# Pediatric Hospital Falls: Patient Risk Assessment and Associated Parent Characteristics

Denise Sackinger

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Brenda Zierler, Chair

Elizabeth Bridges

Karen Thomas

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Denise Sackinger

University of Washington

## Abstract

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Denise Sackinger

Chair of the Supervisory Committee:

Brenda Zierler

Biobehavioral Nursing and Health Informatics

**Background:** Falls account for approximately 42% of adverse events reported in hospitalized children. These falls can result in patient injury which can increase hospital length of stay (LOS) and costs of care and decrease satisfaction with care. It is estimated that one-third to approximately one-half of these falls may be preventable. As a result, regulatory bodies, including The Joint Commission, require that patients be evaluated for fall risk during hospitalization. The current approach to risk assessment focuses on the use of fall risk assessment tools in which nursing staff rate individual patients against characteristics identified as increasing risk of falling in the hospital. Many pediatric fall risk assessment tools were developed based on characteristics specific to the patient population at the organization where the tool was developed. It is not clear if these fall risk assessment tools will be similarly predictive in other pediatric patient populations. Thus, organizations should validate fall risk tool performance in their patient care settings and populations.

Even with the use of validated fall risk assessment tools, hospital falls are difficult to predict and prevent. Parents are present 60 – 83% of the times when children fall in the hospital. It has been hypothesized that parent characteristics such as anxiety, fatigue, and stress may contribute to the risk of pediatric hospital falls by causing parents to be distracted or less vigilant. However, this has not yet been tested.

**Objectives:** This dissertation assesses an existing tool for predicting pediatric hospital falls and evaluates the feasibility of conducting a future study to describe associations of parent characteristics with falls in hospitalized children. These objectives are addressed in three papers. Paper one describes the predictive qualities of the Generalized Risk Assessment for Pediatric Inpatient Falls (GRAF-PIF) risk assessment tool in pediatric inpatient falls over a two-year period at a pediatric hospital. Paper two describes pediatric hospital fall risks identified in employee reports of pediatric falls over a two-year period and from a parent focus group discussion. Paper three evaluates the feasibility of conducting a future study to describe parental demographic and psychophysical characteristics associated with pediatric hospital falls. This paper identifies the sample size needed for an adequately powered future study. Finally, this paper provides recommendations for conducting a future study aimed at testing the association of parent demographic and psychophysical characteristics, specifically, anxiety; depression; fatigue; and sleep disturbance, and pediatric hospital falls.

**Research Design:** A mixed method study was undertaken to address the objectives. An observational case control study using a retrospective review of GRAF-PIF scores and fall incident reports over a two-year period was used to describe predictive qualities of the fall risk assessment tool (paper one). A descriptive qualitative study was used to describe risks for pediatric hospital falls (paper two).

A pilot study using an observational case control design was used to evaluate the feasibility of and identify recommendations for conducting a future adequately powered study to test associations of parent characteristics with pediatric hospital falls (paper three).

**Results:** The sensitivity of GRAF-PIF scores in the study sample (136 fallers and 272 non-fallers) was 61% and specificity was 58%. Results yielded an estimated Receiver Operator Characteristic (ROC) curve with an Area Under the Curve (AUC) of 0.59. For children with high GRAF-PIF scores $\geq$ 2 points, odds of falling was 2.08 times that of children with lower scores. The Interdisciplinary Momentary Confluence of Events Model (IMCEM) provided the framework for categorizing risks associated with child, environmental human, parent or caregiver characteristics from fall incident reports and the parent focus group discussion. Nineteen risk factors were identified in fall incident reports, most of which were patient-level factors. Identified risks from the incident reports fell into more than one risk category thus providing support for the multifactorial nature of fall causation as proposed in the IMCEM. Responses from parent focus group discussions were categorized into 5 groups: 1) changing conditions of the child and environment, 2) distractions, 3) parents functioning as a different part of themselves, 4) lack of knowledge of risks and 5) education considerations. The category of lack of knowledge of risk had three subthemes of “newness”, reliance on healthcare providers and changing conditions and unexpected responses. For the pilot study, only four (28.6%) eligible faller dyads were recruited. Parental stress scores were correlated with anxiety and depression scores. Power calculations indicated a need for 392 fallers and 1,176 non-fallers for a future hypothesis testing study.

**Conclusions:** Sensitivity and specificity of fall risk assessment tools may vary in different populations. The GRAF-PIF was only slightly better than chance at identifying faller versus non-fallers. However, a score of two or more points, was associated with a higher odds of falling. Thus, fall risk assessment tools can be used as part of assessment of patient fall risk assessment. However, use of these tools must be accompanied with a critical evaluation of other factors which may be associated with pediatric hospital falls. Parents are often with children when they fall in the hospital. It is important to identify and describe parent characteristics associated with the child’s fall risk. If parent characteristics are found to be

associated with pediatric hospital fall risk, the healthcare team can partner with parents to identify and develop strategies to mitigate these characteristics to improve safety of the hospitalized child. A study to understand these associations may be limited by the sample size needed for an adequately powered study. A multi-site study should be undertaken to improve the likelihood of recruiting a sufficient sample. This study also provides recommendations for recruiting parent subjects and tool refinement to decrease concerns of multicollinearity among the data.

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**TABLE OF CONTENTS**

**LIST OF TABLES** .......... 2

**LIST OF FIGURES** .......... 3

**CHAPTER 1:** Introduction .......... 4

**CHAPTER 2:** GRAF-PIF Fall Risk Assessment Tool: Predictive Accuracy in a Children's Hospital .......... 17

**CHAPTER 3:** Pediatric Inpatient Fall Risk Characteristics: A Qualitative Study .......... 43

**CHAPTER 4:** Association of Parent Demographic and Psychophysical Characteristics and Pediatric Hospital Falls: A Pilot Study .......... 71

**CHAPTER 5:** Conclusion .......... 111

## LIST OF TABLES

**CHAPTER 2**

**TABLE 1:** Sample Characteristics .................................................... 39

**TABLE 2:** Faller Characteristics .................................................... 40

**TABLE 3:** Single and Multivariable Conditional Logistic Regressions .................. 42

**CHAPTER 3**

**TABLE 1:** Focus Group Characteristics and Themes ...................................... 64

**TABLE 2:** Themes from Fall Reports of Pediatric Inpatient Falls ....................... 65

**CHAPTER 4**

**TABLE 1:** Fall Population Characteristics ............................................. 104

**TABLE 2:** Recruited Subjects' Characteristics ......................................... 106

**TABLE 3:** Parent PROMIS and PIP Scores ................................................ 108

**TABLE 4:** Correlations of PROMIS t – Scores and PIP Scores ............................ 109

**TABLE 5:** Sample Size Calculations for Future Adequately Powered Study ............... 110

# LIST OF FIGURES

**CHAPTER 1**

**FIGURE 1:** Interdisciplinary Momentary Confluence of Events Model………….……… 10

**CHAPTER 2**

**FIGURE 1:** Flow Diagram for Sample Selection ……………………….………….……. 38

**FIGURE 2:** ROC Curve ………………………………..……….……….……….…... 41

**CHAPTER 3**

**FIGURE 1:** Interdisciplinary Momentary Confluence of Events Model ……….…….… 66

**CHAPTER 4**

**FIGURE 1:** Study Instruments …………………………..………….……….………103

**FIGURE 2:** Flow Diagram for Case Sample Recruitment …………………………... 105

# CHAPTER 1: Introduction

A fall is "an unintentional descent…that results in the patient coming to rest" at a lower position (National Database of Nursing Quality Indicators, 2016, p. 2). Falls are the most common cause of hospital accidents in children accounting for about 42% of inpatient accidents (Alemdaroglu et al., 2017; Da Rin Della Mora, Bagnasco, & Sasso, 2012; Fujita, Fujita, & Fujiwara, 2013; Lee, Yip, Goh, Chiam, & Ng, 2013). It is estimated that one-third to almost half (approximately 48%) of pediatric inpatient falls are preventable (AlSowailmi et al., 2018; Jamerson et al., 2014). Injuries from these falls can range from complaints of pain, skin redness/bruising to broken bones, or damage to prior surgical repairs. These injuries can increase the length of hospital stay (LOS) and cost of care and decrease parent satisfaction (AlSowailmi et al., 2018; Razmus, Wilson, Smith, & Newman, 2006). Increased costs are concerning for healthcare organizations as many payers no longer reimburse organizations for care related to events that should "never" happen, such as falls resulting in injury (Garrard, Boyle, Simon, Dunton, & Gajewski, 2016; Hagan & Jones, 2015; Inouye, Brown, & Tinetti, 2009; Opsahl et al., 2016). Additionally, regulatory bodies, including The Joint Commission, require that patient be evaluated for fall risk during hospitalization. Furthermore, as a result of the risk evaluation, strategies need to be implemented to decrease the risk of falling in the hospital.

The current approach to fall prevention focuses on the use of risk assessment tools that include factors which are not amenable to change during the hospitalization (Ryan-Wenger, Kimchi-Woods, Erbaugh, LaFollette, & Lathrop, 2012). Additionally the tools are based solely on patient characteristics, such as age, sex, LOS, presence of an intravenous catheter (IV) and cognitive/physical capabilities to aid in the prediction of fall likelihood (Bagnasco, Sobrero, Sperlinga, Tibaldi, & Sasso, 2010; Franck et al., 2017; Graf, 2005; Hill-Rodriguez et al., 2009; Jamerson et al., 2014; Morse, Black, Oberle, & Donahue, 1989; Pauley, Houston, Cheng, & Johnston, 2014; Razmus & Davis, 2012; Schaffer et al., 2012). As a result, fall risk tools are

only intended to predict falls related to physical or physiologic characteristics of the child. They do not account for extrinsic factors which may contribute to the child's fall risk.

## Utility of Fall Risk Assessment Tools

While pediatric fall risk assessment tools have items that are associated with a child falling in the hospital, these tools are notably inadequate to predict pediatric patient falls. Many of the pediatric fall risk assessment tools were developed based on characteristics specific to the patient population at the organization where the tool was developed (DiGerolamo & Davis, 2017). As such, it is not clear if these pediatric fall prevention risk assessment tools will be similarly predictive in other patient populations. In fact, this was the case when the Humpty Dumpty Falls tool was tested at a smaller pediatric specialty hospital with a smaller sample (Pauley et al., 2014). Notably, the replication study included approximately 1.7 times more patients with neurologic diagnoses than the original study. Using the recommended cut point of 12 points to indicate high fall risk, the sensitivity was higher at 97% in the replication study compared to 85% at the site where the scale was developed (Pauley et al., 2014). However; the specificity and positive predictive values were significantly lower at 4% and 34% respectively, compared to 24% and 53% at the site where the scale was developed (Pauley et al., 2014). In fact, in a comparison of several pediatric fall risk tools including the Generalized Risk Assessment for Pediatric Inpatient Falls (GRAF – PIF) and the Humpty Dumpty Falls tool, Harvey et al. (2010) was unable to conclusively identify one tool as more predictive of pediatric inpatient falls. Validation of several pediatric fall risk tools was conducted solely at the sites where the tool was developed (DiGerolamo & Davis, 2017). Thus, organizations need to validate fall risk tool performance in their patient care settings and populations. Additionally, for the GRAF - PIF, primary reporting of the tool development and validation was disseminated at a conference and published in a conference abstract, (Graf, 2005) but not in a published manuscript.

## Parental Presence

Parents are present for 60 - 83% of pediatric hospital falls (Bagnasco et al., 2010; Jamerson et al., 2014; Lee et al., 2013; Razmus et al., 2006). In a study by Jamerson et al (2014), 90% of parents who were in the child's room at the time of the fall also witnessed the fall occur. In fact, children are more likely to be injured from a fall when a parent or adult is present (Jamerson et al., 2014; Schaffer et al., 2012). While we do not know why this association exists, some hypothesize that parental characteristics including demographic (Almis, Bucak, Konca, & Turgut, 2017) and other characteristics, such as anxiety, fatigue, and stress may contribute to the risk of pediatric inpatient falls (Da Rin Della Mora et al., 2012; Jamerson et al., 2014; Kingston, Bryant, & Speer, 2010; Lee et al., 2013; Ryan-Wenger & Dufek, 2013). Psychophysical characteristics have psychological and physical components that may impact a parent's responses. Psychophysical characteristics such as anxiety, stress, depression, sleep pattern alterations, tiredness, and fatigue may cause parents to be distracted or less vigilant, at moments when other fall risk factors converge (Da Rin Della Mora et al., 2012; Jamerson et al., 2014; Ryan-Wenger & Dufek, 2013).

## Conceptual Model

Currently, pediatric fall prevention strategies do not take into consideration the multi-factorial nature of fall risk (Ryan-Wenger & Dufek, 2013). As such, pediatric fall prevention studies focus on risk prediction tools related to individual child-level risk factors, through fall risk assessment tools (Jamerson et al., 2014; Razmus & Davis, 2012; Schaffer et al., 2012). As such, intervention strategies are focused solely on mitigation of these child risk factors rather than understanding how environmental influences, such as parental characteristics or physical space, are associated with the child falling. The Interdisciplinary Momentary Confluence of Events Model (Figure 1) (Ryan-Wenger & Dufek, 2013) is useful for understanding the multi-factorial nature. This conceptual model guided this dissertation study and will be briefly described below.

## Interdisciplinary Momentary Confluence of Events Model

Ryan-Wagner and Dufek (2013) described falls as the result of a "momentary convergence of child, parent, and caregiver human [characteristics], … and system factors" (p. 4). The Interdisciplinary Momentary Confluence of Events model posits falls are the result of at least two events that momentarily converge and necessitate a quick response to prevent falls (Ryan-Wenger & Dufek, 2013). Central to the model are pediatric falls and injuries. Unmitigated weaknesses in more than one risk category leaves the child vulnerable to falls. Risk categories are divided into intrinsic and extrinsic systems.

**Intrinsic factors.** Intrinsic factors include biomechanical characteristics, child characteristics, and environmental human characteristics (Ryan-Wenger & Dufek, 2013). Biomechanical characteristics are calculations of the impact of forces applied to the child's body to determine the extent of tissue damage and injury severity (Ryan-Wenger & Dufek, 2013). Effects of child and environmental human characteristics impact the severity of injury experienced from a fall. For example, a child characteristic of obesity places the child at greater risk of falling and sustaining an injury. At the same time, the environmental human characteristic of hard, non-carpeted flooring interacts with obesity and impacts the extent of injury resultant from the fall. The model views all intrinsic factors as interacting in a bi-directional manner around the fall event.

Child characteristics include physical, psychological or developmental features of the child that impact one's fall risk. Examples of these characteristics are age, sex, medical diagnosis, medications, treatments, body mass and developmental stage. Developmental stage can impact inpatient falls related to the normal course of development, risk-taking, cognitive ability, and language skills. The normal process of learning to walk increases children's risk for falling. Child characteristics are used in fall risk assessment tools to identify if the child is at high risk of falling. As such, hospital fall prevention strategies include increased attention to

children with these characteristics which place them at higher risk of falling. However, these characteristics are not generally able to be changed during the hospitalization.

Environmental human characteristics are the interactions of the child with their environment which impacts their fall risk and resultant injury (Ryan-Wenger & Dufek, 2013). Environmental human characteristics that can impact fall risk include the condition of the physical environment such as cleanliness, dry floors, removal of unnecessary equipment from the room, etc. (Rosenberg et al., 2016). Unfamiliarity with the hospital environment and characteristics of room layout may place the child at increased risk of falling due to disorientation. The availability and location of frequently used supplies and personal items can affect the child's interactions with the environment and impact fall risk. When these items are not easily accessible, the child may have to over-reach or ambulate without assistance to reach the supplies or personal items, increasing their risk of falling. Environmental human characteristics also include qualities of equipment and construction of the environment. Infants and toddlers often fall or roll-off of objects, (Jamerson et al., 2014) including cribs where the side rails are not completely latched or are left in a lowered position allowing the child to roll out of the crib. The composition of flooring is often a firm covering (such as ceramic tile) over concrete. This construction causes most of the energy of the fall to be absorbed by the floor-child system (Ryan-Wenger & Dufek, 2013) rather than being distributed to a more flexible surface such as a softer floor mat. Currently, fall prevention strategies aimed at environment human characteristics include removal of unnecessary equipment from the room, using appropriately sized beds, keeping the bed in the lowest position to the ground, and ensuring crib rails are in the up position and completely latched. Typically, hospital fall prevention strategies are aimed primarily at mitigating environmental human characteristics and do not account for extrinsic factors that might contribute to pediatric hospital falls.

**Extrinsic factors.** Extrinsic factors include system, caregiver, and parent characteristics. System's characteristics are those factors related to the organization in which

caregivers, parents and children interact. These system's characteristics may include culture related to patient safety, staffing, and skill mix patterns (Ryan-Wenger & Dufek, 2013). Caregiver (hospital staff) factors may include distraction, inattention, fatigue, etc. Associations of caregiver factors and medication errors in pediatric patients have been identified (Alomari, Wilson, Solman, Bajorek, & Tinsley, 2018; Choo, Hutchinson, & Bucknall, 2010; Ryan-Wenger & Dufek, 2013). However; these associations have not been as well identified in relation to pediatric hospital falls (Ryan-Wenger & Dufek, 2013).

Parent characteristics are extrinsic factors related to the parent that may be associated with the child experiencing a fall during hospitalization. Some initial research by Almis et al. (2017) indicated that lower parent education level and smoking are associated with a higher likelihood of the child falling in the hospital. However; further validation of these findings needs to be undertaken. The association of parental characteristics with pediatric hospital falls warrants further investigation as parents are often present when children fall in the hospital, and these children are more likely to be injured from the fall (Bagnasco et al., 2010; Jamerson et al., 2014; Lee et al., 2013; Schaffer et al., 2012). While the association of parental presence with pediatric hospital falls has been identified in several studies (Bagnasco et al., 2010; Jamerson et al., 2014; Lee et al., 2013; Schaffer et al., 2012), there is a lack of understanding as to why this association exists and how to leverage parental presence to decrease these falls. Parental factors such as anxiety, fatigue, and stress may contribute to the association between parent characteristics and falls (Da Rin Della Mora et al., 2012; Jamerson et al., 2014; Lee et al., 2013; Ryan-Wenger & Dufek, 2013). The evidence is clear that having a child in the hospital is stressful for parents (Busse, Stromgren, Thorngate, & Thomas, 2013; Commodari, 2010; Miles, Carter, Riddle, Hennessey, & Eberly, 1989). What is less clear is whether this stress is associated with the safety of their child in the hospital environment.

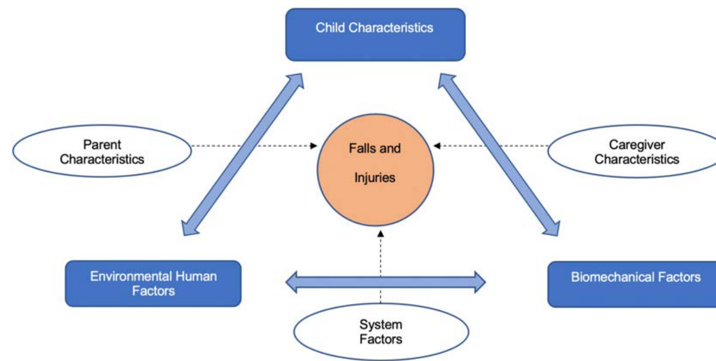


**Figure 1.** Interdisciplinary Momentary Confluence of Events Model (Ryan-Wenger & Dufek, 2013)

## Fall Prevention

The multifactorial nature of pediatric hospital falls necessitates a multifactorial approach to fall prevention. Traditional fall prevention interventions do not account for the momentary nature of when child, environmental human and parent characteristics interact and result in the child falling (Ryan-Wenger & Dufek, 2013). Currently, the focus is on identification of child characteristics through the use of fall risk assessment tools and implementation of interventions to decrease fall risk. However, many commonly used fall risk assessment tools lack adequate sensitivity and specificity to reliably predict children who will fall in the hospital (DiGerolamo & Davis, 2017). Additionally, these tools neglect parental demographic and/or psychophysical characteristics associated with increased risk of their child falling in the hospital. As a result, prevention strategies focus only on identification of patient-level risk characteristics without consideration of the momentary nature of when child, environmental human and parent characteristics interact and result in the child falling. Thus, even with the use of fall risk assessment tools, falls are difficult to predict and prevent (The Joint Commission, 2015).

Parents are often with children during hospitalization. As such, it is important for healthcare providers to understand how they can support and partner with parents to optimize their child's safety during hospitalization. It is clear that having a child hospitalized contributes

to multiple physiological and psychological challenges for parents. However, the association of these characteristics with pediatric inpatient falls has not been well studied.

## Dissertation Elements

This dissertation used a sequential mixed methods study to describe the predictive relationship between GRAF-PIF fall risk assessment scores and pediatric inpatient falls. Additionally, this study described circumstances surrounding pediatric inpatient falls. Finally, this study evaluated the feasibility of conducting a future adequately powered study aimed at identifying and describing parent characteristics associated with pediatric hospital falls. A brief overview of each chapter is presented.

### Chapter 2. GRAF-PIF Fall Risk Assessment Tool: Predictive Accuracy in a Children's Hospital

This chapter describes the predictive qualities of the GRAF-PIF pediatric fall risk assessment tool in pediatric inpatient falls over a two-year period at a pediatric hospital. This chapter presents the sensitivity, specificity and receiver operator characteristic estimate for fall risk scores and hospital falls. Conditional logistic regression was used to calculate odds of falling in the hospital based on patient characteristics and fall risk score.

### Chapter 3. Pediatric Inpatient Fall Risk Characteristics: A Qualitative Study

This chapter highlights the multi-factorial nature of fall risk. Intrinsic and extrinsic fall risk factors identified in fall incident reports and from a focus group discussion with a hospital parent advisory group are presented. The identified intrinsic and extrinsic factors provide support for the Interdisciplinary Momentary Confluence of Event Model to describe the interaction of multiple factors and pediatric hospital falls.

### Chapter 4. Association of Parent Demographic and Psychophysical Characteristics and Pediatric Hospital Falls: A Pilot Study

This chapter evaluates the feasibility of conducting and recruiting a future study to identify and describe demographic and psychophysical characteristics associated with pediatric

hospital falls. Sample size calculations for an adequately powered future study are also presented. Recommendations for subject recruitment and tool refinements are presented.

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# CHAPTER 2

## GRAF-PIF Fall Risk Assessment Tool: Predictive Accuracy in a Children's Hospital

Authors:

Denise Sackinger, MN, RN, CPN, University of Washington and Seattle Children's

Kristen Carlin, MPH, Seattle Children's Research Institute

Brenda Zierler, PhD, RN, FAAN, University of Washington

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## Abstract

Predictive qualities of a pediatric fall risk tool (GRAF-PIF) were evaluated. Pediatric fall risk tools' predictive abilities vary when applied to different populations and settings. This observational study used retrospective review of GRAF-PIF scores, demographic characteristics and fall incident reports for the period of January 2017 – December 2018 in a 407-bed pediatric hospital. One hundred thirty-six fallers were age matched with 272 non-fallers (n = 408). GRAF-PIF sensitivity, specificity, odds ratio and estimated area under the receiver operating characteristic curve were calculated. Odds ratios of falling were calculated across sex and diagnoses. The GRAF-PIF sensitivity in this patient population was 61% and specificity was 58%. Results yielded an estimated ROC curve with an AUC of 0.59. For children with high GRAF-PIF scores, odds of falling was 2.08 times that of children with lower scores. Longer length of stay and cardiac and neurologic diagnoses were associated with higher odds of falling. Musculoskeletal diagnoses were associated with lower odds of falling. While the sensitivity, specificity and ROC AUC were not optimal, a GRAF-PIF score of $\geq$2 points was associated with higher odds of falling. Weakness of tools to predict hospital falls may be due to prevention interventions implemented for those with high scores. Fall risk tools can be utilized to raise awareness of patient characteristics associated with falling. The recommendation is to continue utilization of the GRAF-PIF tool at this pediatric hospital. However, tool utilization should be accompanied with a critical evaluation of other fall risk factors (environmental, system, staff, and caregiver).

GRAF-PIF Fall Risk Assessment Tool: Predictive Accuracy in a Children's Hospital

## Background and Literature Review

A fall is "an unintentional descent…that results in the patient coming to rest" at a lower position (National Database of Nursing Quality Indicators, 2016, p. 2). Falls are the most common cause of hospital accidents in children accounting for about 42% of inpatient accidents (Alemdaroglu et al., 2017; Da Rin Della Mora, Bagnasco, & Sasso, 2012; Fujita, Fujita, & Fujiwara, 2013; Lee, Yip, Goh, Chiam, & Ng, 2013). Pediatric inpatient fall prevalence ranges from 0.4 to 3.8 falls per 1,000 patient days (Almis, Bucak, Konca, & Turgut, 2017; Fujita et al., 2013; Jamerson et al., 2014; E. J. Kim, Lim, Kim, & Lee, 2019; Pauley, Houston, Cheng, & Johnston, 2014; Schaffer et al., 2012). It is estimated that one-third to almost half (approximately 48%) of pediatric inpatient falls are preventable (AlSowailmi et al., 2018; Jamerson et al., 2014). Injuries from these falls can range from complaints of pain, skin redness/bruising to broken bones, or damage to prior surgical repairs. These injuries can increase the length of hospital stay (LOS) and cost of care and decrease parent satisfaction (AlSowailmi et al., 2018; Razmus, Wilson, Smith, & Newman, 2006).

Da Rin Della Mora and Calza, et al. (2012) found that 51.7% of pediatric patients who fell in the hospital received additional interventions which were not previously part of their planned care. While most children recovered from fall related injuries in two to three days, the recovery time ranged from zero to twenty days (Da Rin Della Mora, Calza, et al., 2012). Increased interventions and LOS associated with falls translates into increased healthcare costs related to hospital falls. Increased costs are concerning for healthcare organizations as many payers no longer reimburse organizations for care related to events that should "never" happen, such as falls resulting in injury (Garrard, Boyle, Simon, Dunton, & Gajewski, 2016; Hagan & Jones, 2015; Inouye, Brown, & Tinetti, 2009; Opsahl et al., 2016).

The current approach to fall prevention focuses on the use of risk assessment tools to identify children at higher risk of falling based on characteristics, such as age, sex, LOS,

presence of an intravenous (IV) catheter and cognitive/physical capabilities (Bagnasco, Sobrero, Sperlinga, Tibaldi, & Sasso, 2010; Franck et al., 2017; Graf, 2005; Hill-Rodriguez et al., 2009; Jamerson et al., 2014; Morse, Black, Oberle, & Donahue, 1989; Pauley et al., 2014; Razmus & Davis, 2012; Schaffer et al., 2012). As a result, fall risk tools are intended to predict anticipated physiologic and developmental falls, but not unanticipated physiologic or accidental falls. Many commonly used pediatric fall risk assessment tools lack adequate sensitivity and specificity to reliably predict children who will fall in the hospital (Almis et al., 2017; DiGerolamo & Davis, 2017; Harvey, Kramlich, Chapman, Parker, & Blades, 2010; Ryan-Wenger, Kimchi-Woods, Erbaugh, LaFollette, & Lathrop, 2012). Thus, even with the use of fall risk assessment tools, falls are difficult to predict and prevent (The Joint Commission, 2015).

## Morse Fall Risk Assessment

The Morse Fall Risk Assessment is one of the first widely used fall risk assessment tools. This tool was developed as a result of comparing one hundred adult patients who fell with one hundred patients who did not fall (Morse et al., 1989). Six risk characteristics were identified to be associated with fallers (Morse et al., 1989). These characteristics comprise the scale and include: history of falling, secondary diagnosis, use of ambulatory aid such as a cane; wheelchair; walker; or furniture, IV therapy, gait impairment, and mental status (E. A. Kim, Mordiffi, Bee, Devi, & Evans, 2007; Morse et al., 1989). Each response is weighed with a score between zero and thirty points depending on the relative risk of the characteristic to falling (Agency for Healthcare Research and Quality, 2013; E. A. Kim et al., 2007). Patients are categorized as low (score of less than 25 points), medium (score of 25 to 50 points), or high risk (score of greater than 50 points) of falling (E. A. Kim et al., 2007). Morse found that patients who had fallen were likely to experience repeat falls (Morse et al., 1989). Patients who scored as high risk of falling are more likely to experience an anticipated physiologic fall (Morse et al., 1989). Whereas, low to medium risk scores in fallers were more likely associated with unanticipated or accidental falls (Morse et al., 1989). Morse found IV therapy to be associated

with an increased risk of falling (Morse et al., 1989). The sensitivity and specificity of this tool is 72% – 83% and 29% – 83%, respectively (E. A. Kim et al., 2007). This tool was developed and tested in adults (Morse et al., 1989). Application of this tool to a pediatric sample of one hundred fallers and one hundred non-fallers using the high-risk cut-off of fifty points reduced the sensitivity to 58% and the specificity to 51% (Razmus et al., 2006). Thus, it is clear that adult fall risk assessment tools are not sufficient to predict pediatric fall risk.

### Generalized Risk Assessment for Pediatric Inpatient Falls (GRAF-PIF)

The GRAF-PIF tool is one of the first pediatric specific fall risk assessment tools developed. It is also the most commonly used fall risk assessment tool for hospitalized pediatric patients in American hospitals (Jamerson et al., 2014; E. J. Kim et al., 2019). This tool is used to predict fall risk in children twelve months of age and older. Like other risk assessment tools, this tool is intended to predict risk of anticipated physiological falls; however, this tool is not intended to predict accidental falls, unanticipated physiological or developmental falls (Ryan-Wenger et al., 2012). Similar to the Morse Fall Risk tool, the GRAF-PIF was developed based on a retrospective case control study of two hundred patients (100 fallers and 100 non-fallers) (Graf, 2005, 2011). Five patient level characteristics, which placed a child at greater risk of falling in the hospital were identified (DiGerolamo & Davis, 2017; Harvey et al., 2010; Ryan-Wenger et al., 2012). These characteristics include: LOS of five or more days, anti-seizure medications, musculoskeletal or orthopedic conditions, physical or occupational therapy needs, and absence of an IV catheter (DiGerolamo & Davis, 2017; Graf, 2005, 2011; Harvey et al., 2010; Ryan-Wenger et al., 2012). Each of these items is scored as zero or one point with the exception of the LOS item. Unlike other fall risk tools, GRAF-PIF uses LOS to aid in the determination of fall risk. A LOS of four days or less is scored as zero points, five to nine days is one point and ten or more days is two points. Additionally, a history of a fall in the past month or during the hospitalization automatically places the child at risk for falling again (Graf, 2011), thus these items are scored as two points. A total GRAF-PIF score of two or more points

indicates that the child is at high risk of falling during the hospitalization. The reported positive predictive value was 83.4% (Graf, 2005). Reported sensitivity and specificity were 75% and 76%, respectively (Harvey et al., 2010).

### Utility of Pediatric Fall Risk Assessment Tools

While pediatric fall risk assessment tools have items associated with a child falling in the hospital, these tools are notably inadequate to predict pediatric patient falls (Almis et al., 2017; DiGerolamo & Davis, 2017; Harvey et al., 2010; Ryan-Wenger et al., 2012). Many of the pediatric fall risk assessment tools were developed based on characteristics specific to the patient population at the organization where the tool was developed (DiGerolamo & Davis, 2017). As such, it is not clear if these pediatric fall prevention risk assessment tools will be similarly predictive in other patient populations and settings. In fact, this was the case when the Humpty Dumpty Falls tool was tested at a smaller pediatric specialty hospital with a smaller sample (Pauley et al., 2014) than the original organization. The Humpty Dumpty Falls tool was developed and initially tested at a large pediatric hospital (Nicklaus Children's Hospital) (Gonzalez, Hill-Rodriguez, Hernandez, Williams, & Cordo, 2016; Hill-Rodriguez et al., 2009) with a reported sensitivity of 85%, specificity of 24% and positive predictive value of 53% (Hill-Rodriguez et al., 2009; Ryan-Wenger et al., 2012). Using the recommended cut point of twelve points to indicate high fall risk, the replication study found the sensitivity of the Humpty Dumpty Falls tool to be higher at 97% (Pauley et al., 2014). However; the specificity and positive predictive values were significantly lower, 4% and 34%, respectively than in the original study (Pauley et al., 2014). In fact, in the comparison of several pediatric fall risk tools including the GRAF-PIF and Humpty Dumpty Falls tools, Harvey et al. (2010) was unable to conclusively identify one tool as more predictive of pediatric inpatient falls than another. Validation of many pediatric fall risk tools have been conducted at single sites where the tool was developed (DiGerolamo & Davis, 2017) and not beyond the original site. Thus, organizations should validate fall risk tool performance in their patient care settings and populations.

## Objective

The objective of this study was to describe the predictive qualities of an existing pediatric fall risk assessment tool in pediatric inpatient falls over a two-year period at a pediatric hospital. Specifically, this study aims to test the ability of the GRAF-PIF tool to predict pediatric hospital falls using a retrospective chart review over a two-year period (January 2017 – December 2018) for children who fell and their age matched controls in a children's hospital in the northwest United States. The specific aims of this study are:

1. How well does the GRAF-PIF risk rating, obtained from the EHR, predict hospital falls in children as identified by electronic incident reports of falls? Predictive qualities will be measured by the tool's sensitivity, specificity, estimated area under the receiver operating characteristic (ROC) curve, and odds ratio of falling.
2. How well does the GRAF-PIF risk rating, obtained from the EHR, predict hospital falls in children within subgroups as defined by patient characteristics (sex and diagnosis) as identified by electronic incident reports of falls? These predictive qualities will be measured by odds ratio of falling across patient subgroups.

## Methods

### Study Design

This observational case-control study used retrospective chart reviews to evaluate the predictability of the GRAF-PIF tool. The data were collected in July and August 2019 from hospital admissions between January 2017 and December 2018. Case subjects were identified from hospital fall reports. Case subjects were matched based on age (± 3 months) and the presence of a GRAF-PIF score on the same day of admission as the fall with two patients who were admitted during the study time period but did not a have reported fall. For example, if the case patient fell on day five of admission, the control subjects needed to have a GRAF-PIF score on day five of their admission. Fall related data were extracted from hospital falls' reports.

Demographic data and GRAF-PIF scores were extracted from the Electronic Health Record (EHR).

**Setting**

This study was conducted at a free-standing children's hospital in the northwest United States. The hospital provides inpatient, outpatient, and ambulatory care services across multiple pediatric specialties. The hospital provides services for a range of conditions ranging from low acuity episodic care to high acuity care including long term chronic care, organ transplantation, life support, etc. It serves as a quaternary referral center for a four-state region. The hospital is licensed for 407 inpatient beds with an average daily census of 290 patients. The nurse to patient ratio for acute care units range from one nurse to two to four patients depending on the unit and patient acuity with an overall average ratio of one nurse to three patients. The average two-year fall rate during the study period and for the study units (January 2017 – December 2018) was 1.36 falls per 1,000 patient days which is within the range reported in the literature (0.57 – 2.19 per 1,000 patient days) (Almis et al., 2017; Fujita et al., 2013; Jamerson et al., 2014; Pauley et al., 2014; Schaffer et al., 2012). The organization started tracking parental presence at the time of falls through a mandatory field in the incident reporting system in December 2017. Over the course of the last twelve months of the study period (January – December 2018), parents were reported to be present for 78% of study eligible falls.

**Participants**

The population of interest for this study was pediatric inpatients who had at least one fall reported while during the study period. The sample included all children with at least one fall reported in the hospital's incident reporting system and a documented GRAF-PIF score in the EHR between January 2017 through December 2018. The sample also include two age matched controls for each case. Controls were patients who did not have a reported fall and were admitted during the same two-year time frame. Cases and controls were drawn from the same time period to control for environmental impacts such as changes in staffing, or census.

Cases and controls were matched based on age to control for differences in fall rates based on age especially for younger developmentally appropriate children who are learning ambulation skills. Since longer LOS are associated with increased fall risk (Almis et al., 2017; Graf, 2005, 2011) and are included at a GRAF-PIF item, controls had to have a GRAF-PIF documented on the same day of admission as their case match. For example, if the case fell in the morning of day five of admission after the morning GRAF-PIF was scored, the morning GRAF-PIF on day five of admission was used for each of their age matched controls.

***Inclusion criteria.***

- Child admitted to a Medical, Surgical, Oncology, Rehabilitation, Pediatric Intensive Care Unit (PICU) or Cardiac Intensive Care Unit (CICU) during January 2017 – December 2018
- Documented GRAF-PIF score in the EHR

***Exclusion criteria.***

- Patients who had a suspected intentional fall
- Patients in the NICU - the GRAF-PIF tool is not completed for children less than twelve months of age
- Patients in the psychiatric unit - all patients on the psychiatric unit are considered to be at high risk of falling and the GRAF-PIF is not completed for these patients

**Procedure**

After obtaining Institutional Review Board (IRB) approval from the study site, the principal investigator reviewed the incident reporting system to identify potential case subjects with a staff reported fall during the study time period Free-text description of the incidents were reviewed to ensure the report met the National Database of Nursing Quality Indicators (NDNQI) definition of a fall. While reviewing the fall descriptions, the fall type and injury levels were validated and corrected if necessary, to align with NDNQI definitions. For patients with more

than one fall reported, only data related to first fall during the study period were used. Fall type, injury level, date/time of fall and parental presence at time of fall were obtained from the incident reporting system. Controls were recruited from an existing patient database after cases were identified. Cases were matched based on age with two controls who were admitted at some point during the same study time period. Additionally, cases were matched based on the presence of a documented GRAF-PIF score on the same day of admission as their control match. Data for variables of age (matching variable), sex, admission unit, GRAF-PIF score, dates of admission and discharge and International Classification of Diseases (ICD) code with descriptions were obtained from an existing patient database. GRAF-PIF scores were used as documented in the EHR without attempting to validate or correct responses. Diagnoses were obtained by reviewing ICD diagnosis descriptions and categorizing using pre-determined diagnosis groups. When the ICD diagnosis description did not reveal a clear diagnosis group, the discharge summary was reviewed to identify the primary discharge diagnoses. Data were downloaded into an IRB and HIPAA compliant Research Electronic Data Capture (REDCap) database (Harris et al., 2009). Length of stay at the time of the fall, total LOS and total GRAF-PIF scores were determined by calculated fields in REDCap.

**Instrument**

**GRAF-PIF.** The GRAF-PIF tool was described earlier in this paper. At the study site, fall risk is evaluated using the GRAF-PIF fall risk assessment tool for children twelve months of age and older on admission and every shift (approximately every 12 hours) by nursing staff. The GRAF-PIF tool has been used at the organization for more than ten years.

**Statistical Analysis**

Data were analyzed using STATA version 14 (StataCorp LP, 2015), R version 3.6.0 and RStudio version 1.1.456 (R Core Team, 2019). Data were categorized into one of two groups – fallers and non-fallers. Data related to children who experienced a hospital fall (cases) were

labeled as “faller” data and those who did not experience a hospital fall (controls) were labeled as “non-faller” data.

Descriptive statistics were used to evaluate the sample demographics of age, sex, fall type, admission unit, diagnosis, number of falls, injury level, high GRAF-PIF score by fall type, LOS and GRAF-PIF scores. The total number of data points were evaluated for missing data. Continuous variables were assessed for normality using histograms and Q-Q plots. Since the data are not normally distributed, summaries are reported as medians and interquartile ranges. Categorical data are summarized as frequencies and percentages. Boxplots of each variable by faller group were evaluated for skewness and potential influential and leverage points.

GRAF-PIF scores were dichotomized (< 2 points for low fall risk or ≥ 2 points for high fall risk) based on cut point determined by tool developer. Sensitivity and specificity of dichotomized GRAF-PIF scores were calculated to describe the true positive and true negative rates respectively. Sensitivity and specificity are reported as a percent ranging from 0% - 100%. The sensitivity and specificity were used to estimate the area under the ROC curve (AUC) which describes the overall performance of the GRAF-PIF tool in identifying fallers and non-fallers. The area under the ROC ranges from zero to one. A value of one indicates the tool is perfectly accurate. A value of 0.5 indicates the tool is no better than chance at predicting those who will and will not fall. A value of less than 0.5 indicates the tool is worse than chance. The ROC is beneficial as it incorporates both sensitivity and specificity to provide one number that can be used to evaluate tool performance. To estimate the sensitivity, specificity, and ROC, a random subset of the data was used to fit a conditional logistic regression to half of the sample. This provided model coefficients, which were then evaluated with the other half of the sample, producing the sensitivity and specificity of the GRAF-PIF. ROC is presented in graphical form.

Single variable conditional logistic regression was used to identify associations of GRAF-PIF score, sex, length of stay and diagnosis associated with children experiencing a fall in the hospital. Multivariable conditional logistic regression was used to identify if GRAF-PIF scores

were associated with children experiencing a fall in the hospital controlling for patient characteristics of sex, length of stay and diagnosis. Conditional logistic regression results are presented as odds ratios with 95% CI and *p* values. A *p* value of 0.05 or less was considered statistically significant.

**Results**

Three hundred ninety-six incident reports were reviewed for eligibility as a case subject. Two hundred fifty-seven of these were excluded for not meeting inclusion criteria. Three additional case subjects were excluded after attempts for matching with two controls failed, which was due to a long length of stay prior to the fall. The final sample consisted of 136 case subjects who had a fall reported in the incident reporting system and 272 controls who did not have a fall reported in the incident reporting system during the study time frame (n = 408) (Figure 1. Flow diagram for sample selection).

The faller group had fewer males than the non-faller group. The age of the faller and non-faller group were similar at approximately 7.8 years (93.5 and 94.1 months respectively) for both groups. The units of admission varied by faller group with a higher percentage of fallers admitted to an oncology unit or rehabilitation unit at the time of the fall compared to the control (non-faller) group. Diagnoses also varied by faller group with the faller group having a higher percentage of neurologic/nervous system and cardiac disorders. Length of stay was similar among the fall and non-faller groups. Parents were present for 67.7% of the falls. However, 27 falls did not mention parental presence as this was prior to including this question as a mandatory field in the reporting system. If these falls are excluded (as parents may have been present but not indicated in the report), the rate of parental presence increases to 84.4% (Table 1. Demographic characteristics).

Most fallers only had one reported fall during the study time period (n = 118). However, 18 children experienced more than one fall during the study period (12 had 2 falls, 4 had 3 falls, 1 had 4 falls, and 1 had 5 falls). The most common fall type was accidental (52%) followed by

anticipated physiological falls (24%). Ninety-nine percent of the fallers experienced minor or no injury as a result of the fall. One patient experienced severe injury sustained a skull fracture which was detected on x-ray. Patients fell on days 2 – 13 of their admission with the median occurring on day 6 of admission (Table 2. Faller characteristics).

The sensitivity and specificity of the GRAF-PIF was 61% and 58%. This yielded an area under the ROC curve of 0.59, indicating that the GRAF-PIF performed slightly better than chance at predicting who would and would not fall (figure 2. ROC curve).

In the single variable regression models, sex was not associated with odds of falling in the hospital (*OR* = 1.37, *95% CI* = 0.90 – 2.08, *p* = 0.141). However, longer LOS (*OR* = 1.04, *95% CI* = 1.02 - 1.06, *p* = <0.001) and a GRAF-PIF score of two points or more (*OR* = 2.16, *95% CI* = 1.22 – 3.84, *p* = 0.009) were significantly associated with a higher odds of falling. Hematology/oncology was used as the diagnosis reference group since this was the most common diagnosis in the total sample. Compared to hematology/oncology diagnoses, gastrointestinal/digestive (*OR* = 0.37, *95% CI* = 0.15 – 0.97, *p* = 0.023) and skin/musculoskeletal/orthopedic (*OR* = 0.27, *95% CI* = 0.09 – 0.88, *p* = 0.030) diagnoses were associated with a lower odds of falling while neurologic/nervous system diagnoses were associated with a higher odds of falling (*OR* = 2.28, *95% CI* = 1.06 – 4.91, *p* = 0.034) (Table 3. Single and multivariable conditional logistic regressions).

The multivariable conditional logistic regression model controlled for GRAF-PIF score of two points or more, sex, LOS, and diagnosis. Longer LOS remained significantly associated with falling (*OR* = 1.04, *95% CI* = 1.01 - 1.06, *p* = 0.003). Cardiac (*OR* = 2.37, *95% CI* = 1.05 – 5.35, *p* = 0.038) and neurologic/nervous system diagnoses (*OR* = 2.56, *95% CI* = 1.12 – 5.84, *p* = 0.026) were associated with more than a two-fold increased odds of falling compared to those with a hematology/oncology diagnosis. Skin/musculoskeletal/orthopedic diagnoses remained associated with a lower odds (*OR* = 0.28, *95% CI* = 0.08 – 0.96, *p* = 0.043) of falling compared

to those with a hematology/oncology diagnosis (Table 3. Single and multivariable conditional logistic regressions).

**Discussion**

Primary reporting of the original study describing the development and validation of the GRAF-PIF tool was disseminated at a conference and published in a conference abstract (Graf, 2005) but not in a published manuscript. Even with the lack of verifiable data on the initial development and testing, the GRAF-PIF is the most commonly used fall risk assessment tool for pediatric inpatients (Jamerson et al., 2014; E. J. Kim et al., 2019). In this study, the GRAF-PIF correctly identified 61% of fallers as high risk (sensitivity) and approximately 58% of non-fallers as low risk of falling (specificity). Pediatric fall risk assessment tools are notably weak at predicting resultant falls. This weakness may be due to the fact that interventions are implemented to reduce fall risk for those with high GRAF-PIF scores. Fall risk tools can be utilized to raise awareness of patient characteristics associated with falling.

While the sensitivity, specificity and ROC AUC were not optimal, a GRAF-PIF score of two or more points was associated with approximately twice the odds of falling than for those with a lower score. Musculoskeletal/orthopedic diagnoses may be associated with a lower odds of falling as these patients often received physical therapy services to teach them ambulation skills. Additionally, parents and staff may understand musculoskeletal and orthopedic conditions may place a person at increased risk of falling and therefore may implement more rigorous prevention strategies.

**Limitations**

Limitations of this study include that the study was conducted at a single hospital organization which may not be generalizable to other organizations. The study was an observational study and did not include manipulation of an independent variable thus the study cannot determine causal relationships between GRAF-PIF scores and pediatric hospital falls. The retrospective nature of the study limits the data to what is available in the incident reports

and the EHR. This did not allow for clarification of data or returning to subjects to obtain missing data. Data obtained from the EHR was standard information obtained on all patients. Nurses receive a task reminder in the EHR every twelve hours to complete risk assessment tools, including the GRAF-PIF. This reminder is not resolved until the GRAF-PIF is completed for that twelve - hour period. Therefore, compliance with completion of the GRAF-PIF fall risk assessment was good. Use of GRAF-PIF scores as documented in the chart without attempting to validate that responses were correct is a limitation as it may not reflect the child's true fall risk as determined by the GRAF-PIF tool. However; validation of items may result in inconsistent correction of items related to variations in information sources within the EHR for scale completion. Additionally, validation of items may result in the assignment of incorrect responses as the researcher is dependent on timely and accurate documentation of data in the EHR to validate responses. Any errors in item responses by nurses caring for the patient at the time of tool completion should be randomly distributed across all patients. Additionally, there may be confounding variables other than age for which we have not identified and controlled for in this study. While there are several limitations in this study, efforts were taken to reduce the impacts of these limitations.

**Strengths.**

While conducting this study at a single site is a limitation related to the generalizability of the findings to other organizations, it is a strength for understanding the utility of this fall risk assessment tool for the population cared for at the study setting and may be generalizable to other pediatric hospitals with similar patient populations. The disparity in previously reported sensitivity and specificity with those identified in this study highlights the importance of validating predictive qualities of fall risk assessment tools in the patient care setting and population where the tool will be used.

## Conclusions and Recommendations

Regulatory bodies, including The Joint Commission, require that patients be evaluated for fall risk during hospitalization. This evaluation is often conducted with the use of fall risk assessment tools in which nursing staff rate individual patients against characteristics identified as increasing the risk of falling the hospital. The difficulty in validating the utility of fall risk assessment tools lies in the reality that risk assessment scores drive nurses to implement interventions aimed at increasing awareness of fall risk or preventing falls. It is not possible to determine the true predictability of a fall risk assessment tool without the interference of these preventive interventions.

Statistical analyses may not be the best measurement of the utility of fall risk assessment tools. The utility of fall risk assessment tools may be a function of the actual tool and the process of taking the time to specifically consider characteristics that may place the patient at greater risk of falling. While the accepted method of evaluating patients' fall risk may include the completion of a standardized assessment tool, nurses must critically evaluate patients' risk factors including environmental, caregiver, and staff characteristics, which may place the child a greater risk of falling. Based on the findings of the current study, the recommendation is to continue use of the GRAF-PIF tool at the study organization. However, completion of the tool should be done with a critical evaluation of other factors (environmental, system, staff, and caregiver) that may also contribute to the child's fall risk.

Future research may include evaluation of the inter-rater reliability of GRAF-PIF scale. This can help determine if nurses are responding to the items correctly. Future research may also include concurrently scoring fall risk using other validated assessment tools (such as Humpty Dumpty Falls) to understand if one tool performed better in the specific patient population.

## Other Information

### Funding

No funding was used to support this study.

### Competing Interests

Two of the authors are employees at the study site (DS, and KC). However, they are not employed by any of the units included in the study.

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## Tables and Figures

**Figure 1. Flow diagram for sample selection**

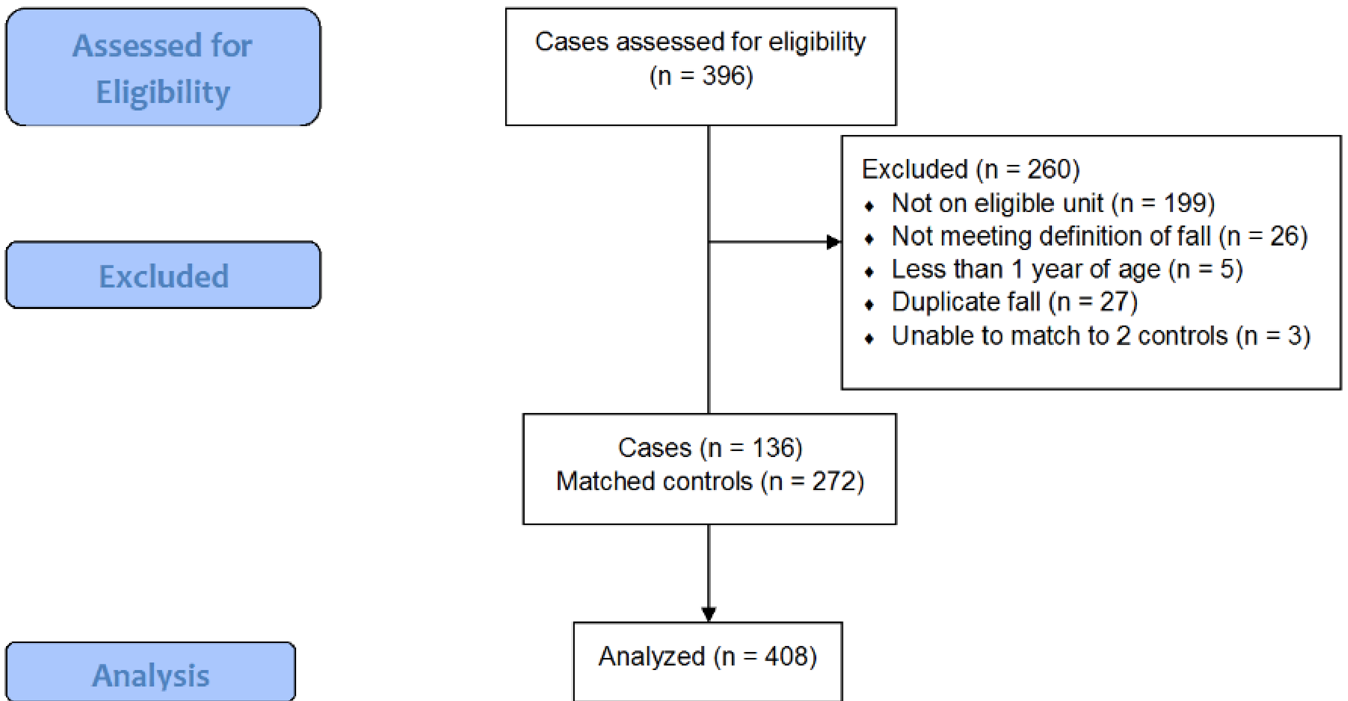


Figure 1. Flow diagram for sample selection

**Table 1. Sample characteristics**

| Characteristic | | Non-Faller (N = 272) n(%) or Median (25th %ile, 75th %ile) | Faller (N = 136) n(%) or Median (25th %ile, 75th %ile) | All subjects (N = 408) n(%) or Median (25th %ile, 75th %ile) |
|---|---|---|---|---|
| Sex | Male | 153(56.2) | 66 (48.5) | 219 (53.7) |
| | Female | 119 (43.8) | 70 (51.5) | 189 (46.3) |
| Age (months) (matching variable) | Months | 94.1 (IQR 39.6, 173.1) | 93.5 (IQR 40.6, 172.1) | 93.7 (IQR 40.1, 173.1) |
| Unit | Surgical | 134 (49.3) | 32 (23.5) | 166 (40.7) |
| | Medical | 57 (21.0) | 36 (26.5) | 93 (22.8) |
| | Oncology | 35 (12.9) | 41 (30.2) | 76 (18.6) |
| | PICU | 29 (10.7) | 9 (6.6) | 38 (9.3) |
| | Rehabilitation | 17(6.2) | 18 (13.2) | 35 (8.6) |
| | CICU | 0 | 0 | 0 |
| Diagnosis | Hematology/Oncology | 45 (16.5) | 26 (19.1) | 71 (17.4) |
| | Respiratory/Pulmonary | 52 (19.1) | 18 (13.2) | 70 (17.2) |
| | Gastrointestinal/Digestive | 49 (18) | 10 (7.4) | 59 (14.5) |
| | Neurologic/Nervous System | 27 (9.9) | 31 (22.8) | 58 (14.2) |
| | Cardiac | 27 (9.9) | 27 (19.9) | 54 (13.2) |
| | Skin/Musculoskeletal/Orthopedic | 27 (9.9) | 4 (2.9) | 31 (7.6) |
| | EENT/Craniofacial | 23 (8.5) | 7 (5.2) | 30 (7.4) |
| | Renal/Urinary | 13 (4.8) | 6 (4.4) | 19 (4.7) |
| | Trauma/Injury/Poisonings | 4 (1.5) | 5 (3.7) | 9 (2.2) |
| | Endocrine/Metabolic | 5 (1.8) | 2 (1.5) | 7 (1.7) |
| Total Length of Stay (days) | | 9 (IQR 3, 21) | 10.5 (IQR 4, 26) | 9 (IQR 3, 23) |
| Total GRAF – PIF Score | Number of Points | 2 (IQR 0.5, 3) (Min 0, Max 8) | 2 (IQR 1,4) (Min 0, Max 8) | 2 (IQR 1,3) (Min 0, Max 8) |
| Fall Risk (GRAF – PIF $\geq$ 2) | No | 122 (44.9) | 47 (34.6) | 169 (41.4) |
| | Yes | 150 (55.2) | 89 (65.4) | 239 (58.6) |

Table 1. Sample characteristics

**Table 2. Faller Characteristics**

| Characteristic | | Faller (N = 136) n(%) or Median ($25^{th}$ %ile, $75^{th}$ %ile) |
|---|---|---|
| Number of Falls per child | | 1 (IQR 1,1) (Min 1, Max 5) |
| Injury | None | 90 (66.2) |
| | Minor | 45 (33.1) |
| | Moderate | 0 |
| | Severe | 1 (0.7) |
| Fall Type | Accidental | 71 (52.2) |
| | Anticipated physiological | 33 (24.3) |
| | Unanticipated physiological | 26 (19.1) |
| | Developmental | 6 (4.4) |
| GRAF – PIF $\geq$ 2 by fall type | Accidental | 44 (49.4) |
| | Anticipated physiological | 26 (29.2) |
| | Unanticipated physiological | 16 (18) |
| | Developmental | 3 (3.4) |
| Parent Present for Fall? | Yes | 92 (67.7) |
| | No | 16 (11.8) |
| | Unknown/Not Reported | 28 (20.6) |
| Length of Stay at Time of First Fall (days) | | 6 (IQR 2, 13) |

Table 2. Faller characteristics

**Figure 2. ROC curve**

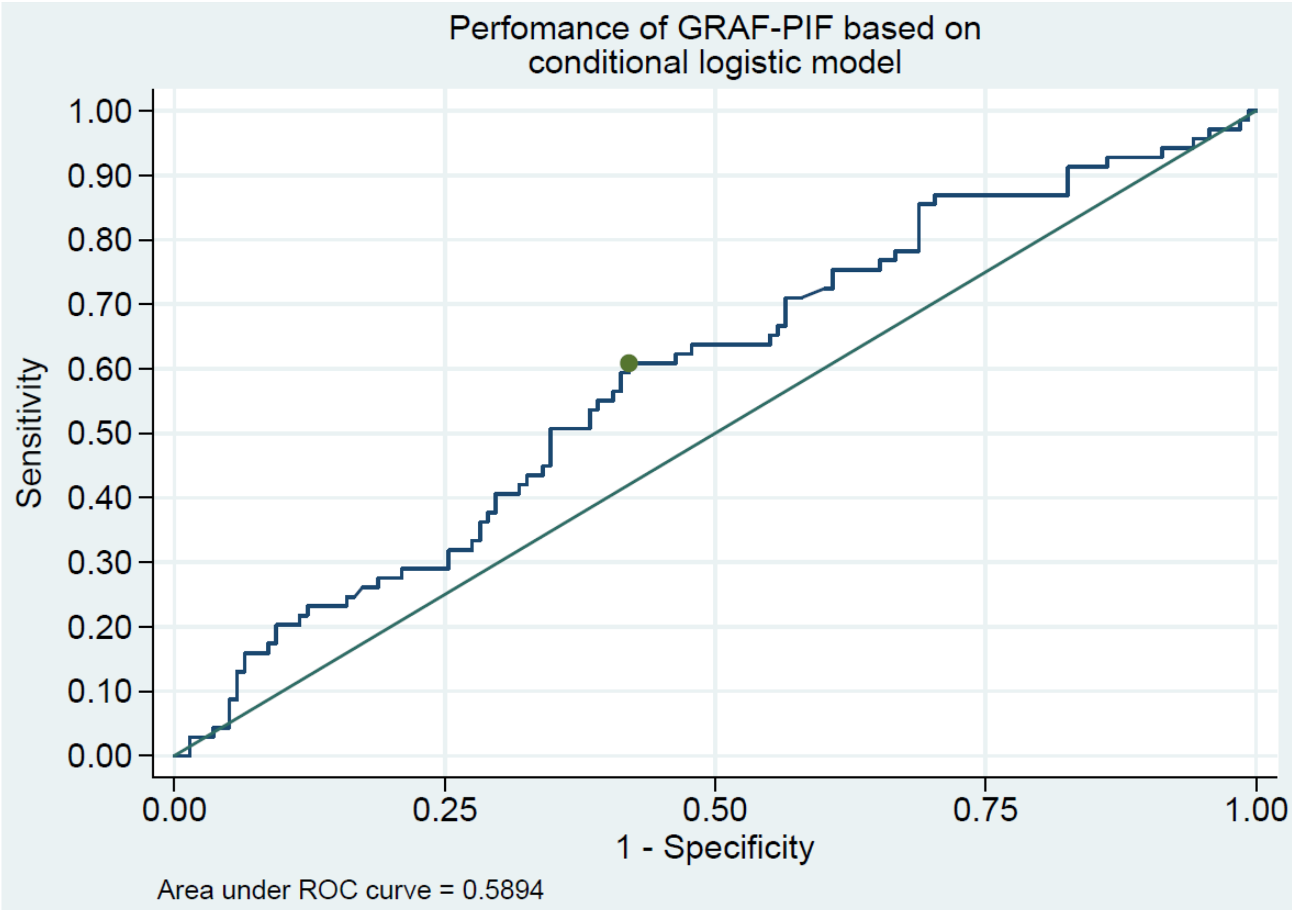


Figure 2. ROC curve for GRAF-PIF score of ≥ 2 points

**Table 3. Single and multivariable conditional logistic regressions**

| Patient characteristics | | OR | 95% CI for OR | *p* value |
|---|---|---|---|---|
| | Single-variable conditional logistic regression | | | |
| Fall Risk | No (GRAF – PIF Score < 2) | 1.0 | Reference | Reference |
| | Yes (GRAF – PIF Score ≥ 2) | 2.16 | (1.22, 3.84) | 0.009** |
| Sex | Male | 1.00 | Reference | Reference |
| | Female | 1.37 | (0.90, 2.08) | 0.141 |
| LOS | | 1.04 | (1.02, 1.06) | <0.001** |
| Diagnosis | Hematology/Oncology | 1.0 | Reference | Reference |
| | Cardiac | 2.04 | (0.94, 4.42) | 0.072 |
| | Endocrine/Metabolic | 0.66 | (0.11, 3.85) | 0.642 |
| | EENT/Craniofacial | 0.46 | (0.17, 1.23) | 0.122 |
| | Gastrointestinal/Digestive | 0.37 | (0.15, 0.87) | 0.023* |
| | Skin/Musculoskeletal/Orthopedic | 0.27 | (0.09, 0.88) | 0.030* |
| | Neurologic/Nervous System | 2.28 | (1.06, 4.91) | 0.034* |
| | Renal/Urinary | 0.81 | (0.25, 2.57) | 0.717 |
| | Respiratory/Pulmonary | 0.57 | (0.27, 1.21) | 0.144 |
| | Trauma/Injury/Poisonings | 2.44 | (0.50, 11.88) | 0.269 |

| Patient characteristics | | OR | 95% CI for OR | *p* value |
|---|---|---|---|---|
| | Multivariable conditional logistic regression | | | |
| Fall Risk | No (GRAF – PIF Score < 2) | 1.00 | Reference | Reference |
| | Yes (GRAF – PIF Score ≥ 2) | 2.08 | (1.05, 4.13) | 0.035* |
| Sex | Male | 1.0 | Reference | Reference |
| | Female | 1.21 | (0.76, 1.93) | 0.423 |
| LOS | | 1.04 | (1.01, 1.06) | 0.003** |
| Diagnosis | | | | |
| | Hematology/Oncology | 1.00 | Reference | Reference |
| | Cardiac | 2.37 | (1.05, 5.35) | 0.038* |
| | Endocrine/Metabolic | 0.98 | (0.15, 6.62) | 0.987 |
| | EENT/Craniofacial | 0.59 | (0.21, 1.66) | 0.321 |
| | Gastrointestinal/Digestive | 0.61 | (0.24, 1.52) | 0.285 |
| | Skin/Musculoskeletal/Orthopedic | 0.28 | (0.08, 0.96) | 0.043* |
| | Neurologic/Nervous System | 2.56 | (1.12, 5.84) | 0.026* |
| | Renal/Urinary | 1.05 | (0.32, 3.44) | 0.941 |
| | Respiratory/Pulmonary | 0.83 | (0.38, 1.86) | 0.657 |
| | Trauma/Injury/Poisonings | 4.98 | (0.78, 31.76) | 0.089 |

*$p \leq 0.05$
**$p \leq 0.01$
Table 3. Single and multivariable conditional logistic regressions

# CHAPTER 3

Pediatric Inpatient Fall Risk Characteristics: A Qualitative Study

Denise Sackinger, MN, RN, CPN, University of Washington and Seattle Children's, Seattle, WA, USA

Kristi Klee, DNP, MA, RN, CPN, Seattle Children's, Seattle, WA, USA

Brenda Zierler, PhD, RN, FAAN, University of Washington, Seattle, WA, USA

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**Correspondence:** Denise Sackinger, Seattle Children's, M/S FA.2.114, PO Box 5371, Seattle, WA, 98145-5005 (denise.sackinger@seattlechildrens.org)

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Abstract

Purpose: Pediatric fall risk assessment tools focus solely on patient-level factors contributing to risk of falling in the hospital. These tools neglect environmental, parent and healthcare employee factors which may contribute to fall risk. The purpose of this study was to describe pediatric inpatient fall risks through identifying themes in employee reports of pediatric falls over a two-year period and from a parent focus group discussion.

Design: Descriptive qualitative study

Methods: The study was conducted in two phases with different samples of participants. The first sample included 171 fall reports and was drawn from the organization's electronic incident reporting system. Falls described occurred in children 5 months to 20 years of age. Fall reports were reviewed and risk factors identified. These risk factors were then presented to a focus group of 12 parents to obtain parent perspectives of pediatric inpatient fall risks. The focus group transcript was subsequently examined for themes to understand parent perspectives of pediatric inpatient fall risks.

Results: Descriptive data from the fall reports yielded 19 risk factors, most of which included patient-level factors (intrinsic risks). The Interdisciplinary Momentary Confluence of Events Model (IMCEM) provided the framework for categorizing risks associated with child, environmental human, parent or caregiver characteristics. Identified risks from the incident reports fell into more than one risk category thus providing support for the multifactorial nature of fall causation as proposed in the IMCEM. Responses from parent focus group discussions were categorized into 5

groups: 1) changing conditions of the child and environment, 2) distractions, 3) parents functioning as a different part of themselves, 4) lack of knowledge of risks and 5) education considerations. The category of lack of knowledge of risk had three subthemes of "newness", reliance on healthcare providers and changing conditions and unexpected responses.

Practice implications: This study highlights the multi-factorial nature of fall risk. Additionally, this study described intrinsic and extrinsic fall risk factors which are not captured by current fall risk assessment tools. This study demonstrates the need for healthcare providers to provide on-going fall prevention and risk identification information and education with parents throughout hospitalization.

*Keywords*: fall, child, pediatric, hospital, inpatient, qualitative, multi-factorial

**What is currently known?** Falls are a common adverse event for hospitalized children. Fall risk assessment tools focus on patient-level risk factors, neglecting environmental, parent, and healthcare employee factors which may contribute to fall risk. Thus, even with the use of fall risk assessment tools, pediatric hospital falls are difficult to predict and prevent.

**What does this article add?** This study describes parents' perceptions of fall risks and the knowledge gap related to factors placing children at risk of falling in the hospital. Initial qualitative support for the ICEM is provided by highlighting the multi-factorial nature of falls and describing intrinsic and extrinsic risk factors not captured by fall risk assessment tools. The need for healthcare providers to provide on-going fall prevention and risk identification information and education with parents throughout hospitalization is demonstrated.

Pediatric Inpatient Fall Risk Characteristics: A Qualitative Study

## Introduction

Falls are the most common adverse event in hospitalized children accounting for about 42% of these events (Alemdaroglu et al., 2017; Da Rin Della Mora, Bagnasco, & Sasso, 2012; Fujita, Fujita, & Fujiwara, 2013; Lee, Yip, Goh, Chiam, & Ng, 2013). While children fall as a natural course of growing and developing, falls in the hospital may be more dangerous. Injuries from hospital falls can range from complaints of pain, skin redness/bruising to broken bones, or damage to prior surgical repairs. These injuries can increase the length of hospital stay (LOS) and cost of care and decrease parent satisfaction (AlSowailmi et al., 2018; Razmus, Wilson, Smith, & Newman, 2006). As a result, regulatory agencies such as the Joint Commission require that patients be assessed for fall risk and interventions put in place to mitigate these risks (Joint Commission, 2015).

The approach to fall risk assessment focuses on the use of standardized fall risk assessment tools. For children, fall risk assessment tools are based solely on patient characteristics, such as age, sex, LOS, presence of an intravenous catheter (IV) and cognitive/physical capabilities to aid in the prediction of fall likelihood (Bagnasco, Sobrero, Sperlinga, Tibaldi, & Sasso, 2010; Franck et al., 2017; Hill-Rodriguez et al., 2009; Jamerson et al., 2014; Razmus & Davis, 2012; Schaffer et al., 2012). Fall risk tools are intended to predict anticipated physiologic falls but not unanticipated, accidental or developmental falls. The current pediatric fall risk tools do not take into consideration parental characteristics which may

be leveraged or strengthened to decrease risk of their child falling in the hospital. Many commonly used pediatric fall risk assessment tools lack adequate sensitivity and specificity to reliably predict children who will fall in the hospital setting (DiGerolamo & Davis, 2017). As a result, prevention strategies focus only on identification of patient-level risk characteristics without consideration of parent and caregiver-level risk characteristics (Fujita et al., 2013; Lee et al., 2013). Thus, even with the use of fall risk assessment tools, falls are difficult to predict and prevent (The Joint Commission, 2015). There is a need to understand the multi-factorial nature of pediatric inpatient falls, which may not be captured with current fall risk assessment tools.

The purpose of this study was to describe risks surrounding pediatric inpatient falls at a children's hospital. This study aimed to:

1. Identify pediatric inpatient fall risks as described in hospital incident reports over a two-year period.
2. Describe parental perceptions of fall risks for pediatric inpatients as identified in a focus group discussion with an established parent advisory council.

## Methods

### Design

A descriptive qualitative study using data from hospital incident reports and a parent focus group discussion was undertaken to derive themes related to fall risks for children in the hospital. Using an interpretive research approach, themes were identified from hospital incident reports and a focus group transcript. Qualitative descriptive studies endeavor to interpret and derive themes with minimal transformation of the data (Sandelowski, 2010). As the aim of this study was to describe and understand risks

surrounding pediatric inpatient falls, a qualitative descriptive design was well suited for this study.

**Participants and recruitment**

**Subjects.** The study was conducted in two phases with different samples of participants. The populations of interest for this study were (1) children who experienced at least one fall in the hospital over a two-year period and (2) parents of children who had been admitted to the hospital at least once. The first sample was drawn from the hospital's incident reports for children admitted to a medical, surgical, oncology, rehabilitation, Pediatric Intensive Care Unit (PICU) or Cardiac Intensive Care Unit (CICU). Falls had to occur between January 2017 through December 2018 and meet the National Database of Nursing Quality Indicators (NDNQI) definition of an inpatient fall. The sample included 171 falls in 144 children and was drawn from the organizational electronic incident reporting system. The falls described occurred in children 5 months to 20 years of age.

The parent sample was a convenience sample composed of members of the organizational Family Advisory Council recruited for participation. The purpose of this council is to represent and advocate for concerns of parents served by the hospital with the goal of improving the care delivered at the organization. Members are recruited by other council members or referred by an employee of the organization or through publicity or outreach recruitment strategies. Members serve two-year terms. The Family Advisory Council is often engaged to provide feedback and make suggestions on matters related to patient and family experiences of care within the health care organization. In the past, council members have provided feedback to hospital

architects on facility design, and on pain management, billing statement improvements, etc. Of the 14 eligible family advisory council members approached for study enrollment, 12 agreed to participate in the focus group discussion. The group consisted of 9 mothers and 3 fathers of children cared for at the organization (range duration of care 6 months to 15 years) (Table 1). Participants had one or two children who previously or currently were receiving care at the organization. Eleven of the parents had a child who received care at the organization within the prior six months.

**Data collection and analysis**

Following IRB approval, risks surrounding pediatric inpatient falls were evaluated through a retrospective review of pediatric inpatient fall event reports. Fall event reports are completed by organization employees after a patient has experienced a fall in the hospital. A new report is completed for each fall the patient experiences. The report is often completed by the employee that initially recognized the fall event. The report may be completed by any employee that observes a fall but is frequently completed by nurses or physical/occupational therapists. The reports are completed electronically and include patient demographic information and other items (from a drop-down list) related to pre-fall status such as fall risks and prevention interventions. Additional items are related to location of the fall including department and location within the department (such as patient room, lobby, hallway, etc.) and role of the person who witnessed the fall (employee or parent). Two unstructured, free-text fields allow for unlimited description of 'what happened' in the fall event and suggestions for improvement/ prevention. The prompts for these boxes are: 1) Describe what happened and 2) Ideas for improvements, with no further prompts for content to be addressed in these fields.

While these fields are not mandatory, the description field is completed for a majority of the reports. The description of what happened are the data analyzed for this study.

The primary and co-investigator independently reviewed hospital incident reports and identified risk factors described in each report. The primary and co-investigator compared and agreed on risk factors for individual fall events. Once event level risk factors were identified, all risk factors were separated from the event descriptions. The risk factors were then compared to identify related themes, such as “wearing own socks”, “not wearing skid-free socks” were classified as related to footwear. Once risk factors were identified, Ryan-Wenger & Dufek’s (2013) Interdisciplinary Momentary Confluence of Events Model (IMCEM) (Figure 1) provided categories for coding identified risk factors. The risk factors were categorized into child, environmental, parent, and caregiver (employee) characteristics by the primary investigator. The co-investigator reviewed the list of risk factors and assigned categories to refute or validate the findings and had no further changes to the list.

The categorized fall risks were presented to the Family Advisory Council at a regularly scheduled meeting to facilitate a focus group discussion. The purpose of this discussion was to obtain qualitative data related to parental perceptions of pediatric inpatient fall risk characteristics. The focus group session lasted approximately thirty minutes. With permission of the group, the discussion was digitally recorded, and handwritten notes were written by a research assistant who was not involved in the discussion or group facilitation. Family Advisory Council members were sent a recruitment email prior to the scheduled meeting and were informed that participation was voluntary. Prior to beginning the focus group discussion, the study was explained,

and informed consent was obtained from participants. Fall risks derived from the incident reports were shared with the participants. Participants were then asked:

- From a parent's perspective, what are factors that place children at risk for falling in the hospital?
- What are your thoughts about whether the concepts of parent anxiety, depression, fatigue, stress and sleep deprivation might be associated with whether their child falls in the hospital?

Digital recording of the focus group was transcribed by an independent HIPAA compliant transcriptionist company. The PI compared the transcribed report with the digital recording for accuracy. The PI and the co-investigator then independently reviewed the focus group transcripts to identify parent described themes related to risks of hospital falls in children. The PI then collated and categorized the focus group themes. The co-investigator then reviewed and validated the categorized themes.

## Results

Nineteen risk factors were derived from hospital incident reports (Table 2). These risks were varied and categorized by environmental human, child, parent and caregiver factors. Not only did most patients have more than one risk factor at the time of the fall but many of the risks could be assigned to more than one category. For example, "the risk of fall despite safety device use" was classified as an environmental human and child factor. In some instances, the manner in which the child utilized the safety device contributed to the fall, for example a child leaning too far forward while using a walker to ambulate. This risk also fell into the environmental human category as in some instances the interaction of the safety device and environment contributed to the fall,

such as when a child was riding down a ramp in a wheelchair and the wheelchair tipped forward. Additionally, the unfamiliar environment and hard floor often contributed to the extent of injuries experienced by the child.

The parent focus group data yielded four themes related to fall risk and an additional theme of education considerations (Table 1). The theme of lack of knowledge of fall risks had three subthemes which were: reliance on healthcare providers, "newness," and unexpected responses of the child. Participants reported not being aware that falls were a concern for children in the hospital. They did not think of their child as being at risk of falling as they thought of falls as a concern for the elderly or those who were not previously healthy.

> "I don't think of necessarily when we think of fall risk, I think of elderly, I think of clear, like, categories of individuals who were a fall risk. I don't always think – seemingly healthy until I landed here – child and what those impacts would be." [Parent #12]

Lack of knowledge was also reflected in the subtheme of reliance on healthcare providers. Parents reported relying on hospital employees to identify environmental factors that placed their child at risk of falling:

> "Between the two of us [parent and healthcare providers], I would assume I'm the one that knows this environment the least." [Parent #3]
>
> "I would assume that I could catch the obvious risk, but there are a lot of hidden risks that I wouldn't know of until a situation happens or almost happens. And that's been my experience when I've been -- when he's fallen. It has usually been something that I didn't even know was a risk." [Parent #3]

Parents relied on healthcare providers to initiate communication related to fall prevention and to proactively make plans “with the parent ahead of time in terms of who’s responsible for supporting the [child] while they go to the bathroom, when they’re pulling an IV pole or something like that, for instance.” [Parent #4]

Parent lack of knowledge of fall risks was reflected in the subtheme of “newness.” “Newness” was described in relation to not only the environment but the constantly changing situations and condition of the child.

> “One area I have seen is just the overall “newness” of the situation. Here’s what I mean by that: you’re in a different room; you have, in some cases, a new condition or an evolving condition. You have different equipment. So, there’s exponentially new things. So, as a parent, I may or may not know how safe or unsafe that situation is because I may or may not know the difference in those factors.” [Parent #3]

In the hospital, patients are in an unfamiliar (“new”) room that is set up similar to a bedroom, but that environment is not the same as their home bedroom.

> “You’re in a room that’s sort of a mock bedroom and things you allow at home, you cannot allow in this room because the floor’s so hard. And I hadn’t really thought that through. Falling off the bed here is different than falling off the bed at home because at home, there’s a carpeted floor or it’s only this far down, and here it’s a lot further and it’s hard and there’s line attachments to the kid and everything. So, it’s just interesting that the environment has a sense of feeling – trying to feel comfortable but it’s not the same, if that makes sense. So, I think, yeah, the newness for sure.” [Parent #9]

The subtheme of newness and theme of parent lack of knowledge of fall risk was also reflected in the subtheme changing conditions (newness) and unexpected responses (lack of knowledge).

> "I feel like the risk of falling for my son, who … hasn't fallen too much, it really -- I felt like he was less safe when his condition was kind of changing. So, I guess that would be part of the newness. As he was either getting worse when he was staying in the hospital or better." [Parent #6]

Children also had unexpected responses for which the parents could not predict or prepare.

> "It's actually new for us and my daughter actually did fall. She's had 12 surgeries or procedures where she's had to be sedated, all here and until she hit puberty, the anesthesia affected her differently. She woke up as like a mean drunk, where she'd never done in the 10 previous surgeries before. And so, her anxiety of trying to get out of the bed and get out of here was real. It was the issue that we came across that was brand new to us that we'd never experienced or even anticipated." [Parent #10]

> "Just like thinking if they're out of the bed, you're like, 'Oh, yeah. You can get out and we'll let you walk with your pole,' but they run. And you're like, 'Oh, I didn't know you were running today' [laughter]. Things like that I think have been maybe … I don't know … issues, just being surprised by either their willpower or their energy level." [Parent #12]

> "One of our earlier post-first experience MRIs -- my daughter handled anesthesia reasonably well and she was still young, so she was under anesthesia for the

MRI early in the morning. And then, we were in clinic in the later afternoon and she was feeling good. Though we had been told that anesthesia can stay in your body and affect you, she ran down the hallway and fell on her face. We don't let her run after anesthesia anymore [laughter] and she didn't get hurt, but it was definitely one of those -- because she seemed okay. She was feeling really spry. She was pulling on us and wanting to run a little and she fell, of course." [Parent #5]

The second theme of interactions of the child with the environment was reflected when parents noted that –

> "the [hospital] rooms aren't always laid out optimally for a child. In my child's room, I may say, 'Oh, I know my child blah, blah, blah. And so, I'm going to move this, I'm going to move this.' But we get the rooms when they're there." [Parent #3]

Patient rooms may not be laid out in a manner which takes into consideration the patient's unique musculoskeletal needs which can place the child at increased risk of falling.

> "this is something that is particularly around equipment and I don't know how many times this comes up. But my son has a defect in one of his arms. So, equipment that would work for every other child is a lot more difficult for him. So, the time he actually fell, … I had to point out to the staff that their expectations of him were unrealistic because of his physical condition. Because they had an expectation, 'Oh, a child this age can use this equipment in this way.' And like, 'You're not taking into consideration that he's off-balance because one of his

arms functions differently.' And so, I don't even know where that falls out, but it was the interplay between equipment and a physical defect with my son." [Parent #3]

Distractions was a theme that was identified in both the incident reports and the focus group discussion. The theme of distractions was reflected in incident reports as times when employees or parents simply looked away from the child and "self-care" distractions when the parent was either resting or using the bathroom. A theme of distractions related to parent and healthcare provider interactions was seen in both the incident reports and the parent focus group discussion. Two of the employee reported falls were at a time when the parent was either receiving discharge instructions by the nurse or receiving new diagnosis education. Parents expressed that often discussions with healthcare providers required them to divert attention from the child to the healthcare provider:

"Just because you and the nurse and the doctors are present doesn't mean that your eyeballs are on the child. So that was something that was personally very interesting was just the number of times I would have someone come into the room and just sort of command all of my attention. Even when I didn't necessarily want to give them all my attention. But they were sort of like-- I think it has to do with just the, 'I've got to get through this conversation. I have a limited amount of time.' And so, sometimes, I would be trying to do something with my child but they're just like, 'I need your attention.' So even though you're physically present, you're not really present. So, that's one issue." [Parent #3]

The theme of parents functioning as a different part of themselves was reflected when focus group members were presented with five possible parent psychophysical characteristics (anxiety, depression, fatigue, sleep deprivation and stress) which some researchers have hypothesized to be associated with pediatric inpatient falls. Parents agreed all of these characteristics are present in parents and may impact fall risk when their child is hospitalized.

> "I can't think of any parent in the hospital that's not always dealing with one or more of those at -- the same time." [Parent #9]
>
> "Yeah ... I mean, it's like you're hard-pressed to find anybody, especially in oncology, that's not all those things." [Parent #9]

Parents reported they were functioning as a different part of themselves, merely trying to survive during the stressful times of hospitalization. They reflected this "different" state may have placed their child at risk of falling.

> "Well, as I'm thinking about all of these feelings and kind of feeling them again as though -- in a hospital stay. There's something that happens physically as well as emotionally with me when I'm in this kind of a situation and I'm not able to function like I normally would. Things are slower. My reaction time is slower. My ability to take in -- maybe if I was trained on how to keep my child from falling, I probably wouldn't remember all the things that I should maybe try to do. And then, yeah, I think as I start thinking about it, I'm definitely feeling like just when I'm in a hospital setting and feeling these kinds of things, I'm not able to function kind of even as a normal parent and here we are with a child who is in just a more critical situation and does need more care from me. So, I think for sure

those -- just my ability to function would definitely affect my ability to help my child not fall." [Parent #6]

"When I think about all of these feelings, I don't realize I had anxiety, depression, fatigue, stress, or sleep deprivation until I'm out of the hospital. So, for a full year, I would think, 'We are handling this very well.' If you would have asked me how I'm doing, I'm like, 'We're fine. He's not dead. We are surviving' and it's not until he gets out, 'I guess I was really tired.' So, I don't know that I would have attributed any of his stuff to me not being on point, because, in my mind, I'm thinking, 'I'm doing the best I can and we're managing.' I just don't necessarily put that -- it's PTSD. I don't know how other parents feel but it's definitely later where I realize I hadn't been myself for six months when I was there. I'm like, 'Yeah, I'm normal,' then people show me text messages. 'I said that [laughter]?' But you don't understand it till later. So, it's hard for me to say how that attributed one way or another because you're functioning as this different part of yourself." [Parent #12]

A strong theme woven through most of the focus group discussion was that of education. While the parents felt "the nurses and doctors did a really good job of explaining a lot of things to us, but they didn't talk to us about falling, specifically. I'm sure there's other things they didn't talk to us about either because there was lots of other things to focus on" [Parent #7]. Parents reported not realizing hospitals falls was a concern for children. Parents often did not remember seeing the fall risk sign in the child's room. However, there were times when they noticed the sign, but the parent was not informed of the characteristics placing the child at risk for falling.

> “I remember when I saw that sign for the first time, when [my son] was in the hospital, and I really wasn't -- the boy was not going to be moving for a long time. But I remember seeing that and actually kind of wishing he was a fall risk. It was a funny thought, but as he became -- it was much, much later that he was moving around more. But I didn't know, and I did not actually get any education at all, at all, at all about that in thinking about that now. But never did. So, education would be very helpful.” [Parent #6]

Parents felt they could better help prevent falls if they were given education on the impact of hospital falls, why their child was at risk of falling and prevention strategies for their child. This education needed to be reinforced for the duration of the child’s hospital stay.

> “it's always a changing game and constant education on that [fall risks] probably would be very helpful.” [Parent #6]

## Discussion

Ryan-Wagner and Dufek (2013) described falls as the result of a “momentary convergence of child, parent, and caregiver human [characteristics], … and system factors” (p. 4). The IMCEM posits falls are the result of at least two events that momentarily converge and necessitate a quick response to prevent falls (Ryan-Wenger & Dufek, 2013). Central to the model are pediatric falls and injuries. Unmitigated weaknesses in more than one risk category leaves the child vulnerable to falls. Risk categories are divided into intrinsic and extrinsic systems.

***Intrinsic factors.*** Intrinsic factors include child characteristics, environmental human characteristics, and biomechanical factors (Ryan-Wenger & Dufek, 2013).

Biomechanical factor risks were not identified in the data. Child characteristics include physical, psychological or developmental features of the child that impact one's fall risk. Examples of these characteristics are age, sex, medical diagnosis, medications, treatments, body mass and developmental stage. Developmental stage can impact inpatient falls related to the normal course of development, risk-taking, cognitive ability, and language skills. The normal process of learning to walk increases children's risk for falling during this vulnerable time. Child characteristics are used in fall risk assessment tools to identify if the child is at high risk of falling. As such, hospital fall prevention strategies include increased attention to children with these characteristics which place them at higher risk of falling.

Environmental human characteristics are the interactions of the child with their environment which impacts their fall risk and resultant injury (Ryan-Wenger & Dufek, 2013). Environmental human characteristics that can impact fall risk include the condition of the physical environment such as cleanliness, dry floors, removal of unnecessary equipment from the room, etc. (Rosenberg et al., 2016). Unfamiliarity with the hospital environment and characteristics of room layout may place the child at increased risk of falling due to disorientation. Environmental human characteristics also include qualities of equipment and construction of the environment. Infants and toddlers often fall or roll-off of objects (Jamerson et al., 2014) which include cribs where the side rails are not completely latched or are left in a lowered position allowing the child to roll out of the crib. The composition of flooring is often a firm covering (such as ceramic tile) over concrete which places the child at greater risk of injury when a fall occurs.

***Extrinsic factors.*** Extrinsic factors include caregiver (healthcare employee) characteristics, parent characteristics, and system factors. System factor risks were not identified in the data. Parent characteristics are extrinsic factors related to the parent that may be associated with the child experiencing a fall during hospitalization. The association of parental characteristics with pediatric hospital falls warrants further investigation as parents are often present when children fall in the hospital, and these children are more likely to be injured from the fall (Bagnasco et al., 2010; Jamerson et al., 2014; Lee et al., 2013; Schaffer et al., 2012). While the association of parental presence with pediatric hospital falls has been identified in several studies (Bagnasco et al., 2010; Jamerson et al., 2014; Lee et al., 2013; Schaffer et al., 2012), there is a lack of understanding as to why this association exists and how to leverage parental presence to decrease these falls. Parental factors such as anxiety, fatigue, and stress may contribute to the association between parent characteristics and falls (Da Rin Della Mora et al., 2012; Jamerson et al., 2014; Lee et al., 2013; Ryan-Wenger & Dufek, 2013). The evidence is clear that having a child in the hospital has been demonstrated to be stressful for parents (Busse, Stromgren, Thorngate, & Thomas, 2013; Commodari, 2010). What is less clear is whether this stress is associated with the safety of their child in the hospital environment. Parental stress, anxiety, and depression have been shown to be associated with pediatric injuries outside of the hospital, too (Acar et al., 2015; McKinlay et al., 2010; Schwebel & Brezausek, 2008).

In this study, the brief employee reports of inpatient fall events focused mainly on intrinsic factors (child and environmental human factors), whereas, the parent focus group provided a robust understanding of extrinsic factors associated with pediatric

hospital falls (parent and caregiver factors). Themes identified in both phases of the study were categorized into four of the six risk categories proposed by Ryan-Wenger and Dufek (2013). Additionally, most of the identified themes fell into more than one of the risk categories thus providing support for the multifactorial nature of inpatient falls as represented in the IMCEM.

This study provides initial qualitative support of the IMCEM in understanding the multifactorial nature of pediatric inpatient falls. Currently, fall prevention strategies are often aimed at providing support to compensate for child factors and mitigate environmental human factors which place children at greater risk for falling in the hospital. This approach to fall prevention does not account for extrinsic factors that might contribute to pediatric hospital falls. Approaches to mitigate extrinsic factors include noticing times when parents are distracted from care of their child as a result of healthcare provider interactions. Constant education on environmental and patient risk factors can help parents to be cognizant of risks and potential outcomes related to hospital falls. As healthcare providers and parents work together to identify and mitigate fall risks from intrinsic and extrinsic factors fall prevention programs will be stronger.

## Limitations

Retrospective use of employee reports of patient fall events was a limitation. These reports were brief free text descriptions of the falls. There were no standard guidelines for how falls were described. Themes could only be derived from text in the reports. No conclusions could be made about information not included in the fall reports. For example, many reports did not state whether the child hit their head when they fell. However, if this information was not included in the report, we could not assume the

child didn't hit their head. We were limited by what employees included in the brief report.

Use of a family advisory council for a focus group discussion was a strength and a limitation. The family advisory council members had varied hospital experiences which was helpful in providing a broad understanding of hospital fall risks. Additionally, nurses and patient care providers were not present for this discussion, so parents likely provided feedback and insights more freely. The limitations in this approach lie in that not all parents had a child who fell in the hospital. However, the group discussion provided parents with knowledge of other's fall experience and allowed participants to reconsider potential fall risks.

## How might this information affect nursing practice?

This study ascertained parents' perceptions of fall risks and highlighted the lack of knowledge this group had about factors that may place a child at greater risk of falling in the hospital. The hospital environment is more familiar to employees than for parents and children. Parents often depend on healthcare providers to identify fall risks specific to their child and to collaboratively plan strategies to decrease risk. Nurses and other patient care providers can help raise the awareness of factors contributing to fall risk and potential consequences of falling in the hospital. As focus group participants in this study indicated, parents of hospitalized children are often not functioning at their best due to a variety of psychophysical characteristics, such as stress, sleep disturbance, fatigue, anxiety and depression. As a result of this different level of functioning, healthcare providers need to continuously provide fall prevention and risk education with patient care interactions.

Tables and Figures

Table 1. Focus group characteristics and themes (n=12).

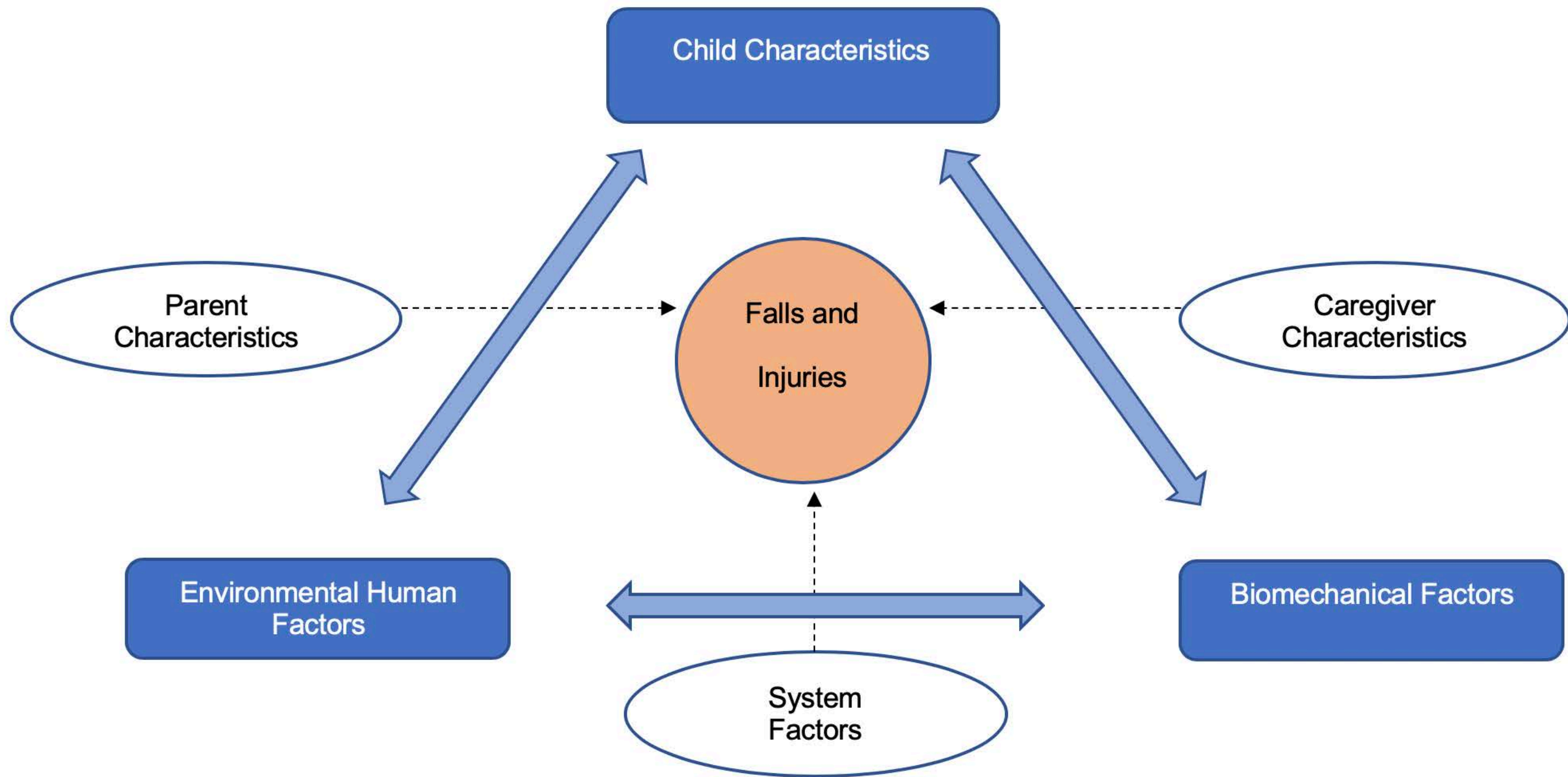
| **Focus group characteristics** | | |
|---|---|---|
| | | n (%) or median (25%ile, 75%ile) |
| Relationship to child | Mother | 9 (75%) |
| | Father | 3 (25%) |
| Number of children who received care at the organization | 1 | 6 (50%) |
| | 2 | 6 (50%) |
| Child ever fallen during hospitalization | No | 8 (75%) |
| | Yes | 4 (33%) |
| Duration of care received by the child | | 80.5 months (45.5,120 months) |
| Duration of time since last received care at the organization | | 1 month (0.5, 12 months) |

| **Focus group themes** |
|---|
| Lack of knowledge of risks |
| "Newness" |
| Reliance on healthcare providers |
| Changing conditions and unexpected responses |
| Interactions of child and environment |
| Distractions |
| Parents functioning as a different part of themselves |
| Education considerations |

Table 2. Themes from fall reports of pediatric inpatient falls (n = 171).

| Environmental Human Factors | Child Factors | Parent Factors | Caregiver (healthcare provider) Factors |
|---|---|---|---|
| Fall despite safety device use | Fall despite safety device use | | |
| | Safety device not used | Safety device not used | |
| | Balance | | |
| | | Self-care | |
| | Clutter | | |
| Toileting/dressing | Toileting/dressing | | |
| Crib/bed | Crib/bed | Crib/bed | |
| | Tip over | | |
| | Seizure | | |
| Slippery floor | Slippery floor | Slippery floor | Slippery floor |
| | Weakness | | |
| Trip | Trip | | |
| Equipment/toys | Equipment/toys | | |
| Running/playing | Running/playing | | |
| Footwear | Footwear | Footwear | Footwear |
| | | Distraction | Distraction |
| Reaching | Reaching | | |
| | Climbing | | |
| | Without help | | |

Figure 1. Interdisciplinary momentary confluence of events model (Ryan-Wenger & Dufek, 2013)



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# CHAPTER 4

## Association of Parent Demographic and Psychophysical Characteristics and Pediatric Hospital Falls: A Pilot and Feasibility Study

Denise Sackinger, MN, RN, CPN, University of Washington and Seattle Children's

Kristen Carlin, MPH, Seattle Children's Research Institute

Brenda Zierler, PhD RN, FAAN, University of Washington

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Abstract

Purpose: The aim of this pilot study was to evaluate feasibility of and determine an adequately powered sample size for conducting a study to describe parental demographic and psychophysical characteristics associated with pediatric hospital falls.

Methods: This observational case-control study enrolled parent-child dyads of children who fell in the hospital and age-matched controls who did not fall. Parents completed demographic, anxiety, depression, fatigue, sleep disturbance and stress questionnaires.

Results: Only four of 14 (28.6%) eligible faller dyads were recruited. Stress scores were correlated with anxiety and depression scores. Power calculations indicated a need for 392 fallers and 1,176 non-fallers for a future hypothesis testing study to identify associations of parent characteristics and pediatric hospital falls.

Conclusions: Parents should be informed that the ultimate goal of the research is to understand additional ways to prevent pediatric hospital falls. To decrease parental distraction during recruitment, researchers should engage volunteers or child life specialists to entertain younger children. Future studies should consider inclusion of non-English speaking subjects and children discharged within the post-fall eligibility time frame. To decrease multicollinearity concerns, the parent stress tool should be omitted. Due to the large number of fallers needed for an adequately powered sample, the feasibility of a future study will be improved by conducting a multi-site study to test associations of parent characteristics with pediatric hospital falls.

Practice Implications: Parent are often present when their child falls in the hospital. The current approach to fall risk assessment focuses solely on patient characteristics, neglecting parental demographic and/or psychophysical characteristics which may be associated with risk of their child falling in the hospital. Associations of parent psychophysical characteristics and pediatric hospital falls need to be studied further. This pilot study tests the feasibility of and provides

recommendations for conducting a study to describe parent characteristics associated with pediatric hospital falls.

## Background

A fall is "an unintentional descent…that results in the patient coming to rest" at a lower position (National Database of Nursing Quality Indicators, 2016, p. 2). Falls account for about 42% of reported adverse events in hospitalized children (Alemdaroglu et al., 2017; Da Rin Della Mora, Bagnasco, & Sasso, 2012; Fujita, Fujita, & Fujiwara, 2013; Lee, Yip, Goh, Chiam, & Ng, 2013). Parents are present for 60 - 83% of these falls (Bagnasco, Sobrero, Sperlinga, Tibaldi, & Sasso, 2010; Jamerson et al., 2014; Lee et al., 2013; Razmus, Wilson, Smith, & Newman, 2006). In a study by Jamerson et al (2014), 90% of parents who were in the child's room at the time of the fall also witnessed the fall occur. In fact, children were more likely to be injured from a hospital fall when a parent or adult was present (Jamerson et al., 2014; Schaffer et al., 2012). While we do not know why this association exists, some hypothesize that parental characteristics including demographic (Almis, Bucak, Konca, & Turgut, 2017) and other characteristics, such as anxiety, fatigue, and stress may contribute to the risk of pediatric hospital falls by causing parents to be distracted or less vigilant (Da Rin Della Mora et al., 2012; Jamerson et al., 2014; Kingston, Bryant, & Speer, 2010; Lee et al., 2013; Ryan-Wenger & Dufek, 2013). The association of parent psychophysical characteristics with pediatric hospital falls has not yet been tested. Psychophysical characteristics have both psychological and physical components which may impact a parent's responses. While researchers are beginning to investigate the association of parent demographic characteristics and pediatric hospital falls (Almis et al., 2017), further research of this association in addition to parental psychophysical characteristics is needed.

### Parent Characteristics Associated with Pediatric Injuries Outside the Hospital

Researchers have hypothesized that the risk of pediatric hospital falls may be impacted by parent characteristics such as anxiety, stress, depression, sleep pattern alterations, tiredness

and fatigue which may cause them to be distracted or less vigilant, at moments when other fall risk factors converge (Da Rin Della Mora et al., 2012; Jamerson et al., 2014; Ryan-Wenger & Dufek, 2013). Associations of parent characteristics and hospital fall injuries have yet to be studied. However, outside of the hospital, decreased parent supervision activities (e.g. watching, listening and proximity) have been found to be associated with injuries requiring medical attention in young children ($OR = 5.39$) (Morrongiello, Corbett, & Brison, 2009). It is unclear if parent supervision activities are impacted by parent psychophysical characteristics such as depression or stress. Some studies found weak to no association of moderate levels of maternal depression with child injury risk (Rhodes & Iwashyna, 2007; Schwebel & Brezausek, 2008). However, a strong association between chronic maternal depression and child injury risk was found ($t = 4.31$, $p < 0.01$) (Schwebel & Brezausek, 2008). Maternal depression has been shown to be associated with decreased social support and increased self-reported stress (Mulvaney & Kendrick, 2005). Lack of social support has been found to be associated with less safe home environments ($OR = 0.43$, *95% CI*: 0.23, 0.81) (Rhodes & Iwashyna, 2007). Parenting stress was not found to be different between injured and non-injured preschoolers ($t = 1.74$, $p = 0.08$) (Bruce, Lake, Eden, & Denney, 2004). However, the number of adverse family events (such as changes in residence, school, sleep habits, health of a family member, etcetera (etc.)) has been found to be associated with increased injuries in children outside of the hospital (McKinlay et al., 2010). In fact, four or more adverse events in the prior year was associated with almost three times the risk of traumatic brain injury in children ($HR = 2.89$) (McKinlay et al., 2010).

## Impact on Parents of Hospitalized Children

It is clear that having a child hospitalized contributes to multiple physiological and psychological challenges for parents. These challenges have been measured as anxiety (Barnes, Tollefson, Hickey, Bares, & Zhang, 2017; Needle, O'Riordan, & Smith, 2009; Rosenberg et al., 2017; Scrimin, Haynes, Altoè, Bornstein, & Axia, 2009; Stremler, Haddad,

Pullenayegum, & Parshuram, 2017), depression (Barnes et al., 2017; Fauman et al., 2011; Stremler et al., 2017), stress (Board, 2004; Commodari, 2010; Garro, Thurman, Kerwin, & Ducette, 2005; Hagstrom, 2017; Hasan Tehrani, Haghighi, & Bazmamoun, 2012; Scrimin et al., 2009), fatigue (Stremler et al., 2014), and sleep alterations (McCann, 2008; Stremler et al., 2014). In fact, Busse et al. (2013) measured the concept of stress using a battery of Patient Reported Outcomes Measures (PROMIS). This battery consisted of short form PROMIS tools to measure parent's anxiety, depression, fatigue, and sleep disturbance (Busse et al., 2013).

Parental difficulties related to their child's hospitalization in acute care and intensive care settings have been studied. As expected, parental anxiety increased when their child was admitted to the intensive care unit (Al Maghaireh, Abdullah, Chan, Piaw, & Al Kawafha, 2016; Needle et al., 2009). For children hospitalized with an acute illness, parental stress increased as the child's length of hospitalization increased (Commodari, 2010; Hasan Tehrani et al., 2012). Interestingly for children with a chronic illness, a planned admission to the Pediatric Intensive Care Unit (PICU) was associated with a 4.6 times greater risk of parent depression as measured by the Beck Depression Inventory (BDI-II) compared to an unplanned admission (Fauman et al., 2011). This finding may be due to the extended period of time spent planning for the admission resulting in greater levels of stress. Stress associated with an unplanned admission may be lower as a result of less time managing the current illness exacerbation or the parent not having time yet to process the severity of situation. Duration of the chronic illness was inversely associated with parental depression (Fauman et al., 2011). Parents of children who had a chronic condition for less than three years reported higher depression scores and those with a chronic condition for at least nine years reported lower depression scores (Fauman et al., 2011). Evidence validates the psychophysical impacts on parents associated with hospitalization of their children. However, there is a gap in knowledge of how these psychophysical impacts are associated with their child's safety in the hospital, specifically risk of falling.

## Parent Characteristics Associated with Pediatric Hospital Falls

The presence of a parent is not a protective factor against pediatric hospital falls (Jamerson et al., 2014; Lee et al., 2013; Razmus et al., 2006). Some propose this may be due to parental distraction, fatigue or stress (Da Rin Della Mora et al., 2012; Fujita et al., 2013; Jamerson et al., 2014; Lee et al., 2013; Ryan-Wenger & Dufek, 2013). However, only one study that attempted to understand parental characteristics associated with pediatric inpatient falls was found (Almis et al., 2017). This observational study was conducted at a 600-bed teaching hospital in Turkey. The pediatric units had 118 beds: 65 general unit, 11 intensive care, 25 neonatal intensive care and 17 emergency department beds. The study was a matched case-controlled observational study. Thirty-nine parent-child dyads of children who fell over the course of approximately one year were matched based on age and gender of the patient and parent with 78 non-faller parent-child dyads (1:2 match). The total sample size was 117 parent-child dyads. Dyads were excluded if the patient or parent had a chronic disease or were taking medications which could cause anxiety, sleep deprivation, restlessness or could increase stress levels. Additionally, if the parent had a known psychiatric disorder the dyad was excluded. Data were collected from a parent questionnaire which included items related to the parent's age, smoking habits, educational level, employment status, patient demographic characteristics including number of siblings, length of stay (LOS), and prior fall history. Additionally, data regarding child age and gender were obtained (Almis et al., 2017).

The study found no difference in age or gender of patients or parents between the faller and non-faller groups. This finding is expected since the sample was matched based on these characteristics. Similar to other studies (Graf, 2005), these results indicated a longer LOS was associated with increased odds of the child falling (*OR* = 2.04, *95% CI*: 1.40, 2.95). No other measured patient characteristics were reported to be associated with odds of falling in this study. Parental characteristics found to be associated with a higher odds of the child falling were lower education level (*OR* = 0.32, *95% CI:* 0.14, 0.69) and smoking (*OR* = 5.80, *95% CI:*

1.19, 28.19). Interestingly, parents who smoked were not present when their child fell. The authors provided no further comment on whether the parents who smoked were not with their child at the time of the fall for reasons related to their smoking habit (Almis et al., 2017).

While this study is novel in that it begins to identify parental characteristics associated with pediatric inpatient falls, there were several limitations. The only parental characteristics included in this study were demographic characteristics, thus omitting psychophysical characteristics, such as anxiety, depression, fatigue, sleep deprivation and stress, hypothesized to be associated with these falls. In fact, the study specifically excluded parents with a psychiatric diagnosis. Additionally, patients or parents who were receiving/taking medications which could increase stress, anxiety, restlessness, or cause sleep deprivation were excluded. Exclusion of parents with these characteristics does not allow for description of associations of these characteristics with pediatric inpatient falls. The authors attributed the findings of increased odds of falling and longer LOS, to increased parent stress, anxiety and distraction (Almis et al., 2017). However; the researchers did not report gathering any data related to stress, anxiety or distraction.

While there is evidence of the association of parent supervision activities and psychophysical characteristics with injuries outside of the hospital, this evidence does not exist for hospital injuries and falls. It is unclear if the hospital experience or environment contributes to changes in parent vigilance with supervision activities. Further research describing parental characteristics associated with pediatric hospital falls is needed, especially in relation to psychophysical characteristics such as anxiety, fatigue, stress, and etc. that can be identified and mitigated during the hospitalization. While the association of parental presence and pediatric hospital falls has been identified (Bagnasco et al., 2010; Jamerson et al., 2014; Lee et al., 2013; Schaffer et al., 2012), there is a lack of understanding as to why this association exists and how to leverage parental presence to decrease these falls. Parents are often with

children during hospitalization. As such, it is key that the healthcare team partners with parents to promote optimal child safety during hospitalization.

While pediatric hospital falls are the most common type of adverse events reported for hospitalized children (Alemdaroglu et al., 2017; Da Rin Della Mora et al., 2012; Fujita et al., 2013; Lee et al., 2013), they are still relatively rare occurrences at a reported prevalence of 0.56 to 2.19 falls per 1,000 patient days (Almis et al., 2017; Fujita et al., 2013; Jamerson et al., 2014; Pauley, Houston, Cheng, & Johnston, 2014; Schaffer et al., 2012). Since falls are unpredictable, pre-fall measurements of parent psychophysical characteristics are not practical. For research purposes, parent characteristic data need to be collected within a defined time period after the fall event to support associations with the event. This time period must be relatively short to limit the impact of parent recall bias. The ability to recruit parents of children who have fallen in the hospital may be limited by at least two factors: 1) parents must be physically available for recruitment during specified post-fall time frame, 2) parents may feel "blamed" for the fall and thus be resistant to participating in this study. As a result, the duration of time needed to recruit a sufficiently powered sample is unclear. Thus, a pilot study was undertaken to evaluate the feasibility of conducting a future study aimed at describing parental demographic and psychophysical characteristics, specifically anxiety; depression; fatigue; sleep disturbance; and stress, associated with pediatric inpatient falls.

## Objective

The aim of the current pilot study was to evaluate the feasibility of conducting a future study to describe parental characteristics associated with pediatric inpatient falls. Feasibility will be addressed by evaluating recruitment, equipment needs, instrument acceptability as well as descriptive data to inform power analysis for future research. This aim was addressed by:

1. Describing the current fall population at a children's hospital over a 2.5-month period.

2. Identifying the number of eligible case subjects (faller parent-child dyads) that can be enrolled for a future study aimed at identifying parent characteristics associated with pediatric hospital falls.
3. Identifying sample size needed for an adequately powered (80%) study to describe parent characteristics associated with pediatric inpatient falls.

## Methods

### Study Design

An observational case-control study was undertaken to evaluate the feasibility of conducting a future study to recruit subjects and describe parent characteristics (demographic and psychophysical) associated with children falling in the hospital.

### Setting

This study was conducted at a free-standing children's hospital in the northwest United States. The hospital provides inpatient, outpatient, and ambulatory care services across multiple pediatric specialties. It serves as a quaternary referral center for a four-state region. The hospital is licensed for 407 inpatient beds with an average daily census of 290 patients. The nurse to patient ratio for acute care units range from one nurse to two to four patients depending on the unit and patient acuity with an average ratio of one nurse to three patients. In the year immediately preceding data collection, the fall rate across units included in the study was 1.08 per 1,000 patient days (January 2019 – December 2019). Parents were reported to be present for 78% of these falls.

### Subjects

The population of interest was parent-child dyads of children who fell in the hospital and parent-child dyads of the child's age matched controls. Parent was defined as a person listed in the medical record as the child's guardian, legal custodian or was permitted to provide consent for care. Child was defined as a patient less 18 years of age. Additionally, since the fall risk assessment tool is completed for children 1 year of age or older, children less than 1 year old

were not included. Since the consent and all data collection tools were in English, potential parent subjects were limited to those who were able to communicate in the English language.

Parent-child dyads of children admitted to a Medical, Surgical, Oncology, Rehabilitation, PICU, and Cardiac Intensive Care Unit (CICU) inpatient units were included in the study. While the Neonatal Intensive Care Unit (NICU) occasionally has a patient who is 1 year of age or older, parent-child dyads in this unit were not included in the study. The NICU has not had a patient fall/drop in the last sixteen quarters. Additionally; while parents are encouraged to stay with their child as much as they desire, they are not permitted to sleep in the NICU room. Similarly, parents do not stay overnight with patients admitted to the Psychiatry and Behavioral Medicine Unit (PBMU) and thus, this unit was not included in the study.

**Inclusion criteria.**

- Parent-child dyads of children hospitalized on a Medical, Surgical, Oncology, Rehabilitation, PICU or CICU Unit
- Ability to understand and communicate (written and verbal) in English
- Fall risk assessment score documented in the Electronic Health Record (EHR) (case subjects must have a score documented prior to the fall)

**Exclusion criteria.**

- Parent-child dyad of children who experienced a suspected intentional fall

## Procedure

Following Institutional Review Board (IRB) approval, potential parent subjects were initially screened by a patient care nurse for interest in learning more about the study. If they expressed interest, potential subjects were approached for recruitment by the Primary Investigator (PI) or a trained research assistant. Potential case subjects were approached within 96 hours after the child experienced a fall on a study eligible unit. Potential control subjects were approached after enrollment of the child's age matched case subject. Case

subjects were identified by review of the hospital's electronic incident reporting system for a fall in the prior 96 hours. Subjects were recruited over a 2.5-month period from January 2020 – mid March 2020.

Cases were parent-child dyads of children who experienced a fall during the hospitalization (prior to completion of data collection tools). Two age matched controls were recruited for each case. Controls were parent-child dyads of children who did not experience a fall during hospitalization prior to data collection. Control subjects were identified by reviewing hospital census for matching characteristic of age (i.e. date of birth within 1 year of case's date of birth). To ensure the independence of the data, only one parent was enrolled for each child subject.

After written informed consent for participation was obtained, the parent was asked to complete the demographic questionnaire, the Pediatric Inventory for Parents (PIP) (Streisand, Braniecki, Tercyak, & Kazak, 2001) and PROMIS tools for anxiety, depression, fatigue, and sleep disturbance in the Research Electronic Data Capture system (REDCap) (Harris et al., 2019; Harris et al., 2009). REDCap is a secure, web-based software platform designed to support data capture for research studies. All of the tools were incorporated into one survey for convenience (to prevent having to move between several surveys) (Figure 1. Study instruments). Electronic devices (iPads) were used to manage the risk of transcriber error of entering responses into the database. Pen and paper versions were available for subjects who were not able to complete tools using the iPad. The estimated time for completion of the tools was 20 - 30 minutes. After completion of the survey, the PI or research assistant reviewed the child's EHR and obtained the child's fall risk assessment score most prior to the fall (case) or the most recent score for control subjects and other child data, such as age, sex, unit of admission, diagnosis and LOS. If the child experienced more than one fall during the admission, this was recorded but data was not re-collected on the parent-child dyad. In the

event that a child of a control dyad experienced a fall, data as a control dyad was used for analysis and the parent-child dyad was not recruited as a case.

PIP scores for each participant were calculated using the PIP scoring sheet (Streisand et al., 2001). Frequency and difficulty scores for each domain (communication, medical care, emotional distress, and role function) were calculated. The four domain scores were then summed for total frequency and distress scores. Surveys were evaluated for missing data. If no more than one response per scoring category was missing, the missing data was imputed with the average of all other scores in the same category. Participant PROMIS tool raw scores were converted to t-scores using the HealthMeasures scoring manuals for each tool. The scoring manual does not provide valid T-scores when there is a missing response for an item. The web-based HealthMeasures scoring system was used to generate T-scores for PROMIS tools with missing data. T-scores were calculated separately for each PROMIS tool.

## Instruments

Parent tools were previously reviewed by an established organizational family advisory council. The council provided feedback on the appropriateness of the concepts and organization of the tool. As a result of the council feedback, the order of the PROMIS tools was revised. The council also provided feedback on how to sensitively approach parents for study recruitment.

### Demographic tool.

An investigator developed, IRB-approved tool was used to gather demographic data on the parent and family. The tool was composed of multiple choice and short answer questions (one- to three-word answers) to illicit information about the parent such as age, gender, race, ethnicity, marital status, education level, smoking status, and relationship to the child. This tool elicited information about the child’s family such as number of adults and children living in the household, working status of the parent(s), and family income. Based on feedback from three

nurses (director of nursing quality and safety, and two clinical nurse specialists), wording of three items were modified to improve clarity.

**PIP.**

The PIP (Streisand et al., 2001) was used to measure parental stress. This parent report tool was developed to assess stress related to caring for an ill child across four domains – Communication, Emotional Distress, Medical Care, and Role Function (Streisand et al., 2001). While initial psychometrics were conducted with parents of children with oncologic disorders, items are general enough to apply to other illnesses (Streisand et al., 2001). This tool has been used to assess parental stress associated with caring for children with other chronic illnesses/conditions such as: diabetes, irritable bowel disease, sickle cell disease and pain (Barakat, Patterson, Tarazi, & Ely, 2007; Cohen, Vowles, & Eccleston, 2010; Gray, Graef, Schuman, Janicke, & Hommel, 2013; Streisand, Swift, Wickmark, Chen, & Holmes, 2005). Face validity was supported through input from parents of children on an oncology unit (Streisand et al., 2001). Construct validity has been supported by significant correlation of total scores with a measure of state anxiety (State–Trait Anxiety Inventory) and a measure of general parenting stress (Parenting Stress Index-Short Form) (Streisand et al., 2001). Internal consistency is supported with Cronbach alphas ranging from 0.77 - 0.96 across various chronic conditions (Gray et al., 2013; Streisand et al., 2001; Streisand et al., 2005).

The PIP is a self-report measure listing 42 medical related situations. Respondents use a 5-point Likert scale to rate the frequency (1=never, 2=rarely, 3=sometimes, 4=often, 5=very often) and difficulty (1=not at all, 2= a little, 3=somewhat, 4=very much, 5=extremely) related to the listed situations. Examples include:

- Difficulty sleeping
- Learning upsetting news
- Feeling confused about medical information

- Feeling helpless over my child's condition

PIP scores were obtained by summing the items for each of the domains separately for frequency and difficulty which yielded a total of eight scores (Communication Frequency, Emotional Distress Frequency, Medical Care Frequency, Role Function Frequency, Communication Difficulty, Emotional Distress Difficulty, Medical Care Difficulty, and Role Function Difficulty). Scores for all of the frequency and difficulty domains were then summed separately to yield a total frequency and a total distress score resulting in two additional scores for this instrument. Scores are measured on a continuum with total scores ranging from 42 – 210 points with higher scores indicating greater frequency or greater distress related to caring for a child with an illness.

**PROMIS tools.**

A battery of PROMIS tools was used to measure parent reported anxiety, depression, fatigue, and sleep-disturbance. PROMIS tools measure concepts of health and well-being across the lifespan with easy to complete questionnaires (Health Measures, 2018; National Institutes of Health, 2013). Short forms of most tools are available with a range of four to ten items (Busse et al., 2013). These tools were developed by a multi-centered group of clinicians, researchers and measurement experts through the support of the National Institutes of Health (Cella et al., 2007). Psychometric properties of PROMIS measures have been evaluated and supported across large, clinically diverse populations. Construct validity of PROMIS item banks is supported by correlation of scores with other tools known to capture the concept of interest:

- Anxiety – Mood and Anxiety Symptom Questionnaire (MASQ) ($r = 0.80$) (Pilkonis et al., 2011)
- Depression – Center for Epidemiologic Studies Depression Scale (CES-D) ($r = 0.83$) (Pilkonis et al., 2011)

- Fatigue – Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-F) (*r* = 0.95 ), Vitality subscale of the Short Form health survey – 36 questions version 2 (SF-36v2) (*r* = 0.89) (Junghaenel, Christodoulou, Lai, & Stone, 2011)
- Sleep Disturbance – Pittsburgh Sleep Quality Index (PSQI) (r = 0.85) (Buysse et al., 2010)

Each of the PROMIS tools use a 5-point Likert scale. The anxiety (7 items), depression (8 items) and fatigue (7 items) tools measure self-reported frequency of events in the past seven days (1=never, 2=rarely, 3=sometimes, 4=often, 5=always). The anxiety tool measures self-reported anxious misery, fear and hyperarousal symptoms (Cella et al., 2010; PROMIS Cooperative Group, 2018a). The depression tool measures negative mood, view of self, affect and engagement (Cella et al., 2010; PROMIS Cooperative Group, 2018b). The fatigue tool measures the experience and intensity of a range of symptoms related to incapacitating exhaustion which affects one's ability to perform routine daily activities and participate in family or social roles (Cella et al., 2010; PROMIS Cooperative Group, 2018c). Example items include:

- I found it hard to focus on anything other than my anxiety (anxiety)
- I felt that I had nothing to look forward to (depression)
- How often were you too tired to think clearly? (fatigue)

The sleep disturbance tool is an 8-item measure of self-reported perceptions related to sleep depth and quality over the last seven days (Cella et al., 2010; PROMIS Cooperative Group, 2018d). One item evaluates perception of sleep quality using possible responses of 1=very good, 2=good, 3=fair, 4=poor, 5=very poor. The other items have possible responses of 1=very much, 2=quite a bit, 3=somewhat, 4=a little bit, 5=not at all. Examples include:

- My sleep was refreshing
- I worried about not being able to fall asleep

For each of the PROMIS tools, the values of each of the items were summed to obtain a raw score for the tool (PROMIS Cooperative Group, 2018a, 2018b, 2018c, 2018d). The raw scores

were then converted to a standardized t-score with a mean of 50 and standard deviation of 10. This allows for scores on various domains to be easily interpreted and compared to scores for other PROMIS domains (Health Measures, 2018). Higher scores indicate a greater amount of the concept being measured, i.e. more anxiety, depression, fatigue, sleep disturbance.

**Generalized Risk Assessment for Pediatric Inpatient Falls (GRAF – PIF).**

The GRAF - PIF tool is one of the first pediatric specific fall risk assessment tools developed. It is also the most commonly used fall risk assessment tool for hospitalized pediatric patients in American hospitals (Jamerson et al., 2014). This tool is used to predict fall risk in children twelve months of age and older. The GRAF - PIF was developed based on a retrospective case control study of two hundred patients (100 fallers and 100 non-fallers) (Graf, 2005, 2011). Five patient level characteristics, which place a child at greater risk of falling in the hospital were identified (DiGerolamo & Davis, 2017; Harvey, Kramlich, Chapman, Parker, & Blades, 2010; Ryan-Wenger, Kimchi-Woods, Erbaugh, LaFollette, & Lathrop, 2012). These characteristics include: LOS of five or more days, anti-seizure medications, musculoskeletal or orthopedic condition, physical or occupational therapy need, and absence of an IV (DiGerolamo & Davis, 2017; Graf, 2005, 2011; Harvey et al., 2010; Ryan-Wenger et al., 2012). Each of these items is scored as zero or one point with the exception of the LOS item. Unlike other fall risk tools, GRAF - PIF uses LOS to aid in the determination of fall risk. A LOS of four days or less is scored as zero points, five to nine days is one point and ten or more days is two points. A score of two or more points indicates the child is at high risk of falling during the hospitalization. Additionally, a history of a fall in the past month or during the hospitalization are scored as two points, automatically places the child at risk for falling again (Graf, 2011). The reported internal consistency of items is adequate (Chronbach $\alpha = 0.77$) (Harvey et al., 2010). The reported positive predictive value is 84% (DiGerolamo & Davis, 2017; Graf, 2005, 2011; Harvey et al., 2010). Reported sensitivity and specificity are 75% and 76% respectively (DiGerolamo & Davis, 2017; Harvey et al., 2010; Ryan-Wenger, Kimchi-Woods, Erbaugh, LaFollette, & Lathrop, 2012).

**Statistical Analysis**

Data were analyzed using SAS/BASE software for Windows Version 9.4 (SAS Institute Inc., 2016), R version 3.6.0 and RStudio version 1.1.456 (R Core Team, 2019). Cases were defined as dyads in which children experienced a fall and controls were defined as dyads in which children did not experience a fall. Descriptive statistics were used to evaluate child, parent and family demographics as well as parent PROMIS t-scores and PIP scores by fall type. The total number of data points were evaluated for missing data. Continuous variables were assessed for normality using histograms and Q-Q plots. Since the data are not normally distributed, summaries were reported as medians and interquartile ranges. Categorical data were summarized as frequencies and percentages. Boxplots of each variable by faller group were evaluated for skewness and potential influential and leverage points. PROMIS t-scores and PIP scores were plotted using a scatterplot to observe if a linear relationship existed. Pearson correlations among individual PROMIS t-scores and each PIP score were calculated. A p-value of 0.05 or less was considered statistically significant indicating the correlated scores measure similar concepts.

Power analysis calculations were conducted using PASS 14 Power Analysis and Sample Size Software (NCSS, 2015). For continuous exposure variables, case sample size was calculated to achieve at least 80% power to detect a mean of paired differences pre-specified by the investigator. Standard deviations were estimated using the range from the pilot control population divided by 5. A value of 0.05 is used to determine statistical significance. For categorical exposure variables, the probability of exposure among control patients was estimated using pilot control data. Since the correlation coefficient for exposure between matched case and control patients could not be estimated from the pilot data and was not known, a value of 0.2 was used. A value of 0.05 was used for significance. The sample sizes were calculated to achieve 80% power to detect the pre-specified odds ratios using a chi-square test.

## Results

During the 2.5-month data collection period, the average daily census was 274 patients per day and the fall rate was 1.33 falls per 1,000 patient days across eligible units. Twenty-two fall reports were reviewed for eligibility as a case subject (Table 1. Fall population characteristics) during the data collection time period. Ninety percent (n = 18) of the fallers experienced one fall and 10% (n = 2) experienced two falls for a total of 20 fallers. Eighty percent of the fallers (n = 16) were 1 – 17 years old and further screened for study eligibility. The majority of these fallers were female (62.5%, n = 10). Half (n = 8) of the falls were considered to be accidental while the other half (n = 8) of falls were related to either anticipated or unanticipated physiological processes, such as weakness, dizziness or musculoskeletal conditions. The vast majority of the falls resulted in no injury (93.75%, n = 15). Parents were present for 75% (n = 12) of these falls.

### Recruitment

The 22 fall reports reviewed for eligibility represented 16 children who met age eligibility criteria (1 – 17 years old). Two of these fallers were excluded due to inclusion criteria of ability to communicate in English language (n = 1) and a fall risk score not documented prior to the fall (n = 1). Fourteen case dyads (70% of all fallers) met study eligibility requirements. However; half (n = 7) of these case dyads were not physically present for recruitment in the 96-hour post fall time period. Four of the children were discharged prior to being approached for recruitment. Three of the parents were not present in the hospital during multiple recruitment attempts in the 96 hours after the fall. Reasons for not being present for recruitment attempts included visitation limitations due to parent distance from the hospital and child protective services restrictions and child discharged from the hospital (n = 4). Thus, seven case dyads were eligible and available for recruitment (35% of all fallers, 50% of eligible fallers).

Of the remaining eligible subjects (n = 7), one parent indicated no interest in learning about the study prior to being approached for recruitment. Another parent declined participation after

being approached for recruitment and learning it was about a fall that occurred. The third parent declined participation due to significant concerns about how the results might be used. The parent expressed concern that if an association was found between parent characteristics and pediatric falls the data could be used post-fall to indicate the child was at risk of falling due to parent stress and no further investigations would be conducted on how falls could be prevented. The final sample included four case dyads (20% of all fallers, 28.6% of eligible fallers) and eight control dyads matched on the child's age and who did not have a reported fall during the study time frame for a total sample size of 12 subjects (Figure 2. Flow diagram for case sample recruitment).

During the recruitment process several parents became distracted either from their child or the informed consent process. When asked if it was still a convenient time to continue with recruitment, two parents asked if recruitment could be continued at a time later in the day. This request was accommodated and both parents consented to study participation. After recruitment, 83.3% (n = 10) of parents completed the study tool within 24 hours. However, 16.7% (n = 2) took two days to complete the study tool. For one of the subjects, lunch had arrived during the consent process. The parent completed the consent process then indicated they needed to feed their child and would complete the tool later. When the parent went to complete the survey, she was unable to find the passcode to unlock the electronic device. No reason was given for delay in survey completion for the other parent as they were not present when the electronic device was collected.

**Equipment Needs**

All parent subjects completed the data collection tool using the electronic device provided by the researcher. None of the parents expressed concerns related to contamination or infection prevention practices related to the use of the electronic device. However, two of the subjects were in respiratory isolation, which highlighted the need for equipment cleaning protocols.

**Instrument Acceptability**

Instrument acceptability was measured by data collection tool completion and missing data rates. All recruited parents completed the study survey. Parents who completed the tool in an uninterrupted sitting reported approximately 20 – 30 minutes for completion. All of the parents responded to at least 93.8% of survey questions. The overall missing data rate was 1%. For the parent and family demographic questions, two items had missing data (parent age = 2 missing, number of children over 18 years of age = 1 missing). This resulted in a missing data rate for the demographic questions of 1.6%. For the PROMIS tools, the fatigue and anxiety tools both had one question with missing data. This resulted in a missing data rate of 0.6% for the PROMIS tools. Four parents had missing data on the PIP tool. Three of the parents had one or two missing items. If a parent had two missing items, the items were for frequency and difficulty for a singular prompt. One parent, who reported they were a stay at home parent did not respond to the prompt of "Being unable to go to work." If the parent had one missing item, the item was for difficulty related to an item in the Emotional Distress domain. One parent had seven missing items, five of these missing items were for difficulty ratings of items which they rated the frequency as "never". The remaining two missing items for this subject were for frequency and difficulty for a singular prompt. The missing data rate for the PIP tool was 1.1%

**Sample**

The study sample included an equal number of male and female children (Table 2. Recruited subjects' characteristics). The median child's age in the faller and non-faller groups were similar at 10 years (120 and 126 months respectively) for both groups. Fallers were admitted to only the medical or rehabilitation units. Across both groups, half (n = 6) of the children had a neurologic diagnosis and all of the fallers (n = 4) had a neurologic diagnosis. The remaining diagnoses were relatively equal among oncology (n = 2), respiratory (n = 1), cardiac (n = 1), musculoskeletal (n = 1) and craniofacial disorders (n = 1) for non-fallers. LOS

was longer among the faller group with a median of 11.5 days compared to non-fallers (5 days). LOS was not included for one outlier non-faller as at the close of data collection the patient remained in the hospital and had been admitted for more than 60 days. Across both groups, 75% (n = 9) were considered to be at risk of falling as determined by a GRAF – PIF fall risk score of two or more points. Parents were present for half of the falls (n = 2).

The median parent age in the faller group was higher at 43 years compared to 35 years for the non-faller group. Across both groups the majority of the parents were Caucasian (83.3%, n = 10), non-Hispanic (91.7%, n = 11) mothers (91.7%, n = 11). Most of the parents across both groups were married or partnered (91.7%, n = 11). None of the parents reported being smokers. In the faller group, the highest level of education was high school for half (n = 2) of the parents, whereas 75% (n = 6) of parents of non-fallers had a bachelor's degree (n = 3) or higher educational level (n = 3). All of the parents considered themselves to be employed or a stay at home parent. Seventy-five percent (n = 3) of the faller parent subjects were stay at home parents, with 37.5% (n = 3) in the non-faller group.

**Conceptual Clarity**

Parent scores for all PROMIS measures were similar across both groups (Table 3. Parent PROMIS and PIP scores). Likewise, PIP scores were similar across both groups for communication frequency, medical care difficulty, role function difficulty and role function difficulty scores. The parents of fallers had lower scores for all other PIP scores. PROMIS anxiety T-scores were shown to be significantly correlated to all PIP scores. Similarly, PROMIS depression T-scores were shown to be correlated to all PIP scores except the communication difficulty score (Table 4. Correlations of PROMIS T – scores and PIP scores).

**Sample Size Calculations**

Sample size of case subjects needed for a future matched case:control (1:3) study are presented in Table 5 (Sample size calculations for future adequately powered study). If child's LOS is used to detect a mean difference of one day, the number of cases needed would be

5,471. However, if the mean difference is expanded to 5 days, which corresponds to LOS range in the GRAF-PIF fall risk assessment tool, the number of cases needed drops significantly to 221. After LOS to detect a mean difference of one day, the variable with the next highest case sample size is parent gender. To detect an odds ratio of 1.5 of the association of parent gender and pediatric hospital falls, 392 case would be needed for an adequately powered study.

## Discussion

### Recruitment strategies

Less than one-third of eligible case dyads were able to be recruited. For half of these case dyads, the parent was unavailable for recruitment either due to the patient being discharged or parent not staying with the child constantly during the admission. The study setting is a referral center for a four-state region. Parents of children who live a distance from the hospital may not be able to be with the hospitalized child due to work or other family obligations. It is unknown if the parent-child dyads of the discharged patients would have agreed to participation. For a future study, inclusion of and recruitment strategies for recently discharged case subjects should be considered.

Eligibility criteria should be revised to include those who communicate in non-English languages and those who do not have a fall risk score documented. PROMIS tools are translated into several languages including Spanish. Prior to undertaking a full-scale study, common language preferences of patients at the study site need to be investigated. All study tools, including the consent form, should be translated into the most common non-English languages. Interpreter services should be engaged for the recruitment process. The pool of eligible case subjects can be further increased by not requiring a fall risk score to be completed prior to recruitment. Since the focus of the future study would be understanding of parent characteristics associated with pediatric hospital falls, the fall risk assessment score requirement could be eliminated without impacting the final results of the study.

Approaching parents for study recruitment while the child was hospitalized posed concerns for distracting the parent from attending to the child. Parents were always asked if it was a convenient time for recruitment procedures. The researcher must be sensitive to care needs of the child to decrease the risk of the child falling as a result of parent distraction during the recruitment and consenting process. Additionally, the parent may be distracted by the child's care needs during the recruitment process and may not fully understand the study purposes and requirements. In a future study, it may be helpful to engage volunteer services or child life specialists to interact with the child to decrease parent distraction and potential risk of a child fall during the recruitment process.

Prior to recruiting subjects for the pilot study, the PI conducted a focus group discussion with a pre-established organizational family advisory council. Council members provided helpful guidance on non-blaming wording which was used in recruitment attempts. Recommendations included acknowledging falls are part of normal growth and development and in the normal course of life. Council members suggested reminding parents that falls in the hospital can be more dangerous than those outside of the hospital. Efforts were taken during recruitment to reinforce the purpose was to understand associations of parent characteristics with pediatric hospital falls in hopes of learning how to assess for these characteristics and provide support to parents. However, some parents may have been concerned a hidden goal was to blame the parent for the fall or that results may be used for reporting the child to child protective services. Parents need to be re-assured the goal is to provide support and identify ways the healthcare team can partner with them to improve the safety of their child in the hospital.

**Equipment Needs**

In the pre-study focus group discussion, council members indicated they had been approached for research studies in the past which used electronic devices for data capture. They indicated that if they been expected to complete the survey immediately at the time of enrollment, they may not have participated. As a result, the researcher left electronic devices

with the parent for survey completion at their convenience. Most subjects completed the survey prior to the end of the day; however, two of the subjects completed the survey within 24-48 hours after recruitment. This practice resulted in the need for more than one electronic device to facilitate enrollment of more than one subject at a time.

An additional consideration for multiple use electronic devices is infection prevention procedures. During the recruitment process, proper protection equipment (masks, gloves, etc) must be used as appropriate. Additionally, the researcher needs to consider containment (sealable plastic container) and cleaning strategies when removing the electronic device from the isolation room. Omitting the use of a cover on the electronic device will make device cleaning easier.

**Instrument Acceptability**

All parents who were successfully recruited, completed the study tool. Furthermore, the percentage of missing data was low. All enrolled parents completed the tool on the electronic device provided. The high completion rate and low missing data rate may be due to the use of multiple-choice answers throughout the tool. Multiple choice responses allow for quicker responses and less cognitive burden on the respondent to think of possible answers. Multiple choice responses also help streamline the data analysis process as the researcher will not have to categorize data after collection. Use of an electronic device allows subjects to directly enter responses into the database without the concern of transcriber error associated with pen and paper tools. Overall, the instrument content (questions) and format (multiple choice responses and electronic device) was acceptable to the subjects.

**Conceptual Clarity**

Pilot studies are intended to evaluate the feasibility of future larger scale studies and are not hypothesis testing studies (Leon, Davis, & Kraemer, 2011). Thus, inferential statistical tests are generally not indicated (Leon et al., 2011). For this reason, testing of associations of parent characteristics with pediatric falls was not conducted in the current study. However, correlations

of PROMIS measures T-scores with PIP scores were evaluated in an attempt to determine if the parent survey tool could be streamlined. Since PROMIS anxiety and depression measures are correlated with all PIP scores, the PIP tool can be omitted in the future study without impacting the ability to test the association of parent psychophysical characteristics. The PROMIS tools are preferred over the PIP tool for several reasons:

1. PROMIS tools are shorter, thus limiting the respondent burden and time for tool completion.
2. PROMIS tools have a standardized approach for dealing with missing data through the use of the HealthMeasures web-based scoring system.
3. PROMIS tools have standardized scores with established standard deviations. This allows for scores on various domains to be easily interpreted and compared to scores for other PROMIS domains (Health Measures, 2018). Whereas, PIP scores are measured on a continuum without established cut points for various levels of stress.

Concerns of multicollinearity among predictor variables can be decreased by eliminating two variables (relationship to child and parent employment status). Parent relationship to the child (mother, father, stepmother, stepfather etc.) is related to parent gender and thus can be omitted in a future study. Parent employment status is the employment status of the person completing the survey (employed, stay at home parent, or unemployed). Whereas, the variable of parent employment type is the employment status of the parental unit in the household. Since parent employment type provides information on number of parents in the house and employment status of the parental unit, this variable should replace the variable relating solely to the employment status of person completing the questionnaire.

**Sample Size Calculation**

Power analysis results support modification of the LOS variable. Recruitment of a case sample size sufficient to detect the effect of a one day mean difference in LOS at a single study site with less than 100 falls per year and an estimated 28.6% successful case recruitment rate

would take several years. Thus, for a future study, the effect size should be expanded to detect a mean difference of 5 days as this drops the case sample size significantly.

The number of cases needed for an adequately powered study to describe parent characteristics associated with pediatric hospital falls is based on the largest number calculated for any single variable in the power analysis. The variable of parent gender 392 cases. Increasing the match to three controls per case slightly increases the power which decreases the number of cases needed. Thus, a 1:3 case:control match should be used for a future study. With a 1:3 match and 392 cases needed for an adequately powered study, a total sample size of 1,568 subjects would be needed for a future study. Recruitment of a sufficient sample at a single research site would likely take several years. Thus, a multi-site study should be undertaken to understand associations of parent characteristics with pediatric hospital falls. A multi-site study would contribute not only to swifter recruitment of subjects but promote generalizability of findings.

## Limitations

This was a pilot study to understand the feasibility of conducting a future adequately powered study to test the association of parent characteristics and pediatric hospital falls. As such the current study was not a hypothesis testing study but does provide recommendations for conducting a hypothesis testing study. Limitations of this study include that the study was conducted at a single hospital organization with very few cases and recommendations may not be generalizable to other organizations.

Another significant limitation of this study was that data collection had to be halted prematurely due to world-wide pandemic conditions (COVID-19). While the number of falls during the 2.5 month data collection period was similar to the prior twelve quarters (3 years), it is unclear if infection prevention practices impacted discharge timing of the patients who were discharged less than 48 hours after the fall. It is also unclear if concerns of virus transmission impacted the parent who was not interested in hearing about the research study.

Data was collected from case parents after the fall had occurred, therefore parent responses to the anxiety, depression, fatigue, sleep deprivation and stress items may not be reflective of those concepts at the time of the fall (recall bias). To help limit this recall bias, case subjects were enrolled within 96 hours of the fall. Parent data was obtained by self – report after consent for participation. We did not have the opportunity to gather data from parents who declined to participate, thus do not know if parents who chose to participate were different from those who declined participation in relation to any of the measured variables (respondent bias).

## Strengths

While several researchers have identified an association of parental presence and pediatric falls, they have merely proposed this association may be related to parental anxiety, distraction, fatigue, sleep disturbance, stress, etc. Researchers have not obtained data to describe if these characteristics are indeed associated with pediatric inpatient falls. This study provides recommendations on conducting a full-scale study to validate findings of a prior study describing the association of parental demographic characteristics while extending findings by adding stress related measures of anxiety, depression, fatigue, and sleep disturbance.

## Practice Implications

The current approach to fall prevention focuses on the use of risk assessment tools based solely on patient characteristics, such as age, sex, LOS, presence of an intravenous catheter (IV) and cognitive/physical capabilities to aid in the prediction of fall likelihood (Bagnasco et al., 2010; Franck et al., 2017; Graf, 2005; Hill-Rodriguez et al., 2009; Jamerson et al., 2014; Morse, Black, Oberle, & Donahue, 1989; Pauley et al., 2014; Razmus & Davis, 2012; Schaffer et al., 2012). For children, these tools neglect parental demographic and/or psychophysical characteristics which may be associated with risk of their child falling in the hospital. As a result, pediatric hospital fall prevention strategies focus only on identification of patient-level risk characteristics without consideration of parent and caregiver-level risk characteristics (Fujita et al., 2013; Lee et al., 2013; Peng, Lee, & Intersoll, 2002). This study

provides recommendations for conducting a study to test the hypothesis of the association of parent stress, sleep disturbance, fatigue, anxiety, and depression with pediatric inpatient falls. It is important to test and describe associations with pediatric hospital falls because a parent is often present with a child during hospitalization. If parent characteristics are found to be associated with pediatric hospital fall risk, the healthcare team can partner with parents to identify and develop strategies to mitigate these characteristics to improve safety of the hospitalized child. This would represent risk factors which are amenable to change during hospitalization whereas, many patient-level factors currently included in fall risk characteristics are not amenable to change during hospitalization.

Keywords

Fall; hospital; inpatient; parent; fall risk; fall prevention

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**Figure 1. Study instruments**

| Study Instruments |
| --- |
| Researcher developed demographic tool (parent and child) |
| PIP (parent) |
| PROMIS anxiety short form 7a (parent) |
| PROMIS depression short form 8a (parent) |
| PROMIS fatigue short form 7a (parent) |
| PROMIS sleep disturbance short form 8a (parent) |
| GRAF-PIF fall risk assessment tool (child) |

**Table 1. Fall population characteristics**

| All faller (N = 20) | | |
|---|---|---|
| Characteristics | | n (%) or Median* |
| Age of fallers | 0 - <1 year old | 1 (5%) |
| | 1 – 17 years old | 16 (80%) |
| | 18+ years old | 3 (15%) |
| **Reported falls in 0 – 17-year olds (N = 16)** | | |
| Age in years | | 7.5 (4 – 12) |
| Gender | Female | 10 (62.5%) |
| | Male | 6 (37.5%) |
| Fall type | Accidental | 8 (50%) |
| | Anticipated physiological | 6 (37.5%) |
| | Unanticipated physiological | 2 (12.5%) |
| Injury level | No injury | 15 (93.75%) |
| | Minor injury | 1 (6.25%) |
| Parent present at time of fall? | Yes | 12 (75%) |
| | No | 4 (25%) |

* Median reported as median ($25^{th}$ %ile – $75^{th}$ %ile) for continuous variables

**Figure 1. Flow diagram for case sample recruitment**

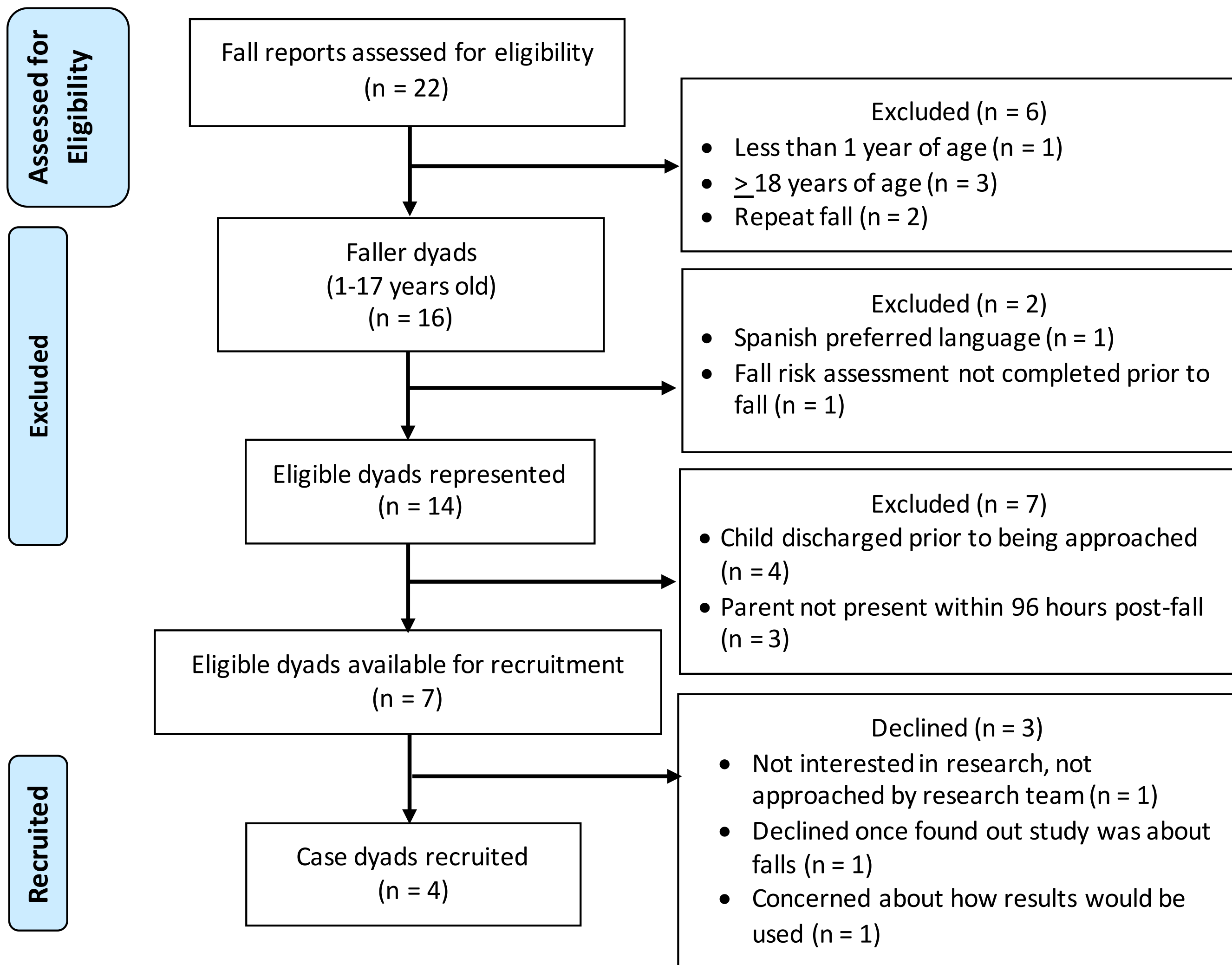

**Table 2. Recruited subjects' characteristics (N = 12)**

**Child characteristics**

| Child Characteristic | | n | Non - Fallers (n = 8) n (%) or Median* | Fallers (n = 4) n (%) or Median* | All subjects (n = 12) n (%) or Median* |
|---|---|---|---|---|---|
| Sex | Male | 12 | 4 (50.0) | 2 (50.0) | 6 (50.0) |
| | Female | | 4 (50.0) | 2 (50.0) | 6 (50.0) |
| Age (months) | Months | 12 | 126 (72-156) | 120 (78-150) | 120 (78-156) |
| Unit | Surgical | 12 | 3 (37.5) | 0 (0.0) | 3 (25.0) |
| | Medical | | 2 (25.0) | 2 (50.0) | 4 (33.3) |
| | Oncology | | 2 (25.0) | 0 (0.0) | 2 (16.7) |
| | Rehabilitation | | 1 (12.5) | 2 (50.0) | 3 (25.0) |
| Diagnosis | Hematology/Oncology | 12 | 2 (25.0) | 0 (0.0) | 2 (16.7) |
| | Respiratory/Pulmonary | | 1 (12.5) | 0 (0.0) | 1 (8.3) |
| | Neurologic/Nervous System | | 2 (25.0) | 4 (100.0) | 6 (50.0) |
| | Cardiac | | 1 (12.5) | 0 (0.0) | 1 (8.3) |
| | Skin/Musculoskeletal/Orthopedic | | 1 (12.5) | 0 (0.0) | 1 (8.3) |
| | EENT/Craniofacial | | 1 (12.5) | 0 (0.0) | 1 (8.3) |
| Total LOS (days) | | 11 | 5 (4-18) | 11.5 (5-43.5) | 8 (4-18) |
| Total GRAF – PIF Score | Number of Points | 12 | 2 (1.5-2.5) | 2.5 (1-3.5) | 2 (1.5-3) |
| Fall Risk (GRAF – PIF ≥ 2) | No | 12 | 2 (25.0) | 1 (25.0) | 3 (25.0) |
| | Yes | | 6 (75.0) | 3 (75.0) | 9 (75.0) |
| Parent present for fall? | No | 4 | | 2 (50) | |
| | Yes | | | 2 (50) | |

**Parent/family characteristics**

| Parent/Family Characteristic | | n | Non-Fallers (n = 8) n (%) or Median* | Fallers (n = 4) n (%) or Median* | All subjects (n = 12) n (%) or Median* |
|---|---|---|---|---|---|
| Parent Age | Years | 10 | 35.0 (32.0-46.0) | 43.0 (37.0-50.0) | 40 (32-46) |
| Parent Ethnicity | Hispanic or Latino | 12 | 1 (12.5) | 0 (0.0) | 1 (8.3) |
| | NOT Hispanic or Latino | | 7 (87.5) | 4 (100.0) | 11 (91.7) |
| Parent Race | Asian | 12 | 0 (0.0) | 1 (25.0) | 1 (8.3) |
| | Caucasian/White | | 7 (87.5) | 3 (75.0) | 10 (83.3) |
| | Unknown/Not reported | | 1 (12.5) | 0 (0.0) | 1 (8.3) |
| Parent Gender | Male | 12 | 1 (12.5) | 0 (0.0) | 1 (8.3) |
| | Female | | 7 (87.5) | 4 (100.0) | 11 (91.7) |

| | | | | | |
|---|---|---|---|---|---|
| Marital Status | Partnered | 12 | 1 (12.5) | 0 (0.0) | 1 (8.3) |
| | Married | | 7 (87.5) | 3 (75.0) | 10 (83.3) |
| | Divorced | | 0 (0.0) | 1 (25.0) | 1 (8.3) |
| Smoker? | No | 12 | 8 (100) | 4 (100) | 12 (100) |
| Parent Education Level | High School | 12 | 1 (12.5) | 2 (50.0) | 3 (25.0) |
| | Associate degree | | 1 (12.5) | 0 (0.0) | 1 (8.3) |
| | Bachelor's Degree | | 3 (37.5) | 1 (25.0) | 4 (33.3) |
| | Graduate Degree | | 3 (37.5) | 1 (25.0) | 4 (33.3) |
| Employment Status | Stay at home parent | 12 | 3 (37.5) | 3 (75.0) | 6 (50.0) |
| | Employed outside the home | | 5 (62.5) | 1 (25.0) | 6 (50.0) |
| Relation to Child | Father | 12 | 1 (12.5) | 0 (0.0) | 1 (8.3) |
| | Mother | | 7 (87.5) | 3 (75.0) | 10 (83.3) |
| | Grandparent | | 0 (0.0) | 1 (25.0) | 1 (8.3) |
| Others in household besides parent and child | No | 12 | 1 (12.5) | 1 (25.0) | 2 (16.7) |
| | Yes | | 7 (87.5) | 3 (75.0) | 10 (83.3) |
| Roles living in house | Father | 12 | 4 (50.0) | 2 (50.0) | 6 (50.0) |
| | Step-father | | 2 (25.0) | 0 (0.0) | 2 (16.7) |
| | Mother | | 1 (12.5) | 1 (25.0) | 2 (16.7) |
| | Step-mother | | 1 (12.5) | 0 (0.0) | 1 (8.3) |
| | Grandparent | | 0 (0.0) | 1 (25.0) | 1 (8.3) |
| | Brothers and sisters | | 4 (50.0) | 2 (50.0) | 6 (50.0) |
| Number children living in the home | | | 3 (2 – 3.25) | 2 (1 – 3) | 3 (1.75 – 3) |
| Parent work | Two parents in home, both parents work outside home | 12 | 3 (37.5) | 0 (0.0) | 3 (25.0) |
| | Two parents in home, one parent works outside the home, one parent works at home | | 1 (12.5) | 1 (25.0) | 2 (16.7) |
| | Two parents in home, one parent works outside home, one parent unemployed | | 4 (50.0) | 2 (50.0) | 6 (50.0) |
| | Single parent, works outside the home | | 0 (0.0) | 1 (25.0) | 1 (25.0) |
| Income | Less than $25,000 | 12 | 1 (12.5) | 2 (50.0) | 3 (25.0) |
| | $25,000 - $49,999 | | 1 (12.5) | 0 (0.0) | 1 (8.3) |
| | $50,000 - $74,999 | | 1 (12.5) | 1 (25.0) | 2 (16.7) |
| | $75,000 - $99,999 | | 1 (12.5) | 0 (0.0) | 1 (8.3) |
| | $100,000 or more | | 4 (50.0) | 1 (25.0) | 5 (41.7) |

* Median reported as median ($25^{th}$ %ile – $75^{th}$ %ile) for continuous variables

**Table 3. Parent PROMIS and PIP scores (N = 12)**

| Parent scores | | | | |
|---|---|---|---|---|
| | n | Non-Fallers (n = 8) Median* | Fallers (n = 4) Median* | All subjects (n = 12) Median* |
| PROMIS T-scores | | | | |
| Fatigue | 12 | 53.0 (50.5-55.8) | 55.1 (53.0-61.5) | 54.4 (51.3-55.8) |
| Sleep Disturbance | 12 | 52.8 (49.6-57.9) | 51.2 (49.6-52.2) | 51.7 (49.6-54.3) |
| Anxiety | 12 | 55.8 (46.0-61.6) | 53.9 (44.5-55.7) | 53.9 (46.0-59.7) |
| Depression | 12 | 48.4 (41.5-55.5) | 49.4 (43.8-56.2) | 49.4 (41.5-55.5) |
| PIP scores | | | | |
| Communication Frequency | 12 | 26 (20-32.5) | 25 (18-28) | 26 (19-30.5) |
| Communication Difficulty | 12 | 20 (11.5-22) | 14 (12-18.5) | 18 (12-21) |
| Medical Care Frequency | 12 | 31 (20.5-32) | 26.5 (18.5-30.5) | 30 (20-32) |
| Medical Care Difficulty | 12 | 19.5 (16-22.5) | 18.5 (15-19) | 19 (16-21) |
| Emotional Distress Frequency | 12 | 47.5 (33.5-56.5) | 44.5 (36.5-45.5) | 44.5 (33.5-52) |
| Emotional Distress Difficulty | 12 | 45 (36.5-51.5) | 41.5 (32-46) | 43.5 (35.5-49.5) |
| Role Function Frequency | 12 | 28.5 (22.5-36) | 27.5 (21-29) | 27.5 (22.5-33.5) |
| Role Function Difficulty | 12 | 25 (22.5-30.5) | 25 (20-25.5) | 25 (22.5-26.5) |
| Total Frequency | 12 | 131 (95-157) | 124.5 (97.5-129.5) | 124.5 (95-150.5) |
| Total Difficulty | 12 | 117.5 (85-121) | 100 (81.5-106.5) | 106.5 (85-118.5) |

* Median reported as median (25th %ile – 75th %ile)

**Table 4. Correlations of PROMIS T – scores and PIP scores (N = 12)**

| | Fatigue | Sleep | Anxiety | Depression | Communication Frequency | Communication Difficulty | Medical Care Frequency | Medical Care Difficulty | Emotional Distress Frequency | Emotional Distress Difficulty | Role Function Frequency | Role Function Difficulty | Total Frequency | Total Difficulty |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PROMIS Fatigue | 1.00 | | | | | | | | | | | | | |
| PROMIS Sleep Disturbance | 0.41 | 1.00 | | | | | | | | | | | | |
| PROMIS Anxiety | 0.23 | -0.08 | 1.00 | | | | | | | | | | | |
| PROMIS Depression | 0.64* | 0.01 | 0.87** | 1.00 | | | | | | | | | | |
| PIP Communication Frequency | 0.36 | 0.49 | 0.71** | 0.65* | 1.00 | | | | | | | | | |
| PIP Communication Difficulty | -0.01 | 0.10 | 0.76** | 0.56 | 0.78** | 1.00 | | | | | | | | |
| PIP Medical Care Frequency | 0.56 | 0.60* | 0.63* | 0.69* | 0.89** | 0.52 | 1.00 | | | | | | | |
| PIP Medical Care Difficulty | 0.10 | -0.10 | 0.91** | 0.75** | 0.67* | 0.83** | 0.60* | 1.00 | | | | | | |
| PIP Emotional Distress Frequency | 0.27 | 0.18 | 0.90** | 0.78** | 0.78** | 0.86** | 0.67* | 0.89** | 1.00 | | | | | |
| PIP Emotional Distress Difficulty | 0.23 | -0.06 | 0.80** | 0.71** | 0.49 | 0.74** | 0.38 | 0.81** | 0.83** | 1.00 | | | | |
| PIP Role Function Frequency | 0.33 | 0.40 | 0.81** | 0.70* | 0.89** | 0.79** | 0.84** | 0.79** | 0.88** | 0.59* | 1.00 | | | |
| PIP Role Function Difficulty | 0.32 | 0.41 | 0.67* | 0.58* | 0.85** | 0.74** | 0.73** | 0.65* | 0.73** | 0.52 | 0.90** | 1.00 | | |
| PIP Total Frequency | 0.39 | 0.42 | 0.84** | 0.77** | 0.94** | 0.81** | 0.89** | 0.82** | 0.92** | 0.65* | 0.97** | 0.85** | 1.00 | |
| PIP Total Difficulty | 0.20 | 0.07 | 0.88** | 0.74** | 0.74** | 0.91** | 0.58* | 0.91** | 0.93** | 0.92** | 0.82** | 0.78** | 0.85** | 1.00 |

PROMIS scores are T-scores

* $p \leq 0.05$

** $p \leq 0.01$

**Table 5. Sample size calculations for future adequately powered study**

| Predictor Variable | Effect Size Type | Effect Size | Number of Cases* (assuming 3 matched controls) |
|---|---|---|---|
| Child LOS | Mean Difference | 1 day | 5,471 |
| Child LOS | Mean Difference | 5 days | 221 |
| Parent Age | Mean Difference | 2 years | 23 |
| Number of children in the house | Mean Difference | 1 child | 10 |
| PROMIS Anxiety | Mean Difference | 10 points | 6 |
| PROMIS Depression | Mean Difference | 10 points | 4 |
| PROMIS Fatigue | Mean Difference | 10 points | 3 |
| PROMIS Sleep Disturbance | Mean Difference | 10 points | 4 |
| Parent Education Level | Odds Ratio | 0.32 | 131 |
| Parent Smoking Status | Odds Ratio | 3.0 | 63 |
| Parent Gender | Odds Ratio | 1.5 | 392 |
| Parent Employment Type | Odds Ratio | 1.5 | 299 |

**case sample sizes calculated to needed to achieve at least 80% power to detect a mean of paired differences (continuous variables) or odds ratio (categorical variables).*

# CHAPTER 5: Conclusion

The multifactorial nature of pediatric hospital falls necessitates a multi-pronged approach to prevention of these falls. The current approach to pediatric fall prevention centers on the use fall risk assessment tools which rate risk based solely on patient characteristics to aid the prediction of fall risk (Bagnasco, Sobrero, Sperlinga, Tibaldi, & Sasso, 2010; Franck et al., 2017; Graf, 2005; Hill-Rodriguez et al., 2009) and implementation of prevention strategies. Fall risk assessment tools are notably inadequate at predicting the occurrence of pediatric hospital falls. Furthermore, performance of these tools may vary based on characteristics unique to the patients within different care settings.

Pediatric hospitalized patients often have a parent present during their hospitalization. In fact, a parent is often present when children fall in the hospital (Bagnasco et al., 2010; Jamerson et al., 2014; Lee, Yip, Goh, Chiam, & Ng, 2013). It is unclear if parent characteristics such as anxiety, depression, fatigue, sleep deprivation, and stress are associated with their child falling in the hospital. In addition to patient level prevention strategies, parents are an important factor that can be utilized to aid in risk identification and prevention of pediatric hospital falls.

In chapter 2 of this dissertation, the predictive qualities of the GRAF-PIF fall risk assessment tool in pediatric hospital falls over a two-year period at a pediatric hospital were described. The sensitivity and specificity of the tool was 61% and 58%, respectively. These results are lower than those reported in other studies (Harvey, Kramlich, Chapman, Parker, & Blades, 2010). The sensitivity and specificity calculated in this study yielded an area under the receiver operator characteristic curve of 0.59. Despite the low area under the receiver operator characteristic curve, the single variable logistic regression model indicated a GRAF-PIF score of two or more points was associated with 2.16 (95% confidence interval = 1.22 - 3.84) times the odds of falling in the hospital.

In chapter 3 of this dissertation, the multi-factorial nature of fall risk was highlighted. Factors associated with pediatric hospital falls were collected from fall incident reports over a two-year period and data from a focus group discussion with an organizational parent advisory group. Risk factors described in fall incident reports underscored the multifactorial nature of hospital falls. However, these described risk factors focused mainly on child and environmental factors. Risk factors from the focus group discussion identified more parent related factors, including parent reliance on healthcare providers to help identify fall risk factors and intervention strategies.

In chapter 4, the feasibility of a study evaluating associations of parent characteristics and pediatric hospital falls is described. This chapter provided recommendations for a full-scale study in relation to subject recruitment, equipment needs, instrument acceptability, and conceptual clarity. Additionally, sample size estimates for an adequately powered future study were presented. Modifications to demographic questions were described to decrease the necessary sample size.

This dissertation provides support for the multifactorial nature of pediatric hospital falls. Risk assessment and prevention strategies must account for the multifactorial nature of these falls. Fall risk identification strategies should not abandon the use of standardized risk assessment tools. However, completion of risk assessment tools must be coupled with a critical evaluation of factors other than the child or environmental characteristics which may contribute to fall risk. One of these factors may be parent psychophysical characteristics which cause them to be distracted or less vigilant when multiple risk factors converge. Implications for practice include conducting a multi-site full-scale study aimed at testing the hypothesis of the association of parent stress, measured as anxiety, depression, fatigue, and sleep disturbance on pediatric hospital falls.

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