STUDY OF PERI-OPERATIVE COMPLICATIONS IN PERSONS WITH DISABILITIES UNDERGOING DENTAL TREATMENT UNDER GENERAL ANESTHESIA AT THE MOUNT SINAI HOSPITAL

by

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

Faculty of Dentistry

University of Toronto

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ABSTRACT

This was a two part study. Part one was a retrospective chart review to ascertain the prevalence and predictors of peri-operative complications in PWD receiving their dental care under general anesthesia (GA). Part two was a prospective survey of parents/caregivers regarding their satisfaction with the service as well as to ascertain the prevalence of post-operative symptoms incurred by patients. In Part 1, the prevalence of complications in PWD was 4 times higher than the 6% stated in the literature for the general population. Time under GA, and no previous history of dental care under GA were significantly related to complications. In Part 2, 100% of patients experienced post-operative symptoms; nonetheless, 92.7% of parents/caregivers were satisfied with the service provided. The prevalence of complications in the PWD in this study was high. Prior to treatment under GA, adequate pre-operative medical evaluations must be completed and time under GA minimized.
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1.0 INTRODUCTION

Dental treatment under general anesthesia (GA) has historically been reserved for persons that have severe anxiety or a disability which precludes them from receiving their required dental care under local anesthesia (LA) (Nunn, Davidson, P, & Storrs, 1995). Very young children may also require dental treatment under GA since they are pre-cooperative (Nunn, Davidson, P, & Storrs, 1995). General anesthesia as defined by The American Society of Anesthesiologists is “a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation” (ASA, 2009). It is estimated that 5%-20% of persons with disabilities (PWD) will require dental treatment under GA over the course of their lifetime as a result of behavioural issues affecting their cooperation and/or their complex medical conditions (Malamed S., 1987; Millam, 1986; Park & Sigal, 2008).

As a group, PWD are more likely to have unmet dental treatment needs and higher incidences of untreated oral disease than the general population (Baens-Ferrer, Roseman, Dumas, & Haley, 2005; Waldman, Perlman, & Fenton, 2005). In a study by Tiller et al, higher untreated caries were found in PWD that lived in community care homes compared to those that lived in residential institutions (Tiller, Wilson, & Gallagher, 2001). Furthermore, PWD often require extensive dental treatment because of their sporadic or in some cases previously non-existent access to professional dental care (Waldman, Perlman, & Fenton, 2005). Due to their need for extensive treatment and serious patient management problems, PWD are often difficult to treat in a conventional dental clinic setting with LA only, thus leading to the recommendation that they be treated under GA (Ananthanarayan, Sigal, & Godlewski, 1998). It has been reported that the need for dental treatment under GA is increasing particularly in patients with severe behavioral disturbances (Maestre, 1996).

The administration of GA is not without risk. Peri-operative complications can occur during dental treatment under GA. Studies examining office based and ambulatory center anesthesia, reported that 65% of complications were intra-operative, 14% were during recovery, and 21% were after discharge (Domino, 2001). Dental and plastic surgery were the most common procedures performed under GA in the office based group (Domino, 2001). The mortality rate reported in the same study ranged from 1:40,000-1:100,000 (Domino, 2001; Messieha, 2009). In other studies, the prevalence of post-operative complications
following general anesthesia ranged from 6%-92% (Matsuura, Hirose, Joh, Sugiyama, Niwa, & Shibutani, 2000; Bridgman, Ashby, & Holloway, 1999).

PWD may have a higher prevalence of peri-operative complications as a result of their co-existing medical conditions (Enever, Nunn, & Sheehan, 2000). It is difficult to determine the true prevalence of complications reported by persons that have cognitive impairments since they may not be able to communicate pain and other peri-operative complications (Enever, Nunn, & Sheehan, 2000). For PWD who cannot communicate, post-operative complications are often reported based on observations made by recovery room nurses, other members of the health care team, or primary caregivers (Enever, Nunn, & Sheehan, 2000; Hung, Chen, Chau, & Tsai, 2005). Furthermore, a significant portion of the published literature that has examined peri-operative complications in PWD is confounded by the lack of control groups (Anders & Davis, 2010).

The lack of comparative studies with control groups in the population of PWD is due in part to the issue of withholding care or information which may be detrimental to the patient’s health and subsequently violate the code of ethics for clinical research (Hulland S., 1997). Therefore most studies have involved the use of comprehensive surveys for parents and/or caregivers of PWD to learn about conditions regarding dental treatment done under GA and also to assess caregiver satisfaction with the service. Parents and caregivers may be more proficient at detecting even slight changes in behaviour that could be a sign of pain thus making them an invaluable source of information in the study of PWD (Enever, Nunn, & Sheehan, 2000).

There are numerous factors that may affect the peri-operative outcomes of GA. However most of the literature pertains to individuals without disabilities. Current literature has demonstrated that the peri-operative complications are no different for patients with and without disabilities (Enever, Nunn, & Sheehan, 2000). Some of the parameters that have been examined as being related to peri-operative GA outcomes are: the anesthetic methods, types of dental treatment rendered, variations in discharge criteria, patient’s behaviour at induction, and the level and training of the recovery room staff (Enever, Nunn, & Sheehan, 2000; Atan, Ashley, Gilthorpe, Scheer, Mason, & Roberts, 2004). There are many factors that may contribute to adverse peri-operative events related to dental treatment under GA. There may be factors in a person’s medical profile that are related to, or predictive for
adverse events under GA. A number of factors may be related to peri-operative outcomes such as: a patient’s medications, anesthetic agents used, duration of GA, type of dental treatment rendered, and/or duration of stay in the recovery room.

1.1 Definition: Persons With Disabilities

According to the Ontario Human Rights Commission, a disability is defined as “physical, mental, and learning disabilities, mental disorders, hearing or vision disabilities, epilepsy, drug and alcohol dependencies, environmental sensitivities, as well as other conditions” (Commission, 2006). According to the aforementioned definition, a disability can be acute or chronic and has the ability to change over time. A person’s disability may or may not be visible. A visible disability is classified as a physical impairment which is tangible; a non-visible disability may be a learning or memory impairment that is not tangible (Koneru, 2008; Sigal M. J., 2010; Commission, 2006).

1.2 Types of Disabilities

Disabilities are either congenital, genetic, or acquired at any point during the course of one’s life due to an external source (Burtner, 1990; Jeng, Wang, Cher, & Lin, 2009). Congenital disabilities may be present before birth, at birth, or up to one month after birth regardless of the cause (Wikipedia, 2011). Genetic disorders are all congenital. They are a result of defects in genes and chromosomes and may be expressed later in life (Wikipedia, 2011). PWD may have physical or mental impairments that prohibit them from fully participating in daily self-maintenance activities and place substantial limitations on major life activities that would otherwise be considered age and developmentally appropriate (AAPD, 2008; Sigal M. J., 2010).

Congenital disabilities may include but are not limited to cognitive or developmental delays, developmental defects, cerebral palsy, Down syndrome and seizure disorder (Hulland S., 1997; Jeng, Wang, Cher, & Lin, 2009). Developmental disabilities are classified as impairments of tasks that are controlled by the brain (Sigal M. J., 2010). Developmental disabilities are defined as those causing functional limitations in 3 or more areas of life such as personal care, language, mobility, self-direction, and personal and economic self sufficiency (Sigal M. J., 2010).
Disabilities can be broken down into three broad categories: mental, physical, and medical (Hulland & Sigal, 2000). Persons with mental disabilities are termed as being developmentally delayed or cognitively impaired. The classification of a developmental delay is based on a person’s score on an Intelligence Quotient (I.Q.) test. A score below 70 which is used as a baseline, indicates a cognitive impairment. An I.Q. ranging from 50-69 is considered a mild delay, from 35-49 is considered a moderate delay, from 20-34 is considered a severe delay, and less than 20 is considered a profound delay (Owens, Dyer, & Mistry, 2010).

PWD may also present with coexisting medical conditions. Some of the most common conditions include: autism, thyroid disorder, diabetes mellitus, heart disease, respiratory disease, and neuromuscular disorders (Ananthanarayan, Sigal, & Godlewski, 1998; Jeng, Wang, Cher, & Lin, 2009; Boynes, Moore, Lewis, Zovko, & Close, 2010). Due to their coexisting medical conditions and an increase in the prevalence of disabilities amongst Canadians, it is important to consider the impact of their disabilities on perioperative complications.

1.3 The Prevalence of Disabilities in Canada

In 2006, 14.3% of the Canadian population had a disability, which represents an increase from 12.4% reported in 2001 (Statistics Canada, 2006). An increase in disabilities has been seen over the years as a result of an aging population, and due to a change in reporting behaviors (Statistics Canada, 2006). In 2006, the incidence of disabilities was 3.7% in children aged 0-14 years, 11.5% in adults aged 15-64 years, and 43.4% in adults over the age of 65 years (Statistics Canada, 2006). As defined by Statistics Canada, an adult is considered to be anyone 15 years of age or older. In 2006, 15.2% of adult females reported having an activity limitation compared to 13.4% of adult men (Statistics Canada, 2006). However the opposite was true for children aged 0-14 years, as 4.6% of boys had a limitation compared to 2.7% of girls (Statistics Canada, 2006). Over the age of 75 years, 57.8% of women reported a disability compared to 54.0% of men (Statistics Canada, 2006).

From 2001 to 2006, the number of PWD in Canada increased by 750,000 people or 21.2%, reaching 4.4 million people (Statistics Canada, 2006). Thus the Canadian national disability incidence rose from 12.4% in 2001 to 14.3% in 2006 (Statistics Canada, 2006).
Approximately 40.0% of this increase can be attributed to the aging population (Statistics Canada, 2006).

Disabilities vary in severity from mild, moderate, severe, to very severe. The severity of a given disability was measured using an index that was based on self-reported answers provided in the 2006 Census. The severity of a disability was based on the frequency and intensity of the activity limitation (Statistics Canada, 2006). Each type of disability was given a score, which was then standardized to a value between 0 and 1. The average scores of all disabilities were added to provide the final score. The final score was used to define the severity of one’s disabilities (Statistics Canada, 2006). All types of disabilities increased from 2001 to 2006 (Statistics Canada, 2006). In 2006, 26.6% of people reported a mild disability, 20.6% reported a moderate disability, 19.2% reported a severe disability and 16.4% reported a very severe disability (Statistics Canada, 2006). Social acceptance of disabilities may account for this increase in reporting (Statistics Canada, 2006).

Disabilities can be physical, intellectual or a combination of both (Statistics Canada, 2006). It is challenging to classify disabilities in children aged 0-4 years since they are constantly undergoing developmental changes (Statistics Canada, 2006). For children aged 0-4 years, five types of disabilities were reported by Statistics Canada including: visual, auditory, chronic health conditions, delay and other (Statistics Canada, 2006). In addition to those disabilities, children aged 5 and above also suffered from disabilities of speech, mobility, agility, learning, development, and psychological as reported by Statistics Canada in 2006.

The incidence of disability in children aged 0-4 years has not changed significantly from 2001-2006. Of the children aged 0-4 years that had at least one or more disability, almost 70.0% reported having a chronic health related condition, which accounted for 1.2% of all children under the age of 5 years (Statistics Canada, 2006). Chronic health conditions were defined as those that caused activity limitations (Statistics Canada, 2006). The most common chronic conditions reported were severe allergies, asthma, attention deficit disorder with or without hyperactivity (ADD/ADHD), and autism (Statistics Canada, 2006). Other conditions that were reported included cerebral palsy, migraines, complex medical care needs and heart conditions (Statistics Canada, 2006).
Of children aged 5-14 years that had at least one or more disability, almost 70% reported having a learning disability and 67.0% reported a chronic health condition (Statistics Canada, 2006). These conditions were more likely to affect boys than girls. Speech delays were reported in 45.0% of children aged 5-14 years, psychological disabilities in 34.5%, developmental delays in 31.0%, and agility related disabilities in 21.3% (Statistics Canada, 2006). The incidence of disability in children aged 5-14 years increased from 4.0% in 2001 to 4.6% in 2006, mostly due to an increase in learning disabilities (Figures 1 and 2) (Statistics Canada, 2006).

Figure 1. Types of Disabilities Among Children Aged 5-14 Years, by Sex in Canada 2006

Types of disabilities among children with disabilities aged 5 to 14 years, by sex, Canada, 2006

In 2006, almost half of all children with disabilities under the age of 5 years reported one disability, with just over 40% reporting two disabilities, and less than 9% reporting three or more disabilities (Statistics Canada, 2006). Of children with disabilities aged 5-14 years, almost 75% had multiple disabilities and 26.3% had a single disability (Statistics Canada, 2006). Amongst those that reported multiple disabilities, 36.5% had 2 to 3 disabilities, 26.2% had 4 to 5 disabilities, and 11.1% had six or more disabilities (Statistics Canada, 2006). Children with an increased number of disabilities were more likely to have severe disabilities (Statistics Canada, 2006).

In 2006, 202,350 children aged 0-14 years reported having disabilities, of which almost 59% had a mild to moderate disability, and 41.7% reported having a severe to very severe disability (Statistics Canada, 2006). Of children with disabilities aged 0-4 years, 63.5% reported having a mild to moderate disability (Statistics Canada, 2006). Of children aged 5-14 years, 33.5% reported having a mild disability, 24.0% reported having a moderate disability, 23.6% reported having a severe disability, and 18.9% reported having a very severe disability (Statistics Canada, 2006).
The most common disabilities reported in adults aged 15 years and above were related to pain, mobility, and agility (Statistics Canada, 2006). In 2006 almost 3 million Canadians, or 11% of the population over the age of 15 years reported at least one of the above disabilities, with 70.0% of these respondents experiencing all three of the above disabilities (Statistics Canada, 2006). Women were more likely to have disabilities relating to pain, mobility, and agility and the incidence increased with age (Statistics Canada, 2006). Other disabilities reported in individuals aged 15 years and over included: auditory, visual, speech, learning, memory, developmental disabilities, memory, psychological and other (Statistics Canada, 2006). Auditory, visual and speech disabilities can be grouped together into a sensory disorder group (Statistics Canada, 2006). In 2006, 1,265,000 adults or 5.0% of the population reported having an auditory disability, 815,000 or 3.2% of the population reported a visual disability, and about 480,000 or 1.9% reported a speech disability (Statistics Canada, 2006). The incidence of sensory disabilities was similar in adult men and women, except that women were more likely to suffer from a sensory disability after the age 65 years (Statistics Canada, 2006).

It has been noted that Canadians have been reporting disabilities that are less visible and thus harder to recognize (Statistics Canada, 2006). Psychological problems, memory loss, learning difficulties, and developmental disabilities are less visible disabilities (Statistics Canada, 2006). These disabilities are a challenge to measure and are reported based on an individual’s subjective perception (Statistics Canada, 2006). In 2006, 500,000 Canadians over the age of 15 years reported emotional, psychological/psychiatric, memory, confusion, and learning disabilities (Statistics Canada, 2006). Overall, the incidence of most disabilities increased with age, particularly after age 65 years, namely disabilities associated with mobility, agility, hearing, seeing, pain, memory loss, and speech (Statistics Canada, 2006). All disabilities did not increase with age (Statistics Canada, 2006). Disabilities that were emotional, psychological, or psychiatric in nature were at their highest at 3.3% between the ages of 45 to 64 years, but after the age of 75 years the incidence dropped to 2.1%. The prevalence of learning disabilities was stable across all age groups however there was a reported increase in prevalence from 14.6% in 2001 to 16.5% in 2006 (Statistics Canada, 2006). The prevalence of developmental disabilities decreased with age, however this may be because Census surveys have not included citizens who live in institutions (Statistics Canada, 2006).
Due to the de-institutionalization that has occurred in Canada over the past thirty years, more young people with developmental disabilities may be living at home and thus may be accounted for in the Census (Statistics Canada, 2006).

With regard to Canadian adults with disabilities, in 2006 18.4% suffered from a single disability, 16.9% with two disabilities, 27.9% with three disabilities, 28.9% with four or five disabilities, and 8.0% suffered six or more disabilities (Statistics Canada, 2006). Thus 81.7% of the population with disabilities had more than one disability or co morbid condition (Statistics Canada, 2006).

Classifying the severity of a disability is dependent on the effect it has on daily life. As discussed before, the severity of a disability can range from mild, to very severe (Statistics Canada, 2006). The severity is dependent on the regularity and amount of the limitation caused by a single or multiple disabilities on the activities of daily living (ADL) (Statistics Canada, 2006). In 2006, 35.4 % of the population with disabilities reported that they experienced mild limitations, 24.8% reported moderate limitations, 26.3% reported severe limitations, and 13.5 % reported very severe limitations in ADL (Statistics Canada, 2006).

Pain and/or discomfort were noted as being the most common cause of limitations on ADL in working aged PWD, and occurred in almost 75.0% of individuals surveyed (Statistics Canada, 2006). The pain was either of a chronic nature in 72.1% of the individuals, or of a cyclical nature in 27.9% of people (Statistics Canada, 2006). Working aged women were more likely to report pain and/or discomfort as the cause of limitations of activity with an incidence of 79.0%, compared to 69.3% of the working age males (Statistics Canada, 2006). Under the age of 65 years, pain and discomfort were the most common cause of limitations of activity, affecting 74.4% of people surveyed (Statistics Canada, 2006). Over the age of 65 years, mobility was the most common cause of limitation of activity, affecting 76.4% of PWD surveyed (Statistics Canada, 2006).

The incidence of disabilities increases with age, particularly after the age of 65 years. Females are more likely than males to have a disability in most age groups. The more disabilities one has, the more severe they are likely to be. Older individuals are more likely to have severe disabilities.
1.4 The Prevalence of Disabilities in Ontario

In 2006, 15.4% of the population or 1.8 million people in Ontario had a disability, compared to 13.5% in 2001 (Statistics Canada, 2006). In Ontario, the most commonly reported disabilities related to pain (10.9%), mobility (10.5%), and agility (10.3%) (Statistics Canada, 2006). Of women over the age of 65 years, 37.2% reported a mobility limitation, compared to 28.1% of men (Statistics Canada, 2006).

1.5 Oral Health Care Needs in Persons With Disabilities

Historically, PWD have been shown to have poorer oral health than people without disabilities (Desai, Messer, & Calache, 2001; Hulland & Sigal, 2000; Vazquez, Garcillan, Rioboo, & Bratos, 2002; Anders & Davis, 2010). PWD often present with poor oral hygiene, gingival disease, periodontal disease at various stages, defects of tooth enamel, untreated caries, increased traumatic injuries to the teeth and mouth, and an increased need for extractions (Hulland & Sigal, 2000; Cumella, Ransford, Lyons, & Burnham, 2000; Vazquez, Garcillan, Rioboo, & Bratos, 2002). Caries rates in PWD are reportedly the same or lower than in people without disabilities (Anders & Davis, 2010). PWD had fewer filled teeth when compared to carious and missing teeth, which was interpreted to mean that when treatment was rendered, it was often in the form of extractions (Anders & Davis, 2010). The inability of PWD to cooperate during dental treatment has played a significant role in tooth loss and the need for extractions (Anders & Davis, 2010). People that are unable to cooperate, may be more likely to have poor oral hygiene and thus less likely to tolerate simple preventive and restorative procedures (Anders & Davis, 2010). As a result, these individuals may more commonly have teeth extracted (Anders & Davis, 2010). In addition to the significant oral findings, PWD are often affected with oro-facial functional difficulties related to speech, swallowing, and mastication (Allison, Hennequin, & Faulks, 2000). Furthermore, PWD had a greater amount of unmet dental treatment needs relative to the general population (Hennequin, Faulks, & Roux, 2000; Hulland & Sigal, 2000; Vazquez, Garcillan, Rioboo, & Bratos, 2002; Desai, Messer, & Calache, 2001; Anders & Davis, 2010). Unfortunately the majority of the data related to the oral health disease status in PWD was specific to the United-States and was reported by parents and/or caregivers thus making it difficult to make generalizations (Koneru, 2008; Crall, 2007).
PWD may not be able to articulate pain or discomfort (Cumella, Ransford, Lyons, & Burnham, 2000). Parents and/or caregivers have reported difficulty in assessing these parameters, further contributing to the unmet dental needs in this population (Cumella, Ransford, Lyons, & Burnham, 2000; Hennequin, Faulks, & Roux, 2000). It is recognized that parents and caregivers play a critical role in fostering a relationship between the dentist and patient. The positive and/or negative views of parents and caregivers concerning oral health related issues can have an impact on the person’s oral health (Cumella, Ransford, Lyons, & Burnham, 2000; Anders & Davis, 2010). Thus, the parental and caregiver knowledge, attitudes and practices regarding oral health can have a profound effect on the individual (Cumella, Ransford, Lyons, & Burnham, 2000; Anders & Davis, 2010).

Identified barriers to obtaining and maintaining an acceptable level of oral hygiene in PWD include the lack of assistance and supervision from primary caregivers, negative or indifferent caregiver attitudes towards oral health, increased concern about the disability rather than oral health, and the lack of dentists willing to treat individuals with special needs (Desai, Messer, & Calache, 2001). A study done by Desai et al in 2001, found that Australian children with disabilities that required daily assistance for toothbrushing had poorer oral hygiene and higher levels of periodontal disease than those children with disabilities that could brush their own teeth. This may be explained by the caregivers unwillingness to provide oral hygiene. Some caregivers reported that they felt fear and disliked the act of toothbrushing for the person with disabilities (Cumella, Ransford, Lyons, & Burnham, 2000). A study reported that very few parents and/or caregivers of PWD had received any formal training regarding oral care and home support, and would welcome such information (Cumella, Ransford, Lyons, & Burnham, 2000).

Another challenge in providing dental care to PWD is related to their inability to cooperate which can result in a greater amount of unmet dental treatment needs (Hennequin, Faulks, & Roux, 2000; Hulland & Sigal, 2000; Desai, Messer, & Calache, 2001). For example, PWD may have limited manual dexterity, poor physical coordination, and altered cognition, all of which would impact their ability to perform the tasks of daily living such as toothbrushing (Anders & Davis, 2010). Furthermore, these limitations would hinder performing an accurate initial clinical and radiographic oral exam, thus making it difficult to
diagnose and assess the individual’s comprehensive dental treatment needs (Hulland & Sigal, 2000).

1.6 Access To Dental Care For Persons With Disabilities

Access to dental care for PWD has historically been limited and difficult to obtain. A disparity has been noted amongst different studies as to how simple or difficult it has been for PWD to receive dental care (Koneru, 2008). Some studies have reported that over 50% of PWD have experienced difficulty in accessing dental care (Koneru, 2008; Finger & Jedrychowski, 1989). While other studies have reported minimal difficulty in accessing dental care, with up to 80% of PWD being able to access care (Koneru, 2008; Burtner, 1990; Bourke & Jago, 1983).

Access to dental care is influenced by many external and internal factors (Koneru, 2008). External factors are those that are not directly related to the individual such as cost, physical barriers to the clinic, or to any facility capable of offering treatment such as a hospital, transportation issues, and practitioner related factors (Koneru, 2008). Internal factors are those that are related to the individual, such as anxiety level about dental treatment, indifference about dental care, inability to tolerate dental treatment, and difficulty or inability in communicating pain (Koneru, 2008). Typically, it was the intrinsic factors that led to the greatest disparity in access to dental care for PWD (Koneru, 2008). In summary, access to dental care for PWD is related to physical, financial, and sociological factors.

For many PWD, their functional limitations, or extrinsic factors have been shown to prohibit them from receiving routine dental care in an environment that is not adequately equipped with the knowledge or staff to treat such patients leading to further fear and anxiety from a patient’s perspective (Desai, Messer, & Calache, 2001). Finances were identified as being another extrinsic factor that would influence access to dental care (Koneru, 2008). A survey of dentists has shown that many do not treat PWD since they do not receive payment that compensates them for the additional time and energy that is required to treat PWD (Burtner, 1990). In Ontario, dental treatment for PWD is funded by government–sponsored plans that pay approximately 60% of the current suggested fee guide for general dentists, which does not even cover office overhead expenses (Sigal M. J., 2010). Factors that have been shown to contribute to this lack of access are dentist’s lack of knowledge and skill in treating individuals with special needs, and the view that non-conventional equipment and
facilities are required (Sigal M. J., 2010). A study reported that a dentist’s willingness to treat PWD was related to whether or not they had previous experience treating PWD (Stiefel, Shaffer, & Bigelow, 1981). Other studies have demonstrated a positive correlation between dental students’ didactic and clinical exposure to PWD and their comfort level in treating these patients in private practice (Sigal M. J., 2010; Waldman, Perlman, & Fenton, 2005; Wolff, Waldman, Milano, & Perlman, 2004). Unfortunately there are very few undergraduate dental programs within North America that have provided their students with both didactic and clinical experience in dealing with PWD (Sigal M. J., 2010; Wolff, Waldman, Milano, & Perlman, 2004).

1.7 Treatment Options For Dental Care Delivery To Persons With Disabilities

PWD may not be able to receive dental treatment in a conventional manner and thus would require additional support systems and treatment strategies to provide their care. When assessing the ability of PWD to withstand and tolerate dental treatment, their functional and cognitive abilities may play a greater role than their medical diagnosis in the decision making process (Desai, Messer, & Calache, 2001). Moreover, the patient’s behavioral assessment in the dental clinic is the primary determinant of the type of behavior management strategies that will be offered (Hulland & Sigal, 2000).

Several factors must be considered prior to deciding on the best treatment option for an individual with a disability. Regarding PWD, and whether treatment should be done under LA, oral sedation or GA, there are many factors that must be assessed: cognitive impairments, fear of dental treatment, inability to sit in the dental chair, extent of treatment needs, difficulty of procedures that can not be easily performed under LA, complex coexisting medical conditions that require peri-operative monitoring, and the presence of complex health care needs that would be better physiologically managed under GA (Glassman, et al., 2009). Additional factors that must also be considered are the urgency of care, risks and benefits of all options, cost, treatment time, effort for patient and provider, success rate of each option, and the availability of support systems for the patient (Glassman, et al., 2009). The potential long term cumulative risk of all treatments must be considered in the decision making process (Glassman, et al., 2009).
Conventionally, dental treatment is provided with LA. If treatment with LA is not possible due to physical, cognitive, medical, and cooperation issues, then alternative options must be explored. Alternative options include both non-pharmacological and pharmacological methods to control behavior such as: treatment with LA and protective stabilization, sedation with nitrous oxide, oral or intravenous agents, and finally GA. With consent, protective stabilization used on a child to facilitate dental treatment in the face of uncooperative behavior is feasible due to the size and strength differential between children and adults (Dougherty, 2009). However in the adult with disabilities, protective stabilization may be impossible and pose a danger to the patient and to the operator (Dougherty, 2009). It has been suggested that parents and caregivers may be less likely to consent to treatment that involves physical and pharmacological restraint due to the perception that it may not be socially acceptable (Park & Sigal, 2008). Nitrous oxide is known to be beneficial in providing anxiolysis however it requires patient acceptance of the nasal hood as well as an understanding that in order for the drug to produce its intended effect, it is essential for the patient to be able to take slow deep breaths through their nose (Dougherty, 2009). For these reasons, if a patient is extremely anxious and fearful, nitrous oxide is usually not successful (Dougherty, 2009)

It is documented that there are various levels of conscious sedation ranging from minimal to deep sedation. Minimal sedation causes a minimally depressed level of consciousness, produced by pharmacological agents. The patient must be able to maintain their airway and protective reflexes, and respond normally to tactile stimulation or verbal commands. Cognitive function may temporarily be affected, however cardiovascular and respiratory functions remain intact. Moderate sedation is defined as a drug induced state that affects consciousness, however the individual must be able to maintain an airway. Patients may respond to purposeful tactile and verbal commands. In patients undergoing moderate sedation, spontaneous ventilation is adequate, and cardiovascular function is usually intact (Glassman, et al., 2009; ASA, 2009). Deep sedation causes depressed consciousness from which it is difficult to arouse a patient, however they will respond non-purposefully to painful stimulation (Glassman, et al., 2009; ASA, 2009). Under deep sedation, the individual may not be able to independently maintain their airway thus ventilation may need to be assisted (Glassman, et al., 2009; ASA, 2009). In patients undergoing deep sedation,
cardiovascular function is usually intact (Glassman, et al., 2009; ASA, 2009). Nevertheless, conscious sedation is used infrequently for PWD, since the outcome is unpredictable for persons with cognitive impairments (Ghezzi, Chavez, & Ship, 2000; Park & Sigal, 2008). Oral and intramuscular sedative agents cannot be titrated resulting in sedation levels deeper than intended, thus placing the patient at risk of airway compromise (Park & Sigal, 2008). Furthermore these agents are known to cause idiosyncratic responses in PWD, with initial hyperactivity, followed by sedation (Ghezzi, Chavez, & Ship, 2000; Park & Sigal, 2008). Intravenous sedation is titratable, however in PWD, it may be difficult or impossible to safely obtain an intravenous line without the use of considerable physical restraint or pre-medication (Park & Sigal, 2008).

General anesthesia is a pharmacologically induced state, which causes a loss of consciousness from which the individual is not arousable via painful stimulation (Glassman, et al., 2009; ASA, 2009). The patient cannot maintain their airway and ventilatory support is usually required (Glassman, et al., 2009; ASA, 2009). Cardiovascular function may also be impaired (Glassman, et al., 2009; ASA, 2009). Thus, dentists treating patients under GA must do so in either an accredited private facility or in a hospital setting. According to Malamed, GA should be reserved for: individuals with extreme anxiety and fear, traumatic procedures, young age, mental or cognitive impairment, and disorientation (Malamed S. E., 2003). PWD who require a significant volume of dental treatment may be referred for treatment under GA, however this factor alone is not universally accepted as being the sole indicator for treatment under GA. In addition, referral for dental treatment under GA is related to the dentist’s perception of the patient’s ability to cooperate (Prabhu, 2008). It is estimated that 5% of the PWD will require dental care under GA during the course of their lives (Ananthanarayan, Sigal, & Godlewski, 1998). GA for general dentistry is known to be available in some hospitals as well as private facilities and clinics (Glassman, et al., 2009). Of all treatment options, GA has the highest reported success rates for the completion of planned treatment, the highest cost, the most risk, and lowest availability (Glassman, et al., 2009). GA for dentistry is not available in all communities and hospitals. When operating rooms for dentistry were available, there were stringent time restrictions, which also lead to increased wait times. Many dentists and physicians are reluctant to provide dental treatment
under GA in a private office or facility due to the inherent costs involved, thus it is sometimes reserved as an option of last choice (Glassman, et al., 2009; Dougherty, 2009).

Prior to proceeding to treatment under GA, a discussion of the advantages and disadvantages must be undertaken with the patient and/or primary caregiver. The advantages of GA reported in the literature are the following:

- patient cooperation is not necessary except for induction to a degree
- rapid onset of anesthesia
- titration of drugs
  - drugs are reversible or have a very short half-life
- patient is unconscious during the treatment
- the patient does not respond to painful stimuli

For the individual with a disability who is unable to cooperate for dental treatment in a clinic setting, the provision of treatment under GA will allow the dentist to do a thorough clinical and radiographic assessment and thus establish a definitive baseline for their oral health (Hulland & Sigal, 2000). The information collected during dental treatment under GA would also be beneficial in developing the long term treatment goals for the patient (Hulland & Sigal, 2000). The disadvantages of dental treatment under GA include the following:

- the patient is unconscious
- specialized training is required to administer GA
- a team approach is required, specialized equipment is necessary
- a recovery area is needed for post-operative monitoring
- greater potential morbidity and mortality than LA
- patients must strictly adhere to fasting guidelines pre-operatively
- patients undergoing GA often require thorough pre-operative evaluations prior to being approved for treatment (Dougherty, 2009)

Dental treatment under GA is usually considered as the option of last resort as it carries with it the most risk, for this reason, alternative behavior management methods are usually attempted first whenever possible before recommending treatment under GA (Dougherty, 2009).

There have been few studies done that have examined the appropriate frequency interval at which repeat treatment under GA should be done for individuals that have a
history of poor cooperation and are unable to obtain treatment in a conventional clinic setting (Dougherty, 2009). It has been estimated that once a patient has received their initial dental treatment under GA, between 4-12% of these individuals will need to return for additional treatment within 5 years (Hulland & Sigal, 2000). This would be dependent on the severity of oral disease and level of oral hygiene. Some individuals may require annual sessions under GA due to poor cooperativity for the treatment of severe periodontal disease, trauma, dental abscesses and other infections (Sigal M., 2010; Hulland & Sigal, 2000; Park & Sigal, 2008).

1.8 The Role of Hospital Based Dental Programs in Delivering Oral Health Care to Persons With Disabilities

All individuals should have the right to access dental care required to maintain their oral health, since it is considered an important part of their overall health (Sigal M. J., 2010). Furthermore, the right to access universal health care must include dental care (Hulland & Sigal, 2000). Hospital based dental programs have played a vital role in the treatment of PWD that are unable to receive their dental care in the community (Park & Sigal, 2008). For persons with severe disabilities, referral is made to centers where there are staff who are experienced and capable of dealing with the sequelae that may arise when treating persons with cognitive, physical and medical impairments (Prabhu 2008). Hospital dental departments, where they exist are ideal locations for the management of persons that have many medical comorbidities, and/or unstable health as there are critical care facilities and staff at the site that are equipped to handle any untoward medical events that may occur (Prabhu, Nunn, Evans, & Girdler, 2008). In summary, PWD can be treated in community dental clinic setting however they are often referred to hospital based dental programs for treatment due to their inability to cooperate in a conventional clinic setting and for the management of their complex medical conditions (Park & Sigal, 2008; Waldman, Perlman, & Fenton, 2005).

Hospital based dental programs can offer different modalities of behavior management such as treatment under LA, sedation, and GA, alone or in combination. Hospital based dental programs provide rapid access for necessary medical consultations as well as treatment under GA should it be required for dental treatment (Hulland & Sigal,
Both in-patient and out-patient services are available depending on the nature of the patient’s medical conditions (Hulland & Sigal, 2000).

Many PWD are treated under GA for their required dental treatment. The administration of GA to PWD that are cognitively impaired is a challenge, as this group of individuals often presents with increased fear and anxiety related to novel stimuli and the separation from parents and caregivers as well as from their familiar surroundings (Ananthanarayan, Sigal, & Godlewski, 1998). These challenges make pre-operative examination and assessment difficult and this could contribute to peri-operative complications. For PWD that have complex medical conditions, another advantage of having dental treatment under GA in a hospital setting is the access to, and availability of non-dental procedures and tests that can be performed intra-operatively if necessary (Park & Sigal, 2008). Individuals who are not able to cooperate for routine dental care for a variety of reasons, are also unable to cooperate for routine evaluations by other health care providers (Ghezzi, Chavez, & Ship, 2000). Non-dental tests that persons with cognitive impairments may have difficulty with include: blood work, PAP smears, electrocardiograms, medical imaging and other potentially invasive procedures (Park & Sigal, 2008).

1.9 American Society of Anesthesiologists (ASA) Physical Status Classification System

The ASA physical status classification was adopted by the ASA in 1963 to classify a patient’s risk prior to surgery and the administration of an anesthetic (Morgan, Mikhail, & Murray, 2006). The ASA classification originally contained five categories however a sixth was added at a later date. The ASA classification is as follows:
### ASA Classification and Description

<table>
<thead>
<tr>
<th>ASA Classification</th>
<th>Description</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 that affects activities of daily living</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 moribund patient who is not expected to survive 24 hours 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>

There are inherent limitations noted with the ASA Classification system. The classification system assumed that a person's physical status and age are related. There are discrepancies in the way that physicians use the ASA classification to assess a patient’s physical status thus the system is not considered to be objective or reliable (Haynes & Lawler, 1995; Prabhu, Nunn, Evans, & Girdler, 2008). Furthermore, the classification system accounts for systemic disease states but does not account for malignancies. The grading system is universally accepted in medical facilities as a way to convey the patient’s medical status (Prabhu, Nunn, Evans, & Girdler, 2008).

It has been observed that an increased ASA status has been related to an increased incidence of complications in the post anesthetic care unit (PACU) (Hines, Barash, Watrous, & O'Connor, 1992). Many patients with ASA classifications of II and III may have significant cognitive impairments that prevent a thorough pre-operative examination and assessment of the airway thus leading to a greater risk of peri-operative complications (Rodriguez, Garcia-Miguel, Cayetano, Peces, Garcia, & Rodriguez, 2008). ASA status alone cannot be the only factor considered when planning patient management (Glassman, et al., 2009). Hospital dental departments typically treat patients under GA that are classified as ASA II to ASA IV due to their limited cooperativity and existing comorbidities (Prabhu 2008). When considering dental treatment under GA for patients that are classified as ASA
IV, extensive pre-operative evaluation must be done which must also include an assessment of the risks versus benefits of treatment versus no treatment since they are at an increased risk of suffering intra-operative morbidity and mortality while under GA (Glassman, et al., 2009; Ghezzi, Chavez, & Ship, 2000; Messieha, 2009). Pre-operative evaluations and discussions must occur between the patient’s primary care provider, medical staff and the family, since individuals with higher ASA classifications carry with them a higher risk of peri-operative complications (Glassman, et al., 2009; Craig & Kitson, 2010).

1.10 Complications and Risks Associated With GA in Patients With and Without Disabilities

In non-verbal PWD, it may be difficult to ascertain a chief complaint or an accurate history of their previous and present condition (Weaver, 1995). It is often the parents and caregivers who report the patient’s past and current medical history. Their reports, however, are often inaccurate particularly if the patient is or has been institutionalized (Park & Sigal, 2008). Parents and caregivers will often seek a dental assessment if they have noticed changes in eating habits or other activities of daily living (ADL) that would be affected by suspected oral pain (Weaver, 1995; Hennequin, Faulks, & Roux, 2000).

When PWD present to a dental clinic, a thorough clinical and radiographic exam may not be possible due to lack of cooperation. This may be attributable to fear, anxiety, failure to understand the implications of the examination, and their physical limitations (Ghezzi, Chavez, & Ship, 2000). If a patient is unable to safely tolerate dental treatment in a conventional clinic setting under LA, then treatment under GA should be considered (Ghezzi, Chavez, & Ship, 2000). The findings on clinical exam as well as extensive medical comorbidities may also suggest a need for a GA (Ghezzi, Chavez, & Ship, 2000).

Once the decision to treat a PWD under GA is made, the risks and the benefits of treatment are discussed with parents or the consent provider (Ghezzi, Chavez, & Ship, 2000). Patients undergoing a GA are required to obtain a pre-operative medical evaluation with a complete history and physical exam to determine if they are medically fit for a GA (Ghezzi, Chavez, & Ship, 2000). The preoperative medical assessments should be done within 30 days of the scheduled GA date to reflect their current health status (Ghezzi, Chavez, & Ship, 2000). In many instances, individuals who have difficulty cooperating for dental treatment, will also have difficulty cooperating for medical examinations and/or diagnostic tests.
Lack of patient cooperation may result in a compromised pre-operative assessment. Therefore, it may be difficult to fully determine anesthetic risk due to incomplete records and evaluations (Ghezzi, Chavez, & Ship, 2000; Messieha, 2009; Boynes, Moore, Lewis, Zovko, & Close, 2010). An incomplete pre-surgical work-up may increase the likelihood of suffering an adverse event while under GA (Messieha, 2009).

The study of peri-operative complications is challenging. There are few studies that compare peri-operative complications in PWD to those without. The cognitive impairment in PWD may result in an under-reporting of post-operative symptoms. As a result, this patient population has historically been excluded from participating in many clinical research studies (Voepel-Lewis, Merkel, Tait, Trzcinka, & Malviya, 2002). Due to an inability of some PWD to report or quantify their symptoms, adverse peri-operative events for PWD are sometimes based on observations made by the PACU nurses and other members of the health care team (Voepel-Lewis, Merkel, Tait, Trzcinka, & Malviya, 2002; Hung, Chen, Chau, & Tsai, 2005). Many symptoms such as dizziness, headache, nausea and headache may go unnoticed by a third party observer (Hung, Chen, Chau, & Tsai, 2005).

To determine the prevalence of symptoms in PWD, it is important to survey parents and/or the primary caregivers as the person with a disability may not be able to communicate their own symptoms. Hosey et al in 2006 showed that parents of children that were cognitively intact who underwent GA for dental extraction, over-reported their child’s anxiety level relative to the child’s own rating (Hosey, Machpherson, Adair, Tochel, Burnside, & Pine, 2006). Proxy reporting should thus be interpreted with caution.

Surveys should be filled out as soon as possible. When asked to recall symptoms or complications around the time of an operation, individuals that have been interviewed or surveyed well after their surgery have poor recall. It would therefore, be ideal to conduct interviews or surveys within the first two post-operative weeks (Grover, Berkowitz, & Lewis, 1994).

Complications relating to treatment under GA can occur both intra and post-operatively. Studies have shown that there is a higher risk of complication upon emergence from anesthesia and following extubation (Rassam, Thomas, Vaughan, & Hall, 1995; Asai,
Koga, & Vaughan, 1998). The complications associated with dental treatment under GA may include the following:

- pain
- nausea
- vomiting
- sore throat
- fever
- headache
- dizziness
- behavior changes upon emergence
- prolonged sedation
- change in vital signs
- hypoxia
- bleeding

Most complications occur within the first 24-72 hours following surgery (Farsi, Ba'akdah, Boker, & Almushayt, 2009).

Pain is typically a subjectively reported complaint (Needleman, Harpavat, Wu, Allred, & Berde, 2008; Merkel, Voepel-Lewis, Shayevitz, & Malviya, 1997; Voepel-Lewis, Merkel, Tait, Trzcinka, & Malviya, 2002). In children and persons with cognitive impairments, prompt and accurate reporting of pain may be difficult (Merkel, Voepel-Lewis, Shayevitz, & Malviya, 1997; Voepel-Lewis, Merkel, Tait, Trzcinka, & Malviya, 2002). One study suggested that crying, body posture, and mobility were reliable and valid indicators of pain in infants, young children, and adults with cognitive impairments (Merkel, Voepel-Lewis, Shayevitz, & Malviya, 1997; Voepel-Lewis, Merkel, Tait, Trzcinka, & Malviya, 2002). Some commonly observed behaviors in response to pain are vocal expressions, non-
cooperation, irritability, facial expressions such as squinting of the eyes or frowning, reduced activity, flexion posturing of the head, movement or flinching, and a change in muscle tone (Voepel-Lewis, Merkel, Tait, Trzcinka, & Malviya, 2002). In persons with physical disabilities, assessing pain by means of increased muscle tone and body positioning may be less reliable (Voepel-Lewis, Merkel, Tait, Trzcinka, & Malviya, 2002). Unfortunately, there is no gold standard behavior assessment tool for PWD and there are very few that are reliable and valid (Voepel-Lewis, Merkel, Tait, Trzcinka, & Malviya, 2002).

Despite all the limitations in accurately reporting pain, it is still important for practitioners and caregivers to be able to assess and classify pain for PWD (Voepel-Lewis, Merkel, Tait, Trzcinka, & Malviya, 2002). The visual analogue scale (VAS) may be a more objective way of interpreting symptoms and complications in PWD. The VAS is an instrument that measures a given characteristic or attitude on a continuum (Gould, 2001). Typically, this is done by asking a subject to place a check mark on a line measuring 10 cm (Gould, 2001). Each end of the line is “anchored” by a verbal description associated with an extreme end of a spectrum. An example would be extreme pain or no pain. The VAS has been used to study many subjective phenomena that are not easily quantifiable (Gould, 2001). It can be used by individuals to describe symptoms or change in behavior over time, which is helpful for healthcare providers since it allows for quantification of subjective data (Chapman, Casey, Dubner, Foley, Gracely, & Reading, 1985; Gould, 2001).

Nausea and vomiting may occur following a GA as a side effect of anesthetic drugs, as a result of ingesting blood after dental procedures, and as a result of anxiety (Enger & Mourino, 1985; Matsuura, Hirose, Joh, Sugiyama, Niwa, & Shibutani, 2000). In a study by Sinclair et al in 1999, it was found that the highest prevalence of nausea and vomiting was seen after ENT, dental, plastic and orthopedic surgeries (Sinclair, Chung, & Mezei, 1999). They also found that the prevalence of nausea and vomiting decreased with the patient’s age in years.

Sore throat and pharyngitis have been shown to occur as a result of trauma upon intubation, prolonged intra-operative coughing on the endotracheal tube (ETT), using an oversized ETT, overinflation of the cuff on the tube, and aggressive intra and post-operative pharyngeal suctioning (Enger & Mourino, 1985). During dental treatment under GA, nasal intubations are preferable to allow convenient oral access. However these are associated
with trauma to the nasal airway and adenoid tissue, and may subsequently cause post-operative swelling, bleeding, pain and infection (Enger & Mourino, 1985).

Fever has been shown to be a post-operative complication (Enger & Mourino, 1985). Fever may be caused as a result of numerous intra-operative factors such as tissue trauma, dehydration, overheating from OR lights or warming blankets, infection, and reactions to anesthetic drugs (Enger & Mourino, 1985). The cause of a post-operative fever is important to ascertain and control to prevent further post-operative complications such as dehydration.

Delayed recovery time may be caused by excessive pre-operative sedation, failure of patients to quickly metabolize anesthetic drugs, hypotension, and hypoxia (Enger & Mourino, 1985). Anesthetic drugs are metabolized at different rates in each patient, and have been shown to be relatively unpredictable in obese (body mass index (BMI) greater than 30 kg/m² or higher) patients and in those with complex medical conditions (Enger & Mourino, 1985; O'Neill & Allam, 2010; Prielipp, 2010). Patients with obesity have reduced cardiovascular and respiratory reserves and are more likely to have existing comorbidities such as hypertension which places them at greater risk for many complications in the peri-operative period including hypoxia (Prielipp, 2010; Tang, Li, Huang, Ma, & Wang, 2011).

General anesthesia has been shown to have an effect on the autonomic nervous system (ANS) (Deschamps & Denault, 2009). Changes in heart rate and blood pressure are controlled by the ANS (Deschamps & Denault, 2009). Significant changes in vital signs such as heart rate and blood pressure may occur in response to physiological end-organ dysfunction and can lead to complications related to the maintenance of respiratory and circulatory physiologic function (Deschamps & Denault, 2009). Deschamps et al reported that intra-operative monitoring of heart rate and blood pressure provides the anesthetist with a marker for the depth of anesthesia, and the effect of induction and maintenance drugs on the patient’s ANS (Deschamps & Denault, 2009). In the peri-operative period, patients that have complex medical conditions such as cardiac disease have been more prone to experience significant changes in vital signs (Deschamps & Denault, 2009). They may be at an increased risk for anesthesia related complications (Deschamps & Denault, 2009). There is evidence indicating that patients experiencing intra-operative hypertension and tachycardia were more likely to be hypertensive in the PACU (Rose, Cohen, & DoBoer, 1996). Subsequently, patients who had hypertension and tachycardia in the PACU were at greater
risk for post-operative mortality or requiring critical care admission (Rose, Cohen, & DoBoer, 1996). It would be ideal to be able to measure autonomic tone directly in order to predict and prevent changes in vital signs, however no such devices are currently available (Narasethkamol, Charuluxananan, Kyokong, Premsamran, & Kundej, 2011).

Pulse oximetry allows the measurement of arterial oxygen saturation (SpO2) (Goldman, Petterson, Kopotic, & Barker, 2000). Hypoxemia or low arterial oxygen saturation may be a serious complication of anesthesia (Ehrenfeld, Funk, Schalkwyk, Merry, Sandberg, & Gawande, 2010). The definition of hypoxemia is not standardized, however many studies have used an oxygen saturation of less than 90% as their baseline value for hypoxemia (Ehrenfeld, Funk, Schalkwyk, Merry, Sandberg, & Gawande, 2010; Moller, et al., 1993). Prior to the use of pulse oximeters in the 1980’s, hypoxemia was the leading cause of anesthesia related deaths (Ehrenfeld, Funk, Schalkwyk, Merry, Sandberg, & Gawande, 2010). Since the widespread use of pulse oximetry in operating rooms, the number of anesthesia related deaths have decreased twenty-fold in the developing world (Ehrenfeld, Funk, Schalkwyk, Merry, Sandberg, & Gawande, 2010).

Research has shown that hypoxemia may also contribute to post-operative behavior changes such as emergence delirium (Key, Rich, DeChristofaro, & Collings, 2010). Emergence delirium has been described as a confused mental state associated with hallucinations, moaning noises, agitation, and uncontrolled movements (Key, Rich, DeChristofaro, & Collings, 2010). Emergence delirium may be caused by anesthetic agents, particularly inhalational agents, pre-operative anxiety, poor peri-operative pain control, unfamiliar environment, and rapid emergence (Key, Rich, DeChristofaro, & Collings, 2010).

Peri-operative monitoring in a hospital or office-based setting is computerized and done mechanically. It is important that all monitoring devices be checked for proper function pre-operatively since any equipment failure may lead to devastating consequences. Equipment failure is a risk of GA, thus it is imperative that operating room staff comply with the standards set forth by advisory and regulatory committees regarding equipment testing and maintenance (Craig & Kitson, 2010).
Risk factors for peri-operative complications include:

- age
- sex
- ASA status
- medication use
- airway anatomy
- time under GA
- duration of stay in PACU

With increasing age, the risk of acquiring a disability or multiple disabilities increases (Statistics Canada, 2006). The type and number of disabilities an individual has may impact their ASA status. However, as mentioned earlier, ASA status is not a direct measure of one’s comorbidities but it does classify anesthetic risk prior to surgery (Ferrier, Spuesens, Le Cassie, & Baatenburg de Jong, 2005). The greater the severity of a disability, the more likely an individual is to have more functional limitations, increased ASA status, and polypharmacy. Age, ASA status, male gender, and time under general anesthesia have been positively correlated with peri-operative complications (Hines, Barash, Watrous, & O'Connor, 1992; Ferrier, Spuesens, Le Cassie, & Baatenburg de Jong, 2005; Rassam, Thomas, Vaughan, & Hall, 1995; Rose, Cohen, & DoBoer, 1996).

Pre-operative GA assessments include airway classification to assess whether a patient has a complicated airway (Caplan, et al., 2003). Difficult airways are those that may be difficult to oxygenate, difficult to manually ventilate, difficult to intubate, or difficult to perform a laryngoscopy on (Caplan, et al., 2003; Walls & Murphy, 2000). Inability to intubate a patient can lead to catastrophic complications not the least of which is death (Rose & Cohen, 1994). Factors that have been associated with a difficult tracheal intubation include: obesity or short neck, diabetes, limited inter-incisor gap, short mandibular length, reduced visibility of the soft palate (Mallampati Classification) and other physical abnormalities of the head and neck (Rocke, Murray, Rout, & Gouws, 1992; Reissell, Orko, Maunusela, & Lindgren, 1990; Allahyary, Ghaemei, & Azemati, 2008). Rose et al suggested obesity and men ages 40-59 were predictors for difficult intubations, while individuals under the age of 40 years were less likely to have difficult intubations (Rose & Cohen, 1994).
Time under GA is also correlated with complications (Seago, Weitz, & Walczak, 1998; Rose, Cohen, & DoBoer, 1996). Time under GA and post-operative pain have also been shown to be predictors of complications in the PACU (Rose, Cohen, & DoBoer, 1996). Thus, the longer one is under GA, the greater is their risk for suffering post-operative complications such as nausea and vomiting. Sinclair et al in 1999 suggested that post-operative nausea and vomiting increased after every thirty minutes in the operating room under GA.

The existing literature about peri-operative complications is difficult to interpret due to variability in patient characteristics, analytic methods, follow up time, operative procedures, and length of surgery (Needleman, Harpavat, Wu, Allred, & Berde, 2008). There is a lack of validated symptom assessment scales in PWD which makes interpreting this literature even more difficult (Needleman, Harpavat, Wu, Allred, & Berde, 2008). One must also be careful to not generalize conclusions from all studies relating to peri-operative complications to the dental patient. This patient population has unique management issues and maybe associated with unique complications and challenges.

1.11 Agents Used During General Anesthesia

General anesthesia may be achieved either with inhalational and/or intravenous (IV) agents. For inhalational agents, the minimum alveolar concentration (MAC) is used to appropriately dose the drugs and is a measure of a drug’s strength (Prielipp, 2010). MAC is defined as the concentration of the inhalational agent required in the lungs to prevent a motor response in 50% of people during a surgical incision (Abraham, Acree, Mintz, & Payne, 2008; Prielipp, 2010). The lower the MAC, the more potent is the inhalational agent (Abraham, Acree, Mintz, & Payne, 2008; Prielipp, 2010). The MAC of an inhalational drug decreases with age, by approximately 6% every decade, and is the highest at 6 months of age and is the lowest after age 80 years (Prielipp, 2010). The MAC is affected by a variety of drugs and patient specific factors such as comorbidities (Prielipp, 2010). There are numerous inhalational agents available for the induction and maintenance of anesthesia however their use is affected by many factors; anesthetist’s training principles, personal choice or preference of the anesthetist, patient specific factors and availability and cost of the drug (Prielipp, 2010).
Three commonly used volatile inhalational anesthetic agents are sevoflurane, desflurane and isoflurane (Dodds, 1999). All drugs have been shown to be relatively non-toxic but have a propensity to induce post-operative nausea and vomiting (PONV) (Prielipp, 2010). Approximately 2-3% of sevoflurane, 0.02% of desflurane, and 0.2% of isoflurane is metabolized (Prielipp, 2010). In comparison to previously used volatile agents, this is a smaller amount metabolized (Prielipp, 2010).

The physiological effects of all three gases are similar. However, sevoflurane was shown to have cardiovascular stability with increasing concentrations (Dodds, 1999). All 3 inhalational agents reduce contractility of the heart, reduce respiration, cause mild muscle relaxation and increase cerebral blood flow (Prielipp, 2010). Sevoflurane does not release catecholamines with sudden changes in concentration. For this reason it has been commonly used in patients with ischemic heart disease (Dodds, 1999; Meyer, 2010). Sevoflurane has been a commonly used inhalational agent for the induction of anesthesia in both adults and children (Dodds, 1999; Viitanen, Baer, & Annila, 2000). The advantages of sevoflurane include its potency, its low blood-gas solubility, its neutral odor, and its lack of airway irritation (Dodds, 1999; Meyer, 2010). Inhalational agents with a low blood-gas solubility have a rapid onset and offset effect (Prielipp, 2010). Characteristics of sevoflurane include a low blood-gas solubility, rapidity of onset, an association with emergence delirium, cost, and an association with increased PONV (Dodds, 1999; Moore, Moore, Elliott, St Leger, Payne, & Kerr, 2003).

Desflurane has been shown to have a relatively more favorable recovery profile than sevoflurane (Dodds, 1999). Desflurane also has a low blood-gas solubility and thus a rapid onset and offset effect. However, it is more frequently associated with emergence delirium, coughing, and respiratory irritation due to its pungent smell (Prielipp, 2010). Thus, desflurane cannot be used for induction.

Isoflurane has greater blood-gas solubility relative to sevoflurane and desflurane and is associated with a longer emergence time (Meyer, 2010). It has an unpleasant odour and acts as an airway irritant and is not an ideal induction agent (Meyer, 2010). Isoflurane is the least likely to cause emergence delirium. It has been associated with an increase in heart rate with small changes in concentration (Key, Rich, DeChristofaro, & Collings, 2010).
Nitrous oxide is an inhalational anesthetic agent with mild analgesic properties (Dodds, 1999). It has been shown to be easily titratable (Litman, 1997). Nitrous oxide depresses the central hypercapnic response and the peripheral hypoxemic centers (Miller, Eriksson, Fleisher, Wiener-Kronish, & Young, 2004). Nitrous oxide has often been used in conjunction with other agents to induce and maintain anesthesia (Dodds, 1999). It is not used as a sole agent under GA because it is a weak agent (Dodds, 1999; Fernandez-Guisasola, Gomez-Arna, Cabrera, & Garcia del Valle, 2010). Nitrous oxide has historically been the least potent anesthetic agent since it has had little effect on organ systems as a result of its high MAC of 104 (Dodds, 1999; Fernandez-Guisasola, Gomez-Arna, Cabrera, & Garcia del Valle, 2010). The MAC of nitrous oxide is 104 (Ropcke, 2001). Reports also indicate that nitrous oxide potentiates nausea and vomiting (Dodds, 1999; Fernandez-Guisasola, Gomez-Arna, Cabrera, & Garcia del Valle, 2010).

Propofol is an anesthetic agent administered intravenously and can be used as a total-intravenous anesthetic (TIVA) or in conjunction with inhalational agents (Dodds, 1999). It is typically associated with a stinging sensation upon injection. Benefits of propofol include rapidity of onset, shortness of duration, and rapidity of recovery. Propofol has also been shown to have an antiemetic effect. One of the drawbacks of this agent is that it can cause significant hypotension in patients with hypovolemia if infused rapidly. Furthermore, it has also been shown to cause a significant fall in tidal volumes and may cause apnea at high doses.

In addition to anesthetic agents, paralytics, analgesics and sedatives are commonly used in combination with the anesthetic agents. Rocuronium and fentanyl are two commonly used drugs. Rocuronium is a non-depolarizing muscle relaxant that is administered IV and has typically been used to create a state of muscle relaxation during endotracheal intubation, and it may also be used during the maintenance of anesthesia (Dodds, 1999; Tang, Li, Huang, Ma, & Wang, 2011). Rocuronium has a rapid onset and a prolonged duration of action often lasting greater than 90 minutes (Dodds, 1999). It has not been associated with cardiovascular instability and is often used in place of succinylcholine as a muscle relaxant (Dodds, 1999).

Fentanyl is an opioid analgesic that is used for peri-operative pain management (Dodds, 1999). It may cause respiratory depression (Dodds, 1999). The onset time is
roughly 5 minutes, and it takes approximately twenty minutes for the respiratory depressant effect of the drug to wear off (Dodds, 1999). Fentanyl has been associated with rapid emergence, higher awareness and post-operative nausea and vomiting (Dawson & Reed, 1980).

1.12 Satisfaction With Service

When treating PWD, assessing satisfaction with the care received provides valuable information. Satisfaction may predict compliance to recommended therapy, and ensure return visits to health care providers, and create a healthy rapport between the patient and care-provider (Prabhu, Nunn, Evans, & Girdler, 2010; Fitzpatrick, Bury, Frank, & Donnelly, 1987; Gerbert, Love, & Caspers, 1996). The literature contains reports of satisfaction surveys administered to patients, parents, and caregivers. Satisfaction surveys are typically given to caregivers or parents when patients are cognitively incapable of providing feedback (Prabhu, Nunn, Evans, & Girdler, 2010). When surveyed, over 80.0% of respondents typically express their satisfaction for any given question (Prabhu, Nunn, Evans, & Girdler, 2010). Interpretation of the satisfaction data that exist in the literature is challenging. Satisfaction research is inherently fraught with bias (Coyle, Helfrick, Gonzalez, Andresen, & Perrott, 2005). Patients may feel compelled to avoid negative evaluation of their care providers and the care they have received due to a fear of compromising their future care (Tong, Chung, & Wong, 1997; Prabhu, Nunn, Evans, & Girdler, 2008).

In addition, interpreting satisfaction data is biased because an individual’s report of satisfaction may be influenced by other factors that are peripheral to the service in question such as availability of parking, interaction with OR staff, communication and rapport with the health care provider, and the sense of participation in their own health care decision making process (Coyle, Helfrick, Gonzalez, Andresen, & Perrott, 2005). When surveying individuals about satisfaction it is imperative to phrase questions in a closed ended and direct manner (Acs, Pretzer, Foley, & Ng, 2001). Questions should be straightforward, and written in simple language that is easy to understand.

Past research has shown that many factors may play a role on the report of satisfaction for a particular service and they include: the individual reporting, symptoms, age, pre-operative anxiety level, socio-economic status (SES), interpersonal skills of the care provider, and whether the questions are episode specific versus being general in nature.
Parents and/or caregivers may need to report satisfaction if the patient is not cognitively capable (Prabhu, Nunn, Evans, & Girdler, 2010). Proxy reporting is biased in that it does not reflect the patient’s direct experience with the care received (Prabhu, Nunn, Evans, & Girdler, 2010).

There are very few studies done that have compared the satisfaction with dental treatment under GA in healthy versus medically compromised individuals. Acs et al. surveyed parents of both healthy and medically compromised children after their dental rehabilitation under GA. The results indicated that the technical component of the treatment rendered was not a determinant of parental satisfaction, but rather it was the improvement of their child’s symptoms (Acs, Pretzer, Foley, & Ng, 2001). In Acs’s study, parents of children with special health care needs were more likely to report improved eating and sleeping patterns. However, both groups of parents were equally satisfied with the service. In 1997, Tong et al. studied factors that were predictive of global patient satisfaction after ambulatory out-patient surgery and found that post-operative symptoms contributed to the patient’s dissatisfaction with the service (Tong, Chung, & Wong, 1997). This finding was corroborated by Coyle et al. who found that post-operative vomiting, recall of intra-operative pain, and intra-operative anesthesia awareness without the ability to communicate, contributed to significant dissatisfaction with the service (Coyle, Helfrick, Gonzalez, Andresen, & Perrott, 2005).

Age, pre-operative anxiety level and SES may affect the reported satisfaction for a particular service. Fitzpatrick et al. reported that individuals from a middle-class SES were more likely to be critical when reporting on satisfaction with a particular service (Fitzpatrick, Bury, Frank, & Donnelly, 1987). Coyle et al. found that individuals over the age of 40 years without pre-operative anxiety were more likely to be satisfied with their dental treatment under GA and children under the age of 10 years were least likely to be satisfied with the service provided (97.4%, P<0.05). Satisfaction for younger children was often reported by parents. Over 95.0% of parents reported satisfaction with the service provided (Coyle, Helfrick, Gonzalez, Andresen, & Perrott, 2005).
The personality and the ability of the care provider to effectively communicate necessary information to the patient also played a role in patient satisfaction (Fitzpatrick, Bury, Frank, & Donnelly, 1987). Fitzpatrick et al found that if the care provider was friendly and had good communication skills, the patient and primary caregiver were more likely to be satisfied with the service provided (Fitzpatrick, Bury, Frank, & Donnelly, 1987). Tong et al found that patient dissatisfaction was related to minor misunderstandings or miscommunications between the patient and the hospital staff. The misunderstandings or miscommunications that were reported by patients included: prolonged pre-operative admission, lack of pre-operative testing, and failure by the surgeon to visit the patient (Tong, Chung, & Wong, 1997).

Despite all of the literature that exists on peri-operative complications and patient satisfaction, there is very little literature that exists for PWD. It is challenging to collect objective data on PWD that are cognitively impaired and are unable to communicate. There exists the need to standardize the way that subjective information can be recorded objectively. This may include recording information from patient charts and conducting surveys. The observations of health care delivery staff and the surveying of parents and primary caregivers for the aforementioned reasons is very important.
2.0 OBJECTIVES AND HYPOTHESES

2.1 Objectives

1. To ascertain the prevalence of peri-operative complications in persons with disabilities at the Mount Sinai Hospital undergoing general anesthesia for their dental care.
2. To compare the prevalence of peri-operative complications from the retrospective chart review with the prevalence in the literature.
3. To compare the prevalence of post-operative symptoms from the survey with the prevalence in the literature.
4. To ascertain the level of satisfaction with the service provided from parents and caregivers.

2.2 Hypotheses

1. The prevalence of peri-operative complications from the chart review will be similar to the prevalence of complications cited in the literature for the general population, which is estimated to be 6.0%.
2. Peri-operative complications can be predicted based on information collected from the patient’s chart.
3. The report of post-operative symptoms in the survey will be greater than 80.0 % and thus higher than that reported in the literature for the general population.
4. Parental and caregiver satisfaction with the service provided will be higher than 80% based on reports in the literature.
3.0 MATERIALS AND METHODS

The Research Ethics Board at Mount Sinai Hospital approved the proposed study based on scientific merit from the Research Committee of the Faculty of Dentistry. The population of interest was persons with disabilities (PWD) treated under general anesthesia (GA) at Mount Sinai Hospital, Toronto, ON. In order to test the hypotheses, the study was carried out in two parts.

3.1 Part 1- Retrospective Chart Review

For part 1 the inclusion criteria were the first 500 PWD treated under GA for dentistry at Mount Sinai Hospital from 2004-2009. The dental treatment was provided by general practice residents and pediatric dental residents and was overseen by 2 staff pediatric dentists. The dental treatment was rendered in the Elective Outpatient Surgery Unit (EOPS) at the Mount Sinai Hospital. Part one was a retrospective chart review to ascertain the prevalence and predictors of peri-operative complications and compare them to those reported in the literature. The range of complications in the general population in the literature varies from 6-92% (Bridgman, Ashby, & Holloway, 1999; Matsuura, Hirose, Joh, Sugiyama, Niwa, & Shibutani, 2000). Previous reports suggest that the prevalence of complications is approximately 6% (Bridgman, Ashby, & Holloway, 1999; Matsuura, Hirose, Joh, Sugiyama, Niwa, & Shibutani, 2000).

Information sheets as well as consent forms were mailed to parents and caregivers of the 500 patients selected for study in December 2009 (Appendices C and D). A pre-paid self-addressed envelope was provided for return of consent forms. Due to a poor initial response rate, a second mailing was done.

Once consent was obtained, the following information was recorded from the patient charts: patient profile, type(s) of the pre-operative medical assessments, method of anesthesia induction, anesthetic maintenance, dental diagnosis, type and duration of dental treatment under GA, time of discharge, and peri-operative complications arising from the anesthesia and/or dental treatment (Appendix A). Based on the literature, the following factors were considered to be peri-operative complications in this study:
1. Peri-operative change in heart rate  
   a. Considered a complication if pharmacological intervention was required to stabilize the heart rate
2. Peri-operative change in blood pressure  
   a. Considered a complication if pharmacological intervention was required to stabilize the blood pressure
3. Intra-operative anesthetic equipment problems
4. Intra-operative oxygen saturation less than 92%
5. Immediate post-operative oxygen saturation less than 92%
6. Immediate post-operative nausea
7. Immediate post-operative vomiting
8. Immediate post-operative bleeding requiring dental attention
9. Post-operative airway problems
10. Complications requiring admission after GA
11. Readmission to hospital after discharge

All information was collected and recorded by the co-investigator onto a spreadsheet on a password-protected computer. The data were encrypted. Each patient was assigned a research code to protect their identity. The data from the chart review were sorted and reviewed.

**3.2 Statistical Analysis Part 1- Retrospective Chart Review**

All data were gathered and entered in Microsoft Office Excel 2007 spreadsheets (Microsoft Corp, Redmond, Wash) and imported into SPSS 15 (SPSS Inc., Chicago, Ill) by the co-investigator. All statistical analyses were undertaken with SPSS 15 software©.

The primary outcome of interest was the prevalence of peri-operative complications. The number of surgeries in which complications occurred was used to calculate the prevalence of peri-operative calculations. Previous reports suggest that the prevalence of peri-operative complications is 6%. We used this figure to calculate the sample size that we would need to be 95% certain that the true proportion estimated by the sample would be accurate with a margin of error of 5% (or between 1-11%). The estimated sample size using these criteria was 81 surgeries.
A total of 88 consent forms were returned. During the five year study period, 88 patients underwent 147 surgeries. Two units of analysis were used in the study. Due to a poor response rate, one unit of analysis used was each individual GA or surgery, providing a sample size of 147. The other unit of analysis used was the number of patients that returned consent forms providing a sample size of 88. Descriptive statistics and a logistic regression analysis were performed on both sample sizes. The larger sample size was analyzed for clustering to assess for confounding of results.

For the logistic regression analysis, multiple independent variables and one dependent variable was chosen. The dependant variable was complications and the outcome was dichotomized. The following independent, or predictor variables were chosen:

- Age
- Sex
- ASA Classification
  - ASA classification was re-coded as ‘mild disease’ (ASA 1 or 2) or ‘severe disease’ (ASA 3 or 4) because there were too few patients with the code 1 (N=1) or 4 (N=3) to be useful in the model
- Current medication use at the time of the GA: Yes or No
- Pre-operative anesthesia evaluation when performed: day surgery unit or Pre-Anesthesia Unit (PAU)
- Day surgery or elective admission
- Pre-operative sedative used: Yes or No
- Difficult airway: Yes or No
- Duration of GA (minutes): Time in to OR until time out of OR
- Time in the Post-Anesthetic Care Unit (PACU) (minutes): Time into PACU until time to discharge

When constructing a multiple logistic regression model, it is important that the predictors are not strongly correlated with each other. Correlated predictors contain redundant information and may lead to significant errors in the model results. Using a contingency analysis, the following statistically significant relationships between the predictor variables were found, indicating that these related predictors should not be included in the same logistic regression:
– ASA Classification & Day surgery/Elective admission (P=0.047)
– ASA Classification & Difficult airway (P=0.0077)
– Pre-operative anesthesia evaluation & Day surgery/elective Admission (P=0.003)
– Pre-operative anesthesia evaluation & Difficult airways (P=0.004)
– Day surgery/Elective admission & Difficult airway (P=0.031)

Relationships among continuous variables were examined in a correlation matrix. Although the correlation between Minutes in PACU and Minutes under GA was statistically significant (p=0.02) in the N= 147 analysis, the correlation coefficient was small (0.18) and as such, it was reasonable to include both of these variables in the model.

Based on the correlation matrix, the predictor variables were reduced to the following:
– Age
– Sex
– ASA Classification
– Current medication use at the time of the GA: Yes or No
– Pre-operative anesthesia evaluation when performed: pre-operating room (OR) or Pre-Anesthesia Unit (PAU)
– Duration of GA (minutes): Time in to OR until time out of OR
– Time in the Post-Anesthetic Care Unit (PACU) (minutes): Time into PACU until time to discharge

### 3.3 Part 2- Prospective Survey
For part 2 the inclusion criteria was the first 100 PWD treated under GA for dentistry at the Mount Sinai Hospital from December 2009 to December 2010. Part 2 was a prospective study that involved surveying parents or their primary caregivers regarding their satisfaction with the service as well as to ascertain the prevalence of post-operative symptoms incurred by patients. The survey included questions about post-operative complications, changes in normal activities of daily living, and overall satisfaction with the service. The survey was based on the current body of published data by experts in the fields

The information sheet and the consent form were provided to the parent/caregiver on the day of surgery in a sealed envelope to be opened at home after their surgery (Appendices E and F). The envelopes were provided to the parent/caregiver by one of two staff pediatric dentists. The parents and caregivers were asked to return the survey in a postage paid envelope within one week of the surgery to ensure optimal memory recall (Grover, Berkowitz, & Lewis, 1994). The parents and caregivers were asked to answer questions using the Visual Analogue Scale (VAS) in order to facilitate comparison of the patient’s post-operative symptoms to their baseline behaviour. Prior to filling out the survey, parents and caregivers were provided with an example of how to use the VAS scale to answer questions (See Appendix B-1). Subsequently, parents and caregivers were asked to fill out four questions that related to four boxes on the page colored white, shades of grey, and black (See Appendix B-2). The individual’s ability to distinguish between lighter and darker colors in relation to one another tested the validity of the VAS and ensured that parents and caregivers were using the VAS correctly. Finally, the parents were asked to fill out the survey (See Appendix B-3). If parents and/or caregivers were unable to reliably fill out Appendix B-2, their data was not included in the analysis. Once the surveys were returned, the data was encrypted and entered into a password protected computer. The prevalence of post-operative complications and overall satisfaction with the service provided were assessed.

3.4 Statistical Analysis Part 2- Prospective Survey

All data were gathered and entered in Microsoft Office Excel 2007 spreadsheets (Microsoft Corp, Redmond, Wash) and imported into SPSS 15 (SPSS Inc., Chicago, Ill) by the co-investigator. All statistical analyses were undertaken with SPSS 15 software©.

The primary outcomes of interest were the prevalence of post-operative complications and the satisfaction with the service provided. For Part 2, mean VAS scores were tabulated for post-operative complications and satisfaction questions. The survey responses were re-coded as follows: the code “n/a” was treated as a missing observation and may be thought of as indicating that the question was not relevant to the patient. In most cases, this would mean that the complication or condition was not experienced by the patient. Similarly, a
value of zero on the VAS scale was also considered to be a missing observation in the sense that the patient did not experience the complication.

Each complication question was followed by a question entitled “Changes seen for _____ days after dental treatment.”, and the reported value was frequently “0”. These values were treated as true values which may mean that the patient experienced the complication for less than a single day and probably on the day of surgery (hence, day 0). The survey data is summarized with mean VAS scores, number of days that changes were seen, and the mode. The mode is a better statistic than the mean to summarize this data set. The most common complications were represented by those that had highest number of patients reporting the complication.
4.0 RESULTS PART 1- RETROSPECTIVE CHART REVIEW

4.1 Descriptive Statistics

The Mount Sinai Hospital Program for PWD treated over 1,000 patients under GA between the years of 2004-2009. The first 500 patients treated under GA were sent information and consent forms via mail to participate in the retrospective chart review. Due to a low response rate of 10.0% for the first mailing, a second mailing was done which produced a total response rate of 17.6%. The data set included information from 88 patients who underwent 147 surgeries.

4.2 Age and Sex Distribution of Study Populations (N=147 And N=88)

Amongst 88 patients 39 (44.0%) were female and 49 (56.0%) were male patients. The patients ranged in age from 16 to 60 years old, with an average age of 30 years. All but one of the patients were cognitively impaired. With the unit of analysis being each individual GA or surgery (N=147), the age class of the majority was between the ages of 26-45 years. With the unit of analysis being each individual patient, the age class of the majority was under the age of 26 years (Tables 1 and 2, Figures 3 and 4).
Most patients under study were 26-45 years of age for N=147

Table 1. Age and Sex Breakdown (N=147)

<table>
<thead>
<tr>
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<tr>
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<tbody>
<tr>
<td></td>
<td>Female</td>
<td>Male</td>
</tr>
<tr>
<td>Under 26</td>
<td>31</td>
<td>30</td>
</tr>
<tr>
<td>26-45</td>
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<td>40</td>
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<td>8</td>
</tr>
<tr>
<td>TOTAL</td>
<td>69</td>
<td>78</td>
</tr>
</tbody>
</table>

Figure 3. Bar Graph of Age (in years) and Sex Breakdown (N=147)
Most patients under study were under 26 years of age for N=88.

Table 2: Age and Sex Breakdown (N=88)

<table>
<thead>
<tr>
<th>Age in Years</th>
<th>Female</th>
<th>Male</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 26</td>
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<td>24</td>
<td>41</td>
</tr>
<tr>
<td>26-45</td>
<td>17</td>
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<td>10</td>
</tr>
<tr>
<td>TOTAL</td>
<td>39</td>
<td>49</td>
<td>88</td>
</tr>
</tbody>
</table>

Figure 4. Bar Graph of Age (in years) and Sex Breakdown (N=88)
4.3 ASA Classification of Study Populations
Most patients (72.0%-74.0%) in both analyses were classified as ASA 3. In both analyses, 19.0% of patients were classified as ASA 2. There were very few patients in either analysis classified as ASA 1 and 4 (Figures 5 and 6).

Figure 5. ASA Distribution of Study Population (N=147)

Figure 6. ASA Distribution of Study Population (N=88)
4.4 Medication Use at the Time of Surgery

Of the 147 surgeries, 114 (78.0%) of the patients were on medications at the time of their surgery compared to 33 who were not (Figure 7). Of the 88 patients, 67 (76.0%) were taking medication at the time of their surgery (Figure 8).

Figure 7. Medication Use at Time of Surgery (N=147)

![Figure 7](image1.png)

Figure 8. Medication Use at Time of Surgery (N=88)

![Figure 8](image2.png)
4.5 Location of the Pre-Operative Anesthesia Evaluation

Of the 147 surgeries, there was a pre-operative anesthesia evaluation in the Pre-Anesthesia Unit (PAU) prior to 33 (22.0%) of the surgeries (Figure 9). Of 88 patients, 21 (24.0%) of the patients had a pre-operative anesthesia evaluation in PAU (Figure 10).

Figure 9. Location of Pre-Anesthesia Evaluation (N=147)

Figure 10. Location of Pre-Anesthesia Evaluation (N=88)
### 4.6 Restraint During Induction

In both analyses, 25.0% and 26.0% required restraint during the anesthetic induction in the N=147 and N=88 analyses respectively (Figures 11 and 12).

**Figure 11.** Restraint During Induction (N=147)

![Pie Chart](image)

**Figure 12.** Restraint During Induction (N=88)

![Pie Chart](image)
4.7 Difficult Airway

Of 147 surgeries, 13 (9.0%) of the surgeries required the presence of a respiratory technician or the use of a fibreoptic bronchoscope or glidescope during surgery, constituting a difficult airway (Figure 13). Of 88 surgeries, 5 (6.0%) of the surgeries required the presence of a respiratory technician or the use of a fibreoptic bronchoscope or glidescope during surgery, constituting a difficult airway (Figure 14).

Figure 13. Difficult Airway (N=147)

![Difficult Airway (N=147)](image)

Figure 14. Difficult Airway (N=88)

![Difficult Airway (N=88)](image)
4.8 Day Surgery Versus Planned Elective Admission

Of the 147 surgeries, 141 were planned as day surgeries and 6 (4.0%) as elective admissions (Figure 15). Two of the 6 planned admissions were high risk for aspiration pneumonia. The third patient had a history of delayed recovery post-operatively and thus was planned to be electively admitted. The other 3 patients that were planned admissions were seen in the PAU and the reason for the preadmission was not listed. Five of the 6 elective admissions were seen in the PAU. Of the 88 surgeries, 4 (5.0%) were planned as elective admissions (Figure 16).

Figure 15. Day Surgery vs. Planned Elective Admission (N=147)

Figure 16. Day Surgery vs. Planned Elective Admission (N=88)
4.9 Types of Dental Treatment Provided

Table 3 shows that in both analyses (N=147 and N=88), all patients had a dental exam prior to treatment and most patients had radiographs taken. Amalgam was placed in over half of all surgeries and composite restorations were placed in almost ¼ of all surgeries. Stainless steel crowns (SSCs) were placed in approximately 10.0% of all surgeries. Almost half of all surgeries involved dental extractions, and only 2/147 surgeries involved root canal therapy.

Table 3. Breakdown of Dental Procedures Performed Under GA (N=147 and N=88)

<table>
<thead>
<tr>
<th>TYPE OF DENTAL TREATMENT</th>
<th>% of Patients in N=147 Analysis Who Had Treatment</th>
<th>% of Patients in N=88 Analysis Who Had Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exam</td>
<td>100.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Radiographs</td>
<td>94.6</td>
<td>96.6</td>
</tr>
<tr>
<td>Cleaning</td>
<td>94.6</td>
<td>97.7</td>
</tr>
<tr>
<td>Amalgam Restorations</td>
<td>53.1</td>
<td>55.7</td>
</tr>
<tr>
<td>Composite Restorations</td>
<td>26.5</td>
<td>21.6</td>
</tr>
<tr>
<td>Stainless Steel Crowns (SSCs)</td>
<td>11.6</td>
<td>9.1</td>
</tr>
<tr>
<td>Root Canal Therapy</td>
<td>1.4</td>
<td>0</td>
</tr>
<tr>
<td>Extraction</td>
<td>49.0</td>
<td>53.4</td>
</tr>
</tbody>
</table>
4.10 Blood Taken Intra-Operatively Due to Medical Request

Of the 147 surgeries, there was blood drawn in 16 (11.0%) of the surgeries intra-operatively for medical purposes (Figure 17). Of 88 patients, 8 (9.0%) of had blood drawn intra-operatively for medical purposes (Figure 18).

Figure 17. Blood Taken in OR (N=147)

Figure 18. Blood Taken in OR (N=88)
4.11 Non-Dental Images Taken As Per Medical Request

Of the 147 surgeries, there were non-dental images taken in 2 (1.0%) of the surgeries (Figure 19). Of the 88 surgeries, there were non-dental images taken in 2 (2.0%) of the surgeries (Figure 20).

Figure 19. Non-Dental Images Taken in OR (N=147)

Figure 20. Non-Dental Images Taken in OR (N=88)
4.12 Comparing Time Under General Anesthesia and Time Spent in the Post-Anesthetic Care Unit

For the 147 surgeries, the minimum duration of surgery was 45 minutes, the average was 118 minutes, and the maximum was 432 minutes (Figure 21). For the same group, the minimum duration of time in PACU was 4 minutes, the average was 81 minutes, and the maximum was 357 minutes (Figure 21). The Pearson correlation between ‘Minutes under GA’ and ‘Time in PACU’ was 0.18 and the P=0.02 thus the two variables were slightly correlated. For the 88 surgeries, the minimum duration of surgery was 45 minutes, the average was 115 minutes, and the maximum was 267 minutes (Figure 22). For the same group, the minimum duration of the time in PACU was 4 minutes, the average was 90 minutes, and the maximum was 357 minutes (Figure 22). The Pearson correlation between ‘Minutes under GA’ and ‘Time in PACU’ was 0.16 and the P=0.14 thus the two variables were slightly correlated, but not significant (Figures 21 and 22).

Figure 21. Time Spend Under GA and in PACU (N=147)

![Diagram showing time spent under general anesthesia and in PACU](image)

Pearson Correlation Coefficient: 0.18
P=0.02
Figure 22. Time Spent Under GA and in PACU (N=88)

Minutes Under GA and Time in Post Anesthesia Care Unit (PACU) (N=88)

Pearson Correlation Coefficient: 0.16
P=0.14
4.13 Distribution of All Complications

Table 4 depicts the prevalence of peri-operative complications. Of 147 surgeries, there were 54 peri-operative complications during 39 surgeries. Of the 54 complications 26 (48.0%) of them occurred intra-operatively, and 28 (52.0%) of them occurred post-operatively. The prevalence of at least one complication was $39/147 = 26.5\%$ for 147 surgeries. Of 88 surgeries, there were 34 peri-operative complications during 22 surgeries. Of the 34 complications, 14 (44.0%) of them occurred intra-operatively, and 19 (56.0%) of them occurred post-operatively. The prevalence of at least one complication was $22/88 = 25.0\%$ for 88 surgeries. The estimated 95.0% confidence interval based on the sample of 147 was 20.4 – 34.7. The estimated complication rate would be between 20.0% and 35.0%. The 95.0% confidence interval around the 25.0% estimate was 16.5 – 34.8 which means that if we were to sample this same population repeatedly, 95 times out of 100 times, the estimated complication rate would be between 16.0% and 35.0%. Confidence intervals were only estimated for the overall complication rate in order to reduce the probability of a type I error associated with multiple testing. The pattern of complications was almost identical regardless of the sample group and differences were not statistically significant (Chi square test of association: $P=0.79$)
Table 4. The Prevalence of Complications (N=147 and N=88)

<table>
<thead>
<tr>
<th>Types of Complications</th>
<th># of Complications (N=147)</th>
<th>Percentage (%)</th>
<th># of Complications (N=88)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-operative desaturation</td>
<td>4</td>
<td>2.7</td>
<td>3</td>
<td>3.4</td>
</tr>
<tr>
<td>Significant intra-operative change in heart rate</td>
<td>4</td>
<td>2.7</td>
<td>2</td>
<td>2.3</td>
</tr>
<tr>
<td>Significant intra-operative change in blood pressure</td>
<td>17</td>
<td>11.6</td>
<td>10</td>
<td>11.4</td>
</tr>
<tr>
<td>Intra-operative equipment failure</td>
<td>1</td>
<td>0.7</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Immediate post-operative nausea</td>
<td>11</td>
<td>7.5</td>
<td>8</td>
<td>9.1</td>
</tr>
<tr>
<td>Immediate post-operative vomiting</td>
<td>7</td>
<td>4.8</td>
<td>6</td>
<td>6.8</td>
</tr>
<tr>
<td>Immediate post-operative bleeding</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Immediate post-operative oxygen desaturation</td>
<td>8</td>
<td>5.4</td>
<td>3</td>
<td>3.4</td>
</tr>
<tr>
<td>Airway problems in PACU</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Complication necessitating admission from EOPS</td>
<td>2</td>
<td>1.4</td>
<td>2</td>
<td>2.3</td>
</tr>
<tr>
<td>Complication necessitating return to hospital</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>TOTAL COMPLICATIONS</td>
<td>54</td>
<td></td>
<td>34</td>
<td></td>
</tr>
</tbody>
</table>
4.14 Comparing Complications in Patients With Single Versus Multiple Surgeries During the Study Period

Tables 5 and 6 show that most patients experienced no complications during their surgeries. Comparing the total number of complications over all surgeries there is no difference in complication frequency between those with a single surgery versus those with multiple surgeries. In both groups, more than 50% of the patients had no complications. The chi square test showed that there was no association between the total number of complications and patient type (single or multiple surgeries).

Figure 23 also shows the data in a different form. Patients with a single surgery (type=0) contributed more observations overall (dark bars) but the shape of the pyramid is roughly symmetrical which means that in both groups, relatively few individuals had multiple complications. The Mann-Whitney test confirms that the two distributions are not statistically significantly different.

Table 5. Number of Surgeries vs. Number of Complications for all Surgeries

<table>
<thead>
<tr>
<th>Patient Type</th>
<th>Number of Surgeries</th>
<th>Number complications for all surgeries</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Single Surgery</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>37</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>22</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Multiple Surgery</td>
<td></td>
<td>59</td>
<td>14</td>
</tr>
</tbody>
</table>

This table has too many cells with small counts thus a chi square test was not possible on these data.
### Table 6. Number of Complications for Single vs. Multiple Surgeries

Data collapsed which allows calculation of chi square:

<table>
<thead>
<tr>
<th>Patient Type</th>
<th>Single Surgery</th>
<th>Multiple Surgery</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>37</td>
<td>22</td>
<td>59</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>4</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>53</td>
<td>35</td>
<td>88</td>
</tr>
</tbody>
</table>

Chi square = 3.4

P = 0.18

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2 or more</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>59</td>
<td>14</td>
<td>15</td>
<td>88</td>
</tr>
</tbody>
</table>
Figure 23: The Prevalence Of Complications In Patients With Single (Dark Bars) Versus Multiple (Grey Bars) Surgeries
4.15 Examining the Total Number of Complications in Individuals With Single Versus Multiple Surgeries in the Study Period

In both groups, most patients experienced no complications. There were 54 complications in this study and 23 were contributed by patients with a single surgery compared to 31 contributed by patients which multiple surgeries. Although it is true that patients with multiple surgeries did in fact contribute more complications to the sample, the difference was not greater than what could be expected due to random chance (Table 7).

Table 7. Total Number of Complications in Individuals with Single vs. Multiple Surgeries in the Study Period

| Total Number of Complications in Individuals with Single Versus Multiple Surgeries in the Study Period (P=0.28) |
|-------------------------------------------------|-----------------|-----------------|-------------|
| Patients with single surgeries                  | Patients with multiple surgeries | Total          |
| Observed                                        | 23              | 31              | 54          |
| Expected (if an equal number come from both patient types) | 27              | 27              | 54          |
4.16 Complication Rate

An alternative way of examining this is to compare the average complication rate per surgery. The average number of complications per surgery was higher for patients with a single surgery (mean=0.43 +/- 0.74) than those with multiple surgeries (mean=0.28 +/- 0.43) but the median for both groups was 0 (no complications). In the multiple surgery group, a mean was calculated for each person and then an overall mean was calculated from those data. This takes into account individual variation.

Again, even expressed as a complication rate per surgery, most patients in both groups had no complications. Since the data are quite non-normally distributed, a non-parametric test was used to compare the median complication rate between the two groups. The test was not significant which means that there is no evidence of any difference between these two groups (P=0.88).

4.17 The Distribution of Complications

There was at least one complication in 39 of 147 surgeries yielding a complication rate of 25%. Twenty-six surgeries had 1 complication, 11 surgeries had 2 complications, and 2 surgeries had 3 complications (Table 8 and Figure 25).

Table 8. Distribution of Complication Frequencies (N=147)

<table>
<thead>
<tr>
<th>Number of Complications/Surgery</th>
<th>Frequency (N=147)</th>
<th>Number of Complications</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>108</td>
<td>0</td>
<td>73.5</td>
</tr>
<tr>
<td>1</td>
<td>26</td>
<td>26</td>
<td>17.7</td>
</tr>
<tr>
<td>2</td>
<td>11</td>
<td>22</td>
<td>7.5</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>6</td>
<td>1.4</td>
</tr>
<tr>
<td>TOTAL</td>
<td>147</td>
<td>54</td>
<td>100</td>
</tr>
</tbody>
</table>
There was at least one complication in 22 of 88 surgeries yielding a complication rate of 25%. Eleven surgeries had 1 complication, 10 surgeries had 2 complications, and 1 surgery had 3 complications (Table 9 and Figure 26).
Table 9. Distribution of Complication Frequencies (N=88)

<table>
<thead>
<tr>
<th>Number of Complications/Surgery</th>
<th>Frequency (N=88)</th>
<th>Number of Complications</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>66</td>
<td>0</td>
<td>75.0</td>
</tr>
<tr>
<td>1</td>
<td>11</td>
<td>11</td>
<td>12.5</td>
</tr>
<tr>
<td>2</td>
<td>10</td>
<td>20</td>
<td>11.4</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>3</td>
<td>1.1</td>
</tr>
<tr>
<td>TOTAL</td>
<td>88</td>
<td>34</td>
<td>100</td>
</tr>
</tbody>
</table>

Figure 26. Bar Graph of the Distribution of Complications Among Surgeries (N=88)
4.18 Multiple Logistic Regression Analysis

Relationships amongst the continuous variables were examined in a correlation matrix. Although the correlation between Minutes in PACU and Minutes under GA was statistically significant, for N=147 analysis, the correlation coefficients were small (0.18 and 0.16 respectively) and as such, it was reasonable to include both of these variables in the model (Figures 27 and 28).

Figure 27. Scatter Plot of Time in PACU vs Time Under GA (N=147)
Seven predictor variables were chosen to examine their effect on the outcome of complications (Table 9). In this model, *Time in PACU* was the only statistically significant predictor of the probability of a patient having a complication in both analyses (Tables 10 and 11). The odds ratio indicates that the odds of a patient having a complication increases (because it is positive) by 0.9% for every minute of time in PACU for the N=147 analysis. The confidence intervals indicate that the true value of the odds ratio could be between 1.001 and 1.017 or the odds increase from 0.1% to 1.7% for every additional minute in PACU (N=147).

The multiple logistic regressions on the outcome “complications” (yes or no) were re-run using a data set with information on a single surgery for each of 88 patients. Thirty-five patients had more than one surgery. In order to avoid repeated measures in the data analysis,
data for a single surgery were selected at random from each of these 35 patients. *Time in PACU* was the only predictor which was statistically significant although duration of GA had a relatively low P value and might be important (Table 11).

**Table 10. Logistic Regression Analysis (N=147)**

<table>
<thead>
<tr>
<th>Predictor Variables</th>
<th>Significance Level</th>
<th>Odds Ratio</th>
<th>Lower</th>
<th>Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>.954</td>
<td>.999</td>
<td>.961</td>
<td>1.038</td>
</tr>
<tr>
<td>Sex</td>
<td>.517</td>
<td>.764</td>
<td>.339</td>
<td>1.724</td>
</tr>
<tr>
<td>ASA</td>
<td>.096</td>
<td>.448</td>
<td>.174</td>
<td>1.153</td>
</tr>
<tr>
<td>Current Medications</td>
<td>.927</td>
<td>1.048</td>
<td>.383</td>
<td>2.870</td>
</tr>
<tr>
<td>Duration of GA</td>
<td>.654</td>
<td>.998</td>
<td>.991</td>
<td>1.006</td>
</tr>
<tr>
<td>Time in PACU</td>
<td>.031</td>
<td>1.009</td>
<td>1.001</td>
<td>1.016</td>
</tr>
<tr>
<td>PAU Evaluation</td>
<td>.432</td>
<td>1.487</td>
<td>.553</td>
<td>4.002</td>
</tr>
</tbody>
</table>

**Table 11. Logistic Regression Analysis (N=88)**

<table>
<thead>
<tr>
<th>Predictor Variables</th>
<th>Significance Level</th>
<th>Odds Ratio</th>
<th>Lower</th>
<th>Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>.626</td>
<td>.987</td>
<td>.935</td>
<td>1.041</td>
</tr>
<tr>
<td>Sex</td>
<td>.533</td>
<td>.689</td>
<td>.213</td>
<td>2.229</td>
</tr>
<tr>
<td>ASA Classification</td>
<td>.157</td>
<td>2.684</td>
<td>.684</td>
<td>10.528</td>
</tr>
<tr>
<td>Current Medications</td>
<td>.767</td>
<td>1.232</td>
<td>.309</td>
<td>4.909</td>
</tr>
<tr>
<td>Duration of GA</td>
<td>.392</td>
<td>1.006</td>
<td>.993</td>
<td>1.019</td>
</tr>
<tr>
<td>Time in PACU</td>
<td>.046</td>
<td>1.011</td>
<td>1.000</td>
<td>1.022</td>
</tr>
<tr>
<td>PAU Evaluation</td>
<td>.410</td>
<td>1.760</td>
<td>.458</td>
<td>6.762</td>
</tr>
</tbody>
</table>
4.19 Comparison Between Time Under General Anesthesia and Time in PACU Between Patients With and Without Complications

For N=147, time spent under GA was not positively related to the occurrence of complications (P=0.54)(Table 12 and Figure 29). For N=147, time spent in the PACU was positively related to the occurrence of complications (P=0.04)(Table 12 and Figures 29 and 30).

Table 12. T-test Comparing Time Under GA and Time in PACU Between Patients With and Without Complications (N=147)

<table>
<thead>
<tr>
<th>Complications</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>T-test P value(^1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minutes under GA</td>
<td>No</td>
<td>107</td>
<td>116.55</td>
<td>61.887</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>40</td>
<td>123.18</td>
<td>51.062</td>
</tr>
<tr>
<td>Minutes in PACU</td>
<td>No</td>
<td>105</td>
<td>73.82</td>
<td>42.335</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>40</td>
<td>98.28</td>
<td>68.106</td>
</tr>
</tbody>
</table>

\(^1\) Equal variance assumed for minutes PACU but not minutes GA
Figure 29. Box Plot Graph Comparing Time Under GA vs. Complications (N=147)

T-test to Compare Minutes Under GA vs. Complications (N=147) (P=0.54)
Figure 30. Box Plot Graph of Time in PACU vs. Complications (N=147)

In the sample of 88 surgeries, patients with complications spent significantly more time under GA (P=0.04) and in PACU (P=0.05) than patients without complications (Table 13, and Figures 31 and 32).

Table 13. T-test Comparing Time Under GA and Time in PACU Between Patients With and Without Complications (N=88)

<table>
<thead>
<tr>
<th>Complications</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>T-test P value³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minutes under GA</td>
<td>No</td>
<td>66</td>
<td>109.42</td>
<td>44.950</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>22</td>
<td>133.36</td>
<td>52.251</td>
</tr>
<tr>
<td>Minutes in PACU</td>
<td>No</td>
<td>65</td>
<td>79.09</td>
<td>45.840</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>22</td>
<td>113.64</td>
<td>73.482</td>
</tr>
</tbody>
</table>

¹ Equal variance assumed for minutes PACU but not minutes GA
Figure 31. Box Plot Graph Comparing Time Under GA vs. Complications (N=88)

T-test to Compare Minutes Under GA vs. Complications (N=88) (P=0.04)
Figure 32. Box Plot Graph of Time in PACU vs. Complications (N=88)

T-test to Compare Minutes in PACU vs. Complications (N=88) (P=0.05)
4.20 Complications in Different Age Classes

For both study groups of N=147 and 88, individuals between the ages of 26-45 years were the most likely to suffer a complication, followed by those under the age of 26 years (Tables 14 and 15, Figures 33 and 34).

Table 14. Complications in Different Age Classes (N=147)

<table>
<thead>
<tr>
<th>COMPlications IN DIFFERENT AGE CLASSES (N=147)</th>
<th>Complications</th>
<th></th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Age Class (years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Under 26</td>
<td>47</td>
<td>14</td>
<td>61</td>
</tr>
<tr>
<td>26-45</td>
<td>48</td>
<td>23</td>
<td>71</td>
</tr>
<tr>
<td>45-60</td>
<td>12</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>Total</td>
<td>107</td>
<td>40</td>
<td>147</td>
</tr>
</tbody>
</table>

Figure 33. Bar Graph of the Percentage of Complications Per Age Class (N=147)
Table 15. Complications in Different Age Classes (N=88)

<table>
<thead>
<tr>
<th>Age Class (years)</th>
<th>Complications</th>
<th>No</th>
<th>Yes</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 26</td>
<td>31</td>
<td>10</td>
<td>41</td>
<td></td>
</tr>
<tr>
<td>26-45</td>
<td>27</td>
<td>10</td>
<td>37</td>
<td></td>
</tr>
<tr>
<td>45-60</td>
<td>8</td>
<td>2</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>66</td>
<td>22</td>
<td>88</td>
<td></td>
</tr>
</tbody>
</table>

Figure 34. Percentage of Complications Per Age Class (N=88)
4.21 Prevalence of Complications Based On Location of Anesthesia Consult

In both analyses of N=147 and 88, patients who had a PAU consult were more likely to suffer a complication, however the results were not statistically significant (Figures 35 and 36).

Figure 35. Percentage of Patients Who Had Complications Based on Location of Anesthesia Consult (N=147)

Figure 36. Percentage of Patients Who Had Complications Based on Location of Anesthesia Consult (N=88)
4.22 Comparison of Mean Time Spent in PACU by Patients With and Without a Pre-Operative Sedative

For both analyses of N=147 and 88, the boxplot graphs depict that there was no significant difference in minutes spent in PACU between patients with and without a pre-operative sedative (Tables 16 and 17, Figures 37 and 38). Boxes enclose the middle 50% of the observations, vertical bars extend to include approximately 90% of the observations while circles and asterisks denote outlying and extreme observations. The median is shown by the horizontal line.

Table 16. T-Test Comparing Mean Time Spent in PACU Between Patients With and Without a Pre-Operative Sedative (N=147)

<table>
<thead>
<tr>
<th>Pre-Operative Sedative</th>
<th>N</th>
<th>Mean (minutes)</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minutes in PACU</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>132</td>
<td>80.15</td>
<td>51.85</td>
<td>4.51</td>
</tr>
<tr>
<td>Yes</td>
<td>13</td>
<td>84.77</td>
<td>51.82</td>
<td>14.37</td>
</tr>
</tbody>
</table>

P=0.76
Figure 37. Box Plot Graphs for Time Spent in PACU for Patients With and Without a Pre-Operative Sedative (N=147)

Time Spent in PACU for Those With and Without a Pre-Operative Sedative (N=147) (P=0.76)
Table 17. T-Test Comparing Mean Time Spent in PACU Between Patients With and Without a Pre-Operative Sedative (N=88)

<table>
<thead>
<tr>
<th>Pre-Operative Sedative</th>
<th>N</th>
<th>Mean (minutes)</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minutes in PACU</td>
<td>No</td>
<td>77</td>
<td>87.34</td>
<td>55.92</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>10</td>
<td>91.60</td>
<td>57.45</td>
</tr>
</tbody>
</table>

Figure 38. Box Plot Graphs for Time Spent in PACU for Patients With and Without a Pre-Operative Sedative (N=88)
4.23 Previous GAs For Dental Care

Of the 147 surgeries, 95 (64.6%) had previous GAs for dental care. Of the 88 surgeries, 44 (50%) had previous GAs for dental care. Using the data set with only one observation per patient (N=88), there was a significant association between previous GA’s for dental care and whether or not a patient experienced a complication. In the N=88 analysis, of the 43 patients that did not have previous GAs for dental care, 16 (16/43=37.2%) had at least one complication. Individuals that did not have a previous GA for dental care were significantly more likely to have a complication. Individuals who had previous GAs for dental care were less likely to have a complication (Figure 40).

The association was not statistically significant in the 147 analysis and given that the overall complication rate was almost identical (22/88=25% versus 40/147=27%) this may mean that some patients are more likely than others to experience complications regardless of their previous GA experience (Figure 39).
Figure 39. Complications in Individuals With and Without Previous GAs for Dental Care (N=147)

Complications in Individuals With and Without Previous GA's for Dental Care (N=147) P=0.22

Figure 40. Complications in Individuals With and Without Previous GAs for Dental Care (N=88)

Complications in Individuals With and Without Previous GA's for Dental Care (N=88) P=0.01
5.0 RESULTS PART 2- PROSPECTIVE SURVEY

Thirty-two surveys were returned, and 27 were correctly filled out. None of the surveys were complete, with many questions left unanswered. Table 18 below shows a summary of the VAS questionnaire answers. For each complication, the value N represents the number of patients that reported each complication. The ‘Days’ variable, represents that most of these complications were only experienced on the day of surgery and for less than 24 hours.

The most commonly occurring complications may be expressed as those with the most people reporting. The most commonly occurring complications in order of highest to lowest were: change in activity level, daytime alertness, drowsiness, agitation, fever and appetite. The most severe complications were represented by those with the highest mean. The most severe complications in order of highest to lowest were: change in activity level, daytime alertness, and attention seeking behavior.
Table 18. Survey Responses for Post-Operative Symptoms

<table>
<thead>
<tr>
<th>POST-OPERATIVE COMPLICATIONS</th>
<th>Number of patients reporting N=27 (%)</th>
<th>Mean VAS Scores (SD)</th>
<th>Mode –# of Days Changes Were Seen</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>17 (63)</td>
<td>6.3 (17.1)</td>
<td>0</td>
<td>1.0 (1.5)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>18 (67)</td>
<td>3.5 (5.0)</td>
<td>0</td>
<td>0.9 (1.4)</td>
</tr>
<tr>
<td>Pain</td>
<td>18 (67)</td>
<td>15.2 (23.9)</td>
<td>0</td>
<td>1.5 (1.4)</td>
</tr>
<tr>
<td>Agitation</td>
<td>20 (74)</td>
<td>13.8 (21.8)</td>
<td>0</td>
<td>2.5 (3.4)</td>
</tr>
<tr>
<td>Headache</td>
<td>16 (59)</td>
<td>6.2 (10.0)</td>
<td>0</td>
<td>2.1 (4.4)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>16 (59)</td>
<td>5.0 (7.6)</td>
<td>0</td>
<td>0.8 (0.9)</td>
</tr>
<tr>
<td>Drowsiness</td>
<td>21 (78)</td>
<td>14.5 (23.8)</td>
<td>0</td>
<td>1.6 (1.3)</td>
</tr>
<tr>
<td>Fever</td>
<td>20 (74)</td>
<td>9.8 (21.8)</td>
<td>0</td>
<td>0.8 (0.9)</td>
</tr>
<tr>
<td>Sore Throat</td>
<td>18 (67)</td>
<td>9.0 (14.9)</td>
<td>0</td>
<td>0.9 (1.1)</td>
</tr>
<tr>
<td>Weakness</td>
<td>17 (63)</td>
<td>10.7 (19.0)</td>
<td>0</td>
<td>1.1 (1.2)</td>
</tr>
<tr>
<td>Daytime Alertness</td>
<td>22 (81)</td>
<td>22.2 (30.9)</td>
<td>1</td>
<td>1.4 (1.3)</td>
</tr>
<tr>
<td>Appetite</td>
<td>21 (74)</td>
<td>20.7 (3.1)</td>
<td>0</td>
<td>2.1 (3.0)</td>
</tr>
<tr>
<td>Activity Level</td>
<td>24 (89)</td>
<td>27.1 (31.6)</td>
<td>1</td>
<td>2.1 (2.8)</td>
</tr>
<tr>
<td>Attention Seeking</td>
<td>18 (67)</td>
<td>17.2 (27.5)</td>
<td>0</td>
<td>2.6 (3.6)</td>
</tr>
</tbody>
</table>
Table 19. Satisfaction Data

<table>
<thead>
<tr>
<th>SATISFACTION DATA</th>
<th>Number of patients reporting N=27 (%)</th>
<th>Mean VAS scores (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Had a positive experience</td>
<td>27 (100)</td>
<td>93.7 (6.6)</td>
</tr>
<tr>
<td>Believes patient had a positive experience</td>
<td>25 (93)</td>
<td>84.5 (20.6)</td>
</tr>
<tr>
<td>Knew who to call in case of concerns</td>
<td>27 (100)</td>
<td>91.1 (17.8)</td>
</tr>
<tr>
<td>Expectations were met</td>
<td>27 (100)</td>
<td>93.1 (8.7)</td>
</tr>
<tr>
<td>Believes GA is the only way for treatment</td>
<td>27 (100)</td>
<td>97.3 (3.3)</td>
</tr>
<tr>
<td>Would use service again</td>
<td>27 (100)</td>
<td>96.4 (4.1)</td>
</tr>
<tr>
<td><strong>MEAN SATISFACTION SCORE</strong></td>
<td>-</td>
<td><strong>92.7%</strong></td>
</tr>
</tbody>
</table>

5.1 Survey Question #3 Re: Pain Meds
Of the 22 people that reported on the administration of pain medication, 10 people administered pain medication and 12 did not. Of the 9 people that reported on prescription pain medication, 4 people administered prescription pain meds and 5 did not. Of the 6 people that reported on the administration of non-prescription medication, 5 people administered non-prescription medication, and 1 did not. Of the 10 people that reported on the patient’s pain severity, 7 reported that the pain was mild, 2 reported it was moderate, and 1 reported it was severe.

5.2 Satisfaction Survey
The satisfaction survey was comprised of six questions. All of the 27 respondents answered all 6 questions except for one of the questions which had 25 respondents. When asked if they had a positive experience, 93.7% of parents/caregivers agreed. When asked if they believed that the patient had a positive experience, only 84.5% agreed. Most parents/caregivers knew who to call in the case of emergency and their expectations were met. When asked about GA as a treatment option, 97.3% agreed that GA was the only way that treatment could have been complete. Most parents/caregivers (96.4%) would use the service again. Overall, the mean satisfaction score was 92.7%.
5.3 Survey Comments
At the end of the survey, parents and caregivers were given the opportunity to make comments. The following comments were made:

- “(Patient’s name) never says anything hurts or is sore. She was crazy until she got the monitor off her finger-she got her bracelets off and she got the IV out-then she drank lots of water and was back to her good natured self again. She got home and ate some soup and had scrambled egg and was good as new. I was very happy with the treatment she received on (date). Thank-you”

- “Following day after treatment, majority of the day was spent sleeping. Her voice was raspy and she had a mild cough. She was not active the day after the treatment. The following day, so day 2 she was back to normal. She was very agitated and angry as well as physical due to the treatment on the following day. I don’t believe that the patient had a positive experience since she was not a willing participant. We have tried alternative treatments and they have not worked.”

- “Let me say how grateful we are to Dr. Sigal and his team. Wait times are too long...could groups of teams travel to different parts of Ontario to offer these services? Could telephone or video conferencing from one hospital to another be done for pre-operative questions?”

- “This is a wonderful service. I can’t imagine doing without it!”

- “As usual, the treatment for and of the patient and his caregivers was top notch. We have been using these dental services for 15 years and your staff at all levels is above reproach. Congratulations on your level of commitment and caring.”

- “I would like to add that the staff of Mount Sinai Hospital Dental Program for Persons with disabilities played the key role in obtaining and coordinating services from gastroenterologist to do a test while my son was under general anesthesia. I greatly appreciated that! Thanks.”

- “1) Everyone was very patient, understanding, knowledgeable dealing with a “disabled” person and also excellent at dealing with parents concerns and anxieties. 2) (Patient’s name)’s nose was itchy and tingly for 5 days +.”
• “Dear Dr. Sigal and Dr. Sharma, in spite of the fact we had to wait four hours, for our appointment for our daughter yesterday, the care we received by the very capable Dr. Lee and his team was exemplary. Regrettably our daughter was left four years without receiving a proper x-ray. Why was this? In future, it is our fervent wish that she be x-rayed every two years, to catch any problems sooner. Dr. Lee was very compassionate, which made the experience less traumatic for us all. He is to be congratulated for his people skills. There also was a lovely vivacious young woman, who unfortunately, we didn’t get her name (she lost her beagle dog for 29 hours) I’m certain you’ll know of whom we speak, stopped and interacted with our daughter every time she passed us by, even though she was obviously busy. She really impressed us and certainly made our daughter’s waiting time much less stressful. Please compliment her for us on her bedside manners. Thank you”

• “As a mother, now I am very pleased with the results. I hope it will last her a long time. I was worried the first 2-3 days, there was a lot of bruising and swelling and she was drooling a lot of pinkish blood. She finally started to swallow on the 3rd day a little better and then started to progress well. Overall I think it good. Thank-you. P.S. it would have been nice to have a follow up appt.”
6.0 DISCUSSION

6.1 Summary of Findings

There were four hypotheses tested in the current study. The following are the hypothesis and a summary of findings from this study, as they relate to either supporting or rejecting the hypothesis.

1. The prevalence of peri-operative complications from the chart review will be similar to the prevalence of complications cited in the literature for the general population, which is estimated to be 6.0%.
   - The prevalence of complications in this study was almost four times higher, and was 26.5% and 25.0% for the N=147 and N=88 analyses respectively. This hypothesis was rejected.

2. Peri-operative complications can be predicted based on information collected from the patient’s chart.
   - In this study, it was found that greater time spent in PACU (N=147 and 88), greater time spent under GA (N=88), and no previous history of dental care under GA (N=88) were significantly related to the occurrence of complications and thus may be predictors of complications. This hypothesis was accepted.

3. The report of post-operative symptoms in the survey will be greater than 80.0% and thus higher than that reported in the literature for the general population.
   - Table 20 compares post-operative symptoms in the present study to other similar studies. The prevalence in the present study was higher as predicted since 100.0% of patients experienced at least one symptom. This hypothesis was accepted.

4. Parental and caregiver satisfaction with the service provided will be higher than 80% based on reports in the literature.
   - The burden of these symptoms on parents and caregivers was relatively low as evidenced by the high satisfaction (92.7%) experienced by parents and caregivers. This hypothesis was accepted.
6.2 Analysis

The results of two separate analyses are presented here. The first analysis was of 147 different general anesthetics for 88 patients. The rationale for the first analysis was to accrue as many events (complications) using the available data in order to better power the logistic regression model. However, one caveat to this approach is the fact that each patient who contributed more than one general anesthetic to the model had similar patient factors. Therefore, if some patients had certain factors that predisposed them to a complication, the outcome variable (complications) may have been concentrated around those patients. To circumvent this problem, a second analysis was conducted consisting of one randomly selected GA for each of the 88 patients to avoid a cluster effect of some patients contributing more than one GA. This study attempted to investigate whether there was a cluster effect in the former of these analyses, by investigating whether there was indeed a higher prevalence of complications in patients who had multiple anesthetics versus those who had just one during the study period. The results suggested that there was no such effect (p = 0.28).

6.3 Prevalence of All Complications

A recent study reviewed PWD undergoing GA from 1995-2001 in Ontario suggested that 40% of all day surgery admissions were for dental procedures (Balogh, Ouellette-Kuntz, & Hunter, 2004). The present study examined the prevalence of peri-operative complications in PWD undergoing GA for dental treatment at Mount Sinai Hospital. The prevalence of complications in the present study was 26.5% and 25.0% for the N=147 and N=88 analyses respectively. More than 50.0% of all complications in this study occurred post-operatively in both analyses.

As mentioned previously, the prevalence of complications in this study was higher than anticipated. A possible explanation for this finding is that treating dentists may not observe intra-operative complications, as these are primarily managed by the anesthetist. Furthermore, complication rates in the literature were reported as low as 6.0% although a wide variety existed as high as 92% (Bridgman, Ashby, & Holloway, 1999; Matsuura, Hirose, Joh, Sugiyama, Niwa, & Shibutani, 2000). There were few reports in the literature pertaining to peri-operative complications in PWD. Thus the prevalence of peri-operative complications of 6.0% was drawn from the general population. The patients in this study were predominantly classified as ASA 3, thus they had a severe systemic disease that
affected their activities of daily living. Their disabilities and co-existing medical conditions may have led to a higher prevalence of peri-operative complications in this study.

Boynes et al studied peri-operative complications in 202 special needs patients that underwent dental treatment under nitrous oxide, oral sedation, intravenous sedation and GA (Boynes, Moore, Lewis, Zovko, & Close, 2010). Their patient population was very similar to the population in the present study, as they were cognitively impaired and had similar ASA classifications (84.7% were ASA II and 14.4% as ASA III). They studied a comprehensive list of complications that were very similar to the complications in the present study: change in HR and BP, nausea and vomiting, airway problems, sore throat, hypoxia and bleeding relating to anesthetic care amongst others. The prevalence of complications in their study was 23.8%, which was very similar to the prevalence of complications in the present study.

Enever et al in 2000 surveyed parents about post-operative symptoms in children with and without disabilities that underwent dental treatment under GA. They found that the prevalence of symptoms was 44.0% and it included the following: post-operative nausea and vomiting (PONV), unexpected drowsiness, and pain. Since a survey was used to collect information, the results were susceptible to recall bias and may have been over-reported. There was no statistically significant difference in the symptoms incurred by children with and without disabilities (Enever, Nunn, & Sheehan, 2000).

Bridgman et al in 1999 studied post-operative symptoms in children after dental treatment for extractions. They found that 92.0% of children complained of symptoms that included pain, crying, nausea, vomiting, bleeding, drowsiness, and reduced appetite (Bridgman, Ashby, & Holloway, 1999). Holt et al studied post-operative complications in 103 children that underwent dental treatment under GA of which 92 had endotracheal tubes. The prevalence of post-operative symptoms was 92% (Holt, Chidiac, & Rule, 1991). These included PONV, oral pain, sore throat, drowsiness, headache, bleeding and muscle pain (Holt, Chidiac, & Rule, 1991). Farsi et al studied post-operative symptoms in 90 children that underwent dental treatment under GA and found that the prevalence of symptoms within the first 24 hours was 99.0% (Farsi, Ba'akdah, Boker, & Almushayt, 2009). The most common symptoms in their study included: difficulty eating, sleepiness, vomiting, pain, dental bleeding, drowsiness, sore throat, psychological changes and fever (Farsi, Ba'akdah,
Boker, & Almushayt, 2009). The prevalence of post-operative symptoms was only 33% by the third post-operative day (Farsi, Ba’akdah, Boker, & Almushayt, 2009).

The prevalence of post-operative symptoms was not recorded as complications in the above studies. The prevalence of symptoms was likely higher in the aforementioned studies since they included the following: immediate post-operative crying in children, immediate post-operative bleeding after extractions, drowsiness, sleepiness, and inability to eat properly. The differences in choice of outcome variable be it “symptoms” or “complications” may account for the differences in prevalence. The word ‘complication’ typically implies that the outcome is unexpected. However, some authors may have used the words symptoms and complications interchangeably.

The type of dental treatment may have had an effect on peri-operative outcomes. Almost 100% of patients in the aforementioned studies underwent extractions, which are typically associated with nausea and vomiting possibly due to swallowing blood post-operatively (Bridgman, Ashby, & Holloway, 1999; Holt, Chidiac, & Rule, 1991; Farsi, Ba’akdah, Boker, & Almushayt, 2009). The present study examined both intra-operative and immediate post-operative complications. The previous studies examined post-operative complications but did not assess peri-operative changes in oxygen saturation, or vital signs such as heart rate (HR) and blood pressure (BP).

6.4 Prevalence of Complications Broken Down By Type

Eleven factors were defined as complications in this study. Changes in intra-operative HR and BP requiring pharmacological intervention were defined as complications. Boynes et al studied peri-operative complications in special needs patients undergoing dental treatment using 4 different anesthetic techniques. Significant changes in HR and BP were numerically defined (Boynes, Moore, Lewis, Zovko, & Close, 2010). In the present study, the BP or HR were not arbitrarily set as a surrogate indicator of a complication. The reason for this decision was that each individual may tolerate a different amount of hypo/hypertension and/or brady/tachycardia. The need for pharmacological intervention was decided upon by the anesthetist when the patient started showing signs of hemodynamic instability. In this study, the rationale for using pharmacological intervention as a complication indicator was to provide a more comprehensive investigation of complications across the study population.
Changes in HR and BP may occur in response to or cause physiological end-organ dysfunction and can lead to complications related to the maintenance of respiratory and circulatory physiologic function (Deschamps & Denault, 2009). Ongoing intra-operative assessment of HR and BP allows the anesthetist to monitor the depth of anesthesia (Deschamps & Denault, 2009). Research has shown that patients with complex cardiac disease were more likely to show changes in HR and BP intra-operatively and were at a higher risk for suffering anesthesia related complications (Deschamps & Denault, 2009). In the present study the prevalence of significant intra-operative change in HR was 2.7 % and 2.3 % for N=147 and N= 88 respectively. The prevalence of significant intra-operative change in BP was 11.6 % and 11.4 % for N=147 and N=88 respectively. Boynes et al revealed a 3.9 % prevalence of hypotension, 0.9 % of which required pharmacological intervention. Boynes et al did not have any patients that experienced hypertension, however this may be due to their definition of hypertension (diastolic pressure greater than 110 mm Hg).

The importance of monitoring vital signs intra and post-operatively was made evident in a study by Rose et al. They studied 18,380 patients that were admitted to the PACU after their surgery under GA. Most patients were ASA I and II patients. They found that patients who experienced intra-operative hypertension and tachycardia were more likely to experience the same in the PACU. Patients that experienced tachycardia and hypertension in the PACU were more likely to have unplanned critical care admissions and a higher risk of mortality. Neither bradycardia nor hypotension, on the other hand, were associated with unplanned critical care admission or mortality (Rose, Cohen, & DoBoer, 1996).

Any intra-operative equipment problem was considered to be a complication in this study. Most peri-operative monitoring is computerized, therefore any problems with equipment in the peri-operative period may have a significant or fatal consequence. Equipment problems have been reported as ‘complications’ in other similar studies, and may occur in any patient population, and are not limited to PWD. A study by Webb et al revealed that anesthesia related complications were first detected (in descending order) by changes in pulse oximetry (27.0%), capnometry (24.0%), electrocardiography (19.0 %), and BP monitor (12.0%) (Webb, et al., 1993). Thus, all devices and monitors must be checked pre-operatively. In the present study, there were no equipment failures in the N=88 analysis.
however there was one failure in the N=147 analysis. This complication occurred in a 23 year old female patient. Her primary diagnoses were developmental delay and seizure disorder. She experienced a sudden decrease end-tidal carbon dioxide, due to mucous plugging of the endotracheal tube. The patient was extubated and re-intubated with a new endotracheal tube.

Narasethkamol et al, studied peri-operative complications in patients receiving general anesthesia (78.5%), spinal anesthesia (19.0%), TIVA (1.2%), conscious sedation (0.6%), and Bier block IV regional anesthetic (0.6%) (Narasethkamol, Charuluxananan, Kyokong, Premsamran, & Kundej, 2011). They found that equipment failure contributed to 13% of the total prevalence of complications incurred in the study. The high prevalence of equipment failure was due to preventable human error in over 40.0% of cases and poor upkeep of equipment (Narasethkamol, Charuluxananan, Kyokong, Premsamran, & Kundej, 2011).

Intra-operative and post-operative oxygen saturation of less than 92% were defined as complications in this study. Hypoxemia may lead to post-operative behavioral changes, it may signal end-organ dysfunction and death, and thus it has been established as the minimal monitoring standard during surgery by the World Health Organization (WHO) (Ehrenfeld, Funk, Schalkwyk, Merry, Sandberg, & Gawande, 2010; Key, Rich, DeChristofaro, & Collings, 2010). There is no standard numerical definition for hypoxemia however previous studies have used 90% as their baseline (Ehrenfeld, Funk, Schalkwyk, Merry, Sandberg, & Gawande, 2010; Moller, et al., 1993). In this study, the rationale for using an oxygen saturation of less than 92% as the baseline for a complication was because the study population consisted of PWD. A lower threshold for detection of complications was chosen as this patient population likely had less reserve to tolerate changes in vital signs. In this study, the prevalence of intra-operative oxygen desaturation was 2.7 % and 3.4 % for N=147 and N=88 respectively. The prevalence of post-operative oxygen desaturation was 5.4 % and 3.4 % for N=147 and N=88 respectively. Thus the prevalence of post-operative oxygen desaturation was higher than the intra-operative desaturation in the N=147 analysis. Based on clinical assessment, height, and, weight measurements, many of the PWD treated at the Mount Sinai are overweight or obese. In a study by El-Metainy et al in 2011, it was shown that individuals that were overweight or obese were more likely to have sleep apnea and thus were more susceptible to peri-operative oxygen desaturation (El-Metainy, Ghoneim, Aridae,
& Wahab, 2011). This may explain the increased prevalence of post-operative oxygen desaturation in this study. Also, there may have been motion artifact since monitors are more likely to give false readings in awake moving patients (Goldman, Petterson, Kopotic, & Barker, 2000). Due to the small sample size, this trend may not have been evident in the N=88 analysis.

Moller et al studied peri-operative oxygen saturation in 20,802 surgical patients that underwent regional and general anesthesia in Denmark. They found that the pulse oximetry failure rate was positively related to increasing ASA classification among participants. There was a 7.2 % failure rate of pulse oximetry monitors when associated with ASA 4 patients. The high failure may have been due to hypoperfusion or to equipment failures (Moller, et al., 1993).

In this study, post-operative nausea and vomiting (PONV) were defined as complications since they were not expected outcomes of dental treatment under GA. PONV may occur as a side effect of the anesthetic drugs, from the ingestion of blood after dental surgery, or due to anxiety (Enger & Mourino, 1985; Matsuura, Hirose, Joh, Sugiyama, Niwa, & Shibutani, 2000). PONV may lead to pain, hematoma formation, wound dehiscence and may delay discharge from hospital (Sinclair, Chung, & Mezei, 1999). The prevalence of PONV has been shown to decrease with increasing age (Sinclair, Chung, & Mezei, 1999). In the present study, the prevalence of post-operative nausea was 7.5 % and 9.1 % and post-operative vomiting was 4.8% and 6.8% in the analyses N=147 and N=88 respectively.

Enever et al in 2000 studied post-operative symptoms in children with and without disabilities after dental treatment under GA. They found a 20.0% prevalence of PONV, and found no difference between children with and without disabilities (Enever, Nunn, & Sheehan, 2000). The prevalence of PONV in Enever et al’s study may have been higher than in the present study because parents as opposed to hospital staff reported on their child’s symptoms in the first study (Enever, Nunn, & Sheehan, 2000). Also, Enever et al reported nausea and vomiting as one symptom. Nausea may be subjectively noted by parents, however vomiting is an objectively recorded symptom. This may have led to the over reporting of nausea. Other studies have suggested that parents tend to over report their child’s symptoms (Hosey, Machpherson, Adair, Tochel, Burnside, & Pine, 2006). Bridgman found that 6.0% of children suffered from immediate post-operative nausea and 11.0% from
post-operative vomiting (Bridgman, Ashby, & Holloway, 1999). The prevalence of post-operative vomiting may have been higher in Bridgman et al.’s study relative to the present study because all of the patient’s in their study had extractions done whereas only approximately half of the surgeries in the present study involved extractions (Bridgman, Ashby, & Holloway, 1999). The ingestion of blood post-operatively is a known cause of PONV (Enger & Mourino, 1985; Matsuura, Hirose, Joh, Sugiyama, Niwa, & Shibutani, 2000).

Holt et al in 1991 studied post-operative symptoms in 103 children that underwent dental treatment and minor oral surgery procedures under GA. Of the 103 patients, 91.0% suffered at least one or more symptoms, some of which included: oral pain (51.0%), sore throat (27.0%), drowsiness (45%), headache (21.0%), nausea (21.0%), vomiting (20.0%), bleeding (29.0%) and muscle pain (12.0%) (Holt, Chidiac, & Rule, 1991). Boynes et al reported a prevalence of nausea and vomiting of 9.4% during the immediate post-operative period and the first 24 post-operative hours (Boynes, Moore, Lewis, Zovko, & Close, 2010). These prevalence rates of PONV were similar to those found in the present study. Farsi et al reported that during the first 24 hours post-operatively, the prevalence of nausea and vomiting was 8.0% and 26.0% respectively. The prevalence of vomiting in Farsi et al’s study was much higher than what was found in the present study. This could be explained by the fact that in Farsi et al’s study, all the participants were children that had extractions done which could have led to the swallowing of blood and subsequent vomiting. Kotiniemi et al studied post-operative symptoms at home in 551 children that underwent GA for a variety of surgeries in 5 different hospitals. None of the patients underwent dental surgery. They found that 13.0% of children experienced PONV. Predictors for PONV included, emetic symptoms in the hospital, pain at home, age greater than 5 years, and the administration of an opioid post-operatively (Kotiniemi, Ryhanen, Valanne, Jokela, Mustonen, & Poukkula, 1997). The prevalence of PONV in Kotiniemi et al’s study was similar to that in the present study.

Post-operative bleeding requiring dental attention was defined as a complication in the present study. A small amount of bleeding from extraction sites usually occurs post-operatively however it is usually managed by the PACU nurses. In this study, there were no instances of post-operative bleeding necessitating dental attention despite the fact that almost
half of the patients in the N=147 analysis and over half of the patients in the N=88 analysis had dental extractions done. This may be a result of the fact that the Mount Sinai Dental Program for PWD was developed over thirty years ago (Sigal M. J., 2010). Clinical practices such as the suturing of all sockets with observed hemostasis prior to drug reversal in the OR and prior to extubation, have led to few instances of post-operative bleeding requiring dental attention. Also, the PACU nurses and other members of the health care team have been well trained in the post-operative care of PWD that have received dental care under GA. Farsi et al studied post-operative complications in 90 children that underwent dental treatment under GA. They found that children who had more than 5 teeth extracted were more likely to suffer from post-operative bleeding. The prevalence of bleeding was reported to be 40% on the first post-operative day and was down to 5.6% by the third post-operative day (Farsi, Ba'akdah, Boker, & Almushayt, 2009). The increased prevalence of post-operative bleeding in the Farsi et al study may be because they collected information about post-operative complications over 72 hours. Holt et al reported that 29.0% of children that underwent GA for their dental care experienced bleeding. Of the 103 children in Holt’s study, 31.0% of the children had disabilities. The prevalence of post-operative bleeding amongst these children was 29%. The higher prevalence could be explained by the fact in the Holt et al study, similar to the Farsi et al study, information was collected regarding post-operative symptoms over a longer time period. They collected information post-operatively on the ward, on the journey home, and once reaching home (Holt, Chidiac, & Rule, 1991).

Airway complications may occur often in the PACU (Tarrac, 2006). In the present study there were no post-operative airway problems. Rose et al showed that the use of a pre-medication with or without opioids as well as the intra-operative use of opioids were significantly related to post-operative respiratory complications. These respiratory complications in Rose et al’s study included unexpected oxygen saturation less than 90%, hypoventilation, and upper airway obstruction requiring an intervention (Rose, Cohen, Wigginsworth, & DeBoer, 1994). Of the 24, 152 studied by Rose et al, 352 or 1.3% of them suffered respiratory complications post-operatively. These patients were at higher risk for suffering cardiac events, prolonged PACU stays and unplanned ICU admissions (Rose & Cohen, 1994).
In the present study, there were 2 patients (N=147 and N=88) that had complications requiring admission. Thus, the prevalence complications requiring admission was 1.4% and 2.3% respectively for the N=147 and N=88 analyses. Patient 1 was a 32 year old male with an unlisted ASA classification. His admitting diagnoses included developmental delay and deafness. He did not have any previous GAs for dental care. His treatment under GA lasted 262 minutes and he spent 215 minutes in the PACU during which he suffered an immediate post-operative oxygen de-saturation of 89%. Post-operatively, the patient’s mother reported that her son had an unrelenting cough for one week pre-operatively which she failed to mention prior to surgery. Based on the medical history provided by the patient’s mother and the anesthetist’s clinical exam, the patient was electively admitted for suspicion of aspiration pneumonia. Patient 2 was a 17 year old male with an ASA classification of 3. His admission diagnoses included developmental delay, autism, undiagnosed anemia, and undiagnosed hyperthyroidism. His treatment under GA lasted 120 minutes and he spent 357 minutes in PACU. Intra-operatively he was found to have a critically low hemoglobin and thus was admitted post-operatively for transfusion therapy. He was diagnosed with severe anemia of unknown origin and hyperthyroidism during his admission. The patient was transfused post-operatively while intubated and was extubated 345 minutes after his surgery. This diagnosis was based on bloodwork done while the patient was under GA. The bloodwork was ordered by the patient’s primary care physician due to the patient’s poor cooperativity. In this case, the patient’s anemia may not have been diagnosed had it not been for his treatment under GA and thus the withdrawal of the patient’s blood intra-operatively. In Kotiniemi et al’s study, 13 (2.4%) patients were unexpectedly admitted overnight: 4 due to post-operative bleeding, 3 due to PONV, 3 due to fever and laryngitis, and 3 due to problems during their journey home (Kotiniemi, Ryhanen, Valanne, Jokela, Mustonen, & Poukkula, 1997). The prevalence of post-operative admissions in Kotiniemi et al’s study was similar to that in the present study.

In this study, there were no complications requiring return to hospital. This may be because parents and primary caregivers were thoroughly warned by the staff pediatric dentists about what to expect post-operatively. When necessary, instructions were also provided in writing. At the Mount Sinai Hospital, one of the discharge criteria on the PACU forms, include the delivery of post-operative instructions either verbally and/or in writing. Holt et al showed that 6 out of 103 parents sought medical attention for their child post-
operatively. Five parents contacted their family doctor; four due to persistent vomiting on the day of surgery, and one due to persistent coughing for a few days post-operatively. One parent sought emergency care for their child due to the loss of intra-oral sutures resulting in persistent oral bleeding. Holt et al did not specify which children sought medical attention post-operatively (Holt, Chidiac, & Rule, 1991).

6.5 Intra-Operative and Post-Operative Complications

In this study, the prevalence of post-operative complications was higher than intra-operative complications in both analyses. The prevalence of post-operative complications was 52.0% and 56.0% for the N=147 and N=88 analyses respectively. Hines et al reported that the prevalence of peri-operative complications in their study was 26.7 % of which 23.7 % were post-operative (Hines, Barash, Watrous, & O'Connor, 1992). They found that the presence of intra-operative hypotension increased the prevalence of post-operative complications in the PACU by 1.6 times. Patients who had intra-operative complications spent more time in the PACU (Hines, Barash, Watrous, & O'Connor, 1992). This can be explained by the fact that both longer GA times and the presence of intra-operative complications may predispose patients to complications in the PACU, and subsequently longer PACU stays (Rose & Cohen, 1994; Sinclair, Chung, & Mezei, 1999).

6.6 Multiple Logistic Regression Analysis

This study examined the effect of seven different predictor variables on the outcome of complications. Multiple logistic regression analysis revealed that Time in PACU was the only statistically significant predictor of the probability of a patient having a complication for both analyses (N=147 and N=88). In order to determine if the predictors in this model were, in fact, causative factors and not just associated with the dependent (outcome) variable (complications), the Bradford Hill criteria for determination of causation were used as a framework (Schunemann H., Hill, Guyatt, Akl, & Ahmed, 2010). These are nine criteria delineated by Austin Bradford Hill, which serve as the epidemiologic basis for determination of causation. They include the following:
- Temporal relationship between predictor and outcome variables
- Strength of the association
- Dose-response relationship
- Consistency of relationship
- Plausibility
- Whether you have ruled out potential alternative explanations
- Whether there is experimental evidence to support a causation
- Whether it is specific. For example, if the predictor variable is present, then does the outcome variable inevitably follow? This is a weaker criteria and not necessary for determination of causation.
- Whether it is coherent. For example, does the existing body of knowledge support the observed relationship?

These criteria were postulated to help confirm the presence of causation. Not all criteria need to be present, but the more criteria that are present, the stronger the likelihood that a certain predictor causes an outcome.

### 6.7 Predictor Variables Used in the Logistic Regression Analysis

In this study, multiple different predictor variables were examined to determine which of these variables could cause complications. Using the logistic regression analysis, it was found that time spent in the PACU was the only statistically significant predictor of complications. Understanding that not all statistical conclusions have meaningful clinical importance, the Bradford Hill criteria were used to further substantiate or refute the statistical findings. Concerning time in PACU, originally it was hypothesized that longer PACU stays may indeed predict complications. The rationale for this decision was that in clinical practice, a longer time in PACU was noted for patients that had complications. While there was indeed a strong associations (p=0.03 and 0.05 for N=147 and 88 respectively) between the two variables, there was not at a temporal relationship as per the Bradford Hill criteria. Some complications (48.0% and 44.0% for N=147 and 88 respectively) happened intra-operatively and the remainder happened post-operatively suggesting that the temporal
relationship was in fact the reverse, and that complications preceded the predictor variable. As an alternative explanation, one may suggest that patients who experience complications are likely to spend more time in the PACU. It is more likely that although the present study found a statistically significant relationship, complications are associated and arguably predictive of time spent in the PACU and not the reverse.

With regards to the other predictors in the logistic regression model (Age, Sex, ASA, current medications, Time under GA, PAU evaluation), none were statistically significant. Some studies have suggested that age, sex, ASA status, and GA time were predictive of complications (Ng, 2009; Farsi, Ba'akdah, Boker, & Almushayt, 2009; Atan, Ashley, Gilthorpe, Scheer, Mason, & Roberts, 2004). The present study failed to corroborate these conclusions. It is possible that age is indeed a predictor of complications. It is certainly plausible that the older one gets, the more likely they are to have other comorbid illnesses that would predispose them to complications. The same is true with ASA status. However, the present study focused on adults aged 16-60 years and did not include patients at the extremes of age. This study did not have extremely young nor extremely old patients in the cohort who would have been more likely to develop complications (Oghalai, Buxbaum, Pitts, & Jackler, 2003). It could then be that in this particular population, age was in fact not a predictor of complications.

Research has shown that sex was a predictor of complications (Farsi, Ba'akdah, Boker, & Almushayt, 2009; Atan, Ashley, Gilthorpe, Scheer, Mason, & Roberts, 2004). There is good biologic plausibility for this. One study suggested that gender differences can account for differences in hemodynamic parameters, specifically ventricular volume indices and ejection fractions (Wexler, et al., 2009). This gender difference can result in different cardiovascular outcomes for both intra-operative and post-operative physiological parameters. Some of our chosen complications including BP, HR and oxygen saturation may have been influenced by gender. Physiological differences between sexes may also partly account for differences in the emergence profiles of men and women.

Sex hormones and their effect on receptor sites for anesthetic agents influence emergence characteristics (Myles, McLeod, Hunt, & Fletcher, 2001). Women emerged faster from anesthesia when propofol and volatile anesthetic gases such as isoflurane and desflurane were used (Myles, McLeod, Hunt, & Fletcher, 2001). Furthermore, they also
suggested that females may have a predilection for PONV, one of the complications in this study, due to hormone changes during their menstrual cycle (Myles, McLeod, Hunt, & Fletcher, 2001). In comparing recovery profiles of 241 men and 222 women after their surgeries under GA, Myles et al found the post-operative complications were higher in women than in men. Women were more likely than men to have a history of PONV and were more likely to be given prophylactic antiemetic agents. Since PONV in women has been related to their menstrual cycle phase, biologic plausibility exists. However, the present study failed to show strength of relationship, consistency and dose-response effect that are necessary to show causation as per the Bradford Hill criteria. Other predictor variables in this study did not demonstrate statistical significance. This could be because there was indeed no causation, or that despite having a sample size that meets the power calculation, this study is simply underpowered to demonstrate causation due to the vast number of complications examined in the study (11).

Time under general anesthesia has also been related to complications (Ferrier, Spuesens, Le Cassie, & Baatenburg de Jong, 2005). Atan et al demonstrated that GA time, gender and the use of LA were all positively related to nausea, sleepiness, and dizziness (Atan, Ashley, Gilthorpe, Scheer, Mason, & Roberts, 2004). In Atan et al’s study, post-operative sedation and nausea were both positively related to time under GA. For every 10-minute increase in GA time, the patient was 15% more likely to feel sedated and 19% more likely to feel nauseous (Atan, Ashley, Gilthorpe, Scheer, Mason, & Roberts, 2004). These findings support experimental evidence, coherence, strength of relationship, and a dose-response association between GA time and complications. Furthermore, there was indeed a temporal relationship as complications happened either during or after the induction of anesthesia. Certainly, these factors support a causative relationship between GA time and complications. The logistic regression model in this study failed to show a relationship between GA time and the outcome variable of complications in both analyses (N=147 and N=88). However, when doing a simple t-test to compare duration of GA in those who had complications versus those who did not, the study revealed a significantly increased duration of GA in the group who had complications (133.4 minutes vs. 109.4 minutes, p = 0.04, Table 13) in the N=88 analysis. In the N=147 analysis, the complication group still had a longer duration of GA, but the results were not statistically significant (123.2 minutes vs. 116.6
98 minutes, $p=0.54$, Table 12). These findings may further corroborate that longer GA times could account for more complications. However, larger studies with a greater number of patients and complications are needed to elucidate this hypothesis.

In a large study, Hines et al. reviewed 15,213 patients who underwent GA for surgery. They revealed a PACU complication rate of 25%, and showed a positive relationship between ASA classification and complications (Hines, Barash, Watrous, & O'Connor, 1992). The present study examined ASA classification and medication use in relation to the occurrence of complications. The results indicated that there was no relationship between either ASA status or the presence of medication use with complications. However, this study was much smaller with far less variability data. For example, over 70% of the patient population in the present study was ASA class III and over 70% of the patients were using medications at the time of surgery. This relative homogeneity of the population would make it difficult to make statistical conclusions about the predictability of ASA status and medication use on the outcome variable.

In this study, it was hypothesized that patients at a higher risk of complications would be identified earlier by the treating dentist and appropriately referred for a pre-anesthesia unit (PAU) consultation. As part of the analysis, the study aimed to determine whether a PAU consultation was indeed predictive of patients who had complications. This predictor was not statistically significant in the logistic regression model. However there was indeed a higher rate of complications in patients who were seen in PAU as compared to those who were evaluated by the anesthesia team the same day of their GA ($36.4\%$ vs. $24.6\%$ for $N=147$; $38.1\%$ vs. $20.9\%$ for $N=88$). These findings suggest that treating dentists do appropriately screen for patients who are likely to have complications, but that PAU evaluations may not necessarily prevent these complications from occurring.

### 6.8 Previous General Anesthetics for Dental Care

Due to the relative rarity of complications (in 39 of 147 GAs, and in 22 of 88 patients), it was decided that an individual's previous GAs for dental care would be excluded as a predictor variable in the logistic regression analysis. However, as an aside, the prevalence of complications in patients who did and did not have previous GAs for dental care was examined. It was found that patients who had previous GAs for dental care were significantly less likely to have a complication in the $N=88$ analysis. In the $N=88$ analysis,
13.3% of patients who had previous GAs for dental care had complications, compared to 37.2% of those who had no previous GAs for dental care (p=0.01). This trend was also apparent for the N=147 analysis however the relationship was not statistically significant (p=0.22). Individuals who have had previous GAs for dental care may be less likely to suffer from complications since they have had numerous medical, and pre-anesthetic evaluations. Individuals who have not had previous GAs for dental care were at increased risk for complications. The patient population in this study tended to be uncooperative given their physical disabilities and cognitive impairments. As such the quality of their medical/pre-anesthetic assessments may have been compromised. Therefore it may have been difficult to determine anesthetic risk for these patients due to incomplete records and evaluations (Boynes, Moore, Lewis, Zovko, & Close, 2010; Ghezzi, Chavez, & Ship, 2000; Messieha, 2009).

6.9 The Use of Restraint During Induction

It is interesting to note that almost a quarter of all surgeries in this study involved the use of restraint during induction (Figures 11 and 12). This further substantiates the fact that the PWD that are treated under GA for their dental care at the Mount Sinai Hospital have limited cooperativity and thus require care under GA.

6.10 The Use of Pre-Operative Sedation

Due to the limited use of pre-operative sedation in this study population (8.8% and 11.4% for N=147 and N=88 respectively), it was electively decided not to include this parameter as a predictor in the logistic regression analysis. A simple t-test was used to compare the time spent in PACU by patients with and without a pre-operative sedative. The pre-operative sedative used in all cases was midazolam. There was no significant difference found in the recovery time for people with or without a pre-operative sedative, however the trend was that patient’s who received pre-operative sedatives spent more time in the PACU. A larger sample size would be needed to further examine whether or no pre-operative sedatives effect time in PACU.
6.11 Subjectively Reported Survey

In order to corroborate the findings regarding complications, parents/primary caregivers were polled to see what they subjectively observed in the patient regarding post-operative symptoms and whether or not they were satisfied with the care received. Parents and caregivers were asked about 14 different subjective complaints that they may have observed post-operatively in the patient (Table 18). The physical complaints were frequently reported (range 59% - 89% of patients reporting the 14 symptoms) and usually disappeared by the second post-operative day. Table 20 summarizes the main findings of post-operative symptoms in this study and compares to them to some relatively similar studies that examined post-operative symptoms in dental and surgical patients. Most of these studies dealt with healthy individuals in contrast to this study which focused on individuals with disabilities. However, Enever et al suggested there were no differences between physically or cognitively delayed individuals (Enever, Nunn, & Sheehan, 2000).

In most studies, a large number of patients reported at least one post-operative symptom. In this study, it was hypothesized that the report of post-operative symptoms in the survey would be higher than reported in the literature for the general population which was about 80.0%. According to the survey, this number was 100%. Each of the 27 people that filled out the survey reported at least one complication. In addition to reporting the prevalence of these post-operative symptoms, the quantification of these symptoms was attempted using a visual analogue scale (VAS). The results of this study show a high prevalence of post-operative symptoms relative to most of the published data. Farsi et al however reported a similar prevalence in their study of 99.0% (Farsi, Ba'akdah, Boker, & Almushayt, 2009). However, most of the existing studies reported only the presence or absence of symptoms. Needleman et al attempted to quantify pain symptoms using a Wong-Baker face pain scale which consists of a gradation of 6 faces with progressively increasing severity of pain (Needleman, Harpavat, Wu, Allred, & Berde, 2008). The results of the present study suggested that although the prevalence of symptoms was high (corroborated by previous studies), the burden of these symptoms on the parent and caregivers was relatively low. The mean VAS scores ranged from 3.5 – 27.1 mm out of a maximum of 100 mm (where 100mm is the most significant change from baseline). One limitation in interpreting the numbers in this study was the relatively low response rate (32%) for the survey.
Table 20. Comparison of Post-Operative Symptoms Experienced by Patients in This Study and in the Literature

<table>
<thead>
<tr>
<th></th>
<th>Sharma (n=27) %</th>
<th>Routh 1979 (n=160) %</th>
<th>Farsi 2009 (n=90) %</th>
<th>Atan 2004 (n=121) %</th>
<th>Smith 1976 (n=95) %</th>
<th>Bridgman 1999 (n=62) %</th>
<th>Needleman 2008 (n=90) %</th>
<th>Enever 2000 (n=55) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>63.0</td>
<td>17.0</td>
<td>7.8</td>
<td>21</td>
<td>30.5</td>
<td>18.0</td>
<td>24.0</td>
<td>20.0</td>
</tr>
<tr>
<td>Vomiting</td>
<td>67.0</td>
<td>6.3</td>
<td>25.6</td>
<td>n/a</td>
<td>8.4</td>
<td>12.0</td>
<td>n/a</td>
<td>20.0</td>
</tr>
<tr>
<td>Pain</td>
<td>67.0</td>
<td>41.3</td>
<td>47.8</td>
<td>74</td>
<td>n/a</td>
<td>19.0</td>
<td>95.0</td>
<td>n/a</td>
</tr>
<tr>
<td>Agitation</td>
<td>74.0</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>85.0</td>
<td>n/a</td>
</tr>
<tr>
<td>Headache</td>
<td>59.0</td>
<td>38.0</td>
<td>n/a</td>
<td>n/a</td>
<td>57.9</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Dizziness</td>
<td>59.0</td>
<td>14.5</td>
<td>n/a</td>
<td>n/a</td>
<td>40.0</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Drowsiness</td>
<td>78.0</td>
<td>39.5</td>
<td>38.9</td>
<td>84</td>
<td>46.3</td>
<td>27.0</td>
<td>58.0</td>
<td>13.0</td>
</tr>
<tr>
<td>Fever</td>
<td>74.0</td>
<td>n/a</td>
<td>21.1</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>15.0</td>
<td>n/a</td>
</tr>
<tr>
<td>Sore Throat</td>
<td>67.0</td>
<td>15.0</td>
<td>34.4</td>
<td>n/a</td>
<td>84.2</td>
<td>n/a</td>
<td>28.0</td>
<td>n/a</td>
</tr>
<tr>
<td>Weakness</td>
<td>63.0</td>
<td>n/a</td>
<td>n/a</td>
<td>68.0</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Daytime Alertness</td>
<td>81.0</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Appetite</td>
<td>74.0</td>
<td>n/a</td>
<td>85.5</td>
<td>n/a</td>
<td>n/a</td>
<td>11.0</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Activity Level</td>
<td>89.0</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Attention Seeking</td>
<td>67.0</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Overall with at least one symptom</td>
<td>100.0</td>
<td>82.5</td>
<td>99.0</td>
<td>n/a</td>
<td>92.0</td>
<td>n/a</td>
<td>44.0</td>
<td></td>
</tr>
<tr>
<td>Response Rate</td>
<td>32.0</td>
<td>80.0</td>
<td>100.0</td>
<td>n/a</td>
<td>89.6</td>
<td>90.0</td>
<td>n/a</td>
<td>100.0</td>
</tr>
</tbody>
</table>
6.12 Parent and Caregiver Satisfaction

Parents and caregivers who responded to the satisfaction survey indicated that they were quite satisfied with the care received (Table 19). With regards to satisfaction of the service provided, it was hypothesized that the satisfaction would be high, and thus greater than 80.0% based on reports from the literature (Prabhu, Nunn, Evans, & Girdler, 2010). The mean satisfaction score in this study was 92.7%, thus this hypothesis was accepted. The survey reported that every parent/caregiver indicated that they had a positive experience, had their expectations met, would use the service again, and the majority (93%) felt that the patient also had a positive experience with the care provided. Similarly, Routh et al found that 98% of 160 patients undergoing surgical procedures in general surgery, gynecology, orthopaedics and dentistry would have the procedure again if needed (Routh, 1979). However, another study with 95 patients who underwent a GA for dental procedures suggested that 22 of 42 patients surveyed had negative comments (Smith & Young, 1976). These patients, however, were healthy patients completing their own satisfaction surveys. A possible explanation for the high satisfaction in the present study may be due to the fact that PWD have trouble accessing dental care and the Mount Sinai Hospital Program for PWD is the only one of its kind in that region. Parents/caregivers may be hesitant to provide negative feedback due to the fear that it will affect the care that the patient receives in the future. Also, there may be a discrepancy between the feelings of parents and caregivers regarding the care received compared to the feelings of the patient.

The positive responses provided on the satisfaction survey seem inconsistent with the high prevalence of symptoms listed in the physical symptom survey. However, the information yielded with the VAS reveals that although the prevalence of the symptoms was high, the relative importance of these symptoms is low. The perceived impact of these symptoms on patients was low which may have contributed to parent/caregiver satisfaction.
7.0 LIMITATIONS OF THE STUDY

7.1 Part 1- Retrospective Chart Review

The limitations of part 1 include:

- The analysis was retrospective. The collection of data was performed posthoc thus errors due to bias and confounding may have been more likely.

- There was a small sample size. Using an estimated figure of 6.0% for the prevalence of peri-operative complications, the power calculation indicated 81 patients were required to have an adequately powered study. However, because 11 different complications were examined, a higher sample size would have increased the reliability and validity of the data.

- There was no control group in the study. Individuals that are treated under GA for their dental care at The Mount Sinai Hospital are treated as such due to behavioral and physical limitations that prevent them from cooperating for treatment under LA. It would not be ethical to treat a control group without disabilities under GA if they were able to cooperate for treatment under LA.

- Two variables in the multiple logistic regression analysis were significantly correlated for the N=147 analysis, but the correlation coefficients were small, 0.18 and 0.16 for N=147 and N=88 respectively. This may have led to confounding of results.

- There was loss of information. In the logistic regression analysis, ASA 1 and 2 patients were combined to represent mild disease and ASA 3 and 4 represented severe disease. This was done because there were not enough ASA 1 and 4 patients in this study. ASA 4 patients are those that have severe systemic disease that is a constant threat to life and thus it may have been better to place these patients in a category of their own.

- Multiple analyses were performed on the same patient. In order to increase the sample size and the number of complications, the unit of analysis used was the total number of GAs in 88 patients between 2004-2009.

- There may have been a possible cluster effect. Individuals who had multiple GAs included in the study may have caused confounding of data. The
individuals may have had patient specific factors in their profiles that made them more likely to have complications. These individuals may have contributed to a greater number of complications. To circumvent this issue, the number of complications incurred by individuals who had a single surgery between 2004-2009 versus those who had multiple surgeries was compared, and no statistically significant difference was found.

- There was a single data abstracter which may have led to error and inaccuracies, yet it provides consistency and eliminates the need for calibration.
- Data in the anesthesia and PACU charts were recorded by different physicians and nurses which may have led to inconsistencies and potential inaccuracies in reporting of data.
- Sampling error. As a result of a poor response rate of 17.6%, the study population was not representative of the whole population of PWD treated at The Mount Sinai Hospital and therefore was not random. This problem could have been countered if there had been a greater sample size.
  - Responder bias is a type of sampling error since the patients that participated in the study, may have taken part because they had no complications, or they had many complications. Therefore, the sample was not representative of the whole population of PWD that are treated at The Mount Sinai Hospital Dental Department.
  - Systematic errors are biases in measurements where the mean of many measurements differ significantly from the actual mean. These may have occurred due to the small sample size.
- Patients were not analyzed according to their medical diagnoses. Many patients had several medical diagnoses which made it not only difficult to make direct comparisons but also to classify the different types of diagnoses. Alternatively, the hope was that in using the ASA classification, the general health of the patients in the study would be depicted while accepting some loss of information.
7.2 Part 2- Prospective Survey

The limitations of Part 2 include:

- There was a small sample size. The response rate was 32% of the 100 consecutive surveys that were distributed. Of the 32 surveys, 5 were discarded due to errors in survey completion and thus the total N=27.
- The surveys were completed anonymously without any patient identifiers. Most of the PWD that were included in the retrospective chart review, had received dental care under GA previously. It would have been interesting to compare the prospective data to the retrospective data to analyze whether the prevalence of symptoms reported was similar in both cases.
- Demographic and medical diagnosis information was not recorded, preventing the analysis of the effect of age, sex, ASA status etc. on the prevalence of complications reported in the survey.
- A control group was not used. Persons without disabilities do not receive dental care under GA at the Mount Sinai Hospital, unless it is for oral surgical procedures. Oral surgical patients were not included in this study.
- There was a single data abstracter.
- Parents and primary caregivers filled out the survey based on their observations. Many of the individuals in this study were non-verbal. This may have led to either an under reporting or over reporting of symptoms.
8.0 CONCLUSIONS

In this study, there was a high prevalence of peri-operative complications, 26.5% and 25.0% for the N=147 and N=88 analyses respectively. The prevalence of peri-operative complications in this study was higher than the prevalence of 6.0% for the general population as cited in the literature, thus the first hypothesis of the study was rejected. There are a few possible explanations for the high prevalence of complications in this study: most of the subjects in this study were classified as ASA 3 and thus may have been more likely to suffer complications. Also, this study included intra and post-operative changes in HR and BP requiring pharmacological intervention, which many studies did not include. These findings are important however they cannot be extrapolated to all PWD due to the limitations of this study, particularly the low sample size.

The main finding from the logistic regression analysis was that time in PACU was significantly related to the occurrence of complications. This may not have been a causative relationship since most complications in this study occurred post-operatively; implying that patients had longer PACU stays because they had complications. Even though the logistic regression analysis did not show a causal relationship between Time Under GA and complications, a simple t-test indicated that there was a significant relationship when analyzing one GA per patient (N=88). Patients that had longer GA times were more likely to have at least one complication. The relationship was not significant for N=147 analysis, however the trend was still apparent. Most PWD that are treated under GA for their dental care at the Mount Sinai Hospital have had repeated GAs for their dental care in the past. This is relevant because the information from previous GAs can be helpful in predicting future anesthetic risk. Also, it was found that patients who did not have previous GAs for dental care, were significantly more likely to have complications in the N=88 analysis. This may be due to limited cooperativity and subsequent lack of adequate pre-operative medical and anesthetic assessments. This relationship was not significant in the N=147 analysis, however the trend was still apparent. Thus, increased time under GA, previously long PACU stays, and no previous history of GAs for dental care may increase the risk of peri-operative complications. Factors in a patient’s profile may be predictive of peri-operative complications, thus the second hypothesis of this study was accepted.
The complications in this study were related to the anesthetic management of patients. The prevalence of complications in this study population of PWD was over four times greater than the prevalence reported in the literature for the general population. The clinical implications of these findings are important for PWD that receive their dental care under GA at the Mount Sinai Hospital. PWD that are treated at the Mount Sinai Hospital may be at greater risk for suffering anesthesia related complications. These findings reinforce the philosophy of care and the model of using GA as a last resort.

The prevalence of post-operative symptoms was 100.0% since all patients reported at least one symptom when surveyed. This was high relative to most reports in the literature thus the third hypothesis of this study was accepted. The prevalence may have been high in this study because parents and caregivers were reporting on behalf of the patient. The survey also indicated that parent and caregiver satisfaction with the service provided was high, despite the high prevalence of post-operative symptoms observed in patients. The mean satisfaction score in this study was 92.7%, which was higher than the 80.0% reported in the literature, thus the fourth hypothesis of this study was accepted. Even with this high prevalence, the VAS scores were low, indicating that the impact of these symptoms was not clinically important. The study conclusions were limited by small sample sizes, low response rates, responder bias, lack of control groups, inability to stratify medical diagnoses, and having a single data abstractor. The literature on dental care for PWD under GA is limited. The vast heterogeneity in the literature suggests a need for further study and elucidation of complications in PWD undergoing dental procedures. This information can be useful in providing the groundwork for future studies of peri-operative complications in PWD.
9.0 FUTURE CONSIDERATIONS

Future studies in this field, should be prospective in design. A larger sample size would be necessary to increase reliability and validity of the data. Patients should be stratified according to their medical diagnoses. The nature of the dental treatment rendered should be compared to the prevalence of complications. Due to a lack of similar institutions in the geographical area, it would be challenging to conduct a multi-institutional study. A consideration may be to conduct a multi-institutional study concurrently examining the pediatric and adult population with special needs.
BIBLIOGRAPHY


## APPENDICIES

### Appendix A

<table>
<thead>
<tr>
<th>Criteria to be recorded from Patient’s chart Medical and Dental</th>
<th>Patient</th>
</tr>
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<tbody>
<tr>
<td>Age</td>
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<tr>
<td>Primary medical diagnosis</td>
<td></td>
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<tr>
<td>Cognitive status of patient</td>
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<tr>
<td>ASA Classification</td>
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<tr>
<td>Current medications</td>
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<tr>
<td>Allergies</td>
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<tr>
<td>Any previous general anesthetics for dental care - record the number</td>
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<tr>
<td>Primary dental diagnosis</td>
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<tr>
<td>Pre-op medical assessment filled out by whom</td>
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<tr>
<td>Pre-op medical consultations (internal med, cardiology, etc.)</td>
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<tr>
<td>Pre-op anesthesia evaluation when performed pre-OR, or in PAU</td>
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<td>NPO status verified</td>
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<tr>
<td>Pre-operative sedative used</td>
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<td>Dose of pre-op sedative administered</td>
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<td>Method of induction (IV/mask inhalation/IM Ketamine)</td>
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<td>Inducing agent</td>
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<tr>
<td>Use of restraint during induction</td>
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<tr>
<td>Induction in OR, PACU or other location</td>
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<tr>
<td>Respiratory technician present / use of fibreoptic bronchoscope or glidescope</td>
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<tr>
<td>Method of maintenance (Nasal/oral ETT tube)</td>
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<td>Agents used for maintenance</td>
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<td>Use of LA</td>
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<td>Type and amount of LA</td>
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<td>*Significant Intra-op change in HR</td>
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<td>*Significant intra-op change in BP</td>
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<tr>
<td>*Intra-op equipment problems</td>
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<tr>
<td>Duration of general anesthetic</td>
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<td>Restorations (SSCs)</td>
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<td>Root canal therapy</td>
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<td>Extractions</td>
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<td>Biopsy</td>
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<td>Other non-dental procedures: bloodwork, imaging, EUA's</td>
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<td>Behaviour in PACU sedated / agitated / cooperative</td>
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<td>Use of restraint in recovery room</td>
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<td>Post-op meds in PACU</td>
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<td>*Immediate post-op nausea in PACU</td>
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<td>*Immediate post-op vomiting in PACU</td>
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<tr>
<td>*Immediate post-op excessive bleeding from surgical site requiring dental attention</td>
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<td>*Immediate post-op oxygen saturation with O2/room air (after extubation)</td>
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<td>*Airway problems in PACU (query post-operative swelling)</td>
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<td>Post op prescriptions given - what</td>
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<td>*Complication necessitating admission from EOPS – details</td>
<td></td>
</tr>
<tr>
<td>*Complication necessitating re-admission/return to hospital (MSH or other) after discharge</td>
<td></td>
</tr>
</tbody>
</table>
Appendix B-1

Instructions: Please answer the following questions by placing a hash mark somewhere along the line.

This questionnaire is an example of how to answer questions using the VAS. The questionnaire below asks you to evaluate some common weather conditions that you may have experienced in the past. The severity of the situation is depicted by placing a vertical mark along the lines below.

First, we will use this type of line to rate temperature as an example.

On a hot day in the middle of the summer, if we asked you to rate how warm it was today; you would probably mark the line as follows:

not warm ___________________________________________________________________________I_________extremely warm at all

On a fall day, you might indicate:

not warm ___________________________________________________________________________extremely warm at all

On a cold day in the winter, you might indicate:

not warm __I________________________________________________________________________extremely warm at all

To practice: Please tell me how warm it is outside today by placing a mark on the line below.

not warm __________________________________________________________________________extremely warm at all
Appendix B-2

Instructions: Please answer the following questions by placing a hash mark somewhere along the line.

1) How black/dark is this square?

Not at all ____________________________ Extremely

2) How black/dark is this square?

Not at all ____________________________ Extremely

3) How black/dark is this square?

Not at all ____________________________ Extremely

4) How black/dark is this square?

Not at all ____________________________ Extremely
Appendix B-3

Post-operative Questionnaire and Satisfaction Survey for Parents and Caregivers of Patients undergoing General Anesthesia for Dental Treatment

PART 1
To answer the questions below, please place a hash mark along the line that corresponds to the symptoms that the patient may have experienced and with regards to possible changes in normal activity level. If you do notice changes from their normal behaviour please write down how many days the changes lasted after their dental treatment had been completed.

Example:

<table>
<thead>
<tr>
<th>Normal Behaviour (No change)</th>
<th>Extreme change from normal</th>
</tr>
</thead>
</table>

Changes seen for ____ days after dental treatment.

START Part 1
1. Nausea

Changes seen for ____ days after dental treatment.
Please answer YES or NO: Did you give the patient anti nausea medications like Gravol?____
If you answered YES, for how many days were the anti nausea medications used?

2. Vomiting

Changes seen for ____ days after dental treatment.
3. Pain

Changes seen for_____days after dental treatment.

Please answer YES or NO for the following:

• Did you give the patient any pain medications?_______
• If you answered YES, were the medication(s) prescription?
• If you answered YES, were the medication(s) non prescription?

Was the pain mild, moderate or severe?________________________

4. Agitation

Changes seen for_____days after dental treatment.

5. Headache

Changes seen for_____days after dental treatment.

6. Dizziness

Changes seen for_____days after dental treatment.

7. Daytime drowsiness

Changes seen for_____days after dental treatment.
8. Fever

Changes seen for _____ days after dental treatment.

9. Sore throat

Changes seen for _____ days after dental treatment.

10. Weakness

Changes seen for _____ days after dental treatment.

11. Affect on daytime alertness

Changes seen for _____ days after dental treatment.

12. Appetite

Changes seen for _____ days after dental treatment.

13. Activity level

Changes seen for _____ days after dental treatment.
14. Attention seeking behavior

Changes seen for ____ days after dental treatment.
Part 2
To answer the following questions, please place a hash mark along the line in response to the following statements:

Example:

Strongly Disagree  Strongly Agree

START Part 2
1. I had a positive experience.

2. I believe the patient had a positive experience.

3. If I needed to, I knew who to call in case I had any concerns after the patient’s treatment.

4. My expectations were met with regards to the postoperative outcomes/complications.

5. I believe that a general anesthetic is the only way that the patient could have gotten his/her dental treatment.
6. If the need arose, I would use these dental services again.

___________________________________________________________________________

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Thank-you for taking the time to fill out this questionnaire. Please return the survey in the postage paid pre-addressed envelope provided.
Appendix C
Retrospective Chart Review Information Sheet

EVALUATION OF PERI-OPERATIVE COMPLICATIONS ASSOCIATED WITH DENTAL TREATMENT OF PATIENTS UNDER GENERAL ANESTHETIC AT THE MOUNT SINAI HOSPITAL

Dear Sir or Madam,

Through the Faculty of Dentistry, Department of Pediatric Dentistry at the University of Toronto, we are writing to invite you to a research study because you are a parent or caregiver to a person with disabilities who have had their dental treatment at Mount Sinai Hospital from 2004-2009. We are following up with regards to information that was sent to you in late December. Please read below as we have made changes to our information sheet as well as our Consent Form for the study.

As a parent or caregiver of a person with disabilities who have had their dental treatment completed at Mount Sinai Hospital under general anesthetic, we would like permission from you to review their medical charts.

The purpose of the research study is to find out more information about the complications that can occur shortly before, during, or after a person’s general anesthetic. The charts will be reviewed by the co-investigator Dr. Vandna Sharma, who is a graduate student working under Dr. Sigal’s direction.

Participation in the study is voluntary and you are not required to participate. If you wish not to participate, the patient’s dental care will not be affected in any way at the Mount Sinai Hospital.

All of the information collected will be kept confidentially. Names of patients’, parents’, or caregivers’ will not be used at any point in the study. Each patient will be represented by number to ensure privacy. The information obtained from the chart review will be stored in a secured computer that is password protected and will be accessible only by, Dr. Vandna Sharma, the co-investigator of the study. No information revealing personal identity will be disclosed or used in any part of the study.

If the person under study will be receiving further dental treatment under general anaesthesia at the Mount Sinai Hospital in the upcoming year, you may also be approached to complete a survey in the future pertaining to this study.

The information and experience surrounding the patient’s general anesthetic are of value to us.

We have provided you with a self-addressed postage paid envelope in which you may mail back the consent form as soon as possible. Please mark on the consent form whether you choose to or choose not to participate. If you choose not to participate, you may advise us of this by mail in the postage paid envelope provided, or by telephone at (416) 979-4750, pick option 1, dial Ext. 3015 then #. Please include the patient’s full name when contacting us.
We hope that you decide to participate in the study.

Sincerely,

Dr. M. Sigal, DDS, MSc, FRCD(C)
Dentist in Chief, The Mount Sinai Hospital
Department Head, Pediatric Dentistry, Faculty of Dentistry, University of Toronto

Dr. V. Sharma DMD
Graduate Student, Pediatric Dentistry, Faculty of Dentistry, University of Toronto
Appendix D

Informed Consent Form for the Retrospective Chart Review

EVALUATION OF PERI OPERATIVE COMPLICATIONS ASSOCIATED WITH DENTAL TREATMENT OF PATIENTS WITH UNDER GENERAL ANESTHETIC AT THE MOUNT SINAI HOSPITAL

Principle Investigator: Dr. Michael Sigal DDS, MSc, FRCD(C), Faculty of Dentistry, University of Toronto and Dentist in Chief at the Mount Sinai Hospital

Co-investigator: Dr. Vandna Sharma DMD

You are asked to take part in a research study because you are a parent or caregiver to a person with disabilities who has had their dental treatment at Mount Sinai Hospital from 2004-2009. An extra copy of this Consent Form has been included to keep for your records.

Purpose

The purpose of the research study is to find out more information about the complications that can occur shortly before, during, or after a persons’ general anesthetic. The medical charts will be reviewed by the co-investigator Dr. Vandna Sharma, who is a graduate student working under Dr. Sigal’s direction. Each chart will be reviewed for information regarding the patient’s medical status, pre-operative consults, the different anesthetic agents used, the type of dental treatment rendered, as well as any post operative complications that occurred. It is our hope to collect detailed information about the complications that can occur surrounding a general anesthetic to improve awareness amongst healthcare providers as well as parents and caregivers. The goal is to collect a large body of information that will add to the quality of care provided to patients.

Risks and Benefits

There are no medical risks if you take part in this study. You may or may not receive any direct benefit from being in this study. Information learned from this study may help other people in the future.

Confidentiality

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your:
• name,
• address,
• date of birth,
• new or existing medical records, that includes types, dates and results of medical tests or procedures.

The information that is collected for the study will be kept in a locked and secure area by the study doctor for 7 years. Only the study team or the people or groups listed below will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital.

Representatives of the Mount Sinai Hospital Research Ethics Board may look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines.

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. You will not be named in any reports, publications, or presentations that may come from this study.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

Questions
In the event that you would like more information about anything that has or has not been discussed pertaining to your participation in the study, please feel free to contact the principle investigator, Dr. Sigal at 416-979-4926 Ext.4320 or the co-investigator Dr. Sharma at 416-979-4750 Ext. 3015.

If you have any questions about your rights as a research participant or have concerns about this study, call Ronald Heslegrave, Ph. D., Chair of the Mount Sinai Hospital Research Ethics Board (REB) or the Research Ethics office number at 416-586-4875. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

Consent
I, ________________________________, understand that the Faculty of Dentistry, University of Toronto is conducting a retrospective chart review of persons with disabilities who have received their dental treatment under general anesthetic at the Mount Sinai Hospital from 2004-2009.
I understand that I may be approached in the future to complete a survey pertaining to this study if the patient receives dental treatment under general anesthetic during the upcoming year at the Mount Sinai Hospital. I understand that participation is completely voluntary and that I can withdraw from the study at any time without affecting the provision of dental care for the patient at the Mount Sinai Hospital.

All questions that I have asked pertaining to the study have been answered to my satisfaction. Any risks and benefits that I may incur as a result of my participation have been discussed with me to my satisfaction. My decision to participate or not, will have no affect the dental care provided to the patient at the Mount Sinai Hospital. My decision to participate or not to participate will be kept confidential.

I understand that my participation is voluntary. I have the right to withdraw at anytime.

Please check mark one of the boxes below.

☐ I hereby DO NOT consent to participate in this study.

- If I choose not to participate, I may advise the investigators of my choice in the following two ways:
  1. by mailing this form in the postage paid envelope provided
  2. via telephone at (416) 979-4750, pick option 1, dial Ext. 3015 and #

- Please include the patient’s full name in the communications mentioned above

Patient’s Signature: __________________________________________

Patient’s Name Printed:________________________________________

Consent Provider’s Name: ______________________________________

Consent Provider’s Relationship to Patient: _______________________

OR

☐ I hereby consent to participate in this study.

Patient’s Signature: __________________________________________

Patient’s name printed:________________________________________

Consent provider’s signature:___________________________________

Consent provider’s name printed:_______________________________
Consent provider’s relationship to patient: _______________________

Date signed: ________________________________________________

Witness signature: ____________________________________________

Witness’ name printed: ________________________________________
Appendix E

Satisfaction Survey Information Sheet

SURVEY OF PARENTS AND CAREGIVERS REGARDING THEIR SATISFACTION AND OVERALL EXPERIENCE WITH THE PATIENT’S GENERAL ANESTHETIC FOR DENTISTRY AT THE MOUNT SINAI HOSPITAL

Dear Sir or Madam,

We are writing to ask for your assistance. Through the Faculty of Dentistry, Department of Pediatric Dentistry at the University of Toronto, we are conducting a survey of parents and caregivers who have had children or clients undergo a general anesthetic for dental treatment between 2009-2010. It is often difficult to obtain accurate information about the post-operative complications that occur in persons with disabilities because of possible communication difficulties. In order to conduct a survey that is applicable to all patients, we would like you, the parent/caregiver to complete a questionnaire about the patient’s post-operative symptoms as well as your satisfaction with the treatment rendered.

The purpose of the study is to find out more information about the complications that can occur shortly after a patient’s general anesthetic as well as the level of satisfaction with our services.

The survey will be given to parents or caregivers of patients undergoing dental treatment under general anesthetic at the Mount Sinai Hospital at the time of discharge. The survey is to be completed by the parent or the caregiver within the first week of treatment and may be mailed back to the researcher along with the consent form in a pre-paid envelope as soon as possible.

Participation in the study is voluntary and you are not required to participate. If you wish not to participate, the patient’s dental care will not be affected in any way at the Mount Sinai Hospital. Our hope is to collect detailed information about the complications that can occur surrounding a general anesthetic so that we can improve awareness amongst healthcare providers as well as parents and caregivers. We would like to know how satisfied parents and caregivers are with our service and if they would use our services again should the need arise. Our goal is to collect a large body of information that will add to the quality of care provided to our patients.

Your decision to participate in this study is voluntary.

All of the information collected will be kept confidentially. Names of patients’, parents’, or caregivers’ will not be used at any point in the study. Each patient will be represented by number that will ensure privacy. Once the surveys have been received, they will be kept in
locked cabinet to which only the co-investigator, Dr. Vandna Sharma will have access. The tabulated data will be stored in a secured computer that is password protected and will be accessible only by the co-investigator, Dr. Vandna Sharma. No information revealing personal identity will be disclosed or used in any part of the study.

The information and experience surrounding the patient’s general anesthetic are of value to us. We hope that you decide to participate in the study.

Sincerely,

Dr. Vandna Sharma on behalf of Dr. M. Sigal, Dentist in Chief at the Mount Sinai Hospital
Appendix F

Informed Consent Form for the Satisfaction Survey

SURVEY OF PARENTS AND CAREGIVERS REGARDING THEIR SATISFACTION AND OVERALL EXPERIENCE WITH THE PATIENT’S GENERAL ANESTHETIC FOR DENTISTRY AT THE MOUNT SINAI HOSPITAL

Co-investigator: Dr. Vandna Sharma DMD
Principle Investigator: Dr. Michael Sigal DDS, MSc, FRCD(C), Faculty of Dentistry, University of Toronto and Dentist in Chief at the Mount Sinai Hospital

You will be left with a copy of this consent form for your records. The information that has been provided to you should give you a general idea of the research being conducted and what is being expected of you. Please feel free to contact the co-investigator at vandna.sharma@utoronto.ca or at 416-586-5145 in the event that you would like more information about anything that has or has not been discussed pertaining to your participation in the study.

I, _______________________________, understand that the Faculty of Dentistry, University of Toronto is conducting a survey of parents and caregivers of persons with disabilities who have had their dental treatment under general anesthetic at Mount Sinai Hospital.

I understand that the consent form and survey were given to me on the day of the patient’s dental treatment under general anesthetic. I understand that the consent form and survey is to be completed within one week from when it is received and sent back to the research team in a pre-paid envelope that has been provided to me. I do not have to answer any questions that I do not want to, and I may choose to stop the survey at any time. All information collected from the surveys will be stored in a password protected computer, accessible only by our co-investigator Dr. Vandna Sharma. I understand that information collected will not have my name, the patient’s name, or any other identifying information on it. Each patient will be represented by a research code. No information will be released or printed that would disclose my name, the patient’s name or any other identifying information. I understand that I can withdraw from the study at any time and that it will not affect the provision of dental care for the patient at Mount Sinai Hospital.

All questions that I have asked pertaining to the study have been answered to my satisfaction. Any risks and benefits that I may incur as a result of my participation have been discussed with me to my satisfaction. My decision to participate or not, will have no affect the dental care provided to the patient at Mount Sinai Hospital. My decision to participate or not to participate will be kept confidential. I understand that my participation if voluntary. I have the right to withdraw at anytime.
I hereby consent to participate in this study.

Participant Signature: _______________________________________

Participant’s name printed: ______________________________________

Relationship to patient: _______________________________________

Dated signed: ________________________________________________

Witness signature: ____________________________________________

Witness’ name printed: _________________________________________