies had unclear randomization, 5 studies had unclear concealment, 3 studies had no blinding
 b. I squared equals 91%

Recommendation 2: The medical anesthesiologist must be the anesthesia provider for moderate sedation. That said, it is upon the guidelines and protocols set by the Philippine Society of Anesthesiologists, they shall decide on the sedatives as he/she deems appropriate to be used on the child, which may include but not limited to: midazolam, ketamine, propofol, fentanyl and atropine. (Low quality of evidence, strong recommendation)

Recommendation 3: The maximum duration of moderate sedation, particularly the intramuscular / intravenous route of sedation, should be confined to 2 hours as much as possible when working on pediatric patients or those with special health care needs. (Low quality of evidence, conditional recommendation)

Summary of Evidence. There is no scientific evidence that recommends the length of time an IV sedation procedure should be accomplished on children.

<u>Explanation</u>. While there is no scientific evidence recommending the length of time of treatment with minimal incidence of complications for a moderate sedation procedure on children, it is the consensus of the PPDSI CPG committee and the stakeholders to make the duration of the treatment as short as possible for lesser complications. Patients can become agitated as treatment time becomes prolonged, which can contribute to more complications.

The dental team must work efficiently to accomplish most in a duration of 2 hours. It is advised to formulate a treatment plan, prioritize procedures that will address sources of odontogenic infection, identify teeth with the best outcomes, and judge whether documentation is essential to the course of dental management (i.e. whether to take pre-operative clinical photos) as this often may cause delays in treatment.

Complicated cases, estimated to be accomplished for longer than 2 hours can have an alternative treatment plan — either the patient can be treated under deep sedation in the confines of the safety of the hospital operating room, or the treatment plan can be modified to complete the treatment within 2 hours. Whatever option is taken, the clinician should keep in mind the safety of the child. While it is reasonable to set a guideline of 2 hours for treatment duration for IV sedation cases, the team should be able to assess the child well medically and to abort the treatment immediately when complications arise.

Recommendation 4: Nitrous oxide may be used for children undergoing dental procedures. (Moderate quality of evidence, conditional recommendation)

<u>Summary of Evidence.</u> There is moderate evidence that demonstrates that nitrous oxide inhalation can improve the behavior of the children in one randomised clinical trial. The study did not show any adverse events. However, in this trial of Veerkamp⁵⁶, his subjects were 6-11 years old. There is no evidence that supports nitrous oxide inhalation can be recommended for those below that age group.

<u>Explanation</u>. Nitrous oxide inhalation sedation seems to be a good option for highly fearful older children, especially those who are needle-phobic. Very young children may not benefit from this. Dentists who offer nitrous oxide inhalation sedation in their practice should undergo additional training on its proper use.

Although nitrous oxide exhibits a superior safety profile with no recorded fatalities or cases of serious morbidity when used within recommended concentrations,⁵⁷ it should be noted that

this method of achieving analgesia/anxiolysis is technique sensitive, thus requiring proper training in manipulation of equipment and titration of the gases. Several contraindications must also be noted, a few of which are the following:58

- 1. Some chronic obstructive pulmonary diseases
- Current upper respiratory tract infections
- 3. Recent middle ear disturbance/surgery
- 4. Severe emotional disturbances or drug-related dependencies
- Treatment with bleomycin sulfate, an anti-neoplastic drug 5.
- Methylenetetrahydrofolate reductase deficiency, an enzyme deficiency of genetic 6. origin, and
- 7. Cobalamin (vitamin B12) deficiency

Summary of findings:

NDO			
N2O compared to place	cebo for pediatric pa	atients undergoing	dental procedures

Patient or population: pediatric patients undergoing dental procedures Setting: Office setting Intervention: N20

Outcomes	Anticipated absolute effects [*] (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of Comments the evidence (GRADE)
	Risk with placebo	Risk with N2O			
Mean behavioral score assessed with: Houpt score Scale from: 1 to 6	-	-	-	52 (1 RCT)	⊕⊕⊕O MODERATE ª
Overall behavior score ordinal scale) issessed with: Houpt or imilar scale from: 1 to 6	-	-	-	56 (1 RCT)	DOBENTE ^a

CI: Confidence interval; SMD: Standardised mean difference

GRADE Working Group grades of evidence High certainty: We are very confident that the true effect lies close to that of the estimate of the effect Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. Randomization was not clear; there was unclear randomization concealment; no blindeding

Dental workers are exposed to nitrous oxide during administration of the anesthetic gas to patients. Occupational exposure should be minimized to prevent short-term behavioral and long -term reproductive health effects.⁵⁹ Nitrous oxide inhibits vitamin B12 metabolism and can cause liver, kidney, and neurological disease.

Recommendation 5: Chloral hydrate should not be used for children undergoing dental

procedures. (Low quality of evidence, strong recommendation)

Summary of Evidence. There is weak evidence from one trial, that following administration of oral chloral hydrate the behavior of children did not improve compared to placebo. Therefore, there is weak recommendation against its use.

Chloral hydrate co	ompared to place	ebo for pediatric	patients und	ergoing dental	procedures		
Patient or population: pediatric patients undergoing dental procedures Setting: Office setting Intervention: Chloral hydrate Comparison: placebo							
Outcomes	Anticipated abs	Anticipated absolute effects* (95% CI)		№ of participants (studies)	Certainty of the evidence (GRADE)	Comments	
	Risk with placebo	Risk with Chloral hydrate					
Not good or better behavior	467 per 1,000	253 per 1,000 (131 to 489)	RR 0.542 (0.280 to 1.047)	60 (1 RCT)	⊕⊕OO LOW ^{a,b}		

CI: Confidence interval; RR: Risk ratio

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. Unclear randomization, unclear concealment, high risk of incomplete outcome assessment

b. Confidence intervals cross 1

Explanation. Chloral hydrate was a popular sedative drug used in pediatric dentistry in the 1980s. Favorable reports and its assumed safety made this an accepted sedative and hypnotic drug of choice among pediatric dentists. But in this trial of Moore⁶⁰, the placebo response was unexpectedly pronounced. While it was interesting to note that there was some improved behavior with an increased dose of chloral hydrate, this was observed only in one third of the children. Therefore, the lack of evidence showing chloral hydrate's effectivity as a sedative for children, the insufficient quality studies and the unavailability of chloral hydrate in the Philippines prompted this committee to give a strong recommendation against its use.

Other routes of administration of sedation. Intranasal and rectal sedation were not included in this guideline because of its limited studies and insufficient evidence. Children accept rectal sedation poorly when compared to oral sedation.⁶¹

APPENDIXES

Appendix 1. CPG Topic Selection and Prioritization

Objective: To identify priority topics for CPG development from key stakeholders based on consensus across different agencies and institutions. Guidelines can be developed for a wide range of topics, including conditions, procedures, signs and symptoms

Criteria for Prioritizaion of CPG Topics:

- I. Disease Burden
 - Prevalence and/or incidence
 - Co-morbidity, morbidity, mortality
 - Quality of life
 - Effects on patients, families, communities, society
- II. Public Contention
 - Public interest surrounding the topic (consumers, patients, clinicians, and others who want an assessment to inform decisionmaking)
- III. Cost-effectiveness
 - Economic evaluation (unit cost of care, indirect costs)
- IV. New Evidence
 - Recent high quality of evidence with potential to change previous recommendations
- V. Potential Impact
 - Potential to improve health outcomes, quality of life
 - Improve decision-making for provider or patient
- VI. Interest of Public or Care Providers
 - Recommendations by practitioners or stakeholders
- VII. Variation in Care
 - Potential to decrease variation in care (prevention, diagnosis, treatment)
 - When the current use is outside the parameters of clinical evidence
- VIII. Sufficiency of Evidence
- Availability of clearly defined and high quality evidence
- IX. Timeliness
 - Urgency for guideline to be developed

From the Manual for Clinical Practice Guideline Development by the Department of Health -Philippines and Philippine Health Insurance Corporation. 1st ed 2018

Appendix 2: General Framework of Research Questions and Corresponding Search Terms Used

1. Among children requiring dental work / restoration, will conscious sedation result in lowering mortality and morbidity (including but not limited to coma, neurologic sequelae, serious adverse effects, poor pain control, poor tolerance, psychological trauma, no amnesia or poor post sedation behavior)?

PECOM Details	Primary search terms	Secondary search terms
Population	Children needing dental extraction / restoration	
Exposure	Conscious sedation	

PECOM Details	Primary search terms	Secondary search terms
Outcome	Mortality Mobidity	Death, coma, neurologic sequelae, serious adverse effects, poor pain control, poor tolerance, psychological trauma, no amnesia or poor post sedation behaviour
Methods	Cohort studies Studies on harm (case - control) Randomized controlled trials (with conscious sedation as one of the treatment arms) Meta -analysis and systematic reviews	

2. Among pediatric patients who require dental procedures / restoration, what types of patients [normal kids (2-19 years old) requiring multiple procedures, uncooperative patients, patients with dental fear/anxiety, patients with special health care needs, patients who incurred dental trauma or patients requiring urgent treatment] will have better treatment outcomes when provided conscious sedation?

PECOM Details	Primary search terms	Secondary search terms
Population	Normal kids (2-19 years old) requiring multiple procedures Uncooperative patients Patients with dental fear/anxiety Patients with special health care needs Patients who incurred dental trauma Patients requiring urgent treatment	
Exposure	Conscious sedation	
Outcome	Mortality Mobidity	Death, coma, neurologic sequelae, serious adverse effects, poor pain control, poor tolerance, psychological trauma, no amnesia or poor post sedation behaviour
Methods	Cohort studies Studies on harm (case - control) Randomized controlled trials (with conscious sedation as one of the treatment arms) Meta -analysis and systematic reviews	

3. Among patients requiring dental procedures / restoration, what procedures will result in better treatment outcomes?

PECOM Details	Primary search terms	Secondary search terms
Population	Pediatric patients requiring dental procedures	
Exposure	Conscious sedation	
Outcome	Mortality Mobidity	Death, coma, neurologic sequelae, serious adverse effects, poor pain control, poor tolerance, psychological trauma, no amnesia or poor post sedation behaviour
Methods	Cohort studies Studies on harm (case - control) Randomized controlled trials (with conscious sedation as one of the treatment arms) Meta -analysis and systematic reviews	

Search	Add to builder	Query	Items found	Time
<u>#25</u>	Add	Search (#15 and #20 and #24)	<u>815</u>	23:14:54
<u>#24</u>	Add	Search (#21 or #23)	<u>95619</u>	23:14:33
#23	Add	Search "Dental Care"[Mesh]	31259	23:14:12
<u>#21</u>	Add	Search Dental procedures	<u>95619</u>	23:13:09
<u>#20</u>	Add	Search (#16 or #19)	222063	23:12:47
<u>#19</u>	Add	Search "Anesthesia and Analgesia"[Mesh]	<u>220745</u>	23:12:25
<u>#16</u>	Add	Search conscious sedation	<u>9878</u>	23:11:22
<u>#15</u>	Add	Search (#1 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14)	4496404	23:11:02
<u>#14</u>	Add	Search no amnesia	<u>13027</u>	23:09:33
<u>#13</u>	Add	Search psychological trauma	<u>13899</u>	23:09:11
<u>#12</u>	Add	Search poor pain control	<u>6748</u>	23:09:01
<u>#11</u>	Add	Search sequelae	<u>2879533</u>	23:07:58
<u>#10</u>	Add	Search serious adverse events	24238	23:07:37
<u>#9</u>	Add	Search Complications	2846772	23:07:12
<u>#8</u>	Add	Search Death	767218	23:06:57
#7	Add	Search ("Mortality"[Mesh]) OR "Morbidity"[Mesh]	803071	23:06:09
#1	Add	Search Mortality	1115392	23:03:57

Philippine Board of Pediatric Dentistry (PBPD)	Eric Hernandez, DMD Carina Delos Reyes, DMD	None None
Philippine Society for Developmental and Behavioral Pediatrics (PSDBP)	Rochelle Pacifico, MD (President) Agnes Falcotelo, MD (Vice President)	None None
Philippine Society of Anesthesiologists, Inc.(PSA)	Angel Gomez, MD (President)	None
Philippine Pharmacists Association (PPHA)	Karen Romero, RPh, MTM Oscar Ocampo, Jr., RPh	None None
Philippine College of Oral and Maxillofacial Surgeons (PCOMS)	Mendelssohn Manalaysay, DMD Lea Alcantara, DMD	None None
Department of Health (DOH)	Rochelle Pambid, DMD	None
PhilHealth	Roberto Balaoing, DMD	None
Autism Society of the Philippines (ASP)	Evalyn Macasaet, MD (Anesthesiologist)	None
Noordhoff Craniofacial Foundation, Inc. (NCFPI)	Dulce Estebaya Cristine Jalimao	None None
Representatives from HMO companies	PACIFIC CROSS Shannen Amoloza Medalyn Zarate PHILAM Ofelia Go	None None None
	Christopher del Rosario	None
PPDSI members who are part of the academe	Lilia Mendoza, DMD Centro Escolar University- Manila	None
	Carmen Sanchez, DMD Centro Escolar University- Makati	None
	Shirley Wong, DMD Centro Escolar University- Malolos	None

Appendix 3: Declaration of Conflict of Interest of PPDSI Stakeholders' Representatives

Albuterol for inhalation	Diazepam	Methylprednisolone	Rocuronium
Amiodarone	Epinephrine (1:1000, 1:10 000)	Midazolam	Sodium bicarbonate
Ammonia spirits	Fentanyl	Naloxone	Succinylcholine
Atropine	Flumazenil	Oxygen	20% lipid emulsion for local anesthetic toxicity
Dextrose	Lidocaine (cardiac lidocaine, local infiltration)	Fosphenytoin	
Diphenhydramine	Lorazepam	Racemic epinephrine	
*The choice of emerge	ency drugs may vary accord	ing to individual or procedu	ural needs

Appendix 4. F	Drugs That May	Relised to	Rescue	Sedated Patient
Appendix 4. L	Jiugs mat May	be used to	Nescue a	Seualeu ralient

Appendix 5: Emergency Equipment That May Be Needed to Rescue a Sedated Patient

Intravenous equipment

Assorted intravenous catheters (eg, 24-, 22-, 20-, 18-, 16-gauge)	Adhesive tape	Extension tubing	Pediatric intravenous boards	
Tourniquets	Assorted syringes (eg, 1 mL, 3 mL, 5 mL, 10 mL, 20 mL, and 60 mL)	Three-way stopcocks	Intraosseus needles	
Alcohol wipes	Intravenous tubing Pediatric drip (60 drops/ mL) Pediatric burette Adult drip (10 drops/ mL)	Intravenous fluid Lactated Ringer solution Normal saline solution D5, 0.25 normal saline solution	Sterile gauze pads	
Assorted intravenous needles: 25-, 22-, 20-, and 18-gauge				
The choice of emergency drugs may vary according to individual or procedural needs.				

Airway Management Equipment

Face masks (infant, child, small adult, medium adult, large adult)	Laryngoscope blades (with extra light bulbs) Straight (Miller) No. 1, 2, and 3 Curved (Macintosh) No. 2 and 3	Yankauer-type suction
Breathing bag and valve set	Endotracheal tubes 2.5, 3.0, and 3.5 mm internal diameter uncuffed and 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 7.0, and 8.0 mm internal diameter cuffed (a cuffed tracheal tube 0.5 size smaller than an uncuffed tube may be used in children >3 months)	Nasogastric tubes
Oropharyngeal airways (infant, child, small adult, medium adult, large adult)	Stylettes (appropriate sizes for endotracheal tubes)	Nebulizer with medication kits
Laryngeal mask airways (1, 1.5, 2, 2.5, 3, 4, and 5)	Surgical lubricant	Gloves (sterile and nonsterile, latex free)
Laryngoscope handles (with batteries)	Suction catheters (appropriate sizes for endotracheal tubes)	

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