REVIEW OF PEDIATRIC DENTISTRY ORAL SEDATION OUTCOMES AND

INFLUENCES

by

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Abstract

Objectives: The UBC Graduate Pediatric Dentistry Program’s oral sedation clinic has evolved since it began in 2011. The study aimed to evaluate the effectiveness and safety of the various sedation regimens used, and to assess how regimens were influenced by the experience and opinions of clinical instructors.

Methods: A retrospective chart review of all oral sedation appointments that took place between March 2011 and May 2014 was completed. The outcome variables of interest were effectiveness and safety. Descriptive and comparative statistics were applied to analyze quantitative data. Six UBC Pediatric Dentistry clinical instructors were invited for interviews through a purposive sampling technique to further understand both their views toward sedation regimens and teaching sedation to graduate students. Thematic analysis was applied to code interview transcripts.

Results: There were 195 oral sedation appointments during the study period. The three most commonly used regimens were: midazolam and hydroxyzine (MZH) (45%); midazolam (MZ) (24%); and meperidine, chloral hydrate, hydroxyzine, and dimenhydrinate (MCHHD) (17%). With respect to safety, vital signs and level of sedation were examined. Children undergoing MZH sedations were rated to be in “deep” sedation 1.4% of the time, compared to 12.5% in the MCHHD group. MZH sedations were rated “effective/very effective” 90% of the time, compared with 88% for MCHHD sedations. Data for sedation level and effectiveness of the MZ group was limited. Domains that emerged from the interviews were safety, effectiveness, preparation, and preferences; with risk tolerance as the overarching theme.
**Conclusion:** MZH and MCHHD have similar effectiveness however MZH has a better safety profile. Clinicians with higher risk tolerance tended to practice sedation more frequently than those with low risk tolerance. Accordingly, high risk tolerance clinicians felt students should learn sedation more extensively than did those with low risk tolerance. Two main recommendations emerged from the study: (1) complete and inclusive sedation records are critical to fully understanding the effectiveness and safety of sedation regimens; 2) clinicians may desire to have self-awareness regarding their risk tolerances in the context of both practicing and teaching oral sedation in pediatric dentistry.
Preface

This thesis is an original work of the author, Zina Alkafaji, with the input and guidance from research committee members Dr. Kavita Mathu-Muju, Dr. Rosamund Harrison, Dr. HsingChi Von Bergmann, Dr. Marissa Garcia, and Dr. Heather Bush.

Statistical analyses were completed by David A. Akers and Dr. Heather Bush from the Department of Statistics, University of Kentucky.
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List of Abbreviations

MZ Midazolam
MZH Midazolam and hydroxyzine
MCHHD meperidine and chloral hydrate and hydroxyzine and dimenhydrinate
SpO2 oxygen saturation
HR heart rate
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Chapter 1: Introduction

The University of British Columbia Graduate Pediatric Dentistry program, which began in August 2010, is a combined hospital- and university-based program for dentists seeking specialty training in pediatric dentistry. A component or module of the program is an oral sedation clinic where child dental patients are treated using oral and inhalational sedation. During these weekly four-hour clinical sessions, one to four patients are treated with the use of oral sedation. Fewer patients were treated in the early years of the program compared to more recent years. Usually one or two clinical instructors supervise three to five graduate students. As the program evolved, a variety of clinical instructors, either pediatric dentists or dental anesthetists, taught in these clinics. Not surprisingly, each instructor brought his or her own experience, training and preference of drug regimen to the program. This study will allow reflection on the early years of sedation training in a new graduate pediatric dentistry program, to inform future program development.

1.1 Pediatric Dentistry Specialty Training Programs

Pediatric dentistry is a clinical dental specialty. Pediatric dentistry specialty programs are offered at four Canadian faculties of dentistry. Each program provides the training required for eligibility to take the National Dental Specialty Examination, leading to fellowship in the Royal College of Dentists of Canada as a certified specialist in pediatric dentistry (CAPD website, October 2016). Numerous pediatric dentistry specialty programs exist in the United States that offer dentists similar training (AAPD website, October 2016).
1.2 Accreditation Standards

Both Canada and the US have standards that Advanced Specialty Education Programs must follow. In Canada, these requirements are set by the Commission on Dental Accreditation of Canada (CDAC), and in the US “standards” are set by the Commission on Dental Accreditation (CODA). Within pediatric dentistry, there are certain key topics that must be taught to trainees; sedation is such a topic. Programs must adhere to these accreditation standards when developing a curriculum for a specialty program.

1.2.1 CDAC

The Commission on Dental Accreditation of Canada (CDAC) is not specific regarding the number of sedation experiences a trainee must complete. The relevant requirement states that instruction must be provided at the in-depth level in “the principles and objectives of conscious sedation, deep sedation, and general anaesthesia as behaviour management techniques, including indications, contraindications and monitoring.” ‘In-depth’ is defined as “thorough knowledge of concepts and theories for the purpose of critical analysis and the synthesis of more complete understanding” (CDAC, 2013). Furthermore, the document suggests that pediatric dentistry programs should provide clinical experiences to graduates so that they can “assume the level of professional responsibility appropriate to the specialty practice of pediatric dentistry and provide those services usually provided in the practice of pediatric dentistry” (CDAC, 2013).

1.2.2 CODA

The U.S. Commission on Dental Accreditation (CODA) recommends that trainees receive didactic and clinical training at the in-depth level with respect to sedation. Furthermore,
“students/residents must complete a minimum of 50 patient encounters in which sedative agents other than nitrous oxide (but may include nitrous oxide in combination with other agents) are used. Of the 50 patients encounters, each student/resident must act as operator in a minimum of 25 sedation cases.” Of the remaining cases, the student can be involved in monitoring the child (CODA, 2016).

1.3 Development of Sedation Program

In developing the pharmacological behaviour management component of a graduate training program in pediatric dentistry, many factors must be considered. Accreditation requirements and provincial, state and/or national guidelines must be taken into account. The training and views of faculty will also play a role, in addition to that of other stakeholders like pediatric dentists in the community and both medical and dental anesthetists.

As part of the requirements for training in pediatric dentistry, the American Academy of Pediatric Dentistry (AAPD) recommends that pediatric dental residents be instructed in the practice of pediatric dental sedation (Ng 2004). Thus, pediatric dentistry graduate programs teach sedation to their students. However, there is substantial variation among programs in the teaching of sedation methods, monitoring, and management of emergencies (Wilson & McTigue, 1989).

A survey of program directors and practitioners revealed their belief that specific training experiences were essential for graduates to be considered proficient (Casamassimo & Wilson, 1999). Such experiences include orthodontics, comprehensive restorative dentistry, general anesthesia experience, and treatment of patients with special needs. Most program directors agreed that at least 10 oral sedation cases were needed for proficiency. Practitioners and program
directors, however, disagreed on the number of submucosal and intravenous sedation cases needed, with practitioners suggesting more cases than program directors (Casamassimo & Wilson, 1999).

It appears that pediatric dentists in practice differ from academics regarding the types and numbers of experiences needed to be a proficient pediatric dentist. The dissonance between the two parties may create friction when developing a sedation program, as members of the community practitioners are often those providing clinical teaching. Indeed, the choice of sedation regimen taught in pediatric dentistry graduate programs seems to be largely anecdotal based on the comfort levels and/or personal preference of the faculty (Wilson et al., 2001).

1.4 Sedation

Medical or dental procedures often induce pain or anxiety in patients. Procedural sedation reduces the discomfort, apprehension, and potential unpleasant memories associated with such procedures, and facilitates performance of the procedure. According to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the College of Dental Surgeons of British Columbia guidelines, there are multiple levels of sedation: minimal, moderate, deep, and general anesthesia (AAP, 1992; CDSBC Sedation Standards, 2016). Minimal sedation is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, respiratory and cardiovascular functions are unaffected (Cote & Wilson, 2006; CDSBC Sedation Standards, 2016). Moderate sedation is defined as 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 (Cote & Wilson, 2006; CDSBC Sedation Standards, 2016).
Deep sedation is defined as a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated verbal or painful stimulation (Cote & Wilson, 2006; CDSBC Sedation Standards, 2016). The CDSBC Sedation Standards further differentiates between moderate and deep sedation by clarifying that a patient whose only response is reflex withdrawal from a painful stimulus is considered to be in deep sedation, not moderate. Finally, general anesthesia is a drug-induced loss of consciousness during which a patient is not arousable, even by painful stimulation. Patients in this state often require assistance in maintaining a patent airway, and cardiovascular function may be impaired (Cote & Wilson, 2006; CDSBC Sedation Standards, 2016).

In the province of British Columbia, if a dentist wishes to practice oral moderate sedation with administration of multiple sedative drugs with or without nitrous oxide/oxygen, he/she must meet certain educational requirements. These include participation in at least 40 hours of didactic instruction and supervised use of sedation concurrent with dental treatment on 20 patients (CDSBC Sedation Standards, 2016).

1.5 Pediatric Dental Patients

Most pediatric dental patients, defined as individuals under age 18, are managed in the dental office with behaviour management techniques such as tell-show-do, voice control, and distraction (Ashley et al., 2011). However, some patients are unable to cooperate due to age or medical conditions, and cannot be managed solely with non-pharmacological behaviour techniques. These patients can either be treated with the aid of sedation in the dental office, or under general anesthesia (Ashley et al., 2011).
Children aged 3-5 years represent the age group most commonly-treated with the aid of sedation (Wilson & Houpt, 2016). Many children of this age do not have the necessary coping skills to tolerate dental treatment (Ashley et al., 2011). Recently, pediatric dentists report that they are increasingly choosing to sedate older school-aged children (i.e. older than 10 years old), likely due to concerns with safety (Wilson & Houpt, 2016).

Sedating a child is different than sedating an adult. It is often necessary to manage behaviour so that procedures can be completed safely which may require a deep level of sedation depending upon the child’s age and development. Children under six years of age are particularly vulnerable to the sedating medication’s effects on respiratory drive, patency of the airway, and protective reflexes (Cote, 2000). Furthermore, studies have shown that it is common for children to pass from the intended level of sedation to an unintended deeper level of sedation (Dial, 2001).

The pediatric airway is more susceptible to obstruction because of a variety of anatomical differences from adults. For example, the tongue is much larger at birth and gradually descends with the larynx by the fourth year of life. Furthermore, the epiglottis is narrow and omega-shaped in children and projects posteriorly causing it to be more prone to obstructing the laryngeal inlet. The small nares and mandible, large tongue, excess of soft tissue plus short neck all result in higher risk of airway obstruction (Mason, 2012).

### 1.6 Sedation candidates

A thorough medical history must be taken for a patient when considering any kind of pediatric sedation. A child with co-morbidities will be at a significantly higher risk to adverse events. It is important to address and understand issues such as allergies, respiratory and
cardiovascular risk factors, impaired metabolic and organ function and the psychosocial makeup of a child. The American Society of Anesthesiologists’ (ASA) Physical Status Classification System (ASA I-IV) describes the patient’s pre-operative physical status. It does not describe surgical risk, which would relate to a number of variables such as the individual anesthetist, anesthetic technique, surgical technique, or nature of the operation (Haynes & Lawler, 1995). To optimize favorable sedation outcomes, only healthy children who are ASA class I, or those with very minor conditions, ASA class II, should be sedated (Wilson, 2004). Children of ASA class III or IV should be managed under general anesthesia in a suitable facility.

In addition, the practitioner should do a physical exam of the airway and tonsils. The Mallampati classification is based on the structures visualized with maximal mouth opening and tongue protrusion in the sitting position. In a Class I airway the soft palate, fauces, uvula and pillars are visualized. In Class IV only the hard palate is visualized (Mason 2012). With respect to tonsils, the Brodsky Tonsil Classification System is used to evaluate the size of tonsils. This is done because the likelihood of airway blockage in a sedated child with enlarged tonsils is increased (Fishbaugh et al, 1997). The percentage of pharyngeal area that is occupied by hypertrophied tonsils is classified from 0 to 4; with 0 having no tonsils visualized and in 4 occupying more than 75% of the pharyngeal area (Mason, 2012). When the tonsils occupy a larger portion of the pharyngeal area, or are “kissing”, respiratory depression secondary to upper airway obstruction can occur, and may be a contraindication to sedation (Fishbaugh et al, 1997).

Further, parents should be questioned regarding history, duration, and frequency of snoring (Wilson, 2004). In addition, BMI should be assessed as there are risk factors associated with high BMI and pediatric sedation because of restricted airway, increased risk of snoring,
It is recommended that children undergoing sedation for a scheduled elective procedure adhere to a fasting protocol in order to minimize the risk of aspirating gastric contents. Interestingly, a prospective case series in emergency room sedations suggests no association between pre-procedural fasting state and adverse events (Agrawal et al, 2003). The British Columbia Children’s Hospital (BCCH) Procedural Sedation and Analgesia Standards and Guidelines suggests that children fast for two hours after receiving clear liquids, four hours after breast feeding, and six hours after ingesting solid foods, formula, or milk other than human milk prior to procedural sedation or general anesthesia (GA) or both (BCCH Procedural Sedation and Analgesia Standards and Guidelines, 2016).

1.7 Sedative Agents

The ideal sedative agent relaxes the patient such that dental treatment can safely, effectively, and non-traumatically be completed. A variety of sedative agents are used, some of which provide only a small margin that can move a patient from moderately sedated to deeply sedated, or even to a state of general anesthesia. Agents such as benzodiazepines, opioids, and antihistamines are commonly used in pediatric dentistry due to their favorable onset, working time, recovery time, and safety profile. Most Canadian and American graduate pediatric dentistry programs use nitrous oxide as a behaviour management adjunct, either alone or in combination with other agents (Wilson et al., 2001). Of programs, 88% use benzodiazepines, likely due to their quick onset and availability of reversal (Wilson et al., 2001). It has been found that in the last ten years, the type of sedative used in graduate pediatric dentistry programs has changed (i.e. ...
from chloral hydrate to midazolam) and emergency drills are practiced more often with an increased number of individuals certified in Advanced Cardiac Life Support (ACLS) and/or Pediatric Advanced Life Support (PALS) (Wilson et al, 2001).

Benzodiazepines are a commonly used agent that seems to have good efficacy and a wide margin of safety (Lourenco-Matharu, 2012). Midazolam (MZ) is an example of a benzodiazepine, and has anxiolytic, amnestic, muscle relaxant, sedative, and hypnotic effects (Krauss & Green, 2006). It has a short onset of about 15-20 minutes, and a working time of about 30-40 minutes. It is commonly used for short emergency dental visits due to its short onset, duration of action and amnesic effects. However, for longer restorative visits the working time needs to be extended with other agents (Musial et al 2003). Paradoxical reactions, characterized by crying, combativeness, and restlessness has been reported in 1-15% of children receiving midazolam (Krauss & Green, 2006). Flumazenil is a drug used to reverse benzodiazepine-induced sedation (Krauss & Green, 2006).

Opioids like meperidine (M) also provide analgesic properties. They have an onset of 30 minutes with peak effect around 1 to 2 hours. Some adverse reactions include respiratory depression and nausea or vomiting (Mason, 2012). Naloxone is an opioid reversal agent that should be available in case of emergency or oversedation (Krauss & Green, 2006).

Antihistamines like hydroxyzine (H), dimenhydrinate (D), and promethazine are commonly used in conjunction with other sedatives for its antiemetic and sedative properties (Musial et al 2003). They generally have an onset is 15 to 30 minutes with a 2 to 4 hour working time, but they have no reversal agent (Krauss & Green, 2006).

Ketamine is considered a general anesthetic at high doses and an analgesic at low doses (Cote, 2008). It produces a phenomenon known as ‘dissociative anesthesia’, which consists of
profound analgesia, sedation, amnesia, and immobilization. After reaching a critical threshold, dissociation abruptly occurs. Such an event is not consistent with JCAHO or CDSBC definitions (mild, moderate, deep, GA) because it does not fit on the classical sedation continuum (Krauss & Green, 2006). It has no reversal agent. It is well-known that ketamine causes hypersalivation and for this reason, is often administered along with an anticholinergic agent such as glycopyrolate (Cote, 2008).

Chloral hydrate (CH), a drug classified as a hypnotic, has been used in dentistry for over 150 years. However, studies now caution its use for a variety of reasons such as its carcinogenic properties, long half-life, and lack of reversal agent (Steinberg, 1993).

Nitrous oxide is an inhaled gas that provides anxiolysis, mild sedation, and some analgesia. It is administered at concentrations between 30–70% with oxygen composing the remainder of the mixture. It has a very quick onset of around one minute and rapid recovery upon discontinuation. It has an excellent safety profile and is used widely in both dentistry and medicine (Krauss & Green, 2006). It is commonly and routinely administered simultaneously with other sedative agents because the amount of disruptive behaviours decreases with the addition of nitrous oxide (Musial et al., 2003).

**1.8 Sedation Regimen**

Many drug regimens are currently used in practice for sedating child patients. However, choice of regimen seems more based on anecdote and personal preference than scientific evidence. The decision of which drug regimen to use in pediatric dentistry sedation procedures should be based on that which is most effective, while still maintaining a wide safety margin.
Trends in use of drug regimens for pediatric dentistry have evolved over the years. In the 1980’s, chloral hydrate was used alone or in combination in 62% of all sedations (Duncan et al., 1983). A decade later chloral hydrate and hydroxyzine in combination with nitrous oxide was the most frequently used regimen (Wilson, 1996). More recently, midazolam has come into favor for its fast onset of action, quick recovery time and amnestic effects (Krausse & Green, 2006).

Meperidine, a narcotic that can reduce arousal from painful stimuli (Chowdhury & Vargas, 2005), has been previously used with chloral hydrate and hydroxyzine (Nathan and West 1987), and more recently with midazolam and hydroxyzine (Musial et al., 2003). Midazolam is an alternate choice to use in the “triple-dose cocktail” instead of chloral hydrate, likely because of recent concerns with chloral hydrate and the perceived safety profile of midazolam (Sheroan et al., 2006). Meperidine has also been used in combination with hydroxyzine (Cathers et al., 2005). Dimenhydrinate, a histamine H1-antagonist under the trade name Gravol, is sometimes used in combination with opioids to offset nausea. It is an over-the-counter antiemetic, with mild sedation as a side effect.

When multiple sedatives are used in conjunction, the sedative effect, and consequently, respiratory depression are additive. Narcotics like meperidine, and antihistamines like hydroxyzine potentiate the action of other sedatives when taken together (Shapira et al., 2004; Roach et al., 2010).

Coupling midazolam and hydroxyzine may be a good combination due to midazolam’s short onset and rapid duration of action plus hydroxyzine’s slower onset and longer duration of action (Shapira et al., 2004). The combination has been reported to produce less crying and movement compared to the use of midazolam alone (Shapira et al., 2004). Others have found that when 1 mg/kg meperidine was added to 1 mg/kg midazolam, the effectiveness and duration of
the sedation was enhanced (Nathan & Vargas, 2002). In contrast, other investigators found that 1 mg/kg oral midazolam alone was just as effective as 0.5 mg/kg midazolam plus 1.0 mg/kg meperidine (Musial et al., 2003).

Ketamine has been used in pediatric dental procedures, especially with the young special needs population (Petros, 1991) and is reported to be comparable to meperidine (Reinmer et al., 1996). Oral ketamine-diazepam regimens were compared; 4 mg/kg versus 8 mg/kg ketamine in conjunction with 0.1 mg/kg diazepam. As one would expect, the higher dose resulted in less negative behaviour and more sleep (Reinmer et al., 1996). Diazepam has been administered to inhibit postoperative ketamine-induced psychic phenomena, however the duration of action of diazepam was not long enough to provide this inhibition. Emesis and prolonged sedation are considered complications of treatment with Ketamine (Reinmer et al., 1996). In another study, 6 mg/kg oral ketamine was administered by a pediatric anesthetist; episodes of vomiting occurred in 40% of subjects (Alfonzo-Echeverri et al., 1993).

1.9 Monitoring

During a sedation procedure, proper monitoring and documentation must be done in order to identify and prevent adverse events. Before the administration of the sedative agents, a baseline assessment of the patient’s vital signs should be recorded. Throughout the procedure, oxygen saturation and heart rate must be consistently monitored, while blood pressure and respiratory rate should be assessed intermittently (AAPD Guidelines, 2016; CDSBC Sedation Standards, 2016). It is recommended that vital signs such as heart rate and oxygen saturation be documented every five minutes in a time-based record. The practitioner should document the name, route, site, time of administration, and dosage of all drugs administered (Cote & Wilson, 2006). Several
devices are used to monitor a patient, such as a pulse oximeter, blood pressure cuff, capnometer, and precordial stethoscope. Visual assessment of the patient, however, supersedes all these methods. The use of nitrous oxide is helpful in assessing ventilation by observing the deflation and subsequent inflation of the reservoir bag. Furthermore, one should be aware of chest movement and auditory cues. Noisy breath sounds, nasal flaring, and a chest wall that appears to “rock” during inspiration all may be signs of airway obstruction (Becker & Casabianca, 2009).

Most guidelines suggest that a pulse oximeter should always be used with any level of sedation (AAPD Guidelines, 2016; CDSBC Sedation Standards, 2016). This device provides a noninvasive continuous monitoring of arterial oxygen saturation (SpO2), and also gives a measure of heart rate in beats per minute (bpm). The probe can be placed on fingers, toes, or ear lobes (Mason, 2012), and comes in different sizes (Cote & Wilson, 2006). It is essential that the probe is properly positioned as displacement may produce false readings (i.e., under- or overestimation of oxygen saturation) (Barker et al., 1993). Patient movement, nail polish and ambient light are further causes of pulse oximeter artifact (Kelleher & Ruff, 1989). An arterial hemoglobin oxygen saturation (SpO2) of 95 is the lower limit of acceptable oxygenation; and an SpO2 of 90 is by definition hypoxemia. Information displayed by a pulse oximeter has a 30-40 second delay (Becker & Casabianca, 2009).

A blood pressure cuff should be placed on a sedated patient so that early signs of adverse events can be identified. Normal blood pressure for a child is age, gender, and height dependent but is usually not higher than systolic 120 mmHg and diastolic 80 mmHg and not lower than systolic 80 mmHg and diastolic 40 mmHg (Kaebler, 2009). Hypotension may be a sign of oversedation, while hypertension reflects pain or stress (Kaebler, 2009).
Capnography is an assessment of carbon dioxide in exhaled air and can alert a clinician if an airway obstruction exists and the patient is not being ventilated ideally (Iwasaki et al, 1989). It is especially useful in situations where the patient is not readily accessible, such as during MRI, CT scans or in darkened rooms. A nasal cannula allows for simultaneous delivery of oxygen and measurement of expired carbon dioxide. This device is associated with high false-positive rates of hypercapnia, but is accurate for detection of complete airway obstruction or apnea (Primosch et al., 2000). Normal end-tidal CO2, the measurement taken by capnometry, is 35 to 38 mm Hg (Becker & Casabianca, 2009).

A precordial stethoscope allows an operator to continuously monitor a patient’s breath sounds and air exchange. Normal breath sounds are continuous, regular, and free of any stridor. Furthermore, one can detect airway obstruction due to liquids or foreign body via precordial stethoscope. This device is similar to a stethoscope but heavier so as to maintain its position over the suprasternal notch, with a cord running to an earpiece placed in the operator’s ear (Becker & Casabianca, 2009).

1.10 Discharge Criteria

There are several methods of assessing whether a patient is ready to be discharged. Children are at risk for adverse events if they are sent home into the care of the parents after only a brief recovery from sedation (Malviya et al., 2004). Oxygen saturation and heart rate monitoring should be done until the patient is fully alert and the recommended discharge criteria are met (Cote & Wilson, 2006). A simple evaluation tool may be the ability of the infant or child to remain awake for at least 20 minutes when placed in a quiet environment (Malviya et al., 2004).
According to the AAPD and CDSBC guidelines’ recommended discharge criteria include six domains. They are as follows: 1) Cardiovascular function and airway patency are satisfactory and stable. 2) The patient is easily arousable and protective reflexes are intact. 3) The patient can talk (if age appropriate). 4) The patient can sit up unaided (if age appropriate). 5) For a very young or handicapped child incapable of the usually expected responses, the presedation level of responsiveness or a level as close as possible to the normal level for the child should be adequate. 6) The state of hydration is adequate (AAPD Guidelines, 2016; CDSBC Sedation Standards, 2016).

The Modified Aldrete Scale provides a systematic way to assess whether a patient has appropriately recovered from sedation procedure and is fit for discharge. There are five domains that must be evaluated: activity, respiration, circulation, consciousness, and oxygen saturation. A score of 9 or 10 is standard to determine readiness for discharge (Aldrete, 1995).

1.11 Adverse Events

The relative success of a sedation can also be evaluated based on the presence or absence of adverse events. Adverse events, like oxygen desaturation, decreased heart and respiratory rates, and, in the worst-case scenario, brain damage or death may occur when a dental procedure is performed on a sedated child. Despite the wide experience and the safe use of sedatives, it is important to recognize that any child can have sensitivity to a drug or that a dispensing error may occur, and that some children may become deeply-sedated even to a state of general anesthesia (Cote, 2008). Sedation deaths involving children have occurred in the United States, and may have resulted from practitioners failing to follow suggested guidelines (Wilson, 2004). In a review of closed malpractice insurance claims, it was found that patient age of three and under,
inadequate monitoring, and sedation in a non-hospital environment were all factors associated with adverse events (Chicka et al., 2012).

Adverse events are usually transitory and with monitoring and vigilance are rectified with no adverse long-term sequelae. An oxygen saturation reading from a pulse oximeter of less than 94% is considered to be a minor desaturation (Barbi et al., 2003) and can be corrected with simple head repositioning or jaw thrust (Dial et al., 2001). Apnea is defined as an absence of breath for more than 10 seconds or an SpO2 of less than 85% (Barbi et al., 2003), and requires bag-valve-mask (BVM) ventilation or an advanced airway (Dial et al., 2001). The normal range for heart rate (beats per minute) for children aged 3 months to 2 years is 100 to 190, 60 to 140 for those age 2 to 10 years, and 60 to 100 for children older than 10 (AHA/PALS). With respect to respiratory rate (breaths per minute), the normal range for a toddler is 24 to 40, for a preschooler 22 to 34, and 18 to 30 for a school-aged child (AHA/PALS). Vital signs outside of these “normal” parameters are considered adverse events. Adverse blood pressure changes would include a drop in mean arterial pressure, and hypotension is defined as one measurement below age-based criteria (Barbi et al., 2003).

Hypoventilation is the most significant adverse event that can occur during a sedation procedure. This can result from both respiratory depression secondary to sedatives and also airway obstruction, and if identified and corrected, is considered a transient adverse event. For example, a relaxed patient can develop anatomical airway obstruction from soft tissues such as the tongue, tonsils, or adenoids. As depth of sedation deepens, the upper airway muscles become more relaxed (Becker & Casabianca, 2009). Extending the head and lifting the chin can usually correct an anatomical obstruction. If this is not effective, then the mandible can be thrust forward to open the airway (Becker & Casabianca, 2009).
Laryngospasm, a potential complication of sedation in which the vocal cords involuntarily contract, is usually accompanied by stridor. It can result from oversedation or irritation of the vocal cords by foreign body or secretions. Management includes continuous positive airway pressure ventilation or a muscle paralyzer like succinylcholine (Barbi et al., 2003). A laryngoscope is required to visualize the vocal cords in order to diagnose laryngospasm.

Some factors that can contribute to adverse events include drug overdose, administration of a drug outside a medical venue, and premature discharge from medical observation. In a sedation-related adverse event analysis, such events were found to be correlated with the use of the drug chloral hydrate (Cote et al., 2000). In a prospective study investigating pediatric sedation for diagnostic imaging, only 48% of children given chloral hydrate returned to baseline activity within eight hours of the procedure; 89% were back to baseline status within 24 hours (Malviya et al., 2000). Prolonged sedation and/or premature discharge can lead to adverse events outside the medical venue. For example, a unsupervised sleeping child in a car seat on the way home from a procedure may end up with upper airway obstruction resulting in hypoxia (Cote et al., 2000).

1.12 Emergency Protocol

Preparation for potential adverse events is of the utmost importance. Drugs, like appropriate reversal agents and ACLS drugs, and equipment of appropriate size must be immediately accessible for management of the airway and resuscitation. SOAPME is an acronym that outlines proper preparation for medical emergencies: Suction, Oxygen source, proper function Airway equipment, appropriate Pharmaceuticals, Monitors, and special Equipment (Cote, 2008).
Recommended equipment include oxygen, bag-mask system for positive pressure ventilation, laryngoscope, suction catheters, emergency cart with appropriate medications, defibrillator. This equipment and medications must be checked on a routine basis to ensure their availability and expiration date (AAPD Guidelines, 2016; CSBC Sedation Standards, 2016).

The CDSBC Sedation Standards outline recommendations and requirements for emergency management. For example, written plans should be outlined, members of the sedation team should be assigned specific roles, and mock emergency drills be performed every three months (CDSBC Sedation Standards, 2016).

1.13 Clinician Evaluation of Sedation Effectiveness

The effectiveness of the drugs administered is based on the clinician’s determination of the depth of the sedation, and also the patient’s behaviour. There appears to be no consensus on a “successful” sedation scale, evidenced by the large number of scales used in clinical research. These scales subjectively assess behaviour so as to define a sedation as successful or unsuccessful. Undesirable behaviours in most of the scales consistently include crying, screaming, head movement, torso movement, and foot movement. Behaviour can be assessed at strategic time points such as preoperative period, local anesthetic period, rubber dam placement, operative period and postoperative period (Sheroan, 2006).

In a Cochrane review of sedation procedures in pediatric dentistry, over thirty different types of behaviour measurement scales were identified from the literature (Lourenco-Matharu, 2012). The Houpt or modified Houpt Scale, was used in over half of the studies; however the remaining studies used a range of methodologies (Lourenco-Matharu, 2012). This evaluation
tool assesses the patients according to four different scales; sleep, movement, crying, and overall behaviour; and assigns points in each one (Houpt, 1985a).

Another widely used scale is the Ohio State Behaviour Rating Scale or Modified Ohio State Behaviour Rating Scale. In this scale, ‘good sedation’ was defined as ‘effective’ in which the child was mostly quiet during and after the procedure. A successful sedation was one in which the child’s sedation was assessed as effective and the child cried, but remained still during the procedure. A ‘sedation failure’ was defined as one in which the child cried and struggled throughout the procedure or whose sedation was assessed as being ineffective (Heard et al, 2010; McCann, 1996; Wilson 1993; Myers, 2004; Primosch, 1999; Shapira, 2004).

1.14 Expectations

1.14.1 Expectations of Parents

Parents have a range of expectations with respect to oral sedation. Pediatric dentists should be aware of the acceptability of practices to parents. For example, the use of restraint is relatively common during an oral sedation procedure to maintain patient safety. Restraint is classified in two ways: active and passive (AAPD Guidelines, 2011). Active is when either a dentist, assistant, or parent hold the patient “down”, whereas in passive restraint a device such as a papoose board acts as the restraint. Of pediatric dentists, 56% use passive immobilization, and 47% use active immobilization for a sedated child (Adair et al., 2004). In a study of acceptability of various behaviour management techniques, parents watched videotapes demonstrating both active and passive restraint (Lawrence, 1991). They tended to rank active restraint as more acceptable than passive restraint (Lawrence, 1991). More recently, 75% of parents felt that protective stabilization should not be necessary during sedation, and 87% preferred to stay with
their child during the appointment (White et al., 2016). Furthermore, the majority of parents felt it was acceptable for their child to sleep through a sedation appointment, whereas only a very small number found it acceptable for the child to be highly reactive (White et al., 2016).

Parental expectations and parenting philosophy have evolved over the years. In the 1980’s, pharmacological behaviour management techniques were rated as unacceptable by the majority of parents (Murphy et al., 1984; Fields et al., 1984). A decade later, parents were much more likely to accept a behaviour management technique like oral sedation if the dentist provided an explanation (Lawrence et al., 1991). Of interest is that parents of lower socioeconomic status and level of education were less likely to express dissatisfaction with a behaviour management procedure. Parents’ expectations play a large role in whether oral sedation is used for their child, and furthermore how the procedure is accomplished.

1.14.2 Expectations of Clinicians

Pediatric dentists’ use and experience of oral sedation varies greatly, and is largely depending on the postgraduate training program they obtained. Previous studies have assessed the extent of oral sedation experiences pediatric dentists had during their training. Previously, 35% of programs reported a decline in the use of sedation (Acs et al, 1990). More recently, program directors have indicated an increase in curriculum time devoted to pharmacological management (Adair et al., 2004). The most consistent trend amongst pediatric dentists over the last 25 years has been an increase in the frequency of sedation use (Wilson & Houpt, 2016).

Furthermore, clinicians have a range of expectations of what they classify a “successful” sedation procedure. Some believe in the use of restraint for all sedated patients, whereas others feel that the need for restraint indicates an inadequate sedation (Wilson & Nathan, 2011). In
contrast, graduate students believe that restraint during sedation is a common and valid intervention and does not equate to a failed sedation (Wilson & Nathan, 2011). Of students, 60% reported that they had a strong comfort level in the selection of drugs based on their training (Wilson & Nathan, 2011).

Program directors and students in the United States estimate that around 25% of patients require oral sedation. There is variability in the use of different sedatives, their combinations and dosages, based on program. The age ranges of children sedated are mostly between two- and nine-years old (Wilson, et al., 2001).

Pediatric dentistry specialty programs must follow recommendations from national and provincial governing bodies to provide their students with the necessary experiences. Sedation is an acceptable behaviour management technique used for pediatric patients unable to cooperate for dental treatment. A variety of sedative agents are available to pediatric dentists in a number of combinations. The lack of “gold standard” gives clinicians the freedom to choose their preferred safe and effective regimens.

1.15 Rationale

The development of the clinical sedation component of the new UBC graduate pediatric dentistry program attracted a variety of clinicians with different sedation practices. Based on the wide range of variability in drug regimens familiar to these pediatric dentists, it is important to systematically assess which drug combinations were safe and effective. Furthermore, the lack of consensus by the dental and medical community with respect to use of sedation, and, accordingly amount and intensity of training of pediatric dentistry graduate students created a need to explore the opinions and practices of the supervising clinicians.
1.16 Study Objectives

The main aim of the current study is to review the sedation regimens used in the first years of the new UBC Pediatric Dentistry Graduate Program and assess each sedation regimen’s effectiveness and safety. The secondary aim is to explore how personal opinion, education, and practice patterns of UBC pediatric dentistry clinical instructors influence the drug regimens utilized, and consequently, the educational experience of trainees. Ultimately, ensuring the safety of pediatric patients in the context of sedation in dentistry is the principal objective of the study.
Chapter 2: Methods

2.1 Study Design

In order to satisfy the aims and objectives of the study, a two-part design incorporated both quantitative and qualitative elements. Phase 1: Retrospective Chart Review component (quantitative) was a review of all patients receiving oral sedations in the UBC graduate pediatric dentistry sedation clinic over a three-year period. Variables on the sedation records were greater than what this study recorded. To meet the objectives of this study, only a subset of variables were chosen. Phase 2: Interview with Pediatric Dentists component (qualitative), involved establishing an inclusive criteria for purposive sampling of the past and present UBC Graduate Pediatric Dentistry faculty members, with the intent of exploring their opinions with respect to their conceptions and views with respect to both the practice and teaching of sedation. Human ethics approval was granted by the UBC RISE Ethics Review Board [Certificate H14-01072].

2.1.1 Phase 1. Retrospective Chart Review

A retrospective chart review was carried out for all graduate Pediatric Dentistry patients who received dental treatment with the aid of oral sedation between March 2011 and May 2014. Records were stored in a hard-copy sedation log, in addition to two Electronic Dental Records software systems: Axium and Romexis.

Inclusion criteria for the study were patients under age 18 who received oral sedation to facilitate dental treatment in the UBC graduate pediatric dentistry clinic between March 2011 and May 2014. There were no exclusion criteria.
2.1.2 Variable Selection and Construction

Independent variables collected from the chart review included: age, gender, weight, height, BMI, ASA class, indication for sedation, tonsil size, baseline vitals (heart rate and oxygen saturation), presedation cooperation level, behavioural interaction, drug dosages, drug combinations, use and dose of nitrous oxide, dose of local anesthetic administered, heart rate, respiratory rate, length of dental procedure, and length of sedation.

Two outcome variables were derived directly from the sedation record. The first, effectiveness, had three components as assessed by the operating dentist: behaviour/responsiveness to treatment, overall effectiveness, and percent of planned treatment completed. ‘Behaviour/responsiveness to treatment’ had five options to be rated by the dentist: ‘Excellent’, the child was quiet and cooperative; ‘Good’, mild objections and/or whimpering but treatment not interrupted; ‘Fair’, crying with minimal disruption to treatment; ‘Poor’, struggling which interfered with operative procedures; and ‘Prohibitive’, active resistance and crying/treatment cannot be rendered. For data analysis, ‘excellent’ and ‘good’ were collapsed into one category. Overall effectiveness of the sedation was rated to be ineffective, effective, very effective, or overly sedated. An overly sedated child would fall into the “deep” or “GA” categories of sedation level. Similarly, ‘effective’ and ‘very effective’ were collapsed, and were chosen as the desired outcomes. Lastly, the dentist was asked to report the percentage of planned treatment that was completed.

The second outcome variable, safety, had two components: sedation level and presence of adverse event. The sedation level was categorized as ‘None’, typical response/cooperative for this patient; ‘Mild’, anxiolysis; ‘Moderate’, purposeful response to verbal commands +/- light
tactile sensation; ‘Deep’, purposeful response after repeated verbal or painful stimulation; ‘GA’, not arousable. For data analysis, ‘mild’ and ‘moderate’ were selected as the desired outcomes.

Presence of an adverse event was defined as at least one episode of oxygen saturation of less than 94%, and heart rate outside of the normal range, (less than 60 or more than 140 (AHA/PALS)).

All data was de-identified and recorded in a database program Excel® Microsoft Corporation (Redmond, WA).

The data were analyzed using descriptive statistics, chi-square analysis, and odds ratios for bivariate analyses. For both chi-square and odds ratio analyses, alpha was determined as .05 to determine whether statistical significance exists in the comparisons. Midazolam (MZ) was the only single-agent regimen, thus was selected as the reference group when calculating odds ratios. Odds ratio is a non-parametric analysis technique similar to chi-square analysis when the purpose of data analysis is comparative statistics (Szumilas, 2010). All statistical analysis was performed using SAS v9.3.

2.2 Phase 2. Interviews with Pediatric Dentists (Qualitative)

The clinical experience of the pediatric dentists teaching in the clinical component of the program influenced the drug regimens used. Therefore, their views on the topic of pediatric oral sedation were explored. To inform program improvement, the pediatric dentists were also interviewed for their conceptions around teaching sedation to pediatric graduate students.
2.2.1 Inclusion Criteria

The principle of purposive sampling was followed in “selecting” instructors to be interviewed (Bernard HR, 2002). The sampling approach was purposive in nature in that it was desired to interview clinicians who both practiced sedation and those who did not. Because of our research design, only a limited number of faculty fulfilled the inclusion criteria and would help achieve the aims of the research. Inclusion criteria for participants were as follows: certified pediatric dentist, past or present part- or full-time UBC Graduate Pediatric Dentistry clinical instructor, and consent to participate in a personal interview. Six potential participants were identified.

2.2.2 Recruitment

An email was sent to the potential participants explaining the study, with an attached consent form (Appendix C). The co-investigator followed up by telephone when no response was received within two weeks.

2.2.3 Data Collection Instrument

A structured interview guide with both ‘closed-ended’ and ‘open-ended’ questions was utilized to guide the discussion (Appendix D). The questions were specifically designed to learn about the participants’ clinical practice, graduate training, and experiences while teaching graduate pediatric dentistry students. Questions were focused closely on teaching issues at UBC. The sessions were audio-recorded to enable transcription and analysis. The co-investigator took hand-written notes during the interview session.
2.3.4 Thematic Analysis

Participants’ confidentiality was maintained by removing names and identifiers from the transcripts. The six phases of thematic analysis were completed (Braun and Clarke 2006). First, the data was reviewed line-by-line by the co-investigator with preliminary “start” codes being extracted from the content. In phase two, large posters were created with each dentist’s de-identified name, in addition to drug regimen they prefer, years in practice, and percentage of patients sedated in their own practice. This was done to evaluate how the codes from the data answer the research question. In the third phase, a list of candidate themes were made for further analysis by placing the color-coded post-its on the board with bullet-points from the transcriptions regarding four concepts: Why? (they practice the way they do), What? (are their own personal preferences), How? (they have prepared for their current practice), and their views on educating future pediatric dentists in the area of sedation.

In phase four, each concept was labeled with the de-identified dentist’s name and these were amalgamated into the following domains: Effectiveness (of drugs), Safety, Professional Background, Fear, Adaptations, and Future Pediatric Dentists’ Education. In the fifth phase, a comprehensive analysis of what the themes contribute to the data was completed. The last recommended phase, member checking, was not done due to time constraints. Due to the structured nature of the interviews, the themes that arose were closely related to the questions. A model was created to represent the relationships between the emergent theme and domains. An independent researcher who was unfamiliar with the subject area and the participants, but an experienced qualitative researcher, validated the thematic analysis and model.
Chapter 3: Results

3.1 Retrospective Chart Review

3.1.1 Baseline Descriptive Characteristics

Over the 3-year study period, 195 sedation appointments were performed on 115 children; 81 children had one sedation appointment, 34 had multiple appointments. Descriptive characteristics of the study sample are summarized in Table 3-1. Children ranged in age from 2 years to 11 years, with the average age being 5.7 years ± 1.1. The majority (n=81/115, 70.4%) of children receiving dental treatment with the use of oral sedation were older than 5 years of age.

The sample was split regarding sex, with slightly more male patients (n=60/115, 52.2%). All children (n=115/115 100%) were ASA Class I and the majority (n=113/115, 98.3%) had no history of allergies and were not taking prescription medications (n=107/115, 93%). The sedation record was modified over time to provide a more detailed record [between March 2011 and June 2012 (Appendix A), and July 2012 to July 2014 (Appendix B)], thus the amount of data available increased over the 3 years of the study. Further, clinicians frequently did not completely record vital information.
Table 3-1 Patient Characteristics at First Visit (n=115)

<table>
<thead>
<tr>
<th>Variables</th>
<th>N(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>24&lt;months&lt;=60</td>
<td>34 (29.6%)</td>
</tr>
<tr>
<td>&gt;60 months</td>
<td>81 (70.4%)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>55 (47.8%)</td>
</tr>
<tr>
<td>Male</td>
<td>60 (52.2%)</td>
</tr>
<tr>
<td>Allergies</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>113 (98.3%)</td>
</tr>
<tr>
<td>Yes</td>
<td>2 (1.7%)</td>
</tr>
<tr>
<td>Medication</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>107 (93.0%)</td>
</tr>
<tr>
<td>Yes</td>
<td>8 (7.0%)</td>
</tr>
</tbody>
</table>

The pre-sedation assessment findings of the study sample are summarized in Table 3-2. These assessments were done prior to every appointment. For this and the remainder of the Results, the analysis was done per “sedation appointment”, not per child. The approach was practical because the lapse in time between appointments and effect of previous experiences made the patients susceptible to change in variables from appointment to appointment. For example, a child’s “presedation cooperation level” may be better at the first visit than at the third visit, and NPO status may vary from one appointment to the next.

The majority of children, (n=143/161, 89%), at presentation to the appointment had good pre-sedation cooperation levels of “cooperates freely” or “cooperates with prompting”. Approximately half of the children, (n=52/114, 45%), were assessed to be “somewhat shy” at presentation to the appointments. The main indication for sedation, (n= 69/119, 58%), was the
assessment of a “fearful” child followed by an “uncooperative”, (n=32/119, 27%), child. Almost all children had a Grade 1 or Grade 2 tonsil size (n=135/137, 99%). At 95% (n=175/185) of the appointments, children had an NPO status of greater than 6 hours.

**Table 3-2 Pre-sedation Assessment**

<table>
<thead>
<tr>
<th>Variables</th>
<th>N(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Presedation cooperation level</strong>*#</td>
<td>161</td>
</tr>
<tr>
<td>1, unable</td>
<td>10 (6.2%)</td>
</tr>
<tr>
<td>2, rarely</td>
<td>8 (5.0%)</td>
</tr>
<tr>
<td>3, cooperates w/prompting</td>
<td>90 (55.9%)</td>
</tr>
<tr>
<td>4, cooperates freely</td>
<td>53 (32.9%)</td>
</tr>
<tr>
<td><strong>Tonsil size</strong>*#</td>
<td>137</td>
</tr>
<tr>
<td>Grade 1: 0-25%</td>
<td>46 (33.6%)</td>
</tr>
<tr>
<td>Grade 2: 26-50%</td>
<td>89 (65.0%)</td>
</tr>
<tr>
<td>Grade 3: 51-75%</td>
<td>1 (0.7%)</td>
</tr>
<tr>
<td>Grade 4: &gt;75%</td>
<td>1 (0.7%)</td>
</tr>
<tr>
<td><strong>Indications for sedation</strong>*#</td>
<td>119</td>
</tr>
<tr>
<td>1: Fearful</td>
<td>69 (58.0%)</td>
</tr>
<tr>
<td>2: Uncooperative</td>
<td>32 (26.9%)</td>
</tr>
<tr>
<td>3: Psyche</td>
<td>17 (14.3%)</td>
</tr>
<tr>
<td>4: Medical</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td><strong>Behavioural interaction</strong>*#</td>
<td>114</td>
</tr>
<tr>
<td>1: Definitely shy</td>
<td>29 (25.4%)</td>
</tr>
<tr>
<td>2: Somewhat shy</td>
<td>52 (45.6%)</td>
</tr>
<tr>
<td>3: Approachable</td>
<td>33 (29.0%)</td>
</tr>
<tr>
<td><strong>NPO</strong>*#</td>
<td>185</td>
</tr>
<tr>
<td>&lt;6 hours</td>
<td>7 (3.8%)</td>
</tr>
<tr>
<td>6 hours</td>
<td>3 (1.6%)</td>
</tr>
<tr>
<td>&gt;6 hours</td>
<td>175 (94.6%)</td>
</tr>
</tbody>
</table>

#Data not available on remaining patients
Pre-operative vital signs were recorded for each sedation appointment. The average presedation systolic blood pressure (SBP) was 106 ±11. The average preoperative heart rate was 92 ±12. The average preoperative oxygen saturation was 98 ±0.62.

Various drug regimens were used (Table 3-3). The most frequently used drug regimen was midazolam and hydroxyzine (MZH) (n=88/195, 45.1%), followed by midazolam (MZ) alone (n=47/195, 24.1%). A less frequently used regimen was meperidine, chloral hydrate, hydroxyzine, and dimenhydrinate (MCHHD) (n=33/195, 16.9%). All other combinations were seldomly used, and therefore were collapsed into an “other” category. Of total appointments, 91% received nitrous oxide in addition to oral sedative(s). In those instances where nitrous oxide was used, the average concentration was 49% ±9. The mean length of sedation, i.e. from the time the sedative was administered until time of discharge, was 1 hour 41 minutes ±43. The average length of procedure, from the commencement to termination of nitrous oxide, was 38 minutes ±30.

**Table 3-3 Drug Regimens**

<table>
<thead>
<tr>
<th></th>
<th>n=195</th>
<th>n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>midazolam + hydroxyzine (MZH)</td>
<td>88</td>
<td>45.1%</td>
</tr>
<tr>
<td>midazolam (MZ)</td>
<td>47</td>
<td>24.1%</td>
</tr>
<tr>
<td>meperidine+ chloral hydrate+ hydroxyzine+ dimenhydrinate (MCHHD)</td>
<td>33</td>
<td>16.9%</td>
</tr>
<tr>
<td>meperidine+ chloral hydrate+ hydroxyzine</td>
<td>13</td>
<td>6.7%</td>
</tr>
<tr>
<td>midazolam+ ketamine+ dimenhydrinate</td>
<td>5</td>
<td>2.6%</td>
</tr>
<tr>
<td>midazolam+ ketamine</td>
<td>3</td>
<td>1.5%</td>
</tr>
<tr>
<td>midazolam+ dimenhydrinate</td>
<td>6</td>
<td>3.1%</td>
</tr>
<tr>
<td>meperidine+ midazolam</td>
<td>1</td>
<td>0.5%</td>
</tr>
</tbody>
</table>
Four clinical instructors supervised the majority of procedures. Dr. A used midazolam (MZ) about half of the time (48%), followed by meperidine, chloral hydrate, hydroxyzine and dimenhydrinate (MCHHD) (17%). Dr. B used midazolam and hydroxyzine (MZH) 73% of the time, and used midazolam (MZ) the remainder of the time. Dr. C used meperidine, chloral hydrate, hydroxyzine and dimenhydrinate (MCHHD) 61% of the time. Dr. D used midazolam and hydroxyzine (MZH) 100% of the time.

3.1.2 Safety

3.1.2.1 Adverse Events

Adverse events are summarized in Table 3-4. With respect to oxygen saturation, the majority of children maintained oxygen saturation above 94% (n=140/178, 79%) during the entire appointment. During a few appointments, the oxygen saturation dropped transiently between 95% and 80% (n=30/178, 15%), while during only a small number (n=8/178, 4.5%) the SpO2 dropped below 80% during the sedation. For appointments for children aged two to ten years, some experienced heart rates below normal values (n=22/178, 12%), while some had higher than expected heart rates for their age (n=56/178, 32%). Blood pressure was recorded for 84 patients. Of these, 3.6% (n= 3/84) had a blood pressure outside of normal range for their age.

Vital signs can either be recorded by an auxiliary staff member whose sole responsibility is to monitor the patients and scribe intermittently, or a receipt can be printed out from the monitor which automatically records the vital signs. The printed out receipt is included in the chart in lieu of hand-written values. About half (n=107/191, 54%) of the vital signs were printed directly from the monitor, while the remaining were scribed by a staff person.
Table 3-4 Adverse Events

<table>
<thead>
<tr>
<th>Variables</th>
<th>N(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Min SpO2 (%)</td>
<td>178</td>
</tr>
<tr>
<td>&lt;80</td>
<td>8 (4.5%)</td>
</tr>
<tr>
<td>81-90</td>
<td>17 (9.6%)</td>
</tr>
<tr>
<td>91-95</td>
<td>13 (7.3%)</td>
</tr>
<tr>
<td>&gt;96</td>
<td>140 (78.7%)</td>
</tr>
<tr>
<td>Heart Rate (HR) wrt age</td>
<td>137</td>
</tr>
<tr>
<td>2 to 10 years</td>
<td></td>
</tr>
<tr>
<td>HR &lt;60</td>
<td>22 (12.5%)</td>
</tr>
<tr>
<td>HR &gt;140</td>
<td>56 (31.6%)</td>
</tr>
<tr>
<td>&gt;10 years</td>
<td></td>
</tr>
<tr>
<td>HR &lt;60</td>
<td>2 (100%)</td>
</tr>
<tr>
<td>HR &gt;100</td>
<td>2 (100%)</td>
</tr>
</tbody>
</table>

3.2.2.1 Sedation Level

Sedation level was another aspect of safety that was assessed (Table 3-5). A majority of the appointments, (n=86/136, 63%), were rated demonstrating moderate sedation, followed by mild (n=40/136, 29%) with a minority in deep (n=7/136, 5%) sedation.

Table 3-5 Sedation Level

<table>
<thead>
<tr>
<th>Sedation Level n=136</th>
<th>n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1=none</td>
<td>3 (2.2%)</td>
</tr>
<tr>
<td>2=mild</td>
<td>40 (29.4%)</td>
</tr>
<tr>
<td>3=moderate</td>
<td>86 (63.2%)</td>
</tr>
<tr>
<td>4=deep</td>
<td>7 (5.5%)</td>
</tr>
</tbody>
</table>
3.1.3 Effectiveness

3.1.3.1 Clinician Assessment of Behaviour during Treatment

During treatment, the behaviour of the child was assessed to be good 27% (n=37/138) of the time, excellent 27% (n=37/138) of the time, and poor or prohibitive 29% (n=40/138), of the time (Table 3-6).

Table 3-6 Clinician Assessment of Behaviour during Treatment

<table>
<thead>
<tr>
<th></th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>37 (26.8%)</td>
</tr>
<tr>
<td>Good</td>
<td>37 (26.8%)</td>
</tr>
<tr>
<td>Fair</td>
<td>24 (17.4%)</td>
</tr>
<tr>
<td>Poor</td>
<td>33 (23.9%)</td>
</tr>
<tr>
<td>Prohibitive</td>
<td>7 (5.1%)</td>
</tr>
</tbody>
</table>

3.1.3.2 Clinician Assessment of Effectiveness

With respect to effectiveness, 84.6% (n=78/137) of sedations were assessed to be effective or very effective (n=37/137, 27%); and 15% (n=21/137) were rated as ineffective (Table 3-7). Over-sedation was rare (n=1/137, 1%).

Table 3-7 Clinician Assessment of Effectiveness

<table>
<thead>
<tr>
<th>Overall effectiveness n= 137</th>
<th>n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ineffective</td>
<td>21 (15.3%)</td>
</tr>
<tr>
<td>Effective</td>
<td>78 (56.9%)</td>
</tr>
<tr>
<td>Very effective</td>
<td>37 (27.0%)</td>
</tr>
<tr>
<td>Overly sedated</td>
<td>1 (0.73%)</td>
</tr>
</tbody>
</table>
For the majority of the cases (n=102/120, 85%), all of the planned treatment was completed during the dental procedure. In only 5% (n=7/120) of the cases, no treatment was completed and the appointment was terminated.

### 3.1.4 Differences in Baseline Characteristics by Regimen

The three most commonly used sedation regimens were compared with the intent of assessing any differences in baseline characteristics by regimen. The remaining, more seldom-used regimens were collapsed into an “other” category. These findings are summarized in Table 3-8. The low frequency of data points for several of the variables for the MZ group has affected our comparisons.

Amongst the three regimens, similarities were present in baseline characteristics, such as sex, age, ASA class, allergies, medications, tonsil size and NPO status. The median age of patients in the MZ group was 65 months (5 years 5 months) with the middle half falling between 54 and 76 months (IQR 53, 76). The median age for the other groups is similar. More patients cooperated freely at baseline in the MZ and MZH groups than the MCHHD group, and the most frequent indication for sedation was a “fearful” patient in all groups.

There was no significant difference in baseline characteristics amongst the sedation regimens, with the exception of history of medication use (p=.01) and behavioural interaction (p=.01). History of medication use was not recorded in the MZ group, which likely explains the difference. For “behavioural interaction”, there were more “shy” children in the MZH group than in the other groups.
Table 3-8 Baseline Characteristics by Regimen

<table>
<thead>
<tr>
<th>Variables</th>
<th>MZ (n= 47)</th>
<th>MZH (n=88)</th>
<th>MCHHD (n= 33)</th>
<th>Other (n= 27)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex, n (%)</td>
<td>25 (53.2%)</td>
<td>43 (48.9%)</td>
<td>20 (60.6%)</td>
<td>14 (51.9%)</td>
<td>0.66</td>
</tr>
<tr>
<td>Age in months - median (IQR)</td>
<td>65.3(5.3, 76.5)</td>
<td>67.6(60.7, 78.3)</td>
<td>65.9(56.3, 78.3)</td>
<td>65.3(52.5, 80.5)</td>
<td>0.42</td>
</tr>
<tr>
<td>Age in months - mean (SD)</td>
<td>67.2 (15.2)</td>
<td>70.0(12.0)</td>
<td>66.4(11.7)</td>
<td>66.2(14.3)</td>
<td>0.64</td>
</tr>
<tr>
<td>Allergies (Yes)</td>
<td>0 (0.0%)</td>
<td>1 (1.1%)</td>
<td>0 (0.0%)</td>
<td>1 (3.7%)</td>
<td>0.40</td>
</tr>
<tr>
<td>Medication (Yes)</td>
<td>0 (0.0%)</td>
<td>3 (3.4%)</td>
<td>2 (6.1%)</td>
<td>5 (18.6%)</td>
<td>0.01</td>
</tr>
<tr>
<td>Preseadation cooperation level</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.08</td>
</tr>
<tr>
<td>1, unable</td>
<td>0 (0%)</td>
<td>2 (3.1%)</td>
<td>5 (17.2%)</td>
<td>1 (5.3%)</td>
<td></td>
</tr>
<tr>
<td>2, rarely</td>
<td>0 (0%)</td>
<td>4 (6.2%)</td>
<td>0 (0.0%)</td>
<td>2 (10.5%)</td>
<td></td>
</tr>
<tr>
<td>3, cooperates w/p</td>
<td>2 (33.3%)</td>
<td>44 (68.8%)</td>
<td>17 (58.6%)</td>
<td>10 (52.6%)</td>
<td></td>
</tr>
<tr>
<td>4, cooperates freely</td>
<td>4 (66.7%)</td>
<td>14 (21.9%)</td>
<td>7 (24.1%)</td>
<td>6 (31.6%)</td>
<td></td>
</tr>
<tr>
<td>Tonsil size</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.06</td>
</tr>
<tr>
<td>Grade 1: 0-25%</td>
<td>3 (23.1%)</td>
<td>26 (38.8%)</td>
<td>8 (25.8%)</td>
<td>9 (36.0%)</td>
<td></td>
</tr>
<tr>
<td>Grade 2: 26-50%</td>
<td>9 (69.2%)</td>
<td>41 (61.2%)</td>
<td>23 (74.2%)</td>
<td>15 (60.0%)</td>
<td></td>
</tr>
<tr>
<td>Grade 3: 51-75%</td>
<td>1 (7.7%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>Grade 4: &gt;75%</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>1 (4.0%)</td>
<td></td>
</tr>
<tr>
<td>Indications for sedation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1:Fearful</td>
<td>4 (57.1%)</td>
<td>36 (60.0%)</td>
<td>18 (58.1%)</td>
<td>11 (55.0%)</td>
<td>0.99</td>
</tr>
<tr>
<td>2: Uncooperative</td>
<td>2 (28.6%)</td>
<td>24 (40.0%)</td>
<td>14 (45.2%)</td>
<td>11 (55.0%)</td>
<td>0.54</td>
</tr>
<tr>
<td>3: Psyche</td>
<td>4 (57.1%)</td>
<td>33 (55.0%)</td>
<td>18 (58.1%)</td>
<td>13 (65.0%)</td>
<td>0.86</td>
</tr>
<tr>
<td>4: Medical</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>2 (6.5%)</td>
<td>2 (10.0%)</td>
<td>0.11</td>
</tr>
<tr>
<td>Behavioural interaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.01</td>
</tr>
<tr>
<td>1: Definitely shy</td>
<td>0 (0.0%)</td>
<td>14 (22.6%)</td>
<td>9 (31.0%)</td>
<td>6 (37.5%)</td>
<td></td>
</tr>
<tr>
<td>2: Somewhat shy</td>
<td>1 (16.7%)</td>
<td>35 (56.5%)</td>
<td>11 (37.9%)</td>
<td>4 (25.0%)</td>
<td></td>
</tr>
<tr>
<td>3: Approachable</td>
<td>5 (83.3%)</td>
<td>13 (21.0%)</td>
<td>9 (31.0%)</td>
<td>6 (37.5%)</td>
<td></td>
</tr>
</tbody>
</table>

3.1.5 Appointment Outcomes by Regimen

Outcome variables for safety and effectiveness for each sedation regimen were compared; results are summarized below.
3.1.5.1 Safety by Regimen

Safety, defined as occurrence of adverse event i.e. heart rate outside normal range and oxygen saturation (SpO2) of less than 94% and sedation level, was compared for each sedation regimen.

In the MZ group 66% (n=27/41) of patients had heart rate outside the normal range (less than 60 or more than 100 (AHA/PALS)), and 43% (n=18/42) of patients had oxygen saturation of less than 94%. In the MZH group 26% (n=21/82) of patients had heart rate outside the normal range, and 2.5% (n=2/80) of patients had an oxygen saturation of less than 94%. In the MCHHD group, 35.5% (n=11/31) of patients had heart rate outside the normal range, and 25.8% (n=8/31) of patients had an oxygen saturation of less than 94%. In the “other” group 32% (n=8/25) of patients had heart rate outside the normal range, and 8% (n=2/25) of patients had an oxygen saturation of less than 94%.

Table 3-9 Adverse Events by Regimen

<table>
<thead>
<tr>
<th></th>
<th>MZ</th>
<th>MZH</th>
<th>MCHHD</th>
<th>Other</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal HR</td>
<td>27 (65.8%)</td>
<td>21 (25.6%)</td>
<td>11 (35.5%)</td>
<td>8 (32.0%)</td>
<td>0.3925</td>
</tr>
<tr>
<td>SpO2&lt;94</td>
<td>18 (42.9%)</td>
<td>2 (2.5%)</td>
<td>8 (25.8%)</td>
<td>2 (8.0%)</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

MZH appointments were most likely to produce mild or moderate sedation levels (n=69/70, 98%); followed by MCHHD appointments (n=27/32, 84%); and lastly MZ appointments (n=5/7, 71.6%).
Table 3-10 Sedation Level by Regimen

<table>
<thead>
<tr>
<th></th>
<th>MZ</th>
<th>MZH</th>
<th>MCHHD</th>
<th>Other</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>1 (14.3%)</td>
<td>0 (0%)</td>
<td>1 (3.1%)</td>
<td>1 (3.8%)</td>
<td>0.00043</td>
</tr>
<tr>
<td>Mild</td>
<td>3 (42.9%)</td>
<td>27 (38.6%)</td>
<td>2 (6.3%)</td>
<td>7 (26.9%)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>2 (28.6%)</td>
<td>42 (60.0%)</td>
<td>25 (78.1%)</td>
<td>17 (65.4%)</td>
<td></td>
</tr>
<tr>
<td>Deep</td>
<td>1 (14.3%)</td>
<td>1 (1.4%)</td>
<td>4 (12.5%)</td>
<td>1 (3.8%)</td>
<td></td>
</tr>
</tbody>
</table>

3.1.5.2 Clinician Assessment of Effectiveness and Behaviour by Regimen

Of the 46 midazolam appointments completed over the study period, only 7 had assessments for “effectiveness”: 72% (n=5/7) of midazolam sedations, 90% (n=64/71) of midazolam and hydroxyzine sedations, 87.5% (n=28/32) of meperidine, chloral hydrate, hydroxyzine, and dimenhydrinate sedations, and 70% (n=18/26) of the “other” group, were rated to be effective or very effective (p-value= 0.0037), as seen in (Table 3-11).

Table 3-11 Clinician Assessment of Effectiveness by Regimen

<table>
<thead>
<tr>
<th></th>
<th>MZ</th>
<th>MZH</th>
<th>MCHHD</th>
<th>Other</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ineffective</td>
<td>2 (28.6%)</td>
<td>3 (9.4%)</td>
<td>3 (9.4%)</td>
<td>8 (30.8%)</td>
<td>0.00037</td>
</tr>
<tr>
<td>Effective</td>
<td>3 (42.9%)</td>
<td>51 (71.8%)</td>
<td>12 (37.5%)</td>
<td>12 (46.2%)</td>
<td></td>
</tr>
<tr>
<td>Very effective</td>
<td>2 (28.6%)</td>
<td>13 (18.3%)</td>
<td>16 (50.0%)</td>
<td>6 (23.1%)</td>
<td></td>
</tr>
<tr>
<td>Overly sedated</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (3.1%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
</tbody>
</table>

Of midazolam appointments 28% (n=2/7) were rated as resulting in “good” or “excellent” behaviour, compared to 51% (n=36/70) of midazolam and hydroxyzine patients, 72% of meperidine, chloral hydrate, hydroxyzine, and dimenhydrinate sedations (n=23/32), and 50% (n=13/26) of the “other” group (p-value=0.1605).
Table 3-12 Clinician Assessment of Behaviour During Treatment by Regimen

<table>
<thead>
<tr>
<th></th>
<th>MZ</th>
<th>MZH</th>
<th>MCHHD</th>
<th>Other</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>1 (14.3%)</td>
<td>15 (20.8%)</td>
<td>14 (43.8%)</td>
<td>7 (26.9%)</td>
<td>0.1605</td>
</tr>
<tr>
<td>Good</td>
<td>1 (14.3%)</td>
<td>21 (29.2%)</td>
<td>9 (28.1%)</td>
<td>6 (23.1%)</td>
<td></td>
</tr>
<tr>
<td>Fair</td>
<td>1 (14.3%)</td>
<td>18 (25.0%)</td>
<td>2 (6.3%)</td>
<td>3 (11.5)</td>
<td></td>
</tr>
<tr>
<td>Poor</td>
<td>4 (57.1%)</td>
<td>14 (19.4%)</td>
<td>6 (18.8%)</td>
<td>9 (34.6%)</td>
<td></td>
</tr>
<tr>
<td>Prohibitive</td>
<td>0 (0%)</td>
<td>2 (5.6%)</td>
<td>1 (3.1%)</td>
<td>1 (3.8%)</td>
<td></td>
</tr>
</tbody>
</table>

All odds ratios for outcomes can be seen in (Table 3-13). The MZH group had a 97% less risk of producing episodes of low oxygen saturation (OR 0.03, 95% CI 0.01-0.16, p < 0.001), 82% less likely to produce abnormal heart rate (OR 0.18, 95% CI 0.08-0.40, p < 0.001), and 27 times more likely to produce the desired sedation levels of mild or moderate (OR 27.62, 95% CI 2.13-359.02, p =0.01). The MCHHD group had a 71% less risk of producing heart rates outside of the normal range (OR 0.29, 95% (0.11, 0.76), p =0.01).

Table 3-13: Odds Ratios for Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>OR (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO2&lt;94%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MZ</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>MZH</td>
<td>0.03 (0.01, 0.16)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>MCHHD</td>
<td>0.46 (0.23, 1.31)</td>
<td>0.14</td>
</tr>
<tr>
<td>HR outside normal range</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MZ</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>MZH</td>
<td>0.18 (0.08, 0.40)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>MCHHD</td>
<td>0.29 (0.11, 0.76)</td>
<td>0.01</td>
</tr>
<tr>
<td>Sedation Level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MZ</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>MZH</td>
<td>27.62 (2.13, 359.02)</td>
<td>0.01</td>
</tr>
<tr>
<td>MCHHD</td>
<td>2.23 (0.31, 14.43)</td>
<td>0.43</td>
</tr>
<tr>
<td>Overall effectiveness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MZ</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>MZH</td>
<td>3.66 (0.59, 22.48)</td>
<td>0.16</td>
</tr>
<tr>
<td>MCHHD</td>
<td>2.81 (0.44, 19.62)</td>
<td>0.30</td>
</tr>
<tr>
<td>Behaviour/response to treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MZ</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>MZH</td>
<td>2.65 (0.48, 14.57)</td>
<td>0.26</td>
</tr>
<tr>
<td>MCHHD</td>
<td>6.39 (1.04, 39.11)</td>
<td>0.04</td>
</tr>
</tbody>
</table>
3.2 Results of Interviews

Six structured interviews were completed, five of which were in person and one of which was done by telephone. The domains understood and interpreted from the data and associated themes are presented accompanied by supporting quotes from participants. An example is shown below for the domain “Effectiveness of Sedation” (Table 3-14).

**Table 3-14:** The “Effectiveness of Sedation” Domain with Codes and Quotes

<table>
<thead>
<tr>
<th>Domain</th>
<th>Code</th>
<th>Quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effectiveness of Sedation</td>
<td>Tolerable</td>
<td>“You want them asleep because that’s where you get your work done.” Dr. C</td>
</tr>
<tr>
<td></td>
<td>Sleeping</td>
<td>“Generally speaking the kind of sedation we do here children do not tend to struggle or cry a lot.” Dr. F</td>
</tr>
<tr>
<td></td>
<td>Awake</td>
<td>“I would rather have an awake, crying patient than a completely still sedated patient just to do the dentistry.” Dr. E</td>
</tr>
<tr>
<td></td>
<td>Crying</td>
<td>“…the goal of sedation is to take an intolerable event and turn it into a tolerable one.” Dr. A</td>
</tr>
<tr>
<td></td>
<td>Struggling</td>
<td></td>
</tr>
</tbody>
</table>

3.2.1 Participant Characteristics

Demographics for each participant were collected such as number of years in practice as a pediatric dentist, location of practice (urban versus rural), percentage of patients sedated in participant’s practice, number of sedations completed per week, number of days per month
allotted for treating children under general anesthesia, drugs used by the participants, and the age range of patients sedated. The features of the participant characteristics are in Table 3-15.

Table 3-15: Participant Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Dr. A</th>
<th>Dr. B</th>
<th>Dr. C</th>
<th>Dr. E</th>
<th>Dr. F</th>
<th>Dr. G</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of interview (min:sec)</td>
<td>32:02</td>
<td>25:36</td>
<td>37:17</td>
<td>25:36</td>
<td>33:13</td>
<td>17:56</td>
</tr>
<tr>
<td># years in practice</td>
<td>17</td>
<td>9</td>
<td>35</td>
<td>10</td>
<td>19</td>
<td>9</td>
</tr>
<tr>
<td>Practice setting</td>
<td>urban</td>
<td>urban</td>
<td>urban &amp; rural</td>
<td>urban</td>
<td>urban</td>
<td>urban</td>
</tr>
<tr>
<td>% Practice Sedated</td>
<td>50</td>
<td>20</td>
<td>80</td>
<td>0</td>
<td>80</td>
<td>0</td>
</tr>
<tr>
<td>Sedations/week</td>
<td>10-15</td>
<td>7</td>
<td>30</td>
<td>0</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>GA days/month</td>
<td>2</td>
<td>1-2</td>
<td>3</td>
<td>12</td>
<td>2</td>
<td>3-4</td>
</tr>
<tr>
<td>Drugs</td>
<td>M, H, CH, MZ, Ketamine Fentanyl</td>
<td>MZ, H</td>
<td>M, H, CH, MZ, Ketamine Fentanyl</td>
<td>N/A</td>
<td>M, H, CH, MZ, Ketamine Fentanyl</td>
<td>N/A</td>
</tr>
<tr>
<td>Age Range</td>
<td>18 mo +</td>
<td>2 yrs +</td>
<td>2-14 yrs</td>
<td>N/A</td>
<td>12 mo +</td>
<td>N/A</td>
</tr>
</tbody>
</table>

3.2.2 Thematic Analysis

Transcripts of the recorded interviews were completed by a third party. Four domains and an overall theme arose from the transcripts. The domains were closely linked to the topics of the
questions in our structured interviews. Each heading of the followings section 3.2.2.2-3.2.2.6 represents a domain, while section 3.2.2.1 represents the overarching theme.

3.2.2.1 Risk Tolerance

Risk tolerance emerged from our interviews as the central theme that informed the other four domains of Effectiveness, Safety, Preferences, and Preparation. Risk tolerance, or an individual’s willingness to take risks, is a notion that has been discussed in the areas of medicine, management, and business (Harrison et al., 2004).

Several dentists expressed their reservations about taking risks with respect to their sedation practice, whereas others felt more comfortable with their skills and knowledge in this area. For example, Dr. E expressed concern about the “unpredictability” of sedative agents, and Dr. B said, “I didn't feel comfortable using chloral hydrate...because patients went deep.” Dr. G echoed his/her colleague by saying,

“...I would have to physically provoke them to wake them up that is when I decided that I no longer wanted to do it [sedation].”

On the other hand, Dr. C made the following statements: “If you and your staff are trained, it’s ok if a patient doesn’t respond to your voice- that’s a good appointment,” and

“You can safely get work done if you’re trained to recognize values and intervene if necessary.”

Dr. A stated:

“You can use the property of certain drugs so that you can actually accomplish everything in one appointment where the time you get to your multiple appointments the kids and the kids beside themselves because they don’t want to be there.”
Dr. F said,

“Our regimens allow us to maybe have the working time to do x-rays as well as the cooperation levels to be allow us to do multiple quadrants of work but UBC does not have that.”

3.2.2.2 Effectiveness of Sedation

A domain that echoed throughout the discussions was the variation in opinion of what constitutes an effective sedation procedure (Table 3-14). Degree of crying, alertness, movement, and struggling are examples of behaviours used as markers of effectiveness. Dr. A defined a failed sedation as “stressful” with “yelling and screaming” and “blood pressure and heart rate outside normal range.” Dr. A also stated that, “…the goal of sedation is to take an intolerable event and turn it into a tolerable one.” Dr. A reported that patients “Fall asleep because they are relaxed....that’s fine.” Similarly, Dr. C said: “You want them asleep because that’s where you get your work done.” Dr. C defines an effective sedation as one where there is “completion of dental treatment in a non-combative and non-fearful way without any psychological abuse.” Dr. F echoed his/her colleagues by saying, “Generally speaking the kind of sedation we do here children do not tend to struggle or cry a lot.”

On the other hand, Dr. E defined a successful sedation as one in which “I got the work done,” regardless of the patient behaviour. Dr. E elaborated as follows:

“I would rather have an awake, crying patient than a completely still sedated patient just to do the dentistry.”

These comments demonstrate the difference in opinion that exists regarding the depth and quality of sedation and how they culminate in “effective” sedation.
3.2.2.3 Patient Safety

The interviewees consistently referred to patient safety as an important aspect of sedation practice (Table 3-16). Safety, largely considered the absence of adverse events requiring intervention, is an integral part of sedation practice. In order to ensure this, all of them reported administering drugs to their patient based on weight. Dr. A expressed a desire to keep within a “safe range” or give “…least amount of drugs as possible”. When questioned how one chooses which sedative agent to use, Dr. B referred to the availability of reversal agents as a rationale for choosing particular sedatives and in addition stated the following: “My concern is to protect the airway because we work around the airway.” Dr. F stated: “I choose drugs because they are safe and effective.” Dr. C stated that “…capnography allows you to increase the depth of sedation,” and that he/she uses monitors to get information about vital signs instead of waking a sleeping patient. The analysis made it evident that safety is an important factor considered by pediatric dentists. However, the way in which they seek safety for their patients may differ.
**Table 3-16: The “Patient Safety” Domain with Codes and Quotes**

<table>
<thead>
<tr>
<th>Domain</th>
<th>Code</th>
<th>Quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Safety</td>
<td>Safety</td>
<td>“I choose drugs because they are safe and effective.” Dr. F</td>
</tr>
<tr>
<td></td>
<td>Airway</td>
<td>“Use them because they are safe. Can achieve conscious sedation. Does not affect airway as much as narcotic drugs. Recovery is fast. Onset is fast also. There is a reversal agent.” Dr. E</td>
</tr>
<tr>
<td></td>
<td>Monitoring</td>
<td>“My concern is to protect the airway because we work around the airway.” Dr. B</td>
</tr>
<tr>
<td></td>
<td>Reversal</td>
<td>“…anybody that was getting sleepy or the eyes were closing we would always put them on [pulse oximetry].” Dr. E</td>
</tr>
</tbody>
</table>

**3.2.2.4 Preparation/Training**

In response to questioning regarding the practitioner’s additional post-graduate training in the area of sedation, some reported that they had done extensive continuing education, while others had done minimal training (Table 3-17). Dr. A was PALS/ACLS-certified, completed courses in IV (intravenous) sedation held by and geared towards medical personnel and that he/she aims to “understand pharmacology….to be better prepared.” Dr. C stated that following graduation from his/her post-graduate training, he/she “…pursued CE with a passion.” Dr. F
said that following his/her training, he/she “...visited other practitioners and learned different regimens from them,” in addition to completing an IV sedation certification course twice. On the contrary, Drs. E and G reported that they had not done any further formal sedation training, but adapted the sedation practices of the dentists they joined. Amongst the participants of the study, a wide range exists regarding the pursuit of additional training in the area of sedation, from very in-depth and extensive formal training to observing colleagues to minimal or no continuing education courses.

Table 3-17: The “Preparation/Training” Domain with Codes and Quotes

<table>
<thead>
<tr>
<th>Domain</th>
<th>Code</th>
<th>Quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation/Training</td>
<td>Continuing Education (CE)</td>
<td>“...pursued CE with a passion.” Dr. C</td>
</tr>
<tr>
<td></td>
<td>Learning from others</td>
<td>“...visited other practitioners and learned different regimens from them,”</td>
</tr>
<tr>
<td></td>
<td>Extra training</td>
<td>“No [extra training or continued education in oral sedation].” Dr. G</td>
</tr>
</tbody>
</table>

3.2.2.5 Behaviour Management Preferences

Another domain that became evident was the way in which a pediatric dentist chooses to manage their patients from a behaviour perspective (Table 3-18). Behaviour management of the pediatric dental patient can be either non-pharmacologic (i.e. communicative or Tell-Show-Do) or pharmacologic (sedation or general anesthesia). Furthermore, the level of sedation that a clinician feels comfortable practicing appeared to differ from one interviewee to the next. Dr. B stated that in his practice “Parents are against GA and are ok to hold their child down for me, but I would rather not.” Dr. B previously expressed a low tolerance for risk. Dr. E, whose
preference was lighter sedations, felt that “speed is a good thing to have.” On the contrary, Dr. C, a risk-tolerant individual, stated: “I wasn’t happy getting 50% of work done and having children cry and scream,” and argued for increased monitoring to deepen sedation levels. Dr. A elaborated that his/her sedation practice is “…more civilized but comes with great responsibility. Patients are happier.” Dr. A reported that oftentimes patients have “trauma”, “fear” from childhood experiences at the dentist. Dr. C said that “physical comfort” is important and that “sedation is used for good kids too… it’s an insurance policy”. Dr. G’s preferences differed with the following statement: “I would rather have general anesthesia monitored by a pediatric anesthetist versus sedation that may not work.” On a similar wavelength, Dr. E said: “GA is sort of the easier solution for complete control of situation makes it easier for the dentist.”

In summary, a practitioner’s own preferences and comfort with child behaviour during treatment, in addition to the preferences of parents, play a part in their sedation practices. Furthermore, more risk tolerant pediatric dentists are more likely to sedate, whereas those with lower risk tolerance will lean towards other behaviour management techniques. Parents’ expectations and preferences about sedation were rarely mentioned.
**Table 3-18:** The “Behaviour Management Preferences” Domain with Codes and Quotes

<table>
<thead>
<tr>
<th>Domain</th>
<th>Code</th>
<th>Quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behaviour Management Preferences</td>
<td>General anesthesia (GA)</td>
<td>“Parents are against GA and are ok to hold their child down for me, but I would rather not.” Dr. B</td>
</tr>
<tr>
<td></td>
<td>Sedation</td>
<td>“Sedation is used for good kids too…it’s an insurance policy”. Dr. C</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“I would rather have general anesthesia monitored by a pediatric anesthetist versus sedation that may not work.” Dr. G</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“GA is sort of the easier solution for complete control of situation makes it easier for the dentist.” Dr. E</td>
</tr>
</tbody>
</table>

### 3.2.2.6 Future Pediatric Dentists’ Training

Participants were questioned regarding the kind of training pediatric dentistry trainees should receive in relation to sedation. Five out of six participants felt that trainees should be exposed to multiple regimens. Dr. B felt “...it is better to be exposed to multiple protocols because you never know what you will feel comfortable with.” Dr. F felt the students should be able to “deal with side effects”. With respect to the depth of sedation that should be taught Dr. C “...would rather have a student who knows how to deal with a deeply sedated patient”, whereas Dr. B felt only the “...basic technique of sedation should be taught in school”. Dr. G thought “they should be exposed to light to moderate sedation”.
Opinions differed about the role of a dental anesthetist in a pediatric dentistry oral sedation clinic. Some felt that he/she is an important personnel to have present, while others felt it is redundant and unnecessary. The range of views is displayed with quotes by Dr. E and Dr. A.

Dr. E, who is risk intolerant, explains that he/she is in favor of a dental anesthetist:

“I think they [dental anaesthesiologist] are more comfortable with recognition to be able to train somebody to watch whereas I think it is not that the pediatric dentist cannot do it, but I think for our program in particular, adding the dental anaesthesiologist was more of protecting our regimen by making sure we have skilled back up for what we are trying to introduce.”

Dr. A, alternatively, is risk tolerant and does not see the need for a dental anaesthetist in a graduate pediatric dentistry program.

“I don’t think the presence of a dental anaesthetist is needed at every oral sedation unless they are actually do oral sedations and can add to your education. If they don’t do oral sedations then it is just a matter of the higher ups trying to cover their butt by having a dental anaesthetist there because you are not going to have a dental anaesthetist when they actually do your sedations in your office I don’t think.”

The four domains’ “effectiveness”, “safety”, “preparation”, and “preferences” interaction with “risk tolerance” informed the views of instructors on how pediatric dentistry graduate students should be taught sedation.

3.2.3 Proposed Risk Tolerance Model

A model was constructed to represent the interactions between the four domains of effectiveness, preparation, safety, preferences, and an individual’s level of risk tolerance (Figure
The model utilized a Venn diagram to reflect the interaction of risk tolerance with the four domains. As the circles containing the “effectiveness”, “preparation”, “preferences”, and “safety” domains changed in proximity, the area of overlap also changed in size. The surface area at their junction is risk tolerance. The distance between the four circles of “effectiveness”, “preparation”, “preferences”, and “safety” was determined using data from the qualitative component. For example, if a clinician defined “effective” sedation as one where the child is mostly quiet and sleeping with little crying or struggling, the circle would move medially. If the clinician would rather have an awake, crying child during sedation, the circle would move distally. For “preparation”, if the participant has completed numerous and extensive CE courses in sedation, the circle would move medially. If the participant has not completed further training in the field of sedation, the circle moves distally. For “behaviour management preferences”, if the clinician used no pharmacologic behaviour management techniques at all, the circle would be move distally, and if he/she treated most patients under general anesthesia or deep sedation, the circle would move medially. If a clinician gave examples regarding how he or she practiced such that “patient safety” was ensured, such as weight-based dosing or use of monitoring, then the circle would move medially. However, if the clinician did not demonstrate “safe” practice, then the circle would be distal.

Following analysis of the group of six participants of the current study, it became evident that the domains of “effectiveness” and “preparation” interacted to influence “risk tolerance”; and that the domains of “preferences” and “safety” circles are fixed. The cross-sectional nature of the interviews represent these two themes, since all the participants had strong preferences regarding how they would like to practice, and all considered themselves to be practicing safely.
3.2.3.1 Application of Risk Tolerance Model

The model was applied to the two participants considered the most and least “risk tolerant” of the participants based on quotes from the data. In Dr. C’s model (Figure 3-3), the “effectiveness” and “preparation” circles overlap almost fully due to their importance in his/her practice, making him/her risk tolerant. As a result, the area created for “risk tolerance” is large. In Dr. E’s model (Figure 3-4), the circles are further away from one another resulting in a small area for risk tolerance, making him/her risk intolerant.

Quotes were used from the data to determine the position of the “effectiveness” circle. For example, Dr. C describes the sedations that he/she provides:

“Patient is non-combative, non-fearful and not psychologically abused. In other words, they had their care with physical comfort. Really important for me is physical comfort. This does not happen to a lot of pediatric dental offices. You are singing to the patient and telling them it is going to be fine as it is only 10 more minutes but that child is really uncomfortable and sometimes it is hurting them. I don’t think they are getting physical comfort sometimes.”

On the other hand, Dr. E’s sedation approach and definition of effectiveness is very different:

“I always believe that I would rather have an awake crying patient than a completely still sedated patient just to do the dentistry. I would rather have responsiveness. So I think speed is a good thing to have because I think we focus so much on the dentistry that we want to get out of a situation that might potentially turn on you knowing the unpredictability of some oral combinations.”

These statements display the range of views on what comprises an effective sedation, and influence the position of the circles in the individualized models.
Dr. C discussed how he/she prepared for sedation practice following graduation from his/her graduate pediatric dentistry program.

“I took IV training program at U of T plus any sedation course I could get my hands on and also joined the American Dental Society of Anesthesia which has wonderful continuing education courses for anybody who does sedation.”

Dr. C explained his/her desire to obtain further training by likening pediatric dentists to their colleagues in medicine.

“It makes you realize we are not alone in this. Everybody faces it every day trying to do a lumbar puncture on a 3-year-old. Trying to get a radial graft of their leg while they are moving around. It is not just pediatric dentistry but those people have found solutions and we are still dealing with Nitrous and Midazolam with an 80% failure rate.”

Although Dr. E does not currently practice sedation, he/she did so following graduation from his/her graduate program. When questioned whether continuing education courses were taken following graduation, Dr. E answered, “No.” Dr. E reported that he/she used regimens that were taught in his/her graduate program, and also used regimens similar to those of colleagues.

“I also worked with a practitioner who used a hydroxyzine and nitrous regimen in a home sedation so we would prep the night before and then two hours and one hour prior so it was an old protocol and I learned that from him.”

The extent and types of preparation and training differ greatly amongst the two clinicians, again influencing the position of the “preparation” circle in the model, and subsequently affecting the surface area in “risk tolerance”. Based on the quotes above and the position of the circles, Dr. C is considered “risk tolerant” and Dr. E “risk intolerant.”
The themes of safety and preference remain immutable, since all of our clinicians’ beliefs that they are practicing safely and their personal preferences regarding how they would like to practice do not change. For example, Dr. C stated that he/she “…never had a case with any respiratory depression,” suggesting that he/she is a safe clinician. Furthermore, he/she uses monitoring to ensure safety.

“For example, Dr. C stated that he/she “…never had a case with any respiratory depression,” suggesting that he/she is a safe clinician. Furthermore, he/she uses monitoring to ensure safety.

“Then I can see because of the amazing monitor we have there now that we ordered, I know what their respiration is, I know what their CO2 is and what is the problem. Rather than guessing whether their eyes are open or closed, you look at the monitor and you get 5 parameters about their vital signs.”

On the contrary, Dr. E stressed the role of visual monitoring in safety.

“I think also just to be aware of patient monitoring is a really important skill. Just to look at the patient and know what is going on rather than relying on at looking at monitors.”

Although the two clinicians may differ on how they ensure safety for their patients, they both make efforts to practice safely, and highlight safety as a key component of sedation. Dr. E ensures safety by staying within the realm of minimal sedation. Dr E. explains the benefits of minimal sedation “…they’re responsive and going to come out of it quickly”.

The clinicians’ preferences on how they would like practice were discussed during the interviews. Dr. E stated:

“I think the goal of sedation is to try to accomplish the dentistry and build some confidence in coping and if they need adjunct to build their coping skills but eventually you are going want to wean them off that and make them into good dental patients.”

On the other hand, Dr. C says:
“So sedation is not always for kids who are bad or act out it is for kids who are great too. Insurance policy. Just like if you go for any medical procedure, you are going to be sedated and yet you are a cooperative patient.”

The two differ in opinion on the indication for use of sedation.

Clinicians’ views on graduate pediatric dentistry students’ training in sedation are informed by the sum of the domains and the overall theme of risk tolerance. Risk tolerance, which is influenced by the interaction of the four domains, in turn informs Dr. C, who has high risk tolerance, believes in extensive training for students in the field of sedation.

“They should definitely have the skills to administer parental sedation including IV, IM, and maybe intranasal. Also they should have the facility to back that up and follow that up for recovery, etc.”

When questioned whether students should be taught one or multiple regimes, Dr. C said, “Multiple regimens. All the patients are so different.” When asked what level of sedation a graduate pediatric dentistry student should be trained in, Dr. C said:

“Striving for moderate quite often. That way you will actually have success and complete the two quadrants of dentistry. The patient who had it done comfortably but you have to have all the skills to have them go because from time to time they will go into deep as well. If you are trained and monitoring correctly with the staff then it is not a problem at all.”

The high risk tolerance and personal practice of Dr. C play a large role in his/her views on how pediatric dentistry graduate students should be taught sedation.

On the contrary, Dr. E, with low risk tolerance, believes students should be taught entry-level pediatric sedation.
“Depending on how the dentist is going to practice, I think if they are more comfortable doing deeper sedation, they have to be prepared to add the resources. I think for a training program, entry level, they should be aiming for mild to moderate sedation and nothing beyond that. Again, speed was the reinforced factor and we made short appointments so that we were not doing too much in one appointment. The drug regimens were very limited. They were not combinations. We used Midazolam alone or Midazolam and Nitrous or nothing in our training program. I think they should learn one protocol very well.”

Dr. C’s opinion is that students should be receive enough training to be proficient in deep sedation, be exposed to various routes of sedation including parenteral, and learn multiple regimens. Dr. E believes in entry-level training where minimal and moderate sedation are taught, and that one regimen should be taught. These views are a reflection of their personal sedation practices and largely their risk tolerances.
Figure 3-1 Risk Tolerance Model  
Figure 3-2 Dr. C’s Risk Tolerance Model  
Figure 3-3 Dr. E’s Risk Tolerance Model
Chapter 4: Discussion

This study aimed to assess outcomes of safety and effectiveness of a newly-introduced pediatric dentistry clinical sedation module and to investigate the experience and opinions of supervising clinicians.

4.1 Quantitative Component

The three most common drug regimens used in the present study were midazolam (MZ), midazolam and hydroxyzine (MZH), and meperidine, chloral hydrate, hydroxyzine, and dimenhydrinate (MCHHD). These are regimens that have been reported to be used commonly in pediatric dentistry (Wilson and Houpt, 2016). The first regimen, midazolam alone, involves the least number of sedatives, whereas the third one uses four drugs, including meperidine, a narcotic that potentiates the action of other sedatives when taken together (Shapira et al., 2004).

4.1.1 Safety

Safety, the first outcome variable assessed, was defined in two ways. The first part of the definition is the presence of an adverse event based on the assessment of vital signs, which are recorded every five minutes during the dental procedure (heart rate outside normal range, and oxygen saturation less than 94%). Heart rate can either be above or below the normal range for the patient’s age. If it is below, it is considered to be bradycardia and can occur secondary to the use of sedatives. If it is above, it may indicate that the child is upset, crying, or struggling. Both extremes are undesirable as they put undue stress on the child’s hemodynamic status. Oxygen saturation of less than 94% reflects decreased amounts of oxygen in the blood as a result of the sedatives’ depression of the central nervous system. The resultant respiratory depression, if left unidentified and/or uncorrected, can be fatal (Becker and Casabianca 2009).
The other part of the definition of “safety” was based on sedation levels of ‘Deep’ or ‘GA’ are negative indicators of safety, because of the partial or total loss of protective airway reflexes, respectively (AAPD 2016). The target range of for pediatric dentistry oral sedation is ‘mild’ or ‘moderate’, as it allows for safe and effective completion of treatment (AAPD 2016). We analyzed adverse events and depth of sedation to better evaluate the safety of the three most common drug regimens used at UBC

4.1.1.1 Adverse Events

Upon embarking on the retrospective chart review, we sought to learn whether “true” adverse events requiring use of reversal agent or efforts to resuscitate occurred. Following completion of data collection and analysis, it became evident that true adverse events did not occur during the study period. Alternatively, “transient” adverse events that were easily corrected (i.e. “head tilt chin lift” maneuver) or motion artifacts were recorded.

Midazolam is a benzodiazepine with a rapid onset and 20-30 minutes of working time. In medicine, it is may be used in children for a variety of reasons. These include children who require a short and painful procedure in an outpatient setting, the facilitation of general anesthesia induction, and separation of the child from family (Feld et al., 1990). An increase in struggling and crying behaviours can be associated with increased heart rate in children, which may be considered an adverse event (Chowdury and Vargas, 2005). Due to midazolam’s short duration of action, it is likely that the patients became “un-sedated” prior to completion of the procedure in many cases, which may explain the frequent occurrence of increased heart rate in MZ appointments. Furthermore, the short working time of midazolam puts the clinicians at a disadvantage, as many are still novice pediatric dentists who have not yet fully developed their speed and/or clinical skills. In the midazolam (MZ) group, 43% (n=18/42) of patients had low
oxygen saturation. The high prevalence may be explained by artifact such as patient movement (Becker & Casabianca, 2009). In a 2005 study comparing chloral hydrate, hydroxyzine and meperidine to midazolam regimens, significantly more children sedated with midazolam experienced elevations of heart rate and low oxygen saturation (Chowdury & Vargas, 2005). These findings were attributed to false readings related to movement or disruptive behaviours, respectively, similar to our own findings.

Hydroxyzine was used in conjunction with midazolam in the UBC program. Hydroxyzine is an anti-histamine with antiemetic and sedative properties. It is used to potentiate CNS depression and has been used in conjunction with chloral hydrate to facilitate ECGs in preschoolers (Roach et al., 2009). Its peak effectiveness is around 2 hours with a relatively long half-life of 7 hours ± 2 (Simons, 1989).

In the appointments where the MZH drug regimen was used, 73% (n=59/81) had abnormal heart rates, and 2.5% (n=2/80) experienced low oxygen saturation. It might be expected that this group would have greater occurrence of low oxygen saturation due to the addition of another sedative, however such was not the case. This finding may be explained by the fact that vital signs were monitored electronically by the pulse oximeter device during the appointments in the early months of the program in which midazolam alone was used. With the evolution of the program, the introduction of a graduate student whose sole responsibility was to document vital signs was introduced. This type of monitoring likely omits readings that were considered artifacts. Such accuracy was not possible with electrical monitoring alone.

In research to determine whether clinically relevant differences exist between manually and automatically recorded physiological data obtained during general anesthesia, manual record-keeping resulted in loss of clinically relevant information (Schalkwyk et al., 2011). Three
times as many artifacts were identified in automated records as in manual ones, demonstrating a
degree of selectivity in the data recorded in the manual records. This finding supports our
observations. Both the CDSBC and AAPD sedation guidelines suggest that support personnel in
addition to the practitioner “whose responsibility is to monitor appropriate physiologic
parameters and assist in any supportive or resuscitation measures, if required” should be present
(CDSBC Sedation Standards, 2016; AAPD Guidelines, 2016). This protocol is currently in place
at UBC.

In our study, abnormal heart rate occurred in 80.6% of MCHHD appointments (n=25/31),
an observation similar to the other two groups. Low oxygen saturations was recorded during
25.8% (n=8/31) of appointments, which is comparatively more than the MZH group. This
observation would be expected due to the addition of drugs such as meperidine, a narcotic and
respiratory depressant, and chloral hydrate, a sedative and hypnotic (Krauss & Green, 2006).

4.1.1.2 Level of Sedation

Sedation level was subjectively assessed by the clinician at completion of the
appointment. In the MZ group, 14.3% (n=1/7) of patients were assessed to have been deeply
sedated, a drug-induced depression of consciousness with partial or complete loss of protective
airway reflexes (AAPD Guidelines, 2016). Upon further examination of the record of the patient
who was assessed to be deeply sedated it became evident that the patient exhibited poor
behaviour and the sedation was rated as ineffective. Likely, the assessment of “deep” sedation
was an error. The original sedation record used at the beginning of the program did not require
the dentist to rate sedation level. Thus, of the 48 midazolam sedations completed, only 7 had
sedation levels that were assessed, and 1 was assessed to be deep. The missing data for the
midazolam group is an acknowledged limitation of the study and such “missing data” is a consistent challenge in a retrospective clinical study.

The MCHHD group had proportionately more deep sedations ratings than the MZH. This is consistent with what we would expect when more sedatives are used, as a deeper level of sedation is more likely (Krauss & Green, 2006). When odds ratios were calculated, those in the MZH group were 27 times more likely to achieve a “mild” or “moderate” level of sedation, which is the target range for pediatric dentistry oral sedations. However, the wide confidence intervals demonstrate the large variability present in the data, in addition to the small sample sizes.

In conclusion, adverse events in the present study included abnormal heart rate, low oxygen saturation, and sedation levels of “deep”. These transient adverse events can be explained by struggling behaviour of patient, monitor artifact, and clinician error, respectively.

4.1.2 Effectiveness

Effectiveness is an important component of a sedation assessment. As our second outcome variable, a child’s ‘Behaviour/Response to Treatment’, and the ‘Overall Effectiveness’ of the sedation were assessed by the treating dentist following the procedure.

4.1.2.1 Behaviour/Response to Treatment

MZ appointments had more ‘poor’ or ‘prohibitive’ behaviours compared to the MZH or MCHHD sedations. However, comparisons of MZ to MZH and MCHHD must be mindful of the limited amount of data available for the MZ group. In a previous investigation of pediatric patients receiving midazolam as a pre-induction anxiolytic, 9-17% of patients were reported to
display behaviours such as fear, combativeness, and crying at the time of anesthetic induction (Feld et al., 1990). Midazolam is a benzodiazepine with a short working time of approximately 30 minutes, thus patients were more likely to become “un-sedated” during the appointment (Krauss & Green, 2006). UBC sedation appointments were longer than the anticipated MZ working time.

Researchers using the North Carolina Behaviour Rating System compared behaviour in MMZH or MCHH groups (Sheroan et al., 2006). They found more disruptive behaviours in the group which used MZ instead of CH, especially during rubber dam placement and initiation of dental handpiece-use. Although they found no statistically significant difference in behaviour between the two groups, behaviour was slightly better in the CH group. However, there were slightly more hemoglobin desaturations in the CH group (Sheroan et al., 2006). These findings echo the observations made in the present study; UBC patients who received CH were rated to have better behaviour than those who did not. However, it is important that a clinician always weigh the risk against the benefit when making a choice of which sedative to use, as concern has been raised regarding the relationship of CH to adverse events (Cote et al., 2003).

4.1.2.2 Overall Effectiveness

Overall effectiveness was another important aspect of the sedations assessed by the dentist. MZH and MCHHD sedation appointments were consistently rated to be more effective than MZ sedations. A previous study comparing MZ alone versus MZ and M found similar outcomes (Musial et al, 2003). All three most frequently used sedation regimens in the current study, had good effectiveness rating by the operator. However, it is important to note the limited data in the midazolam group.
One factor to consider is the subjectivity of rating effectiveness of sedation, which will be further discussed in the qualitative findings. Discrepancies between operator and independent rater have been documented by Sheroan et al., 2006 in ratings of behaviour and effectiveness. When an independent rater viewed video taped sedations, they tended to rate them as more effective than the operator did (Sheroan et al., 2006). Calibration amongst clinicians may give more validity to evaluation of behaviour and effectiveness for research purposes (Dallman et al., 2001).

In summary, safety and effectiveness of sedations completed in the UBC Pediatric Dentistry program from March 2011-May 2014 were assessed. MZH and MCHHD had similar effectiveness, however MZH had a better safety profile with fewer episodes of deep sedation.

### 4.2 Qualitative Component

#### 4.2.1 Risk Tolerance

Risk can be defined as “the chance that a hazard will give way to harm” (Royal Society, 1992). Individuals differ inherently from each another, and one’s risk propensity is a core personality trait (Josef et al., 2016). The Domain-Specific Risk-Taking Scale (DOSPERT) assesses an individual’s risk in domains such as ethics, health, finances, recreations, and social decisions (Weber et al., 2002). It is unclear whether risk-taking tendencies diminish with age as the data is conflicting (Josef et al., 2016).

Healthcare professionals undergo many instances in practice requiring the weighing and assessing of risk during healthcare delivery. In a study that examined the attitudes of general practitioner physicians in Europe, it was postulated “different cultures, forms of medical education, and legal systems may lead to differences in attitudes to risk taking.” (Grol et al.,
A diverse group of clinicians with varying backgrounds were interviewed in this study, and accordingly, a range of risk tolerances were discovered.

Research has demonstrated that inherent risk propensity influences clinical behaviour. A “risk-taking scale” was used to assess the relationship between emergency room physicians’ risk attitudes and admission rate of patients with chest pain (Pearson et al., 1995). The six-item scale was derived from the Jackson Personality Inventory, which defines a risk-seeker as “a person who enjoys adventures and is unconcerned with danger”, whereas a “risk avoider” is considered to be cautious, hesitant and security-minded” (Jackson, 1975). Patients triaged by risk-averse physicians were twice as likely to be admitted than if triaged by risk-seeking physicians (Pearson et al., 1995). Furthermore, a study assessing physician risk attitudes in pediatric emergency room physicians found that physicians with 15 or more years of experiences had higher risk aversion scores (Baldwin et al., 2005). This is contrary to the findings of the present study, as the pediatric dentist who displayed the most risk tolerance also had been practicing the longest (35 years).

Risk can also influence continuing medical education (CME) preferences. Risk seekers prefer hands-on learning and assimilators whereas the risk-averse tend towards lectures and theory (Robinson, 2002). This finding echoes those of the present study. The most risk tolerant pediatric dentist discussed continuing education courses that involved simulation in depth.

“Human simulation on these high definition dummies can give you such a real life experience that is the key thing to achieve your safety training to be able to face these sedated children and only recently it is really becoming available.” (Dr. C).

By assessing characteristics of the participants, one can better understand their risk tolerance, and consequently their sedation practice profile. For example, Dr. C, considered to have a high risk tolerance, sedates 80% of patients that require treatment, uses an extensive
number of sedative agents, and sedates a wide range of patients (ages 2-14). Dr. C has practiced in both rural and urban settings. It may be speculated that practice in a rural setting may offer an environment in which a clinician must be more risk tolerant due to lack of alternative resources such as access to general anesthesia. Dr. C believes in extensive CE including simulation work and has a wealth of knowledge and extensive experience in the field of pediatric dentistry sedation, which may collectively increase his/her risk tolerance threshold.

In contrast, Dr. E has practiced as a pediatric dentist for 10 years in urban settings, does not currently practice sedation, and demonstrates risk intolerance. Dr. E has access to general anesthesia in a hospital setting, making the need to practice sedation less important. It is interesting to note that both clinicians completed their graduate pediatric dentistry training at the same institution, however chose very different paths as pediatric dentists. Whether this is due to outside circumstances or inherent risk tolerance is difficult to determine from our investigation.

4.2.2 Effectiveness of Sedation

Degree of crying, alertness, movement, and struggling are commonly rated as indicators for effectiveness of pediatric dentistry sedations. Moreover, general behaviour is rated based on number of treatment interruptions (Fuks et al., 1994; Musial et al., 2003). Assessments of behaviour range from ‘Excellent’ (patient is quiet and cooperative) to ‘Prohibitve’, (active resistance and crying wherein treatment cannot be rendered). From the interviews, it became apparent that pediatric dentists’ definition of an ‘effective’ sedation procedure varied greatly. Furthermore, the threshold for crying or struggling behaviours differed. For example, some were more comfortable with screaming and crying as long as the dentistry is completed whereas others want to minimize such outbursts. Those that accepted less-than-ideal behaviour were commonly
more risk-intolerant, whereas those that strived for excellent quiet behaviour were risk-tolerant, in relationship to sedation practices.

4.2.3 Patient Safety

Most clinicians today rely on monitoring so that they may practice safer sedations. Guidelines state that certain monitors i.e. pulse oximeter are required to be used during sedation procedures (AAPD Guidelines, 2016), however the pediatric dentists interviewed in this study who generally used a wider variety and number of sedative agents reported that they were using more advanced monitoring such as capnography. These were the same risk tolerant participants who reported using multiple sedative agents in combinations that may result in deeper levels of sedation. A recent meta-analysis of procedural sedation found that respiratory depression is 17 times more likely to be detected when capnography is used during procedural sedation (Waugh et al, 2011). It can be argued that for a patient only mildly or moderately sedated, and by CDSBC definition, easily-arousable, more advanced monitoring may not be necessary (AAP, 1992).

Weight-based dosing was universal amongst the interviewees, a practice supported by guidelines (Wilson & Cote, 2006).

4.2.4 Preparation/Training

The risk tolerant dentists who pursued extensive continuing education courses also had practices that were heavily “sedation-dependent”. On the other hand, risk-intolerant dentists whom had not taken many continuing education courses in the area of sedation were in most instance not practicing sedation at all. All of our participants agreed that if a pediatric dentist practices sedation routinely, then he/she has a professional obligation to further their education and stay updated in the area of sedation. In a survey of members of the International Association
of Pediatric Dentistry and the European Academy of Pediatric Dentistry, 91% of respondents indicated an interest in continuing education on the topic of sedation, even though only 45% did not routinely practice sedation (Wilson & Alcaino, 2011). Furthermore, 90% of the respondents felt that CE was crucial in maintaining proficiency and safety (Wilson & Alcaino, 2011).

4.2.5 Behaviour Management Preferences

Management of a pediatric patient’s behaviour is an important component of delivery of treatment. Non-pharmacologic techniques rely primarily on the dentist’s communicative skills, whereas pharmacologic behaviour management utilizes sedative agents to facilitate dental treatment. The interviewee’s comments suggested that clinicians have preferences regarding the type of behaviour management techniques they provide. Provision of dental treatment under general anesthesia was preferred by those instructors who were risk-intolerant. Those same clinicians were more likely to use communicative techniques so that treatment can be provided under local anesthetic, without the use of sedatives. The risk intolerant clinicians suggested that GA offers a controlled environment in which they do not have to monitor the child’s vital signs but can instead can focus on the dental component. On the contrary, risk tolerant instructors were more apt to offer in-office sedation to their patients. Considering sedation is reported to have an average failure rate of 30% (Wilson & Alcaino, 2011), it is understandable that some practitioners tend toward reliable GA. Due to the limited resources and high costs associated with general anesthesia (Lee et al., 2000), the need for an alternative approach is obvious, and certain personality-types (Pearson et al., 1995) are willing to offer sedation to their patients. “Personality-type” of instructors was not objectively assessed in our study.
4.2.6 Future Pediatric Dentists’ Training

During their time as clinical instructors, Drs. A and C taught the MCHHD regimen about half the time, which was considerably more often than their counterparts. The MCHHD regimen uses four sedative agents, which are additive in effect, and resulted in more frequent moderate to deep sedations. The practitioners told us that they use pharmacologic behaviour management techniques such as oral sedation in their own practice 80% of the time. Those that were classified as risk-tolerant did not see a need for a dental anesthetist and preferred students to learn multiple sedative regimens and to a level of deep sedation. These clinicians can be considered “experts” in the field of pediatric dentistry sedation and bring a wealth of experience to students. Pediatric dentistry graduate students are considered “novices” in the field of pediatric sedation. Teachers are prone to having “expert blind spots” when teaching novices (Walker & von Bergmann, 2015). Experts do not have to think about every step of the procedure and do not make the same mistakes that novices make. Furthermore, they may be blind to the areas novices struggle with in learning a task (Walker & von Bergmann, 2015). This is important in the field of pediatric sedation as “critical incidents” may put a child patient at risk of harm. For this reason, instructors may want to be aware of their own “expert blind spots”.

Risk-intolerant pediatric dentists felt that only the basic technique of sedation should be taught and liked the idea of having additional personnel present in a learning environment. Indeed, Dr. E reported that he/she does not use oral sedation in his/her current practice at all, and felt students should be taught one sedation regimen only, whereas the remainder of the participants liked the idea of teaching multiple protocols. Dr. E felt speed of treatment delivery should be emphasized rather than depth of sedation.
In an international survey of pediatric dentists, most respondents felt that nitrous oxide and oral sedation should be taught, in addition to other routes such as intravenous (Wilson & Alcaino, 2011). This finding suggests a desire by the international community of pediatric dentists to add a broad range of sedation modalities to their arsenal of behaviour management techniques (Wilson & Alcaino, 2011). However, it is doubtful that all such modalities can be mastered by trainees in an already densely-packed graduate training program.

When developing the clinical sedation component of a graduate pediatric dentistry program, one must consider the variety of opinions present in the community as they may contribute to what graduate students are taught, while still adhering to regulatory guidelines and accreditation requirements. In addition to being aware of “expert blind spots”, a clinical instructor may desire to have self-awareness regarding his/her own risk tolerance. By being cognizant of these areas, a clinician can better understand how to direct his/her students.

The rationale behind the choice of drug regimens taught in the clinic, as discovered from the chart review, became clearer following the interviews. Each clinician brought his/her own level of risk tolerance to the graduate program, which in turn played a role in their view on teaching sedation to graduate pediatric dentistry students.

4.3 Study Strengths

This study has given a new Canadian graduate pediatric dentistry program the opportunity to reflect on the initial years of its sedation module. By assessing the safety and effectiveness of the drug regimens used, it is a valuable internal audit and exercise in quality assurance. Furthermore, the interviews provided an opportunity to unpack the complex relationship between clinicians’ risk tolerance and sedation practice/teaching.
4.4 Study Limitations

The study is not without its limitations. A retrospective study is understandably inferior to a prospective study. Additionally, over the 3 years of the chart review numerous dental providers and clinical instructors were involved in patient care, making standardization of the data very difficult. As discussed previously, many of the outcome variables also involved a degree of subjectivity i.e. assessing behaviour, introducing a range of thresholds and personalities to a primary outcome variable. We sometimes found a discrepancy between data from scribed sedation log and print-outs from monitors, making it difficult to know which was more accurate. Furthermore, there were unexpected amounts of missing data. Data was limited for some variables, making it difficult to detect statistical significance, and even creating the need to discard variables. Of note is that the sedation record, the main data source, evolved and improved from 2011 to 2012 with much more data points and information in the latter.

The qualitative component also has limitations. Due to the highly structured-nature of the interviews, the domains that emerged were not “de novo” but closely followed the topic of our questions. Had the interview been less structured, different themes may have emerged. ‘One-on-one’ structured interviewing may encourage or discourage the expression of particular opinions, also known as response bias. Further, our qualitative study design did not extend to students, certified dental assistants (CDAs), anesthetists, or parents and focused only on the clinical instructors. Analysis of the qualitative data has an element of subjectivity, but emerging domains and our central theme of “risk tolerance” were validated by discussion with an independent researcher and with the supervisory committee.
4.5 Conclusions

The three most commonly used regimens over the early years of the UBC graduate pediatric dentistry program were MZ, MZH, and MCHHD. Safety and effectiveness were assessed in a variety of ways. The regimens resulted in mostly mild and moderate sedations, which is the target range for a pediatric dental specialist. The prevalence of transient adverse events like oxygen desaturation was low, and those that were recorded may have been due to an artifact like patient movement. Any prevalence of abnormal heart rate was attributed to crying and/or struggling behaviours. Behaviour during treatment was good or excellent in about half the cases, and sedations were effective or very effective most of the time. When assessing the three most commonly used regimens, MZH and MCHHD had similar effectiveness, however MCHHD had more cases of “deep” sedation, decreasing its safety profile. The remaining differences in outcomes were not statistically significant. With respect to the quantitative data of this study, it is important to be cognizant of the limitations of this retrospective study e.g. missing data in the MZ group.

It became evident from the interviews of a relationship between “risk tolerance” and four domains. The effectiveness of a sedation, preparation or training for sedation practice, behaviour management preferences, and views on safety interact with inherent risk tolerance in a dynamic fashion. These factors collectively shape an individual’s opinion on how pediatric dentistry trainees should be educated in the area of sedation.

4.6 Recommendations

Seven recommendations emerged from this study:
1). Encouraging clinical instructors and students to understand their personal risk tolerance level for it can influence their sedation practice. Faculty members in the development phase of a clinical sedation component of a pediatric dentistry graduate program usually decide collectively what kind of curriculum they would like their students to be taught. If the aim is to provide entry-level sedation skills, clinical instructors should implement sedation regimens that accordingly fulfill the target sedation level. Clinicians have inherent risk tolerance that can influence their sedation practices and consequently their views on training students in the field of sedation. Clinical instructors and students may choose to have self-awareness regarding their risk tolerance levels so that they better understand how it informs their clinical decisions.

2). A graduation pediatric dentistry program should give students the basic skills they need via “entry-level” sedations taught by “middle-ground” risk tolerant instructors since students come with their own range of risk tolerances, which will likely influence their practice in the future. Supporting clinical instructors with the ability to teach students who present with a range of risk tolerances and long-term practice goals can strengthen a graduate pediatric dental program.

3). Providing an entry-level sedation regimen to students may be a reasonable solution. As suggested by many of the interviewees, after completion of a graduate program, a clinician can decide how he/she will practice and pursue additional training as needed. The extremes can either choose to not practice sedation at all or to continue developing their skills in the field by pursuing CE courses following qualification as a specialist in pediatric dentistry.

4). Pediatric dentistry graduate programs establishing a sedation component could use the interview guide of this study and modify it to better understand potential clinical instructors. The interview guide used in this study aimed to better understand a clinician’s views on sedation in
pediatric dentistry, and subsequently a model was created to demonstrate the relationship of risk tolerance to sedation practice. Ultimately, views regarding the specific manner in which students should be taught sedation will shape the program in which these clinicians teach.

5). By providing sedation records that are user-friendly with large text and adequate space in which to write the necessary information, we can help enforce a better record keeping. As per CDAC guidelines, graduate students in a pediatric dentistry program must be educated in the fundamentals of sedation. As a result of the chart review, the importance of a complete and inclusive sedation record became evident, as one of the main findings was missing data from our early sedation records. Completion of the sedation record by the trainee must be stressed and enforced.

6). Integrate sedation records into the electronic health records, such that submission cannot be completed without an appropriately filled out form. The attending pediatric dentist (clinical instructor) should always ensure completion of the form before “signing off” the patient record.

7). To deepen the understanding of risk tolerance, longitudinal studies whereby clinicians are interviewed at various points in their career over time in the context of sedation practice in pediatric dentistry can shed light to (i) implications for education program, and (ii) whether set-points exist for risk tolerance in pediatric dentists.

The findings of this study are limited to one program. Future studies should consider expanding it to consider the input of parents, graduate students, clinic auxiliary staff and perhaps even the medical and dental anesthesia community should be sought in further qualitative explorations.
Bibliography


Appendix A: Sedation Record 2011

PROCEDURAL CONSCIOUS SEDATION RECORD

DATE: ____________________________

PATIENT NAME: ____________________________ F M AGE: _______ (y-m)

PRE-OP BEHAVIOURAL ASSESSMENT: (- -) (-) (+) (+++) RESPONSIBLE PARENT ____________________________

PRE-OP PHYSICAL ASSESSMENT: Med Hx update: ____________________________ No changes

☐ NPO ___ hrs ☐ COLD ☐ FEVER ☐ COUGH ☐ OTHER: ____________________________

PULSE ____________________________ SaO₂ ____________________________

MEDICATIONS: WEIGHT__________ Kg.

☐ Midazolam _________mg. Mixed with ____________________________

Given by: ____________________________ Time: ___________ Dosage checked by: ____________________________

☐ N₂O/O₂: Premed taken: Y N

% N₂O _______ @ FR _____________ L

PROCEDURES: Tx start: _________ am/pm Tx end: _________ am/pm

☐ X-rays ☐ Pro/F ☐ Ag/Co SSC ☐ Pulp therapy ☐ extraction ☐ other__________ ☐ Tx aborted

MONITORS: ☐ visual ☐ pulse-ox ☐ capnography ☐ pre-cordial ☐ other ______________

RESTRANST: ☐ none ☐ full body ☐ mouth prop ☐ by parent ☐ other ______________

BEHAVIOURAL ASSESSMENT:

<table>
<thead>
<tr>
<th>Behaviour</th>
<th>Asleep</th>
<th>Awake &amp; responsive</th>
<th>Crying</th>
<th>Screaming</th>
<th>Struggled</th>
<th>Other</th>
</tr>
</thead>
<tbody>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>After meds</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>During Tx</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
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<tr>
<td>Post-Tx</td>
<td></td>
<td></td>
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<tr>
<td>Discharge</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Overall: ☐ Interactive ☐ Non-Interactive

Discharge Time: __________ am/pm

Written instructions given: SED p/o SSC LA EXT PRE-OP

Signature: ____________________________ Instructor: ____________________________
# Appendix B: Sedation Record 2012

## SEDATION RECORD

<table>
<thead>
<tr>
<th>Study ID:</th>
<th>Age: ____ yr ____ mths</th>
<th>Date:________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergies:</td>
<td></td>
<td></td>
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<tr>
<td>Weight:</td>
<td>___ kg</td>
<td>BMI score:</td>
</tr>
<tr>
<td>Tonsil Size:</td>
<td>____ %</td>
<td></td>
</tr>
<tr>
<td>Preoperative Health conditions:</td>
<td>Healthy/__________</td>
<td>ASA □ I □ II</td>
</tr>
</tbody>
</table>

### Indications for sedation:
- □ Fearful/anxious patient for whom basic behaviour guidance techniques have not been successful.
- □ Patient unable to cooperate due to lack of psychological or emotional maturity and/or mental, physical or medical disability
- □ To protect patient’s developing psyche
- □ To reduce patient’s medical risk

### Preoperative assessment on the day of sedation:
- □ NPO No □ Yes, since ______ am/pm
- □ Change in medical hx No □ Yes, ______________
- □ Change in medications No □ Yes ______________
- □ Recent respiratory illness No □ Yes ______________
- □ Clear chest and nasal cavities No □ Yes ______________

### Vital Signs:
- Blood Pressure _______/_______ mmHg
- SpO2 ________ %
- Pulse ______bpm

### Premeditation cooperation level:
- □ Unable/unwilling to cooperate
- □ Rarely follows requests
- □ Cooperates with prompting
- □ Cooperates freely

### Behavioural interaction:
- □ Definitely shy and withdrawn
- □ Somewhat shy
- □ Approachable

### Drug dosage calculations:

#### Midazolam
- 0.3-1.0mg/kg; MAX 20mg
- Route PO
  - _____ kg X _____ mg/kg = _____ mg ÷ 5.0 mg/1 mL = _____ mL

#### Hydroxyzine (Atarax)
- 1 mg/kg; MAX 20mg
- Route PO
  - _____ kg X _____ mg/kg = _____ mg ÷ 5.0 mg/1 mL = _____ mL

#### Dimenhydrinate (Gravol)
- 0.5mg/kg; MAX 75 mg
- Route PO
  - _____ kg X _____ mg/kg = _____ mg ÷ 3.0 mg/1 mL = _____ mL

#### Ibuprofen (10mg/kg)
- Route PO
  - _____ kg X _____ mg/kg = _____ mg ÷ 20 mg/1 mL = _____ mL

#### Maximum dosage of Lidocaine 2% with 1:100,000 epinephrine
- Route PO
  - _____ kg X 7 mg/kg = _____ mg
  - _____ (____ mg/kg) Route PO
  - _____ kg X _____ mg/kg = _____ mg ÷ ___ mg/___ ml = ______
  - _____ (____ mg/kg) Route PO
  - _____ kg X _____ mg/kg = _____ mg ÷ ___ mg/___ ml = ______

#### Flumazenil:
- Route IV or SM not to exceed 0.2mg/min and a total dose of 1 mg
  - _____ kg X 0.01 mg/kg = _____ mg ÷ 0.1 mg/mL = _____ mL

#### IM Succinylcholine:
- Route IM (Emergency Laryngospasm)
  - _____ kg X 3mg/kg = _________ mg, ÷ 20mg = ______
<table>
<thead>
<tr>
<th>Time:</th>
<th>SaO2:</th>
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</thead>
<tbody>
<tr>
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<tr>
<td>100</td>
<td>80</td>
</tr>
<tr>
<td>60</td>
<td></td>
</tr>
</tbody>
</table>

**Discharge Criteria:**
- Orientated
- Vital Signs Stable
- BP: __________ HR: __________
- Ambulatory

Modified Aldrete Criteria Score: __________

**Discharge Time:** __________

In company of: __________

**Sedation Level:**
- None: typical response/cooperation for this patient
- Mild: anxiolysis
- Moderate: purposeful response to verbal commands +/- light tactile sensation
- Deep: purposeful response after repeated verbal or painful stimulation
- GA: not arousable

**Behaviour/responsiveness to treatment:**
- Excellent: quiet and cooperative
- Good: mild objections and/or whimpering but treatment not interrupted
- Fair: crying with minimal disruption to treatment
- Poor: struggling what interfered with operative procedures
- Prohibitive: active resistance and crying; treatment cannot be rendered

**Overall effectiveness:**
- Ineffective
- Effective
- Very effective
- Overly sedated

Graduate Student signature: _____________________  Instructor’s signature: _____________________
Appendix C: Interview Consent Form

A review of pediatric dentistry oral sedation outcomes

Subject Information and Consent Form

Principal Investigator: Kavita R. Mathu-Muju, DMD, MPH, FRCD(C)
Faculty of Dentistry, University of British Columbia

Study Team Contact Number: Zina Alkafaji (***).***-****

You are being invited to take part in this research study because you have taught in the UBC Graduate Pediatric Dentistry Program. We are interested in learning about your practice as a pediatric dentist, in particular with relation to oral sedation.

There is much variation from one pediatric dentist to another regarding the use of oral sedatives. The purpose of this study is to explore the different regimens that have been used in the UBC Pediatric Dentistry Graduate Program and compare their effectiveness and safety. Furthermore, we would like to explore the philosophical foundations of clinicians' approach to oral sedation. We do not anticipate that we will find major difference in outcome between different sedation regimens, but foresee a variety of philosophies from one clinician to the next.

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences. Before you decide, it is important for you to understand what this research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks, and discomforts.

If you wish to participate in this study, you will be asked to sign this form. Please take time to read the following information carefully and to discuss it before you decide. This study is being conducted by the Faculty of Dentistry at the University of British Columbia. The principal investigator, Dr. Kavita Mathu-Muju, and the graduate student, Dr. Zina Alkafaji will have access to the study material.

Becoming a participant in this study entails a 20-30 minute face-to-face interview with one of the primary investigators/graduate student, Dr. Zina Alkafaji. The interview will be recorded and later transcribed. Risks to participants will be minimized and all identities will be kept confidential.

Your confidentiality will be respected. However, research records identifying you may be inspected in the presence of the Investigator or his or her designee and by representatives the University of British Columbia Clinical Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a subject in this study. Only this number will be used on any research-related information collected about you during the course of this study, so that your identity [i.e. your name or any other information that could identify you] as a subject in this study will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without
your consent unless required by law. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.).

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected and also give you the right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

The data collected will be de-identified and stored in electronic form. The data will be analyzed internally by staff of the Faculty of Dentistry at the University of British Columbia. The recordings will be destroyed after the conclusion of the study and not be used for any other purpose. The Principal Investigator, Dr. Kavita Mathu-Muju and graduate student, Dr. Zina Alkafaji, will have access to the recordings. The participant’s identity will be protected by de-identifying the participant. This is done by using a unique study number.

By signing this form, you do not give up any of your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and professional duties. You will not incur any personal expenses as a result of participation. You will not be paid for participating in this study. You may withdraw from the study at any time without any consequences. For further questions about the study please contact Dr. Alkafaji at (778) 898-6059.

If you have any concerns or complaints about your rights as a research subject and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Services by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).
**A review of pediatric dentistry oral sedation outcomes**

My signature on this consent form means:

- I have read and understood the subject information and consent form.
- I have had the opportunity to ask questions and have had satisfactory responses to my questions.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.

I will receive a signed copy of this consent form for my own records.

I consent to participate in this study.

<table>
<thead>
<tr>
<th>Subject’s Signature</th>
<th>Printed name</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>Signature of Person Obtaining Consent</td>
<td>Printed name</td>
<td>Study Role</td>
</tr>
</tbody>
</table>
Appendix D: Interview Questions

Oral Sedation Interview Questions

Background:

• How long have you practicing as a pediatric dentist?
• Do you consider your practice to be urban or rural?

Personal Practice:

• What proportion of your practice is sedated?
• How many children receive sedations in an average week?
• Do you have GA privileges? How often do you go to GA (#GA’s per month)
• Which drugs do you use? Why do you choose those drugs?
• What age range do you consider suitable for sedation?
• What is the typical working time for your sedated patients?
• What are your evaluation criteria for deciding to deliver treatment with the use of sedation?
• How do you determine drug dosages?
• What criteria do you use to determine if a sedation has been successful?
• Do you use a lot of communicative management with your sedated patients?

Training:

• Can you tell me about the sedation training that you had in your post-graduate program?
• Did you do any extra training or continuing education in oral sedation?
• Has the sedation protocol you use in practice changed over time? How?

Educational:

• What skills and knowledge should a new graduate have with respect to sedation? Why?
  o What level of sedation (mild, moderate, deep) should graduate pediatric dentistry students
    train to do (if they don’t answer this in the first half of the question)? (Clarify that all trainees
    must know to manage if a child moves into deep sedation, but you want to know what level
    of sedation they should routinely administer).
• How can trainees integrate behaviour management (i.e. tell-show-do) in their sedation procedures?
• What do you think of the sedation records? Old vs. new? (Show it them) Could it be better? Do you
  use a sedation record in your practice?

Opinion of UBC Training:

• Give a preamble of what we do now. (Midazolam+Hydroxyzine+Meperidine plus dental anesthetist
  plus pediatric dentist) and get their opinion.
• Does the UBC protocol differ from your residency training? How?
• Do you think residents should learn one protocol very well, or be exposed to multiple protocols? Keep in mind that 20 cases is the requirement for a sedation permit in BC (and the requirement for accreditation in US programs)
• What responsibility do you think individual practitioners have to enhance their sedation training with CE courses after completing their training program?
• What opportunity does a dental anesthetist who teaches in the pediatric dentistry sedation clinic have?