Children's response to pediatric continuous glucose monitoring (CGM) sensor insertion: the role of intervention and individual differences

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Children's Response to Pediatric Continuous Glucose Monitoring (CGM) Sensor Insertion: The Role of Intervention and Individual Differences

by

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A Dissertation

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Abstract

Research indicates that nonpharmacological interventions are effective at reducing pain and distress during pediatric procedures. Certified child life specialists often perform these interventions. However, child life delivered procedural interventions have not been well studied in outpatient settings. Additionally, while characteristics that influence pediatric distress levels are known, their impact on procedural response in the presence of nonpharmacological interventions is not fully understood. In particular, the contribution of temperamental negative affect (NA) and effortful control (EC) are relatively unstudied in this context. The present study examined procedural response in a sample of 28 diabetic children and adolescents aged 2-18 years undergoing outpatient continuous glucose monitor (CGM) insertion. A child life specialist was present throughout the appointment to provide intervention. Results indicated that anxiety and fear increased across the procedure, while distress levels were highest immediately prior to insertion. Intervention usage by child life appeared to vary based on procedural phase, child age, temperament, and trait anxiety. However, distraction emerged as the most utilized intervention across phases. The relationship between NA, EC, and procedural response was tested directly in this sample. No relationship between NA and response were found. However, EC emerged as a strong predictor of reduced procedural anxiety, fear, and distress. These findings suggest that high levels of EC may help children to better focus on and implement child life interventions, thus improving their efficacy.
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Introduction

Invasive medical procedures can cause significant distress for children and their parents. These negative procedural experiences can lead to the development of future medical-related anxieties and subsequent maladaptive coping. Children with chronic medical conditions, such as type 1 diabetes, experience more frequent medical procedures than same aged peers (Dahlquist et al., 2002). One such invasive procedure experienced by some diabetic children is the insertion of a continuous glucose monitoring (CGM) sensor.

Cognitive and behavioral interventions can help children alter both their perception of pain and their behavioral distress reactions (Uman, Chambers, McGrath, & Kisely, 2008). An increasing number of hospitals employ child life specialists to deliver these non-pharmacological interventions for the management of pain and distress, however, research into the efficacy of child-life administered intervention is limited (Bandstra et al., 2008). Moreover, research suggests that children respond differently to interventions based on individual difference characteristics such as child age, sex, and temperament (Young, 2005).

The objective of the current study is to investigate response to CGM sensor insertion with child life present in children with diabetes type 1. The goal is to better understand the nature of interventions delivered by child life specialists in an outpatient clinic setting as well as elucidate the relationship between temperamental factors and procedural response (as measured by anxiety, fear, and distress levels during procedure). Specifically, this study will examine the effect of temperamental negative affect and effortful control on children's response to overall procedure and child life intervention.
Diabetes

Insulin is a hormone that plays an important role in metabolism by controlling the levels of glucose present in the bloodstream (Sonksen & Sonksen, 2000). Metabolic diseases characterized by high blood glucose levels are collectively known as diabetes mellitus. Specific diabetic diseases include type 1, type 2, and gestational among others. Of these, type 1 diabetes is the most commonly diagnosed in childhood, accounting for roughly 90% of all pediatric cases in western countries (Craig, Hattersley, & Donaghue, 2009).

Type 1 diabetes is characterized by a lack of insulin secretion by the pancreas. This occurs when the immune system attacks pancreatic insulin-producing β cells. Both genetic and environmental factors play a role in the development of type 1 diabetes. For instance, research has revealed several genes associated with the disease. Additionally, viruses and toxins are linked to diabetes onset (Craig, Hattersley, & Donaghue, 2009). Symptoms of type 1 diabetes in children usually include frequent urination, excessive thirst, blurred vision, and weight loss. To obtain diagnosis, elevated blood glucose levels (≥ 200 mg/dl) must also be detected (Craig, Hattersley, & Donaghue, 2009). Diagnostic rates appear to increase with age, with the highest incidence occurring in late childhood/early adolescence. Meanwhile, rates of diagnosis appear comparable between male and female children (Soltesz, Patterson, & Dahlquist, 2007).

Type 1 diabetes is associated with numerous short and long term complications. For instance, inadequate management of the disease can result in acute conditions such as hypoglycemia and diabetic ketoacidosis (Silverstein et al., 2005). Hypoglycemia occurs when blood glucose levels become too low. This condition arises from excessive insulin administration, inadequate carbohydrate intake, or over-exercise (Clarke, Jones, Rewers, Dunger, & Klingensmith, 2009). Accordingly, hypoglycemia is a commonly occurring complication,
particularly among young children with type 1 diabetes (Silverman et al., 2005). Symptoms of hypoglycemia include increased heart rate, sweating, blurred vision, irritability, poor concentration, headache, and nausea among others. Severe hypoglycemia can result in loss of consciousness, seizures, coma, and even death (Clarke et al., 2009). The magnitude of consequences from hypoglycemia often causes considerable fear in pediatric patients and their families. Unfortunately, the fear of low blood glucose often results in decreased insulin usage (Clarke et al., 2009).

Diabetic ketoacidosis (DKA) is another acute complication from type 1 diabetes. Unlike hypoglycemia, DKA occurs when the body lacks sufficient amounts of insulin, resulting in hyperglycemia and excessive ketone production. This in turn leads to dehydration, nausea, and loss of consciousness (Wolfsdorf et al., 2009). This condition is typically seen in children who are nonadherent with insulin administration or at initial diagnosis of type 1 diabetes (Silverman et al., 2005).

The frequent occurrence of acute complications associated with diabetes can lead to more chronic conditions. For instance, research suggests that frequent or severe hyper and hypoglycemia experienced during childhood can impact cognitive functioning (Parentie et al., 2008). Additional long-term effects are also associated with poor glycemic control. For instance, type 1 diabetics can go on to develop retinopathy, neuropathy, nephropathy, and/or macrovascular disease (Donaghue, Chiarelli, Trotta, Allgrove, & Dahl-Jorgensen, 2009).

**Diabetes: management.** A diagnosis of diabetes requires lifelong management. For children with the disease, daily regimens consist of monitoring insulin and blood glucose levels along with adequate diet and exercise. For instance, type 1 diabetic children typically receive multiple doses of insulin throughout the day. These can be administered via injection of insulin or by
insulin pump (Daneman, 2006). Typically, insulin injections are received before snacks, meals, and bedtime. Alternatively, the insulin pump delivers a continuous level of insulin to the child throughout the day and requires calibration of higher doses before meals (Silverstein et al., 2005).

Blood glucose monitoring is also a vital part of the daily regimen for type 1 diabetics. This entails the use of a device that measures blood glucose concentrations from small samples of blood belonging to the child. Based on the results, children or their caretakers are able to determine whether insulin administration is warranted and the appropriate level to use (Silverstein et al., 2005). According to the American Diabetes Association 2016 Guidelines, four or more blood glucose tests are recommended per day for type 1 diabetic children. These measurements are most helpful when taken before meals, during exercise, and overnight.

Also of importance is attention to and modification of one’s diet and exercise. Children with type 1 diabetes are encouraged to eat a healthy diet of proteins, carbohydrates, and fats. However, special attention must be paid to the amount of carbohydrates ingested in this population. This is because appropriate doses of insulin must be calibrated based off the amount of carbohydrates present in each meal (Daneman, 2006). Additionally, meal regularity is vital for diabetic children to maintain optimal levels of glycemic control. Furthermore, regular exercise is encouraged amongst pediatric diabetics, though blood glucose monitoring and insulin adjustments are recommended during periods of activity (Silverstein et al., 2005).

**Diabetes: continuous glucose monitoring.** New technologies have arisen in attempt to further improve diabetes management. One such development is the continuous glucose monitoring system (CGM) for the measurement of blood glucose levels. The CGM consists of a
sensor, which measures blood glucose levels, and a monitor, which calibrates and relays “real-time” glucose measures (Kaufman et al., 2001; Diabetes Research Group, 2007). The device is also equipped with alarms that alert to high and low blood glucose levels that can be programmed based on the individual child (Diabetes Research Group, 2007).

Use of a continuous glucose monitoring system can be particularly beneficial in pediatric diabetics over traditional methods of blood glucose testing. This is because children with type 1 diabetes tend to have increased variability in blood glucose levels due to frequent fluctuations in meals and activity levels (Kaufman et al., 2001). Additionally, children are at a greater risk of nocturnal hypoglycemia then adults (Boland et al., 2001). Thus several blood glucose readings during the day may not capture all hyper or hypoglycemic episodes during a 24-hour period. Furthermore, because children are often reluctant to engage in frequent finger sticks in order to test glucose levels this can lead to decreased compliance with traditional testing methods (Chase et al., 2001). Research has shown that use of CGM systems in children significantly increases glycemic control (Deiss et al., 2006).

The CGM contains both subcutaneous and external components. The sensor component is inserted beneath the skin via injection (Boland et al., 2001). It is connected to the monitor, which can be attached to clothing, via thin cable (Kaufman et al., 2001). Each sensor can be used for up to 72 hours, after which it must be removed and a new one inserted (Boland et al., 2001). Research reveals that some pediatric diabetics experience pain and discomfort upon sensor insertion and removal. In fact, a study by Ramchandani, Arya, Ten, and Bhandari (2011) found that pain was the most disliked aspect of CGM use. Additionally, Patton, Dolan, Smith, Thomas, and Powers (2011) reported that some young children in their study displayed anticipatory anxiety with regard to sensor insertion.
**Pediatric Procedural Response**

Children with diabetes experience numerous medical interventions. These include at-home care such as blood glucose testing and insulin injections, hospital stays for severe hypoglycemia or DKA, and/or clinic-based procedures such as initial pump and CGM insertion and calibration (Silverstein et al., 2005). Such medical procedures during childhood are often experienced as both painful and distressing. Pain is considered a subjective phenomenon comprised of sensory, emotional, cognitive, and behavioral components (American Academy of Pediatrics, 2001). Meanwhile, distress is characterized by negative affect and observable behaviors such as crying, screaming, and verbalizing discomfort (Uman et al., 2008; Benore & Enlow, 2013). Importantly, distress is often considered an observable proxy for pain, however it can be influenced by other internal and external variables (Kleiber & Harper, 1999).

Pain and distress management is paramount during a medical procedure. Ineffective control can lead to patient restraint, inaccurate results, or inability to complete the procedure (Duff, Gaskell, Jacobs, & Houghton, 2012). Additionally, ineffective pain management has many important long-term outcomes. Specifically, procedural pain is related to both memory and future medical experiences (Young, 2005). For instance, children who display distress behaviors during procedures may be less likely to accurately remember event details. These children may over-emphasize negative aspects of the procedure, thus instilling fear of future medical events (Chen, Zeltzer, Craske, & Katz, 2000; Salmon, Price, & Pereira, 2002). Additionally, experiencing childhood procedural pain and distress is associated with medical fear and avoidance into adulthood (Pate, Blount, Cohen, & Smith, 1996). Fear and avoidance of necessary medical procedures is particularly problematic in pediatric diabetic samples, as it may lead to
DKA, hypoglycemia, retinopathy, neuropathy, nephropathy, macrovascular disease, and even death (Silverman et al., 2005; Donaghue et al., 2009).

**Individual differences in the experience of distress.** Research has shown differential pain and distress responding to pediatric procedures. These may be explained in part by individual differences in child patients (Uman et al., 2008; Blount et al., 2009). Such differences include child age, sex, temperament, anxiety level, and previous experience with medical procedures (Young, 2005).

Studies have consistently shown that age is correlated with adverse procedural experiences with younger children appearing to experience more distress and endorse greater pain levels than older children (Young, 2005; Blount et al., 2009). Jay, Ozolins, Elliott, and Caldwell (1983) looked at the relationship between procedural distress and individual factors in pediatric cancer patients. They found that younger children (ages 2-7) displayed significantly more procedural distress than older children. Additionally, a study conducted by Kazak, Penati, Brophy, and Himelstein (1998) revealed that child age is inversely related to distress during invasive procedures. Researchers suggest that young children’s increased procedural distress may be due to their lack of understanding of the situation and its temporary nature (Piira, Hayes, Goodenough, & von Baeyer, 2006). Additionally, older children have been found to display more coping behaviors during procedures, which may better enable them to manage pain and distress (Manne, Bakeman, Jacobsen, & Redd, 1993).

Sex differences have also been found in distress and pain responses to pediatric procedures (Blount et al., 2009; Schechter, Bernstein, Beck, Hart, & Scherzer, 1991). When studying individual differences that affect child distress during immunizations, Schechter et al. (1991) found the boys recovered from distress more quickly than girls. Additionally, findings
from Tsao et al. (2004) suggest that boys had higher pain tolerance than girls during a cold pressor task. These results are consistent with research findings that show adult females report higher levels of pain than adult males (Young, 2005). While results from child studies have been mixed, they suggest that male-female differential pain responses become more apparent with age (Blount et al., 2009). For instance, in a pain tolerance task, girls demonstrated lower pain tolerance than boys in a 10-14 age group. In contrast to research with older children, some studies have found that pain tolerance did not differ by sex in a younger age group (e.g., Piira, Taplin, Goodenough, & von Baeyer, 2002).

Anxiety is related to procedural response as well (Young, 2005). Specifically, the experience of pain is linked to heightened anxiety and distress responses (Koller & Goldman, 2011). Tsao et al. (2004) found that total anxiety, social anxiety, and separation anxiety were related to increases in pain endorsement in a child and adolescent sample. In a study of children undergoing immunizations, anxiety prior to the procedure predicted increased procedural pain. These results are consistent with theories suggesting that anxiety increases perception and sensitivity to sensory stimuli (Bearden, Feinstein, & Cohen, 2012). Additionally, pediatric research suggests the pain-specific fears lead to heightened anxiety during procedures (Cramton & Gruchala, 2012). Anticipatory anxiety and fears related to the medical experience, in turn, increase the probability of procedural pain and distress (Blount, Piira, Cohen, & Cheng, 2006).

Another individual difference that affects children's reactions to medical procedures is their prior experience with medical procedures (Frank, Blount, Smith, Manimala, & Martin, 1995). In a study of child distress during immunization, Frank et al. (1995) found that previous medical experience significantly predicted immunization distress levels. Specifically, previous experience was associated with increased levels of distress (Frank et al., 1995). Additional
research suggests this relationship may be influenced by the quality of previous medical experience. For instance, Dahlquist et al. (1986) found that children with previous negative medical experiences demonstrated more distress during a later medical procedure than children with less negative past experiences. Moreover, Salmon, Price, and Pereira (2002) demonstrated that children who remembered crying during a past procedure provided less accurate details surrounding event. This inaccurate recollection likely impacts children’s perception of future procedures, leading to increases in distress (Salmon et al., 2002).

The effects of temperament on children’s response to procedural pain and distress have been extensively studied (Blount et al., 2009). Rothbart defines temperament as “constitutionally based individual differences in reactivity and self-regulation” (Rothbart, 2004 p. 82). Negative affectivity, along with extraversion, is considered a reactive temperamental dimension. It is defined by shyness, discomfort, anger, frustration, fear, sadness, and low soothability (Rothbart, 2004). Regulatory components of temperament help manage an individual’s reactivity. Rothbart’s dimension of effortful control refers to an individual’s self-regulatory capacities and is best described as the voluntary ability to restrain a dominant response in order to initiate a non-dominant response. Effortful control is made up of attentional control and inhibitory control (Graziano, Keane, & Calkins, 2010). Research suggests that effortful control abilities arise during toddlerhood and progress throughout childhood, though large individual differences exist (Eisenberg, 2005; Rothbart, Sheese, & Posner, 2007). Pediatric studies focusing on effortful control suggest that it serves protective functions against pain and procedure related distress (Muris et al., 2007; Salmon & Pereira, 2002). Specifically, effortful control may enable children to disengage from threatening stimuli and to better attend to interventions designed to distract them from pain and distress (Salmon & Pereira, 2002).
Research findings have shown that variations in children's temperament characteristics are associated with differential responses to pediatric medical procedures (Ranger & Campbell-Yeo, 2008). A review by Ranger and Campbell-Yeo (2008) revealed that activity level (the proportion of active versus inactive states) and mood (the ratio of friendly/happy behaviors versus negativity/crying) were most consistently related to pediatric pain response. For instance, higher levels of activity and lower mood were related to increased pain. In addition to these variables, lower levels of threshold (level of stimulation required to produce response), intensity (degree of behavioral response), and activity may predict higher pain and distress responses (Lee & White-Traut, 1996; Helgadottir & Wilson, 2004). A study of adolescents by Muris et al. (2007) also found that temperamental anger and fear are positively related to pain response. Of note, the variables of threshold, low mood, anger, fear, and intensity are related to the higher order temperamental construct of negative affectivity. Accordingly, research also suggests that negative affect is related to pain intensity in young children (Helgadottir & Wilson, 2004; Cramton & Gruchala, 2012).

In addition to studies showing relations between negative affectivity and pain response, some studies have also examined relations between emotion regulation and pain. For example, in a study of children undergoing a voiding cystourethrogram, Salmon and Pereira (2002) found that children rated higher in effortful control exhibited more coping and less distress behaviors during the procedure. Additionally, research on pain catastrophizing in a young adolescent sample suggests that attentional and inhibitory control, components of effortful control, are positively related to lower levels of pain catastrophizing (Muris et al. 2007).
**Influence of contextual variables.** Aside from child characteristics, some of the variations in pediatric pain response may relate to external variables, such as parental anxiety (Blount et al., 2009). Pediatric medical procedures typically occur in the presence of a parent. This is done to increase child support and reduce distress. However, parental presence has been shown to increase child distress in some instances (Blount, Davis, Powers, & Roberts, 1991). Specifically, studies have found that parental use of reassurance, criticism, and apology increases child distress during procedures (Blount, Powers, Cotter, Swan, & Free, 1994). For instance, Chambers, Craig, and Bennett (2002) discovered that girls whose mothers used reassurance during a cold pressor task endorsed higher pain levels than those whose mothers used neutral expressions or distraction. Certain parental behaviors may serve as a proxy for parental anxiety and effectively communicate this anxiety to the child. A study of children undergoing painful procedures related to chronic medical conditions (including cystic fibrosis, diabetes, and nephrotic syndrome) demonstrated that both parent anxiety and nurturance were related to child distress behaviors (Kleiber & McCarthy, 2006). Accordingly, Dahlquist et al. (2005) found that parental state anxiety accounts for 17% of the variance in child procedural distress, with greater parent anxiety leading to increased child distress. To the best of my knowledge, no research studies focusing exclusively on parental presence during pediatric diabetic procedures have been reported in the literature.

**Interventions**

According to Cramton and Gruchala (2012) numerous techniques exist for the management of pediatric procedural pain and distress. These interventions can be pharmacological, non-pharmacological, or a combination of both. Pharmacological options for targeting pain include local anesthetics such as lidocaine and systemic medications like
acetaminophen and codeine. Sedative and anxiolytic drugs are also used to manage distress associated with these procedures.

Non-pharmacological techniques are often used during pediatric procedures. These strategies do not carry the risks and expense associated with many pharmacological agents (Jay, Katz, Elliott, & Seigel, 1987; Sandy et al., 2011). Additionally, they often reduce the need for anesthetics and other medications (Sandy et al., 2011). These approaches frequently address pre-procedural preparation as well as child maladaptive thoughts and behaviors during procedure (Cramton & Gruchala, 2012). Research has found that providing children with age-appropriate procedural information prior to undergoing a medical procedure is often beneficial. Specifically, this builds child trust in parents and staff involved in the procedure, instills appropriate expectations, and reduces uncertainty (Jaaniste, Hayes, & von Baeyer, 2007).

Cognitive and behavioral interventions can help children alter their perception of pain and their behavioral distress reactions (Uman et al., 2008). Such interventions include hypnosis, breathing exercises, modeling, guided imagery, and distraction (Blount et al., 2009). While support has been found for each of these techniques, research suggests that distraction may be the most effective approach. (Powers, 1999; Uman et al., 2008; Blount et al., 2009). Distraction interventions focus children’s attention away from procedural elements toward alternate stimuli. They are thought to reduce pain perception by diverting cognitive resources away from processing of pain signals. Accordingly, distraction from threatening stimuli also reduces distress reactions (Kleiber & Harper, 1999). Research has demonstrated that distraction has a moderate effect on distress reduction (Kleiber & Harper, 1999) and it notably reduces pain during procedures such as immunizations (DeMore & Cohen, 2005).
Distractors may require passive attendance or active involvement (Kleiber & Harper, 1999). Active distraction techniques utilize multiple senses and include interactive toys, guided imagery, and virtual reality. Meanwhile, passive forms of distraction usually require visual and/or auditory attention and include listening to music, watching TV, or listening to stories (Koller & Goldman, 2011). Notably, active distraction is often considered more effective at reducing pain and distress than passive distraction. When examining three different distraction interventions for children undergoing pelvic exam, Berenson, Wiemann, and Rickert (1998) found that children who engaged in more active forms of distraction experienced less distress than those utilizing passive techniques. Additionally, a study of children undergoing cold pressor trials found that active distraction was more effective than passive at improving individual’s pain tolerance and threshold from baseline (Dahlquist et al., 2007). However, passive forms of distraction are found to benefit children who find multisensory distraction too difficult to perform during pediatric procedures (Koller & Goldman, 2011). For instance, MacLaren and Cohen (2005) examined active and passive distraction conditions among children undergoing venipuncture. Results indicated that children engaging in passive distraction experienced less distress than those utilizing an active technique. Currently, best practice often includes both pharmacological and non-pharmacological techniques that can be adapted to the needs of each patient (Cramton & Gruchala, 2012).

Another well-established intervention for pediatric procedural distress is information giving. Young and Fu (1988) found that educational play interventions appeared to lower children’s objective response (as measured by heart rate) to procedural pain. Similarly, providing complete procedural narration has also been shown to reduce distress in young children (Salmon, McGuigan, & Pereira, 2006). In a 2002 study, Claar, Walker, and Smith determined that children
appraised an esophagogastroduodenoscopy as less threatening when they were provided with pre-procedural information. Through structural equation modeling, they found that information allowed children to more accurately appraise the procedure, leading to reduced anxiety, which in turn lead to lower distress (Claar et al., 2002).

The efficacy of relaxation techniques has also been studied in pediatric procedures. A review of the literature suggests that breathing exercises reduce child procedural pain and distress (Chambers, Taddio, Uman, & McMurtry, 2009). For instance, teaching young children how to “blow out” air during an injection resulted in less observable distress (French, Painter, & Coury, 1994). Similarly, guided imagery has been proven effective at reducing pain and anxiety associated with tonsillectomy/adenoidectomy in children and adolescents (Huth, Broome, & Goode, 2004). However certain relaxation skills (i.e. progressive muscle relaxation and imagery) have been found to be too conceptually complex to use with younger children (Dahlquist, 1999).

Interventions involving empathy and reassurance are considered supportive in nature. Findings have notably been mixed regarding this intervention strategy. Techniques such as reassurance have been linked to increased child procedural distress (Blount, Davis, Powers, & Roberts, 1991). In fact, use of reassurance has been shown to result in more distress than control conditions during pediatric procedures (Manimala, Blount, Cohen, 2000). However, research on infants and toddlers has also demonstrated that supportive behaviors (i.e. parental comforting) may be equally as effective as distraction during immunizations (Cramer-Berness & Friedman, 2005). Additionally, nurse soothing and physical supportive care (i.e. touch) has been associated with reduced distress in children undergoing lumbar punctures (Vannorsdall, Dahlquist, Pendley, & Power, 2004).
**Differential response to intervention.** Research has shown that interventions for pediatric procedural distress have differential effects on children. These varying responses appear to be influenced by individual differences in the child and parent attributes. Specifically, variables such as patient age, quality of previous medical experience, and temperament, as well as parent anxiety seem to contribute to intervention effectiveness.

A 1999 meta-analytic review by Kleiber and Harper suggested that age serves as an important moderator of interventions. Thus, children may respond better to different procedural interventions based on age. For example, Piira, Hayes, Goodenough, and von Baeyer (2006) found that children aged 7-9 who received a distraction intervention had a higher pain tolerance than those who received a sensory focusing intervention. However, this difference was not seen in children aged 10-14. That authors of this study suggested that some forms of intervention such as sensory focusing, may require more advanced cognitive capabilities than distraction in order to be effective. Similar findings were seen in a study of pediatric leukemia patients. Within this context, distraction and hypnosis were equally effective for reducing pain and anxiety in older children (ages 7-10), but only hypnosis intervention led to decreased distress in younger ones (ages 3-6) (Kuttner, Bowman, & Teasdale, 1988).

Previous experiences with medical procedures also impact children’s reactions to intervention. For instance, in a study of immunization distress, a robot-led distraction intervention was more effective for children who reported high levels of pain during a previous vaccination (Beran, Ramirez-Serrano, Vanderkooi, & Kuhn, 2013). A study of child distress during an outpatient throat culture demonstrated that negative past medical experience may impact children’s ability to successfully engage in passive distraction (Dahlquist et al., 1986).
Thus, children with particularly negative past medical experiences may benefit the most from targeted interventions.

Results have shown that temperamental variations may be associated with differential responses to pediatric procedural interventions (Ranger & Campbell-Yeo, 2008). Young and Fu (1988) reported that children with higher levels of rhythmicity reported more pain following a blood test regardless of pre-procedural intervention group. Additionally, in a group of children receiving lumbar punctures, cognitive behavioral intervention was most effective at reducing distress in high pain sensitive children (Chen, Craske, Katz, Schwartz, & Zeltzer, 2000). Of note, pain sensitivity was derived from a measure examining the children's perceptual sensitivities and sensation-seeking/avoidance characteristics, which are temperament-related attributes.

Of importance, several other temperamental dimensions may influence response to intervention, specifically negative affectivity (NA) and effortful control (EC). NA has been frequently examined in the context of pediatric procedural response (Connelly & Neville, 2010; Crampton & Gruchala, 2013; Helgadottir & Wilson, 2004). However, EC has been studied less often in this context (Salmon & Pereira, 2002). Importantly, these two dimensions may prove more parsimonious than other temperament variables used in prior pediatric research. For instance, past studies examining the role of temperament in pediatric pain and distress have mostly used Thomas and Chess’ temperament model composed of nine categories: activity, rhythmicity, approach, adaptability, intensity, mood, persistence, distractibility, and threshold (Schechter et al., 1991; Lee & White-Traut, 1996; Ranger & Campbell-Yeo, 2008) Yet, factor analyses suggest that these categories can be subsumed by the higher order factors of negative affectivity, surgency-extraversion, and effortful control (Rothbart, Ahadi, Hershey, & Fisher, 2001; Rothbart, 2004).
Research on temperamental NA and its lower order factors suggests that it may impact response to pediatric procedural interventions. Although, temperamental NA is associated with greater subjective pain intensity, it also increases the likelihood of experiencing negative emotions such as anxiety and fear in response to stressful situations, such as pediatric procedures (Rueda & Rothbart, 2009; Helgadottir & Wilson, 2004). A study by Hur et al. (2015) found that high levels of trait negative affect impaired individuals' ability to attend in situations eliciting state negative affect. While interventions exist to reduce pain and associated distress during medical procedures, the experience of anxiety may reduce the ability to attend to the interventions. This is because anxious individuals tend to focus attention toward, rather than away, from threatening information such as pain (Janssen, 2002). Therefore higher levels of temperamental negative affectivity may impact children’s ability to effectively utilize distraction-based interventions for pediatric procedures.

While important on their own, research suggests that negative affectivity and effortful control may interact to impact intervention efficacy. Specifically, individuals high in temperamental negative affectivity may require greater attentional control capabilities to divert attention from threatening stimuli toward coping endeavors (Derryberry & Reed, 2002). Derryberry and Reed (2002) examined the effects of attentional control and trait anxiety on attentional bias to threat among college students. They found that individuals high in trait anxiety were less able to disengage from threatening stimuli. However, this relationship was dependent on levels of attentional control. For instance, subjects with high trait anxiety and high attentional control were better able to disengage from threat than highly anxious individuals with low attentional control (Derryberry & Reed, 2002). Of import, the interactive relationship between negative affect and effortful control has also been found in youth samples. One study examining
Effortful control and temperamental NA in a sample of adolescents found that high levels of effortful control weakened the relationship between temperamental fearfulness and frustration and subsequent psychopathology (Oldehinkel, Hartman, Ferdinand, Verhulst, & Ormel, 2007). Additionally, Lonigan and Vasey (2009) found a relationship between NA and effortful control on threat bias in a school-aged sample. Specifically, attentional bias to threat was found only for children high in NA and low in effortful control (Lonigan & Vasey, 2009). While this relationship has never been tested in a pediatric procedural setting, individual differences in negative affect and effortful control may greatly affect a child’s ability to attend to and therefore benefit from procedural interventions.

Parental anxiety and associated behaviors also affect intervention efficacy. Dahlquist and Pendley (2005) found that parent anxiety greatly influenced the response to a distraction intervention during chemotherapy injections. Results showed that the intervention was less successful at reducing distress for children whose parents reported higher levels of state anxiety (Dahlquist & Pendley, 2005). Additionally, parent performance of distraction coaching significantly influenced child response to a parent-led distraction intervention during intravenous needle insertion (McCarthy et al., 2010), suggesting that performance may have been influenced by parent’s own anxiety about the procedure.

**Child Life Specialists as Interventionists**

Efforts have been made to effectively address the psychosocial wellbeing of children in healthcare settings. Specifically, the profession of child life specialist was developed in order to meet these needs. Child life specialists’ role in medical settings is to promote coping through education, preparation, intervention, and therapeutic play as well as provide familial support. In
order to be certified, child life specialists must hold a bachelors or masters degree, complete a supervised internship, and pass an accrediting examination (Child Life Council, 2006).

An increasing number of hospitals employ child life specialists to deliver non-pharmacological interventions for the management of pain and distress. Currently, there are 600 child life programs worldwide employing nearly 5,000 specialists (Child Life Council, 2016). Often, these specialists provide procedural information and numerous distress management techniques to children and families. These techniques include behavioral and cognitive strategies, as well as therapeutic play, art, and comforting (Bandstra et al., 2008). Research on child life interventions though very limited, suggests that they are helpful. For instance, Stevenson, Bivins, O'Brien, and Del Rey (2005) examined the effect of child life intervention during peripheral venous angiocatheter insertion on procedural distress. They found that children who received child life intervention experienced less anticipatory distress than children receiving standard care (Stevenson et al., 2005). Additionally, Tyson, Bohl, and Blickman (2014) found that child life specialist intervention with pediatric patients undergoing imaging procedures reduced parent and nurse- perceived child pain and distress. Moreover, research on child life intervention during laceration repair in the emergency room has revealed decreases in observable distress as well as improved parent satisfaction with services (Gursky, Kestler, & Lewis, 2010). Of importance, information on what types of child life interventions are effective is lacking and no research on outpatient child life services, such as those performed in pediatric endocrinology clinics, exists at this time to the knowledge of this author.
Purpose

There is extensive research to suggest that non-pharmacologic interventions are effective at reducing pain/distress during pediatric procedures (Uman et al., 2008). However, research on the administration of procedural interventions by child life specialists in outpatient settings is essentially non-existent. Additionally, while characteristics that influence pediatric distress levels are known, their impact on differential efficacy on procedural interventions is not well understood. Specifically, the impact of temperamental effortful control has been under-studied in this context. This study seeks to better understand the nature of interventions delivered by child life in an outpatient clinic setting as well as elucidate the relationship between temperamental factors and procedural response in the presence of intervention.

This study had five aims. (1) The first was to gain a better understanding of the relations between child characteristics, intervention use, and procedural response. Based on the literature, it was expected that temperament, anxiety, age, gender, and quality of past medical experience would be related to distress during the procedure. Specifically, negative affect and anxiety were hypothesized to positively correlate with distress, whereas effortful control, positive past medical experience, and age were predicted to correlate negatively. Girls were expected to display more observable distress behaviors than boys. Child temperament, anxiety, and age were hypothesized to correlate with intervention selection. Moreover use of empirically supported interventions such as distraction was anticipated to have an inverse relationship with child procedural distress. (2) The second goal of the study was to better understand variations in child distress and anxiety levels throughout the sensor insertion appointment. Children were hypothesized to experience the most distress during the positioning phase of the procedure. (3) Third, the study examined if intervention selection differed within and across phases of the procedure. Distraction was
proposed to be the most frequent intervention used throughout. (4) Fourth, and most importantly, the study sought to determine the effects of temperamental negative affectivity and effortful control on intervention response, as measured by procedural distress levels during intervention. It was hypothesized that effortful control would moderate the effect of negative affectivity on intervention efficacy. Children with greater levels of effortful control were expected to be better able to attend to the intervention, resulting in decreased distress levels even among children higher in temperamental negative affectivity. (5) Finally, the study sought to determine whether parent anxiety and child distress during intervention influences parental efficacy for sensor insertion at home. It was expected that parents who experience high levels of state anxiety and high levels of distress during the procedure, and whose children also experience high levels of distress during the procedure, would feel less capable of performing CGM sensor insertions in the home.

Method

Participants

A total of 32 children (59.4% male) and at least one parent per child enrolled (78.1% mothers) were recruited for the study. The mean age of the child sample was 10.30 years old (SD = 4.22) with a range from 2 to 17 years of age. Of these participants, 28 received child life specialist intervention (n = 87.5%; M = age 9.73, SD = 3.98; 57.1% male), which was considered standard care for this procedure. Four children did not receive intervention due to specialist unavailability at time of appointment. The following statistics were derived from the intervention sample (n = 28). Demographic data received from 23 of these participants indicated that most parents were college educated (mothers = 72.9%, fathers = 59.1%) and married (78.3%).
Participating families were primarily middle class (90.1% with annual income above $40,000) and ethnically identified as Caucasian and Asian (95.3%, 4.3%, respectively). Overall, sample ethnic and financial demographics were representative of the community at large.

With regard to disease-specific factors, the mean age of diabetes diagnosis was 6.9 years of age ($SD = 4.00$). In their lifetime, most children were hospitalized an average of 1.74 times ($SD = 0.96$). They attended a range of 1-3 ($M = 1.59$) medical appointments within the past 365 days, with the majority being diabetes-related (71.70%). At the time of appointment, 75% of participants already had an insulin pump in place. Preliminary analyses showed there was no significant relationship between pump status and procedural response ($t=.14, p = 0.89$)

**Location**

The study took place in the Pediatric Endocrinology Department of Albany Medical Center. Albany Medical Center is an academic medical facility, which serves 25 counties in eastern upstate New York. The Pediatric Endocrinology Department functions to provide outpatient services to the region’s children with endocrine disorders, such as diabetes type 1 and 2. The Endocrinology Department employs one child life specialist and one nurse educator; therefore all children receiving intervention had the same staff. Within the intervention condition, 27 appointments were for initial CGM sensor placement, while one was for follow-up placement. The majority of insertions were performed exclusively by the nurse educator (60.7%), however, several involved parent training (39.3%). The Dexcom sensor was utilized in all instances (Dexcom, 2016).
Measures: Behavioral Ratings During Medical Procedure

**Staff Procedure Rating Scale.** The Staff Procedure Rating Scale was used by the nurse educator to rate the child’s level of fear, anxiety, distress, cooperation, and pain during the CGM sensor appointment. All items were rated on a VAS-scale from 0 (not at all) to 10 (extremely). Staff also rated parental anxiety and helpfulness during the procedure. These ratings were gathered for 3 time points: before the procedure, during CGM placement, and during sensor insertion. Only child fear, anxiety, distress, and pain was examined in this study. Based on high intercorrelation of variables, child anxiety and fear composite scores were used in repeated measures analyses. For regression analyses, a composite variable of average nurse-rated child distress (generated from mean of positioning and insertion fear, anxiety, and distress) was utilized.

**Parent Procedure Rating Scale.** This parent report form asked the child’s mother or father to rate their child’s level of fear, anxiety, distress, cooperation, and pain. All items were rated on a VAS-scale from 0 (not at all) to 10 (extremely). Parents were also asked to rate their own level of anxiety, perceived helpfulness, and how helpful they believed child life was during the procedure. Ratings were obtained for three time-points: prior to the procedure, during the positioning phase, and during sensor insertion. Individual ratings were utilized in analyses.

**Child Post-Procedure Rating Scale.** The Child Post-Procedure Rating Scale is a self-report measure used to rate child procedural fear and anxiety. Children rate items using a VAS-scale from 0 (Not at all) to 10 (Extremely). Free response questions also ask about things parent(s) and nurse(s) did to make them feel better during the procedure. This measure was completed by children aged 8 and older. Individual ratings were utilized in analyses.
Child Life Documentation Form. The child life specialist completed this form by providing a detailed account of the techniques and interventions used with the child for 3 time points: before the procedure, during placement, and during sensor insertion. The total time of intervention was also recorded. Interventions and techniques used by the child life specialist and child behaviors and suggestions were coded by research staff into categories which included: child life specialist-initiated passive distraction, active distraction, physical supportive care, verbal supportive care, cognitive relaxation strategies, behavioral relaxation strategies, procedural information (see Table 1 for definitions). Category creation was based on review of pediatric procedural coping literature. Specifically, studies described distraction, information-giving, and relaxation as effective coping strategies during medical procedures (Berenson et al., 1998, Uman et al., 2008). Additionally, scripts were reviewed in depth to determine appropriateness of selected categories. Acceptance of child life intervention as well as child rejection of strategy use was coded. Notably, 70.7% of children refused at least one child life initiated coping intervention. Two of the study investigators (Rater A and Rater B) were trained using a coding rubric. Each coder reached above 90% agreement with a gold standard. Once trained, Rater A coded all documented responses while Rater B double-coded 25% of the sample. Of the 25% of the data that were double-coded, inter-rater reliability for each code was computed with Cohen’s kappa. The resulting intraclass correlation (ICC) value of all responses coded by Rater A and B was 0.94, indicating excellent reliability between raters. Differences in response codes within these items were resolved by agreeing on a consensus code. Coping responses were then re-categorized into 4 overarching categories: distraction, supportive care, relaxation strategies, and procedural information (see Table 1), and subsequently re-coded as belonging to one of the four types listed above. Since multiple intervention techniques were
provided for many of the participants, base rate frequencies within each phase were recorded.

Frequencies of interventions varied from 0 to 4 within time points. To avoid error inflation, frequency responses were weighted. Accordingly, for each phase the number of interventions falling under each of the 4 higher-order categories was divided by the overall number of interventions utilized in that phase. Thus, interventions and techniques were changed into proportion scores that summed to 1 within each time point (pre-procedure, positioning, and insertion).

**Measures: Parent Questionnaires**

*General Information Form.* This parent-report form was designed to gather demographic information including their marital status, years of education, income, occupation, ethnicity, child’s ethnicity, and child’s age. Disease-specific questions inquired about child’s age at diagnosis of diabetes, familial incidence of diabetes, child hospitalization history, and parental concerns about child health. For the purposes of this study, age at diagnosis and maternal education were utilized for analyses.

*Medical Experience Form.* This parent-report form provided information on their child’s experiences with several aspects of diabetes care. These included frequency and type of medical appointments and procedures, as well as the child’s typical response to medical visits, procedures, and standard diabetes care (i.e. blood glucose testing, insulin injections). Typical child response to medical visits involving painful procedures was examined in analyses.

*Children’s Behavior Questionnaire- Very Short Form* (CBQ-VSF; Putnam, S. P., & Rothbart, M. K. (2006)). The CBQ-SF is a 36-item parent-report measure of child temperament. Parents are asked to rate items on a 7-point scale from 1 (extremely untrue) to 7 (extremely true) based on their child’s typical reactions to a variety of situations. This questionnaire has been
normed for 3-8 years old, though it has been approved for use in children as young as 2 years of age (S. Putnam, personal communication 3/13/2015). For the purposes of this study, the Negative Affectivity and Effortful Control factors will be examined. Both factors were transformed into z-scores to enable comparison with EATQ-r results. During enrollment, two 9 year olds and one 11 year old received CBQ forms. Their results were not included in analyses. Study Cronbach’s alphas were .72 (EC) and .88 (NA).

*Early Adolescent Temperament Questionnaire-Revised Parent Report* (EATQ-R; Ellis, L. K., & Rothbart, M. K., 2001). The EATQ-R is a 62-item parent-report measure assessing temperament in children between the ages of 9 and 15, though it’s use has been approved for children as old as 18 (S. Putnam, personal communication 3/13/2015). Parents are asked to rate items on a 5-point scale from 1 (almost always untrue) to 5 (almost always true). The alpha values for the subscales that inform the four domains range from .65-.86 (Muris & Meesters, 2009). This questionnaire was provided to parents of children aged 9-18 years old. For the purposes of this study, the Negative Affectivity (comprised of aggression, depressive mood, and frustration subscales) and Effortful Control (comprised of activation control, attention, and inhibitory control subscales) factors will be examined. Cronbach’s alphas for NA and EC were (.88 and .94, respectively.) These factors were standardized into z-scores to facilitate comparison with CBQ results.

*Preschool Anxiety Scale* (PAS; Spence, S. H., Rapee, R., McDonald, C., & Ingram, M.; 2001). The PAS is a 34-item parent-report measure assessing anxiety in children between the ages of 2 and 6 years old. Parents are asked to rate items on a 5- point scale from 0 (Not true at all) to 4 (Very often true). Scores yield an overall anxiety rating along with 5 subscales: generalized anxiety, social anxiety, obsessive compulsive disorder, physical injury fears, and
separation anxiety. Subscales and total anxiety scores were standardized in order for comparison with SCAS-P scores. Cronbach’s alphas for subscales and total scale in this study ranged from .73 to .97. For the purposes of this study, only Total Anxiety (alpha = .97) and Physical Anxiety (alpha = .73) scales were examined.

Spence Children’s Anxiety Scale Parent Version (SCAS-P; Nauta, M. H., Scholing, A., Rapee, R. M., Abbott, M., Spence, S. H., & Waters, A.; 2004). The SCAS-P is a 38-item parent-report measure assessing anxiety in children between the ages of 6 and 18. Parents are asked to rate items on a 4-point scale from 0 (never) to 3 (always). Scores yield an overall anxiety rating along with 6 subscales: panic/agoraphobia, generalized anxiety, social phobia, obsessive compulsive, physical injury fears, and separation anxiety. For the purposes of this study, the questionnaire was provided to parents of children aged 7-18 years old. Subscale scores were standardized into z-scores to facilitate comparison with PAS scores. Cronbach’s alphas for subscales and total scale in this study ranged from .52 to .90. For the purposes of this study, only Total Anxiety (alpha = .91) and Physical Anxiety (alpha = .61) scales were utilized.

The State-Trait Inventory for Cognitive and Somatic Anxiety (STICSA; Ree, French, Macleod, & Locke, 2008) is a 21-item self-report measure that assesses cognitive and somatic anxiety. The items are rated on a 4-point Likert scale, ranging from 1 (not at all) to 4 (very much so). The version assessing state anxiety, or how the person feels “right now”, was used in this study to assess parent anxiety. Both cognitive and somatic anxiety subscales (alphas = .81, and .76) were examined via correlative analyses in relation to other study variables.

Maternal Self-Efficacy for Diabetes Management Scale (Leonard, B. J., Skay, C. L., & Rheinberger, M. M.; 1998). This is a 17-item scale designed to measure parent confidence in managing specific tasks related to their child’s diabetes. Parents are asked to rate items on a 5-
point scale from 1 (Not confident at all) to 5 (Very confident with help). Two items have been added to the original scale and one original item omitted to better assess perceived parent efficacy related to continuous glucose monitor insertion and calibration. Responses to the items related to CGM self-efficacy were averaged to create a composite CGM parental efficacy score (alpha = .80). This was examined via correlational analyses in relation to other study variables.

**Procedure**

_*AMC Pediatric Endocrinology Clinic:_* Data collection began after study approval by the Albany Medical Center Institutional Review Board (IRB of record). All families of children who were scheduled for CGM sensor insertion at Albany Medical Center during the months of July 2015 through June 2016 were asked to participate in this study by the nurse educator prior to start of their appointment. The child life specialist was made available to all families, however, during the recruitment period for this study, 4 participants did not receive child life intervention due to child life unavailability at time of scheduled appointment. Following the conclusion of the appointment, the nurse educator formerly consented both parents and children to participate in the study. At this time, the family was given several questionnaires about the child’s distress, temperament, anxiety, and parent’s state anxiety and perceived competence (see questionnaire listed above). Participants were given the option to complete the questionnaires on site or to mail forms to the study coordinator, with the majority deciding to return forms by pre-stamped envelope. Following the appointment, the nurse educator completed ratings of procedural distress at baseline, positioning, and sensor insertion. Additionally, child life specialists provided written documentation of all intervention techniques used with each child.

**Results**
Characteristics of Sample

Stable child characteristics that may influence intervention response were examined first (Table 2). Due to small sample size, Kendall’s Tau was utilized to determine relationships between these variables (Table 3). This non-parametric test of correlation is considered more accurate than Spearman’s correlation coefficient when examining data from a small sample (Field, 2009). To reduce the likelihood of type 1 error, significance levels were corrected using the Benjamini-Hochberg procedure (Benjamini & Hochberg, 1995). A significant relationship was found between parent-rated child Physical Injury Fears and Total Anxiety as measured by the Spence scales. Similarly, physical injury fears were associated with past procedural response, indicating that parents who viewed their children as fearful of injury also reported poorer response to past painful medical procedures. Furthermore, effortful control and negative affect were inversely correlated. Point-biserial correlations demonstrated that variables were not significantly related to sex of the participant.

Inter-correlations among Ratings of Children's Procedural Response

Descriptive statistics for the nurse, parent, and child procedural ratings are presented in Table 4. Total distress, anxiety/fear, and pain ratings were computed for each rater and examined via Kendall’s Tau correlations (Table 5). Following Benjamini-Hochberg correction, parent, child and nurse ratings across the procedure were largely unrelated. However, nurse ratings of child procedural response were fairly consistent. For instance, nurse ratings of anxiety/fear and distress were positively related. Notably, nurse rating of pain was not correlated with any other affective variables (fear, anxiety, distress). Parent ratings of distress and anxiety/fear were also highly inter-correlated with anxiety/fear increasing as distress increased. There were no significant relationships among child ratings.
The Relation between Parent Self-Reported Anxiety and Procedural Response Ratings

The relationship between parent self-report of anxiety and the procedural distress ratings were examined. Parent self-report of anxiety during the procedure was significantly related to child report of anxiety/fear ($\tau = .55 \ p = .03$) indicating that parents who reported that they were more anxious also had children who also experienced more anxiety. Of interest, parent ratings of perceived child pain were related also to report of parent’s anxiety during procedure ($\tau = .44 \ p = .01$), suggesting that parent’s own affective response to procedure may impact perception of child pain.

The Relation between Child Characteristics and Procedural Response Ratings

Based on past research, a relationship was expected to exist between procedural ratings, child age, child gender, previous medical experience, as well as child anxiety and temperament (Table 6). Results indicated a significant correlation between age and child pain ratings such that as age increased, pain report decreased. Gender was related to parental perception of child distress ($r_{pb} = -.44, \ p = .05$). Specifically, girls were viewed as exhibiting more distress than boys. Furthermore, parents who reported more negative procedural response histories for their children also rated them as more fearful/anxious during the current procedure. Similarly, negative procedural response history was correlated with increased distress as reported by the nurse. Meanwhile, parent-rated child physical and total anxiety were positively correlated parent perception of child’s procedural fear. Finally, higher negative affectivity as reported by parent was related to higher parent-reported anxiety/fear.

Variation in Anxiety, Fear, and Distress throughout Procedure
Variations in anxiety, fear, and distress throughout the procedure were examined through two statistical analyses. First, changes in anxiety and fear were assessed by a one-way repeated measures ANOVA. The 3-level fixed categorical repeated factor was procedural phase (pre-procedural, positioning, insertion). Mean scores of nurse-reported anxiety and fear were utilized for each phase since distress scores were only taken for positioning and insertion phases (Pre-procedural: \(M = 4.00, SD = 2.68\); Positioning: \(M = 4.45, SD = 3.04\); Insertion: \(M = 4.54, SD = 3.08\)). Mauchly Test of Sphericity was not significant, so no correction was utilized for degrees of freedom, \(\chi^2(2) = 4.96, p = .08\).

The result from the within-subjects test of the main effect of procedural phase on child distress was significant \((F(2, 54) = 4.87, p = .01)\). Polynomial contrasts revealed that anxiety and fear increased linearly as the procedure progressed. However, Bonferroni contrasts indicated that mean differences in anxiety/fear within the pre-procedural, positioning and insertion phases were not significant.

A paired t-test was performed to elucidate the relationship positioning and insertion distress levels. The bootstrapped analysis based on 5,000 samples showed a significant difference between distress based on phase of the procedure. On average, distress during the positioning phase \((M= 4.00, SE = 0.59)\) was greater than during insertion \((M=3.29, SE = 0.53)\), \((\text{Cohen’s } d= 0.23, 95\% \text{ CI [0.25-1.25]}, t = 2.79, p=0.03)\).

**Inter-correlations among Child Life Interventions**

Kendall’s Tau correlational analyses were performed to better assess the relationship between Child Life intervention choice and child age, temperament, and anxiety (Descriptives: Table 7; Correlations: Table 8). Intervention usage within phases were correlated. Specifically,
as pre-procedural relaxation increased, information giving decreased. Within the positioning phase, information giving was positively correlated with support.

The child life specialist’s intervention usage during the pre-procedural phase appeared related to intervention selection in later phases. For instance, use of distraction during positioning was correlated with increased distraction interventions during insertion. Meanwhile, use of pre-procedural relaxation correlated with greater use of relaxation and information during positioning.

**Correlations between Child Characteristics and Child Life Interventions**

Further correlational analyses showed significant relationships between child life intervention usage and certain child characteristics. Child age was significantly related to pre-procedural distraction (τ= -.56, p< .001) as well as information giving during insertion (τ= .31, p= .04). Specifically, older children appeared to receive less pre-procedural distraction and more information during insertion. Higher negative affect was related to more pre-procedural support (τ= .40, p= .05). Meanwhile, effortful control was correlated with distraction usage during insertion such that as effortful control scores increased, so did distraction usage (τ= .43, p= .03). Child total anxiety scores were inversely correlated to pre-procedural use of relaxation strategies (τ= -.42, p= .02). Neither effortful control nor negative affect were related to number of rejected interventions.

**Correlations among Child Life Interventions and Nurse-Rated Procedural Response**

Intervention usage also related to nurse-reported child distress levels during the procedure. Ratings of nurse-reported anxiety/fear, and distress across phases were negatively correlated with use of pre-procedural relaxation (Pre-Procedural: Anx/Fear τ= -.34 p= .03,
Positioning: Anx/Fear $\tau =-.44 \ p=.01$, Distress $\tau =-.47 \ p=0.003$, Insertion: Anx/Fear $\tau =-.52 \ p=.001$, Distress, $\tau =-.42 \ p=.01$). These findings indicate that relaxation interventions administered prior to treatment may improve procedural response in later phases.

**Child Life Intervention Variation throughout Procedure**

Descriptive information on weighted percent of Child Life procedural interventions is presented in (Table 7). A 4 (intervention) by 3 (phase) repeated measures ANOVA was performed to analyze how intervention use changes across the procedure. The 3-level fixed categorical repeated factor was procedural phase (pre-procedural, positioning, insertion). The 4-level fixed categorical repeated factor was type of intervention (Information, Supportive, Distraction, Relaxation). Examination of the Mauchly Test of Sphericity showed that correlations between the repeated factors were not independent for phase (phase: $\chi^2(2) = 22.45, \ p< .01$), intervention (intervention: $\chi^2(5) = 25.71, \ p< .01$), or the interaction of the two (phase x intervention: $\chi^2(20) = 45.94, \ p< .01$). Accordingly, the Greenhouse-Geisser corrected degrees of freedom were used throughout.

The results from the within-subjects tests on the main effects of phase and intervention as well as the interaction between effects were all significant ($p< .01$). For the significant main effect of phase ($F(1.27,34.21) = 9.22, \ p=.003$), Bonferroni contrasts revealed that more interventions were utilized during the pre-procedural phase of the procedure than in the positioning phase ($p< .01$). Similarly, more interventions were employed during the insertion phase of procedure than in the positioning phase ($p< .01$). The significant main effect of type of intervention was also examined using Bonferroni contrasts ($F (1.80,48.56) = 19.97, \ p< .001$). Results show that distraction was utilized significantly more than supportive care and relaxation
Additionally, procedural information was used more frequently than relaxation and supportive care (p<.05).

The interaction effect between phase and type of intervention used was significant (F(4.02,108.64) = 13.53, p< 0.001). This indicates that the phase of the procedural differentially influenced intervention selection (Figure 1). Bonferroni contrasts were examined to determine how intervention selection differed within phases. Results revealed that information was utilized more than support (p=.02) and relaxation (p=.01) within the pre-procedural phase. During positioning, distraction was more utilized than all other strategies (p<.05). Finally, information was used significantly more than distraction, relaxation, and support during insertion (p<.01). Contrasts were also analyzed to determine how intervention utilization changed across phases. For instance, distraction was used more in positioning than in other phases (p<.05). Support was used more in the pre-positioning phase than during insertion (p<.01). Additionally, Relaxation was used more in insertion than positioning and information was used more in pre-procedural and insertion phases (p<.01).

**Temperament Characteristics and their Relationship to Procedural Response: A Moderation Model Predicting Procedural Response**

Multiple regression analysis was performed to determine the relationship between temperament and procedural distress. Specifically, tests were performed to determine if effortful control moderates the relation between negative affect and procedural distress. Based on component analysis of variables (Field, 2009), a mean composite of nurse-reported procedural response variables (mean of child anxiety, fear, and distress) during the positioning and insertion phases was created (M=4.21, SD = 2.99). Prior to running analyses, Pearson correlations between variables were assessed. A significant relationship emerged between Effortful Control and
Procedural Response ($r = -.54, p = .03$). Since age was not correlated with distress or temperament variables, it was not used as a covariate as intended. The moderation model was tested using the Hayes Process Macro (model 1, 5,000 bootstrap samples, Hayes, 2013). Predictor variables were mean centered to correct for multicollinearity. Results revealed that the overall model was not significant (Distress: $R^2 = .35$, $F(3,12) = 2.13$, $p = 0.15$). Based results from correlation analyses, a bootstrapped simple regression model based off 5,000 samples was run with effortful control as the sole predictor of intervention response. The model was significant ($R^2 = .29$, 95% CI [-2.91 - -0.13], $B = -1.68$, $p = 0.05$), indicating that effortful control explained 29% of the variance in procedural response (Table 9).

**Procedural Response and Parent Efficacy**

Parent belief surrounding their own ability to perform CGM sensor insertions for their child was analyzed (Table 10). Notably most parents indicated high self-efficacy surrounding their ability to independently perform sensor insertions ($M = 4.13$, $SD = 1.05$). Correlational analyses revealed that Parent self-efficacy was not significantly related to parent anxiety during procedure or child distress levels.

**Discussion**

The first aim of this study was to elucidate the relationship between child variables, intervention use, and procedural response. It was predicted that negative affect and anxiety would positively correlate with distress, anxiety, and fear ratings while quality of past medical experience and age would relate negatively. Female gender was also expected to correlate with elevated distress levels. Results partially supported these assumptions. Fear of physical injury was positively associated with parent-rated anxiety and fear while higher total anxiety was positively associated with parent ratings of child distress during procedure. This finding is
consistent with research indicating that “trait-like” anxiety increases the likelihood of situational distress (Lau, Eley, & Stevenson, 2006). Similarly, increased negative affect was related to elevated parental ratings of anxiety and fear during procedure, however it did not correlate with nurse ratings. Since negative affect includes some subtle emotional expressions, such as frustration or sadness, nurses may be less likely to pick up on these displays than parents.

Child-reported procedural pain levels were found to be lower for older participants. This could indicate that young children have a harder time separating pain and distress constructs than older children or that older children are better able to assess and compare procedural pain in relation to other painful experiences. Notably, child age was unrelated to parent and nurse distress ratings. Since past research consistently demonstrates age as a predictor of distress level, this response might speak to parent and nurse ability to gauge developmentally appropriate procedural responses. For instance, the nurse may expect younger children to react more negatively to the procedure and this belief could influence distress scores within that age group. Accordingly, if a similar degree of distress was observed in an older child, it might be rated as a more extreme display. Poorer quality of past medical experiences, as measured by typical child response to procedural pain, was related to higher levels of nurse-reported distress and parent-reported anxiety and fear. This result was in line with hypotheses and past pediatric research (Dalhquist et al., 1986). As predicted, girls were viewed as more distressed during procedure by parent report. This rating likely reflects parent views on the appropriateness of emotional expression in daughters versus sons (Fischer, 2000).

With regard to interventions, distraction was predicted to relate inversely to procedural distress. However, results showed only pre-procedural relaxation as associated with decreased distress, anxiety, and fear across phases. Pre-procedural relaxation likely reduces state anxiety
and apprehension at the beginning of the appointment, which carries over into the treatment phases (positioning and insertion) of intervention. This finding is consistent with research indicating the efficacy of relaxation interventions for pediatric procedural pain and distress (Uman et al., 2008). However, the significant finding for relaxation versus distraction interventions within this sample may be related to with whom and how these interventions were used. It appears that distraction was utilized more ubiquitously throughout procedure while relaxation strategies were only used with certain participants, specifically those with lower Total Anxiety ratings. Therefore, results may overestimate the effect of relaxation and under-estimate the importance of latent anxiety to procedural response.

When examined in relation to child characteristics, pre-procedural distraction interventions were correlated with age. This intervention was utilized more frequently with younger children, which is consistent with research findings that distress is more effective than other interventions in this age group (Piira et al., 2006). This selective use of intervention may be based on younger children’s shorter attention span and their lower perceived need for detailed procedural information. Accordingly, older children were provided with more information during treatment. Temperament was also related to intervention selection such that children higher in NA received more pre-procedural support. In this instance, child life specialists may utilize support to modify an observable pre-existing negative affective state rather than attempt other interventions, which would require full attention and cooperation. Notably, this study found that children higher in EC were provided with more distraction interventions. This finding suggests that children with high attentional and inhibitory control are more receptive to interventions that require attention shifting. Through their increased cognitive control abilities, these children are
more likely to effectively utilize distraction interventions to reduce distress, anxiety, and fear than peers lower EC.

The next aim of the study was to determine how anxiety, fear, and distress levels might vary across the procedure. Based on knowledge of procedural components, distress was expected to be highest during the positioning phase. This was due to expected elevations of anticipatory anxiety for insertion as well as inability to see frequently utilized application sites (i.e. buttocks, back of arm). The decision to use nurse ratings of distress was based on concerns related to parent reporting bias. Similar to results from study of procedural distress by Giramonti et al. (2012), parent self-reported anxiety highly correlated with parent-reported procedural pain. Parent ratings of procedural response also seemed influenced by the child’s gender and past response to painful procedures. When looked at together across phases, nurse-reported anxiety and fear were shown to increase linearly as the procedure progressed. Consistent with hypothesis, when distress scores between positioning and insertion phases were examined, greater distress levels were found for the positioning phase. These findings highlight the importance of child life presence and intervention during all phases of the appointment. However, intervention may be particularly important during positioning, even though no pain is associated with this phase.

Data from child life intervention indicated a wide range of intervention use for the CGM sensor procedure. Consistent with hypothesis, distraction was more utilized than relaxation and supportive care. Information-giving was also used more than supportive and relaxation strategies. Overall, child life strategy use was in line with current research-based evidence on effective intervention components. Results suggested that child life strategy selection also differed based on procedural phase. Specifically, information was utilized more than relaxation
and support pre-procedurally and more than distraction, relaxation, and support during insertion. During positioning, distraction was most frequently used. These findings are notable for several reasons. Meta-analyses on studies of coping interventions for pediatric procedures report that providing cognitive behavioral approaches (including procedural information) and distraction are highly effective (Uman et al., 2008). Information during pre-procedural phase is likely instrumental at reducing distress through increasing understanding and predictability of the procedure. Similarly, explaining the insertion process and associated sensations likely decreases uncertainty and normalizes the initial physical experience of the CGM. It is also fitting that distraction was most utilized during positioning, which had the highest mean distress level of all phases. Distraction has been shown to be the most beneficial intervention for distress reduction during pediatric needle-related procedures (Uman et al., 2008).

The next aim of the study was to determine the relationship between temperament and procedural response (as measured by distress, anxiety, and fear). Contrary to hypotheses, negative affect was not a significant predictor of procedural response. This again suggests that it is less related to staff-rated observable distress, though a relationship may be detected using a different distress measure. However, this finding may also indicate that positioning and insertion were so universally upsetting that negative affect did not impact the overall reaction. A strong predictive effect of effortful control on procedural response was discovered, which partially supports the hypothesized temperament relationship. This suggests that effortful control abilities may be most influential at modulating distress reactions during positioning/insertion phases, where distress, anxiety, and fear levels were highest. Distress modulation likely occurs through voluntary shifting of attentional focus from distressing aspects of insertion to child life intervention techniques (Salmon & Perriera, 2002).
The final study aim was to determine if parent and child procedural responses impacted parent-reported confidence in future sensor insertion. Notably, parent state anxiety and child procedural distress was not related parenting self-efficacy for CGM insertion and calibration. This seems to indicate state variables are less likely to modify fixed beliefs on efficacy. Instead, past effectiveness with diabetes care likely relates more to confidence in future disease management (Bandura, 1977). It is important to note that the majority of parents reported high confidence in their ability to perform sensor insertions at home. This may reflect the overall effectiveness of nurse training during insertion appointment.

This study provides support for the relationship between temperament and procedural response. It also gives additional insight into intervention selection and use by child life. Moreover, it suggests that intervention selection may impact procedural response. Limitations were present, though, specifically related to sample size. All children scheduled for CGM sensor insertion appointments (n= 32) over roughly 10 months were consented for the study. Though consent rate was 100%, not all parents and children returned measures. Moreover, sample size was directly related to overall population size. According to the Juvenile Diabetes Association, roughly 15,000 US children are diagnosed with diabetes type 1 each year (2011). Of these, only a small subset opts for CGM. The potential subjectivity of distress ratings may also have interfered with validity of findings. Specifically, they may have obscured the relationship between negative affect, effortful control, and procedural response. Parent and nurse VAS ratings have been demonstrated as valid measures of child pain (Blount, Bunke, Cohen, & Forbes, 2001). However, objective measures (i.e. OSBD and CAMPIS-r) are the current gold standard in procedural distress research (Blount & Loiselle, 2009). Gold standard measures were not utilized in the current study due to length and complexity of scoring. Instead, short, face-
valid measures were provided to parents and nurses to facilitate increased likelihood of participation.

Finally, there was no control group who did not receive child life intervention due to its adoption as standard practice for CGM insertion appointments at Albany Medical Center. Thus, intervention efficacy was unable to be directly assessed. An RCT design would better elucidate the whether interventions truly impact distress response.

Future studies should continue to investigate the relationship between child temperament, procedural distress, and intervention efficacy across pediatric medical populations. In order to ensure detection of effects, a large medical sample and objective, normed procedural distress measures should be utilized. A better understanding of what interventions work best for individual patients is essential to improving procedural experience. Effective reduction in pre-procedural and procedural distress, anxiety, and fear will likely lead to shorter appointments, higher rates of medical adherence, and better patient-provider relationships. Additionally, research should continue to explore the effectiveness of interventions provided by child life specialists. Child life specialists now function within hospital and outpatient settings as the main provider of non-pharmacological procedural intervention. Yet the service is often under-utilized (Madhok, Milner, Teele, & Finkelstein, 2007). If child life administered intervention effectiveness can be demonstrated across different medical procedures, this may increase utilization of child life services in inpatient and outpatient medical environments.
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Term Recall of an Invasive Medical Procedure: A Preliminary Investigation.

Sandy, N. S., Nguyen, H. T., Ziniel, S. I., Minnillo, B. J., Penna, F. J., Franceschi, A. M.,


### Table 1

*Child Life Intervention Categories*

<table>
<thead>
<tr>
<th>Higher-Order Category</th>
<th>Strategy</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distraction</td>
<td>Passive Distraction</td>
<td>TV, music, being read/spoken to, movies</td>
</tr>
<tr>
<td></td>
<td>Active Distraction</td>
<td>Non-procedural conversation, singing, blowing bubbles, electronic games/tablets</td>
</tr>
<tr>
<td>Supportive Care</td>
<td>Physical Supportive Care</td>
<td>Hand-holding, hugging</td>
</tr>
<tr>
<td></td>
<td>Verbal Supportive Care</td>
<td>Normalization, validation, apologizing</td>
</tr>
<tr>
<td>Relaxation</td>
<td>Behavioral Relaxation</td>
<td>Squeezing/hugging toy, progressive muscle relaxation, deep breathing, tactile stimulation (massage, sensory toys)</td>
</tr>
<tr>
<td></td>
<td>Cognitive Relaxation</td>
<td>Guided imagery, counting to 10, thinking pleasant thoughts</td>
</tr>
<tr>
<td>Information</td>
<td>Educational Play</td>
<td>Explaining elements of the procedure through use of dolls, toys, play medical equipment, or pictures</td>
</tr>
<tr>
<td></td>
<td>Procedural Talk</td>
<td>Explaining elements of the procedure, providing information on what will be seen, felt, or heard</td>
</tr>
</tbody>
</table>
Table 2

Descriptive Statistics for Child Characteristics

<table>
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<th>M</th>
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<th>Min - Max values</th>
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<td>1.00 - 5.00</td>
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<td>16.33</td>
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<td>CBQ Effortful Control (EC)</td>
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<td>CBQ Negative Affect (NA)</td>
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<td>EATQ-r Effortful Control (EC)</td>
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Table 3

Correlations between Child Variables

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<td>-0.62*</td>
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<td>Age at Diagnosis (6)</td>
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<td>-0.23</td>
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</table>

* Correlation is significant after Benjamini-Hochberg correction (2-tailed).
### Table 4

**Descriptive Statistics of Distress Variables**

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<td>Child Fear</td>
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<td>2.59</td>
<td>0.00 - 9.00</td>
</tr>
<tr>
<td>Parent</td>
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<tr>
<td>Child Anxiety</td>
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</tr>
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<tr>
<td>Child Anxiety</td>
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<td>Child Fear</td>
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<td>Parent Anxiety</td>
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<td><strong>Insertion</strong></td>
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<td>2.99</td>
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<td>0.00 - 10.00</td>
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<td>Child Pain</td>
<td>1.76</td>
<td>1.55</td>
<td>0.00 - 6.00</td>
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<tr>
<td>Parent Anxiety</td>
<td>2.93</td>
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<td><strong>Procedure: Child</strong></td>
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<td>Anxiety</td>
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<td>0.75</td>
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<td>Fear</td>
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<td>0.00 - 2.00</td>
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<td>0.92</td>
<td>0.00 - 3.00</td>
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<tr>
<td>Pain</td>
<td>1.45</td>
<td>1.51</td>
<td>0.00 - 4.00</td>
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</tbody>
</table>

*Note.* Nurse n=28, Parent n=21, Child n=11
Table 5

*Correlations of Procedural Response Variables*

<table>
<thead>
<tr>
<th>Procedural Response</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>
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</thead>
<tbody>
<tr>
<td>Child-Rated</td>
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<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Distress (2)</td>
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<td></td>
<td>0.02</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>Pain (3)</td>
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<td></td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>Nurse-Rated</td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Anx/Fear (4)</td>
<td>0.00</td>
<td>-0.28</td>
<td>0.24</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distress (5)</td>
<td>-0.04</td>
<td>-0.39</td>
<td>0.26</td>
<td>0.84*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain (6)</td>
<td>0.61</td>
<td>0.21</td>
<td>0.28</td>
<td>0.04</td>
<td>0.04</td>
<td></td>
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<tr>
<td>Parent-Rated</td>
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<td></td>
</tr>
<tr>
<td>Anx/Fear (7)</td>
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<td>0.41</td>
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<td>0.19</td>
<td>0.22</td>
<td>0.01</td>
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<tr>
<td>Distress (8)</td>
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<td>0.60</td>
<td>-0.15</td>
<td>0.32</td>
<td>0.32</td>
<td>0.07</td>
<td>0.63*</td>
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<td>Pain (9)</td>
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<td>-0.40</td>
<td>-0.23</td>
<td>0.13</td>
<td>0.07</td>
<td>-0.07</td>
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</tbody>
</table>

*Note.* *Correlation is significant after Benjamini-Hochberg correction (2 tailed)*
Procedural responses based on total scores.
<table>
<thead>
<tr>
<th>Child Variables</th>
<th>Anx/Fear</th>
<th>Distress</th>
<th>Pain</th>
<th>Anx/Fear</th>
<th>Distress</th>
<th>Pain</th>
<th>Anx/Fear</th>
<th>Distress</th>
<th>Pain</th>
<th>Parent Anxiety</th>
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</thead>
<tbody>
<tr>
<td>Age</td>
<td>-0.33</td>
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<td>-0.69*</td>
<td>-0.10</td>
<td>-0.13</td>
<td>-0.14</td>
<td>0.00</td>
<td>-0.02</td>
<td>-0.17</td>
<td>-0.28</td>
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<tr>
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<td>-0.28</td>
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<td>-0.48*</td>
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<td>-0.21</td>
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<tr>
<td>EC</td>
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<td>-0.30</td>
<td>-0.31</td>
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<td>0.25</td>
<td>-0.02</td>
<td>-0.07</td>
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<td>0.05</td>
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<tr>
<td>Physical Injury Fears</td>
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<td>0.25</td>
<td>0.21</td>
<td>0.29</td>
<td>-0.07</td>
<td>0.49*</td>
<td>0.29</td>
<td>0.03</td>
<td>0.10</td>
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<td>Anxiety (Total)</td>
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<td>0.27</td>
<td>0.33</td>
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<td>0.41*</td>
<td>0.30</td>
<td>0.08</td>
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</table>

**Note.** * Correlation is significant after Benjamini-Hochberg correction (2-tailed)

Procedural Ratings based on total scores.

( ) = indicated for not enough variance.
Table 7

*Descriptive Statistics for Child Life Intervention*

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<th>Intervention</th>
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<th>Positioning</th>
<th>Insertion</th>
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<td>Mean (SD)</td>
<td>Mean (SD)</td>
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<td>.19(.25)</td>
</tr>
<tr>
<td>Support</td>
<td>.20(.24)</td>
<td>.07(.18)</td>
<td>.04(.11)</td>
</tr>
<tr>
<td>Relaxation</td>
<td>.12(.27)</td>
<td>.00(.00)</td>
<td>.11(.18)</td>
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<tr>
<td>Information</td>
<td>.44(.28)</td>
<td>.11(.28)</td>
<td>.62(.27)</td>
</tr>
</tbody>
</table>

*Note.* Mean proportion score for each participant (n=28) who received intervention.
Table 8

Correlations of Child Life Interventions with Distress and Child Characteristics

<table>
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<tr>
<th></th>
<th>1</th>
<th>2</th>
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<td>-0.14</td>
<td>-0.44*</td>
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<td>-0.18</td>
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<td>Support (6)</td>
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<td>0.44*</td>
<td>-0.32</td>
<td>-0.17</td>
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<tr>
<td>Information (8)</td>
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<td>-0.06</td>
<td>0.50*</td>
<td>-0.30</td>
<td>-0.37</td>
<td>0.49*</td>
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<td>Distraction (9)</td>
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<td>-0.13</td>
<td>0.08</td>
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<td>0.08</td>
<td>0.27</td>
<td>-0.13</td>
<td>-0.05</td>
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<td>-0.15</td>
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<td>Relaxation (11)</td>
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<td>-0.04</td>
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<td>Information (12)</td>
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<td>0.08</td>
<td>-0.06</td>
<td>-0.03</td>
<td>-0.15</td>
<td>-0.02</td>
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<td>0.02</td>
<td>-0.39</td>
<td>-0.21</td>
</tr>
</tbody>
</table>

Note. * Correlation is significant after Benjamini-Hochberg correction (2-tailed).
Interventions correspond with percent of intervention use within phase.
(.) indicated for intervention with no variance.
Table 9

*Does EC predict procedural response?*

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Predictors</th>
<th>Coefficient (B)</th>
<th>SE</th>
<th>t</th>
</tr>
</thead>
<tbody>
<tr>
<td>Response</td>
<td>Constant</td>
<td>3.48</td>
<td>0.61</td>
<td>5.30**</td>
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<tr>
<td>EC</td>
<td></td>
<td>-1.68</td>
<td>0.73</td>
<td>-2.39*</td>
</tr>
</tbody>
</table>

Note. B-unstandardized coefficient; * p<.05, **p<.01.
Response corresponds with averaged anxiety, fear, and distress across positioning/insertion.
Table 10

**Parent Efficacy Regarding Sensor Insertion**

<table>
<thead>
<tr>
<th>Confidence in Ability to insert/calibrate CGM</th>
<th>Parent Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not confident at all</td>
<td>0.00</td>
</tr>
<tr>
<td>Somewhat confident with help</td>
<td>10.00</td>
</tr>
<tr>
<td>Very confident with help</td>
<td>25.00</td>
</tr>
<tr>
<td>Somewhat confident without help</td>
<td>20.00</td>
</tr>
<tr>
<td>Very confident without help</td>
<td>45.00</td>
</tr>
</tbody>
</table>

Response Frequencies based on Maternal Self Efficacy Questionnaire n= 20.
Figure 1. Interaction between Phase and Intervention

Error bars represent standard errors.

*Figure 1. Interaction Effects of Phase on Intervention Strategy Usage.*

Error bars represent standard errors.