Children's Pain: PICU Nurses' Beliefs and Responses to Virtual Human Vignettes

BY

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THESIS
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I would like to dedicate this thesis to the many remarkable educators and mentors I have encountered over the years, who have imparted their wisdom and have inspired me to take on new challenges, particularly my aunt Rebecca Bilott, my dissertation chair and advisor Dr. Catherine Vincent, Dr. Katherine Pakieser-Reed, and Dr. Perle Cowen. I’d also like to recognize my first educators, my parents, for their endless love, patience, and encouragement. Lastly, I dedicate this thesis to my husband, Geoffrey Scott, for without his continued support, I could not have achieved this goal.
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<th>Description</th>
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<tr>
<td>FACS</td>
<td>Facial Action Coding System</td>
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<td>PBPQ</td>
<td>Pain Beliefs and Practices Questionnaire</td>
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<tr>
<td>PI</td>
<td>Primary Investigator</td>
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<td>PICU</td>
<td>Pediatric Intensive Care Unit</td>
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<td>PNKAS</td>
<td>Pediatric Nurses’ Knowledge and Attitudes Survey</td>
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<td>VH</td>
<td>Virtual Human</td>
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SUMMARY

A cross-sectional, mixed-methods study was conducted to describe and compare pediatric intensive care unit (PICU) nurses’ assessment and intervention choices in response to virtual human vignettes (computer-generated patient scenarios) as well as their beliefs regarding children’s pain management. Additionally we sought to determine the effect of child behavior (smiling, grimacing), and pain type (post-operative, sickle cell vaso-occlusive crisis) on PICU nurses’ pain ratings and morphine dose choices among vignettes (virtual human and written). Forty PICU nurses responded to 4 virtual human vignettes. Vignette patients differed only in pain type and behavior. The nurses participated in semi-structured interviews about their pain assessment and pain intervention choices and completed the Pain Beliefs and Practices Questionnaire.

Nurses most often described the child’s diagnosis, behavior, verbal expression of pain, and vital signs as important components of their pain assessment and choices to intervene for pain. Faulty beliefs related to the risks of opioid analgesics and the pharmacodynamics of intravenous analgesics were prevalent. Beliefs consistent with best practice included: ability to experience pain while receiving sedatives, ability to treat pain at multiple points along the pain pathway, and harmful effects of pain.

Significant multivariate effects were identified for facial expression and vignette type. The children in the vignettes (virtual human and written) that were grimacing, received higher pain ratings and morphine doses than the children that were smiling. Nurses also rated pain higher and provided more morphine to the children within the written vignettes.

This dissertation includes three chapters: an introduction to the original research conducted for this dissertation, and two manuscripts for publication. I present the results of this study in the first manuscript and describe the process employed to develop and validate the virtual human vignettes used in the research in the second manuscript. In the appendices, I have included approval letters for this research from the Institutional Review Boards at the University of Illinois at Chicago and Ann and Robert H. Lurie Children’s Hospital of Chicago and license agreements for reprinted figures; last, is my vita.
I. INTRODUCTION

Background

Inadequate pain management is one of the most often reported adverse events in the Pediatric Intensive Care Unit (PICU) (Agarwal et al., 2010; Grant, Scoppettuolo, Wypij, & Curley, 2012; Larsen, Donaldson, Parker, & Grant, 2007). In a retrospective chart review of patients from 15 different PICUs in the United States, uncontrolled pain (pain rated greater than 5 out of 10 for 2 hours or more) was the second most frequently occurring adverse event; of the 146 uncontrolled pain events, 120 (82.2%) were preventable (Agarwal et al., 2010). Uncontrolled pain, in an already critically-ill child, can have life-threatening physiological consequences (Anand, Sippell, & Aynsley-Green, 1987; Anand & Hickey, 1992). Furthermore, painful experiences can lead to more intense responses to (Peters et al., 2005; Taddio, Goldbach, Ipp, Stevens, & Koren, 1995; Taddio, Katz, Ilersich, & Koren, 1997; Weisman, Bernstein, & Schechter, 1998) and increased analgesic requirements (Peters et al., 2005) for subsequent procedures. The presence of pain may also impact important healthcare decisions; 76% of parents who made end-of-life decisions for a child in a PICU identified pain as an important factor in considering withdrawal of life-sustaining treatment (Meyer, Burns, Griffith, & Truog, 2002).

Nurses play an important role in managing children’s pain, including assessing for pain, implementing interventions, and evaluating intervention effectiveness (American Society for Pain Management Nurses, Emergency Nurses’ Association, American College of Emergency Physicians, & American Pain Society, 2010; Baulch, 2010; Hamrin, 2002; Nash et al., 1999; Oware-Gyekye, 2008). Regrettably, nurses’ inaccurate beliefs regarding children’s pain and knowledge deficits related to pain assessment and management have contributed to hospitalized children’s unrelieved pain (Manworren, 2000; Vincent & Denyes, 2004; Vincent & Gaddy, 2009). PICU nurses’ beliefs regarding the ability of children to tolerate pain better than adults, consequences of pain, and the ability of vital signs to return to baseline despite persistent pain, have varied extensively (Pederson & Bjerke, 1999). Also, deficits have been noted in PICU nurses’ knowledge of children’s pain assessment (Pederson & Bjerke, 1999; Pederson, Matthies, & McDonald, 1997; Ramelet, 1999) as well as pharmacologic and non-
pharmacologic interventions for pain (Pederson et al., 1997). Moreover, PICU nurses have relied upon vital sign changes as an indicator of pain when administering analgesics (Coffman et al., 1997; Curley et al., 1992; Pederson & Bjerke, 1999; Ramelet, 1999) despite the lack of vital sign specificity to pain (Arbour & Gélinas, 2010; Curley et al., 1992; Foster, Yucha, Zuk, & Vojir, 2003; Gélinas, Tousignant-Laflamme, Tanguay, & Bourgault, 2011).

For children with sickle cell disease, additional barriers to effective pain management include the unpredictability of vaso-occlusive pain, sociocultural differences between the children and their health professionals (e.g., class, race, ethnicity), and health professionals’ concerns of drug addiction (Elander, Marczewska, Amos, Thomas, & Tangayi, 2006; Pack-Mabien, Labbe, Herbert, & Haynes, 2001; Wright & Adeosun, 2009). Nurses may also have difficulty relating to pain from sickle cell disease in contrast to pain from trauma or surgery (Pack-Mabien et al., 2001). These barriers may explain in part why children admitted with sickle cell disease report moderate to high pain levels throughout the duration of their hospitalization (Beyer, 2000; Jacob et al., 2003, 2007; Jacob & Mueller, 2008; Zempsky et al., 2008).

Vignettes or “stories about individuals and situations which make reference to important points in the study of perceptions, beliefs, and attitudes” (Hughes, 1998, p. 381) have been used as a research methodology because they are more efficient and cost-effective than assessing actual behavior (Schigelone & Fitzgerald, 2004). Vignettes allow researchers to manipulate variables of interest and to control for variables that may influence results (Schigelone & Fitzgerald, 2004). Written vignettes have been used to assess pediatric nurses’ pain assessment and analgesic administration choices (Griffin, Polit, & Byrne, 2007; Hamers, Van Den Hout, Halfens, Abu-Saad, & Heijltjes, 1997; Vincent & Gaddy, 2009; Vincent, Wilkie, & Szalacha, 2010). More recently, virtual human (VH) vignettes, or computer-generated patient scenarios, have been used to evaluate nurses’ pain-related decision making for adults (Hirsh, George, & Robinson, 2009; Hirsh, Jensen, & Robinson, 2010). VH vignettes present nurses with animated patients that exhibit differing facial expressions and behaviors. Characteristics of the virtual humans can be manipulated to allow for comparisons (Hirsh et al., 2009; Hirsh et al., 2010).
Statement of the Problem

Studies regarding PICU nurses’ pain beliefs, assessment, and intervention choices are few and more than a decade old (Coffman et al., 1997; Curley et al., 1992; Manworren, 2000; Pederson & Bjerke, 1999; Pederson et al., 1997). More often, researchers have studied pediatric floor nurses (Gimbler-Berglund, Ljusegren, & Enskar, 2008; Hamers, Abu-Saad, Halfens, & Schumacher, 1994; Shrestha-Ranjit & Manias; Vincent & Denyes, 2004; Vincent & Gaddy, 2009; Vincent, Wilkie, & Szalacha, 2010; Vincent, Wilkie, & Wang, 2010) or do not distinguish nurses’ responses by clinical area (Griffin et al., 2007; Habich et al., 2012; Nash et al., 1999; Rieman, Gordon, & Marvin, 2007).

Little is known about PICU nurses’ pain intervention choices. Differences between pediatric floor and ICU nurses’ are likely; in one study (Jacob & Puntillo, 1999) floor nurses administered morphine at prolonged intervals while PICU nurses administered morphine consistently at the prescribed frequency. Other studies in which investigators evaluated PICU nurses’ analgesic administration focused on pain indicators leading to medication but investigators did not evaluate situations when children aren’t medicated or how the type, dose, or timing of the analgesic is chosen (Coffman et al., 1997; Curley et al., 1992).

It has been speculated that PICU nurses’ reliance upon vital signs for pain assessment is due to their care of continuously monitored, mechanically ventilated and sedated children (Pederson & Bjerke, 1999; Pederson et al., 1997; Ramelet, 1999). Still, as few as 30% of PICU patients have been reported to be intubated and mechanically ventilated (Khemani, Markovitz, & Curley, 2009). Only 3 of the 25 children in Coffman et al.’s (1997) study were intubated and 68% were preschool age or older; yet nurses identified the child’s verbalization of pain as an indicator to administer analgesia in just 37 of 112 observations. Because many children in PICUs may be able to verbalize pain, further evaluation of nurses’ pain management in children able to self-report is warranted.

Though written vignettes have been frequently used in pediatric nursing pain studies, there are some limitations to this methodology. Choice of words may cause bias (Barter & Renold, 2000; Waltz, Strickland, & Lenz, 2010) and any ambiguity or misapprehension of words may compromise the
equivalence of participants’ interpretations (Salomon, Tandon, & Murray, 2001). Use of video for a visual experience of a vignette could better simulate real-life experiences (R. Hughes & Huby, 2002). However, use of actors may decrease authenticity (Williams, 2002); additionally, video-recording actual children in pain and controlling for individual differences may not be feasible.

**Significance of the Study**

In 1997, researchers (Coffman et al., 1997) called for better descriptions of PICU nurses’ analgesic administration choices; no studies to date have been identified which do so. In fact, no studies have been reported with PICU nurses exclusively in the past decade. The contributions of this study are a crucial next step in this program of research. Before nurse clinicians and researchers can develop interventions aimed at improving nurses’ management of critically ill children’s pain, a better understanding of PICU nurses’ most common misconceptions related to the assessment and management of children’s pain is required. The mixed methods design of this study provided rich information, allowing for a more comprehensive view of PICU nurses’ assessment and intervention choices.

Use of the Knowledge Use in Pain Care (KUPC) (Latimer, Ritchie, & Johnston, 2010) as the conceptual framework for this study is significant. As a relatively young framework, no publications in which this theory was used to guide research have been identified. The use of the KUPC to guide content analysis of qualitative data allowed for evaluation of nurses’ responses at both the individual and group levels; also, additional content to be considered for inclusion in the framework was identified.

Also, no other pediatric pain studies were identified in which VH vignettes were used; our description of VH vignette development and validation, and application in a study with PICU nurses, may help to guide the design and use of VH vignettes in future studies. Also, in using VH vignettes and written vignettes, this study has allowed for some comparison of the different vignette types in eliciting nurses’ responses.
Specific Aims

The aims of this study were to:

1. Describe PICU nurses’ responses to VH vignettes regarding pain assessment and intervention choices for children with different behaviors (smiling, grimacing) and with different pain types (post-operative, sickle cell vaso-occlusive crisis) (interview)

2. Describe PICU nurses’ beliefs regarding children's pain, pain assessment, and pain management [Pain Beliefs and Practices Questionnaire (PBPQ)]

3. Compare PICU nurses’ beliefs (PBPQ) and their responses to VH vignettes (interview)

4. Determine the effect of child behavior (smiling, grimacing) and pain type (post-operative, sickle cell) on PICU nurses’ pain ratings and morphine dose choices among vignette types (written and VH)
References


II. CHILDREN'S PAIN: PICU NURSES' BELIEFS AND RESPONSES TO VIRTUAL HUMAN VIGNETTES

Background

Inadequate pain management is one of the most frequently reported adverse events in Pediatric Intensive Care Units (PICU) (Agarwal et al., 2010; Grant, Scoppettuolo, Wypij, & Curley, 2012; Larsen, Donaldson, Parker, & Grant, 2007). Uncontrolled pain (defined as pain greater than or equal to 6/10 for more than two hours) was the second most frequently occurring adverse event across 15 PICUs in the United States (Agarwal et al., 2010); the majority of uncontrolled pain events are preventable (Agarwal et al., 2010; Larsen et al., 2007). Consequences of unrelieved pain are profound; immediate physiologic responses such as increases in intracranial pressure, heart rate, respiratory rate, blood pressure, blood glucose, and stress hormones as well as decreases in oxygen saturation (Bouza, 2009; Mitchell & Boss, 2002; Peters et al., 2005) can lead to life-threatening complications (Anand, Sippell, & Aynsley-Green, 1987; Anand & Hickey, 1992). Furthermore, infants and young children exposed to painful procedures have demonstrated a more intense pain response to subsequent procedures (Peters et al., 2005; Taddio, Goldbach, Ipp, Stevens, & Koren, 1995; Taddio, Katz, Ilersich, & Koren, 1997; Weisman, Bernstein, & Schechter, 1998) and an increased analgesic requirement for subsequent surgeries (Peters et al., 2005). Children with sickle cell disease are at further risk for unrelieved pain due to the variability of vaso-occlusive pain, sociocultural differences between them and health professionals, and health professionals’ concerns of drug addiction (Elander, Marczewska, Amos, Thomas, & Tangayi, 2006; Pack-Mabien, Labbe, Herbert, & Haynes, 2001; Wright & Adeosun, 2009). These additional risk factors may explain in part why children admitted with pain related to sickle cell disease report moderate to high pain levels throughout the duration of their hospitalization (Beyer, 2000; Jacob et al., 2003, 2007; Jacob & Mueller, 2008; Zempsky et al., 2008). Additionally, nurses may have difficulty relating to the pain from sickle cell disease in contrast to pain from trauma or surgery (Pack-Mabien et al., 2001).
PICU Nurses’ Pain Management

Responsible for pain assessments, implementation and evaluation of pain interventions, and patient and family education, nurses have an integral role in managing children’s pain (American Society for Pain Management Nurses, Emergency Nurses' Association, American College of Emergency Physicians, & American Pain Society, 2010; Baulch, 2010; Nash et al., 1999; Oware-Gyekye, 2008). Unfortunately, nurses’ poor understanding of pharmacodynamics, faulty beliefs regarding opioid analgesics, and use of pain behaviors over children’s self-report have been identified as contributors to hospitalized children’s unrelieved pain (Manworren, 2000; Vincent & Denyes, 2004; Vincent & Gaddy, 2009). Pediatric nurses have been noted to provide less analgesics to children than that available by provider order (Jacob & Puntillo, 1999; Vincent & Denyes, 2004), even when pain was present (Vincent & Denyes, 2004).

However, studies in which PICU nurses’ pain beliefs, assessment, and intervention choices were evaluated are few and more than a decade old (Coffman et al., 1997; Curley et al., 1992; Manworren, 2000; Pederson & Bjerke, 1999; Pederson, Matthies, & McDonald, 1997). To date, most researchers have studied pediatric floor nurses (Gimbler-Berglund, Ljusegren, & Enskar, 2008; Hamers, Abu-Saad, Halfens, & Schumacher, 1994; Shrestha-Ranjit & Manias; Vincent & Denyes, 2004; Vincent & Gaddy, 2009; Vincent, Wilkie, & Szalacha, 2010; Vincent, Wilkie, & Wang, 2010) or do not distinguish nurses’ responses by clinical area (Griffin, Polit, & Byrne, 2007; Habich et al., 2012; Nash et al., 1999; Rieman, Gordon, & Marvin, 2007). PICU nurses’ beliefs regarding children’s ability to tolerate pain better than adults, the serious consequences of pain, and the ability of children’s vital signs to return to baseline despite persistent pain has varied widely (Pederson & Bjerke, 1999). Similar to pediatric floor nurses, deficits in PICU nurses’ knowledge of children’s pain have also been noted (Manworren, 2000; Pederson et al., 1997). In two studies, PICU nurses demonstrated deficiencies in their knowledge of children’s pain and pain management (Manworren, 2000; Pederson et al., 1997). PICU nurses most often incorrectly answered test items related to pain assessment, pain facts, and medications (Pederson et al., 1997). Similar to more current studies evaluating pediatric floor nurses (Vincent & Denyes, 2004; Vincent &
Gaddy, 2009; Vincent, Wilkie, & Szalacha, 2010; Vincent, Wilkie, & Wang, 2010) researchers have found PICU nurses’ pain assessment inconsistent with best practice. PICU nurses did not consistently identify children’s self-report as the preferred method of pain assessment for children able to self-report, dismissed parental report of a child’s pain, and failed to appreciate the severe consequences of pain (Pederson & Bjerke, 1999).

Little is known about PICU nurses’ pain intervention choices. Differences between pediatric floor and ICU nurses’ are likely. For example, in Jacob and Puntillo’s study (1999) floor nurses administered morphine at prolonged intervals while PICU nurses administered morphine consistently at the prescribed frequency. To date investigators have reported pain indicators leading to PICU nurses’ analgesic administration (Coffman et al., 1997; Curley et al., 1992); however, PICU nurses’ choices regarding the type of intervention, dose (when offered a range), or timing of medication administration have not been described. When making analgesia administration choices, PICU nurses in one study identified significantly more pain indicators for patients admitted for trauma than non-trauma (Coffman et al., 1997). PICU nurses’ most frequently relied upon vital signs as a pain indicator when administering analgesics (Coffman et al., 1997; Curley et al., 1992; Pederson & Bjerke, 1999; Ramelet, 1999) despite the lack of vital sign specificity to pain (Arbour & Gélinas, 2010; Carnevale & Razack, 2002; Curley et al., 1992; Foster, Yucha, Zuk, & Vojir, 2003; Gélinas, Tousignant-Laflamme, Tanguay, & Bourgault, 2011). It has been speculated that PICU nurses’ reliance upon vital signs is due to their care of continuously monitored, mechanically ventilated and sedated children (Pederson & Bjerke, 1999; Pederson et al., 1997; Ramelet, 1999). Still, as few as 30% of PICU patients have been reported to be intubated and mechanically ventilated (Khemani, Markovitz, & Curley, 2009); only 3 of the 25 children in Coffman et al.’s (1997) study were intubated and 68% were preschool age or older; yet nurses identified the child’s verbalization of pain as an indicator to administer analgesia in just 37 of 112 observations. Because many children in PICUs may be able to verbalize pain, further evaluation of nurses’ pain management for this population is warranted. Additionally, to improve instances of
unrelieved pain, understanding PICU nurses’ choices to withhold analgesia may be equally as important as understanding their indicators to intervene.

**Virtual Human Vignettes**

Vignettes, or “stories about individuals and situations which make reference to important points in the study of perceptions, beliefs, and attitudes” (Hughes, 1998) have frequently been used to assess pediatric nurses’ assessment of pain and analgesic administration choices (Griffin et al., 2007; Hamers, Van Den Hout, Halfens, Abu-Saad, & Heijltjes, 1997; Vincent & Gaddy, 2009; Vincent, Wilkie, & Szalacha, 2010). However, written vignettes have been criticized for their simplicity and decreased need for interpretation as compared to real-life experiences (Hughes & Huby, 2002). More recently, virtual human (VH) vignettes have been used to evaluate nurses’ pain-related decision making for adults (Hirsh, George, & Robinson, 2009; Hirsh, Jensen, & Robinson, 2010). Unlike written vignettes, VH vignettes present animated patients that can exhibit different facial expressions and behaviors. By providing a consistent visual experience, VH vignettes may better simulate real-life experiences with patients (Hughes & Huby, 2002) and decrease the risk of unintended variances in nurses’ responses due to the subjective interpretation of words. A VH vignette has not been reported in a pediatric pain study previously and may provide greater insight into PICU nurses’ pain assessment and intervention choices.

**Purpose/Aims**

Therefore, the aims of this study were to:

1. Describe PICU nurses’ responses to VH vignettes regarding pain assessment and intervention choices for children with different behaviors (smiling, grimacing) and with different pain types (post-operative, sickle cell vaso-occlusive crisis) (open-ended interview)

2. Describe PICU nurses’ beliefs regarding children's pain, pain assessment, and pain management [Pain Beliefs and Practices Questionnaire (PBPQ)]

3. Compare PICU nurses’ beliefs (PBPQ) and their responses to VH vignettes (open-ended interview)

4. Determine the effect of child behavior (smiling, grimacing) and pain type (post-operative, sickle cell) on nurses’ pain ratings and morphine dose choices among vignette types (written and VH)
Theoretical Framework

The theoretical framework used for this study is the Knowledge Use in Pain Care (KUPC) conceptual model (Latimer, Ritchie, & Johnston, 2010). Developed from theory and evidence related to pediatric pain and knowledge use, the KUPC addresses nurses’ delayed adoption of pediatric pain management research results into clinical practice. There are 4 components of the KUPC model (see Figure 1): nurse, child, organizational, and sociopolitical. These components are believed to influence nurses’ knowledge use and ultimately pain care outcomes in children, including assessment, management, and documentation (Latimer et al., 2010). Characteristics of the individual nurse (education/experience, critical thinking disposition, and empathy and wellness) are suggested to predict the quality of a nurse’s clinical practice. Nurses’ judgments regarding management of pain in children are proposed to be the result of the nurse’s critical thinking ability, beliefs about pain (knowledge and attitudes), and any barriers or facilitators within the work environment. Characteristics of the child include the child’s age (developmental level and verbal abilities) and acuity of illness. Latimer, Ritchie, and Johnston (2010) suggest that the nurses’ ability to assess a child’s pain, based upon the child’s age and acuity, mediates the child’s pain outcome. The KUPC factor of organization includes providing nurses with opportunities to increase knowledge and skills, information (access to data and clinical expertise), support to act autonomously, and resources (supplies, equipment, and time) to accomplish adequate pain management (Latimer et al., 2010). The sociopolitical context of the KUPC includes external influences on organizational and practice choices such as policies and guidelines from professional organizations (Latimer et al., 2010).

The KUPC incorporates individual nurse characteristics in the context which the nurse practices; thus, in this study, the KUPC allowed for a more comprehensive understanding of PICU nurses’ pain beliefs and their pain assessment and intervention choices. Components of the KUPC model which are specifically addressed in this study include: nurse (education, experience, and critical thinking disposition), child (age and acuity), and pain care outcomes (assessment and management). The critical thinking disposition of the nurse in this study also included pain beliefs (knowledge and attitudes). Child
characteristics included: acuity (pain type: sickle cell vaso-occlusive crisis or abdominal surgery), and age (this included the associated activity of age, the child’s verbal expression or self-report of pain). While organizational and sociopolitical components were not directly measured in this study, we evaluated interview transcripts for presence of these KUPC components. Pain care outcomes included nurses’ assessment (pain ratings) and management (intervention choices) for the children in the vignettes.

**Methods**

**Design**

A cross-sectional, mixed-methods design was applied to accomplish the specific aims of this study. We used directed content analysis of open-ended semi-structured interviews and statistical analysis of nurse demographics, PBPQ responses, frequency of code endorsements, and pain ratings and intervention choices in response to the VH vignettes.

**Sample**

We recruited a convenience sample of 40 nurses to participate in the proposed study from 2 urban hospitals in the Midwest; one PICU within an academic medical center and the other within a large children’s hospital. Inclusion criteria for subjects consisted of registered nurses working at least 20 hours a week for the past year and providing care to patients in a PICU. We excluded PICU nursing employees who did not provide direct patient care and nurses working in a PICU in an advanced practice role. A sample size of 34 was determined by an a priori power analysis to achieve sufficient power for a paired samples t-test (alpha 0.05, two-tailed) to detect the calculated treatment effects of 0.5 – 0.87 of behavior (smile and grimace) for nurses’ pain ratings and morphine dose administration (Vincent, Wilkie, & Wang, 2010). Because no prior data for the effects of diagnosis and vignette type on nurses’ ratings and morphine administration were available, a medium treatment effect of 0.5 was used. Additionally, the sample size was deemed sufficient to obtain information-rich data from the interviews for qualitative descriptive analysis (Patton, 2002) and to allow for maximal variation in nurse attributes such as years of experience or nursing degree (Neergaard, Olesen, Andersen, & Sondergaard, 2009; Sandelowski, 2000).
**Data Collection Procedures**

Once approval was obtained from the appropriate Institutional Review Boards, nurses were recruited through email, flyers, and individual/group meetings on the hospital units. Nurses interested in participating in the study scheduled a 45-minute appointment with the primary investigator (PI) for a convenient time and locale outside of their scheduled working hours. A majority of the nurses (39 of 40) chose to meet the PI in their hospital of employment, at a private area, before or after a scheduled shift.

At the onset of the appointment, consent was obtained. Once the nurses completed a demographic survey, they were instructed on navigation of the VH vignettes with a practice vignette (child with neutral facial expression, diagnosis of asthma); a 24 inch LCD monitor was used to display the VH vignettes from the PI’s laptop computer. Nurses completed a short form to record their pain rating and intervention choices in response to each VH vignette. The nurses were encouraged to view all of the VH vignette components as often as needed. Sequence of the viewing of the VH vignettes was randomly assigned to lessen the risk of an order effect among the vignettes. After responding to all four of the study VH vignettes, an open-ended semi-structured interview with the nurses was audio-recorded; the VH vignettes were available to the nurses to refer to as they described their pain assessment and intervention choices. Interviews were approximately 10 to 20 minutes in length. Following the interview, the nurses completed the PBPQ. Field notes were taken during the appointments.

**Instruments**

The PICU nurses responded to 3 instruments: a demographic form, 4 VH vignettes (written responses and open-ended interview), and the PBPQ. Each of these instruments is described below.

**Nurse demographics.** All participating nurses completed a researcher-developed demographic form. In addition to age, sex, race, and ethnicity, it included: highest nursing degree obtained, years of pediatric nursing experience, years of PICU nursing experience, most common age group cared for in the preceding 3 months and frequency caring for children in pain for the preceding 3 months.

**Virtual human (VH) vignette development.** Four VH vignettes were developed from the PBPQ simulated pain management practices vignettes (Vincent, Wilkie, & Wang, 2010). In the PBPQ
vignettes, 10-year-old boys in their first day after abdominal surgery are described. All rate their pain as 8/10 and have stable vital signs, but in each pair, one boy smiles and jokes and the other grimaces. The PBPQ vignettes are based on case studies from Manworren’s (2001) Pediatric Nurses’ Knowledge and Attitudes Survey (PNKAS) regarding pain, which were validated with pediatric nurses, including PICU nurses. For the PBPQ vignettes, nurses rate the pain of each child from 0 to 10 and indicate the dose of analgesia they would provide in milligrams (0mg, 1mg, 2mg, 3mg) (Vincent, Wilkie, & Wang, 2010).

We adapted these scenarios for the VH vignettes and included additional patients with pain from sickle cell vaso-occlusive crisis. The VH vignettes were developed following Adler, Trainor, Siddall, and McGahie’s (2007) case development and review process for high-fidelity simulation case scenarios. A more detailed description of the development and validation of the VH vignettes can be read elsewhere (see VH vignette manuscript). The PBPQ vignette scenarios were scripted for translation to a simulator and revised based on feedback from PICU nursing content experts. Once the content and flow of the cases were established, they were translated into a VH vignette using the Lifelike Responsive Avatar Framework, a process that allows the development of realistic avatars in a short period of time (Lee et al., 2010). An expert certified in the Facial Action Coding System (FACS) (Eckman, Friesen, & Hager, 2002) guided the development of the virtual patient’s facial expressions and determined consistency in the intensity and frequency of the facial movements between the vignettes with similar expressions.

The VH vignettes depict the child in his room in the PICU. The nurses can view the child’s behaviors, vital signs on the monitor, and reported level of pain. They are also able to view flowsheets from the patient’s medical record for the patient’s sex, age, reason for admission (type of patient’s pain), and vital signs and pain ratings for the past 2 hours. A medication administration form provides information regarding analgesics ordered and last dose of administration. Patients in the VH vignettes are of the same race (African American), sex (male), age (10 years old), report the same pain levels (8 out of 10), and have the same provider orders for analgesics. The only variance between the VH vignettes is the child’s facial expression (grimacing or smiling/joking) and pain type (post-operative day 1 after abdominal surgery and sickle cell vaso-occlusive crisis). The vignette combinations are as follows:
Vignette #1: child with recent abdominal surgery, smiling and joking

Vignette #2: child with recent abdominal surgery, exhibiting facial grimacing

Vignette #3: child with sickle cell vaso-occlusive crisis, smiling and joking

Vignette #4: child with sickle cell vaso-occlusive crisis, exhibiting facial grimacing

Written responses to vignettes and semi-structured interview. Nurses were asked to respond to each VH vignette as if assigned to the care of the patient in their PICU. They documented: (a) their rating of the child's level of pain on a scale from 0 to 10, (b) if they would intervene for the child’s pain, and (c) how they would intervene for the pain if they chose to do so. In the semi-structured interview, nurses were asked what they were thinking about as they chose a rating for the child’s pain and were encouraged to share their pain assessment strategies. Next, the nurses were asked what they were thinking about when making a choice about the pain intervention. If a nurse reported that he/she would administer the prescribed analgesic, he/she was asked to determine what dose would be administered from the provided range. Nurses were encouraged to share anything else they felt was important for the PI to know regarding the assessment and management of children’s pain. Finally, each nurse was asked whether he/she believed the scenarios were consistent with his/her own professional experiences with children in pain. If differences were expressed, the nurses were encouraged to share these differences.

Pain Beliefs and Practices Questionnaire (PBPQ). Vincent, Wilkie, & Wang’s (2010) PBPQ was adapted for use within this study to better suit our population of PICU nurses and to better compare nurses’ responses to the VH vignettes with their responses to the PBPQ vignettes. The PBPQ is comprised of three content areas: total beliefs, opioid kinetics, and simulated pain management practice. Content validity of the original PBPQ is supported (Vincent, Wilkie, & Wang, 2010). Content of the revised PBPQ was reviewed by PICU nursing content experts and revisions were made as needed. The total beliefs content of the original PBPQ consists of 26 items regarding the legitimacy of children’s self-report of pain, the effects of unrelieved pain, and the use of analgesics. Nurses rate these items from 1 (do not agree at all) to 6 (agree very much). The total beliefs score (range of 1 to 6) is calculated as the mean score for the 26 items; higher means reflect beliefs consistent with effective pain management. Total
beliefs items from the original PBPQ were adapted from the Pediatric Nurses’ Knowledge and Attitudes Survey Regarding Pain (PNKAS) (Manworren, 2001) and from the Barriers Questionnaire (Ward et al., 1993). Additional items were included based on research findings (Vincent, Wilkie, & Wang, 2010). The authors report an internal consistency of Cronbach’s alpha 0.83 at pretest and 0.85 at posttest for the total beliefs items (Vincent, Wilkie, & Wang, 2010). Because PICU nurses do care for children receiving continuous infusions of sedatives, a question was added to the total beliefs section regarding children’s ability to experience pain while receiving sedatives. Thus 27 items were included for this study.

The original PBPQ opioid kinetics score consists of 16 open-ended items in which nurses record the time of peak effects (8 questions) and duration of action (8 questions) for intravenous morphine, intravenous hydromorphone, and oral oxycodone. The opioid kinetics score is the sum of items answered correctly; higher scores indicate more accurate beliefs (Vincent, Wilkie, & Wang, 2010). Internal consistency of nurses’ responses were supported for this content of the PBPQ with 73.1% of nurses reporting the same morphine peak for four different items and 71% reporting the same morphine duration (Vincent, Wilkie, & Wang, 2010). For our revised opioid kinetics items, repetitive items were removed and the oral oxycodone questions were replaced with two questions regarding the peak effect and duration of intravenous fentanyl. With a total of 6 items, the possible range for the opioid kinetics scores was 0 to 6. A PICU clinical pharmacist was consulted for the revisions of the opioid kinetics questions.

The simulated pain management practices component of the original PBPQ includes 16 items in response to 8 vignettes (8 items for pain assessment and 8 items for opioid administration) (Vincent, Wilkie, & Wang, 2010). Nurses respond to two items for children experiencing post-operative pain, rating the child’s pain from 0 to 10 and indicating the dose of analgesic they would provide (from a provider order with a range of doses for either morphine, hydromorphone, or oral oxycodone) (Vincent, Wilkie, & Wang, 2010). The PBPQ vignettes are based on case studies from Manworren’s (2001) PNKAS, which were previously validated with pediatric nurses, including PICU nurses. For the pain assessment items, a pain rating matching the child’s self-report of 8 is considered correct. For the opioid administration items, providing an increased dose of the analgesic is considered a correct response
because the children have been reporting moderate to high pain since their last analgesic dose and have no signs of negative effects from the analgesic. Responses are rated as correct or incorrect with resulting scores of 0 to 8 for simulated pain assessment and 0 to 8 for simulated opioid dose. Higher scores indicate better pain management practices (Vincent, Wilkie, & Wang, 2010). Vincent et al. (2010) reported internal consistency in nurses’ responses to similar questions for pain assessment, with 76.9% of nurses rating the same value for the four items in which the child is smiling/joking and 88.5% for the four items in which the child is grimacing. For the current study, the vignettes were adapted to mimic the 4 VH vignettes; all of the patients were prescribed morphine and two of the patients were diagnosed with sickle cell vaso-occlusive crisis; nurses were scored on 2 items for each of the 4 vignettes (1 for pain assessment and 1 for opioid administration), with a possible range score of 0 to 8.

Analysis

Qualitative content analysis of the interviews was conducted. Operational definitions were developed for the KUPC factors of child, nurse, organization, and sociopolitical and the associated tasks and activities. Once the accuracy of the transcriptions of the interviews was determined, a directed content analysis approach (Hsieh, 2005) was used to identify codes consistent with the KUPC model (based on the operational definitions previously determined). Text which did not fit the KUPC model was given a new code and later analyzed to determine whether the new code could be categorized within the KUPC or would need a separate code. The codes were revised as needed and transcripts re-evaluated. NVivo software was used to assist with data analysis. Once coding was complete, we analyzed subgroups by number of nurses’ endorsements.

SPSS statistical software was used to analyze quantitative data. Descriptive statistics were employed to analyze nurses’ demographic information and PBPQ results. Bivariate relationships were examined using cross tabulations, correlations, Fisher’s exact tests, and paired t-tests. Finally, multifactorial analysis was conducted using MANOVA.
Results

Demographic Information

A total of 40 PICU nurses participated in the study. The nurses ranged in age from 22 to 56 years old with a mean age of 34.9 ($SD = 10.15$). Nurses were majority female (92.5%) and identified their ethnicity and race as non-Hispanic and white (77.5%). Three of the nurses identified as Latino (7.5%) and the remaining nurses reported their race as Asian (12.5%), African-American (2.5%), and Hawaiian-Pacific Islander (2.5%). One RN identified as both Latino and African-American. Ninety-five percent of the nurses reported their highest nursing degree to be at a baccalaureate ($n = 32$) level or higher ($n = 6$).

The nurses’ years of PICU experience ranged from 1 to 29 years ($M = 9.19, SD = 8.7$) and they all reported caring for children experiencing pain weekly for the past three months. The age groups nurses ($n = 31$) reported they most frequently care for in the PICU included children aged 1-3 years (45.2%), 4-9 years (32.3%), less than one year (16.1%), and 10-15 years (6.5%). Eight of the nurses chose all of the age groups and therefore could not be included in analysis for this item.

PICU Nurses’ Responses to Virtual Human Vignettes

Qualitative description of nurses’ thinking. The codes most frequently identified (50% of nurses or greater) regarding the nurses’ pain assessment and administration choices are listed in Table 1. We describe them here as they relate to the KUPC factors; no content was identified related to the sociopolitical factor.

Child. Within the KUPC, key tasks of the child element include acuity and age; the associated activities of these tasks include high vs. low acuity and developmental and verbal expression respectively. When coded, child factors were considered any time the nurse brought up a quality or characteristic of the child in the VH vignette as a part of their thinking when rating the child’s pain and selecting a pain intervention. During the coding process two additional key tasks of the child which were not explicitly addressed in the KUPC were identified: behavior and vital signs. Thus, all codes fell into four categories (subcategories): acuity (diagnosis of sickle cell disease or abdominal surgery), age (verbal expression - child’s pain rating), behavior (smile, grimace), and vital signs. The most frequently identified child
factors described by the nurses for their pain assessment included (in rank order): smile, grimace, child’s pain rating, vital signs, sickle cell disease, and abdominal surgery. The most frequently identified child factors for pain management included (in rank order): sickle cell disease, abdominal surgery, child’s pain rating, vital signs, smile, and grimace.

*Behavior (smile and grimace).* Though not identified in the KUPC as a specific component of the child factor, nurses most often identified the child’s facial expressions as a part of their thinking about assessment when rating the pain of the children in the VH vignettes. Though the nurses addressed the facial expressions of the smiling and grimacing patients at a similar frequency, their thinking related to the expressions contrasted. The grimacing expression was most often discussed as verifying the presence of pain. One nurse comment included, “He does grimace in the observation which leads me to believe that he is in pain just like the physical evidence of him showing like the grimacing, that something is hurting him”. On the other hand, the smiling expression was often explained as a reason for rating the child lower than his reported pain. “Well, he was awake and smiling, so I assess his pain to not be very severe.”

The nurses similarly differentiated the two expressions when explaining their pain interventions: “I wouldn’t necessarily given him morphine, but if none of those other interventions worked I’d probably give him a milligram because he was smiling” and “…but he grimaced. So because of his facial reaction I gave him a little bit more morphine. I gave him 2 (milligrams).”

*Age (verbal expression, child’s pain rating).* In the KUPC both developmental and verbal expression of pain are considered components of the child factor. Second to facial expressions in the nurses’ discussion regarding their pain assessment of the children was the child’s current pain rating. Comments regarding the child's pain rating were generally brief, such as “he ranked his pain high” and “if he says 8, I’m putting 8”.

When making pain intervention choices, nurses often described the child’s high pain rating as substantiating intervention. One nurse stated, “He’s 10 years old and obviously an 8 when he’s saying his acceptable level is a 2, he needs treatment for his pain. So I would give him morphine also.”
Acuity (diagnosis). In relation to acuity, though not specifically described within the KUPC, nurses most often mentioned the child’s diagnosis. The child’s diagnosis was discussed similarly for the children with sickle cell vaso-occlusive crisis and the children with post-operative pain (see Table 1). The nurses often referred to the patients’ diagnoses as supporting the presence of pain. For example one nurse stated, “He is a sickle cell child and they do have pain” and another, “I mean everything looks pretty good, but despite all this he just came out of surgery, so I’m sure there’s pain.”

Diagnosis was the most prevalent code among the nurses when discussing intervention choices. As with assessment, nurses often referred to the diagnosis as a legitimate reason for pain and cause for treatment. Nurses said: “He just had surgery so he’s more than likely in some discomfort. So I would’ve given him morphine” and, “I would say because of the nature of sickle cell I would tend to medicate even if he didn’t look distressed.”

Vital Signs. In regards to vital signs, nurses regularly pointed out the child’s normal vital signs as a part of their assessment, making statements such as “he had stable vital signs” and “vitals were fine”. Often after noting the child’s stable vital signs, nurses would add the expectation that changes in vital signs were anticipated with pain, most often heart rate and blood pressure. For example, one nurse said, “Well, I was just looking at first his vital signs which they were just stable, 80, no increase in heart rate or blood pressure.”

In relation to pain management, stable vital signs were most often denoted as reason to discount the severity of pain and to provide lesser treatment. One nurse commented, “… but I wouldn’t give him morphine because his vitals are stable,” and another, “-well, his vital signs were stable, so I probably would’ve started with the lowest dose and then gone up if I needed to.”

Nurse. Of the KUPC nurse factor, the most frequent codes were consistent with the tasks of critical thinking and experience. Latimer et al. (2010) describe a nurse’s critical thinking disposition as an interchange between active thought process and beliefs. The key factor of experience was operationalized to include nurses’ descriptions of past professional experiences working with children in pain. Therefore transcripts were evaluated for evidence of these two key tasks. The most common codes regarding
assessment (in rank order), included beliefs the diagnosis is painful, a noted active thought process—
incongruity of the child’s pain rating with other assessment components, beliefs behaviors are indicators
of pain, and the experience of behavioral inconsistencies in children’s pain expression. Though several
critical thinking codes were identified for pain management, they were not as prevalent (< 50%) among
the nurses.

**Critical thinking disposition (beliefs – diagnosis is painful and observed behaviors).** PICU nurses
(70%) noted a belief regarding the presence of pain with the patients’ diagnoses. These comments
included nurses’ understanding of the pain type and often precluded with the words “I know” or “I think”.
Examples include: “…but I know abdominal surgery is very painful and the first day is the worst because
the anesthetic is starting to wear off” and “Yeah, I think I rated him at a six just because I know sicklers
have so much pain.” More nurses described beliefs for the patients with sickle cell disease (50%) than the
children with abdominal surgery (35%). Nurses also described beliefs related to behavior when assessing
a child for pain. These beliefs varied from the need to validate pain ratings with behavior, how a child
rating a pain of 8 should appear, and the belief that children’s behavior with pain can vary dramatically.
Quotes include: “…I guess if I’m seeing a child at an 8 or a 9 I guess I would expect him to be squirming,
yeah grimacing, maybe even tearing up” or “See, expressions to me, they mean nothing.”

**Critical thinking disposition (active thought process – incongruity).** Frequently the nurses noted
inconsistencies in the child’s pain rating and other assessment indicators. When this occurred, they
seemed to weigh their assessment findings with their beliefs to arrive at a pain rating. The most frequent
incongruity noted was between the child’s pain rating and behavior; nurses also noted (less frequently)
incongruity between the child’s rating and vital signs. One nurses’ active thought process included:

I think even though his vital signs were still – I mean, for a ten-year-old those are probably pretty
good vital signs without the elevated heart rate or elevated blood pressure. I guess in my head
I’m still thinking sickle cell and a vasoocclusive crisis and then just thinking chronic pain and that
these kids always have it anyway, so even though they’re smiling they may still be in pain. They
just may not be physically showing it.
Experience (behavioral inconsistencies). During the interviews, nurses (72.5%) shared their experiences in the PICU assessing children reporting pain, most often while discussing behavioral inconsistencies among children. The behavioral inconsistencies included descriptions of when two children rate the same number but have differing behaviors and when children rate a higher pain score, but display behaviors the nurses believe do not support the pain rating. An example is:

I took care of probably three sickle cellers in like a 2-week span and 2 of them were exactly like these 2. One was visibly in pain. One of them was like cracking jokes and in this horrible vaso-occlusive crisis and with like chest pain and everything and playing video games and playing board games.

Organization. Latimer et al (2010) describe organizational factor as the nurses’ access to power, including opportunity, information, support, and resources at work. The KUPC organization key tasks most frequently coded among the nurses were information and support. This included the associated activities of information -data and exchange between nurse and physician (we also included exchange with advanced practice nurses and so refer to nurse-physician exchange as nurse-provider exchange).

Information (data). In regards to data, the nurses often described referring to the patient’s last documented morphine dose to determine a pain intervention. Sometimes nurses considered the last dose as reason to increase the dose they would administer “…it looked like he had only gotten 2 milligrams at five, so see what 3 milligrams does” or as reason to follow suit “I know that he got 2 milligrams, so I think off the bat I could try to give the exact same thing the other nurse did”. Other nurses described the desire to see the patient’s pattern of doses over time “…but I would look back and see how often he’s been getting it. Have we been giving it every two hours on the hour?”

Information (exchange between nurse and provider). In regards to provider exchange, nurses frequently described contacting a physician or advanced practice nurse to obtain a different medication for the patient or different method of delivery (such as patient controlled analgesia). They also described contacting the provider if interventions did not relieve the child’s
pain. One nurse said: “I would let the doc’s know and maybe they want to add something else to it like Toradol.”

Support (autonomy to act on clinical judgment). The third organizational code most often identified by nurses (55%) was the organizational key task of support and the associated activity of autonomy to act on clinical judgment (Latimer et al., 2010). Nurses most frequently described using the existing or requesting a new “as needed” pain order to intervene for the child’s pain. This type of order provided the nurses with the autonomy to treat the patient’s pain when the nurse determined it necessary. Nurses’ comments most often included the ability to provide medication and/or increase the morphine dose for the patient because of the available medication order, such as “… he can get it every two hours” and “he has it written so if he needs it then I’ll give it to him”.

Nurses’ choices: pain ratings and interventions. Less than half (see Table 2) of the nurses rated the children’s pain level the same as the child’s self-report (8/10) for all 4 of the VH vignettes. Similar to our findings in response to the PBPQ, more nurses agreed with the child’s self-report of 8 for the grimacing children (sickle cell 42.5%, post-operative 45%) than the smiling children (sickle cell 37.5%, post-operative 35%). Eight times the smiling child’s pain was rated by a nurse as 0. Similar to the pain ratings, nurses provided pharmacologic interventions more often to the grimacing children (95%) than the smiling children (post-operative 55%, sickle cell 57.5%). The grimacing children also (post-operative 31.6%, sickle cell 40%) received an increased dose of morphine (3mg) more often than the smiling children (post-operative 10%, sickle cell 25%).

The majority of instances in which a nurse chose only to provide a non-pharmacologic intervention were for the smiling children (See Table 3). Six times the smiling children were denied treatment of any type, as opposed to only one of the grimacing children denied treatment. Of the non-pharmacologic interventions, distraction was most often chosen (see Table 3). Heat or cold packs (the second most frequent non-pharmacologic measure described) were chosen more often for the patients with sickle cell disease (30%) than the children with post-operative pain (grimace 20% - smiling 25%).
Nurses’ Beliefs

Pain Beliefs and Practices Questionnaire. The nurses’ PBPQ scores ranged widely (see Table 4). The total beliefs items of the PBPQ were tested for internal consistency, resulting in a Cronbach’s alpha of 0.72. Nurses’ total beliefs responses were least consistent with effective pain management for items regarding the risks of opioid analgesic administration for patients experiencing acute pain - including: respiratory depression ($M = 2.2, SD = 1.26$), physical dependence ($M = 2.68, SD = 1.36$), deep sedation ($M = 3.13, SD = 1.24$), and tolerance ($M = 3.13, SD = 1.34$). The nurses’ reported beliefs were most closely aligned with physiologic and analgesic related items: children’s ability to experience pain while receiving sedatives ($M = 5.65, SD = 0.58$), the ability to treat pain at multiple points along the pain pathway ($M = 5.55, SD = 0.68$) including combining opioids with non-opioids ($M = 5.28, SD = 0.82$), and the harmful physiological and psychological effects of pain ($M = 5.53, SD = 0.68$).

Within the opioid kinetics items, PICU nurses most often reported a time within the appropriate range for the peak effect (65%) and duration (75%) of intravenous fentanyl and the duration (67.5%) of intravenous morphine (see Table 5). Hydromorphone duration (30%) and morphine peak (41%) were least often reported within an appropriate timeframe. All of the nurses reporting an inaccurate length of duration for morphine and hydromorphone, underestimated the time. In response to the PBPQ simulated pain management practices content (written vignettes) (see Table 6), the nurses’ pain ratings more frequently matched the child’s self-report of 8 for the grimacing children (sickle cell 60.5%, post-operative 60.5%) than the smiling children (sickle cell 41%, post-operative 35.9%). Similarly, all of the nurses chose to administer a dose (1-3mg) of morphine to the grimacing children, while greater than 25% of the nurses chose 0 milligrams of morphine for the smiling children.

PBPQ items and qualitative description codes. Each of the 27 PBPQ total beliefs items was compared to the qualitative description codes; complementing codes and items were paired. As a result, 13 PBPQ items were associated with 21 codes (see Table 7). The most codes (n = 12), and many of the most prevalent codes (50% of nurses or greater) were associated with items regarding pain assessment, specifically the legitimacy of self-report in children. The PBPQ items associated with the most prevalent
codes amongst the nurses were related to vital signs, behavior, the child’s pain rating, increasing morphine dosage, the effectiveness of non-pharmacological methods for moderate/severe pain, and adjusting doses to the child’s response. Nurses’ PBPQ ratings for these 6 items were grouped into 3 categories – those that most agree with beliefs consistent with effective pain management (rated 5 or 6), moderate responses (rated 3 or 4), and those that least agree with beliefs consistent with effective pain management (rated 1 or 2). Cross tabulations of these items and their associated codes are located in Tables 8 and 9. Given that the sample size was large enough to test for a large effect size (0.6 effect size, alpha 0.05, power 0.8), Fisher’s exact tests for the PBPQ ratings and associated codes were conducted; the number of qualitative description codes present in a nurses’ interview significantly differed by PBPQ response (disagrees, mid-response, and agrees with item) for the item in which behavior is not relied upon to verify a child’s pain report \( p < 0.05 \). Of the nurses that disagreed with the item, 100% had associated behavioral codes (described behavior during pain assessment) identified within their interview transcripts. Of the nurses that agreed with the item, 57% had a behavioral code present.

Three of the lowest scored PBPQ total beliefs items were matched to qualitative description codes; while nurses weren’t specifically asked about their analgesic administration concerns during the interviews, some did express concerns of respiratory depression \( n = 4 \), over-sedation \( n = 7 \), and tolerance \( n = 3 \). Though nurses scored higher in response to PBPQ items regarding addiction, 6 nurses expressed drug-seeking concerns for a child within the VH vignettes. Of note, addiction concerns were only described for the patients experiencing a sickle cell vaso-occlusive crisis. One discrepancy in the nurses’ PBPQ reported beliefs and their expressed beliefs during the interviews was found. Though the PBPQ item regarding the reliability of children greater than age 8 to report pain intensity was one of the items most agreed with \( M = 5.17, SD = 0.87 \), codes related to the unreliability of children to report pain were present for 17 of 40 (42.5%) nurses.

**Comparisons of Pain Ratings and Intervention Choices in Response to Vignettes**

Paired t-tests were conducted to compare the PICU nurses’ pain ratings and morphine doses chosen for the children in the 4 VH vignettes and the 4 PBPQ vignettes. Differences in pain assessments
among the children in the vignettes were previously reported (see VH vignette manuscript); on average, nurses rated the pain significantly lower for children who were smiling than for the children who were grimacing, regardless of pain type.

The mean morphine dose nurses chose for the children in the VH vignettes who were smiling (sickle cell $M = 1.11, SD = 1.28$, post-operative $M = 0.73, SD = 1.06$) was lower than that chosen for the children who were grimacing (sickle cell $M = 1.81, SD = 1.2$, post-operative $M = 1.7, SD = 1.16$). This was a significant difference when compared between patients with the same pain type (sickle cell $t(39) = 3.54, p = 0.001$, post-operative $t(37) = 4.74, p < 0.001$). Though no difference in morphine dose was identified between the two grimacing children in the VH vignettes, $t(37) = 1.2, p = 0.238$, there was a statistical difference between the two smiling patients, $t(39) = 2.18, p < 0.05$; the smiling child with surgery received significantly less morphine than the smiling child with sickle cell disease.

Similarly, in response to the PBPQ vignettes, nurses chose significantly lower doses of morphine for the smiling children (sickle cell $M = 1.51, SD = 1.19$, post-operative $M = 1.59, SD = 1.16$) than the grimacing children (sickle cell $M = 2.49, SD = 0.72$, post-operative $M = 2.46, SD = 0.68$) of the same pain type [sickle cell $t(38) = 6.00, p < 0.001$; post-operative $t(38) = 6.09, p < 0.001$]. However, significant differences were not found for the morphine doses between the smiling children and the grimacing children [smiling, $t(38) = 0.53, p = 0.60$; grimacing $t(38) = 0.33, p = 0.74$].

Paired t-tests were also conducted to compare between the PICU nurses’ morphine doses chosen for the children within the two types of vignettes (written or VH). Both the written and the VH vignettes had the same morphine order for the patients ranging from 1 to 3 milligrams. For the VH vignettes, nurses responded to an open-ended interview question and shared how they would most likely intervene in practice. For the PBPQ, the nurses chose a morphine dose from a fixed response: 0mg, 1mg, 2mg, 3mg. Overall, nurses provided greater amounts of morphine to children in the written PBPQ vignettes than to children in the corresponding VH vignettes: sickle cell smiling, $t(38) = 2.11, p < 0.05$; sickle cell grimace, $t(38) = 3.50, p = 0.001$; post-operative smiling, $t(38) = 4.56, p < 0.001$; post-operative grimace, $t(36) = 3.90, p < 0.001$. 
Effect of Behavior, Pain Type, and Vignette Type on Pain Ratings and Morphine Doses

Because our pain care outcomes of pain rating and morphine dose were sequential (conceptually related) and upon preliminary analysis -strongly correlated, r (310) = 0.592, p < 0.001 (written and VH vignettes combined), a 2 x 2 x 2 MANOVA was conducted to test the effect of child behavior, pain type, and vignette type upon the nurses’ pain ratings and morphine doses. A post-hoc power analysis revealed an observed power of 1 for the corrected model, behavior (smiling or grimacing), and vignette type (PBPQ or VH). However, observed power for pain type was 0.11. Because the Box M test was significant (p < 0.001), Pillai’s trace is reported. Significant multivariate effects were identified for facial expression [Pillai’s trace 0.18, F (2, 303) = 34.08; p < 0.001, ηp² = 0.18] and vignette type [Pillai’s trace 0.10, F (2, 303) = 16.13; p < 0.001, ηp² = 0.10]. Univariate Fs were significant for facial expression for pain rating [F (1, 304) = 51.05, p < 0.001] and morphine dose [F (1, 304) = 52.85, p < 0.001] as well as for vignette type for pain rating [F (1, 304) = 3.96, p < 0.05] and morphine dose [F (1, 304) = 31.22, p < 0.001]. The significant univariate differences are presented in Table 10 (behavior) and Table 11 (vignette type). No interactions were found between the variables. Because data screening revealed multivariate normality to be slightly violated, bootstrapped confidence intervals (95%) were computed. No differences in the results were identified, confirming our original MANOVA findings.

Discussion

The purpose of this study was to describe and compare PICU nurses’ assessment and intervention choices in response to VH vignettes and their beliefs regarding children’s pain management. Additionally we sought to determine the effect of child behavior (smiling, grimacing), and pain type (post-operative, sickle cell) on PICU nurses’ pain ratings and morphine dose choices among vignettes (written and VH). Overwhelmingly, results substantiated PICU nurses’ use of behavior to assess and intervene for pain over the child’s self-report, even when the child was able to articulate pain presence and intensity.
PICU Nurses’ Responses to VH Vignettes

It is not surprising that the most prevalent codes for pain assessment and intervention choices amongst the PICU nurses were related to the child factor within the KUPC, as our study aims were directed at characteristics of the child. Most of the nurses considered objective characteristics of the child (diagnosis, vital signs, and behavior), when rating the child’s pain and making an intervention choice. When objective characteristics were considered incongruous with the child’s pain ratings, many nurses described thinking through their assessment findings, the child’s pain rating, and their beliefs to make a choice. This finding supports the KUPC proposition of nurses’ critical thinking (beliefs and active thought processes) in relation to pain care outcomes (Latimer et al., 2010).

The PICU nurses’ use of physical findings (vital signs and behavior) to verify pain is consistent with older PICU nursing literature (Coffman et al., 1997; Curley et al., 1992) as well as more recent studies with pediatric floor nurses (Vincent & Gaddy, 2009; Vincent, Wilkie, & Szalacha, 2010). Because many of the nurses in this study also described reliance upon vitals and behavior as a part of their professional experience, it is likely that nurses’ individual beliefs regarding the verification of a child’s pain report with physical findings have been shaped in part by collective beliefs within their intensive care units. These findings are supported by past studies with PICU nurses in which self-report was not as valued as other physical indicators (Pederson et al., 1997). Also, when asked which age category represented children they had cared for most often in the past 3 months, 9.4% of the nurses who appropriately responded to the item (N = 32) chose an age range of 10 years old or older. The nurses’ decreased exposure to older children may also have influenced their pain assessments and likelihood to accept the ten-year old child’s pain rating in the vignettes.

Second to the child factor codes, the most prevalent pain intervention codes were related to the KUPC factor of organization: use of the as needed pain order, exchange with providers, and consideration of past interventions. Thus, it is possible that future interventions directed at organizational factors and collective beliefs may influence nurses’ pain intervention choices.
When rating the pain of the children within the VH and written vignettes, nurses rated the smiling children’s pain lower than the grimacing children. Over half the time, all of the children were rated lower than their self-report. Not only were pain ratings lowered, but in 5% of cases (VH and written), nurses completely discounted the child’s self-report and rated a 0 for the child’s pain. Pain interventions similarly favored the children that were grimacing; children in the VH vignettes that were grimacing received more pharmacologic interventions and pharmacologic interventions paired with non-pharmacologic interventions than the smiling children. All of the grimacing children in the written vignettes received morphine; yet, over a quarter of the children that were smiling were given none. Grimacing children in both the PBPQ vignettes and the VH vignettes received the 3 mg dose of morphine more often than the smiling children. Non-pharmacological interventions were often chosen for patients in the VH vignettes (both smiling and grimacing); however, nearly one quarter of children was only offered a non-pharmacologic intervention. The vast majority of these children were smiling. These findings are contrary to previously reported pediatric and PICU nurses’ knowledge and attitudes regarding pain, in which nurses’ most often answered questions correctly regarding non-pharmacologic interventions -agreeing that children can be distracted and still feel pain and that non-drug techniques should be used in combination with pain medications (Habich et al., 2012).

**PICU Nurses’ Beliefs and Comparison of Beliefs and Codes**

PBPQ results suggest that the PICU nurses’ understanding of pharmacodynamics and the risks associated with opioid analgesics is not consistent with effective pain management. These misconceptions likely contributed to the nurses’ choices to decrease or withhold a child’s available morphine dose. Our findings are consistent with past studies in which PICU nurses scored poorly on questions related to the peak effect and duration of analgesics and sedatives (Pederson et al., 1997) and the likelihood of respiratory depression (Habich et al., 2012). Nurses’ beliefs consistent with best practice included: ability to experience pain while receiving sedatives, ability to treat pain at multiple points along the pain pathway, and harmful effects of pain.
Of the PBPQ items matched to qualitative codes, only the item related to nurses’ use of behavior to verify pain had a significant relationship with its associated codes; nurses in higher agreement with the item had significantly fewer codes in which the child’s behavior was described as a consideration during pain assessment. The lack of statistical significance for the remaining pairs of PBPQ items could be related to the modest sample size of the study. However, these findings could also indicate a discrepancy between the nurses’ perceived (idealistic) beliefs and their beliefs expressed or choices made when encountering a complex patient situation (e.g. incongruity between pain rating and child’s behavior).

**Pain Ratings and Intervention Choices Compared**

Results of paired t-tests and MANOVA indicate a difference in PICU nurses’ pain ratings and morphine doses between smiling and grimacing children (regardless of vignette type), and between children in the VH vignettes and children in the written vignettes. The resultant effect sizes for both facial expression and vignette type indicated a strong effect. The nurses’ reliance on behaviors (facial expressions) to assess and intervene for pain is apparent and is further supported by the frequency of qualitative description codes related to behavior. Diagnosis did not have a significant effect on nurses’ pain ratings or morphine dose (though a significant difference between morphine doses for the smiling children in the VH vignettes was found for the paired t-test). Because of our sample size (N = 40), limited statistical power (observed power 0.10) may have played a role in our ability to detect an interaction between behavior and pain type. However, statistical differences were not found in the paired t-tests for morphine doses between smiling patients in the PBPQ. Nurses also described both of the patients’ diagnoses as likely to cause pain, suggesting that nurses’ medication administration may not be impacted by diagnosis, if the diagnoses both have cause for pain. Though significant differences between the vignette types were identified for both pain rating and morphine dose, the effect of the vignette type upon pain rating was small, while the effect upon morphine dose was large. Differences between the vignette types are likely related to the differing methods to deliver information to the nurses (visual or written) and to collect data
(open-ended interview or multiple choice items). Because the PICU nurses did not have a visual referent for the children in the written vignettes, they may have scored the children’s pain ratings more generously (closer to 8). In choosing a pain intervention, when the nurses were responding to the written vignettes, they were limited to a morphine dose. This multiple choice item likely inflated the nurses’ intention to provide morphine as it was the only intervention they could choose. Nurses that would have otherwise provided non-pharmacological measures or oral analgesics may have been inclined to choose a morphine dose rather than not intervening at all.

Because of the differences in written and VH vignette methods, inferences regarding nurses’ responses between these two forms of vignette are inconclusive. However, the usefulness of a VH vignette over a written vignette to anchor nurses’ responses to visual events (such as pain assessments) should be further investigated.

**Limitations and Strengths**

Limitations of this study include a modest convenience sample of PICU nurses within an urban setting, findings may not be generalizable. Our sample size may have impacted the ability to identify significant relationships between nurses’ pain beliefs and their associated qualitative codes or a small treatment effect for diagnosis upon nurses’ pain assessments and intervention choices. As previously mentioned, the differing methods between the written vignettes and VH vignettes prohibited our ability to make inferences about the differences in performance of the two instruments in eliciting nurses’ responses. And finally, a limitation of all vignette studies is the inability to conclude that the PICU nurses’ simulated responses are consistent with actual patient care (Hughes, 1998). Furthermore, these vignettes represent only a small subset of patients within a PICU; for example, children in a PICU can vary substantially in age, diagnosis, and level of acuity. These results cannot be generalized to patients of differing characteristics.

However, findings of this study are consistent with older literature, in which PICU nurses relied upon physical indicators (vital signs and/or behavior) for pain assessment (Coffman et al., 1997) and
medication administration (Curley et al., 1992) with actual patients. Our use of open-ended interviews, in which nurses could choose any pain intervention and share their experiences with patients in the PICU, likely enhanced the consistency of the nurses’ responses with their practice.

**Conclusion**

Though reliance on vital signs and behavior could be a result of the critical nature and lack of verbal expression of children in the PICU, our findings suggest that even when presented with children able to verbalize pain, many PICU nurses still rely on behavioral and physiological indicators; neither of which is specific to pain. Because pain is a subjective experience which nurses cannot physically measure, it is possible that as they are exposed to children in pain, they become accustomed to witnessing these physical cues and develop their own visual scale of a child’s pain intensity. Many of the PICU nurses described how they believed a high pain rating should appear or noted that the smiling children didn’t look like an 8/10. In cases of patients unable to self-report, these cues are an important part of pain assessment. However, when nurses impose these indicators on children old enough to reliably report pain, poorly managed pain can result.

The findings of our study are consistent with past research with pediatric floor nurses, suggesting that children within the PICU of comparable age and ability to verbalize pain could be at similar risk for unalleviated pain. Consequently, interventions directed at pediatric floor nurses may also be successful within PICUs for this patient population. Future studies which identify characteristics of critically ill children at greatest risk for uncontrolled pain would be useful to determine interventions to prevent this adverse event from occurring.
References


Table 1

**KUPC Factors, Categories, Subcategories, and Codes Most Frequently Described by Nurses Regarding Pain Assessment and Pain Management Choices**

<table>
<thead>
<tr>
<th>KUPC Factor</th>
<th>Category</th>
<th>Subcategory</th>
<th>Code Frequency for Pain Care Outcomes (number of nurses/percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Assessment n (%)</td>
</tr>
<tr>
<td>Child Acuity</td>
<td>Diagnosis*</td>
<td>Abdominal surgery</td>
<td>23 (57.5)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sickle cell</td>
<td>26 (65)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Child's Current Pain</td>
<td>30 (75)</td>
</tr>
<tr>
<td>Age</td>
<td>Verbal Expression</td>
<td>Grumace</td>
<td>30 (75)</td>
</tr>
<tr>
<td>Behavior*</td>
<td>Facial Expression*</td>
<td>Smile</td>
<td>33 (82.5)</td>
</tr>
<tr>
<td>Nurse</td>
<td>Vital Signs*</td>
<td>Vital signs</td>
<td>29 (72.5)</td>
</tr>
<tr>
<td>Critical</td>
<td>Active thought</td>
<td>Incongruity</td>
<td>26 (65)</td>
</tr>
<tr>
<td></td>
<td>process</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Beliefs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Experience</td>
<td>Experiences</td>
<td>Behavioral inconsistencies</td>
<td>20 (50)</td>
</tr>
<tr>
<td></td>
<td>with children in</td>
<td></td>
<td>21 (52.5)</td>
</tr>
<tr>
<td></td>
<td>pain*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organization Information</td>
<td>Past Documentation*</td>
<td>Medication administered</td>
<td>28 (70)</td>
</tr>
<tr>
<td></td>
<td>Exchange (with</td>
<td>Provider exchange</td>
<td>21 (52.5)</td>
</tr>
<tr>
<td></td>
<td>other professionals)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Support</td>
<td>Autonomy to act</td>
<td>As needed order</td>
<td>22 (55)</td>
</tr>
</tbody>
</table>

* Not specifically described within the KUPC but interpreted to coincide with the related KUPC factor.
Table 2

*Frequency and Percentage of Pain Care Outcomes Chosen by Nurses for VH Vignette Patients (Nurses’ Ratings of Child’s Pain Level From 0 – 10 and Pain Intervention Choice Types)*

<table>
<thead>
<tr>
<th>KUPC Pain Care Outcome</th>
<th>Type of Pain</th>
<th>Sickle Cell (n = 40)</th>
<th>Sickle Cell (n = 40)</th>
<th>Post-operative Smile (n = 40)</th>
<th>Post-operative Grimace (n = 40)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
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<tr>
<td><strong>Assessment</strong> (Nurses’ Pain Rating)</td>
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<tr>
<td>0</td>
<td></td>
<td>3 (7.5)</td>
<td>0</td>
<td>5 (12.5)</td>
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</tr>
<tr>
<td>1</td>
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<td>0</td>
<td>2 (5)</td>
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<tr>
<td>2</td>
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<td>7 (17.5)</td>
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<td>3</td>
<td></td>
<td>5 (12.5)</td>
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<td>1 (2.5%)</td>
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<tr>
<td>4</td>
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<td>4 (10)</td>
<td>5 (12.5)</td>
<td>6 (15)</td>
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<td>5</td>
<td></td>
<td>1 (2.5)</td>
<td>8 (20)</td>
<td>3 (7.5)</td>
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<td>2 (5)</td>
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<td>5 (12.5)</td>
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<tr>
<td>7</td>
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<td>14 (35)</td>
<td>18 (45)</td>
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<td>9</td>
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<td>0</td>
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<td>10</td>
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<tr>
<td><strong>Management</strong> (Intervention)</td>
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<tr>
<td>Pharmacologic only</td>
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<td>12 (30)</td>
<td>23 (57.5)</td>
<td>13 (32.5)</td>
<td>23 (57.5)</td>
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<td>Combination pharm/non-pharmacologic</td>
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<td>11 (27.5)</td>
<td>15 (37.5)</td>
<td>9 (22.5)</td>
<td>14 (35)</td>
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<tr>
<td>Non-pharmacologic only</td>
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<td>14 (35)</td>
<td>2 (5)</td>
<td>15 (37.5)</td>
<td>2 (5)</td>
</tr>
<tr>
<td>No treatment</td>
<td></td>
<td>3 (7.5)</td>
<td>0</td>
<td>3 (7.5)</td>
<td>1 (2.5)</td>
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### Table 3

*Frequency and Percentage of Pain Interventions Chosen by Nurses for VH Vignette Patients*

<table>
<thead>
<tr>
<th>Pain Intervention</th>
<th>Type of Pain</th>
<th>Sickle Cell Smile (n = 40)</th>
<th>Sickle Cell Grimace (n = 40)</th>
<th>Post-operative Smile (n = 40)</th>
<th>Post-operative Grimace (n = 38*)</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
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<tr>
<td><strong>Pharmacologic</strong></td>
<td></td>
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<tr>
<td>Morphine (intravenous)</td>
<td></td>
<td>19 (47.5)</td>
<td>31 (77.5)</td>
<td>15 (38.5)</td>
<td>29 (76.3)</td>
</tr>
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<td>Morphine 1 mg</td>
<td></td>
<td>3 (7.5)</td>
<td>5 (12.5)</td>
<td>5 (12.5)</td>
<td>5 (13.2)</td>
</tr>
<tr>
<td>Morphine 2 mg</td>
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<td>6 (15)</td>
<td>10 (25)</td>
<td>6 (15)</td>
<td>12 (31.6)</td>
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<tr>
<td>Morphine 3 mg</td>
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<td>10 (25)</td>
<td>16 (40)</td>
<td>4 (10)</td>
<td>12 (31.6)</td>
</tr>
<tr>
<td>Non-opioid</td>
<td></td>
<td>4 (10)</td>
<td>10 (25)</td>
<td>7 (17.5)</td>
<td>5 (12.5)</td>
</tr>
<tr>
<td>Oral opioid/non-opioid</td>
<td></td>
<td>1 (2.5)</td>
<td>1 (2.5)</td>
<td>2 (5)</td>
<td>4 (10.5)</td>
</tr>
<tr>
<td>Morphine/non-opioid</td>
<td></td>
<td>1 (2.5)</td>
<td>4 (10)</td>
<td>2 (5)</td>
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<tr>
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<td></td>
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<tr>
<td>Distraction</td>
<td></td>
<td>18 (45)</td>
<td>12 (30)</td>
<td>19 (47.5)</td>
<td>13 (33.3)***</td>
</tr>
<tr>
<td>Heat/Cold</td>
<td></td>
<td>12 (30)</td>
<td>12 (30)</td>
<td>7 (17.5)</td>
<td>8 (10.3)***</td>
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<tr>
<td>Reposition</td>
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<td>2 (5)</td>
<td>4 (10)</td>
<td>7 (17.5)</td>
<td>4 (20.5)***</td>
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<tr>
<td>Other</td>
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<td>2 (5)</td>
<td>1 (2.5)</td>
<td>2 (5)</td>
<td>3 (7.7)***</td>
</tr>
</tbody>
</table>

* unable to determine answer for 2 nurses
**some nurses chose multiple non-pharmacologic interventions
***n = 39, unable to determine answer for one nurse
Table 4

*PICU Nurses’ Pain Beliefs and Practices Questionnaire Scores*

<table>
<thead>
<tr>
<th>PBPQ Component</th>
<th>Range</th>
<th>Mean (SD)</th>
<th>PBPQ Total Possible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Beliefs (n = 40)</td>
<td>3.63-5.48</td>
<td>4.31 (0.42)</td>
<td>6</td>
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<tr>
<td>Opioid Kinetics (n = 40)</td>
<td>1-6</td>
<td>3.4 (1.46)</td>
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<tr>
<td>Assessment Score (n = 37)</td>
<td>0-4</td>
<td>1.91 (1.71)</td>
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</tr>
<tr>
<td>Opioid Dose Score (n = 39)</td>
<td>0-4</td>
<td>1.77 (1.53)</td>
<td>4</td>
</tr>
</tbody>
</table>
Table 5

Range of Responses and Frequency and Percentage of Correct Responses to PBPQ Opioid Kinetics Items

<table>
<thead>
<tr>
<th>Opioid Kinetics Item</th>
<th>Range</th>
<th>Correct Responses n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intravenous Morphine Peak (n = 39)</td>
<td>30 sec – 1 hour</td>
<td>16 (41)</td>
</tr>
<tr>
<td>Intravenous Morphine Duration (n = 40)</td>
<td>30 min -4 hours</td>
<td>27 (67.5)</td>
</tr>
<tr>
<td>Intravenous Hydromorphone Peak (n = 40)</td>
<td>1 min – 3 hours</td>
<td>20 (50)</td>
</tr>
<tr>
<td>Intravenous Hydromorphone Duration (n = 40)</td>
<td>15 min - 4 hours</td>
<td>12 (30)</td>
</tr>
<tr>
<td>Intravenous Fentanyl Peak (n = 40)</td>
<td>30 sec – 2 hours</td>
<td>26 (65)</td>
</tr>
<tr>
<td>Intravenous Fentanyl Duration (n = 40)</td>
<td>20 min – 3 hours</td>
<td>30 (75)</td>
</tr>
</tbody>
</table>
Table 6

*Frequency and Percentage of Pain Care Outcomes (Pain Rating and Morphine Dose) Chosen by Nurses for PBPQ Written Vignette Patients*

<table>
<thead>
<tr>
<th>Pain Care Outcome</th>
<th>Type of Pain</th>
<th>(n = 39)</th>
<th>(n = 38)</th>
<th>(n = 39)</th>
<th>(n = 38)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Smiling</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>0</td>
<td>Sickle Cell</td>
<td>4 (10.3)</td>
<td>4 (10.3)</td>
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<td>1</td>
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<td>2</td>
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<td>3 (7.7)</td>
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<td>3</td>
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<td>5 (12.8)</td>
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<td>6 (15.4)</td>
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<td>4</td>
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<td>8 (20.5)</td>
<td>3 (7.9)</td>
<td>7 (17.9)</td>
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<td>2 (5.3)</td>
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<td>2 (5.3)</td>
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<td>8</td>
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<td>Grimacing</td>
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<td>Sickle Cell</td>
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</table>

Morphine (intravenous)

<table>
<thead>
<tr>
<th></th>
<th>Smiling</th>
<th>Sickle Cell</th>
<th>Sickle Cell</th>
<th>Post-operative</th>
<th>Post-operative</th>
<th>(n = 39)</th>
<th>(n = 39)</th>
<th>(n = 39)</th>
<th>(n = 39)</th>
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<tbody>
<tr>
<td>Morphine 0 mg</td>
<td>11 (28.2)</td>
<td>0</td>
<td>10 (25.6)</td>
<td>0</td>
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</tr>
<tr>
<td>Morphine 1 mg</td>
<td>8 (20.5)</td>
<td>5 (12.8)</td>
<td>7 (17.9)</td>
<td>4 (10.3)</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Morphine 2 mg</td>
<td>9 (23.1)</td>
<td>10 (25.6)</td>
<td>11 (28.2)</td>
<td>13 (33.3)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Morphine 3 mg</td>
<td>11 (28.2)</td>
<td>24 (61.5)</td>
<td>11 (28.2)</td>
<td>22 (56.4)</td>
<td></td>
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</tr>
</tbody>
</table>
Table 7

**PBPQ total beliefs items with corresponding qualitative descriptive codes**

<table>
<thead>
<tr>
<th>PBPQ Beliefs Item (M, SD)</th>
<th>Corresponding Codes (Nurses with code identified)</th>
<th>Code Description</th>
<th>Example Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observable vital sign changes not relied on to verify report (M = 3.55, SD = 1.34)</td>
<td>Child Assessment: Considering vital signs (n = 27)</td>
<td>Describes child’s vital signs when rating his pain</td>
<td>“…but I looked at his vital signs and they were stable. He didn’t have any tachycardia and his blood pressure was normal, saturating fine. “So usually I base pretty high pain with some sort of vital sign changes.”</td>
</tr>
<tr>
<td></td>
<td>Nurse Beliefs: Vital signs to verify pain (n = 27)</td>
<td>Supports using vital sign changes as a method to verify the presence of pain</td>
<td>“I rated him a six just because his vitals were normal but he was grimacing and he rated himself an eight.” “But vital signs are a huge one. We see it in the vital signs and a lot of times these kids are intubated and sedated and you see it in their vital signs. Even if they’re paralyzed you see it in their vital signs.”</td>
</tr>
<tr>
<td></td>
<td>Nurse Active Thought: Incongruity -vital signs and pain rating (n = 13)</td>
<td>Noted incongruity between child’s pain rating and vital signs</td>
<td>“…or they’ll be sleeping and wake up – what’s your pain? ‘Ten’ or ‘eight,’ you know what I mean? So you know it can’t possibly be that” “But I do think that kids tend to – a lot of times they’ll be playing videogames and they’ll say it’s an eight. So it seems like it’s not that reliable an indicator.”</td>
</tr>
<tr>
<td></td>
<td>Nurse Experience: Use of vital signs (n = 9)</td>
<td>Describes past nursing experiences in which vital signs are used to verify pain</td>
<td>“I think his facial expression told me. I mean, he is smiling.”</td>
</tr>
<tr>
<td>Child may sleep in spite of severe pain (M = 4.22, SD = 1.36)</td>
<td>Nurse Beliefs: Behavior -sleeping Sleep possible (n = 3) Sleep incongruous (n = 3)</td>
<td>Describes beliefs regarding sleep and the ability to experience pain</td>
<td>“…he rated himself an eight. He wasn’t crying, so I felt like eight would be more when tears are coming and you’re kind of a little more distressed.” “Like I would see like constant grimacing or an infant – like constant crying or something like that” “-we see different faces for the same number, you know?”</td>
</tr>
<tr>
<td>Child older than 8 years can reliably report pain intensity (M = 5.17, SD = 0.87)</td>
<td>Nurse Beliefs: Child unreliable (n = 17)</td>
<td>Describes why children are often unreliable reporters of pain</td>
<td></td>
</tr>
<tr>
<td>Observable behavioral changes not relied on to verify report (M = 3.25, SD = 1.45)</td>
<td>Child Assessment: Considering facial expression (n = 35)</td>
<td>Describes thinking about the child’s facial expression when rating his pain</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nurse Active Thought: Incongruity -behavior and pain rating (n = 20)</td>
<td>Notes incongruity between child’s pain rating and vital signs when describing pain assessment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Experience: Use of behavior (n = 9)</td>
<td>Describes past nursing experiences in which behavior is used to verify pain</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Experience: Varying behavior with pain (n = 10)</td>
<td>Describes variances in behavior between children with pain</td>
<td></td>
</tr>
<tr>
<td>Most accurate judge of child’s pain intensity is the child</td>
<td>Nurse Beliefs: Pain is what the child says (n = 19)</td>
<td>Supports the child’s pain rating</td>
<td>“I always take what the patient says as their pain.”</td>
</tr>
<tr>
<td>-----------------------------------------------------------</td>
<td>-----------------------------------------------------</td>
<td>---------------------------------</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>(M = 5.03, SD = 0.89)</td>
<td>Assessment: Child’s current pain (n = 30)</td>
<td>Describes thinking about the child’s pain rating when assessing pain</td>
<td>“I mean, honestly they looked like they’re all about a two or a three but based off of them then saying that it was an eight, taking that into account, I then ranked them differently.”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“so that’s the one thing I would be worried about is respiratory depression”</td>
<td>“…”</td>
</tr>
<tr>
<td>Respiratory depression rarely occurs</td>
<td>Nurse Beliefs: Respiratory depression concern (n = 4)</td>
<td>Describes concerns regarding administering morphine and respiratory depression</td>
<td>“…like, are you really in pain or, like, are you just chasing the drugs?”</td>
</tr>
<tr>
<td>(M = 2.20, SD = 1.26)</td>
<td></td>
<td>Mentions drug seeking in context of sickle cell diagnosis and administration of opioids</td>
<td>“…I wouldn’t want to snow him and put him out basically”</td>
</tr>
<tr>
<td>Not a real danger of addiction</td>
<td>Nurse Beliefs: Sickle cell and drug seeking (n = 6)</td>
<td>Describes concerns regarding administering morphine and risk of over sedation</td>
<td>“…plus they get tolerant to it (morphine) kind of quick.”</td>
</tr>
<tr>
<td>(M = 4.48, SD = 1.47)</td>
<td></td>
<td>Describes patient tolerance to morphine</td>
<td>“I mean if – so if he got two milligrams at five and if he tells me that it didn’t work then I would give him more.”</td>
</tr>
<tr>
<td>Not a real danger of deep sedation</td>
<td>Nurse Beliefs: Sedation concern (n = 7)</td>
<td>Chooses a morphine dose of 3 mg for a VH vignette patient</td>
<td>“…I gave him the three milligrams of morphine at the seven o’clock assessment when he said that his pain was an eight out of ten.”</td>
</tr>
<tr>
<td>(M = 3.13, SD = 1.24)</td>
<td></td>
<td>Describes thinking about the child’s current pain rating when choosing an intervention</td>
<td>“…Well, his pain only went down to a six with the two milligrams…”</td>
</tr>
<tr>
<td>Not a real danger of tolerance</td>
<td>Nurse Beliefs: Medication tolerance (n = 3)</td>
<td>Describes referring to child’s past pain ratings when choosing an intervention</td>
<td>“So, I would intervene with distraction initially and then see where that gets us.”</td>
</tr>
<tr>
<td>(M = 3.13, SD = 1.34)</td>
<td>Pain Care Outcome: Morphine 3 milligrams (n = 20)</td>
<td>Chooses a non-pharmacologic intervention as sole intervention for VH vignette patient</td>
<td>“I think for their wellbeing and their healing I think they need to be comfortable”</td>
</tr>
<tr>
<td>Increased dosages of morphine provide increased relief</td>
<td>Child’s current pain rating (Management) (n = 27)</td>
<td>Describes the need to relieve the child’s pain to prevent harmful consequences</td>
<td></td>
</tr>
<tr>
<td>(M = 4.13, SD = 1.45)</td>
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<td></td>
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<tr>
<td>After initial dose, adjust doses to child’s response</td>
<td>Organization Information: past pain ratings (n = 15)</td>
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<tr>
<td>(M = 5.15, SD = 1.00)</td>
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<tr>
<td>Nonpharmacological methods alone not effective to relieve moderate/severe pain</td>
<td>Pain Care Outcome: Non-pharmacologic intervention only (n = 21)</td>
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<tr>
<td>(M = 3.78, SD = 1.37)</td>
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<tr>
<td>Harmful physiological and psychological effects</td>
<td>Nurse Beliefs: Unrelieved pain is harmful (n = 4)</td>
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<tr>
<td>(M = 5.53, SD = 0.68)</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 8

Cross tabulation of PBPQ items related to PICU nurses’ beliefs regarding pain assessment and their corresponding qualitative description codes

<table>
<thead>
<tr>
<th>PBPQ Item</th>
<th>PBPQ Item Response Categories</th>
<th>Number of Qualitative Description Codes for Nurse</th>
<th>Total Count</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Codes in Disagreement</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Count</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expected Count</td>
<td></td>
</tr>
<tr>
<td>Observable behavioral changes are not relied upon to verify a child’s pain report*</td>
<td>Disagrees</td>
<td>1.8</td>
<td>7.7</td>
</tr>
<tr>
<td></td>
<td>(scored 1-2)</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Mid Response</td>
<td>2.4</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>(scored 3-4)</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Agrees</td>
<td>0.9</td>
<td>3.3</td>
</tr>
<tr>
<td></td>
<td>(scored 5-6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Most accurate judge of pain intensity is the child</td>
<td>Disagrees</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>(scored 1-2)</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Mid Response</td>
<td>2.2</td>
<td>3.3</td>
</tr>
<tr>
<td></td>
<td>(scored 3-4)</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Agrees</td>
<td>5.8</td>
<td>8.7</td>
</tr>
<tr>
<td></td>
<td>(scored 5-6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Observable vital sign changes are not relied upon to verify a child’s pain report</td>
<td>Disagrees</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>(scored 1-2)</td>
<td>1.8</td>
<td>3.5</td>
</tr>
<tr>
<td></td>
<td>Mid Response</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>(scored 3-4)</td>
<td>3.9</td>
<td>7.7</td>
</tr>
<tr>
<td></td>
<td>Agrees</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>(scored 5-6)</td>
<td>1.4</td>
<td>2.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expected Count</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Count</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expected Count</td>
<td></td>
</tr>
</tbody>
</table>

Fisher’s exact test: * significance = 0.05
Table 9

Cross tabulation of PBPQ total beliefs items related to PICU nurses’ pain management and their corresponding VH vignette choices (qualitative description codes)

<table>
<thead>
<tr>
<th>PBPQ Item</th>
<th>PBPQ Item Response Categories</th>
<th>Number of Qualitative Description Codes for Nurse</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Increased dosages of morphine provide increased relief</td>
<td>Disagrees (scored 1-2)</td>
<td>Count</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expected Count</td>
</tr>
<tr>
<td></td>
<td>Mid Response (scored 3-4)</td>
<td>Count</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expected Count</td>
</tr>
<tr>
<td></td>
<td>Agrees (scored 5-6)</td>
<td>Count</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expected Count</td>
</tr>
<tr>
<td></td>
<td>Total Count</td>
<td></td>
</tr>
</tbody>
</table>

| Non-pharmacological methods alone not effective to relieve moderate/severe pain | Disagrees (scored 1-2) | Count | 2 | 4 | 1 | 7 |
|                                                                             | Expected Count         |                                | 3.3 | 2.5 | 1.2 | 7 |
|                                                                             | Count                  |                                | 10 | 7 | 6 | 23 |
|                                                                             | Expected Count         |                                | 10.9 | 8.1 | 4 | 23 |
|                                                                             | Count                  |                                | 7 | 3 | 0 | 10 |
|                                                                             | Expected Count         |                                | 4.8 | 3.5 | 1.8 | 10 |
|                                                                             | Total Count            |                                |                              | 40 |

| After initial dose, adjust doses to child’s response | Disagrees (scored 1-2) | Count | 0 | 1 | 0 | 1 |
|                                                      | Expected Count         |                                | 0.2 | 0.6 | 0.2 | 1 |
|                                                      | Count                  |                                | 0 | 5 | 2 | 7 |
|                                                      | Expected Count         |                                | 1.2 | 4.2 | 1.6 | 7 |
|                                                      | Count                  |                                | 7 | 18 | 7 | 32 |
|                                                      | Expected Count         |                                | 5.6 | 19.2 | 7.2 | 32 |
|                                                      | Total Count            |                                |                              | 40 |
Table 10

**Univariate Differences in Pain Ratings and Morphine Doses Between Behaviors**

<table>
<thead>
<tr>
<th>Dependent Variable</th>
<th>df</th>
<th>df error</th>
<th>F</th>
<th>Partial η²</th>
<th>Behavior</th>
<th>Means</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lower bound</td>
</tr>
<tr>
<td>Pain rating</td>
<td>1</td>
<td>304</td>
<td>51.05*</td>
<td>0.14</td>
<td>Smile</td>
<td>4.84</td>
<td>4.45</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Grimace</td>
<td>6.74</td>
<td>6.36</td>
</tr>
<tr>
<td>Morphine dose</td>
<td>1</td>
<td>304</td>
<td>52.85*</td>
<td>0.15</td>
<td>Smile</td>
<td>1.24</td>
<td>1.07</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Grimace</td>
<td>2.13</td>
<td>1.96</td>
</tr>
</tbody>
</table>

* * p < 0.001
Table 11

*Univariate Differences in Pain Ratings and Morphine Doses between Vignette Types*

<table>
<thead>
<tr>
<th>Dependent Variable</th>
<th>df</th>
<th>df error</th>
<th>F</th>
<th>Partial $\eta^2$</th>
<th>Behavior</th>
<th>Means</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lower bound</td>
</tr>
<tr>
<td>Pain rating</td>
<td>1</td>
<td>304</td>
<td>3.96*</td>
<td>0.01</td>
<td>Virtual</td>
<td>5.51</td>
<td>5.14</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Written</td>
<td>6.05</td>
<td>5.67</td>
</tr>
<tr>
<td>Morphine dose</td>
<td>1</td>
<td>304</td>
<td>31.21**</td>
<td>0.09</td>
<td>Virtual</td>
<td>1.33</td>
<td>1.17</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Written</td>
<td>2.03</td>
<td>1.85</td>
</tr>
</tbody>
</table>

*p < 0.05

**p < 0.001
Figure 1. Knowledge Use in Pain Care Model Components. Reprinted from Journal of Pediatric Nursing, 25, Latimer, Ritchie, & Johnston. Individual nurse and organizational context considerations for better knowledge use in pain care, Page 275, Copyright 2010 with permission from Elsevier.
III. DEVELOPMENT OF A VIRTUAL HUMAN VIGNETTE TO EXPLORE NURSES’ ASSESSMENT AND INTERVENTION CHOICES FOR CRITICALLY ILL CHILDREN’S PAIN

Background

The purpose of this paper is to describe the development and validation of virtual human (VH) vignettes to elicit responses from pediatric intensive care unit (PICU) nurses regarding their pain assessment and intervention choices for children. The VH vignettes were one part of a mixed-methods study in which PICU nurses’ beliefs regarding children’s pain were evaluated and their simulated assessment and pain management practices were compared for children with differing behavior (smiling and grimacing) and differing pain types (post-operative and sickle cell vaso-occlusive crisis). We also sought to compare the nurses’ responses to the VH vignettes with matching written vignettes.

Uncontrolled pain, or pain rated as greater than 6/10 for more than two hours, is the second most frequently occurring adverse event in pediatric intensive care units (PICUs) in the United States; sadly, most of these pain events are preventable (Agarwal et al., 2010; Larsen, Donaldson, Parker, & Grant, 2007). Not only can painful events lead to significant physiologic consequences in children (Bouza, 2009; Mitchell & Boss, 2002; Peters et al., 2005), but they can also lead to more intense pain responses and increased analgesic requirements with future procedures (Peters et al., 2005; Taddio, Goldbach, Ipp, Stevens, & Koren, 1995; Taddio, Katz, Ilersich, & Koren, 1997; Weisman, Bernstein, & Schechter, 1998). Responsible for pain assessments, implementation and evaluation of pain interventions, and patient and family education, nurses have an integral role in managing children’s pain (American Society for Pain Management Nurses, Emergency Nurses' Association, American College of Emergency Physicians, & American Pain Society, 2010). However, pediatric nurses’ dependence on pain behaviors over children’s self-report, poor grasp of pharmacodynamics, and inaccurate beliefs regarding opioid analgesics, have been noted to contribute to children’s unalleviated pain in the hospital (Manworren, 2000; Vincent & Denyes, 2004; Vincent & Gaddy, 2009).
Within a PICU, nurses may encounter patients of varying ages, developmental levels, diagnoses, acuity, pain types, pain behaviors, and ordered pain treatments; comparing nurses’ pain management practices with so many confounding variables is a challenge. Likewise, the changing clinical condition of these patients complicates evaluating nurses’ pain management practices even for the same patient from shift-to-shift. For this study, our desire was to have a consistent patient experience from which nurses could respond. Vignettes or “stories about individuals and situations which make reference to important points in the study of perceptions, beliefs, and attitudes” (Hughes, 1998, p. 381) have been widely used as a research methodology to elicit responses from study participants. Vignettes not only allow researchers to manipulate variables of interest in ways that may not be possible in real life, but are often more cost effective and efficient than assessing actual behavior (Schigelone & Fitzgerald, 2004). These stories of individuals provide a context from which participants can respond, and offer insight into how judgments and actions interrelate with beliefs and meanings (Barter & Renold, 2000). For these reasons, the written vignette (often referred to as a case study), has been used to assess pediatric nurses’ assessment and analgesic administration choices (Armstrong, Pegelow, Gonzalez, & Martinez, 1992; Griffin, Polit, & Byrne, 2007; Hamers, Van Den Hout, Halfens, Abu-Saad, & Heijltjes, 1997; Vincent & Gaddy, 2009; Vincent, Wilkie, & Szalacha, 2010).

However, the use of written vignettes present some challenges. First, the way in which any research instrument is written may cause bias or cue a socially desirable or “correct” response (Barter & Renold, 2000; Waltz, Strickland, & Lenz, 2010). Second, any ambiguity or misapprehension of words may compromise the equivalence of participants’ interpretations (Salomon, Tandon, & Murray, 2001) of the vignettes. This variation in interpretation is likely more of a risk when words replace what is normally a visual experience. For this reason, vignettes applying visual experiences (i.e. video), have been proposed to have a sounder basis for the simulation of real-life experiences (Hughes & Huby, 2002). However, use of video has its own limitations –including a possible lack of authenticity when facial expressions are feigned by actors (Williams, 2002), and controlling for subtle differences between individuals recorded.
More recently, VH vignettes have been used to evaluate nurses’ pain-related decision making for adult patients (Hirsh, George, & Robinson, 2009; Hirsh, Jensen, & Robinson, 2010). VH vignettes have similar benefits for research as written vignettes, but also eliminate some of the potential shortcoming. VH vignettes present participants with animated patients, that exhibit differing facial expressions and behaviors, which may be carefully manipulated to allow for comparisons. To our knowledge, this type of vignette has not been applied in a pediatric pain study and may help to elicit greater insight into PICU nurses’ beliefs regarding children’s pain, pain assessment practices, and pain intervention choices.

**Development Process**

For the development of the VH vignettes, Adler, Trainor, Siddall, and McGahie’s (2007) case development and review process for high-fidelity simulation case scenarios was followed (see Figure 2). There are 5 phases to this process: case concept, review and revision by content experts, case outline and flow development, case translation into simulator program, and pilot testing. Adler et al.’s (2007) process was chosen because it is consistent with other expert’s publications regarding the use of past research and content experts in the development of vignettes (Hughes, 1998; Schigelone & Fitzgerald, 2004), and addresses needs unique to the development of a VH vignette, including opportunities to correct for problems during translation of the case concept into the simulator program and during pilot testing. Each phase of this development process for our four VH vignettes will be described. Table 12 provides a more detailed example of this process for the grimacing child vignettes.

**Case Concept**

The case concept for the VH vignettes derived from written vignettes in the simulated pain management component of Vincent, Wilkie, and Wang’s (2010) Pain Beliefs and Practices Questionnaire (PBPQ). The PBPQ vignettes are based on case studies from the Pediatric Nurses’ Knowledge and Attitudes Survey (PNKAS) regarding pain (Manworren, 2000, 2001), an instrument validated with pediatric nurses (PICU nurses included). Within the PBPQ vignettes, 10-year-old boys one day after abdominal surgery are described (Vincent, Wilkie, & Wang, 2010). All rate their pain as 8/10 and have stable vital signs, but in each pair, one boy smiles and jokes and the other grimaces. For the PBPQ, nurses
rate the pain of each child in the vignettes from 0 to 10 and indicate the dose that they would provide (if any) of analgesia ordered. Content validity and internal consistency of the PBPQ was established.

In addition to the post-operative patients described within the PBPQ vignettes, we wanted to include patients with a different diagnosis—sickle cell vaso-occlusive crisis. This population was included because children with sickle cell disease report moderate to high pain levels throughout their time in the hospital (Beyer, 2000; Jacob et al., 2003, 2007; Jacob & Mueller, 2008; Zempsky et al., 2008) and have additional risk factors for uncontrolled pain (Elander, Marczewska, Amos, Thomas, & Tangayi, 2006; Pack-Mabien, Labbe, Herbert, & Haynes, 2001; Wright & Adeosun, 2009). Children with sickle cell disease may also be at risk for uncontrolled pain due to nurses’ inability to identify with pain from vaso-occlusive crisis as compared to pain from trauma or surgery (Pack-Mabien et al., 2001).

The final case concept included four vignettes in which patients are of the same sex (male), age (10 years old), have similar (stable) vital signs, report the same pain levels (8 out of 10), and have the same provider orders for analgesia. However, the children exhibit differing behaviors (facial grimace or smiling) and have differing types of pain (post-operative or sickle cell vaso-occlusive crisis). These four vignettes provide an opportunity to compare nurses’ assessment and intervention choices for children when behavior and/or diagnosis differ.

Vignette #1: child with recent abdominal surgery, smiling
Vignette #2: child with recent abdominal surgery, exhibiting facial grimacing
Vignette #3: child with sickle cell vaso-occlusive crisis, smiling
Vignette #4: child with sickle cell vaso-occlusive crisis, exhibiting facial grimacing

**Review and Revision by Content Experts**

Feedback from content experts is an essential component of achieving realism of a vignette. Realism of the story/situation is arguably the most important aspect of developing a vignette as it is tied to the sensitivity and accuracy (validity) of the instrument (Hughes, 1998; Lanza, 1988; Schoenberg & Ravdal, 2000). Three categories of realism have been proposed for successful simulated patient events: physical, semantical (conceptual), and phenomenal (emotional/experiential) (Dieckmann, Gaba, & Rall,
Physical realism refers to those tangible/quantifiable aspects of the simulation (i.e., weight, length, color). Semantical realism entails ensuring that information provided through the vignette is conceptually sound and may be easily interpreted by participants. Phenomenal realism consists of the complete experience of the simulation, including emotions, beliefs, and reasoning (Dieckmann et al., 2007; Rudolph et al., 2007). The degree of each type of realism within any simulation is dependent upon the goals of the simulation (Dieckmann et al., 2007). In this section, we will address both the physical and semantical categories of realism as they relate to the VH vignettes and the use of content experts. Because phenomenal realism is reliant upon the participants’ response to the simulation, it will be addressed within the discussion of this paper.

Though physical realism in a paper/pencil vignette is of negligible consequence, in the case of a VH vignette, some physical realism is necessary to achieve semantical realism. For example, the facial behaviors, or movements of the face of the virtual patient must imitate physical reality in order for participants to recognize the patterns of these movements as an expression, such as a smile or a grimace (P. Diekmann, personal communication, April 13, 2013). We used the Facial Action Coding System (FACS), a reliable method of detecting and measuring facial movements (Eckman, Friesen, & Hager, 2002), to guide the development of the virtual humans’ expressions. FACS is comprised of 44 discernible facial movements, called action units. To ensure the action units were accurate and consistent across patients, the expertise of a coder certified in FACS was obtained.

Given that all virtual experiences lack many aspects of physical realism (touch, smell, weight), high semantical realism was desired to help bridge differences between the VH vignettes and actual patient encounters. To strengthen semantic realism, content experts were used. Because the written PBPQ vignettes were previously reviewed by nurses with expertise in pain management research (Vincent, Wilkie, & Wang, 2010), the main focus of the expert review of the revised PBPQ written vignettes was for applicability within a PICU. Four advanced practice nurses, with an average of 9.5 years of experience as pediatric nurses, were asked to provide feedback regarding the vignettes; these experts were chosen
because of their clinical expertise, current roles in which they regularly encounter critically ill children, and familiarity with the PICU staff nurse role and responsibilities.

The content experts were asked to examine the revised PBPQ vignettes for plausibility, comprehensiveness of the data provided, appropriateness of the medications ordered, and level of complexity of the scenario for the specific aims of the study. All experts agreed that the information provided in the vignettes was plausible, comprehensive, and complex enough to elicit PICU nurses’ responses regarding their pain assessment and intervention choices, and to determine if these responses comply with best practice standards for the management of children’s pain. One content expert suggested revision of the pain medication order in the vignettes, in which a dose range is provided for intermittent morphine (1mg to 3mg as needed, every 2 hours), due to recommendations of accreditation agencies. Though not prohibited, medication orders with a dose range do require an institution-specific policy which addresses these types of medication orders (Gordon et al., 2005; Pasero, Manworren, & McCaffery, 2007). Concerned that the elimination of the dose range would constrain nurses’ responses, we chose to keep the range order within the vignettes. The PICU content experts also provided suggestions for additional variables to consider (e.g. patient acuity); unfortunately, the addition of variables for this study would have been prohibited by the resources required to develop the volume of additional VH vignettes to adequately compare for differences, but can be considered for future research.

Case Outline and Flow Development

In order to adapt the vignettes from written to a virtual experience, scripts were developed. These scripts outlined in detail what the nurses would see and how they would be able to navigate the information provided. The goal was to eliminate written information in the form of sentences/paragraphs, and to instead provide information in a way consistent with the nurses’ experience on the unit (e.g., visualize patient and vitals on a monitor and review history and medications in an electronic record format). Also, because there was a desire to compare nurses’ responses to the VH vignettes with their responses to the PBPQ written vignettes, it was important for the content and flow of these two forms of vignettes to remain consistent.
During the VH vignette script development, certain aspects of the vignettes not previously addressed in the PBPQ vignettes needed to be determined. Areas in need of outlining included the patient’s appearance (e.g. race, hair, and clothing) and appearance of the environment (e.g. equipment in room). The decision was made for all of the virtual patients to be African American, as children of this race experiences the highest incidence of sickle cell disease in the United States (Centers for Disease Control and Prevention, 2011). Simple hair, a hospital gown, and an environment which only allowed a view of the patients’ bed were also decided upon. Additionally, adapting these vignettes visually to the PICU environment required current vital signs to be presented on a bedside monitor, necessitating the addition of pulse oximetry and electrocardiography. Normal values and waveforms were chosen for these two measures.

Flow development included the order in which nurses would encounter the information and step-by-step details of the nurses’ view of the virtual patient, including the patient’s body movements, timing of the movements, facial expressions (e.g. exact facial actions, how long grimace/smile last, frequency of facial actions) and the “camera” view of the patient (e.g. angle, distance from patient). As previously mentioned, the order of information presented was designed to mimic the flow of information in the PBPQ vignettes. Body movements of each of the patients were chosen to be the same in order to avoid a confounding variable of patient mobility. A review of the literature was conducted to determine FACS action units for each expression. No literature was identified in which the facial actions of hospitalized ten-year-olds experiencing acute pain were described. In fact, little literature exists for school age children. However, because consistencies in both expressions have been noted across the lifespan (Gilbert et al., 1999; Messinger, Cassel, Acosta, Ambadar, & Cohn, 2008; Schiavenato, 2008; Williams, 2002), commonly reported AUs were chosen (described in the following section). The view of the VH was chosen to zoom into the patient’s face, to allow for closer view of the facial expression.

**Case Translation into Simulator Program and Correcting Steps**

The next phase of the case development and review process is case translation into the simulator program, and includes revising steps which do not translate well into the simulator (Adler et al., 2007).
Content within the vignettes to be translated included the virtual human, virtual human environment, vital signs, patient information, and pain medication ordered. Once each of the content areas of the VH vignettes was translated and revised accordingly, they were compiled as a webpage (html), to form the complete VH Vignette (see Figure 3).

**Virtual human.** The Lifelike Responsive Avatar Framework (Lee et al., 2010), a process of creating realistic avatars in a shortened period of time, was applied to develop the virtual humans for the four VH vignettes. Photos of African American boys, 9 to 11 years old, were used to form the base head models of the four virtual humans (Figure 3). Initial facial actions and other movements were then programmed based on the provided script. For the smile, action units (AU) 6 (cheek raiser) and 12 (lip corner puller) were decided upon (a smile of enjoyment) (Schmidt & Cohn, 2001) and AUs 4 (brow lowerer), 6 (cheek raiser), 9 (nose wrinkler), and 27 (mouth stretch) were chosen for the grimace (Wilkie, 1995; Williams, 2002). Dynamic facial wrinkles coupled with the facial movements were enabled with a normal texture map. Refinement of the expressions was an iterative process, achieved through multiple exchanges with the FACS expert. During these sessions, limitations of the software in achieving realistic responses of the entire face to some of the action units were identified. These limitations required further manipulation of the facial actions; especially problematic was the lower face of the grimace. For the final configuration, AUs 4, 6, 7, 9, 20, and 25 with a wrinkle intensity of 0.6 at the peak of the grimace were programmed for the animation (see Figure 4, bottom right). The smile expression was a result of the open-smile template from the Lifelike Responsive Avatar Framework, with slight lip stretcher (AU20) and lips part (AU25) and a wrinkle intensity of 0.7 at the peak of smile animation (Figure 4, top right).

The final configurations were applied to all four base head models, resulting in eight animations (one smile and one grimace for each). The FACS expert evaluated the two expressions of the four base head models for equivalence in presence and intensity of the action units. Due to the facial structure of some of the base models, equivalence of action units could not be attained. Two problematic facial
expressions (from two different base models) were excluded from use in the study. The remaining two models were randomly assigned to expression for the vignettes (smile or grimace). All of the models were then randomly assigned without replacement to diagnosis (sickle cell vaso-occlusive crisis or abdominal surgery). Videos of the four virtual humans with the assigned expressions were submitted to the PICU nursing content experts for review. All experts agreed that the VH expressions were recognizable as a child’s smile or grimace. Lastly, a fifth virtual human was developed with a neutral facial expression, to use as a practice vignette with the nurses prior to responding to the study vignettes.

**Virtual human environment.** To decrease the time required to build a virtual environment for the patient, a prefabricated virtual hospital room was purchased. However, the purchased environment lacked many of the standard devices in an intensive-care room which nurses would expect to see at the head of the bed (e.g. oxygen and medical air connections, suction set-up). The decision was made to maintain a close-up view of the patient for the entire video clip within the VH vignette, thus, keeping the viewers’ attention focused on the patient’s facial expression, and not an unrealistic background.

**Vital Signs.** A patient monitor simulator was programmed with the desired vital signs for the patients, including heart rate, blood pressure, respiratory rate, oxygen saturation, and heart rhythm. The monitor screen was video-taped for two-minutes. This video was separated into four 30-second video clips, one for each patient.

**Patient Information.** Content from the written PBPQ vignette was included in a “screen shot” of the patients’ electronic record in the format of a nursing flowsheet. The screenshot was created in Microsoft® PowerPoint. Content included the patients’ age, diagnosis, vital signs for the past two hours, and numeric pain rating every half hour for the past two hours. The patient’s report of an acceptable pain level of 2 was also shown. The same flowsheet template was used for each of the study patients with the only variance being the patient’s diagnosis. Because no audio was included in these VH vignettes to allow the nurses to hear the patient report his pain, an additional screen was created with the patients’ current pain rating of 8 and his acceptable pain level of 2.
**Medication Ordered.** Also created in Microsoft® PowerPoint was a medication administration record for the patients. Nurses were able to view the patients’ medications ordered “as needed” for pain. This included the ordered drug, dose, route, frequency, and the administration history for the past 2 hours.

**Pilot Testing and Correcting for Issues**

The VH vignettes were piloted in a cross-sectional, mixed-methods study of PICU nurses’ beliefs about children’s pain and their reported pain assessment and intervention practices. We report here information related to the pilot of the VH vignettes as it relates to the vignette realism. This includes the nurses’ recognition of the virtual patients’ intended facial expressions (smile or grimace), a comparison of nurses’ pain ratings for the VH vignettes and the written PBPQ vignettes, and nurses’ reports of the VH vignette’s consistency with their professional experience.

**Methods**

**Sample**

A convenience sample of 40 PICU nurses was recruited from two urban hospitals in the Midwest, a university-based hospital, and a large children’s hospital. Inclusion criteria consisted of working in a PICU for at least 20 hours a week for the past year as a staff nurse. The sample size of 40 provided adequate power (0.87 -0.99) for paired samples t-test to detect the calculated treatment effects of 0.5 – 0.87 of behavior (smile and grimace) for nurses’ pain ratings and morphine dose administration (Vincent, Wilkie, & Wang, 2010) and a medium treatment effect (0.46) for diagnosis and vignette type (alpha 0.05, two-tailed). Of the 40 nurses who participated, the majority were female (92.5%) and identified their race as white (82.5%). The nurses’ years of PICU experience ranged from 1 to 29, with a mean of 9.2 years (SD 8.7). Ninety-five percent of the nurses indicated a highest nursing degree at the baccalaureate level or higher. All of the nurses reported caring for children in pain each week for the preceding 3 months.

**Procedures**

Upon approval from the appropriate Institutional Review Boards, nurses were recruited to participate in the study. When a nurse expressed interest in taking part in the study, a 45-minute appointment was scheduled with the primary investigator (PI) for a convenient date and time. Most nurses
chose to meet the PI at a private location in their hospital of employment before or after a scheduled shift. During the appointment, once consent was obtained and a demographic survey was completed, each nurse was walked through the components of the practice VH vignette. The VH vignettes were displayed on a 24 inch monitor from the PI’s laptop. A wireless mouse was provided to ease screen navigation. Nurses were informed to view each vignette component and were encouraged to view components as often as desired. A short form was provided for nurses to rate the child’s pain and record if and how they would intervene. Nurses were asked to respond as if they were viewing actual patients assigned to them at the beginning of their shift. The order in which the nurses viewed the four VH vignettes was randomly assigned without replacement to decrease a risk of order effect between the vignettes.

Once all four of the study vignettes were viewed and the short pain rating and intervention forms completed, a semi-structured interview was conducted. During this interview, nurses were asked to share what they were thinking when they rated the patient’s pain and determined whether or not to intervene. They were able to refer to the VH vignettes on the computer while discussing their choices. At the end of the interview, the nurses were asked how consistent they believed the VH vignettes were with their professional experience with children in pain. This question was intentionally included to elicit nurses’ opinions regarding the realism, both physical and semantical, of the VH vignettes, as well as to capture aspects of the phenomenal realism of the vignettes.

**Analysis**

Interview transcripts were reviewed to: (a) Verify nurses’ recognition of the intended facial expressions (smile or grimace) of the virtual humans. (b) Determine if nurses believed the VH vignettes were consistent with their professional practice. (c) Describe any reported dissimilarity between the VH vignettes and nurses’ actual experiences with children in pain. Frequencies were calculated for how often nurses described the patients’ expression accurately as a smile or grimace and how often they reported the VH vignette as consistent with their professional practice. When nurses described inconsistencies between the vignettes and practice, these differences were noted and tallied. The nurses’ 8 responses to the VH vignettes (pain ratings and morphine doses) were evaluated for internal consistency (Cronbach’s
Paired t-tests were performed to evaluate differences in nurses’ pain ratings among the VH vignettes and to compare pain ratings between the VH vignettes and the PBPQ written vignette.

**Results**

**Recognition of Facial Expressions**

Though the PICU nurses were not asked to specifically comment on the virtual patients’ facial expressions, many did refer to the expressions when sharing their pain assessment and intervention choices. To determine the frequency at which nurses accurately identified the virtual patient’s intended expressions (smile and grimace), transcripts of the semi-structured interviews were analyzed. Nurses each viewed 4 vignettes, resulting in a total of 160 viewings; one audio recording was interrupted, resulting in transcripts related to 159 viewings (79 grimaces and 80 smiles). Of these 159 views, nurses commented on the child’s facial expression 129 times (grimace n = 60, smile n = 69). Of the nurses who described the VH facial expressions, 98.4% (127/129) described the intended expression. For the smiling patients, 100% of the nurses who described the facial expression described it accurately; nurses used the word smile or smiling in 87% of the views (60/69) and for the remaining 9 views, used terms consistent with a smile, such as “happy” to describe the patient’s expression. For the two grimacing patients, nurses used the words grimace or wince to describe the expression 83.3% of the time (50/60). An additional 13% also referred to the expression as “showing pain” or “distressed” (8/60). Two nurses used the word smile or smiling to describe the facial expression of a vignette with a grimacing patient (3.3%). Both of these nurses were recalling the facial expression of the virtual patient during the interview without actually visualizing the expression.

The nurses completed 8 items in response to the four VH vignettes (4 pain ratings and 4 intervention choices); when evaluated for internal consistency, the resulting Cronbach’s alpha was 0.89.

**Comparison of Pain Assessments**

Nurses rated their assessment of the children’s pain from 0 to 10 for the VH vignettes and the written PBPQ vignettes. A total of 8 vignettes were rated, one written and one virtual of each: sickle cell (smiling and grimacing), and post-operative (smiling and grimacing). Among the VH vignettes, nurses’
pain ratings were not significantly different between the smiling children with sickle cell vaso-occlusive crisis ($M = 4.94, SD = 2.89$) and the smiling children who had surgery ($M = 4.49, SD = 2.94$), $t(39) = 1.50, p = 0.14$. The same was true between the grimacing children with sickle cell vaso-occlusive crisis ($M = 6.24, SD = 2.01$) and the grimacing children who had surgery ($M = 6.45, SD = 1.88$), $t(39) = 1.07, p = 0.29$. However, a significant difference was identified between the smiling and grimacing children of the same pain type in the VH vignettes; smiling children with sickle cell vaso-occlusive crisis were rated lower than grimacing children with sickle cell vaso-occlusive crisis, $t(39) = 4.61, p < 0.001$, and smiling children with abdominal surgery were rated lower than grimacing children with abdominal surgery, $t(39) = 5.86, p < 0.01$.

Similarly, for the written PBPQ vignettes, no statistically significant differences were found between the nurses’ pain ratings for the smiling children with sickle cell vaso-occlusive crisis ($M = 5.05, SD = 2.85$) and the smiling children who had surgery ($M = 4.87, SD = 2.80$), $t(38) = 1.22, p = 0.23$. The same was true between the grimacing children in the PBPQ with sickle cell vaso-occlusive crisis ($M = 7.16, SD = 1.39$) and the grimacing children who had surgery ($M = 7.16, SD = 1.46$), $t(37) = 0.000, p = 1.00$. A significant difference was identified between the smiling and grimacing children of the same pain type; smiling children with sickle cell vaso-occlusive crisis were rated lower than grimacing children with sickle cell vaso-occlusive crisis, $t(37) = 6.01, p < 0.001$, and smiling children with abdominal surgery were rated lower than grimacing children with abdominal surgery, $t(37) = 6.30, p < 0.001$.

When nurses’ pain ratings for children in the VH vignettes were compared to children in the written PBPQ vignettes, no differences were identified between the smiling children, $t(38) = 0.58, p = 0.57$. However, a statistically significant difference was found between the grimacing children, $t(37) = 3.79, p = 0.001$. Grimacing children’s pain in the written PBPQ vignettes was rated significantly higher ($M = 7.16, SD = 1.40$) than grimacing children’s pain in the VH vignettes ($M = 6.44, SD = 1.83$). This difference was present between the VH vignette and the written PBPQ vignette regardless of pain type (grimacing sickle cell $t(37) = 3.33, p < 0.01$, grimacing post-operative $t(37) = 3.38, p < 0.01$).
Consistency with Professional Practice

At the end of the interview, nurses were asked “how consistent were these vignettes with your professional experience as a PICU nurse?” Nurses (65%) endorsed the consistency of the VH vignettes with their experiences with PICU patients. Two audio recordings were interrupted and thus, not included in the analysis. The remaining nurses (30%) neither confirmed nor denied comparability of the vignettes with actual practice. They instead elaborated upon their experiences managing patients’ pain in the PICU.

Examples of nurses’ comments supporting the consistency of the vignettes with their professional experiences included: “So, yeah, it’s a good picture of what we see. I didn’t see anything up here that I haven’t seen a million times” and “In the sense that we’re looking at the patient itself, how they are sitting, smiling, wincing, that kind of stuff, their vital signs, those are consistent with pain assessment in real life”. Often, the nurses noted similarities in the patients’ diagnoses as well as their behaviors:

I think they match pretty well. A lot of the sicklers that we have, they can either show that they’re in a lot of pain or they’re very stoic in their facial expressions because they live with this pain. So I thought it was appropriate to show a patient with the vaso-occlusive crisis because it can be either way and patients having had abdominal surgery and in pain is correct. So, I mean, I think the – I think it was all very similar to what I deal with.

Additionally, several nurses commented on the similarities of the VH vignettes with patient experiences. One nurse stated:

I took care of probably three sickle cellers in like a 2-week span and two of them were exactly like these two… One was visibly in pain. One of them was like cracking jokes and in this horrible vaso-occlusive crisis and with like chest pain and everything and playing video games…”

Some differences between the vignettes and actual practice were described. Ten of the nurses (25%) believed it would be helpful to have additional patient information (i.e. more detailed pain assessments, physical assessment details, and additional medical history, past pain experiences and
interventions, and prior hospitalizations); some also mentioned a desire to interact with the patient and ask questions. Eleven (27.5%) of the nurses noted differences in the medication orders from usual unit practices (e.g. medication, frequency, dosing, or route). The most frequent discrepancy noted between practice and the VH vignettes was the patients’ stable vital signs. Forty percent of the nurses (16/40) anticipated vital sign changes with a patient report of pain.

**Correcting for Issues**

During the testing of the VH vignettes with the PICU nurses, no issues were identified. The PICU nurses were able to independently navigate the VH vignettes after going through a practice vignette; furthermore, they were able to assimilate the information within the vignettes to appropriately answer interview questions. Considerations for future studies in which VH vignettes are applied are discussed in the following section.

**Discussion**

In this paper we have shared our process in developing and piloting 4 virtual human vignettes intended for the elicitation of responses from PICU nurses regarding their pain assessments and intervention choices. Overall, the physical realism of the vignettes was endorsed by the PICU nurses’ high percentage of recognition of the smiling and grimacing facial expressions. It is unclear whether the two nurses that identified a grimacing child’s expression as smiling interpreted the intended expression inaccurately or if they failed to recall the correct vignette, as they were not viewing the virtual patient at the time of the interview. Due to the high recognition rate of the rest of the viewings, it was likely inaccurate recollection.

A high Cronbach’s alpha (0.89) supports the internal consistency of the nurses’ responses to the VH vignettes. Additionally, the differences between nurses’ pain ratings for smiling and grimacing children among VH vignettes supports the validity (physical realism and consistency) of the expressions. Because pediatric nurses have previously been identified to rely heavily on patient behavior for pain assessments (Vincent & Denyes, 2004; Vincent & Gaddy, 2009), it is not surprising that they would rate the children similarly based on facial expression, regardless of diagnosis. The difference in pain ratings
between the VH vignettes with opposing facial expressions, not only supports past study findings, but also the nurses’ ability to differentiate the expressions (physical realism). Because pain ratings varied by child behavior, the similar ratings among the VH vignettes with coinciding facial expressions additionally supports the equivalence (consistency) of the intensity of the expressions among vignettes.

Differences in nurses’ pain ratings between the grimacing children in the VH vignettes and the grimacing children in the PBPQ may be attributed to the nurses’ perceptions of the intensity of the grimaces viewed in the VH vignettes, versus an imagined grimace in the written vignette. During the interviews, one-fifth of the nurses discounted the intensity of the grimaces of the virtual children, pointing out the brevity and infrequency of the grimacing or the child’s behavior before and after the grimace. Comments included: “So all those things led me to believe that he is having some pain but he looked pretty comfortable for the most part besides an occasional grimace. So slightly more than an acceptable pain level” and “He looks okay. He’s looking around. He looks like he’s distractible, but the one wince, I can see he’s in pain, but he’s not distressed.” These findings suggest that the VH vignette may be useful in understanding the influence of the frequency, length of time, and intensity of facial expressions on nurses’ assessments of patients’ pain.

Additionally, nurses verified that the VH vignette information was consistent with their professional practice, often providing examples of similar encounters with patients in the PICU. The greatest inconsistency identified between the VH vignettes and practice was the patients’ unchanged vital signs. However, this noted inconsistency may be more of an indicator of PICU nurses’ common use of vital sign changes to identify/confirm pain (Coffman et al., 1997; Curley et al., 1992) rather than an inaccurate patient depiction. Vital signs may easily be adjusted within the VH vignette application; variations in vital signs could be considered for future studies.

Though a simulated experience is not experienced phenomenally the same as clinical practice, the nurses’ ability to relate the VH vignettes to their patient care experiences within the PICU substantiates both the vignettes’ semantical and phenomenal realism (Dieckmann et al., 2007). Dieckmann et al. (2007) suggest that in a successful simulation “participants experience the simulation scenario relevant to
the goal of the session and they are able to make semantical sense of the scenario despite its physical differences from the clinical situation” (2007, p. 185). Based on this description, the nurses’ ability to identify the patients’ facial expressions, interpret the information provided, respond to questions regarding their nursing practice, and identify similarities and differences between the vignettes and their professional experiences, the application of these VH vignettes was effective.

Limitations of this study include the limited ability to generalize findings and a lack of literature to support the grimacing children’s facial action units, and a possible order effect between the VH vignettes and the written PBPQ vignettes. The small sample size of this study hinders the generalizability of findings. Furthermore, as is the case with all types of vignettes, we cannot confirm that PICU nurses’ responses to the VH vignettes are the same as their responses to children in actual practice (Hughes, 1998). These snapshots of patients may not fully capture other influencing factors (e.g. parental opinion), nor do they comprehensively address the PICU population, which includes a wide range of ages, diagnoses, and levels of acuity. Also, a dearth of literature prevented us from confirming that the VH facial expressions coincided with hospitalized children of this age and diagnoses. Because nurses responded to the VH vignettes and then completed the PBPQ, it is possible that the VH vignettes influenced their responses to the PBPQ. However, the nurses’ responses to both types of vignettes are similar to nurses’ responses to similar vignettes in a prior study in which the smiling children are rated lower than the grimacing children for pain (Vincent, Wilkie, & Szalacha, 2010). A future study in which nurses are randomly assigned to vignette type, would allow for a better comparison of the virtual and written vignettes.

However, the design of this study helped to address some of these limitations. In the use of interviews, nurses could discuss additional influencing factors in their pain management practice. By asking how consistent the VH vignettes were with their professional practice, we were not only able to validate the vignettes with this population, but were also able to incite further discussion regarding the nurses’ personal experiences managing children’s pain. The use of a previously validated case concept
(PBPQ), PICU nursing content experts, and a certified FACS coder also contributed to the strength of the VH vignettes’ design.

In utilizing VH vignettes, we were not only able to control for differences among patients, but were also able to provide nurses with a consistent visual experience from which to respond. Additionally, the nurses’ desire for additional patient information and to ask the children questions regarding their pain, speaks to the potential of applying interactive VH vignettes. This application would address another criticism of vignettes, the inability to provide interaction and feedback (Hughes, 1998). Future implications for this methodology in research are expansive. VH vignettes may be developed to compare healthcare professionals’ responses to countless variations in patient characteristics and may be utilized as a training intervention. As technology improves the ease of developing realistic virtual experiences, future studies examining the value of this technique as compared to other forms of vignettes (written, video) are warranted.
References


**Table 12.**

*Example of Case Development and Review Process for Grimacing Child*

<table>
<thead>
<tr>
<th>Case Development and Review Process Phase</th>
<th>VH Vignette Development Example</th>
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<tbody>
<tr>
<td><strong>Case Concept</strong></td>
<td>Portion of PBPQ written vignette: “... As you enter his room, he is lying quietly in bed and grimaces as he turns in bed.”</td>
</tr>
<tr>
<td><strong>Expert Review</strong></td>
<td>PBPQ based on previously validated vignette and reviewed by pain research experts. Four advanced practice nurses working with critically ill children reviewed PBPQ vignettes for applicability to PICU.</td>
</tr>
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</table>
| **Outline/Flow**                        | 1. Nurse clicks on “Observe Patient” icon.  
   2. Video of patient begins to play, view is a bust shot of patient in bed.  
   3. Boy sitting upright, with neutral expression, turns to left (~ 5 sec.)  
   4. As boy begins to face forward, begins to grimace (~ 3 sec.)  
      FACS action units desired: 4 brow lowerer, 6 cheek raise, 9 nose wrinkle, 27 mouth stretcher  
   5. Camera moves from bust shot to closer view of child’s face as grimace completes (~ 2 sec.)  
   6. Returns to neutral face (~ 5 sec.). Total time 15 seconds. |
| **Translation to Simulator**            | 1. Base head model developed from photograph  
   2. Maximal intensity grimace developed, facial actions and wrinkles  
   3. Movement of head/body programmed  
   4. Hair/clothing programmed  
   5. Placed model in a virtual hospital bed and room  
   6. Video of virtual patient captured |
| **Revisions**                           | Multiple revisions to facial movements/wrinkles throughout each step of the translation process in collaboration with certified FACS coder  
   Appearance of virtual patient and limitations of software lead to revisions in the final configuration of programmed action units and included: AU 4 brow lowerer, 6 cheek raise, 7 lids tight, 9 nose wrinkle, 20 lip stretch, and 25 lips part.  
   FACS coder reviews grimaces of all models, determines inequality in expressions due to facial structures. Individual adjustments made and one base model grimace eliminated for possible use in study. |
| **Pilot**                               | Advanced practice nurses view video and confirm grimace is consistent with their experiences with grimacing children.  
   Video of virtual patient combined with other components of VH vignette and piloted in study with 40 PICU nurses.  
   Results reviewed for nurses’ recognition of expression as a grimace and compared to PBPQ grimacing vignette responses. |
Figure 2. Case Development and Review Process. Reprinted from *Ambulatory Pediatrics*, 7(2), Adler, Trainor, Siddall, & McGahie, Development and evaluation of high-fidelity simulation case scenarios for pediatric resident education, Page 183, Copyright 2007 with permission from Elsevier.
Figure 3. Virtual human vignette application. Screen shots from a completed VH vignette: top row from left to right consists of 1) the main graphical user interface 2) nursing flowsheet/patient information. Center row 1) virtual patient 2) patient monitor. Bottom 1) medication administration record 2) patient’s current pain rating.
Figure 4. Formation of base head models. Examples of photographs of children (left, top and bottom) used to develop the base head models for two virtual human vignettes. Top facial expressions include a neutral expression (center) and smile (right). Bottom facial expressions include a neutral expression (center) and grimace (right).
APPENDIX A

UNIVERSITY OF ILLINOIS
AT CHICAGO

Office for the Protection of Research Subjects (OPRS)
Office of the Vice Chancellor for Research (MC 672)
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

Approval Notice
Initial Review (Response to Modifications)

June 11, 2012

Cynthia LaFond
Women, Child, & Family Health Science
Women, Children, and Family Health Science
845 S Damen, M/C 802
Chicago, IL 60612
Phone: (708) 710-6677 / Fax: (312) 996-8871

RE: Protocol # 2012-0418
“Children's Pain: PICU Nurses' Beliefs and Responses to Virtual Human Vignettes”

Please be sure to submit an Amendment for Non-UIC research sites added to this study. The outside sites must be listed on Appendix K and the letters of support provided for each. Please note that Appendix K and the letters of support must be accompanied by an Amendment Form when submitted to the UIC IRB.

Please submit the transcription agreement via an Amendment. Please note that the transcription agreement must be accompanied by an Amendment Form when submitted to the UIC IRB.

Dear Ms. LaFond:

Your Initial Review (Response to Modifications) was reviewed and approved by the Expedited review process on June 11, 2012. You may now begin your research

Please note the following information about your approved research protocol:

**Protocol Approval Period:** June 11, 2012 - June 10, 2013

**Approved Subject Enrollment #:** 40

**Additional Determinations for Research Involving Minors:** These determinations have not been made for this study since it has not been approved for enrollment of minors.
APPENDIX A (continued)

**Performance Sites:**
UIC

**Sponsor:**
UIC College of Nursing PhD Student Research Award, International Nursing Association for Clinical Simulation Deborah Spunt Research

**PAF #:**
Not available, Not available

**Grant/Contract No:**
Not available, Not available

**Grant/Contract Title:**
Not available, International Nursing Association for Clinical Simulation Debra Spunt Mini-grant

**Research Protocol(s):**

a) Children's Pain: PICU nurses' beliefs and responses to VH Vignettes; Version 1

**Recruitment Material(s):**

a) Email; Version 1; 05/30/2012
b) Flyer; Version 2; 05/30/2012

c) Meeting Script; Version 1; 05/30/2012

**Informed Consent(s):**

a) Informed Consent; Version 2; 05/30/2012
b) Waiver of Informed Consent granted under 45 CFR 46.116(d) for recruitment purposes only

Your research meets the criteria for expedited review as defined in 45 CFR 46.110(b)(1) under the following specific categories:

(6) Collection of data from voice, video, digital, or image recordings made for research purposes. (7) Research on individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

**Please note the Review History of this submission:**

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Please remember to:

→ Use your research protocol number (2012-0418) on any documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements on the enclosure,
APPENDIX A (continued)

"UIC Investigator Responsibilities, Protection of Human Research Subjects"

Please note that the UIC IRB has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact OPRS at (312) 996-1711 or me at (312) 996-9299. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Marissa Benni, M.S.
IRB Coordinator, IRB # 2
Office for the Protection of Research

Subjects

Enclosure(s):

1. **UIC Investigator Responsibilities, Protection of Human Research Subjects**
2. **Informed Consent Document(s):**
   a) Informed Consent; Version 2; 05/30/2012
3. **Recruiting Material(s):**
   a) Email; Version 1; 05/30/2012
   b) Flyer; Version 2; 05/30/2012
   c) Meeting Script; Version 1; 05/30/2012

cc: Rosemary C. White-Traut, Women, Child, & Family Health Science, M/C 802
    Catherine Vincent, Women, Child, & Family Health Science, M/C 802
November 16, 2012

Cynthia LaFond
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Chicago, IL 60612
Phone: (708) 710-6677 / Fax: (312) 996-8871

RE: Protocol # 2012-0418
“Children's Pain: PICU Nurses' Beliefs and Responses to Virtual Human Vignettes”

Dear Ms. LaFond:

Members of Institutional Review Board (IRB) #2 have reviewed this amendment to your research and/or consent form under expedited procedures for minor changes to previously approved research allowed by Federal regulations [45 CFR 46.110(b)(2)]. The amendment to your research was determined to be acceptable and may now be implemented.

Please note the following information about your approved amendment:

**Amendment Approval Date:** November 12, 2012

**Amendment:**
Summary: UIC Amendment # 1(response to modifications) dated November 4 2012 (received 11/5/12) is an investigator-initiated amendment to [1] add a consent and recruitment documents for Ann and Robert Lurie Children's Hospital of Chicago as an added site (Appendix K, support letter 10/15/12, Adult ICF version 1 8/12/12, Flyer version 2 11/4/12, Email version 2 11/4/12); [2] revise the recruitment documents to change the time to complete participation from 90 minutes to 45 minutes (Flyer UIC version 3 9/25/12, Email UIC version 3 10/15/12); [3] submit revised consent (Informed Consent version 3 10/28/12); [4] add Carrie Alden of Lurie Children's Hospital of Chicago as key research personnel (Appendix P).
APPENDIX A (continued)

Approved Subject Enrollment #: 40
Performance Sites: UIC, Ann and Robert Lurie Children's Hospital
Sponsor: UIC College of Nursing PhD Student Research Award, International Nursing Association for Clinical Simulation Deborah Spunt Research
PAF#: Not available, Not available
Grant/Contract No: Not available, Not available
Grant/Contract Title: Not available, International Nursing Association for Clinical Simulation Debra Spunt Mini-grant

Recruiting Material(s):
  a) Email UIC; Version 3, 10/15/2012
  b) Flyer UIC; Version 3, 09/25/2012
  c) Flyer; Version 2, 11/04/2012
  d) Email; Version 2, 11/04/2012

Informed Consent(s):
  a) Adult ICF; Version 1, 08/12/2012
  b) Informed Consent; Version 3, 10/28/2012

Please note the Review History of this submission:

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Please be sure to:

→ Use only the IRB-approved and stamped consent document(s) and/or HIPAA Authorization form(s) enclosed with this letter when enrolling subjects.

→ Use your research protocol number (2012-0418) on any documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements on the enclosure, "UIC Investigator Responsibilities, Protection of Human Research Subjects"

Please note that the UIC IRB #2 has the right to ask further questions, seek additional information, or monitor the conduct of your research and the consent process.

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further
APPENDIX A (continued)

help, please contact the OPRS at (312) 996-1711 or me at (312) 413-1835. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Kathleen Loviscek, M.S.
IRB Coordinator, IRB # 2
Office for the Protection of Research Subjects

Enclosure(s):

1. UIC Investigator Responsibilities, Protection of Human Research Subjects
2. Informed Consent Document(s):
   a) Adult ICF; Version 1, 08/12/2012
   b) Informed Consent; Version 3, 10/28/2012
3. Recruiting Material(s):
   a) Email UIC; Version 3, 10/15/2012
   b) Flyer UIC; Version 3, 09/25/2012
   c) Flyer; Version 2, 11/04/2012
   d) Email; Version 2, 11/04/2012

cc: Catherine Vincent (faculty advisor), Women, Child, & Family Health Science, M/C 802
    Barbara McFarlin, Women, Child, & Family Health Science, M/C 802
December 7, 2012

Cynthia LaFond
Women, Child, & Family Health Science
Women, Children, and Family Health Science
845 S Damen, M/C 802
Chicago, IL 60612
Phone: (708) 710-6677 / Fax: (312) 996-8871

RE: Protocol # 2012-0418
“Children's Pain: PICU Nurses' Beliefs and Responses to Virtual Human Vignettes”

Dear Ms. LaFond:

Members of Institutional Review Board (IRB) #2 have reviewed this amendment to your research and/or consent form under expedited procedures for minor changes to previously approved research allowed by Federal regulations [45 CFR 46.110(b)(2)]. The amendment to your research was determined to be acceptable and may now be implemented.

Please note the following information about your approved amendment:

Amendment Approval Date: December 6, 2012
Amendment: Summary: UIC Amendment #2 dated November 23, 2012 (received 12/03/2012) is an investigator-initiated amendment regarding the following: (1) Remove the faculty sponsor, Dr. Catherine Vincent, from Lurie Children's Hospital consent form per Lurie Children's Hospital IRB request, and (2) Request that Lurie Children's Hospital site coordinator, Carrie Alden, maintain copies of all site participant's consent forms and data. (Included: revised consent, Adult ICF, v.1, 11/4/2012; revised Protocol, v.2, 11/23/2012; Lurie Children's IRB approval, 11/13/2012).

Approved Subject Enrollment #: 40
Performance Sites: UIC, Ann and Robert Lurie Children's Hospital
Sponsors: UIC College of Nursing PhD Student Research
APPENDIX A (continued)

Award, International Nursing Association for Clinical Simulation Deborah Spunt Research

PAF#: Not applicable, Not applicable
Grant/Contract No: Not applicable, Not applicable
Grant/Contract Title: Not applicable, International Nursing Association for Clinical Simulation Debra Spunt Mini-grant

Research Protocol:
   a) Children's Pain: PICU nurses' beliefs and responses to VH Vignettes; Version 2, 11/23/2012
   c) Adult ICF; Ann & Robert H. Lurie Children’s Hospital of Chicago-Lurie Children’s IRB #2013-15202 Version 1, 11/04/2012

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Please be sure to:

→ Use only the IRB-approved and stamped consent document enclosed with this letter when enrolling subjects.
→ Use your research protocol number (2012-0418) on any documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements on the enclosure, "UIC Investigator Responsibilities, Protection of Human Research Subjects"

Please note that the UIC IRB #2 has the right to seek additional information, or monitor the conduct of your research and the consent process.

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact the OPRS at (312) 996-1711 or me at (312) 355-2764. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Betty Mayberry, B.S.
IRB Coordinator, IRB # 2
Office for the Protection of Research Subjects
APPENDIX A (continued)

Enclosures:

4. **UIC Investigator Responsibilities, Protection of Human Research Subjects**
5. **Data Security Enclosure**
6. **Informed Consent Document:**
   a) Adult ICF; Ann & Robert H. Lurie Children’s Hospital of Chicago-Lurie Children’s IRB #2013-15202 Version 1, 11/04/2012

cc: Catherine Vincent, Faculty Sponsor, M/C 802
    Barbara McFarlin, Women, Child, & Family Health Science, M/C 802
APPENDIX A (continued)

UNIVERSITY OF ILLINOIS
AT CHICAGO

Office for the Protection of Research Subjects (OPRS)
Office of the Vice Chancellor for Research (MC 672)
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

Approval Notice
Amendment to Research Protocol and/or Consent Document – Expedited Review
UIC Amendment # 3

February 6, 2013

Cynthia LaFond
Women, Child, & Family Health Science
Women, Children, and Family Health Science
845 S Damen, M/C 802
Chicago, IL 60612
Phone: (708) 710-6677 / Fax: (312) 996-8871

RE: Protocol # 2012-0418
“Children's Pain: PICU Nurses' Beliefs and Responses to Virtual Human Vignettes”

Dear Ms. LaFond:

Please note that this Amendment was inadvertently submitted under the wrong Protocol (2011-1057) and is letter is to document that the IRB has noted the mistake and has made the appropriate changes.

Members of Institutional Review Board (IRB) #2 have reviewed this amendment to your research and/or consent form under expedited procedures for minor changes to previously approved research allowed by Federal regulations [45 CFR 46.110(b)(2)]. The amendment to your research was determined to be acceptable and may now be implemented.

Please note the following information about your approved amendment:

Amendment Approval Date: July 24, 2012

Amendment: Summary: UIC Amendment #3 dated July 17, 2012 (received 7/18/12) is an investigator-initiated amendment to submit a revised instrument, Pain Beliefs and Practices Questionnaire (Version 2, 7/4/12). Two questions previously deleted are added back, formatting has been revised and instructions reworded.

Approved Subject Enrollment #: 40
APPENDIX A (continued)

**Performance Sites:**
UIC, Ann and Robert Lurie Children's Hospital

**Sponsor:**
UIC College of Nursing PhD Student Research Award, International Nursing Association for Clinical Simulation Deborah Spunt Research

**PAF#:**
Not available, Not available

**Grant/Contract No:**
Not available, Not available

**Grant/Contract Title:**
Not available, International Nursing Association for Clinical Simulation Debra Spunt Mini-grant

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Please be sure to:

- Use your research protocol number (2012-0418) on any documents or correspondence with the IRB concerning your research protocol.

- Review and comply with all requirements on our website, "UIC Investigator Responsibilities, Protection of Human Research Subjects" ([http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0924.pdf](http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0924.pdf))

  "J BVAMC Investigator Responsibilities for Performing Research Involving Human Subjects"

Please note that the UIC IRB #2 has the right to ask further questions, seek additional information, or monitor the conduct of your research and the consent process.

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact the OPRS at (312) 996-1711 or me at (312) 355-0816. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Alison Santiago, MSW, MJ
IRB Coordinator, IRB #2
Office for the Protection of Research Subjects

cc: Catherine Vincent (Faculty Sponsor), Women, Child, & Health Science, M/C 802
Barbara McFarlin, Women, Child, & Family Health Science, M/C 802
APPENDIX A (continued)

UNIVERSITY OF ILLINOIS AT CHICAGO

Office for the Protection of Research Subjects (OPRS)
Office of the Vice Chancellor for Research (MC 672)
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

Approval Notice
Continuing Review (Response To Modifications)

June 18, 2013

Cynthia LaFond
Women, Child, & Family Health Science
Women, Children, and Family Health Science
845 S Damen, M/C 802
Chicago, IL 60612
Phone: (708) 710-6677 / Fax: (312) 996-8871

RE: Protocol # 2012-0418
“Children's Pain: PICU Nurses' Beliefs and Responses to Virtual Human Vignettes”

Dear Ms. LaFond:

Your Continuing Review (Response To Modifications) was reviewed and approved by the Expedited review process on June 17, 2013. You may now continue your research.

Please note the following information about your approved research protocol:

Please note that this research did not have Institutional Review Board (IRB) approval beginning on June 10, 2013; approval re-commenced on June 17, 2013. Any research activities conducted during this time were done without IRB approval and were not compliant with UIC’s human subject protection policies, The Belmont Report, UIC’s Assurance awarded by the Office for Human Research Protection (OHRP) at HHS, and with the federal regulations for the protection of human research subjects, 45 CFR 46.

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</tr>
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<tr>
<td>Grant/Contract Title:</td>
<td>Not applicable, Not applicable, International Nursing Association for Clinical Simulation Debra Spunt Mini-grant, Not applicable</td>
</tr>
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</table>
Research Protocol:
   b) Children's Pain: PICU nurses' beliefs and responses to VH Vignettes; Version 2, 11/23/2012

Recruitment Material:
   d) N/A-closed to enrollment

Informed Consent:
   c) N/A-closed to enrollment

Your research meets the criteria for expedited review as defined in 45 CFR 46.110(b)(1) under the following specific categories:
(6) Collection of data from voice, video, digital, or image recordings made for research purposes., (7) Research on individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

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Please remember to:
→ Use your research protocol number (2012-0418) on any documents or correspondence with the IRB concerning your research protocol.
→ Review and comply with all requirements on the enclosure,
  "UIC Investigator Responsibilities, Protection of Human Research Subjects"
  (http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0924.pdf)

Please note that the UIC IRB has the right to seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact OPRS at (312) 996-1711 or me at (312) 355-2764. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Betty Mayberry, B.S.
IRB Coordinator, IRB # 2
Office for the Protection of Research Subjects

cc: Barbara McFarlin, Women, Child, & Family Health Science, M/C 802
    Catherine Vincent, Faculty Sponsor, Women, Child & Family Health Science, M/C 802
    OVCR Administration, M/C 672
APPENDIX B

IRB APPROVAL
EXPEDITED NEW SUBMISSION

TO: Carrie Alden, RN
Cardiovascular Thoracic Surgery, Mailbox 22

PROTOCOL TITLE: Children's Pain: PICU Nurses' Beliefs and Responses to Virtual Human Vignettes

IRB #: 2013-15202
IRB APPROVAL DATE: November 13, 2012
IRB EXPIRATION DATE: October 31, 2013

The Ann & Robert H. Lurie Children's Hospital of Chicago Institutional Review Board (Lurie Children’s IRB) reviewed and approved, via expedited review as authorized by 45 CFR 46.110 the above-named protocol.

This research was reviewed and approved under expedited review category #7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

If any modifications or adverse effects occur in the project before your next scheduled review, you must submit them to the IRB immediately for review. Except in emergency situations, no change to the protocol may be implemented until you have received an IRB approval letter for the change.

Federal regulations require that an IRB conduct continuing review of research not less than once per year, regardless of whether initial approval was via full board or expedited procedures. Please note the expiration date for your current IRB approval and be aware that you must submit a progress report for IRB review prior to the expiration in order to obtain IRB approval for the next approval period. If the current approval expires and you do not obtain approval for another approval period, research on this study, including subject enrollment, must cease until you regain approval. If you have questions about your obligations as principal investigator, please contact the ORIC staff as listed on the ORIC website: http://www.childrensmrc.org/researchadministration/oric/irb2.

YOUR OBLIGATIONS AS PRINCIPAL INVESTIGATOR:

As the Principal Investigator, you are ultimately responsible for the conduct of the study, the protection of the rights and welfare of human subjects and adherence to the Lurie Children's IRB
APPENDIX B (continued)

and hospital policies and procedures (Lurie Children's IRB Policy and Procedure Manual), including, but not limited to Section 5: Investigator Responsibilities and the following:

1. Perform the project by qualified personnel according to the approved protocol and ensure that all individuals who will interact with subjects and/or have access to identifiable research data have completed the human subject protection education requirement.

2. Submit the continuing review progress report for review and an approval in advance of the expiration date.

3. Do not implement changes in the approved protocol or consent form(s) without prior IRB approval (except to eliminate apparent immediate hazards to safeguard the wellbeing of human subjects).

4. If written consent is required, obtain the legally effective written informed consent from human subjects or their legally responsible representative using only the currently approved Lurie Children's IRB stamped consent form(s).

5. Follow the IRB Adverse Events, Other Unanticipated Problems, and Violations reporting criteria.

6. If this study is a sponsored study, you may NOT begin work on this study including subject enrollment until your contract/award is fully executed. Please contact the Office of Sponsored Programs for information about the status of the clinical trial agreement or grant award.

Best wishes for a successful study.

Sincerely,

Marilyn Lamm, Ph.D., Vice Chair
Institutional Review Board
Ann & Robert H. Lurie Children’s Hospital of Chicago
APPENDIX C

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APPENDIX C (Continued)

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Principal Investigator. International Nursing Association for Clinical Simulation and Learning, Deborah Spunt Research Mini Grant (awarded $500.00)

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