Mortality and Morbidity in Office-Based Deep Sedation and General Anaesthesia for Dentistry in Ontario

by

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A thesis submitted in conformity with the requirements for the degree of Master of Science

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Abstract

Objectives: To estimate the prevalence of mortality and serious morbidity for office-based deep sedation and general anesthesia (DS/GA) for dentistry in Ontario from 1996-2015.

Materials & Methods: Data were collected retrospectively in two phases. In Phase I, cases involving injury or death for dentistry under DS/GA, sourced from the Chief Coroner of Ontario and the Royal College of Dental Surgeons of Ontario were reviewed. Phase II involved a survey of all registered providers of DS/GA where they estimated the number of DS/GA administered. Prevalence was calculated using Phase I and Phase II findings.

Results: The estimated prevalence of mortality is 0.8 deaths per 1 million cases, and the estimated prevalence of serious morbidity is 0.25 per 1 million cases.

Conclusions: The mortality and morbidity rates found in this study fit within the lower end of the range of mortality and morbidity reported by similar studies for office-based DS/GA in dentistry.
Acknowledgements

This thesis was completed with the help and support of several individuals to whom I would like to extend my gratitude.

This study would not have been possible without the participation of the Office of the Chief Coroner of Ontario, the Royal College of Dental Surgeons of Ontario, and the Professional Liability Program. I would like to express my gratitude and appreciation to the individuals and their teams whose tireless efforts have been instrumental in facilitating data collection: Mr. Irwin Fefergrad, Dr. Dirk Huyer, Mr. Andrew Stephen, Mr. Alan Lachapelle, and Mr. Kevin Marsh. I would also like to thank Drs. Michelle Tang and Bryan Waxman from the Canadian Association of Dental Anaesthesiologists and Dr. Ian Furst from the Ontario Society of Oral Maxillofacial Surgeons for their assistance in advancing our survey tool to their members. I would also like to extend my sincere appreciation to my research assistant, Zane Haji, whose hard work and dedication to this project was invaluable.

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Dr. Alia El-Mowafy – Toronto, Canada, September 2017.
Table of Contents

ACKNOWLEDGEMENTS .............................................................................................................. iii

TABLE OF CONTENTS ........................................................................................................ iv

LIST OF FIGURES .................................................................................................................. vi

LIST OF TABLES .................................................................................................................... vii

LIST OF APPENDICES .......................................................................................................... viii

CHAPTER 1 ................................................................................................................................. 1

1.0 PROBLEM .......................................................................................................................... 1

1.1 – STUDY RATIONALE ...................................................................................................... 1

1.2 – RESEARCH QUESTION ............................................................................................... 2

1.3 – OBJECTIVES ................................................................................................................ 2

CHAPTER 2 ................................................................................................................................. 3

2.0 – INTRODUCTION ............................................................................................................ 3

2.1 – RISKS OF ANAESTHESIA .......................................................................................... 5

2.2.0 – DEFINITION OF MORTALITY .................................................................................. 5

2.2.1 – DEFINITION OF MORBIDITY ................................................................................ 6

2.2.2 – CLOSED CLAIMS DATA AND SEVERITY OF INJURY SCORING ............................. 6

2.3 – MORTALITY RATES IN MEDICAL ANAESTHESIA ...................................................... 9

2.4 – MORTALITY RATES IN DENTAL ANAESTHESIA ...................................................... 10

2.5 – STRENGTHS AND LIMITATIONS IN EXISTING LITERATURE ................................. 21

2.6 – SUMMARY OF THE LITERATURE .............................................................................. 22

CHAPTER 3 METHODS .......................................................................................................... 25

3.0 – STUDY DESIGN .............................................................................................................. 25

3.1 – PHASE I: MORTALITY AND MORBIDITY .................................................................. 25

3.1.1 – PARTICIPATING ORGANIZATIONS ....................................................................... 25

3.1.2 – DATA COLLECTION .............................................................................................. 27

3.1.3 – INCLUSION CRITERIA ............................................................................................ 29

3.1.4 – MODIFIED SEVERITY OF INJURY SCORE (mSIS) ............................................... 30

3.1.5 – STANDARDIZED CASE SUMMARY .................................................................... 31

3.2 – PHASE II: TOTAL NUMBER OF ANAESTHETICS ....................................................... 32

3.2.1 – PARTICIPATING DS/GA PROVIDERS ..................................................................... 32

3.2.2 – SURVEY DESIGN .................................................................................................. 32

3.2.3 – PARTICIPANT RECRUITMENT .............................................................................. 34
List of Figures

FIGURE 1: FLOW-CHART FOR CASES FORWARDED FROM OFFICE OF THE CHIEF CORONER OF ONTARIO.................................................................39
FIGURE 2: FLOW-CHART FOR CASES FORWARDED FROM RCDSO (PLP & PCRA)...40
List of Tables

TABLE 1: CHARACTERISTICS OF THE LEVELS OF SEDATION AND GENERAL ANAESTHESIA (RCDSO, 2012).................................................................3

TABLE 2: SEVERITY OF INJURY SCORING SYSTEM (CHENEY ET AL., 1989)........8

TABLE 3: MORBIDITY RATES IN DENTAL ANAESTHESIA LITERATURE...........10

TABLE 4: MORTALITY RATES IN DENTAL ANAESTHESIA LITERATURE..........11

TABLE 5: ODDS OF DYING BY VARIOUS CAUSES AS DETERMINED BY THE U.S. NATIONAL SAFETY COUNCIL (NSC, 2013)..........................23

TABLE 6: INTERNAL TEAM ROLES..............................................................28

TABLE 7: CASE INCLUSION CRITERIA..........................................................29

TABLE 8: MODIFIED SEVERITY OF INJURY SCORE (MSIS).........................31

TABLE 9: AMERICAN SOCIETY OF ANESTHESIOLOGISTS PHYSICAL STATUS CLASSIFICATION SYSTEM (ASA, 2014).................................42

TABLE 10: SUMMARY OF MORTALITY AND SERIOUS MORBIDITY CASES INCLUDED IN DATASET.................................................................45

TABLE 11: MSIS SCORES ACCORDING TO AGE..............................................46

TABLE 12: SURVEY RESPONSE RATE............................................................46

TABLE 13: PROVIDER GROUP VALUES FOR YEARS IN PRACTICE.....................47

TABLE 14: PROVIDER GROUP VALUES FOR NUMBER OF ANAESTHETICS ADMINISTERED.................................................................48

TABLE 15: NUMBER OF ANAESTHETICS ESTIMATED FROM SURVEY RESPONSES....................................................................................49

TABLE 16: NUMBER OF ANAESTHETICS ESTIMATED FOR NON-RESPONDERS....50

TABLE 17: TOTAL ESTIMATED NUMBER OF ANAESTHETICS ADMINISTERED 1996-2015.................................................................51

TABLE 18: ESTIMATED MORTALITY AND SERIOUS MORBIDITY RATES.........51

# List of Appendices

APPENDIX A: OFFICE OF THE CHIEF CORONER OF ONTARIO INVITATION TO PARTICIPATE…………………………………………………………………75

APPENDIX B: PROFESSIONAL LIABILITY PROGRAM INVITATION TO PARTICIPATE…………………………………………………………………78

APPENDIX C: STANDARDIZED CASE SUMMARY……………………………………………………………..81

APPENDIX D: ANAESTHESIA PROVIDER INFORMED CONSENT……………………………………………….83

APPENDIX E: SURVEY TOOL………………………………………………………………...85

APPENDIX F: RESEARCH AGREEMENT WITH OFFICE OF THE CHIEF CORONER OF ONTARIO………………………………………………………………………86

APPENDIX G: UNIVERSITY OF TORONTO’S HEALTH SCIENCE RESEARCH ETHICS BOARD APPROVAL…………………………………………………………….89
CHAPTER 1

1.0 - Statement of the Problem

There is a lack of recent data in Ontario regarding morbidity and mortality events related to deep sedation and general anaesthesia (DS/GA) for dentistry in Ontario. Specifically, data are lacking in our understanding of what happens outside of hospital settings, or the number of deaths or injury events that occur in dental offices or surgicentres in relation to the number of general anaesthetics provided in these settings.

1.1 - Study Rationale

Morbidity and mortality reports provide insight into incidents leading to patient harm and to identify issues that can lead to harm in order to allow for improvements in patient care (Cook and Macdougall-Davis, 2012). The prevalence of mortality for dentistry under DS/GA in Ontario was last investigated by Nkansah et al. (1997) two decades ago. Since this time, studies have shown increased use of monitors that may contribute to patient safety. D’Eramo et al. (1992, 2003) reported an increase in the use of pulse oximetry by almost 20% over a 12-year span. This may have an effect on the prevalence of critical incidents, especially those of a respiratory nature, and mortality and critical incident rates in Ontario may have declined as a result. In addition, the prevalence of serious morbidity in the Ontario patient population undergoing DS/GA for dental treatment is yet to be established. Providing an indication of the prevalence of serious morbidity in the context of DS/GA for dentistry in Ontario would be a new contribution to the literature. Documenting and describing any critical incidents that occur is an important evidence-based approach to modifying practice in ways that could enhance safety. The publication of the type of morbidity cases occurring in outpatient dental anaesthesia in Ontario
may aid clinicians in identifying issues in practice that could lead to harm, and potentially prevent them from occurring. Finally, estimating the prevalence of mortality and serious morbidity for office-based DS/GA for dentistry in Ontario represents valuable information to clinicians as part of the informed consent process from patients.

1.2 - Research Question

What is the prevalence of mortality and serious morbidity for patients undergoing deep sedation and general anaesthesia for dental procedures when performed outside of a hospital facility by Royal College of Dental Surgeons of Ontario (RCDSO) registered providers from 1996-2015?

1.3 - Objectives

The objective of this study was to estimate the mortality rate for outpatient anaesthesia in dentistry in Ontario modeling the methodology used in Nkansah et al. (1997). Additionally, this study aimed to estimate the prevalence of serious morbidity in this same context.
CHAPTER 2

2.0 - Introduction

Dentists require the cooperation of their patients for a dental appointment to be successful. There are many instances in which a patient finds it difficult or is simply unable to cooperate. This situation may be due to various factors including anxiety, cognitive dysfunction, the presence of syndromes or other medical co-morbidities (Aartman et al., 2000). Whereas non-pharmacological management of these instances is appropriate, various levels of sedation may be necessary to ensure compliance with dental treatment. For some patients, sedation may also be a reasonable option to facilitate both efficient and comfortable treatment when extensive dental care is needed, allowing longer treatment times and reducing the number of visits required (Malhotra, 2008). The spectrum of sedation levels ranges from minimal sedation to general anaesthetic (Table 1; RCDSO, 2012).

Table 1.
Characteristics of the Levels of Sedation and General Anaesthesia (RCDSO, 2012)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Minimal Sedation</th>
<th>Moderate Sedation</th>
<th>Deep Sedation</th>
<th>General Anaesthesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consciousness</td>
<td>maintained</td>
<td>maintained</td>
<td>obtunded</td>
<td>unconscious</td>
</tr>
<tr>
<td>Responsiveness</td>
<td>to either verbal command or tactile stimulation</td>
<td>may require either one of or BOTH verbal command and tactile stimulation</td>
<td>response to repeated or painful stimuli</td>
<td>unarousable, even to pain</td>
</tr>
<tr>
<td>Airway</td>
<td>maintained</td>
<td>no intervention required</td>
<td>intervention may be required</td>
<td>intervention usually required</td>
</tr>
<tr>
<td>Protective Reflexes</td>
<td>intact</td>
<td>intact</td>
<td>partial loss</td>
<td>assume absent</td>
</tr>
<tr>
<td>Spontaneous Ventilation</td>
<td>unaffected</td>
<td>adequate</td>
<td>may be inadequate</td>
<td>frequently inadequate</td>
</tr>
<tr>
<td>Cardiovascular Function</td>
<td>unaffected</td>
<td>usually maintained</td>
<td>usually maintained</td>
<td>may be impaired</td>
</tr>
<tr>
<td>Required Monitoring</td>
<td>basic</td>
<td>increased</td>
<td>advanced</td>
<td>advanced</td>
</tr>
</tbody>
</table>
For the purpose of this study, I will focus on the areas of DS and GA as is now commonly accepted (RCDSO, 2012):

*Deep sedation: A controlled state of depressed consciousness accompanied by partial loss of protective reflexes, including inability to respond purposefully to verbal command (p.20).*

*General anesthesia: A controlled state of unconsciousness accompanied by partial or complete loss of protective reflexes, including an inability to maintain an airway independently and respond purposefully to physical stimulation or verbal command (p. 20).*

In Ontario, a state of DS/GA can be administered by any specialized dentist or physician who is registered with the Royal College of Dental Surgeons of Ontario (RCDSO). Physicians eligible to administer DS/GA include those who hold an anaesthesia specialty designation, those who have completed a 12-month “Family Medicine Anesthesia” program, or those who have met the requirements of their governing body to request a change in their scope of practice and have active privileges to support similar procedures in hospital (RCDSO, 2012). Dentists eligible to register include those who hold a specialty certificate in Dental Anaesthesiology in Ontario, those who have successfully completed a post-graduate anaesthesia program in a university and/or a teaching hospital over a minimum of 24 consecutive months, or those who have successfully completed a formal post-graduate program in oral and maxillofacial surgery that is certified in Ontario (RCDSO, 2012). In Ontario, these dentists may also practice in a team model as the operator while administering the anaesthetic and dental treatment simultaneously. This is considered practicing as the dentist-anaesthetist, and it involves a team-based approach to care with each member of the team having a specific role (RCDSO, 2012). While many dentists
choose to operate in the team model, others solely administer the anaesthetic to facilitate dental
procedures for their colleagues. DS/GA for dentistry is unique from DS/GA performed for other
health procedures, as most providers of DS/GA provide this service almost entirely in an
outpatient setting where the majority of patients treated are healthy or have well controlled
systemic disease. This is quite different from the patient populations seen in the hospital setting
where patients present for both emergent and elective treatment with various levels of co-
morbidities, often along with more invasive surgical procedures.

2.1 - Risks of Anaesthesia

It is well known within the profession that administering anaesthesia is not without risk.
Respiratory and cardiovascular depression are well known dose-dependent side effects of
medications routinely administered to achieve a state of DS/GA. Complications or adverse
events in anaesthesia can be defined as unplanned, unintended, unexpected, and undesirable
patient outcomes. Such events range from death to physiological injury (Bosack, 2015).

2.2.1 - Definition of Mortality

Death or mortality has variable operational definitions in the anaesthesia literature. The Joint
Commission on Accreditation of Healthcare Organizations (JCAHO) defines perioperative
mortality as the, “Death of patients during or within two post-procedure days” (Lagasse, 2002).
The Australian and New Zealand College of Anaesthetists further defines death attributable to
anesthesia into three categories: (1) Where it is reasonably certain that death was caused by
anaesthesia or other factors under the control of the anesthesiologist; (2) Where there is some
doubt whether death was entirely attributable to the anaesthesia or other factors under control of
the anesthesiologist; and (3) Where death was caused by both anaesthesia and surgical factors
(Australian and New Zealand College of Anaesthetists, 2005). These are important parameters to
define in order to ensure that mortality data are truly representative of clinical practice.

2.2.2 - Definition of Morbidity

Morbidity is defined as any complication that occurs peri-operatively due to anaesthesia
excluding death (Derrington and Smith, 1987). The outcomes that constitute morbidity lie on a
spectrum from mild or intermediate morbidity, where there is no threat to the patient’s life or
well-being, to severe morbidity that leads to permanent disability or injury (Derrington and
Smith, 1987). There are various manifestations of mild or moderate morbidity. Postoperative
nausea and vomiting, inadequate anaesthesia, syncope, laryngospasm, and bronchospasm are all
eamples of morbidity that are typically mild in nature. In this study, I will focus on severe or
major morbidity that results in irreversible insult such as brain damage, stroke, or myocardial
infarction (Bosack, 2015).

2.2.3 - Closed Claims Data and Severity of Injury Scoring

Mortality in the practice of anaesthesia has largely been reported from closed claims data.
“Closed claim” means a claim that has been settled or otherwise disposed of by the insuring
entity, self-insurer, facility or provider. A claim may be closed with or without an indemnity
payment to a claimant (Commissioner, 2008). In June of 1975, the National Association of
Insurance Commissioners (NAIC) began the collection of data on medical malpractice claims
that had or had not resulted in an indemnity payment (Brunner, 1984). Prior to this, there was no registry that had a record of all malpractice claims that had been filed in the United States (U.S.). The committee members devised a uniform reporting system for each claim which collected data on the following amongst other things: date and place of injury, clinician’s credentials, original diagnosis, operation/treatment procedure, action which caused the claim to be filed, severity of injury, misadventures in procedures/diagnosis, and indemnity paid (Brunner, 1984). The severity of injury score (SIS) in each claim was based on a severity of injury scale that had been established by insurance companies. Injuries were given a score from 1-9, where scores 1-4 were temporary injury, scores 5-8 were permanent injury, and a score of 9 equated with death (Brunner, 1984). The severity of injury scale published in this study was all encompassing of those that occurred due to the surgery or factors under the control of the anaesthesiologist. In 1988, the Committee on Professional Liability of the American Society of Anesthesiologists (ASA) conducted a standardized case review of claims where anaesthetic mishaps had occurred. The review included claims from 17 insurance companies across the U.S. In total, they reviewed 1175 claims (Cheney et al., 1989). To collect data, anaesthesiologists visited the insurance companies on premises to review the claims. Most closed claim files contained a hospital record, anaesthetic record, statements from involved health care personnel, expert and peer opinions, deposition, summaries, and outcome reports (Cheney et al., 1989). The reviewers used a standardized form to record data. This form was similar to the one used by Brunner 1984, but it paid more attention to details of the anaesthetic management. The case summaries included: patient characteristics, surgical procedure, personnel present, anaesthetic records and consent, monitors used, anaesthetic technique and agents used, critical incidents, clinical cues, complications/outcomes, if the claim became litigious, and the amount of award or settlement
(Cheney et al., 1989). This was also accompanied by a brief summary of the events that occurred as interpreted by the reviewer as well as an assessment of the appropriateness of the anaesthetic care and management. Appropriate care was defined as “that which met the standard of care for a prudent anaesthesiologist practicing anywhere in the U.S. at the time of the event”. Inappropriate care was defined as, “that below the standard of care”, and care was assessed as inappropriate, “if shortcuts were taken, if the patient was not appropriately or continually monitored, if serious errors in judgement were made” (Cheney et al., 1989). A standardized tool was found to be beneficial in the review of claims or cases made available by organizations to ensure that all elements of the case that may have contributed to the outcome were captured and represented in the dataset. Each claim also received a severity of injury score (SIS). The SIS is more in line with the aims of this study as this study will not explore emotional or minor temporary injury than the scale used by Brunner et al.1984 (Table 2).

<table>
<thead>
<tr>
<th>Severity Score (scale)</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>No obvious injury (0)</td>
<td></td>
</tr>
<tr>
<td>Emotional Injury (1)</td>
<td>Fright, awareness during anaesthesia, pain during anesthetic</td>
</tr>
<tr>
<td>Temporary Injury:</td>
<td></td>
</tr>
<tr>
<td>Insignificant (2)</td>
<td>Lacerations, contusions, delayed stay in recovery</td>
</tr>
<tr>
<td>Minor (3)</td>
<td>Fall in hospital or on way home, delayed recovery</td>
</tr>
<tr>
<td>Major (4)</td>
<td>Brain damage, nerve damage, unable to work, prolonged hospitalization</td>
</tr>
<tr>
<td>Permanent Injury:</td>
<td></td>
</tr>
<tr>
<td>Minor (5)</td>
<td>Damage to organs, nondisabling injuries</td>
</tr>
<tr>
<td>Significant (7)</td>
<td>Loss of eye, deafness, loss of one kidney or lung</td>
</tr>
<tr>
<td>Major (7)</td>
<td>Paraplegia, loss of use of limb, blindness, brain damage</td>
</tr>
<tr>
<td>Grave (8)</td>
<td>Severe brain damage, quadriplegia, lifelong care or fatal prognosis</td>
</tr>
<tr>
<td>Death (9)</td>
<td></td>
</tr>
</tbody>
</table>
2.3 - Mortality Rates in Medical Anaesthesia

There have been a number of anaesthetic mortality rates reported in the literature such as 1 in 400,000 (L. Fleisher, 2013). Since the rate is so low, a large sample size would be required to accurately estimate the mortality rate which is an important point to consider when reviewing this area of the literature. Mortality can be an adverse event of not only the anaesthetic but also the surgery or procedure itself. Data in this area should be delineated as to the specific cause.

Kluger and Bullock (2002) found that the risk of mortality associated with routine elective moderate-risk surgery was low. In their sample of patients, they found the risk of mortality to be 1.6%. Complications that were frequently encountered in this population in descending frequency were gastrointestinal, pulmonary, renal, and infectious. The authors mention that these complications were not found to be directly related to the type nor the site of surgery (Kluger and Bullock, 2002). This would imply that these complications were associated with the anaesthetic.

ASA closed claims reports found that adverse respiratory events were the most common cause of death and permanent brain damage from 1975-1985 (Caplan et al., 1990). However, during that period, utilization of capnography and pulse oximetry were low. The use of capnography was first established in North America in 1978 (Harper, 2005), and pulse oximeters were first made available worldwide in the early 1980s (Severinghaus, 2007). These monitors, which were added to the standards of basic anaesthesia monitoring by the ASA in 1986, were expected to markedly decrease the incidence of complications especially those of a respiratory nature (ASA, 1986).

Surprisingly, the 2009 ASA closed claims report revealed that adverse respiratory events remained the leading cause of death in outpatient anaesthesia despite increases in monitored anaesthetic care and in the use of pulse oximetry and capnography. The 2009 ASA report concluded that 80% of anaesthetic mishaps were caused by human error (Metzner et al., 2009).
The risk associated with anaesthesia in the office-based setting as compared to in hospital is unclear. Vila and colleagues reported a 10% increase in morbidity and mortality rates for office based procedures when compared to those done in hospital (Vila H, Soto R, Cantor AB, 2003), whereas other studies have shown the risk to be low (Fletcher, J. et al., 2001). An accurate estimation of the safety of anaesthesia administered in office is difficult to discern due to the lack of data with appropriate sample sizes.

2.4 - Mortality Rates in Dental Anaesthesia

Several studies have estimated mortality rates in dental anaesthesia in North America. They differ in their methodology, provider groups, and anaesthetic modality which means they are not easily compared to one another. Table 3 and Table 4 provide summaries of published mortality and morbidity rates.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Study Design</th>
<th>Time Span (yrs)</th>
<th>Serious Morbidity Rate</th>
<th>Provider Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>D’Eramo and Edward (1992)</td>
<td>retrospective: survey</td>
<td>5</td>
<td>2 in 74,871 (~1 in 37,400)</td>
<td>Oral Surgeons</td>
</tr>
<tr>
<td>Flick et al. (1998)</td>
<td>retrospective: survey</td>
<td>1</td>
<td>0 in 151,335</td>
<td>General Dentists, Oral Surgeons, Periodontists, and Dental Anesthesiologists</td>
</tr>
<tr>
<td>D’Eramo (1999)</td>
<td>retrospective: survey</td>
<td>4</td>
<td>0 in 137,099</td>
<td>Oral Surgeons</td>
</tr>
<tr>
<td>D’eramo et al. (2003)</td>
<td>retrospective: survey</td>
<td>5</td>
<td>1 in 137,898</td>
<td>Oral Surgeons</td>
</tr>
<tr>
<td>Flick et al. (2007)</td>
<td>retrospective: survey</td>
<td>10</td>
<td>2 cases reported</td>
<td>Dentists, Dental Anesthesiologists, Oral Surgeons</td>
</tr>
<tr>
<td>Perrott et al. (2003)</td>
<td>prospective cohort: survey</td>
<td>1</td>
<td>0 in 24,367</td>
<td>Oral Surgeons</td>
</tr>
<tr>
<td>Braidy et al (2011)</td>
<td>retrospective: chart review</td>
<td>5</td>
<td>0 in 1,167</td>
<td>Oral Surgeons</td>
</tr>
</tbody>
</table>
Most of the mortality data available in dental anaesthesia have been presented in studies analyzing retrospective or closed claims data. D’Eramo (1992) conducted one of the first studies examining both morbidity and mortality rates in dental anaesthesia. This study eventually became a series as it was repeated in 1995 and again in 1999; each study by these authors was published separately. The series, which has come to be known as, “The Massachusetts experience” involved a survey of the members of the Anaesthesia Committee of the Massachusetts Society of Oral and Maxillofacial Surgeons (MSOMS).

### Table 4.
Mortality Rates in Dental Anaesthesia Literature (All modalities)

<table>
<thead>
<tr>
<th>Authors</th>
<th>Study Design</th>
<th>Time Span (yrs)</th>
<th>Published Rate/ million cases</th>
<th>Provider Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>D’Eramo and Edward (1992)</td>
<td>retrospective: survey</td>
<td>5</td>
<td>1</td>
<td>Oral Surgeons</td>
</tr>
<tr>
<td>Flick et al. (1998)</td>
<td>retrospective: survey</td>
<td>1</td>
<td>6.6</td>
<td>General Dentists, Oral Surgeons, Periodontists, and Dental Anesthesiologists</td>
</tr>
<tr>
<td>D’Eramo (1999)</td>
<td>retrospective: survey</td>
<td>4</td>
<td>0</td>
<td>Oral Surgeons</td>
</tr>
<tr>
<td>Nkansah et al. (1997)</td>
<td>retrospective: survey, closed claims, coroner data</td>
<td>23</td>
<td>1.4</td>
<td>Dental Anesthesiologists, Oral surgeons, and Physician anesthesiologists</td>
</tr>
<tr>
<td>Deegan (2001)</td>
<td>retrospective: closed claims review</td>
<td>12</td>
<td>1.3</td>
<td>Oral Surgeons</td>
</tr>
<tr>
<td>D’Eramo et al. (2003)</td>
<td>retrospective: survey</td>
<td>5</td>
<td>1.17</td>
<td>Oral Surgeons</td>
</tr>
<tr>
<td>Flick et al. (2007)</td>
<td>retrospective: survey</td>
<td>10</td>
<td>1.83</td>
<td>Dentists, Dental Anesthesiologists, Oral Surgeons</td>
</tr>
<tr>
<td>Bennett et al. (2014)</td>
<td>retrospective: closed claims review</td>
<td>14</td>
<td>2.9</td>
<td>Oral Surgeons</td>
</tr>
</tbody>
</table>
The first survey was conducted in 1989. The survey was sent by mail, and it was followed up with two reminders that were also sent by mail. Providers that had not responded by the third mailing were encouraged by telephone to participate. The questions in the survey inquired about number of patients seen per week on average, anaesthetic techniques, and mortality or morbidity that had been encountered by clinicians. The survey had 100% response rate from 147 members (D’Eramo E, 1992). Based on the participants’ responses, it was determined that each oral surgeon treated an average of 60.2 patients per week: 10.8 were treated under GA, 14.8 were treated under parenteral sedation with local anaesthesia, 5.8 were treated under conscious sedation and local anaesthesia, and 28.8 were treated with local anaesthesia alone. The definition of parenteral sedation used by D’Eramo et al is similar to the RCDSO definition of deep sedation, and I assume that is what was meant by parenteral sedation in the study. The oral surgeons in D’Eramo et al (1992) worked an average of 47 weeks in 1989. To calculate the total number of anaesthetics, the average number of weeks was multiplied by the average number of patients treated per week, and this number was then multiplied by the total number of members. This number was then extrapolated to represent the number of anaesthetics administered by this provider group in the 5-year period from 1985-1989 which was, 2,082,805 (D’Eramo, E., 1992). It is the denominator in the mortality rate calculation (ie. Number of mortalities/2,082,805). The methodology used in this study to calculate the denominator does not account for members who may have only been in practice for 4 years or less from 1985-1989 which may have caused there to be an inflated number of total number of anaesthetics administered in the study. Inflation of the denominator would under-estimate the mortality rate published by the articles. Furthermore, since almost half of the patients treated per week only received local anaesthesia, it is important to mention here that the total anaesthetic count is largely represented by cases performed with
local anaesthesia only. In the D’Eramo et al study (1992) there were two reported cases of cardiac arrest where both patients died. The mortality rate reported by the authors was two in 2,082,805 cases (or 1 in 1,000,000 cases). The authors do not specify if cardiac arrest occurred in cases where patients received a level of sedation or local anaesthesia only. Therefore, it is not possible to calculate a mortality rate for DS/GA from the data presented in this article. There were two cases of serious morbidity where patients suffered myocardial infarction, and they were both cases where the patient was under general anaesthesia. The serious morbidity rate for GA calculated from the data published by these authors is 2 in 74,871 or 1 in 37,435 cases.

In 1995, this same research group repeated the survey using the same provider groups (D’Eramo et al, 1999). There was a 100% response rate to the survey by 151 active members of MSOMS. The mean number of patients treated per week by each clinician was 44. Ten of these patients were treated with GA, 9 of them were treated with parenteral sedation, and the remaining patients were either treated with conscious sedation and local anaesthesia or local anaesthesia alone. Again, over half the sample of the total anaesthetics administered in this study is represented by cases where DS/GA was not used. The published mortality rate for this study was 0 in 1,588,365 (0 in 1,000,000) for the period of 1990-1994 (D’Eramo, E., 1999). Interestingly, the authors mention that there were two responses by clinicians to the question if any deaths had occurred within one week post-operatively. Both of these deaths occurred within 3 days of treatment and were not included in the dataset. The question of inquiry about death in the survey sent to clinicians was as follows, “Have any patients you have treated experienced cardiac arrest during or immediately following (within 24 hours) treatment in your office in the past 5 years?” (D’Eramo E.M., 1999). Although the authors do not specify why these two deaths weren’t included in the mortality rate, it may be because these cases did not fit within their definition of
mortality. Although mortality was not clearly defined, it seems reasonable to assume from the wording of this question that the inclusion for mortality cases was cardiac arrest that occurred within 24 hours post-operatively. There were no reports of cases of serious morbidity under parenteral sedation or general anaesthesia. Thus, the serious morbidity rate was 0 in 137,099 (D’Eramo E.M., 1999).

D’Eramo et al (2003) repeated this survey a second time in 1999, again within the same provider group, and included mortality rates for the preceding four years. The methodology, number of actively practicing clinicians, and overall case count was very similar to the previous studies. At this time, the mortality rate was found to be two in 1,706,100 (1.17 in 1,000,000 cases) (D’Eramo et al., 2003) revealing a slight increase in the mortality rate from 1989 to 1999. This study also examined the prevalence of adverse events or morbidity occurring within this provider group, and there was one serious morbidity event reported. It was a case of myocardial infarction. This results in a serious morbidity rate of 1 in 137,898 (~0%) The data published in these series of studies by D’Eramo, E and D’Eramo et al., highlight that the risk of both mortality and serious morbidity in dental anaesthesia is rare. The studies also inquired about monitors that clinicians routinely used as a part of their practice while administering an anaesthetic. They found an increase in the use of pulse oximetry from 71% in the 1992 study (D’Eramo, 1992) to 92% in the 2003 study (D’Eramo et al., 2003), which likely explained the decrease in the use of the precordial stethoscope from 98% to 42%. These rates correlate with the increasing use of pulse oximetry in medical anaesthesia practice within this period (Metzner et al., 2009).
Another retrospective study by Deegan (2001) estimated the mortality rate in the U.S. from 1988 to 1999. The study was based on closed claims data from American Association of Oral and Maxillofacial Surgeons (AAOMS) National Insurance Company, which insured the majority, about 55%, of practicing U.S. oral surgeons at the time (Deegan, 2001). In the twelve-year span, AAOMS handled 136 claims that ranged from trivial issues such as a patient crying upon waking from sedation, to wrongful death. Thirty-seven of these claims involved death or brain damage that occurred both in hospital and office. Several of the claims that occurred in hospital involved adverse events that occurred when the oral surgeon was not in the operating room. Regardless of whether the oral surgeon administered the anaesthetic or not, some states in the U.S. appoint liability on the attending surgeon (Deegan, 2001). These claims were not included in the dataset. This allowed the dataset to be representative of office-based dental anaesthesia as only claims that occurred in office were included. There were a total of 21 office deaths and one case of brain damage. This study included various levels of anaesthesia such as, local anaesthesia as well as conscious sedation within the survey. Out of 21 total deaths, three occurred when only local anaesthesia was used, there were nine deaths under conscious sedation, and nine deaths occurred under deep sedation (Deegan, 2001). The authors did not include the deaths that occurred under local anaesthesia in the dataset. The total deaths that occurred in office under conscious or deep sedation, and the case of brain damage made up the numerator in the calculation of the mortality rate.

Each oral surgeon insured by the AAOMS was surveyed annually regarding the number of anaesthetics they had administered. The average for each oral surgeon over the 12 years was 579 anaesthetics per year. The insurance company also kept record of how many years each oral
surgeon had been insured by them. This was used to infer the number of years each one had been in practice. The total number of anaesthetics administered in the twelve-year span was calculated by multiplying the total number of years in practice for all oral surgeons by 579. This resulted in a total number of 14,206,923 anaesthetics administered from 1988-1999 (Deegan, 2001). This number was used as the denominator for mortality rate calculation. The study found an office mortality rate of one death in every 747,732 anesthetics (1.3 in 1,000,000 cases). Since this study included both conscious and deep sedation within the dataset, it is less relevant. Accordingly, it is difficult to make any inferences from these data in relation to the mortality rate for DS/GA.

A study conducted in Illinois, (Flick et al., 2007), surveyed dentists to retrospectively determine mortality over the ten-year period from 1996 to 2005. In addition to questions regarding mortality, the survey also inquired about anaesthesia emergencies encountered by the clinician, and the type of monitors used. The study found a mortality rate of two in 1,000,000 cases (Flick et al., 2007). Both cases occurred under GA. This calculation is based on the two deaths reported by the authors and the total number of anaesthetics which was 1,091,210 in the 10-year period. One patient died on the same day of treatment, and the other patient died 5 days later in hospital. Although the authors did not explicitly define mortality within a specific time frame, it appears that they were inclusive of cases where the sequelae of complications lead to death since the second patient died 5 days post-operatively. There was one case of serious morbidity under GA where a patient developed atrial fibrillation and required the insertion of a pacemaker 1 month later (Flick et al., 2007). It is not clear if this was caused by medication administration during the case, however the authors did include this case in their dataset of those who suffered long term morbidity. This may have been an attempt by the authors to be inclusive of all possible cases that occurred within the period. However, if the patient had a pre-existing atrial fibrillation and the
atrial fibrillation was not caused by administration of anaesthesia, it would be inappropriate to include this case within the dataset. Of the 109,121 patients who were treated under parenteral sedation or GA, there was also one case of serious morbidity where a patient suffered a mild stroke. Thus, the serious morbidity rate based on the data published by Flick et al. 2007, is 2/109,121 (~ 1 in 50,000). A limitation of this study was its methodology, as it relied on the practitioners’ reports of incidents. Further, it must be noted that the survey also gathered data concerning mild and moderate sedations. It is possible that these cases were under the care of dentists who did not have the same level of training in dealing with emergencies as dental anesthesiologists, oral surgeons, or physician anesthesiologists. The rates reported in this study cannot be inferred to represent morbidity and mortality rates of deep sedation and general anaesthesia, as this study’s rate included cases where the conscious level of sedation was used. Like those of the Deegan (2001) study, Flick et al.’s (2007) rates are not comparative with the aims of my study.

The most recent closed claims study was published by Bennett, Kramer, and Bosack (2014). In this study, retrospective data were obtained from the Oral Maxillofacial Surgeon National Insurance Company (OMSNIC) insurance company, which insured approximately 80% of oral and maxillofacial surgeons in the U.S. in 2014. Bennett et al. (2004) reported that, out of 39,392,000 office-based anesthetics administered in the 14-year period from 2000 to 2014, 113 resulted in death or brain injury. The authors postulated that one such event occurred every 6.4 weeks, which would represent a mortality rate of 2.9 in 1,000,000 cases (Bennett et al., 2015). The methodology in the article of the retrospective review was vague, and it was not clear how the authors had come to these conclusions. Further details were sought from OMSNIC (L.
Estabrooks, personal communication, October 7, 2015.), and a presentation with details of the
data for Bennett et al (2014) was provided (Estabrooks, 2014). It reported that in the period from
2000-2014, 415 claims had been filed. The total number of anaesthetics administered in this
same time period was 42,792,419; 71% of these were GAs and 29% were termed “sedation
anesthetics”. This total amount was calculated based on the number of OMSNIC policy holders
(64,259) multiplied by the average number of anaesthetics administered by each one of them per
year (641-666) (Estabrooks, 2014). Although there was no clear definition of the term “sedation
anesthetics”, it is likely that this term was used to describe cases where a level of sedation below
GA was administered. Of the 415 claims that were filed, 157 of these claims related to death or
brain damage; 121 of those cases occurred in office and 36 occurred in hospital (Estabrooks,
2014). This number is higher than the number of in-office deaths that was published in the article
(113) by Bennett et al. Seven of the claims that related to death were cases when death occurred
in the post-operative period after the patient had taken prescribed pain medications at home. It is
possible that the authors chose not to include these deaths within the dataset, but again, it is not
clear. In terms of the serious morbidity that was presented in these data, there were 3 cases of
stroke that occurred (Estabrooks, 2014). This would result in a serious morbidity rate of
3/42,792,419 (~ 1 in 14,000,000). This is similar to other rates published by studies in the same
provider group. The author of the presentation postulated that, “1 in every 531 OMS (oral
maxillofacial surgeon) will experience and office anesthetic death per year, and 1 in 18 OMS
will experience an office anaesthetic death during a 30 year practice”. It is not clear how these
conclusions were made from the dataset.
Perrott et al. (2003) conducted one of the few studies of a prospective cohort design in dental anaesthesia. Seventy-nine oral maxillofacial surgeons from 58 sites reported on patient demographics, intravenous fluids, monitors, anesthetic technique, adverse events, and patient outcomes, as well as patient satisfaction, over the period of January 2001 to December 2001. The sites were all ambulatory settings either in the community, dental school, or hospital-based practice (Perrott, Yuen, Andresen, and Dodson, 2003). This study was dependent on participating clinicians inputting data into an online system. The data were cross-checked with an audit of redacted chart records that were also forwarded to the investigators. The total number of DS/GA included in the sample size was 24,737, which is much smaller than previous publications (D’Eramo et al., 1992, 1999, 2003; Deegan, 2001; Nkansah, Haas, and Saso, 1997). There was no prevalence of death or serious morbidity in this study. The major limitation of this study’s design was that the time span was short and the sample size was not sufficiently large so the study was under-powered. Although this was not reported as a limitation by the authors, the previous published rates have a low prevalence meaning a large sample size would be necessary to give the study adequate power which this study did not possess. With a small sample size, it is difficult to capture rates that accurately represent mortality and morbidity.

To date, Nkansah, Haas, and Saso (1997) is the only study aimed at determining dental anaesthesia mortality rates in Ontario. This study reviewed the twenty-three year period from 1973 to 1995. Two surveys were sent to all clinicians who were registered with the RCDSO and eligible to administer DS/GA in Ontario at the time. The first survey was sent out in 1990 with a response rate of 65%, and the second survey was sent out in 1995 with a response rate of 72.2% (Nkansah, et al. 1997). The number of anaesthetics administered within the time was estimated
from survey responses. Data were extrapolated based on clinicians’ responses as well as the number of eligible clinicians registered each year to estimate the total number. The number of anaesthetics estimated based on survey responses in 1995 was used to represent the years from 1991-1995, and the estimate based on the 1990 survey was used to represent all years before 1991 (Nkansah et al., 1997). This resulted in a total estimate of 2,830,000 anaesthetics being administered in the 23 year period. This study was unique in its methodology in that it not only used closed claims data to estimate mortality cases, but it also involved the Office of the Chief Coroner of Ontario. Cases where an anaesthesia-related death occurred in a dental office under DS/ GA in the same period were reviewed. Only cases where the autopsy and incident reports implied that the cause of death was related to the anaesthesia or sedation were included in the dataset. Five cases of death were disclosed from the case review. One death occurred where a dental anaesthesiologist administered the anaesthetic, three where an oral surgeon did, and one by a physician. This last case was not included in the dataset as it did not fit the study’s inclusion criteria that the anaesthetic had to be administered either by a dental anaesthesiologist or an oral and maxillofacial surgeon. This yielded a mortality rate of 1.4 in 1,000,000 cases (Nkansah et al., 1997). The authors review of closed claims data was consistent with these findings. It is worth noting that the authors mention that there were other reports of death in the dental setting. Since the anaesthetics were administered by physicians, they too were not included in the dataset (Nkansah et al., 1997). One limitation of the study was that it depended upon the accuracy of the practitioner’s report regarding the number of anaesthetics administered. However, this appears to be a common method for estimation of the total number amongst most publications mentioned in this review (D’Eramo et al., 1992, 1999, 2003; Flick et al., 1996) This is likely because the data were compiled from private clinics in the community which may have their own databases.
Another limitation is that the inclusion criteria did not include all provider groups eligible to administer anaesthesia in the dental office setting at the time, and thus it did not capture all possible cases. Nevertheless, this approach arguably provided an accurate estimate of the mortality cases.

2.5 - Strengths and Limitations in Existing Literature

All of the preceding studies have limitations. Estimation of the numerator in morbidity and mortality studies presents challenges depending on the methodology in both retrospective and prospective techniques. Retrospective studies dependent on closed claims data are limited in that insurance companies have no obligation to report these data. If these incidents are not litigated or cases are settled, they are sequestered and not represented within these datasets (Bosack, 2015). It is important to understand the extent of the limitations inherent in closed claims data since they often provide the only source of morbidity and mortality incident reports. Critical incident reports often are published within medical anaesthesia literature. The Harvard Medical Practice Study (1991) reported that adverse events led to litigation in only 1.5% of adverse events experienced by patients. This figure highlights how closed claims cases and actual incidence reports can differ markedly (Cook and Macdougall-Davis, 2012). To further confuse the matter, most of the malpractice cases in this study were not associated with an adverse event experienced by a patient (Cook and Macdougall-Davis, 2012). This situation indicates the degree of the disconnect between critical incidents and closed claims (Cook and Macdougall-Davis, 2012). Retrospective studies that surveyed anesthetic providers regarding serious morbidity and mortality incidents have been impeded by the clinicians’ fear that voluntary reporting might result in punishment or other negative consequences for the provider (Bosack, 2015). Prospective
data have been hindered by the limitations inherent in the design of prospective cohort studies. These studies are time consuming, expensive, and require the follow-up of large sample sizes (Grimes & Schulz, 2002). To be sure, conducting a prospective cohort study over a 20-year span would be an arduous and time-consuming process, although it would provide the most accurate representation of the mortality rate. Of the retrospective studies available, the methodology executed by Nkansah et al. (1997) resulted in one of the strongest studies conducted to date. Since almost all deaths occurring in Ontario are registered with the Office of the Chief Coroner of Ontario, incorporating these data captured a mortality rate that more closely represented the number of actual anaesthesia-related deaths.

The denominator of the mortality rates reported in past studies was either gathered from an insurance company database in closed claims studies, or was estimated from the number of anesthetics administered during a certain time period (Bennett et al., 2015; Deegan, 2001). Nkansah et al. (2007), Flick et al. (1997), and D’Eramo et al. (1996, 2003), all estimated the number of anesthetics that had been administered through survey response data. Clinicians estimated the number of anesthetics they had administered either by reviewing their computer database, estimating the average anesthetics they administered in a day or even in a week (Nkansah et al., 1997). As a result, the primary limitation of these data centres on the estimation of an event. The reported rates do not represent a true value, but an estimated value. However, in the absence of a universal database into which all clinicians can input their daily or weekly anesthetic cases, it is difficult to obtain accurate values for the number of anesthetics rendered.

2.6 – Summary of the Literature
While death and injury are rare in dental anaesthesia, this is a critical topic for patients and providers of DS and GA, as it forms the basis of informed consent. The studies investigating mortality and morbidity in dental anaesthesia have, for the majority, been carried out retrospectively and examined the provider group of oral maxillofacial surgeons. Both dental and physician anaesthesiologists are provider groups that frequently work in the dental environment, and they are underrepresented in the mortality and morbidity literature. Overall the published morbidity rates in ambulatory anaesthesia for dental procedures are low and range from 1 in 37,000 to 1 in 138,000 (Table 3). The published mortality rates are also low ranging from 1 death per 1 million cases to 6.6 deaths per 1 million cases (Table 4). To gain perspective on the published mortality rates, Table 5 displays the odds of dying by various causes as determined by the U.S. National Safety Council (NSC, 2013).

<table>
<thead>
<tr>
<th>Cause of Death</th>
<th>Odds of Dying</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart Disease and Cancer</td>
<td>1 in 7</td>
</tr>
<tr>
<td>Chronic Lower Respiratory Disease</td>
<td>1 in 27</td>
</tr>
<tr>
<td>Unintentional Poisoning By and Exposure to Noxious</td>
<td>1 in 103</td>
</tr>
<tr>
<td>Substances</td>
<td></td>
</tr>
<tr>
<td>Motor Vehicle Crash</td>
<td>1 in 113</td>
</tr>
<tr>
<td>Fall</td>
<td>1 in 133</td>
</tr>
<tr>
<td>Pedestrian Incident</td>
<td>1 in 672</td>
</tr>
<tr>
<td>Choking from Inhalation and Ingestion of Food</td>
<td>1 in 3,408</td>
</tr>
<tr>
<td>Pedacyclist Incident</td>
<td>1 in 4,337</td>
</tr>
<tr>
<td>Air and Space Transport Incidents</td>
<td>1 in 9,737</td>
</tr>
<tr>
<td>Lightning Strike</td>
<td>1 in 174,426</td>
</tr>
</tbody>
</table>

The highest published mortality rate in the studies reviewed above was by Flick et al., (2007) of 6.6 deaths per million cases. This rate could be compared to the odds of dying in a motor vehicle crash which is 1 in 113 crashes. Although the events are different in the sense that individuals do not electively choose to be in a motor vehicle crash as they would choose to receive a DS/GA
in a dental office, the statistics do lend important context to a critical topic. Through advances in
technology and evolving standards of practice, one assumes that mortality and morbidity in
Ontario for office-based DS/GA for dental procedures remains low. However, it has been almost
20 years since mortality prevalence was last investigated and reported, leaving a significant
knowledge gap regarding the current safety record.

CHAPTER 3

Methods

3.0 - Study Design

This descriptive study utilized retrospective data to estimate the prevalence of morbidity and
mortality in DS/GA for dental procedures. The methods closely parallel a previous study by
Nkansah et al. (1997), which estimated the prevalence of mortality of GA/DS in dentistry over a
23-year period.

In this study, the prevalence of mortality and morbidity was estimates using two phases. Phase I
aimed to describe the numerator (events occurring), which was collected using institutional
contacts. Phase II aimed to describe the denominator (number of anesthetics administered),
which was collected by a survey of Ontario clinicians providing DS/GA services to dental
patients in the out-of-hospital (ambulatory) setting.

3.1 – Phase I - Mortality and Morbidity

3.1.1 - Participating Organizations
Similar to the model in Nkansah et al. (1997), data on events occurring were obtained by contacting two regulatory sources, the Office of the Chief Coroner of Ontario (OCCO) and the RCDSO. Information from the RCDSO was obtained from two divisions, the Professional Conduct and Regulatory Affairs (PCRA), and the Professional Liability Program (PLP).

The Coroner’s office in Ontario is called to investigate deaths that are sudden and unexpected or appear to be from unnatural causes. They may also become involved if there are concerns regarding the care an individual received prior to death. Certain deaths must be reported to the coroner under the Coroner’s Act including, amongst others, “deaths that occur suddenly and unexpectedly” (Office of the Chief Coroner and Forensic Pathology, n.d.). Since it would be unexpected for a patient to die as the result of DS/GA for dentistry, this aspect of the Coroner’s Act may allow cases that occur in this setting to be captured within their records. The results of an investigations into a death may be shared with immediate family members or a representative upon request (Office of the Chief Coroner and Forensic Pathology, n.d.).

The PCRA department of the RCDSO contains reports where a complaint would have been made against a clinician, and the PCRA investigates the complaint. Furthermore, the PCRA publishes summaries of the decisions made by the Discipline Committee in a quarterly magazine, “Dispatch” available to RCDSO members, and it provides the same versions online which are available to members of the public. This is required by law under the Regulated Health Professions Act, 1991 (RCDSO, 2017a). The RCDSO maintains that these publications are beneficial to clinicians as they allow them to understand what constitutes professional misconduct, incompetence, the consequences, and gives direction about practice standards and professional behavior (RCDSO, 2017a).
The PLP’s purpose is to protect the public (RCDSO, 2017b). The PLP provides malpractice insurance to all the RCDSO members as a part of the yearly registration fees to the College. The mandatory membership in the PLP ensures that any patient who files a claim against a dentist will have access to funds to compensate his or her injuries due to negligence (RCDSO, 2017b). Dentists are expected to report any incidents for which a patient may make a claim against them. In working with both the PCRA and the PLP, the aim was to collect any claims within the registry related to DS/GA.

### 3.1.2 - Data Collection

Following approval by the Research Ethics Board at the University of Toronto (Approval Protocol#33203, Appendix G), an official written letter of request for research was sent to the OCCO (Appendix A) and the RCDSO (Appendix B) to outline the aim and methods of the study as well as to ensure patient and provider confidentiality. Cases or claims within the database or registry of these organizations that occurred in the time span from 1996 to 2015 reporting deaths or serious morbidity related to DS/GA were of interest. All the organizations contacted by the investigators agreed to participate in the study. The organizations arranged their own internal teams to supervise the data collection process, and relevant reports would be disclosed to the principal investigator (PI).

A research agreement was made between the investigators and the Coroner’s office (Appendix F)). This outlined, amongst other things, that the OCCO would use their electronic database to conduct their search. The electronic database was established in 2002, and thus the OCCO was unable to search for any cases that would have occurred in the period from 1996-2002. The OCCO used the keywords: “dental”, “dental surgery”, “dental extractions”, and “GA” to search
for files that would be of interest to the investigators. Complete case files extracted from the
database were provided, with identifying information redacted, to the PI (AE). Case files were
reviewed on site and extracted into a standardized template “Standardized Case Summary”
(Appendix C).

The PLP and RCDSO’s internal team conducted a manual search of their registry to locate files
involving DS/GA from 1996-2016. Cases were reviewed on site by the internal research team
only. Redacted summary information regarding cases where DS/GA was administered for a
dental procedure were forwarded in a narrative form by the internal research team to the PI.
Upon request, the internal research team further extracted data of relevant cases into the
standardized template.

Table 6 summarizes the roles the internal teams from the OCCO and the RCDSO’s PCRA and
PLP fulfilled in the data collection from their records.

<table>
<thead>
<tr>
<th>Table 6. Internal team roles</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OCCO</strong></td>
</tr>
<tr>
<td>• Team set-up by organization</td>
</tr>
<tr>
<td>• Electronic search of computer database from 2002 onwards using keywords: “dentist, dental, anesthesia, anaesthesia, sedation, and sedated”.</td>
</tr>
<tr>
<td>• Redacted case files reviewed on site by PI.</td>
</tr>
<tr>
<td>• Data from relevant cases extracted into standardized template by PI.</td>
</tr>
</tbody>
</table>
3.1.3 - Inclusion Criteria

Cases that were forwarded by the organizations to the research team were reviewed to establish if they met inclusion criteria. The inclusion criteria are listed in Table 7.

<table>
<thead>
<tr>
<th>Case Inclusion Criteria</th>
<th>Mortality Data</th>
<th>Morbidity Data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Must be in outpatient dental setting</td>
<td>• Must be in outpatient dental setting</td>
</tr>
<tr>
<td></td>
<td>• Deep sedation or general anaesthesia administered</td>
<td>• Deep sedation or general anaesthesia administered</td>
</tr>
<tr>
<td></td>
<td>• Occurred within 30 days post operatively</td>
<td>• Occurred within 30 days post-operatively</td>
</tr>
<tr>
<td></td>
<td>• Cause of death is reasonably certain to be caused by anaesthesia or factors under the control of the clinician administering anaesthesia.</td>
<td>• Must be considered within the spectrum of “serious morbidity” (mSIS 2-4).</td>
</tr>
</tbody>
</table>

Firstly, for inclusion in the study cases had to have occurred in an outpatient dental facility such as a dental office or a surgicentre. Cases that occurred in hospital were excluded from the dataset. Secondly, cases involving DS/GA were of interest, and cases under minimal or moderate sedation were excluded. Thirdly, cases must have occurred in a post-operative period of 30 days. Past studies investigating mortality and morbidity in dental anaesthesia have had a post-operative...
period of 24 hours or 2-4 days (Bennett, et al., 2015; D’Eramo et al., 2003; D’Eramo, 1992; 1999). This creates a limitation to the dataset if a patient died later than 4 days post-operatively. For example, if a patient was transferred from an outpatient facility to hospital and admitted to ICU, and then died 15 days later. This case would not be captured with a short post-operative period. The investigators in this study decided that a post-operative period of 30 days would be more inclusive and increase the probability of capturing all reported events of mortality and morbidity providing it occurred within 30 days of treatment. Finally, the cases also had to meet the researchers’ definition of mortality or morbidity. Mortality was defined as the cause of death was reasonably certain to be due to anaesthesia or factors under the control of the clinician administering anaesthesia. This definition was modeled after the Australian and New Zealand College of Anaesthetists’ definition of death attributable to anaesthesia (Australian and New Zealand College of Anaesthetists., 2005). Morbidity cases of interest were those where permanent or severe injury had occurred.

3.1.4 - Modified Severity of Injury Score (mSIS)

A standardized tool was found to be beneficial in the review of claims or cases made available by organizations to ensure that all elements of the case that may have contributed to the outcome were captured and represented in the dataset (Brunner, 1984; Cheney et al, 1989). The SIS established by Cheney et al., in 1989 was specific to the practice of anaesthesiology, whereas the scale used in Brunner, 1984 was used for malpractice in medicine overall. The scale used by Cheney et al. 1989, was more appropriate to grade the level of injury in DS/GA for dentistry. The SIS included emotional and minor injury (Scores 1-3) where no permanent injury was sustained by the patient. Since emotional or temporary injury was not of interest in this current study, the scale was modified. The modified SIS (mSIS) is outlined in Table 8. Any cases that
involved permanent injury (an mSIS of 2-4) were considered serious morbidity.

<table>
<thead>
<tr>
<th>mSIS</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Temporary Injury</strong></td>
<td></td>
</tr>
<tr>
<td>Major (1)</td>
<td>Brain damage, nerve damage, unable to work, prolonged hospitalization</td>
</tr>
<tr>
<td><strong>Permanent Injury:</strong></td>
<td></td>
</tr>
<tr>
<td>Minor (2)</td>
<td>Damage to organs (AKI), Nerve damage</td>
</tr>
<tr>
<td>Major (3)</td>
<td>Loss of vision or hearing, Myocardial Infarction, Stroke</td>
</tr>
<tr>
<td>Grave (4)</td>
<td>Severe brain damage, quadriplegia, lifelong care or fatal prognosis</td>
</tr>
<tr>
<td><strong>Death (5)</strong></td>
<td></td>
</tr>
</tbody>
</table>

*Note. AKI: Acute Kidney Injury*

### 3.1.5 - Standardized Case Summary

This study also used a standardized case summary sheet to record details of morbidity and mortality cases, similar to Cheney et al., (1989) (Appendix C). The PI extracted information from the case files into the standardized case summary, noting the following key parameters: patient demographics, medical history, dental procedure, care providers present and their clinical credentials, the anaesthetic technique used, sedative agents that were administered, the critical incidents, clinical cues of an impending critical incident, and the clinical outcome. The standardized case summary was used in the abstraction of every case file, and ensured consistency in the recording of all factors that could have contributed to the harm that occurred. After abstracting and reviewing the details of the case file, every case was assigned a modified Severity of Injury Score (mSIS) to stratify the spectrum of harm amongst cases.
3.2 - Phase II - Total Number of Anaesthetics

3.2.1 - Participating DS/GA Providers

All clinicians registered with the RCDSO as being eligible to administer DS/GA were eligible for this study. Survey participants included any health care practitioners who had been approved by the RCDSO to administer DS/GA in the dental setting. These clinicians include dental anaesthesiologists, oral and maxillofacial surgeons, and qualified physicians (anaesthesiologists and Family Medicine Anaesthesia graduates).

3.2.2 - Survey Design

A mail-based survey was chosen to estimate the number of anesthetics administered by clinicians in the 20 year period from 1996-2015. The overall response rate in Nkansah et al. (1997), was 72.3% using a mail-based survey design. A web-based survey method was considered but rejected given web-based surveys can have lower response rates (Fan and Yan, 2010; Kongsved, 2007). Literature suggests that web based surveys have, on average, a 10% lower response rate when compared to mail and telephone surveys (Fan and Yan, 2010). However, it should be noted that studies have shown web based surveys are, “superior with respect to completeness of data” (Kongsved, 2007).

The survey consisted of four questions (Appendix E). Clinicians were asked the following: (1) What provider group they belonged to: a) Dental Anaesthesiologists, b) Oral Maxillofacial Surgeons, c) Medical Anaesthesiologists, or d) Family Medicine Anaesthesia graduates.
Secondly (2), they were asked to estimate the number of anesthetics administered in the calendar year 2015. Thirdly (3), Clinicians were asked what method they used to estimate the number of anesthetics administered in 2015, and reported whether they used a) computer data from the whole year, b) computer data from an average month and multiply the number of anesthetics by 12, c) a manual count of the whole year, d) a manual count of an average month multiplied by 12, or e) another method. The same question and choices were given to clinicians in Nkansah et al.’s 1997 survey. Lastly (4), they were asked how many years they had been practicing dental anaesthesia since 1996. The aim of data gathered from survey responses was to use the number of anesthetics administered by clinicians in 2015 to extrapolate the number of anesthetics administered in Ontario over the 20-year period from 1996-2015. The final question, regarding number of years in practice since 1996, allowed the number of anesthetics provided by the clinician in question one to be multiplied by the number of years in practice. This allowed for a reasonably accurate and comprehensive estimate of the total number of anaesthetics administered by the clinician during the 20 year period under investigation. This question was not used in Nkansah et al.’s (1996) study, but it was included in the survey to capture any increase in practice by provider groups and to avoid over-inflating the total denominator.

The questions included in the survey were designed to elicit specific responses from study participants, producing accurate estimates by the clinicians (Dillman, 2007). The second and fourth questions asked respondents for simple numeric answers. The third question had, ready-made answers to produce consistent responses of techniques clinicians used to calculate their estimates (Dillman, 2007).
3.2.3 - Participant Recruitment

In Ontario, all providers of DS/GA require a Member Authorization permit. Participants in the survey were recruited from the list of authorized members. The list of dentist and physician providers who can administer deep sedation and general anaesthesia is searchable on the RCDSO website, accessible via member login. As the PI is an RCDSO member, the information of registered DS/GA provider names and addresses were easily and reliably obtained. Online search yielded that there 27 Dental Anaesthesiologists, 219 Oral Maxillofacial Surgeons, and 328 Physician Anaesthesiologists registered with the RCDSO to administer DS/GA in dental office. Thus, 584 clinicians were eligible to be recruited as participants for the survey tool.

Two identical packages were mailed to all study participants, the first on October 1st, 2016 and the second on February 15th, 2017. Each package contained a paper invitation letter (Appendix D) as well as a survey. The invitation letter was approved by the University of Toronto Research Ethics Board. It was printed on a University of Toronto, Faculty of Dentistry letterhead to increase its salience (Dillman & Smyth, 2007). The invitation letter also served as informed consent for survey participants. It was outlined that participation was voluntary, anonymous, and by returning a completed survey, informed consent was granted by the participant. In each package, a pre-stamped return envelope addressed to the PI was also included to assure anonymity. In addition to the two identical packages sent by mail to study participants, reminder emails were also sent out to encourage participation in the study and increase response rates. Personal contact was established with professional associations in the community that offered to aid the investigators in encouraging their members to respond to the survey. The Canadian
The Academy of Dental Anaesthesia (CADA) sent a reminder email to Dental Anaesthesiologists on January 4, 2017. Similarly, the Ontario Society of Oral & Maxillofacial Surgery (OSOMS) sent out a reminder email to its members also on January 4, 2017. The RCDSO also sent a reminder email to all eligible study participants on March 7th, 2017.

In summary, two mail-based survey packages were sent to all participants. All Dental Anaesthesiologists and Oral Maxillofacial Surgeons received two email-based reminders. The first was sent by CADA or OSOMS to their respective members, and the second one was sent by the RCDSO. Physician Anaesthesiologists received one email-based reminder from the RCDSO. The CADA and OSOMS reached out to the investigators to offer their aid in encouraging their members to participate. For this reason, Dental Anaesthesiologists and Oral Maxillofacial Surgeons received two email-based reminders while Physician Anaesthesiologists received only one. Since a third party representing physician anaesthesiologists did not contact the investigators, it was not possible to send out two email reminders. The emails were sent by these third-parties, and the investigators did not have any direct role in the email reminders. Phase II data collection lasted a total of 26 weeks. Data collection was closed on March 30th, 2017.

3.2.4 - Calculation of Mortality and Morbidity

The mortality and morbidity data obtained from Phase I via the OCCO, PLP, and the RCDSO were totaled separately to provide the numerator value for the number of deaths or serious morbidity that occurred. The data from Phase II were used as the denominator of the total number of anaesthetics administered from 1996-2015. These data were used to both estimate the number of DS/GA cases provided from survey responders, and also extrapolate the number of cases provided by survey non-responders.
To estimate the number of cases by responders, the response to question 2 (estimated anaesthetics in 2015) and question 4 (number of years in practice) were multiplied by one another. This resulted in the total estimated number of anaesthetics administered in the 20-year period for that specific clinician. This value for every clinician was then summed together. The total sum provides the number of anaesthetics administered by the survey responders from 1996-2015. Data collected from study participants was also utilized to extrapolate the numbers of cases by non-responders. This was done by taking an average of the responses to question 2 (estimated anaesthetics in 2015) and of question 4 (number of years in practice) for each provider group. This method was based on the estimation computed by Bennett et al. 2015 (Estabrooks, 2014). Bennett et al. (2015) estimated the average number of anaesthetics administered per provider in the time span they investigated by multiplying the number of policy holders by the average number of anaesthetics administered per provider. The technique in this study mirrors this practice. In summary, the final estimate of cases over the period from 1996-2015 in this study involved the following calculations for each provider group:

Calculation 1

\[(\text{Avg # of years in practice})(\text{Avg # of anaesthetics administered per provider})\]

\[= \text{ Estimated Avg # of Anaesthetics administered in per provider in 20 years (A)}\]

Calculation 2

\[(A)(\text{# of non – responders})\]

\[= \text{ Estimated Avg # of Anaesthetics Administered by NonResponders in 20 years (B)}\]
In calculation 1, the average of the number of years in practice was used to capture any increases or decreases in trends of practice by provider groups. This would minimize over or under inflation of the final denominator.

The values of B for each provider group were then summed to compute a total number of anaesthetics administered by the non-responders in each provider group. This total was added to the total anaesthetics administered from survey responses, and this value would be the total for the final denominator in this study.

Final values of mortality OR morbidity prevalence was therefore represented as:

\[
\frac{\text{# of events in mortality OR morbidity}}{(A + B)}
\]

The final mortality and morbidity prevalence was then adjusted to per million cases for ease of comparison to studies found in literature.
CHAPTER 4

4.1- Phase I Results

4.1.1 - Case Inclusion and Exclusion

The internal team from the OCCO searched their electronic database from 2002 – 2015. Since the database was established in 2002, they were unable to review records prior that occurred in 1996-2002. Using the keywords, “dentist, dental, anesthesia, anaesthesia, sedation, sedated,” 42 cases were recovered from the database (Figure 1). Forty of these cases were excluded from the dataset as they did not fit the inclusion criteria. These cases involved death related to oral infection, bacteremia, and airway obstruction due to Ludwig’s Angina amongst other causes that were not related to DS/GA. The two cases remaining received DS/GA for a dental procedure. Upon review of the case files, one case was found to be performed in a hospital facility. Thus, it did not fit the investigator’s inclusion criteria of the case occurring in a dental office or surgicenter facility outside of the hospital environment, and the case was excluded. Therefore one case was included in the final dataset from the original 42 cases forwarded by the Coroner’s office.
There were two internal teams from the RCDSO. One team reviewed the records in the PLP’s database, and the second team reviewed the records in the PCRA’s database. The teams conducted a manual search and forwarded all cases of morbidity or mortality that related to sedation or GA. In total, four cases were forwarded from the RCDSO (Figure 2). The PLP forwarded two cases, one involved death, and one involved serious morbidity. The PCRA also forwarded two cases to the investigators. One of these cases occurred under conscious sedation, and therefore it did not fit the inclusion criteria of having the level of DS/GA administered and was excluded. Therefore in total three cases were included in the final dataset from the RCDSO; two of these cases involved mortality, and one case related to serious morbidity. The details of each case are reported in Section 4.1.2 and 4.1.3. The richness of the individual case details reflects the amount of information recorded and available regarding the death or injury. Not all cases provided to the PI had similar richness of detail. All available pertinent details of the cases that were forwarded to the PI are included in Section 4.1.2.
4.1.2 - Cases from the Office of the Chief Coroner of Ontario

One case from the OCCO met the inclusion criteria for this study (Case 1). It involved a 9-year-old male and resulted in death. His health history included mild developmental delay and history of seizure disorder. Medication history included anticonvulsant medications, discontinued at the age of three. His parents indicated he had been an active and otherwise healthy child. The coroner recorded in his report that the child was of a slight build, his growth was consistent with age, and he had no dysmorphic features. On the day of event, the patient presented to a dental anaesthesiologist for dental restorations and extractions under general anaesthesia. The personnel present in the operatory were the Dental Anaesthesiologist, Registered Nurse, and a Dental assistant. Nasotracheal intubation was performed. Forty-five minutes into the procedure, the Dental Anaesthesiologist noticed the patient had become bradycardic, with the heart rate dropping from 100 bpm to 45 bpm. Atropine 0.6 mg was administered, anesthetic gases were turned off, and 100% Oxygen was administered. The bradycardia briefly resolved, but then the heart rate dropped to 20 bpm. Epinephrine 0.5 mg was administered. The bradycardia continued...
and another dose of epinephrine was administered. There was no mention of cardiopulmonary resuscitation (CPR) being performed in the coroner’s report. Emergency medical services (EMS) were contacted for help. While waiting for EMS, the patient’s heart rate rose to 154 bpm. EMS arrived at 13:05, and CPR was initiated at 13:06. The patient was transferred to the hospital, and he was found to be in asystole at 13:15. Full resuscitation was performed with defibrillation until the patient’s heart electrocardiogram (ECG) rhythm returned to normal sinus rhythm and he had return of spontaneous circulation. The patient spent 43 minutes in resuscitation. The hospital record showed that his blood had an acidotic pH, he had suffered pulmonary edema, and he had severe cardiac decompensation with an ejection fraction of 30%. A normal left ventricular ejection fraction is greater than 50% (Sanderson et al., 2007). At this point, the decision was made to transfer him to a nearby children’s hospital. The patient remained hypotensive despite the administration of several agents to support his blood pressure. The record from the children’s hospital reports that he suffered devastating neurological injury due to the prolonged cardiac arrest. He suffered a second cardiac arrest the following morning and was pronounced dead. The autopsy revealed that the patient had a cardiac anomaly that would increase the risk of sudden and unexpected death. This anomaly would not have been revealed in the pre-operative anaesthetic evaluation. It could have only been revealed with medical imaging such as invasive coronary angiography or coronary magnetic resonance angiography which were not indicated in this asymptomatic patient (Kate, Weustink, & Feyter, 2008). This case received and mSIS of 5.
4.1.3 - Cases from the RCDSO: Professional Liability Program (PLP) and Corrections and Disciplines

Three cases were included in the dataset from the RCDSO; two cases related to mortality, and one case related to severe morbidity. The first case of mortality identified from PCRA records (Case 2) involved a 9 year old female requiring exodontia under DS/GA prior to orthodontic treatment. Indications for DS/GA included needle phobia. This patient had been seen for preoperative consultation by the oral surgeon. Her health history indicated a diagnosis of muscular dystrophy. The patient was not taking any medications at the time. The coroner had outlined concern regarding the American Society of Anesthesiologists (ASA) physical status classification (ASA, 2014) that was given to this patient by the oral maxillofacial surgeon (See Table 9). The oral maxillofacial surgeon had classified the patient as an ASA II. The coroner’s report stated she had significant respiratory compromise as a sequelae of the disease, and that they believed the patient to be an ASA IV. There is no record of additional medical consultation prior to administration of DS/GA.

Table 9.

<table>
<thead>
<tr>
<th>ASA PS Classification</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASA I</td>
<td>A normal healthy patient</td>
</tr>
<tr>
<td>ASA II</td>
<td>A patient with mild systemic disease</td>
</tr>
<tr>
<td>ASA III</td>
<td>A patient with severe systemic disease</td>
</tr>
<tr>
<td>ASA IV</td>
<td>A patient with severe systemic disease that is a constant threat to life</td>
</tr>
<tr>
<td>ASA V</td>
<td>A moribound patient that is not expected to survive without the operation</td>
</tr>
<tr>
<td>ASA VI</td>
<td>A declared brain-dead patient whose organs are being removed for donor purposes</td>
</tr>
</tbody>
</table>
The patient presented to the oral maxillofacial surgeon on the day of surgery for the planned procedure of exodontia under DS. Upon procedure completion and emergence from anaesthesia, the patient was on 100% Oxygen when she began to desaturate. She was observed to be having an airway obstruction, and her oxygen saturation was dropping rapidly. The diagnosis of laryngospasm was made, and 100% oxygen was administered with an ambu-bag and positive pressure ventilation (PPV). The laryngospasm could not be broken with PPV, and succinylcholine 20 mg was administered intramuscularly via the submental route. The laryngospasm successfully broke and oxygen saturation rose to 98%. EMS was called at this point for assistance. The patient suffered five more laryngospasms, all broken with a dose of 20 mg of succinylcholine. Several unsuccessful attempts at intubation were made by the oral surgeon in office. The patient was transferred to hospital where she is initially stable. Later in the day she developed respiratory arrest. The patient could not be intubated. An emergency tracheotomy was performed, and the patient died subsequent to cardiac arrest. Based on the repeated doses of succinylcholine that were administered and the patient’s concomitant diagnosis of muscular dystrophy, it is plausible this patient may have suffered muscle breakdown (rhabdomyolysis) and hyperkalemic cardiac arrest subsequent to the administration of succinylcholine. This case received an mSIS of 5.

The second case of mortality came from PLP records (Case 3). It involved an 18 year old male with asthma. He presented to an oral maxillofacial surgeon for exodontia of his third molars under GA administered by a physician anaesthesiologist. There were also two registered nurses present during the procedure. The patient was induced with propofol 200 mg, rocuronium 25 mg, and lidocaine 20 mg. He was nasotracheally intubated with a number 6.0 endotracheal tube.
After intubation, the patient was not easily manually ventilated, and the anesthetic monitors indicated extremely high airway pressures. There was no air entry on lung auscultation. It was felt that the patient was experiencing acute status asthmaticus on anaesthetic induction and was treated as such according to the report. Details of which medications were used to manage the attack were not included. The position of the tube was assessed and confirmed by the anaesthesiologist. The patient progressed into cardiac arrest losing pulse and blood pressure. EMS was called, and the patient was transferred to hospital. CPR was administered. Upon removal of the endotracheal tube, a fold approximately 2-3 cm proximal to the distal tip of the tube caused an occlusion that was reinforced by inflation of the cuff. The cause of death was prolonged hypoxia, resulting in hypoxic ischemia encephalopathy and cardiac arrest. The total time the patient was without oxygen was approximately 276 minutes. This case also received an mSIS of 5. The case did move to settlement, and the amount paid to the family is unknown by the PLP as it was paid by the physician anaesthesiologists’ insurer.

The case of severe morbidity also came from the PLP records (Case 4). It involved a 50 year old male patient. The patient presented for full clearance of their dentition in the maxilla and several other teeth in the mandible (13 teeth in total) to be performed by an oral maxillofacial surgeon under GA administered by a physician anaesthesiologist. The patient had neurofibromatosis, cervical spine fusion, gastric feeding tube insertions, history of tracheotomy, recurrent cough, difficulty swallowing (dysphagia), difficulty breathing when lying down (orthopnea), and chronic obstructive pulmonary disease with recurrent pneumonia. During the procedure, the patient’s oxygen levels were noted to vacillate at various instances. He appeared cyanosed and had declining oxygen saturation levels. The patient was bleeding from one or more tooth sockets.
An oral airway was inserted and the patient was manually ventilated. EMS services were contacted. Paramedics intubated, stabilized, and transferred the patient to hospital where he received an emergency tracheotomy. A chest x-ray in hospital confirmed that the patient had aspirated in the right lung. The case report indicated that the fluid aspirated was likely blood since the patient was actively bleeding from several sockets. The patient suffered serious neurological deficits, and he now requires 24-hour care. This case reached settlement for the patient in the amount of $344,640.73. This case is an mSIS score of 4.

### 4.1.4 – Summary of Phase I Results

A total of 4 cases were included in this dataset: three cases of mortality, and one severe case of severe morbidity. Table 10 summarizes the distribution of cases according to provider groups. Two cases were performed by a physician anaesthesiologist, one case by an oral maxillofacial surgeon, and one by a dental anaesthesiologist. Table 11 summarizes the distribution of cases amongst age groups. Two cases with an mSIS score of 5 occurred in the 0-10 yo group and one occurred in the 18yo+ group. A case with an mSIS score of 4 also occurred in the 18yo + age group.

<table>
<thead>
<tr>
<th></th>
<th>PA</th>
<th>DA</th>
<th>OMFS</th>
</tr>
</thead>
<tbody>
<tr>
<td>mSIS = 5</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>mSIS = 4</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

*Note: PA = physician anesthesiologist, DA = dentist anaesthesiologist, OMFS = oral maxillofacial surgeon.*

mSIS = modified severity of injury score.
Table 11.

mSIS scores according to age

<table>
<thead>
<tr>
<th></th>
<th>0-10yo</th>
<th>10-17 yo</th>
<th>18 yo +</th>
</tr>
</thead>
<tbody>
<tr>
<td>mSIS = 5</td>
<td>2</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>mSIS = 4</td>
<td>-</td>
<td>-</td>
<td>1</td>
</tr>
</tbody>
</table>

4.2 - Phase II Results

4.2.1 - Survey Tool Results

Data collected from survey responses were inputted into an excel document to total and average values for each provider group. The overall survey response rate was 39.2%. The survey response rate per provider group was as follows: 100% response rate for dental anaesthesiologists, 53.4% response rate for oral & maxillofacial Surgeons, and 22.9% response rate for physician anaesthesiologists (Table 12).

Table 12.

<table>
<thead>
<tr>
<th>Provider Group</th>
<th>Survey Response Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DA</td>
<td>37/37 = 100%</td>
</tr>
<tr>
<td>OMFS</td>
<td>117/219 = 53.4%</td>
</tr>
<tr>
<td>PA</td>
<td>75/328 = 22.9%</td>
</tr>
<tr>
<td>Overall</td>
<td>229/584 = 39.2%</td>
</tr>
</tbody>
</table>
The average number of anesthetics administered per provider group over the year were as follows: dental anaesthesiologists - 570 oral & maxillofacial surgeons – 664, physician anaesthesiologists 296. The dental anaesthesiologists recorded on average 13.1 years in practice over the 20 year study period. The oral & maxillofacial surgeons recorded on average 15.6 years in practice, and finally, the physician anaesthesiologists recorded on average 11.5 years (Tables 13 and 14).

Oral & maxillofacial surgeons had the highest average value for anaesthetics administered per provider over the 20 year study period (10373 anaesthetics/provider over 20 year period). The dental anaesthesiologists were in the middle, recording an average of 7445 anaesthetics administered per provider over the 20 year study period. The physician anaesthesiologists recorded the lowest value of the three groups at an average of 3400 anaesthetics administered/provider over the 20 year study period.

<table>
<thead>
<tr>
<th>Provider Group</th>
<th>Lowest Reported Years in Practice</th>
<th>Mean Reported Years in Practice</th>
<th>Highest Reported Years in Practice</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAs</td>
<td>2</td>
<td>13</td>
<td>20</td>
<td>6.18</td>
</tr>
<tr>
<td>OMFS</td>
<td>3</td>
<td>16</td>
<td>20</td>
<td>5.47</td>
</tr>
<tr>
<td>PAs</td>
<td>0</td>
<td>11</td>
<td>20</td>
<td>6.45</td>
</tr>
</tbody>
</table>
4.2.2 - Extrapolation of Survey Results

The results from survey participants for the 2015 year were multiplied to account for the 20 year period from 1996-2015. It was estimated that the total number of anaesthetics provided by survey responders in all provider groups was 1,823,822 from 1996-2015. Dental anaesthesiologists had administered 257,957, oral maxillofacial surgeons administered 1,273,643, and physician anaesthesiologists administered 292,222. These results are summarized in Table 15.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>DAs</td>
<td>67</td>
<td>570</td>
<td>1440</td>
<td>371.52</td>
</tr>
<tr>
<td>OMFS</td>
<td>24</td>
<td>664</td>
<td>2330</td>
<td>614.32</td>
</tr>
<tr>
<td>PAs</td>
<td>0</td>
<td>296</td>
<td>2880</td>
<td>581.62</td>
</tr>
</tbody>
</table>
Table 15.

<table>
<thead>
<tr>
<th>Provider Group</th>
<th># of Anaesthetics Administered by Survey Responders from 1996-2015 (20 yrs period)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAs</td>
<td>257,957</td>
</tr>
<tr>
<td>OMFS</td>
<td>1,273,643</td>
</tr>
<tr>
<td>PAs</td>
<td>292,222</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,823,822</strong></td>
</tr>
</tbody>
</table>

With respect to the study non-responders, survey responder data were extrapolated to account for the number of anaesthetics administered by non-responders. Non-responders consisted of oral & maxillofacial surgeons and physician anaesthesiologists. It was estimated that they administered a total of 1,918,246 anaesthetics over the 20 year study period. This was calculated by carrying out the calculations below for each provider group. The results of these calculations can be seen in Table 16.

Calculation 3

\[
(Avg \# \text{ of years in practice})(Avg \# \text{ of anaesthetics administered per provider})
\]

\[
= Estimated Avg \# \text{ of Anaesthetics administered in per provider in 20 years (A)}
\]

Calculation 4

\[
(A)(\# \text{ of non – responders})
\]

\[
= Estimated Avg \# \text{ of Anaesthetics Administered by NonResponders in 20 years (B)}
\]
The total value calculated for the non-responders was slightly higher than the 1,823,822 administered anaesthetics reported by the survey participants over the 20 year study period. Together, these two values indicate that over the 20 year study period, the responders and non-responders administered a total of 3,742,068 anaesthetics (see Table 17).

Table 16.
Number of Anaesthetics Estimated for Non-responders

<table>
<thead>
<tr>
<th>Provider Group</th>
<th>Survey Response Rate (%)</th>
<th>Survey Non-Response Rate (%)</th>
<th># of Non-Responders</th>
<th>Avg # of Anaesthetics Administered/Provider (20 yrs)</th>
<th>Estimated # of Anaesthetics Administered (20 yrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental Anaesthesiologists</td>
<td>37/37= 100%</td>
<td>100%-100%</td>
<td>37-37= 0</td>
<td>7445</td>
<td>0</td>
</tr>
<tr>
<td>Oral &amp; Maxillofacial Surgeons</td>
<td>117/219= 53.4%</td>
<td>100%-53.4%</td>
<td>219-117= 102</td>
<td>10,373</td>
<td>102 x 10,373= 1,058,046</td>
</tr>
<tr>
<td>Medical Anesthesiologists</td>
<td>75/328= 22.9%</td>
<td>100%-22.9%</td>
<td>328-75= 253</td>
<td>3400</td>
<td>253 x 3400= 860,200</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1,918,246</td>
</tr>
</tbody>
</table>
Table 18.

Estimated Mortality and Serious Morbidity Rates

<table>
<thead>
<tr>
<th>Type of Injury</th>
<th>Rate</th>
<th>Per Million Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>3 in 3,742,068</td>
<td>0.8 in 1 million</td>
</tr>
<tr>
<td>Morbidity</td>
<td>1 in 3,742,068</td>
<td>0.25 in 1 million</td>
</tr>
</tbody>
</table>

4.3 – Mortality and Morbidity Rates

Table 18 summarizes the calculated mortality and morbidity rates according to the results of Phase I and Phase II of this study. There was a total of 3 deaths and a total of 3,742,068 anaesthetics administered in the 20 year study period from 1996-2015. This is adjusted to a rate of 0.8 deaths per 1 million cases. There was one case of serious morbidity in the same period, and this adjusts to 0.25 serious injury occurring per 1 million cases.
CHAPTER 5

5.0 – Discussion

The purpose of this study was to estimate the prevalence of mortality for DS/GA in dentistry in Ontario from 1996-2015, which has not been estimated for two decades since Nkansah et al.’s 1997 study. Secondly, it was to estimate the prevalence of serious morbidity for DS/GA in dentistry in Ontario.

5.1 – Findings: Prevalence of Mortality

Previous reports of mortality rates in dental anaesthesia were reviewed (Chapter 2), and have ranged from 1 to 7 deaths per 1 million cases (Table 4). The mortality rate reported for this study is 0.8 deaths per one million cases. This is slightly less than the rate published by Nkansah et al. (1997) of 1.4 deaths per 1 million cases, and it is the lowest mortality rate published to date in dental anaesthesia literature. This may be because of the projected increase in the use of the pulse oximeter and capnography since the Nkansah’s (1997) study as demonstrated by D’Eramo et al., (2003). Continuous pulse oximetry only became part of the RCDSO’s guidelines in 1995 (Gardner, 2017), and this would likely increase detection of hypoxia and emergencies of a respiratory nature.

Somri et al. (2012) hypothesized that the decrease in claims related to anesthesia from 1975 to 2000 was due to improved training, the use of safer drugs, and increased focus on patient safety (Somri et al., 2012). These factors likely also contributed to the decreased mortality rate exhibited in this study. The dental anaesthesia specialty program at the University of Toronto in Ontario was previously a 12 month duration, and it is now of 36 month duration, the majority of
which is dedicated to clinical training. Most dental anaesthesia training programs in the United States have now also transitioned program length from 24 months to 36 months. Guidelines for the accreditation of these programs are clearly laid out to ensure competency in all aspects of managing patients under anaesthesia (Commission on Dental Accreditation, 2015).

These RCDSO standards of practice are reviewed every five years with a focus on patient safety. The practice model in Ontario for dental anaesthesia involves team based anaesthetic care. The RCDSO 2012 standards of practice for DS/GA describe, “the anesthetic team”. The anaesthetic is administered through the combined efforts of the members of the team which allows a dentist to administer the anaesthetic simultaneously with dental treatment (RCDSO, 2012). The members include: the dentist-anesthetist (dental anaesthesiologist or oral maxillofacial surgeon), the anesthetic assistant (a registered nurse, respiratory therapist, or an anesthesia assistant), the operative assistant, the recovery supervisor, and the office assistant. The operative assistant role is to keep the operative field free of fluids and foreign objects that may interfere with the patient’s airway. The recovery supervisor’s role is to monitor the patient through recovery and discharge; they are under the dentist’s supervision. The office assistant functions to attend to the logistics of the office so that the anesthetic team is not disturbed. However, if a dental anaesthesiologist or physician anaesthesiologist is solely administering the anaesthetic, then an anaesthetic assistant or recovery supervisor are not required as members of the team (RCDSO, 2012). This model not only ensures that the members of the team administering the anaesthetic are not distracted from monitoring the patient, but it also means there are several trained individuals attending to the patient’s well-being. Every member of the team has a clear role, and closed-loop communication between team members is encouraged. This attentiveness to patient care is essential when a clinician is administering both the anaesthetic and dental treatment. A
team member may alert the entire team when there is a clinical cue of an impending adverse event. The RCDSO also requires that all dentists and physicians administering DS/GA provide evidence of successful completion of advanced cardiac life support (ACLS), and if they are providing care for patients under 12 years of age, they must also show evidence of PALS training.

The group of studies conducted by D’Eramo et.al. (1992, 1999, 2003), all took place in Massachusetts, U.S.A. The regulations for DS/GA by the Massachusetts board of registration in dentistry are similar to those of the RCDSO regarding personnel who should be present. However, they only require three team members: the dentist-anaesthetist, a person responsible to monitor and observe the patient, and a person to assist the operating dentist. The guidelines also state that if the person responsible for monitoring the patient is an appropriately trained professional, they may also direct and/or administer the DS/GA (Board of Registration in Dentistry, 2005). However, unlike the RCDSO regulation, there is no specifications regarding the credentials of the anaesthesia assistant. The RCDSO clearly states that the person who fills this role must be a registered nurse. In addition, the Massachusetts board only requires members involved in DS/GA to have completed training in CPR (Dentistry, 2005). Basic Life Support training is not as comprehensive as ACLS regarding the management of peri-operative adverse events. The differences in regional standards for the administration of DS/GA between Ontario and Massachusetts may have contributed to the slightly higher prevalence of adverse events occurring in ‘The Massachusetts Experience’ studies as compared to the prevalence of morbidity and mortality incidents reported in our study.
Differences in practice models also exist in Deegan et al.’s 2001 study and Bennett et al.’s 2015 study. These were both retrospective reviews of closed claims, and they included data widespread from the U.S.A. Although the American Dental Association (ADA) has guidelines in place for the use of sedation and GA by dentists, there are wide regional differences in safety standards, guidelines, and regulations from state to state. Ultimately, the ADA defers dentists to comply with the laws, rules, and regulations implemented by their state (ADA, 2016). The wide regional differences in standards of care in the U.S.A., and their potential impact on patient safety, may be one reason for the higher reported prevalence rates in Deegan et al. (2001) and Bennett et al.’s (2015) publications as compared to the prevalence found in this study.

5.2 – Findings: Prevalence of Morbidity

Previous rates of morbidity in dental anaesthesia were reviewed (Chapter 2) and have ranged from 1 in 37,000 to 1 in 364,000 (Table 3). The serious morbidity rate in this study was found to be 0.25 in 1 million cases or a prevalence of 1 case of serious injury in 3,742,068. Therefore, the serious morbidity rate found in this study is relatively low. It is not surprising that the serious morbidity rates found in this study for dentistry under DS/GA are low. In comparison to other surgeries, dental treatment is considered a peripheral or superficial procedure. Several large scale studies have shown that morbidity rates for superficial procedures performed in the ambulatory setting are low (Fleisher, 2007). Furthermore, the majority of anaesthetics provided in the outpatient dental office setting are on healthy patients (ASA I and II), who by definition have limited comorbidities that would put them at greater risk for DS/GA. Therefore, the patient case selection for healthy patients in this environment may be a contributing factor for low morbidity.
In addition, the factors outlined above that contributed to the low mortality prevalence likely also contributed to the low prevalence of morbidity.

5.3 – Communicating the Risk

These findings are valuable information to clinicians who require informed consent from their patients to proceed with care, as this study has provided a new estimate of how this risk be communicated to patients in informed consent discussions. The logarithmic community cluster classification based on Calman’s verbal scale has been employed by several authors to describe the relative risk of adverse events in anaesthesia in patient-centered and relatable terms (Calman, 1997). It allows clinicians to communicate risk to patients by using the likelihood of a complication or disease process occurring in a community as a reference. For example, a complication that would be likely for a sibling to experience would have a greater chance of occurring than a complication that only one person in a large town would experience. Jenkins and Baker (2003) summarized studies reporting predicted incidences of complications of anaesthesia in relation to Calman’s verbal scale to lend perspective on the risk. We have added published dental anaesthesia mortality and morbidity rates to their graphical representation to illustrate where the predicted mortality and morbidity rates related to dentistry under DS/GA lie (Table 19). However it should be mentioned, that it can be challenging to compare mortality and morbidity studies due to differences in their objectives, study design, populations, and time span (Jenkins & Baker, 2003). When examining Table 19, all published dental anaesthesia morbidity and mortality rates to date coincide with Calman’s verbal scale of very low to minimal risk. Even the highest reported serious morbidity rate in dental anaesthesia by D’Eramo and Edward (1992) of 1:37 400 coincides with a very low risk according to the scale. The mortality and morbidity
rates calculated from the findings of this study are interesting in that this is the first study to coincide with a level of negligible risk. It suggests that patients could be presented with risk on a magnitude of “winning the lottery”—which in everyday life is easily understandable as a highly rare event. It is important, however, in any discussion of risk to note that, no matter how low, events can and do occur. Communicating the risk effectively to patients remains dependent on several factors including their severity, vulnerability, controllability, familiarity, acceptability, and their framing or presentation (Jenkins & Baker, 2003).

Table 19.

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Calman’s Verbal Scale</th>
<th>Community Examples</th>
<th>Community Examples</th>
<th>Medical anaesthesia examples</th>
<th>Reported dental anaesthesia rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:1-9</td>
<td>Very High Sibling</td>
<td>Genetic dominant</td>
<td>Postoperative Nausea and Vomiting 1:4</td>
<td>Dizziness 1:5</td>
<td></td>
</tr>
<tr>
<td>1:10-99</td>
<td>High Family</td>
<td>Genetic recessive</td>
<td>Headache 1:5</td>
<td>Oral trauma 1:20</td>
<td></td>
</tr>
<tr>
<td>1:100-999</td>
<td>Moderate Street</td>
<td>Death of any cause (1:100)</td>
<td>Difficult intubation 1:50</td>
<td>Peri-operative death 1:200</td>
<td></td>
</tr>
<tr>
<td>1:1000-9999</td>
<td>Low Village</td>
<td>Traffic deaths/yr (1: 8000)</td>
<td>Awareness without pain 1:300</td>
<td>Failure to intubate 1:500</td>
<td></td>
</tr>
<tr>
<td>1:10 000 – 99 999</td>
<td>Very Low Small Town</td>
<td>Accidental deaths at home/yr (1: 11 000)</td>
<td>Aspiration 1:3000</td>
<td>Cardiac arrest (local anaesthesia) 1:3000</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Failure to intubate and ventilate 1:5000</td>
<td>Anaphylaxis 1:10 000</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Serious morbidity reported by D’Eramo and</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incidents</td>
<td>Within-Site Incident Rate</td>
<td>Provider Group</td>
<td>Data Source, Year</td>
<td></td>
<td></td>
</tr>
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<td>-------------------------------</td>
<td>---------------------------</td>
<td>--------------------------------</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac arrest (GA)</td>
<td>~1:15 000</td>
<td>Edward (1992)</td>
<td>1:37,400</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death related to anaesthesia</td>
<td>1:50 000</td>
<td>Serious morbidity reported by</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loss of vision (GA)</td>
<td>1:125 000</td>
<td>Deegan (2001)</td>
<td>1:364 280</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death due solely to anaesthesia</td>
<td>1:180 000</td>
<td>Mortality reported by Bennet et</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>al. (2014)</td>
<td>1:344 828</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Nkansah et al. (1997)</td>
<td>1:714 285</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>El-Mowafy et al. (mortality)</td>
<td>1:1 250 000</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(morbidity)</td>
<td>1:3 742 068</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5.4 – Findings: Prevalence According to Provider Groups

In Chapter 4, Table 10 illustrated the incidents occurring according to provider group. Overall there were four incidents; two occurred with a physician anaesthesiologist, one with a dental anaesthesiologist, and one with an oral maxillofacial surgeon. The incidents occurring are too few to make any conclusions regarding differences in safety between provider groups. Additionally, the incidents themselves vary in the type of harm that occurred. There is inadequate data to identify any themes or patterns of practice that contributed to injury according to provider group. To adequately assess this, a prospective review of data from an established surveillance system that is comprehensive should be implemented to discern any future differences between the groups.

In regard to the physician provider group, we found that there were more specialties than physician anaesthesiologists and family medicine anaesthesia graduates registered with the
RCDSO to administer DS/GA. Physician anaesthesiologists made up 66.1% of this provider group, service not listed accounted for 20.5%, Family medicine 12.2%, Emergency medicine 0.6%, Pediatrics 0.3%, and Internal Medicine 0.3%. These credentials were verified through each physician’s registration available to the public on the College of Physicians and Surgeons of Ontario’s website. This is an interesting finding since these other specialties do not seem to fit the criteria of the RCDSO’s DS/GA standards of practice for registration with the college to administer DS/GA previously outlined in Chapter 2. The physicians from other specialties may not have had an equal level of training in providing DS/GA in an office when compared with specialist anaesthesiologists or even family medicine anaesthesia graduates, as sedation and anaesthesia training is not routine among these other specialties. It is assumed that these physicians may have provided evidence to the college that they have active privileges to provide similar procedures in hospital. Understanding the reason for these physicians deciding to participate in this area of practice is worth noting but beyond the scope of this current study.

5.5 – Findings: Individual Case Review

A review of the management of the cases included in the dataset follows. The intention of this retrospective review is not to criticize the work of colleagues who were involved in these cases. It is to speculate on the causes, themes, or patterns that led to injury or death of the patients involved for the purpose of avoiding similar error (if any) by clinicians who may encounter similar cases in future.

Case 1 involved a 9 year old male who presented to a dental anaesthesiologist’s office for dental treatment under general anaesthesia and unfortunately suffered cardiac arrest. He was pronounced dead in hospital. The autopsy revealed that the patient had a congenital cardiac...
anomaly called, anomalous aortic origin of the coronary artery from the opposite sinus (AAOCA). This is an anomaly that is known to have a risk of sudden cardiac death (Cheezum M.K., Liberthson R.R., Shah N.S., Villines T.C., O’Gara P.T., Landzberg M.J., 2017). The dental anaesthesiologist involved in this case was found to not be at fault as this anomaly would not have been detected in the pre-operative anaesthetic evaluation. Patients with this anomaly are typically asymptomatic. Patients who are symptomatic present with chest pain, palpitation, or and exertional syncope. Even when symptomatic, patients will still have a normal physical exam, electrocardiogram, and a normal stress exercise test (Cheezum et al., 2017). The diagnosis of this condition is typically incidental, and revealed with medical imaging such as invasive coronary angiography or coronary magnetic resonance angiography which were not indicated in this asymptomatic patient (Kate et al., 2008). On review of the management of this case based on the Coroner’s report, it was noted that CPR was not performed even though a heart rate of 20 bpm in this 9 year old male had been recorded. According to pediatric advanced life support (PALS) recommendations, CPR is recommended on paediatric patients with a pulse less than 60 bpm. This recommendation acknowledges that children are heart-rate dependent, and a pulse less than 60 bpm could be indicative of cardiac output insufficient to meet physiological needs (Chameides, L ; Samson, R ; Schexnayder; Hazinski, 2011). Therefore, in addition to the administration of atropine or epinephrine, the management of bradycardia should involve continued support of airway, ventilation, oxygenation, and chest compressions if indicated. It also recommends the use of emergency transcutaneous pacing if bradycardia is unresponsive to ventilation, oxygenation, chest compressions, and medications, especially if the bradycardia is associated with congenital or acquired heart disease (Caen et al., 2015). The use of chest compressions or transcutaneous pacing may have been an appropriate management strategy for
this patient. Refractory bradycardia despite adherence to the PALS algorithm could also be a clinical cue to the clinician that the patient may have an unknown cardiac anomaly. These are important points for clinicians that may encounter a similar case of refractory bradycardia. Furthermore, it would be critical during a similar event to ensure routine pulse checks, as bradycardia observed on a monitor can either be true bradycardia (pulse present) or pulseless electrical activity (PEA). As the management for each is dramatically different (bradycardia; support airway, oxygenation, ventilation, medications, pacing and chest compressions if less than 60 bpm vs. PEA; CPR and epinephrine) the use of pulse checks to confirm the assessment of bradycardia on a monitor is essential in guiding patient care. As PALS recommendations are made from the best available evidence, a patient-centred approach to care should always include both knowledge of changes and adherence to these standards. This implies regular re-training according to the current expiry of two-year intervals, or at minimum, re-training whenever guidelines are updated, approximately every five years.

Case 2 involved a 9 year old female with muscular dystrophy who presented to an oral maxillofacial surgeon for exodontia under DS/GA. She suffered several laryngospasms upon emergence from anaesthesia and was treated with a depolarizing muscle relaxant, succinylcholine. She died later that day subsequent to cardio-respiratory arrest. This patient was seen by the oral maxillofacial surgeon in a preoperative consultation, but a consult with the patient’s primary care physician was not requested. This may have alerted the clinician to the patient’s disease state and the status of her respiratory health since this seemed to be a point of contention in the Coroner’s report. Due to a diagnosis of muscular dystrophy, administration of succinylcholine would have been a relative contraindication to administration of this medication, as patients with myopathic disease states are prone to having this complication of muscle
breakdown (rhabdomyolysis) and hyperkalemic cardiac arrest (Gurnaney, Brown, & Litman, 2009). A nondepolarizing muscle relaxant is an alternative treatment for laryngospasm in patients with myopathic disease states as they do not result in rhabdomyolysis whereas the depolarizing muscle relaxants can (Campbell et al., 2016). Another option is the administration of the hypnotic agent, propofol (D’souza, N; Garg, 2008). The PCRA report of this case indicated that several attempts were made at intubation by the oral maxillofacial surgeon in office prior to the patient being transferred to hospital. When she suffered respiratory arrest in the emergency room, physicians attempted to intubated her, and were unable. Repeated instrumentation of the airway may have led to airway edema that made later intubation attempts impossible. Attempts at laryngoscopy should be limited with any device according to the ASA difficult airway algorithm (Hagberg, Gabel, and Connis, 2013).

Case 3 involved an 18 year old male with asthma who died on induction of anaesthesia due to an undetected obstruction in the endotracheal tube which left him hypoxic. The use of a checklist to assess the cause of the loss of a patent airway could have positively impacted the outcome of this case. The concept of the use of checklists in surgery and anaesthesia to improve perioperative morbidity and mortality was brought about by publication of the WHO Surgical Safety Checklist in 2008. The hospitals that participated in the WHO’s pilot study of the checklist saw an overall reduction in the mortality rate from 1.5% to 0.8%. In-patient complications decreased from 11% to 7% (Walker, Reshamwalla, and Wilson, 2012). Evidence-based checklists can aid a clinician in addressing key interventions that if omitted may lead to serious adverse outcomes. They decrease reliance on memory alone to manage an emergency. Checklists contribute to team communication and increase situational awareness amongst team members (Walker et al., 2012). Both Stanford Anaesthesia and the Harvard group have introduced crisis checklists for
commonly encountered intra-operative emergencies during anaesthesia. The Harvard group exhibited that when these checklists were used in the form of a cognitive aid in simulations, there was a six-fold reduction in failure to adhere to critical interventions when compared to clinicians’ depending solely on memory (Walker et al., 2012). These cognitive aids should be a part of every anaesthesiologists’ armamentarium. This is especially important in the office-based environment when the anaesthesiologist is likely the only skilled clinician to manage the emergency. The use of a checklist can aid in considering all possible factors contributing to an emergency since memory may fail even the most skilled clinicians in a high pressure situation.

Case 4 involved a 50 year-old male with neurofibromatosis, cervical spine fusion, gastric feeding tube, history of tracheotomy, recurrent cough, dysphagia, orthopnea, and chronic obstructive pulmonary disease with recurrent pneumonia. This patient ultimately aspirated blood into his right lung, and he suffered severe neurological deficits. Likely, the most important point to address in this case is the appropriateness for office-based anaesthesia. Patients with significant comorbidities are not ideal for office-based dental anaesthesia. Patients with an ASA class I or II are ideal for this setting. ASA III patients that are optimized and well controlled may also be appropriate (L. Fleisher, 2013). A diagnosis of cervical spine fusion could have made this patient’s airway difficult to manage (Durga and Sahu, 2014). This situation could be particularly difficult in the office-based environment where there are less resources and personnel available for assistance when compared to a hospital setting. This event emphasizes the importance of case selection in risk mitigation. Another consideration in this case is the level of anaesthesia that was administered. Providing a minimal-moderate sedation and maintaining airway protective reflexes may have facilitated dental treatment without the same risk of aspiration associated with DS/GA.
5.6 - Limitations

The study design employed was retrospective in nature. For collection of morbidity and mortality data, a prospective design would have been ideal. However, since the reported prevalence of morbidity and mortality in DS/GA for dentistry is low (1-7 per 1 million cases (Table 4)), detecting a complication with a prospective study would require a long study period. For example, Hausman and Rosenblatt in 2003 report that when the risk of complication is 1:100,000, and the sample size is 100,000, the likelihood of failing to detect a complication is 36.8% (L. Fleisher, 2013). This likelihood demonstrates that a prospective study would have to be conducted over a very long period to accurately estimate the prevalence of morbidity and mortality. This was not feasible for the investigators, and the retrospective review of case files was employed. Retrospective review of closed claims has been used by several investigators to explore morbidity and mortality (Bennett et al., 2015; Deegan, 2001).

Phase I findings of mortality and morbidity were based on case reports and identified through the cooperation of two organizations, the RCDSO and the OCCO. The RCDSO and the OCCO participated in the Nkansah et al., (1997) study, and as this study used a similar methodology, they were again approached regarding collection of morbidity and mortality data. The OCCO conducted a search of their electronic database which was established in 2002 using keywords (Table 6). Any cases of interest that occurred from 1996-2002 would not have been captured by their search. Further, the OCCO only investigates 15% of deaths in Ontario; this would include any death considered to be of a sudden and unexpected nature (Office of the Chief Coroner and Forensic Pathology, n.d.) Death as a complication of dental treatment under DS/GA would certainly be unexpected. However, if the cause of death was not directly attributed to the DS/GA in the final
Coroner’s report, it could be missed through this keyword search method. The search method employed by the RCDSO’s internal teams was a manual review of records. Although the search methods employed have limitations, currently, they are the only avenue of access to these cases in Ontario. Without a surveillance system in place for the collection of morbidity and mortality incidents in dental anaesthesia, the profession must rely on retrospective review of closed claims and Coroner’s records. In Phase I of the results, it should be noted that there was no overlap between cases forwarded from the RCDSO and OCCO. Intuitively, a case of mortality that came up in the RCDSO’s records should also have been in the records of the OCCO and vice versa. The lack of overlap highlights that the search method used by the internal teams may not have been comprehensive despite best efforts, and due to errors by the individuals screening cases. This also seems to emphasize the difficulty of accessing information without a database designed prospectively to capture this data.

Phase II findings were based on the responses to the survey. The number of anaesthetics administered in the above-mentioned period was estimated with a survey tool. Survey participants were clinicians eligible to administer DS/GA in the dental setting, and that included dental anaesthesiologists, medical anaesthesiologists, and oral and maxillofacial surgeons. The overall survey response rate of 39.2% was within the range of reported response rates of Canadian dentists and physicians. Surveys of Canadian dentists have reported response rates ranging from 17-38% (Adams et al., 2017; Gaffen and Haas 2009; Patodia et al., 2017). Survey of Canadian physicians have been reported to be higher in the range of 54 -66% (Peng and Castano, 2005; Sheehan et al., 2011). The response rate for dental anaesthesiologists was 100% which allowed us to compute a relatively accurate estimate of the number of anaesthetics they may have administered in the 20-year period. The response rate for oral maxillofacial surgeons
(53.4%) and for medical anaesthesiologists (23%), and both being less than 100%, means that the estimates of the number of deep sedation and general anaesthesia cases could have either inflated or deflated, due to the less representative sample size. Interestingly, the physician response rate was lower than compared with surveys of Canadian physicians in the literature (Peng and Castano, 2005; Sheehan et al., 2011). The physician group received only one email-based and one paper-based reminder in addition to the initial survey package. This was one less email-based reminder than the other provider groups, which may have contributed to the lower response rate. We used several methods known to increase response rates including: follow-up mailings, a real stamp on the return envelope, a letter of salience in the survey package (Parashos, Morgan, and Messer, 2005). Although non-response bias cannot be assessed based on the data collected due to the anonymity of the survey and the absence of demographic data, there may have been involvement of cognitive and social processes influencing the behavior of respondents (Parashos et al., 2005). Dental anaesthesiologist and oral maxillofacial surgeons could be more motivated than physician anaesthesiologists to respond to the survey since it directly relates to their practice. In-office dental procedures are likely a small portion of physician anaesthesiologists’ practice. This situation may have led to the provider’s group lower response rate since responders are more concerned or interested in the survey topic (Parashos et al., 2005).

The way in which survey questions were formulated may have had an impact on the nature of the data reported. Clinicians indicated how many years they had been in practice since 1996. The response to this question was used as the multiplier to extrapolate the number of anaesthetics each clinician administered in the 20 year period, based on their reported number of DS/GA services provided in the calendar. While this assumes a steady state over time, is unlikely
clinicians performed the same number of anaesthetics each year they were in practice as they did in the calendar year 2015, and so variability in this number was not captured in the calculation. However, by asking the question of the number of years in practice, it helped to ensure data from clinicians who had been in practice for a shorter period would not over-inflate the total number of anaesthetics administered. Another limitation is that the data collected from responders was averaged and extrapolated to estimate the anaesthetics performed by the non-responders to the survey. Since the response rate in the physician anaesthesiologist group was lowest at 23%, the data collected from this provider group could have been the least accurate. This would result in possible over or under estimation of the final number of anaesthetics administered by this group once the data was extrapolated for non-responders. In retrospect, wording question 2 differently to be inclusive of retired clinicians may have revealed additional data. Since the question specifically asked about number of anaesthetics administered in 2015, clinicians who may have retired prior to 2015 may have not responded. The attrition due to retirement was not accounted for in the design of this study; this may have led to under-estimation of the total number of anaesthetics administered in the time period of inquiry.

5.7 – Strengths

The key strength of this study is collecting data from three different sources: the OCCO, the PLP of the RCDSO, and the PCRA of the RCDSO. Past studies have relied on personal report from clinicians of mortality and morbidity events (D’Eramo et al., 2003; D’Eramo, 1992; 1999; Flick, et al., 1996; 2007). Avoiding this method of reporting was a strength of this study. While the lack of overlap between organizations was concerning and points to the need for a centralized mechanism to collect information on patient injury, the use of more than one source of information for collecting mortality and morbidity events was important. Had only a single
source been approached, available case information would have been missed. Collecting case
details from a third party eliminated the possibility that clinicians may not be forthcoming with
events due to fear of judgement or repercussions. A final strength is the level of detail we
obtained for these cases. Although the type of records available varied, the level of detail was
thorough for each case. This helped investigators to comprehend how harm ensued. This is
important information if these cases are to be used as a learning tool for clinicians.
6.0 Conclusion

This study investigated the prevalence of mortality and serious morbidity events for dental procedures under DS/GA performed outside of a hospital facility from 1996-2015. The mortality rate was found to be 0.8 deaths per 1 million cases, and the serious morbidity rate was found to be 0.25 per 1 million cases or a prevalence of 1 case of serious injury in 3,742,068 cases. The prevalence of mortality for dentistry under DS/GA in Ontario found is comparable to the rate reported by Nkansah et al., in 1997. The range of mortality rates reported in the dental anaesthesia literature range from 0-7 deaths per 1 million cases (Table 4). The rate found in this study fits within the lower end of this range. The serious morbidity rate was found to be low indicating that serious injury rarely occurs as a sequela of dentistry under DS/GA. The findings are important in that few studies provide an indication of patient safety for dentistry under DS/GA, and this study has been able to fill this knowledge gap.

There are several implications of these results. For patients, this information can be used to enhance their informed consent for these procedures. An updated, accurate estimation of mortality and morbidity in Ontario enriches communication with patients regarding the risks they are assuming when undergoing DS/GA care for dentistry. It may also act as motivation to seek treatment if patients have concerns related to the safety of this procedure and can be reassured that risks are negligible. Furthermore, the case details from this study can impact clinicians by the description of events and possible alternate management, which can educate the community and prevent future similar errors. The cases included in this dataset provide insight and reaffirm the importance of patient selection for anaesthesia in office, pre-operative consultation with a primary care physician for patients with progressive disease or several comorbidities, the use of
candidacy is not a substitute for further training, and it is important to ensure that the professional community has the analytical capacity to review these incidents. Without this, the benefit of incident reporting is minimal.

Future research in this area could focus on the establishment of a surveillance system and piloting different techniques. It could also explore the prevalence of mortality and morbidity events for dentistry under DS/GA in Canada overall. DS and GA are valuable services for those who cannot receive dental treatment in a conventional manner, and it is our duty to ensure that patient safety remains the most important aspect of this procedure.
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RE: REQUEST AND CONSENT FOR INFORMATION

Dear Dr. Huyer,

I am a graduate student at the University of Toronto at the Faculty of Dentistry in the discipline of Dental Anaesthesia. I am writing you this letter to ask for your participation in a research project that I am currently conducting. This study is entitled “Mortality and Morbidity in Outpatient Deep Sedation and General Anaesthesia for Dentistry in Ontario”. It has been approved by the University of Toronto Research Ethics Board (ethics protocol # ____).

The purpose of this study is to determine the mortality rate associated with the administration of deep sedation and general anesthesia in the outpatient dental setting in the past twenty years (1996-2015). Furthermore, the study aims to determine the number and types of serious morbidity that have occurred within the same setting and time period. I hope to obtain elements of this data through cooperation with your organization.

The reason your organization is being approached is because you participated in a similar study with the Faculty of Dentistry at the University of Toronto. The primary researcher at the time was Dr. Peter Nkansah. He used the same methodology that is being proposed in this study. We found this to be a robust method of data collection on mortality, and we hope we can gain the same cooperation from your organization as Nkansah et al. did in 1997¹. I have enclosed a copy of this previously published study for your review.

Dr. Dirk Huyer
Ministry of Community Safety
and Correctional Services
18th Floor
25 Grosvenor Street
Toronto ON
M7A 1Y6

Your participation would entail forwarding the researchers any cases in your records where death was reasonably certain to be caused by anesthesia or factors under the control of the anesthesiologist. These cases should have occurred in the dental outpatient setting where the level of deep sedation or general anesthesia was administered. Once the data is in our possession, it will only be viewed by the researchers, and the cases will be assigned a case number. Working copies will have all patient and clinician identifiable information such as name and office address redacted prior to computer entry. Although files will be locked in a safe and secure cabinet at the Faculty of Dentistry, redacting identifiable data will further protect both patients and clinicians. Computer entry will be done in a secure environment at the Faculty of Dentistry. I appreciate that this is highly sensitive data, and it is not necessary to know neither patient nor clinician identity to analyze these cases. Once working copies have been recorded, all hard copies of records will be destroyed according to the university’s regulation on the disposal of confidential documents. We plan to disseminate the results by presenting our research at at clinical conferences in the dental anesthesia community as well as incorporating it into our teaching program at the Faculty of Dentistry. I would be more than happy to forward you a copy of the final results of the study.

Participation is voluntary, and you may decline to answer any question or any part of the procedure involved in data collection. The potential benefit of participating in this study is that your organization would be aiding in a matter of public safety. It is important for both the public and the profession of dentistry to be aware of the risk of mortality involved in a deep sedation or general anesthesia procedure when administered in the dental office.

The research study you are participating in may be reviewed for quality assurance to make sure that the required laws and guidelines are followed. If chosen, (a) representative(s) of the Human Research Ethics Program (HREP) may access study related data and/or consent materials as part of the review. All information accessed by the HREP will be upheld to the same level of confidentiality that has been stated by the research team. If you have any questions please contact the Human Research Ethics Program at ethics.review@utoronto.ca or 416-946-3273.

It would be a great pleasure to have your cooperation in this study that is of great importance to public safety, and we hope that you will kindly accept. **If you agree to participate, please sign this form and retain a copy for yourself. Please return the original form in the enclosed self-addressed stamped envelope.** Once I receive your response by mail, I will contact you directly regarding data collection procedures. Please do not hesitate to contact me if you have any questions.

Sincerely,

Alia El-Mowafy, BDS

Enc. Nkansah et al. (1997)
CONSENT ON BEHALF OF ORGANIZATION

I, _________________________________, understand the information presented about the study entitled “Mortality and Morbidity in Outpatient Deep Sedation and General Anaesthesia for Dentistry in Ontario” and agree to participate.

_________________________________  _____________________________
Signature of Participant                        Date
APPENDIX B: Professional Liability Program Invitation to Participate

STUDY
Mortality and Morbidity in Outpatient Deep Sedation and General Anaesthesia for Dentistry

RESEARCH TEAM

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Affiliation</th>
<th>Address</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alia El-Mowafy</td>
<td>DDS</td>
<td>Faculty of Dentistry</td>
<td>Room 129, 124 Edward Street</td>
<td><a href="mailto:alia.el.mowafy@mail.utoronto.ca">alia.el.mowafy@mail.utoronto.ca</a> 647-622-6411</td>
</tr>
<tr>
<td>Carilynne Yarascavitch</td>
<td>BSc DDS MSc Dip ADBA</td>
<td>Faculty of Dentistry</td>
<td>Room 130, 124 Edward Street</td>
<td><a href="mailto:c.yarascavitch@dentistry.utoronto.ca">c.yarascavitch@dentistry.utoronto.ca</a> 416-979-4900 Ext. 4331</td>
</tr>
<tr>
<td>Daniel Haas</td>
<td>BSc, DDS, BScD, PhD FRCD(C)</td>
<td>Faculty of Dentistry</td>
<td>124 Edward Street</td>
<td><a href="mailto:daniel.haas@dentistry.utoronto.ca">daniel.haas@dentistry.utoronto.ca</a> 416-979-4910 Ext4383</td>
</tr>
<tr>
<td>Carlos Quiñonez</td>
<td>DMD, MSc, PhD, FRCD(C)</td>
<td>Faculty of Dentistry</td>
<td>124 Edward Street</td>
<td><a href="mailto:carlos.quinonez@utoronto.ca">carlos.quinonez@utoronto.ca</a> 416-979-4908 Ext4491</td>
</tr>
</tbody>
</table>

Royal College of Dental Surgeons
6 Crescent Road
Toronto, ON M4W 1T1
phone: 416-961-6555
toll-free: 1-800-565-4591
fax: 416-961-5814 Attention: Complaints

RE: REQUEST AND CONSENT FOR INFORMATION

Dear Registrar,

I am a graduate student at the University of Toronto at the Faculty of Dentistry in the discipline of Dental Anaesthesia. I am writing you this letter to ask for your participation in a research project that I am currently conducting. This study is entitled “Mortality and Morbidity in Outpatient Deep Sedation and General Anaesthesia for Dentistry in Ontario”. It has been approved by the University of Toronto Research Ethics Board (ethics protocol # ____).

The purpose of this study is to determine the mortality rate associated with the administration of deep sedation and general anesthesia in the outpatient dental setting in the past twenty years (1996-2015). Furthermore, the study aims to determine the number and types of serious morbidity that have occurred within the same setting and time period. I hope to obtain elements of this data through cooperation with your organization.

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cooperation from your organization as Nkansah et al. did in 1997\(^1\). I have enclosed a copy of this previously published study for your review.


Your participation would entail forwarding the researchers any closed claims cases you have in your records where a patient suffered serious morbidity when the level of deep sedation or general anesthesia was administered in a dental office. Examples of serious morbidity are brain damage, permanent physical disability, myocardial infarction, or stroke. Once the data is in our possession, it will only be viewed by the researchers, and the cases will be assigned a case number. Working copies will have all patient and clinician identifiable information such as name and office address redacted prior to computer entry. Although files will be locked in a safe and secure cabinet at the Faculty of Dentistry, redacting identifiable data will further protect both patients and clinicians. Computer entry will be done in a secure environment at the Faculty of Dentistry. I appreciate that this is highly sensitive data, and it is not necessary to know neither patient nor clinician identity to analyze these cases. Once working copies have been recorded, all hard copies of records will be destroyed according to the university’s regulation on the disposal of confidential documents. We plan to disseminate the results by presenting our research at clinical conferences in the dental anaesthesia community as well as incorporating it into our teaching program at the Faculty of Dentistry. I would be more than happy to forward you a copy of the final results of the study.

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It would be a great pleasure to have your cooperation in this study that is of great importance to public safety, and we hope that you will kindly accept. **If you agree to participate, please sign this form and retain a copy for yourself. Please return the original form in the enclosed self-addressed stamped envelope.** Once I receive your response by mail, I will contact you directly regarding data collection procedures. Please do not hesitate to contact me if you have any questions.

Sincerely,
CONSENT ON BEHALF OF ORGANIZATION

I, ____________________________, understand the information presented about the study entitled “Mortality and Morbidity in Outpatient Deep Sedation and General Anaesthesia for Dentistry in Ontario” and agree to participate.

__________________________________  ____________________________
Signature of Participant               Date
APPENDIX C: Standardized Case Summary

Location of data review: RCDSO / Office of the Coroner
Type of File: PLP closed claim, RCDSCO complaint, RCDSO discipline, or Coroner Case

Patient Characteristics:
Age: _____  Sex: _____  Weight: ____, Height: ____, BMI: ____  ASA: _____

Existing Medical Conditions: ____________________________________________________
____________________________________________________________________________

Medications: _________________________________________________________________
_____________________________________________________________________________

Anaesthetic Record:
Personnel Present (Credentials): ________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________

Procedure: ___________________________________________________________________

Induction: ___________________________________________________________________

Airway management:
Nasal ETT  NPA
ETT  Shoulder Roll
Oral RAE  Nasal Hood

Monitors:
Pulse Oximeter (SpO₂)  Capnography (ETCO₂, RR)
Blood Pressure  3 Lead ECG
Thermometer  Spirometry (TV)
Airway Pressure
Maintenance:__________________________________________________________________

Emergence: ___________________________________________________________________

Critical incidents Encountered & Management:

•

•

•

•

Clinical Cues:

Severity of Injury Score (SIS)

• Temporary: Major (1) Brain damage, prolonged ICU stay

• Permanent:
  o Minor (2) Acute Kidney Injury, Nerve Damage,
  o Major (3) MI, CVA
  o Grave (4) Hypoxic Brain Damage, quadriplegia, lifelong care or critical prognosis

• Death (5)

Brief Summary of Case:

Reason for claim/ complaint/ discipline/ : __________________________________________

Did Claim move to litigation or settlement? _______________________________________
Dear Dr. [NAME]:

I am a graduate student at the University of Toronto at the Faculty of Dentistry in the discipline of Dental Anaesthesia. I am writing you this letter to ask for your participation in a research project that I am currently conducting. My study is entitled, “Mortality and Morbidity in Outpatient Deep Sedation and General Anaesthesia for Dentistry in Ontario”. The purpose of this study is to determine the mortality rate and the number and types of serious morbidity associated with the administration of deep sedation and general anesthesia in the outpatient dental setting in the past twenty years (1996-2015). It has been approved by the University of Toronto Research Ethics Board (ethics protocol # ____).

WHY ARE YOU BEING CONTACTED?

According to RCDSO records, you are registered to provide deep sedation/general anaesthesia services for Dentistry in Ontario. I need to estimate the number of anesthetics administered during this time period. I am contacting you to request that you provide information on the number of anaesthetics you administered for dental procedures from January 1, 2015 to December 31, 2015.

PARTICIPATION IS VOLUNTARY

A brief survey has been included in this package and we invite you to participate. Participation is voluntary, and you may decline to answer any of the questions that are a part of this survey.
By returning this survey to us, you will be providing your consent to be a part of the study. It should take you no longer than ___ minutes to complete the entire survey. We have provided a stamped and addressed envelope for you to return your completed survey.

**IS THIS CONFIDENTIAL?**

Yes. Your responses will be anonymous. It is not necessary to know your identity as a clinician. Your responses will be entered into a computer database in a secure environment at the Faculty of Dentistry and will only be reviewed by the researchers. Once working copies have been recorded, all hard copies of records will be destroyed according to the university’s regulation on the disposal of confidential documents.

**WHAT ARE THE BENEFITS OF THIS STUDY?**

There are no direct benefits to you from participating in this study. However, we hope that there may be some benefit to the patient-clinician relationship in the form of improved communication of anesthetic risk in the dental environment. Currently, our best estimate of risk is based on a 1997 study by Nkansah et al. performed two decades ago. The advent of new technologies and changes in anaesthetic technique may have improved safety. In addition, no data concerning serious morbidity in the Ontario patient population undergoing deep sedation or general anesthesia for dental treatment has been published. New information may aid our research team in identifying themes of practice that may lead to harm. We plan to disseminate the results by presenting our research at clinical conferences in the dental sedation community, with the hope that any findings may contribute to the prevention of future harm. If you are interested in a copy of our completed study, please contact me directly and I will be very happy to forward you a summary of our findings when available.

It would be a great pleasure to have your cooperation in the completion of this survey, and we hope that you will kindly accept. Thank you for your time, as it is only with your assistance that this research project can be successful. Please do not hesitate to contact me if you have any questions.

Sincerely,

Alia El-Mowafy, BDS

Enc. Survey
APPENDIX E: Survey Tool

1. Please check which of the following provider groups you belong to:
   □ Dental Anaesthesiologist
   □ Oral Maxillofacial Surgeon
   □ Medical Anaesthesiologist

2. In the 12-month period from January 1, 2015 – December 31, 2015, how many deep sedations/ general anaesthetics did you administer?

___________________________________________________________________

3. How did you calculate this number? (check one of the following options)
   □ Computer data from the whole year
   □ Computer data from a typical month, multiplied by 12
   □ Manual count of the whole year
   □ Manual count from a typical month, multiplied by 12.
   □ Other (please explain):

   ________________________________________________________________
   ________________________________________________________________

4. Since 1996, how many years have you been practicing anaesthesia in the out-patient dental setting?

   ________________________________
   ________________________________

Please place the completed questionnaire into the enclosed stamped and addressed envelope and return it by March 15, 2017. Please feel free to add any additional comments:

   ________________________________________________________________
   ________________________________________________________________
   ________________________________________________________________

Thank you for your time
APPENDIX F: Research Agreement with Office of the Chief Coroner of Ontario
DATA SHARING AGREEMENT

THIS AGREEMENT dated January 17, 2017 is made between:

HER MAJESTY THE QUEEN IN RIGHT OF THE PROVINCE OF ONTARIO
as represented by

The Minister of Community Safety and Correctional Services

(hereinafter referred to as the "Ministry")

– and –

University of Toronto
(hereinafter referred to as the "Researcher")

WHEREAS Alia El-Mowafy of the University of Toronto is the principal investigator for this research project;

AND WHEREAS the Researcher is interested in determining the mortality rate associated with the administration of deep sedation and general anesthesia in the outpatient dental setting;

AND WHEREAS the Researcher is interested in researching the incidence of such effects for the years 2001 to 2015, inclusive;

AND WHEREAS the purpose of the research is to determine the number and types of serious morbidity that have occurred within the study time period;

AND WHEREAS, in order to conduct their research, the Researcher has requested access to coroner investigation file records that are in the custody and under the control of the Ministry;

AND WHEREAS the Ministry wishes to share the information contained in the Records with the Researcher for the purposes of conducting the Study entitled "Mortality and Morbidity in Outpatient Deep Sedation and General Anaesthesia for Dentistry in Ontario;"

NOW THEREFORE the parties hereto understand and promise to abide by the following terms and conditions:

1. The parties hereto agree to comply with all applicable laws, regulations and guidelines.

2. The Researcher acknowledges that he/she will only have access to the Records on Ministry premises.

3. The Researcher undertakes not to seek or obtain copies of the Records made available by the Ministry.

4. The Researcher will not use the information in the Records for any purpose other than the following research purpose:
   - Determining the mortality rate associated with the administration of deep sedation and general anesthesia in the outpatient dental setting

5. The Researcher shall be responsible for management of the Study.

6. The Researcher undertakes not to give access to, use or disclose personal information, in a form in which the individual to whom it relates can be identified, to anyone. For greater certainty, personal information
shall have the same definition as in Section 2(1) of the Freedom of Information and Protection of Privacy Act, R.S.O. 1990, c. F.31, as may be amended from time to time.

7. Before disclosing personal information to any persons, the Researcher shall enter into a confidentiality agreement with those persons to ensure that they will not disclose the personal information to any other person. Any such agreement shall be approved with respect to form and content by the Ministry before being signed by such other person. The Researcher shall provide the Ministry with executed copies of all such agreements.

8. The Researcher agrees that the Ministry may, in its sole and absolute discretion, carry out security checks on any individuals who will have access to any personal information contemplated by this Agreement.

9. The Researcher shall hold the data obtained from the Records in secure storage. The Researcher shall destroy any and all individual identifiers in the information once the Study is completed. The Researcher shall notify the Ministry in writing upon the destruction of personal identifiers in the information obtained from the Ministry’s Records.

10. The Researcher agrees to provide the Ministry with a copy of the collected abstracted data, on a secure USB key, within ten (10) Business Days of collecting the data. For greater certainty, Business Day means any working day, Monday to Friday inclusive, but excluding statutory and other holidays, namely: New Year’s Day; Family Day; Good Friday; Easter Monday; Victoria Day; Canada Day; Civic Holiday; Labour Day; Thanksgiving Day; Remembrance Day; Christmas Day; Boxing Day and any other day which the Ministry has elected to be closed for business.

11. The Researcher shall provide the Ministry with interim reports, if any. In addition, the Researcher shall provide the Ministry with a copy of a draft final report, if any, for review and comment prior to the finalization of the report.

12. The Researcher shall discuss with the principal investigator the involvement of the member of the OCC or Ontario Forensic Pathology Services (OFPS) staff in a manner in keeping with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship (http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html).

The nature of the OCC/OFPS staff members’ participation as an author (or not) should be mutually agreed upon before the research is commenced. In certain research, the role may evolve, in which discussions regarding authorship should occur at the earliest time this evolution is recognized.

13. Upon review and discussion of the draft final report, if any, by the Ministry, the Researcher shall consider the representations of the Ministry and incorporate the Ministry’s comments prior to finalizing the final report. The Researcher shall provide a final report to the Ministry upon its completion and forward a copy of all publications arising from [abstract] data obtained from the Ministry.

14. The Researcher shall keep the information in a physically secure location to which access is given only to the Researcher. The Ministry reserves the right to inspect such location, during business hours, provided that the Ministry gives the Researcher twenty-four hours prior written notice of such inspection.

15. The Researcher shall not contact any individual to whom personal information relates, or the next of kin of such individual, directly or indirectly.

16. The Researcher agrees that any method of transportation of the data must be secure and is subject to the approval of the Ministry.
17. The Researcher agrees to indemnify the Ministry, its employees and agents, against all costs, losses, expenses and liabilities incurred as a result of a claim or proceedings related to this Agreement, unless it was caused by the negligence or willful act of an employee of the Ministry while acting within the scope of his or her employment duties. The Researcher further agrees to indemnify the Ministry, its employees and agents, against all costs, losses, expenses and liabilities incurred as a result of a claim or proceeding resulting from a breach of Copyright law.

18. Notices under this Agreement shall be in writing and sent by personal delivery, or by ordinary prepaid mail.

Notices to the parties shall be sent to the following addresses:

Ministry: Office of the Chief Coroner
(Branch) 25 Morton Shulman Avenue
Toronto, Ontario
M3M 0B1

Contact: Andrew Stephen

Principal Investigator: Alia El-Mowafy
Faculty of Dentistry, University of Toronto
Room 129, 124 Edward Street
Toronto, Ontario
M5G 1G6

19. The parties may designate in writing to each other a change of address at any time.

20. The parties shall notify each other in writing immediately upon becoming aware that any of the conditions set out in this Agreement have been breached.

21. This Agreement and the rights, obligations and relations of the parties shall be governed by and construed in accordance with the laws of the Province of Ontario and in particular the Freedom of Information and Protection of Privacy Act and the federal laws of Canada applicable herein. The parties do hereby attorn to the jurisdiction of the Courts of the Province of Ontario.

22. The parties agree that sections 4, 7, 8, 10, 13, 14, 16, 18, 21 and 22 shall survive termination of this Agreement.

Acknowledgement
Having read this Agreement, I hereby agree to act in accordance with all terms and conditions herein.

SIGNED 20th day of March, 2017
APPENDIX G: University of Toronto’s Health Science Research Ethics Board Approval

[Image of document]

We are writing to advise you that the Health Sciences Research Ethics Board (REB) has granted approval to the above-named research protocol under the REB’s delegated review process. Your protocol has been approved for a period of one year and ongoing research under this protocol must be renewed prior to the expiry date.

Any changes to the approved protocol or consent materials must be reviewed and approved through the amendment process prior to its implementation. Any adverse or unanticipated events in the research should be reported to the Research Oversight and Compliance Office - Human Research Ethics Program as soon as possible.

Please ensure that you submit an Ethics Renewal Form or a Study Completion/Closure Report 15 to 30 days prior to the expiry date of your current ethics approval. Note that ethics renewals for studies cannot be accepted more than 30 days prior to the date of expiry.

If your research is funded by a third party, please contact the assigned Research Funding Officer in Research Services to ensure that your funds are released.

Please note, all approved research studies are eligible for a routine Post-Approval Review (PAR) site visit. If chosen, you will receive a notification letter from our office. For information on PAR, please see http://www.research.utoronto.ca/wp-content/uploads/documents/2014/09/PAR-Program-Description-1.pdf.

Best wishes for the successful completion of your research.