School of Nursing and Midwifery

The Development of a Multidimensional Pain Assessment Scale for Critically ill Preverbal Children

Anne-Sylvie Ramelet

This thesis is presented for the Degree of
Doctor of Philosophy
of
Curtin University of Technology

July 2006

DECLARATION

To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgment has been made.

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university.

Signature: ……

Date: 10 July 2006

LIST OF PUBLICATIONS SUBMITTED AS PART OF THE THESIS

Ramelet, A. S., Huijer Abu-Saad, H., McDonald, S., & Rees, N. (2004). The challenges of pain measurement in critically ill young children: A comprehensive review. *Australian Critical Care, 17*(1), 33-45. (See Chapter Two)

Ramelet, A. S., Abu-Saad, H. H., Bulsara, M., McDonald, S., & Rees, N. (2006). Capturing postoperative and procedural pain responses in critically ill infants aged 0 to 9 months. *Pediatric Critical Care Medicine, 7*(1), 19-26. (See Chapter Four)

Ramelet, A. S., Rees, N., McDonald, S., Bulsara, M., & Huijer Abu-Saad, H. (Submitted). The Multidimensional Assessment of Pain Scale (MAPS): Development and preliminary psychometric testing. (See Chapter Five)

Ramelet, A. S., Rees, N. W., McDonald, S., Bulsara, M., & Huijer Abu-Saad, H. (Submitted). Clinical validation of the Multidimensional Assessment Pain Scale (MAPS) in preverbal critically ill children. (See Chapter Six)

Note. Permission to include the papers as part of this thesis has been obtained from all joint authors of the papers cited above. All joint authors also provided details of the contribution that they made to each paper (Appendix A).

ABSTRACT

Adequate pain assessment is a pre-requisite for appropriate pain management. If pain remains untreated in critically ill young children, it can have dramatic short- and long-term consequences on their health and development.

Apart from humanitarian reasons, the assessment of pain has been recognised in some parts of the world as the fifth vital sign and thus should be part of standard practice of pain management. The evaluation of pain in preverbal children is, nevertheless, challenging for health professionals, as they cannot rely on self-report when making their assessment. Observational pain instruments have been developed to facilitate this task, but none of these existing instruments are appropriate for the postoperative critically ill young child.

The aim of this research was to provide a clinically valid pain instrument for health professionals to use in practice for the evaluation of the pain and the effectiveness of pain treatment in critically ill young children.

This thesis presents research that was conducted in three phases to (a) describe pain, (b) develop, and (c) test the pain instrument. Conceptualisation of pain and psychometric theory informed the conceptual framework for this study. An observational design was used in Phase One of the study to define pain behaviour in critically ill infants. Correlational design was used in Phase Two and Three to determine the association between the newly developed pain scale and other pain assessment instruments.

Phase One of the study was conducted in the paediatric intensive care units of two tertiary referral hospitals. Eight hundred and three recorded segments were generated from recordings of five critically ill infants, aged between 0 and 9 months, who had undergone major surgery. Results indicated significant physiological and behavioural changes in response to postoperative pain and when postoperative pain was exacerbated by painful procedures.

Using the pain indicators observed in Phase One, in Phase Two the Multidimensional Assessment Pain Scale (MAPS) was developed and tested for reliability and validity in 43 postoperative preverbal children from the same settings. Internal consistency and interrater reliability were moderate and good, respectively. Concurrent and convergent validity was good.

In Phase Three, the MAPS' response to analgesics and clinical utility was demonstrated in a convenience sample of 19 postoperative critically ill children aged between 0 and 31 months of age at a tertiary referral hospital in Western Australia.

Development of a pain instrument is a complex and lengthy process. This study presents the preliminary psychometric properties that support the validity and clinical utility of the Multidimensional Assessment Pain Scale. The MAPS is a promising tool for assessing postoperative pain in critically ill young children, and its clinical validity will be strengthened with further testing and evaluation.

ACKNOWLEDGMENTS

I wish to thank and acknowledge the Commonwealth government for an Australian Postgraduate Award and the 'Fondations de Recherche en Soins – FORESO' in Lausanne, Switzerland for providing financial support toward this study.

I wish to thank the many nurses who gave their time, dedication, and invaluable assistance to the conduct of this study. I am also indebted to the parents and children who took part in this study. Without them and their willingness to participate, this study would not have been possible.

A special thank you in extended to many colleagues and friends at Princess Margaret Hospital for Children, in particular Dr Alan Duncan, Kevin Cropper, and Fenella Gill for their support and advice. I also wish to gratefully acknowledge Dr Jacques Cotting, Claire-Lise Chollet, and the nurses at the 'Centre Hospitalier Universitaire Vaudois' for their support and their invaluable contribution to this research.

I also would like to express my gratitude to my supervisors for their generous and ongoing support. In particular, special thanks to my Principal Supervisor, Associate Professor Nancy Rees for her guidance and enthusiasm, encouragement and ability to challenge and inspire more ideas when I thought all had been said. My sincere appreciation to my Co-Supervisors Professor Sue McDonald and my Associate Supervisor Professor Huda Huijer Abu-Saad for their continuous encouragement and valuable comments.

I also would like to gratefully acknowledge Max Bulsara for his invaluable advice in statistics and tireless patience.

And finally, I am particularly thankful to my beautiful family: Laurent my husband for his love and continuing encouragement throughout this precarious process. My gorgeous boys Zachary and Maxim, who both joined our family at the time I thought this thesis was near completion, yet who gave me so much joy and laughter that helped me keep things in perspective.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

CHAPTER ONE

Introduction

This thesis presents a comprehensive account of the development of a pain assessment instrument designed for critically ill preverbal children who undergo major surgery. It aims to describe the pain responses specific to this group of vulnerable children and, using these pain indicators, to develop and test a new pain assessment instrument to assist health professionals in their clinical judgments. Providing a valid pain instrument is important because it provides a mean for standard accurate assessment, which is a prerequisite for optimal pain management and ultimately better health outcomes.

This chapter provides a background to the prevalence of pain in paediatric intensive care units and the short- and long-term consequences of pain in critically ill infants. It also highlights the difficulty of assessing pain in this population and the lack of appropriate pain instruments. An overview of the strategies chosen to address these issues and the objectives of this study are then presented. Finally, the chapter concludes with an overview of the layout of the thesis, followed by the glossary of terms.

Background to the Study

Over 7300 children are admitted to the paediatric intensive care units (PICU) in Australia and New Zealand each year. Approximately half of these children are

under three years of age and require surgery (Australian and New Zealand Paediatric Intensive Care Registry, 2004). Due to the nature of their illness, this vulnerable group of children is routinely subjected to various diagnostics, surgical or therapeutic invasive procedures that can result in pain (Porter & Anand, 1998). In addition, the stress associated with the intensive care environment, emanating from high levels of noise, constant lights, hectic space and unfamiliar faces, is likely to exacerbate the pain experienced (Carroll & Cook, 1993).

Historically, perception of pain in infants has been a subject of debate amongst scientists. The belief that infants could not remember pain contributed to a great deal of unnecessary suffering in this vulnerable population (Andrews & Fitzgerald, 1997). However, research advances in the last two decades have shown that the newborn does have the anatomical and functional components required to both perceive and remember pain (Anand & Hickey, 1987). Premature infants are at particular risk of experiencing pain due to the immaturity of their central nervous system and the rapid brain development occurring in the last trimester of gestation (Anand, 2000). Several longitudinal studies have demonstrated that substantial pain experience in early human life, independent of morphine exposure, may have long-term effects on the individual stress responses in vulnerable infants. This stress response is the probable cause for permanent damage to pain processing mechanisms (Fitzgerald, 2005), with implications for future pain experience. For instance, infants who were subjected to repetitive or prolonged untreated pain after birth demonstrated a lower pain threshold during routine immunisation at four and six months when compared to infants without this poorly managed pain experience (Grunau, Weinberg, & Whitfield, 2004; Grunau, Whitfield, & Petrie, 1994; Grunau, Whitfield, Petrie, & Fryer, 1994; Taddio,

Goldbach, Ipp, Stevens, & Koren, 1995). Other long-term consequences observed in animal studies included preference for alcohol, increased anxiety, defensive withdrawal behaviour, and decreased pain threshold (Anand, 2003).

Compared with healthy or moderately ill infants, the consequences of unrelieved pain in PICU patients may be more dramatic due to the severity of their illness. In essence, if pain remains inadequately treated in this group, they may experience physical and psychological stress resulting in severe deterioration of their metabolic and major organ systems as well as psychological disturbance (Anand, 2003). Anand and Hickey (1992) demonstrated that deep anaesthesia and postoperative analgesia with high doses of opioids reduced stress, complications, and mortality in neonates undergoing cardiac surgery. Consequently, administration of analgesics and sedatives is common practice in the critically ill (Park & Sladen, 1995). Although this combination of drugs has demonstrated its benefit in reducing pain and being relatively safe for use in infants (Harte, Gray, lee, Steer, & Charles, 1997; Jacqz-Agrain, Daoud, Burtin, Desplanques, & Beaufils, 1994; Wagner & O'Hara, 1997), the complications due to their side effects can be significant. In essence, accumulation of drugs due to altered drug metabolism may develop in children with multi-organ failure and result in prolonged intubation, increased risks of complications, and unnecessary physical and psychological suffering (Gill, 1996). Risk of severe abstinence symptoms when analgesics are tapered too abruptly is another complication (Ducharme, Carnevale, Clermont, & Shea, 2005; Franck, Naughton, & Winter, 2004). The long-term consequences of critical care admission on children include greater prevalence of medical fears and posttraumatic stress behaviour among children who are exposed to a greater number of pain exposures in

the intensive care unit (Rennick, Johnston, Dougherty, Platt, & Ritchie, 2002; Rennick et al., 2004).

Despite overwhelming evidence about the short- and long-term consequences of unrelieved pain, pain management in critically ill infants and children remains less than optimal (Beyer, McGrath, & Berde, 1990; Breau, Camfield, McGrath, & Finley, 2003; Franck, 1987; Jacob & Puntillo, 1999; Porter, Wolf, Gold, Lotsoff, & Miller, 1997; Simons et al., 2003). Critically ill children, whose communication is impaired, are at higher risk of experiencing pain. Results from the Thunder Project II, a large survey of pain management in acute and critical care settings in North America, showed that most common pain-inducing procedures, including dressing change, turning, tracheal suctioning, and wound drain removal, to name a few, were not appropriately treated in the majority of critical care patients, including children (Puntillo et al., 2001). A prospective study of procedural pain and analgesia in neonates by Simons et al. (2003) showed that clinicians thought that most neonatal intensive care unit procedures are painful, but only a third of the neonates received appropriate analgesia.

Inadequate pain treatment may be a result of a lack of standardised approach to pain management in infants and children (Ely, 2001; Furdon, Eastman, Benjamin, & Horgan, 1998). This remains a current problem as demonstrated by Long et al. (2005) who surveyed analgesia and sedation practice in all Australian and New Zealand paediatric intensive care units and showed that, although a combination of opioids and benzodiazepines was the first choice regime for the majority of the units, half did not have standardised guidelines.

To overcome this problem, and to highlight the ethical and legal importance of pain control, national government health agencies in North America (Joint Commission on Accreditation on Healthcare Organizations, 2001) and in Australasia (National Health and Medical Research Council, 2005a; The Royal Australasian College of Physicians, 2005a) continue to develop and update recommendations and guidelines to assist health professionals in the management of pain. Other professional bodies, such as the International Evidence-based Group for Neonatal Pain (Anand & International Evidence-Based Group for Neonatal Pain, 2001) the American Academy of Pediatrics & Canadian Paediatric Society (American Academy of Pediatrics & Canadian Paediatric Society, 2000) and the International Association for the Study of Pain (Finley, Franck, Grunau, & von Baeyer, 2005) have also published consensus statements and guidelines for the prevention and management of pain and stress in the newborn and older children. One universal key point that emerges from these recommendations is that adequate assessment of pain is paramount for accurate treatment of pain. The International Evidence-based Group for Neonatal Pain highlighted that "particularly careful assessment is required in critically ill infants as they do not mount vigorous behavioural responses to pain" (Anand & International Evidence-Based Group for Neonatal Pain, 2001, p. 1).

The presence or the level of pain experienced by critically ill infants is difficult to evaluate for a variety of reasons. These include (a) the subjective nature of pain (Lindblom et al., 1986); (b) the complexities of assessing pain in preverbal infants, who are unable to communicate their pain; (c) the difficulty of differentiating between pain and other causes of agitation (Broome & Tanzillo, 1990; Ramelet,

1999); (d) the lack of accurate pain indicators for the critically ill infant; (e) and contextual factors such as severity of illness, restraints, intubation, alterations in state of consciousness; (f) drug effects associated with sedatives, neuromuscular blockades, neuroleptics, and others (Abu-Saad, 1998; Abu-Saad, Bours, Stevens, & Hamers, 1998; Franck & Miaskowski, 1997; Porter, Wolf, & Miller, 1998). To overcome the difficult task of assessing pain in infants, a few pain assessment tools have been developed for use in critically ill infants.

Existing pain assessment scales designed for use in infants are either uni-dimensional or multidimensional, and have been developed to assess mainly acute pain (Abu-Saad, 1998; Abu-Saad et al., 1998; Franck & Miaskowski, 1997; Gibbins, Stevens, & Asztalos, 2003). Uni-dimensional scales are limited to one or more behavioural pain characteristics, and because pain is a multidimensional phenomenon, the validity and clinical value of these types of scales are questionable. A multidimensional scale including behavioural and physiological indicators is considered a more valid representation of the concept of pain (Abu-Saad, 1999).

Problem Statement

Several comprehensive reviews of neonatal and paediatric pain instruments have been published over the past decade (Abu-Saad, 1998; Abu-Saad et al., 1998; Franck & Miaskowski, 1997; Gibbins et al., 2003; Stevens, Johnston, & Gibbins, 1999). Numerous pain measures have been developed for preterm and term neonates, but most of them have been developed for research purposes and have limited utility in the clinical setting. In addition, the majority of the pain scales have been developed from pain indicators observed in healthy or moderately sick infants experiencing

acute painful stimuli. The pain indicators used in these measures, including cry and body movements may not reflect longer-lasting pain in critically ill infants and, therefore, may not be appropriate for use in this population. It is the paucity of research in this area and the lack of appropriate assessment tools that has encouraged the researcher to undertake this study.

Rationale for the Study

Despite evidence that the newborn infant is capable of experiencing pain and remembering it and that inadequate pain relief may have dramatic consequences on the survival of critically ill infants, pain management in this population remains at a suboptimal level. Ideal management of pain in this vulnerable group can be achieved only if pain can accurately be identified. The assessment of pain in critically ill infants is mainly performed by the bedside nurse. In the absence of available information on how critically ill infants respond to pain as well as the lack of an appropriate pain assessment scale for use in this group of infants, nurses and health professionals rely on their subjective judgments about pain. However, their judgment may be influenced by various factors and can thus be inconsistent and inaccurate, resulting in inadequate pain management (Abu-Saad & Hamers, 1997; Aslan, Badir, & Selimen, 2003; Ely, 2001; Erkes, Parker, Carr, & Mayo, 2001; Romsing, Moller-Sonnergaard, Hertel, & Rasmussen, 1996; Watt-Watson, Stevens, Garfinkel, Streiner, & Gallop, 2001). The use of an appropriate pain measure would, therefore, provide a more objective means to determine the presence and possibly the level of pain in individual critically ill infants.

Purpose of the Study

The purpose of the study was to develop a valid clinical assessment tool for assessing postoperative pain in critically ill preverbal children. Using an ethological method of observation, it was possible to capture, describe, interpret, and analyse pain behaviour in critically ill infants who underwent major surgery, then develop a pain measure and establish its psychometric properties. This study first explored the behaviour exhibited by critically ill infants over the postoperative period, then used the pain indicators defined in the first phase of the study to develop a pain measure for postoperative critically ill infants. The two final stages of the study tested the measure for psychometric properties and clinical utility.

Research Questions, Objectives, and Hypotheses

The following research questions provided guidance throughout the development of the study:

- What indicator(s) best describe pain in postoperative critically ill infants?
- How do these pain indicators vary over time?
- What are the psychometric properties of the MAPS?
- What is the MAPS' clinical validity?

The specific objectives of this study were to:

- Describe pain behaviour and the associated physiologic responses in critically ill infants during the postoperative period.
- Develop a pain assessment tool specifically for critically ill preverbal children.

- Evaluate the psychometric properties of the pain assessment tool, namely interrater reliability, internal consistency, content, convergent, and concurrent validity.
- Examine the clinical validity of the pain assessment tool, namely the MAPS response to the effect of analgesics (construct validity), internal consistency, and feasibility.

The following hypotheses were tested to establish the psychometric properties of the developed pain assessment tool:

- There is a positive correlation between MAPS and two instruments, the face, leg, activity, cry, and consolability (FLACC) and the visual analogue scale (VAS).
- Pain scores decrease significantly after the administration of an appropriate dose of morphine given intravenously.

Methodology

The research questions were addressed through a multi-design study comprising three phases:

- Phase One involved an observational design, including video recordings of the participants. Video recordings were viewed using ethological principles of observation, resulting in detailed description of postoperative pain behaviour in critically ill infants.
- Phase Two included the development of the pain assessment tool and establishment of preliminary psychometric properties, including face and content validity, interrater reliability, and convergent and concurrent validity.

- Phase Three assessed the clinical validity of the pain assessment tool using a hypothesis-testing approach and clinical utility was evaluated using a questionnaire completed by nurses.

In this study, the conceptualisation of pain in nonverbal children, described by Merskey (1997, p. 121), formed a framework for the description of pain in critically ill preverbal children. This model suggests that adequate assessment of pain requires that several criteria be met: (a) an adequate brain structure must be present to make possible the occurrence of consciousness and pain; (b) typical pain behaviour must be present; (c) any other causes must be excluded; and (d) a likely cause of pain must be present. Theory of instrument development informs Phases Two and Three of the study (Johnston, 1998). A detailed description of this study methodology is presented in Chapter Three.

Significance of the Study

The importance of this study is that it exposes the importance of pain assessment in young children's postoperative intensive care as well as the lack of appropriate measures for this vulnerable group. Information derived from this study, including description of pain behaviour in critically ill infants and the provision of a new pain assessment tool, can be utilised to provide a more valid and standardised approach to postoperative pain assessment in this group. Recommendations made for improved pain assessment and management are of greater utility to nurse clinicians, nurse educators, and nurse researchers in their endeavour to prevent unnecessary suffering. Ultimately, it is the young critically ill children in intensive care units who will

benefit from improved pain assessment and management, and better health outcomes.

Overview of the Thesis

This thesis is presented in seven chapters. Four of these chapters are presented in the form of journal articles that have been either published or submitted for publication in international peer-reviewed journals. Chapter One outlines the background and the rationale of the study, provides the research questions and objectives, gives an overview of the thesis outline with a glossary of terms. Chapter Two includes an article published in the journal *Australian Critical Care*. This paper presents a comprehensive review of the literature that is relevant to pain assessment in preverbal children and provides a discussion on the challenges of pain assessment in the critically ill preverbal child. Chapter Three gives an account of the research methodology of the study, including ethical considerations. Results of Phase One are presented and discussed in Chapter Four in the form of a journal article published in the journal *Pediatric Critical Care Medicine*. Results of Phase Two and Phase Three are shown and discussed in Chapters Five and Six, respectively, both in the form of a journal article submitted for publication in the journal *Pediatric Anesthesia*. To conclude the thesis, Chapter Seven presents a summary of the major findings of the study, discusses the implications of the study findings and makes recommendations relevant to nursing research, nursing education, and nursing practice in paediatric postoperative pain management.

Glossary of Terms

The following terms were used in this thesis and defined as:

Infant: includes term neonates (one who were born at 37 weeks' gestation) and infants aged between 1 and 12 months. It is acknowledged that this is an operational definition for the purpose of this study that does not accurately reflect the definition of infants commonly used.

Young children: children who are aged between 0 and 36 months and in their preverbal stage of development. Both terms 'young children' and 'preverbal children' are used interchangeably throughout this thesis.

Critically ill patient: one who is at risk of life threatening health problems or is experiencing a life-threatening condition that may occur as a result of major complications occurring in the perinatal period, serious injuries from accidents, major interventions involving vital organs, or failure of one or more of the body's vital organs as a result of disease, infection, or complications from treatment.

Postoperative pain: pain experience by children recovering from surgery while in hospital

Breakthrough pain: pain that occurs incidentally while the patient is receiving a continuous intravenous infusion of analgesics.

Paediatric intensive care unit: Paediatric tertiary referral intensive care unit based in a capital city.

Critical Care Nurse Specialist: A registered nurse who provides competent and holistic care for the critically ill patient through the integration of an advanced level of knowledge, skills and humanistic values.

CHAPTER TWO

The challenges of pain measurement in critically ill young children: A comprehensive review.

The previous chapter introduced the study, outlined the subject of the investigation and the methods used to conduct the study. A brief account of the significance of pain assessment in critically ill infants was also presented. The purpose of this chapter is to discuss the many challenges of pain measurement in critically ill children, provide a comprehensive review of the pain measures for children aged between 0 and 3 years, and consider their applicability to this group of children.

This chapter is presented in the format of a journal article that was published in *Australian Critical Care* (2004) 17, 33-45. The paper was co-authored by Supervisors Professor Huda Huijer Abu-Saad, Professor Sue McDonald, and Associate Professor Nancy Rees who were happy to have it included in this thesis.

Abstract

This article addresses the issues in measuring pain in critically ill children, provides a comprehensive review of the pain measures for children aged between 0 and 3 years, and discusses their applicability to this group of children.

When children are critically ill, pain can only exacerbate the stress response that already exists, to the extent that homeostasis cannot be maintained. Severity of illness is thus likely to affect physiologic and behavioural pain responses that would normally be demonstrated in healthy children. The problem of differentiating pain from other constructs adds to the complexity of assessing pain in non-verbal children. A pain measure to be useful clinically must be adapted to the developmental age of the target population.

Search of electronic databases and other electronic sources was supplemented by hand review of relevant journals to identify published and unpublished pain measures for use in children aged between 0 and 3 years. Twenty eight pain measures were identified in the literature: 11 for neonates only, 11 for children aged between 0 and 3 years, and six for children more than 12 months. These measures vary in relation to their psychometric properties, clinical utility, and the context in which the study was performed. These measures may not be suitable for the critically ill young child, because the items included were derived from observations of healthy or moderately sick children and may not reflect pain behaviour in those who are critically ill. It is therefore recommended to develop new pain scales for this population of compromised children.

Email: Anne-Sylvie.Ramelet@health.wa.gov.au

Introduction

More than in other paediatric populations, critically ill children are particularly exposed to pain as, in addition to their medical or surgical condition, they undergo numerous potentially painful diagnostic and treatment-related procedures (Porter & Anand, 1998). In this vulnerable group of patients, the experience of pain may exacerbate the stress response that already exists, as well as cause severe clinical complications, delay recovery, increase the risk of mortality, and have long-term psychological consequences (Anand, Coskun, Thrivikraman, Nemernoff, & Plotsky, 1999; Anand & Hickey, 1987, 1992; Grunau, Oberlander, Whitfield, Fitzgerald, & Lee, 2001; Grunau, Whitfield, & Petrie, 1994; Grunau, Whitfield, Petrie et al., 1994; Porter, Grunau, & Anand, 1999). Despite this evidence, pain management in critically ill children and neonates remains below an optimal level (Bauchner, May, & Coates, 1992; Johnston, Collinge, Henderson, & Anand, 1997; Ludwick, Hall, & Gaines, 1995; Pederson & Bjerke, 1999). Factors that contribute to poor pain management in this group of children include a lack of management plan (Carroll et al., 1999); knowledge deficit amongst physicians, pharmacists, and nurses (Clarke et al., 1996; Coyne et al., 1999; Lebovits et al., 1997); and difficulty in assessing pain.

Adequate assessment of pain is the key determinant for appropriate management, yet is particularly challenging in critically ill young children. In addition to their obvious inability to verbalise their experience, critically ill young children may not be able to express their pain through behaviour due to intubation, sedation with or without pharmacological paralysis, and/or neurological impairment. Furthermore, there is a decrease or a lack of pain responses in the critically ill infant (Andrews & Fitzgerald, 1997; De Jonghe et al., 2000; Franck & Miaskowski, 1997; Johnston, Stevens, Yang,

& Horton, 1995; Johnston et al., 1999); pain responses in young infants can vary (Fuller & Conner, 1996); and it is difficult to differentiate pain from other constructs (e.g. anxiety) (Andrews & Fitzgerald, 1997). The severity of illness, the variety of pathologies, the broad age range, and different types of pain are other factors likely to affect behavioural and physiological pain responses, adding to the complexity of pain assessment in critically ill children.

Self-report is considered the gold standard of pain assessment by the International Association for the Study of Pain (International Association for the Study of Pain, 1994). However, in preverbal children, health professionals have to rely on observational cues and clinical judgment to assess the presence and characteristics of pain (Abu-Saad, 1998). To facilitate pain assessment, numerous observational pain measures have been developed for neonates and preverbal children. However, the relevance of these measures, as reported in several reviews, varies greatly in relation to their psychometric properties, clinical utility and feasibility, and the context in which the study was performed (Abu-Saad et al., 1998; Franck & Miaskowski, 1997; Stevens, 1998). Recently, two articles addressed the issue of pain measurement in vulnerable infants, the premature neonate and infants with cognitive and/or neurological impairment in particular (Craig, Korol, & Pillai, 2002; van Dijk, Peters, Bouwmeester, & Tibboel, 2002). Little attention, however, has been given to older infants/children who are critically ill. This may be due to the complexity of investigating pain in an uncontrolled environment, where it is difficult to predict pain because of the recommended practice of providing analgesia and sedation in critically ill children (National Health and Medical Research Council, 2005a).

Nevertheless, appropriate pain relief in this vulnerable group of children is none less important and can only be achieved by accurate assessment.

The objectives of this article are to discuss the issues in measuring pain in critically ill children, to provide an updated review of the existing pain measures for children aged between 0 and 3 years, and to determine whether these existing pain measures are applicable for this age group of critically ill children. The term neonates (birth-28 days) and infants (1-12 months) is used throughout the text and refers to specific age groups of preverbal children (0-3 years) included in this review.

Issues in Measuring Pain in Critically ill Young Children

The measurement of pain in the critically ill young child is complicated by factors affecting pain responses, such as the child's severity of illness, likely to modify typical pain behaviour that would normally be observed in healthy children. The variability in pain responses due to children's different age and type of pain is another factor making the process of pain assessment even more complex. An additional issue in measuring pain in this group of children includes the difficulty in differentiating between pain and other constructs, such as stress, agitation, and sedation.

Factors affecting pain responses

The deleterious effect of pain on critically ill infants has been well documented, especially in premature infants (Anand et al., 1999; Anand & Hickey, 1987, 1992). Critically ill infants and young children are exposed to a potential or actual life

threatening condition (Australian College of Critical Care Nurses Inc., 2002) that can occur as a result of premature birth, trauma, surgery, or failure of one or more of the body's vital organ(s) as a result of illness (Australian and New Zealand Paediatric Intensive Care Registry, 2004). When critically ill, pain can only exacerbate the stress response that already exists, to the extent that homeostasis cannot be maintained. In this condition, severity of illness is likely to affect physiologic and behavioural pain responses that would normally be demonstrated in healthy or moderately sick children. There is, however, a lack of information on how severity of illness impacts on pain responses.

Pain responses have been shown to be inhibited in premature infants. However, diminished behavioural responses do not necessarily indicate an absence of pain, but in critically ill infants may be an indication of pain. Infants, not only because of their severity of illness but also their developmental age, may not have the physiologic and behavioural ability to respond to pain (Johnston et al., 1995; Johnston et al., 1999; Stevens & Johnston, 1994).

Developmental age seems to modulate pain responses (Craig, 1997), but pain responses can vary between individuals of the same age. The greatest variability occurs during the neonatal period due to neonates' immature neural system (Fitzgerald, 2000). Consequently, it is difficult to differentiate between motor reflexes and pain behaviour at this age (Stevens, Johnston, & Grunau, 1995). This variability, however, decreases over the first year of life (Piek & Carman, 1994). Developmental age is a factor that affects not only how a child expresses his/her pain, but also determines the choice of a pain measure. Pain in preverbal children is

primarily a sensory and emotional experience that is related to Piaget's sensorimotor stage of development (Twycross, 1999). During this stage, which lasts from birth to approximately age 2, understanding is based on immediate sensory experience and actions. Unlike mature humans, the inability to understand and give meaning to pain, as well as the incapacity to verbalise their negative experiences and develop coping mechanisms, make preverbal children more vulnerable to pain (Craig, 1997; Craig et al., 2002).

The type of pain is also likely to modulate pain responses. There are essentially two different types of acute pain that critically ill infants may experience: immediate pain or established acute pain. Immediate pain is typically caused by surgery, invasive procedures, or injury; the response is immediate and can last seconds to minutes. Established acute pain (including postoperative pain) results from the inflammatory process following tissue damage and can last hours to days (National Institute of Nursing Research, 1994). Only, a few investigators focused their work on defining postoperative pain indicators (Buttner & Finke, 2000; van Dijk et al., 2000). Most pain research in preverbal children address immediate pain response, because it is more predictable and measurable. Immediate pain response was described in healthy or moderately sick infants during circumcision (Benini, Johnston, Faucher, & Aranda, 1993; Butler-O'Hara, LeMoine , & Guillet, 1998; Howard, Howard, & Weitzman, 1994; Weatherstone et al., 1993), intra-muscular injection (Grunau, Johnston, & Craig, 1990; Johnston, Stevens, Craig, & Grunau, 1993; Taddio, Nulman, Koren, Stevens, & Koren, 1995), and heel sticks (Johnston et al., 1999; Larsson, Tannfeldt, Lagercrantz, & Olsson, 1998; Lindh, Wiklund, & Hakansson, 1999; Overgaard & Knudsen, 1999; Stevens, Johnston, Franck et al., 1999; Stevens,

Johnston, Taddio et al., 1999). Description of immediate pain caused by common paediatric intensive care procedures such as endotracheal tube suctioning is, however, limited (Franck & Miaskowski, 1997).

Pain and other constructs

Pain and agitation are two conditions that require different treatment. Although critical care nurses are responsible for this task, they were unable to differentiate between pain and agitation when asked to describe each condition using a list of physiologic and behavioural cues (Ramelet, 1999). It is difficult to differentiate pain from other constructs, such as agitation or stress, because these conditions are interrelated. Pain causes stress that can be categorised as physiologic stress (evidenced by an increase in heart rate), hormonal stress (e.g. increase in endogenous norepinephrine), metabolic stress (e.g. increase in serum lactate), or behavioural stress (e.g agitation) (Anand & Hickey, 1987, 1992). While pain may result in agitation, agitation in the critically ill child can be caused by other conditions (see Table 1).

Table 1. Factors causing agitation

Physiologic Factors	Psychological Factors
Pain	Sleep deprivation
Hypoxia	Unfamiliar environment
Adverse reaction to medication	Separation from a parent
Drug intoxication/withdrawal	ICU stressors (e.g. noise, light)
Brain injury	Mental disorder
Metabolic Disorders	Physical discomfort
Sepsis	

In an attempt to differentiate pain and agitation, Broome and Tanzillo (1990) suggested that agitation may be the result of chronic pain rather than acute pain.

However, in a more recent study (Debillon et al., 1994), agitation was observed in neonates experiencing both immediate pain and established pain. In this latter research, procedural pain was characterised by an immediate behavioural response accompanied by physiologic cues, whereas established pain was characterised by a prolonged agitated state with no associated physiologic signs.

Determining pain in deeply sedated and chemically paralysed children is even more complex, as in a deep sedation state in which the patient's consciousness is depressed to a degree that she/he cannot be easily aroused (Joint Commission on Accreditation on Healthcare Organizations, 2001) or in a paralysed state, where spontaneous pain behaviour is impaired. Physiologic indices, pupil size and presence of tears may be the only reliable indicators of pain in these patients (Anand, 1998; Curley et al., 1992).

Review of Pain Measures for Young Children

An extensive review of the literature was performed to identify all published pain measures developed for infants and children aged from birth to 3 years. In order to ensure a comprehensive recall of pain measures, the following keywords or combination of keywords were included: pain, distress; scale, measure, tool; assessment, measurement; infant, neonate, child, toddler, paediatric, and pediatric. Searches were restricted to English, French, and German languages. Electronic databases such as MedLine, Cochrane Library, CINAHL, and electronic full text ScienceDirect were searched for material published between 1986 and December 2002. Electronic journals related to pain were also reviewed. Websites of the International Association for the Study of Pain (www.iasp-pain.org), Pediadol

(www.pediadol.org), and Pediatric Pain – Science Helping Children (http://is.dal.ca/~pedpain/pedpain.html) were identified using Internet search engines. Messages regarding pain measures from the pediatric pain mailing list (PEDIATRIC-PAIN@IS.DAL.CA) and the Pediatric Intensive Care Unit mailing list (PICU-Nurse-International@yahoogroups.com) were reviewed by topics and date (January 2000-December 2002). The electronic search was supplemented by hand searching relevant journals and cross-referencing with reference lists in key articles. Unpublished material describing pain measures was also included when sufficient data were available. Inclusion criteria for this review included all articles that reported one or several psychometric aspect(s) of a pain measure that was tested in children aged between 0 and 3 years. Published and unpublished studies, in which a pain measure was used in this same population, were excluded if the aim was not to test the pain measure for either reliability, validity, or clinical utility.

Out of 67 articles retrieved, 32 were included in this review. Out of these 32 articles, 28 pain measures for use in children aged between 0 and 3 years were identified. Eleven measures were specifically designed for the neonate (birth to 28 days), tested or in the process of being tested in this population only. Eleven scales were tested in young children, including neonates; and the remaining six measures were developed for children older than 12 months (see Table 2).

Table 2. Pain measures tested in different age groups

Measures	Age in months							
	0	6	12	18	24	30	36	Max. age in years
PIPP								
PAIN								
SUN								
PAT								
DSVNI								
N-PASS								
CRIES	→3 months							
NIPS								
EDIN								
DAN								
LIDS								
IBCS								
MIPS	4-30 weeks							
POCIS			→4 years					
PEPPS			→24 months					
TPPPS			→5 years					
CFCS			→6 years					
CHEOPS			→7 years					
NFCS	→18 months							
COMFORT								
RIPS								
POPS								
NAPI								
CHIPPS								→5 y
BPS								
MBPS		4-6						
FLACC								→7 y
OPS								→13 y

Table 2. Note. PIPP: Premature Infant Pain Profile (Stevens, Johnston, & Horton, 1993); PAIN: Pain Assessment In Neonates (Hudson-Barr et al., 2002); SUN: Scale for use in Newborns (Blauer & Gertsmann, 1998); PAT: Pain Assessment Tool (Hodgkinson, Bear, Thorn, & Van Blaricum, 1994); DSVNI: Distress Scale for Ventilated Newborn Infants (Sparshott, 1996); N-PASS: Neonatal-Pain, Agitation, and Sedation Scale (personal communication, Pulchaski, May 2001); CRIES: an acronym for Crying, Requires O2, Increased vital signs, Expressions, and Sleepless (Krechel & Bildner, 1995); NIPS: Neonatal Infant Pain Scale (Lawrence et al., 1993); EDIN: Echelle Douleur Incomfort Nouveau-né (Debillon et al., 1994; Debillon, Zupan, Ravault, Magny, & al., 2001); DAN: Douleur Aigue du Nouveau-né (Carbajal et al., 1997); LIDS: Liverpool Infant Distress Score (Horgan, Choonara, Al-Waidh, Sambrooks, & Ashby, 1996); IBCS: Infant Body Coding System (Craig, Whitfield, Grunau, Linton, & Hadjistavropoulos, 1993); MIPS: Modified Infant Pain Scale (Buchholz, Karl, Pomietto, & Lynn, 1998); NFCS: Neonatal Facial Coding System (Craig et al., 1993); BPS: Behavioral Pain Score (Robieux, Kumar, Radhakrishnan, & Koren, 1991); MBPS: Modified Behavioral Pain Score (Taddio, Nulman et al., 1995); FLACC: an acronym for Face, Legs, Activity, Cry and Consolability (Merkel, Voepel-Lewis, Shayevitz, & Malviya, 1997); OPS: Objective Pain Scale (Norden et al., 1991); POCIS: Pain Observation Scale for Young Children (Boelen van der Loo, Scheffer, de Haan, & de Groot, 1999); PEPPS: Preverbal, Early Verbal Pediatric Pain Scale (Schultz et al., 1999); TPPPS: Toddler-Preschooler Postoperative Pain Scale (Tarbell, Cohen, & Marsh, 1992); CFCS: Child Facial Coding System (Gilbert et al., 1999); CHEOPS: Children's Hospital of Eastern Ontario Pain Scale (Suraseranivongse, Santawat, Kraiprasit, & Petcharatana, 2001) COMFORT: (Ambuel, Hamlett, Marx, & Blumer,

1992; van Dijk et al., 2000); RIPS: Riley Infant Pain Scale (RIPS), POPS: Postoperative Pain Scale, and NAPI: Nursing Assessment of Pain Intensity (Joyce, Schade, & Keck, 1994); CHIPPS: Children and Infants Postoperative Pain Scale (Buttner & Finke, 2000; Buttner et al., 1998).

Applicability/Suitability of Pain Measures

To determine whether the existing pain measures are applicable for critically ill young children, several criteria should be addressed. The items that can be included in the measure should be described in detail and supported by several studies. The components should also describe the population of patients of interest, and the context in which the study was performed should be described (Stevens, 1998).

Generation of Items

Items can be generated from the literature, clinical experts' opinion, or clinical population (direct observations and video recordings). Clinical experts who work closely with a specific population of patient are able to identify items that they have observed in situations they believe to be related to pain. However, items generated from a clinical population of children observed in situations where it would be reasonable to assume that they are experiencing pain seems to be the most appropriate method (Johnston, 1998). For instance, a pain measure including items that were observed in critically ill children experiencing postoperative pain and/or painful procedures that are commonly performed in ICU would be an "ideal" instrument for this group of children.

The original COMFORT scale (Ambuel et al., 1992) and the NIPS (Lawrence et al., 1993) were constructed by experienced PICU nurses who responded to a questionnaire. The COMFORT scale was originally developed to measure the level of distress in paediatric intensive care patients, was shown to be a valid measure of the level of sedation (Marx et al., 1994), and was later validated as a pain measure (van Dijk et al., 2000). The inconsistency of the validation of the COMFORT scale makes its construct validity and clinical utility questionable, resulting in difficulty of interpreting the COMFORT scores and making decisions based upon those scores. The PEPPS was developed through focus groups by seven paediatric nurses with 7 to 18 years experience. Videos of neonates in pain were used for the development of the EDIN and the LIDS. How the items were selected was reported in the majority of the studies, except for the SUN, the N-PASS, the OPS, and the DAN.

Pain measures can be categorised as composite measures or behavioural measures. Composite measures include a combination of physiologic, behavioural and other items (Table 3). Behavioural measures include behavioural items (Table 4).

Table 3. Items in composite measures

Composite measures	Physiologic items	Behavioural items			Other items	Source of items	Scoring system S/A* (Total score)
		Facial expressions	Cry/Verbal expressions	Body movements			
PIPP	HR, SaO2	Brow bulge, eye squeeze, nasolabial furrow			Behavioral state Gestational age	Literature Clinical observations Experts	7 items 0-3 S (0-21)
PAIN	HR, SaO2	✓	✓	Extremity movements	Breathing pattern State of arousal	From CRIES and NIPS	7 items 0-2 A (0-10)
SUN	HR-MAP	✓		✓	Breathing pattern CNS state	Not specified	7 items 0-4 S (0-28)
PAT	HR, SaO2, BP	✓	✓	Posture	Breathing pattern Sleep Colour, Nurse's perception	Literature	10 items 0-2 A (0-20)
DSVNI	HR, BP, SaO2, Temperature are not scored, but are indicative of stress	✓		✓	Colour	From 5 other measures	3 items 0-3 A (0-8)
N-PASS	HR-RR-BP-SaO2	✓	Crying irritability	✓	Behaviour state Extremities tone	Not specifed	5 items 0-2 S (0-10)
CRIES	HR-BP-SaO2	✓	✓		Sleep	Literature Experts	5 items 0-2 S (0-10)

Table 3. Items in composite measures (cont.)

Composite measures	Physiologic items	Behavioural items			Other items	Source of items	Scoring system S/A* (Total score)
		Facial expressions	Cry/Verbal expressions	Body movements			
COMFORT	BP-HR	✓	✓ (added to initial scale)	✓	Breathing pattern Calmness/Alertness Muscle tone	initially developed by experts to measure distress (Ambuel et al., 1992)	9 items 1-5 S (9-45)
OPS	BP		Cry and Verbal expressions	✓	Agitation	Not specified	5 items 0-2 S (0-10)
MIPS	HR-BP-SaO2	✓	Quality of cry	Spontaneous movements, fingers and toes flexion	Responsiveness Sleep Consolability Sociability Tone sucking	Adapted from clinical scoring system (Attia, Amiel-Tison, Mayer, Shinder, & Barrier, 1987)	13 items 0-2 A (26-0) †
PEPPS	HR	✓	✓	✓	Consolability Sociability	Literature Experts Theory	7 items 0-4 A (0-26)

* S=symmetric/A=asymmetric

† higher score means no pain (0=the worst pain)

Measures highlighted in bold are postoperative measures. The ones that are not highlighted are measures assessing procedural pain.

Table 4. Items in uni and multidimensional measures

Unidimensional measures	Behavioural items			Other items	Source of items	Scoring system S/A* (Total score)
	Facial expressions	Cry	Body movements			
NFCS	✓				Adapted from FACS	10 items 0-1 S (0-10)
CFCS	✓				Videos	13 items S (0-13)
IBCS			✓		Videos	5 items 0-1 S (0-5)
Multidimensional measures						
NAPI	✓	✓	✓	Response to touch	Adapted from CHEOPS	4 items 0-3 A (0-11)
RIPS	✓	✓	✓	Responsiveness Consolability	Adapted from (Joyce et al., 1994)	6 items 0-3 S (0-18)
POPS	✓	Quality of cry	✓	Response to touch Consolability Muscle tone	Adapted from clinical scoring system (Barrier, Attia, Mayer, Amiel-Tison, & Shinder, 1989)	7 items 0-2 S (0-14)
NIPS	✓	✓	✓	Breathing pattern State of arousal	Literature	6 items 0-2 A (0-13)
EDIN	✓	✓		Sleep Consolability Sociability	Observations videos	5 items 0-3 S (0-15)

Table 4. Items in uni and multidimensional measures (cont.)

Multidimensional measures	Behavioural items			Other items	Source of items	Scoring system S/A* (Total score)
	Facial expressions	Cry	Body movements			
DAN	✓	✓	✓		Not specified	3 items 0-4 A (0-10)
LIDS	✓	Cry quality, Cry quantity	✓	Sleep, Excitability Muscle tone	Videos	8 items 0-5 S (0-40)
BPS	✓	✓	✓		Adapted from CHEOPS	3 items 0-3 A (0-8)
MBPS	✓	✓	✓		Adapted from BPS	3 items 0-4 A (0-10)
FLACC	✓	✓	✓	Activity Consolability	Experts	5 items 0-2 S (0-10)
POCIS	✓		✓	Breathing pattern Consolability	Adapted from CHEOPS and NIPS	7 items S (0-7)
TPPPS	✓	✓	rub or touch painful area		Literature	7 items 0-1 S (0-7)
CHEOPS	✓	✓	✓	Response to touch Child verbalisation	Experts	6 items A (4-13)
CHIPPS	✓	✓	✓	Motor restlessness	Literature (Buttner et al., 1998)	5 items 0-2 S (0-10)

* S=symmetric/A=asymmetric

Physiological items

Differences between the physiological items represented in the pain measures lie in the type and number of items. Increase in heart rate (expressed in percentage or in actual value) was included in all composite measures, except the OPS. Increased heart rate in response to acute pain has been well demonstrated in neonates, infants (Benini et al., 1993; Bozette, 1993; Howard et al., 1994; Lindh et al., 1999; Oberlander, O'Donnel, & Montgommery, 1999; Stevens et al., 1993), and older children with various severity of illness (Tobias, Martin, oakes, Rao, & Wetzel,

1993). Blood pressure was another item commonly used in the measures. There is, however, less evidence to support increased blood pressure with acute pain (Ludwick et al., 1995; Tobias et al., 1993).

Other physiologic items that are ventilation markers (respiratory rate, oxygen saturation, and/or breathing pattern) were included in the PIPP, the NIPS, the PAT, the DSVNI, the N-PASS, the CRIES, the COMFORT, and the POCIS. Changes in respiratory rate were observed in non-ventilated neonates experiencing acute pain (Craig et al., 1993; Howard et al., 1994). In another study by Benini et al. (1993), decreased oxygen saturation was described in neonates undergoing circumcision. These ventilation markers are, however, influenced by the mechanical ventilation settings, such as the ventilator rate, fraction of inspired oxygen (FiO_2), the adequacy of the tidal volume and mean airway pressure, and the mode of the ventilator (Duncan, 1998), thus may not be useful pain indicators in ventilated children. In addition, children suffering from severe respiratory distress may not have the physiologic capacity to increase their respiratory rate in response to pain.

Physiologic items can vary greatly with stressors other than pain, such as haemodynamic instability, medications, mechanical ventilation, fear, anxiety, or general discomfort, and thus may not be specific enough to discriminate between painful and nonpainful stimuli (Franck & Miaskowski, 1997). However, physiologic parameters have been shown to be valuable indicators for critically ill young children in pain and have the advantage of being readily available to the critical care setting (van Dijk et al., 2001). It is, therefore, recommended to take them into consideration with behavioural items when measuring pain in critically ill young children.

Behavioural and other items

The measures reviewed in this article included behavioural items comprising facial expressions, cry or verbal expressions, body movements, state of arousal, and consolability, as well as other items such as gestational age, sociability, colour, and nurses' perception of pain intensity.

The extensive work of Grunau and Craig, and others (Craig, Hadjistavropoulos, Grunau, & Whitfield, 1994; Gilbert et al., 1999; 1990; Johnston et al., 1993; Lilley, Craig, & Grunau, 1997) demonstrated clearly that specific facial expressions (brow bulge, eye squeeze, naso-labial furrow, open lips, stretch mouth, lip purse, taut tongue, chin quiver) have been shown to be valid pain indicators in infants of different age and different type of pain. All measures, except the OPS, included an inconsistent number of facial expressions, as an item ranging from one to 13 items. Differences between pain measures remain in the definitions of facial expressions. For instance, the LIDS comprises a 6-point category for facial expressions, with extensive definition for each point. Defined subtle facial expression, such as nasolabial furrow, can, however, be difficult to evaluate in intubated patients who have their endotracheal tube taped around the upper lip. Other measures simply defined the facial expressions as a grimace; a term that has the ability to depict a number of detailed facial expressions.

The majority of the measures (n=18) include the item cry and/or verbal expressions. The definition of cry varies from presence or absence of cry to extensive definitions of cry quality and frequency. It is, however, difficult for health professionals to evaluate the quality of cries at the bedside, unless computerised recording equipment

is available for spectrographic analysis. The characteristics of cry including duration, frequency, latency, pitch, and harmonics, have been explored extensively during painful stimuli in infants (Bozette, 1993; Broome & Tanzillo, 1990; Grunau et al., 1990; Johnston et al., 1993; Stevens et al., 1993; Stevens, Johnston, & Horton, 1994). There is no doubt that high pitch, short and frequent cries can indicate pain, but alone may not always be specific for pain (Fuller & Conner, 1995). In addition, the quality of cries can be altered by neurologic (e.g. raised intracranial pressure) and metabolic disorder (Duncan, 1998). Last, but not least, many critically ill children who are more likely to experience numerous painful stimuli, cannot vocalise their experience, because they are pharmacologically compromised and/or intubated. In critically ill children, the absence or the presence of tears may be a useful indicator of pain (Curley et al., 1992), yet was not mentioned in any of the pain measures.

Body movements are commonly used in pain measures. An increase of body movements usually indicates the highest pain intensity, except for the DSVNI and the N-PASS, in which limited movement or immobility is considered as a sign of severe pain. Craig et al. (1993) reported that facial expressions and body movements were less vigorous in premature infants than in older infants. It seems logical to extrapolate these findings to older vulnerable children, as severity of illness is likely to affect body responses to pain, especially post major surgery where children may limit their body movements when experiencing pain.

State of arousal is an item that was included in 18 measures. The wording differs between measures, including behavioural or CNS state, sleep, central nervous system state, excitability, responsiveness, sociability, activity, agitation, and alertness, but

the definitions provided are similar. In these eighteen measures, an increased state of arousal (agitation) indicates pain, thus assuming that children who do not respond to stimulation are pain free. However this assumption may not be true for critically ill children and extremely premature infants, as they may not be able to demonstrate a behavioural response to pain due to the severity of their illness or their level of sedation (Craig et al., 2002).

Consolability, which relates to the ability to pacify the child, is another item included in six measures with little evidence of the value of this item in evaluating pain (van Dijk, Peters et al., 2002). It is difficult to assess consolability when parents are not present. Nurses who are seen as strangers may have difficulties soothing toddlers, who are frightened by unfamiliar faces at this age.

Contextual factors

Gestational age, birthweight, Apgar score and indices of risk of mortality, type of surgery, and requirement of intensive care are relevant contextual factors to determine the severity of illness of a patient. For neonates, gestational age and birthweight may give some indications about their clinical conditions, as one can assume that extreme prematurity is classified as critical illness due to high risk of mortality in this group of neonates. The Apgar score provides relevant clinical information directly after birth, yet may not reflect the severity of illness at the time of investigation. The risk of mortality indices, such as the Clinical Risk Index for Babies (CRIB)(Rautonen, Makela, Boyd, Apajasalo, & Pohjavuori, 1994), the American Society of Anestesiologists Physical Status (ASA PS) classification for operative risk (American Society of Anesthesiologist, 1999), the pediatric risk of

mortality score (PRISM) (Pollack, Ruttimann, & Getson, 1988), or the Paediatric Index of Mortality (PIM) (Shann, Pearson, Slater, & Wilkinson, 1997) give an accurate picture of the severity of illness and are commonly used in PICUs. The requirement of intensive care is another factor influencing the definition of the critically ill. For the purpose of this review, it was assumed that infants admitted in a postanaesthesia care unit (PACU) or recovery room, or a day-surgery ward, were either healthy or moderately sick. Those transferred directly to an intensive care unit were potentially critically ill because of major surgery, very low birthweight, low Apgar score, or requirement for ventilation support. The type of surgery predicts the extent of the tissue damage and is important for anticipating postoperative care, including pain management. However, the experience of pain is subjective and changes over the time of the healing process. It is, therefore, important for an appropriate choice of pain measure to be made, to be able to identify with accuracy the patient's clinical condition at the time of investigation.

All neonatal measures were tested in extreme premature infants, except the DSVNI and the N-PASS that had not been tested, and the LIDS that did not provide any information. Gestational age, birthweight, and Apgar score were reported in all neonatal studies.

In the 15 postoperative pain measures, types of surgery varied between minor and major surgery with an observation time varying between 30 minutes and 72 hours post surgery. The COMFORT scale was the only measure that was validated in critically ill children after major surgery. All other measures included a variety of

surgery in infants and children experiencing different severity of illness and pain intensity.

Information about the underlying clinical condition of the participants was not provided in the majority of the studies. In the studies that included this information, there are many inconsistencies between measures as demonstrated in Table 5.

Table 5. Pain measures designed for children aged 0-3 years

Note. References cited in Table 5 are listed in Appendix C as well as in the thesis reference list.

Two studies (Broadman, Rice, & Hannallah, 1988; Buttner & Finke, 2000) reported the participants as being either healthy, moderately sick, or severely ill according to the American Society of Anesthesiologist (ASA) physical status classification system (American Society of Anesthesiologist, 1999). A few studies described the clinical conditions of the participants in terms of medical diagnosis (Debillon et al., 2001), clinical stability, oxygen requirement (Craig et al., 1993), and mechanical ventilation (Blauer & Gertsmann, 1998; van Dijk et al., 2000) at the time of observations. In several studies, the participants were possibly intubated and/or ventilated at the time of investigation, but only one reported the percentage of participants who required some respiratory support at the time of observation (van Dijk et al., 2000). The neonates and young children involved in the validation of the PIPP, NIPS, EDIN, SUN, LIDS, IBCS, CRIES, NFCS, and COMFORT scales were considered critically ill as defined by the above criteria, but in none of them was the risk of mortality mentioned.

Psychometric Properties

Reliability and validity are two important aspects that determine the psychometric properties of a pain measure. Reliability is defined as the extent to which pain measurement is consistent and free from random errors. Interrater reliability (consistency or agreement among observers using the same measure) and internal consistency (homogeneity with which the items within the measure reflect the same concept) are described in Table 5. Validity refers to whether a pain instrument accurately measures pain and not something else (LoBiondo-Wood & Haber, 1994). There are three components of validity: content (theory), construct (pain), and criterion (gold-standard) validity (see Table 5). Furthermore, a measure should also

demonstrate some clinical utility and feasibility, which depends on the extent to which health professionals can rely on data as accurate and meaningful indicators of pain for a particular population of interest (Stevens, 1998). Clinical utility and feasibility are of paramount importance for the acceptability of a measure in clinical practice.

As seen in Table 5, the extent to which the pain measures were tested for reliability and validity varied enormously in terms of sample size, methods, and context. For instance, the strength of the CHIPPS is the large sample size used to apply rigorous methods of validation in different settings and populations of young children. The PIPP was also extensively validated in a large number of infants, and used in ventilated neonates (Anand, Coskun et al., 1999), in very low birth weight infants to measure the efficacy of sucrose treatment (Stevens, Johnston, Franck et al., 1999), and in other premature babies to determine the efficacy of EMLA cream (Stevens, Johnston, Taddio et al., 1999). The NFCS is another pain measure that demonstrated validity for preterm, full term and older infants in different contexts (Hadjistavropoulos, Craig, Grunau, & Whitfield, 1997). These results reinforce the construct validity of these measures. One might assume that postoperative pain decreases over time, but in reality this may not be true, because pain treatment seems to be more aggressive in the immediate postoperative period, especially if the patient is intubated. In fact, in a study by Van Dijk (2000), the participants' pain scores were particularly low, as postoperative analgesia was routinely provided. Specificity and sensitivity were examined in several measures. Most measures are specific to pain (true positive) and sensitive to no pain situations (true negative). However, none of

the measures examined its sensitivity in relation to concepts other than pain, such as anxiety. In this respect, most measures lack sensitivity (Franck, 2002).

Criterion validity was established in most cases by comparing the measure under study to another validated pain measures (see Table 5). High correlation was expected as the measures had similar items. Other measures, such as the NFCS, the BPS, and the TPPS, used physiologic variables (heart rate and systolic blood pressure, respectively) as a criterion for pain.

Only a few measures demonstrated some aspects of clinical utility and feasibility. Clinical utility, including readability, understandability, time, scoring, and relevance of the items was evaluated in three measures (Blauer & Gertsmann, 1998). The authors reported that NAPI and RIPS were preferred over POPS, but all were acceptable. The NFCS and the PIPP were shown to be applicable at the bedside with minimal instructions and practice required for adequate clinical use (Ballantyne, Stevens, McAllister, Dionne, & Jack, 1999; Grunau, Oberlander, Holsti, & Whitfield, 1998). Good clinical utility and feasibility were also reported for the CHEOPS, OPS, TPPPS, and FLACC (Suraseranivongse et al., 2001).

The number of items and scoring system are other factors to consider when evaluating the feasibility of a measure. The number of items or categories to which a score is attributed differed between pain measures and varied between three and 13 items. Seven plus or minus two items are, however, recommended to optimise reliability (Johnston, 1998).

The scoring system varied *between* measures resulting in different total scores. This difference in scoring makes the interpretation of pain scores difficult. To facilitate implementation and use in institutions, a standardised 0-10 scoring system was recommended for paediatric pain assessment tools (von Bayer & Hicks, 2000). The scoring system given for each item also varied *within* measures. For instance, in the CHEOPS cry can be scored 1, 2, or 3 and facial 0, 1, or 2. One study reported that the SUN was preferred over the Comfort scale and the NIPS for its consistency and scale symmetry (Blauer & Gertsmann, 1998). The asymmetry in scoring each item represents an additional drawback to the feasibility of a measure.

Conclusion

Critically ill children are particularly exposed to pain. Unrelieved pain may have dramatic consequences in this vulnerable group of children. Optimal management of pain can only be achieved through adequate recognition of pain behaviour. Nevertheless, for health professionals, the assessment of pain in critically ill young children is particularly challenging, due to factors such as severity of illness and age that are likely to affect pain responses and in addition to the difficulty in differentiating pain from other constructs.

A comprehensive review of the literature revealed 28 pain measures for preverbal children, including 11 neonatal measures. How the measures were developed differed greatly; some were constructed based on experts' opinions or the literature, some were modified from other existing measures, and others were developed from observations of video recorded behaviour. Generating items from children observed in situations where it would be reasonable to assume that they are experiencing pain

seems to be the most appropriate method for tool development. The measures in this review were shown to be valid and reliable, but the context in which the studies were performed varied enormously. They also lacked information to determine whether they are suitable for critically ill young children or not. Six neonatal measures (PAIN, SUN, NFCS, IBCS, NIPS, and EDIN) and one measure, the COMFORT scale, included critically ill infants and critically ill preverbal children, respectively. The authors conclude that PAIN, SUN, NFCS, IBCS, NIPS, and EDIN are recommended for use in critically ill premature and term newborns, as they were specifically developed for this group of infants. For older critically ill children aged between 0 and 36 months, the COMFORT scale is the only valid measure available, with the limitation that it does not discriminate between pain and sedation.

Recommendations

Because of the lack of evidence determining how critically ill children respond to procedural and postoperative pain, it is important to investigate this area further. A rigorous method of observation using videos in clinical situations where it is assumed that critically ill children are experiencing pain is warranted. When investigating pain in context where analgesia is routinely provided, such as in an intensive care situation, level of sedation should be measured together with pain as some analgesics (e.g. opioids) can produce sedation and mask pain behaviour.

It is also argued that new pain assessment tools should be developed specifically for critically ill young children, based on pain behaviour observed in them.

CHAPTER THREE

Methodology of the Study

This thesis describes the development and initial testing of a pain assessment instrument for critically ill preverbal infants, and is based on a process of instrument development that is derived from psychometric theory. From this perspective, instrument development involves four main stages:

- conceptualisation of the phenomenon of interest;
- development of the instrument;
- establishing the psychometric properties of the instrument; and
- evaluation of the clinical utility of the instrument.

Chapter Three provides a discussion of the four stages of instrument development as a backdrop to the specific methods used in each phase of this study and detailed elsewhere in this thesis.

Step One: Conceptualisation of the Phenomenon

The process of instrument development should begin with a clear definition of the concept to be measured, in this study, postoperative pain (Beck, 1999; De Vellis, 2003). Pain is a concept difficult to define, as it is a subjective and personal experience (American Pain Society, 1992). Numerous authors have sought to define this complex phenomenon in physiological, psychological, as well as philosophical terms (Mahon, 1994; North American Nursing Diagnosis Association, 1992), but the

following definition of the International Association for the Study of Pain (IASP) remains the reference for most researchers:

"An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage...Pain is always subjective. Each individual learns the application of the word through experiences related to injury in early life..." (Merskey & Bogduk, 1994a, p. 1).

This definition, however, has caused much debate recently amongst scientists and clinicians (Anand & Craig, 1996a, 1996b; Craig, 1997; Merskey, 1996, 1997; Wall, 1997). Firstly, the subjectivity of the pain experience and the emphasis on self-report implies that the subject is aware of his/her experience and is able to report it. This assumption, however, cannot apply to those who are limited in their capacity to self-report pain, including preverbal children, developmentally delayed, comatose, pharmacologically impaired, mentally ill, demented, verbally handicapped individuals, as well as non-human species (Craig, 1997). Secondly, the conclusion that can be drawn from the statement "…each individual learns the application of the word through experiences related to injury in early life…" (Merskey & Bogduk, 1994a, p. 1) is that newborn infants cannot experience pain because they have not as yet learnt the word. This would have major consequences for the assessment and management of pain in this group of children (Craig, 1997; Shapiro, 1999). Finally, the concept of consciousness in relation to the application of the IASP definition of pain to nonverbal humans has been extensively discussed (Anand, Rovnaghi, Walden, & Churchill, 1999; Chapman & Nakamura, 1999), but as Casey (1999) notes, theories related to consciousness have limited utility in understanding pain because the neural mechanisms of pain and consciousness are significantly different.

Casey suggests that some degree of consciousness present at some level might be sufficient for the capacity of experiencing pain. This view accords with the assumption that the infant's pain has mainly sensory and emotional components (Sweet, McGrath, & Symons, 1999), and that the cognitive component of self-awareness is not necessary for the perception of pain. It has been suggested also that individuals whose cognition is impaired have defensive and adaptive reactions to pain in order to survive (Anand, Rovnaghi et al., 1999).

As a result of this debate, Merskey (1997), who formulated the original pain definition in the mid 1960's, suggested an alternative model for the diagnostic of pain (often called pain behaviour) in subjects who are not capable of reporting pain. This model proposes that adequate assessment of pain relies on several criteria being met:

1. an adequate brain structure must be present to make possible the occurrence of consciousness and pain;
2. typical pain behaviour must be present;
3. any other causes must be excluded; and
4. a likely cause of pain must be present.

"…criteria 1), 2), and 3) together should lead to the conclusion of probable pain, while all four criteria should equal inferred pain" (Merskey, 1997, p. 121).

In this study, pain is conceptualised as "… an inherent quality of life, which occurs in all viable organisms with a nervous system…the actual experience of pain must precede verbal reports of pain, and that the relationships between feeling pain and

reporting pain are highly context dependent" (Anand, Rovnaghi et al., 1999, p 64-65). This new perspective of pain is applicable to critically ill preverbal children, as it recognises that even premature infants have the full anatomical and functional abilities to perceive pain and that biochemical, physiological and behavioural responses are valid pain indicators. This multidimensional conceptualisation of pain coupled with Merskey's criteria (cited above), form the theoretical underpinning for this study. This has been described more completely in Chapter Four.

Step Two: Development of the Instrument

Conceptualisation of the phenomenon of interest predicates developing an instrument to measure the phenomenon. Instrument development is largely a process of establishing face and content validity. Face validity indicates that a measure 'appears' to test what it is supposed to, and is considered to be an important step in scale development, because it reflects whether a measure appears applicable in clinical practice. Content validity is defined as 'the extent to which an instrument adequately samples the research domain of interest when attempting to measure phenomena' and represents an essential step in the construction of new instruments (Wynd, Schmidt, & Schaefer, 2003, p. 509). Face and content validity are both subjective measures, but in comparison, the test of content validity is considered to be more scientifically valid (Gross Portney & Watkins, 1993).

Lynn (1986) suggested a two-phase process for establishing content validity. The first phase, also called the 'developmental phase', includes identification of the domain of content through a comprehensive literature review, selection of the items, and construction of the instrument, including the scoring system and instructions for

use. The second phase, or 'judgment/quantification phase', is the experts' evaluation of the content validity using a Likert-type rating scale. The proportion of experts who agree with the relevance of the items included in the measure provides an accurate measure of content validity.

Developmental Phase

Identification of the domain of content

An extensive review of the literature of pain in infants and young children was performed to identify the indicators relevant to the population of interest, namely critically ill preverbal children. Several reviews on the subject have already been published (Abu-Saad, 1998; Finley, 1998; Hensley, 1999; Warnock & Lander, 2004). To complement the existing literature, a review on pain measurement and its challenges in critically ill infants and young children was performed and is presented in Chapter Two of this thesis (Ramelet, Huijer Abu-Saad, McDonald, & Rees, 2004).

Selection of items

The selection of items for observational measures is paramount, as the items will reflect the components of the construct of pain. In this study, due to the limited data on how critically ill infants display pain behaviour, the items selected for the development of an observational pain scale were generated from direct observation of children who could best reflect the experience of the target population, as recommended by Finley and McGrath (Finley & McGrath, 1998). The items were selected from the item bank developed in the first phase of the study (presented in Chapter Four). This process was complemented by a review of the literature. The

following criteria were applied to the selection of relevant literature for this stage of instrument development (Finley & McGrath, 1998):

- articles should describe pain responses that can be included in the measure
- the components should be described in the population of patients of interest
- the components should be described in detail
- if there is a level of responses related to the components, it also should be explained
- the number of articles referring to each component should be reasonable.

Construction of the scale

The process of a scale construction involves arranging the items selected in a chosen scoring system, providing definitions for each item and establishing instructions for clinical use. In this study, a 0 to 10 scoring system was chosen as a common metric for paediatric pain measures (von Bayer & Hicks, 2000). The remaining items were grouped, by the researcher, into five categories and global statements were created on a 3-point scale. Each statement included a comprehensive definition for adequate scoring. A minimum score of 0 represented no pain and a maximum score of 10 extreme pain. This stage of instrument development was one focus of Phase Two of this study, and is detailed in Chapter Five.

Judgment/quantification phase.

In the 'judgment/quantification phase', a panel of experts evaluates the scale and rates the items that are relevant to the domain of content, in this context 'pain'. This

is an objective method for quantitatively measuring content validity (Lynn, 1986). In this study, a questionnaire was developed and pilot tested to collect information on the relevance, the clarity, and the complexity of the new pain tool (see Appendix C). The relevance of the item was evaluated by six paediatric intensive care nurse specialists using a four-point Likert-type ordinal scale. A four-point scale was used in order to dictate a directional decision and avoid any tendency for scores to cluster around a central score (Lynn, 1986). The definitions of the Likert-type scale were 1=relevant, 2=quite relevant (needs minor revisions), 3=somewhat relevant (needs major revisions), and 4=not relevant. According to Lynn, ratings of 1 and 2 are considered 'content valid' and ratings of 3 and 4 'content invalid'. The proportion of items that received a rating of 1 or 2 by the experts (100% in this study) provided the content validity index (CVI) (Wynd et al., 2003). Experts were also asked to evaluate the wording of the items and definitions, as reported by Beck (1999). Clarity and complexity of the MAPS items were similarly assessed using a four-point Likert-type ordinal scale (Beck, 1999). Finally, the expert panellists were asked to provide qualitative comments on the items with which they disagreed. The results are presented in Chapter Five also.

Step Three: Establishing Psychometric Properties

After selection and initial validity testing of items for inclusion, instrument development proceeds to the third stage of establishing reliability and validity of the total instrument. The measurement of reliability and validity is integrated in psychometric theory. Reliability is defined as how free from error is the true score. It is the replicability or the extent to which similar results can be reproduced over time

using the same instrument. Reliability of an instrument may be assessed by measuring the degree of internal consistency and interrater reliability. Test-retest correlation, which results from administering the same measurement instrument twice to the same group, is also a common measure of reliability, but was not an appropriate test in this study because pain varies over time. Validity, on the other hand, is the extent to which an instrument measures the construct it is intended to measure, which is postoperative pain in the context of this study (Nunnally & Bernstein, 1994). A common evaluation of validity in measurement instruments is to assess the degree of construct validity. Several approaches can be used to establish construct validity, including the hypothesis-testing approach, the convergent approach, the contrasted-groups approach, and the factor analytic approach (LoBiondo-Wood & Haber, 1994). Hypothesis-testing and convergent approaches are commonly used to test the construct validity of pain measures and were chosen to test the construct validity of the MAPS for their validity in a relatively small sample (Stevens, 1998). Data collection forms were developed and pilot tested for measurements at set times on eight occasions after surgery (Appendix D) and before and after boluses of morphine (Appendix E).

Internal consistency

Internal consistency, also called homogeneity, is a preliminary requirement for both reliability and construct validity of a scale (American Educational Research Association, American Psychological Association, & National Council on Measurement in Education, 1999; Nunnally & Bernstein, 1994). Internal consistency is the extent to which items measure the same concept. If the items of the MAPS are reliable, they should reflect the true pain score, and any variance should be

attributable solely to differences between subjects, not error (Gross Portney & Watkins, 1993, p. 62). An item correlation coefficient greater than 0.50 is indicative of the MAPS' internal consistency. Internal consistency of the MAPS was assessed in two different situations, at set times during the postoperative period (Chapter Six) and in response to a potent dose of analgesics (Chapter Seven).

Interrater Reliability

Consistency in measurement is of major importance to the validity of any research study, whether one individual does all the measurement or several raters are involved. Due to the changing nature of pain over time and the impracticality of videorecording, test-retest reliability could not be performed in this study. However, the variation between the raters (or assessors) who attributed the same pain scores in the same group of subject, namely interrater reliability, was tested. Pain scores, derived using the newly developed pain assessment instrument 'MAPS' were attributed simultaneously and independently by two blind assessors. To optimise the reliability of the data, staff involved in data collection attended a rigorous training program that is described in detail in Chapter Six.

Construct Validity

The establishment of construct validity is a complex process that often involves several studies. Phase Two of this thesis presents the first attempt to validate the MAPS and provide some evidence to support its construct. A commonly used method is to assess how two measures believed to reflect the same phenomenon (in this instance pain) would converge (convergent approach). The measure chosen for

this test was the FLACC (acronym for face, legs, activity, cry and consolability). The FLACC is a measure that recently demonstrated validity and reliability in PICU children from 3 years of age (Manworren & Hynan, 2003), and in postoperative children aged between 2 and 7 years (Merkel et al., 1997; Willis, Merkel, Voepel-Lewis, & Malviya, 2003). It includes 5 categories of pain behaviours: face, legs, activity, cry, and consolability, each of which is scored 0, 1, or 2, resulting in a total score ranging between 0 (= no pain) and 10 (maximum pain). The FLACC was used simultaneously with the MAPS to establish convergent validity and the results are presented in Chapters Five and Six.

The hypothesis approach testing was another method used to support the construct validity of the MAPS. In Phase Three of this study, it was hypothesised that pain scores would decrease after the administration of a potent dose of morphine (see Chapter Six).

Criterion-related Validity

Criterion-related validity is based on the ability of one measure to predict results on another measure. One component of criterion-related validity is concurrent validity. Concurrent validity is useful in situations where a new measure is potentially more efficient than another more established method of measurement. The newly developed measure to be tested is usually compared with a "gold standard" or criterion measure (Gross Portney & Watkins, 1993). However, as there is no "gold standard" for pain assessment in non-verbal patients, the criterion measure selected for this exercise was the VAS observer (VAS_{obs}). The VAS is commonly used as an observational measure to report pain intensity in preverbal children (Lawrence et al.,

1993; Peters et al., 2003; Robieux et al., 1991; Taddio, Nulman et al., 1995; Tarbell et al., 1992; van Dijk et al., 2000). Concurrent validity of the VAS_{obs} and other pain scales was shown to vary considerably, but correlation coefficients tend to increase when observers are trained or experts (van Dijk, Koot, Saad, Tibboel, & Passchier, 2002). Therefore, in this study, trained clinical nurses (CNs) with expertise in pain assessment were asked to attribute a pain score independently of each other using the VAS (VAS_{CN}). The VAS_{CN} was used concurrently with the MAPS to establish concurrent validity at set times during the postoperative period (see Chapter Five) and in response to analgesia (Chapter Six).

Clinical Utility

Even if a measure has sound psychometric properties, if it is not feasible for use in a clinical setting or does not provide useful clinical information, then it is of little value to a clinician (Polgar & Barlow n.d.; Stevens & Gibbins, 2002). These characteristics determine the clinical utility of an assessment tool, the determination of which represents the final stage in instrument development. Although a crucial stage in the development process, clinical utility is a characteristic that has received little attention in the literature.

Clinical utility testing aims to determine the usefulness of a measure in a particular setting with a specific population (Abu-Saad et al., 1998). For a measure to be clinically useful or possess clinical utility, it must evolve toward high levels of acceptability and convenience for those who use it. Although clinical utility has not been clearly defined, it includes the following components (American Educational Research Association et al., 1999; Johnston, 1998; Stevens & Gibbins, 2002):

- Availability and ease of use
- Administration time
- "Learnability" and clinician's qualifications
- Format
- Scoring and information derived
- Meaningful and relevant information obtained

For successful implementation of an assessment tool into practice, the tool should rate highly in all of the above components. Clinical utility of the MAPS was assessed using a questionnaire that was developed and pilot tested for this purpose, and included questions addressing the components cited above (Appendix F). Questions on (a) administration time (e.g. time required to perform pain assessment), (b) format (overall layout of the scale), and (c) acceptability (perceived usefulness of the scale) were included. Each question was rated on a 5-point Likert-type scale. The definitions of the Likert-type scale were 1=very useful, 2=useful, 3=undecided, 4=not useful, and 5=not useful at all. The questionnaire also included a question regarding administration time and several open-ended questions for recommendations or other comments. The questionnaire was sent by internal mail to all staff nurses, six months after the introduction of the MAPS for clinical use. The results are presented in Chapter Six.

Ethical Considerations for the Study

Research in children presents scientific, ethical and practical challenges. Children are considered a vulnerable group and require special consideration for participation in

research (Rischbieth & Blythe, 2005). It is the health professionals' and institutional ethics committees' duty to weigh the risks and burdens of paediatric research participation against the potential benefits. It is fundamental that research conducted with children has high scientific merit and integrity and is undertaken with proper respect, beneficence, and justice for the paediatric participants (The Royal Australasian College of Physicians, 2005b).

Scientific and ethics approval to conduct this study was obtained from the University Graduate Studies Committee and the Human Research Ethics Committee at Curtin University of Technology's, Perth. Following ethics approval from the university, the study proposal was submitted to the Ethics Committee of both hospitals. The study proposal submitted to the hospital in Lausanne, Switzerland, was translated by the principal investigator, using the back translation technique. Back translation was performed by the PICU medical Director, who is fluent in English, followed by a final review by both parties to ensure the validity of the translated study proposal.

Gaining Informed Consent

Respect for persons requires that participation in research usually occurs after the participant has made a voluntary decision, based on sufficient information and understanding, and free of coercion or inappropriate incentives. The term of 'informed consent' is applied to this process and assumes that the recipient is competent to make a decision (The Royal Australasian College of Physicians, 2005b). Essential elements for competence recognised by common law include comprehension and retention, belief and balancing information so as to choose (Leaver, 2005). Consent to medical treatment, and by comparison to research, can be

given by a young person of any age as long as they possess the capacity to make that decision. No minimum age limit has been formally set in the *National Statement on Ethical Conduct in Research Involving Humans,* but Leaver (2005) suggests that competence required for consent can be assumed at 7 years of developmental age. For children under this age, surrogate consent must be obtained by, in all but special circumstances, the parents or the legal guardian. The parents or the legal guardian, then, have the ethical and the legal responsibility for weighing information and making decisions in the best interests of their child. However, parents, whose child has been admitted to an intensive care unit, are subject to enormous psychological stress and may feel loss of control. In these circumstances, parents' mental ability to consent may be impaired (Downer, 1996). The assessment of parental competence to consent, therefore, is paramount for ensuring that informed consent takes place and the child's best interests are protected.

In Phase One and Two of this study, permission was given by the hospitals to approach parents or guardians of infants meeting the inclusion criteria of the study. Parents or legal guardians were given written and verbal information about the study by the principal investigator (Appendix G and Appendix H), and asked to provide written consent for their child to be included in the study (Appendix I and Appendix J). They were fully informed of the nature of their child's participation in the study, including that no drugs would be withdrawn and no additional interventions would be performed for the purpose of the study. They were provided with information about the purpose, methods, demands, risks and burdens of the study. They were advised of their right to choose not to participate in the study, and to withdraw at any time, without prejudice. They were also informed of the measures that would be

taken by the researcher to ensure their child's and their own confidentiality and that no participants would be individually identified in reports or publications. Finally, all parents or guardians were provided with information on how to contact the researcher and the Director of the Clinical Care Unit if necessary.

In Phase Three, the PICU nurses working in the Western Australian institution were invited to participate in the study by completing an anonymous questionnaire. As consent to participate in the study was implied by the voluntary return of the completed questionnaire, no written consent was necessary for this phase of the study.

Potential Benefits to Participants

The *Helsinski Declaration* stipulates "…legally incompetent minor… should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons" (World Medical Association, 2000, paragraph 24, p. 3-4). In accordance with the Helzinski Declaration, the Paediatrics and Child Health Division of the Royal Australasian College of Physicians recommends that research in children should be conducted in situations where it will "ensure optimal diagnosis, assessment…of disease during childhood, advance the health and welfare of children, contribute to understanding the pathophysiology of childhood disease, …, and improve the methodology of research in children" (The Royal Australasian College of Physicians, 2005b, p. 9). This research met all of these conditions.

Potential Risks

The potential risks associated with participation in a study must be adequately and transparently disclosed to research participants or, in this instance, to the parents/legal guardians. Information about the potential risks and benefits must be clearly explained in written form so that parents/legal guardians can adequately 'weigh up' the research risks against the benefits and make a decision in the best interests of their child or the community (Rischbieth & Blythe, 2005). Evaluation of the impact of the research on the family structure and function should also be considered (Gonzales, Dever, & Singleton, 1997; The Royal Australasian College of Physicians, 2005b).

Observational research, such as this study, is considered "minimal risk" to research participants (The Royal Australasian College of Physicians, 2005b). For critically ill children, minimal risk occurs when the degree of risk implied by participation in research is no more than the risk posed by their disease process and standard therapy (Rischbieth & Blythe, 2005). In this study, potential risks related to video recordings were identified. Health professionals who cared for the participants may have felt scrutinised and challenged in their professional practice. The parents or guardians of the participants may have felt intimidated and uncomfortable in the presence of the camera. In addition, the prospect of giving consent for their child's participation in the study might have caused additional stress for parents while they were dealing with having a critically ill child in intensive care.

Risk Management Procedures

The risks of physical, psychological, social, and economical harm related to participation in this study were minimised by implementing procedures specific to this study in order to meet the NHMRC recommendations (National Health and Medical Research Council, 2002). These included the following:

- Information related to the study provided to parents/guardian was given by the principal investigator in a private room, at a time considered appropriate by the health team (Casarett, Karlawish, Sankar, Hirschman, & Asch, 2001).
- Consent to participate in this study was entirely voluntary and participants were free to withdraw at any time with no prejudice.
- Confidentiality was assured by using de-identified data. No participant was individually identified in reports or publications.
- All registered nurses and other health professionals were informed of the purpose of the study and received appropriate training prior to the commencement of each phase of this study.
- The camera audio was turned off during recording to make participants and health professionals feel at ease as much as possible and to ensure they could not be identified.
- Video recording was focused on the child, so that appearance of health professionals was minimised.
- The institutions' protocol was in place in the occurrence of adverse events related to the study.

Formatted: Bullets and Numbering

Confidentiality

The confidentiality of all participants was assured throughout the conduct of the study. Coding systems were applied to the video recordings, the participants' medical records, and all data collection forms. No individual unit or person was individually identified in the final report or publications. Video recordings will not be used for purpose other than the study without consent. All data and information related to this study has been kept in strict confidentiality and locked in filing cabinet accessible to the principal investigator only. Records will be kept in a secure place for five years following completion of the study and destroyed after this time.

Concluding Remarks

The different stages of instrument development described in this chapter provided a theoretical framework for the conduct of this study. Every effort was made to ensure that each stage was unbiased and accurate and met the standards for psychometric testing and the ethical requirements for conducting research in children. Altogether, the multi-stage process of instrument development described has been applied rigorously and systematically throughout and therefore supports the integrity of the study. The findings of the different stages of instrument development are described in detail throughout this thesis. A review of the literature relevant to pain assessment in critically ill young children is presented in Chapter Two. The construction and psychometric testing of the instrument, and testing its clinical utility, are described in detail in the next three chapters, Chapter Four, Five, and Six, respectively.

CHAPTER FOUR

Results – Phase One

Capturing Postoperative Pain Responses in Critically ill Infants aged 0 to 9 months

The previous chapter presented the process of tool development, based on psychometric theory. This chapter presents the results of the first phase of this process. This includes the conceptualisation of pain in infants and a detailed description of pain observed in critically ill infants who had major surgery.

This chapter is also presented in the format of a journal article that was accepted for publication in *Pediatric Critical Care Medicine 2006;7(1):19-26* and selected as a feature article for continuing education. The paper was co-authored by Supervisors Professor Huda Huijer Abu-Saad, Professor Sue McDonald, and Associate Professor Nancy Rees, and biostatistician Max Bulsara who were happy to have it included in this thesis.

Abstract

Objectives: The purpose of this study was to describe physiologic and behavioural pain behaviours in postoperative critically ill infants. A secondary aim was to identify how these pain responses vary over time.

Design: This observational study was conducted in the pediatric intensive care unit at two tertiary referral hospitals. Using ethological methods of observation, video recordings of postoperative infants were viewed to depict different situations of pain and no pain, and then coded using a reliable checklist.

Patients: 803 recorded segments were generated from recordings of five critically ill infants aged between 0 and 9 months who had undergone major surgery.

Measurements and main results: There was an 82% agreement between the two coders. Multivariate analyses showed that physiologic responses differed only when adjusted for time. Significant decreases in systolic and diastolic arterial pressure ($p<0.001$ and $p=0.036$, respectively) were associated with postoperative pain exacerbated by painful procedures on day 2. On day 3, however, heart rate, arterial pressure (systolic, diastolic, and mean), and central venous pressure significantly increased ($p<0.05$) in response to postoperative pain. Indicators included vertical stretch of the mouth, hand twitching, and jerky leg movements for postoperative pain and increase in respiratory distress, frown, eyes tightly closed, angular stretch of the mouth, silent or weak cry, jerky head movements, fist, pulling knees up, and spreading feet for postoperative pain exacerbated by painful stimuli.

Conclusions: Findings support the ability to capture different intensities of postoperative pain in critically ill infants, beyond neonatal age. These pain indicators can be used for the development of a pain assessment tool for this group of infants.

Introduction

Infants who are critically ill and in pain are at risk of developing serious and life-threatening complications because their ability to maintain homeostasis in a state of stress is restricted (Mitchell, 1999). To avoid complications and promote recovery, effective treatment of pain is of paramount importance.

Effective pain management relies on early recognition of the signs and symptoms of pain, which is best achieved by self-report. Although self-report remains the accepted gold standard for the assessment of pain (Merskey & Bogduk, 1994b), it is inappropriate for nonverbal children (Anand, Rovnaghi et al., 1999). Health professionals, therefore, have to rely on pain responses and other contextual cues, such as age and diagnosis, to determine the presence and severity of pain in infants (Abu-Saad & Hamers, 1997; Craig et al., 2002). Several reviews of infants' pain responses have been published in the last few years (Abu-Saad et al., 1998; Franck & Miaskowski, 1997; Stevens, Johnston, & Gibbins, 1999). A more recent review by Warnock and Lander (2004) revealed that the pain indicators most commonly used in infants were a) behavioral, including cries, facial expressions, and body movements; b) physiologic; and c) biochemical.

Most of these studies investigated pain, typically by observing responses at baseline and during a painful stimuli for a short period of time (mainly ranging between 10

and 60 seconds) (Warnock & Lander, 2004). The main types of procedures associated with painful stimuli included heel lance (Harrison, Evans, Johnston, & Loughnan, 2002; Johnston et al., 1999; Lindh et al., 1999; Stevens, Johnston, Taddio et al., 1999; Taddio, Shah, Gilbert-MacLeod, & Katz, 2002), intra-muscular injection (Cohen Reis, Kraus Roth, Syphan, Tarbell, & Holubkov, 2003; Grunau et al., 1990; Lindh, Wiklund, Blomquist, & Hakansson, 2003; Taddio, Katz, Ilersich, & Koren, 1997), and circumcision (Butler-O'Hara et al., 1998; Howard et al., 1994; Porter, Porges, & Marshall, 1988). However, information on the participants' severity of illness was limited but when specified, participants of these studies were either healthy infants or sick as a result of premature birth.

The utility of pain indicators observed in healthy infants is limited for the assessment of pain in critically ill infants. For instance, measurement of the acoustics of cries is problematic in the intensive care environment, as the noise level and other monitors may interfere with the recording technology used (Franck & Miaskowski, 1997). Furthermore, interpretation of cry in intubated infants must be cautious as these infants may only be able to demonstrate signs of silent cry and tears (Curley et al., 1992). Other cues, such as facial expressions, are reported valid and reliable indicators of pain in infants (Craig et al., 1994; Grunau & Craig, 1987, 1990; Grunau et al., 1990; Grunau et al., 1998; Johnston et al., 1993; Taddio et al., 1997), older children (Gilbert et al., 1999; Lilley et al., 1997) and adults (Hadjistavropoulos, LaChapelle, Hadjistavropoulos, Green, & Asmundson, 2002) of diverse severities of illness. However, some expressions might be difficult to assess in infants receiving oxygen therapy, as the devices may mask the upper lip and mouth stretches. In addition, the physiologic pain responses frequently reported in the literature, though

being sensitive to pain and relatively easy to ascertain at the bedside, can be influenced by various other physiologic conditions. Biochemical responses also lack specificity and cannot be measured at the bedside. A novel measure, heart rate variability, may provide valuable information on the regulation of the autonomic nervous system and sensitivity at different levels of pain intensity (Lindh et al., 1999; Morison, Grunau, Oberlander, & Whitfield, 2001; Porter et al., 1988). Further investigation needs to occur prior to clinical application, especially in infants with organ failure (Rosenstock, Cassuto, & Zmora, 1999).

The existing pain measures are inappropriate for this group of infants, as they mostly include indicators that were observed in either healthy or sick premature infants (Ramelet et al., 2004). One of these pain measures, the comfort scale, initially developed to measure distress in the paediatric intensive care patients (Ambuel et al., 1992), is the only measure that was validated for postoperative pain in critically ill children aged between 0 and 36 months (van Dijk et al., 2000). This measure, though widely used in PICUs (Azzam, Pascucci, Curley, & Laussen, 2001; Crain, Slomin, & Ollack, 2002; Curley & Molengraft, 1995; Curley, Thompson, & Arnold, 2000; Nadkarni et al., 1999; Summer & Puntillo, 2001), does not discriminate between pain and other causes of distress, making the interpretation and clinical application of the COMFORT score difficult.

Clearly, there is insufficient data on how postoperative critically ill infants beyond the neonatal stage respond to pain, and existing pain measures may not include appropriate indicators of pain for this population. As further validation of a non-specific measure will not improve its specificity (Franck, 2002), it seemed judicious

to develop a new pain measure that would include indicators of pain observed in situations where it would be reasonable to assume that these children are experiencing pain (Johnston, 1998). In the intensive care environment, critically ill infants are likely to experience breakthrough pain during the postoperative period and during painful procedures. Therefore, the objective of this observational study was to describe pain behaviour and the associated physiologic responses in critically ill infants during the postoperative period. A secondary aim was to identify how these pain indicators varied over time. This study was conducted as part of a larger study that aimed to develop and validate a pain measure for postoperative critically ill infants. This phase of the study aimed to answer the following research questions:

- What indicator(s) best describe pain in postoperative critically ill infants?
- How do these pain indicators vary over time?

Materials and Methods

This observational study was conducted in the pediatric intensive care units (PICU) at two tertiary referral hospitals, in Western Australia (site I) and Switzerland (site II). The sample for this study consisted of 803 recorded segments of behaviours observed in five postoperative critically ill infants. Given the descriptive nature of the study, the small number of subjects was appropriate for the methodology (Morse & Bottorf, 1990). Rather than the number of subjects, it is the large number of observations that made the parameter estimates more robust and likely to be the true reflection of the actual values. Subjects were aged between 0 (≥37 weeks gestational age at birth) and 12 months, who required major chest elective surgery, and were

admitted to the intensive care unit immediately after surgery. Surgical newborn infants were included in the study, as they were transferred to the PICU during the immediate postoperative period. Infants were excluded from the study if they presented with neurological or developmental impairments or altered muscle tone.

Scientific and ethical approval was obtained from each hospital's ethics committee. Consent was gained from parents or guardians the day prior to surgery. Each patient was videotaped after having obtained permission from the nursing and medical staff responsible for their care. Each infant received routine care, and was videotaped between 08:00 am and no later than 09:00 p.m., so that the lighting required for videorecording would not disturb the infants' day-night cycle.

On admission, each infant was connected immediately to a monitor (Philips® model M1167A opt.A68) that recorded, as part of routine procedures, heart rate (HR) and rhythm, intraarterial blood pressure, central venous pressure (CVP), oxygen saturation (SaO_2), respiration rate (RR), and end-tidal CO2 ($ETCO_2$). Physiologic and behavioural responses were recorded simultaneously for a period of up to six hours on days one, two and three after surgery (up to a total of 18 hours). As soon as the infant was settled into the unit, videorecording commenced using super high-grade tapes in a colour-VHS camera mounted on a tripod at the end or the head of the bed to provide a direct anterior view of the infant's gross-motor behaviour and facial expressions. A time-date generator was used to superimpose a digital-time display on the video and was calibrated with that of the monitor used, so that a specific event could be selected and coded in relation to physiologic parameters. To ensure accuracy of the observations and facilitate analyses, VHS data were transformed into

a digital format and edited using Macromedia Director® a multimedia computer program for Macintosh®.

Total amount, infusion rate and additional boluses of analgesics, sedatives, and other drugs given during the study period were documented on a separate sheet. Demographic data including age, gender, weight, medical diagnosis, type of surgery, and medical history were also documented.

Two levels of data analysis were conducted in this study: qualitative and quantitative. As opposed to previous research models, where researchers typically compared behaviours between painful and non-painful stimuli in controlled environments (Grunau & Craig, 1987; Grunau et al., 1990; Stevens, 1990; Warnock & Sandrin, 2004), postoperative pain in this study was determined using the principles of an ethological approach. "Ethology is a method of systematically observing, analysing, and describing behaviour within the context in which it occurs" (Morse & Bottorf, 1990, p. 54). Ethology has been used for the study of human behaviour (Kitchin & Hutchinson, 1996; Penrod, Morse, & Wilson, 1999), including infants' pain behaviour (Cote, Morse, & James, 1991; Warnock, 2003). In this study, it was assumed that regardless of the amount of analgesia and/or sedation given, breakthrough pain could be captured in infants who exhibited typical physiologic/behavioural responses. Analyses of the videorecorded behaviour were undertaken using an observation technique that develops from an inductive phase to a more structured deductive phase.

The inductive phase included the identification of patterns of behaviours and the development of a checklist, using recordings from a pilot infant. To identify patterns of behaviour (e.g pain or no pain), the pilot infant's videotape was viewed in real-time and slow motion and interpreted using the following four criteria: a) likely cause for pain, b) intact brain function, c) typical expressions of behaviour, and d) exclusion of other causes for behaviour (Merskey, 1997, p. 121). Medication, hemodynamic status, type of painful procedure and other environmental stimuli, as well as other psychological factors (e.g. departure of parent) were considered during this process. Four categories depicting different patterns of behaviour were identified: (a) deeply sedated: the infant was not responding to noxious stimuli: (this category is not presented in this paper as there was no significant difference between deeply sedated and no pain); (b) no pain: the infant was at rest or was sleeping with no external stimuli or interventions, and no apparent behavioural or physiological pain was observed; (c) postoperative pain (PO pain): the infant was responding to external stimuli, including interventions considered non-painful (e.g. chest auscultation). Other causes for the behaviour had also been excluded (e.g. crying at parents' departure or sudden decrease of blood pressure following change of inotropic drugs); and (d) postoperative pain exacerbated by painful procedures - (POP pain): the infant was responding to painful interventions (e.g. chest drain removal, endotracheal suctioning).

The checklist was then developed from observations of the pilot infant following the process described by Cote et al. (1991). Label codes from the Neonatal Facial Coding System (Grunau & Craig, 1987) and the Infant Body Coding System (Hadjistavropoulos et al., 1997) were used to describe observed facial expressions

and body movements when appropriate. The initial checklist was refined (clarification of the definitions and omission of redundant items) until acceptable agreement (>90%) between two independent observers was reached. Agreement was calculated using the following formula (Gross Portney & Watkins, 1993, p. 516):

$$\%Agreement = \frac{(\text{number of exact agreements})}{(\text{number of possible agreements})} \times 100 .$$

A value above 80% is indicative of good reliability. The refined checklist comprised 76 behavioural codes grouped into 16 categories (Table 6).

Table 6. Checklist of Behavioural Codes

Ventilation	**Breathing pattern**
mechanical (fully ventilated)	normal
trigger (initiating ventilator breath)	distressed (tachypnea, use of accessory muscles, coughing, gagging on tube)
handbag (intubated, disconnected from ventilator)	signs of crying (cannot assess breathing because of cry)
disconnected from ventilator (intubated)	
CPAP mask	
spontaneous (extubated)	
Body position change	**Arms movements**
unchanged	no movements
repositioning	limited (movements that do not reach its purpose)
	well-modulated purposeful movements
	pulling/resisting movements
	free jerky movements
Forehead	**Arms restraint**
smooth	no restraint
frown	restrained
Eyes movements	**Hands movements**
open and alert	no movements/relaxed
closed relaxed	purposeful grasping
tightly closed	twitching
	fist
Mouth position	**Torso movements**
closed relaxed	no movements/relaxed
horizontal stretch	limited movements
vertical stretch	twisting
angular stretch (cry)	jerky uplifting of torso and buttocks
Mouth movements	**Legs movements**
no movements	no movement/relaxed
non-nutritive sucking	limited (movements that do not reach its purpose)
mouthing (soundless speech)	stretching legs
gagging	resisting
crying	pulling knees up (in one motion)
	free jerky movements
Head movements	**Feet movements**
no movements	no movements/relaxed
limited movements	spreading toes
well modulated, purposeful movements	grasping
jerky movements (abrupt movements from side to side)	twitching
Touch by person A	**Touch by person B**
no contact	no contact
equipment	equipment
endotracheal tube	endotracheal tube
restraining	restraining
physiotherapy	physiotherapy
endotracheal suctioning	endotracheal suctioning
soothing	soothing
chest auscultation	chest auscultation
tape removal	disinfection of wound
oxygen mask repositioning	chest drains removal
urine catheter flush	stiches removal

Due to the unpredictability of pain responses, a non-randomised time-sampling method was used to select segments of the five infants' videorecording (Morse & Bottorf, 1990, p. 58). For practicability reasons, a ten-second segment was selected every five minutes of the total recording time for each participant. Ten-second segments have been reported as sufficient to observe a behavioural response to painful and non-painful stimuli (Craig et al., 1993). Each segment was attributed a category of behaviour (e.g. no pain or PO pain) and coded using the checklist. Ten percent of these segments were randomly selected and coded independently by the second trained observer to establish interrater reliability, using the formula cited above.

The deductive phase consisted of quantifying the items and then, using descriptive and multivariate analysis, determining the best predictors (Morse & Bottorf, 1990). Data analyses were carried out using the Statistical Package for the Social Sciences (v.11.5, SPSS, Chicago, IL) and multivariate analyses using the Statistical Analysis System (v.8, SAS, Cary, NY). Descriptive statistics were generated to describe the characteristics of the sample and the distribution of the behavioural responses observed in each category. Multivariate statistics were used to predict the pain responses observed in the 803-videorecorded segments. Responses observed in the no pain group were compared with those observed in the pain groups (PO and POP pain). If the difference between the groups was significant, further analysis was conducted to compare pain responses between PO and POP pain. Due to an unbalanced design (missing values at random) with repeated measures, Generalized Linear Mixed Model (GLMM) was used to calculate an unbiased estimate of the mean for continuous data (Cnaan, Laird, & Slasor, 1997).

Ordinal data were dichotomised into binary format (e.g. movements and no movements). If there was a difference between movements and no movements, the type of movements was further analysed by creating another binary variable (e.g. limited movements and other movements). This procedure was carried out for each indicator that occurred more than 20% of the time. Generalized Estimating Equations (GEE) modelling, using the GENMOD procedure was used to identify variables that could best predict PO and POP pain. GEE modelling provided an estimate of the association between binary outcome (behaviour) and predictor variables (e.g. painful stimuli). This model takes into account the potential association with pain responses among several observations for a given subject (Carlin, Wolfe, Coffey, & Patton, 1999; Svensgaard, Bangdiwala, Marshall, & Waller, 1996). An estimated odds ratio corresponds to the likelihood of the behaviour being present in the different categories: no pain, postoperative pain, and postoperative pain exacerbated by painful procedures (POP pain).

Results

Demographics of the five postoperative cardiac infants, aged between 7 days and 9 months, are presented in Table 7. Eight hundred and three videorecorded segments of these infants were included in the study. Interrater reliability of the checklist used for analysing these segments showed 82% agreement between the two observers.

Table 7. Demographics of the participants

	Infant one	Infant two	Infant three	Infant four	Infant five
Age	8 months	7 months	9 months	7 days	9 months
Weight	7.6 Kg	5.6 Kg	8.3 Kg	2.8Kg	7.6 Kg
Gender	Male	Female	Male	Female	Male
Diagnosis	TGA[a]	Truncus[b]	TF[c]	CoA[d]	TF[c]
Surgical procedure	Glenn	Total repair	Total repair	Total repair	Total repair
Morphine in mcg/Kg/h					
Median (range)	20 (30)	5 (40)	20 (20)	10 (30)	14 (20)
Midazolam in mcg/Kg/h					
Median (range)	70 (100)	0 (100)	100 (100)	None	30 (100)
Number of days	3	3	2	3	3
Number of hours	19	10.5	10.5	19	13
Number of observations	219	137	141	140	166

[a] Transposition of Great Arteries; [b] Truncus Arteriorius; [c] Tetralogy of Fallot; [d] Coartation of Aorta

Physiologic Indicators That Best Describe Pain in Postoperative Critically ill Infants

Physiologic indicators that changed significantly in response to postoperative pain when compared to no pain, included increases in heart rate from 145 bpm to 147 bpm ($p=0.04$), mean and diastolic arterial pressure (from 67 mmHg to 68 mmHg, $p=0.04$) and (from 53 mmHg to 54 mmHg, $p=0.01$), and CVP (from 14 cmH_2O to 16 cmH_2O, $p<0.001$) . In response to POP pain, one variable, CVP, increased significantly from 14 cmH_2O to 17 cmH_2O ($p<0.001$) compared to no pain. No significant differences were found in the six remaining physiologic indicators.

How physiologic indicators varied over time

Comparison of no pain and PO and POP pain, when adjusted for time, provided statistically and clinically different results from the collated data presented above. *On day one*, there were no significant changes (p>0.05) between no pain and the two categories of postoperative pain for all physiologic variables. *On day two*, the mean central venous pressure (CVP) increased significantly from 14.5 cmH_2O to 16.0 cmH_2O (p=0.002) in response to PO pain. All remaining variables (HR, MAP, $ETCO_2$, SaO_2, and RR) did not change significantly in response to PO pain. In response to POP pain, significant decreases were noted in systolic arterial pressure (89 mmHg to 82 mmHg, p<0.001) and diastolic arterial pressure (53.0 mmHg to 50.5 mmHg, p=0.036). *On day three*, the four variables (HR, SBP, MAP, and DBP) increased significantly in response to PO and POP pain (Figure 1).

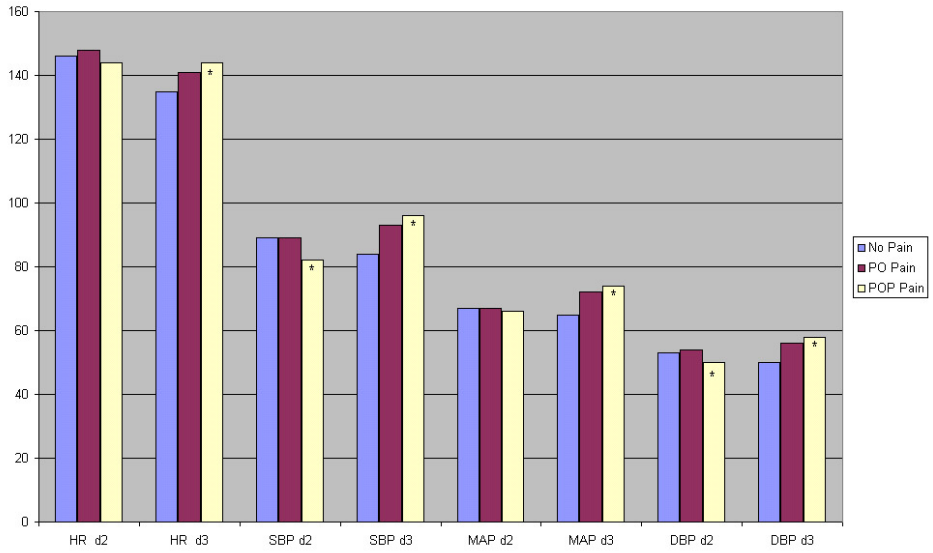

Figure 1. Physiologic responses to PO and POP pain when compared to no pain on day two (d2) and day three (d3). HR: heart rate in beats per min.; SDB: systolic blood pressure in mmHg; MAP: mean arterial pressure in mmHg; DBP: diastolic blood pressure in mmHg

* significant at p<0.001 when compared to no pain.

Behavioural indicators that best describe pain in postoperative critically ill infants

Preliminary analyses consisted of computing the frequency and percent occurrence of the behavioural indices for the three behavioural categories: no pain, PO and POP pain (Table 8). GEE analyses revealed that, when compared to no pain, infants experiencing PO and POP pain were more likely to develop or increase existing respiratory distress and show typical facial expressions and body movements (See Table 9).

Table 8. Behavioural indicators by category of no pain, PO and POP pain

Behavioural indicators[a]	No pain	PO pain[b]	POP pain[c]
	Count (percent within category)		
Breathing pattern			
Normal	245 (93)	228 (70)	6 (15)
Distressed	19 (7)	63 (19)	23 (55)
Crying	-	37 (11)	13 (31)
Forehead			
Smooth	245 (94)	154 (49)	5 (13)
Frown	17 (6)	163 (51)	34 (87)
Eyes			
Closed relaxed	240 (91)	64 (20)	3 (7)
Tightly closed	23 (9)	145 (46)	32 (80)
Open	-	108 (34)	5 (13)
Mouth position			
Closed mouth	212 (88)	103 (36)	3 (9)
Vertical stretch	3 (2)	93 (33)	5 (15)
Angular stretch	-	43 (15)	22 (65)
Mouth movements			
No movements	236 (97)	136 (50)	7 (20)
Crying	-	55 (20)	21 (60)
Head movements			
No movements	261 (99)	121 (37)	10 (24)
Jerky	-	92 (28)	27 (64)
Arms movements			
No movements	259 (99)	134(41)	6 (15)
Limited movements	1 (1)	78 (24)	15 (37)
Pulling	-	66 (20)	19 (46)
Hand movements			
No movements	244 (96)	107 (37)	4 (13)
Twitching	1 (1)	73 (25)	8 (27)
Fist	8 (3)	52 (18)	15 (50)
Torso movements			
No movements	261 (100)	158 (48)	10 (25)
Limited	-	45 (14)	9 (22)
Twisting	1 (0)	111 (34)	19 (48)
Legs movements			
No movements	243 (98)	92 (28)	2 (5)
Limited	2 (1)	70 (22)	8 (20)
Resisting	2 (1)	6 (2)	9 (23)
Pulling knees up	-	46 (14)	12 (30)
Jerky	-	89 (27)	7 (17)
Feet movements			
No movements	183 (97)	43 (20)	0 (0)
Spreading	1 (1)	23 (10)	12 (46)
Grasping	4 (2)	87 (40)	10 (39)
Twitching	-	67 (30)	4 (15)

Note Table 8. [a] indicators that occurred more than 20% of the time in at least one of the category are presented in this table; [b] PO Pain: postoperative pain; [c] POP pain: postoperative pain exacerbated by a painful stimuli

Table 9. Significant factors associated with predicting behaviour of PO and POP pain compared to no pain

Behavioural indicators	PO pain [a]		POP pain [b]	
	Odds Ratio	95% CI	Odds Ratio	95% CI
Respiratory distress	4.4	1.9 - 10.1	40.4	19.8 - 82.2
Frown	14.7	6.7 - 32.4	100.5	36.0 - 280.7
Eyes tightly closed	24.8	10.4 - 59.6	62.4	18.9 - 206.2
Mouth movements	34.2	11.7 - 99.8	109.3	25.7 - 465.5
Open mouth	4.5	3.7 - 5.4	30.5	7.7 - 121.6
Head movements	140.1	16.9 - 1162.6	185.4	17.7 - 1944.4
Arms movements	183.8	33.2 - 1017.4	428.2	70.0 - 2616.8
Hand movements	34.5	12.5 - 95.6	99.7	24.7 - 403.3
Torso movements	265.5	60.7 - 1162.1	711.6	139.4 - 3632.6
Leg movements	308.6	49.5 - 1922.3	1488.8	128.7 - 1722.3
Feet movements	60.42	13.5 - 270.5	-	-

[a] PO Pain: postoperative pain; [b] POP pain: postoperative pain exacerbated by a painful stimuli

Additional GEE analyses revealed that when compared to POP pain, infants experiencing *PO pain* were more likely to display vertical stretch of the mouth (OR = 3.42; 95% CI 2.23 to 5.25), hand twitching (OR = 2.89; 95% CI 2.22 to 18.51), and jerky leg movements (OR = 3.74; 95% CI 1.16 to 12.06). When compared to PO pain, infants experiencing *POP pain* were more likely to show signs of respiratory distress (OR = 0.15; 95% CI 0.07 to 0.32), frown (OR = 0.15; 95% CI 0.06 to 0.36), eyes tightly closed (OR = 62.36; 95% CI 2.94 to 5.33), angular stretch of the mouth (OR = 0.19; 95% CI 0.08 to 0.46), silent or weak cry (OR = 0.49; 95% CI 0.44 to 0.55), jerky head movements (OR = 0.32; 95% CI 0.19 to 0.55), fist (OR = 0.15; 95% CI 0.03 to 0.74), pulling knees up (OR = 0.22; 95% CI 0.07 to 0.70), and spreading feet (OR = 0.20; 95% CI 0.04 to 0.97). No significant difference was found between PO and POP pain for torso and arms limited movements, twisting, pulling arms, and grasping and twitching feet.

How behavioural indicators varied over time

As most behavioural indicators were not present in the no pain group, comparison to this group could not be done. Day three was therefore used as the intercept for the following GEE analyses. *On day one* when compared to day three, infants were less likely to demonstrate respiratory distress ($p<0.001$), eyes tightly closed ($p=0.003$), mouth movements ($p<0.001$), mouth position ($p=0.031$), head movements ($p=0.046$), hands movements ($p=0.025$), arms movements ($p=0.004$), and torso movements ($p=0.017$). There was no significant difference in the remaining behavioural indicators between day one and day three.

On day two, when compared to day three infants were more likely to demonstrate respiratory distress ($p=0.025$), frown ($p<0.001$), eyes tightly closed ($p<0.001$), mouth movements (p=.001), and stretch of the mouth ($p<0.001$). There was no significant difference in the remaining behavioural indicators between day two and day three.

Discussion

While there are many studies of pain in infants, none to our knowledge has explored the different pain behaviours in postoperative critically ill infants. In addition, this study is unique in the sense that it explored a range of physiologic and behavioural responses, over time, and offers new information on how critically ill infants respond to postoperative pain and postoperative pain exacerbated by painful stimuli.

An interesting result of our study was related to the physiologic changes observed in both pain groups. Significant increases in heart rate and blood pressure were noted in

response to PO pain, but not to POP pain. This can be explained by a lack of statistical power to detect a difference, due to the small number of observations in the POP pain category. In addition, although the difference of two heartbeats per minute and one mmHg is statistically significant, it is unlikely to be clinically relevant. However, when adjusted for time, GLM analyses of the physiologic variables provided different results.

On day one postsurgery, no significant physiologic changes were noted in response to both PO and POP pain. This probably reflects appropriate management of pain and sedation at this time when the participants remained intubated and deeply sedated.

On day two and in contrast with other studies (Cohen Reis et al., 2003; Taddio, Goldbach et al., 1995; Taddio et al., 1997; Walden et al., 2001), there was, in response to POP pain, an eight and five percent decrease in systolic and diastolic blood pressure, respectively. This physiologic response could be explained by an increased vagal reflex associated with severe pain (Porter et al., 1988), as the type of procedures (chest drain removal and/or endotracheal suctioning) performed at this postoperative stage were likely to cause pain of high intensity. Indeed, chest drain removal and endotracheal suctioning were reported in a national survey as the most painful interventions by adults and older children who underwent cardiac surgery (Puntillo, 2003). On the same day and in response to postoperative pain, physiologic parameters failed to change significantly when compared to no pain. This later finding is in accord with recent postoperative pain reports. In a study involving preverbal children post major surgery, Van Dijk et al. (2000) reported a weak

correlation between physiologic parameters (heart rate and mean arterial pressure) and behaviour (alertness, calmness, respiratory response, crying, physical movement, muscle tone, and facial tension) in the immediate postoperative period.

On day three of our study, however, heart rate and blood pressure increased significantly in response to both PO and POP pain. One explanation of these results for postoperative pain could be that by day three, physiologic instability that occurs in the immediate postsurgery period has resolved, resulting in the infants' physiologic capacity to respond to pain in this way. These results are supported by previous studies that have demonstrated increased heart rate and blood pressure in infants experiencing procedural pain (Abu-Saad, 1998; Franck & Miaskowski, 1997)

In our study, the GEE statistical model permitted determination of which behaviour was likely to occur more frequently in the two pain situations (PO versus POP pain). Specific postoperative pain indicators included the following expressions: vertical stretch of the mouth, hand twitching, and jerky leg movements. Specific indicators of POP pain included development of or increase in respiratory distress, frown, eyes tightly closed, angular stretch of the mouth, silent or weak cry, jerky head movements, fist, pulling knees up, and spreading feet. There are similarities between PO and POP pain indicators, as shown by our study where eyes tightly closed, frown, and horizontal stretch of the mouth were also observed in infants experiencing postoperative pain. These findings were supported by another study that explored postoperative pain behaviour in infants aged 0-18 months, using the NFCS, the modified COMFORT scale, and plasma concentrations of catecholamine and morphine (Peters et al., 2003). This later study showed that a) the NFCS (initially

validated for procedural pain) was significantly correlated with the modified COMFORT postoperative scale and b) a reduction of the NFCS to 5 items increased the specificity without reducing the sensitivity of the pain scale. These items included brow bulge, eye squeeze, nasolabial furrow, horizontal stretch of the mouth, and taut tongue.

In our study of critically ill infants, pain indicators new to our knowledge include description of breathing pattern, silent or weak cry, and limited body movements. These findings were partly supported by another study conducted in PICU, in which children who experienced painful procedures grimaced, became rigid, winced, and closed their eyes (Morris et al., 2002). Severely ill infants may not have the physiologic ability to respond vigorously to pain due to their prematurity or their severity of illness (Franck & Miaskowski, 1997), as demonstrated by studies involving vulnerable infants whose responses to pain include limited or absence of body movements (Grunau, Holsti, Whitfield, & Ling, 2000; Stevens, Johnston, Franck et al., 1999). However, similar responses were also observed in healthy infants experiencing extreme distress during circumcision, including breath holding, and exhausted cry and weak sounding, strained movements of head and neck, fist, and intentional upper limbs movements (Warnock & Sandrin, 2004). Diminished response may be a sign of a lack of physiologic ability to respond to pain of extreme intensity.

These results were generated using a rigorous observational method and patterns of behaviour were consistent with theoretical assumptions, suggesting that the behavioural and physiologic responses depict pain in postoperative critically ill

infants. It is, nevertheless, possible that the responses observed during the postoperative period may have been influenced by other factors, such as hunger, thirst, or other emotional distress. However, because distress is an inherent component of pain (Breau, McGrath, Camfield, Rosmus, & Finley, 2000; Warnock & Sandrin, 2004), probable postoperative pain could not be ignored in the observation process. To validate the interpretation process in which the diagnostic of pain was made, all criteria of the conceptualisation of pain in infants were present and every effort was made to identify other causes for the observed response (e.g. sudden decreases in blood pressure following change in the administration of inotropic drugs).

This study provides a novel description of pain behaviour in critically ill infants beyond neonatal age. In contrast to the work of Warnock (2003), who provided a very detailed description of facial expressions, body movements, and limbs position, the checklist used in this study included comprehensive descriptions of pain behaviour in real time and in the context in which the behaviour occurred (in this instance the intensive care environment). Findings of our study also support the use of ethological principles of observation to capture different intensities of postoperative pain in critically ill infants beyond neonatal age. This approach aimed to describe how postoperative critically ill infants respond to pain over a 3-day period and provide pain indicators that could be easily observed by health professionals in clinical practice. These pain indicators formed the basis for the development of a pain assessment tool that has been used in the next phase of the larger study, which aimed to develop and validate a pain measure for postoperative critically ill infants.

CHAPTER FIVE

Results - Phase Two

Development and Preliminary Psychometric Testing of the Multidimensional Assessment of Pain Scale: MAPS

The previous chapter introduced the first phase of tool development, and described the pain indicators observed in postoperative critically ill infants. This chapter presents Phase Two of the thesis, and describes the development process of the Multidimensional Assessment of Pain Scale (MAPS) and the results of the preliminary psychometric testing of the scale. The MAPS was developed using a selection of items that were described in Phase One of the study as well as items described in the literature. Following the construction of the MAPS, including face and content validity, a series of psychometric tests were undertaken to establish the internal consistency of the scale, Interrater reliability, and convergent and concurrent validity. These preliminary psychometric analyses provided the initial psychometric properties essential for the clinical use of a new instrument. This preliminary testing also provided important information to guide further testing of the MAPS.

This chapter is also presented in the format of a journal article that has been submitted for publication in the peer-reviewed journal *Pediatric Anesthesia*. The paper was co-authored by Supervisors Associate Professor Nancy Rees, Professor Sue McDonald, and Professor Huda Huijer Abu-Saad, and biostatistician Max Bulsara who were happy to have it included in this thesis.

Abstract

Background: This study aimed to test the preliminary psychometric properties of the Multidimensional Assessment Pain Scale (MAPS), a clinical instrument developed for assessing postoperative pain in critically ill preverbal children.

Methods: The MAPS was developed using pain indicators observed in postoperative critically ill infants. Content validity was established by a panel of experts. The scale was tested for validity and reliability in 43 postoperative children aged 0 to 31 months admitted to the paediatric intensive care units of two tertiary referral hospitals, one in Western Australia and one in Switzerland. Pain was measured concurrently by three independent assessors using the MAPS, the Face, Leg, Activity, Cry, and Consolabilty scale (FLACC) and the Visual Analogue Scale (VAS) to assess concurrent and convergent validity.

Results: Internal consistency was moderate (r=0.68). Interrater reliability of the MAPS was good (Kappa 0.68 - 0.84) for all categories and moderate for breathing pattern (Kappa 0.54). Excellent interrater reliability was shown for total MAPS (ICC 0.91). Agreement measurements between MAPS and FLACC and MAPS and VAS showed that the risk of measurement error was small.

Conclusion: The development and initial validation of the MAPS provides health professionals with a tool to facilitate and standardise pain assessment in critically ill preverbal children. Although its psychometric properties are promising, the MAPS requires further psychometric testing, including responsiveness to analgesic effect (currently in progress).

Introduction

Unrelieved pain in critically ill children may have dramatic short and long-term consequences (Anand, Grunau, & Oberlander, 1997; Bhutta & Anand, 2002; Grunau, 2002; Porter et al., 1999). To avoid these as well as unnecessary suffering, it is essential to treat pain promptly and appropriately. This task, however, presents many challenges to health professionals. The adequacy of pain management relies largely on the accuracy of pain assessment. Self-report is considered the gold standard for pain assessment, but is not possible in preverbal children. Consequently, health professionals have to rely on physiological measures and behavioural cues to determine the presence and severity of pain in these children. However, up to now these cues have been described typically in healthy or moderately sick infants (Franck & Miaskowski, 1997; Warnock & Lander, 2004), and may therefore have limited relevance for pain assessment in young children who are critically ill (Ramelet et al., 2004).

Numerous instruments have been developed in attempts to maximise accuracy of pain assessment in infants and older children, but only two measures, the COMFORT scale (van Dijk et al., 2000) and more recently the FLACC scale (Manworren & Hynan, 2003) have been evaluated in critically ill children after surgery. The COMFORT scale was designed originally to assess distress in ventilated children (Ambuel et al., 1992) and demonstrated validity as a measure for assessing the effects of sedation (Azzam et al., 2001; Brunow de Carvalho, Lucas da Silva, Paulo, Fonseca, & Belli, 1999; Marx et al., 1994; Nadkarni et al., 1999; Reed, Yamashita, Marx, Myers, & Blumer, 1996). The original COMFORT scale comprises eight items (alertness, calmness, respiratory response, physical movement,

muscle tone, facial tension, mean arterial pressure, and heart rate) measured on a 5-point rating scale, providing a total score ranging between 8 (no pain) and 40 (maximum pain). Because these items were also defined as pain indicators, the COMFORT scale was recently validated as a measure of postoperative pain in preverbal children (van Dijk et al., 2000) and in children admitted to a paediatric intensive care unit (PICU) (Carnevale & Razack, 2002). As a result of item analyses in this latter study, the physiological component of the COMFORT scale was removed, despite behaviour-physiology correlations rising with increasing pain intensity (van Dijk et al., 2001). Irrespective of the version used, the lack of differentiation on the COMFORT scale between sedation and pain is problematic for the clinician, who makes decisions about which medication, sedative or analgesic, would best meet the patient's needs. To facilitate clinicians' decision-making, Van Dijk et al. (2000) added an observational VAS (VAS_{obs}) score to the COMFORT assessment. However, the adequacy of a VAS_{obs} rating is dependent on the observer's level of expertise and competence in pain assessment, and cannot be always assumed. Indeed, underestimation of pain in children by nurses is well documented in the literature (Beyer et al., 1990; Colwell, Clark, & Perkins, 1996). Furthermore, VAS_{obs} optimal cut-off points for the administration of analgesics have yet to be determined, limiting its utility in clinical practice (van Dijk, Koot et al., 2002).

The FLACC scale, acronym for Face, Leg, Activity, Cries, and Consolability, is another measure that has been validated in the PICU population (Manworren & Hynan, 2003). Sensitivity to change was evaluated in a small sample of children (n=22) admitted in a PICU, by comparing FLACC scores before and after analgesic

administration. The FLACC scale was shown to be sensitive to administration of analgesics, including opioids, non-opioids, or a combination of both.

The FLACC scale as well as the modified version of the COMFORT scale ($COMFORT_{behaviour}$) comprise one behavioural dimension only. Recent data suggest that physiologic measures may add some value to the diagnosis of high postoperative pain intensity. In a validation study involving paediatric intensive care children aged 0 to 36 months, Van Dijk et al. (2001) reported that the correlation between the COMFORT scale's behavioural and physiologic items increased with pain intensity. Our previous work also suggests that heart rate and blood pressure vary in postoperative infants experiencing painful procedures when compared to baseline measures (Ramelet, Abu-Saad, Bulsara, McDonald, & Rees). Further, based on the theoretical underpinning of pain as a multidimensional phenomenon (Merskey & Bogduk, 1994b), it is recommended that both dimensions be taken into account for its assessment (Abu-Saad & Hamers, 1997).

Existing pain measures may not include indicators that are specific to the critically ill preverbal child and evaluating such a measure would not make it more specific or sensitive (Franck, 2002). The objective of this study was, therefore, to develop and test the preliminary psychometric properties of the Multidimensional Assessment Pain Scale (MAPS) as an accurate clinical instrument for assessing postoperative pain in critically ill preverbal children. The hypothesis for this study was "there is a positive correlation between MAPS and two other pain assessment instruments (FLACC and VAS)".

Materials and Methods

Selection of the Items

Thirty six items were selected from the total of 64 items that were identified in our previous study, which provided a detailed description of the behavioural and physiological responses observed in a sample of critically ill infants in pain (Ramelet et al., 2006). This process was supplemented by a search of the literature to compile a list of valid pain indicators for sick infants (Abu-Saad et al., 1998; Franck & Miaskowski, 1997; Ramelet et al., 2004). This list of pain indicators was compared with the items identified in our previous study to ensure that all relevant items were considered in this selection process. Items that could not be measured easily at the bedside or that would not be routinely monitored were excluded to ensure the instrument would be clinically useful. Although the majority of the selected pain indicators were observed in infants (0-9 months of age), the authors felt it important to extend the psychometric tests of the newly developed scale to older children (0 to 3 years), as this age group represents the majority of the children admitted to PICUs (Australian and New Zealand Paediatric Intensive Care Registry, 2004). Furthermore, children in this age category have common characteristics in relation to pain expression, such as the inability to verbalise their experience of pain and the ability to display similar facial expressions in response to pain (Johnston et al., 1993).

Construction of the Scale

A 0 to 10 scoring system was chosen as a recommended metric for paediatric pain measures, whereby a minimum score of 0 indicated no pain and a maximum score of 10 extreme pain (von Bayer & Hicks, 2000). The 36 items were grouped into five categories and global statements were created on a 3-point scale. This meant that a total score between 0 and 10 was achieved after scoring each category between 0 and 2. Each category statement included a comprehensive definition for adequate scoring. For instance, frown, eyes tightly closed, and vertical pull at the corners of the mouth with lips partially or completely parted were defined as a grimace. The scale was named the Multidimensional Assessment Pain Scale as it contained physiologic and behavioural dimensions. Creation of an acronym (MAPS) that could be easily remembered was also considered in this process. To ensure face and content validity, a multidisciplinary panel of seven independent experts, all volunteers, commented on the clarity, complexity, and relevance of the MAPS and its definitions. The final version of the MAPS and definitions of each component category are presented in Tables 10 and 11.

Table 10. Scoring System of the Multidimensional Assessment of Pain Scale©

Categories	0	1	2	Score
Vital signs HR and/or BP	Within baseline	More than 10 bpm increase and/or more than 10 mmHg increase	More than 10 bpm decrease and/or more than 10 mmHg decrease	
Breathing pattern	No change	Development or increase of Respiratory distress	Severe Respiratory distress	
Facial expressions	Relaxed	Grimace	Grimace associated with silent or weak cry	
Body movements	No movements or Purposeful movements	Restless	Rigid and/or limited Body movements	
State of arousal	Calm or asleep	Hyperreactive	Shut down	
Total Score				

Table 11. Definitions of the each Category of the Multidimensional Assessment of Pain Scale

Definitions
Vital signs Record baseline measures when the child has been stabilised and is comfortable. • Score 0 if heart rate and blood pressure measures are consistently within baseline measures • Score 1 if heart rate increased more than 10 bpm and/or blood pressure (SBP or DBP) increased more than 10 mmHg compared with baseline measures. • Score 2 if heart rate decreased more than 10 bpm and/or blood pressure (SBP or DBP) decreased more than 10 mmHg compared with baseline measures.
Breathing Pattern • Record baseline measure at the beginning of each shift when the child is obviously asleep or comfortable with no external stimuli • Score 0 if there is no change in breathing pattern compared to baseline measure. • Score 1 if there is an increase in rate and work of breathing and/or paradoxical breathing. For the intubated patient, it may also include fighting the ventilator (↑ Respiratory distress) • Score 2 if respiratory distress is severe and compromising oxygenation
Facial Expressions • Score 0 if the infants' face is relaxed, with eyes closed relaxed, mouth closed relaxed, and smooth forehead. • Score 1 if the infant grimaces (frown, eyes tightly closed, and distinct vertical pull at the corners of the mouth with lips partially or completely parted). • Score 2 if the infant shows frequent grimace is associated with silent cry (tears associated with angular stretch mouth in the intubated patient) or weak cry (non-intelligible, low-pitched sounds; moaning) • Please note that silent cry that is associated with the departure of a parent cannot be scored.
Body movements • Score 0 if the infant demonstrates purposeful or no movements of head, torso, arms, hands, legs and feet. • Score 1 if the infant is restless demonstrating jerky leg movements, twitching hands and feet, twisting or writhing • Score 2 if the infant shows rigid body movements that are stiff, firm and unbending (including pulling knees up, spreading feet, fist clenched, twisting/writhing and/or limited torso movements) or limited body movements that are naturally limited in its purpose and or slow in motion.
State of arousal • Score 0 if the infant is calm or asleep (no external stimulus is required to elicit purposeful or calm movements, awakens easily) • Score 1 if the infant is hyperreactive: highly or excessively responsive or reactive to a non-painful stimulus (noise, touch, light, etc.) (Increased state of arousal) • Score 2 if the infant's behaviour is shutdown: decreased physical alertness and activity; does not communicate; or no eyes contact.

Translation

As data collection was undertaken in one non-English setting, the pain measures (MAPS and FLACC) were translated into French by the bilingual principal investigator, whose first language is French. The instruments were back translated by an independent bilingual registered nurse, who did not read the original English version. The authors adhered to standard translation practices, including blind back translation, and expert evaluation of equivalence by bilingual and French speaking nurses (American Educational Research Association et al., 1999; Tang & Dixon, 2002; White & Elander, 1992). In this study, discussion amongst translators and two senior nurses who were not previously involved in the translation process was used to rephrase any unclear or incorrect statements in the French versions.

Staff Training

Prior to other psychometric testing, all nursing and medical staff attended an introductory tutorial on the subject of the study protocol. Self-learning packages, including background information on pain, pharmacology, and the standardised sedation and pain management protocol of the unit were distributed to all nurses. Finally, the clinical nurses involved in data collection were asked to demonstrate competency in using the MAPS in a random selection of 20 video clips (similar clips were used in the pilot testing) organised in forms of three vignettes, and in real time at the bedside. Issues pertaining to the study protocol, including use of the pain measures, were discussed directly with the principal investigator. In addition, a total of eight clinical nurses were trained to use the MAPS and three senior medical registrars to use the FLACC.

Reliability and Validity

These psychometric tests were conducted in the paediatric intensive care unit (PICU) at a tertiary referral hospital in Western Australia and in Vaud, Switzerland. A convenience sample of approximately 40 critically ill preverbal children aged between 0 and 36 months, requiring major chest or abdominal elective surgery, and admitted to the intensive care unit immediately after surgery was drawn from the paediatric intensive care population. Children were excluded from the study if they were 36 weeks or less gestational age and/or presented with neurological impairments or altered muscle tone.

After scientific and ethics approval from the hospital committees, parents or guardians of infants who met the inclusion criteria of the study were approached by the principal investigator for consent prior to admission to the intensive care unit. On arrival in the unit and once the child had been stabilised, baseline measures were recorded. Heart rate, invasive blood pressures, and respiratory rate were continuously recorded on a calibrated monitor (Agilent® version 6.00.11). Neuromuscular blockade and cardiac pacing were assessed and documented on arrival and at each time point of observations. Up to eight measurements of pain were performed by two independent raters - the bedside nurse and the clinical nurse on duty- over a maximum period of 48 hours postsurgery. Pain measurements were attributed using three measures: the MAPS (see Tables 10 and 11), the Visual Analogue Scale (VAS) (van Dijk, Koot et al., 2002) and the FLACC (Merkel et al., 1997).

The VAS is a 10 cm-horizontal continuous line, with anchors of 0="no pain" and 10="the worst possible pain" at both extremities (McGrath, Unruh, & Finley, 1995;

Wewers & Lowe, 1990). The VAS is commonly used as an observational measure to report pain intensity in preverbal children (Lawrence et al., 1993; Peters et al., 2003; Robieux et al., 1991; Taddio, Nulman et al., 1995; Tarbell et al., 1992; van Dijk et al., 2000). Concurrent validity of the VAS observer (VAS_{obs}) and other pain scales can vary considerably, but correlation coefficients tend to increase when observers are trained or experts (van Dijk, Koot et al., 2002).

The FLACC is a measure that recently demonstrated validity and excellent reliability in PICU children from 3 years of age (Manworren & Hynan, 2003), and in postoperative children aged between 2 and 7 years (Merkel et al., 1997; Willis et al., 2003). It includes 5 categories of pain behaviours: face, legs, activity, cry, and consolability, each of which is scored 0, 1, or 2, resulting in a total score ranging between 0 (= no pain) and 10 (maximum pain).

To avoid judgmental bias, the VAS_{obs} score was administered first by a trained clinical nurse and senior medical registrar on duty, both with expertise in pain assessment. Immediately after that, the same clinical nurse and senior medical registrar administered the MAPS and the FLACC score, respectively. Simultaneously and independently, the bedside nurse attributed another MAPS score. The VAS_{obs} and the FLACC were used concurrently with the MAPS to establish concurrent and convergent validity, respectively.

Data analyses were carried out using SPSS (Statistical Package for the Social Sciences) version 11.5 (SPSS Inc., 2003). Data indicating neuromuscular blockade and/or regular cardiac pacing at the time of observation were excluded from further

analyses. Reliability analyses consisted of assessing the MAPS' internal consistency by calculating Cronbach's alpha coefficient and interrater reliability, using Cohen's Kappa statistic for categorical data. The Kappa statistic is a chance-corrected measure of agreement between two raters (in this study, the bedside nurse and a clinical nurse) on the same rating (the MAPS score). In practice, a Kappa value greater than 0.80 represents excellent agreement, where a value below 0.40 represents poor agreement no better than chance (Altman, 1996; Portney & Watkins, 1993). For continuous data on the interval and ratio scales (total MAPS and physiologic parameters, respectively), intra-class correlation (ICC) reliability coefficient was calculated using variance estimates obtained through an analysis of variance. ICC represents the degree of correspondence and agreement among two or more raters on the same rating. A Cronbach's alpha coefficient above 0.75 is indicative of good reliability (Portney & Watkins, 1993).

Convergent and concurrent validity of the MAPS was measured by assessing agreement between MAPS and FLACC and MAPS and VAS_{obs} using a statistical method described by Bland and Altman (1986). The method is based on the differences between measurements on the same subject by two different measures. The difference between two methods, the standard deviation of the difference, and the mean difference were calculated; the mean difference representing the estimated bias, the difference and standard deviation the random fluctuations around the mean. The difference was plotted against the average of two measures (MAPS and FLACC, MAPS and VAS_{obs}). The 95% limits of agreement and the mean difference plus or minus 2 standard deviations demonstrate how far apart pain scores attributed by two measures were likely to be for most children in the study population. To evaluate

whether there was any considerable difference in agreement, a linear regression analysis was performed. An increasing regression line shows that the difference in agreement increased as pain score increased.

Results

Demographic Results

Forty-three children aged between 0 and 31 months (median 9.5, IQR 3.9) participated in this study. The majority (n=30, 61.2%) were intubated and ventilated at the time of observation and were ventilated for a period ranging from 2.5 to 402 hours (median 26, IQR 28). Risk of death estimated by the Paediatric Index of Mortality (PIM) scores ranged between 0.2% and 19.6% (median 1.31%, IQR 1.21%). The mean weight of this sample was 7.4 Kg (±2.9). Other background characteristics of these children are presented in Table 12.

Table 12. Characteristics of the participants

Characteristics		Count (%)
Gender	Male	23 (53.5)
	Female	20 (46.5)
Ethnic background	Caucasian	35 (81.3)
	African (central and north Africa)	3 (7.0)
	Asian (central and south-east asia)	2 (4.7)
	Native Australian/New Zealander	1 (2.3)
	Mixed race	2 (4.7)
Type of surgery	Cardiac	30 (69.8)
	Cranial vault remodelling	5 (11.6)
	Thoracotomy	2 (4.7)
	Laparatomy	2 (4.7)
	Other	4 (9.3)
Complications	None	38 (88.4)
	Cardiac arrest	2 (4.7)
	Renal failure	1 (2.3)
	Chest reopening (bleed)	1 (2.3)
	Failed extubation [a]	1 (2.3)

[a] Failed extubation was defined as a need to reintubate within 4 hours post extubation.

Reliability

Examination of the correlation matrix showed no redundant items. The item total correlations ranged from 0.10 to 0.65. Overall Cronbach's alpha coefficient for the 5-item MAPS was 0.68. The internal consistency test also showed that Cronbach's alpha would increase to 0.86 if the item 'vital signs' was deleted.

Interrater reliability of the MAPS, represented by Kappa's statistic, was good to excellent for 4 categories, ranging from 0.68 to 0.84 (Table 13). Interrater reliability for breathing pattern was moderate (0.54). Excellent interrater reliability was shown by intra-class correlation coefficients for total MAPS (r=0.91), VAS_{obs} (r=0.89), HR (r=0.99), SBP (r=0.98), DBP (r=0.98), MAP (r=0.99), and RR (r=0.98).

Table 13. Kappa's for each Multidimensional Assessment of Pain Scale

MAPS categories[a]	Kappa	Number of paired assessments
Vital signs	0.73	241
Breathing	0.58	239
Facial expressions	0.74	239
Body movements	0.68	239
State of arousal	0.84	239

[a] Paired assessments of staff nurses with trained nurses were used to calculate Kappa

Construct and Convergent Validity

Figure 2 shows the Bland and Altman plot of the differences between the MAPS and the FLACC scales against the mean. The mean of the differences was 0.44 (CI 0.18 to 0.71). The limits of agreement were –1.22 to 2.09. The regression line shows that the difference in agreement decreased as pain scores increased, but was not significant (F=1.55, df= 39, p=0.22).

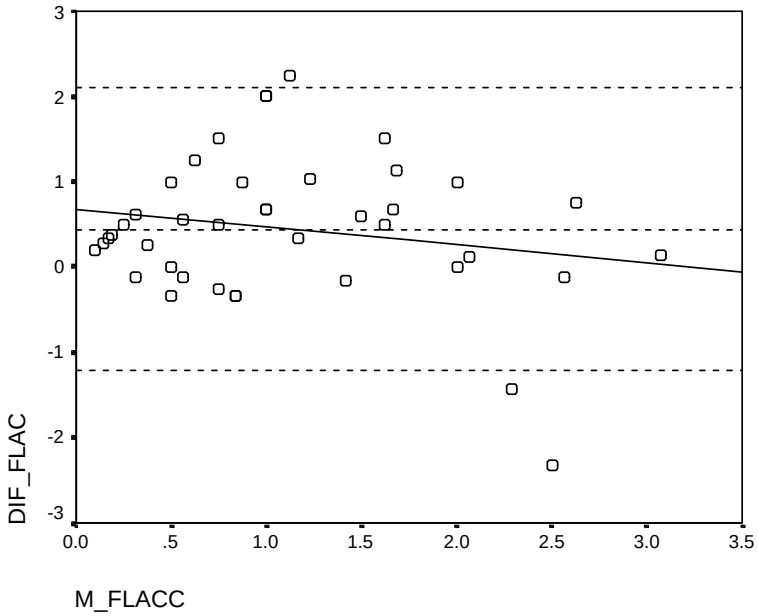

Figure 2. Agreement between MAPS and FLACC mean pain score, with 95% limits of agreement (upper and lower broken lines), mean of the difference (middle broken line) and regression line.

Criterion-related and Concurrent Validity

Comparison of the MAPS with $VAS_{obs,}$ using the method described by Bland and Altman, showed a mean of the differences of 0.25 with a confidence interval of 0.02 to 0.49; the limits of agreement were –1.24 to 1 (Figure 3.).

The regression line shows that the difference in agreement decreased as pain scores increased, but was not significant (F=2.83, df=41, p=0.100).

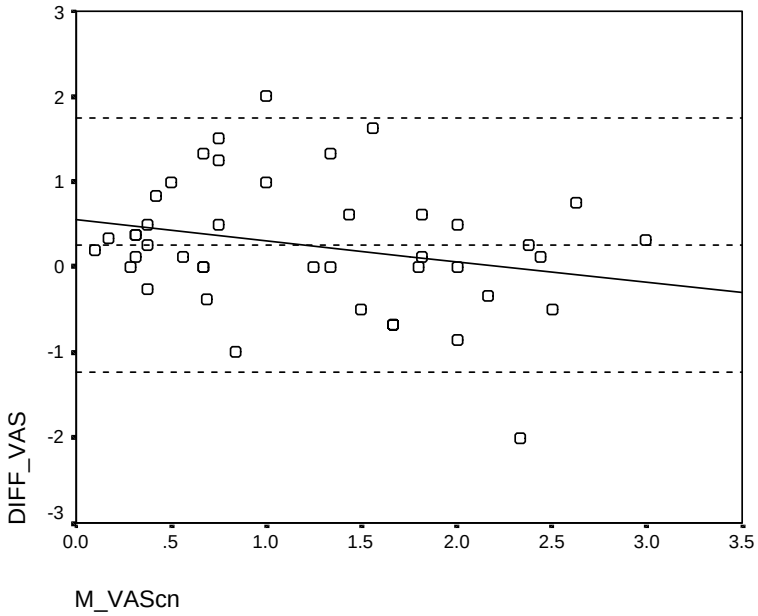

Figure 3. Agreement between MAPS and VAS_{obs} mean pain score, with 95% limits of agreement (upper and lower broken lines), mean of the difference (middle broken line) and regression line.

Discussion

The tool developed in this study is unique in that, unlike previous studies, the items included in the MAPS, were generated from observations of critically ill infants experiencing postoperative pain as well as postoperative pain exacerbated by painful procedures. The authors felt that it was important for clinicians to have a pain measure that could detect postoperative pain as well as pain caused by common ICU procedures (e.g. endotracheal suctioning, positioning, chest drains removal, etc.). While the main categories of the MAPS (vital signs, breathing, facial expressions, body movements, and state of arousal) are not different to those of existing measures, the components of the categories of the extreme end of the scale (extreme pain) are

novel. To the authors' best knowledge, the PICU MAPS is the first pain scale that includes decreased heart rate and/or blood pressure, severe respiratory distress compromising oxygenation, sustained grimacing associated with silent or weak cry, rigid or limited movements, and decreased physical activity with no eye contact as to define the worst pain.

Construction of the MAPS included items that were observed in postoperative critically ill infants experiencing pain (Ramelet et al., 2006). As these pain indicators were based on a small sample, the selection of items was supplemented by the literature. However, due to limited availability of data (Ramelet et al., 2004) and based on psychometric theory for the development of new pain instrument (Nunnally & Bernstein, 1994; Stevens, 1998), the authors felt it was important to select the indicators that would best describe postoperative pain in critically ill children. Face and content validity, translated in terms of clarity, relevance, and complexity, were established by a panel of experts in pain assessment and paediatric critical care. Although content validity is highly subjective and the least empirical validity test, it represents an essential step in the development of new measures (Gross Portney & Watkins, 1993; Nunnally & Bernstein, 1994).

Good internal consistency of the 5-category MAPS was demonstrated by a Cronbach's alpha coefficient greater than 0.50 (Bland & Altman, 2002). Homogeneity of the scale would, however, improve considerably if the vital signs category was deleted. However, based on item analysis theory, it would be inappropriate to remove this item relying on one value only (American Educational Research Association et al., 1999). Compared to other behavioural items, vital signs

achieved the lowest item total correlation. This might be explained by the multidimensional nature of the MAPS (physiologic and behavioural dimensions). Another point to consider is the validity of the baseline measures, as they were difficult to ascertain in the haemodynamically unstable patient. However, to ensure baseline measures were as accurate as possible, they were rigorously measured when the patient was stabilised. In instances where the patient could not be haemodynamically stabilised, normal range for the age and condition of the patient were used as baseline measures. Furthermore, reliability of the vital signs scoring was excellent as demonstrated by an ICC coefficient greater than 0.90. Nevertheless, the limited value of physiological parameters in determining pain when correlated with the behavioural indicators of the COMFORT scale was demonstrated in other studies (Carnevale & Razack, 2002; van Dijk et al., 2000). Further investigation of the relationship between physiologic and behavioural pain responses revealed, however, that the physiology-behaviour correlation improves with increasing pain intensity, suggesting that the combination of both dimensions may confirm the diagnosis of a higher intensity of postoperative pain, but not moderate pain (van Dijk et al., 2001). In our study, it was however not possible to assess the extreme end of the scale (extreme pain), as 89% of the MAPS scores were under 4. This reflects the difficulty in validating pain measures in current practice where pain management is part of standard practice.

Interrater reliability was good for all MAPS categories with the exception of breathing pattern. This may be explained by individual differences in clinical expertise at assessing the quality of breathing, especially in intubated patients. In a comparable study, Van Dijk et al. (2000) reported similar results for the COMFORT

respiratory response (Kappa 0.54), and suggested that evaluation of the respiratory response should be limited to nursing documentation. However, because nursing records are not always reliable (Brooks, 1998; Cairns & Ramelet, 2004; Sirken, Bercini, & Jobe, 1990), the assessment of pain could be misinterpreted if based on records only. For future reference, it should be emphasised that evaluation of the quality of breathing should be based on the last 30 minute-trend rather than a 2-minute observation time.

MAPS was compared with FLACC and VAS_{obs} to assess convergent and concurrent validity, respectively. Bland and Altman plot provides information on a possible relationship between the measurement error and the true value as well as where the difference lies (White & Van den Broek, 2004). The narrow confidence intervals reported in this study reflect a small risk of measurement error. In addition, the limits of agreement and the regression lines showed that the difference in agreement decreased as pain score increased, but the difference was not significant. Nevertheless, a difference of 2 points can be clinically relevant, especially when the difference is situated close to the cut off value for making decisions about administering analgesia. The difference in agreement was more apparent between the MAPS and VAS_{obs} when compared with FLACC, suggesting that observational pain measures are more objective than numerical pain scales. Numeric scales may be less objective because they require the assessor to judge pain, and are thus more directly sensitive to value systems of the assessor, whereas observational pain measures require a judgment of a behaviour, once removed from the actual pain and therefore not as exposed to values of the assessor. The difficulty of establishing the validity of VAS_{obs} in children who cannot self-report was highlighted by van Dijk and

colleagues (van Dijk, Koot et al., 2002) who reported a large variation between VAS_{obs} and other paediatric pain scoring tools (r = 0.42 - 0.86). Nevertheless, every attempt was made in this study to reduce assessment bias by training the assessors.

The large proportion of cardiac children in this sample limits somewhat the generalisation of the results to the population of postoperative PICU patients. It is, therefore, recommended for future validation of the MAPS to include a more heterogenous sample. The MAPS measures physiologic and behavioural responses of the critically ill preverbal child experiencing postoperative pain. However, it should be emphasised that contextual factors that are known to modulate pain (e.g. biological or emotional) must be considered in the interpretation of the pain scores and in the process in making decisions about the most effective treatment. Finally, the MAPS is not applicable to chemically paralysed children, as it includes behavioural responses as indicators of pain. Although this group of children represents a minority of the PICU population, it should not be overlooked. Further research in chemically paralysed children is therefore warranted.

Conclusions

Pain assessment in nonverbal children is challenging and is even more difficult in those who are critically ill. However, this should not impede health professionals delivering optimal analgesia. The development and preliminary validation of the MAPS provides health professionals with a tool to facilitate and standardise pain assessment in critically ill preverbal children. The establishment of construct validity is, however, a complex process, often involving several studies and several approaches. Although the MAPS psychometric properties are promising, the

instrument requires further testing in response to analgesic effect to provide further evidence of construct validity and evaluation of its feasibility and practicability for use in clinical practice (this is currently in progress).

CHAPTER SIX

Results - Phase Three

Clinical validation of the Multidimensional Assessment of Pain Scale: MAPS

The previous chapter introduced the development process and the preliminary testing of the MAPS. Further testing in situations where children would be likely to experience pain of higher intensity was recommended. The results of Phase Three of the study, which aimed to test the clinical validity and utility of the Multidimensional Assessment of Pain Scale (MAPS) in these situations and represents the final stage of tool development.

This chapter is also presented in the format of a journal article that has been submitted for publication in the peer-reviewed journal *Pediatric Anesthesia*. The paper was co-authored by Supervisors Associate Professor Nancy Rees, Professor Sue McDonald, and Professor Huda Huijer Abu-Saad, and biostatistician Max Bulsara who were happy to have it included in this thesis.

Abstract

Background: The Multidimensional Assessment Pain Scale (MAPS) was developed for assessing postoperative pain in critically ill preverbal children. This follow-up validation study aimed to evaluate the clinical validity and utility of this 5-category 10-point pain measure.

Methods: The MAPS response to analgesics was tested in a convenience sample of 19 postoperative critically ill children aged between 0 and 31 months of age at a tertiary referral hospital in Western Australia. The MAPS was tested against the Face, Leg, Activity, Consolability, and Cry (FLACC) instruments and the observer Visual Analogue Scale (VAS_{obs}). Clinical utility of the MAPS was also evaluated.

Results: MAPS scores decreased significantly by 4 points (40% of total score) after the administration of a potent dose of morphine ($p<0.001$). Risk of measurement error between MAPS and FLACC and MAPS and VAS_{obs} was small as shown by the Bland & Altman plots. Congruent with our previous study, the internal consistency of the MAPS improved when the physiologic item was deleted (Cronbach's alpha 0.79-0.64). However, the actual values of heart rate, systolic, mean, and diastolic arterial pressure were shown to decrease significantly at 15, 30, and 60 minutes after a potent bolus of morphine ($p<0.001$). The MAPS also demonstrated clinical feasibility.

Conclusions: This study showed that the MAPS is sensitive to the effect of a potent rescue dose of morphine. Based on internal consistency analyses, use of a revised

version of the MAPS is recommended for clinical application, as it reflects the physiologic response to severe pain in critically ill infants.

Introduction

Pain assessment in critically ill young children presents many challenges for health professionals because they cannot rely on their patient's self-report that may be further complicated by the nature of their illness. To assist health professionals in recognising pain and evaluating the effectiveness of its treatment, national government agencies recommend that standardised assessment of children's pain should be performed using pain measures appropriate for the child's developmental age, type of pain, and clinical condition (American Pain Society, 1992; National Health and Medical Research Council, 2005a). However, the paucity of appropriate pain instruments for this population of children makes it difficult to apply these recommendations (Ramelet et al., 2004).

To specifically address this issue, the Multidimensional Assessment Pain Scale (MAPS) was developed for use in postoperative critically ill children aged between 0 and 36 months. The preliminary psychometric properties of the MAPS were reported in a previous article (Ramelet et al., 2006). Interrater reliability was established prior to data collection. Interrater reliability was good for the majority of categories (Kappa 0.68-0.84) and excellent for the overall score (ICC 0.91), although item analyses indicated that internal consistency would improve if the category of vital sign was deleted (Ramelet et al., 2006). Agreement between MAPS and two other

pain measures, namely FLACC and VAS observer (VAS_{obs}) was good. Although the psychometric properties of the MAPS are promising, further testing is required, especially in situations where children are likely to experience high pain intensity (MAPS score of 4 and above) (Ramelet et al., 2006).

Establishing the validity of a scale comes from multiple processes and involves several studies (Jensen, 2003) and for successful clinical application, a pain measure should not only be reliable and valid, but also clinically useful (Gibbins et al., 2003). For instance, if a measure's intended use is to determine the administration and the effect of analgesics, it must reflect changes in response to analgesics. The MAPS currently lacks this aspect of validity.

The objectives of this study were, therefore, to (i) evaluate the MAPS' response to the effect of analgesics in preverbal critically ill children following major surgery; (ii) assess concurrent and convergent validity of MAPS before and after administration of intravenous morphine; (iii) examine the internal consistency of the MAPS at different levels of pain intensity and determine the value of vital sign item; and iv) determine the clinical utility of the MAPS.

Patients and Methods

Staff Training

Training of nursing staff prior to this study was described in a previous article (Ramelet et al., 2006). In summary, it consisted of a face-to-face tutorial and practical application of the MAPS using a random selection of video recordings of

infants experiencing pain, and in real time at the bedside. Issues pertaining to the study protocol were discussed directly with the principal investigator. Nurses involved in data collection using the MAPS' scoring for this study did not directly care for the participants. Registered nurses caring for the participants received explanation by the Principal Investigator at the bedside prior to data collection. It was emphasised then that the nurse's or physician's decision to give rescue analgesia must be based on clinical judgment only.

Reliability and Validity

Setting and sample

Psychometric testing of the MAPS was performed in the paediatric intensive care unit (PICU) at a tertiary referral hospital for children in Western Australia. A convenience sample of 19 critically ill ventilated preverbal children aged between 0 and 36 months of age, requiring major elective surgery, and admitted to the PICU immediately after surgery was drawn from the PICU population. Children were excluded from the study if they were 36 or less weeks of gestational age, or if they presented with neurological or developmental impairments, or altered muscle tone.

Procedure

After scientific and ethics approval from the hospital committee, and prior to subjects' admission to the intensive care unit, the Principal Investigator sought consent of parents or guardians of children meeting the inclusion criteria of the study. Within 45 minutes of arrival in the unit and once the child had been stabilised, baseline measures were recorded. Heart rate, invasive arterial pressure, and

respiratory rate were recorded continuously on a monitor (Agilent® version 6.00.11) that had been calibrated on arrival. When rescue analgesia, in the form of a standardised dose of intravenous morphine (50-100 mcg/Kg), was judged to be required by the bedside nurse, the trained clinical nurse on duty and the nurse researcher were called to the bedside. After chemical paralysis used in surgery wore off and before rescue intravenous morphine bolus, and 15, 30, and 60 minutes post analgesic administration, a pain score was measured simultaneously and independently by the bedside nurse using VAS_{obs}, the nurse researcher using FLACC, and the clinical nurse using MAPS. This was repeated for up to three rescue doses for each of the participants. Episodes in which morphine boluses were given preventively (e.g. prior to a painful procedure) as well as those given concurrently with midazolam boluses were excluded from the study.

Instruments

The MAPS was developed to measure postoperative pain in critically ill preverbal children (Ramelet, Rees, McDonald, Bulsara, & Huijer Abu-Saad, Submitted). It comprises 5 categories, including vital signs (heart rate and blood pressure), breathing pattern, facial expressions, body movements, and state of arousal (Table 14). Each category is attributed a score of 0, 1 or 2 for the calculation of a possible total score ranging between 0 (no pain) and 10 (extreme pain). Interrater reliability for the MAPS was excellent (ICC=0.91). The agreement between MAPS and FLACC and MAPS and VAS_{obs} showed that the risk of measurement error was small.

Table 14. The Multidimensional Assessment of Pain Scale©

Categories	0	1	2	Score
Vital signs HR and/or BP	Within baseline	More than 10 bpm increase and/or more than 10 mmHg increase	More than 10 bpm decrease and/or more than 10 mmHg decrease	
Breathing pattern	No change	Development or increase of Respiratory distress	Severe Respiratory distress	
Facial expressions	Relaxed	Grimace	Grimace associated with silent or weak cry	
Body movements	No movements or Purposeful movements	Restless	Rigid and/or limited Body movements	
State of arousal	Calm or asleep	Hyperreactive	Shut down	
Total Score				

The VAS_{obs} is a 10 cm-horizontal continuous line, with anchors of 0="no pain" and 10="the worst possible pain" at the left and right extremities, respectively (McGrath et al., 1995; Wewers & Lowe, 1990). The VAS is commonly used as an observational measure to report pain intensity in preverbal children (Lawrence et al., 1993; Peters et al., 2003; Robieux et al., 1991; Taddio, Nulman et al., 1995; Tarbell et al., 1992; van Dijk et al., 2000). Concurrent validity of the VAS_{obs} and other pain scales can vary considerably, but correlation coefficients tends to increase when observers are trained or experts (van Dijk, Koot et al., 2002). In this current study, nurses involved in this study were specifically trained and demonstrated competency in pain assessment prior to data collection. The VAS_{obs} and the MAPS were used concurrently and independently to evaluate the MAPS concurrent validity before and after administration of a potent dose of morphine.

The FLACC is a measure that recently demonstrated validity and reliability in PICU children from 3 years of age (Manworren & Hynan, 2003), and in postoperative

children aged between 2 and 7 years (Merkel et al., 1997; Willis et al., 2003). It includes 5 categories of pain behaviours: face, legs, activity, cry, and consolability, each of which is scored 0, 1, or 2, resulting in a total score ranging between 0 (no pain) and 10 (maximum pain). The FLACC was used simultaneously with the MAPS to establish convergent validity.

Clinical Utility

Clinical utility was assessed using a questionnaire, developed based on the definition of clinical utility by Stevens and Gibbins (Stevens & Gibbins, 2002). Questions on i) time (e.g. time required to perform pain assessment), ii) format (overall layout of the scale), and iii) acceptability (perceived usefulness of the scale) were included. Each question was rated on a 5-point Likert-type scale. The definitions of the Likert-type scale were 1=very useful, 2=useful, 3=undecided, 4=not useful, and 5=not useful at all. The questionnaire also included open-ended questions for recommendations or other comments. The pilot tested questionnaire was sent by internal mail to all staff nurses six months after the introduction of the MAPS for clinical use. The completion of the questionnaire was voluntary and anonymous. Consent was assumed by the return of the questionnaire into a sealed box placed in the unit.

Analyses

All descriptive and multivariate statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) version 11.5 for Windows. Descriptive statistics were used to analyse the participants' demographics as well as their responses to the clinical utility questionnaire. Response to analgesics was

evaluated using a hypothesis-testing approach. It was assumed that pain scores would decrease after administration of an appropriate rescue dose of intravenous morphine. Pain scores were averaged across number of boluses at baseline, 15, 30, and 60 minutes for each participant and to allow for analyses without violating the assumption of independence. The non-parametric Friedman test was performed to determine whether there was significant decreases in pain scores between baseline and 15, 30, and 60 minutes after administration of morphine.

Concurrent validity was assessed using MAPS and VAS_{obs}. Convergent validity was assessed by comparing MAPS and FLACC. Degree of agreement between MAPS and VAS_{obs} and MAPS and FLACC was calculated using a statistical method described by Bland & Altman (1986). The Bland and Altman plot evaluates whether a new instrument provides equivalent information to an existing instrument. The method is based on the differences between measurements on the same subject by two different measures. The difference between two methods, the standard deviation of the difference, and the mean difference were calculated; the mean difference representing the estimated bias, the difference and standard deviation of the random fluctuations around the mean. The difference was plotted against the average of two measures (MAPS and VAS_{obs}). The 95% limits of agreement and the mean difference plus or minus 2 standard deviations demonstrate how far apart pain scores attributed by two measures are likely to be for most children in the study population. To evaluate whether there was any considerable difference in agreement, a linear regression analysis was performed. An increasing regression line shows that the difference in agreement increased as pain score increased.

Reliability analyses consisted of assessing the MAPS' internal consistency by calculating Cronbach's coefficient alpha for each subject's pain score at each time points (before bolus administration, and again at 15, 30 and 60 minutes following bolus administration).

Results

Nineteen children aged between 4 days and 31 months (median 7.5 months, interquartile range 8.25) participated in this study. The majority (n=18, 94.7%) were intubated and ventilated at the time of observation. The mean weight of this sample population was 7.12 Kg (±2.55). Other background characteristics of these children are presented in Table 15.

Table 15. Demographic Characteristics of the participants

Characteristics		Count (%)
Gender	Male	11 (57.9)
	Female	8 (42.1)
Ethnic background	Caucasian	15 (78.9)
	Asian (central and south-east Asia)	2 (10.5)
	Native Australian/New Zealander	1 (5.3)
	Mixed race	1 (5.3)
Type of surgery	Cardiac	14 (73.7)
	Cranial vault remodelling	2 (10.5)
	Thoracotomy	2 (10.5)
	Laparotomy	1 (5.3)

All scoring was performed in the first 24 hours after surgery. Continuous infusions of morphine were commenced in all participants immediately on arrival in the unit and running at the mean rate of 23.5 mcg/kg/h (SD 15). In addition, a total of 36 boluses (mean 1.61, SD 0.76) of morphine were given during the study period. All participants (100%) required one bolus only, 53% required two, and 30% received

three during the study period. Infants aged 6 months or less (n=8, 42%) were administered a 50mcg/Kg/dose of morphine given as a rapid intravenous push with syringe. Children aged 7 months and older (n=11, 58%) received a 100mcg/Kg/dose. Analgesia was complemented by midazolam infusions running at a median rate of 4.8 mcg/Kg/h (range 0-172) in 14 participants (74%).

Response to Analgesia

Descriptive statistics showed that pain scores equal or greater than 4 represented 80% of the scores before and 30 % after the administration of rescue intravenous morphine bolus. The median MAPS pain scores was 5 (range 1 to 8) before administration of a rescue intravenous morphine bolus, and, following administration, 0 (range 0 to 6), 0 (range 0 to 3), and 1 (range 0 to 4) at 15 minutes, 30 minutes, and 60 minutes , respectively (Figure 4).

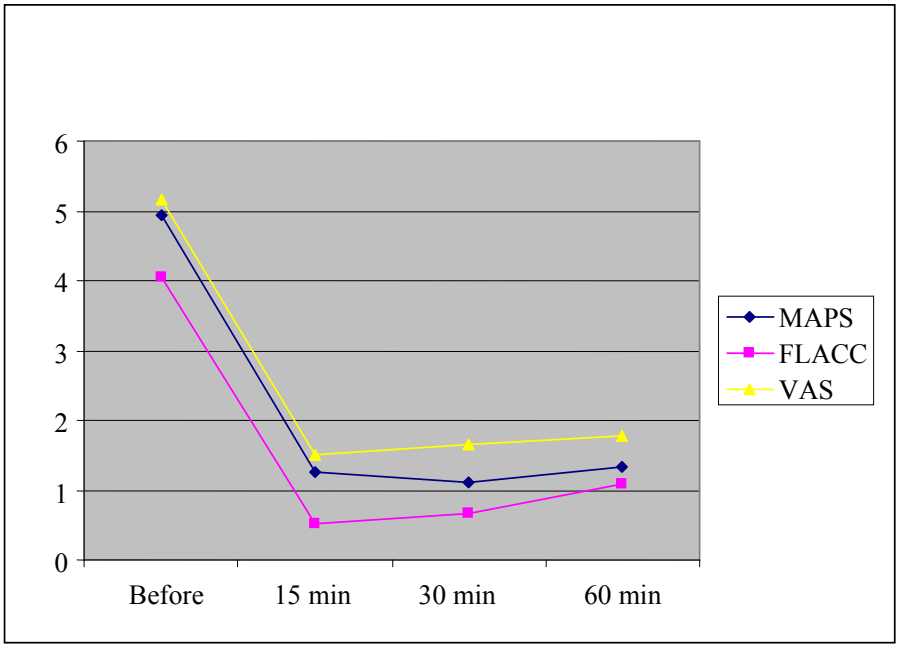

Figure 4. Mean pain scores of averaged boluses before and after administration of morphine bolus

Results from the Friedman Test showed a significant decrease in pain scores between before and after administration of opioid boluses measurements (z^2 = 32.92, $p<0.001$). However, there were no significant differences between pain scores at 15, 30 and 60 min (z^2 = 2.08, p = 0.353) and at 30 and 60 min (z^2 = 0.82, p = 0.366) after the administration of a bolus of opioid.

Comparison of the MAPS with FLACC using the method described by Bland and Altman showed a mean of the differences of -0.12 ; the limits of agreement were –3.71 to 3.78 (Figure 5). Comparison of the MAPS with the VAS_{obs} using the same

method showed a mean of the differences of -0.29; the limits of agreement were 1.78 to -2.37 (Figure 6).

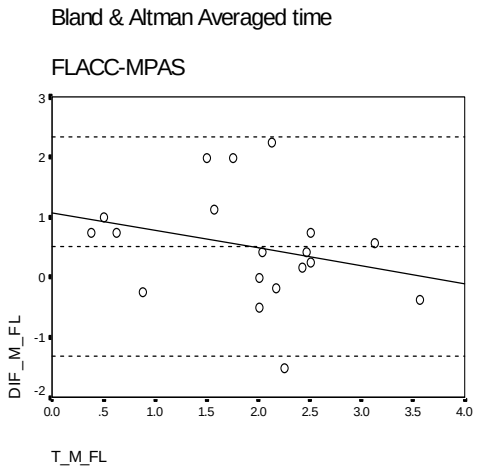

Figure 5. Agreement between MAPS and FLACC mean pain score, with 95% limits of agreement (upper and lower broken lines), mean of the difference (middle broken line) and regression line.

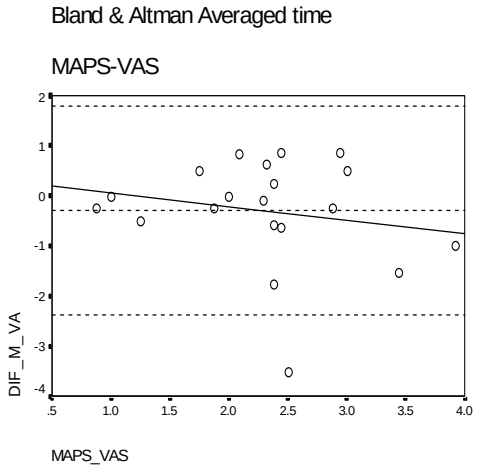

Figure 6. Agreement between MAPS and VAS_{obs} mean pain score, with 95% limits of agreement (upper and lower broken lines), mean of the difference (middle broken line) and regression line.

Internal consistency, represented by Cronbach's alpha coefficient, was 0.62 at baseline, 0.80 at 15 min, 0.37 at 30 min, 0.26 at 60 min. If item 'vital signs' was deleted, internal consistency of the MAPS at baseline, 15 min, 30 min, and 60 min would improve r=0.64, 0.79, 0.67 and 0.71, respectively.

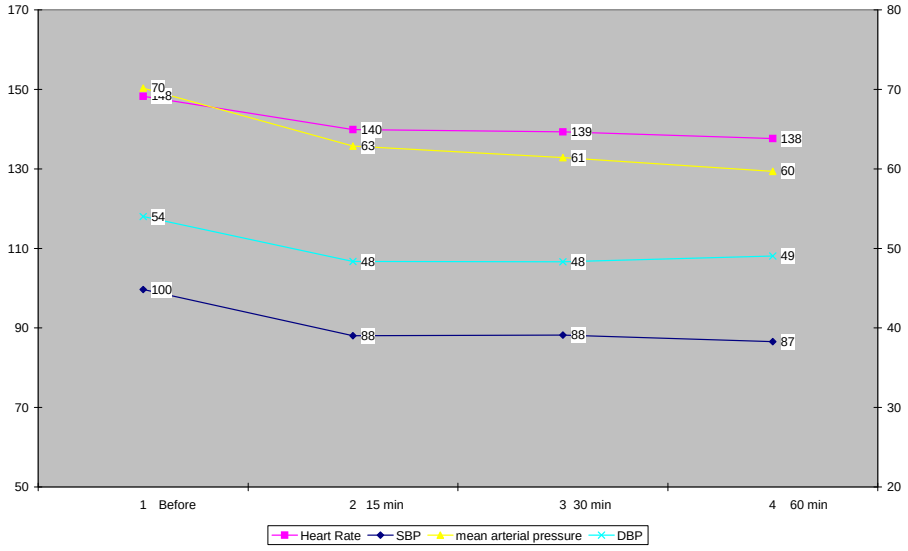

Figure 7. Physiologic parameters before and 15 min., 30 min., and 60 min. after the administration of a bolus of morphine.

Figure 7 shows a 7% decrease in heart rate, 13% in systolic, 14% in mean, and 9% in diastolic blood pressure after the administration of a potent dose of morphine. The Friedman Test showed a significant decrease in heart rate between before and after administration of opioid boluses measurements (z^2 = 27.13, $p<0.001$). GLM analyses also showed a significant decrease in systolic ($p<0.001$), mean ($p<0.001$), and diastolic arterial pressure ($p<0.001$) after boluses.

The clinical utility of the MAPS was evaluated by seventeen nurses (57% response rate) who returned the completed questionnaire. Out of the 17 respondents, the majority (n=8, 53.3%) were critical care nurse specialists, six (40%) were registered nurses, and one (6.7%) was an undergraduate student. They reported that the MAPS was useful in titrating drugs in preverbal children (median 2, range 4) and moderately simple (median 2, range 4). The median total duration of observation was estimated at 2 minutes (range 9) and the mean assessment time was 35.3(±26) seconds.

Discussion

The results of this study support the MAPS' clinical validity, demonstrated by significant decreases in MAPS scores following the administration of an appropriate dose of morphine. One method to measure the effectiveness of analgesic treatment is by calculating the percentage of change as a result of the intervention (Buttner & Finke, 2000; Stevens & Gibbins, 2002). In our study, this was demonstrated by a clinically significant reduction of a four-point pain score (40% of total MAPS score) after the administration of a bolus of morphine. Similar to these findings, the authors of the FLACC reported a 40% score reduction from pre- to post-analgesia in 85% of preverbal children who received different analgesics, including intravenous opioid, oral non-opioid or a combination (Manworren & Hynan, 2003). Another validation study of the Toddler-Preschooler Postoperative Pain (PPPS) by Suraseranivongse et al. (2001), showed a mean pain score reduction of 2.18 points (31%) following medication. Although the magnitude of change in pain scores that is clinically

relevant has not been clearly defined (Stevens & Gibbins, 2002), these reports support our findings.

In this study, agreement between the MAPS and two other pain measures (FLACC and VAS_{obs}) was acceptable, confirming the MAPS' concurrent and convergent validity. Similar to our previous study, the difference in agreement was more apparent between the MAPS and VAS_{obs} than with FLACC, suggesting that observational measures are more accurate than numerical scales. The need for additional analgesia was determined by the nurses caring for the child. One could argue that the bedside nurse's judgment was unreliable, and expert opinions should have been sought. However, expert nursing judgment is difficult to define as it depends not only on experience and competency, but also by specific knowledge base, personal attitudes, and standards of practice in place (Adams et al., 1997) In this study, competency and knowledge base were ensured by providing compulsory specific training to all nurses involved in data collection prior to commencement of the study to minimise bias. In the absence of a gold standard in paediatric pain assessment, expert $VAS_{obs,}$ remains the best method available to test the concurrent validity of a newly developed pain instrument (van Dijk, Koot et al., 2002).

Results of our preliminary validation study showed that internal consistency of the MAPS would improve if the item "vital signs" was deleted (Ramelet et al., Submitted). In this previous work, postoperative infants who were subjected to the most painful procedures (e.g. chest drain removal) experienced a decrease (between 5 and 8%) in their systolic and diastolic pressure. After long-lasting painful stimuli, infants' behavioural response decreased or shut-down as a result of probable

exhaustion. In this study, the MAPS internal consistency, in other word how the items fit together, was re-evaluated at the different time points of observation (before and at four set time points after rescue-bolus of morphine). Internal consistency of the 5-item MAPS was excellent before the administration of the bolus, but varied greatly at 15 and 60 minutes after bolus, as demonstrated by a Cronbach's alpha ranging between 0.80 and 0.26, respectively. However, congruent with our preliminary report (Ramelet et al., Submitted), homogeneity of the MAPS would be good at all time-points if the vital signs item was deleted. The work by Van Dijk et al. (2001) showed a poor relationship between behaviour and physiological parameters (heart rate and mean arterial pressure) within the COMFORT scale. However, results of their study also showed that the correlation between the COMFORT physiological parameters and the COMFORT behavioural items improved with increasing pain intensity, suggesting that physiological measures remain valid indicators of severe pain. Based on this argument, it was, therefore suspected that the measurement assigning numeric value of "vital sign" was the cause of the inconsistency, rather than the item itself. Further analyses showed that the actual values of HR, SBP, MAP, and DBP decreased consistently after an appropriate dose of morphine. Although these findings are incongruent with what has been reported in other paediatric intensive care pain studies (Carnevale & Razack, 2002; van Dijk et al., 2000), they confirm that critically ill young children experience a physiological response to severe postoperative pain. While it remains unclear whether physiologic measures add any value to the diagnostic of pain (Sweet et al., 1999), clinicians are not ready to discount them as such (Foster, 2001). In addition to being readily available at the bedside, physiologic measures remain commonly used for the diagnosis of pain in the PICU (Ramelet, 1999), especially in chemically

paralyzed children (Suominen et al., 2004). Based on these results and the supporting literature, a revised version of the MAPS has been suggested and the scoring system of the "vital signs" item (score of 2) changed to score 2 if heart rate and/or blood pressure increase by 20% or more (Figure 8).

Categories	**0**	**1**	**2**	**Score**
Vital signs HR and/or BP	Within baseline	More than 10% increase	More than 20% increase	
Breathing pattern	No change	Development or increase of Respiratory distress	increased Respiratory distress with silent or weak cry	
Facial expressions	Relaxed	Grimace	Grimace associated with silent or weak cry	
Body movements	No movements or Purposeful movements	Restless	Rigid and/or limited Body movements	
State of arousal	Calm or asleep	Hyperreactive	Shut down	
Total Score				

Figure 8. The revised Multidimensional Assessment of Pain Scale©

Although there is some degree of variance in the definitions of clinical utility (Stevens & Gibbins, 2002), components of instruction, cost, time, acceptability, and format are commonly described in the literature. In our study, the PICU MAPS was reported as clinically useful for the titration of analgesics and moderately simple to use. Although, it's recognised that institutional loyalty may have influenced the respondents' judgment, the short assessment time, clinical utility and user-friendly format is likely to contribute to nurses' acceptance of the tool in their practice. Nevertheless, further evaluation of the MAPS' clinical utility in an institution to

which the principal investigator is not affiliated is recommended. Further psychometric testing of the revised MAPS in the PICU population is also warranted.

The revised MAPS is likely to assist clinical judgment. However, it should be noted that pain scores should be interpreted in the clinical context of the assessment and that no pain instrument should be implemented on its own. To improve pain management and ultimately health outcomes, use of integrated protocols for pain and sedation coupled with adequate staff education is warranted (Blenkharn, Faughnan, & Morgan, 2002; National Health and Medical Research Council, 2005a; The Royal Australasian College of Physicians, 2005a).

Conclusions

The establishment of validity is a complex process, often involving several studies and several approaches. This study provided additional support to the MAPS' validity as demonstrated by the decrease in total pain score derived from observation of physical and behavioural cues after the administration of a potent dose of morphine. Further evaluation of the MAPS' internal consistency showed that the vital sign item did not correlate with the other items of the MAPS. However, this was more likely to be due to the wording of the item rather than the item itself, as confirmed by significant decreases in heart rate and blood pressures following adequate dose of opioids. The MAPS was modified accordingly and further testing in different age groups and different type of patients is underway. The MAPS also showed good clinical utility and feasibility. The final version of the MAPS is a valid

and reliable pain instrument that was specifically designed for critically ill young children, and is likely to assist clinical judgment.

CHAPTER SEVEN

Recommendations and Conclusions

"Children's pain matters-for the child, for the family, and for the society"

(Finley et al., 2005, p. 4)

Why does children's pain matter? Children and infants, even premature newborns, have the anatomical components to feel pain (Fitzgerald, 2005). As observed poignantly by Albert Schweitzer "Pain is a more terrible lord of mankind than even death itself" (Brennan & Cousins, 2004, p. 1). What is perceived painful by an adult is likely to cause as much, if not greater pain, in children and infants (Finley et al., 2005). Recent evidence suggests that if pain remains untreated early in life, it can have profound and long-term effects on social and physical development, and can cause permanent damage to the nervous system, which will affect future pain experience and general development (Andrews & Fitzgerald, 2002; Grunau, 2002; Peters et al., 2005; Rennick et al., 2002; Rennick et al., 2004). While it is clear that pain in children must be adequately treated, it is widely acknowledged that the recognition of pain using valid pain instruments is a prerequisite of effective pain management (National Health and Medical Research Council, 2005a; Royal College of Nursing Institute, 1999). Although numerous pain instruments are available for neonates undergoing procedural pain, none were found adequate for postoperative critically ill infants (Ramelet et al., 2004). This study aimed to address this gap by developing a pain assessment tool that would not only be valid and reliable, but also practical for use in this particularly vulnerable population of children.

This multiphase research contributed to the body of knowledge of pain and pain assessment in young children in several ways. It provided a detailed description of critically ill infants' physiologic and behavioural responses to postoperative pain over an extended period, which permitted the creation of an item bank for the development of a pain assessment tool for this vulnerable group of children. To the author's best knowledge, this is the first study that has used ethological principles of observation to describe pain in critically ill children. Using this observation technique and based on the conceptual pain model described by Merskey (1997), it was possible to depict not only postoperative pain but also postoperative pain exacerbated by procedures. There is no evidence that the numerous neonatal and paediatric pain assessment scales described in the literature have been tested for their validity and utility in assessing procedural pain as well as more lasting pain, such as postoperative pain. In this regard, the MAPS provides flexibility in usage and has a clear advantage over other pain scales available currently.

This study used rigorous methods of psychometric testing, which provided the information necessary to revise the MAPS for clinical use. However, it is understood that adequate pain assessment does not necessarily lead to adequate management of pain. Therefore particular attention in the development and implementation of future strategies designed to improve postoperative pain management in critically ill children through appropriate assessment of pain needs to be addressed.

Improving Nursing Assessment and Management of Pain

The knowledge and understanding of pain behaviour in critically ill young children drawn from this study is likely to impact on nursing management of pain in the

paediatric intensive unit in several ways. Firstly, the use of the MAPS in the clinical setting would support standard pain assessment in this group. However, reliance on any pain instrument alone would be inappropriate because the management of pain is largely context-dependent. Secondly, the development and implementation of an evidence-based guideline for the management of pain, taking other contextual factors into consideration, would assist health professionals in their clinical judgments and decision-making about therapeutic options to achieve the best possible clinical outcomes (Donnelly & Lynch-Smith, 2004). Thirdly, measuring the quality of pain assessment and management is essential to ensure practice has a positive impact on patients' pain and other health outcomes (Miaskowski, 2001). Finally, implementation of these approaches would not be successful without adequate professional education. These four proposed strategies are discussed in detail below.

Standard Assessment of Pain

Results from a recent national survey by Long et al. (2005) showed that the majority of the paediatric intensive care units in Australia do not use a pain assessment tool in their practice. This is somewhat alarming, since governmental and accreditation agencies, as well as other consensus groups, recommend the use of standard pain instruments as part of best practice (Agency for Health Care Policy and Research, 1992; National Health and Medical Research Council, 2005a). This research provides health professionals with a standardised pain assessment scale that is developmentally appropriate, valid and clinically useful for critically ill young children. The MAPS' properties support assessment of both postoperative pain and postoperative pain exacerbated by procedural pain, and are particularly useful in a setting where children are often exposed to pain experiences (Porter & Anand, 1998;

Puntillo et al., 2001). The fact that the MAPS can be used to assess not only long-lasting pain, but also pain caused by common ICU procedures, is a clear advantage over other pain assessment instruments available currently. Its use will reduce the number of pain measures used in the PICU, which in turn is likely to facilitate the implementation and the sustained use of the new tool in this setting.

The sustained use of pain assessment tools is, however, challenging. Bourbonnais et al. (2004) described three factors that could complicate the use of assessment tools: (a) the subjective nature of pain, (b) the lack of meaning associated with scores generated by pain instruments, and (c) the lack of specificity of treatment goals in pain management. The perception of pain is a complex phenomenon comprising multiple dimensions, but as described previously, pain in preverbal children is mainly a sensory and emotional experience. In that regard, the MAPS accurately reflects the sensory and emotional components of pain in critically ill preverbal children, as it was developed using physiological and behavioural responses observed directly in this group of children experiencing pain. The lack of meaning associated with scores generated by pain instruments is problematic, and health professionals, nurses particularly, will not comply to the implementation of a new pain instrument if the obtained pain score has no clinical meaning (van Dijk, Peters, & van Deventer, 2005). To address this issue, a theoretical cut-off score of four points for MAPS has been calculated, prompting the assessor to take action if the MAPS score is four or above. This is an essential component of the scale to guide decision-making about treatment. With regard to the third factor, treatment goals in pain management need to be established with consideration of the contextual circumstances. Haemodynamic and respiratory status, level of sedation, individual

response to medication, fatigue, agitation, and other emotional symptoms are important factors that may impact upon pain assessment and management, especially in young children who are compromised by the severity of their illness. To minimise the risk of pain, undersedation and oversedation, concomitant assessment of pain and monitoring of the level of sedation is particularly important, because analgesics, and opioids in particular, have sedative effects that cannot be measured by the MAPS or any other pain scales (Feeley & Gardner, 2006).

Development and Implementation of an Evidence-Based Guideline for the Management of Pain and Sedation.

Implementation of pain and sedation assessment instruments alone may lead to inappropriate management. Guidelines and protocols for the management of pain and sedation, if appropriately developed and implemented, are likely to help organise assessment and documentation of pain in a consistent and systematic manner, guide decision-making, and treat pain in a prompt and appropriate manner (Donnelly & Lynch-Smith, 2004). Such guidelines would be complementary to the MAPS, assist in the assessment procedure, and provide a mean to achieve a high standard of pain management practices.

Development of clinical practice guidelines is a systematic process that should be informed by the NHMRC guidelines for this process (National Health and Medical Research Council, 1999, 2005b). According to these recommendations, clinical practice guidelines should be developed by a multidisciplinary development

guideline committee, the initial task of which is to determine the need for and scope of the guideline, define the purpose and target audience and identify the health outcomes that will improve as a result of the guideline implementation. The background work of this research provides the information required to complete this first stage of clinical practice guideline development. The multidisciplinary team involved in this research consisted of intensivists, anaesthetists, nurse clinicians and nurse academics, and pharmacists, who identified the need for and scope of the guideline. This process was supported by a comprehensive review of the literature, which highlighted the need for the development of a pain assessment scale in critically ill young children as well as a protocol to assist decision-making and taking appropriate actions.

Nurse-led pain protocols have been shown to prompt nurses to intervene without delay, reduce the duration of mechanical ventilation and the intensive care unit length of stay, reduce the amount of sedatives administered without compromising the level of comfort and reduce the risk of drug-related side effects (Alexander, Carnevale, & Razack, 2002; Andrews & Wills, 1992; Brook et al., 1999; Ramelet, 2003). Additional benefits include improved pain management documentation, decreased nursing care time and cost (Furdon et al., 1998). Puntillo and colleagues (2002) developed a pain assessment and intervention notation (P.A.I.N) algorithm for critical care nursing practice. This algorithm comprises three steps to prompt nurses to (a) assess the patient's pain, (b) assess for potential problems influencing a decision to administer opioid analgesia (for instance, oversedation or haemodynamic instability), and (c) consider different pain treatment options. This comprehensive pain assessment has the advantage of taking into consideration the contextual

circumstances and gives the bedside nurse the autonomy to treat pain. In a detailed evaluation of the P.A.I.N, nurses who participated in the initial development and implementation of the algorithm thought that their experience with using the algorithm would have a lasting effect on their practice and would be especially helpful to critical care nurses with no or limited experience (Puntillo et al., 2002). For critically ill children in the PICU, a similar approach for the development of pain and sedation treatment protocols in the form of an algorithm is recommended. In addition to using the MAPS to assess pain in critically ill young children, introduction of a sedation score to monitor the level of sedation would be highly beneficial, since the MAPS does not assess the level of sedation. An algorithm with different treatment options should be considered. Existing guidelines and consensus statements should assist with the development of such algorithms (Agency for Health Care Policy and Research, 1992; Anand & International Evidence-Based Group for Neonatal Pain, 2001; National Health and Medical Research Council, 2005a; Royal College of Nursing Institute, 1999; The Royal Australasian College of Physicians, 2005a). In addition to pain, other factors that may impact on how nonverbal children perceive and express their pain should be evaluated. As stated by Craig (personal communication, April 7, 2003) there are intrapersonal determinants, such as age, severity of illness, brain function, and contextual determinants, such as social, biological and environmental context, and the relationship between the assessor and the child in pain, that play a crucial role in a nonverbal child's communication of pain. The model of communication of pain in nonverbal children published by Craig et al. (2002) could be used as a theoretical framework for the development of the guideline for the management of pain and sedation and could be the focus of further research.

Clinical practice guidelines should be developed, disseminated and implemented in such a way that health practitioners and consumers (patient and family in this instance) are aware of them and use them. Dissemination of the findings and recommendations of this research should occur at multiple levels: department, organisation, university, and other relevant professional specialty groups. Locally, findings of this research have been available to the target audience, specifically, nurses, medical practitioners, pharmacists, anaesthetists and other health practitioners who are involved with the care of PICU patients. Verbal and written information sessions in the form of seminars, interviews, and educational lectures were given to the staff nurses and the paediatric intensive care postgraduate students. The researcher felt it was important to feedback to all involved in this research to facilitate subsequent implementation and sustained use of the MAPS. Findings of this research have also been either published or submitted for publication in international peer-reviewed journals (see Chapters Two, Four, Five, and Six) and presented at local, national, and international conferences on intensive care and paediatric pain (see List of Conference Presentations in Appendix L).

Prior to implementation of the MAPS, it would be equally important to identify the potential barriers to implementation (National Health and Medical Research Council, 1999). Some of these barriers may include a lack of diffusion of information, users' attitudes and belief about pain, the new instrument, or the guideline, a lack of openness about utilisation of a new tool, and inadequate organisational infrastructure (Bourbonnais et al., 2004). In some respects, the conduct of this research would have helped overcome some of these barriers, as the staff nurses and intensivists were

directly involved in the process of the development and testing of the MAPS. Bourbonnais et al. (2004) reported that individuals who participated in the research process were interested because of the partnership aspect of the project, thus were supportive of the proposed changes. They also reported that the increased awareness of pain consequent of conducting the research in the setting where the change was implemented facilitated the process. Clearly, this would represent an advantage for the implementation of the MAPS. Further, the specificity of the guideline to the population of critically ill young children is an advantage for direct use with this group. Other strategies to facilitate implementation of the MAPS and the guideline would be to identify opinion leaders and 'champions' in the clinical setting. These individuals possess characteristics that are highly regarded and would be able to influence the practice of their peers and support the implementation process (Bourbonnais et al., 2004; Puntillo et al., 2002). Finally, a plan to evaluate the impact of the MAPS and the guideline would be the final step following implementation to measure the impact of practice upon patient's outcomes (National Health and Medical Research Council, 1999).

Quality Improvement in Pain Management

Having clinical practice guidelines, policies, and protocols in place is no guarantee of effective decision-making and pain management (Davis & Taylor-Vaisey, 1997; Rees, 2000; Woolf, Grol, Hutchinson, Eccles, & Grimshaw, 1999). Despite their benefits, clinical guidelines and protocols have the potential to prevent individualised care and thus lead to inappropriate standardised care (Hewitt-Taylor, 2004; Woolf et al., 1999). Monitoring of the appropriateness and effectiveness of pain management,

as part of a pain quality improvement initiative would help to improve and maintain high quality standards of pain management practices. Such a program would also facilitate the sustained use of pain assessment instruments, such as the MAPS, in the clinical setting (Joint Commission on Accreditation for Healthcare Organizations, 2003).

The process of developing a quality improvement program in pain management can be done at the level of the organisation or at unit-level. In the instance of this study, a unit-based approach would be recommended because of the specific needs of PICU patients. The findings of this research highlight the inability of critically ill children to respond to pain in a way similar to healthy children, thus requiring specific pain assessment strategies. In addition, pain management in the intensive care unit differs greatly from the wards. Treatment of pain for common ICU procedures often include large dose of opioids and sedatives which may result in a depressed state of consciousness, and an inability to both maintain a patent airway independently and respond purposefully to stimulation. Due to the potential for serious adverse effects, these procedures should be performed in the intensive care setting, where there are staff trained in paediatric advanced life support and where adequate resuscitation equipment is available (American Academy of Pediatrics, 2002).

Planning of the pain quality improvement program is an essential step of the process and starts with the formation of a multidisciplinary pain management steering committee. For the critical care area, the committee may be representative of clinical nurse specialists, department heads, intensivists and consultants, researchers, physiotherapists, and chaplains (Joint Commission on Accreditation for Healthcare

Organizations, 2003; Miaskowski, 2001). The role of the committee would be to establish clear goals and objectives, and to determine the unit's relationship with the organisation's pain service and other relevant services. Quality improvement initiatives may include (a) development and implementation of pain management guidelines based on the best evidence available, (b) professional education, and (c) conduct of an audit to evaluate the effectiveness of the change implemented.

Professional education

Implementation of the MAPS as well as an interventional protocol to facilitate assessment and decision-making in the clinical setting would not be successful without appropriate staff training and education. Truman et al. (2005) used different strategies in the education phase of the implementation process of sedation and delirium assessment scales in two medical intensive care units. These successful strategies comprised display of posters and unit-wide seminars attended by staff nurses. Seminars were conducted in forms of workshops using bulletin boards, handouts, laminated pocket cards, and case studies, followed by bedside demonstration rounds. The education training was staged two to three monthly over a maximum of nine months. In addition, descriptions of the scales were added to the nurse preceptor packets and use of the scales was incorporated into the competency checklist. Van Dijk et al. (2005) developed a CD-ROM for an interactive form of training of the use of the COMFORT scale in clinical practice. Input from the existing personnel, such as nurse educators, clinical development nurses, nurse managers, and clinical nurses, is also an important factor for successful implementation. Finally, educational updates and inclusion of pain content in nursing orientation programs are initiatives to increase and sustain staff nurses' knowledge.

Similar strategies would be recommended to facilitate the implementation and use of the MAPS in the clinical setting.

Professional education should, however, not be limited to the provision of staff education to ensure nurses have the knowledge necessary for appropriate use of the MAPS. Findings of this research are likely to impact more broadly on nursing education at different levels. Undergraduate nursing education alone cannot prepare nurses sufficiently for the practice at the advanced level, such as postgraduate paediatric nursing and paediatric critical care (Aslan et al., 2003; van Hulle Vincent, 2005). In addition to the essential components of pain education included in the IASP nursing curricula (International Association for the Study of Pain, 2006) and the IASP core curriculum for professional education in pain (IASP Task Force on Professional Education, 2005), education programs at the advanced level require more in-depth examination and critical analysis of pain theory, conceptual models, and research evidence (Australian College of Critical Care Nurses Inc., 2002; International Association for the Study of Pain, 2006; Royal College of Nursing Institute, 1999).

The teaching strategies used seem as important as the content taught. Current nursing education format does not appear to be preparing nurses to manage pain adequately in the clinical area and changing nurses' attitudes and knowledge (Knoblauch & Wilson, 1999; Twycross, 2002; Watt-Watson et al., 2001). Innovative teaching strategies, which support problem-based and adult learning, should be used and evaluated with relation to changes in practice over time. Teaching rounds, case studies, and research utilisation programs are problem-based learning strategies that

have been shown to make teaching more relevant to nurses and encourage reflective, critical and active learning (Ochieng, 1999; Twycross, 2002). For the education about the assessment and management of pain in young critically ill children, teaching strategies that facilitate adult learning are recommended.

Audit

Evaluation of the success of the implementation of changes in pain management would be a required step to ensure the changes improve practice and patients' outcomes. This can be carried out by reviewing medical records and compliance with protocol, and assessing staff competency, knowledge and attitudes. The Australian College of Critical Care Nurses (ACCCN) competency standards (Australian College of Critical Care Nurses Inc., 2002) could serve as benchmarks to evaluated PICU staff competency. Review of individual's performance in all aspects of the 20 competency standards would be regarded as evidence of superior and/or effective performance. The critical care competency standards that are particularly relevant to pain management include:

- maintains a physical and psychological environment which promotes safety, security and optimal health
- acts to enhance the dignity and integrity of individuals, (c) facilitates informed decision-making
- employs the skills of effective communication
- manages therapeutic interventions and regimes
- integrates comprehensive patient assessment and interpretive skills
- evaluates and responds effectively to changing situations
- develops and manages a plan of care to achieve desired outcomes

- protects the rights of patients
- demonstrates accountability for nursing practice
- demonstrates and contributes to effective, ethical decision-making
- recognises own abilities and level of professional competence
- engages in and contributes to evidence-based critical care practice
- collaborates with the critical care team.

Knowledge and attitudes of staff can be tested using valid questionnaires, such as the Pediatric Nurses' Knowledge and Attitudes Survey regarding pain (Manworren, 2001).

Other evaluation strategies may include direct observation of care (e.g. care during a painful procedure) to evaluate the treatment use, effectiveness and/or complications; conduct of a point prevalence study to determine the prevalence and nature of pain experienced in the PICU; survey of staff satisfaction with clinical utility of the MAPS and protocols; survey of patient and family satisfaction/involvement with pain care; and assessment of patients' status and outcomes over time. Patients outcomes may be measures of pain intensity, pain-related complications, length of time to extubation, length of stay in ICU, incidence of drug-related side effects (Furdon et al., 1998). When data are collected and analysed, dissemination of the results is important to further develop pain improvement strategies and improve performance (Joint Commission on Accreditation for Healthcare Organizations, 2003). These strategies would be recommended to evaluate the effectiveness of the MAPS in the clinical setting and further support the scale's clinical utility as well as facilitating continuous improvement of pain management practices.

Implications for Nursing Research

As previously stated, psychometric testing of new instruments is a lengthy process. This research provided the minimum requirement of reliability and validity for use of the MAPS in clinical practice. However, further psychometric testing needs to be undertaken to support the clinical validity of the revised MAPS and its benefits over other existing pain instruments. For instance, investigation of the utility of the MAPS in response to different types of analgesics is recommended. Franck (2005) stated that there is an imbalance in pain-related research topics, resulting in some areas being under-researched and other over-researched. Therefore, more research of the effectiveness of analgesia is needed, and this could be measured using the MAPS. Clinical utility in different types of clinical scenarios is also warranted. For instance, investigation of the MAPS' utility in assessing procedural pain only and postoperative pain due to various types of surgery would potentially enhance its use in practice. Discriminant validity of the MAPS also needs to be established, and this could be achieved by comparing the MAPS with an instrument that would measure a different construct, such as sedation. The MAPS has also the potential to be useful in older children whose communication is impaired, because it includes items that were also observed in non-communicative critically ill adults (Puntillo, Morris, Thompson, et al. 2004). Therefore, further investigation is recommended in older children.

The author of this thesis has acknowledged the responsibility of implementing some of the recommendations cited above. Future quality improvement initiatives should be conducted in a rigorous and systematic way similar to research. Ethics approval may be obtained if the activity is likely to represent risks or burdens for patients, families, and health care providers beyond those of their routine care or if the activity is inconsistent with National Privacy Principles (National Health and Medical Research Council, 2003). These quality improvement initiatives, including the implementation of standardised pain assessment, using the MAPS, and the development, implementation, and evaluation of an integrated guideline for the management of pain, are essential to demonstrate the positive impact upon patients' outcomes.

The author also recognises the need for a multi-disciplinary collaborative approach to pain research. This approach would have several advantages, including the formation of a group of expert researchers, the ability to conduct multi-centre studies and to be competitive with grant applications, and to undertake quality paediatric pain research that would be more meaningful, efficient, and relevant to clinicians, patients and their families.

Conclusions: Development of a Multidimensional Assessment Pain Scale for Critically ill Preverbal Children

Development of pain assessment instruments is a lengthy and complex process that involves several studies. This multi-phase research presents the first stages in the process of tool development for assessing pain in postoperative critically ill children. This process presented several challenges, because these children were compromised by the severity of their illness, their level of impaired communication, and the stage

of their development. However, the method of observation used in the first phase of this study allowed the researcher to capture responses to pain in the context these children would normally experience pain. Through detailed descriptions and analyses of these experiences it was then to define pain indicators in this group. Following a rigorous process of tool development, the Multidimensional Pain Assessment Scale was constructed and then tested in different clinical scenarios to establish its reliability, validity, and clinical utility. Results from these tests support the MAPS psychometric properties for use in practice.

The Multidimensional Pain Assessment Scale has the potential to facilitate continuous assessment and documentation of the intensity of pain in critically ill young children, to influence decision-making in the presence of clinical expertise and to evaluate the effectiveness of therapeutic actions. Assessment of pain, using a clinically valid tool, such as the MAPS, should be part, not the entirety, of standard nursing care provided in the paediatric intensive care unit. Integration of the MAPS with an evidence-based clinical practice guideline for the management of pain in critically ill young children would enhance compliance, patients' care and health outcomes.

REFERENCES

Abu-Saad, H. H. (1998). Assessment of pain in infants. *Research and Clinical Forums, 20*(4), 31-44.

Abu-Saad, H. H. (1999). *Decision making and pediatric pain relief in nursing.* Paper presented at the The 6th International Congress on Pediatric Emergency and Intensive Care, Abano Terme, Italy.

Abu-Saad, H. H., Bours, J. J. W., Stevens, B., & Hamers, J. P. H. (1998). Assessment of pain in the neonate. *Seminars in Perinatology, 22*(5), 402-416.

Abu-Saad, H. H., & Hamers, J. P. (1997). Decision-making and paediatric pain: a review. *Journal of Advanced Nursing, 26*, 946-952.

Adams, A., Pelletier, D., Duffield, C., Nagy, S., Crisp, J., & Mitten-Lewis, S. (1997). Determining and discerning expert practice: A review of the literature. *Clinical Nurse Specialist, 11*(5), 217-222.

Agency for Health Care Policy and Research. (1992). Acute pain management: Operative or medical procedures and trauma (Clinical Practice guideline No1) (AHCPR Publication No. 92-0032).

Alexander, E., Carnevale, F. A., & Razack, S. (2002). Evaluation of a sedation protocol for intubated critically ill children. *Intensive and Critical Care Nursing, 18*, 292-301.

Altman, D. G. (1996). *Practical statistics for medical research* (1st ed.). London: Chapman & Hall.

Ambuel, B., Hamlett, K. W., Marx, C. M., & Blumer, J. L. (1992). Assessing distress in pediatric intensive care environments: The COMFORT scale. *Journal of Pediatric Psychology, 17*(1), 92-109.

American Academy of Pediatrics. (2002). Guidelines for monitoring and management of paediatric patients during and after sedation for diagnostic and therapeutic procedures: Addebdum. *Pediatrics, 110*(4), 836-837.

American Academy of Pediatrics, & Canadian Paediatric Society. (2000). Prevention and management of pain and stress in the neonate. *Pediatrics, 105*(2), 454.

American Educational Research Association, American Psychological Association, & National Council on Measurement in Education. (1999). *Standards for educational and psychological testing*. Washington, WA: American Educational Research Association.

American Pain Society. (1992). *Principles of analgesic use in the treatment of acute pain and cancer pain*. Stockie: American Pain Society.

American Society of Anesthesiologist. (1999). *The ASA physical status classification system*. Retrieved January 7, 2002, from www.asahq.org

Anand, K. J., Barton, B. A., McIntosh, N., Lagercrantz, H., Pelausa, E., Young, T. E., et al. (1999). Analgesia and sedation in preterm neonates who require ventilatory support: results from the NOPAIN trial. Neonatal Outcome and Prolonged Analgesia in Neonates. *Archives of Pediatrics and Adolescent Medicine, 153*(4), 331-338.

Anand, K. J. S. (1998). Pain and pain management during infancy. *Research and Clinical Forums, 20*(4), 43.

Anand, K. J. S. (2000). Effects of perinatal pain and stress. In E. A. Mayer & C. B. Saper (Eds.), *The biological basis for mind interactions* (Vol. 122, pp. 117-129): Elsevier Science BV.

Anand, K. J. S. (2003). *Mechanisms of pain: Immediate and long-term effects in critical illness.* Paper presented at the 4th World Congress on Pediatric Intensive Care, Boston, MA.

Anand, K. J. S., Coskun, V., Thrivikraman, K. V., Nemernoff, C. B., & Plotsky, P. M. (1999). Long-term behavioral effects of repetitive pain in neonatal rat pups. *Physiology and Behavior, 66*(4), 627-637.

Anand, K. J. S., & Craig, K. D. (1996a). Editorial new perspective on the definition of pain. *Pain, 67*(1), 3-6.

Anand, K. J. S., & Craig, K. D. (1996b). Re: Reply to letters to the editor from Merskey & Wall. *Pain, 67*, 210.

Anand, K. J. S., Grunau, R. E., & Oberlander, T. (1997). Developmental character and long-term consequences of pain in infants and children. *Child and Adolescent Psychiatric Clinic of North America, 6*, 703-724.

Anand, K. J. S., & Hickey, P. R. (1987). Pain and its effects in the human neonate and fetus. *New England Journal of Medicine, 7*(21), 1321-1329.

Anand, K. J. S., & Hickey, P. R. (1992). Halothane-morphine compared with high-dose sufentanil for anesthesia and postoperative analgesia in neonatal cardiac surgery. *New England Journal of Medicine, 326*(1), 1-9.

Anand, K. J. S., & International Evidence-Based Group for Neonatal Pain. (2001). Consensus statement for the prevention and management of pain in the newborn. *Archives of Pediatric and Adolescent Medicine, 155*, 173-180.

Anand, K. J. S., Rovnaghi, C., Walden, M., & Churchill, J. (1999). Consciousness, behavior, and clinical impact of the definition of pain. *Pain Forum, 8*(2), 64-73.

Andrews, K., & Fitzgerald, C. E. (2002). Wound sensitivity as a measure of analgesic effects following surgery in human neonates and infants. *Pain, 99*(1-2), 185-195.

Andrews, K., & Fitzgerald, M. (1997). Barriers to optimal pain management in infants, children, and adolescents: biological barriers to paediatric pain management. *Clinical Journal of Pain, 13*(2), 138-143.

Andrews, K., & Wills, B. (1992). A systematic approach can reduce side-effects: A protocol for pain relief in neonates. *Professional Nurse, 78*(8), 528-531.

Aslan, F. E., Badir, A., & Selimen, D. (2003). How do intensive care nurses assess patients' pain? *Nursing in Critical Care, 8*(2), 62-67.

Attia, J., Amiel-Tison, C., Mayer, M.-N., Shinder, S. M., & Barrier, G. (1987). Measurement of postoperative pain and narcotic administration in infants using a new clinical scoring system. *Anesthesiology, 67*, 532A.

Australian and New Zealand Paediatric Intensive Care Registry. (2004). *Report of Australian and New Zealand Paediatric Intensive Care Registry 2002*. Adelaide, South Australia.

Australian College of Critical Care Nurses Inc. (2002). *Competency standards for specialist critical care nurses* (2nd ed.). Perth, Western Australia: Ink Press International.

Azzam, M. A., Pascucci, R., Curley, M. A. Q., & Laussen, P. C. (2001). Comparison of the bispectral index (BIS) with the Comfort score to assess sedation in the pediatric intensive care unit *Critical Care Medicine, 28*(Suppl. 12), A115.

Ballantyne, M., Stevens, B., McAllister, M., Dionne, K., & Jack, A. (1999). Validation of the premature infant pain profile in the clinical setting. *Clinical Journal of Pain, 15*(4), 297-303.

Barrier, G., Attia, J., Mayer, M.-N., Amiel-Tison, C., & Shinder, S. M. (1989). Measurement of postoperative pain and narcotic administration in infants

using a new clinical scoring system. *Intensive Care Medicine, 1*(Suppl.15), S37-39.

Bauchner, H., May, A., & Coates, E. (1992). Use of analgesic agents for invasive medical procedures in pediatric and neonatal intensive care units. *Journal of Pediatrics, 121*, 647-649.

Beck, C. T. (1999). Content validity exercises for nursing students. *Journal of Nursing Education, 38*(3), 133-135.

Benini, F., Johnston, C., Faucher, D., & Aranda, J. V. (1993). Topical anesthesia during circumcision in newborn infants. *Journal of the American Medical Association, 270*(7), 850-853.

Beyer, J. E., McGrath, P. J., & Berde, C. B. (1990). Discordance between self-report and behavioral pain measures in children aged 3-7 years after surgery. *Journal of Pain and Symptom Management, 5*(6), 350-356.

Bhutta, A. T., & Anand, K. J. (2002). Vulnerability of the developing brain. Neuronal mechanisms. *Clinics in Perinatology, 29*(3), 357-372.

Bland, J. M., & Altman, D. G. (1986). Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet, i*, 307-310.

Bland, J. M., & Altman, D. G. (2002). Validating scales and indexes. *British Medical Journal, 324*(7332), 606-607.

Blauer, T., & Gertsmann, D. (1998). A simultaneous comparison of three neonatal pain scales during common NICU procedures. *The Clinical Journal of Pain, 14*(1), 39-47.

Blenkharn, A., Faughnan, S., & Morgan, A. (2002). Developing a pain assessment tool for use by nurses in an adult intensive care unit. *Intensive and Critical Care Nursing, 18*(6), 332-341.

Boelen van der Loo, W. J. C., Scheffer, E., de Haan, R. J., & de Groot, C. J. (1999). Clinimetric evaluation of the pain observation scale for young children in children aged between 1 and 4 years after ear, nose, and throat surgery. *Developmental and behavioural Pediatrics, 20*(4), 222-227.

Bourbonnais, F. F., Perreault, A., & Bouvette, M. (2004). Introduction of a pain and symptom assessment tool in the clinical setting-lessons learned. *Journal of Nursing Management, 12*, 194-200.

Bozette, M. (1993). Observation of pain behavior in the NICU: an exploratory study. *Journal of Perinatal and Neonatal Nursing, 7*(1), 76-86.

Breau, L. M., Camfield, C. S., McGrath, P. J., & Finley, G. A. (2003). The incidence of pain in children with severe cognitive impairments. *Archives of Pediatrics & Adolescent Medicine, 157*(12), 1219-1226.

Breau, L. M., McGrath, P. J., Camfield, C., Rosmus, C., & Finley, G. A. (2000). Preliminary validation of an observational pain checklist for persons with cognitive impairments and inability to communicate verbally. *Developmental Medicine & Child Neurology, 42*(9), 609-616.

Brennan, F., & Cousins, M. J. (2004). *Pain Clinical Updates, 12*(5), 1-4.

Broadman, L. M., Rice, L. H., & Hannallah, R. S. (1988). Testing the validity of an objective pain scale for infants and children [Abstract]. *Anesthesiology, 69*, A770.

Brook, A. D., Ahrens, T. S., Schaiff, R., Prentice, D., Sherman, G., Shannon, W., et al. (1999). Effect of a nursing-implemented sedation protocol on the duration of mechanical ventilation. *Critical Care Medicine, 27*(12), 2609-2615.

Brooks, J. T. (1998). An analysis of nursing documentation as a reflection of actual nurse work. *Medsurg Nursing, 7*(4), 189-198.

Broome, M. E., & Tanzillo, H. (1990). Differentiating between pain and agitation in premature neonates. *The Journal of Perinatal and Neonatal Nursing, 4*(1), 53-62.

Brunow de Carvalho, W., Lucas da Silva, P. S., Paulo, C. S., Fonseca, M. M., & Belli, L. A. (1999). Comparison between the Comfort and Hartwig sedation scales in pediatric patients undergoing mechanical lung ventilation. *Sao Paulo Medical Journal, 117*(5), 192-196.

Buchholz, M., Karl, H. W., Pomietto, M., & Lynn, A. (1998). Pain scores in infants: a modified infant pain scale versus visual analogue. *Journal of Pain & Symptom Management, 15*(2), 117-124.

Butler-O'Hara, M., LeMoine , C., & Guillet, R. (1998). Analgesia for neonatal circumcision: A randomised controlled trial of EMLA cream versus dorsal penil nerve block. *Pediatrics, 101*(4), 5.

Buttner, W., & Finke, W. (2000). Analysis of behavioural and physiological parameters for the assessment of postoperative analgesic demand in newborns, infants and young children: a comprehensive report on seven consecutive studies. *Paediatric Anaesthesia, 10*(3), 303-318.

Buttner, W., Finke, W., M., H., Reckert, S., Vsianska, L., & Brambrink, A. (1998). Entwicklung eines Fremdbeobach-tungsbogens zur Beurteilung des postoperativen Schmerzes bei Sauglingen. [Development of an observational scale for assessment of postoperative pain in infants]. *Anasthesiologie, Intensivmedizin, Notfallmedizin, Schmerztherapie, 33*(6), 353-361.

Cairns, M., & Ramelet, A. S. (2004). Adequacy of the use of nursing documentation in a PICU [Abstract]. *Australian Critical Care, 17*(4), 168.

Carbajal, R., Paupe, A., Hoenn, E., Lenclen, R., Martin, O., & Dan, M. (1997). Une échelle comportementale d'évaluation de la douleur aigue du nouveau-né [A behavioural assessment tool for newborns in acute pain]. *Archives Pediatriques, 4*(7), 623-628.

Carlin, J. B., Wolfe, R., Coffey, C., & Patton, G. C. (1999). Tutorial in biostatistics - Analysis of binary outcomes in longitudinal studies using weighted estimating equations and discrete-time survival methods: prevalence and incidence of smoking in an adolescent cohort. *Statistics in Medicine, 18*(18), 2655-2679.

Carnevale, F. A., & Razack, S. (2002). An item analysis of the COMFORT scale in a pediatric intensive care unit. *Pediatric Critical Care Medicine, 3*(2), 177-184.

Carroll, K. C., Atkins, P. J., Herold, G. R., Mlcek, C. A., Shively, M., Clopton, P., et al. (1999). Pain assessment and management in critically ill postoperative and trauma patients: A multisite study. *American Journal of Critical Care, 8*(2), 105-117.

Carroll, K. C., & Cook, C. (1993). The role of analgesics and sedatives in the managment of pain and agitation during weaning from mechanical ventilation. *Critical Care Nursing Quarterly, 15*(4), 68-77.

Casarett, D., Karlawish, J., Sankar, P., Hirschman, K. B., & Asch, D. A. (2001). Obtaining informed consent for clinical pain research: Patients' concerns and information needs, *Pain, 92*, 71-79.

Casey, K. L. (1999). A neurologist's perspective on pain and consciousness. *Pain Forum, 8*(3), 124-126.

Chapman, C. R., & Nakamura, Y. (1999). Pain and consciousness: A constructivist approach. *Pain Forum, 8*(3), 113-123.

Clarke, E. B., French, B., Bilodeau, M. L., capasso, V. C., Edwards, A., & Empoliti, J. (1996). Pain management knowledge, attitudes and clinical practice: the

impact of nurse' s characterictics and education. *Journal of Pain and Symptom Management, 11*(1), 18-31.

Cnaan, A., Laird, N. M., & Slasor, P. (1997). Using the general linear mixed model to analyse unbalanced repeated measures and longitudinal data. *Statistics in Medicine, 16*(20), 2349-2380.

Cohen Reis, E., Kraus Roth, E., Syphan, J. L., Tarbell, S. E., & Holubkov, R. (2003). Effective pain reduction for multiple immunization injections in young infants. *Archives of Pediatric and Adolescent Medicine, 157*, 1115-1120.

Colwell, C., Clark, L., & Perkins, R. (1996). Postoperative use of pediatric pain scales: children's self-report versus nurse assessment of pain intensity and effect. *Journal of Pediatric Nursing, 11*(6), 375-382.

Cote, J. J., Morse, J. M., & James, S. G. (1991). The pain response of the post-operative newborn. *Journal of Advanced Nursing, 16*, 378-387.

Coyne, M. L., Reinert, B., Cater, K., Dubuisson, W., Smith, H., Parker, M. M., et al. (1999). Nurses' knowledge of pain assessment, pharmacologic and nonpharmacologic interventions. *Clinical Nursing Research, 8*(2), 153-165.

Craig, K. D. (1997). Implications of concepts of consciousness for understanding pain behaviour and the definition of pain. *Pain Research and Management, 2*(2), 111-117.

Craig, K. D., Hadjistavropoulos, H. D., Grunau, R. V. E., & Whitfield, M. F. (1994). A comparison of two measures of facial activity during pain in the newborn child. *Journal of Pediatric Psychology, 19*(3), 305-318.

Craig, K. D., Korol, C. T., & Pillai, R. R. (2002). Challenges of judging pain in vulnerable infants. *Clinics in Perinatology, 29*, 445-457.

Craig, K. D., Whitfield, M. F., Grunau, R. V. E., Linton, J., & Hadjistavropoulos, H. D. (1993). Pain in the preterm neonate: Behavioral and physiological indices. *Pain, 52*, 287-299.

Crain, N., Slomin, A., & Ollack, M. M. (2002). Assessing sedation in the pediatric intensive care unit by using BIS and the COMFORT scale. *Pediatric Critical Care Medicine, 3*(1), 11-14.

Curley, M. A. Q., McDermott, B., Berry, P., Hurley, J., Mackey, C., McAleer, D., et al. (1992). Nurses' decison making regarding the use of sedatives and analgesics in pediatric ICU. *Heart & Lung, 21*(3), 296.

Curley, M. A. Q., & Molengraft, J. A. (1995). Providing comfort to critically ill pediatric patients: isoflurane. *Critical Care Nursing Clinics of North America, 7*(2), 267-674.

Curley, M. A. Q., Thompson, J. E., & Arnold, J. H. (2000). The effect of early and repeated prone positioning in pediatric patients with acute lung injury. *Chest, 118*(1), 156-153.

Davis, D. A., & Taylor-Vaisey, A. (1997). Translating guidelines into practice. A systematic review of theoretic concepts, practical experience and research evidence in the adoption of clinical practice guidelines. *Canadian Medical Association Journal, 157*, 408-416.

De Jonghe, B., Cook, D., Appere-De-Vecchi, C., Guyatt, G., Meade, M., & Outin, H. (2000). Using and understanding sedation scoring systems: A systematic review. *Intensive Care Medicine, 26*(3), 275-285.

De Vellis, R. F. (2003). *Scale development theory and applications* (2nd ed. Vol. 26). Thousands Oaks, CA: Sage Publications, Inc.

Debillon, T., Sgaggero, B., Zupan, V., Tres, F., Magny, J. F., Bouguin, M. A., et al. (1994). Sémiologie de la douleur chez le prématuré [Semiology of pain in the premature infant]. *Archives Pédiatriques, 1*, 1085-1092.

Debillon, T., Zupan, V., Ravault, N., Magny, J. F., & al., e. (2001). Development and initial validation of the EDIN scale, a new tool for assessing prolonged pain in preterm infants/commentary. *Archives of Diseases in Childhood, Supplement*, F36.

Donnelly, J., & Lynch-Smith, D. (2004). Analgesia and sedation protocols. *Critical Care Extra, Advanced Journal Nursing, 104*(5), 72EE-72HH.

Downer, K. (1996). Assessment of parental competence to consent to treatment for their child. *Nursing in Critical Care, 1*(1), 6-8.

Ducharme, C., Carnevale, F. A., Clermont, M. S., & Shea, S. (2005). A prospective study of adverse reactions to the weaning of opioids and benzodiazepines among critically ill children. *Intensive and Critical Care Nursing, 21*(3), 179-186.

Duncan, A. W. (1998). *Paediatric intensive care*. London: BMJ Books.

Ely, B. (2001). Pediatric nurses' pain management practice: Barriers to change. *Pediatric Nursing, 27*(5), 473-480.

Erkes, E. B., Parker, V. G., Carr, R. L., & Mayo, R. M. (2001). An examination of critical care nurses' knowledge and attitudes regarding pain management in hospitalized patients. *Pain Management Nursing, 2*(2), 47-53.

Feeley, K., & Gardner, A. (2006). Sedation and analgesia management for mechanically ventilated adults: Literature review, case study and recommendations for practice. *Australian Critical Care, 19*(2), 73-77.

Finley, A. G. (1998). Paediatric pain: A year in review. *Current Opinion in Anaesthesiology, 11*, 295-299.

Finley, G. A., Franck, L. S., Grunau, R. E., & von Baeyer, C. L. (2005). Why children' s pain matters. *Pain Clinical Updates, XIII*(4), 1-6.

Finley, G. A., & McGrath, P. J. E. (1998). *Measurement of pain in infants and children* (Vol. 10). Seatle, WA: IASP Press.

Fitzgerald, M. (2000). Development of the peripheral and spinal pain system. In K. J. S. Anand, B. J. Stevens & P. J. McGrath (Eds.), *Pain in neonates, 2nd revised and enlarged edition* (Vol. Pain Research and Clinical Management, pp. 9-21). Amsterdam, The Netherlands: Elsevier.

Fitzgerald, M. (2005). The development of nociceptive circuits. *Nature Reviews Neuroscience, 6*, 507-520.

Foster, R. L. (2001). Nursing judgment: The key to pain assessment in critically ill children, *Journal of the Society of Pediatric Nurses 6*(2), 90.

Franck, L. (1987). A national survey of the assessment and treatment of pain and agitation in the neonatal intensive care unit. *Journal of Obstetric, Gynecologic, and Neonatal Nursing, 16*(6), 387-393.

Franck, L. (2002). Some pain, some gain: reflections on the past two decades of neonatal pain research and treatment. *Neonatal Network, 21*(5), 37-41.

Franck, L. (2005). Research with newborn participants: Doing the right research and doing it right. *The Journal of Perinatal & Neonatal Nursing, 19*(2), 177-186.

Franck, L., & Miaskowski, C. (1997). Measurement of neonatal responses to painful stimuli: A research review. *Journal of Pain and Symptom Management, 14*(6), 343-378.

Franck, L. S., Naughton, I., & Winter, I. (2004). Opioid and benzodiazepine withdrawal symptoms in paediatric intensive care patients. *Intensive and Critical Care Nursing, 20*(6), 344-351.

Fuller, B. F., & Conner, D. A. (1995). The effect of pain on infant behaviors. *Clinical Nursing Research, 4*(3), 253-273.

Fuller, B. F., & Conner, D. A. (1996). Distribution of cues across assessed levels of infant pain. *Clinical Nursing Research, 5*(2), 167-184.

Furdon, S. A., Eastman, M., Benjamin, K., & Horgan, M. J. (1998). Outcomes measures after standardised pain management strategies in postoperative patient in the neonatal intensive care unit. *Journal of Perinatal and Neonatal Nursing, 12*(1), 58-69.

Gibbins, S., Stevens, B., & Asztalos, E. (2003). Assessment and management of acute pain in high-risk neonates. *Expert Opinion on Pharmacotherapy., 4*(4), 475-483.

Gilbert, C. A., Lilley, C. M., Craig, K. D., McGrath, P. J., Court, C. A., Bennett, S. M., et al. (1999). Postoperative Pain Expression in Preschool Children: Validation of the Child Facial Coding System. *Clinical Journal of Pain, 15*(3), 192-200.

Gill, A. M. (1996). drug handling in critically ill children. *Care of the Critically Ill, 12*(1), 6-9.

Gonzales, R., Dever, R., & Singleton, K. A. (1997). Conflicting demands between functional and legal family units. *DCCN - Dimensions of Critical Care Nursing, 16*(2), 96-100.

Gross Portney, L., & Watkins, M. P. (1993). *Foundations of clinical research: Applications to practice*. Stamford, CT: Appleton & Lange.

Grunau, R. E. (2002). Early pain in preterm infants: A model of long-term effects. *Clinics in Perinatology, 29*, 373-394.

Grunau, R. E., Holsti, L., Whitfield, M. F., & Ling, E. (2000). Are twitches, startles, and body movements pain indicators in extremely low birth weight infants? *Clinical Journal of Pain, 16*, 37-45.

Grunau, R. E., Oberlander, T., Whitfield, M. F., Fitzgerald, C. E., & Lee, S. K. (2001). Demographic and therapeutic determinants of pain reactivity in very low birth weight neonates at 32 weeks' postconceptional age. *Pediatrics, 107*(1), 105-112.

Grunau, R. E., Weinberg, J. A., & Whitfield, M. F. (2004). Neonatal procedural pain and preterm infant cortisol response to novelty at 8 months. *Pediatrics, 114*(1), 77-84.

Grunau, R. V. E., & Craig, K. D. (1987). Pain expression in neonates: Facial action and cry. *Pain, 28*(3), 395-410.

Grunau, R. V. E., & Craig, K. D. (1990). Facial activity as a measure of neonatal pain expression. In D. C. Tyler & E. J. Krane (Eds.), *Advances in pain research therapy* (Vol. 15, pp. 147-155). New York: Raven Press Ltd.

Grunau, R. V. E., Johnston, C. C., & Craig, K. D. (1990). Neonatal facial and cry responses to invasive and non-invasive procedures. *Pain, 42*, 295-305.

Grunau, R. V. E., Oberlander, T., Holsti, L., & Whitfield, M. F. (1998). Bedside application of the Neonatal Facial Coding System. *Pain, 76*, 277-286.

Grunau, R. V. E., Whitfield, M. F., & Petrie, J. H. (1994). Pain sensitivity and temperament in extremely low-birth-weight premature toddlers and preterm and full-term controls. *Pain, 58*(3), 341-346.

Grunau, R. V. E., Whitfield, M. F., Petrie, J. H., & Fryer, E. L. (1994). Early pain experience, child, and family factors, as precursors of somatization: a prospective study of extremely premature and fullterm children. *Pain, 56*(2), 353-359.

Hadjistavropoulos, H. D., Craig, K. D., Grunau, R. E., & Whitfield, M. F. (1997). Judging pain in infants: behavioural, contextual, and developmental determinants. *Pain, 73*, 319-324.

Hadjistavropoulos, T., LaChapelle, D. L., Hadjistavropoulos, H. D., Green, S., & Asmundson, G. J. (2002). Using facial expressions to assess musculoskeletal pain in older persons. *European Journal of Pain, 6*(3), 179-187.

Harrison, D., Evans, C., Johnston, L., & Loughnan, P. (2002). Bedside assessment of heel lance pain in the hospitalised infant. *Journal of Obstetric, Gynecologic, and Neonatal Nursing, 31*(5), 551-557.

Harte, G. J., Gray, P. H., lee, T. C., Steer, P. A., & Charles, B. G. (1997). Haemodynamic responses and population pharmacokinetics of midazolam following administration to ventilated, preterm neonates. *Journal of Paediatrics and Child Health, 33*, 335-338.

Hensley, R. L. (1999). A review of operations management studies using scale development techniques. *Journal of Operations Management, 17*, 343-358.

Hewitt-Taylor, J. (2004). Clinical guidelines and care protocols. *Intensive and Critical Care Nursing, 20*, 45-52.

Hodgkinson, K., Bear, M., Thorn, J., & Van Blaricum, S. (1994). Measuring pain in neonates: evaluating an instrument and developing a common language. *The Australian Journal of Advanced Nursing, 12*(1), 17-22.

Horgan, M., Choonara, I., Al-Waidh, M., Sambrooks, J., & Ashby, D. (1996). Measuring pain in neonates: an objective score. *Pediatric Nursing, 8*(10), 24-27.

Howard, C. R., Howard, F. M., & Weitzman, M. L. (1994). Acetaminophen analgesia in neonatal circumcision: The effect on pain. *Pediatrics, 93*(4), 641-646.

Hudson-Barr, D., Capper-Michel, B., Lambert, S., Palermo, T. M., Morbeto, K., & Lombardo, S. (2002). Validation of the Pain Assessment in Neonates (PAIN) Scale withthe Neonatal Infant Pain Scale (NIPS). *Neonatal Network, 21*(6), 15-21.

IASP Task Force on Professional Education. (2005). *Core curriculum for professional education in pain* (3rd ed.). Seattle: IASP Press.

International Association for the Study of Pain. (1994). IASP Pain Terminology: IASP Press.

International Association for the Study of Pain. (2006). *Outline curriculum on pain for nursing*. Seattle: IASP Press.

Jacob, E., & Puntillo, K. A. (1999). A survey of nursing practice in the assessment and management of pain in children. *Pediatric Nursing, 25*(3), 278.

Jacqz-Agrain, E., Daoud, P., Burtin, P., Desplanques, L., & Beaufils, F. (1994). Placebo-controlled trial of midazolam sedation in mechanically ventilated newborn babies. *The Lancet, 3*, 646-650.

Jensen, M. (2003). Questionnaire validation: A brief guide for readers of the research literature. *The Clinical Journal of Pain, 19*(6), 345-352.

Johnston, C., Stevens, B., Yang, F., & Horton, L. (1995). Differential response to pain by very premature neonates. *Pain, 61*, 471-479.

Johnston, C. C. (1998). Psychometric issues in the measurement of pain. In G. A. Finley & J. McGrath (Eds.), *Measurement of pain in infants and children*. Seattle, WA: IASP Press.

Johnston, C. C., Collinge, J. M., Henderson, S. J., & Anand, K. J. S. (1997). A cross-sectional survey of pain and pharmacological analgesia in Canadian neonatal intensive care units. *The Clinical Journal of Pain, 13*, 308-312.

Johnston, C. C., Stevens, B., Craig, K. D., & Grunau, R. V. E. (1993). Developmental changes in pain expression in premature, full-term, two- and four-month-old infants. *Pain, 52*, 201-208.

Johnston, C. C., Stevens, B., Franck, L., Jack, A., Stremler, R., & Platt, R. (1999). Factors explaining lack of response to heel stick in preterm newborns. *Journal of Obstetric, Gynecologic, & Neonatal Nursing, 28*(6), 587-594.

Joint Commission on Accreditation for Healthcare Organizations. (2003). *Improving the quality of pain management through measurement and action*. Oakbrook Terrace, Il: Joint Commission Resources, Inc.

Joint Commission on Accreditation on Healthcare Organizations. (2001). *Joint Commission on Accreditation of Healthcare Organizations pain standards for 2001*. Retrieved January 09, 2001, from www.jcaho.org

Joyce, B. A., Schade, J. G., & Keck, J. F. (1994). Reliability and validity of preverbal pain assessment tools. *Issues in Comprehensive Pediatric Nursing, 17*, 121-134.

Kitchin, L. W., & Hutchinson, S. (1996). Touch during preterm infant resuscitation. *Neonatal Network, 15*(17), 45-51.

Knoblauch, S. C., & Wilson, C. J. (1999). Clinical outcomes of educating nurses about pediatric pain management. *Outcomes Management for Nursing Practice April/June, 3*(2), 87-89.

Krechel, S. W., & Bildner, J. (1995). CRIES: A new neonatal postoperative pain measurement score. Initial testing of validity and reliability. *Paediatric Anaesthesia, 5*, 53-61.

Larsson, B. A., Tannfeldt, G., Lagercrantz, H., & Olsson, G. L. (1998). Venipuncture is more effective and less painful than heel lancing for blood tests in neonates. *Pediatrics, 101*(5), 882-886.

Lawrence, J., Alcock, D., McGrath, P., Kay, J., MacMurray, S. B., & Dulberg, C. (1993). The development of a tool to assess neonatal pain. *Neonatal Network, 12*(6), 59-66.

Leaver, A. (2005). *Consent to research: absolute and universal or flexible?* Paper presented at the 2005 National Ethics in Human Research Conference.

Lebovits, A. H., Florence, I., Bathina, R., Hunko, V., Fox, M. T., & Bramble, C. Y. (1997). Pain knowledge and attitudes of healthcare providers: Practice characteristic differences. *Clinical Journal of Pain, 13*(3), 237-243.

Lilley, C. M., Craig, K. D., & Grunau, R. E. (1997). The expression of pain in infants and toddlers: Developmental changes in facial action. *Pain, 72*, 161-170.

Lindblom, U., Merskey, H., Mumford, J. M., Nathan, P. W., Noordenbos, W., & Sunderland, S. (1986). Pain terms a curent list with definitions and notes on usage. *Pain, Suppl. 3*, 215-221.

Lindh, V., Wiklund, U., Blomquist, H. K., & Hakansson, S. (2003). EMLA cream and oral glucose for immunization pain in 3-month-old infants. *Pain, 104*(1-2), 381-388.

Lindh, V., Wiklund, U., & Hakansson, S. (1999). Heel lancing in term new-born infants: An evaluation of pain by frequency domain analysis of heart rate variability. *Pain, 80*, 143-148.

LoBiondo-Wood, G., & Haber, J. (1994). *Nursing research: Methods, critical appraisal and utilization* (3rd ed.). St . Louis, MI: Mosby.

Long, D., Horn, D., & Keogh, S. (2005). A survey of sedation assessment and management in Australian and New Zealand paediatric intensive care patients requiring prolonged mechanical ventilation. *Australian Critical Care, 18*(4), 152-157.

Ludwick, F., Hall, L., & Gaines, S. K. (1995). Examining management of pain for infants following cardiothoracic surgery. *Dimensions of Critical Care Nursing, 14*(3), 136-143.

Lynn, M. R. (1986). Determination and quantification of content validity. *Nursing Research, 35*, 382-385.

Mahon, S. M. (1994). Concept analysis of pain: Implications related to nursing diagnoses. *Nursing Diagnosis, 5*(1), 14-25.

Manworren, R. C. B. (2001). Development and testing of the pediatric nurses' knowledge and attitudes survey. *Pediatric Nursing, 27*(2), 151-158.

Manworren, R. C. B., & Hynan, L. S. (2003). Clinical validation of FLACC: Preverbal patient pain scale. *Pediatric Nursing, 29*(2), 140.

Marx, C. M., Smith, P. G., Lowrie, L. H., Hamlett, K. W., Ambuel, B., Yamashita, T. S., et al. (1994). Optimal sedation of mechanically ventilated pediatric critical care patients. *Critical Care Medicine, 22*(1), 163-170.

McGrath, P. J., Unruh, A., & Finley, G. A. (1995). Pain measurement in children. *Pain Clinical Updates, III*(2).

Merkel, S. I., Voepel-Lewis, T., Shayevitz, J. R., & Malviya, S. (1997). The FLACC: A behavioral scale for scoring postoperative pain in young children. *Pediatric Nursing, 23*(3), 293-297.

Merskey, H. (1996). Response to editorial: New perspectives on the definition of pain. *Pain, 66*, 209.

Merskey, H. (1997). Pain, consciousness and behaviour. *Pain Research and Management, 2*(2), 118-122.

Merskey, H., & Bogduk, N. (1994a). *IASP Pain terminology*. Retrieved May 10, 2004, from http://www.iasp-pain.org/terms-p.html

Merskey, H., & Bogduk, N. (1994b). *Introduction to the 1986 list*. Retrieved June 20, 1997, from www.halcyon.com/iasp/

Miaskowski, C. (2001). Monitoring and improving pain management practices. A quality improvement approach. *Critical Care Nursing Clinics of North America, 13*(2), 311-317.

Mitchell, P. (1999). Understanding a young child's pain. *The Lancet, 354*(9151), 1708.

Morison, S. J., Grunau, R. E., Oberlander, T. F., & Whitfield, M. F. (2001). Relations between behavioral and cardiac autonomic reactivity to acute pain in preterm neonates. *Clinical Journal of Pain, 17*(4), 350-358.

Morris, A. B., Stanik-Hutt, J., Thompson, C. I., White, C., Wild, I., & Puntillo, K. A. (2002). *Are we hurting our children? Procedural pain in acute care settings [Abstract]*. Paper presented at the World Pain Congress, San Diego, CA.

Morse, J. M., & Bottorf, J. L. (1990). The use of ethology in clinical nursing research. *Advance in Nursing Sciences, 12*(3), 53-64.

Nadkarni, V., Griffith, P., Tice, L., Brown, J., Cullen, E., McCloskey, J., et al. (1999). The Comfort score can reliably be extended for use in sedated PICU patients with abnormal baseline muscle tone. *Critical Care Medicine, 27*(1), A114.

National Health and Medical Research Council. (1999). *A guide to the development, implementation and evaluation of clinical practice guidelines*. Canberra: NHMRC.

National Health and Medical Research Council. (2002). *The human research handbook*. Canberra, Australia: NHMRC.

National Health and Medical Research Council. (2003). *When does quality assurance in health care require independent ethical review?* Canberra: NHMRC.

National Health and Medical Research Council. (2005a). *Acute pain management: Scientific evidence* (No. 1864960426). Canberra, Australia: National Health and Medical Research Council.

National Health and Medical Research Council. (2005b). *NHMRC additional level of evidence and grades for recommendations for developers of guidelines. Pilot program 2005 - 2006*. Canberra: NHMRC.

National Institute of Nursing Research. (1994). *Symptom management: Acute pain* (No. NIH Pub No 94-2421). Washington, DC: Department of Health and Human Services, US Public Health Service, National Institute of Health.

Norden, J., Hannallah, R., Getson, P., O'Donnel, R., Kelliher, G., & Walker, N. (1991). Reliability of an objective pain scale in children [Abstract]. *Anesthesia and Analgesia, 72*, S199.

North American Nursing Diagnosis Association. (1992). *Nursing diagnoses; Definitions and classification 1992-1993*. Philadelphia: North American Nursing Diagnosis Association.

Nunnally, J. A., & Bernstein, I. (1994). *Psychometric theory* (3rd ed.). NY: McGraw-Hill.

Oberlander, T. F., O'Donnel, M. E., & Montgommery, C. J. (1999). Pain in children with significant neurological impairment. *Developmental and Behavioural Pediatrics, 20*(4), 235-243.

Ochieng, B. M. N. (1999). Use of reflective practice in introducing change on the management of pain in a paediatric setting, *Journal of Nursing Management* (Vol. 7, pp. 113-118).

Overgaard, C., & Knudsen, A. (1999). Pain-relieving effect of sucrose in newborns during heel prick. *Biology of the Neonate, 75*, 279-284.

Park, G. R., & Sladen, R. N. (1995). *Sedation and analgesia in the critically ill*. Carlton Victoria, Australia: Blackwell Science Ltd.

Pederson, C., & Bjerke, T. (1999). Pediatric pain management: A research-based clinical pathway. *Dimensions of Critical Care Nursing, 18*(3), 42.

Penrod, J., Morse, J., & Wilson, S. (1999). Comforting strategies used during nasogastric tube insertion. *Journal of Clinical Nursing, 8*(1), 31-38.

Peters, J. W. B., Koot, H. M., Grunau, R. E., De Boer, J. B., Van Druenen, M., J., Tibboel, D., et al. (2003). Neonatal Facial Coding System for assessing postoperative pain in infants: Item reduction is valid and feasible. *Clinical Journal of Pain, 19*(6), 353-363.

Peters, J. W. B., Schouw, R., Anand, K. J. S., Van Dijk, M., Duivenvoorden, H. J., & Tibboel, D. (2005). Does neonatal surgery lead to increased pain sensitivity in later childhood? *Pain, 114*(3), 444-454.

Piek, J. P., & Carman, R. (1994). Developmental profiles of spontaneous movements in infants. *Early Human Development, 39*, 109-126.

Polgar, J. M., & Barlow, I. (n.d.) Measuring the Clinical Utility of an Assessment: The Example of the Canadian Occupational Performance Measure. Retrieved May16, 2005, from http://www.seatingandmobility.ca/ISS2002/ToSunnyHill2/iss2002html/007_MeasuringtheClinicalUtilityofanAssessment.htm

Pollack, M. M., Ruttimann, U. E., & Getson, P. R. (1988). The pediatric risk of mortality (PRISM) score. *Critical Care Medicine, 16*, 1110-1116.

Porter, F. L., & Anand, K. J. S. (1998). Epidemiology of pain in neonates. *Research and Clinical Forums, 20*(4), 9-18.

Porter, F. L., Grunau, R. E., & Anand, K. J. S. (1999). Long-term effects of pain in infants. *Developmental and Behavioral Pediatrics, 20*(4), 253-261.

Porter, F. L., Porges, S., & Marshall, R. E. (1988). Newborn pain cries and vagal tone: parallel changes in response to circumcision. *Child Development, 59*, 495-505.

Porter, F. L., Wolf, C. M., Gold, J., Lotsoff, D., & Miller, J. P. (1997). Pain and pain management in newborn infants: A survey of physicians and nurses. *Pediatrics, 100*(4), 626-632.

Porter, F. L., Wolf, C. M., & Miller, J. P. (1998). The effect of handling and immobilization on the response to acute pain in newborn infants. *Pediatrics, 102*(6), 1383-1389.

Portney, L. G., & Watkins, M. P. (1993). Statistical measures of reliability. In *Foundations of clinical research: applications to practice* (pp. 505-528). Stamford, CO: Appleton & Lange.

Puntillo, K. A., Morris, A. B., Thompson, C. I., Stanik-Hutt, J., White, C. A., & Wild, L. R. (2004). Pain behaviors observed during six common procedures: Results from Thunder Project II. *Critical Care Medicine, 32*(2), 421-427.

Puntillo, K. A. (2003). Pain assessment and management in the critically ill: Wizardry or science? *American Journal of Critical Care, 12*(4), 310-316.

Puntillo, K. A., Stannard, D., Miaskowski, C., Kehrle, K., & Gleeson, S. (2002). Use of a pain assessment and intervention notation (P.A.I.N.) tool in critical care nursing practice: Nurses' evaluations. *Heart & Lung, 31*, 303-314.

Puntillo, K. A., White, C., Morris, A. B., Perdue, S. T., Stanik-Hutt, J., Thompson, C. L., et al. (2001). Patients' perceptions and responses to procedural pain: results from Thunder Project II. *American Journal of Critical Care, 10*(4), 238-251.

Ramelet, A. S. (1999). Assessment of pain and agitation in critically ill infants. *Australian Critical Care, 12*(3), 92-96.

Ramelet, A. S. (2003, June). *Protocol-guided sedation and analgesia improves clinical practice in paediatric intensive care.* Paper presented at the 9th Australian and New Zealand Paediatric and Neonatal Intensive Care Meeting, Cairns, Australia.

Ramelet, A. S., Abu-Saad, H. H., Bulsara, M., McDonald, S., & Rees, N. (2006). Capturing postoperative and procedural pain responses in critically ill infants aged 0 to 9 months. *Pediatric Critical Care Medicine, 7*(1), 19-26.

Ramelet, A. S., Huijer Abu-Saad, H., McDonald, S., & Rees, N. (2004). The challenges of pain measurement in critically ill young children: A comprehensive review. *Australian Critical Care, 17*(1), 33-45.

Ramelet, A. S., Rees, N., McDonald, S., Bulsara, M., & Huijer Abu-Saad, H. (Submitted). The Multidimensional Assessment of Pain Scale (MAPS): Development and preliminary psychometric testing.

Rautonen, J., Makela, A., Boyd, H., Apajasalo, M., & Pohjavuori, M. (1994). CRIB and SNAP: assessing the risk of death for preterm neonates. *Lancet, 21*(343), 1272-1273.

Reed, M. D., Yamashita, T. S., Marx, C. M., Myers, C. M., & Blumer, J. L. (1996). A pharmacokinetically based propofol dosing strategy for sedation of the critically ill, mechanically ventilated pediatric patient. *Critical Care Medicine, 24*(9), 1473-1481.

Rees, N. W. (2000). *Nursing management of postoperative pain: Perceived care and actual practice.* Unpublished Doctor of Philosophy, Curtin University of Technology, Perth, Western Australia.

Rennick, J. E., Johnston, C. C., Dougherty, G., Platt, R., & Ritchie, J. A. (2002). Children's psychological response after critical illness and exposure to invasive technology. *Developmental and Behavioral Pediatrics, 23*(3), 133-144.

Rennick, J. E., Morin, I., Kim, D., Johnston, C. C., Dougherty, G., & Platt, R. (2004). Identifying children at high risk for psychological sequelae after pediatric intensive care unit hospitalization. *Pediatric Critical Care Medicine, 5*(4), 358-363.

Rischbieth, A., & Blythe, D. (2005). *Ethics handbook for researchers* (1st ed.). Melbourne, Australia: Australian and New Zealand Intensive Care Society Clinical Trials Group.

Robieux, I., Kumar, R., Radhakrishnan, S., & Koren, G. (1991). Assessing pain and analgesia with a lidocaine-prilocaine emulsion in infants and toddlers during venipuncture. *Journal of Pediatrics, 118*(6), 971-973.

Romsing, J., Moller-Sonnergaard, J., Hertel, S., & Rasmussen, M. (1996). Postoperative pain in children: Comparison between ratings of children and nurses. *Journal of Pain and Symptom Management, 11*(1), 42-46.

Rosenstock, E. G., Cassuto, Y., & Zmora, E. (1999). Heart rate variability in the neonate and infant: analytical methods, physiological and clinical observations. *Acta Paediatrica, 88*(5), 477-482.

Royal College of Nursing Institute. (1999). *Clinical practice guideline: The recognition and assessment of acute pain in children*. London: Royal College of Nursing Institute.

Schade, J. G., Joyce, B. A., Gerkensmeyer, J., & Keck, J. F. (1996). Comparison of three preverbal scales for postoperative pain assessment in a diverse pediatric sample. *Journal of Pain & Symptom Management, 12*(6), 348-359.

Schiller, C. (1998). *Clinical utility of two neonatal pain assessment measures.* Unpublished Master of Science in Nursing, University of Toronto, Unpublished.

Schultz, A. A., Murphy, E., Morton, J., Stempel, A., Messenger-Rioux, C., & Bennett, K. (1999). Preverbal, Early Verbal Pediatric Pain Scale (PEPPS):

development and early psychometric testing. *Journal of Pediatric Nursing: Nursing Care of Children & Families, 14*(1), 19-27.

Shann, F., Pearson, G., Slater, A., & Wilkinson, K. (1997). Paediatric index of mortality (PIM): A mortality prediction model for children in intensive care. *Intensive Care Medicine, 23*, 201-207.

Shapiro, B. S. (1999). Implications for our definitions of pain. *Pain Forum, 8*(2), 100-102.

Simons, S. H. P., Van Dijk, M., Anand, K. S., Roofhooft, D., Van Lingen, R. A., & Tibboel, D. (2003). Do we still hurt newborn babies? *Archives of Pediatrics and Adolescent Medicine, 157*, 1058-1064.

Sirken, M. G., Bercini, D. H., & Jobe, J. B. (1990). National Center for Health Statistics data line. *Public Health Reports, 105*, 538-539.

Sparshott, M. M. (1996). The development of a clinical distress scale for ventilated newborn infants: Identification of pain and distress based on validated behavioural scores. *Journal of Neonatal Nursing, 2*(2), 5-11.

SPSS Inc. (2003). SPSS Base 11.5. Chicago, IL: SPSS Inc.

Stevens, B. (1998). Composite measures of pain. In G. A. Finley & P. J. McGrath (Eds.), *Measurement of pain in infants and children* (Vol. 10). Seattle: IASP Press.

Stevens, B., & Gibbins, S. (2002). Clinical utility and clinical significance in the assessment and management of pain in vulnerable infants. *Clinics in Perinatology, 29*, 459-468.

Stevens, B., & Johnston, C. (1994). Physiologic responses of premature infants to a painful stimulus. *Nursing Research, 43*(4), 226-231.

Stevens, B., Johnston, C., Franck, L., Petryshen, P., Jack, A., & Foster, G. (1999). The Efficacy of developmentally sensitive interventions and sucrose for relieving procedural pain in very low birth weight neonates. *Nursing Research, 48*(1), 35-43.

Stevens, B., Johnston, C., & Gibbins, S. (1999). Pain assessment in neonates. In K. J. S. Anand, B. J. Stevens & P. J. McGrath (Eds.), *Pain in neonates* (Vol. 10, pp. 101-134). Amsterdam: Elsevier Science.

Stevens, B., Johnston, C., Taddio, A., Jack, A., Koren, G., & Aranda, J. (1999). Management of pain from heel lance with lidocaine-prilocaine (EMLA)

cream: Is it safe and efficacious in preterm infants? *Developmental and Behavioural Pediatrics, 20*(4), 216-221.

Stevens, B. J. (1990). Development and testing of a pediatric pain management sheet. *Pediatric Nursing, 16*, 543-548.

Stevens, B. J., Johnston, C. C., & Grunau, R. V. E. (1995). Issues of assessment of pain and discomfort in neonates. *Journal of Obstetric, Gynaecologic and Neonatal Nursing, 24*(9), 849-854.

Stevens, B. J., Johnston, C. C., & Horton, L. (1993). Multidimensional pain assessment in premature neonates: A pilot study. *Journal of Obstetric, Gynaecologic and Neonatal Nursing, 22*(6), 531-541.

Stevens, B. J., Johnston, C. C., & Horton, L. (1994). Factors that influence the behavioral pain responses of premature infants. *Pain, 59*, 101-109.

Summer, G. J., & Puntillo, K. A. (2001). Management of surgical and procedural pain in a critical care setting. *Critical Care Nursing Clinics of North America, 13*(2), 233-242.

Suominen, P., Caffin, C., Linton, S., McKinley, D., Ragg, P., Davie, G., et al. (2004). The cardiac analgesic assessment scale (CAAS): a pain assessment tool for intubated and ventilated children after cardiac surgery. *Pediatric Anesthesia, 14*(4), 336-343.

Suraseranivongse, S., Santawat, U., Kraiprasit, K., & Petcharatana, S. (2001). Cross-validation of a composite pain scale for preschool children within 24 hours of surgery. *British Journal of Anaesthesia, 87*(3), 400-405.

Svensgaard, W. D., Bangdiwala, S. I., Marshall, S. W., & Waller, A. E. (1996). Repeated measures analysis of binary outcomes: Applications to injury research. *Accid. Anal. and Prev., 28*(5), 571-579.

Sweet, S. D., McGrath, P., & Symons, D. (1999). The roles of child reactivity and parenting context in infant pain response. *Pain, 80*, 655-661.

Taddio, A., Goldbach, M., Ipp, M., Stevens, B., & Koren, G. (1995). Effect of neonatal circumcision on pain responses during vaccination in boys. *The Lancet, 345*, 291-292.

Taddio, A., Katz, J., Ilersich, A. L., & Koren, G. (1997). Effect of neonatal circumcision on pain response during subsequent routine vaccination. *The Lancet, 349*, 599-603.

Taddio, A., Nulman, I., Koren, b. S., Stevens, B., & Koren, G. (1995). A revised measure of acute pain in infants. *Journal of Pain and Symptom Management, 10*(6), 456-463.

Taddio, A., Shah, V., Gilbert-MacLeod, C., & Katz, J. (2002). Conditioning and hyperalgesia in newborns exposed to repeated heel lances. *Journal of the American Medical Association, 288*(7), 857-861.

Tang, S. T., & Dixon, J. (2002). Instrument translation and evaluation of equivalence and psychometric properties: the Chinese Sense of Coherence Scale. *Journal of Nursing Measurement, 10*(1), 59-76.

Tarbell, S. E., Cohen, T., & Marsh, J. L. (1992). The Toddler-Preschooler postoperative Pain Scale: An observational scale for measuring postoperative pain in children aged 1-5. Preliminary report. *Pain, 50*, 273-280.

The Royal Australasian College of Physicians. (2005a). *Guideline statement: Management of procedure-related pain in children and adolescents*. Sydney: Paediatrics & Child Health Division, The Royal Australasian College of Physicians.

The Royal Australasian College of Physicians. (2005b). *Pediatric Policy on "Ethics of Research in Children"*. Sydney, Australia: The Royal Australasian College of Physicians.

Tobias, J. D., Martin, L. D., oakes, L., Rao, B., & Wetzel, R. C. (1993). Postoperative analgesia following thoracotomy in children: Interpleural catheters. *Journal of Pediatric Nursing, 288*(11), 1466-1470.

Truman, B., Gordon, S. M., Peterson, J. F., Shintani, A. K., Jackson, J. C., Foss, J., et al. (2005). Large-scale implementation of sedation and delirium monitoring in the intensive care unit: A report form two medical centers. *Critical Care Medicine, 33*(6), 1199-1205.

Twycross, A. (1999). Children's cognitive level and their perception of pain. In A. Twycross, A. Moriarty & T. Betts (Eds.), *Pediatric pain management a multidimensional approach* (pp. 25-37). Oxon, UK: Radcliffe Medical Press Ltd.

Twycross, A. (2002). Educating nurses about pain management: The way forward. *Journal of Clinical Nursing, 11*(6), 705-714.

van Dijk, M., De Boer, J. B., Koot, H. M., Duibenvoorden, H. J., Passchier, J., BouWmeester, N., et al. (2001). The association between physiological and

behavioral pain measures in 0- to 3-year-old infants after major surgery. *Journal of Pain and Symptom Management, 22*(1), 600-609.

van Dijk, M., De Boer, J. B., Koot, H. M., Tibboel, D., Passchier, J., & Duivenvoorden, H. J. (2000). The reliability and validity of the COMFORT scale as a postoperative pain instrument in 0 to 3-year-old children. *Pain, 84*, 367-377.

van Dijk, M., Koot, H. M., Saad, H. H., Tibboel, D., & Passchier, J. (2002). Observational visual analogue scale in pediatric pain assessment: useful tool or good riddance? *Clinical Journal of Pain, 18*(5), 310-316.

van Dijk, M., Peters, J. W. B., Bouwmeester, N. J., & Tibboel, D. (2002). Are postoperative pain instruments useful for specific groups of vulnerable infants? *Clinics in Perinatology, 29*, 469-491.

van Dijk, M., Peters, W. B., & van Deventer, P. (2005). The COMFORT Behavior Scale. A tool for assessing pain and sedation in infants. *Advanced Journal of Nursing, 105*(1), 33-36.

van Hulle Vincent, C. (2005). pediatric Pain Management Sometimes Lacking. *American Journal of Maternal and Child Nursing, 30*(3), 177-183.

von Bayer, C., & Hicks, C. L. (2000). Support for a common metric for pediatric pain intensity scales. *Pain Research and Management, 5*(2), 157-160.

Wagner, B. K., & O'Hara, D. A. (1997). Pharmacokinetics and pharmacodynamics of sedatives and analgesics in the treatment of agitated critically ill patients. *Clinics of Pharmacokinetics, 33*(6), 426-453.

Walden, M., Penticuff, J. H., Stevens, B., Lotas, M. J., Kozinetz, C. A., Clark, A., et al. (2001). Maturational changes in physiologic and behavioral responses of preterm neonates to pain. *Advances in Neonatal Care, 1*(2), 94-106.

Wall, P. D. (1997). Definition of pain needs clarification. *British Medical Journal, 314*, 1201.

Warnock, F. (2003). An ethogram of neonatal distress behavior in response to acute pain (newborn male circumcision). *Infant Behavior and Development, 26*, 398-420.

Warnock, F., & Lander, J. (2004). Foundations of knowledge about neonatal pain. *Journal of Pain and Symptom Management, 27*(2), 170-179.

Warnock, F., & Sandrin, D. (2004). Comprehensive description of newborn distress behavior in response to acute pain (newborn male circumcision). *Pain, 107*, 242-255.

Watt-Watson, J., Stevens, B., Garfinkel, P., Streiner, D., & Gallop, R. (2001). Relationship between nurses' pain knowledge and pain management outcomes for their postoperative cardiac patients. *Journal of Advanced Nursing, 36*(4), 535-545.

Weatherstone, K. B., Rasmussen, L. B., Erenberg, A., Jackson, E. M., Claflin, K. S., & Leff, R. D. (1993). Safety and efficacy of a topical anesthetic for neonatal circumcision. *Pediatrics, 92*, 710-714.

Wewers, M. E., & Lowe, N. K. (1990). A critical review of visual analogue scales in the measurement of clinical phenomena. *Research in Nursing and Health, 13*, 227-236.

White, M., & Elander, G. (1992). Translation of an instrument. The US-Nordic Family Dynamics Nursing Research Project. *Scandinavian Journal of Caring Sciences, 6*(3), 161-164.

White, S. A., & Van den Broek, N. R. (2004). Methods for assessing reliability and validity for a measurement tool: a case study and critique using the WHO haemoglobin colour scale. *Statistics in Medicine, 23*, 1603-1619.

Willis, M. H., Merkel, S. I., Voepel-Lewis, T., & Malviya, S. (2003). FLACC Behavioral Pain Assessment Scale: a comparison with the child's self-report. *Pediatric Nursing, 29*(3), 195-198.

Woolf, S. H., Grol, R., Hutchinson, A., Eccles, M., & Grimshaw, J. (1999). Clinical guidelines: Potential benefits, limitations, and harms of clinical guidelines. *British Medical Journal, 318*, 527-530.

World Medical Association. (2000). *Declaration of Helsinski, Ethical Principles for Medical Research Involving Human Subjects, amended by 52nd WMA General Assembly*. Edinburgh, Scotland: World Medical Association.

Wynd, C. A., Schmidt, B., & Schaefer, M. A. (2003). Two quantitative approaches for estimating content validity. *Western Journal of Nursing Research, 25*(5), 508-518.

APPENDIX A

Joint Authors' Declarations

APPENDIX B

References for Table 5

APPENDIX C

Phase Two

Content Validity Data Collection Form for Expert Participants

APPENDIX D

Phase Two

Survey Sheet for Data Collection – postoperative observations

APPENDIX E

Phase Three

Survey Sheet for Data Collection – before and after boluses observations

APPENDIX F

Phase Three

Clinical Utility Data Collection Form for Nurse Participants

APPENDIX G

Phase One

Parents Information Sheet and Informed Consent Form (English version)

APPENDIX H

Phase One

Parents Information Sheet and Informed Consent Form (French version)

APPENDIX I

Phases Two and Three

Parents Information Sheet and Informed Consent Form (English version)

APPENDIX J

Phases Two and Three

Parents Information Sheet and Informed Consent Form (French version)

APPENDIX K

Copyright and Release of Thesis for Examination Form

&

Permission to use Copyright Material

APPENDIX L

Conference Presentations Abstracts

Ramelet, A. S., Bulsara, M., Huijer Abu-Saad, H., McDonald, S., & Rees, N. (2001). Postoperative pain in the critically ill infant [Abstract]. *Neonatal, Paediatric and Child Health Nursing, 4*(4), viii.

Ramelet, A. S., Bulsara, M., Huijer Abu-Saad, H., McDonald, S., & Rees, N. (2002, October). *Pain assessment in preverbal children postcardiac surgery.* Paper presented at the 27th Australian and New Zealand Annual Scientific Meeting on Intensive Care and 8th Australian and New Zealand Paediatric and Neonatal Intensive Care Conference, Perth, Australia

Ramelet, A. S., Abu-Saad, H. H., Bulsara, M., McDonald, S., & Rees, N. (2003, June). *Developing a pain instrument for critically ill young children: A new approach.* Paper presented at the International Symposium on Paediatric Pain, Sydney.