

EARLY OUTCOMES FROM MILD TRAUMATIC BRAIN INJURY FROM CHILD
AND PROXY PERSPECTIVES

DISSERTATION

Presented in Partial Fulfillment of the
Requirements for the Degree of
Doctor of Philosophy in Nursing

Barry University

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2009

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by

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Abstract

Background: Approximately 70-90% of traumatic brain injuries are mild, with a worldwide incidence greater than 600 per 100,000 people. Previous studies of health-related quality of life (HRQoL) after a mild traumatic brain injury (mTBI) have not included child perspectives or children discharged from the Emergency Department.

Purpose: This study evaluates, from perspectives of children and their proxies, whether children who have sustained an mTBI return to pre-injury levels of HRQoL by 1-month post-injury and whether their HRQoL is different from that of mild non-brain injured or uninjured children at either time point. It also compares child/proxy dyad ratings of the child's HRQoL.

Theoretical Framework: Haas' model of the middle range theory HRQoL is the foundation for this research. It includes subjective and objective indicators and physical, psychological, social, and role dimensions. HRQoL was operationalized using the PedsQL™ 4.0 Generic Core Scales and Cognitive Functioning Scale.

Methods: A nonexperimental, prospective longitudinal descriptive design was used to evaluate the HRQoL of mTBI, mild non-brain injured, and uninjured children ages 5-17, from child and proxy perspectives. Pre-injury interviews were conducted in person; 1-month interviews were conducted via telephone. Injured child/proxy dyads were met in the Emergency Department within hours of injury; only those with a maximum hospitalization of 24 hours were included in the study. Uninjured children were age- and gender-matched with mTBI children. Data were analyzed using the paired *t*-test, Wilcoxon matched pairs signed-rank test, ANOVA, Kruskal-Wallis, and regression.

Results: Children sustaining an mTBI and uninjured children had similar ratings of HRQoL at baseline and at 1-month, whereas mild non-brain injured children and their proxies both rated 1-month post-injury physical HRQoL statistically significantly lower than pre-injury levels. Child HRQoL ratings were statistically significantly lower than proxy ratings on all but the PedsQL™ Cognitive Functioning Scale at both time points.

Conclusions: These mTBI children did not experience differences between pre-injury and 1-month post-injury HRQoL. Further evaluation is indicated in cases where disparities are noted. Clinical significance of child/proxy HRQoL rating incongruence is limited as a result of small to medium effect sizes.

ACKNOWLEDGEMENTS

Although my name appears as the single author of this work, it would not have been possible without the support of many other individuals. I would like to thank Dr. Mary Bear, my committee chair, for providing invaluable direction and support throughout my doctoral studies. She has encouraged my growth as a scholar and taught me how observe the world around me from multiple perspectives. I would also like to thank my other committee members: Dr. Peter Wludyka, for the hours spent ensuring that my statistical analyses were correct, and Dr. Andra Hanlon, for providing thought-provoking feedback that improved this study. My thanks also go to Pam Selby for being a superb editor.

The opportunity to pursue doctoral studies as a member of the Barry University School of Nursing's first "Orlando Cohort" was an unexpected and incredible gift given to my classmates and me from Drs. Pegge Bell, Mary Bear, and Claudette Spalding. Many thanks to them for obtaining a State of Florida Succeed Grant and subsequent funding from Blue Cross/Blue Shield of Florida and the North Dade Medical Foundation. It has been a gift of knowledge and friendship.

It was my honor to receive the 2008 American Pediatric Surgical Nurses Association Research Award, proceeds from which helped cover expenses of this study.

I would like to thank staff members in the Pediatric Emergency Departments and Level I Trauma Center who helped recruit injured participants. Their willingness to provide potential participants with flyers about this study is truly appreciated.

It would have been impossible to conduct this study without willing children with mild traumatic brain injuries, mild non-brain injuries, and those who were uninjured and

their proxies. Their enthusiasm for this research provided frequent boluses of encouragement.

I extend thanks to Joseph J. Tepas III, MD for being such an incredible mentor and friend. Early in our nearly 25 years as pediatric surgical colleagues, he introduced me to the world of pediatric trauma. Throughout our years together, he has led by example and supported my professional choices.

I would also like to thank my family and friends for understanding the huge time commitment my doctoral studies involved and for their support throughout the process. Particular thanks go to my husband for having shouldered more than his share of our joint responsibilities and for his encouragement along the way.

DEDICATION

To my parents, for believing in me and teaching me to follow my dreams,

and

to all children who have sustained mild traumatic brain injuries and families who have held anxious vigil, fearful of how the injury may change their child's life. I hope my research helps stimulate others to further investigate subjective ramifications of mild traumatic brain injuries in children.

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CHAPTER ONE: INTRODUCTION

Background of the Study

Impact of Pediatric Trauma and Mild Traumatic Brain Injuries

Injuries occur very commonly in children, with approximately 5 million under the age of 15 being treated for trauma-related reasons in emergency departments (EDs) in the United States in 2004 and undocumented numbers either receiving treatment in outpatient facilities or not being seen by a health care provider for the injuries sustained. Injuries account for roughly 15% of all medical spending for children between the ages of 1 and 21. Of the estimated \$347 billion annual cost of unintentional pediatric injuries, \$257 billion is related to “lost quality of life” (Danseco, Miller, & Spicer, 2000). In addition, it has been shown that up to 40-50% of children hospitalized for a traumatic brain injury (TBI; Hawley, Ward, Magnay, & Long, 2004) or having an injury severity score (ISS) of ≥ 4 (Valadka, Poenaru, & Dueck, 2000) may have long-term cognitive, behavioral, or functional deficits. Thus, injuries in children significantly impact the nation’s health care system in prevalence, long-term negative health effects, and the resulting financial ramifications.

The National Children’s Study has named pediatric injury as one of its ten priority theme areas, indicating its importance. This longitudinal cohort population study will start enrollment in 2007-2008 and follow 100,000 children who represent the diverse socioeconomic and cultural backgrounds found in the U.S. from birth through 21 years of age (United States Department of Health and Human Services [USDHHS], 2004). Extensive prospective population-based data on childhood injury will be provided by this longitudinal study.

There were 448,000 children from 0-14 years of age with traumatic brain injuries (TBI) who were seen in emergency departments, were hospitalized, or who died in 2003 in the U.S. (Centers for Disease Control and Prevention [CDC], n.d.). Rates of TBI from these three venues per 100,000 persons were 188.5 and 520.5 for 0-4 year olds and 5-14 year olds, respectively. Of these, 404,000 (90%) were ED visits, with 91.9% of 0-4 year olds and 88.3% of 5-14 year olds with a TBI discharged from the ED. Some children considered to have a mild traumatic brain injury (mTBI) may be hospitalized, as would any child whose TBI is more severe. These ED numbers, therefore, represent only those children brought to an ED following their mTBI and not hospitalized.

The problems associated with mTBI are not isolated to the United States. The World Health Organization (WHO) Collaborating Centre for Neurotrauma at the Karolinska Institute in Stockholm published results of their systematic review of adult and pediatric mTBI literature published between 1980 and 2000 throughout the world. In this series of articles in a supplement of the *Journal of Rehabilitation Medicine*, Carroll and colleagues reported that approximately 70-90% of traumatic brain injuries were considered to be minor, with the incidence of mTBI patients who receive treatment in a hospital setting ranging from 100 to 300 per population of 100,000 persons (Carroll, Cassidy, Peloso, Garritty, & Giles-Smith, 2004). When those not treated in a hospital were included, the estimated true incidence of mTBI worldwide increased to over 600 per 100,000 persons (Cassidy et al., 2004).

Significance of Measuring Outcomes from Pediatric Trauma

Trauma outcomes studies initially focused on mortality rates, but as survival rates significantly improved, the need for more sensitive outcomes measures became evident.

The first instrument that provided such measurements in patients who had sustained a TBI was the Glasgow Outcome Scale (Jennett & Bond, 1975). In the late 1980s, health care providers began to develop objective instruments, such as the pediatric Functional Independence Measure (WeeFIM; McCabe, 1991) and questions from the Rand Health Insurance Study (Wesson et al., 1989), to measure children's functional and/or cognitive abilities, measures that could be used to compare outcomes of groups of children and to evaluate improvement in an individual child's outcome over time (Granger, Hamilton, Keith, Zielezny, & Sherwin, 1986). These objective instruments may also be used to evaluate treatments and resource utilization, and to compare aggregate data from different treating facilities.

The WHO Collaborating Centre Task Force on mTBI found 30 studies that evaluated outcomes and factors related to prognosis from mTBI in children (Carroll, Cassidy, Peloso, Borg et al., 2004). While nearly half of these studies involved caregiver perspectives of the child's behavior (Basson et al., 1991; Bijur, Haslum, & Golding, 1990; Farmer, Singer, Mellits, Hall, & Charney, 1987; Fay et al., 1993; Fay et al., 1994; Fletcher, Ewing-Cobbs, Miner, Levin, & Eisenberg, 1990; Greenspan & MacKenzie, 1994; Jaffe, Polissar, Fay, & Liao, 1995; Kinsella, Ong, Murtagh, Prior, & Sawyer, 1999; Light et al., 1998; Ponsford et al., 1999; Rivara et al., 1992; Rivara et al., 1993; Rivara et al., 1996), input from the child's perspective was not considered. More recently, a concept analysis of health-related quality of life (HRQoL) in children by this author (Pieper, 2007) found that only 60% of 76 articles focusing on the meaning of HRQoL in pediatric populations included the children's perspectives. Thus, while researchers

acknowledge the importance of hearing the children's voices, many still only indirectly attempt to obtain information about them.

Subjective Outcomes Assessments

Objective instruments continue to be quite valuable in the care of injured children; however, they do not assess the subjective impact of an injury on the children themselves. Studies in the 1970s found that although sociologists could explain 15% of the variation between individual's quality of life by means of objective data, psychologists were able to explain 50% of that variation using subjective components (Haas, 1999). The most recent movement in assessment of outcomes from pediatric trauma has been toward those subjective indicators that evaluate what children and their caregivers consider important (McCarthy, 2007). This changes the focus from health care providers' perspective to the people who must live with the situation. Their responses provide specific, comprehensive insight into important quality of life issues related to the child's status after an mTBI—knowledge highly useful for a number of purposes. First, limited health care resources may focus on areas caregivers and children perceive most impacted by an mTBI. Thus health care providers of future mTBI children will be able to provide anticipatory guidance based on experiences of others who have actually lived through similar circumstances. Caregiver knowledge of the expected recovery trajectory supplies them with information about what is considered a normal part of their child's recovery as opposed to when their child's healthcare provider should be consulted.

Ethical Considerations

Published research that includes children's perceptions is found infrequently. One reason may be related to Principle 1 of the Nuremberg Code ("The Nuremberg Code,"

1949), which asserts that “voluntary consent of the human subject is absolutely essential.” Although the Nuremberg Code was not completely followed in the United States, this principle may have deterred some American researchers from conducting studies with children because of their inability to provide consent. Since that time, ethical mandates to protect children who participate in research have been promulgated in both the United States and internationally. Subsection D, *Additional Protections for Children Involved as Subjects in Research*, was added to Title 45, Part 46 of the United States Code of Federal Regulations in 1983 (USDHHS, 2005). An example of an international ethical mandate is Guideline 14 of the Council for International Organizations of Medical Sciences (CIOMS) report, entitled *Research Involving Children* (2002). Because of extra protections required for working with vulnerable populations such as children, some researchers may elect to work with participants with whom they can waive these restrictions.

Purpose of the Study

Mild traumatic brain injuries are a common occurrence in children worldwide. Until the early 1980s, children who sustained an mTBI were thought to suffer no long-term consequences (Boll, 1983). However, it has since been demonstrated that this is not true for all children (Anderson, Catroppa, Morse, Haritou, & Rosenfeld, 2001; Bijur et al., 1990; Dennis & Barnes, 2001; Massagli et al., 2004; McKinlay, Dalrymple-Alford, Norwood, & Fergusson, 2002; Ponsford et al., 2001; Wrightson, McGinn, & Gronwall, 1995), as will be discussed in chapter 2.

The only published study to evaluate children’s subjective outcomes from mTBI compared the children’s self-efficacy to their levels of physical activity participation and

athletic competence (Gagnon, Swaine, Friedman, & Forget, 2005). These researchers found that although the children had returned to their pre-injury levels of functioning as measured the day after the injury, their self-efficacy remained significantly below their reported pre-injury levels. Knowing that some children have significant objective sequelae following an mTBI, and that even those who did not may still have significant subjective sequelae, it is important to determine the subjective impact of having sustained an mTBI to elucidate how the injury has affected the children themselves. Therefore, this study addresses the issue of the subjective impact of having sustained an mTBI on those it directly and indirectly affects, the children and their caregiver proxies respectively, by comparing their reported levels of the child's health-related quality of life in the week preceding and at one month following an mTBI.

Theoretical Framework

The theoretical framework that was used for this research is that of health-related quality of life (HRQoL), a subset of the concept of quality of life (QoL). While QoL is a concept that has been in use since the time of Aristotle (McKeon, 2001), who is first credited with using it (Bredow & Peterson, 2004), it remains ambiguous (Mandzuk, 2005). A term used by multiple disciplines, each focuses on aspects of the concept important to that discipline (Anderson & Burckhardt, 1999; Farquhar, 1995). Its ambiguity is amplified in that it cannot be directly measured (Lawford & Eiser, 2001) and each dimension that contributes to an individual's QoL may also be a result of it (Meeberg, 1993). Sociologists in the 1960s determined that their objective measures accounted for only 15% of the variation in an individual's QoL (Haas, 1999). In the 1970s, psychologists found that over 50% of the variation in QoL was explained by

subjective components such as satisfaction and happiness (Haas). Thus it is important to include both subjective and objective measures when attempting to elucidate either QoL or HRQoL.

The first time the term *health-related quality of life* (HRQoL) was found in a publication was in 1987 (Torrance). Torrance referred to the combination of two of the components that directly impacted an individual's QoL, physical and emotional functioning, as HRQoL. He focused on the negative impact of physical and emotional "disabilities" and disagreed with the WHO's inclusion of *social and spiritual functioning* in the definition of health (acknowledging them, however, as important to an individual's overall QoL). Creation of the term *HRQoL* was an attempt to exclude components of QoL not directly related to health, such as freedom and economic factors, from evaluations of the impact of illness, injuries, and treatments (Guyatt, Feeny, & Patrick, 1993). Recognizing that non-medical consequences of healthcare choices may be as important to the patient as those traditionally used to compare outcomes (Meeberg, 1993), social, and at times spiritual, functioning are included as components of HRQoL. It has been noted that far more effort has been put into the development and validation of instruments meant to measure HRQoL than into clarification of the theoretical framework itself (Davis et al., 2006; Wood-Dauphinee, 1999). This has contributed to the difficulty in comparing results from different studies using HRQoL as an outcomes measure.

Definition

There is no universally accepted definition of HRQoL; however, most definitions have developed based on the definition of health published in the *Constitution of the World Health Organization*. It maintains that "health is a state of complete physical,

mental and social well-being and not merely the absence of disease or infirmity” (WHO, 1946). The WHO Quality of Life (WHOQOL) Group consensus definition of *quality of life* is “individuals’ perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns” (WHOQOL, 1995). They considered the concept subjective and multidimensional, including at least physical, psychological, and social dimensions, and that it incorporate an individual’s positive and negative perceptions. However, others emphasize the importance of including *both* objective and subjective determinations when assessing QoL (Cummins, 2005; Meeberg, 1993).

Conceptual Model

The model of HRQoL proposed by Haas (1999) provides a visual representation of this concept (see Figure 1). Subjective and objective influences on each of the dimensions the WHOQOL group deemed the minimum necessary, (i.e., physical, psychological, and social) are demonstrated. Haas’ dimension of spiritual functioning is replaced in the figure with that of role functioning (Pieper, 2008). Haas stipulates subjective indicators as *well-being* and objective ones as *functional status*. The influence of an individual’s satisfaction with life on their well-being is also shown.

Functional status is not exclusively related to physical functioning; rather, it is an objective measure of how well a child is able to function within all four dimensions of the model. Historically, most outcomes measures used with injured children have been objective measures of their functional abilities in some but not all of the dimensions included in this model. Instruments commonly include mobility and activities of daily living evaluations (Chen, Bode, Granger, & Heinemann, 2005; Haynes & Sullivan, 2001;

Kothari, Haley, Gill-Body, & Dumas, 2003). While these objective evaluations are important to health care providers, subjective interpretations of the dimensions contributing to HRQoL are generally of greater importance to children and their caregivers (Grilli et al., 2006). Subjective interpretations provide additional information regarding the child's level of effort required and feelings evoked while striving to achieve a particular level of observable functioning (Ware, 1987). Objective and subjective perspectives of each dimension are thus important in determination of a child's HRQoL.

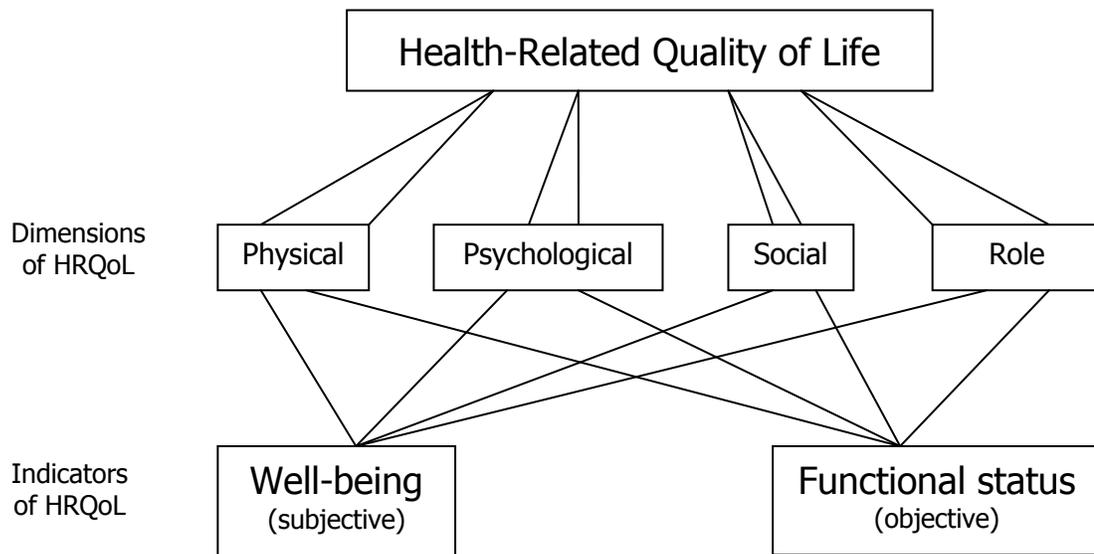


Figure 1. Conceptual model of health-related quality of life. *Note.* From “Clarification and Integration of Similar Quality of Life Concepts,” by B. K. Haas, 1999, *Image: Journal of Nursing Scholarship*, 31, p. 219. Copyright 1999 by Sigma Theta Tau International. Adapted with permission.

The physical dimension of HRQoL evaluates the child's mobility, self-care capabilities, and other physical activities. There is generally closer agreement between child and proxy perspectives of the physical dimension than those that are less observable, such as the psychological and social dimensions (Eiser & Morse, 2001).

Mental health, emotions, behavior, and cognitive functioning are aspects of the psychological dimension, whereas interpersonal relationships and social resources are encompassed by the social dimension (Ware, 1987). Role functioning is an evaluation of limitations the child may have relative to his or her usual role, such as being a student, due to health-related issues (Ware).

Conceptual Issues Related to Children

There are two issues that confound assessment of the concept of HRQoL in children pertinent to this study: the meaning of HRQoL to children and differences between self-report and proxy-report.

Meaning of HRQoL to Children

The variables that impact HRQoL in children within each dimension and the relative importance of each dimension are affected by children's ages and developmental levels. It is therefore important to have children at different ages and developmental levels involved in determining how the concept of HRQoL is operationalized in HRQoL instruments designed for use in pediatric populations (Detmar, Bruil, Ravens-Sieberer, Gosch, & Bisegger, 2006; Varni, Seid, & Rode, 1999). More research is needed before the meaning of HRQoL to very young children can be elucidated because of difficulties related to their developmental level, such as language skills and ability to understand the questions and time sequences (Theunissen et al., 1998).

Self-Report Versus Proxy-Report

An individual's HRQoL is a personal perception (Gill & Feinstein, 1994; Sullivan, 2003), however a number of studies have used proxy perspectives of the child's HRQoL, generally provided by a parent or guardian, instead (Cox et al., 2005; Schweer et al.,

2006). Limbers, Newman, and Varni note that “parent proxy-reports typically explain only 10% to 25% of the variance in child self-report HRQOL outcomes” (2007, p. 2) and several studies have evaluated differences between self-report and proxy-report. Eiser and Morse (2001) reviewed 14 articles that used 10 different instruments to measure HRQoL that addressed child-proxy concurrence. They found that concurrence was better in the physical and worse in the emotional and social areas evaluated. Whenever possible, they recommend that HRQoL information be collected from both the child and the proxy, noting two important factors: each respondent provides a different, and valuable, contribution to the understanding of a child’s HRQoL, and children generally do not determine if, when, or by whom they will receive health care. Rather, it is the child’s proxy who makes those decisions, thus making their assessment of the child’s HRQOL important to the care the child actually receives.

This is consistent with the conceptual model (see Figure 1), in which the child’s perspective is represented by *well-being*, or subjective indicators, and the proxy’s perspective by *functional status*, or objective indicators. Each has its own perspective of the physical, psychological, social, and role dimensions of HRQoL, which when combined provide a more robust evaluation of the concept that would either alone.

Definitions of Key Terms

Theoretical and operational definitions of terms key to this study are as follows.

Mild Traumatic Brain Injury (mTBI)

Theoretical Definition

An mTBI is a non-penetrating injury caused by external forces to the head with at least one of the following results: (a) any transient period of altered consciousness,

confusion, or disorientation; (b) any amnesia surrounding the time of injury lasting a maximum of 24 hours; (c) transient signs of neurological dysfunction; or (d) any loss of consciousness lasting a maximum of 30 minutes (CDC, 2003).

Operational Definition

For the purpose of this study, the operational definition of an mTBI was one recommended by WHO's Collaborating Centre Task Force on Mild Traumatic Brain Injury (Carroll, Cassidy, Holm, Kraus, & Coronado, 2004): an acute non-penetrating injury caused by external forces to the head in which a Glasgow Coma Scale of 13 to 15 was evident upon presentation to the healthcare provider or 30 minutes post-injury, whichever occurred later. At least one of the following neurological deficits must also have occurred: (a) loss of consciousness for a maximum of 30 minutes, (b) amnesia for events immediately preceding or following the injury lasting a maximum of 24 hours, (c) disorientation or confusion, or (d) transient neurological symptoms that may have included seizures, other focal neurological signs, or a non-operative intracranial lesion. In addition, the child required hospitalization for a maximum of 24 hours and did not have any significant associated injuries, such as an extremity fracture.

Pediatric Health-Related Quality of Life

Theoretical Definition

The construct pediatric HRQoL is dynamic and multidimensional. It includes the child's physical, emotional, social, and role functioning and well-being from the perspective of the child and the child's caregivers or other designated proxies (Pieper, 2007).

Operational Definition

HRQoL was operationalized in this study by means of two instruments, the Pediatric Quality of Life Inventory 4.0 (PedsQL™ 4.0) Generic Core Scales questionnaires (see Appendix B) and the PedsQL™ Cognitive Functioning Scale (see Appendix C). There are separate instruments for children 5-7, 8-12, and 13-18 years and their parent/legal representative proxies.

Research Questions and Hypotheses

Health-related quality of life has not previously been used as an outcome measure after mTBI in children. Therefore, the hypotheses for this nonexperimental prospective quantitative study were non-directional.

Research Questions

The following research questions were investigated by this study:

1. Do children who have sustained an mTBI return to their pre-injury HRQoL within one month of injury?
2. Is the 1-month post-mTBI HRQoL of children different from the HRQoL of 1-month post mild non-brain injured children or from that of uninjured children?
3. Do child-proxy dyads each rate the child's HRQoL at the same level?

Hypotheses

These research questions were addressed by means of the following null hypotheses.

1. There will be no statistically significant difference between pre-injury and 1-month post-injury health-related quality of life (HRQoL) in children who have sustained an mTBI as rated by the child.

2. There will be no statistically significant difference between pre-injury and 1-month post-injury HRQoL in children who have sustained an mTBI as rated by the proxy.
3. There will be no statistically significant difference between baseline and 1-month post-injury HRQoL of mTBI children and the HRQoL of children with a mild non-brain injury or uninjured children at the same time points as rated by the children.
4. There will be no statistically significant difference between baseline and 1-month post-injury HRQoL of mTBI children and the HRQoL of children with a mild non-brain injury or uninjured children as rated by the proxies.
5. There will be no statistically significant difference between the children's HRQoL as rated by the children and their proxies at either time point.

Assumptions and Limitations of the Study

There are two components to the assumption that the instrument used to measure the children's health-related quality of life, the PedsQL™ 4.0, accurately reflects HRQoL. One is that the children correctly interpret what they are asked on the instrument. The other is that the children and their caregivers provide honest assessments of the child's status during the defined time period prior to completing the instrument. The validity and reliability of the PedsQL™ 4.0 has previously been tested with healthy children and pediatric patient populations, including those with traumatic brain injuries (McCarthy et al., 2005).

Threats to Internal Validity

There are a number of threats to the internal validity of this study. Because this is not a longitudinal population study, the mTBI, of necessity, occurred prior to participants having completed a baseline assessment of the child's HRQoL. Although this methodology has been used in other studies of children following mTBI (Anderson et al., 2001; Gagnon et al., 2005; Goldstrohm, 2002; McCarthy et al., 2005; McCarthy et al., 2006; Necajauskaite, Endziniene, & Jureniene, 2005; Roberson, 2004), it remains a threat to the internal validity of the study. To reduce this threat and in an attempt to diminish the effects of the injury on memories of the child's pre-injury HRQoL, baseline assessments were obtained within hours of the injury.

Selection bias is problematic because participants were self-selected from those who met study criteria. Those who agreed to participate may have had pre-existing differences from those who declined. Using repeated measures of within-subject evaluation of HRQoL decreased these threats to internal validity. However, repeated use of the same instrument may have also influenced participant responses. There was a minimum of 4 weeks between the two evaluations, a time frame that may be of sufficient length to ameliorate testing effects. Potential threats to internal validity were evaluated in combination to determine the overall direction and degree of the bias they produced on study results.

Threat to External Validity

Participants were self-selected from among children treated for isolated mTBI in the emergency departments of the two institutions in a large northeast Florida city where the vast majority of children are seen. Because both institutions were in an urban setting, it is possible that results will not be generalizable to rural settings. It is also possible that

different results could be obtained if the study were to be replicated in a different part of the United States or another country.

Significance of the Study

“Despite the overwhelming burden on the health of the world’s population from injurious events, injury is a phenomenon that is underrepresented in the scholarly writings in the discipline of nursing” (Sommers, 2006). This is evident in relation to the mTBI literature, as was demonstrated by results of the systematic review conducted by the WHO Collaborating Centre Task Force on Mild Traumatic Brain Injury. Ninety percent of the relevant mTBI literature was located in Medline (Carroll, Cassidy, Peloso, Garritty et al., 2004). Their subsequent search of PsycINFO yielded another 4.8% of unique citations; whereas only 2.8% of citations that were not found in either of those two databases were found CINAHL.

Nurse researchers need to better understand how children who have sustained an mTBI (and their caregivers) perceive the mTBI’s impact on the child’s life. One method for accomplishing this is to accurately measure both child and caregiver perceptions of the child’s HRQoL. Once such knowledge has been acquired, nurses may use it during routine nursing care to provide research-based anticipatory guidance and thus decrease the anxiety levels of injured children and their families. This information will also allow families to recognize when the child is not progressing as well as should be expected and needs to be seen by an appropriate healthcare provider.

Research that demonstrates subjective outcomes measures important to children who have sustained an mTBI could be used in conjunction with current objective outcomes measures to improve our ability to evaluate treatments and better allocate

limited health care resources. Nurses who currently compare aggregate data from different treating facilities would also be able to include data regarding outcomes important to children in future comparisons.

Summary

Large numbers of children annually sustain an mTBI. Currently only approximately half of pediatric mTBI outcome studies include caregiver perspectives and far fewer attempt to obtain information directly from the injured children. This study has increased our body of knowledge by obtaining data from those most impacted by the injury, the children and their caregivers. The theoretical framework used is HRQoL, a concept that includes subjective and objective indicators. The meaning of HRQoL to the children and self-report versus proxy-report are two conceptual issues related to HRQoL presented, as are the theoretical and operational definitions of mTBI and pediatric HRQoL used for the purposes of this study. Research questions and associated null hypotheses that were addressed are presented. Assumptions, limitations, and the significance of the study are discussed.

CHAPTER TWO: REVIEW OF THE LITERATURE

Introduction to the Literature Review

This review of the literature first briefly addresses the most common etiologies of injuries and mild traumatic brain injury (mTBI) in children, followed by a discussion of studies of functional and cognitive outcomes from the injury. The next section concerns child and proxy perceptions. Published research of post-TBI health-related quality of life (HRQoL) in children is discussed. The chapter concludes with a summary of the existing literature regarding outcomes of children who have sustained an mTBI and how the proposed study will complement that knowledge.

A literature search was conducted to determine what is already known about outcomes from mild traumatic brain injury (mTBI) in children. The Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO, ProQuest® Dissertations and Theses, and PubMed databases were searched. Keywords used for the first three databases were *mild traumatic brain injury*, *children*, and *outcome*. PubMed was searched using a combination of the Medical Subject Heading (MeSH) terms *brain injuries*; *quality of life*; and *child or adolescent*. Because PubMed MeSH terms do not delineate the severity of traumatic brain injury, abstracts were subsequently reviewed for citations that included outcomes from pediatric mTBI. All database searches were restricted to references written in English. While emphasis was placed on citations published between 2001 and 2007, earlier publications were included if they contributed to this study.

Etiology

The leading causes of nonfatal injuries in 5 to 17 year olds seen in American Emergency Departments are unintentional falls (25.5%) and collisions with an object, either moving or stationary (23.8%) (Office of Statistics and Programming, n.d.). In studies published since 2000, the most common injury mechanism for children with mTBI was falls, ranging from 40% (Ponsford et al., 2001) to 82% (Anderson et al., 2001). An mTBI in children associated with a motor vehicle (including passenger/driver, pedestrian, bicycle, etc.) ranged from 6% (McKinlay et al., 2002) to 27% (Hawley et al., 2004). In a study by Hawley et al., 17% of their mTBI population was comprised of child pedestrians who had been struck by a motor vehicle.

Functional and Cognitive Outcomes

The prevailing attitude until the early 1980s was that children recovered completely from mTBI and that any subsequent symptoms were caused by something else (Boll, 1983). However, Dr. Thomas J. Boll's review of mTBI in children caused considerable debate because of the author's conclusion that "the disruption in coping capacity and attendant breakdown in usual behavioral patterns cause more psychosocial and academic-economic hardship than have begun to be appreciated" (p. 74). Although children were included in the population of only one study incorporated in Boll's analysis, this review drew attention to the need for study of mTBI in children to determine if there were actually significant consequences from them.

Two recent reviews of studies of prognosis from mTBI included populations of children in the literature. The related points from these reviews will be examined.

Subsequently, the thirteen studies of outcomes of children with mTBI published between 2001 and 2007 will be discussed.

Previous Reviews

One previous review included 40 studies published from 1970 through 1995 (nearly half between 1990-1995) that included groups of mTBI children and reached specific conclusions about them (Satz, Zaucha, McCleary, & Light, 1997).

Methodological limitations found in these quantitative studies were as follows: (1) fewer than 20 participants were involved in 13 of the studies, (2) different definitions of mTBI were used, causing eligibility criteria to vary (particularly problematic when more severe TBI patients are combined with the mTBI group because it cannot be determined whether adverse results are simply due to the inclusion of more severely injured children or whether results can be generalized to other groups of mTBI children), and (3) the population for all but one study was drawn from hospitalized children, excluding milder TBI cases.

Satz et al. (1997) found different study designs, with 8 being retrospective, 14 prospective, and 17 cross sectional. Frequency and lengths of time post-injury at which data were collected also varied, from single data collection points at less than a month to 10 years, to a maximum of seven collection points over 5 years. Other issues included those related to control group composition, how pre-existing behavioral or academic problems and other confounding variables were addressed, and the outcomes measures utilized. The age at injury is another variable that must be considered when evaluating the generalizability of study results. Infants, in particular, are frequently excluded from studies of mTBI because of methodological difficulties. Comparing different older age

groups of children also poses challenges as they are at different levels of brain maturation and development. What would be considered normal for a preschooler is very different from that expected of an adolescent. The conclusions these authors drew from their analysis is that children at the mild end of mTBI had no adverse neuropsychological outcomes as a result of their injury, nor were there academic or psychosocial problems related to the mTBI. The authors did, however, have some recommendations for future mTBI studies, particularly related to strengthening the methodology by meeting at least four of the following criteria:

- (a) control groups (non-injured or other-injured); (b) longitudinal design with follow-up assessment; (c) clear definition of *mild injury*, with no inclusion or pooling of more severe injuries; (d) $n \geq 20$ mild cases; (e) standardized tests; and (f) control for pre-injury risk factors (Satz et al., 1997, p. 123).

Carroll, Cassidy, Peloso, et al. (2004) reviewed the international literature related to mTBI (in both adults and children) published between 1980 and 2000 and found that only a limited number of studies met their inclusion criteria. Longitudinal design, identification of mTBI participants without delay after the injury, and the presence of a case- or cohort control group were identified as important criteria overall strength of study design. There were 31 studies of mTBI in children included in their analysis, of which 6 were classified as Phase I - descriptive; 22 as Phase II - exploratory analyses comparing possible predictors or control group results; and none as Phase III - confirmatory studies that evaluated strength of the relationship between a specific predictor and the outcome while controlling for potential confounding variables.

Two of the Phase II cohort studies found that if post-concussion symptoms were present, they generally lasted no longer than 2 to 3 months. In addition, the majority of other studies observed minimal short- or long-term behavioral or cognitive functioning consequences from mTBI in children. Strength of study methods and consistency of results prompted reviewers to conclude that mTBI-related problems are temporary. However, they also acknowledged and discussed two methodologically sound studies where statistically significant differences in the mTBI children's outcomes were found (Carroll, Cassidy, Peloso, Borg et al., 2004).

One is of interest because the population consisted of children who were injured between 2.5 and 4.5 years of age (Wrightson et al., 1995). They were evaluated within one month of their mTBI, at 6 and 12 months post-injury, and at 6.5 years of age. Each evaluation consisted of two, 1-hour sessions within a week in which the child completed multiple standardized study instruments. All but one evaluation occurred in the children's homes; the remaining one took place at the child's school at age 6.5 years. Fifty-seven mTBI children and 77 non-TBI controls (injured and from the same emergency department) completed the 12-month evaluations. At 1-month post-injury, there were no statistically significant differences between the groups. However, at 6 and 12 months post injury and 6.5 years of age, the mTBI children had worse performance on a time limited test, called *visual closure scores*, in which they were to locate objects hidden within a picture ($p = .0001$, $p = .0016$, and $p = .015$, respectively). The mTBI children were also significantly more likely to have sustained another mTBI within the first 6 months following their initial mTBI ($p = .0023$). Forty-seven of the mTBI children and 52 of the control group remained in the study when the children reached 6.5 years of age. There

was a significant correlation between low reading scores at 6.5 years of age and low visual closure scores at 6 and 12 months post-injury ($p < .05$ and $p < .01$, respectively). The authors propose that this singular deficit could be a result of particularly rapid development of the involved portion of the brain at the time of the injury. It does not damage previously established skills, but prevents further normal development of the skill. This is an example of the importance of conducting long-term longitudinal studies of infants and young children who have sustained mTBI.

The other study that demonstrated a statistically significant difference in mTBI children was a nested cohort study of the British Birth Cohort. This is a longitudinal population study of approximately 13,000 children who were born in a 7-day period in 1970 (Bijur et al., 1990). Thorough parental interviews occurred when the children turned 5 and 10 years of age. At the age 10 interview, parents were asked if their children had sustained any injury for which they had sought medical care in the previous 5 years. If the children had been seen at a hospital, parents provided information used to locate the medical record from the visit, and thus corroborate parents' history. The mTBI cohort consisted of 114 children with International Classification of Diseases, 9th Revision, Clinical Modifications (ICD-9-CM) codes reflecting a concussion or loss of consciousness in conjunction with a brain injury, who were seen in the ED or hospitalized no longer than overnight (49 children). One control group consisted of injured children of the same age range who were also seen either in the ED or hospitalized overnight, but whose injuries involved long bone fractures, burns, or lacerations of the arms or legs. The other control group was a random sample of 1726 children who had not sustained an injury for which medical care was sought between 5

and 10 years of age. The only outcome noted to be statistically significantly different for children with mTBI was mean teacher-reported hyperactivity. There were no statistical differences between outcomes of mTBI children who were discharged from the ED and those who were hospitalized overnight.

Current Literature

Thirteen studies, including three dissertations, were published between 2001 and 2007 regarding outcomes of children with mTBI, each of which will be discussed in this section. Each was evaluated using the criteria Satz et al. (1997) recommended. As discussed in the previous section, those authors recommended that to be considered a methodologically strong study, at least four of their six criteria needed to be met. Two of the studies met only two of the Satz et al criteria (Dennis & Barnes, 2001; Necajauskaite et al., 2005). They, and one meeting four (Hawley et al., 2004) and one meeting five (Wetherington, 2006) of the criteria, were retrospective, cross sectional studies. The remaining studies were all longitudinal, with Roberson (2004) meeting four of the criteria and the remaining studies meeting either five (Anderson et al., 2001; Gagnon, Swaine, Friedman, & Forget, 2004b; Massagli et al., 2004; Ponsford et al., 2001) or all six of the Satz et al. criteria (Gagnon, Swaine, Friedman, & Forget, 2004a; Gagnon et al., 2005; Goldstrohm, 2002; McKinlay et al., 2002).

Three studies were conducted in Canada by the same group of researchers (Gagnon et al., 2004a, 2004b, 2005). The 2004 studies used the same patient populations of 38 mTBI, ages 7 to 16 years. Inclusion criteria were that the children had been seen in the hospital for a period of hours to overnight, met the American Congress of Rehabilitation Medicine definition of an mTBI (Mild Traumatic Brain Injury Committee

of the Head Injury Interdisciplinary Special Interest Group of the American Congress of Rehabilitation Medicine, 1993), and had a normal neurologic evaluation at discharge from the hospital. Children with pre-existing problems (e.g., diagnosed with learning disabilities or attention deficit disorder, taking Ritalin on a regular basis, attending a special needs school because of learning or behavior problems, or fracture/other potential balance impediment) were excluded from both studies. The control group consisted of 38 uninjured friends of the mTBI children who were matched by age, gender, and pre-injury physical activity levels. Gagnon and associates mentioned that use of *friend sampling* helped to limit the effect of other potential confounding variables between the two groups, such as socioeconomic status. All standardized tests were conducted in the children's homes by an experienced pediatric physical therapist. Group identification of the children was not disclosed to the therapist. Three evaluations occurred for both groups, timed to match Weeks 1, 4 and 12 post-injury for the mTBI patients.

One of these studies evaluated the children for response speed using a subtest of the Bruininks-Oseretsky Test of Motor Proficiency (Gagnon et al., 2004b). The age equivalent mTBI group scores on the response speed subtest were worse than the control group scores at 1 week ($p < .001$) and 12 weeks ($p < .001$). The mTBI group also showed significant improvement over time, both between weeks 1 and 4 ($p = .03$) and between weeks 1 and 12 ($p = .009$). The authors noted that the study needed to be continued for a longer period of time to determine when the response speed of the mTBI children would return to normal or remain stable.

The other study evaluated the children's balance using a different subtest of the Bruininks-Oseretsky Test of Motor Proficiency (Gagnon et al., 2004a). Although mTBI

children's balance improved between Weeks 1 and 12 post-injury ($p = .003$), it was statistically worse than the control group's at each time point ($p < .001$ at Week 1, $p = .001$ at Week 4, and $p = .007$ at Week 12). Continued significant balance deficits of the mTBI children relative to the control group at 12 weeks' post-injury warrant repetition of this study over a longer period of time.

A limitation of both studies was use of the Rivermead Post-Concussion Symptoms Questionnaire, an instrument previously used only in adult populations, with no mention of it having been adapted for a pediatric population. It was noted that although mTBI children had significantly more post-concussive symptoms at each evaluation point ($p < .001$), their symptoms significantly decreased over time ($p < .001$). In addition, neither the number of post-concussive symptoms reported nor any other injury-related variable analyzed was related to the children's response speed scores (Gagnon et al., 2004b).

The only mTBI study that included the children's perspectives was one that evaluated their self-efficacy post-mTBI (Gagnon et al., 2005). The same control group criteria and friend sampling technique used in their 2004 studies just discussed were also used in this study of the self-efficacy of 34 mTBI children 8 to 16 years of age who were admitted to the hospital as a result of their injury. They found that although the children had returned to their pre-injury levels of physical activity participation and athletic competence, their self-efficacy scores at 12 weeks' post-injury were significantly lower than their pre-injury levels as reported one day post-injury ($p < .001$ for physical activities, $p < .05$ for athletic skills). One limitation of this study was that the pre-injury self-efficacy levels were reported the day following the injury. Another limitation is that

there was no formal psychometric testing of the instrument used to evaluate self-efficacy prior to its use in this study. It would have also been a stronger study if a control group of children who had sustained non-TBI injuries (requiring same activity restrictions as those of mTBI group) had been included.

Dennis and Barnes (2001) conducted the other Canadian study. It was a cross-sectional study of the language comprehension of school-aged children and adolescents in Toronto who had sustained either a mild or severe TBI. The criteria used to define each of these TBI groups were provided. The control group consisted of age- and gender-matched children from the same school system attended by the TBI groups. Controls had average reading and language arts skills and no neurological or learning disabilities.

All children were interviewed to evaluate their literal, non-literal, inferential, and intentional language comprehension. The researchers used effect sizes to compare differences between groups. They found that children who had sustained an mTBI had literal comprehension levels comparable to the control group; inference comprehension depended on the particular task. The effect size comparing mTBI children to controls on coherence inferences was large (approximately -0.58), wherein the mTBI children performed better. However, on the elaborative and pragmatic inferences, the mTBI children performed less well, with effect sizes approximately 0.32 and 0.65, or medium and large, respectively. The mTBI group also had worse intentional language comprehension than the control group, with moderate to very large effect sizes on the three tasks of ironic criticism, deceptive praise, and speech acts. This study had a number of limitations, including small sample size. Children's ages were not reported and the most specific reference to length of time post-injury was "many years after they were

injured” (Dennis & Barnes, 2001, p. 465). The evaluation instruments were non-standardized and there was no control for pre-injury risk factors.

Another cross-sectional study was undertaken in Lithuania (Necajauskaite et al., 2005). This study evaluated children who had sustained a single mTBI with those who sustained mild injuries to other parts of their bodies when they were between 4 and 16 years of age. Cases were matched for hospital admission date, age, and gender. Data analysis included 102 case-matched pairs of children who were between 1 and 5 years post-injury (median 27 months). Further criteria for inclusion in the study were not provided, nor were there any controls for pre-injury risk factors. The children’s parents or caregivers were requested to complete two sets of non-standardized postal questionnaires regarding their child’s health status and the presence of post-concussive symptoms. The first questionnaire included the previous year and the previous month, and did not overtly mention the child’s injury. The second questionnaire subsequently asked for the same information relative to the time prior to and shortly after the injury.

The number of reported headaches was significantly lower in the previous month than in the previous year ($p = .001$); however, there was no difference in frequency between the two groups. The learning capabilities of the mTBI children were still sufficient that they and control group children participated in equal numbers in classes taught using the advanced school curriculum. After a year post-injury, there was no statistical difference between the groups in the frequency of any post-concussion symptoms, in spite of responses indicating that more children in the mTBI group had suffered from pre-injury headaches ($p = .01$).

One of two studies conducted in Melbourne, Australia had a study population of 17 mTBI children from 3 to 7 years of age and 35 uninjured controls who were matched for age, gender, pre-injury level of function, and socioeconomic status (Anderson et al., 2001). Parents completed several standardized instruments regarding their children's status pre-injury and at 0-3, 12, and 30 months post-injury. A child psychologist conducted a battery of intelligence, receptive/expressive language skills, memory, language comprehension, and verbal/spatial learning tests with each child at the same post-injury time points. No significant differences were found between the two groups for demographic, psychosocial, or other risk factors, or for either behavioral or intellectual functioning at any time point. Memory skills as measured by story recall significantly increased over time in both groups ($p < .001$), but mTBI children had lower story recall at each evaluation ($p < .05$). The only other statistically significant difference was that mTBI children had lower verbal fluency skills at the 30-month evaluation ($p < .05$). These authors postulated that young children are particularly vulnerable to even a mild brain injury that occurs during development of these two skills, both of which are high-level language skills. To meet the criteria of Satz et al. (1997), however, this study should have had a sample size of at least 20 children.

The other study conducted in Melbourne, Australia involved children 6 to 15 years of age in intervention and non-intervention control groups (45 and 47 children with minor non-brain injuries, respectively) and mTBI groups (61 and 58 children respectively; Ponsford et al., 2001). The intervention consisted of an interview with the parent and child and neuropsychological evaluation of the child at one week post-injury. The intervention group of mTBI children also received a booklet that provided

anticipatory guidance about mTBIs, including possible symptoms, their natural history, and how to manage them. An interview and neuropsychological evaluation were conducted at 3 months post-injury for all study participants. Children in the mTBI groups had significantly more problems with memory ($p < .03$), while the control groups had significantly more anxiety ($p < .04$). Children in the mTBI groups were found to have significantly more previous TBIs, pre-injury stressors such as family breakdowns, learning difficulties, and pre-existing psychological or neurological problems described by parents during the interview at one week post-injury. Twenty percent of the mTBI children still had significant problems 3 months post-injury. However, families of children with mTBI in the intervention group reported significantly fewer behavioral changes and symptoms 3 months post-injury than did those in the control group.

The British study (Hawley et al., 2004) involved parental postal questionnaires of the King's Outcome Scale for Childhood Head Injury (KOSCHI). Children who were 5 to 15 years of age at the time of injury and required hospitalization for varying degrees of TBI (419 mild, 58 moderate, and 218 severe) were included in the study groups. There was a control group of 45 parents of children with no history of a TBI who were of the same age and gender as the study groups. The definition of mTBI used in this study was that of the British Society of Rehabilitation Medicine and includes those with a Glasgow Coma Score of 13 to 15 after initial resuscitation and a maximum loss of consciousness of less than 15 minutes. It allows for inclusion of children with skull fractures. The researchers independently analyzed questionnaire responses from parents of children with and without skull fractures. Moderate disability was reported in 51% of those with skull fractures and 42% of those without skull fractures, but these differences were not

statistically significant. A statistically significant relationship was found between worse KOSCHI scores and social deprivation ($p = .001$).

There were a number of limitations found in this study. The retrospective cross sectional design was a problem in that the children were between less than 1 year and 6 years post-injury, making it difficult to compare results. Only those parents with more severe mTBI children met inclusion criteria for this study. Some results compared the entire TBI group to the control group, rendering it impossible to isolate results for those with an mTBI.

Roberson (2004) compared groups of 65 mild, 84 complicated-mild, and 52 moderate TBI children 4 to 15 years old at the time of injury to each other and to existing normative data “as soon as possible” (Roberson, 2004, p. 24) after the injury (0.10 to 2.2 months) and at 3, 6, and 12 months post-injury. Definitions for each of the TBI categories were provided. The difference between mild and complicated-mild TBI was assessed by the presence of either a depressed skull fracture, an intracranial lesion evident on computed tomography (CT) taken at the time of injury, or the presence of a focal intracranial lesion on the 3-month post-injury magnetic resonance imaging (MRI) in the latter group. The MRI was part of the research protocol and not standard of care for children with these injuries. Standardized objective outcomes measures included the Vineland Adaptive Behavioral Scales, California Verbal Learning Test - Children’s version (CVLT-C), Grooved Pegboard Test, Tower of London, Porteus Mazes, and the coding section of the third edition of the Wechsler Intelligence Scale for Children (WISC-III Coding).

The data source for baseline evaluation of the Vineland Adaptive Behavioral Scales was parent or caregiver perceptions of children's pre-injury status as described at the initial post-injury interview. No significant differences on the performance of the groups of TBI children were found on this instrument. However, all three TBI groups scored below the 50th percentile for behavioral functioning at all evaluation points, including their pre-injury baseline as measured 0.10 to 2.2 months post-injury.

The only significant difference between children who had sustained a mild or a mild-complicated TBI was on the WISC-III Coding scale at baseline ($p = .0047$), with those sustaining an mTBI performing better. However, the children with a mild-complicated TBI performed significantly better than those children with a moderate TBI on some of the instruments. Overall performance of children with moderate TBI on the CVLT-C was significantly worse than that of children with complicated-mild TBI ($p = .008$ after Bonferroni adjustment), and was reported to have remained significant at each time point. Limited evidence of statistical significance is provided, with the narrative describing statistically significant differences between children with mild-complicated and moderate TBI across all evaluation points of some instruments and data in a table including only a single time point for each instrument or subsection thereof. The fine motor performance of children in the mild-complicated TBI group was reported to be significantly better than that of the children with moderate TBI as assessed by the Grooved Pegboard Test. Similar initial results were obtained for the average errors per trial on the Porteus Mazes for these two groups. However, differences between all groups in their rates of error decreased over time, leading the author to speculate that these group disparities would continue to fade.

Wetherington (2006) conducted a cross-sectional study of 3 year-olds who had sustained a mild (31) or moderate to severe (20) TBI prior to their second birthday and had been treated at one of the nine hospitals in North Carolina with a pediatric intensive care unit. Criteria for TBI classification were described. The control group consisted of a convenience sample of 31 normally developing children attending daycare centers or preschools and matched to the TBI sample children based on maternal education, with age, race, and gender also considered.

Parents completed the Child Behavior Checklist—Scales of Independent Behavior-Revised, Early Development Form (SIB-R), the Self-Report Family Inventory, and the maternal education section from the Hollingshead Index. Children completed the Mullen Scales of Early Learning, a measure of overall development. It was hypothesized that children who had sustained a TBI would have significantly greater social and behavioral impairments than children in the control group, but no differences were found among any of the groups. The author noted it was possible that injured children may demonstrate impairments in these areas as they enter school and continue to develop.

Goldstrohm (2002) evaluated neurocognitive, behavioral, familial, and pre-injury factors in 29 preschoolers between the ages of 3 and 6 who had been hospitalized as a result of mild to moderate TBI in either of two pediatric trauma units in Pittsburgh. The inclusion criteria for each TBI group were described, including definitions of the three subcategories of mild (minimal, very mild, and mild). There were two control groups of 3 to 6 year old children, one of which consisted of 33 children hospitalized in the same units for mild to moderate non-brain injuries. The other control group consisted of 34

uninjured local children. There were two evaluation points, one during initial post-injury hospitalization once the child was medically stable, and the other at 6 months post-injury.

Children were evaluated with the following standardized instruments: the Children's Orientation and Amnesia Test, Child Behavior Checklist, Attention Deficit Disorder Evaluation Scale – Home Version, Parenting Stress Index, Conners' Global Index – Parent Version, and portions of the Stanford-Binet Intelligence Scale, Bracken Basic Concept Scale, and NEPSY (a developmental neuropsychological assessment). Parents also completed a form regarding their child's medical, psychiatric, and developmental history and a checklist of their child's post-concussion symptoms. Although the TBI group demonstrated significant improvements in developmental and cognitive evaluations between the two study points, results remained significantly worse than those of the uninjured control group.

Identified risk factors were pre-existing cognitive or behavioral problems and family stress. It was also noted that “the most likely predictor of a head injury is a previous head injury” (Goldstrohm, 2002, p. 108). This study thus emphasizes the importance of including children who have pre-existing behavioral problems or cognitive delays, or who have sustained a previous brain injury in TBI research. By excluding them from a study sample, the true pediatric TBI population is not represented.

Massagli et al. (2004) used the definition of mTBI that the CDC uses in their surveillance studies to evaluate the correlation between mTBI and future psychiatric illness. Their longitudinal population study included 490 children under the age of 15 who had been diagnosed with mTBI in an emergency department, hospital, or outpatient clinic in 1993 and who were members of a specific health maintenance organization

(HMO) in Washington State. For each study participant, three HMO members matched for age and gender were included as the control group ($n = 1470$). Children with a previous ICD-9-CM diagnosis of a TBI were excluded from participation in either group. Computerized HMO records were searched for the presence of psychiatric diagnoses, services, or medications for the year prior to the injury and for the 3 subsequent years.

The incidence of psychiatric illness over the 3-year period was statistically greater in the mTBI group (30%) compared to controls (20%, $p = .0001$) in those children who had no previous diagnosis of a psychiatric illness. Incidence was greatest in the first year post-injury, with hyperactivity, in particular, being noted. For those with pre-injury diagnosis of a psychiatric illness (55% and 63%, respectively), there was no statistical difference in results for mTBI and control groups. Previous diagnosis of a psychiatric illness was a strong predictor of subsequent psychiatric diagnoses independent of mTBI exposure. Over the 3-year study period, the relative risk of future psychiatric diagnoses in the control subgroup (those with a psychiatric history) was 6.21 compared to those without such a history ($p < .0001$), and 2.74 for mTBI children with a psychiatric history as compared to those without a prior psychiatric diagnosis ($p < .0001$). Massagli and colleagues' findings suggested that children with an existing psychiatric illness are at greater risk for future psychiatric illnesses than are children who sustain an mTBI. Limitations of this study are that the diagnoses of a psychiatric illness were made by a large number of providers, many of whom were not psychiatrists. In addition, it was possible that children in either the control or mTBI groups sustained another TBI during the 3-year study period.

A nested cohort study was conducted in New Zealand as part of the Christchurch Health and Development Longitudinal Study (McKinlay et al., 2002). The sample consisted of 1265 children who were hospital-born in Christchurch during a nearly 4-month period in 1977. Parents were interviewed on an annual basis; additional data sources included medical record verification of reported hospital events, teacher interviews, and standardized testing of the children. Children who sustained a TBI between 0 and 10 years of age for which medical attention was sought had to meet four additional criteria to be included in the mTBI group: (a) diagnosed with a concussion or be suspected of having had a concussion, (b) experienced a maximum loss of consciousness of 20 minutes, if any, (c) hospitalized for a maximum of 2 days, if any, and (d) no evidence of skull fracture. The mTBI group ($n = 132$) was subdivided into those children who were hospitalized ($n = 36$) and those treated on an outpatient basis ($n = 96$). Children who sustained multiple TBIs were grouped according to the most severe TBI sustained. Children were also grouped by age at time of injury, either 0 to 5 or 6 to 10 years of age. Children who had sustained TBIs while in both age groups were excluded. The control group consisted of all children in the birth cohort who had not sustained a TBI. The number of children in this group varied between 613 and 807, depending on the variable and missing data.

No significant differences were found between the groups on academic or cognitive evaluations. In the hospitalized mTBI group, however, teachers rated the conduct of children statistically worse than either the outpatient mTBI group or the controls ($p < .004$ and $p < .001$, respectively). When there was control for 12 confounding variables, no statistical difference was found between the outpatient mTBI

and control groups with respect to hyperactivity and inattention. Even so, the hospitalized mTBI group was statistically more likely to have these problems than the outpatient mTBI group ($p < .003$) or the controls ($p < .001$). These results were consistent across evaluations from parents, teachers, and both combined. A limitation of this study is that criteria for inpatient versus outpatient management of mTBI may vary not only between institutions, but also between providers at the same institution.

Child and Proxy Perceptions of Children's HRQoL Outcomes

Objective outcomes measurements and caregiver evaluation of the behavior of children who have sustained an mTBI do not provide a complete measure of how the injury has affected the children themselves. It was well documented in 1972 that over 50% of the variance in quality of life is accounted for by subjective factors (Haas, 1999). Those currently addressing appropriate indicators of outcomes from traumatic injuries in children have come to the same conclusion: "Consideration of children's health-related quality of life (HRQOL) after injury is a critical aspect of outcome in assessing the effectiveness of trauma care" (McCarthy, 2007, p. S122). Despite the evidence, only one study could be found that included children's perceptions as outcome measures of mTBI (Gagnon et al., 2005). Even when HRQoL is assessed post-injury, only proxy perceptions may be obtained (Borders, Brannon-Goedeke, Arif, & Xu, 2004; Davey et al., 2005; Ding et al., 2006; McCarthy et al., 2005; McCarthy et al., 2006; Schweer et al., 2006; Slomine et al., 2006; Sturms, van der Sluis, Groothoff, Eisma, & den Duis, 2002), thus omitting children's subjective perceptions. Some researchers who studied injured children in general included children's perceptions of their post-injury HRQoL (Holbrook et al.,

2007; Sturms, van der Sluis, Groothoff, ten Duis, & Eisma, 2003; Sturms et al., 2005; Vollrath & Landolt, 2005; Winthrop et al., 2005).

Alternatively, three studies have been published evaluating HRQoL in children who have sustained a more severe TBI (McCarthy et al., 2005; McCarthy et al., 2006; Stancin et al., 2002). In the two McCarthy et al. studies, one of the inclusion criteria was that the children's TBI had to be of sufficient severity to warrant hospitalization for at least one night. Stancin et al. had the additional requirement that the TBI had to be moderate or severe.

McCarthy et al.(2005) assessed the reliability and validity of the Pediatric Quality of Life Inventory (PedsQL™ 4.0) by comparing it to results on the Behavior Rating Inventory of Executive Function (BRIEF). Parents or caregivers of 391 children who had sustained either a TBI or an extremity fracture between ages 5 and 15 and who had been treated at one of four American Level I pediatric trauma centers participated in this prospective cohort study at 3 and 12 months post-injury. An additional interview occurred within 3 weeks of the child's initial hospitalization to collect pre-injury data. A survey research company conducted all interviews over the telephone, with the PedsQL™ 4.0 taking approximately 6 minutes and the BRIEF 8 minutes to complete. The PedsQL™ 4.0 consists of 23 items that assess 4 domains: physical, emotional, social, and school functioning. In addition to this generic instrument, caregivers completed the 6-item PedsQL™ Cognitive Functioning Scale. The BRIEF is a 72- item instrument used to measure 8 domains of executive function in children. Caregivers were also asked to assess how well their children were able to solve problems, concentrate, think, and

remember things compared to their pre-injury status, with response options of *much worse*, *worse*, or *the same*.

Cronbach's alpha results indicated that the reliability of the PedsQL™ 4.0 (.74 to .93 at 3 months and .80 to .92 at 12 months) and BRIEF (.82 to .98 at 3 months and .84 to .98 at 12 months) were good to excellent and that all subscales on both instruments met criteria for group comparisons. Additionally, 7 of the 11 BRIEF subscales and the PedsQL™ 4.0 total scale had sufficient internal consistency reliability for use with individual patients (Cronbach's alpha \geq .90). Good test-retest reliability was found on both instruments, with an average of 9 days between assessments.

Factor analysis demonstrated differences between where individual items of some domains were found on the PedsQL™ 4.0 and where they most highly loaded, making interpretation of results relative to the domains they theoretically evaluate more difficult. Factor loading for the five school functioning items split between two factors. Two of the physical functioning items loaded more highly on the emotional functioning factor, and two of the social functioning items loaded more highly on the physical functioning factor. All emotional and cognitive functioning items loaded most highly on their respective factors. In addition, the PedsQL™ Cognitive Functioning Scale discriminated better among the TBI children than did the BRIEF.

Limitations of this study include that it evaluated only the reliability and validity of the PedsQL™ 4.0 proxy-report versions, not the child self-report versions. Results can be generalized to children whose injuries are severe enough to require hospitalization at least overnight, but cannot be generalized to those with an mTBI that does not.

In a subsequent prospective cohort study from the same four Level I pediatric trauma centers, McCarthy et al. (2006) used the PedsQL™ 4.0 and the PedsQL™ Cognitive Functioning Scale to evaluate caregiver assessments of the HRQoL of 330 (75% of those eligible) 5 to 15-year-old children who had sustained a TBI necessitating hospitalization of at least overnight. The researchers' definitions of mild, moderate, and severe TBI were based strictly on Abbreviated Injury Scale (AIS) scores. By considering AIS scores of 2 or 3 to be mTBI, they included some children more commonly considered to have sustained a moderate TBI in the mTBI group. Children were not excluded from the study if they had other, non-brain injuries, particularly confounding responses to the physical functioning domain items. There were significant differences between those who participated and those who did not, with enrollees more likely to have health insurance ($p < .05$) and shorter hospitalizations ($p \leq .01$). Differences between participants who did or did not complete all three interviews were also described.

Telephone interviews by a survey research company were conducted, as in the 2005 study by McCarthy et al. Median time to the initial interview, where pre-injury baseline information was collected, was 16 days. At that time, demographic information was obtained and the General Functioning scale of the Family Assessment Device was completed. Subsequent assessments occurred at 3 and 12 months post-injury. Children who had sustained a moderate or severe TBI had significantly lower scores of overall HRQoL, and physical, school, and cognitive domains ($p < .05$); however, this level of significance is only specified "between at least 2 of the study groups" (McCarthy et al., 2006, p. 256). An interesting graph, using data from previous studies that have employed the PedsQL™ 4.0, depicts the relative HRQoL levels of each of the TBI groups at 12

months post-injury, healthy children, and children with a number of other chronic conditions.

A pre-existing psychosocial problem was significantly related to lower levels of HRQoL in all domains ($p \leq .05$). Lower HRQoL scores were also found to be related to living in a single-parent household, having Medicaid or no health insurance, and unhealthy family functioning (all $p \leq .05$). This study would have been strengthened had children directly participated by means of child versions of the PedsQL™, available for children starting at age 5, used by their caregiver proxies.

The only study in which TBI children's perceptions of their HRQoL was elucidated as an outcome indicator of TBI did not include children whose TBIs were mild (Stancin et al., 2002). They compared HRQoL in children who had sustained moderate TBI ($n = 42$), severe TBI ($n = 42$), or who had been hospitalized for isolated orthopedic injuries ($n = 50$) between the ages of 6 and 12. This publication presented results of outcomes measured at approximately 4 years post-injury, excluding results from the 6 and 12-month post-injury assessments. The only difference noted between participants who remained in the study at 4 years post-injury and those who did not was the lower socioeconomic status of the latter group, with the highest attrition rate in the orthopedic group.

The only statistically significant difference in the children's reports of their HRQoL was between the severe TBI and orthopedic group in behavior ($p < .05$). However, parental reports were significantly different between those two groups for the psychosocial summary score and the sub-domains of behavior, mental health, general health perceptions, and parental impact-time (all $p < .05$). In addition, parental reports in

sub-domains of general health perceptions and parental impact-emotional were both $p < .05$ between moderate TBI children and orthopedic groups. No injury related factors were associated with levels of HRQoL, but pre-injury problems with behavior or school performance, lower socioeconomic status, and pre-existing family dysfunction were all predictors of lower HRQoL as reported by parents.

Summary

Scientific recognition that not all children completely recover from an mTBI has occurred only in the past 25 years. There is still little published research regarding outcomes in children from this injury. Methodologically strong studies have demonstrated that there are a few statistically significant objective differences between children who have sustained an mTBI and control groups, particularly in those children at the more severe end of the mTBI spectrum.

The only published research that addresses children's own perceptions of changes resulting from an mTBI evaluates self-efficacy relative to pre-injury levels of physical activity participation and athletic competence (Gagnon et al., 2005). All other mTBI studies obtaining data directly from children focus on objective functional and cognitive outcomes measures. The few published studies that evaluate HRQoL after a TBI in children exclude all but those with injuries necessitating at least overnight hospitalization. The single study that includes self- and proxy-report of HRQoL completely excludes mTBI children, evaluating only those who sustained more severe TBI (Stancin et al., 2002). The present research addressed this gap by evaluating HRQoL outcomes from mTBI in children from the perspectives of both the children and their caregiver proxies. It

included children who were seen in an emergency department and were either discharged or required a maximum hospitalization of 24 hours.

CHAPTER THREE: METHODS

This chapter discusses study design, including design strengths and weaknesses. A review of the research questions and study sample and setting is presented, followed by information regarding protection of human subjects and data collection procedures. Information regarding the instrument used to measure HRQoL, including other studies documenting its reliability and validity as a measure of HRQoL in children, is communicated. The final section of this chapter describes how study data was analyzed.

Overview of Design

This was a nonexperimental, prospective longitudinal descriptive study using a convenience sample to determine HRQoL of children who have sustained an mTBI. The independent variable, mTBI, already occurred for the child to be included as a study participant. An experimental design would necessitate manipulation of the independent variable after random group assignment, obviously unethical in this situation. Two control groups were used, uninjured and mild non-brain injured children. Friend sampling (Gagnon et al., 2004a, 2004b, 2005) of the mTBI group was attempted to obtain equivalent gender and age participants in the uninjured group, which would have controlled for potential confounding variables such as socioeconomic status and maturation.

Prospective longitudinal studies collect data over time in order to obtain information from subjects at different points of time relative to the independent variable; in this case, the mTBI event. To obtain pre-injury data prospectively would require a population study. This was well beyond the scope of the current study and, as discussed in Chapter 2, that of most studies of injured children. A limitation of these non-

population studies is that pre-injury information is collected after the injury has already occurred, and thus may not accurately reflect the pre-injury situation.

Research Questions

The following research questions were investigated by this study:

1. Do children who have sustained an mTBI return to their pre-injury HRQoL within one month of injury?
2. Is the 1-month post-mTBI HRQoL of children different from the HRQoL of 1-month post mild non-brain injured children or from that of uninjured children?
3. Do child-proxy dyads each rate the child's HRQoL at the same level?

Hypotheses

These research questions were addressed by means of the following null hypotheses. Due to the lack of previous research on this topic, there was no basis for the use of directional hypotheses.

1. There will be no statistically significant difference between pre-injury and 1-month post-injury health-related quality of life (HRQoL) in children who have sustained an mTBI as rated by the child.
2. There will be no statistically significant difference between pre-injury and 1-month post-injury HRQoL in children who have sustained an mTBI as rated by the proxy.
3. There will be no statistically significant difference between baseline and 1-month post-injury HRQoL of mTBI children and the HRQoL of children with a mild non-brain injury or uninjured children at the same time points as rated by the children.

4. There will be no statistically significant difference between baseline and 1-month post-injury HRQoL of mTBI children and the HRQoL of children with a mild non-brain injury or uninjured children as rated by the proxies.
5. There will be no statistically significant difference between the children's HRQoL as rated by the children and their proxies at either time point.

Sample and Setting

Participants in the mTBI and mild non-brain injury groups were self-selected from among children treated in the emergency departments of the two institutions in a large northeast Florida city where the vast majority of children are seen. The study investigator conducted information sessions with staff at each of these emergency departments regarding the research. A script (see Appendix D) and flyers (see Appendices E [mTBI] and F [mild non-brain injury]) for each injured study group were available for staff members to share with the legal guardians accompanying children who met study inclusion criteria, listed on each flyer.

Child participants in any of the study groups had to be 5 to 17 years old, have at least one parent/legal representative who was able to speak, read, and write in English, and have a working telephone. Those in either of the injured groups must have been seen in the Pediatric Emergency Department and/or Trauma Center due to a traumatic injury and have been discharged home in less than 24 hours. Children eligible to participate in the mild non-brain injury group sustained injuries such as fractures, sprains, dislocations, lacerations, bruises, or burns.

Children eligible to participate in the mTBI group were diagnosed with an mTBI according to the criteria recommended by the WHO's Collaborating Centre Task Force

on Mild Traumatic Brain Injury (Carroll, Cassidy, Holm et al., 2004): an acute non-penetrating injury caused by external forces to the head in which a Glasgow Coma Scale of 13 to 15 was evident upon presentation to the healthcare provider or 30 minutes post-injury, whichever occurred later. At least one of the following neurological deficits must also have occurred: (a) loss of consciousness for a maximum of 30 minutes, (b) amnesia for events immediately preceding or following the injury lasting a maximum of 24 hours, (c) disorientation or confusion, or (d) transient neurological symptoms that may have included seizures, other focal neurological signs, or a non-operative intracranial lesion. In addition, the child did not have any significant associated injuries.

Friend sampling (Gagnon et al., 2004a, 2004b, 2005) of children in the mTBI group was attempted to attain participants for the uninjured group. Uninjured children were gender- and age-matched to the children in the mTBI group. In these Gagnon et al. studies, mTBI families were asked to identify friends of their mTBI children willing to participate as study controls. Eight of their 34 mTBI participants (24%) were unable to do so. In those cases, gender- and age-matched children of the researchers' friends and colleagues were used (Gagnon et al., 2005). While friend sampling is an acceptable way to control for socioeconomic status and other potential unidentified variables, these variables would not be exactly matched between friends. As discussed in Chapter 5, no friends of the mTBI children were enrolled in this study as uninjured participants.

Determination of Sample Size

A priori power analysis determination of the sample size needed was made using G*Power 3.0.1 software (Faul, Erdfelder, Lang, & Buchner, 2007) and anticipated participation rates based on that of previous studies. As discussed in Chapter 2, Satz et al.

(1997) recommended that an mTBI sample size of at least 20 was needed for a methodologically strong study. Because differences need to be clinically, not just statistically, significant, a large effect size (0.5) was used in power analysis calculations. Other parameters used to determine an appropriate sample size include a significance level (α), or probability of a Type I error, of 0.05 (thus the probability of rejecting a true null hypothesis would be 5%). The conventional probability of accepting a false null hypothesis (β), also known as a Type II error, is 20% (Polit & Beck, 2004). Therefore a power ($1-\beta$) of 0.8 was used in the calculations.

Hypotheses 1 and 2 involve measuring the HRQoL of the mTBI group at two time points. Using a two-tailed paired *t*-test and the above parameters, 34 mTBI subjects were needed. Hypotheses 3 and 4 compare the HRQoL of mTBI, mild non-brain injured, and uninjured children pre-injury and 1-month post-injury. Calculation of sample size for multiple regression with two predictors, study group and time, and the above parameters resulted in 23 participants. Hypothesis 5 involves comparing child-proxy dyads of HRQoL responses for each child at each time point and was analyzed using a two-tailed *t*-test with the same parameters. Thus, this hypothesis required a sample size of 34 as well.

Percentages of those eligible who agreed to participate in previous studies of children sustaining a TBI ranged from 77% (Gagnon et al., 2005) to 91% (McCarthy et al., 2005). Between 72% (McCarthy et al., 2005) and 100% (Gagnon et al., 2005) of those eligible remained in these studies 3 months post-injury. To be conservative, oversampling for this study was based on the average retention rate (86%) of these

studies, resulting in an a priori sample size of 40 mTBI child-proxy dyads. The total a priori sample size was thus 120 child-proxy dyads.

Protection of Human Subjects

Permission to conduct this study was obtained from the Institutional Review Boards (IRBs) at Barry University and the University of Florida in Jacksonville, and from the Institutional Review Committee (IRC) at Baptist Medical Center Downtown in Jacksonville, Florida. Participation in this study was completely voluntary. Participants could chose not to answer any particular question posed by the researcher and could withdraw from the study at any time without any resulting consequences.

Confidentiality was maintained to the extent permitted by law. Any published results will refer only to aggregate data. There are no participant identifiers or information that could link participants to any published material. The researcher's dissertation committee had access to de-identified data. Hard copies of study data have been retained in a locked file cabinet in the researcher's office, with consent forms kept separately from the study data. Electronic data was and continues to be maintained in HIPAA compliant, encrypted database. Data will be retained for 5 years.

There are ethical implications with regards to research involving children, including their ability to assent to participate in research. The United States Department of Health and Human Services *Protection of Human Subjects Research* does not provide clear guidelines on this topic, stating that an IRB's determination of when assent should be obtained is to be based on the children's "ages, maturity, and psychological state" (2005). This study will follow the instructions of the institution requiring assent from children of the youngest age, and thus obtain assent from all children ages 6 to 17.

Currently available data indicate that most children do not understand the moral concept of helping someone else without the potential for personal consequences until they reach about the age of 14 (Wendler, 2006). However, it is important to explain the proposed research to them at their level of comprehension (American Academy of Pediatrics Committee on Bioethics, 1995). Children may also not be able to predict if participating in a study will cause them distress until after they have actually become involved. It is, therefore, particularly important for researchers to pay attention to whether a child is becoming distressed while partaking in a study, and if so, to stop (Wendler).

The risks of participating in this research were minimal. For the mTBI and mild non-brain injured groups, the risks included the psychological consequences of being reminded of the injury. If a child felt uncomfortable for any reason, the parent/legal representative was in close enough proximity that the child could go directly to her/him. Approaching potential participants while they were being seen in the Pediatric Emergency Department/Trauma Center could have also caused them discomfort. This risk was minimized by the investigator being sensitive to this possibility and offering to return later to discuss the study. Children and parents/legal representatives were informed that in the event participants became upset as a result of the study, they would be provided with a phone number for assistance through Psychological Services for Trauma/Critical Care, Department of Surgery, at one of the participating facilities. These trauma psychologists are familiar with psychological consequences that may occur in children and adults following a traumatic injury. One hour of psychological counseling would have been provided at no cost to the study participant; however, no participants requested these services.

Procedures for Data Collection

Recruitment Procedures

Legal guardians of mTBI and mild non-brain injured children were approached regarding the study while at the hospital for the injury. Staff members read information about the study from a script (see Appendix D). Legal representatives who were interested in participating or learning more about the study notified the child's nurse. The nurse then contacted the investigator to request she come to that clinical area to meet with the potential participants.

Upon arrival in the clinical area, the investigator took the parent/legal representative to a private space in close proximity to the child's ED room and provided more detailed information about what the study entailed for them and their child. When the child's parent/legal representative was still interested, the investigator thoroughly reviewed the consent form with the parent/legal representative. The parent/legal representative was given the opportunity to freely ask questions, to decline participation, or to decline to make a decision about participating at that time. If the parent/legal representative gave consent for their own and their child's study participation, both the parent/legal representative and the investigator signed the consent form for the hospital where they were located. A copy of the consent was given to the parent/legal representative. Included on the consent form were the names and telephone numbers of the principal investigator and her Dissertation Committee Chair. The telephone number for the Institutional Review Board/Committee at the involved hospital was also on the consent form. Parents/legal representatives were instructed to call any of these numbers should they have any questions regarding the study.

Once consent had been obtained, the parent/legal representative was asked to wait outside the child's room in the Pediatric ED. After allowing the child to see that his/her parent/legal representative was immediately outside the room, the investigator privately explained the study to the child. This explanation included what was expected of the child, that the child could decide not to answer all of the questions on the questionnaire, and that he/she could stop at any time. Once all of the child's questions were answered, the investigator asked for the child's assent. For those children who agreed, the parent/legal representative was asked to come into the room to witness the child signing the age-appropriate assent form. The parent/legal representative and the investigator also signed the assent form. If the child was unable to read the assent form, the investigator read it to the child in the presence of the parent/legal representative. The child and parent/legal representative each received a copy of the assent form.

Friend sampling (Gagnon et al., 2004a, 2004b, 2005) of children in the mTBI group was attempted to acquire participants for the uninjured control group. Participants in the mTBI group were requested to locate a parent/legal representative of a same age and gender friend of the mTBI child who would be willing to participate in the uninjured control group for this study. Those who were willing to do so were given the investigator's business card to share with that potential participant. The parent/legal representative of the uninjured friends were to call the investigator, who would then provide the same information about the study as noted above for the parent/legal representative of the mTBI and mild non-brain injured children. Because mTBI participants either did not wish to, or were unable to, locate appropriate friends for the uninjured control group, children of the same age and gender and their parents/legal

representatives from among the investigator's colleagues and acquaintances were invited to participate. Arrangements were made for the investigator, parent/legal representative, and the uninjured child to meet at a mutually agreed upon location with private space available. At that meeting, the same consent and assent process described above was followed.

Interview Procedures

Demographics and background information were obtained from parents/legal representatives after consent and assent were obtained. Standardized survey instruments were used in these initial face-to-face interviews and subsequent telephone interviews. Surveys collect self-report data, the accuracy of which depends on the respondent. Although traditionally it has been recommended that face-to-face interviews be conducted when possible (Polit & Beck, 2004), studies have shown comparable results using telephone interviews (McCormick, Workman-Daniels, Brooks-Gunn, & Peckham, 1993; Pettigrew, Wilson, & Teasdale, 2003), including telephone interviews with children (Baxter et al., 2003). Strengths of telephone interviews include that they are a relatively inexpensive way to collect survey data. The interviewer is able to conduct the interviews from a place of their choosing, where neither travel time nor physical safety factors are an issue. In addition, respondents may be less biased by the interviewer via telephone than when participating in face-to-face interviews (Marcus & Crane, 1986). Reliability of telephone interviews when structured interview formats are used has been shown to be good. When using the test-retest method of reliability testing between in-person and telephone interviews for the Glasgow Outcome Scale and the extended

Glasgow Outcome Scale, Pettigrew, Wilson, and Teasdale (2003) obtained K_w values of 0.92 for both scales.

There are a number of weaknesses related to the use of telephone interviews in general, and others that are more prevalent when they are used with children. Those that are related to telephone interviews in general include lack of a telephone within the household, disconnected telephones, changed telephone numbers, and people either not being available at the telephone number(s) provided or choosing not to answer the telephone. The latter issue has become more common as more people have caller ID on their telephones and do not answer when they do not recognize who is attempting to reach them. If participants agree to participate in a study, are aware that they will be contacted by the interviewer within a particular time frame, and are given the interviewer's telephone number, they may be more likely to answer when the interviewer calls. The time of telephone contact needs to be convenient for the participants. Other issues with telephone interviews include those of call waiting and poor cell phone reception (Baxter et al., 2003), and the inability to use visual aids (Marcus & Crane, 1986). In some situations, researchers also need to collect observational data, in which case in-person interviews are required. Siemiatycki (1979) noted that responses to sensitive questions were more likely to be answered in postal interviews than in telephone interviews.

It is particularly difficult to establish telephone rapport between a pediatric participant and an interviewer, especially in cases where they have had no previous contact. It is important to conduct the interview when the child is not fatigued or otherwise distracted. In addition, problems related to children's more limited attention

spans may occur more frequently in telephone interviews than those conducted in person because eye contact, which may help to keep them focused, is not possible (Baxter et al., 2003). In spite of these limitations, previous studies have successfully used telephone interviews with the 23 item PedsQL™ 4.0 Generic Core Scales and the 6 item PedsQL™ Cognitive Functioning Scale to measure HRQoL in children after a TBI (McCarthy et al., 2005; McCarthy et al., 2006; Slomine et al., 2006).

mTBI and mild non-brain injured children and their parents/legal representatives completed the initial questionnaires within hours of the injury while the child was in the Pediatric Emergency Department. Uninjured child and parent/legal representative participants completed the initial questionnaires immediately after their consent and assent were obtained. Participants were asked to respond to the questions based on the week immediately preceding the injury. One-month post-injury questionnaires were conducted via telephone interview; responses were to be based on the prior week. Every attempt was made to have parent/legal representative and child participants answer the study questions in isolation, however this cannot be guaranteed during telephone interviews. At the beginning of each telephone interview, parent/legal representative and child participants were asked if they had any questions prior to proceeding with the questionnaires.

Instruments

The literature was reviewed for instruments that met the following requirements. They (a) were designed to measure generic HRQoL, as opposed to disease specific instruments; (b) contained measures for young children; and (c) had published psychometric results from populations of American children. The Child Health

Questionnaire (CHQ) and Pediatric Quality of Life Inventory™ (PedsQL™) met these criteria. The reliability of both instruments is similar, with that of the CHQ ranging from 0.62 to 0.94 and that of the PedsQL™ from 0.70 to 0.93 (Rajmil et al., 2004). Both have demonstrated construct and convergent validity. The PedsQL™ has child versions for 5-7, 8-12, and 13-18 year olds, whereas the CHQ child version is for 10-18 year olds, thus eliminating the perspectives of all children under the age of 10. In addition, the CHQ consists of 87 items and takes approximately 20 minutes to complete; the PedsQL™ has only 23 items and takes approximately 6 minutes to complete (McCarthy et al., 2005). The PedsQL™ Cognitive Functioning Scale (see Appendix C; Varni, Burwinkle, Katz, Meeske, & Dickinson, 2002) will be used in addition to the PedsQL™ 4.0 Generic Core Scales (see Appendix B) to evaluate HRQoL in this study because of the increased possibility of cognitive impairment following a brain injury (McCarthy et al., 2006). The internal consistency reliability of these instruments for this study population will be calculated.

The PedsQL™, first published in 1999, was developed as a generic HRQoL assessment instrument for use in children with chronic health conditions (Varni et al., 1999). Parent and child versions are available for children ages 5-7, 8-12, and 13-18. The four domains included are physical, emotional, social, and school functioning. The internal consistency as measured using Cronbach's alpha of the individual scales ranges from 0.68 to 0.80 for the child self-report and 0.75 to 0.88 for the proxy-report (Varni, Seid, & Kurtin, 2001). The Cronbach's alpha of the psychosocial and physical summary scores and the total score were 0.83, 0.80, and 0.88, respectively, for the child self-report.

Proxy-report Cronbach's alphas were 0.86, 0.88, and 0.90 for the same scores, respectively.

McCarthy et al. (2005) evaluated the reliability and validity of the parent version of the PedsQL™ 4.0 Generic Core Scales supplemented with the PedsQL™ Cognitive Functioning Scale for a population of TBI children ages 5 to 15 who required at least one night of hospitalization at any of four level I pediatric trauma centers. Telephone interviews were conducted with the child's parent or guardian by a professional survey research company within 3 weeks of the injury to ascertain the child's pre-injury HRQoL and obtain background information. Subsequent interviews were conducted by the same company at 3 and 12 months post-injury. Of the 541 eligible children, 491 (91%) were enrolled in the study, 433 (80%) initial interviews were completed, 391 (72%) 3 months post-injury interviews were completed, and the number of those who participated in the 12 month post-injury interviews is not clear.

Using Cronbach's alpha, it was determined that the internal consistency reliability of the PedsQL™ (including the PedsQL™ Cognitive Functioning Scale) was .74 to .93 at 3 months post-injury and .80 to .92 at 12 months post-injury. Cronbach's alpha levels of the individual scales were not sufficient to meet the criteria suggested to evaluate individual scores, however, the total scale did. Factor analysis demonstrated that only the cognitive and emotional functioning scales loaded all items most strongly on single factors. The remaining three scales each loaded on two factors apiece. The opinion of these authors is that "despite these shortcomings, the results of our reliability and validity evaluation suggest that the PedsQL™ is a promising instrument for measuring the health and well-being of children with TBI" (McCarthy et al., 2005).

Two abstracts were published in which the PedsQL™ was used to evaluate the HRQoL of children with TBI. One compared post-injury results using the PedsQL™ and the Health Utilities Index Mark 3 (HUI3) and found the former to be a more sensitive measure of differences in functional health status than the latter. In the other (Curran et al., 2004), although they found significant differences of at least $p = 0.003$ in all domains of the PedsQL™ between children with moderate or severe TBI and the control group at 1 and 6 months post-injury, they found no differences in HRQoL between children with mTBI and the control group at either time point.

Other published studies in which the PedsQL™ was used to measure HRQoL in injured children include that of Ding et al. (2006) and McCarthy et al. (2006). The first study involves children with an extremity fracture; the latter involved children with TBI. Willis, Gabbe, Butt, and Cameron (2006) compared English language instruments that could be used to evaluate outcomes in populations of injured children, including both the CHQ and the PedsQL™. While noting that the psychometric properties of none of the instruments included had been meticulously evaluated, their determination was that “the PedsQL™ 4.0 generic core scale could be feasible for administration as a routine outcome measure for paediatric trauma patients” (p. 1194).

Varni, Limbers, and Burwinkle (2007) evaluated the reliability and validity of the children’s self-report versions of the PedsQL™ 4.0 Generic Core Scales using 8,591 children between the ages of 5 and 16. Of these children, 5491 (63.9%) were healthy, 142 (1.7%) had mild acute illnesses, 2627 (30.6%) were chronically ill, and 331 (3.9%) were missing this information. Children were grouped by their ages in years, with between 332 (16 year olds) and 932 (6 year olds) in each group. Thirty percent of the children

completed the PedsQL™ either in a face-to-face or telephone interview; the remaining 70% of the surveys were sent via the postal service. A 5-point Likert scale is used for children over the age of 7 and for parent proxy-reports; a 3-point Likert scale is used for children ages 5 to 7 (see Appendix B). Missing responses were less than 3% across all ages, with the majority involving 5 to 7 year olds' responses to the School Functioning Scale. Excluding this scale, the maximum percent of missing responses was 1.5%.

Internal consistency reliability was assessed using Cronbach's alpha (α) by age group. As can be seen in Table 1, social and, particularly, school functioning do not meet the 0.70 Cronbach's alpha threshold recommended for comparing groups (Bland & Altman, 1997).

Table 1

Internal Consistency Reliability of Child Self-Reports

PedsQL™ Generic Core Scale	<u>Minimum Cronbach's α</u>		<u>Maximum Cronbach's α</u>	
	A	Age Group (in years)	A	Age Group (in years)
Total Scale	0.86	5/6	0.92	13/14
Physical Health	0.70	6	0.87	14/16
Psychosocial Health Summary	0.82	5/6	0.89	11/13
Emotional Functioning	0.70	5/6	0.81	13/15/16
Social Functioning	0.68	5/6	0.83	14
School Functioning	0.59	5	0.79	13

Note. From “How Young can Children Reliably and Validly Self-Report Their Health-Related Quality of Life?: An Analysis of 8,591 Children Across Age Subgroups with the PedsQL™ 4.0 Generic Core Scales,” by J. W. Varni, C. A. Limbers, and T. M. Burwinkle, 2007, *Health and Quality of Life Outcomes*, 5, p.6-9.

Construct validity of each scale, summary scale, and the total scale was demonstrated by comparing responses from healthy and chronically ill children by age group (Varni et al., 2007). Healthy children had statistically significantly higher HRQoL for each PedsQL™ scale, summary score, and total score in each age group. Most effect sizes were medium to large. Intraclass correlations between child self-reports and parent proxy-reports for all of the scales, both summary scores, and the total score were statistically significant ($p < .001$), with agreement ranging between poor to fair and moderate.

Data Analysis

Demographics of the study population are portrayed using descriptive statistics. The first and second hypotheses, comparing pre-injury and 1-month post-injury HRQoL in children who have sustained an mTBI as rated by the child (Hypothesis 1) and by the proxy (Hypothesis 2) were analyzed using a paired *t*-test and its non-parametric equivalent, the Wilcoxon matched pairs signed-rank test, respectively. The independent variable is time and the dependent variable is HRQoL response. The third and fourth hypotheses compared pre-injury and 1-month post-injury HRQoL of mTBI children and the HRQoL of children with a mild non-brain injury or uninjured children as rated by the children (Hypothesis 3) and by their proxies (Hypothesis 4). The independent variables in these hypotheses are the injury type, or lack thereof, and time. The dependent variable is HRQoL response. Hierarchical regression was used to analyze these hypotheses. The fifth hypothesis compared child-proxy dyad ratings of the child's HRQoL at each time point. The independent variable is the respondent; the dependent variable is the HRQoL responses. This hypothesis was analyzed using one-way ANOVA to determine if there were significant differences among mTBI, mild non-brain injury, and uninjured groups of children and proxies, followed by a two-tailed *t*-test for the data meeting parametric assumptions. The remaining data were analyzed using the Kruskal-Wallis and Wilcoxon matched pairs signed-rank tests for the same purposes. Limbers, Newman, and Varni (2007) found equivalent factor loading for 5 through 16 year old respondents when Multigroup Confirmatory Factor Analysis of the PedsQL™ 4.0 Generic Core Scales was performed. Therefore, within each study group (mTBI, mild non-brain injury, and uninjured), all child participants were analyzed as a single group.

Paired t-Test

A paired *t*-test is a parametric test that compares the group means of a single group at two separate times. Assumptions of parametric tests are that: (a) measurements involve at least an interval scale, (b) study populations have normal distribution, (c) participants in each study group are not influenced by participants in another study group, and (d) homogeneity of variance, i.e., variances for each variable are the same throughout all study data (Field, 2005). Because the distance between categories in a Likert scale, the scale used for PedsQL™ responses, is not equal, it is actually an ordinal scale (Duffy & Jacobsen, 2005). However, Likert scale data is often treated statistically as interval data, as is in the case of published studies in which the PedsQL™ has been used (for example, Upton et al., 2005; Varni, Seid, Knight, Uzark, & Szer, 2002; Zeller & Modi, 2006). Data were entered into SPSS version 16.0 from which histograms, scatterplots, and boxplots were created to observe data distribution and determine if there were any outliers. Distributions were evaluated for skewness and kurtosis by means of their *z*-scores and were evaluated using the Kolmogorov-Smirnov and Shapiro-Wilk tests to determine if they were significantly different from normal distributions (Field).

Responses from members of different study groups were independent. In those cases where HRQoL was measured at more than one time or compared child-proxy responses, the responses were statistically evaluated as dependent pairs. Data were tested to determine whether they met parametric assumptions. Those that did not were analyzed using the nonparametric equivalent of the paired *t*-test, the Wilcoxon matched pairs signed-rank test (see below).

In the case of the first hypothesis, the paired *t*-test was used to compare pre-injury and 1-month post-injury HRQoL scores for the mTBI children. The resulting *t*-statistic was evaluated at the .05 level of significance for a two-tailed test. The degrees of freedom used were equal to the number of children for whom there were both HRQoL scores minus one. If the significance of the resulting *t*-statistic had been less than .05, it would have indicated that the difference between HRQoL scores at the two time points had a 95% chance of being a result of the independent variable, time, rather than simply a result of individual variation (Field, 2005).

The paired *t*-test was also used to compare child/proxy dyad responses at each time point for Hypothesis 5. The same procedure described above was adhered to with the following exception. For this hypothesis, degrees of freedom were calculated by subtracting one from the total number of child/proxy dyad HRQoL scores obtained.

Wilcoxon Matched Pairs Signed-Rank Test

The Wilcoxon matched pairs signed-rank test is used when data do not meet the parametric assumptions necessary for the paired *t*-test (Munro, 2005). Differences between paired scores are calculated and ranked. Smallest absolute differences are ranked first, excluding those in which there is no difference. When multiple differences are of equal value, the average of those ranks is assigned to each of the differences. The sign of the difference is included with the rank; positive and negative ranks are then summed individually. The lower of these sums is the test statistic, which can then be converted into a *z*-score in conjunction with the mean of the test statistics and the sample size, excluding those for whom there was no difference. The significance is $p < .05$ for *z*-scores with an absolute value larger than 1.96 (Field, 2005).

One-Way ANOVA

An ANOVA is also a parametric statistic, requiring that the same assumptions mentioned above be met. However, it is used to compare differences between at least three groups by means of the F -ratio statistic. The F -ratio is a comparison of the variation within and between groups. When the variation between groups is much larger than that within groups, it is likely that the independent variable has affected the variation between groups (Polit & Beck, 2004). The significance depends on the F -ratio obtained from study data, whether or not the hypothesis is directional and degrees of freedom.

Kruskal-Wallis Test

The non-parametric equivalent of the one-way ANOVA is the Kruskal-Wallis test. As with the Wilcoxon matched pairs signed-rank test, it also ranks the data, starting with the lowest score, independent of the group from which the data comes. The test statistic, H , is calculated from the summed ranks for each group, and total and group sample sizes. The significance of H is determined from the chi-square distribution, with degrees of freedom equivalent to the number of groups minus one (Field, 2005).

Hierarchical Regression

Regression is a parametric test to evaluate the relationship between one or more independent variables (predictors) and a single dependent (outcome) variable that distinguishes between the effects of each independent variable. Assumptions of regression are that: (a) the relationship of predictor and outcome variables is linear, (b) residual variances are equivalent for all predictor variable levels, and thus demonstrate homoscedasticity; (c) residuals for different observations are not correlated, (d) residuals are normally distributed, and (e) predictor variables are not correlated with variables that

influence the outcome variable but are excluded from the model (Allison, 1999; Field, 2005). A linear model is created that best fits the data based on the method of least squares. In linear regression, the equation from which the model is derived includes the Y intercept, or the value of Y where the line crosses zero on the X axis; the slope of the line; and the residuals, or differences between the model-predicted and observed values for each data point (Field).

In multiple regression, each predictor variable has a coefficient that potentially effects the slope of the line. The outcome value is determined from summing these coefficients, the Y intercept, and the residuals (Field, 2005). Hierarchical regression, one form of multiple regression, was used to analyze Hypotheses 3 and 4.

Summary

This was a nonexperimental, prospective longitudinal descriptive study to evaluate the HRQoL of children who have sustained an mTBI. Children ages 5-17 and their caregiver proxies completed face-to-face interviews based on the child's HRQoL the week prior to the mTBI and telephone interviews 1-month post-injury to determine if children return to their pre-injury levels of HRQoL within one month of injury as rated by the children and by their proxies. Their responses were compared to similar control groups of (a) mild non-brain injured children and (b) uninjured children to determine if there are differences between the HRQoL of mTBI children and that of either control group as rated by the children and by their proxies. The final evaluation compared child and proxy ratings of each child's HRQoL at both time points.

CHAPTER FOUR: FINDINGS OF THE STUDY

Introduction

The purpose of this study was to assess the subjective impact of having sustained an mTBI on those directly and indirectly affected, children and their caregiver proxies. Children ages 5 to 17 and their parents/legal representatives were met by the researcher while in the Pediatric Emergency Department due to an mTBI. At that time, children and their proxies individually completed age-appropriate PedsQL™ 4.0 Generic Core Scales and the PedsQL™ Cognitive Functioning Scale, measures of health related quality of life (HRQoL). The same questionnaires were completed by each participant one month later via telephone interview with the researcher. There were also two child/proxy control group dyads, those with mild non-brain injuries and an uninjured group. The same interview procedures occurred with these participants; however, the initial interview with uninjured children/proxies occurred in a mutually agreed upon location with access to a private space. Baseline and 1-month evaluations of children's HRQoL were compared by group for children and proxies. Child and proxy ratings of the child's HRQoL at each time point were also compared.

Pearson's chi-square and one-way analysis of variance (ANOVA) were used to compare demographic characteristics of the study groups. The internal consistency reliability of study instruments was evaluated using Cronbach's α . Hypotheses were tested using paired *t*-tests, Wilcoxon signed-rank test, and hierarchical regression.

This chapter presents study findings, including a description of the sample, the internal consistency reliability of the PedsQL™ 4.0 Generic Core Scales and the

PedsQL™ Cognitive Functioning Scale for this sample, and restatement of study hypotheses. Statistical analyses for each hypothesis and resulting findings are elucidated.

Sample Description and Reliability of Study Instruments

A convenience sample of 120 child-proxy dyads was used for this non-experimental, prospective longitudinal descriptive study, with 40 dyads in each of three groups. A priori power analysis and participation rates of previous studies determined the sample size. The study group consisted of children who had sustained an mTBI and their proxies. In addition, there were two child-proxy control groups: mild non-brain injured children and uninjured children. Baseline interviews were conducted between June and December, 2008. Child participants in all study groups had to be 5 to 17 years old; have at least one parent/legal representative who was able to speak, read, and write in English; and have a working telephone.

mTBI and mild non-brain injured participants were recruited from two Pediatric Emergency Departments and the Trauma Center in the same northeast Florida city. Staff members shared study flyers (see Appendices E [mTBI] and F [mild non-brain injury]) with the parents/legal representatives accompanying patients who met study criteria. If further interest in the study was indicated, the investigator was notified. The investigator is, therefore, unaware of the total number of potential study participants or how those who did participate may differ from those who either declined or were not approached. All injured children had to be released from the hospital within 24 hours to be included for participation, a criterion explained to those being admitted by the investigator during the initial interview. Three potential mTBI participants completed the baseline interview but remained in the hospital longer than 24 hours. Once determined ineligible, the

investigator called each parent/legal representative to thank them for their interest in participating.

Friend sampling was attempted with all mTBI participants. In some cases, families had just moved to the area and children had not yet made friends. Other parents/legal representatives stated they did not know the parents of their children's friends. Some children did not have friends of the same age and gender. Some parents/legal representatives asked the investigator if the parent/legal representative of one of their children's friends had contacted the investigator. Apparently some parent/legal representatives in the study had contacted the parents/legal representatives of potential uninjured study participants. Despite the success of this method for other researchers (Gagnon et al., 2004a, 2004b, 2005), no uninjured participants were recruited in this manner (see limitations). Thus, the entire uninjured study group consisted of children age- and gender-matched to the mTBI children and their proxies recruited from among the investigator's friends and colleagues. It was anticipated that friend sampling would control for socioeconomic factors and other potential unidentified variables; consequently, this study did not include a socioeconomic questionnaire.

Demographic Characteristics

Demographic data collected included the age, race/ethnicity, and gender of children and proxies. Descriptive analyses and comparisons of demographics of the three groups were performed (see Table 2). Child/proxy gender, child/proxy race, proxy marital status, and proxy highest educational level were collected as categorical data. Chi-square tests were therefore used to compare these variables between the three groups. There are four chi-square assumptions: (a) data are categorical, (b) sample size is large

enough that none of the cells will be empty, (c) categories are mutually exclusive, and (d) there is a theoretical basis for the categories (Munro, 2005). The only assumption not initially met was the second one relative to highest educational level and race. This was rectified by combining categories so that no cell would be empty; all cells then had an expected frequency greater than the recommended 5 (Field, 2005; Munro).

Table 2

Study Population Demographics

Variable	Mild non-brain						Chi-square or ANOVA	Statistical significance
	Uninjured		injury		mTBI			
Child gender (male)	32	(80)	25	(62.5)	32	(80)	$\chi^2 = 4.262$	$p = .119$
Child age in years (<i>M, SD</i>)	12.1	(3.24)	10.3	(3.15)	12.1	(3.24)	$F = 4.186$	$p = .018$
Child/proxy race (white)	39	(97.5)	21	(52.5)	22	(55)	$\chi^2 = 23.646$	$p = .000$
Proxy gender (female)	37	(92.5)	36	(90)	37	(92.5)	$\chi^2 = .218$	$p = .897$
Proxy age in years (<i>M, SD</i>)	42.6	(5.68)	38.0	(9.10)	38.0	(5.64)	$F = 5.823$	$p = .004$
Proxy marital status (married/partner)	36	(90)	29	(72.5)	27	(67.5)	$\chi^2 = 6.242$	$p = .044$
Proxy education: College graduate	30	(75)	10	(25.6)	16	(41)		
Some college	9	(22.5)	18	(46.2)	10	(25.6)	$\chi^2 = 24.991$	$p = .000$
No college	1	(2.5)	11	(28.2)	13	(33.3)		

Note. Values are *n* and percentages unless otherwise noted. Total *n* = 40 in each group with the exception of mTBI and mild non-brain injured proxy highest educational level where *n* = 39.

There were statistically significant differences ($p < .0005$) between groups based on race and proxy highest educational level. Differences were related to the uninjured control group, of which 97.5% were white and 75% college graduates among the proxies. Marital status was significantly different among uninjured child proxies ($p < .05$), with 90% married or living with a partner compared to 75% of proxies in the mild non-brain injured group and 69% in the mTBI group.

One-way analysis of variance (ANOVA) was used to compare the mean ages of children and proxies. Because sample sizes were equal for each group, assumptions that needed to be (and were) met for this test were as follows: (a) each group is distinct and (b) the dependent variable is measured on an interval scale (Lowry, 2009). Statistically significant differences were found in child ($p < .05$) and proxy ($p < .005$) ages between groups, with mTBI and uninjured children averaging an age of 12.1 and those with mild non-brain injuries averaging an age of 10.3. mTBI and mild non-brain injury proxy groups both had an average age of 38.0; the uninjured group was 42.6. In the demographic variables of child and proxy genders, no statistically significant differences were found.

Mechanisms of injury (see Table 3) were not significantly different between the mTBI and mild non-brain injured groups [$\chi^2(8) = 12.476, p = .131$]. The most frequent injuries sustained by children in the mild non-brain injury group were fractures and sprains (see Table 4). Eighty-six percent of fractures involved the forearm, while 67% of sprains involved a lower extremity.

Table 3

Mechanisms of Injury

Mechanism of injury	mTBI		Mild non-brain injury	
Fall	20	(50)	23	(57.5)
Struck	9	(22.5)	6	(15)
Motor vehicle crash	5	(12.5)	1	(2.5)
Bicycle	2	(5)	2	(5)
Unarmed fight	2	(5)	0	(0)
Pedestrian vs. car	1	(2.5)	3	(7.5)
Motorcycle crash	1	(2.5)	0	(0)
ATV	0	(0)	1	(2.5)
Cutting/piercing	0	(0)	4	(10)

Note. Values are *n* and percentages. *n* = 40 in each group.

Table 4

Injuries Sustained by Mild Non-Brain Injured Children

Injury Sustained	<i>n</i>	Percent
Fracture	14	35
Sprain	12	30
Laceration	10	25
Contusions	2	5
Abrasions	1	2.5
Dislocation	1	2.5

Note. *n* = 40.

Reliability of Study Instruments

Cronbach's α was used to evaluate the internal consistency reliability of the PedsQL™ 4.0 Generic Core Scales and the PedsQL™ Cognitive Functioning Scale (see Table 5). Children's reports of their physical health at baseline and 1-month evaluations and school functioning at 1-month did not meet minimum reliability criterion recommended for group comparisons (.70; Bland & Altman, 1997). Proxy reports of the total score for the PedsQL™ 4.0 Generic Core Scales at baseline and the PedsQL™ Cognitive Functioning Scale at baseline and 1-month evaluations were above the minimum value Bland and Altman recommend for individual clinical application (.90).

Table 5

*Internal Consistency Reliability for PedsQL™ 4.0 Generic Core Scales and PedsQL™**Cognitive Functioning Scale*

Scale	<u>Baseline</u>		<u>1 Month</u>	
	Child	Proxy	Child	Proxy
Total Generic Score	.879 ^b	.912 ^c	.883 ^d	.893 ^f
Physical Health	.612 ^a	.889 ^c	.628 ^d	.802 ^e
Psychosocial Health	.870 ^b	.889 ^b	.875 ^d	.878 ^e
Emotional Functioning	.720 ^a	.820 ^a	.717 ^d	.772 ^e
Social Functioning	.755 ^b	.765 ^b	.771 ^d	.754 ^d
School Functioning	.764 ^a	.792 ^a	.633 ^d	.746 ^d
Cognitive Score	.864 ^b	.936 ^a	.809 ^d	.932 ^e

Note. ^a*n* = 120. ^b*n* = 119. ^c*n* = 118. ^d*n* = 116. ^e*n* = 115. ^f*n* = 114.

Findings from Each Hypothesis

All uninjured participants and 95% of both mTBI and mild non-brain injury participants completed baseline and 1-month follow-up evaluations. Data from the 116 child/proxy dyads completing both evaluations were used to analyze Hypotheses 1 through 4 and the 1-month evaluation for Hypothesis 5 (see reiteration of hypotheses in next section). Data from all 120 child/proxy dyads were used in the baseline analysis of Hypothesis 5. The PedsQL™ 4.0 Generic Core Scales and the PedsQL™ Cognitive Functioning Scale for children use a three-point Likert scale; all others use a five-point Likert scale. Each analysis included the following comparisons: (a) total PedsQL™ 4.0 Generic Core Scales, (b) physical PedsQL™ 4.0 Generic Core Scales subscale, (c)

psychosocial PedsQL™ 4.0 Generic Core Scales subscale, and (d) PedsQL™ Cognitive Functioning Scale.

Hypothesis Testing

Hypothesis 1

The first hypothesis was that there would be no statistically significant difference between pre-injury and 1-month post-injury HRQoL in children who sustained an mTBI, as rated by the child. This hypothesis was tested using a two-tailed paired *t*-test. To use this test, the assumption that differences are approximately normally distributed must be met (Elrod, n.d.; Garson, 2008). The assumption of normality was assessed using boxplots, histograms, and Q-Q plots of children's responses to the PedsQL™ 4.0 Generic Core total scale, physical and psychosocial subscales, and to the PedsQL™ Cognitive Functioning Scale. *Z* skewness and *z* kurtosis scores were calculated to determine the degree of skewness and kurtosis, respectively. Kolmogorov-Smirnov and Shapiro-Wilk tests were also used to assess differences for normality. Significance levels $p < .05$ on these tests indicate that data distribution deviates from normal. Although the Kolmogorov-Smirnov test was significant for both physical and psychosocial subscales ($D(38) = .15, p < .05$), the significance of the generally more accurate Shapiro-Wilk test (Field, 2005) was $p > .05$ for all scales. Thus the assumption of data normality was met.

Baseline and 1-month mean responses by mTBI children to the PedsQL™ 4.0 Generic Core total scale, physical and psychosocial subscales, and to the PedsQL™ Cognitive Functioning Scale were all found to be significantly correlated, at $p < .05$ for the physical subscale and $p < .0005$ for the others. No statistically significant differences were found between the mTBI children's mean pre-injury baseline and 1-month post-

injury responses for any of these scales (see Table 6); the null hypothesis was therefore accepted.

Table 6

Hypothesis 1: Pre-Injury vs. 1-Month Post-Injury HRQoL as Reported by mTBI Children

	Mean	SE	<i>r</i>	<i>p_r</i>	<i>t</i>	<i>d</i>	CI		<i>p_t</i>
							Lower	Upper	
Total Generic Score									
Baseline	82.49	2.13							
1 Month	81.75	2.37	.64	.000	.38	0.74	-3.18	4.66	.705
Physical Subscale									
Baseline	87.83	1.79							
1 Month	87.26	1.85	.36	.026	.28	0.57	-3.60	4.74	.782
Psychosocial Subscale									
Baseline	79.62	2.48							
1 Month	78.82	2.97	.65	.000	.35	0.80	-3.89	5.50	.729
Cognitive Score									
Baseline	78.73	2.97							
1 Month	75.77	3.42	.72	.000	1.22	2.96	-1.94	7.86	.229

Note. $n = 38$, $df = 37$, r = correlation coefficient, p_r = significance of correlation

coefficient, t = t statistic, d = difference between the two means, CI = 95% Confidence

Interval of the difference, p_t = significance of t statistic.

Hypothesis 2

The second hypothesis was that there would be no statistically significant difference between pre-injury and 1-month post-injury HRQoL in children who have sustained an mTBI, as rated by their proxies. These data did not meet assumptions for parametric testing. The nonparametric equivalent of the paired *t*-test, Wilcoxon matched pairs signed-rank test (Brace, Kemp, & Snelgar, 2006), was therefore used to analyze data for this hypothesis. Because there were no statistically significant differences between mean baseline and 1-month post-mTBI HRQoL proxy responses (see Table 7), the null hypothesis was accepted.

Table 7

Hypothesis 2: Pre-Injury vs. 1-Month Post-injury HRQoL as Reported by Proxies of mTBI Children

	<i>z</i>	N-Ties	<i>p</i>
Total Generic Score	-.510	33	.610
Physical Subscale	-1.277	31	.201
Psychosocial Subscale	-.349	33	.727
Cognitive Score	-.746	27	.456

Note. *n* = 38.

Hypothesis 3

Hierarchical regression was used to analyze the third hypothesis to determine if there were statistically significant differences between baseline and 1-month post-injury HRQoL of mTBI children and HRQoL of children with mild non-brain injury/uninjured children at the same time points as rated by the children. Assumptions of regression were

checked as follows: (a) P-P plots of regression standardized residuals demonstrated linearity, (2) scatter plots of standardized observed versus predicted residuals illustrated homoscedasticity, (3) Durban-Watson tests showed that residuals from different observations were independent, and (4) histograms of frequencies versus regression standardized observed residuals had fairly normal distributions; assumptions were thus met.

Graphic depictions of the mean response for each group of children to the PedsQL™ 4.0 Generic Core total scale, physical subscale, and psychosocial subscale, and to the PedsQL™ Cognitive Functioning Scale at baseline and one month later are found in Figures 2 through 5, respectively.

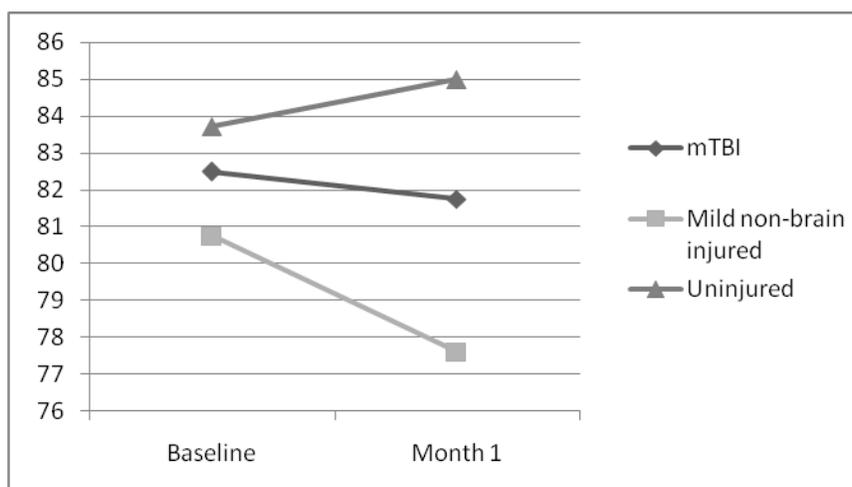


Figure 2. Mean child responses to PedsQL™ 4.0 Generic Core total scale pre-injury and 1-month post-injury in children with mild traumatic brain injury ($n = 38$), mild non-brain injury ($n = 38$), and uninjured children ($n = 40$).

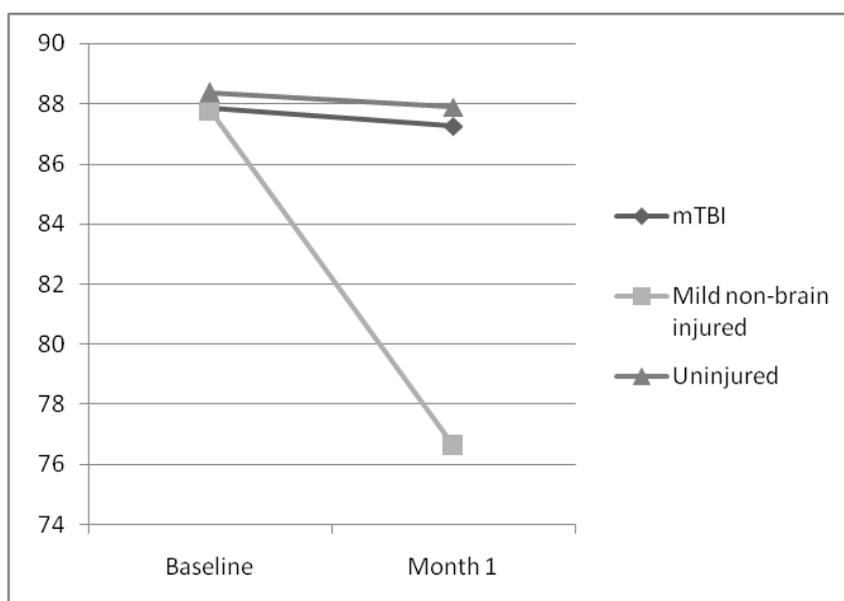


Figure 3. Mean child responses to PedsQL™ 4.0 Generic Core physical subscale pre-injury and 1-month post-injury in children with mild traumatic brain injury ($n = 38$), mild non-brain injury ($n = 38$), and uninjured children ($n = 40$).

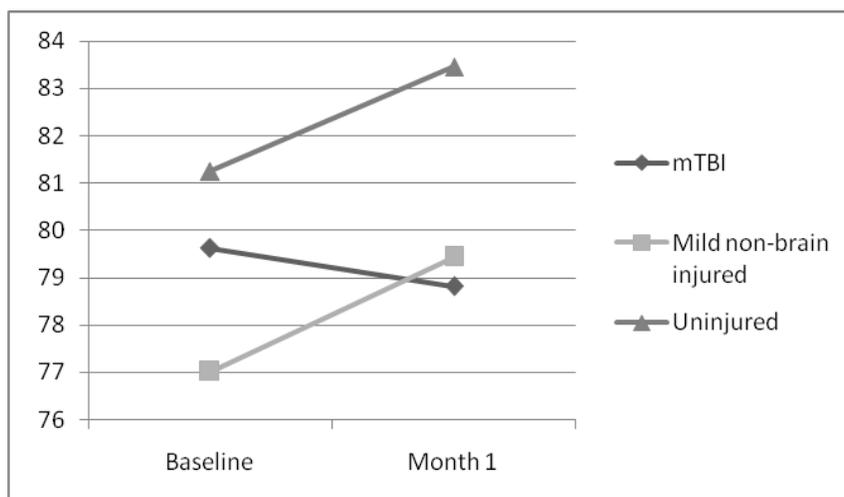


Figure 4. Mean child responses to PedsQL™ 4.0 Generic Core psychosocial subscale pre-injury and 1-month post-injury in children with mild traumatic brain injury ($n = 38$), mild non-brain injury ($n = 38$), and uninjured children ($n = 40$).

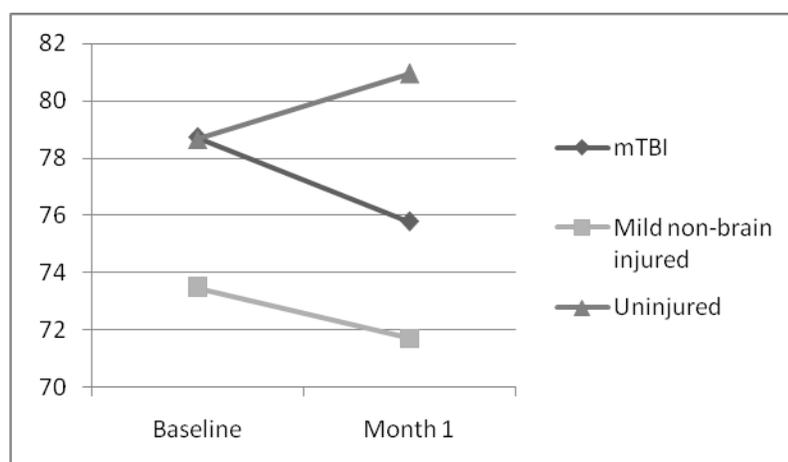


Figure 5. Mean child responses to PedsQL™ Cognitive Functioning Scale pre-injury and 1-month post-injury in children with mild traumatic brain injury ($n = 38$), mild non-brain injury ($n = 38$), and uninjured children ($n = 40$).

Hierarchical regression was used to determine if there were statistically significant differences in children's perception of their 1-month post-injury HRQoL, based on sustaining an mTBI, a mild non-brain injury, or remaining uninjured (see Table 8). Pre-injury HRQoL was entered as a covariate or predictor of 1-month post-injury HRQoL in the model on the first step. Group membership was included in an exploratory fashion in the second step. HRQoL at 1-month post-injury was found to be positively correlated to pre-injury HRQoL on all measures (see Table 8). Dummy indicator variables were created for group membership. Coefficients for those in the mTBI group are in the mTBI column; those in the mild non-brain injury group in that labeled non-brain injury, and those in the uninjured group were the baseline group against which the other two were compared. Differences between reported pre-injury baseline (BL) HRQoL and 1-month post-injury HRQoL were significantly lower in children with mild non-brain injuries (NB) when compared to either mTBI or uninjured children (UI) for both the

PedsQL™ 4.0 Generic Core total scale and the PedsQL™ 4.0 physical subscale. Based on this model, which accounts for only 18% of the variance, mTBI and uninjured children were predicted to rate their 1-month post-injury physical HRQoL 8.0 greater than the mild non-brain injured children (see Figure 6 and equations on next page).

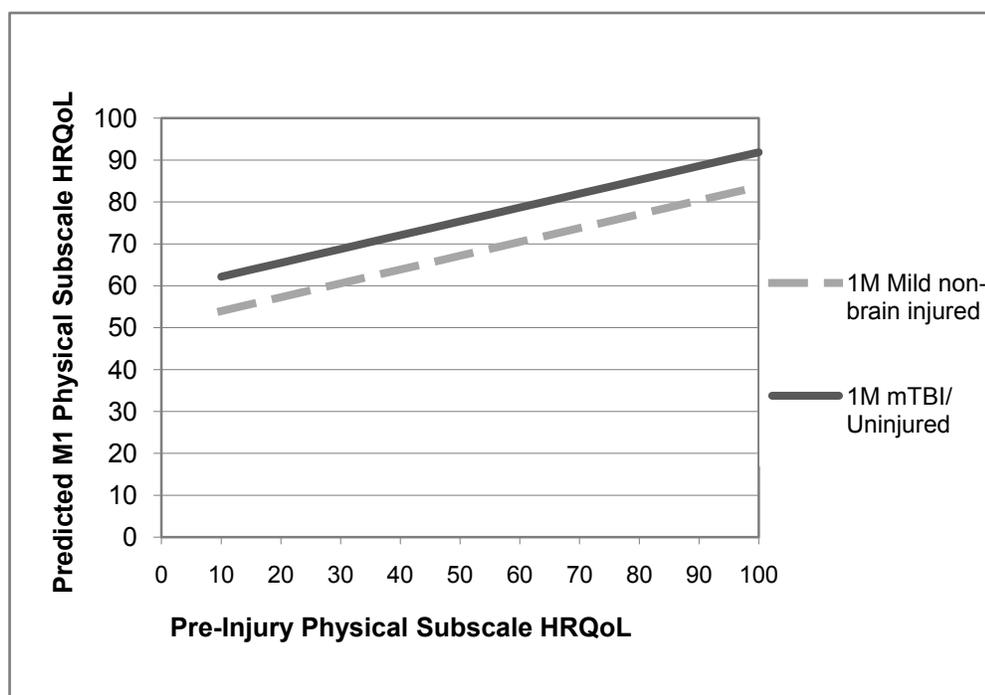


Figure 6. Predicted 1-month post-injury child responses to the PedsQL™ 4.0 Generic Core physical subscale in children with mild traumatic brain injury ($n = 38$), mild non-brain injury ($n = 38$), and uninjured children ($n = 40$).

There were no significant differences between groups for either the PedsQL™ 4.0 psychosocial subscale or the PedsQL™ Cognitive Functioning Scale. Because of the statistically significant differences on some of the scales, the null hypothesis was rejected. However, there were no statistically significant differences between how mTBI and uninjured children rated their HRQoL at either time point. The following predicted 1-month HRQoL equations were formulated based on these analyses:

PedsQL™ 4.0 Generic Core total scale (accounting for 44% of variance)

$$\text{Predicted NB} = 28.40 + (.66 \times \text{BL total score}) - 4.24$$

$$\text{Predicted mTBI and UI} = 28.40 + (.66 \times \text{BL total score})$$

PedsQL™ 4.0 physical subscale (accounting for 18% of variance)

$$\text{Predicted NB} = 58.87 + (.33 \times \text{BL physical subscale score}) - 8.02$$

$$\text{Predicted mTBI and UI} = 58.87 + (.33 \times \text{BL physical subscale score})$$

PedsQL™ 4.0 psychosocial subscale (accounting for 48% of variance)

$$\text{Predicted all groups} = 23.65 + (.71 \times \text{BL psychosocial subscale score})$$

PedsQL™ Cognitive Functioning Scale (accounting for 48% of variance)

$$\text{Predicted all groups} = 22.28 + (.70 \times \text{BL cognitive score})$$

Table 8

Hypothesis 3: Predicted 1-Month HRQoL in mTBI, Mild Non-Brain Injured, and Uninjured Children as Reported by Children

	Y intercept	Baseline	mTBI	Non-brain injury	R^2
Total Generic Score					
coefficient	28.40	.66	-.08	-4.24	.44
<i>p</i> value	.000	.000	.300	.041	
Physical Subscale					
coefficient	58.87	.33	-.02	-8.02	.18
<i>p</i> value	.000	.001	.856	.000	
Psychosocial Subscale					
coefficient	23.65	.71	-.05	-.06	.48
<i>p</i> value	.000	.000	.492	.360	
Cognitive Score					
coefficient	22.28	.70	-.06	-.07	.48
<i>p</i> value	.000	.000	.377	.278	

Note. $n = 38$ for mTBI and mild non-brain injury groups; $n = 40$ for uninjured group.

Hypothesis 4

Hypothesis 4 was that there would be no statistically significant differences between baseline and 1-month post-injury HRQoL of mTBI children and the HRQoL of children with mild non-brain injury as rated by proxies. This hypothesis was also tested using hierarchical regression with baseline scores entered as the first step, followed by stepwise entry of group membership. Assumptions of parametric tests for these data were

met. Graphic depictions of mean response for each group of proxies to PedsQL™ 4.0 Generic Core total scale, physical subscale, and psychosocial subscale, and to PedsQL™ Cognitive Functioning Scale at baseline and one month later are found in Figures 7 through 10, respectively.

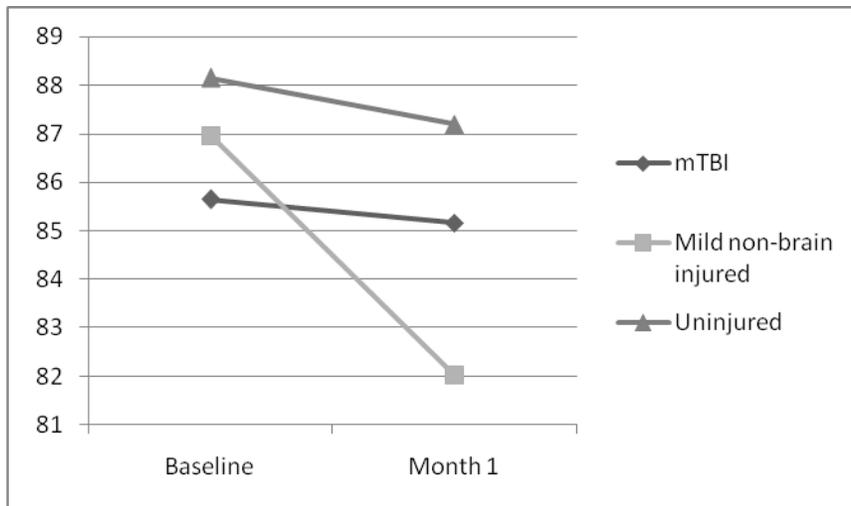


Figure 7. Mean proxy responses to PedsQL™ 4.0 Generic Core total scale pre-injury and 1-month post-injury in children with mild traumatic brain injury ($n = 38$), mild non-brain injury ($n = 38$), and uninjured children ($n = 40$).

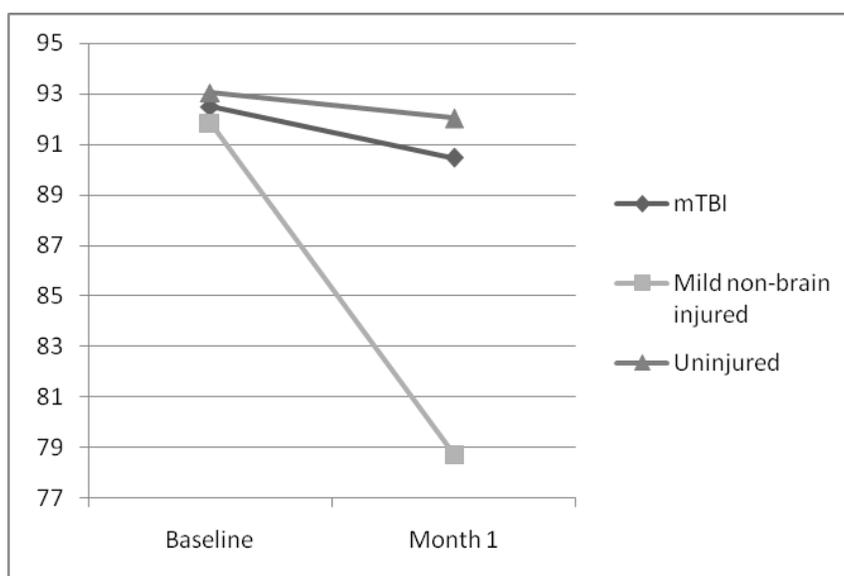


Figure 8. Mean proxy responses to PedsQL™ 4.0 Generic Core physical subscale pre-injury and 1-month post-injury in children with mild traumatic brain injury ($n = 38$), mild non-brain injury ($n = 38$), and uninjured children ($n = 40$).

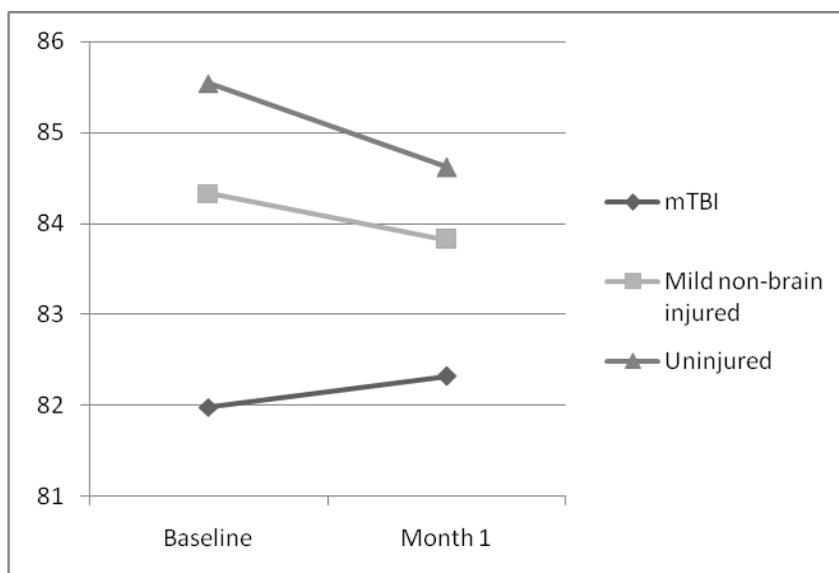


Figure 9. Mean proxy responses to PedsQL™ 4.0 Generic Core psychosocial subscale pre-injury and 1-month post-injury in children with mild traumatic brain injury ($n = 38$), mild non-brain injury ($n = 38$), and uninjured children ($n = 40$).

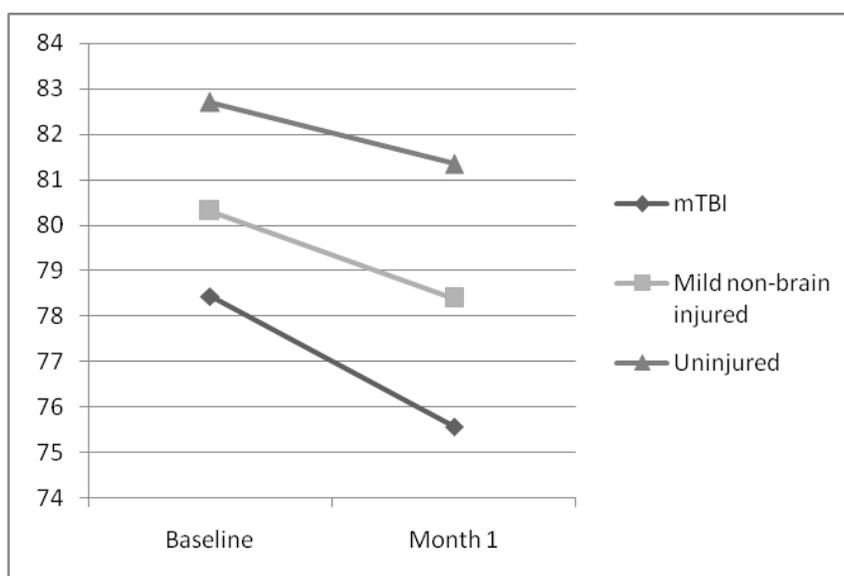


Figure 10. Mean proxy responses to PedsQL™ Cognitive Functioning Scale pre-injury and 1-month post-injury in children with mild traumatic brain injury ($n = 38$), mild non-brain injury ($n = 38$), and uninjured children ($n = 40$).

Hierarchical regression was used to determine if there were statistically significant differences in proxy perceptions of children's 1-month post-injury HRQoL, based on their injury classification using the same procedure described for Hypothesis 3 (see Table 9). The only scale on which a difference was noted was the PedsQL™ 4.0 physical subscale, on which proxies of children who had sustained mild non-brain injuries rated children's physical HRQoL statistically significantly lower 1-month post-injury than proxies of either mTBI or uninjured children. This null hypothesis was therefore also rejected although proxies of mTBI and uninjured children did not statistically differ in how they rated children's HRQoL at either time point. The following predicted 1-month HRQoL equations were formulated based on these analyses:

PedsQL™ 4.0 Generic Core total scale (accounting for 11% of variance)

$$\text{Predicted all groups} = 55.32 + (.34 \times \text{BL total score})$$

PedsQL™ 4.0 physical subscale (accounting for 15% of variance)

$$\text{Predicted NB} = 83.71 - 12.46 = 71.25$$

$$\text{Predicted mTBI and UI} = 83.71$$

PedsQL™ 4.0 psychosocial subscale (accounting for 22% of variance)

$$\text{Predicted all groups} = 43.50 + (.48 \times \text{BL psychosocial subscale score})$$

PedsQL™ Cognitive Functioning Scale (accounting for 42% of variance)

$$\text{Predicted all groups} = 19.21 + (.74 \times \text{BL cognitive score})$$

Table 9

Hypothesis 4: Predicted 1-Month HRQoL in mTBI, Mild Non-Brain Injured, and Uninjured Children as Reported by Proxies

	Y intercept	Baseline	mTBI	Non-brain injury	R^2
Total Generic Score					
coefficient	55.32	.34	.04	-.15	.11
<i>p</i> value	.000	.000	.685	.096	
Physical Subscale					
coefficient	83.71	.08	-.05	-12.46	.15
<i>p</i> value	.000	.416	.648	.000	
Psychosocial Subscale					
coefficient	43.50	.48	-.03	.02	.22
<i>p</i> value	.000	.000	.721	.843	
Cognitive Score					
coefficient	19.21	.74	-.06	.01	.42
<i>p</i> value	.005	.000	.442	.880	

Note. $n = 38$ mTBI and mild non-brain injury groups; $n = 40$ uninjured group.

Hypothesis 5

Hypothesis 5 was that there would be no statistically significant difference between children's HRQoL as rated by the children and their proxies at either time point. Data comparing child and proxy responses on the pre-injury PedsQL™ 4.0 Generic Core psychosocial subscale and PedsQL™ Cognitive Functioning Scale and on the 1-month PedsQL™ 4.0 Generic Core total scale met the assumption of normality. One-way

ANOVA and paired *t*-tests were used to analyze these data. The remaining measures did not meet parametric assumptions; consequently, the Kruskal-Wallis and Wilcoxon matched pairs signed-rank tests were used to analyze data for these measures.

Neither ANOVA nor the Kruskal-Wallis test demonstrated statistically significant differences between mTBI, mild non-brain injured, and uninjured groups for child versus proxy responses on the PedsQL™ 4.0 Generic Core total scale, physical subscale, and psychosocial subscale, nor on the PedsQL™ Cognitive Functioning Scale (see Table 10). All groups of child responses were therefore grouped together and compared to the combined proxy group responses for each measure at each time point. Correlation between child/proxy dyad scores was statistically significant for all scales except the pre-injury physical subscale and PedsQL™ Cognitive Functioning Scale (see Table 11). Children reported their HRQoL to be significantly lower than did their proxies on all scales except the PedsQL™ Cognitive Functioning Scale at both time points (see Table 12), with small to medium effect sizes for measures analyzed with the paired *t*-test. Confidence intervals for pre-injury psychosocial subscale and 1-month post-injury PedsQL™ 4.0 Generic Core total scale indicate that there is a 95% chance the true population mean of child/proxy differences is between -7.87 and -1.24 for the former and -6.32 and -.34 for the latter. This null hypothesis was therefore also not supported.

Table 10

Hypothesis 5: Comparison of mTBI, Mild Non-Brain Injured, and Uninjured Child vs. Proxy Perceptions of Children's HRQoL

Variable	<i>H</i> (Kruskal-Wallis) or <i>F</i> (ANOVA/Welch test)	<i>df</i>	<i>p</i>
Baseline ^a			
Total Generic Score	<i>H</i> = .12	2	.94
Physical Subscale	<i>H</i> = 2.05	2	.36
Psychosocial Subscale	<i>F</i> = .39	2	.68
Cognitive Score	<i>F</i> = .10	2	.90
1 Month ^b			
Total Generic Score	<i>F</i> = .208	2/77.28	.71
Physical Subscale	<i>H</i> = .791	2	.67
Psychosocial Subscale	<i>H</i> = 1.397	2	.50
Cognitive Score	<i>H</i> = 1.051	2	.59

Note. ^a*n* = 40 child/proxy dyads each in mTBI, mild non-brain injury, and uninjured groups; ^b*n* = 38 child/proxy dyads each in mTBI and mild non-brain injury groups and 40 child/proxy dyads in uninjured group.

Table 11

Hypothesis 5: Correlations Between Child and Proxy Perceptions of Children's HRQoL

Variable	Correlation	<i>p</i>
Baseline (<i>n</i> = 120 dyads)		
Total Generic Score	.216	.018
Physical Subscale	.173	.058
Psychosocial Subscale	.248	.006
Cognitive Score	.122	.186
1 Month (<i>n</i> = 116 dyads)		
Total Generic Score	.247	.008
Physical Subscale	.296	.001
Psychosocial Subscale	.255	.006
Cognitive Score	.230	.013

Table 12

Hypothesis 5: Child vs. Proxy Perceptions of Children's HRQoL

	<i>z</i> (Wilcoxon*) or <i>t</i> (paired <i>t</i> -test)	<i>df</i>	N-Ties	Mean	SE	<u>CI</u>		<i>p</i>
						Lower	Upper	
Pre-injury (<i>n</i> = 120)								
Total Generic Score	-3.59		110					.000
Physical Subscale	-4.420		94					.000
Psychosocial Subscale	-2.72	119		-4.56	1.67	-7.87	-1.24	.007
Cognitive Score	-1.58	119		-3.85	2.44	-8.69	.98	.117
1 Month Post-Injury (<i>n</i> = 116)								
Total Generic Score	-2.20	115		-3.33	1.51	-6.32	-.34	.030
Physical Subscale	-1.992		98					.046
Psychosocial Subscale	-1.964		110					.049
Cognitive Score	-.965		98					.335

Note. *Wilcoxon matched pairs signed-rank test

Summary

A convenience sample of 120 self-selected child/proxy dyads participated in this study of children's HRQoL. Baseline data consisted of 40 dyads each in the mTBI, mild non-brain injury, and uninjured groups. Five null hypotheses were tested using the PedsQL™ 4.0 Generic Core total scale, physical and psychosocial subscales, and the PedsQL™ Cognitive Functioning Scale. The first and second hypotheses compared pre-injury and 1-month post-injury HRQoL in mTBI children as rated by children and proxies, respectively. No statistically significant difference was found for either hypothesis. The third and fourth hypotheses compared the HRQoL of children who sustained an mTBI to those with mild non-brain injuries or who were not injured at baseline and one month later from children's and proxies' perspectives, respectively. Children who had sustained mild non-brain injuries rated their 1-month post-injury physical and total HRQoL significantly lower than did either the mTBI or uninjured children. Proxies of the mild non-brain injured children rated their children's physical HRQoL significantly lower than the proxies of children in the other two groups. The final hypothesis compared how children and their proxies rated the child's HRQoL at each time point. Children rated their physical, psychosocial, and total generic HRQoL at baseline and one month later statistically significantly lower than did their proxies. The data from this study thus support the null hypothesis only for Hypotheses 1 and 2.

CHAPTER FIVE: SUMMARY AND DISCUSSION

The primary purpose of this study was to assess the subjective impact of children who have sustained an mTBI on those directly and indirectly affected, children and their caregiver proxies. The conceptual framework guiding this research employed health-related quality of life (HRQoL), operationalized by appropriate age-level PedsQL™ 4.0 Generic Core Scales and PedsQL™ Cognitive Functioning Scale. Two dyad control groups consisted of children with mild non-brain injuries and proxies, and uninjured children and proxies. All participants completed study instruments at two time points one month apart. Comparisons were made of pre-injury and 1-month post-injury HRQoL of children sustaining an mTBI from perspectives of both children and proxies. Differences between reported HRQoL by group (mTBI, mild non-brain injury, or uninjured) from child/proxy perspectives were evaluated, as were differences between each child/proxy dyad's evaluation of the child's HRQoL at both time points. This chapter includes a summary of findings and a discussion of their implications for nursing. Study strengths and limitations are presented, as are recommendations for future study directions.

Summary of Findings

A convenience sample of 120 child-proxy dyads was used for this non-experimental, prospective longitudinal descriptive study, with 40 dyads enrolled in each of three groups. All uninjured dyads ($n = 40$) completed study questionnaires at both time points, whereas two dyads in each of the injured groups did not complete the 1-month evaluation ($n = 38$ in both injured groups). Children in the mild non-brain injury group were statistically significantly younger than those in the other two groups. The larger number of white uninjured participants was statistically significant. Proxies in this group

were also significantly older, more likely to identify themselves as being married/having a partner, and to have more formal education. Mechanisms of injury for children (e.g., falls) were similar in both injured groups.

Changes in HRQoL of mTBI Children

Children sustaining an mTBI and their parents/legal representatives were met in the Pediatric Emergency Department, Trauma Center, or hospital room while the child was being seen as a result of the mTBI. Participants who had been enrolled but remained in the hospital longer than 24 hours were excluded from the study. Children who remained slightly confused while the researcher was present were contacted the next day via telephone to ensure that they really wanted to be in the study and to complete the pre-injury questionnaires.

Child Perspective

Paired *t*-test analysis revealed no statistically significant difference in reported pre-injury and 1-month post-injury HRQoL by the 5-17 year-old children who sustained mTBIs on any of the study measures, i.e., the PedsQL™ Generic Core total scale, physical and psychosocial subscales, and the PedsQL™ Cognitive Functioning Scale. This indicates that one month after having sustained an mTBI, the children did not notice a significant change in their HRQoL. Thus, Hypothesis 1, that there would be no statistically significant difference between pre-injury and 1-month post-injury HRQoL in children who had sustained an mTBI (as rated by children), was accepted.

The only previous study of children's perceptions after an mTBI did not measure HRQoL (Gagnon et al., 2005). These researchers evaluated children's self-efficacy and found that 12 weeks after an mTBI, 8 to 16-year-old children still reported significantly

lower self-efficacy. This was despite their return to pre-injury levels of physical activity participation and athletic competence.

Although mean differences between mTBI child-reported pre-injury and 1-month post-injury HRQoL on each measure were not statistically significant, each was lower post-injury (see Table 6). The mean difference on the PedsQL™ Cognitive Functioning Scale was 2.96; all others were $\leq .80$. mTBI children in the current study perceived that their HRQoL was minimally affected by the mTBI. It is possible that mTBI children may not have been expected to fully resume their previous activities. Over an extended period of time, children may report lower HRQoL as they are expected to return to pre-injury functional levels.

Proxy Perspective

Proxy differences between reported pre-injury and 1-month post-mTBI HRQoL of their children did not meet parametric assumptions, so differences were analyzed using Wilcoxon matched pairs signed-rank test. The test yielded no statistically significant differences in HRQoL of their children at the two time points. Thus Hypothesis 2, that there would be no statistically significant difference between pre-injury and 1-month post-injury HRQoL in children who have sustained an mTBI (as rated by proxies), was also accepted.

Mean levels of proxy-reported 1-month post-injury HRQoL were also all lower than pre-injury levels; again, not statistically significantly so. Children who have sustained an mTBI are discharged with activity restrictions. Proxies would therefore not expect the child to return to their pre-injury level of functioning within one month, and

therefore may not yet have noticed any problems. Over a more extended period of time, proxies may report changes to the children's HRQoL.

Group Differences in HRQoL

Hierarchical regression was used to compare HRQoL of mTBI children with children sustaining a mild non-brain injury or uninjured at the two time points, from perspectives of both children and proxies. Children with mild non-brain injuries reported statistically significantly lower HRQoL on the PedsQL™ Generic Core total scale and physical subscale. Their proxies, who also perceived that the children had lower physical subscale HRQoL, did not rate their PedsQL™ Generic Core total scale statistically differently from that of proxies in the other groups. When considering that 65% of the mild non-brain injured children sustained fractures or strains, their reported lower physical HRQoL was not surprising. One month post-injury, these children still had casts and/or prescribed activity limitations, both of which were perceived by dyads to significantly alter children's physical HRQoL. There were no statistically significant differences between any of the baseline and 1-month HRQoL measures for mTBI and uninjured children as reported by dyads in these groups. Thus, the hypotheses that there would be no statistically significant difference between baseline and 1-month post-injury HRQoL of mTBI children and the HRQoL of children with a mild non-brain injury or uninjured children at the same time points—as rated by the children (Hypothesis 3) or their proxies (Hypothesis 4)—were both rejected.

Comparisons with Previous Studies

Previous published studies of HRQoL in TBI children included only those children with more severe injuries, requiring at least overnight hospitalization (McCarthy

et al., 2005; McCarthy et al., 2006) or diagnosed with either moderate or severe TBI (Stancin et al., 2002). Neither of the McCarthy studies included child reports. Stancin et al. compared child and proxy reports of HRQoL in children with moderate TBI, severe TBI, and isolated orthopedic injuries requiring hospitalization at approximately 4 years post-injury. Parent (50 items) and child (87 items) versions of the Child Health Questionnaire were used to evaluate HRQoL. The only significant difference reported by children was between those with severe TBI and those with orthopedic injuries sub-domain of behavior. Parents reported significant differences between these two groups on the psychosocial summary score and for sub-domains of behavior, mental health, general health perceptions, and parental impact-time. Parents also reported significant differences between children with moderate TBI and orthopedic injuries in the sub-domains of general health perceptions and parental impact-emotional.

Ponsford et al. (2001; 1999) found significantly more reported memory problems in the mTBI group during interviews of children with mTBI and minor non-brain injuries conducted 3 months post-injury. Participants were asked to rate the frequency, intensity, and duration of ten post-concussion symptoms, including memory. Child and proxy ratings of the child's pre-injury and 1-month post-injury on the PedsQL™ Cognitive Functioning Scale, on which four of six questions involve memory, were not significantly different in the current study. A possible reason for this difference is that the questions were different. In the Ponsford studies, questions related to post-concussion symptoms. In the current study, questions focused on whether the child/proxy perceived that any post-concussion symptoms present affected the child's HRQoL.

Child vs. Proxy Perceptions of Children's HRQoL

Average baseline and 1-month differences between child and proxy responses on the PedsQL™ Generic Core total scale, physical and psychosocial subscales, and the PedsQL™ Cognitive Functioning Scale were compared by group (mTBI, mild non-brain injured, or uninjured). No statistically significant difference between groups was found, indicating that group membership did not affect differences between child and proxy responses. Child and proxy responses to each of these measures were therefore compared as single groups. On all but the PedsQL™ Cognitive Functioning Scale at both time points, children reported their HRQoL to be significantly lower than that reported by their proxies. Hypothesis 5, that there would be no statistically significant difference between children's HRQoL, as rated by children and their proxies at either time point, was, therefore, not supported. However, effect sizes for these differences were small to medium, limiting their clinical significance.

These results contrast with those of Eiser and Morse (2001), who conducted a systematic review of child versus proxy responses to HRQoL measures. These researchers found responses to be more congruent for observable areas of functioning, particularly the physical domain. In this study, the unobservable area of cognitive functioning demonstrated greatest child/proxy congruence. It is noteworthy that of those differences significant in the current study, children's ratings were all lower than those of their proxies. In short, children perceived they had more problems with physical and psychosocial functioning than did their proxies, indicating that even if both child and proxy acknowledged the same problems, their perceptions of its importance to the child's HRQoL were different in these areas. The statistical significance of pre-injury child/proxy differences was greater than at 1-month post-injury. It is possible that, as a

result of the study questionnaires, increased communication between child/proxy dyads occurred in the areas addressed. Thus, although study results may be biased, improved communication regarding children's HRQoL would likely have benefited individual dyads.

Davis et al. (2007) conducted a qualitative study with 8 to 12-year-old children and one parent of each child to elucidate possible reasons for incongruence in child/proxy responses on the KIDSCREEN 27, a European generic HRQoL instrument. They found that children were more likely to give extreme answers (always/never) and to give their rating prior to explaining their rationale for the rating. In addition, children generally cited a single example as the reason for the rating. In contrast, parents were more likely to give less extreme answers, explaining they were not always with the child and therefore may have possibly missed situations in which the extreme answer was untrue. There were also times when parents reported responding as they thought their child would respond, rather than how the parents, themselves, perceived the situation. Parents tended to cite multiple examples prior to assigning an item a rating. Only rarely did discordant responses result from parents and children interpreting questionnaire items differently.

Implications for Nursing

Education

Nursing students need to be provided research-based information on which to build their nursing practice. This study adds to the knowledge base regarding post-mTBI HRQoL in children. In general, neither children nor their proxies recognized a statistically significant change in children's HRQoL one month after having sustained an mTBI. This research demonstrates, however, that children who sustain mild non-brain

injuries may have significantly lower physical HRQoL one month after their injuries. Being aware of the extent to which such an injury affects a child may help nursing students, and practicing nurses, to better understand what a mild non-brain injury may mean to a child's perception of self.

Children in this study rated their HRQoL, excluding cognitive HRQoL, significantly lower than did their proxies. This provides a strong rationale for nurses to learn the best methods of obtaining information from *both* children and their proxies regarding HRQoL, as children may perceive problems where proxies do not.

Practice

In a qualitative study of mTBI adolescents and their parents, Gagnon et al. (2008) found the most commonly discussed theme to emerge was the need for information, including what to expect as a result of the injury. The current study provides researched-based answers to that question. Some are applicable at the individual clinical level, while others can be applied only at the group level based on Cronbach's α results.

Proxy responses to the PedsQL™ Cognitive Functioning Scale met criteria for individual clinical application, Cronbach's $\alpha \geq .90$ (Bland & Altman, 1997). It was also the only scale on which there were no statistically significant differences between child and proxy responses. This indicates that health care providers may provide anticipatory guidance to individual children who have sustained an mTBI (along with their proxies) and that, based on results, the mTBI may cause no significant difference in the child's cognitive HRQoL one month after having sustained it.

The PedsQL™ Generic Core Scale met the recommended reliability for group comparisons, Cronbach's $\alpha \geq .70$ (Bland & Altman, 1997). Health care providers may,

therefore, share with mTBI children and their families that, in general, the HRQoL of children who have experienced an mTBI is not significantly different 1-month post-injury than it was in the week preceding the injury. Children and families will know that if they notice the child's HRQoL to be significantly decreased one month after an mTBI, it is not typical and that the child needs to be evaluated by an appropriate health care provider. Health care providers, aware of a child's mTBI, also have the opportunity to assess for changes in the child's HRQoL during subsequent visits and should make subspecialist referrals as needed.

Research

This study provides evidence regarding child/proxy perceptions of children's HRQoL one month after having sustained an mTBI. As previously mentioned in this chapter, earlier studies of HRQoL in TBI children included children whose TBI were more severe than those in this study's population (McCarthy et al., 2005; McCarthy et al., 2006; Stancin et al., 2002), and only one of these studies contained children's perspectives (Stancin et al.). The purpose of this study was to explore the extent to which mTBI children and their proxies perceived a change in the child's HRQoL as a result of the injury. Results revealed no significant difference from either of their perspectives; however, over time, deficits in HRQoL may be exhibited. Longer-term studies are needed to fill this gap in knowledge.

It is recommended that future pediatric trauma outcome studies include HRQoL measures from child and proxy perspectives. A previous study of children with orthopedic injuries (Varni, Seid et al., 2002) demonstrated that proxies rated the child's HRQoL statistically significantly lower on the PedsQL™ 4.0 Generic Core Scales total

scale, and on physical and psychosocial subscales. The children's physical subscale ratings were statistically significantly lower than that of their healthy peers when initially seen in an orthopedic clinic for a fracture. However, approximately 7.5 months later, these differences had disappeared. Because of the number of participants needed for statistical analyses, it may be necessary to conduct multi-institutional studies of HRQoL outcomes subsequent to other types of pediatric trauma. HRQoL following hepatic or splenic injuries would be of particular interest because, despite lack of outward evidence of injury, these children are discharged with activity restrictions lasting weeks to months.

This study demonstrated that telephone interviews with children may not only be employed but are often happily anticipated by the children. Upon receiving the 1-month post-injury telephone call, one proxy said that her child had been asking when the "study lady" was going to call him. Allowing children to share perspectives of their own HRQoL provides a more complete picture than that obtained from proxy interviews only. It is recommended that future studies of children's HRQoL include both children's and proxies' perspectives.

Public Policy

The worldwide economic situation is in crisis. Available healthcare resources must be even more carefully allocated than in the past. It is essential that their distribution be based on what is important to those they directly impact. This study demonstrates that at 1-month post-injury, mTBI children and their proxies do not perceive that the injury has changed the child's HRQoL. However, 1-month post-injury may be too short a time period to accurately reflect any but the most obvious differences. Prior to allocating

limited healthcare resources elsewhere, longer term HRQoL studies of mTBI children are needed.

Strengths of the Study

A major innovative strength of this study is the inclusion of subjective data as reported by the children themselves. The only other published study in which subjective opinions of mTBI children was reported was that of Gagnon et al. (2005). In that study, researchers focused on self-efficacy related to mTBI children's levels of physical activity participation and athletic competence. Another strength includes the incorporation into the study's design of all six recommendations made by Satz et al. (1997, see Chapter 2) for strong mTBI studies. In addition, the a priori power analysis used to determine appropriate sample size is a strength. Due to the need for differences to be clinically significant, a large effect size (.05) was used in power analysis calculations. Other parameters used in the calculations were a significance of 0.5 and power of 0.8. Based on the different statistical analyses utilized, the largest adequate sample size needed was 34; a minimum of 38 participants remained in each of the groups at the 1-month post-injury evaluation.

Inclusion of a theoretical framework, HRQoL, strengthened the study. HRQoL was operationalized by means of established study instruments that had already demonstrated reliability and validity in studies involving US children and their proxies. In addition, internal consistency reliability of instruments for the current study population was determined. Nearly all met requirements for at least group comparisons.

Pre-injury data in previous studies of HRQoL in injured children were obtained a median of 9 (Ding et al., 2006) to 16 (McCarthy et al., 2006) days post-injury. Although

it was difficult for the researcher to be constantly available to meet participants while they were being seen in a Pediatric Emergency Department or the Trauma Center, pre-injury recollections were much more recent and less biased because the post-injury time frame was so short. The researcher initially met with each participant in person. The importance of this, in combination with the consistency of having the same person conduct initial and follow-up telephone interviews, was evident in terms of children's compliance in responding to follow-up interviews one month later. Early concerns as to how children would respond to telephone interviews were dispersed when calls were met with enthusiasm. "I remember you! Can we do the questions again?" was commonly heard. One mother said that when her young daughter heard the message on their answering machine, she wailed, "But Mommy, I wanted to talk to her!"

The investigator had some initial reservations as to whether parents/legal representatives who were of different ethnic and socioeconomic backgrounds from that of the investigator would be receptive to participating in the study. Very early in the study this issue was also negated. In discussing the study with a proxy who was of a different ethnic and socioeconomic background than the investigator, he stated: "No one has ever asked us what it means to us. Thank you for doing this study."

Children with pre-existing behavioral problems and/or learning disabilities were not excluded from this study population to increase generalizability of the results. Although some studies exclude children with such pre-existing problems (Anderson et al., 2001; Gagnon et al., 2004a, 2004b, 2005; Goldstrohm, 2002; Roberson, 2004), other studies specifically do not (McCarthy et al., 2006; Ponsford et al., 2001; Ponsford et al., 1999). The most common pre-existing psychological problem proxies identified was

attention deficit hyperactivity disorder (ADHD). There was no statistically significant difference in the proxy-reported number of children with ADHD by group (5 mTBI, 3 each mild non-brain injury/uninjured).

Another strength of this study was that the vast majority of children in the geographic area where the study was conducted are seen in the two involved hospitals. They have the only Pediatric Emergency Departments in the area; the Level I Trauma Center is the only trauma center for the entire region. Thus, study participants were recruited from among nearly all of those children seen for their injuries in a hospital setting in northeast Florida.

Limitations of the Study

A major limitation of the study is common to all but population-based trauma research: pre-injury data was collected post-injury. However, as mentioned above, the time frame post-injury was hours as opposed to greater than a week in other studies.

Another limitation is related to the uninjured control group. It was hoped that the uninjured children would consist of an age- and gender-matched friend sample of mTBI children to control for socioeconomic factors and other potential confounding or unidentified variables (Gagnon et al., 2004a, 2004b, 2005). Unfortunately, as described in Chapter 3, no friends of mTBI children were enrolled as uninjured participants. Differences between populations of northeast Florida and Montreal, Canada, where the studies of Gagnon et al. were conducted, include that the current study community may have a more mobile population; a large US Navy presence exists there, and families are relocated based on the needs of the Navy. In addition, any family that relocates and has school-aged children is more likely to move during the children's summer vacation.

Having participant recruitment start in June may have made the recruitment of the friend sample more difficult. Proxies of mTBI children who had just moved to the area stated that their children had not yet made local friends. Others said they did not know the parents/legal representatives of their children's friends.

Although this study did not include a socioeconomic questionnaire because of the anticipated friend sample, questions regarding home zip code and age, highest educational level, and marital status of participating proxies were included in the demographic and background information collected. As discussed in Chapter 4, uninjured participants were significantly different from injured participants with regards to race and proxy age, marital status, and education. Socioeconomic variables have been related to significant differences in outcomes from TBI (Hawley et al., 2004; McCarthy et al., 2006; Stancin et al., 2002). That their influence on participants in this study cannot fully be measured is a study limitation. There were no statistically significant differences between pre-injury and 1-month post-injury HRQoL of mTBI and uninjured children from either the children's or proxies' perspectives in this study.

Another limitation is the generalizability to other populations of mTBI children. It is unknown how frequently children are taken to their primary care providers' offices, an outpatient clinic, or receive no medical attention after having sustained an mTBI. In addition, it is unknown how well the study population represents even the local population of children who met study criteria during the recruitment phase. The researcher was only notified of those who were both approached by the Pediatric Emergency Department or Trauma Center staff and whose proxies expressed an interest in participating in the study. The pace in Emergency Departments and Trauma Centers

varies, but at times it is extremely hectic. Staff priority must obviously be patient care. Comments such as “I had someone earlier today who would have been good for your study, but I forgot to ask them” were noted. An anecdotal observation was that female teenage mTBI patients were much more likely to decline study participation than their male counterparts, decreasing how well the study population represents the general mTBI population.

One study criteria was that participants have a working telephone. While this may have been true at the time of enrollment, it was not always so one month later. Fortunately, both cellular telephones and telephone number portability between carriers have decreased the difficulty of contacting participants via telephone. During the initial interview, participants were asked the preferred time of day to contact them for the 1-month questionnaires. In spite of this, multiple attempts were sometimes required to reach participants.

It was impossible to determine if all children were independently responding to study questions during telephone interviews. In at least one case, the researcher heard someone in the background prompting a young child’s answers. Another time a child turned angrily to someone and said, “She’s asking *me* how I feel!”

Future Study Recommendations

A number of recommendations for future studies of mTBI children may be based on the findings of the current study, one of which is currently underway. The IRB and IRC, from the two hospitals where injured participants were recruited, simultaneously approved this study and a continuation of it, with additional data collection points at 3, 6, and 12 months. Participants signed two separate consents and assents at the time of

enrollment. The 12-month study will provide evidence of child and proxy perspectives of how the HRQoL of children who have sustained an mTBI changes over the course of the first year after an mTBI. It will also compare child and proxy ratings of mTBI children's HRQoL to that of the mild non-brain injured and uninjured control groups. A multi-institutional replication of the 12-month study in different parts of the country, with the addition of more socioeconomic information, would help demonstrate how generalizable the findings are to a larger portion of children in the US.

The ability to collect pre-injury data before an injury occurs is an ongoing issue in the realm of trauma research. One possibility as to how such data could be obtained is to have students who participate in sports activities and their proxies complete HRQoL questionnaires during pre-season physicals. Coaches and proxies would know which, if any, children on the team sustained an mTBI during the season and when it occurred. Children and proxies could complete the same HRQoL questionnaires at the end of each season. Many children could participate for a period of years, providing longer-term assessment of the impact of an mTBI on HRQoL.

Obviously, studies of HRQoL of mTBI children over a longer period of time are needed. Because one of the ten priority theme areas of the National Children's Study (United States Department of Health and Human Services, 2004) is pediatric injury, the longitudinal cohort population study of 100,000 American children followed from birth through age 21 will provide vast opportunities for research regarding pediatric mTBI. Extensive pre-injury data will have been collected prior to the occurrence of the mTBI. In addition, years of post-injury follow-up will provide valuable information about possible effects of an mTBI many years after the injury. Because the study end point is age 21,

data will be collected after most children make the transition from living with their family of origin to living on their own or with their peers. Such a transition places significantly more stress and responsibility on the child, which may cause post-mTBI deficits to be revealed.

Conclusions

The purpose of this study was to evaluate the subjective impact of having sustained an mTBI on those it directly and indirectly affects, the children and their caregiver proxies, respectively, by comparing reported levels of the child's HRQoL in the week preceding and at one month following an mTBI. This nonexperimental, prospective longitudinal descriptive study used a convenience sample of 120 child/proxy dyads, 40 dyads in each of three groups: mTBI, mild non-brain injury, and uninjured. The children's HRQoL was evaluated from child and proxy perspectives at both time points by means of the PedsQL™ Generic Core Scales and the PedsQL™ Cognitive Functioning Scale.

While mTBI children and their proxies rated the child's HRQoL differently, neither child nor proxy participants perceived there to be a statistically significant change in the child's HRQoL as a result of the mTBI. In addition, the difference between the mTBI children's pre-injury and 1-month post-injury HRQoL was not statistically significantly different from the change reported in uninjured children's HRQoL by those dyads.

Proxies demonstrated significant concern regarding what to expect as result of the mTBI their children experienced. This study provides evidence that in order to help families in need of understanding what to expect one month after such an injury, health

care providers may share information about HRQoL gathered from other child/proxy dyads who have undergone the same experience. This will allow families of children who exhibit significant decreases in their HRQoL to recognize that their child needs further health care provider evaluation. Studies extending for a longer period of time post-injury are needed to determine if the HRQoL of mTBI children will decrease at some point in the future as a result of the injury.

This is the first study to elucidate mTBI children's perceptions of their own HRQoL. It provides evidence that it is possible and rewarding to obtain children's subjective opinions about their HRQoL and adds another dimension to our growing body of knowledge regarding mTBI in children.

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Research with Human Subjects
Protocol Review

Date: May 22, 2008

Protocol Number: 080514
Title: Early Outcomes from Mild Traumatic Brain Injury from Child and Proxy Perspectives

Approval Date: May 20, 2008

Name: Ms. Pam Pieper
Address:

Sponsor: Dr. Mary Bear
School: Barry University: Orlando Campus

Dear Ms. Pieper:

Your protocol has been reviewed and accepted as exempt from further review. You may proceed with data collection.

We have received the modifications received made by Wolfson Children's Hospital and approved of these as well.

As principal investigator of this protocol, it is your responsibility to make sure that this study is conducted as approved by the IRB. Any modifications to the protocol or consent form, initiated by you or by the sponsor, will require prior approval, which you may request by completing a protocol modification form.

It is a condition of this approval that you report promptly to the IRB any serious, unanticipated adverse events experienced by participants in the course of this research, whether or not they are directly related to the study protocol. These adverse events include, but may not be limited to, any experience that is fatal or immediately life-threatening, is permanently disabling, requires (or prolongs) inpatient hospitalization, or is a congenital anomaly cancer or overdose.

The approval granted expires on May 30, 2009. Should you wish to maintain this protocol in an active status beyond that date, you will need to provide the IRB with and IRB Application for Continuing Review (Progress Report) summarizing study results to date.

Appendix A

If you have questions about these procedures, or need any additional assistance from the IRB, please call the IRB point of contact, Mrs. Barbara Cook at ([REDACTED]) or send an e-mail to [REDACTED]@barry.edu . Finally, please review your professional liability insurance to make sure your coverage includes the activities in this study.

Sincerely,

[REDACTED]

Doreen C. Parkhurst, M.D., FACEP
Chair Institutional Review Board
Assistant Dean, SGMS &
Program Director, PA Program
Barry University
Box SGMS
11300 NE 2 Avenue
Miami Shores, FL 33161

cc: Dr. Mary Bear

.....
Note: The investigator will be solely responsible and strictly accountable for any deviation from or failure to follow the research protocol as approved and will hold Barry University harmless from all claims against it arising from said deviation or failure.

UF Institutional Review Board

UNIVERSITY of FLORIDA

Health Science Center / Jacksonville
College of Medicine
Institutional Review Board

FWA00005790

580 West Eighth Street
Tower II, 9th Floor, Suite 9015
Jacksonville, FL 32209
(904) 244-9478
(fax) (904) 244-9035

MEMORANDUM

DATE: April 24, 2008

TO: Pam Pieper, MSN, ARNP-CS

FROM: Sheila Heim, CIP [REDACTED]
Coordinator, Institutional Review Board for
Alan Halperin, MD
Chair, Institutional Review Board

SUBJECT: Expedited Review of UFJ 2008-47

TITLE: Early Outcomes From Mild Traumatic Brain Injury From Child and Proxy Perspectives

Your request for approval of the above study under the classification of expedited has been reviewed and as IRB Chair I am pleased to inform you that your study is now approved under the expedited category(s):

- ___ 1. Clinical studies of drugs and devices only when:
 - a. An investigational new drug application (IND) or investigational device exemption (IDE) is not required, and there is no significant increase in risk or decrease in acceptability of risk, or
 - b. The device is cleared or approved for marketing and is being used in accordance with its labeling.
- ___ 2. Collection of blood samples by finger, heel, or ear stick, or venipuncture no more than twice weekly as follows:
 - a. From healthy non-pregnant adults weighing at least 110 pounds, in amounts less than 550 ml per 8 weeks.
 - b. From other adults and children, considering the health and habitus of the subjects, in amounts less than 50 ml or 3 ml per kg (whichever is less) per 8 weeks.
- ___ 3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
 - a. Hair and nail clippings (non-disfiguring).
 - b. Deciduous teeth at exfoliation or indicated extraction
 - c. Permanent teeth excreta at indicated extraction
 - d. Excreta and external secretions including sweat
 - e. Uncannulated saliva
 - f. Placenta removed at delivery
 - g. Amniotic fluid at the time of rupture of the membrane prior to or during labor
 - h. Supra- and sub-gingival dental plaque during routine prophylactic scaling
 - i. Mucosal and skin cells by buccal scraping or swab, skin swab, or mouth washings.
 - j. Sputum after saline mist nebulization

Appendix A

SUBJECT: Expedited Review of UFJ 2008-47

TITLE: Early Outcomes From Mild Traumatic Brain Injury From Child and Proxy Perspectives

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Examples:

- a. Physical sensors that do not involve input of significant amounts of energy or invasion of privacy.
- b. Weighing or testing sensory acuity.
- c. Electro-cardiography, electro-encephalography, thermography, detection of naturally- occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography.
- d. Moderate exercise, muscular strength testing, body composition assessment and flexibility testing where appropriate for age, weight and health.

5. Research involving materials (data, documents, records, specimens) that have been or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (such as studies of perception, cognition, motivation, identity, language, communication, cultural beliefs and practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

You must inform the Board of any modifications or changes to this research (protocol or consent changes) since they could affect its expedited status.

Please note the category of informed consent listed below that has been approved for this study.

You have been granted approval to conduct this study using the enclosed stamped, IRB-approved consent form. This consent must be photocopied and used when enrolling subjects into this project.

OR

You have been granted a waiver of documentation of informed consent, in lieu of a verbal consent.

OR

You have been granted a waiver of informed consent.

Your protocol is approved until 4/24/2009 at which time you will need to submit a regular continuing review report in order to continue the study.

Thank you for informing the Board of your proposal.

UF | Institutional Review Board
UNIVERSITY of FLORIDA

Health Science Center / Jacksonville
College of Medicine
Institutional Review Board

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Tower II, 9th Floor, Suite 9015
Jacksonville, FL 32209
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MEMORANDUM

DATE: April 30, 2008

TO: Pam Pieper, MSN, ARNP-CS

FROM: Sheila Heim, CIP [REDACTED]
Coordinator, Institutional Review Board for
Alan Halperin, MD
Chair, Institutional Review Board

SUBJECT: Approval of Amendment to Protocol UFJ 2008-47

TITLE: Early Outcomes From Mild Traumatic Brain Injury From Child and Proxy Perspectives

On 4/29/2008 the IRB reviewed and APPROVED the amendments below.

Revision to protocol:

- 1) incorrect appendices originally submitted and approved
Amended appendices B, C, F, and G submitted
- 2) revised appendices I and J ('review copy' deleted)

Thank you for keeping the IRB informed about your research project, thereby allowing us to keep accurate files. If the IRB staff can be of any further assistance, please feel free to call the office at [REDACTED]

UF | Institutional Review Board
UNIVERSITY of FLORIDA

Health Science Center / Jacksonville
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Institutional Review Board

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580 West Eighth Street
Tower II, 9th Floor, Suite 9015
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MEMORANDUM

DATE: April 30, 2008
TO: Pam Pieper, MSN, ARNP-CS
FROM: Sheila Heim, CIP [REDACTED]
Coordinator, Institutional Review Board for
Alan Halperin, MD
Chair, Institutional Review Board
SUBJECT: Approval of Amendment to Protocol UFJ 2008-47
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Thank you for keeping the IRB informed about your research project, thereby allowing us to keep accurate files. If the IRB staff can be of any further assistance, please feel free to call the office at [REDACTED]



820 Prudential Drive, Suite 413
 Jacksonville, Florida 32207
 Phone: 904.202.2127
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 e-baptisthealth.com

Institutional Review Committee

May 21, 2008

Pam Pieper, MSN, ARNP, BC
 Pediatric Surgery
 UFHSC-J
 653 W 8th Street, Box FC-12
 Jacksonville, FL 32209

Dear Ms. Pieper:

The Institutional Review Committee (IRC) of Baptist Medical Center (BMC) is in receipt of the requested changes to the following protocol:

#08-19, "Early Outcomes from Mild Traumatic Brain Injury from Child and Proxy Perspectives" (One month study)

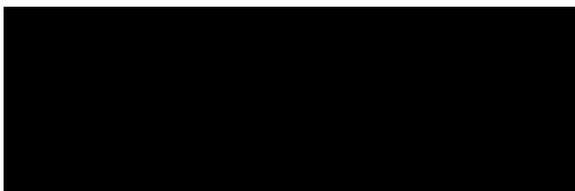
-Protocol submission checklist; study summary letter dated 14 April 2008; protocol, version date 2008; staff script; Mild Traumatic Brain Injury flyer; Mild Non-Brain Injury flyer; consent document, version date 21 May 2008; University of Florida consent document, version 2008; Assent document ages 6-12, version date 21 May 2008; Assent document ages 13-17, version date 21 May 2008; Demographics and Background Information form; Pediatric Quality of Life, Ages 13-18, version 4.0; Pediatric Quality of Life Inventory, Parent Report for Teens ages 13-18, version 4.0; Pediatric Quality of Life Inventory Child Report ages 8-12, version 4.0; Pediatric Quality of Life Inventory Parent Report for Children ages 8-12, version 4.0; Pediatric Quality of Life Inventory Young Child Report ages 5-7, version 4.0; Pediatric Quality of Life Inventory Parent Report for Young Children Ages 5-7, version 4.0; Pediatric Quality of Life Inventory Parent Report for Toddlers ages 2-4, version 4.0; Peds QL Cognitive Functioning Scale Teen Report ages 13-18; Peds QL Cognitive Functioning Scale Child Report ages 8-12; Peds QL Cognitive Functioning Scale Parent Report for Children ages 8-12; Peds QL Cognitive Functioning Scale Young Child Report ages 5-7; Peds QL Cognitive Functioning Scale Parent Report for Young Children ages 5-7; Peds QL Cognitive Functioning Scale Parent Report for Toddlers ages 2-4; Peds QL Administration Guidelines; NCI Training Certificate; University of Florida Research and Information Privacy Certificate of Completion.

Appendix A

Enclosed is the stamped consent document with the approval and expiration dates that must be used for enrolling new subjects. As previously stated, the anniversary date for this protocol is May 8, 2009. At that time, please submit a report of your experiences with this study.

Should you have any questions, please contact the IRC office. The BMC IRC meets the requirements in 21 CFR 56 (Rev.), 45 CFR 46 (Rev.) and ICH (E6) GCP guidelines.

Good luck with this endeavor!



Michael Joyce, MD, PhD
Chairman
Institutional Review Committee

ID#

Date: _____

PedsQLTM

Pediatric Quality of Life Inventory Acute Version

Version 4.0

TEEN REPORT (ages 13-18)

DIRECTIONS

On the following page is a list of things that might be a problem for you. Please tell us how much of a problem each one has been for you during the past 7 days by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

In the past 7 days, how much of a problem has this been for you ...

ABOUT MY HEALTH AND ACTIVITIES (<i>problems with...</i>)	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for me to walk more than one block	0	1	2	3	4
2. It is hard for me to run	0	1	2	3	4
3. It is hard for me to do sports activity or exercise	0	1	2	3	4
4. It is hard for me to lift something heavy	0	1	2	3	4
5. It is hard for me to take a bath or shower by myself	0	1	2	3	4
6. It is hard for me to do chores around the house	0	1	2	3	4
7. I hurt or ache	0	1	2	3	4
8. I have low energy	0	1	2	3	4

ABOUT MY FEELINGS (<i>problems with...</i>)	Never	Almost Never	Some-times	Often	Almost Always
1. I feel afraid or scared	0	1	2	3	4
2. I feel sad or blue	0	1	2	3	4
3. I feel angry	0	1	2	3	4
4. I have trouble sleeping	0	1	2	3	4
5. I worry about what will happen to me	0	1	2	3	4

HOW I GET ALONG WITH OTHERS (<i>problems with...</i>)	Never	Almost Never	Some-times	Often	Almost Always
1. I have trouble getting along with other teens	0	1	2	3	4
2. Other teens do not want to be my friend	0	1	2	3	4
3. Other teens tease me	0	1	2	3	4
4. I cannot do things that other teens my age can do	0	1	2	3	4
5. It is hard to keep up with my peers	0	1	2	3	4

ABOUT SCHOOL (<i>problems with...</i>)	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard to pay attention in class	0	1	2	3	4
2. I forget things	0	1	2	3	4
3. I have trouble keeping up with my schoolwork	0	1	2	3	4
4. I miss school because of not feeling well	0	1	2	3	4
5. I miss school to go to the doctor or hospital	0	1	2	3	4

ID# _____
Date: _____

PedsQLTM
Pediatric Quality of Life
Inventory
Acute Version

Version 4.0

PARENT REPORT for TEENS (ages 13-18)

DIRECTIONS

On the following page is a list of things that might be a problem for **your teen**. Please tell us **how much of a problem** each one has been for your teen during the **past 7 days** by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

Appendix B

PedsQL 2

In the past 7 days, how much of a problem has your teen had with ...

PHYSICAL FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. Walking more than one block	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports activity or exercise	0	1	2	3	4
4. Lifting something heavy	0	1	2	3	4
5. Taking a bath or shower by him or herself	0	1	2	3	4
6. Doing chores around the house	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Low energy level	0	1	2	3	4

EMOTIONAL FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or blue	0	1	2	3	4
3. Feeling angry	0	1	2	3	4
4. Trouble sleeping	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. Getting along with other teens	0	1	2	3	4
2. Other teens not wanting to be his or her friend	0	1	2	3	4
3. Getting teased by other teens	0	1	2	3	4
4. Not able to do things that other teens his or her age can do	0	1	2	3	4
5. Keeping up with other teens	0	1	2	3	4

SCHOOL FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with schoolwork	0	1	2	3	4
4. Missing school because of not feeling well	0	1	2	3	4
5. Missing school to go to the doctor or hospital	0	1	2	3	4

ID#

Date: _____

PedsQLTM
Pediatric Quality of Life
Inventory
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Version 4.0

CHILD REPORT (ages 8-12)

DIRECTIONS

On the following page is a list of things that might be a problem for you. Please tell us how much of a problem each one has been for you during the past 7 days by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

Appendix B

PedsQL 2

In the past 7 days, how much of a problem has this been for you ...

ABOUT MY HEALTH AND ACTIVITIES (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. It is hard for me to walk more than one block	0	1	2	3	4
2. It is hard for me to run	0	1	2	3	4
3. It is hard for me to do sports activity or exercise	0	1	2	3	4
4. It is hard for me to lift something heavy	0	1	2	3	4
5. It is hard for me to take a bath or shower by myself	0	1	2	3	4
6. It is hard for me to do chores around the house	0	1	2	3	4
7. I hurt or ache	0	1	2	3	4
8. I have low energy	0	1	2	3	4

ABOUT MY FEELINGS (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. I feel afraid or scared	0	1	2	3	4
2. I feel sad or blue	0	1	2	3	4
3. I feel angry	0	1	2	3	4
4. I have trouble sleeping	0	1	2	3	4
5. I worry about what will happen to me	0	1	2	3	4

HOW I GET ALONG WITH OTHERS (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. I have trouble getting along with other kids	0	1	2	3	4
2. Other kids do not want to be my friend	0	1	2	3	4
3. Other kids tease me	0	1	2	3	4
4. I cannot do things that other kids my age can do	0	1	2	3	4
5. It is hard to keep up when I play with other kids	0	1	2	3	4

ABOUT SCHOOL (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. It is hard to pay attention in class	0	1	2	3	4
2. I forget things	0	1	2	3	4
3. I have trouble keeping up with my schoolwork	0	1	2	3	4
4. I miss school because of not feeling well	0	1	2	3	4
5. I miss school to go to the doctor or hospital	0	1	2	3	4

ID#

Date: _____

PedsQLTM
Pediatric Quality of Life
Inventory
Acute Version

Version 4.0

PARENT REPORT for CHILDREN (ages 8-12)

DIRECTIONS

On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past 7 days** by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

Appendix B

PedsQL 2

In the past 7 days, how much of a problem has your child had with ...

PHYSICAL FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. Walking more than one block	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports activity or exercise	0	1	2	3	4
4. Lifting something heavy	0	1	2	3	4
5. Taking a bath or shower by him or herself	0	1	2	3	4
6. Doing chores around the house	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Low energy level	0	1	2	3	4

EMOTIONAL FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or blue	0	1	2	3	4
3. Feeling angry	0	1	2	3	4
4. Trouble sleeping	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. Getting along with other children	0	1	2	3	4
2. Other kids not wanting to be his or her friend	0	1	2	3	4
3. Getting teased by other children	0	1	2	3	4
4. Not able to do things that other children his or her age can do	0	1	2	3	4
5. Keeping up when playing with other children	0	1	2	3	4

SCHOOL FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with schoolwork	0	1	2	3	4
4. Missing school because of not feeling well	0	1	2	3	4
5. Missing school to go to the doctor or hospital	0	1	2	3	4

ID#	_____
Date:	_____

PedsQLTM

Pediatric Quality of Life Inventory Acute Version

Version 4.0

YOUNG CHILD REPORT (ages 5-7)

Instructions for interviewer:

I am going to ask you some questions about things that might be a problem for some children. I want to know how much of a problem any of these things might be for you.

Show the child the template and point to the responses as you read.

If it is not at all a problem for you, point to the smiling face

If it is sometimes a problem for you, point to the middle face

If it is a problem for you a lot, point to the frowning face

I will read each question. Point to the pictures to show me how much of a problem it is for you. Let's try a practice one first.

	Not at all	Sometimes	A lot
Is it hard for you to snap your fingers			

Ask the child to demonstrate snapping his or her fingers to determine whether or not the question was answered correctly. Repeat the question if the child demonstrates a response that is different from his or her action.

Appendix B

PedsQL 2

Think about how you have been doing for the past 7 days. Please listen carefully to each sentence and tell me how much of a problem this is for you.

After reading the item, gesture to the template. If the child hesitates or does not seem to understand how to answer, read the response options while pointing at the faces.

PHYSICAL FUNCTIONING (problems with...)	Not at all	Sometimes	A lot
1. Is it hard for you to walk	0	2	4
2. Is it hard for you to run	0	2	4
3. Is it hard for you to play sports or exercise	0	2	4
4. Is it hard for you to pick up big things	0	2	4
5. Is it hard for you to take a bath or shower	0	2	4
6. Is it hard for you to do chores (like pick up your toys)	0	2	4
7. Do you have hurts or aches (Where? _____)	0	2	4
8. Do you ever feel too tired to play	0	2	4

Remember, tell me how much of a problem this has been for you for the past 7 days.

EMOTIONAL FUNCTIONING (problems with...)	Not at all	Sometimes	A lot
1. Do you feel scared	0	2	4
2. Do you feel sad	0	2	4
3. Do you feel mad	0	2	4
4. Do you have trouble sleeping	0	2	4
5. Do you worry about what will happen to you	0	2	4

SOCIAL FUNCTIONING (problems with...)	Not at all	Sometimes	A lot
1. Is it hard for you to get along with other kids	0	2	4
2. Do other kids say they do not want to play with you	0	2	4
3. Do other kids tease you	0	2	4
4. Can other kids do things that you cannot do	0	2	4
5. Is it hard for you to keep up when you play with other kids	0	2	4

SCHOOL FUNCTIONING (problems with...)	Not at all	Sometimes	A lot
1. Is it hard for you to pay attention in school	0	2	4
2. Do you forget things	0	2	4
3. Is it hard to keep up with schoolwork	0	2	4
4. Do you miss school because of not feeling good	0	2	4
5. Do you miss school because you have to go to the doctor's or hospital	0	2	4

How much of a problem is this for you?

Not at all



Sometimes



A lot



ID#	_____
Date:	_____

PedsQLTM

Pediatric Quality of Life Inventory Acute Version

Version 4.0

PARENT REPORT for YOUNG CHILDREN (ages 5-7)

DIRECTIONS

On the following page is a list of things that might be a problem for your child. Please tell us how much of a problem each one has been for your child during the past 7 days by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

Appendix B

PedsQL 2

In the past 7 days, how much of a problem has your child had with ...

PHYSICAL FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. Walking more than one block	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports activity or exercise	0	1	2	3	4
4. Lifting something heavy	0	1	2	3	4
5. Taking a bath or shower by him or herself	0	1	2	3	4
6. Doing chores, like picking up his or her toys	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Low energy level	0	1	2	3	4

EMOTIONAL FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or blue	0	1	2	3	4
3. Feeling angry	0	1	2	3	4
4. Trouble sleeping	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. Getting along with other children	0	1	2	3	4
2. Other kids not wanting to be his or her friend	0	1	2	3	4
3. Getting teased by other children	0	1	2	3	4
4. Not able to do things that other children his or her age can do	0	1	2	3	4
5. Keeping up when playing with other children	0	1	2	3	4

SCHOOL FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with school activities	0	1	2	3	4
4. Missing school because of not feeling well	0	1	2	3	4
5. Missing school to go to the doctor or hospital	0	1	2	3	4

ID# _____
Date: _____

PedsQLTM

Cognitive Functioning Scale

Standard Version

TEEN REPORT (ages 13-18)

DIRECTIONS

On the following page is a list of things that might be a problem for you. Please tell us **how much of a problem** each one has been for you during the past **ONE** month by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

Appendix C

PedsQL 2

In the past ONE month, how much of a problem has this been for you ...

COGNITIVE FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Some- times	Often	Almost Always
1. It is hard for me to keep my attention on things	0	1	2	3	4
2. It is hard for me to remember what people tell me	0	1	2	3	4
3. It is hard for me to remember what I just heard	0	1	2	3	4
4. It is hard for me to think quickly	0	1	2	3	4
5. I have trouble remembering what I was just thinking	0	1	2	3	4
6. I have trouble remembering more than one thing at a time	0	1	2	3	4

ID# _____
Date: _____

PedsQLTM

Cognitive Functioning Scale

Standard Version

PARENT REPORT for TEENS (ages 13-18)

DIRECTIONS

On the following page is a list of things that might be a problem for your child. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

Appendix C

PedsQL 2

In the past ONE month, how much of a problem has this been for your child ...

COGNITIVE FUNCTIONING (problems with...)	Never	Almost Never	Some- times	Often	Almost Always
1. Difficulty keeping his/her attention on things	0	1	2	3	4
2. Difficulty remembering what people tell him/her	0	1	2	3	4
3. Difficulty remembering what he/she just heard	0	1	2	3	4
4. Difficulty thinking quickly	0	1	2	3	4
5. Trouble remembering what he/she was just thinking	0	1	2	3	4
6. Trouble remembering more than one thing at a time	0	1	2	3	4

ID#	_____
Date:	_____

PedsQLTM

Cognitive Functioning Scale

Standard Version

CHILD REPORT (ages 8-12)

DIRECTIONS

On the following page is a list of things that might be a problem for you. Please tell us how much of a problem each one has been for you during the past **ONE** month by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

PedsQL 2

In the past ONE month, how much of a problem has this been for you ...

COGNITIVE FUNCTIONING (problems with...)	Never	Almost Never	Some- times	Often	Almost Always
1. It is hard for me to keep my attention on things	0	1	2	3	4
2. It is hard for me to remember what people tell me	0	1	2	3	4
3. It is hard for me to remember what I just heard	0	1	2	3	4
4. It is hard for me to think quickly	0	1	2	3	4
5. I have trouble remembering what I was just thinking	0	1	2	3	4
6. I have trouble remembering more than one thing at a time	0	1	2	3	4

ID# _____
Date: _____

PedsQLTM

Cognitive Functioning Scale

Standard Version

PARENT REPORT for CHILDREN (ages 8-12)

DIRECTIONS

On the following page is a list of things that might be a problem for your child. Please tell us how much of a problem each one has been for your child during the past ONE month by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

Appendix C

PedsQL 2

In the past ONE month, how much of a problem has this been for your child ...

COGNITIVE FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Some- times	Often	Almost Always
1. Difficulty keeping his/her attention on things	0	1	2	3	4
2. Difficulty remembering what people tell him/her	0	1	2	3	4
3. Difficulty remembering what he/she just heard	0	1	2	3	4
4. Difficulty thinking quickly	0	1	2	3	4
5. Trouble remembering what he/she was just thinking	0	1	2	3	4
6. Trouble remembering more than one thing at a time	0	1	2	3	4

ID#	_____
Date:	_____

PedsQL™

Cognitive Functioning Scale

Standard Version

YOUNG CHILD REPORT (ages 5-7)

Instructions for interviewer:

I am going to ask you some questions about things that might be a problem for some children. I want to know how much of a problem any of these things might be for you.

Show the child the template and point to the responses as you read.

If it is not at all a problem for you, point to the smiling face

If it is sometimes a problem for you, point to the middle face

If it is a problem for you a lot, point to the frowning face

I will read each question. Point to the pictures to show me how much of a problem it is for you. Let's try a practice one first.

	Not at all	Sometimes	A lot
Is it hard for you to snap your fingers			

Ask the child to demonstrate snapping his or her fingers to determine whether or not the question was answered correctly. Repeat the question if the child demonstrates a response that is different from his or her action.

Think about how you have been doing for the past few weeks. Please listen carefully to each sentence and tell me how much of a problem this is for you.

After reading the item, gesture to the template. If the child hesitates or does not seem to understand how to answer, read the response options while pointing at the faces.

Cognitive Functioning (PROBLEMS WITH...)	NOT AT ALL	SOME-TIMES	A LOT
1. Is it hard for you to keep your attention on things	0	2	4
2. Is it hard for you to remember what people tell you	0	2	4
3. Is it hard for you to remember what you just heard	0	2	4
4. Is it hard for you to think quickly	0	2	4
5. Do you have trouble remembering what you were just thinking	0	2	4
6. Do you have trouble remembering more than one thing at a time	0	2	4

How much of a problem is this for you?

Not at all



Sometimes



A lot



ID# _____
Date: _____

PedsQLTM

Cognitive Functioning Scale

Standard Version

PARENT REPORT for YOUNG CHILDREN (ages 5-7)

DIRECTIONS

On the following page is a list of things that might be a problem for your child. Please tell us how much of a problem each one has been for your child during the past ONE month by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

Appendix C

PedsQL 2

In the past ONE month, how much of a problem has this been for your child ...

COGNITIVE FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. Difficulty keeping his/her attention on things	0	1	2	3	4
2. Difficulty remembering what people tell him/her	0	1	2	3	4
3. Difficulty remembering what he/she just heard	0	1	2	3	4
4. Difficulty thinking quickly	0	1	2	3	4
5. Trouble remembering what he/she was just thinking	0	1	2	3	4
6. Trouble remembering more than one thing at a time	0	1	2	3	4

Staff Script

A doctoral student is conducting a study about children who have injuries like _____ (child's name)'s. Here is a flyer that explains the study. If you would like more information, I will be happy to ask her to come meet with you while you are here today.

Health-Related Quality of Life in Children after a Mild Traumatic Brain Injury

If all of the following apply to your child:

1. 5-17 years old
2. Being seen in the Pediatric Emergency Department and/or Trauma Center due to a traumatic injury
3. Expect to be sent home in less than 24 hours
4. Diagnosis of a mild traumatic brain injury
 - Temporary confusion after the injury,
 - Amnesia: doesn't remember the injury, *OR*
 - Loss of consciousness of less than 30 minutes
5. At least one legal guardian can speak, read, and write in English
6. You have a working telephone

Will you help us to learn more?

Pam Pieper, a nursing PhD student at Barry University, is conducting this study to try to learn more about children's health-related quality of life after they have had a mild traumatic brain injury. If you and your child participate in the study, you will each be asked to complete a questionnaire about problems your child may have as a result of the injury on two separate occasions. The first time will be while you are in the emergency room. That time the questions will need to be answered about how your child was during the week before the injury. The second time will be over the telephone at 1 month after the injury. The questions will need to be answered about how your child has been during the previous week. The questionnaires take approximately 6 minutes to complete.

It is important to compare how a child who has had a mild traumatic brain injury is doing relative to healthy children who have not been injured. You will also be asked to have a parent of one of your child's friends who would be interested in participating call the researcher. They will each be asked to complete the same questionnaires as you and your child do.

Interested?

Please let one of the emergency department staff members know if you are interested in more information about this study. Pam Pieper will be contacted to meet with you while you are here today.

Note: This flyer was printed on lilac paper.

Health-Related Quality of Life in Children after a *Mild Non-Brain Injury*

If all of the following apply to your child:

1. 5-17 years old
2. Being seen in the Pediatric Emergency Department and/or Trauma Center due to a traumatic injury
3. Expect to be sent home in less than 24 hours
4. Diagnosis of a traumatic injury that doesn't involve the brain, such as
Fractures Sprains Dislocations
Lacerations Bruises Burns
5. At least one legal guardian can speak, read, and write in English
6. You have a working telephone

Will you help us to learn more?

Pam Pieper, a nursing PhD student at Barry University, is conducting this study to try to learn more about children's health-related quality of life after they have had an injury. If you and your child participate in the study, you will each be asked to complete a questionnaire about problems your child may have as a result of the injury on two separate occasions. The first time will be while you are in the emergency room. That time the questions will need to be answered about how your child was during the week before the injury. The second time will be over the telephone at 1 month after the injury. The questions will need to be answered about how your child has been during the previous week. The questionnaires take approximately 6 minutes to complete.

Interested?

Please let one of the emergency department staff members know if you are interested in more information about this study. Pam Pieper will be contacted to meet with you while you are here today.

Note: This flyer was printed on pink paper.

BIOSKETCH: PAMELA PIEPER, MSN, ARNP, PNP-BC**Education**

Barry University, Miami Shores, FL. PhD in Nursing, projected completion 2009
 University of Florida, Jacksonville, FL. Pediatric Nurse Practitioner, 1991
 University of Alabama in Birmingham. Birmingham, AL. MSN, Pediatric Nursing,
 1983
 Cornell University-NY Hospital School of Nursing, NY, NY. BSN, 1979
 Franklin and Marshall College, Lancaster, PA. BA in Biology, 1976

Employment

1979-1981 Pediatric Unit Staff Nurse; Anne Arundel General Hospital. Annapolis, MD
 1981-1984 Infant Intensive Care Unit Staff Nurse, Surgical/Non-infectious Nursery
 Staff Nurse; The Children's Hospital of Alabama. Birmingham, AL
 1984-1986 Surgery Clinic Coordinator; Nemours Children's Hospital. Jacksonville, FL
 1984-1987 Pediatric Clinical Nurse Specialist (CNS); Medi-Kid, Inc. Children's Medical
 Day Care Center. Jacksonville, FL
 1986-1987 Pediatric Surgery CNS; University Hospital of Jacksonville. Jacksonville, FL
 1987-1989 Neonatal Intensive Care Unit Staff Nurse; Wolfson Children's Hospital.
 Jacksonville, FL
 1988-1989 Nutritional Support Team Inpatient Nurse Clinician; Wolfson Children's
 Hospital. Jacksonville, FL
 1990-1996 Clinical Instructor; University of Florida College of Nursing. Jacksonville,
 FL/Pediatric Surgery CNS and Pediatric Trauma Nurse Coordinator (TNC)
 1996-2000 Clinical Assistant Professor; University of Florida College of Nursing.
 Jacksonville, FL/Pediatric Surgery CNS/Nurse Practitioner (NP) and
 Pediatric TNC
 2000-2003 Clinical Associate Professor; University of Florida College of Nursing.
 Jacksonville, FL/Pediatric Surgery CNS/NP and Pediatric TNC
 2003-
 present Clinical Associate Professor; University of Florida College of Nursing.
 Jacksonville, FL/Pediatric Surgery CNS/NP and Traumatic Brain Injury
 Research Coordinator

Selected Professional Memberships

1979 - present American Nurses' Association
 1983 – present Sigma Theta Tau
 1985 – present Florida Nurses' Association
 1991 – present Pediatric Nursing Council of Northeast Florida, Founding Member
 1991 – present American Pediatric Surgical Nurses' Association, Charter Member
 1991 – 1994 Membership Chairman
 2003 – 2006 President Elect/President/Immediate Past President

Honors

1992 Nurse Educator of the Year, University Medical Center, Jacksonville, FL
 2001 Appointed to the Florida Brain and Spinal Cord Injury Advisory Council
 2002 American Pediatric Surgical Nurses Association Founder's Award

2003 Great 100 Nurses of Northeast Florida

2006 Appointed to the Florida Emergency Services for Children Advisory Council

Selected Publications (previous 2 years)

Tepas, J. J. III, Leaphart, C. L., **Pieper, P.**, Beaulieu, C. L., Spierre, L. R., Tuten, J. D., & Celso, B. G. (2009). The effect of delay in rehabilitation on outcome of severe traumatic brain injury. *Journal of Pediatric Surgery, 44*, 368-372.

Leaphart, C. L., Graham, D., **Pieper, P.**, Celso, B. G., & Tepas, J. J. III. (2009).

Surgical quality improvement: A simplified method to apply national standards to pediatric trauma care. *Journal of Pediatric Surgery, 44*, 156-159.

Pieper, P. (2008). Ethical perspectives of children's assent for research participation: Deontology and utilitarianism. *Pediatric Nursing, 34*, 319-323.

Tepas, J. J. III, Leaphart, C. L., Celso, B. G., Tuten, J. D., **Pieper, P.**, & Ramenofsky, M. L. (2008). Risk stratification simplified: The worst injury predicts mortality for the injured child. *Journal of Trauma, 65*, 1258-1263.

Pracht, E. E., Tepas, J. J. III, Langland-Orban, B., Simpson, L., **Pieper, P.**, & Flint, L. M. (2008). Do pediatric patients with trauma in Florida have reduced mortality rates when treated in designated trauma centers? *Journal of Pediatric Surgery, 43*, 212-221.

Brown, N. T., Flanigan, L. M., McComiskey, C. A., & **Pieper, P.** (Eds.). (2007). *Nursing care of the pediatric surgical patient* (2nd rev. ed.). Boston: Jones and Bartlett.

Pieper, P. (2007). Pediatric trauma. In N. T. Browne, L. M. Flanigan, C. A. McComiskey, & P. Pieper (Eds.). *Nursing care of the pediatric surgical patient* (2nd rev. ed., pp. 445-464). Boston: Jones and Bartlett.

Selected National Presentations (previous 2 years)

Early health-related quality of life outcomes after a mild traumatic brain injury from child and proxy perspectives. Poster presentation; Southern Nursing Research Society 2009 Conference in Baltimore, MD on February 14, 2009.

Health-related quality of life in children: A concept analysis. Poster presentation; 17th Annual Scientific Meeting of the American Pediatric Surgical Nurses Association in Phoenix, AZ on May 26-28, 2008.

Clinical presentation and surgical outcome of necrotizing enterocolitis: Impact of gestational age. Poster presentation; 16th Annual Scientific Meeting of the American Pediatric Surgical Nurses Association in Orlando, FL on May, 21-24, 2007.

Research Support

2008 Principal Investigator. American Pediatric Surgical Nurses Association Research Grant (\$500).

2006 – 2011 Sub-investigator. Biomarkers of Brain Pathology in Adult Patients with Traumatic Brain Injury. Center for Traumatic Brain Injury Studies, University of Florida, Gainesville, Florida. National Institutes of Health RO1 NS052831 (\$109,113)

2003 – 2006 Clinical Coordinator. Robert Wood Johnson Foundation Injury Free Coalition for Kids at Shands Jacksonville (\$160,660).