RANDOMIZED CONTROL TRIAL OF THE EFFICACY OF PARENT-DIRECTED
PRESURGERY SHAPING AND EXPOSURE TO ANESTHETIC MASK FOR
PREVENTION OF PREOPERATIVE ANXIETY IN CHILDREN

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Kirstie Lauren Walker, candidate for the degree of Doctor of Philosophy in Clinical Psychology, has presented a thesis titled, *Randomized Control Trial of the Efficacy of Parent-Directed Presurgery Shaping and Exposure to Anesthetic Mask for Prevention of Preoperative Anxiety in Children*, in an oral examination held on November 10, 2017. The following committee members have found the thesis acceptable in form and content, and that the candidate demonstrated satisfactory knowledge of the subject material.

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0.1 Abstract

The detrimental effects of children’s anxiety during anesthesia induction are well-documented. Though pharmacological approaches (e.g., sedative) are efficacious, they have potential negative consequences. As such, non-pharmacological approaches (e.g., parental presence, anesthetic mask exposure) may be preferable. Recent research has demonstrated the utility of a parent-directed intervention involving exposure to the anesthetic mask in increasing child compliance and decreasing anxiety at anesthetic induction. In the mentioned study, anesthetic mask exposure occurred on the day of surgery, and employing the mask exposure intervention earlier may be beneficial. The current randomized control trial examined the efficacy of parent/guardian-directed anesthetic mask exposure and shaping practice for the prevention of child preoperative anxiety, with a specific focus on the timing of exposure. Participants included children (n = 110) ages 4 to 7 years undergoing a day surgery dental procedure and their parents/guardians. Families were randomly assigned to one of three groups: (1) parent/guardian-directed anesthesia mask exposure/shaping practice at least three times in the week prior to surgery (Group 1); (2) parent/guardian-directed anesthesia mask exposure/shaping practice at least once on the morning of surgery (Group 2); (3) no exposure to the anesthesia mask prior to anesthetic induction (Group 3). The primary outcome measure was child anxiety which was observer-rated at five time points (admission, holding area, transfer to OR, anesthetic induction, and post-surgery) using the modified Yale Preoperative Anxiety Scale. Results demonstrated significant differences in observer-rated child anxiety at anesthetic induction across groups. Specifically, Group 2 demonstrated significantly lower observer-rated anxiety than Group
3 with a medium effect. A significant interaction was observed between these two groups over time (i.e., admission to anesthesia induction). Group 2 also demonstrated the best anesthesia induction compliance (i.e., significantly lower scores than Group 3). The current results suggest that the timing of the delivery of anesthesia mask exposure (i.e., on the day of surgery) as an intervention to address preoperative anxiety in children, at least in the day surgery setting of this investigation, may be an important consideration. The current results inform the integration of this simple, cost-effective strategy into clinical practice.
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1.0 Introduction

Anxiety in children undergoing surgery is common (referred to as preoperative or perioperative anxiety), occurring in 40 to 60% of cases (Wright, Stewart, Finley, & Buffett-Jerrott, 2007) and is associated with difficulties both pre- and postoperatively.

For example, preoperative difficulties can include noncompliant behaviour at anesthesia induction (Proczkowska-Bjorklund & Svedin, 2004), requiring restraint (Burton, 1984), and inconsolable crying, screaming, and thrashing (Mountain, Smithson, Cramolini, Wyatt, & Newman, 2011). Postoperative negative consequences have ranged from emergence agitation or delirium (i.e., combative movements, thrashing, excitability, disorientation, and inconsolable crying during emergence from anesthesia; Mountain et al., 2011; Nasr & Hannallah, 2011) to negative postoperative behavioural changes (Kain, Wang, Mayes, Caramico, & Hofstadter, 1999; Lumley, Melamed, & Abeles, 1993).

Various interventions have been utilized to address and/or prevent child preoperative anxiety and associated negative consequences. Pharmacological intervention (e.g., midazolam, a benzodiazepine with amnestic and anxiolytic properties) is a common approach, but has drawbacks (e.g., contraindicated for certain child temperaments [Finley, Stewart, Buffet-Jerrott, Wright, & Millington, 2006] and increasing anxiety at subsequent procedures [Chen, Zeltzer, Craske, & Katz, 2000]). Given the drawbacks of pharmacological approaches, the utility of non-pharmacological intervention has been examined. Such approaches include parent presence (e.g., Kain, Mayes, Caramico et al., 1996; Wright et al., 2007; Yip, Middleton, Cyna, & Carlyle, 2011), child modeling through video (e.g., Abrams, 1982; Ferguson, 1979; Vernon, 1973), hypnosis, music therapy, and acupuncture (see Wright et al., 2007 for review), maternal voice recordings
(Kim, Oh, Kim, Kwak, & Na, 2010), clowns trained in pediatric distraction techniques (e.g., Golan, Tighe, Dobija, Perel, & Keidan, 2009; Vagnoli, Caprilli, & Messeri, 2010; Vagnoli, Caprilli, Robiglio, & Messeri, 2005; Yun, Kim, & Jung, 2015), and preoperative preparation programs in the hospital (e.g., Kain, Caldwell-Andrews et al., 2007; Kain, Mayes, & Caramico, 1996; Visintainer & Wolfer, 1975). Non-pharmacological approaches may be preferred as there are no significant drawbacks to the child or family; however, some of the latter interventions, especially the comprehensive preparation programs, have been identified as too time intensive and/or expensive to be sustained in the hospital environment.

Anesthetic mask exposure is an intervention with preliminary support. A few recent studies have found anesthetic mask exposure to be a highly effective intervention for preoperative anxiety in children (e.g., Aydin et al., 2008; Lan, Huang, Finley, & Zuo, 2012; MacLaren & Kain, 2008; Mahajan, Grover, & Kumar, 2007; Malhotra, Dutta, & Kumar, 2001; Shawky, 2005). Research examining the effectiveness of exposure to the anesthetic mask alone and at varying time points before surgery has been an area of focus. With the timing of intervention in mind, the current research investigation aimed to build on the findings of these initial studies, systematically examining the importance of the timing of anesthesia mask exposure as a method of surgery preparation for children (i.e., either prior to the day of surgery or on the day of surgery).

The following sections include an overview of child preoperative anxiety, underlying factors, and related negative consequences, a synopsis of interventions for preoperative anxiety, including pharmacological and non-pharmacological methods, a brief historical examination of surgery preparation programs and their current
application, and a review of anesthetic mask exposure and shaping practice and rationale.
Lastly, the current investigation is described in detail.

1.1 Preoperative Anxiety in Children

Preoperative anxiety is characterized by subjective feelings of tension, worry, apprehension, and nervousness in relation to the surgical setting or surgical procedure (Kain et al., 1997). Preoperative anxiety is common, occurring in 40-60% of children scheduled for surgery (Wright et al., 2007). Experiencing anxiety preoperatively, especially elevated levels, has been linked to several negative consequences, both in the pre- and postoperative periods. The link with negative consequences has been recognized for decades (e.g., Jackson, 1942) and the repercussions of preoperative anxiety have been thoroughly examined in recent years. The negative consequences of preoperative anxiety, contributing factors, and associated implications for future medical encounters are reviewed herein; but first, potential explanations for child preoperative anxiety are explored.

1.1.1 Why are children anxious during the preoperative period? Early research evidence highlighted a variety of sources of anxiety during the surgery experience, including fears of separation from parents and the home environment, loss of control, unfamiliar routines, hospital procedures, and surgical instruments (Corman, Hornick, Kritchman, & Terestman, 1958; Schwartz, Albino, & Tedesco, 1983; Vernon, Foley, Sipowicz, & Schulman, 1965). More recently, qualitative studies have added to this line of inquiry (e.g., Przybylo, Tarbell, & Stevenson, 2005; Smith & Callery, 2005; Wennstrom, Hallberg, & Bergh, 2008). For example, children ages 7-11 years have reported anxiety around obtaining information, knowledge of procedures and anesthesia,
timing of events, the hospital environment, loss of family support, and feelings of pain (Smith & Callery, 2005), while children ages 6-9 years endorsed the fear of being forced into an unpredictable and distressing situation that they would have to endure (Wennstrom et al., 2008). Children and adolescents (ages 5-18 years) who had previously experienced surgery reported that the anesthetic mask made them feel claustrophobic, and they had difficulty breathing with the mask on (Przybylo et al., 2005). Research indicates greater cognitive capacity of older children (age 7 years and older) may lead to anticipatory fear of choking, “going to sleep”, or pain in relation to the anesthesia mask (Lumley et al., 1993).

In an observational study of the impact of the anesthesia mask, 293 children ages 2-10 years scheduled for day surgery participated (MacLaren Chorney & Kain, 2009). In general, children cried and resisted the anesthetic mask up to 57% of the time they were observed. A previous surgical experience was not a contributing factor to current distress. A significantly higher proportion of 2- and 3-year-old children showed distress behaviours than did 4-6-year-olds. Results from MacLaren Chorney and colleagues indicated more than 40% of children displayed distress during anesthesia induction. Approximately 17% of children showed “significant distress” at anesthetic mask placement, characterized by at least three of the following: attempts to escape the procedure, verbal protests, crying, screaming, or verbally communicating fear or sadness. The most common behaviour was nonverbal resistance (i.e., tried to push anesthesia mask away) occurring 18% of the entire observation period and 42% of the time in which the anesthesia mask was placed (MacLaren Chorney & Kain, 2009). Based on such studies, child anxiety surrounding the day surgery and/or hospital experience has been
summarized as originating from five general anxieties: separation from parents; the unfamiliar hospital environment; painful procedures; the surgery itself; and anesthesia induction (Tan & Meakin, 2010). Yet, anesthetic induction appears to be the most anxiety-provoking time point when examining the observed trajectory of anxiety ratings across existing research (e.g., Fortier, Del Rosario, Martin, & Kain, 2010; Kain et al., 1997; Lumley et al., 1993; MacLaren Chorney & Kain, 2009; Schwartz et al., 1983).

1.1.2 Negative consequences of preoperative anxiety. Several negative consequences have been linked to elevated preoperative anxiety in children such as avoidance and/or restraint at anesthetic induction, increased pain, emergence agitation or delirium, and postoperative negative behaviour change (Abramowitz, Deacon, & Whiteside, 2011; Burton, 1984; Gorski, Slifer, Kelly-Suttka, & Lowery, 2004; Kain, Wang et al., 1999; Mountain et al., 2011; Vernon, Shulman, & Foley, 1966). Researchers have also evidenced that greater anxiety and distress in anticipation of a surgical procedure may result in more pain during the procedure (Kain, Mayes, Caldwell-Andrews, Karas, & McClain, 2005; Gorski et al., 2004) or postoperatively (Chieng, He, & Chan, 2012). For example, children with high observer-rated preoperative anxiety experience greater parent-reported and self-reported postoperative pain and analgesic consumption (Kain et al., 2005). Further, preoperative anxiety causes elevated cortisol (i.e., a steroid hormone released by the body when under stress), which is associated with longer wound healing time, diminished immune response, increased infection rates, as well as fluid and electrolyte imbalances with possible perioperative and postoperative repercussions (Kiecolt-Glaser, Page, Marucha, MacCallum, & Glaser, 1998; Wilson et al., 2016). Restraint of a child to facilitate anesthetic induction, occurring to
approximately 25% of children, is among the most unfavourable consequences (Burton, 1984). The latter is not only distressing for the child, but also for the medical team members involved.

Elevated levels of preoperative anxiety are also associated with negative behaviours post-surgery. Specifically, preoperative anxiety has been demonstrated to lead to emergence agitation that is behaviour characterized by combative movements, thrashing, excitability, disorientation, and inconsolable crying during emergence from anesthesia (Mountain et al., 2011). Emergence agitation may lead to child injuries, disruption of the surgical site and dressings, drains, or even removal of intravenous catheters, and the possible requirement of extra nursing care, especially in the post-anesthesia care unit (PACU). Medication administered to treat emergence agitation (e.g., analgesics and benzodiazepines) may delay discharge from the PACU and sometimes from the hospital (Nasr & Hannallah, 2011).

The emergence of new negative behaviours upon discharge from the hospital has been demonstrated in children who experienced elevated levels of preoperative anxiety. In a study of 42 children ages 4-10 years undergoing day surgery procedures, over half of the sample demonstrated at least one new negative behaviour at 2-weeks post-surgery according to mother-report with the Post Hospital Behaviour Questionnaire (PHBQ; Vernon et al., 1966), while a minority of children (11%) developed relatively severe behaviour problems within 2-weeks of surgery, especially separation anxiety and aggressiveness (Lumley et al., 1993). The severity of postoperative problems was associated with elevated levels of anxiety during anesthesia induction (Lumley et al., 1993). In a more extensive study of 119 children ages 2-10 years undergoing day surgery
procedures, 53% of children exhibited negative behaviour change at 2-weeks post-surgery (as measured by the PHBQ; Kain, Mayes, O’Connor, & Cicchetti, 1996). At 6-months post-surgery, 20% of the sample continued to demonstrate negative behaviour changes. New negative behaviours persisted for one year in 7% of children. Of note, the maladaptive behaviours were of limited magnitude for most children. For example, at 2-weeks post-surgery, 33% of parents reported only one to three negative behaviour changes. The two most common behavioural changes reported were having bad dreams or waking up crying at night (21%) and getting upset when left alone for a few minutes (19%). In contrast, more severe behavioural changes, such as new onset of enuresis, were present in 0.8% of children. At one year, the primary negative behaviour was being upset when someone mentioned physicians or hospitals (Kain, Mayes, O’Connor et al., 1996).

Kain, Wang, and colleagues (1999) later examined the relationship between preoperative anxiety and the development of negative postoperative behaviours in 91 children ages 1-7 years undergoing day surgery procedures. A significant positive association was observed between child anxiety at anesthesia induction and child agitation upon arrival to the PACU. The most anxious children (i.e., those in the upper 50% of observer-rated anxiety) at the time of anesthesia induction were 3.5 times more likely than children in the lower 50% to display negative behaviour changes post-surgery. The rate of emergence of new negative behaviours upon discharge was comparable to earlier researcher (i.e., Kain, Wang et al., 1999).

1.1.3 Factors contributing to preoperative anxiety. There are several factors that have been explored as potential predictors of preoperative anxiety in children. The factors include gender, age, temperament, and previous surgery experience. Research
associated with each factor as a potential predictor of child preoperative anxiety is reviewed below.

1.1.3.1 Gender. Overall, gender has not significantly predicted preoperative anxiety at anesthesia induction (e.g., Cumino et al., 2013; Davidson et al., 2006; Ferguson, 1979; Finley et al., 2006; Kain, Caramico et al., 1998; Lumley et al., 1993; Patel et al., 2006; Proczkowska-Bjorklund & Svedin, 2004; Proczkowska-Bjorklund, Gustafsson, & Svedin, 2010; Tan & Meakin, 2010; Tiedeman, 1997; Vagnoli et al., 2010; Wright, Eisner, Stewart, & Finley, 2010; Wolfer & Visintainer, 1979). The absence of significant prediction may occur because associated studies typically include preschool and early school-age children, for whom gender differences may be less explicit in the experience of anxiety than for youth; however, some intervention studies with older children have demonstrated gender differences (e.g., Kim et al., 2010; Melamed & Siegel, 1975). In their study of a peer modeling film intervention to reduce preoperative anxiety for 60 children ages 4-12 years undergoing overnight-stay hospitalization and surgery, Melamed and Siegel (1975) found a significant age and gender interaction. Younger girls (younger than 7 years) and older boys (7 years and older) exhibited the most behaviour problems at anesthesia induction; in a control film group, older girls exhibited the most behaviour problems at anesthesia induction. In the Melamed and Siegel study, gender was examined as a covariate despite no reported baseline differences in gender. Similarly, in a study of maternal voice recordings for children ages 2-14 years undergoing day surgery procedures, girls showed significant attenuation of emergence agitation with their mothers’ voice recording playing, whereas boys did not (Kim et al., 2010). The authors found no baseline gender differences between the experimental and
control groups. Accordingly, gender differences observed in previous studies may be associated with the intervention itself (i.e., boys and girls may respond to the intervention differently), rather than actual gender differences in baseline preoperative anxiety. As previously eluded to and reviewed in the next section, age may be a contributing factor to the divergent results.

1.1.3.2 Age. Research has demonstrated some conflicting findings with regards to the relationship between age and anxiety at induction of anesthesia. One large-scale intervention study of 2122 children ages 6 months to 14 years (grouped into five age brackets) undergoing day surgery procedures demonstrated that age was not a predictor of distress at anesthesia induction (Holm-Knudsen, Carlin, & McKenzie, 1998). Contrarily, other studies found that younger children are more anxious even after receiving an intervention designed to decrease their anxiety when compared to older children (e.g., Abramowitz et al., 2011; Kain, Mayes, & Caramico, 1996; Kain, Mayes, Caramico et al., 1996; Kain, Mayes, Weisman, & Hofstadter, 2000; Proczkowska-Bjorklund et al., 2010; Vernon & Thompson, 1993). For example, Kain, Mayes, Weisman and colleagues (2000) found in their study of 56 children ages 3-10 years undergoing day surgery procedures that increased child anxiety was negatively associated with age. That is, younger children experienced more anxiety in the holding area and at anesthesia induction compared to older children. The difference in anxiety influenced by age may be due to younger children’s reduced comprehension of available information, making the situation more anxiety-provoking for younger than for older children.

One research team (Tan & Meakin, 2010) has noted that children express anxiety toward anesthesia and surgery differently in the preoperative period based upon their age.
The researchers indicated that children ages 1-3 years often do not respond well to separation from parents and have a limited understanding of what is happening to them, though they can be fairly easily distracted with toys at anesthesia induction. Children ages 3-6 years have more awareness of what is happening, but they often misinterpret the surgical environment as being more dangerous and scary than it needs to be. Finally, children ages 7-12 years have the greatest capacity to understand the preoperative process and require the most explanation. Any opportunities to involve children ages 7-12 years in preparation (e.g., hold the anesthesia mask, watch a preparatory DVD, read a story about the experience) will likely decrease their anxiety (Tan & Meakin, 2010).

Ascertaining actual age-related differences across the available literature is difficult because a wide age range is often present (e.g., 2-10 or 2-12 years; Caldwell-Andrews, Blount, Mayes, & Kain, 2005; Cameron, Bond, & Pointer, 1996; Cray, Dixon, Heard, & Selsby, 1996; Davidson et al., 2006; Kain, Caldwell-Andrews, Maranets, Nelson, & Mayes, 2006; Kain, Caldwell-Andrews et al., 2007; Kain, Caramico et al., 1998; Kain, Mayes, & Caramico, 1996; Kim et al., 2010; MacLaren Chorney & Kain, 2009; McGraw & Kendrick, 1998; Messeri, Caprilli, & Busoni, 2004; Patel et al., 2006; Shawky, 2005; Visintainer & Wolfer, 1975).

1.1.3.3 Temperament. Temperament, or aspects of one’s personality including susceptibility to emotional stimulation, typical intensity and speed of emotional response, and quality of prevailing mood (Buss & Plomin, 1975), is a variable often included in preoperative anxiety research. Temperament is examined as a potential predictor of children’s anxiety level in the preoperative period and at anesthesia induction (e.g., Finley et al., 2006; Fortier et al., 2010; Fortier & Kain, 2015; Kain et al., 2006; Kain,
Caramico et al., 1998; Kain, Mayes, & Caramico, 1996; Kain, Mayes, Caramico et al., 1996; Kain, Mayes, O’Connor et al., 1996; Kain, Mayes, Weisman et al., 2000; Kain, Wang et al., 1999; Lan et al., 2012). The available results have been mixed. For example, in a study of 40 children ages 4-6 years undergoing day surgery procedures, Finley and colleagues (2006) found that parent-reported levels of impulsivity (as measured by the Emotionality, Activity, Sociability, Impulsivity Temperament Survey [EASI; Buss & Plomin, 1984]) were positively associated with adverse reactions to anesthesia induction, but only for children who received midazolam (as compared to a placebo control group). Using the same measure, other studies have found that elements of children’s temperament including low activity and high impulsivity (Kain, Mayes, O’Connor et al., 1996; Kain, Mayes, Weisman et al., 2000), high emotionality (Fortier & Kain, 2015; Kain, MacLaren et al., 2007; Kain, Mayes, & Caramico, 1996), and low sociability (Fortier et al., 2010; Kain, Mayes, Weisman et al., 2000), were positively associated with preoperative anxiety. Sociability was an independent predictor of child anxiety after controlling for age, cognitive ability, and parent coping style (Kain, Mayes, Weisman et al., 2000). Further, highly impulsive children have been shown to be at risk of developing increased general anxiety and separation anxiety postoperatively (Kain, Mayes, O’Connor et al., 1996).

Kain et al. (2005) found no relationship between temperament (measured via the EASI) and observer-rated child anxiety. Similarly, a more recent study using the EASI found no relationship between emotionality or impulsivity and preoperative child anxiety; however, a relationship between emotional inhibition and preoperative anxiety was significant when measured by a different scale with higher internal consistency (Wright,
Stewart, & Finley, 2013). Concerns about the internal consistency of the individual EASI subscales have arisen (see Finley et al., 2006; Wright, Stewart et al., 2013; Walker, Ammaturo, & Wright, 2017); nevertheless, the EASI has been the primary measure of temperament. Temperament remains an important variable to consider in preoperative anxiety research, playing an key role in children’s responses to premedication and their levels of general preoperative anxiety at specific time points (e.g., holding area, separation from parents).

1.1.3.4 Previous surgeries. Children who have previously experienced surgery with general anesthesia are often excluded from research due to the potential for the previous surgery experience to influence the children’s anxiety towards their currently scheduled surgery (e.g., Aydin et al., 2008; Cumino et al., 2013; Davidson et al., 2006; Ferguson, 1979; Golan et al., 2009; Kain, Caramico et al., 1998; Kain, Mayes, Caramico et al., 1996; Lan et al., 2012; Patel et al., 2006; Proczkowska-Bjorklund et al., 2010; Vagnoli et al., 2010; Vagnoli et al., 2005; Visintainer & Wolfer, 1975; Yun et al., 2015; Zuwala & Barber, 2001). In other cases, previous surgery/general anesthesia has not been an exclusion criterion, and appears absent in the analyses (e.g., Caldwell-Andrews et al., 2005; Hannallah & Rosales 1983; Kain, Caldwell-Andrews et al., 2007; Kain, Hofstadter et al., 2000; Kain, MacLaren et al., 2007; Kim et al., 2010; McGraw & Kendrick, 1998; Messeri et al., 2004; Mountain et al., 2011; Twersky, Hartung, Berger, McClain, & Beaton, 1993; Wright, Stewart, Finley, & Raazi, 2014). Children who have experienced a surgical procedure may react differently than children who have not because they have been through the process before; however, a number of studies in the current literature have shown no differences in preoperative anxiety between children who had a previous
surgery experience and those who had not (Finely et al., 2006; Kain et al., 2006; Kain, Wang et al., 1999; MacLaren Chorney & Kain, 2009; MacLaren & Kain, 2008; Wright et al., 2010; Wright, Stewart et al., 2013). For example, MacLaren Chorney and Kain (2009) found no differences in observer-rated preoperative anxiety in children ages 2-10 years who had previous experience with day surgery (n = 102) and those who did not (n = 191). One can speculate that a child’s reaction to a current surgery or medical procedure may have been influenced by previous positive or negative experiences; nevertheless, the available studies did not explore previous surgery experience quality. The existing literature examining the association between previous negative medical experiences and future anxiety is subsequently reviewed.

1.1.4 Negative experience associated with future anxiety. Memories of negative medical encounters may be carried forward into the future creating a host of problems. In one literature review, previous negative medical encounters (i.e., negative memories of previous hospital experiences, pediatrician, or dentist visits) lasted into adolescence and had detrimental psychological and physical health consequences (Ahmed, Farrell, Parrish, & Karla, 2011). For example, one study retrospectively examined a group of adults (ages 19-79 years) who had high levels of anxiety surrounding dental procedures, to the point of refusing dental care (De Jongh, Fransen, Oosterink-Wubbe, & Aartman, 2006). The researchers examined the cause of the participants’ dental anxiety as well as its severity and consequences. Among the 141 individuals, 73% reported experiencing at least one traumatic incident in their life with the two most commonly reported incidents being dental trauma or trauma around medical treatment. Symptoms that arose from this trauma included a high level of trauma-related
symptoms typical of posttraumatic stress disorder (PTSD), particularly re-experiencing (43%) and avoidance (41%). About half of the sample reported suffering from some PTSD symptoms, while approximately 14% had symptoms that would meet full diagnostic criteria for PTSD. The consequences of dental fear or phobia led to both psychosocial impairment as well as deteriorating oral health for the participants as a result of the avoidance of regular dental care (De Jongh et al., 2006).

In a child study of past trauma, noncompliant behaviour (i.e., resisting intravenous needle insertion or anesthetic mask placement) was seen in 16% of 102 children ages 2-7 years. The researchers found that prior traumatic hospital events and negative reactions when vaccinated were significant predictors of this noncompliant behaviour (Proczkowska-Bjorklund & Svedin, 2004). Accordingly, negative experiences can strongly impact an individual’s future attitude towards necessary medical care and can create significant difficulties around future treatments. There is no existing research that has causally demonstrated that a poor preoperative experience was associated with preoperative anxiety during a subsequent surgery; nevertheless, based on the aforementioned information regarding the associated negative consequences of preoperative anxiety both pre- and postoperatively, and the potential for the negative effects of preoperative anxiety to be carried forward to future medical treatments, it is important that researchers examine if and how preoperative anxiety can be reduced or eliminated in children. A historical examination of interventions employed to address preoperative anxiety in children follows.

1.2 Interventions for Preoperative Anxiety in Children
Several interventions for preoperative anxiety in children have been examined since the mid-1900s. These interventions can be classified into two main categories: pharmacological and non-pharmacological. The main pharmacological intervention that has been extensively implemented and reviewed is midazolam (a benzodiazepine with amnestic and anxiolytic properties). Midazolam is considered an efficacious intervention; however, it also has a number of negative side effects. A review of midazolam is presented herein. Subsequently, non-pharmacological approaches are reviewed, including parent presence at induction of anesthesia (PPIA), and various types of preparation activities and programs both within and outside of the hospital. Finally, recent advances in employing anesthetic mask exposure and shaping practice as an intervention to address anxiety during the preoperative period are reviewed.

1.2.1 Pharmacological approaches. The use of pharmacological interventions to alleviate child anxiety in the preoperative period has been a highly-researched topic for the last two decades. One widely used pharmacological approach that has demonstrated efficacy is midazolam. Also known by the trade name Versed®, midazolam is the pharmacological agent of choice to address preoperative anxiety in the day surgery setting because of its rapid onset and relatively short duration, meaning that drug effects should largely subside by the time most children are ready to be discharged from day surgeries (Kain et al., 2004; Wright, Finely, Lee, Raazi, & Sharpe, 2013). Other positive effects include a reduction of total anesthetic requirements, decreased risk of aspiration, decreased acidic stomach content, and increased analgesia (Abdallah & Hannallah, 2011). Further, midazolam appears advantageous by producing anterograde amnesia (i.e., memory usually becomes impaired within 10 minutes after taking midazolam), and such
amnesia may be beneficial for children requiring repeated interventions (Abdallah & Hannallah, 2011); however, the amnesic benefit is debated by other researchers as discussed below (e.g., Stewart, Buffett-Jerrott, Finley, Wright, & Valois Gomez, 2006). The most common oral dose given to children is 0.5 mg/kg, though 0.25 to 1.0 mg/kg have been described in the research literature; higher doses of midazolam appear not to offer additional benefits, and may cause more adverse side effects (Abdallah & Hannallah, 2011).

The use of midazolam as a preoperative intervention for children has been thoroughly reviewed (Strom, 2012; Wright et al., 2007; Yip et al., 2011) and established as an efficacious intervention, despite negative side effects associated with using midazolam preoperatively. Specifically, the widespread use of premedication is limited by risk of physical side effects (e.g., dizziness, nausea) and the need for greater staff presence to supervise children while medicated (MacLaren & Kain, 2008). Researchers note that secondary and adverse effects to midazolam, and the amnestic properties, may include a paradoxical effect of behavioural changes and agitation (e.g., Cray et al., 1996; McGraw & Kendrick, 1998; Watson & Visram, 2003).

The link between midazolam and emergence agitation has often been observed (e.g., Cohen, Drewsen, & Hannallah, 2002; Cray et al., 1996; Dahmani et al., 2010; Kuratani & Oi, 2008; Mountain et al., 2011). In one investigation, 7 of 26 children who received midazolam before a day surgery procedure developed postoperative agitation unrelated to pain, compared with 1 of 18 children in the control group (Cray et al., 1996). The children who developed postoperative agitation had, all but one, been judged as calm, cooperative, or asleep in the anesthetic room, indicating that even with a smooth
anesthetic induction, negative postoperative behaviours can emerge when using midazolam. Administration of midazolam preoperatively can also cause delays in hospital discharge, especially for short procedures (e.g., pressure-equalizing myringotomy). Cray and colleagues (1996) also found the time from the end of surgery to emergence was longer in the midazolam group, as was discharge time from the day ward.

Along with emergence agitation, midazolam has been linked to negative postoperative behavioural changes upon discharge from the hospital (e.g., Calipel, Lucas-Polomeni, Wodey, & Ecoffey, 2005; McGraw, 1993; McGraw & Kendrick, 1998). McGraw (1993) examined the association of preoperative administration of midazolam and postoperative behaviour changes in 44 children ages 1-10 years undergoing day surgery procedures. Half of the children received oral midazolam (0.5 mg/kg) while the other half received a placebo. Only 18% of the placebo group experienced negative postoperative behavioural changes (e.g., nightmares, increased general fearfulness, food rejection), compared with 50% of the midazolam group (McGraw, 1993). The effect of midazolam on postoperative behaviour was subsequently examined with 70 children ages 1-10 years undergoing day surgery procedures (McGraw & Kendrick, 1998). Midazolam was considered to be effective in that children in the midazolam group cried and resisted the anesthesia mask significantly less than children in the placebo group; however, at one-week follow-up, 54% of children who had received midazolam were experiencing negative behavioural changes (e.g., nightmares, night terrors, food rejection, anxiety, and negativism), compared with 23% of children who received a placebo.

Calipel and colleagues (2005) compared midazolam with hypnosis as preoperative anxiety-reducing interventions and their relation to the development of
postoperative behaviour problems in 50 children ages 2-11 years undergoing day surgery procedures. A significantly greater proportion of children in the midazolam group experienced negative postoperative behaviour change one day post-surgery (62% versus 30% for hypnosis group) and seven days post-surgery (59% versus 26% for hypnosis group). In contrast, another study found that children premedicated with midazolam experienced less emergence agitation, nausea, and vomiting, and experienced fewer negative postoperative behavioural changes upon returning home than a control group of children who received acetaminophen only (Kain, Mayes, Wang, & Hofstadter, 1999).

Not all researchers support the contention that memory impairment from preoperative use of midazolam (e.g., Abdallah & Hannallah, 2011) is a positive outcome (e.g., Chen et al., 2000; Proczkowska-Bjorklund et al., 2010; Stewart et al., 2006; Watson & Visram, 2003). Specifically, researchers were concerned about the implications of such memory impairments, coupled with findings that children premedicated with midazolam have been seen to display anticipatory anxiety at subsequent medical procedures (Chen et al., 2000). Research in the area has demonstrated that while midazolam appears to preserve implicit memory (i.e., unconscious memory of previously performed tasks or experienced events), anterograde amnesia (i.e., impairments in learning new information) may be induced (Kain, Hofstader et al., 2000; Stewart et al., 2006; Twersky et al., 1993). A randomized control trial (RCT) of 23 children ages 3-6 years undergoing day surgery procedures was conducted to determine the effects of midazolam on explicit and implicit memory (Stewart et al., 2006). At 10 minutes post-midazolam administration, children were shown a series of animal picture cards. After children returned to the day surgery room post-surgery, they were administered picture memory tests examining both implicit
and explicit memory (Stewart et al., 2006). Relative to placebo, midazolam reduced post-surgery performance on the explicit memory task of recognition of animal pictures, while implicit memory was not affected. The results suggested that midazolam-induced attentional impairments may partially contribute to recognition memory impairments observed in children (Stewart et al., 2006), which makes sense given the important role of attention during encoding for later explicit memory retrieval (Mulligan, 1998).

The aforementioned research is consistent with reports of children previously administered midazolam who continue to display anticipatory anxiety at subsequent medical procedures because children may not have a complete memory of the previous experience, even if it was pleasant (Chen et al., 2000). Thus, suggestions that the amnestic effects of midazolam may be beneficial for children should be tempered by cautions that the memory interference may have negative consequences (Stewart et al., 2006). Children may wake up from surgery and not realize their operation has been performed, which could increase the incidence of emergence agitation and negative behaviour change (Watson & Visram, 2003). Had the child retained the memory of a neutral or positive anesthesia induction, a subsequent surgical procedure may not induce such distress. Without the memory of the previous anesthesia induction, subsequent surgery experiences may be perceived as novel and distressing (Wright, et al., 2007).

Further concerns regarding the use of midazolam in the preoperative period include difficulties with timing of administration, delays in discharge, universal utility, and the impact of willingness to be premedicated. Midazolam has a peak effect time of approximately 20 minutes and if the surgery schedule is changed it is difficult to know when to give the medication (Cray et al., 1996). Child anxiety scores have been observed
to not consistently decrease after midazolam premedication; as such, predicting which children should receive the sedative can be a difficult task as midazolam does not universally lead to a calm and cooperative child during induction of anesthesia (Cray et al., 1996; Finley et al., 2006; Kain, MacLaren, et al., 2007). For example, in a study by Finley and colleagues (2006) of 40 children ages 4-6 years, children were randomly assigned to receive midazolam or placebo before their day surgery procedure. Despite the results indicating that children who received midazolam were less distressed at induction of anesthesia overall, children in the midazolam group with higher levels of impulsive temperament demonstrated higher levels of observer-rated anxiety and adverse reactions to anesthesia induction, suggesting that high levels of trait impulsivity may contraindicate the use of midazolam as a preoperative medication for these children (Finley et al., 2006).

Age may also influence the universal utility of midazolam. Specifically, Kain, MacLaren and colleagues (2007) identified children younger than 4 years of age (in a sample of 262 children ages 2-10 years undergoing day surgery procedures) as “non-responders”, because extreme levels of distress remained despite adequate blood levels of midazolam for an effect. This was the case for 14% of the total sample (Kain, MacLaren et al., 2007).

Willingness to be premedicated (i.e., compliance with request to ingest the premedication via drink) is also a factor to consider when evaluating the overall appropriateness of employing midazolam as a premedicant for children. For example, one study examined children’s willingness to be premedicated and its effects on postoperative behaviour in 49 children ages 3-6 years premedicated with midazolam before their day surgery procedure (0.5 mg/kg; Proczkowska-Bjorklund et al., 2010). Two weeks after surgery, children were brought by their parent into a play area with neutral toys (i.e.,
books, papers and pens for drawing, a jigsaw puzzle) and medically-oriented toys (i.e., a bed and large doll, a popular TV-bear dressed in operating room [OR] clothes, a toy anesthetic machine, and clothing like that used by the parent and personnel during anesthetic induction). Children were more likely to avoid the medical play equipment if they had taken the premedication unwillingly, or were younger. Further, there was a positive association between the child not wanting to talk about his or her hospital experience and the child being premedicated unwillingly. Therefore, some evidence suggests that unwillingness to be premedicated with midazolam may have a negative impact on a child’s attitude and reaction towards future medical procedures and experiences.

There appear to be numerous potential drawbacks to employing midazolam as a premedicant; nevertheless, midazolam is routinely used (particularly in the United States [e.g., Kain et al., 1997], not as frequently in Canada [Wright, Finley, Lee, Raazi, & Sharpe, 2013]) and is a demonstrated efficacious method to alleviate child anxiety in the preoperative period. Given the potential drawbacks of midazolam, non-pharmacological alternative interventions have been sought and are reviewed in the next section.

1.2.2 Non-pharmacological approaches. The following sections review a number of types of non-pharmacological approaches to anxiety reduction for children, employed from the 1940s to present. The review concludes with the most commonly researched and utilized methods of preparation, including PPIA, comprehensive preparation programs, and anesthetic mask exposure and shaping practice.

1.3 Preparation Programs—An Overview
Child anxiety surrounding hospitalization and surgery does not appear to have become an area of study in medical or psychological research until the mid-1900s. In 1942, Jackson outlined ideas to combat child anxiety around hospitalization that had arisen by that time including: honestly and factually telling the child about his/her upcoming procedure and potential for pain; taking time to encourage the child’s voluntary cooperation so as to minimize the use of restraint; decreasing the wait time before an uncomfortable test, treatment, or procedure; and moving the child to positive surroundings with play opportunities as quickly as possible after a procedure.

In the 1960s, systematic examination of child anxiety throughout the hospitalization experience began. Vernon and colleagues (1966) created the Post Hospital Behaviour Questionnaire (PHBQ) which is considered the gold standard for assessing behaviour postoperatively (Kain, 2000). The measure allows researchers to study changes in children’s behaviour following discharge from the hospital (Vernon et al., 1966). In the 1970s, the focus of research was on methods to address child anxiety about hospitalization or surgery that took place both in the hospital and at home. Clinical research and practice suggested that the success of preventing medical anxiety may be increased when children acquired coping skills for upcoming procedures prior to the day of surgery or hospitalization, as opposed to trying to adjust once the child was in an anxiety-provoking situation, and that teaching age-appropriate coping skills to non-anxious children would potentially enhance future experiences (Kendall, Lerner, & Craighead, 1984). For example, two studies examined at-home versus in-hospital preoperative preparation to reduce child anxiety toward hospitalization and surgery in 84 children ages 3-12 years undergoing day surgery procedures. The researchers found that...
children in the at-home preparation group with a nurse were significantly less anxious and upset and significantly more cooperative than those in the in-hospital preparation group (Visintainer & Wolfer, 1975; Wolfer & Visintainer, 1979).

Having a nurse come into the home and provide supportive care in the hospital for every child undergoing surgery is extremely costly and difficult to sustain in the long term. In trying to make preparation more cost-effective, Ferguson (1979) examined 82 children ages 3-7 years who either received a visit from a nurse one week before their overnight-stay surgery (at-home preparation) or watched a peer modeling film of a calm child experiencing typical hospital procedures (viewed one week before surgery). Results suggested that the peer modeling video was more effective at reducing child anxiety than the nurse visit, and required less time and fewer resources to implement.

The 1980s saw an explosion of research on the topic of preparing children for hospitalization, specifically surgery. Research in this decade focused on the development of more creative at-home preparation programs without an in-hospital component (e.g., modeling films; Abrams, 1982; preparation programs; Campbell, Clark, & Kirkpatrick, 1986; Wolfer, Gaynard, Goldberger, Laidley, & Thompson, 1988). A valid measure to assess child anxiety during hospitalization or at anesthesia induction had yet to be created; as such, most studies up to this point employed parent-report of the child’s general behaviour, upset, or attitude during the hospital stay (Campbell et al., 1986).

In 1993, Vernon and Thompson conducted the first meta-analysis (n = 22 studies) of research that evaluated experimental interventions (e.g., parent presence, modeling film, preoperative role play, puppets) for child anxiety reduction (with their measure, the PHBQ). The mean weighted effect size was .44 (95% CI 0.10), meaning that
psychological distress was less likely to have been maintained in children who received an experimental intervention than children who did not receive any intervention (Vernon & Thompson, 1993). The benefits of the interventions persisted for up to 4-weeks post-surgery, but were lesser for children of younger ages (Vernon & Thompson, 1993).

Most notably in the 1990s was Dr. Zeev Kain and colleagues’ initial contributions to the literature and establishment as a prolific research team. Through their research, Kain and colleagues demonstrated that high anxiety in children undergoing surgery is associated with poor clinical and psychological outcomes and should be prevented. Along with clinical trials, Kain and colleagues significantly contributed to this area of research through the creation of the Yale Preoperative Anxiety Scale (YPAS; Kain et al., 1995) and its revision (mYPAS; Kain et al., 1997). The YPAS was designed to assess observer-rated preoperative anxiety in children ages 2 years and older (Kain et al., 1995). Being able to utilize a valid observer-rated measure of child anxiety rather than solely relying on parent-report is extremely valuable as the objectivity of measurement improves and anxiety can be measured at specific times during the day surgery process (especially at induction of anesthesia) when the parent may not be present (Kain et al., 1997). Kain and colleagues also created the Induction Compliance Checklist (Kain, Mayes, Wang, Caramico, & Hofstadter, 1998) which is an observer-rated scale developed and validated to examine children’s cooperation at the point of anesthesia induction. The measure is considered clinically meaningful as a score of 6 or higher out of 11 indicates that a child’s behaviour significantly interferes with the anesthesiologist’s ability to give anesthesia using a mask (e.g., uncontrollable crying, screaming, thrashing, requiring restraint; MacLaren & Kain, 2008).
In the 1990s there was an exponential increase in the development of preoperative methods of preparation, with strategies including: informational puppet shows; relaxation and coping strategies; modeling films; printed material or interactive teaching books; play therapy; and hospital tours (Lynch, 1994; O’Byrne, Peterson, & Saldana, 1997; Margolis et al., 1998). In the 2000s, intervention approaches still included hospital tours (Rice, Glasper, Keeton, & Spargo, 2008), intervention from child life specialists (Brewer, Gleditsch, Syblik, Tietjens, & Vacik, 2006), therapeutic play (William, Lopez, & Lee, 2007), and information books (Felder-Puig et al., 2003), but interventions also expanded to include a number of alternative methods such as hypnosis, music therapy, and acupuncture, as well as behavioural preparation programs (see Wright et al., 2007 for review).

More recently, researchers have investigated several approaches to address preoperative anxiety, including information booklets (Kassai et al., 2016; Tabrizi et al., 2015), maternal voice recording played during the perioperative period (Kim et al., 2010), distraction through humour (Berger, Wilson, Potts, & Polivka, 2014), music (Bradt, Dileo, & Shim, 2013), and videos (Kerimoglu, Neuman, Paul, Stefanov, & Twersky, 2013; Kim, Jung, Yu, & Park, 2015; Lee et al., 2012). One creative idea with mixed results involved clowns trained in pediatric distraction techniques being present prior to and during anesthetic induction (Costa Fernandes & Arriaga, 2010; Golan et al., 2009; Liguori et al., 2016; Vagnoli et al., 2010; Vagnoli et al., 2005; Yun et al., 2015). Three salient researched interventions are 1) parent presence at induction of anesthesia; 2) comprehensive preparation programs; and 3) anesthetic mask exposure and shaping practice. Each of these interventions is reviewed herein.
1.3.1 Parental presence. One of the non-pharmacological approaches that has been heavily reviewed and debated is parental presence at induction of anesthesia (PPIA; e.g., Kain, Mayes, Caramico et al., 1996; Wright et al., 2007). Potential benefits of PPIA may be the reduced need for sedative premedication and elimination of anxiety associated with separation from parents. Mixed findings have been observed across studies where parents have been given a choice regarding whether to be present or absent during anesthetic induction versus studies that employ random assignment. Specifically, in an early trial examining PPIA versus a control group, one parent of each of the 50 non-premedicated children ages 1-5 years undergoing day surgery procedures was present during induction of anesthesia (Hannallah & Rosales, 1983). Families were allowed to decide which parent would be present during anesthetic induction. Ratings of anxiety at anesthesia induction for the PPIA group were compared to an age-matched control group of 50 children whose parents were not present at induction. The presence of a parent resulted in a significant decrease in the number of very upset or resistant children during the preoperative and anesthesia induction periods, when compared to the control group. Most parents were calm and supportive during anesthesia induction, and there were no complications related to their presence (Hannallah & Rosales, 1983). Similarly, in a study of 74 children ages 1-8 years undergoing day surgery procedures, the utility of PPIA was examined against parent absence with 38 parents expressing a desire to be present during anesthesia induction and being allowed. Other parents (n = 36) either chose not to accompany their child, or were not permitted to do so by the anesthesiologist. Overall, PPIA was predictive of reduced anxiety at anesthesia induction compared to the parent-absent group (Cameron et al., 1996).
Research employing random assignment of PPIA has demonstrated different results. A Cochrane review of five RCTs examining the use of PPIA against a control group demonstrated no significant decreases in observer-rated child anxiety as a function of parental presence (Yip et al., 2011). The non-significant findings for PPIA against a control group have been found in seven studies (Bevan et al., 1990; Kain, Mayes, Caramico et al., 1996; Kain, Mayes et al., 1998; Kain, Mayes et al., 2000; Kain et al., 2003; Palermo, Tripi, & Burgess, 2000; Wright et al., 2010). Further, a systematic review that included both randomized and nonrandomized control trials of PPIA found that six of nine RCTs reported non-significant findings for parental presence on child distress or affect. In contrast, all five studies with a non-randomized PPIA group claimed significant findings, with four of these studies concluding that parental presence resulted in significantly lower levels of child distress (Piira, Sugiura, Champion, Donnelly, & Cole, 2005). The results suggested that parental election to be present or not appears key in the effectiveness of PPIA for reducing child anxiety.

PPIA has been compared against midazolam, and in the majority of cases, PPIA has been found to be less effective (e.g., Arai et al., 2007; Kain, Mayes et al., 1998; Kain, Mayes, Wang et al., 2000). Adding parent presence to 0.5 mg/kg midazolam resulted in no additive benefit over midazolam alone in terms of reducing anxiety (Arai et al., 2007; Kain, Mayes, Wang et al., 2000). Most parents thought their presence made the anesthesiologist’s job easier (68%); that said, anesthesiologists believed that most parents either had no effect (38%) or made the job more difficult (21%; Kain, Mayes, Wang et al., 2000).
The efficacy of PPIA has also been compared against distraction (i.e., Kim et al., 2015; Matziou, Chrysostomou, Vlahioti, & Perdikaris, 2013; Patel et al., 2006). Distraction is a parent behaviour that has been found to be helpful in reducing child distress in both the preoperative anxiety and child pain literature (Ahmed et al., 2011; Blount, Landolf-Fritsche, Powers, & Sturges, 1991; Manimala, Blount, & Cohen, 2000); however, even when parents are taught age-appropriate distraction techniques, they are not always effective at reducing preoperative anxiety (e.g., Watson, Srinivas, Daniels, & Visram, 2002). If children can be effectively distracted without relying on the parent to lead the distraction, this would be a more efficient and sustainable alternative as parents may not be allowed into the OR, or may not engage in helpful behaviour promoting child coping (e.g., distraction) despite training. For example, distraction with a handheld video game was most effective in reducing anxiety at induction of anesthesia in 112 children ages 4-12 years when compared to parent presence without distraction and compared to premedication (Patel et al., 2006). Further, distraction via watching an animated cartoon video was more effective in reducing child anxiety at anesthesia induction in 117 children ages 2-7 years than PPIA + video distraction and PPIA alone (Kim et al., 2015). Children in the video group were also significantly more cooperative during anesthesia induction than children in the other two groups. The results highlighted the utility of distraction over parental presence during the preoperative period to reduce child anxiety.

In sum, research evaluating both the effectiveness and efficacy of parental presence has demonstrated mixed findings; however, a couple of caveats are important to consider when evaluating this subset of research. First, research methodology appears to significantly influence the findings in this area. Specifically, results from studies
employing a RCT design (where parents are randomly assigned to be present or absent at anesthetic induction) do not support the efficacy of PPIA for alleviating child anxiety or distress. Rather, methodologies where anesthesiologists selectively allow parents or parents decide themselves if PPIA would be appropriate appear to support the utility of this intervention (e.g., Cameron et al., 1996; Messeri et al., 2004). Second, allowing parental presence without adequate preparation may have a negative effect, causing more distress if parents exhibit behaviours such as excessive reassurance, criticism, or commands (Ahmed et al., 2011). Research in hospitals or surgical centres where parents are provided appropriate preparation, including information about anesthesia, what to expect if present, what to do during anesthetic induction, and how to use effective relaxation or distraction techniques would likely garner different results.

1.3.1.1 Parent factors influencing child anxiety. A recent systematic review identified factors that appear to increase child anticipatory distress to painful medical procedures: parent distress promoting behaviors; parent situational distress; parent anticipation of distress; and parent anxious predisposition (Racine et al., 2016). Most research focuses on parent anxious behaviour. In general, parent anxiety has been shown to be associated with child anxiety in both clinical studies (e.g., Beidel & Turner, 1997; Rosenbaum et al., 1988) and experimental studies (e.g., Burstein & Ginsburg, 2010; Turner, Beidel, & Roberson-Nay, 2005). Further, parental anxiety and anxious behaviour can affect child anxiety in the preoperative setting (Elkins & Roberts, 1983; Kain, Mayes, O’Connor et al., 1996; Kain et al., 2006; Messeri et al., 2004; Wright et al., 2007; Wright et al., 2014; Zuwala & Barber, 2001). From an etiological standpoint, some children may inherit an anxious temperament that is apparent at an early age (e.g., heightened tendency
to avoid perceived threats), while other children who do not have an anxious temperament will still be affected by modeling of anxious behaviour by their parent(s) and learn to react to the world (e.g., new environment such as day surgery) from an anxious viewpoint (Abramowitz et al., 2011).

In the context of day surgery, the child’s loss of consciousness at induction of anesthesia has been found to be anxiety-provoking for the majority of parents who are present (Messeri et al., 2004), and going into the OR may increase parents’ anxiety, thereby increasing the child’s anxiety (Wright et al., 2007). In an initial prospective, longitudinal study, Kain, Mayes, O’Connor et al. (1996) examined the association between parental anxiety and child anxiety during the day surgery experience and its effects on postoperative behaviour in 163 children ages 2-10 years. Children with self-rated anxious parents demonstrated higher levels of anxiety in the preoperative holding area than children of self-rated non-anxious parents. The authors also found that higher self-rated anxiety in mothers in the holding area was predictive of children’s negative behavioural change at 2-week follow-up. They concluded that maternal anxiety likely mediates the child’s response to difficult situations through simple modeling of anxiety (Kain, Mayes, O’Connor et al., 1996).

In a study of 39 children ages 2-14 years experiencing overnight-stay surgical procedures, a positive association was demonstrated between child anxiety at anesthesia induction and parent state and trait anxiety (Messeri et al., 2004). There was a significant difference in the presence or absence of anxiety depending on whether the mother or father accompanied the child to the OR. Mothers were more effective at reducing child
anxiety than fathers despite having higher anxiety than fathers generally (Messeri et al., 2004).

Recent research has found that interventions for children can reduce parent anxiety. Specifically, parents have been found to be less anxious when their child received preparation compared to parents of children who did not receive preparation (e.g., Yun et al., 2015; Zuwala & Barber, 2001), and when their child received midazolam compared to children who did not (Kain, Mayes, Wang et al., 2000). Likewise, researchers have examined preparation specifically to reduce parent anxiety, and subsequently reduce child anxiety. Skipper and Leonard (1968) conducted a field experiment to test the effectiveness of reducing hospitalized children’s anxiety indirectly through reducing mothers’ anxiety. Mothers were given extra information about hospital procedures by a nurse, encouraged to ask questions, and invited to express their concerns to the nurse. Maternal anxiety reduction due to nurse intervention was related to child anxiety reduction, both during and after hospitalization (Elkins & Roberts, 1983).

More recently, 80 children ages 1-10 years undergoing day surgery procedures and their parents participated in a parental-preparation intervention aimed at reducing parent and thereby child anxiety (Zuwala & Barber, 2001). Half of the parents received information via videotape and a pamphlet about mask induction of anesthesia, while the control group parents received only the standard information pamphlet. Parents’ heart rate was monitored throughout the day surgery experience. Heart rate of parents in both groups progressively increased from admission to post-review of the pamphlet, watching the video, going to the OR, and at anesthesia induction; however, the increase was only significant in the control group. Self-reported parent anxiety at induction of anesthesia
was the same in both groups, but lower postoperatively in the intervention group. Post-hospital behaviours were better (i.e., more quiet and cooperative, less anxious, disturbed, turbulent, or uncontrollable) in children of parents in the intervention group at 2-weeks post-surgery (Zuwala & Barber, 2001).

Examining parent behaviours specifically, certain behaviours have demonstrated an association with increased or decreased child distress in medical situations. Desirable adult behaviours include nonprocedural talk (e.g., about friends, toys, movies, favourite games), humour, medical reinterpretation (i.e., reframing medical procedures and equipment as something fun and positive), and providing developmentally appropriate procedural information (Martin et al., 2011). The desirable behaviours serve to distract children from their emotions and help to reframe a new, anxiety-provoking environment as something that is manageable and understandable, which in turn lowers anxiety levels and increases coping behaviour. In contrast, undesirable adult behaviours include reassuring statements, empathizing, and apologizing (Blount et al., 1989). In 77 children ages 4-7 years receiving immunizations, 40% of children whose parents reassured them required restraint, whereas only 10% of children whose parents distracted them required restraint (Blount et al., 1997). Suggesting control over situations where the child does not actually have any control was also identified as undesirable (e.g., “Are you ready to go?”) as this undermines the child’s sense of self-efficacy (Martin et al., 2011).

In an effort to examine parent-child interactions during anesthesia induction researchers have used versions of the Child-Adult Medical Procedure Interaction Scale (CAMPIS; Blount et al., 1997), including the CAMPIS-Revised (Wright et al., 2014) and the perioperative CAMPIS (Caldwell-Andrews et al., 2005; MacLaren Chorney et al.,
Each version measures child distress behaviours (e.g., physical request of support, crying, screaming, verbal resistance, physical resistance, flailing, and required restraint of the child). It also measures adult distress-promoting behaviours (e.g., reassurance, apologies, giving control to child, criticism, and provision of physical comfort).

A recent study to examine parent-child interactions at induction of anesthesia was for 32 children ages 3-6 years receiving outpatient dental surgery (Wright et al., 2014). Trained observers assessed child procedural distress and adult distress-promoting behaviours. A variety of parental distress-promoting behaviours were noted. The association between parental provision of reassurance and child distress was significant, as was the association between parents giving control to the child and child distress. However, the examination of sequential relations revealed that parental reassurance did not lead to increased child distress. Rather, child distress preceded increased parental provision of reassurance. Wright and colleagues (2014) note that the provision of reassurance during anesthesia induction or other anxiety-provoking medical procedures is likely complex as experimental research has demonstrated elevations in child anxiety during a painful medical procedure while a parent provided reassurance (i.e., McMurtry, McGrath, & Chambers, 2006). Ultimately, parents require preparation regarding what behaviours to engage in and not to engage in during the preoperative period, especially if present during anesthetic induction (Wright et al., 2014).

In a study of 146 children ages 2-10 years undergoing day surgery procedures and their parents (MacLaren Chorney et al., 2013), children were significantly less likely to become distressed after an adult used empathy, distraction, or coping/assurance talk. Conversely, if a child was already distressed, he or she was significantly more likely to
remain distressed if an adult used reassurance or empathy. Further, children were more likely to display coping behaviour (e.g., distraction, nonprocedural talk) after an adult modeled such coping behavior (MacLaren Chorney et al., 2013).

Overall, for a multitude of reasons extending from lack of demonstrated efficacy of PPIA in RCTs, to concerns about having parents present by anesthesiologists, to the notion that parents typically are not adequately prepared to be present during anxiety-provoking situations such as anesthetic induction, the blanket use of PPIA has not been accepted. In fact, findings from survey research suggest that the use of PPIA varies widely across hospitals and countries (i.e., Wright, Finley et al., 2013).

1.3.2 Comprehensive preoperative preparation. Most importantly in the 1990s and 2000s, anxiety-prevention research moved towards development and evaluation of comprehensive preoperative preparation programs. When preparing children for hospitalization or surgery, knowing how much children understand about illness and the purpose of the medical procedure is important. Research indicates that, although children are capable of talking about health and illness at an early age, their understanding is limited (Short & Malik, 2009). For example, children ages 2-7 years might give explanations for illness based on superstition, magic, or punishment for misdemeanor. Children’s knowledge of physiological explanations of illness, infection, and treatment is thought to not be well-developed until age 11-12 years. The type, style, and amount of information provided to parents to read to young children or presented to children should take the age of the child and their likely knowledge into account (Short & Malik, 2009).

Kain, Mayes, and Caramico (1996) created a preparation program and examined its effectiveness for reducing preoperative anxiety in 102 children ages 2-10 years
undergoing day surgery procedures. The program consisted of providing information about the perioperative experience, a hospital orientation tour, and medical play (i.e., role rehearsal with a doll) related to the specific surgery of the child. Children were offered an opportunity to participate in perioperative activities including listening to the doll’s heart, attaching ECG leads, playing with an intravenous cannula, and putting the doll “to sleep” using an anesthesia mask. The preparation was individual and modified based on the age of the child. The timing of the preparation ranged from 1-10 days prior to surgery. On separation to the OR, children older than 6 years were least anxious if they received the intervention 5 to 7 days prior to surgery, experienced moderate levels of anxiety if they did not receive the intervention, and were most anxious if they received the intervention one day prior to surgery. Similarly, parents of children 6 years and older were least anxious on separation to the OR if they received the program 5 to 7 days prior to surgery and most anxious if they received the program only one day prior to surgery. On the other hand, children 2-3 years old who received the intervention were rated by the observers as being more anxious at the preoperative holding area than children who did not receive the intervention, regardless of its timing (Kain, Mayes, & Caramico, 1996). The study did not measure child anxiety at induction of anesthesia.

Research examining behavioural preparation programs indicates that the most effective components include modeling, parental involvement, and coping skills instruction (Wright et al., 2007). For example, Kain, Mayes and colleagues (1998) sought to determine whether a comprehensive behavioural preparation program for children undergoing day surgery procedures was more effective than a limited behavioural program. Several days before surgery, 75 children ages 2-12 years randomly received
either: (1) an OR tour; (2) a tour and modeling-based program via videotape; or (3) a tour and modeling and coping-based program (Kain, Mayes et al., 1998). Children who received the most comprehensive program with coping-based instruction exhibited less anxiety immediately after the intervention, in the holding area on the day of surgery, and at separation to the OR. In contrast, no differences were found among the groups during induction of anesthesia, in the recovery room, or 2-weeks postoperatively. The authors concluded that children who received the most comprehensive preoperative preparation program exhibited the lowest levels of anxiety during the preoperative period, but not during the intraoperative or postoperative periods (Kain, Mayes et al., 1998).

The most comprehensive surgery preparation program to-date (that is published in peer-reviewed literature) is the ADVANCE program (Kain, Caldwell-Andrews et al., 2007). ADVANCE contains multiple components, including: distraction (with a handheld video game); video modeling; education before the day of surgery; PPIA; coaching of parents by researchers (e.g., advising parents to limit reassurance); and exposure/shaping practice with an anesthesia mask. Of the many program components, the one with the most salience to the current investigation is parental use of exposure and shaping practice to teach children to accept the anesthesia mask, as would be expected of them in the OR.

In this particular study, 408 children ages 2-10 years undergoing day surgery procedures were randomly assigned to either PPIA, midazolam, ADVANCE, or a control group. Three to seven days prior to surgery (informed by previous research suggesting that preparation has the most utility 5 to 7 days prior to surgery [Kain, Mayes & Caramico, 1996]), parents of those in the ADVANCE group were given an anesthetic mask practice kit, including an anesthetic mask, hairnet, and facemask. Also included in the kit was a
pamphlet that provided specific instructions for parents about how to use the psychological principles of exposure and shaping to teach their child to perform the behaviours that would be expected of them in the OR (e.g., getting onto the table) and, more specifically, about exposure to and practice with the anesthetic mask (Kain, Caldwell-Andrews et al., 2007).

Results demonstrated that children in the ADVANCE group were significantly less anxious while in the holding area as compared to the midazolam, PPIA, and control groups. Most importantly, the anxiety of children in the ADVANCE group was significantly lower at induction of anesthesia than anxiety of children in the PPIA and control groups, and similar to the anxiety of children in the midazolam group. Children in the ADVANCE group were the least likely to exhibit severe emergence delirium symptoms and need restraint in the PACU when compared to children in the control, midazolam, and PPIA groups (10% vs. 24%, 21%, and 16%, respectively; Kain, Caldwell-Andrews et al., 2007). Overall, ADVANCE was significantly more effective in reducing child anxiety during the preoperative process than the other three standard treatments frequently employed.

ADVANCE has demonstrated impressive results and incorporated the most up-to-date empirically supported components; however, the program was not easily adopted, likely due to the ongoing costs associated with implementation. The hospital setting requires simple, easy-to-implement interventions that do not require extra effort by the health care team and do not impact the busy day surgery process. In order to determine what component(s) of ADVANCE were key to decreasing child anxiety, Fortier, Blount, Wang, Mayes, and Kain (2011) statistically dismantled the ADVANCE program, looking
specifically at the 96 children (ages 2-10 years) in the ADVANCE group. Results suggested that exposure to and shaping with the anesthesia mask at home, and parental use of distraction were both effective components (e.g., mask effect size Cohen’s $d = .70$). Specifically, anxiety scores for children in the anesthesia mask practice group were relatively stable over time (i.e., from the holding area to the OR, and at induction of anesthesia), but increased significantly for the control group (Fortier et al., 2011).

The results are critical for highlighting the importance of anesthetic mask exposure and shaping; unfortunately, the study did not address the sufficiency of each component (i.e., anesthesia mask exposure and shaping) when used alone for reducing children’s preoperative anxiety as they were utilized within the context of the comprehensive, family-based intervention program. For example, providing a handheld video game (Patel et al., 2006), video modeling (Ferguson, 1979; Vernon, 1973), and parent distraction (Blount et al., 1997) have all shown to be effective at reducing anxiety, and thus examining all the components together confounds the results. The authors suggest that additional research is required to determine which of the intervention components can be eliminated in an effort to streamline the intervention without limiting effectiveness (Fortier et al., 2011).

1.3.3 Anesthesia mask exposure and shaping practice. Opinions differ as to which is the least distress-inducing method of anesthetic induction for pediatric patients: inhalation or intravenous. In the United States (Canadian data is not available), inhalation induction of anesthesia is the most common technique because it is evidenced as less objectionable to children, who often have an exaggerated fear of needles (Aguilera, Patel, Meakin, & Masterson, 2003). As indicated, the anesthesia mask has been a focal point for
recent intervention research because anesthesia induction is the most anxiety-provoking time point in the day surgery experience (as evidenced by the most elevated observer-rated anxiety scores) and because children report that the mask is a significant source of fear within the context of the day surgery experience (e.g., Przybylo et al., 2005).

Employing a preoperative preparation program that targets the most widely used method of anesthesia induction (i.e., inhalation) and one of the key sources of fear during the preoperative period (i.e., the anesthesia mask), that can be completed by parents, may ultimately reduce child anxiety, creating a more positive surgical experience and provide a helpful model for future medical procedures, save time and money, and reduce the burden on the health care team to prepare children. The effectiveness of anesthetic mask exposure has been examined in several studies employing the mask in unique ways that are reviewed herein (e.g., Aydin et al., 2008; Lan et al., 2012; MacLaren & Kain, 2008; Mahajan et al., 2007; Malhotra et al., 2001; Shawky, 2005).

Malhotra and colleagues (2001) examined the utility of making the anesthetic mask less anxiety-provoking for 60 children ages 3 years and older undergoing day surgery procedures. Children were visited by the anesthesiologist the evening before their surgery. The anesthesiologist showed the children a catalogue of stickers and asked them to mark their stickers of choice. The stickers were placed on the reservoir bag that is attached to the anesthetic mask (that the children were told was a balloon for them to blow up in OR) before surgery. On the day of surgery, the reservoir bag was shown to the children with the stickers affixed. Children were instructed to inflate the “balloon” while looking at the stickers. This technique reportedly facilitated the physician-child relationship, enhanced cooperation, and increased child acceptance of the anesthetic mask.
(Malhotra et al., 2001). In most cases however, an anesthesiologist would not be available to visit each child the day before surgery due to the anesthesiologist’s busy schedule, surgery reschedules, children living out of town, costs associated with this intervention, and other factors. An ideal intervention would not increase the workload of members of the health care team.

Another study with the goal to make the anesthesia mask less frightening examined the effect of a whistle fitted on the anesthetic reservoir bag for 60 children ages 2-6 years undergoing a day surgery procedure (Mahajan et al., 2007). The whistle would make noise only when the child breathed in from the bag. This was demonstrated to the child right before anesthesia induction and acted not only as an audible signal to ensure the child inhaled the gases, but also served to make the anesthetic mask a bit more fun (e.g., “can you make the whistle be as loud as possible?”). Once the child was asleep, the whistle was easily removed from the bag. Thus, the burden on health care staff was very minimal. Results suggested that this technique was helpful to 88% of participants (i.e., with full cooperation at anesthesia induction; Mahajan et al., 2007). Notable limitations to this study include the lack of a comparison group and standardized measures of anxiety or distress.

Shawky (2005) designed a three-dimensional mask of common characters that are popular among children, for example, animals or cartoon characters. The character masks were made of colored thin foam sheets with openings for the eyes, nose, and mouth, allowing connection with the anesthetic mask. The character/anesthetic mask was attached to the child’s ears and behind their head with rubber bands. The child was then given a mirror to look at his or her character face. During the study, 56 children ages 2-10
years undergoing day surgery procedures chose the character mask they liked. One parent was present during anesthesia induction. In the OR, the anesthesiologist connected the suitable sized anesthetic face mask to the character mask, and then applied it to the child’s face. When the child lost consciousness, the character mask was removed. Only 7 children (12.5%) refused the application of the character/anesthetic mask. Parents were asked to rate the anesthetic induction as indifferent, good, or excellent. Of the 49 children who accepted the character/anesthetic mask, parent ratings were as follows: 42 excellent, 5 good, and 2 indifferent (Shawky, 2005).

A limitation to Shawky’s (2005) study was that a standardized, observed-rated measure of child distress or anxiety was not employed. Shawky (2005) touted the new character mask as a successful tool useful for making mask induction of anesthesia more acceptable to children; however, the lack of a comparison group using typical masks makes it difficult to determine the comparative effectiveness of the character masks. Further, from a commercial point of view, the creation and sizing of these hand-made character masks and their widespread availability may be an issue. The mask studies conducted by Shawky (2005), Mahajan and colleagues (2007), and Malhotra and colleagues (2001) could also not be suitable for slightly older children who may find such methods too childish.

In a study of 50 children ages 3-7 years undergoing day surgery procedures that was designed to examine the efficacy of anesthesia mask exposure, Aydin and colleagues (2008) randomly assigned participants to an (1) information group where families were given conventional verbal information, or (2) an anesthesia mask group where families were given conventional verbal information and a scented anesthesia mask the day before
surgery. A significant improvement in this study over previous studies was that families were allowed to take the anesthesia mask home to play with along with instructions for safe use. The morning of surgery, children in the anesthesia mask group were given another mask to play with during the pre-anesthesia evaluation. This involved showing the anesthesia mask attached to a corrugated line ending with an anesthesia balloon, holding the mask, and breathing and blowing up the balloon. At the time of surgery, all children were administered 0.3mg/kg oral midazolam (Aydin et al., 2008).

Children in the information and anesthesia mask groups did not differ in their observer-rated anxiety at separation from parents (Aydin et al., 2008). Anxiety was significantly lower and acceptance of the anesthesia mask was significantly higher for children in the anesthesia mask group than the information group at anesthesia induction. In turn, total mask time was significantly lower in the anesthesia mask than the information group (Aydin et al., 2008). The results provide some support for the effectiveness of anesthesia mask exposure in alleviating preoperative anxiety in children as well as highlight some additive benefits such as shortening anesthesia induction duration, however there are some methodological limitations to note. First, the administration of midazolam somewhat confounds these results as the reader is unable to clearly evaluate the benefits of the anesthesia mask exposure and practice alone. Also, how frequently the child played with the anesthesia mask remains unknown. As such, the reader is unable to ascertain the necessary dosage of exposure (e.g., number of times).

A subsequent study sought to improve upon methodology of Aydin and colleagues (2008) by incorporating midazolam as a variable of interest (Lan et al., 2012). The authors assigned 160 children ages 3-7 years undergoing day surgery procedures to
one of four groups: (1) anesthesia mask preconditioning + saline solution; (2) midazolam; (3) anesthesia mask preconditioning + midazolam; and (4) control (saline solution). Saline and midazolam were administered via intravenous. The anesthesia mask preconditioning involved the anesthesiologist coaching the child through placing the mask on their face and blowing into the breathing bag twice on the day before surgery. The child was also asked to practice prior to sleep that night (Lan et al., 2012).

Observer-rated anxiety upon entering the OR was significantly lower in the anesthesia mask + saline and anesthesia mask + midazolam groups compared to the saline and midazolam groups (Lan et al., 2012). At induction of anesthesia however, children in the midazolam and anesthesia mask + midazolam groups had significantly lower scores than children in the anesthesia mask + saline and saline groups. Three days postoperatively, the researchers again assessed the child’s response to an anesthesia mask being placed on his or her face to determine mask fear (e.g., struggling against the mask). Anesthesia mask fear was highest in the saline group (23%) followed by the midazolam group (15%) while the anesthesia mask + saline and anesthesia mask + midazolam groups had significantly lower rates of fear (2.5%; Lan et al., 2012).

While anesthesia mask preconditioning the day before surgery was effective at reducing child anxiety upon entering the OR, the anxiolytic effect did not last to anesthetic induction where children who received midazolam or anesthesia mask preconditioning with midazolam had the lowest anxiety (Lan et al., 2012). Postoperatively, anesthesia mask conditioning did contribute to lower mask fear, both with and without midazolam. Some children had their parents present during anesthesia induction, which may have confounded the results. Further, this intervention required the
anesthesiologist to teach children and their parents how to use the anesthesia mask the day before surgery, again increasing the burden on members of the health care team.

MacLaren and Kain (2008) examined the efficacy of mask exposure and practice to alleviate preoperative anxiety in 112 children ages 2-7 years undergoing day surgery procedures. Children were randomly assigned to one of two groups: (1) control group who received standard care; or (2) treatment group who received a standardized exposure and shaping intervention with an anesthetic mask the morning of surgery (MacLaren & Kain, 2008). Parents were provided a copy of the instructions for the anesthesia mask exposure and shaping procedure and were coached by trained research assistants to carry out the procedure. The exposure and shaping procedure reinforced successive approximations of desired behaviour during anesthesia induction. The procedure began with children being given the anesthesia mask to play with. Children were given verbal praise and stickers while playing with the anesthesia mask (MacLaren & Kain, 2008).

The following approximations were provided sequentially in MacLaren and Kain’s (2008) study: (1) child holds the anesthesia mask to his/her mouth; (2) child breathes into the anesthesia mask while holding it over his/her mouth; (3) child breathes into the anesthesia mask while parent holds it over the child’s mouth; (4) child breathes into the anesthesia mask while holding it over his/her own mouth and nose; (5) child breathes into the anesthesia mask while parent holds it over child’s mouth and nose; and (6) child crawls onto the examination table and breathes into the anesthesia mask while parent holds it over his/her mouth and nose. Results demonstrated that child anxiety in the treatment group increased significantly from the holding area to separation from parents compared to the control group; however, children’s anxiety in the control group
increased significantly from separation from parents to anesthesia induction compared to the treatment group. While 15 children in the control group (26.8%) were categorized as noncompliant at anesthesia induction, only 3 children in the treatment group (7.0%) were categorized as such. Parents of children in both groups were equally anxious. Overall, children who received the exposure and shaping intervention were significantly more compliant at anesthesia induction and evidenced smaller increases in anxiety from baseline than children in the control group.

The intervention employed by MacLaren and Kain (2008) included very brief training for parents and relatively little coaching by research assistants, thus minimizing demands placed on the health care team. The intervention could be easily incorporated into standard patient flow in most surgery centres (MacLaren & Kain, 2008). Though providing an anesthesia mask to every family costs money (i.e., costs associated with the mask itself and postage), inefficiency in the OR has far greater cost implications for hospitals, especially day surgery clinics (Aydin et al., 2008).

Despite better management of anxiety at anesthesia induction, children who were exposed to the anesthesia mask before induction showed greater increases in anxiety following this exposure than time-matched children who were not exposed to the mask beforehand (MacLaren & Kain, 2008). The results make sense given the typical trajectory of anxiety responses during exposure procedures in that exposure procedures elicit initial anxiety (Simpson, Neria, Lewis-Fernandez, & Schneier, 2010). In fact, children’s anxiety remained high following the intervention and did not return to baseline before children were taken to the OR (MacLaren & Kain, 2008). Because of the tendency for increased anxiety as the time of surgery nears, the exact timing of the preoperative program is
important. As mentioned, Kain, Mayes and Caramico (1996) found that both parents and children were most anxious when a preoperative preparation program was given the day before surgery. The researchers concluded that preoperative preparation was most beneficial in reducing anxiety when it was implemented 5 to 7 days before surgery. Accordingly, anesthesia mask exposure and shaping practice in the week before surgery should reduce anxiety for children preoperatively and during anesthetic induction.

1.3.3.1 Exposure principles. The behavioural principal of exposure, which can be utilized for therapeutic purposes (i.e., exposure therapy), is rooted in the theory that gradual contact with an anxiety-provoking stimulus or situation resulting in neutral or positive consequences will lead to new learning about that situation or stimulus, thereby reducing anxiety (Simpson et al., 2010). The reductions can be accomplished through thought (i.e., imaginal exposures) or by staging encounters with the situation or stimulus (i.e., in-vivo exposures). Through repeated exposure exercises, people habituate to their evoked anxiety, facilitating their ability to approach previously avoided situations (i.e., desensitization; Simpson et al., 2010). The habituation model assumes that anxiety reduction during an exposure trial is noted and learned, and that repeated exposure trials confirm this learning and form new, coping-focused memories of confronting anxiety. Repeated exposure modifies the associations between anxious feelings and certain situations or stimuli by presenting incompatible information that is believed to emerge as a result of neutral experiences. As a result of repeated exposures, the perception of harm from the stimulus is lowered, as is anxiety associated with the stimulus (Kamphuis & Telch, 2000). In many cases, the key to anxiety extinction is to stay in the anxiety-
provoking situation until anxiety decreases and these competing, non-threatening associations are made (Simpson et al., 2010; Tryon, 2005).

Effective exposure programs generally consist of the following components in order: (1) select target behaviour (e.g., accepting the anesthesia mask); (2) assess current level of performance (i.e., baseline child anxiety); (3) select initial and subsequent behaviour steps; (4) employ reliable reinforcer (e.g., stickers, specific praise); and (5) reinforce successive approximations (O’Donohue, Fisher, & Hayes, 2003). A method of selecting the desired behaviour steps is called *shaping*. Shaping is appropriate for any task that can be broken into smaller steps. The behaviour has “been shaped” when the final desired behaviour is performed in a specific context under specific instructions (e.g., in the OR under the direction of an anesthesiologist or nurse; O’Donohue et al., 2003).

Exposure therapy can be helpful to reinforce appropriate behaviour and compliance with medical procedures. Sometimes noncompliant behaviours in pediatric patients have been reinforced in some way, and this learning must be undone (Gorski et al., 2004). For example, a child may respond to an aversive stimulus (e.g., needles, restraint, sedatives) with negative verbalizations, aggression, blocking of the procedure, or attempts to escape. The behavioural responses to an aversive stimulus are negatively reinforced if they lead to escape or avoidance of the procedure. The responses may also be positively reinforced if members of the health care team or caregivers provide excessive attention to these behaviours or attempt to calm the child with preferred items or activities. As a result, the behaviours may become more likely for avoiding future procedures. When the child is allowed to escape, the anxiety reduction experienced reinforces the use of noncompliant, distress behaviours to escape future medical
procedures (Gorski, et al., 2004). Exposure therapy could be employed to target the avoidance and escape behaviours. The learning gained from interacting and coping with anxiety-provoking stimuli should decrease avoidance and escape behaviours naturally (Simpson et al., 2010).

Distributed exposure practice offers more opportunities to generalize gains by engaging with anxiety across multiple contexts and over time (Simpson et al., 2010). Distributed practice may be especially appropriate if children are younger, allowing more time for them to learn and adjust; further, the exposure steps can be smaller if implemented well ahead of time. Starting with small exposures will inform the clinician of the child’s response and appropriate pace of further exposures. Premature over-exposure to high-anxiety situations or stimuli can increase anxiety to extreme levels that are difficult to recover and learn from (Simpson et al., 2010).

Younger children tend to have more concrete cognitive abilities, think more in the present, have a lesser understanding of emotions, and are more dependent on their parents than older children (Abramowitz et al., 2011). Rather than contraindicating the use of exposures, such cognitive limitations necessitate the use of primarily behavioural interventions with concrete, simple steps and child-oriented explanations of anxiety that are developmentally appropriate (Jaaniste, Hayes, & von Baeyer, 2007). Treatment with young children involves teaching parents how to assist their child with exposures since young children are more dependent on their parents for comfort and support. Interventions will need to provide ample modeling as well (Abramowitz et al., 2011). Verbal, pictorial, or written cues and prompts could be incorporated in training to help the child remember what to do when in the actual situation (O’Donohue et al., 2003).
Some research has demonstrated that only older children and adolescents require a cognitive component in exposure therapy; for young children, in-vivo exposure works well alone (Kendall et al., 1984). In the 1970s, exposure therapy was recognized as not requiring relaxation training. This realization provided greater applicability of the procedure as training in relaxation can be demanding and tedious for children (King, Heyne, Gullone, & Molloy, 2001).

One way for parents to support their child in the exposure process, along with setting up the exposure, is to provide their child with specific praise for progress made toward the final goal (e.g., “I like how you breathed deeply” rather than “good job!”). In a case study of three boys with medical noncompliance, hospital staff specifically reinforced any attempts at compliance or appropriate behaviours (rather than reprimanded the children for noncompliance), and found healthier behaviours began to be shaped (Gorski et al., 2004). The children were noted to display more positive social interactions with members of the health care team and to make more positive remarks about their medical care, which in turn improved the quality of staff attitudes toward and interactions with the children.

Exposure therapy has been used to help people confront many types of fears, whether through virtual reality (e.g., Parsons & Rizzo, 2008), in-vivo for the elimination of phobias (e.g., Waters et al., 2014) or trauma symptoms (e.g., Paunovic & Ost, 2001). In pediatric health, exposure therapy is used preventatively to discourage trauma from potentially anxiety-provoking situations (e.g., medical procedures). In a case study of a 4-year-old and 6-year-old both with cystic fibrosis, the use of exposure therapy was successful in teaching them to allow medical professionals to conduct necessary tests.
The children went from complete noncompliance for one year, to 100% compliance in just six sessions (Ward, Brinkman, Slifer, & Paranjape, 2010).

Based upon existing research, anesthesia mask exposure and shaping practice prior to the day of surgery represents a simple, cost-effective intervention to address preoperative anxiety in children and is likely to pose no burden on the health care team during the busy day surgery process. Although research to-date has demonstrated that anesthesia mask exposure is an effective method to prevent preoperative anxiety in children, the importance of the timing (i.e., prior to the day of surgery versus day of surgery) of the exposure is unknown. Therefore, conducting a RCT to examine the efficacy of parent-directed anesthesia mask exposure and shaping practice to prevent preoperative anxiety in children scheduled for a day surgery procedure, with a focus on elucidating the importance of the timing of exposure, represents a novel investigation. The primary purpose, hypotheses, methodology, analyses, results, and implications of the current investigation are outlined in the following sections.

2.0 Purpose

The current research built upon findings from several seminal studies reviewed above. The present RCT was designed to examine the efficacy of parent/guardian-directed exposure and shaping practice to an anesthetic mask as a stand-alone intervention for the prevention of preoperative anxiety in children (employing MacLaren and Kain’s [2008] mask exposure protocol), with a specific focus on the timing of anesthesia mask exposure and shaping practice. MacLaren and Kain’s study examined anesthesia mask exposure and shaping practice only on the day of surgery; however, previous research (e.g., Kain, Caldwell-Andrews et al., 2007; Kain, Mayes, & Caramico,
1996) indicates that anesthesia mask exposure may have a greater effect at an earlier time point (i.e., during the week prior to surgery). Therefore, in the current investigation the efficacy of anesthesia mask exposure and shaping practice occurring the week before surgery was explored.

3.0 Hypotheses

There were four primary hypotheses:

Hypothesis 1: It was hypothesized that participants would systematically vary on observer-rated anxiety (via mYPAS) as a function of group membership (i.e., children in the group who received anesthesia mask exposure and shaping practice during the week prior to surgery [Group 1] would have lower observer-rated anxiety scores than children in the group who received anesthesia mask exposure and shaping practice on the day of surgery [Group 2] and children in the group who received no anesthesia mask exposure and shaping practice [Group 3]) throughout the day of surgery (i.e., at admission, in the holding area, at transfer to the OR, and post-surgery) and at induction of anesthesia.

Hypothesis 2: It was hypothesized that participants would systematically vary in anesthetic induction compliance (via ICC) as a function of group membership (i.e., children in the group who received anesthesia mask exposure and shaping practice during the week prior to surgery [Group 1] would have lower observer-rated anesthetic induction compliance scores [i.e., better compliance] than children
in the group who received anesthesia mask exposure and shaping practice on the day of surgery [Group 2] and children in the group who received no anesthesia mask exposure and shaping practice [Group 3]).

Hypothesis 3: It was hypothesized that observer-rated anxiety scores (via mYPAS) throughout the day of surgery for the group that received anesthesia mask exposure and shaping practice on the day of surgery (Group 2) would be similar to those reported in benchmark study findings (MacLaren & Kain, 2008).

Hypothesis 4: It was hypothesized that parent/guardian state anxiety (via State-Trait Anxiety Inventory-state version [STAI-S]; Spielberger, Gorush, Lushene, Vagg, & Jacobs, 1983) would systematically vary as a function of group membership (i.e., parents/guardians of children in the group who received anesthesia mask exposure and shaping practice during the week prior to surgery [Group 1] would have lower STAI-S scores than parents/guardians of children in the group who received anesthesia mask exposure and shaping practice on the day of surgery [Group 2] and the group who received no anesthesia mask exposure and shaping practice [Group 3]) throughout the day of surgery (i.e., admission and post-surgery).

The current study hypotheses were pre-registered on February 10, 2016 through Open Science Framework (registration number: osf.io/wc4k8). As previously mentioned, past research has found that child temperament (via EASI) relates to higher anxiety and
lower cooperation at anesthesia induction (via mYPAS and ICC); however, results have differed based on whether or not children received midazolam (Finley et al., 2006), and the specific aspects of temperament that relate to higher anxiety at induction of anesthesia have varied (Fortier et al., 2010; Kain, Mayes, & Caramico, 1996; Kain, Mayes, Caramico et al., 1996; Kain, Mayes, O’Connor et al., 1996). Because of the mixed findings in the literature thus far, there are no specific hypotheses in this regard and analyses of interactions between child temperament (via EASI) and anxiety and compliance at anesthesia induction (via mYPAS and ICC) are considered exploratory. Further, no hypotheses were developed regarding the relationships between frequency of anesthesia mask practice and baseline measures of parent/guardian state and trait anxiety (via STAI-S and STAI-T) with child observer-rated anxiety (via mYPAS) and compliance (via ICC) at anesthesia induction, but these associations were explored.

4.0 Method

4.1 Participants

According to a power analysis using G*Power software (Faul, Erdfelder, Lang, & Buchner, 2007), with a medium effect expected, a sample size of 99 children was necessary to conduct the analyses of interest (mixed design ANOVAs with three groups). Child participants ranged in age from 4 to 7 years, with a mean age of 5.04 years (SD = 1.06; see Table 1 for demographic information for the full sample, as well as for each of the three groups individually, including parent/guardian relationship status and highest level of education, and who accompanied the child on the day of surgery). As mentioned, a methodological concern with many of the studies in this research area is the wide age range of participants (i.e., ages 2-12 years). By employing a narrower age range, this
limits the developmental variability of the present sample (e.g., cognitive capacity, understanding). Children were fairly evenly split across sex, with 54.9% of children being male. Ethnicity was grouped into three categories: Caucasian/White, Aboriginal/First Nations, and Other (i.e., non-Caucasian and non-Aboriginal). The majority of child participants were identified by their parents/guardians as Caucasian ($n = 53; 46.9\%$), followed by Aboriginal ($n = 36; 31.9\%$), and Other ($n = 24; 21.2\%$).

Only 11 child participants ($9.7\%$) had been previously diagnosed with a medical or mental health condition. These included asthma ($n = 3$), speech delay/impairment ($n = 2$), attention deficit hyperactivity disorder (ADHD; $n = 2$), septo-optic dysplasia ($n = 1$), Wilm’s Tumor ($n = 1$), environmental allergies ($n = 1$), febrile seizures ($n = 1$), cleft lip ($n = 1$), eczema ($n = 1$), and PTSD ($n = 1$). Only two children were on medication (Concerta for ADHD; $n = 2$). A minority of children ($n = 18; 16.2\%$) had experienced previous surgery with general anesthesia, ranging from one to three times. These included dental surgery ($n = 9$), myringotomy ($n = 2$), eye duct surgery ($n = 1$), tumor removal ($n = 1$), repair of arm fracture ($n = 1$), tonsillectomy and adenoidectomy ($n = 1$), circumcision ($n = 1$), cleft lip repair ($n = 1$), tick removal from ear canal ($n = 1$), removal of part of colon and gallbladder ($n = 1$), and abscess removal ($n = 1$).

Parents/guardians ranged in age from 20 to 66 years, with a mean age of 34.38 years ($SD = 8.172$). Parents/guardians were more disparate than children across sex, with 84.1% of parents/guardians who responded to the questionnaires being female. Similar to the ethnicity of child participants, most parents/guardians identified themselves as Caucasian ($n = 52; 46.0\%$), followed by Aboriginal ($n = 37; 32.7\%$), and Other ($n = 23; 20.4\%$).
Table 1

*Descriptive Statistics for Demographic Variables*

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<th>Full Sample $n$</th>
<th>Group 1 $n$ (%)</th>
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<td>3 (8.1)</td>
<td>5 (13.2)</td>
<td>8 (21.1)</td>
</tr>
<tr>
<td>Divorced</td>
<td>4 (3.5)</td>
<td>2 (5.4)</td>
<td>2 (5.3)</td>
<td>0</td>
</tr>
<tr>
<td>Separated</td>
<td>3 (2.7)</td>
<td>2 (5.4)</td>
<td>1 (2.6)</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>2 (1.8)</td>
<td>0</td>
<td>0</td>
<td>2 (5.3)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>11 (9.7)</td>
<td>4 (10.8)</td>
<td>1 (2.6)</td>
<td>6 (15.8)</td>
</tr>
<tr>
<td>Completed high school</td>
<td>27 (23.9)</td>
<td>9 (24.3)</td>
<td>7 (18.4)</td>
<td>11 (28.9)</td>
</tr>
<tr>
<td>Some university/College</td>
<td>32 (28.3)</td>
<td>9 (24.3)</td>
<td>16 (42.1)</td>
<td>7 (18.4)</td>
</tr>
<tr>
<td>certificate</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>University degree(s)</td>
<td>30 (26.5)</td>
<td>9 (24.3)</td>
<td>10 (26.3)</td>
<td>11 (28.9)</td>
</tr>
<tr>
<td>Trade School</td>
<td>8 (7.1)</td>
<td>4 (10.8)</td>
<td>2 (5.3)</td>
<td>2 (5.3)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (1.8)</td>
<td>0</td>
<td>1 (2.6)</td>
<td>1 (2.6)</td>
</tr>
<tr>
<td><strong>Accompanying Person</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother only</td>
<td>52 (46.0)</td>
<td>17 (45.9)</td>
<td>15 (39.5)</td>
<td>20 (52.6)</td>
</tr>
<tr>
<td>Father only</td>
<td>8 (7.1)</td>
<td>2 (5.4)</td>
<td>4 (10.5)</td>
<td>2 (5.3)</td>
</tr>
<tr>
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<td>Count</td>
<td>Percentage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------------------------</td>
<td>---------</td>
<td>------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother and Father</td>
<td>33</td>
<td>(29.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>(32.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>(36.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>(18.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (grandmother, mother</td>
<td>19</td>
<td>(16.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>and grandmother, mother and aunt</td>
<td>6</td>
<td>(16.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>(13.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>(21.1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note.* Group 1 = children who received anesthesia mask exposure/shaping practice in the week before surgery. Group 2 = children who received anesthesia mask exposure/shaping practice on the day of surgery. Group 3 = children who did not receive anesthesia mask exposure/shaping practice before surgery.
Participants were children scheduled to receive dental surgery as a day surgery procedure (e.g., extractions, fillings, caps/crowns), under general anesthesia via anesthesia mask induction at Prairieview Surgical Centre in Saskatoon, SK. Children were excluded from participation if they had a history of central nervous system disease, liver disease, renal disease, cancer, or neurological or cognitive impairment or disease. Children with a history of gastro-esophageal reflux disease were also excluded, as anesthesia induction was standardized to inhalation by mask and children with this condition are less likely to undergo anesthesia induction by mask and/or be at greater risk for complications with mask induction (e.g., laryngospasm; Cheong et al., 1999).

For participants in Group 1, the range of times practiced with the anesthesia mask was 0-54 (M = 10.30; SD = 12.539). For participants in Group 2, the range of times practiced with the anesthesia mask was 0-26 (M = 9.45; SD = 6.612). Two children (one in Group 1 and one in Group 2) remained in their assigned groups despite practicing zero times because they were shown the anesthesia mask, held and played with it, but refused to put it on their face. Across all three groups, the time of surgery ranged from 40 to 215 minutes (M = 90.63; SD = 29.486). The time for a child to wake after surgery ranged from 5 to 85 minutes (M = 30.23; SD = 15.421). A parent/guardian accompanied each child to the OR. No parent/guardian was so anxious or upset that he/she was not allowed to be present during anesthesia induction or asked to leave the OR by the anesthesiologist or OR staff during anesthesia induction. No child received sedative premedication. All children were given a mixture of acetaminophen and ibuprofen (15 ml/kg) presurgically to reduce postoperative pain.

4.2 Measures
4.2.1 Demographics measure (Appendix A). Parents/guardians were asked to complete a brief demographics measure. The measure asked basic demographic questions about themselves and their child.

4.2.2. Modified Yale Preoperative Anxiety Scale (mYPAS; Kain et al., 1997; Appendix B). The mYPAS was designed to assess observer-rated preoperative anxiety in children age 2 years and older. The 27-item measure has five behavioural categories: activity, facial expression (emotional expressivity), alertness and arousal, vocalizations, and interaction with parents/guardians. Each scale is scored from 1 to 4, with the exception of vocalizations, that is scored from 1 to 6. Partial weights for each scale are calculated and then added together to obtain a total score for each time point that ranges from 23.33 through 100 with higher scores indicating greater anxiety (Kain et al., 1997). For example, for two categories containing four and six items, with a score of 1 in each category, the calculation is: (1/4 + 1/6)*100/2 = total adjusted score.

Using the child version of the STAI (STAI-C), convergent validity of the measure was established for children ages 5-12 years (Kain et al., 1997). The mYPAS can reliably be scored in under one minute (Kain et al., 1997). Good intra- and inter-observer reliability has been established (kw = .63 - .90; Kain et al., 1995; Watson & Visram, 2003) as well as reliability and validity against the STAI-C (r = .79, p = 0.01; Kain et al., 1997). In the current study, the mYPAS was used to assess child anxiety by trained observers at five time points during the peri-surgical process: admission, holding area, transfer to OR, anesthesia induction, and post-surgery. Due to the setup of the surgical centre, there was not a separate holding area as there typically is in hospitals. Instead, the holding area rating was completed once a nurse took the child’s vitals and gave them
acetaminophen and ibuprofen. This was considered a transitional time and involved the child which may influence their anxiety. For sake of clarity and consistency with prior research, the term “holding area” is still employed in this investigation.

In the current investigation, a secondary rater was present for 50% of the participants (i.e., 55 participants). Interrater reliability was assessed using one-way mixed, absolute, single-measures intraclass correlations (ICCs) to assess the degree to which coders provided absolute consistency (i.e., similarity in actual score) in their ratings of anxiety across participants at anesthesia induction. The resulting correlation fell in the excellent range of agreement, ICC = .989. This value was higher than values reported in previous studies using this measure (e.g., .66-.91, Kain et al., 1997; .73-.91, Kain, MacLaren, et al., 2007; at least .80, Kain, Caldwell-Andrews et al., 2007).

4.2.3 Induction Compliance Checklist (ICC; Kain, Mayes et al., 1998; Appendix C). The ICC is an 11-item observer-rated measure developed and validated to examine children’s cooperation at the point of anesthesia induction. An age range for which this measure has been shown to be reliable and valid is not given; however, the authors use the scale for children ages 2-10 years (Kain, MacLaren et al., 2007; Kain, Mayes et al., 1998; Kain, Mayes, Wang et al., 2000). The items are rated dichotomously as present or absent, and a score of 0 is considered a “perfect” induction (i.e., no behaviours exhibited that could interfere with anesthesia induction).

In the same fashion as the mYPAS, a secondary rater was present for 50% of the participants (i.e., 55 participants). Interrater reliability was assessed using ICCs. The resulting correlation fell in excellent range of agreement, ICC = .979. The intraclass
correlation value is similar to that reported in previous studies using this measure (e.g., .978; Kain, MacLaren, et al., 2007; .995 - .998; Kain, Mayes et al., 1998).

4.2.4 Emotionality, Activity, Sociability, Impulsivity Temperament Survey (EASI; Buss & Plomin, 1984; Appendix D). The EASI is a 20-item parent/guardian-report measure of child temperament that is comprised of four subscales: Emotionality, Activity, Sociability, and Impulsivity. Items are rated on 5-point Likert scales with higher scores indicating higher facets of that temperamental style. Scores range from 5 to 25 for each temperament. Test-retest reliability of the parent-rated EASI has been poor to good ($r = .58 - .80$) over an interval of one week (Watson & Visram, 2003). Cronbach’s alpha in the present sample ranged from poor to acceptable: $\alpha = .713$ for Emotionality, $\alpha = .630$ for Activity, $\alpha = .523$ for Sociability, and $\alpha = .552$ for Impulsivity. This variability is consistent with the literature (Walker et al., 2017).

4.2.5 State Trait Anxiety Inventory (STAI; Spielberger et al., 1983; Appendix E). The STAI is an adult self-report measure of state and trait anxiety. The first set of 20-items is designed to assess state (situational) anxiety (STAI-S) while the second set of 20-items is designed to assess trait (baseline) anxiety (STAI-T). Items are rated on 4-point Likert scales with scores ranging from 20-80. Higher scores indicate greater anxiety. Internal consistency coefficients for the scale have ranged from $\alpha = .86 - .95$ (Spielberger et al., 1983). Test-retest reliability has varied between $r = .73 - .86$ (Watson & Visram, 2003). Adequate to good content validity has been demonstrated when measured against the Taylor Manifest Anxiety Scale (Taylor, 1953) and Cattell and Scheier’s Anxiety Scale Questionnaire (Cattell & Sheier, 1963; Julian, 2011). In the current study, parents/guardians were asked to complete the STAI at three time points (i.e., in the week
prior to surgery, at admission, and post-surgery). Both versions were used at baseline, but only the STAI-S was used on the day of surgery. For the current investigation, the internal consistency of the STAI-S was excellent at baseline (α = .945), admission (α = .937), and post-surgery (α = .949). The internal consistency of the STAI-T at baseline was good (α = .882).

4.3 Procedure

Harmonized ethics approval from the University of Regina, University of Saskatchewan, and Regina Qu’Appelle Health Region, as well as from the Saskatoon Health Region Research Ethics Boards were obtained (Appendix H). Recruitment took place between May 2016 and May 2017. Approximately 1 week prior to surgery, parents/guardians of children undergoing surgery were contacted by phone and invited to participate (see Figure 1). At the time of first contact, parents/guardians were asked questions pertaining to the exclusion criteria. Further, the tasks involved in the research study (e.g., reading and responding to questionnaires in the English language, accessing the internet, and reading and following written instructions in the English language) were explained to parents/guardians and they were asked if there were any relevant barriers that would preclude their participation. Families were then randomized into one of three groups: Group (1) parent/guardian-directed anesthesia mask exposure/shaping at least three times in the week prior to surgery; Group (2) parent/guardian-directed anesthesia mask exposure/shaping at least once (due to time available) on the morning of surgery; or Group (3) no exposure to the anesthesia mask prior to anesthetic induction (i.e., control group). Group 1 was asked to practice anesthesia mask exposure and shaping at least three times to try to ensure adequate practice for the child’s anxiety to decrease close to
baseline before surgery (e.g., very anxious children may not progress through the entire exercise during their first practice session). This was motivated by the ADVANCE study that had parents and children review the videos and educational materials twice in the week before surgery (Kain, Caldwell-Andrews et al., 2007).
Figure 1. Overview of participants at each study point.
The study design was parallel, so each group only received one intervention. Based on a computer-generated random number table from the Research Randomizer program (Urbaniak & Plous, 2016), participants were randomized into one of the three experimental conditions following Consolidated Standards of Reporting Trials (CONSORT) guidelines. The randomization sequence was made a priori, and all participants were randomized in strict order as assigned by the random number table. Unfortunately, it was not possible for the researcher to be blinded to group assignment; however, a blind secondary observer was present to reduce bias as well as for interrater reliability on the observer-rated measures (50% of participant observations).

Once a parent/guardian agreed to participate, they were emailed a link to SurveyMonkey™ where they read and completed the adult consent and child assent forms and questionnaires including a demographic form (Appendix A), the STAI-T and STAI-S (Appendix E), and the EASI (Appendix D) with instructions to have them completed prior to the day of surgery. The researcher brought paper copies on the day of surgery in cases where the families did not or could not complete the questionnaires on SurveyMonkey™. If they were in Group 1, an anesthesia mask, practice pamphlet (Appendix F), and practice tracker sheet (Appendix G) were mailed to them. If they were in Group 2, they were given the anesthetic mask and practice pamphlet on the morning of surgery. If they were in Group 3 (control group) they were not exposed to the anesthesia mask prior to surgery. On the day of surgery, all parents/guardians filled out the STAI-S at admission and post-surgery. For all participants, child anxiety was observer-rated (via mYPAS) at five time points (i.e., admission, holding area, transfer to OR, anesthetic
induction, and post-surgery) by the researcher and research assistants trained as observers. The ICC was also completed at anesthesia induction for all children.

4.4 Intervention

Participants in Group 1 had the anesthesia mask and exposure/shaping instructions mailed to their home one week before surgery. The intervention used the same instruction pamphlet as that of MacLaren and Kain’s study (2008) except that a hairnet and adult face mask were not used; as such, the pamphlet was modified to remove those components. Further, the child was not given stickers, and this study did not involve the researcher or research assistants training the parents/guardians in the use of the exposure protocol because the goal was for this intervention to be able to take place purely by parent/guardian direction, with no extra support required. The pamphlet provided parents/guardians with instructions on how to direct the shaping procedure with their child. Instructions for the following approximations were provided sequentially: (a) child holds anesthesia mask to his/her mouth; (b) child breathes into anesthesia mask while holding mask over his/her mouth; (c) child breathes into anesthesia mask while parent/guardian holds mask over his/her mouth; (d) child breathes into anesthesia mask while holding mask over his/her mouth and nose; (e) child breathes into anesthesia mask while parent/guardian holds mask over his/her mouth and nose; and (f) child breathes into anesthesia mask while parent/guardian holds mask over his/her mouth and nose while lying on a bed, imagining they are in the dentist office (Appendix F). Parents/guardians in Group 1 were asked to practice the exposure/shaping steps with their child at least three times prior to the day of surgery, and to record the number of times they practiced on the practice tracker sheet provided (Appendix G). On the day of surgery, parents/guardians in
Group 2 were provided an anesthesia mask and the same instructional pamphlet described above and asked to practice the anesthesia mask exposure and shaping steps with their child at least once in the waiting room prior to surgery.

4.5 Analytic Procedure

Statistical analyses were performed using the Software Package for the Social Sciences (SPSS: version 22.0). The analytic procedure consisted of five stages: (1) description of participant flow; (2) data preparation; (3) descriptive statistics; (4) preliminary analyses; and (5) primary analyses.

4.5.1 Description of participant flow. The flow of participants through the study was described as per the CONSORT guidelines. The diagram describes recruitment and screening (e.g., reasons potential participants declined to participate, and reasons for potential participant exclusions), participant assigned treatment conditions, treatment phases, and post-surgery measurement (see Figure 1). Data suitable for the primary analyses are outlined.

4.5.2 Data preparation. The data (i.e., questionnaire total scores, observer-rated ICC and weighted mYPAS scores) were prepared by screening each case for appropriateness. Cases were excluded that were considered inappropriate (e.g., significant deviation from study protocol). Also, skewness, kurtosis, and homogeneity of variance were examined.

4.5.3 Descriptive statistics. Descriptive statistics were computed for all demographic variables as well as measure subscale and total scores. Means and standard deviations were computed for continuous measures. Percentages were computed for categorical variables.
4.5.4 Preliminary analyses. Preliminary analyses were conducted to assess for differences among groups. First, potential group differences on key demographic variables (i.e., parent/guardian sex, age, and ethnicity, child age, sex, ethnicity, previous medical conditions, and previous surgeries), the EASI and STAI-T via univariate ANOVAs were completed. Second, associations between demographic variables and study measures of interest were examined. Specifically, the relationship between child age, number of previous surgeries, time of surgery, and time to wake were examined for relationships with observer-rated child anxiety or anesthesia induction compliance through bivariate correlations. Third, relationships between child sex and ethnicity were examined for relationships with child observer-rated anxiety or anesthetic induction compliance through a t-test and one-way ANOVA, respectively. Fourth, exploratory analyses around the interaction between child temperament, frequency of mask practice, and parent/guardian state and trait anxiety with observer-rated child anxiety and compliance at anesthesia induction were conducted via bivariate correlations.

4.5.5. Primary analyses. Hypothesis testing was conducted through the primary analyses. The following analyses are presented in accordance with the hypothesis they are designed to examine. To examine Hypothesis 1 (i.e., *Children in Group 1 would have the lowest observer-rated anxiety throughout the day and at induction of anesthesia, followed by children in Group 2 and Group 3*), a one-way mixed design ANOVA (3 group [Group 1, 2, 3] by 5 time [admission, holding area, transfer to the OR, induction, post-surgery]) was conducted. Post-hoc tests were completed where any main effects were found to determine where differences occurred. Further, a univariate ANOVA was conducted to examine the effect of group at anesthesia induction specifically. Finally, a 2
(Group [Group 2 & 3]) by 2 (time [admission, induction]) mixed design ANOVA was conducted to assess for an interaction effect between significantly different groups over time; this determines whether the groups were truly equal at baseline and differed significantly due to the intervention, rather than relying on randomization alone to ensure equality of the groups at baseline.

To examine Hypothesis 2 (i.e., *Children in Group 1 would be most compliant [observer-rated] at induction of anesthesia, followed by children in Group 2 and Group 3*), a univariate ANOVA was computed to examine differences in anesthesia induction compliance (via ICC from rater 1) across Groups 1, 2, and 3. Post-hoc tests were completed where any main effects were found to determine where differences occurred.

To explore Hypothesis 3 (i.e., *Observer-rated anxiety levels for children in Group 2 would be similar to the benchmark study [MacLaren & Kain, 2008]*)), t-tests comparing the current results to the results of MacLaren and Kain (2008) for child observer-rated anxiety were conducted where data were available. Regarding Hypothesis 4 (i.e., *Parent/guardian state anxiety would vary by group and parents/guardians of children in Group 1 would have lower STAI-S scores than parents/guardians of children in Group 2 and Group 3 over the day of surgery [admission and post-surgery]*)), a 2 time (admission and post-surgery) by 3 group (Groups 1, 2, 3) mixed design ANOVA was conducted.

**5.0 Results**

**5.1 Participant Data Flow**

Figure 1 shows the CONSORT diagram and flow of participants through the study. Potential participants declined to participate for reasons including: the child had previous surgery and/or likely would not benefit from participation ($n = 27$); no reason
given \((n = 11)\); not interested in participating in research \((n = 7)\); no time to participate \((n = 5)\); worry that participation/preparation would make the child more anxious \((n = 3)\); and the parent/guardian was too anxious \((n = 2)\). In addition, most potential participant exclusions from the research occurred when the parent/guardian did not speak or understand English sufficiently well to participate in significant elements of the study (e.g., understanding the consent form, completing questionnaires, reading instructions; \(n = 13\)). The remaining exclusions involved the child not meeting the study criteria \((n = 5)\). After exclusion, 37 children in Group 1 had complete data (measured by complete mYPAS observations at anesthesia induction), 37 children in Group 2 had complete data, and 36 children in Group 3 had complete data.

5.2 Data Preparation

The overall data set was first screened to ensure appropriateness prior to conducting the aforementioned statistical analyses. Since the data (i.e., primary outcome measure of mYPAS scores) had the potential to vary significantly (e.g., some parents/guardians and children would not be anxious at all while others would be extremely anxious), scores at the extremes were not considered outliers. Rather, when there was an observable deviation from the study protocol (i.e., children were allowed to play a video game or were shown a video by the anesthesiologist at anesthesia induction), there was the potential for those children’s data to differ as a function of this deviation in protocol; thus, those cases were removed \((n = 4)\).

5.2.1 Skewness and kurtosis. The data were then screened for normality; skewness and kurtosis values were calculated for all continuous variables of interest in the primary analyses and divided by their standard errors. The standardized values were
then compared to a critical value of ±1.96 for skewness (Field, 2013) and ±7 for kurtosis (West, Finch, & Curran, 1995). As depicted in Table 2, across all three groups the sample did not demonstrate normal population distribution on the Sociability subscale of the EASI, the STAI-S at post-surgery, the mYPAS at any time point, or the ICC. The $F$-statistic of ANOVA is robust to violations of normality when group sizes are the same (Field, 2013); accordingly, there was no need to transform data. Bootstrapping was nonetheless used to ensure robust $p$-value estimates where appropriate.
Table 2

*Skewness and Kurtosis for Study Measures Employed in Primary Analyses*

<table>
<thead>
<tr>
<th>Measure</th>
<th>$M$ ($SD$)</th>
<th>Skewness ($SE$)</th>
<th>Z-Score Skewness</th>
<th>Kurtosis ($SE$)</th>
<th>Z-Score Kurtosis</th>
</tr>
</thead>
<tbody>
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<td><strong>Baseline</strong></td>
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<td></td>
</tr>
<tr>
<td>STAI-S</td>
<td>38.544</td>
<td>0.399 (0.271)</td>
<td>1.472</td>
<td>-0.321 (0.535)</td>
<td>-0.600</td>
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<tr>
<td></td>
<td>(11.605)</td>
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<tr>
<td>STAI-T</td>
<td>35.054</td>
<td>0.253 (0.229)</td>
<td>1.105</td>
<td>0.017 (0.455)</td>
<td>0.037</td>
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<td></td>
<td>(7.841)</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>EASI Emotionality</td>
<td>12.558</td>
<td>0.326 (0.227)</td>
<td>1.436</td>
<td>-0.553 (0.451)</td>
<td>-1.226</td>
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<tr>
<td></td>
<td>(3.780)</td>
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<td></td>
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</tr>
<tr>
<td>EASI Activity</td>
<td>16.097</td>
<td>-0.148</td>
<td>-0.652</td>
<td>-0.427 (0.451)</td>
<td>-0.947</td>
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<tr>
<td></td>
<td>(3.937)</td>
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<tr>
<td>EASI Sociability</td>
<td>19.124</td>
<td>-0.587</td>
<td>-2.586</td>
<td>0.097 (0.451)</td>
<td>0.215</td>
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<tr>
<td></td>
<td>(3.018)</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>EASI Impulsivity</td>
<td>14.018</td>
<td>0.162 (0.227)</td>
<td>0.714</td>
<td>-0.402 (0.451)</td>
<td>-0.891</td>
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<tr>
<td></td>
<td>(3.346)</td>
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<td><strong>Day of Surgery</strong></td>
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<tr>
<td>Admission STAI-S</td>
<td>37.290</td>
<td>0.161 (0.226)</td>
<td>0.712</td>
<td>-0.995 (0.449)</td>
<td>-2.216</td>
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<tr>
<td></td>
<td>(11.678)</td>
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<tr>
<td>mYPAS admission</td>
<td>26.553</td>
<td>2.601 (0.224)</td>
<td>11.612</td>
<td>7.000 (0.444)</td>
<td>15.766</td>
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<tr>
<td></td>
<td>(6.623)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Value 1</td>
<td>Value 2</td>
<td>Value 3</td>
<td>Value 4</td>
<td>Value 5</td>
</tr>
<tr>
<td>--------------------------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
</tr>
<tr>
<td><strong>mYPAS holding area</strong></td>
<td>25.612</td>
<td>6.256</td>
<td>27.929a</td>
<td>49.593</td>
<td>111.696b</td>
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<td></td>
<td>(6.857)</td>
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</tr>
<tr>
<td><strong>mYPAS transfer to OR</strong></td>
<td>30.259</td>
<td>2.519</td>
<td>11.196a</td>
<td>6.074</td>
<td>13.619b</td>
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<td>(14.181)</td>
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</tr>
<tr>
<td><strong>mYPAS induction</strong></td>
<td>47.232</td>
<td>0.782</td>
<td>3.460a</td>
<td>-1.100</td>
<td>-2.461</td>
</tr>
<tr>
<td></td>
<td>(29.265)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>mYPAS post-surgery</strong></td>
<td>38.560</td>
<td>1.220</td>
<td>5.422a</td>
<td>0.975</td>
<td>2.186</td>
</tr>
<tr>
<td></td>
<td>(16.867)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ICC</strong></td>
<td>1.748</td>
<td>1.214</td>
<td>5.372a</td>
<td>0.228</td>
<td>0.510</td>
</tr>
<tr>
<td></td>
<td>(2.477)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Post-surgery</strong></td>
<td>33.053</td>
<td>0.832</td>
<td>3.665a</td>
<td>0.270</td>
<td>0.599</td>
</tr>
<tr>
<td><strong>STAI-S</strong></td>
<td>(11.492)</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

*Note.* STAI = State Trait Anxiety Inventory-State Version; STAI-T = State Trait Anxiety Inventory-Trait Version; EASI = Emotionality, Activity, Sociability and Impulsivity Scale; mYPAS = Modified Yale Preoperative Anxiety Scale; ICC = Induction Compliance Checklist.

aValue exceeded critical value of ±1.96, \( p < .05 \) (Field, 2013).

bValue exceeded critical value of ±7, \( p < .05 \) (West et al., 1995).
5.2.2 Homogeneity of variance. Homogeneity of variance for the mYPAS and ICC was examined through Levene’s test as well as variance ratios. On the mYPAS, the variances were equal across Groups 1, 2, and 3 for observer-rated child anxiety at admission, transfer to the OR, and post-surgery; however, for child anxiety in the holding area, $F(2, 112) = 11.162, p < .001$, and at anesthesia induction, $F(2, 112) = 8.230, p < .001$, there were significant differences between the three groups. There were also significant differences between the three groups for observer-rated child compliance at anesthesia induction (measured via ICC), $F(2, 112) = 5.411, p = .006$. Comparing the variance ratios against a critical value of 2.4 (Field, 2013), these significant differences remained. Therefore, homogeneity of variance was violated for mYPAS holding and induction, and the ICC; the results for these variables should be interpreted with caution.

5.3 Descriptive Statistics

Descriptive statistics were computed for all demographic variables as well as measure subscale and total scores (Table 3). Means and standard deviations were computed for continuous measures. Percentages were computed for categorical variables.

5.4 Preliminary Analyses

5.4.1 Group differences across demographic variables. A series of univariate ANOVAs were completed to examine potential group differences on key demographic variables (i.e., parent/guardian sex, age, and ethnicity, child age, sex, ethnicity, previous medical conditions, and previous surgeries), the EASI and the STAI-T (Table 4). Instead of relying solely on $p$-value to identify a significant difference, a small effect
Table 3

*Descriptive Statistics for Study Measures by Group*

<table>
<thead>
<tr>
<th>Measure</th>
<th>Sample Range</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Sample</td>
<td>Group 1</td>
<td>Group 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N</td>
<td>M (SD)</td>
<td>N</td>
</tr>
<tr>
<td>Baseline</td>
<td></td>
<td>27</td>
<td>36.96 (10.85)</td>
<td>27</td>
</tr>
<tr>
<td>STAI-S</td>
<td>20-70</td>
<td>34</td>
<td>34.74 (7.29)</td>
<td>37</td>
</tr>
<tr>
<td>STAI-T</td>
<td>20-60</td>
<td>34</td>
<td>13.41 (3.60)</td>
<td>37</td>
</tr>
<tr>
<td>EASI Emotionality</td>
<td>5-21</td>
<td>34</td>
<td>15.76 (4.07)</td>
<td>37</td>
</tr>
<tr>
<td>EASI Activity</td>
<td>11-25</td>
<td>34</td>
<td>19.21 (2.84)</td>
<td>37</td>
</tr>
<tr>
<td>EASI Sociability</td>
<td>6-22</td>
<td>34</td>
<td>14.24 (3.15)</td>
<td>37</td>
</tr>
<tr>
<td>Day of Surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admission STAI-S</td>
<td>20-64</td>
<td>35</td>
<td>36.37 (11.19)</td>
<td>37</td>
</tr>
<tr>
<td>Measure</td>
<td>Group 1</td>
<td>Group 2</td>
<td>Group 3</td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>---------</td>
<td>---------</td>
<td>---------</td>
<td></td>
</tr>
<tr>
<td>mYPAS admission</td>
<td>23.33-58.33</td>
<td>25.63 (5.84)</td>
<td>26.67 (6.57)</td>
<td></td>
</tr>
<tr>
<td>mYPAS holding area</td>
<td>23.33-85.00</td>
<td>25.23 (3.93)</td>
<td>25.60 (9.90)</td>
<td></td>
</tr>
<tr>
<td>mYPAS transfer to OR</td>
<td>23.33-91.67</td>
<td>30.90 (16.57)</td>
<td>29.44 (14.15)</td>
<td></td>
</tr>
<tr>
<td>mYPAS induction</td>
<td>23.33-100.00</td>
<td>51.35 (31.82)</td>
<td>39.61 (24.31)</td>
<td></td>
</tr>
<tr>
<td>mYPAS post-surgery</td>
<td>23.33-91.67</td>
<td>36.16 (14.85)</td>
<td>35.61 (15.98)</td>
<td></td>
</tr>
<tr>
<td>ICC</td>
<td>0-9</td>
<td>2.19 (2.65)</td>
<td>1.11 (2.05)</td>
<td></td>
</tr>
<tr>
<td>Post-surgery STAI-S</td>
<td>20-71</td>
<td>29.17 (9.80)</td>
<td>35.08 (13.39)</td>
<td></td>
</tr>
</tbody>
</table>

**Note.** Group 1 = children who received anesthesia mask exposure/shaping practice in the week before surgery. Group 2 = children who received anesthesia mask exposure/shaping practice on the day of surgery. Group 3 = children who did not receive anesthesia mask exposure/shaping practice. Values are rounded up to two decimals places; STAI = State Trait Anxiety Inventory-State Version; STAI-T = State Trait Anxiety Inventory-Trait Version; EASI = Emotionality, Activity, Sociability and Impulsivity Scale; mYPAS = Modified Yale Preoperative Anxiety Scale; ICC = Induction Compliance Checklist.
## Table 4

*Group Differences on Demographic Variables and Study Measures*

<table>
<thead>
<tr>
<th>Variable</th>
<th>$F$</th>
<th>$df$</th>
<th>$\eta^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parent/guardian sex</td>
<td>0.438</td>
<td>2, 108</td>
<td>0.008</td>
</tr>
<tr>
<td>Parent/guardian age</td>
<td>0.104</td>
<td>2, 108</td>
<td>0.002</td>
</tr>
<tr>
<td>Parent/guardian Ethnicity (Aboriginal, White/Caucasian, Other)</td>
<td>3.211*</td>
<td>2, 108</td>
<td>0.056</td>
</tr>
<tr>
<td>Child age</td>
<td>0.172</td>
<td>2, 108</td>
<td>0.003</td>
</tr>
<tr>
<td>Child sex</td>
<td>0.035</td>
<td>2, 108</td>
<td>0.001</td>
</tr>
<tr>
<td>Child Ethnicity (Aboriginal, White/Caucasian, Other)</td>
<td>3.812*</td>
<td>2, 108</td>
<td>0.066</td>
</tr>
<tr>
<td>Child medical or mental health condition</td>
<td>1.619</td>
<td>2, 108</td>
<td>0.029</td>
</tr>
<tr>
<td>Child previous surgical procedure</td>
<td>0.621</td>
<td>2, 108</td>
<td>0.011</td>
</tr>
<tr>
<td>EASI Emotionality</td>
<td>0.684</td>
<td>2, 108</td>
<td>0.012</td>
</tr>
<tr>
<td>EASI Activity</td>
<td>1.083</td>
<td>2, 108</td>
<td>0.020</td>
</tr>
<tr>
<td>EASI Sociability</td>
<td>0.726</td>
<td>2, 108</td>
<td>0.013</td>
</tr>
<tr>
<td>EASI Impulsivity</td>
<td>0.414</td>
<td>2, 108</td>
<td>0.008</td>
</tr>
<tr>
<td>Admission STAI-S</td>
<td>0.479</td>
<td>2, 108</td>
<td>0.009</td>
</tr>
<tr>
<td>STAI-T</td>
<td>0.003</td>
<td>2, 108</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*Note.* Benchmarks for $\eta^2$ are as follows: .01 = small effect, .06 = medium effect, .14 = large effect. EASI = Emotionality, Activity, Sociability and Impulsivity Scale; STAI = State Trait Anxiety Inventory-State Version; STAI-T = State Trait Anxiety Inventory-Trait Version.  
* $p < .05.$
size was accepted and comparing the effect of interest to the total amount of variance in the data. If the difference was associated with a medium or large effect size, the groups were considered significantly different from each other, and that variable was incorporated in the primary analyses. There were two significant differences: child ethnicity and parent/guardian ethnicity. Specifically, there were more Caucasian children in Group 1 than Group 3, $F(2, 108) = 3.812, p = .025, \eta^2 = 0.056$. There were also more Caucasian parents/guardians in Group 1 than Group 3, $F(2, 108) = 3.211, p = .044, \eta^2 = 0.066$. Accordingly, 6% of the total variance appeared to be explained by child ethnicity and 7% appeared to be explained by parent/guardian ethnicity. The effect sizes were considered medium (Field, 2013), which meant child and parent/guardian ethnicity were analyzed as part of the primary hypotheses.

5.4.2 Associations between demographics and study measures of interest.
Bivariate correlations were computed between child age, number of previous surgeries, length of surgery, and time to wake with observer-rated child anxiety (via mYPAS), and anesthesia induction compliance (via ICC). Successively, the variables of child sex and ethnicity were examined for statistically significant relationships with child anxiety and anesthesia induction compliance through a $t$-test and one-way ANOVA, respectively. No significant associations were observed between child age and child anxiety at anesthesia induction, $r(109) = .004, 95\% \text{ CI } [-.173, .194], p = .968, R^2 < .001$ or with child compliance at anesthesia induction, $r(109) = .010, 95\% \text{ CI } [-.170, .207], p = .919, R^2 < .001$. Number of previous surgeries was also not significantly associated with child anxiety at anesthesia induction, $r(109) = .064, 95\% \text{ CI } [-.139, .258], p = .511, R^2 = .004$, or with child compliance at anesthesia induction, $r(109) = .096, 95\% \text{ CI } [-.131, .298], p =$
.322, $R^2 = .009$. The length of surgery did not correlate significantly with child anxiety at anesthesia induction, $r(104) = -.175$, 95% CI [-.343, .009], $p = .076$, $R^2 = .031$. A significant relationship was found with child compliance at anesthesia induction, $r(104) = -.213$, 95% CI [-.375, -.040], $p = .030$, but the effect size was small, $R^2 = .045$. No relationship was found between time to wake after surgery and child anxiety, $r(100) = .023$, 95% CI [-.217, .249], $p = .822$, $R^2 < .001$, or compliance, $r(100) = .047$, 95% CI [-.201, .295], $p = .640$, $R^2 = .002$, at anesthesia induction. No significant sex differences were observed for child anxiety, $t(105.242) = .457$, 95% CI [-7.779, 14.004], $p = .648$, Cohen’s $d = 0.091$, or compliance, $t(105.605) = .687$, 95% CI [-.531, 1.295], $p = .494$, Cohen’s $d = 0.141$, at anesthesia induction. No significant ethnic differences in child anxiety at anesthesia induction were observed, $F(2, 107) = 0.963$, $p = .385$, $\eta^2 = 0.028$.

Similarly, no significant ethnic differences in child compliance at anesthesia induction were observed, $F(2, 1077) = 1.695$, $p = .188$, $\eta^2 = 0.033$.

5.4.3 Exploratory analyses. Bivariate correlations were computed between the measures of child temperament (i.e., via the EASI temperament facets of Emotionality, Activity, Sociability, and Impulsivity), frequency of anesthesia mask practice, as well as parent/guardian state and trait anxiety (via the STAI-S and STAI-T) with child observer-rated anxiety (via mYPAS) and compliance (via ICC) at anesthesia induction (Table 5). The two-tailed analyses were conducted without a priori hypotheses because the respective relationships are less clear in the literature. For example, some studies show no relationship between child temperament and anxiety (e.g., Kain et al., 2005; Wright, Stewart et al., 2013), and other studies found relationships with various temperament
Table 5

Correlations Among Study Measures Across Groups

<table>
<thead>
<tr>
<th>Measure</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
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<tbody>
<tr>
<td>Baseline</td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>1. STAI-S</td>
<td>-</td>
<td>.265*</td>
<td>.103</td>
<td>-0.041</td>
<td>-0.263*</td>
<td>0.028</td>
<td>0.616***</td>
<td>0.219</td>
<td>0.137</td>
<td>-0.146</td>
<td>0.040</td>
<td>0.117</td>
<td>0.063</td>
<td>0.135</td>
</tr>
<tr>
<td>2. STAI-T</td>
<td>-</td>
<td>-0.229*</td>
<td>-0.001</td>
<td>-0.301**</td>
<td>0.201*</td>
<td>0.403***</td>
<td>0.294**</td>
<td>-0.009</td>
<td>0.082</td>
<td>0.001</td>
<td>0.122</td>
<td>0.131</td>
<td>0.095</td>
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</tr>
<tr>
<td>3. EASI Emotionality</td>
<td>-</td>
<td>0.135</td>
<td>-0.330***</td>
<td>0.360***</td>
<td>-0.042</td>
<td>-0.022</td>
<td>-0.003</td>
<td>0.103</td>
<td>0.155</td>
<td>0.177</td>
<td>-0.084</td>
<td>0.133</td>
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</tr>
<tr>
<td>4. EASI Activity</td>
<td>-</td>
<td>0.186</td>
<td>0.576***</td>
<td>0.050</td>
<td>-0.036</td>
<td>0.015</td>
<td>-0.158</td>
<td>-0.173</td>
<td>0.006</td>
<td>-0.017</td>
<td>-0.100</td>
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<tr>
<td>5. EASI Sociability</td>
<td>-</td>
<td>-0.102</td>
<td>-0.258**</td>
<td>-0.106</td>
<td>-0.190*</td>
<td>-0.186</td>
<td>-0.178</td>
<td>-0.107</td>
<td>-0.185</td>
<td>-0.052</td>
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</tr>
<tr>
<td>6. EASI Impulsivity</td>
<td>-</td>
<td>-0.006</td>
<td>0.009</td>
<td>-0.063</td>
<td>0.006</td>
<td>-0.141</td>
<td>0.080</td>
<td>0.052</td>
<td>-0.027</td>
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<tr>
<td>Day of Surgery</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>7. Admission STAI-S</td>
<td>-</td>
<td>0.371***</td>
<td>-0.001</td>
<td>0.060</td>
<td>0.053</td>
<td>0.208*</td>
<td>0.132</td>
<td>0.173</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>8. Post-surgery STAI-S</td>
<td>-</td>
<td>0.021</td>
<td>0.010</td>
<td>-0.004</td>
<td>0.032</td>
<td>0.439***</td>
<td>-0.036</td>
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<tr>
<td>9. mYPAS admission</td>
<td>-</td>
<td>-0.166</td>
<td>0.249**</td>
<td>0.145</td>
<td>0.246*</td>
<td>0.077</td>
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<tr>
<td>10. mYPAS holding area</td>
<td>-</td>
<td>0.318**</td>
<td>0.049</td>
<td>0.060</td>
<td>-0.019</td>
<td></td>
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<tr>
<td>11. mYPAS transfer to OR</td>
<td>-</td>
<td>-0.495***</td>
<td>0.163</td>
<td>0.504***</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>12. mYPAS induction</td>
<td>-</td>
<td>0.250**</td>
<td>0.916***</td>
<td></td>
<td></td>
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<tr>
<td>13. mYPAS post-surgery</td>
<td>-</td>
<td>-0.167</td>
<td></td>
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<tr>
<td>14. ICC</td>
<td>-</td>
<td></td>
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</tbody>
</table>

Note. STAI-S = State Trait Anxiety Inventory-State Version; STAI-T = State Trait Anxiety Inventory-Trait Version; EASI = Emotionality, Activity, Sociability and Impulsivity Scale; mYPAS = Modified Yale Preoperative Anxiety Scale; ICC = Induction Compliance Checklist.

*p < .05. **p < .01. ***p < .001.
facets (e.g., Finley et al., 2006; Kain, MacLaren et al., 2007; Kain, Mayes, Caramico et al., 1996; Kain, Mayes, O’Connor et al., 1996; Kain, Mayes, Weisman et al., 2000). The analyses also informed decisions regarding variables potentially included in primary analyses as covariates.

First, bivariate correlations were computed between child temperament facets and observer-rated child anxiety and compliance at anesthesia induction to examine potential relationships. No significant relationships emerged between child anxiety at anesthesia induction and Emotionality, $r(107) = .177$, 95% CI [-.034, .374], $p = .068$, $R^2 = .031$, Activity, $r(107) = .006$, 95% CI [-.181, .193], $p = .954$, $R^2 < .001$, Sociability, $r(107) = -.107$, 95% CI [-.302, .073], $p = .272$, $R^2 = .011$, or Impulsivity, $r(107) = .080$, 95% CI [-.103, .272], $p = .415$, $R^2 = .006$. Further, no significant relationships emerged between child compliance at anesthesia induction and Emotionality, $r(107) = .133$, 95% CI [-.072, .338], $p = .173$, $R^2 = .018$, Activity, $r(107) = -.100$, 95% CI [-.256, .077], $p = .304$, $R^2 = .010$, Sociability, $r(107) = -.052$, 95% CI [-.248, .124], $p = .593$, $R^2 = .352$, or Impulsivity, $r(107) = -.027$, 95% CI [-.194, .159], $p = .783$, $R^2 = .001$.

Second, frequency of exposure to the anesthesia mask (for those in Groups 1 and 2) and observer-rated child anxiety and compliance at anesthesia induction was explored (no formal hypothesis was generated due to the lack of research in this area). No statistically significant relationships were identified between the frequency of anesthesia mask practice and anxiety at anesthesia induction, $r(74) = .037$, 95% CI [-.154, .268], $p = .757$, $R^2 = .001$, or compliance at anesthesia induction, $r(74) = .036$, 95% CI [-.147, .260], $p = .762$, $R^2 = .001$. 
Third, bivariate correlations were computed between parent/guardian state and trait anxiety at baseline and observer-rated child anxiety and compliance at anesthesia induction to examine potential relationships. No significant relationships were identified between child anxiety at anesthesia induction and parent/guardian state anxiety, $r(75) = .117$, 95% CI [-.155, .333], $p = .316$, $R^2 = .014$, or trait anxiety, $r(106) = .122$, 95% CI [-.113, .300], $p = .214$, $R^2 = .015$. No significant relationships were identified between child compliance at anesthesia induction and parent/guardian state anxiety, $r(75) = .135$, 95% CI [-.119, .328], $p = .248$, $R^2 = .018$, or trait anxiety, $r(106) = .095$, 95% CI [-.185, .248], $p = .333$, $R^2 = .009$. Therefore, none of the aforementioned variables in any of the three sets of bivariate correlations were included as covariates in the primary analyses.

5.5 Primary Analyses

5.5.1 Hypothesis 1. To address the first hypothesis (i.e., Children in Group 1 would have the lowest observer-rated anxiety throughout the day of surgery and at induction of anesthesia, followed by Group 2 and Group 3), a one-way mixed design ANOVA (3 group [Group 1, 2, 3] by 5 time [admission, holding area, transfer to OR, induction, post-surgery] with Helmert contrasts was conducted for the mean mYPAS scores from rater 1. However, first two univariate ANOVAs examining the effect of parent and child ethnicity were conducted to determine if ethnicity played a significant role in children’s observer-rated anxiety at baseline (i.e., admission). The results for parent ethnicity were non-significant, $F(2, 110) = 0.210$, $p = .881$, as were the results for child ethnicity, $F(2, 111) = 0.233$, $p = .792$, indicating that ethnicity was not a significant predictor of child observer-rated anxiety.
Examining the results of the mixed design ANOVA, Box’s M was statistically significant; however, because the sample sizes across the groups are almost identical, and Pillai’s trace is considered robust, the analysis was able to be completed (Field, 2013). Mauchley’s test indicated that the assumption of sphericity had been violated, $\chi^2(9) = .086, p < .001$; therefore, degrees of freedom and statistical significance were corrected using Huynh-Feldt estimates of sphericity ($\varepsilon = .527$).

A significant main effect for time was observed, $F(2.107, 225.487) = 43.056, p < .001, \eta_p^2 = .287$ (i.e., large effect). To further examine this, pairwise comparisons with LSD post-hoc tests (i.e., equivalent to no adjustment, chosen because of the low number of tests run) of mYPAS scores at consecutive time points were examined (Table 6). Child anxiety at admission ($M = 26.692, SE = 0.652$) significantly differed from the holding area ($M = 25.177, SE = 0.388$) with anxiety at admission being higher. The difference between child anxiety at holding significantly differed from transfer to the OR ($M = 29.706, SE = 1.281$) with anxiety at holding being lower. The difference between child anxiety at transfer to the OR significantly differed from anesthesia induction ($M = 47.836, SE = 2.785$), with anxiety being lower at transfer to the OR. Finally, the difference between child anxiety at anesthesia induction significantly differed from post-surgery ($M = 38.359, SE = 1.549$), with anxiety being higher at anesthesia induction.

The results also demonstrated a significant effect for group, $F(2, 107) = 3.350, p = .039, \eta_p^2 = .059$ (i.e., medium effect). The contrast between time and group was not significant with Huynh-Feldt correction, $F(4.215, 225.487) = 1.702, p = .147, \eta_p^2 = .031$. To further examine the main effect of group, pairwise comparisons with LSD post-hoc tests were examined (Table 7). The estimated marginal mean observer-rated child anxiety
Table 6

Pairwise Comparisons of Mean Differences in Child Anxiety Across Consecutive Time Points

<table>
<thead>
<tr>
<th>Time point 1</th>
<th>Time point 2</th>
<th>$M_{diff}$</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admission</td>
<td>Holding area</td>
<td>1.515*</td>
<td>0.630</td>
</tr>
<tr>
<td>Holding area</td>
<td>Transfer to OR</td>
<td>-4.529*</td>
<td>1.332</td>
</tr>
<tr>
<td>Transfer to OR</td>
<td>Induction</td>
<td>-18.130***</td>
<td>2.437</td>
</tr>
<tr>
<td>Induction</td>
<td>Post-surgery</td>
<td>9.477*</td>
<td>2.856</td>
</tr>
</tbody>
</table>

*p < .05, **p < .01, ***p < .001.
Table 7

Pairwise Comparisons of Mean Differences in Observer-Rated Child Anxiety Across Group

<table>
<thead>
<tr>
<th>Group comparison</th>
<th>M_{diff}</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2</td>
<td>3.286</td>
<td>2.188</td>
</tr>
<tr>
<td>1 3</td>
<td>-2.387</td>
<td>2.203</td>
</tr>
<tr>
<td>2 3</td>
<td>-5.673**</td>
<td>2.203</td>
</tr>
</tbody>
</table>

*Note.* Group 1 = children who received anesthesia mask exposure/shaping practice in the week before surgery. Group 2 = children who received anesthesia mask exposure/shaping practice on the day of surgery. Group 3 = children who did not receive anesthesia mask exposure/shaping practice. *p < .05, ** p < .01, ***p < .001
score for Group 2 ($M = 30.568, SE = 1.547$) was significantly lower than for Group 3 ($M = 36.241, SE = 1.568$). The estimated marginal mean anxiety score for Group 1 ($M = 33.854, SE = 1.547$) did not significantly differ from Group 3. Accordingly, our initial hypothesis was not supported; instead, children in Group 2 had the lowest anxiety, followed by Group 1, then Group 3.

Visual examination of Figure 2 suggested a significant difference in mYPAS scores across groups at anesthesia induction. A univariate ANOVA was completed to examine the effect of group at this particular time point. The overall effect of group was not significant, $F(2, 107) = 2.552, p = .083, \eta_p^2 = .046$ (i.e., small to medium effect). However, examining the parameter estimates, Group 2 significantly differed from Group 3 at anesthesia induction, $t = -2.068, 95\%$ CI $[-27.696, -0.582], p = .041, \eta_p^2 = .038$ (see Table 8 for pairwise comparisons with LSD post-hoc tests).

Finally, a 2 group (Groups 2 and 3) by 2 time (admission and induction) mixed design ANOVA was conducted to assess for an interaction effect between significantly different groups over time; this determines whether the groups were truly equivalent at baseline (i.e., admission) and differed significantly due to the intervention, rather than relying on randomization alone to ensure equality of the groups at baseline. A significant main effect for time was observed, $F(1, 71) = 37.094, p < .001, \eta_p^2 = .343$ (i.e., large effect). There was a significant increase in child observer-rated anxiety for Groups 2 and 3 between admission ($M = 27.223, SE = 0.843$) and anesthesia induction ($M = 46.079, SE = 3.254$). A significant main effect was also observed for group, $F(1, 71) = 4.524, p = .037, \eta_p^2 = .060$ (i.e., medium effect). Pairwise comparisons with LSD post-hoc tests showed that Group 2 differed significantly from Group 3 ($M_{diff} = -7.671, SE = 3.607, p = \ldots$)
Figure 2. Child observer-rated anxiety (via mYPAS) at the five time points (admission, holding, transfer to OR, induction of anesthesia, post-surgery). mYPAS range = 23.3 - 100.00.
Table 8

*Bootstrapped Pairwise Comparisons of Mean Differences in Observer-Rated Child Anxiety at Anesthetic Induction Across Group*

<table>
<thead>
<tr>
<th>Group comparison</th>
<th>$M_{diff}$</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2</td>
<td>12.342</td>
<td>6.792</td>
</tr>
<tr>
<td>1 3</td>
<td>-1.797</td>
<td>6.839</td>
</tr>
<tr>
<td>2 3</td>
<td>-14.139*</td>
<td>6.839</td>
</tr>
</tbody>
</table>

*Note.* Group 1 = children who received anesthesia mask exposure/shaping practice in the week before surgery. Group 2 = children who received anesthesia mask exposure/shaping practice on the day of surgery. Group 3 = children who did not receive anesthesia mask exposure/shaping practice.  

* $p < .05$, ** $p < .01$, *** $p < .001$. 


.037). Most importantly, a significant interaction was observed between time and group, $F(1, 71) = 4.365, p = .040, \eta^2_p = .058$ (i.e., small to medium effect). The significant interaction demonstrates that children in Group 2 were equally anxious at admission as children in Group 3 (i.e., the randomization was effective in that children experienced similar levels of anxiety at admission), then significantly differed in their level of anxiety at induction of anesthesia, likely due to the intervention.

### 5.5.2 Hypothesis 2

To address the second hypothesis (i.e., *Children in Group 1 would be most compliant [observer-rated] at induction of anesthesia, followed by children in Group 2 and Group 3*), a univariate ANOVA, using Helmert contrasts, comparing observer-rated compliance of children in Groups 1, 2, and 3 at the anesthesia induction (via ICC from rater 1) was conducted. The results approached a significant difference across groups in compliance at anesthesia induction, $F(2,107) = 2.838, p = .063, \eta^2_p = .050$ (i.e., small to medium effect). When examining the specific contrasts, Group 1 did not significantly differ from Group 3 ($p = .223$), but Group 2 significantly differed from Group 3 ($p = .044$) when examining pairwise comparisons with LSD post-hoc tests ($M_{diff} = -1.167, SE = 0.574, p = .133$). Therefore, our initial hypothesis was not supported; instead, children in Group 2 had the best induction compliance, while children in Group 1 did not differ from the control group (Group 3).

### 5.5.3 Hypothesis 3

To explore Hypothesis 3 (i.e., *Children in Group 2’s anxiety levels would be similar to the benchmark study [MacLaren & Kain, 2008]*) $t$-tests were conducted comparing the current study results to the results of MacLaren and Kain (2008) for observer-rated child anxiety (via mYPAS) at the points where data were
available from the aforementioned study (Table 9). Significant differences were observed between mean mYPAS ratings in the current investigation and those in MacLaren and Kain’s at holding area and transfer to the OR; however, mean mYPAS ratings at anesthesia induction (the most anxiety provoking and clinically meaningful time point) across the research were consistent. Thus, Hypothesis 3 was partially supported.

5.5.4 Hypothesis 4. To assess Hypothesis 4 (i.e., Parent/guardian state anxiety would vary by group, and parents/guardians of children in Group 1 would have lower STAI-S scores than parents/guardians of children in Group 2 and Group 3 throughout the day of surgery [admission and post-surgery]), a 2 time (admission and post-surgery) by 3 group (Group 1, 2, 3) mixed design ANOVA was conducted. As with Hypothesis 1, first two univariate ANOVAs of parent and child ethnicity were examined for differences in parent STAI-S at admission. Neither parent ethnicity, $F(2, 109) = 0.151, p = .860$, nor child ethnicity, $F(2, 109) = 0.360, p = .699$, was a significant predictor of parent self-reported anxiety at admission. Examining the results of the mixed design ANOVA, Box’s M was not significant. A significant main effect was observed for time, $F(1, 106) = 11.646, p < .001, \eta^2_p = .099$ (i.e., large effect). Examination of the pairwise comparisons with LSD post-hoc tests for time revealed a significant difference between admission and post-surgery, $M_{diff} = 4.274, SE = 1.252, p = .001$ (Figure 3). A significant main effect was not observed for group, $F(2, 106) = 1.873, p = .159, \eta^2_p = .034$, nor was the interaction of time and group significant, $F(2, 106) = 1.439, p = .242, \eta^2_p = .026$. Accordingly, while parent/guardian anxiety decreased from pre- to post-surgery in general, the decrease did not differ significantly based on their group assignment, which meant Hypothesis 4 was not supported.
### Table 9

*Comparison of Means and Standard Deviations of the Modified Yale Preoperative Anxiety Scale Between the Current and Benchmark Study*

<table>
<thead>
<tr>
<th>Measure</th>
<th>Current Group $M$ (SD)</th>
<th>MacLaren &amp; Kain (2008) $M$ (SD)</th>
<th>$t$</th>
<th>95% CI</th>
<th>Cohen’s $d$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holding area</td>
<td>23.96 (1.64)</td>
<td>31.37 (10.99)</td>
<td>4.06***</td>
<td>-11.04, -3.77</td>
<td>0.943</td>
</tr>
<tr>
<td>Transfer to OR</td>
<td>27.52 (10.73)</td>
<td>35.82 (13.74)</td>
<td>3.00**</td>
<td>-13.81, -2.79</td>
<td>0.67</td>
</tr>
<tr>
<td>Induction</td>
<td>39.10 (24.36)</td>
<td>44.88 (23.30)</td>
<td>1.10</td>
<td>-16.28, 4.72</td>
<td>0.24</td>
</tr>
</tbody>
</table>

*Note.* Values have been rounded to two decimal places. $df = 80$. $n = 37$ in current investigation, $n = 45$ in MacLaren & Kain (2008). Group 2 = children who received anesthesia mask exposure/shaping practice on the day of surgery. *$p < .05$, **$p < .01$, ***$p < .001$.*
Figure 3. Parent/guardian anxiety [via State Trait Anxiety Inventory-State Version (STAI-S)] at the admission and post-surgery. STAI-S range = 20-80.
6.0 Discussion

The current investigation was designed to examine the efficacy of parent/guardian-directed exposure and shaping practice with an anesthetic mask as a stand-alone intervention for the prevention of preoperative anxiety in children (employing MacLaren and Kain’s [2008] mask exposure protocol), with a novel focus on the timing of anesthesia mask exposure and shaping practice. There were two timings of the parent/guardian-directed anesthesia mask intervention examined (i.e., in the week before surgery or on the day of surgery) against a control group (i.e., no anesthesia mask exposure). The primary objectives of the research achieved through employing a RCT design were four-fold: (1) to explore whether participants would systematically vary on observer-rated anxiety as a function of group membership (with children in Group 1 [i.e., anesthesia mask exposure/shaping practice in the week before surgery] experiencing the lowest observer-rated anxiety followed by children in Group 2 [i.e., anesthesia mask exposure/shaping practice on the day of surgery], then Group 3 [i.e., no anesthesia mask exposure before surgery]) throughout the day of surgery, but especially at induction of anesthesia; (2) to examine if participants would systematically vary in observer-rated anesthetic induction compliance as a function of group membership (with children in Group 1 showing the best induction compliance, followed by children in Group 2, then Group 3); (3) to investigate if observer-rated anxiety throughout the day of surgery for the group that received anesthesia mask exposure and shaping practice on day of surgery (Group 2) would be similar to that reported in the benchmark study (MacLaren & Kain, 2008); and (4) to examine parent/guardian self-reported state anxiety for systematic variance as a function of group membership from admission to post-surgery (with
parents/guardians of children in Group 1 experiencing the lowest anxiety, followed by parents/guardians of children in Group 2, then Group 3). The RCT results and how they relate to the hypotheses are discussed, followed by an examination of strengths and limitations of the investigation, with recommendations for future research.

6.1 Preliminary Findings

Potential group differences on key demographic variables (i.e., parent/guardian sex, age, and ethnicity, child age, sex, ethnicity, previous medical conditions, and previous surgeries), child temperament, and parent/guardian trait anxiety were examined. Despite randomization, more Caucasian children (and parents/guardians) were in Group 1 than Group 3. Since the effect sizes of child and parent/guardian ethnicity were each medium, these variables were incorporated into the main analyses.

Relationships between specific demographic variables (i.e., child age, number of previous surgeries, length of surgery, and time to wake) with observer-rated child anxiety, and anesthesia induction compliance were also examined. Only one significant relationship was observed; specifically, there was a positive correlation between length of surgery and observer-rated child compliance at anesthesia induction. Children were unaware of their surgery length, suggesting against an intentional bias effect. In any case, the effect size was small and so the variable was not incorporated as a covariate in the main analyses.

Child age, observer-rated anxiety, and compliance at anesthesia induction were not significantly associated. The literature in the area is mixed and the current investigation’s results are consistent with some prior research showing no correlation (e.g., Holm-Knudsen et al., 1998), but inconsistent with other studies that found a
significant correlation between age and anxiety (e.g., Abramowitz et al., 2011; Kain, Mayes, & Caramico, 1996; Kain, Mayes, Caramico et al., 1996; Kain, Mayes, Weisman, & Hofstadter, 2000; Proczkowska-Bjorklund et al., 2010; Vernon & Thompson, 1993). The non-significant associations between child age and observer-rated anxiety and compliance in the current investigation may be explained by the restricted age range employed (i.e., 4 to 7 years) as compared to other studies, indicating that children of similar ages who have a comparable understanding of their surgical experience were recruited. An objective of the current investigation was to use a narrower age range in order to limit the influence of age on the results; as such, differences in child anxiety across groups could more reliably be considered due to the intervention, rather than significant age differences as in previous studies (e.g., 2-12 years; Caldwell-Andrews et al., 2005; Cameron et al., 1996; Cray et al., 1996; Davidson et al., 2006; Kain, et al., 2006; Kain, Caldwell-Andrews et al., 2007; Kain, Caramico et al., 1998; Kain, Mayes, & Caramico, 1996; Kim et al., 2010; MacLaren Chorney & Kain, 2009; McGraw & Kendrick, 1998; Messeri et al., 2004; Patel et al., 2006; Shawky, 2005).

The number of previous child surgeries and observer-rated anxiety and compliance at induction of anesthesia were also not significantly correlated. Children who had experienced a previous surgery were not any less anxious or more compliant than children who had never previously experienced surgery. The non-significant correlations between number of child previous surgeries and anxiety or compliance at induction of anesthesia are consistent with prior research that also found previous surgeries did not reduce child anxiety at subsequent surgical procedures (Finely et al., 2006; Kain et al., 2006; Kain, Wang et al., 1999; MacLaren & Kain, 2008; MacLaren
Chorney & Kain, 2009; MacLaren Chorney et al., 2013; Wright et al., 2010; Wright, Stewart et al., 2013).

No significant relationships were observed between child temperament and observer-rated child anxiety at induction of anesthesia. The absent relationships are consistent with results from Kain et al. (2005) and Wright, Stewart et al. (2013) who found no relationship between temperament and anxiety. The internal consistency of three of the EASI scales was poor; therefore, the EASI psychometric properties may have precluded any significant effects. Had an alternative measure been used with higher internal consistency (as in Wright, Stewart et al., 2013), a different result may have emerged. There were also no significant relationships observed between parent/guardian self-reported state and trait anxiety and child observer-rated anxiety and compliance at anesthesia induction. The resultant lack of a relationship between parent and child anxiety was inconsistent with some previous literature (e.g., Beidel & Turner, 1997; Burstein & Ginsburg, 2010; Racine et al., 2016; Rosenbaum et al., 1988; Turner et al., 2005), but consistent with other studies (Kain, MacLaren et al., 2007; Kain, Mayes, & Caramico, 1996).

6.2 Primary Results

6.2.1 Hypothesis 1. The results did not support Hypothesis 1. There was a statistically significant effect for time with a large effect size. Overall, significant changes in anxiety throughout the day of surgery were observed as expected, with the exception of between the admission and holding area time points where child anxiety decreased; the different structure of the surgical setting compared to most hospitals (i.e., that the admission and holding area time points are the same) may have partially accounted for
the unexpected decrease in child anxiety between these time points. Further, if children were admitted with high anxiety due to fear of the unknown, by the holding area time point, their fear of the unknown may have decreased as they would be more aware of the process, potentially decreasing their anxiety. This speculation cannot be assessed with the current data. Child anxiety peaked at anesthesia induction and decreased after surgery. The observed anxiety trajectory, increasing throughout the day surgery experience (but with a decrease from admission to holding area), peaking at anesthesia induction is consistent with the trajectory described in the literature (Finley et al., 2006; Fortier et al., 2010; Fortier et al., 2011; Kain, Caldwell-Andrews et al., 2007; Kain et al., 1997; Lumley et al., 1993; MacLaren Chorney & Kain, 2009; Schwartz et al., 1983).

The analyses demonstrated a statistically significant effect for group with a medium effect size. Overall, Group 2 (i.e., children who received anesthesia mask exposure/shaping practice on the day of surgery) had significantly lower observer-rated child anxiety scores than Group 3 (i.e., children who did not receive pre-surgical anesthesia mask exposure), but Group 1 (i.e., children who received anesthesia mask exposure/shaping practice in the week before surgery) did not have significantly lower anxiety than Group 3. As such, instead of supporting the hypothesis that children in Group 1 would have the lowest anxiety, followed by children in Group 2, children in Group 2 were the least anxious overall. Further, Group 2 was the only intervention group to differ significantly from the control group (Group 3). While the overall mean for Group 1 was lower than that of Group 3, this difference was not statistically significant. Perhaps with a larger sample size this difference would have reached statistical significance. Closer examination of the results demonstrated that the significant group
difference occurred at the point of anesthesia induction. While effect of group at this particular time point was not statistically significant overall, Group 2 differed significantly from Group 3 (small effect size); the mean for Group 1 was lower than Group 3, but not significantly. The second analysis supports that at the most critical, anxiety-provoking time point (i.e., anesthesia induction) anesthesia mask exposure and shaping employed on the day of surgery reduced child anxiety compared to no intervention. Finally, Groups 2 and 3 (i.e., the two groups that significantly differed) were compared between admission (baseline) and induction of anesthesia time points. A significant interaction between time and group was observed, supporting that randomization led to children in Groups 2 and 3 having equivalent levels of anxiety at baseline, while their anxiety significantly differed at induction of anesthesia in the expected direction (i.e., children in Group 2 displayed significantly lower anxiety), likely due to the mask exposure/shaping intervention.

The current results were inconsistent with previous reports in the literature. Previous results from the preoperative literature indicated that children were most anxious when a preoperative preparation program was given too close to surgery and that preoperative preparation was most beneficial in reducing anxiety when implemented 5 to 7 days before surgery (Kain, Mayes, & Caramico, 1996). The finding that preparation may be most effective if offered in the week before surgery, coupled with the speculation that anesthesia mask exposure and shaping may be more effective if it occurs prior to the day of surgery (MacLaren & Kain, 2008), led to the hypothesis that anesthesia mask exposure in the week before surgery would be most efficacious in reducing observer-rated preoperative child anxiety.
Exposure therapy researchers have evidenced distributed practice as particularly important for young children because more time may be required for them to learn and adjust (Simpson et al., 2010). Accordingly, distributed practice during the week prior to surgery was assumed best. Children in the current investigation were exposed to the anesthesia mask for a sufficient amount of time on the day of surgery to allow for distributed practice, decreasing anxiety at anesthesia induction. Anecdotally, children in Group 2 often practiced using the anesthesia mask with their parent(s)/guardian(s), then played, watched TV, or engaged in other activities for a substantial amount of time before being called into surgery (wait time was 1-2 hours).

The current results indicate that preoperative preparation involving providing children and their parents/guardians with an anesthesia mask and a practice protocol before surgery is helpful for reducing child anxiety at anesthesia induction. At least for the surgical setting assessed, preoperative preparation via exposure to the anesthesia mask was most helpful when given on the day of surgery. The described intervention could easily be integrated into surgical centres as part of child and family admission. The intervention appears to require minimal resources and staff time. The surgical setting for the current investigation may differ from typical hospitals (e.g., physical set-up of setting, protocol), as such, these findings will need to be replicated within a hospital setting. Nevertheless, there will be centres where the intervention may not be possible or easily integrated on the day of surgery. In such cases, mailing the anesthesia mask and practice protocol ahead of time with other preparatory or information materials may be helpful for the child.
6.2.2. Hypothesis 2. The current results did not support Hypothesis 2. Instead, the results demonstrated that group differences in child observer-rated compliance at anesthesia induction approached statistical significance overall with a small to medium effect size. When examining the individual group differences, children in Group 2 (who received anesthesia mask exposure on the day of surgery) were significantly more compliant at anesthesia induction than children in Group 3 (who did not receive presurgical anesthesia mask exposure), with children in Group 1 (who received anesthesia mask exposure the week prior to surgery) not differing significantly in compliance from children in Group 3. The small to medium effect of the intervention on improving child compliance at anesthesia induction for children in Group 2 is highly relevant considering the low cost and ease of implementation of the intervention, and the high costs (emotionally and financially) of child noncompliance at anesthesia induction.

6.2.3. Hypothesis 3. The results partially supported Hypothesis 3. The results demonstrated that observer-rated child anxiety (indexed by mean mYPAS ratings) in the current investigation was consistent with observer-rated child anxiety in the benchmark study at anesthesia induction (i.e., MacLaren & Kain, 2008). Significant differences in observer-rated child anxiety were observed between the current investigation and the benchmark study at both holding area and transfer to the OR time points. Children in the current investigation were less anxious in the holding area, perhaps because of consistency of location between admission and holding areas as described previously, differing from the structure in most hospitals. The surgical centre involved with the current investigation is a smaller centre providing care to significantly fewer patients on a given day than many hospital OR settings (maximum 5 patients at one time), which may
have reduced participant anxiety. Further, children in the current investigation did not separate from their parents/guardians at transfer to the OR as they did in MacLaren and Kain’s study, which likely also reduced anxiety. Importantly, child anxiety was not significantly different at the most anxiety-provoking and clinically meaningful time point (i.e., induction of anesthesia) across the two studies, despite the differences between the two settings. The nonsignificant difference in child anxiety at induction of anesthesia across studies lends support to the integrity of the intervention protocol as well as the generalizable effectiveness of the anesthesia mask intervention in reducing child anxiety.

6.2.4. Hypothesis 4. The current results did not support Hypothesis 4. Overall, parent/guardian state anxiety decreased from pre- to post-surgery, but anxiety did not differ significantly based on group assignment. The current results are difficult to compare to other research where the postoperative assessment time point is not included (e.g., Fortier et al., 2011; Fortier et al., 2015; Kain, Caldwell-Andrews et al., 2007). The postoperative assessment time point may have been excluded because postoperative pain may confound the assessment of child anxiety, and possibly impact the measurement of parent/guardian anxiety. Parent/guardian anxiety may not change significantly from pre- to post-surgery if the child is in distress post-surgery. Instead, parent/guardian anxiety may be maintained although the source of the distress for the child may not be anxiety but in fact pain. Postoperative pain was not assessed in the current study; therefore, it is not possible to determine how much pain impacted child anxiety post-surgery. The potential variability in child anxiety postoperatively may offer a potential explanation for lack of change in parent anxiety over time. Despite research showing that interventions for children can also alleviate parent anxiety (e.g., Elkins & Roberts, 1983; Kain, Mayes,
Wang et al., 2000; Yun et al., 2015; Zuwala & Barber, 2001), such changes were not evident in the current investigation. The anesthesia mask exposure intervention may not alleviate parent/guardian anxiety because the onus is on the parent/guardian to complete the intervention with their child; however, such speculation cannot be addressed with the current data. Future research may seek to garner information about how the parents/guardians feel about delivering the intervention.

6.3 Strengths and Limitations

Previous studies have examined the utility of the anesthesia mask exposure and shaping protocol for reduction in child preoperative anxiety (e.g., Kain, Caldwell-Andrews et al., 2007; Maclaren & Kain, 2008); however, the current investigation was the first RCT to specifically compare three different preparation conditions, with a focus on timing of preparation, to ascertain optimal efficacy of the intervention. Another strength of the current investigation was its consistency in methodology. All child participants had a parent/guardian accompany them into the OR, and no child received midazolam preoperatively. Midazolam, in particular, has been demonstrated as a significant confounding factor when examining the efficacy or effectiveness of interventions (e.g., Aydin et al., 2008), and inconsistency in parent presence can influence the results as well (e.g., Lan et al., 2012). The current investigation employed more rigorous research methodology than some previous studies that did not employ a control group (e.g., Mahajan et al., 2007; Malhotra et al., 2001; Shawky, 2005) or did not use validated measures (Shawky 2005). Further, the intervention used in the current investigation did not require extra effort by the health care team as in other studies (e.g.,
home visits; Malhotra et al., 2001; Visintainer & Wolfer, 1975; Wolfer & Visintainer, 1979).

The current investigation also has limitations that provide direction for future research. The first limitation was the inability to blind the first rater to the conditions of the study since the first rater was also the principal investigator and a third person was not available to conduct the randomization. Further, by attending the surgeries, the first rater was aware of who was in which group based on the need to provide them with an anesthesia mask. To counter this, secondary raters who were blind to the study hypotheses were utilized, though this was not a perfect solution. Secondary raters were not entirely blind to each participant’s study condition as they saw the child receive an anesthesia mask in some cases and not in others. Further, while secondary raters were trained in the use of the observational measures, they did not practice on samples of children since access to videos or other means of practice were not available.

Nevertheless, the excellent inter-rater reliability for the mYPAS and ICC supported the validity of the anxiety and compliance ratings (i.e., ICC = .989 and .979, respectively).

Second, many researchers monitor children’s anxiety once they return home from surgery (e.g., Calipel, et al., 2005; Kain, Mayes, O’Connor et al., 1996; Kain, Wang et al., 1999; Lumley et al., 1993; McGraw, 1993; McGraw & Kendrick, 1998; Vernon et al., 1966). The purpose of the present investigation was to focus on the acute effect of anxiety reduction at anesthesia induction, and this purpose was achieved; however, not collecting follow-up data prevented extending the longer-term outcomes of the current intervention (i.e., beyond the day of surgery).
Third, statistically, the assumptions of normality of the data and homogeneity of variance were violated; however, the F-statistic of ANOVA is robust to violations of normality, and bootstrapping was used to ensure robust p-value estimates where appropriate. Further, the EASI demonstrated poor internal consistency across most subscales in the current investigation which may limit the accuracy of the results surrounding this measure (e.g., examining the relationship of temperament to the main variables of interest); as well, the measure’s poor reliability in the present sample may have diminished the likelihood of discovering statistically significant effects. However, the EASI is one of few appropriate measures of temperament for this age group (i.e., children, not infants), is short enough to be feasibly completed in the busy surgical setting, and is the measure most commonly used in this literature (Finley et al., 2006; Fortier et al., 2010; Kain et al., 2005; Kain, Caramico et al., 1998; Kain, Mayes, Weisman et al., 2000; Wright, Stewart et al., 2013), allowing for the simplest comparison across studies.

As a fourth limitation, it is always important to consider the feasibility of an intervention. The current intervention was chosen due to its simple, parent/guardian-directed approach so as to not burden the health care team, and its time and cost effectiveness. However, it is recognized that in some centres it may be easier to prepare children for their surgeries beforehand (i.e., it may be more efficient for a centre to mail an anesthesia mask and practice protocol to families with other preparation material) rather than to give families the anesthesia mask on the day of surgery. If the anesthesia mask exposure intervention would be more feasible to provide before the day of surgery,
the findings of this investigation indicate that the intervention will not negatively affect child anxiety.

6.4 Future Directions

There are several potential future research directions that deserve mention. First, if a research team plans to replicate (and possibly extend) this study, a double-blind RCT research design should be used. While secondary raters blind to the study hypotheses were utilized, there is a chance that both the first and second raters experienced some bias from not being completely blind to study conditions that could have impacted their ratings. A double-blind design would control for this potential. Second, future researchers should follow children and their parents/guardians once they return home to examine the long-term (i.e., one day to several months) impact of this intervention on child anxiety. A long-term follow-up would allow researchers to comment on the potential continuing effects and possibly provide more evidence in support of the importance of this intervention. Third, the surgical setting employed in the current study may be different from typical hospitals (e.g., physical set-up of setting, protocol); as such, future research should replicate these findings within a hospital setting. Finally, future researchers may seek to garner information about how parents/guardians feel about delivering the intervention in order to speak more directly to the speculation that this anesthesia mask exposure intervention did not alleviate parent/guardian anxiety because the onus is on parents/guardians to complete the intervention with their child.

7.0 Implications

The fields of psychology, anesthesiology, and nursing have collaborated over the years to develop strategies to alleviate the anxiety of children undergoing surgery.
Building on recent developments in child preoperative preparation research, this investigation introduced children to the anesthesia mask before their surgery in an attempt to increase familiarity and comfort with the often anxiety-provoking apparatus and have an anxiolytic effect throughout the day surgery experience, particularly at mask induction of anesthesia. An anesthetic mask intervention was chosen as anesthetic induction is the most anxiety-provoking time point in the day surgery experience (as evidenced by the most elevated observer-rated anxiety scores) and because children report that the anesthetic mask is a significant source of fear (Przybylo et al., 2005).

The intervention requires no extra effort by members of the health care team, and requires minimal, independent parent/guardian training (i.e., parents/guardians read the exposure protocol pamphlet without researcher direction). Anesthesia mask exposure and shaping practice represents a relatively inexpensive, effective preoperative preparation option for children undergoing day surgery procedures. Providing families with an anesthesia mask on the day of surgery that the child will use for their actual induction (if this meets appropriate health/sanitation requirements) does not cost the medical facility extra money, and the intervention’s resultant decrease in child anxiety creates cost-savings, both in the short-term through expediting the surgery and discharge process, and potentially in the long-term as well (e.g., facilitating routine primary health care services, reducing future admissions related to mental health difficulties resulting from negative medical experiences). Being less anxious on the day of surgery should improve the child’s surgery experience and post-surgery outcomes and negate the traumatizing effects of restraint at anesthesia induction, as well as reduce distress of parents/guardians and the health care team, and maintain timely completion of the day surgery process. Also, being
conscious of their anesthesia induction and experiencing it in a neutral or positive manner may facilitate children’s future positive inductions (Wright et al., 2007). Therefore, the integration of this intervention in surgical settings across the country would be a simple means of improving the day surgery experience for patients, families, and health care providers.

The current investigation, using a rigorous methodology, supplements the existing armamentarium of child preoperative anxiety research; specifically, the gap in knowledge around when exposure and shaping preparation with the anesthesia mask is most helpful. Educating the health care team, including surgeons, anesthesiologists, and nurses about the benefits observed in this trial and the cost-effectiveness of the mask intervention will hopefully lead to wide-spread implementation of this relatively simple preparation option. Employing a preoperative preparation intervention that targets the most widely used method of anesthesia induction (i.e., inhalation), one of the key sources of anxiety during the perioperative period (i.e., the anesthesia mask), and that can be completed by parents/guardians ultimately reduces child anxiety, creates a more positive surgical experience, provides a helpful model for future medical procedures, saves time and money, and reduces the burden on the health care team to prepare children.
8.0 References


Julian, L. J. (2011). Measures of anxiety: State-Trait Anxiety Inventory (STAI), Beck Anxiety Inventory (BAI), and Hospital Anxiety and Depression Scale-Anxiety (HADS-A). *Arthritis Care & Research, 63*(S11), S467-S472. doi: 10.1002/acr.20561


improves perioperative outcomes in children: A randomized controlled trial.

*Anesthesiology, 106*(1), 65-74. doi: 10.1097/00000542-200701000-00013


10.1213/00000539-199812000-00007


10.1542/peds.2005-2920


surgery. *Journal of Clinical Anesthesia, 12*(7), 549-554. doi:10.1016/S0952-8180(00)00214-2


Appendix A
Demographics Form

1. Parent sex
   Male    Female

2. Parent age
   _____ years

3. Parent ethnicity
   _____White/Caucasian   _____Black/African   _____Hispanic
   _____Asian            _____Aboriginal/First Nations   _____Middle Eastern
   _____Mixed Ethnicity  _____Other (please specify)

4. Parent marital status
   _____Married           _____Single            _____Common law
   _____Divorced          _____Separated          _____Other

5. Parent highest level of education
   _____Less than high school   _____Completed High school
   _____College certificate/some university   _____Trade School
   _____University degree(s)   _____Other (please specify)

6. Child age
   _____ years

7. Child sex
   Male    Female
8. Child ethnicity

_____White/Caucasian      _____Black/African      _____Hispanic
_____Asian                  _____Aboriginal/First Nations    _____Middle Eastern
_____Mixed Ethnicity      _____Other (please specify)

9. Has your child previously been diagnosed with a medical or mental health condition?

YES   NO

10. If yes, please list:

________________________________________________________________

11. Is your child currently taking any prescribed medication(s)?

YES   NO

12. If yes, please list:

________________________________________________________________

13. Has your child had any previous surgical procedures with general anesthesia?

YES   NO

14. If yes, how many previous surgeries?

_____

15. If yes, please list the previous surgical procedures.

________________________________________________________________________
Appendix B

Modified Yale Preoperative Anxiety Scale (mYPAS)

<table>
<thead>
<tr>
<th></th>
<th>Admission</th>
<th>Holding area</th>
<th>Transfer to OR</th>
<th>Induction</th>
<th>Post-surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Activity</td>
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<tr>
<td>B. Vocalizations</td>
<td></td>
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<td></td>
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<tr>
<td>C. Emotional</td>
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<tr>
<td>Expressivity</td>
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<td></td>
<td></td>
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<tr>
<td>D. State of Arousal</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>E. Use of Parents</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**A. Activity**
1 = Looking around, curious, playing with toys, reading (or other age-appropriate behaviour); moves around holding area/treatment room to get toys or go to parent; may move toward operating room equipment
2 = Not exploring or playing, may look down, may fidget with hands or suck thumb (blanket); may sit close to parent while waiting, or play has a definite manic quality
3 = Moving from toy to parent in unfocused manner, nonactivity-derived movements; frenetic/frenzied movement or play; squirming, moving on table, may push mask away or clinging to parent
4 = Actively trying to get away, pushes with feet and arms, may move whole body; in waiting room, running around unfocused, not looking at toys or will not separate from parent, desperate clinging

**B. Vocalizations**
1 = Reading (nonvocalizing appropriate to activity), asking questions, making comments, babbling, laughing, readily answers questions but may be generally quiet; child too young to talk in social situations or too engrossed in play to respond
2 = Responding to adults but whispers, “baby talk,” only head nodding
3 = Quiet, no sounds or responses to adults
4 = Whimpering, moaning, groaning, silently crying
5 = Crying or may be screaming “no”
6 = Crying, screaming loudly, sustained (audible through mask)

**C. Emotional expressivity**
1 = Manifestly happy, smiling, or concentrating on play
2 = Neutral, no visible expression on face
3 = Worried (sad) to frightened, sad, worried, or tearful eyes
4 = Distressed, crying, extreme upset, may have wide eyes

**D. State of apparent arousal**
1 = Alert, looks around occasionally, notices/watches what anesthesiologist does with him/her (could be relaxed)
2 = Withdrawn, child sitting still and quiet, may be sucking on thumb or face turned into adult
3 = Vigilant, looking quickly all around, may startle to sounds, eyes wide, body tense
4 = Panicked whimpering, may be crying or pushing others away, turns away

E. Use of parents
1 = Busy playing, sitting idle, or engaged in age appropriate behaviour and doesn’t need parent; may interact with parent if parent initiates the interaction
2 = Reaches out to parent (approaches parent and speaks to otherwise silent parent), seeks and accepts comfort, may lean against parent
3 = Looks to parent quietly, apparently watches actions, doesn’t seek contact or comfort, accepts it if offered or clings to parent
4 = Keeps parent at distance or may actively withdraw from parent, may push parent away or desperately clinging to parent and not let parent go
## Appendix C

### Induction Compliance Checklist (ICC)

<table>
<thead>
<tr>
<th>Checklist</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perfect induction (does not exhibit negative behaviours, fear, or anxiety)</td>
<td></td>
</tr>
<tr>
<td>Crying, tears in eyes</td>
<td></td>
</tr>
<tr>
<td>Turns head away from mask</td>
<td></td>
</tr>
<tr>
<td>Verbal refusal, says “no”</td>
<td></td>
</tr>
<tr>
<td>Verbalization indicating fear or worry, “where’s mommy” or “will it</td>
<td></td>
</tr>
<tr>
<td>hurt?”</td>
<td></td>
</tr>
<tr>
<td>Pushes mask away with hands, pushes nurse/anesthetist with hands/feet</td>
<td></td>
</tr>
<tr>
<td>Covers mouth/nose with hands/arms or buries face</td>
<td></td>
</tr>
<tr>
<td>Hysterical crying, may scream</td>
<td></td>
</tr>
<tr>
<td>Kicks/flails legs/arm, arches back, and or general struggling</td>
<td></td>
</tr>
<tr>
<td>Requires physical restraint</td>
<td></td>
</tr>
<tr>
<td>Complete passivity, either rigid or limp</td>
<td></td>
</tr>
</tbody>
</table>

### Total Score

*Total score = the number of categories checked (perfect score = 0)

**Check all behaviours observed
Appendix D

Emotionality, Activity, Sociability, Impulsivity Temperament Survey (EASI)

Please rate each of the following items about your child. Scale: 1-5 with 1 being a little and 5 being a lot.

1. Child gets upset quickly
2. Child cries easily
3. Child is easily frightened
4. Child is easy going or happy-go-lucky
5. Child has a quick temper
6. Child is always on the go
7. Child is off and running as soon as he wakes up in the morning
8. Child cannot sit still long
9. Child prefers quiet games such as colouring or blocks to more active games
10. Child fidgets at meals or similar occasions
11. Child likes to be with others
12. Child makes friends easily
13. Child tends to be shy
14. Child is independent
15. Child prefers to play by himself rather than with others
16. Child tends to be impulsive
17. Learning self-control is difficult for the child
18. Child gets bored easily
19. Child learns to resist temptation easily
20. Child goes from toy to toy quickly
Appendix E

State Trait Anxiety Inventory State Version (STAI-S)

**Directions:** A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel right now, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement, but give them answer which seems to describe your present feelings best.

**Scale:** Not at all (1); Somewhat (2); Moderately so (3); Very much so (4).

1. I feel calm.
2. I feel secure.
3. I am tense.
4. I feel strained.
5. I feel at ease.
6. I feel upset.
7. I am presently worrying over possible misfortunes.
8. I feel satisfied.
9. I feel frightened.
10. I feel comfortable.
11. I feel self-confident.
12. I feel nervous.
13. I am jittery.
15. I am relaxed.
16. I feel content.
17. I am worried.
18. I feel confused.
19. I feel steady.
20. I feel pleasant.
State Trait Anxiety Inventory Trait Version (STAI-T)

**Directions:** A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you generally feel, that is, *most of the time*. There are no right or wrong answers. Do not spend too much time on any one statement, but give them an answer which seems to describe your present feelings best.

**Scale:** *Almost Never* (1); *Sometimes* (2); *Often* (3); *Almost Always* (4).

1. I am happy.
2. I am content.
3. I am satisfied with myself.
4. I feel pleasant.
5. I feel secure.
6. I lack self-confidence.
7. I feel inadequate.
8. I feel like a failure.
9. I am a steady person.
10. I wish I could be as happy as others seem to be.
11. I make decisions easily.
12. I am ‘calm, cool, and collected’.
13. I feel rested.
14. Some unimportant thought runs through my mind and bothers me.
15. I worry too much over something that doesn’t really matter.
16. I get in a state of tension or turmoil as I think over my recent concerns and interests.
17. I have disturbing thoughts.
18. I take disappointments so keenly that I can’t put them out of my mind.
19. I feel that difficulties are piling up so that I can’t overcome them.
20. I feel nervous and restless.
Appendix F

Induction Mask Practice Information Sheet

This practice is based on psychological principles of shaping and exposure, which have been shown to be effective ways to lower anxiety and prepare for medical procedures.

One way to help your child is to familiarize him or her with the anesthesia induction mask. The more comfortable your child is with putting the mask on and breathing through it, the less anxious he or she will be about the induction mask on the day of surgery. Repeated practice is the key. Here is a six-step plan for practice.

First, read through each step, so you understand the entire procedure. Also, take a look at the “How to Practice” section before beginning. As you work through each step, be sure to offer plenty of praise and encouragement to your child. Repeat these steps (three times or more) (at least once), until your child can do it comfortably. Try to make the practice fun for your child!

What to Do

Step One: Let your child handle and play with the induction mask. Explain the item (e.g., when you go in for your surgery, the dentist will use a mask just like this).

Step Two: When your child appears comfortable with the mask, ask him or her to try holding the mask over his or her mouth only (not the nose). Once your child can do this, ask him or her to try breathing through the mask. If your child is hesitant, you could first put the mask over your own mouth, just to show how it’s done.

Step Three: This time, you will be the one to hold the induction mask and place it gently over your child’s mouth (not over the nose yet) while he or she breathes through the mask. You might say “Let me take a turn doing it.”

Step Four: Ask your child to try holding the mask (by himself or herself again) over his or her mouth and nose this time. Once the mask is in place, ask your child to practice breathing through the mask (demonstrating on yourself if needed).

Step Five: As in step three, this time you will hold the mask over your child’s mouth and nose, and ask him or her to breathe through the mask. Offer plenty of praise and encouragement, particularly as your child completes each step.

Step Six: Repeat step five, this time asking your child to imagine that they are at the dentist’s and that you are the dentist who will be helping them with the mask. Ask your child to practice after climbing onto a bed, pretending it is the bed in the dentist’s office.

How to Practice
Move at your child’s pace, going as quickly or as slowly as he or she is comfortable. If your child has difficulty or becomes anxious, go slower or return to the last step he or she could do comfortably. Try taking some breaks between the steps. When you return, begin by repeating the last successful step before moving on.

If your child spontaneously puts the mask over his or her mouth and nose and breathes through it during step one, feel free to skip to step four as long as your child remains comfortable. You can move more quickly as long as your child is comfortable with each step.

Feel free to use plenty of humor and make this into a fun game with your child.

If your child says the mask smells funny, you might say, “That’s right, it sure smells like plastic, doesn’t it,” and then continue to praise your child for breathing through the mask.

**Things to Say**

- “You are learning how to do this very well”.
- “This is the hardest part. Everything after this will be easy because you will be asleep”.
- “You’re a pro. That is all you will have to do when you go to the OR.”
- “Look how deeply you can breathe through the mask! Great job!”
- “All this practice will make it so much easier for you when we go to the dentist’s”.
- “You’ll do the same thing at the dentist’s. The dentist will help you with the mask while you breathe just like you’re doing now.”

**Safety Consideration**

Please supervise your child while using the mask and do not allow your child to bite the mask.
Appendix G

Practice Tracker Sheet

I Practiced Using the Mask for my Surgery Today!!

<table>
<thead>
<tr>
<th>Day</th>
<th>What Step I Practiced Up to Today</th>
<th>How Many Times I Practiced</th>
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Appendix H
Research Ethics Board Approval and Renewal Forms

UNIVERSITY OF
SASKATCHEWAN

April 1, 2016

Dr. Kristi Wright
Department of Psychology
University of Regina
3737 Wascana Parkway
Regina, SK S4S OA2

RE: Understanding and Preventing Preoperative Anxiety in Children

Student: Kirstie Walker

U of R File# 2016-002; U of S File#: BEH 16-84

Your application for research ethics review has undergone a harmonized review by the University of Saskatchewan and University of Regina. In accordance with the Research Ethics Review Reciprocity Agreement signed by the University of Saskatchewan, University of Regina, and Regina Qu'Appelle Health Region, the University of Saskatchewan REB accepts the Certificate of Approval issued by the University of Regina REB. This letter permits you to conduct research activities as approved by the University of Regina, provided that you maintain a valid and up-to-date Certificate of Approval.

All continuing ethics reviews will be conducted by the University of Regina REB. The University of Regina is authorized to share all communications pertaining to this file with the University of Saskatchewan REB at their discretion. The University of Regina
Saskatchewan REB may provide input into continuing ethical review activities, as agreed upon by both REBs.

The University of Saskatchewan REB reserves the right to revoke the privileges described in this letter at any time in order to conduct their own independent research ethics review of your project. Such a decision would be communicated to you and the University of Regina REB in writing.

Best wishes for your continuing research endeavours.

Sincerely,

Vivian Ramsden, Chair
University of Saskatchewan
Behavioural Research Ethics Board

cc: University of Regina Research Ethics Board
Saskatoon Health Region

DATE: April 6, 2016
TO: Dr. Kristi Wright
Department of Psychology University of Regina
FROM: Dr. Rob Weiler
Acting Vice-President Practitioner Staff Affairs
Saskatoon Health Region
RE: RESEARCH ETHICS BOARD (REB) BEH-16-84
PROJECT NAME: Understanding and Preventing Preoperative Anxiety in Children
PROTOCOL N/A

Saskatoon Health Region is pleased to provide you with operational approval of the abovementioned research project.

Kindly inform us when the data collection phase of the research project is completed. We would also appreciate receiving a copy of any publications related to this research. As well, any publications or presentations that result from this research should include a statement acknowledging the assistance of Saskatoon Health Region.

We wish you every success with your project. If you have any questions, please feel welcome to contact Shawna Weeks at 655-1442 or email shawna.weeks@saskatoonhealthregion.ca

Yours truly,

Dr. Ro
Acting Vice-President Practitioner Staff Affairs
Saskatoon Health Region

cc: Dr. Mateen Raazi, Department of Anesthesiology, SHR
Dr. Shane Sheppard, Medical Director, Prairieview Surgical Centre Dr. Mohamed Nanji, CEO & President, Surgical Centres Inc.
University of Regina
Research Ethics Board
Certificate of Approval

REB # 2016-002

Investigator(s)  Kirstie Walker  Mateen Raazi
Department  Psychology
Funder:  Unfunded
Supervisor:  Dr. Kristi Wright

Title:  Understanding and Preventing Preoperative Anxiety in Children

APPROVED ON:  03-Feb-16  RENEWAL DATE:  03-Feb-17

APPROVAL OF:

Application For Behavioural Research Ethics Review

Letters of Initial Contact (Appendix A)

Parent Consent Form (Appendix B)

Child Assent Form (Appendix C)

Demographics Form (Appendix D)

State Trait Anxiety Inventory (STAI) (Appendix E)

Emotionality, Activity, Sociability, Impulsivity Temperament Survey (EASI) (Appendix F)

Modified Yale preoperative Anxiety Scale (mYPAS) (Appendix G)

Induction Compliance Checklist (ICC) (Appendix H)

Induction Mask Practice Information Sheet (Appendix I)

Practice Tracking Sheet (Appendix J)

RCT Flow Diagram (Appendix K)

FULL BOARD MEETING  DELEGATED REVIEW __X__
The University of Regina Research Ethics Board has reviewed the above-named research project. The proposal was found to be acceptable on ethical grounds. The principal investigator has the responsibility for any other administrative or regulatory approvals that may pertain to this research project, and for ensuring that the authorized research is carried out according to the conditions outlined in the original protocol submitted for ethics review. This Certificate of Approval is valid for the above time period provided there is no change in experimental protocol, consent process or documents.

Any significant changes to your proposed method, or your consent and recruitment procedures should be reported to the Chair for Research Ethics Board consideration in advance of its implementation.

ONGOING REVIEW REQUIREMENTS
In order to receive annual renewal, a status report must be submitted to the REB Chair for Board consideration within one month of the current expiry date each year the study remains open, and upon study completion. Please refer to the following website for further instructions: http://www.uregina.ca/research/for-faculty-staff/ethics-compliance/human/forms1/ethics-forms.html.

Dr. Larena Hoeber, Chair
University of Regina Research Ethics Board

Please send all correspondence to: Research Office
University of Regina
Research and Innovation Centre 109
Regina, SK S4S 0A2
Telephone (306) 585-4775
Fax: (306) 585-4893
research.ethics@uregina.ca