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# EVALUATING NEONATAL FACIAL PAIN EXPRESSION: IS THERE A PRIMAL FACE OF PAIN?

by

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A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the College of Nursing at the University of Central Florida Orlando, Florida

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#### **ABSTRACT**

Pain assessment continues to be poorly managed in the clinical arena. A review of the communication process in pain assessment is carried out and the hierarchical approach often recommended in the literature -with self-report as its "gold-standard," is criticized as limited and simplistic. A comprehensive approach to pain assessment is recommended and a model that conceptualizes pain assessment as a complex transaction with various patient and clinician dependant factors is proposed. Attention is then focused on the pediatric patient whose pain assessment is often dependent on nonverbal communicative action. The clinical approaches to pain assessment in this population –mainly the use of behavioral/observational pain scales and facial pain scales, are explored. The primal face of pain (PFP) is identified and proposed theoretically as an important link in the function of facial pain scales. Finally, the existence of the PFP is investigated in a sample of 57 neonates across differences in sex and ethnic origin while controlling for potentially confounding factors. Facial expression to a painful stimulus is measured based on the Neonatal Facial Coding System (NFCS) and applying an innovative computer-based methodology. No statistically significant differences in facial expression were found in infant display thereby supporting the existence of the PFP.

To Gabrielle and André, my impulse for being.

#### **ACKNOWLEDGMENTS**

Many thanks to the patience and helpful guidance of my committee: Jacquie Byers, Patricia Robinson, Diane Wink, and Piotr Windyga. Two people without whom this would not be possible: Paul Scovanner –computer vision extraordinaire, and Ken Craig –an inspiration in pain research. Thanks to the administration and staff at Winnie Palmer Hospital for Women and Children, and the College of Nursing. Thanks to my family.

# TABLE OF CONTENTS

LIST OF FIGURES	ix
LIST OF TABLES	X
CHAPTER ONE: INTRODUCTION	1
References	4
CHAPTER TWO: PAIN ASSESSMENT AS A TRANSACTION: BEYOND THE "GOLD-	
STANDARD"	5
The Problem with Self-Report	5
Communication Problems: The Patient	7
Communication Problems: The Clinician.	8
A Call for a Conceptual Shift.	10
Comprehensive Views of Pain	11
Pain Assessment as a Transaction.	12
Discussion	15
Conclusion	16
Tables	17
Figures	19
References	21
CHAPTER 3: PAIN ASSESSMENT AND FACIAL EXPRESSION IN THE PEDIATRIC	
PATIENT: THE PRIMAL FACE OF PAIN	27
A Rich History: Evolution	27
Nature and Nurture Revisited	28

Decoding the Face of Pain	29
The Primal Face of Pain	31
Clinical Tools: Behavioral/Observational	31
Clinical Tools: Facial Pain Scales.	33
Implications for Nursing Practice	34
Tables	36
Figures	38
References	39
CHAPTER 4: MEASURING NEONATAL FACIAL PAIN EXPRESSION: EVID	ENCE FOR
THE PRIMAL FACE OF PAIN?	45
Abstract	45
Introduction	46
Methods	47
Study design and sample	47
Data collection	48
Video analysis	49
Computerized image measurement	50
Point-pair method.	51
Baseline and reaction images	51
Computing facial action movement	52
Point-pair calculation	52
Statistical analyses	53
Results	54

Sample characteristics	54
Gross movement and cry	54
Fine facial activity: Point-Pairs	54
Discussion	55
Figures	63
References	65
APPENDIX A: DISSERTATION PROPOSAL	68
APPENDIX B: LETTERS OF IRB APPROVAL	111
APPENDIX C: INFORMED CONSENT FORM	115
APPENDIX D: CERTIFICATE OF HUMAN PROTECTION CONTINUING EDUC	CATION122
APPENDIX E: CURRICULUM VITAE	124

### LIST OF FIGURES

Figure 1: Skeptic Patient-Clinician Relationship in Pain Assessment	19
Figure 2: Pain Assessment as a Transaction	20
Figure 3: Facial Areas Involved in Pediatric Pain Expression	38
Figure 4: Point-Pairs	63
Figure 5: Sample-Point Pair Measurements	64

### LIST OF TABLES

Table 1: Communication Factors Affecting Self-Report	17
Table 2: Comprehensive Views of Pain.	18
Table 3: Examples of Patient Contributing Factors in Pain Assessment	18
Table 4: Examples of Clinician Contributing Factors in Pain Assessment	19
Table 5: Examples of Possible Results or Issues in Intervening Steps	19
Table 6: Facial Coding Systems in Pediatric Pain	36
Table 7: Tools Employing Facial Expression in Pediatric Pain Assessment	37
Table 8: Inclusion/Exclusion Criteria	58
Table 9: NFCS Facial Action and Point-Pair Comparison	58
Table 10: Sample Distribution by Sex and Ethnicity	59
Table 11: Sample Characteristics.	59
Table 12: Point-Pair Mean and Range	60
Table 13: Point-Pair Mean By Sex and Ethnicity	61
Table 14: MANCOVA Summary Table	62

#### **CHAPTER ONE: INTRODUCTION**

There is a recent focus on pain fueled by the events of the current War in Iraq which bring to life an increase in human suffering as well an estimated financial burden in excess of \$340 billion over the next few years (Carmichael, Henig, Ephron, & Scelfo, 2007). Pain assessment and measurement is of particular relevance to the proper recognition and treatment of the problem. The overarching subject of this work is the clinical assessment of pain; specifically, its communication, or the junction between patient and clinician.

An exploration of the current methodology for clinical pain assessment is our starting point. Chapter 2 seeks to establish the inherent weakness in the current and narrow conceptualization of pain measurement as a "5<sup>th</sup> vital sign." The argument is made that a hierarchical approach to pain assessment with "self-report" as its "gold-standard" is mechanistic and ignores other important variables. The introduction of a model that is more comprehensive and inclusive of biological and sociocultural factors for both patient *and* clinician is proposed. Of particular relevance here is perhaps the inclusion and emphasis of the concurrent role of the clinician in pain assessment. Not recognizing the importance of the subjective experience of the clinician –and all that this entails in the process of identifying pain in a patient, is pivotal in the broad underestimation and mismanagement of the problem. The proposed *Pain Assessment as a Transaction* is an attempt to illustrate the importance of communication and understanding between patient and clinician in order to achieve more positive clinical outcomes.

The emphasis on communication highlights the reliance on non-verbal signs as a means to assess pain in the clinical environment. Chapter 3 provides an in-depth look at the role of facial expressions and their relevance to pain assessment. In particular, the role of facial

expressions in infants is explored with a historical look at theoretical origins, as well as a practical review of the tools and methods currently utilized to measure pain clinically in this population. The concept of *The Primal Face of Pain* (PFP) is introduced as a potential pivotal reason to facilitate the function and appropriate application of facial pain scales. Specifically, it is proposed that the PFP is evolutionary in nature –it serves an adapting function to survival; it is present at birth; and it is modified in time through developmental and sociocultural means. The display and recognition of the PFP are proposed as the instrumental reasons underpinning the application of facial pain scales. The usefulness and limitations of these measurement tools in the clinical area are discussed.

Chapter 4 concludes with an investigation to the presence of the PFP. The hypothesis that a primal display of pain is present and universal in humans is tested. 57 neonates are evaluated for commonality of facial response to a painful stimulus. Innovative computer methods based on an established facial coding system are employed to measure fine facial motor movement. Facial expression is thus measured across 7 anatomical points and compared by sex and ethnicity. No statistical differences were found in the infant facial display. These findings support the existence of the PFP and highlight the role that sociocultural and developmental factors have in modifying the facial expression of pain, and thus their influence in the pain assessment process in general.

The impact that pain has on individuals and society at large is immense. The ability to treat this problem begins with the capacity to detect it. Facial expressions are an integral part of the communication of pain and serve as key elements in pain assessment; particularly for those who are not able to verbalize their pain level. The existence of the PFP offers a glimpse at a common and objective means to both explain current tools and perhaps develop improved

methods in pain measurement. The theoretical impact of the presence of a universal human pain display, as well as the clinical implications of such an expression, can begin to be explored.

## References

Carmichael, M., Henig, S., Ephron, D., & Scelfo, J. (2007). The changing science of pain. *Newsweek, 149(23)*, 40-47.

# CHAPTER TWO: PAIN ASSESSMENT AS A TRANSACTION: BEYOND THE "GOLD-STANDARD"

Forty years ago, McCaffery introduced the now conventional maxim that "Pain is what the person says it is and exists whenever he or she says it does" (McCaffery, 1968). This conceptualization of pain brought the individual to the forefront and made patients the experts in their pain experience. Such an approach to pain assessment rings true with nursing in particular as an example of patient advocacy and ethical clinical treatment (Ferrel, 2005). Moreover, this notion helped lay the foundation for what was to become the "gold-standard" of pain assessment: self-report. More recently, the popularization of pain as the "5<sup>th</sup> vital sign" has made self-report assessment scales ubiquitous in practice. However, despite its rich history and noble intentions a preponderance of evidence supports that pain, or more precisely its assessment, is *not* based solely, or primarily, upon the subjective report of patients. Evidence is presented here that supports the notion that clinically "pain," far from a personal statement taken at face value, is most likely a complex transaction between patient and clinician, and quite possibly, one poorly reflecting the patient's self-report. This work focuses on the discrepancies between the current clinical application of self-report in pain assessment -as evidenced particularly by the movement for pain assessment as the 5<sup>th</sup> vital sign, and the empirical usefulness of self-report and complexities of pain assessment in general. A more comprehensive model for pain assessment is proposed.

#### The Problem with Self-Report

Clinically, self-report of pain intensity is commonly expressed in adults by a numeric range (e.g. ranging from zero or "no pain," to ten or "the worst pain"); by using a visual

analogue scale (e.g. VAS, 10cm line anchored at extremes "no pain," and "pain as bad as it could be"); or by a scale based on descriptive adjectives (e.g. "no pain," to "extremely intense pain"), (Jensen & Karoly, 2001). Depending on a child's cognitive and developmental state, self-report scales commonly associated with this population are in the form of facial pain scales (e.g. graphic facial displays showing different degrees of pain expression), (McGrath & Gillespie, 2001). Together, these attempts at quantifying the self-report, often referred to as the "gold-standard" for pain assessment, are at the frontline of clinical practice. However, for a gold-standard, self-report is fraught with limitations.

Perhaps the most glaring limitation of self-report is that it excludes a large number of patients because of the cognitive and communicative burden it exacts. That is, because self-report naturally requires a coherent expression of pain, the strategy is thereby problematic with some of our most vulnerable populations including the cognitively impaired (Abbey et al., 2004), the critically ill (Shannon & Bucknall, 2003), infants and young children (Walker & Howard, 2002). For those whom the strategy is aimed for –those developmentally appropriate and communicatively and cognitively intact, self-report still has a large potential for bias and error. A source of these problems lies in the communication process between patient and clinician, and the complexities it engenders.

An inherent assumption in pain assessment is that the patient wants to minimize their pain, and the clinician wants to treat it. After all, pain is the number one reason people seek healthcare, and caring the clinician's professional role. If this is the case, then two further assumptions are key. One, that the patient is speaking the truth, and secondly, that the clinician is listening. That is, in order for "whatever the patient says" to honestly reflect his or her pain, one must assume candid disclosure on part of the patient, and receptive belief in it by the

clinician. Unfortunately, this is far from the case. Various patient and clinician factors conspire to sabotage the clarity of this process.

#### Communication Problems: The Patient

There are many factors that complicate the assumption that the patient is "speaking the truth" in the self-report. For example, patients may suppress or mask their report of pain.

Reasons for this include a fear from negative consequences, such as it representing a worsening of their condition; a fear of tolerance or addiction to medications; concern with medication side effects; and a belief that pain can not be relieved (Ameringer et al, 2006; Calvillo & Flaskerud, 1993; Cleeland et al., 1994; Ersek, Kraybill, & Pen, 1999). Patients may also suppress pain to avoid noxious treatments or avert playing the "sick role" (Craig, 2007). Spiers (2006) points at another reason for pain suppression by noting that adult patients may not be as forthcoming in expressing their pain in the hopes that their stoic behavior may help them "save face" or remain in control in an exposed or perilous situation –in the home-care setting in this case. Stoicism may also be culturally associated (Finnström & Söderhamn, 2006; McCarthy et al., 2004) but care must be taken not to stereotype (Abbotts et al., 1999). Children too have reported suppressing pain, and in this case, mostly for fear of embarrassment in front of their peers, and to avoid worrying their parents (Larochette, Chambers & Craig, 2006).

Alternatively, at the other extreme, patients may exaggerate their report of pain. Reasons for this include efforts to obtain narcotics –the so-called drug seeking behaviors (Vukmir, 2004), and malingering –avoiding responsibilities or seeking compensation (Mendelson & Mendelson, 2004; Mittenberg et al., 2002). Children may falsely report pain in an attempt to seek attention (Larochette, Chamber & Craig, 2006). Of course, we must wonder what effect these behaviors

have in creating or perpetrating a skeptic clinician-patient relationship; for example, bias from clinicians towards patients they feel are "drug seeking" (McCaffery et al., 2005). In fact, interestingly, distrust between clinician and patient itself has also been implicated in patients' exaggerating or "fitting" clinical symptoms in an attempt to establish credibility with their provider (Werner, Isaksen & Malterud, 2004; Werner & Malterud, 2003). Thus, in circular feedback fashion, pain assessment appears not only to be "created"—pain presented and evaluated, between patient and clinician, but also heavily influenced by the level of trust between the dyad (Figure 1). Perhaps most important is the effect that exaggeration may have on clinician judgment. Birdwell and colleagues (1993) found that given the same clinical scenario, clinicians overwhelmingly ignored a histrionic presentation of chest pain over one that was not histrionic.

The incidence of pain deception (suppression or exaggeration) is hard to ascertain, partly because of methodological issues and partly because people work hard to avoid discovery of dishonesty (Craig, 2007; Craig, Hill, & McMurtry, 1999; Mittenberg et al., 2002). Nevertheless, scrutiny in the veracity of the self-report appears to not only be warranted but also routinely performed by clinicians.

#### Communication Problems: The Clinician

Patient self-report is but one strategy used by clinicians to assess pain. Other strategies include behavioral observation (e.g. guarding and body movement), cuing into facial expression (e.g. grimacing) and physiological monitoring (e.g. vital signs) (Donovan, 2002; Odhner, 2003). Kim and colleagues (2005) noted that in a post-surgical setting the leading strategy in pain assessment was not what the patient said (e.g. self-report), but rather how the patient looked (e.g.

behavioral observation, facial expression, and vital signs). A retrospective study of critical care patients noted that behavioral and physiologic pain indicators were utilized 97% of the time, compared to 29% for self-report (Gelinas et al., 2004). Similarly, Katsma and Souza (2000) found in the long-term-care setting that nurses doubted the self-report of patients and were more likely to cue into facial expression. Interestingly in this study, the more experienced the nurse, the less likely they were to believe the patient's self-report. McCaffery and Ferrell (1997) documented the lack of trust of nurses in the patient self-report in a review of studies spanning three decades. It appears that when it comes to pain assessment, clinicians tend not to believe their patients; or at least, give greater importance to behavioral displays when in disagreement with self-reports of emotion (Craig & Prkachin, 1983; Puntillo et al., 2006). For example, McCaffery and colleagues found nurses were most likely to give pain medications to a grimacing patient than to a smiling one (McCafferey, Ferrell & Pasero, 2000).

Reasons for this are complex. A myriad of personal factors appear to influence or bias not just the patient, but also the clinician's response to the self-report. Previously implicated factors include patient's demographics such as age, gender, and ethnicity; as well as other sociocultural factors and nuances such as the patient's lifestyle, socioeconomic status, litigation status, attractiveness, and friendliness (Calvillo & Flaskerud, 1993; Chibnall & Tait, 2005; Hadjistavropoulos, Ross, & Von Baeyer, 1990; McCaffery & Ferrell, 1997; Tait & Chibnall, 1997; Tait et al., 2006). Other clinician-dependent factors include their level of empathy, level of exposure to pain, personal beliefs about pain, and professional group membership –such as physician or nurse (Dalton et al., 1998; Goubert et al., 2005; Pillai-Ridell & Craig, 2007). Not surprisingly, patient personality and the clinician's perception of the patient affect the clinician's feelings and views towards them (Holmqvist, 2000; Wilkinson, 1996). There is also recent

evidence that situational or work contextual factors affect pain assessment. Manias, Bucknall & Botti (2005) found reason to believe that nurse's workload affected their pain assessment with high levels of work activity associated with ignoring patient's pain cues including their verbal report. Lastly, an underexplored factor may be that the very nature of clinical practice is based on professional evaluation and judgment. The discrepancy between patient self-report and clinician response may partly be the result of clinicians critically seeking —and not finding, confirmatory evidence. [Insert Table 1 here].

#### A Call for a Conceptual Shift

The fervor for self-report is such, that it is advocated as the single most reliable indicator of the existence and intensity of pain and should be "the *primary* source of information, since it is more accurate than the observation of others" (Joint Commission, 2000, p.13). As "gold-standard" it is supposed to mean that this is the *best tool* we have available for the job (Claassen, 2005). Viewed hierarchically, self-report is recommended to antecede all assessment techniques, *even with nonverbal patients* like elders with dementia, infants, and intubated/unconscious patients (Herr et al., 2006). Such is the inertia behind self-report that pain is now to be assessed, per regulatory and professional organizations, as the "5<sup>th</sup> vital sign" (American Pain Society, 1999; Department of Veterans Affairs, 2003; Frasco, Sprung, & Trentman, 2005). These proposals are no doubt intended to highlight the importance of pain assessment; the indispensability of its care. However, to conceptualize pain as "a vital sign" inherently places it in the context of the other four (pulse, temperature, respiration and blood pressure): they are fairly quick, physiologically rooted, objective, and easily obtainable in the clinical environment. That is, *self-report*, in the form of the common pain rating ("on a scale of 0-10...") fits the

mechanics of these criteria. This terminology and conceptualization of pain assessment is misleading since self-report is far from precise, objective and predictable as vital signs.

Compared to the discrete physiologic data that are vital signs, pain assessment is complex, evolving and subjective; rather than an absolute measure it is most likely a dynamic process.

Still, the idea that "pain is whatever the patient says it is" remains a seductive ideal. Philosophically, this maxim carries a sense of democracy, of fairness, about self-expression and the principle of allowing patients to be the authority in defining their pain intensity. However, self-report as von Baeyer states is an oversimplification (2006). On its own, self-report is naïve pain assessment and an illusion of an infinitely more complex phenomenon. In fact, in the context of the 5<sup>th</sup> vital sign, self-report may not positively affect or may even jeopardize pain management. Mularski and colleagues (2006) found that routinely measuring pain "by the 5<sup>th</sup> vital sign" did not improve quality of pain management in a sample of military veterans. Moreover, Taylor, Voytovich and Kozol (2003), caution the 5<sup>th</sup> vital sign campaign as potentially leading to over sedation in postoperative patients. It is understood that pain is multifaceted, with cognitive and emotional components, with biophysiological and sociocultural determinants (Craig, Korol, & Pillai, 2002; International Association for the Study of Pain, 1994; Melzack, 1999). We must therefore conceptualize pain assessment within that same context, and not in a reductionist's view.

#### Comprehensive Views of Pain

There is no lack of conceptual models to illustrate the complexities of the phenomenon that is pain. For example, Melzack's exposition on the neuromatrix (itself an expansion of his earlier work with Wall, 1965) relies heavily on a comprehensive biological model that

encompasses even the molecular level, and includes environmental and behavioral modifiers (1999). Bates and colleagues (1987; 1993) incorporate the role of ethnicity in pain, while Izard and colleagues contribute a developmental psychological perspective that although not focused specifically on pain, expounds upon the interplay of the biologic, the social and their effect on expression of emotions (Izard, 1977; Izard & Abe, 2004; Izard et al, 1995). Most recently, Frantsve and Kerns (2007) highlight the importance of communication in chronic pain management in the context of shared medical decision making (SMD). SMD is viewed as a process of collaboration, dynamic in nature and affected by demographic and situational factors from both the patient and clinician. More specifically to pain assessment, Craig and colleagues present a multifactor model that highlights the importance of both verbal (e.g. self-report) and non-verbal (e.g. facial expression) communication (Craig, Korol,& Pillai, 2002; Hadjistavropoulos & Craig, 2002; Prkachin & Craig, 1995). See Table 2 for a summary of key points of these models. A model that borrows from these works is presented here, one conceptualizing pain assessment as a patient-clinician transaction [Figure 2].

#### Pain Assessment as a Transaction

Pain assessment is a process, an ongoing and dynamic exchange between the patient-clinician dyad, purposeful and goal oriented in nature. That is, as mentioned earlier, it is believed that patients want relief from pain and that clinicians want to provide care. Thus, as illustrated on Figure 1, a level of trust underlies this process. The exchange of meaning from patient to clinician (and back) in this process is the essence of the "transaction."

The aforementioned conceptual models thoroughly cover most of the *contributing* factors. Specifically, biological, developmental/psychological and sociocultural factors are

recurring themes in the identified models (Table 2). In essence, contributing factors mediate the pain assessment process for both patient and clinician. Together, these factors make up the history and state of the two players in the transaction. Table 3 lists examples of patient factors. Interestingly, although sociocultural factors have been implicated at length in pain from a *patient* perspective -for example patient ethnicity and access to care (Nguyen et al., 2005) and patient gender (Vallerand & Polomano, 2000), there is a void in the literature when it comes to *clinician* gender and ethnicity and their effect on pain assessment. If sociocultural forces are at work on the patient, it would be a safe assumption that they too are at work on the clinician. Nevertheless, sociocultural forces are at work in terms of clinician attitude depending on the ethnic background of their patients. Ferguson and Candib's (2002) review found that patient ethnicity and language influences quality of care; with minorities, especially those not proficient in English, less likely to engender empathic attitudes from clinicians. Other clinician social biases and preferences have already been mentioned.

Additional clinician-dependent factors that deserve more discussion here are experience/empathy, and contextual/situational (see Table 4 for examples of clinician factors). Experience refers to both personal factors such as knowledge and exposure to pain. Knowledge refers to skills, special training and or general familiarity with relevant pain assessment matter such as pathophysiology, recognition of signs and symptoms, treatment options and interventions, documentation and communication abilities; the kind of clinician personal competence often implicated in poor pain management (Eder, Sloan, & Rodd, 2003; Johnston et al., 2005; Rupp & Delaney, 2004; Twycross, 2002). Exposure refers to repetitive experiences with pain leading to "institutional insensitivity," or a habituation and lack of sensitivity to pain on part of the clinician (Pillai-Riddell & Craig, 2007; von Baeyer, Johnson, & McMillan, 1984;

Xavier Balda et al., 2000). Related to this is the concept of empathy which implies greater sensitivity to other's pain based on ones own experience (Danziger, Prkachin, & Willer, 2006; Goubert et al., 2005). Contextual and situational factors highlight influences that largely lie outside of the clinician personal control or experience such as staffing or workload issues, and interdisciplinary communication (Frantsve & Kerns, 2007; Manias, Bucknall & Botti, 2005).

The assessment process begins with a pain stimulus that may or may not be physiologic in origin (International Association for the Study of Pain, 1994). It is also worth mentioning that intensity of pain stimulus does not necessarily match intensity of pain experienced (Mader et al., 2003). The pain experience is intimately subjective and defines the meaning of pain for the patient. Note that expression following experience implies that pain is real to the patient regardless of their ability to express it. The ability to express is of course modulated by various clinical factors affecting verbal and/or non-verbal behaviors. At this point it is important to note that the *intervening steps*, the steps occurring in between the different phases of the *assessment* process (and represented in the model with a triangular icon), take place along a sliding scale. That is, responses can occur along two extremes highlighted in the circle graphic. Thus, rather than absolutes, responses vary in degree across a gradient. Pain display varies from suppressed to exaggerated, and would include "appropriate" as a middle term. Display is not limited to behavioral actions, but it includes all aspects of human pain expression including physiologic sings. This step along with assessment marks the patient/clinician boundary. In the model, trust and scrutiny delineate the boundary.

Assessment, in the clinician domain, implies all of the clinical skills and tools utilized in evaluating pain (domains are demarcated by the slashed boxes). Here, the clinician begins building a clinical picture, or begins to translate the meaning of the patient's pain to make it his

or her own. Interpretation of this meaning leads to a level of agreement: anywhere from agreeable with the patient's meaning (resonant) to disagreeable with the patient's meaning (dissonant). This agreement is punctuated with a clinical Judgment.

The term *social judgment* was previously used in a similar context by Tait (2007). "Clinical judgment" is used here based on the broader concept of the various contributing factors, and based on health repercussions on the patient that the judgment clearly carries.

Judgment is the final evaluation and interpretation of the patient's meaning of pain; it is the culmination of the assessment and the clinician's definition of pain for the patient. Judgment is followed by intervention which implies treatment, -or a lack thereof, and covers the range of therapeutic options in pain. The effectiveness of the intervention or the outcome will in turn have a range of negative to positive consequences upon the patient's experience, where the cycle once again starts. If the exchange of meaning between patient and clinician in this process is the essence of the "transaction" than the success of this transaction is based on the approximation between the two. In other words, given our assumptions, more positive outcomes will come when patient/clinician meaning is most similar. And the opposite is true, the more dissimilar the meaning from clinician to patient is, the more negative the outcome.

#### Discussion

The model is a comprehensive attempt at conceptualizing the forces at work in pain assessment and several issues can be highlighted. First, the model is not a tool for pain assessment. It is not meant to supplant the VAS for example. However, it clearly outlines the problems and limitations with its current use, specifically when viewed in the "5<sup>th</sup> vital sign" context. Self-report of pain has obvious utility but it is strictly tied to a complex context. For

example, in contrast to the philosophy that "pain is what the patient says it is," the model clearly illustrates two domains (patient/clinician dyad). Whereas self-report places the burden on the patient (pain is what they say it is), the model defines two separate meanings for pain —the patient's *and* the clinician's. In fact, the argument could be made that judgment and intervention tilt the balance or burden onto the clinician. This conceptualization refocuses responsibility on the clinician who clinically is managing treatment and thus *should* bear the burden of pain assessment.

When compared to a hierarchical approach to pain assessment, the model is more fluid, and emphasizes a dynamic and active negotiation. It highlights the need for an interactive and comprehensive pain assessment that extends beyond the expedient and convenient "5<sup>th</sup> vital sign" approach. Calls and suggestions for a holistic approach to pain assessment (Davidhizar & Giger, 2004) can be framed into research questions using the model. For example, how does clinician's ethnicity affect clinician's assessment and agreement with the patient? How does workload or institutional setting affect clinician judgment? What factors lead to a positive trusting patient/clinician dyad? What are the links between critical thinking and scrutiny? Does mindful acknowledgement of the burden of "judgment" by the clinician affect his/her "intervention"? These are but a few potential research directions incited by the model.

Additionally, from a practical point and given this comprehensive perspective, the model may also lead to the design and test of more effective assessment tools.

#### Conclusion

A hierarchical approach to pain assessment with self-report as a "gold-standard" is at best incomplete. Pain is not a slogan, nor its' assessment a vital sign. Clinically, we have to be

willing to go beyond this current methodology and view pain assessment for the complex interaction that it is. The model of pain assessment as a transaction exposes the key factors in the process; it also refocuses attention on the clinician and the burden of intervention. Finally, the model helps frame future research directions and possible interventions in a comprehensive context.

#### **Tables**

Table 1: Communication Factors Affecting Self-Report

Patients: Why They Are Not Saying It	Clinicians: Why We Are Not Hearing It
<ol> <li>Inability to communicate.</li> <li>Fear of negative medical consequences (addiction, tolerance, unrelieved pain).</li> <li>Fear of indicating a worsening condition.</li> <li>Avoidance of noxious treatments or "sick role."</li> <li>Desire to save face/maintain control.</li> <li>Fear of embarrassment/avoid worrying parents (children).</li> <li>Playing of a cultural role.</li> <li>Perceived disempowerment</li> <li>Clinician skepticism/distrust.</li> <li>Deliberate deception (malingering, seeking narcotics).</li> </ol>	<ol> <li>Preference and reliance in other assessment techniques.</li> <li>Suspicion, distrust.</li> <li>Level of exposure to pain, "institutional insensitivity."</li> <li>Personal beliefs about pain.</li> <li>Lack of empathy.</li> <li>Increase workload affects cuing into self-report.</li> <li>Personal nuances/preferences.</li> <li>Biases/stereotypes.</li> <li>Incompetence, poor clinical knowledge/skills.</li> <li>Critical evaluation/judgment.</li> </ol>

Table 2: Comprehensive Views of Pain

Source	Theory/Model	Key Points	
Melzack (1999) expansion on Gate Control Theory (Melzack & Wall, 1965).	The Neuromatrix	Comprehensive genetic and neurohormonal processes in pain. Biophysiologic linked with personal variables such as culture and personality	
Bates and colleagues (1983; Bates, Edwards and Anderson, 1997).	Biocultural Model of Pain	Ethnocultural attitudes and emotion influence the perception of pain.	
Izard and colleagues (Izard, 1977; Izard & Abe, 2004; Izard et al, 1995).	Differential Emotions Theory (DET).	Expression of emotions is the result of neural/genetic processes which are modulated developmentally and environmentally (e.g. learned).	
Craig and colleagues (Craig, Korol,& Pillai, 2002; Hadjistavropoulos & Craig, 2002; Prkachin & Craig, 1995).	The Communications Model of Pain		
Frantsve & Kerns (2007).	Shared Medical Decision Making (SMD) and Chronic Pain	Pain management as a process of collaboration between clinician and patient; bidirectional and dynamic.	

Table 3: Examples of Patient Contributing Factors in Pain Assessment

Biological	Developmental/	Sociocultural
	Psychological	
• Disease processes,	• Age.	• Ethnicity, cultural origin.
pathophysiology.	• Stress.	Gender.
• Drug influences (e.g.	Wanting to regain	Access to healthcare.
anesthetics, analgesics, illicit).	control or credibility.	
• Disabilities (e.g. amputation,		
facial paralysis).		

Table 4: Examples of Clinician Contributing Factors in Pain Assessment

Experience/	Contextual/	Sociocultural
Empathy	Situational	
• Interpersonal/communication	<ul> <li>Workload, rushed</li> </ul>	• Patient preferences or biases
skills.	clinical encounters.	(e.g. socioeconomic status,
Knowledge, clinical	<ul> <li>Interdisciplinary</li> </ul>	physical appearance).
competence.	communication,	• Clinician demographics (e.g.
• Sensitivity to other's pain.	follow-up.	age, gender, education).
	<ul> <li>Facility resources</li> </ul>	Clinician ethnic background,
	(e.g. staffing, proper	personal views on pain.
	documentation)	

Table 5: Examples of Possible Results or Issues in Intervening Steps

<b>Clinical Factors</b>	Display	Agreement	Outcome
From verbal to non-verbal	From suppression	From dissonance to	From negative to
• Level of consciousness.	to exaggeration	resonance	positive
• Intubation.	• "Saving face."	<ul> <li>Varying degrees</li> </ul>	• Pain persistence.
• Age.	• Histrionic.	of patient-clinician	• Pain relief.
	• Vital signs,	concordance.	Overmedication.
	physiologic data.		

Figures

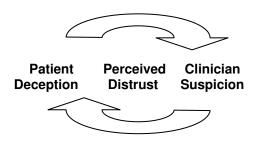


Figure 1: Skeptic Patient-Clinician Relationship in Pain Assessment

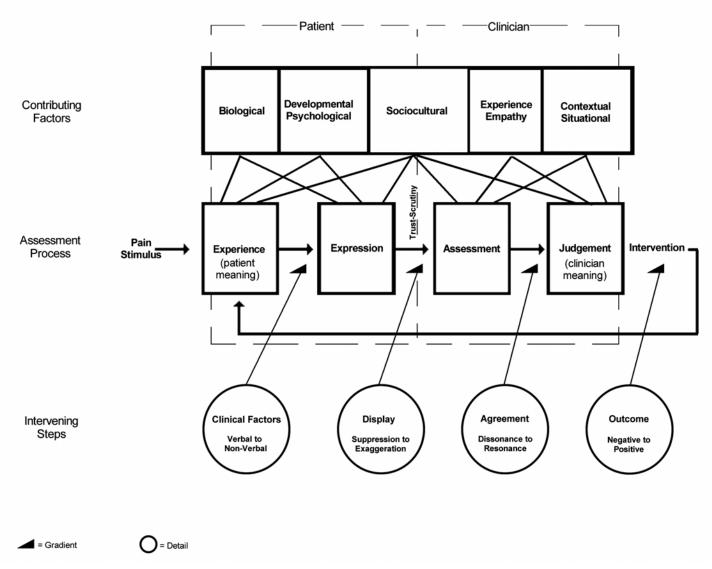


Figure 2: Pain Assessment as a Transaction

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# CHAPTER 3: PAIN ASSESSMENT AND FACIAL EXPRESSION IN THE PEDIATRIC PATIENT: THE PRIMAL FACE OF PAIN

Pain is a challenging foe in pediatric care. One of the reasons for this is the difficulty in assessing the phenomenon in children. A clinical strategy widely employed is the observation of facial expression as a means of measuring pain in children. Although discussion of the extent of the role of nonverbal communication in humans (including facial expression) is controversial (Scollon & Scollon, 2000), it is undeniable that it plays an especially significant role in the pediatric patient who may lack verbal abilities because of illness or developmental maturity. This article explores the history, theory and application of facial expression in pediatric pain assessment. Additionally, the *primal face of pain* is discussed as a concept of particular relevance to the workings and applications of facial pain scales.

# A Rich History: Evolution

The preoccupation with facial expressions has a long and rich history. The pseudoscience of physiognomy, or the belief that personality traits could be "read" in the face, goes back to ancient Egypt, Arabia, and to China prior to Confucius. Students and practitioners of physiognomy included Pythagoras, Aristotle, Hippocrates and Galen (Fridlund, 1994). However, it was Darwin who first formed a scientific approach to the study of facial expressions (Darwin 1899). In regard to pain expression in infants he notes: "Whilst thus screaming their eyes are firmly closed, so that the skin around them is wrinkled, and the forehead contracted in a frown. The mouth is widely opened with the lips retracted in a peculiar manner, which causes it to assume a squarish form; the gums or teeth being more or less exposed." (page 66).

Ekman and colleagues, with about forty years of research on the subject, propose that many facial expressions are biologically based, constant across cultures, and serve basic universal communicative functions in the language of emotions (Ekman, 1977; Ekman, 1992; Ekman, 1999a, b; Ekman, Sorenson, & Friesen, 1969). Pain, although not purely an emotion, does have an emotional component (International Association for the Study of Pain, 1994) that has been associated with a prototypical facial expression across the lifespan (Prkachin, 1992; Prkachin & Craig, 1995; Williams, 2002).

The basic premise of this evolutionary view is that the ability to display certain emotions is hardwired. Williams (2002), makes a compelling case in expounding the importance of infants to be able to express distress in order to ensure their survival. Simply put, those humans equipped to attract help through their facial expression from a parent (e.g. *display* pain) are more likely to survive than those who do not. Conversely, the expression of pain requires the ability from the parent to *recognize* it as "pain" or a distress call (Soltis, 2004; Williams, 2002). Thus the function of the expression of distress, in its most primal form, is species survival. Given its importance, it is not surprising that humans inherit this ability; we simply can not afford to learn the behavior to express it. However, this does not mean that learning does not have a role in the expression of pain.

### Nature and Nurture Revisited

Data illustrating facial expressions of pain are more consistent in infants than in adults (Craig, Prkachin & Grunau, 2001) leading one to believe that exposure, experience and normal human development may lead to modulation of facial display. Ekman (1977) first proposed a biocultural model to explain this phenomenon in which hardwired or "involuntary" emotional

displays are modulated through learned behavior. Fridlund (1994) termed this a "two factor" model which is composed of the innate, hardwired behavior, and the fact that the behavior is censored or modified according to sociocultural conventions. Izard and colleagues have found patterns of modulation to facial expression in young children which they attribute to developmental factors -physiologic maturation and social interaction (Izard et al, 1995; Izard & Abe, 2004). Sociocultural factors like ethnicity have also been implicated in both the adult and pediatric experience of pain (Ibrahim et al, 2003; Munoz, 2004; Portenoy et al, 2004; Rosmus et al, 2000). Additional contextual and personal factors like previous exposure to pain, pathophysiological status, and concurrent affective states may also play a role (Craig, Korol and Pillai, 2002). Thus, a complex interplay of factors including biological substrates, developmental maturation, personal and contextual and the exposure to sociocultural environments all appear to modulate the facial expression of pain.

### Decoding the Face of Pain

Table 1 lists facial coding systems used primarily in research to evaluate pain expression in children. The Facial Action Coding System (FACS) is the oldest and most widely used tool for coding facial expressions in general (Ekman & Friesen, 1978). The FACS identifies 44 discrete facial action units (AU) each representing the movement of a facial muscle or group of muscles. The Baby FACS is an adaptation of the FACS for infants (Oster, 2003). Craig et al (2001) summarize facial movements coded by the FACS consisting of 13 distinct actions. Williams (2002) summarizes facial movements coded by the FACS as consisting of 11 distinct actions. Both of these summaries overlap in their findings. Prkachin and Mercer (1989) found 5 facial actions associated with adult expression of pain (also included in the summaries above).

Similarly, Patrick and colleagues observed 5 facial actions associated with pain expression in adult females (Patrick, Craig & Prkachin, 1986). Further, Prkachin (1992) proposed that just 4 actions carry the bulk of facial information about pain: brow lowering, narrowing and closing of eyes, nose wrinkling and upper lip.

Perhaps the complexity associated with the use of the FACS has lead to the development of other coding systems specifically developed for children (Craig, Prkachin and Grunau, 2001). Facial coding systems in children include the Maximally Discriminative Facial Movement Coding System (MAX), Neonatal Facial Coding System (NFCS), and the Child Facial Coding System (CFCS).

MAX, a tool for infants that uses prototypical expressions or templates, consists of coding facial expression in three anatomical areas: forehead and brows, eyes and nose, and mouth and chin (Izard, 1983; Izard, Hembree & Huebner, 1987; Mercer & Glen, 2004; Sullivan & Lewis, 2003). MAX has also been used to research facial expressions other than those associated with pain (Izard & Abe, 2004; Sullivan & Lewis, 2003). The NFCS was developed from a subset of facial actions (AUs) from the FACS and consists of coding for the presence or absence of 10 AUs, 5 of which have consistently been associated with pain in term neonates (Craig et al, 1994; Grunau & Craig, 1987; Grunau, Johnston and Craig, 1990); while the CFCS was derived from both the FACS and NFCS to detect pain in toddlers and school-aged children, and consists of 13 AUs (Breau et al 2001; Gilbert et al., 1999). All of these tools are well researched with good psychometric properties (See "Source" in Table 1 for references). Picture 1 illustrates the facial areas expressive of pain.

### The Primal Face of Pain

A review of the research demonstrates the existence of a "prototypical face of pain," with similar descriptions for facial pain expression emerging across age groups and coding systems. In fact, it is proposed that if facial expression of pain is present at birth (as an evolutionary view holds), and if developmental/sociocultural factors mediate this expression (as the various "two factor" views hold), it would then follow that newborns would most faithfully portray the *primal face of pain (PFP)*: a basic inborn expression associated with the communication of distress and untouched by mediating factors linked to developmental maturity or sociocultural influence.

#### Clinical Tools: Behavioral/Observational

Facial expression is perhaps the biggest determinant and most consistent cue in judging pain in children (Fuller & Conner, 1996; Hadjistavropoulos et al, 1997; Johnston & Strada, 1986; Pillai Riddell, Badali, & Craig, 2004), even above cry (Grunau & Craig, 1987; Howard & Thurber, 1998). Thus, clinical tools employing facial expression abound and fall into two categories: behavioral/observational tools, and facial pain scales (FPSs).

Behavioral/observational tools are generally used with nonverbal patients (e.g. post-operatively, unconscious/critically ill children, and neonates) and are either unidimensional – focusing on behavioral/body activity, or multidimensional –additionally including physiologic measures such as oxygen saturation, heart rate etc. (Duhn & Medves, 2004). These scales are by definition *not* for self-report but rather they are used as proxy tools; generally by a clinician, researcher or parent as observer. Literature reviews report over 20 behavioral/observational scales (Byers & Thornley, 2004; Duhn & Medves, 2004; Ramalet et al., 2004; von Baeyer & Spagrud, 2007) all of which essentially have some component of facial expression. The utility of

facial expression as a means to clinically assess pain is evident. However, the manner in which facial expression is employed in these behavioral/observational tools varies greatly. For example the Neonatal Pain Assessment Tool (Friedrichs et al., 1995) holds a very loose interpretation of "grimace" in its rating scheme, while the Pain/Discomfort Scale reported by Hannallah et al. (1987) employs an even more vague descriptor of "crying" (e.g. not specific as to degree of vocalization and/or grimace). In contrast, the PIPP incorporates 3 specific AUs from the NFCS found to contribute significantly to facial expression (Stevens et al., 1996). Variation in substance and psychometric strengths is not the only difference among all clinical pain tools, but in particular with behavioral/observational tools, a careful review of the application of the tool must be considered since they are generally developed with a very specific population in mind (e.g. premature infants, term newborns, post-operative patients etc.). Additionally, a caveat to keep in mind is that facial expressions quantified as "pain" may or may not be indicative of the phenomenon itself. Alternative explanations to facial grimacing may include fear, anger, or sadness; expressions which although have unique facial activity retain some overlapping presentation with the pain expression (Williams, 2002). Conversely, the absence or decreased expression of pain behaviors may not be indicative of decreased or absent pain, particularly in children whose physical expression may be affected by an underlying disease process (Nader, et al, 2004; Oberlander et al, 1999) or treatment such as sedation (Ista, et al, 2005). Thus, the clinical utility of a behavioral/observational tool is determined not merely by its psychometric properties but is also closely tied to the clinical setting and individual context.

### Clinical Tools: Facial Pain Scales

Facial pain scales (FPSs) are very common and broadly used in the clinical assessment of pain. In contrast to behavioral/observational tools, FPSs were developed for verbal, school-aged children primarily as self-report tools. There is evidence to indicate that subtle graphic differences such as a "happy face" anchoring in an FPSs like the Wong & Baker scale (1988) biases pain rating towards higher levels (Chambers et al., 1999; Chambers et al., 2005). In spite of this, it is well documented that FPSs are successful in quantifying the self-report of pain with a preference by users for the cartoon-like depictions (Chambers et al., 1999; Luffy & Grove, 2003). It is proposed here that the reason for their success lies in the possibility that FPSs may be graphically stereotyping "a painful expression" with the obvious purpose of cuing the child to their own experienced pain. Their "bare bones" depiction of a complex phenomenon such as pain harkens back to a prototypical and universal expression of pain. That is, FPSs portray to some degree the primal face of pain (PFP).

Although FPSs vary widely in the format of facial display (for example cartoons, photographs), their underlying assumption is that children can match their level of pain (internal construct) to a visual/graphic (external construct) corresponding to a number scale indicating the pain intensity (e.g. 0-10). That is, in using FPSs, children are not matching their own facial display of pain to a graphic. The child *knows* their pain level. Thus, it is a reasonable conclusion that the internal construct children are intuitively referencing is the primal face of pain; that basic inborn expression associated with the communication of distress. Therefore, a plausible explanation as to *why FPSs work* is that they do two things: portray the primal face of pain (PFP) and children recognize this and match it to their experience to communicate their pain intensity.

It is safe to assume that by the time a child is of appropriate age for FPS use –possibly older than 6 years old at the earliest (Stanford, Chambers & Craig, 2006), he or she has been exposed to and experienced some degree of developmental and sociocultural modulation to their display of pain. That is, according to the "two factor" theories, the virginal expression of the PFP will most likely have been modified to some extend by then. Thus, theoretically, evaluation by an outside rater –that is pain assessment by proxy, would not be valid as the FPS is based on the PFP which would by then be potentially modified in an older aged child who has both the exposure/life experience as well as the ability to censor pain expression (Larochette, Chambers, & Craig, 2006); not to mention contextual factors that might affect the clinical presentation – pathology, medications etc. (Craig, Korol and Pillai, 2002). In fact, empirically, this is the case with FPSs notoriously imprecise when it comes to research measuring agreement between clinicians or parents and children's report (Chambers et al., 1999, Chambers et al., 2005; St-Laurent-Gagnon, Bernard-Bonnin, & Villeneuve, 1999; Singer, Gulla, & Thode, 2002; Vetter & Heiner, 1996).

If the success of FPSs as self-rate tools is based upon the internal reference to the PFP, it would then follow that this internal construct is out of the reach of an external rater. Thus, FPSs are not appropriate pain proxy measures in school-aged children. More importantly, this highlights the problem with relying on facial expression as a means to externally assess pain in children. [Insert Table 2].

## Implications for Nursing Practice

The study of facial expressions is a fascinating subject with important relevance to the area of pediatric pain assessment. The three main methods that use facial expression in pediatric

pain assessment were presented and contrasted (facial coding schemes, behavioral/observational tools, and facial pain scales). Pediatric pain tools abound and they are *not* all created equal. Behavioral/observational and FPS scales must be applied only after careful consideration of psychometric quality and appropriate clinical context. The complexities of just this one variable facial expression in pain assessment is evident; thus, the application of untested instruments in pain assessment is not recommended (Duhn & Medves, 2004). Finally, the concept of the primal face of pain explains the utility of FPSs as well as their inaccuracies, and warns against the application of FPSs in their current state of development as a proxy tool in pediatric pain measurement. Reliance on facial expression as a means to externally assess pain in school-aged children must be tempered by the fact that this practice has been shown to be notoriously inaccurate.

Tables

Table 6: Facial Coding Systems in Pediatric Pain

	FACS*	NFCS*	CFCS*	MAX*
Use/ Method	Used in assessing a variety of facial expressions in adults and children. 44 facial actions (AUs). Specifically and comprehensively in pain: brow lower, cheek raise, lids tight, nose wrinkle, nasolabial deepen, upper lip raise, lip corner pull, lip stretch, lips apart, jaw drop, lids droop, eyes closed, blink	Developed for use in both term and premature neonates 10 AUs: brow lowering, eyes squeezed shut, deepening of nasolabial furrow, open lips, vertical mouth stretch, horizontal mouth stretch, taut tongue, chin quiver, lip purse, and tongue protrusion (as a "no pain" sign in term infants only).	Developed for use in toddlers and schoolaged children. 13 AUs: brow lowering, squint, eye squeeze, nose wrinkle, nasolabial furrow, cheek raiser, upper lip raise, lip corner pull, vertical mouth stretch, horizontal mouth stretch, blink, flared nostril, open lips.	Used to assess other emotions associated with facial expression. Used in infants, provides a system for judging brow, eye and mouth movement. The "pain expression" associated with it consists of brows lowered and drawn together, forehead in vertical furrows or bulge between brows, nasal root broadened and bulged; eye fissure scrounged, eyes tightly closed; mouth angular, squarish and open, or open and tense.
Source	Craig et al, 2001; Craig et al, 1994; Lilley, Craig & Grunau, 1997; Patrick, Craig & Prkachin, 1986; Prkachin, 1992; Prkachin & Mercer, 1989; Williams, 2002.	Barr et al, 1992; Craig et al, 1994; Grunau & Craig, 1987; Grunau, Johnston & Craig, 1990; Grunau et al, 1998; Grunau et al, 2006; Johnston et al, 2003; Morison et al, 2003; Ogawa et al, 2005.	Breau et al, 2001; Cassidy et al, 2002; Gilbert et al 1999; Goodman & McGrath, 2003; Hadden & von Baeyer, 2005	Izard, 1983; Izard & Abe, 2004; Izard, Hembree & Huebner, 1987; Mercer & Glenn, 2004; Sullivan & Lewis, 2003.

<sup>\*</sup>FACS = Facial Action Coding System, NFCS = Neonatal Facial Coding System, CFCS = Child Facial Coding System, MAX = Maximally Discriminate Facial Movement Coding System.

Table 7: Tools Employing Facial Expression in Pediatric Pain Assessment

Type	Purpose	Population	Examples
Facial Coding	Primarily research	Varies	See Table 1
Systems			
Behavioral/	Observation, proxy	Pre-verbal (e.g. neonates),	CRIES <sup>1</sup> , FLACC
Observational Tools	rating	Non-verbal (e.g.	revised <sup>2</sup> , PIPPS <sup>3</sup> ,
		cognitively impaired)	
Facial Pain Scales	Developed as self-	School-aged children	FPS-R <sup>4</sup> , OUCHER <sup>5</sup> ,
	report tools but also		Wong-Baker FACES
	applied by proxy		Scale <sup>6</sup>

<sup>&</sup>lt;sup>1</sup>CRIES: Crying, Requires oxygen, Increased vital signs, Expression, Sleepless (Krechel & Bildner, 1995).

<sup>&</sup>lt;sup>2</sup>FLACC revised: Face, Legs, Activity, Cry, Consolability (Malviya et al., 2006).

<sup>&</sup>lt;sup>3</sup>PIPPS: Premature Infant Pain Profile (Stevens et al., 1996).

<sup>&</sup>lt;sup>4</sup>FPSR-R: Faces Pain Scale Revised (Hicks et al., 2001).

OUCHER: (Beyer, Denyes & Villarruel, 1992).

<sup>&</sup>lt;sup>6</sup>FACES: (Wong & Baker, 1988).



Figure 3: Facial Areas Involved in Pediatric Pain Expression

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# CHAPTER 4: MEASURING NEONATAL FACIAL PAIN EXPRESSION: EVIDENCE FOR THE PRIMAL FACE OF PAIN?

#### Abstract

Facial movement in response to a heel-stick was measured in term neonates using an innovative computer approach consisting of point-pair comparison across two images; one before and one after the heel-stick. The existence of the primal face of pain (PFP), a universal facial expression to pain hardwired and present at birth, was evaluated across sex and three ethnic backgrounds (African American, Caucasian and Hispanic/Latino) while controlling for feeding type (bottle, breast, or both), behavioral state (awake or asleep), and use of epidural and/or other perinatal anesthesia. No statistically significant differences in facial expression were found in infant display thereby supporting the existence of the PFP.

#### Introduction

The ability to express pain is thought to be present at birth as an adaptation to species survival (Williams, 2002). An evolutionary view proposes that facial expression of emotions in general is a hardwired ability that is modulated through learned behavior (Ekman, 1977; Fridlund, 1994). Specifically to pain, Craig and colleagues' (Craig, Korol, & Pillai, 2002) *Sociocommunication Model of Infant Pain* proposes that the facial expression of pain in infants is a product of both biological and social factors. That is, it can be theorized that infants are equipped with a "primal face of pain" (PFP), an inborn ability to display distress like pain, which is censored or modulated through various developmental and sociocultural factors (Schiavenato, 2007). Supporting this is evidence that facial expressions of pain are more consistent in infants than in adults (Craig, Prkachin, & Grunau, 2001). However, although a consistent display of pain has been observed even across various stimuli (Prkachin, 1992), evidence supporting a universal display of pain in infants has not been conclusive and remains poorly understood.

For example, much has been said about the role of culture and race/ethnicity in the expression and overall assessment and treatment of pain (Green et al., 2003; Rahim-Williams et al., 2007; Rosmus, Johnston, Chan-Yip, & Yang, 2000). What is not clear though is to what extent are these environmental factors (e.g. cultural norms on communication and expression) versus possible inborn genetic differences governing facial display. Indeed, although consistently measured in medical research, the labels of "race" and "ethnicity" are obscure in meaning at best (Winker, 2004; Winker, 2006). Similarly, gender/sex differences are reported in pain research and while some can be attributed to social norms (Pool, Schwegler, Theodore, & Fuchs, 2007; Robinson, Wise, Gagnon, Fillingim, & Price, 2004) others, as is the case of studies

in newborns, can not. Guinsburg and colleagues (2000) found more facial expression on term and pre-term females, while Holditch-Davis and colleagues (Holditch-Davis, Brandon, & Schwartz, 2003) found that pre-term males displayed more facial expression. On the other hand, Fuller (2002) found no differences between the sexes in facial expression at 2 weeks to 6 months of age; while Grunau and Craig (1987) found no sex differences in newborn expression but did find differences in the speed of response with males quicker to facial display than females.

Thus, the universality of an inherited facial expression for pain -the PFP that an evolutionary view would purport is in question. The ability to assess the existence of the primal face of pain is an important means to elucidating the interplay between biological and sociocultural processes in pain expression. The purpose of this study is to compare the facial expression of term newborns to a painful stimulus, across sex and ethnic backgrounds, while controlling for possible confounding effects, using computer methods to measure facial movements.

#### Methods

Study design and sample

This prospective observational study used a quota sampling technique to recruit "well" neonates at the newborn nursery of a large metropolitan hospital who were: (a) term (37-43 weeks gestation) without gestational or delivery complications or history of maternal drug use (see Table 1 for inclusion/exclusion criteria), and (b) represented a specific sex and ethnic origin: males and females ascribed as Asian, or African-American, or Caucasian, or Hispanic/Latino. The hospital's convention of assigning the infant's "race" according to the mother's stated race at the time of admission was applied. To avoid potential confounding effects of cesarean

anesthesia, only vaginal births were included. Metabolic screening (e.g. "PKU test") is Statemandated and the heel-stick required for blood collection was thus chosen as the common pain stimulus in the study. Hospital protocol required the procedure take place 24 hours after beginning oral feeding and before discharge. The heel-stick was carried out by hospital staff per normal protocol using a standard lancet device. The procedure was recorded using a tripod digital video camera (Kodak Z740) aimed at the neonate's head and chest. The picture was focused on the neonate's face; sound was recorded and the staff member was instructed to state "stick" immediately prior to engaging of lancet. Recorded event consisted of a brief baseline prior to the event, the heel-stick, and the immediate reaction following it. Total analyzed video time did not exceed 30 seconds per newborn.

#### Data collection

The study was approved by both university and hospital human subject committees (Institutional Review Boards) and parental consent was obtained in advance. A chart review was performed to derive demographic and medical history data including sex, ethnicity/race, gestational age, postnatal age, birth measurements, Apgar scores, and evidence of pregnancy or delivery complications. Use of epidural (epi) and, or other perinatal anesthesia (meds) was noted for potentially interactive neurobehavioral effects (Beilin et al., 2005; Ransjo-Arvidson et al., 2001). Similarly, feeding type (feed) -bottle, breast or both, was tracked to control for potential differences in bonding and/or maternal contact and interaction (Winberg, 2005). Behavioral state (state) is implicated in pain expression with infants that are awake expressing more pain response (Ahn, 2006; Grunau & Craig, 1987; Johnston et al., 1999; Stevens & Johnston, 1994). Behavioral state was scored at baseline as either asleep, characterized by closed eyes; or awake,

characterized by open eyes. Soothing techniques were utilized on fussing/whimpering infants to ensure a non-crying baseline. These infants were coded *awake* with eyes open or closed.

Thus, the use of epidural and, or other perinatal anesthesia, the behavioral state, and the type of feeding were considered possible confounding variables to control for in the study. The research questions are:

- 1. Are there significant differences in facial pain expression between male and female term newborns, after removing the effect of perinatal anesthesia, feeding type, and behavioral state?
- 2. Are there significant differences in facial pain expression by ethnic categories in term newborns, after removing the effect of perinatal anesthesia, feeding type, and behavioral state?
- 3. Is there a significant interaction on facial pain expression between sex and ethnic origin in term newborns, after removing the effect of perinatal anesthesia, feeding type, and behavioral state?

### Video analysis

The examination of facial expression to pain identified the Neonatal Facial Coding System, NFCS (Grunau, Oberlander, Holsti, & Whitfield, 1998), as an objective tool commonly used in this population and specifically designed for coding pain action. Facial action coded with the NFCS and consistently associated with pain in term neonates includes brow bulging, eyes squeezed shut, deepening of the naso-labial furrow, open mouth, and taut tongue (Craig, Hadjistavropoulos, Grunau, & Whitfield, 1994; Grunau & Craig, 1987; Grunau, Johnston, & Craig, 1990; Stevens et al., 2007). These actions are generally coded for presence/absence in

video analyses and point to anatomical engagement (e.g. area of facial movement) but not to degree or intensity of involvement. A scheme was developed that allowed for the measurement of (a) *gross movement and cry* (taut tongue, cry), and (b) *fine facial activity* (other implicated facial action based on the NFCS as listed above). Gross movement and cry were evaluated by the principal investigator (a trained and certified NFCS rater) by viewing digital video recordings played back in real time on a computer with frame by frame manipulation software and noting the presence/absence of taut tongue and/or cry. These actions were looked at independently because of their previous stated involvement in pain expression and because they were not conducive to our computerized image measurement methods.

# Computerized image measurement

Fine facial activity is an innovative approach to measuring *intensity* of NFCS associated pain behavior by means of digital image analysis and measurement. Recent advances in computer vision are exploring systems with the potential for automatic recognition of facial actions and identification of expressed emotion (Bartlett et al., 2006; Susskind, Littlewort, Bartlett, Movellan, & Anderson, 2007). These computer systems use the Facial Action Coding System (FACS) developed by Ekman and Friesen (1978), the oldest and most widely used tool for coding facial expression in general. The NFCS was derived from the FACS (Grunau and Craig, 1987; Craig et al., 1994). A technique proposed by Pantic and Patras (2005) was attempted to track facial action and measure movement. They proposed using particle filtering to track 20 facial points in a video image assuming a stationary head or small head rotations. Unfortunately, this technique could not be utilized due to very active head rotations following the heel-stick in the study neonates. Thus, a point-pair method that used facial points rather than

basing the measurement on moving video was used. Measurement was based on two still images (baseline and reaction) for comparison to overcome the issue of head movement. That is, rather than relying on automatic tracking on video which is very sensitive to rotational movement, manual assignment of points in a "before" (baseline, prior to heel-stick) and in an "after" (reaction, following heel-stick) image was utilized. The difference in number of pixels between the images indicates movement in the areas between the points.

# Point-pair method

Seven pairs of points that coincide anatomically with the pain facial actions associated with the NFCS were used for data analysis (Table 2). Because nasolabial furrowing or deepening of a portion of the face is difficult to measure in a flat two-dimensional image, a substitute measure was developed (point-pairs 4 and 5). Based on facial action common to both the NFCS and FACS (Craig et al., 1994), "cheek raise" was used as a proxy for nasolabial furrowing. A point on the infraorbital triangle itself is difficult to obtain because of the relative lack of anatomical landmarks in the area. Therefore, the alar-facial groove was chosen as a readily identifiable area, and its movement was anchored at the ipsilateral medial canthus which is an assumed reference point with relative stability in facial expression. The remaining point-pairs correspond more directly to the facial action associated with the NFCS (Picture 1).

## Baseline and reaction images

Baseline image was defined as a "neutral" or non-crying/non-grimacing still immediately before the heel-stick. Reaction image was defined as the still displaying the initial moment of maximal expression following the heel-stick. Time-wise, baseline instantly preceded heel-stick, and reaction occurred almost immediately after heel-stick. Specifically, for reaction, the facial

action after the heel-stick but before any potentially intervening act such as squeezing of heel for blood was used. Rad Video Tools (Rad Game Tools, Kirkland, WA) was used to convert the digital video file into a series of still images (jpegs) from which to choose baseline and reaction pictures. IrfanView (Irfan Skiljan, www.irfanview.net) was used to examine and select the two images.

## Computing facial action movement

The goal was to measure movement, in pixels, in particular facial areas implicated in neonatal pain expression by tracking change between point-pairs. To preclude issues of image size and differences in infant anthropometrics, *percent of facial width* was utilized as the standardized unit of measurement. Each child's face-width was measured twice at both baseline and reaction, and the average was used to *scale* all subsequent point-pair pixel measures. The child's hairline or ears (depending on which was best visible) was used at eyebrow height as landmarks for face-width measurement. Point-pair locations were assigned and measured in order at both baseline and reaction pictures (see Table 2 for anatomical locations). All computer measurements were performed by the principal investigator.

### Point-pair calculation

Each point pair consisted of the pixel distance between 2 points  $(x_1,y_1)$  and  $(x_2,y_2)$  calculated as:

*Pixel distance* = 
$$\sqrt{(x_1-x_2)^2 + (y_1-y_2)^2}$$

The final point-point pair output, expressed as a percent of face-width, was the computed distance between the two test points divided by the scale and multiplied by 100:

Or,

Point-pair = 
$$\frac{100 * \sqrt{[(x_1-x_2)^2 + (y_1-y_2)^2]}}{\sqrt{[(Scale_x_1-Scale_x_2)^2 + (Scale_y_1-Scale_y_2)^2]}}$$

Point-pairs were calculated for both baseline and reaction images. Point-pair change, net movement between images, was calculated as:

*Point-pair change* = (reaction point-pair)-(baseline point-pair)

The above calculations were done in Matlab (MathWorks Inc., Natick, MA). Picture 2 illustrates measurement of all 7 point-pairs at both baseline and reaction.

## Statistical analyses

The dependent variables (DVs) consisted of each of the 7 *point-pairs*. The independent variables (IVs) were *ethnicity* and *sex*. In analyzing the effects of the IVs on the DVs it was important to control for the effects of behavioral state (*state*), type of feeding (*feed*) and use of medications; epidural (*epi*) and/or other perinatal anesthesia (*meds*). Multivariate analysis of covariance (MANCOVA) was the statistical procedure chosen. Intra-rater reliability on the 7 point-pair measurements was assessed with calculations of Pearson's r. All statistical tests were performed on SPSS (SPSS Inc., Chicago, IL).

### Results

## Sample characteristics

A quota sample of 20 participants divided equally by sex was attempted for each of 4 four ethnic/race groups. 19 African Americans, 19 Caucasians, and 19 Hispanic/Latino were recruited and retained for analysis. Only 5 Asian neonates (3 females) were initially recruited and retained for analysis primarily because of low availability of this ethnic group in our population (Table 3). Therefore, the Asian group was excluded from further analyses due to its very small and unrepresentative group size. Characteristics of neonates are presented in Table 4. The mean postnatal age was 36 hours, while mean gestational age was 39 weeks. The mean birth weight was 3361 grams. 77% (44) of mothers had epidurals while 10% (6) had other than epidural anesthesia. The sample was 53% (30) awake prior to the heel-stick; while 37% (21) was breastfed, 21% (12) bottle fed and 42% (24) had a combination breast and bottle feedings.

### Gross movement and cry

Although not originally an assigned variable head movement was conspicuously noted in video analysis and added for coding with 86% (49) of the infants moving their head sideways following the heel-stick. The behavior was displayed more frequently than cry, which was present in 58% (33) of the sample. Two other behaviors previously associated with NFCS measurement were taut-tongue, displayed 49% (27) of the time; and chin-quiver, not noted at all.

# Fine facial activity: Point-Pairs

Fourteen cases were randomly selected to be rescored 24 hours apart to assess intra rater reliability on measurement of the 7 facial point-pairs. Correlations were calculated for both

baseline and reaction pictures. Pearson's r ranged from 0.40-0.97 with a mean of 0.76 indicating good intra rater agreement. Table 5 lists overall mean and ranges for point-pairs; Table 6 presents similar data by ethnicity and sex.

MANCOVA was conducted to determine the effect of ethnicity and sex on facial display after a painful stimulus while controlling for behavioral state, type of feeding, use of epidural anesthesia and use of other perinatal anesthesia. Results are presented on Table 7. There is no significant interaction between sex and ethnicity on the combined DV of point-pairs (Wilk's Lambda=0.76, F(14, 82)=0.86, p=0.61). There is no significant main effect between sex and the combined DV of point-pairs (Wilk's Lambda=0.87, F(7, 41)=0.84, p=0.56) and no significant main effect between ethnicity and the combined DV of point-pairs (Wilk's Lambda=0.80, F(14, 82)=0.67, p=0.79). The covariates did not significantly influence the combined dependent variable.

### Discussion

An innovative approach to measurement of facial expression to a painful stimulus was introduced. The point-pair method described here allows the use of parametric statistics and may enhance current facial coding schemes like the NFCS by progressing from a categorical level of measurement to a continuous measurement level. Measures of intensity of expression permit detailed comparison of fine facial movement and the exploration of the universality of the primal face of pain (PFP). Existence of this common facial display of pain at birth is supported by our findings across sex and the three ethic backgrounds evaluated (African American, Caucasian and Hispanic/Latino) while controlling for possible confounding effects (feeding method, behavioral state, and epidural and/or other perinatal anesthesia). Interestingly, the fact that there was no

statistical difference in pain expression at birth among infants suggests both the primacy of biology as well as importance of the sociocultural in the development of pain display differences.

A product of a MANCOVA model is that dependent variables (DVs) are combined into a newly created DV consisting of a linear combination of all original DVs (Mertler & Vannatta, 2005). Thus the DV can be construed as "overall facial expression" since it is made up of 7 different facial points or anatomical areas involved in the facial expression of pain. This arrangement ideally suits the research questions. Nevertheless, it is important to note that there are differences between point-pair intensities, with subtle but perhaps important variations in *range*. Table 5 shows that the mouth (point-pairs 6 and 7) has the widest range of movement and that those points are the only ones with positive means—indicating an opening of the mouth or pairs of points moving away from each other. The remaining point-pairs have a negative mean, indicating a drawing in or closing between pairs. That is, as expected, the PFP consists of opening of the mouth, drawing in of the brows, closing of the eyes, and raising of the cheeks. Yet, *minimum* and *maximum* measurements for all pairs are across negative (closing or drawing in) *and* positive (opening or drawing out) movement. This illustrates either true subtle differences in movement of certain areas involved in expression, and/or measurement error.

One possible contribution to measurement error is the almost ubiquitous head turning associated with the pain response, which made the face a moving target and point-pair measurement challenging. Intra-rater reliability, although on average good (r=0.76), was lowest among point-pairs less central to the face and more susceptible to head turning (such as 4 and 5) and highest among point-pairs more central to the face (such as mouth points 6 and 7). Future refinement in this methodology will have to address the issue. Also, the head-turning behavior

may in fact be worthy of further exploration as a clinical sign since it appears to be more common than cry.

Previous exposure to pain has been implicated as a predictor of pain response in newborns (Johnston, et al., 1999; Holsti, Grunau, Whifield, Oberlander, & Lindh, 2006); not accounting for this variable may be a limitation of the study. However, the relatively young age of the neonates (mean of 36 hours postnatal age) and their healthy status minimizes exposure to repeated painful stimuli associated with higher postnatal age and complications of prematurity. Possible previous pain exposure in this group could include an intramuscular injection (hepatitis B immunization), and circumcision in males. It is worth noting again that no differences by sex were found. Sample size was a limitation most notably leading to the exclusion of Asians. Support for the "universality" of the PFP will no doubt be strengthened by its identification and presence in many ethnic groups.

The commonality of a facial pain display at birth strengthens an evolutionary view of facial expressions. Additionally, it has been suggested that the PFP is at work as a prototype reference in school-age groups using facial pain scales (Schiavenato, 2007). If this is the case, further research into the PFP may help to advance the application and development of measurement tools in this population. Finally, the existence of a common facial expression at birth begs questions about its subsequent modulations and how these are assessed or interpreted in the clinical setting.

Discernment of what constitutes pain expression is of utmost importance in its assessment and management. The presence of a universal human facial pain display has theoretical (and perhaps practical) consequences in measurement tools like facial pain scales, which are based on a common understanding of facial expression in the evaluation of pain.

Further, the role of the sociocultural context in sculpting pain expression is highlighted by the existence of the PFP, a seemingly common beginning to the expression of pain.

### **Tables**

Table 8: Inclusion/Exclusion Criteria

- 1. Vaginal delivery
- 2. Term pregnancy (37-43 week gestation)
- 3. No history of pregnancy complications
- 4. No history/evidence of genetic or congenital disorders
- 5. No history of substance abuse during pregnancy
- 6. Appar scores at one and five minutes > 6

Table 9: NFCS Facial Action and Point-Pair Comparison

NFCS Facial Action*	Corresponding Point-Pair		
1. Brow bulge	Point-pair 1: between the medial borders of the eyebrows; to track horizontal brow movement		
2. Eye squeeze	2. Point-pair 2 (right side), point-pair 3 (left side): from mid eyebrow to mid lower eyelid		
3. Nasolabial furrow, cheek raise (proxy)	3. Point-pair 4 (right side), point-pair 5 (left side): from medial canthi to alar-facial groove		
4. Horizontal mouth/lip movement	4. Point-pair 6: between lip corners		
5. Vertical mouth/lip movement	5. Point-pair 7: between medial upper and lower lip vermilion border		

<sup>\*</sup>Craig et al., 1994.

Table 10: Sample Distribution by Sex and Ethnicity

Ethnicity	Sex		Total
	Female	Male	
African American	9	10	19
Asian*	3	2	5
Caucasian	10	9	19
Hispanic Latino	10	9	19
Total	32	30	62

<sup>\*</sup>Group excluded from further analyses.

Table 11: Sample Characteristics

	Result
Mean gestational age	39 weeks
Mean postnatal age	36 hours
Mean Birth Weight	3361 grams
Mothers with epidural anesthesia	77%
Mothers with other perinatal anesthesia	10%
Awake	53%
Breastfeeding	37%
Bottle feeding	21%
Both bottle and breast	42%

Table 12: Point-Pair Mean and Range

	Minimum	Maximum	Mean	Range	Std. Deviation
Point-Pair 1	-19.58	7.03	-4.83	26.61	6.08
Point-Pair 2	-9.17	3.83	-1.90	13.00	2.89
Point-Pair 3	-6.85	5.27	-1.93	12.12	2.71
Point-Pair 4	-5.33	2.06	-1.19	7.38	1.84
Point-Pair 5	-8.94	2.65	-1.01	11.60	1.97
Point-Pair 6	-12.18	23.96	5.01	36.14	6.73
Point-Pair 7	-8.16	38.68	7.86	46.84	9.25

Table 13: Point-Pair Mean By Sex and Ethnicity

				Std.
	Sex	Ethnicity	Mean	Deviation
D : ( D : 1	Б 1	African	4.04	5.01
Point-Pair 1	Female	American	-4.94	5.91
		Caucasian	-4.02	7.08
		Hispanic Latino African	-6.87	6.44
	Male	American	-1.82	3.68
	Muic	Caucasian	-5.58	5.48
		Hispanic Latino	-5.92	7.52
		African		,,,,
Point-Pair 2	Female	American	-1.45	2.32
		Caucasian	-2.49	2.67
		Hispanic Latino	-2.72	2.91
		African		
	Male	American	-1.21	3.50
		Caucasian	-1.81	3.76
		Hispanic Latino	-1.62	2.31
Point-Pair 3	Female	African American	-1.61	2.02
romeran 3	remate	American Caucasian	-1.61 -2.16	2.02
		Hispanic Latino	-2.16 -2.76	2.24
		African	-2.70	2.91
	Male	American	-1.03	3.17
		Caucasian	-1.39	3.28
		Hispanic Latino	-2.60	2.73
		African		
Point-Pair 4	Female	American	-1.90	1.43
		Caucasian	-0.16	1.33
		Hispanic Latino	-1.62	2.33
		African	1.60	1.50
	Male	American	-1.60	1.79
		Caucasian	-0.75	1.51
		Hispanic Latino African	-1.15	2.26
Point-Pair 5	Female	American	-0.62	1.96
1 Ollit-1 all 3	1 Ciliaic	Caucasian	-0.53	1.35
		Hispanic Latino	-0.86	1.04
		African	0.00	1.01
	Male	American	-1.87	3.33
		Caucasian	-0.97	1.93
		Hispanic Latino	-1.18	1.58
		African		
Point-Pair 6	Female	American	5.96	4.07
		Caucasian	3.89	7.67
		Hispanic Latino	5.77	6.41
	Mala	African American	0.70	7.05
	Male	American Caucasian	0.78 9.11	7.05 2.71
		Hispanic Latino	5.08	8.94
		African	2.00	0.71
Point-Pair 7	Female	American	4.68	5.34
		Caucasian	10.27	11.30
		Hispanic Latino	7.76	4.88
		African		
	Male	American	5.11	5.53
		Caucasian	7.40	10.01
		Hispanic Latino	11.95	14.79

Table 14: MANCOVA Summary Table

Fiffect					Hypothesis	Error		Partial Eta	Observed
Wilks' Lambda   0.96   0.27   7   41   0.96   0.04   0.12	Effect		Value	F		df	Sig.	Squared $\eta^2$	Power a
Hotelling's Trace Roy's Largest Root	Intercept	Pillai's Trace	0.04	$0.27^{b}$	7	41	0.96	0.04	0.12
Roy's Largest   Root		Wilks' Lambda	0.96	$0.27^{b}$	7	41	0.96	0.04	0.12
Root		Hotelling's Trace	0.05	$0.27^{b}$	7	41	0.96	0.04	0.12
EPI				L.					
(use of epidural)         Wilks' Lambda         0.89         0.72 b         7         41         0.65         0.11         0.27           Roy's Largest Root         0.12         0.72 b         7         41         0.65         0.11         0.27           MEDS         Pillai's Trace Root         0.16         1.14 b         7         41         0.36         0.16         0.43           (other         Wilks' Lambda         0.84         1.14 b         7         41         0.36         0.16         0.43           anesthesia)         Hotelling's Trace Roy's Largest         0.19         1.14 b         7         41         0.36         0.16         0.43           STATE (behavioral Wilks' Lambda         0.88         0.77 b         7         41         0.61         0.12         0.29           state)         Hotelling's Trace Roy's Largest         0.13         0.77 b         7         41         0.61         0.12         0.29           FEED         Pillai's Trace Roy's Largest         0.15         1.02 b         7         41         0.61         0.12         0.29           Feeding)         Pillai's Trace Roy's Largest         0.17         1.02 b         7         41         0.43									
cpidural)         Hotelling's Trace Roy's Largest Root         0.12         0.72 b         7         41         0.65         0.11         0.27 b           MEDS         Pillai's Trace Root         0.12         0.72 b         7         41         0.65         0.11         0.27 b           MEDS         Pillai's Trace Wilks' Lambda         0.84         1.14 b         7         41         0.36         0.16         0.43 b           (other         Wilks' Lambda         0.84         1.14 b         7         41         0.36         0.16         0.43 b           Root         0.19         1.14 b         7         41         0.36         0.16         0.43 b           STATE Root         Pillai's Trace Root         0.12         0.77 b         7         41         0.61         0.12         0.29 b           (behavioral Wilks' Lambda         0.88         0.77 b         7         41         0.61         0.12         0.29 b           (behavioral Wilks' Lambda         0.88         0.77 b         7         41         0.61         0.12         0.29 b           FEED         Pillai's Trace         0.13         0.77 b         7         41         0.61         0.12         0.29 b <t< td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></t<>									
Roy's Largest Root	*								
Root	epidural)		0.12	0.72 b	7	41	0.65	0.11	0.27
MEDS			0.12	o <b>70</b> h	_	4.1	0.65	0.11	0.07
(other anesthesia)         Wilks' Lambda Roy's Largest         0.84 Roy's Largest         1.14 b         7         41 0.36         0.16 0.43         0.43 anesthesia)           Roy's Largest Root         0.19 1.14 b         7         41 0.36         0.16 0.43         0.43           STATE Root         0.19 1.14 b         7         41 0.36         0.16 0.43         0.43           STATE (behavioral)         Wilks' Lambda         0.88 0.77 b         7         41 0.61 0.12 0.29         0.29           state)         Hotelling's Trace Root         0.13 0.77 b         7         41 0.61 0.12 0.29         0.29           FEED Roy's Largest Root         0.13 0.77 b         7         41 0.61 0.12 0.29         0.29           Feeding)         Hotelling's Trace Root         0.15 1.02 b         7         41 0.43 0.15 0.38         0.15 0.38           Feeding)         Hotelling's Trace Root         0.17 1.02 b         7         41 0.43 0.15 0.15 0.38         0.38           SEX         Pillai's Trace Root         0.17 1.02 b         7         41 0.43 0.15 0.15 0.38         0.38           SEX         Pillai's Trace Root         0.14 0.84 b         7         41 0.43 0.15 0.13 0.32         0.32           ETHN Root         0.14 0.84 b         7         41 0.56 0.13 0.30 0.13 0.32 </td <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td>									
Anesthesia   Hotelling's Trace Roy's Largest Root									
Roy's Largest Root	`								
Root	anesthesia)		0.19	1.14	7	41	0.36	0.16	0.43
STATE			0.19	1 14 <sup>b</sup>	7	41	0.36	0.16	0.43
(behavioral state)         Wilks' Lambda (Roy's Largest Roy's Largest Root         0.13 (0.77 b)         7 (10.61)         0.12 (0.29)         0.29 (0.29)           FEED         Pillai's Trace (type of Wilks' Lambda (Roy's Largest Root         0.15 (0.15 (0.10) (0.10) (0.15 (0.15) (0.15 (0.15) (0.15 (0.15) (0.15 (0.15) (0.15 (0.15) (0.15 (0.15) (0.15 (0.15 (0.15) (0.15 (0	STATE								
Hotelling's Trace Roy's Largest Root									
Roy's Largest Root	`								
Root         0.13         0.77 b         7         41         0.61         0.12         0.29           FEED         Pillai's Trace         0.15         1.02 b         7         41         0.43         0.15         0.38           (type of         Wilks' Lambda         0.85         1.02 b         7         41         0.43         0.15         0.38           Feeding)         Hotelling's Trace Root         0.17         1.02 b         7         41         0.43         0.15         0.38           SEX         Pillai's Trace Wilks' Lambda         0.87         0.84 b         7         41         0.43         0.15         0.38           SEX         Pillai's Trace Wilks' Lambda         0.87         0.84 b         7         41         0.56         0.13         0.32           Hotelling's Trace Root         0.14         0.84 b         7         41         0.56         0.13         0.32           ETHN         Pillai's Trace Root         0.20         0.68         14         84         0.79         0.10         0.39           (ethnicity)         Wilks' Lambda         0.80         0.67 b         14         82         0.79         0.10         0.38           S	State)		0.13	0.77	,		0.01	0.12	0.25
(type of Feeding)         Wilks' Lambda         0.85         1.02 b         7         41         0.43         0.15         0.38           Feeding)         Hotelling's Trace Roy's Largest Root         0.17         1.02 b         7         41         0.43         0.15         0.38           SEX         Pillai's Trace Wilks' Lambda         0.87         0.84 b         7         41         0.56         0.13         0.32           Hotelling's Trace Roy's Largest Root         0.14         0.84 b         7         41         0.56         0.13         0.32           ETHN Pillai's Trace Hotelling's Trace Roy's Largest Root         0.20         0.68         14         84         0.79         0.10         0.39           Hotelling's Trace Roy's Largest Root         0.17         1.00 c         7         42         0.44         0.14         0.38           SEX *         ETHN Pillai's Trace Roy's Largest Root         0.17         1.00 c         7         42         0.44         0.14         0.38           SEX *         ETHN Pillai's Trace Roy's Largest Root         0.25         0.84         14         84         0.62         0.12         0.49           Hotelling's Trace Roy's Largest Root         0.30         0.87         14			0.13	$0.77^{b}$	7	41	0.61	0.12	0.29
Feeding) Hotelling's Trace Roy's Largest Root	FEED	Pillai's Trace	0.15	1.02 b	7	41	0.43	0.15	0.38
Roy's Largest Root	(type of	Wilks' Lambda	0.85	1.02 b	7	41	0.43	0.15	0.38
Root         0.17         1.02 b         7         41         0.43         0.15         0.38           SEX         Pillai's Trace         0.13         0.84 b         7         41         0.56         0.13         0.32           Wilks' Lambda         0.87         0.84 b         7         41         0.56         0.13         0.32           Hotelling's Trace         0.14         0.84 b         7         41         0.56         0.13         0.32           ETHN         Pillai's Trace         0.20         0.68         14         84         0.79         0.10         0.39           (ethnicity)         Wilks' Lambda         0.80         0.67 b         14         82         0.79         0.10         0.39           Hotelling's Trace         0.23         0.66         14         80         0.80         0.10         0.38           SEX *         ETHN         Pillai's Trace         0.25         0.84         14         84         0.62         0.12         0.49           Wilks' Lambda         0.76         0.86 b         14         82         0.61         0.13         0.50           Hotelling's Trace         0.30         0.87         14         <	Feeding)	Hotelling's Trace	0.17	$1.02^{b}$	7	41	0.43	0.15	0.38
SEX         Pillai's Trace         0.13         0.84 b         7         41         0.56         0.13         0.32           Wilks' Lambda         0.87         0.84 b         7         41         0.56         0.13         0.32           Hotelling's Trace         0.14         0.84 b         7         41         0.56         0.13         0.32           ETHN         Pillai's Trace         0.20         0.68         14         84         0.79         0.10         0.39           (ethnicity)         Wilks' Lambda         0.80         0.67 b         14         82         0.79         0.10         0.39           Hotelling's Trace         0.23         0.66         14         80         0.80         0.10         0.38           SEX *         ETHN         Pillai's Trace         0.25         0.84         14         84         0.62         0.12         0.49           Wilks' Lambda         0.76         0.86 b         14         82         0.61         0.13         0.50           Hotelling's Trace         0.30         0.87         14         80         0.59         0.13         0.50           Roy's Largest         0.30         0.87         14	,	Roy's Largest							
Wilks' Lambda		Root	0.17		7	41	0.43	0.15	
Hotelling's Trace	SEX	Pillai's Trace	0.13		7	41	0.56	0.13	0.32
Roy's Largest   Root   0.14   0.84   7   41   0.56   0.13   0.32		Wilks' Lambda	0.87			41	0.56	0.13	
Root   0.14   0.84   7   41   0.56   0.13   0.32			0.14	$0.84^{\rm  b}$	7	41	0.56	0.13	0.32
ETHN Pillai's Trace 0.20 0.68 14 84 0.79 0.10 0.39 (ethnicity) Wilks' Lambda 0.80 0.67 b 14 82 0.79 0.10 0.39 Hotelling's Trace Roy's Largest Root 0.17 1.00 c 7 42 0.44 0.14 0.38 SEX *  ETHN Pillai's Trace 0.25 0.84 14 84 0.62 0.12 0.49 Wilks' Lambda 0.76 0.86 b 14 82 0.61 0.13 0.50 Hotelling's Trace Roy's Largest Wilks' Lambda 0.76 0.87 14 80 0.59 0.13 0.50 Roy's Largest			0.4.4	0 0 4 h	_		0	0.40	
(ethnicity)         Wilks' Lambda Hotelling's Trace Roy's Largest Root         0.80 0.23         0.66 0.66         14 14 14         82 80         0.79 0.80         0.10 0.38         0.39 0.38           SEX * ETHN         Pillai's Trace Wilks' Lambda Hotelling's Trace Roy's Largest         0.25 0.30         0.84 0.86         14 14 82         84 0.62         0.12 0.12         0.49 0.50 0.50									
Hotelling's Trace Roy's Largest Root 0.17 1.00° 7 42 0.44 0.14 0.38  SEX * ETHN Pillai's Trace 0.25 0.84 14 84 0.62 0.12 0.49 Wilks' Lambda 0.76 0.86° 14 82 0.61 0.13 0.50 Hotelling's Trace 0.30 0.87 14 80 0.59 0.13 0.50 Roy's Largest									
Roy's Largest Root         0.17         1.00°         7         42         0.44         0.14         0.38           SEX * ETHN         Pillai's Trace Wilks' Lambda         0.25         0.84         14         84         0.62         0.12         0.49           Wilks' Lambda Hotelling's Trace Roy's Largest         0.30         0.87         14         80         0.59         0.13         0.50	(ethnicity)								
Root         0.17         1.00 °         7         42         0.44         0.14         0.38           SEX *         ETHN         Pillai's Trace         0.25         0.84         14         84         0.62         0.12         0.49           Wilks' Lambda         0.76         0.86 b         14         82         0.61         0.13         0.50           Hotelling's Trace         0.30         0.87         14         80         0.59         0.13         0.50           Roy's Largest         0.30         0.87         14         80         0.59         0.13         0.50			0.23	0.66	14	80	0.80	0.10	0.38
SEX *         Pillai's Trace         0.25         0.84         14         84         0.62         0.12         0.49           Wilks' Lambda         0.76         0.86 b         14         82         0.61         0.13         0.50           Hotelling's Trace         0.30         0.87         14         80         0.59         0.13         0.50           Roy's Largest         0.30         0.87         14         80         0.59         0.13         0.50			0.17	1.00°	7	42	0.44	0.14	0.29
ETHN Pillai's Trace 0.25 0.84 14 84 0.62 0.12 0.49 Wilks' Lambda 0.76 0.86 14 82 0.61 0.13 0.50 Hotelling's Trace Roy's Largest 0.30 0.87 14 80 0.59 0.13 0.50	CEV *	NOOL	0.17	1.00	/	42	0.44	0.14	0.38
Wilks' Lambda Hotelling's Trace Roy's Largest  0.76 0.86 <sup>b</sup> 0.86 <sup>b</sup> 14 82 0.61 0.13 0.50 0.50		Pillai's Trace	0.25	0.84	1.4	84	0.62	0.12	0.49
Hotelling's Trace Roy's Largest 0.30 0.87 14 80 0.59 0.13 0.50	211111								
Roy's Largest									
			0.50	0.07	17		0.57	0.13	0.50
			0.27	1.61 <sup>c</sup>	7	42	0.16	0.21	0.59

Computed using alpha = .05

b Exact statistic

The statistic is an upper bound on F that yields a lower bound on the significance level. Design: Intercept+EPI+MEDS+STATE+FEED+SEX+ETHN+SEX \* ETHN c

d

# Figures

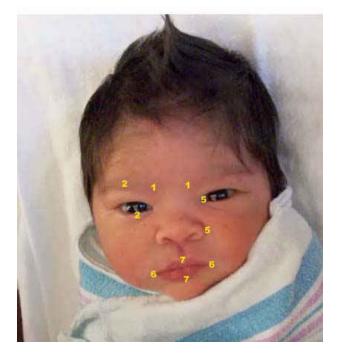


Figure 4: Point-Pairs

Distance between point-pairs is measured and compared between *baseline* and *reaction* images. \*Point-pairs 3 and 4 not shown for graphic clarity



a. Baseline



Figure 5: Sample-Point Pair Measurements



b. Reaction



b. Reaction

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# **APPENDIX A: DISSERTATION PROPOSAL**

# Evaluating Newborn Infant Facial Pain Expression:

Is there a Primal Face of Pain

Dissertation Proposal

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#### Abstract

Pain assessment continues to be ill managed in the clinical setting. Facial Pain Scales (FPSs) are pain assessment tools generally used with school-aged children. The implicit theoretical basis of the success of FPSs has seldom been explored. Explanations as to why and how these assessment tools work (and *not* work) have not been addressed. We support the existence of a universal pain expression that is evolved in nature, present at birth, and modulated through sociocultural factors. We term this facial pain expression the Primal Face of Pain (PFP), and propose it to be key in understanding the function of FPSs. This is a descriptive study which will observe, quantify and digitally reproduce the PFP as present in newborns. We will record facial response to a painful stimulus across a varied group of infants. We will use the Neonatal Facial Coding System (NFCS) to identify facial muscle groups associated with the expression. Digital analysis of such muscle movements will allow for their precise measurement. These data (what movement and how much movement), will serve as a foundation for graphic reproduction of the PFP. Measurement and graphic depiction of the PFP will lead us to explore the theoretical consequences of its existence, particularly as related to pediatric pain assessment and the valid use of FPSs. Further, we hope this work will lay a foundation for the further development and refinement of FPSs.

## Specific Aims

Pain is the number one reason people seek healthcare. Still, recent evidence suggests that clinicians poorly assess, treat and document this important and ubiquitous phenomenon (Alexander & Manno, 2003; Eder, Sloan, & Rodd, 2003; Gelinas et al, 2004; Hamers et al, 1998; Johnston et al. 2005). Pain assessment and measurement, is of particular relevance to the proper recognition and treatment of the problem. The "gold-standard" in pain measurement is said to be the self-report (McCaffery & Pasero, 1998). This is a valid and perhaps most common way of assessing pain. In the adult patient, it usually takes the form of inquiry as to what the current pain level is, "on a scale of 0-10 with zero being no pain and ten being the worst pain ever." Clinical tools for this process include the visual analog scale (VAS) among others (see Appendix 1 for examples). But, proper utilization of this method requires at the least verbal or communicative ability, and a cognition or developmental level that understands the abstraction and rating of pain in numbers or other qualifiers. In other words, self-report places a particular cognitive and communicative burden on the patient. This requirement is particularly problematic for various populations such as the cognitively impaired (Abbey et al., 2004), the critically ill (Shannon & Bucknall, 2003), and infants and children (Walker & Howard, 2002).

In the case of school-aged children, self-report tools have been adapted to include the use of adjectives, numeric qualifiers, and the use of facial depictions of pain -mostly line drawings or "happy faces," in the form of scales graphically depicting "least" to "most" pain (see Appendix 2 for examples). These *facial pain scales* (**FPS**s) are widely used and their validity is generally accepted (Anderson, 2005; Paul, Zelman, Smith, & Miaskowski, 2005). However, little is known as to why or how these scales are successful. Particularly vexing is the fact that although these scales seem to work well as a self-report tool, they are generally *not* helpful as "proxy"

reports of pain. That is, on those occasions when an observer –generally a parent or clinician, uses the FPS to rate the child's pain (Chambers et al., 1999; St-Laurent-Gagnon, Bernard-Bonnin, & Villeneuve, 1999; Singer, Gulla, & Thode, 2002). Clinically, sometimes this may be the only option in measuring pain in a child that is non-communicative because of a developmental, linguistic, or pathological state. However, again, experimentally when a child's report is compared to a parent's or clinician's, the adults report poorly matches the child's.

A self-evident factor underlying the success of FPSs is that the graphics in the scales somehow capture and represent the child's experience of pain. That is, the external representation of facial expression in the cartoon or figure in the FPS is in some way depicting the personal and complex experience of pain in the child. The purpose of this study is to analyze this assumption. We aim to investigate the facial expression of pain and provide further evidence that a universal, hardwired expression of pain, **phylogenic** in origin, is present at birth. We call this expression the *Primal Face of Pain* (**PFP**). We will observe and quantify facial muscles and their degree of involvement in pain expression. We also aim to use those measurements in the development of a graphic illustration of the PFP.

Our research questions are:

- 1. Is there a common facial expression upon receiving a painful stimulus among healthy termnewborns?
- 2. Does this facial expression vary by **race/ethnicity** or **sex**?
- 3. Once observed and quantified, can we reproduce this facial expression in a digital environment?

Background and Significance

FPSs are assumed to work because of an underlying relationship between the graphic depiction of pain in the scale, and the internal experience of pain by the child. The key, and only articulated variable in the majority of these scales and their graphics, is *facial expression* (an exception to this is the Oucher Scale which also graphically depicts in a static form gender, race, and more vaguely, age. See Appendix 2 for reference and illustration). The preoccupation with facial expressions has a long and rich history. Physiognomy, or the belief that personality traits could be "read" in the face, goes back to ancient Egypt, Arabia, and to China prior to Confucius. Students and practitioners of physiognomy included Pythagoras, Aristotle, Hippocrates and Galen (Fridlund, 1994). However, it was Darwin who first formed a scientific approach to the study of facial expressions (Darwin 1872/1965), and it is this evolutionary approach that lays the foundation to our theoretical context.

Facial Expressions: The Evolutionary Perspective

Ekman and colleagues, with over thirty years of research on the subject, propose that many facial expressions are constant across cultures and serve basic universal communicative functions in the language of *emotions* (Ekman, 1977; Ekman, 1999; Ekman, Sorenson, & Friesen, 1969). The phenomenon of pain itself is construed to have an *emotional* component (International Association for the Study of Pain, IASP, 1979). Further, Prkachin has proposed that pain may in fact have a universal display (1992). These facial displays have been documented in adults, children, and both term and premature neonates (see Table 1 "Facial Coding Systems in Pain" for a comprehensive list of muscles involved in said facial expressions). Empirically, at least four facial coding systems have been used to document the facial expression of pain (Table 1), with a stereotypical picture, or recurrent observation of the presence and movement of certain facial muscle groups, beginning to emerge. It is this "picture"

that is the focus of our current work. But if pain is universally expressed, why would it be so; what would be its function; and more important to our study, what would it look like?

Williams (2002), makes a compelling case in expounding the importance of infants to be able to express distress in order to ensure their survival. Simply put, those humans equipped to attract help through their facial expression from a parent (i.e. display pain) are more likely to survive than those who do not. Cry has also been associated in a similar manner (Soltis, 2004). Conversely, the expression of pain requires the ability from the parent to recognize it as "pain" or a call for help (Soltis, 2004; Williams, 2002). In the matter of recognition of facial pain display, evidence suggests that we are equipped to perceive pain in others when we are as young as 5 years old (Deyo, Prkachin & Mercer, 2004). The dyad between pain expression and pain recognition seems to be important enough to be formed very early in life. Further evidence supporting the role of facial expression in species survival can be found in children suffering environmental deprivation (i.e. the congenitally blind) who nevertheless show full facial expression in spite of the lack of external visual cues (Fridlund, 1994). Similarly, research into those suffering from facial paralysis illuminates the functionality and perhaps necessity of facial expression by noting difficulties in communication and socialization for those unable to fully form facial expressions (Ekman, 1999a; Fridlund, 1994).

Thus, we define the *Primal Face of Pain* (PFP) as this original communicative adaptation, phylogenic and universal in nature, with the protective function of enlisting aid by expressing distress. But if the PFP exists, what does it look like; and is the PFP the same or does it vary across ethnicity or sex? Answers to these questions lead us to a second and complimentary line of theoretical work: the sociocultural modulation of facial expressions of pain.

Modulation of Facial Expressions: The Sociocommunication Model of Infant Pain

Data illustrating facial expressions of pain are more consistent in infants than in adults (Craig, Prkachin & Grunau, 2001) leading one to believe that exposure, experience and normal human development may lead to modulation of facial display. Ekman (1977) first proposed a biocultural model to explain this phenomenon in which hardwired or "involuntary" emotional displays are modulated through learned behavior. Fridlund (1994) terms this a "two factor" model which is composed in one hand of the innate, hardwired behavior. On the other hand, the behavior is censored or modified according to sociocultural conventions. Izard and colleagues have found patterns of modulation to facial expression in young children which they attribute to developmental factors -physiologic maturation and social interaction (Izard et al, 1995; Izard & Abe, 2004). Additionally, sociocultural factors like ethnicity have been implicated in both the adult and pediatric experience of pain (Ibrahim et al, 2003; Munoz, 2004; Portenoy et al, 2004; Rosmus et al, 2000). Thus, biological maturation and the exposure to sociocultural environments that comes with the lived experience would appear to potentially modify the original, innate expression that is the PFP.

There is no lack of theoretical models to illustrate the interplay between the biologic and the sociocultural in the phenomenon of pain. For example, Melzack's exposition on the neuromatrix relies heavily on a comprehensive biological model that encompasses even the molecular level, but nevertheless includes environmental and behavioral modifiers (1999). Bates (1987) incorporates the role of ethnicity in pain, while Davidhizar (1999) emphasizes sensitivity to cultural factors, such as ethnicity, in the delivery of care to the pediatric patient. From a developmental psychological perspective, differential emotions theory (DET) also expounds upon the interplay of the biologic (maturation of neural systems), and the social (normative

infant to other interactions) and their effect on facial expressions –although not specifically pain (Izard, 1977; Izard & Abe, 2004; Izard et al, 1995). A good illustrative model of the phenomenon at hand is Craig and colleagues' (2002) *Sociocommunication Model of Infant Pain* (see Figure 1). The model is particularly relevant to our study because of its inclusion of *pain expression*.

In this model, "biological substrates" and "personal history" affect the pain experience. These variables, to a *newborn* in particular, would signify his/her physiology and/or prenatal experience (i.e. strictly congenital factors). Presumably, due to their brief social and cultural exposure, newborns have the least "social context" of any human being affecting their facial pain expression. Additionally, because of their developmental immaturity, they would have less capacity for self-regulating facial expression. In other words, if there is a genetically programmed display of pain in humans –the PFP, newborns are apt to display it most faithfully due to their developmental stage, lack of sociocultural exposure and their consequential effect in behavioral modulation. Thus, the study of a "primal face of pain" relies on the investigation of expression of pain in newborns.

FPSs and the PFP: What's the Big Deal?

Two assertions arise from our analysis offering support to the relevance and potential role of the PFP. First, it is well documented that facial pain scales (FPSs) are successful in quantifying the self-report of pain in school-aged children with a preference by users for the cartoon-like depictions such as those in the popular Wong & Baker scale (Luffy & Grove, 2003). That is, regardless of actual likeness to a "real" human face, these scales work well. Their success may in part be due to their "neutrality;" the fact that these scales function across gender and race/ethnicity (Belville & Seupaul, 2005; Hicks et al., 2001; Luffy & Grove, 2003). It is

proposed here that the reason for their success lies in the fact that cartoons highlight (emphasize, exaggerate) certain facial features, as anyone familiarized with a caricature could attest. That is, these cartoon scales work because they are graphically stereotyping "a painful expression" with the obvious purpose of cuing the child to their own experienced pain. Their "neutrality" and "bare bones" depiction of a complex phenomenon such as pain harkens back to a prototypical and universal expression of pain; that is the PFP. FPSs work because they cue the child to that primal, hardwired mechanism of facial display of pain.

Supporting evidence for this assertion leads us to a second postulate. When school-aged children use an FPS, they are attempting to identify their personal *experienced* pain with the graphic at hand. That is, they are not attempting to match their *expressed* pain with the scale. We know of no studies that use a mirror to aid the child in comparison or matching of their expression with the FPS. In other words, *in the use of FPSs, children match their internal experienced pain against their internal reference, the PFP; and this is what is attained in a child's pain self-report.* 

In the Sociocommunication Model of Infant Pain, the social context modulates pain expression (Figure 1). Thus, we can posit that school-aged children –at least 4-5 years of age, the target population in FPSs; have "some" level of sociocultural modulation to their pain expression. In other words, school-aged children are not likely to express the PFP as a newborn would due to the effects of their lived experience. It would then follow that school-aged children's facial expressions of pain would not be a valid measure of comparison against an FPS which is in fact cueing onto the PFP. That is, we can infer that the use of FPSs by someone external to the child would not be a valid attempt to measure the internal and personal workings of a match between experienced pain and its graphic reference the PFP. In fact, empirically this

is the case with mounting data supporting the inaccuracies of a **proxy rater** in the measurement of a child's pain with an FPS (Chambers et al., 1999; St-Laurent-Gagnon, Bernard-Bonnin, & Villeneuve, 1999; Singer, Gulla, & Thode, 2002).

The proposition for the existence and illustration of the "primal face of pain" is important in as much as it potentially represents an objective and universal visual and graphic mode of pain expression. Further, theoretical support for the PFP possibly explains the problems with proxy ratings, and attests to their invalidity.

The Relevance of Facial Expressions in Pain: Facial Coding Systems

In adults, a recent study supported, through the use of electromyogram, the involvement and significance of facial expressions after a painful stimulus (Wolf et al, 2005). In infants, facial expression appears to be perhaps the biggest determinant and most consistent cue in judging infant pain (Fuller & Conner, 1996; Hadjistavropoulos et al, 1997; Johnston & Strada, 1986; Pillai Riddell, Badali, & Craig, 2004), even above cry (Howard & Thurber, 1998). Table 1 summarizes the methodology used in documenting facial expression of pain. Although other pain scales have been developed that incorporate a measurement of facial expression in them, [such as the PIPP (Premature Infant Pain Profile, Stevens et al, 1996) and the NIPS (Neonatal Infant Pain Scale, Lawrence et al, 1993)], these scales can be characterized as "behavioral/observational tools," meaning that they include additional assessment information such as physiologic and other behavioral measures. These scales are not included since they are not specific to facial expression and its measurement such as the following.

The Facial Action Coding System (**FACS**) is the oldest and most widely used tool for coding facial **expressions** in general (Ekman & Friesen, 1978). The FACS identifies 44 discrete facial action (**FA**) units each representing the movement of a facial muscle or group of muscles.

Craig et al (2001) summarize facial movements coded by the FACS (not specifically in newborns) as consisting of 13 distinct actions. Williams (2002) summarizes facial movements coded by the FACS, again, not specific to newborns, as consisting of 11 distinct actions. Both of these summaries overlap in their findings. Prkachin and Mercer (1989) found 5 facial actions associated with adult expression of pain (also included in the summaries above). Similarly, Patrick and colleagues observed 5 facial actions associated with pain expression in adult females (Patrick, Craig & Prkachin, 1986). Further, Prkachin (1992) proposed that just 4 actions carry the bulk of facial information about pain: brow lowering, narrowing and closing of eyes, nose wrinkling and upper lip raising (an interesting side note about this study is that the findings were consistent across four different pain modalities).

Perhaps the complexity associated with the use of the FACS has lead to the development of other coding systems specifically developed for children (Craig, Prkachin and Grunau, 2001). Facial coding systems in children include the Maximally Discriminative Facial Movement Coding System (MAX), Neonatal Facial Coding System (NFCS), and the Child Facial Coding System (CFCS).

MAX, a tool used in infants, consists of coding facial expression in three anatomical areas: forehead and brows, eyes and nose, and mouth and chin (Izard,1983; Izard, Hembree & Huebner, 1987; Mercer & Glen, 2004). MAX has also been used to research facial expressions other than those associated with pain (Izard & Abe, 2004; Sullivan & Lewis, 2003). The NFCS was developed from a subset of facial actions (FAs) from the FACS and consists of coding for the presence or absence of 10 FAs (Grunau & Craig, 1987; Craig et al, 1994), while the CFCS was derived from both the FACS and NFCS to detect pain in toddlers and school-aged children, and consists of 13 FAs (Breau et al 2001; Gilbert et al., 1999).

Overall, a glance at Table 1 may start to convince us of a "stereotypical face of pain" with similar descriptions for facial pain expression emerging across age groups and coding systems. In fact, it appears that all these disparate reports and methods seem to herald the existence of the PFP. What is lacking in the literature and what we propose in this project, is the theoretical cohesiveness herewith and the prospective attempt at documenting and illustrating the PFP; an endeavor that although alluded to has yet to be presented. To achieve this we propose the following.

### Research Design and Methods

## Facial Coding System

Craig and colleagues' (2002) Sociocommunication Model of Infant Pain (Figure 1) illustrates the interplay between sociocultural influence (among other variables) and pain expression. A deduction from this model is that newborns have the least social or cultural exposure affecting their facial expression of pain. That is, in our pursuit of the PFP, newborns are the prime subject for its documentation. As such, based on the review of currently available facial coding systems (see discussion above) the NFCS is the most appropriate tool because of its specific design: intended population, newborns; intended expression, pain. Further, there exists ample evidence supporting the validity and reliability of the NFCS as well as its use in observational and interventional studies (Benini et al, 1993; Craig et al, 1994; Grunau & Craig, 1987; Grunau et al, 2006; Morison et al, 2003; Ogawa et al, 2005; Sweet & McGrath, 1998; Taddio et al, 1997).

### **Participants**

As stated above, neonates are our population of interest. Because of potential differences in findings between pre-term and term infants (Craig et al, 1993; Grunau et al, 1998; Johnston et al, 1993), and potential intervening pathological factors (Mercer & Glenn, 2004), we will limit our sample to healthy term-neonates. The timing for observation will be of utmost importance. The underlying intent is to balance sociocultural exposure (i.e. closest to birth as possible) with the trauma and eventfulness of the birth experience. Another factor to consider in timing is occurrence of painful stimulus. Painful stimulus will be elicited by hospital staff through a routine heel stick in the course of the infant's hospitalization. The procedure type will be determined based upon the institution's protocol (i.e. phenylketonuria screening). However, due to potential differences in the level of invasiveness and/or induced pain by each type of procedure (i.e. a heel stick vs an immunization), and the facial response elicited (Grunau, Johnston & Craig, 1990), only one type of procedure will be chosen and applied across the sample.

Sex may be considered a "biological substrate" within the Sociocommunication Model of Infant Pain (Figure 1). Specifically, Guinsburg and colleagues (2000) found differences in facial pain expression between sexes with females expressing more facial features than males. Similarly, Grunau & Craig found sex differences in cry as an expression of pain (1987). Thus, inclusion of both male and females is important in the current project. The inclusion of a racially/ethnically diverse sample is of importance and something called for but seldom reported in previous facial expression of pain research (LeResche & Dworkin, 1984). Due to the impreciseness of race/ethnicity as a meaningful biological marker, it is considered here a "social context" variable (National Institutes of Health, 2003; Winker, 2004). Racial/ethnic self-designation of the infant by the parent will be used and classified according to current US Census

Bureau standards (US Census Bureau, 2000). Participants will be representative of the four largest racial/ethnic groups in the US: White (non-Hispanic), Black/African American (non-Hispanic), Hispanic/Latino and Asian (US Census Bureau, 2003).

Due to the exploratory nature of this work, participants will comprise of a quota sample consisting of 40 newborns divided each equally by race/ethnicity. Exclusion criteria will include history of maternal complications during pregnancy; evidence or history of genetic or congenital disorders; substance abuse during pregnancy; less than 38 or greater than 42 weeks of gestation (that is only term newborns); and appar scores at one and five minutes less than 7 -indicating significant clinical distress associated with the birth process (see Table 2 for listing). Vaginal deliveries only will be included to avoid potential confounding effects of anesthesia. Participant facial response to the painful stimulus shortly after birth (depending upon institutional protocol for timing of painful procedure but thought to be within the first 24-48 hours postnatally) will be recorded in the following manner (please refer to Appendix 5 for a listing of patient and data protection initiatives in the study).

#### Measures

As is the case with the NFCS implementation, slow motion video recording will be used as a means of capturing facial reaction to the pain stimulus. Pilot work before data gathering will be conducted to determine technical and procedural details such as infant and camera positioning, video image size and resolution, and length of time to record. Videos for each participant will be reviewed and coded as to the presence/absence of each of nine FAs immediately after receiving the painful stimulus. This initial step is important because it will not only provide evidence to support or refute the NFCS in coding pain expression, but it will also help to isolate relevant FAs for further analysis.

After reviewing videos with the NFCS for the presence of relevant FAs, these will be further analyzed digitally for degree of involvement and movement using video editing software (see Table 3, "Methods and Software"). The goal is to go beyond research that has previously noted presence/absence of FA, and to document the actual degree of intensity of each FA involved in producing the facial expression. Descriptive statistics (range, average etc) will be gathered on the movement intensity for each of the nine FAs. These measurements will then be used to digitally reconstruct and illustrate this archetype pain expression, the PFP. After obtaining data on FA intensity, reconstruction and illustration of the PFP will be performed using photographic and/or morphing/animation software. Exact methodology (i.e. software applications) for digital reconstruction of the PFP will depend on trial and error for the ideal technique. Techniques under consideration include the use of a photograph to edit digitally (i.e. starting off with a "real human face"), versus modeling and rendering an image entirely digitally (see Table 3 for specifics). Since we are collecting visual physical data on the newborn, infant anthropometric measures (head circumference, length and weight) will also be collected in anticipation of potential interactions.

### Potential Significance

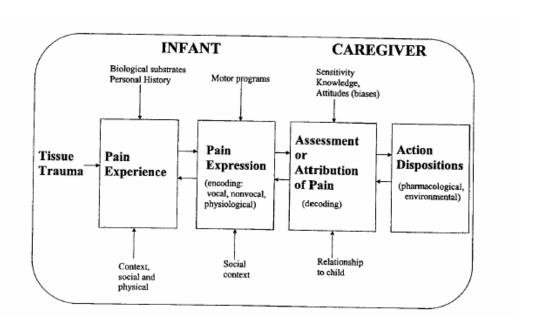
The proposition and support for the existence of the *Primal Face of Pain* (PFP) has deep theoretical significance in the study of the pain phenomenon; particularly as it relates to the interaction between biologic and social factors, and their practical impact on the assessment of pain in children. Specifically, practical applications of this research include the illustration and documentation of the PFP; a phenomenon that although previously alluded to, has not been graphically reproduced or quantified to this extent.

Further, this research has potential significance on the clinical use and application of facial expressions as measurement of pain; for example, the validity of proxy ratings with facial pain scales (FPSs). And lastly, this research has the potential significance of affecting the development of new approaches for improving current pain measurement methodology; for example, the utilization of a computer-based FPS that is based on the documentation and illustration of the PFP as presented here (See Figure 2 for a schematic of the work).

# Figures

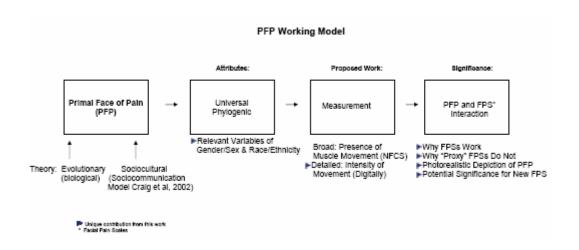
- 1. A Sociocommunication Model of Infant Pain
- 2. Primal Face of Pain, Working Model

Figure 1. A Sociocommunication Model of Infant Pain



Source: Craig, K. D., Korol, C. T., Pillai, R. R. (2002). Challenges of judging pain in vulnerable infants. Clinics in Perinatology, (20), 455-457.

Figure 2: Primal Face of Pain, Working Model



# Tables

- 1. Facial Coding Systems in Pain
- 2. Subject Criteria
- 3. Methods & Software

Table 1. Facial Coding Systems in Pain

	FACS*	NFCS*	CFCS*	MAX*
Use/ Method	Used in assessing a variety of facial expressions in adults and children. 44 facial actions (FAs). Specifically and comprehensively in pain: brow lower, cheek raise, lids tight, nose wrinkle, nasolabial deepen, upper lip raise, lip corner pull, lip stretch, lips apart, jaw drop, lids droop, eyes closed, blink	Developed for use in both term and premature neonates 10 FAs: brow lowering, eyes squeezed shut, deepening of nasolabial furrow, open lips, vertical mouth stretch, horizontal mouth stretch, taut tongue, chin quiver, lip purse, and tongue protrusion (as a "no pain" sign in term infants only).	Developed for use in toddlers and schoolaged children. 13 FAs: brow lowering, squint, eye squeeze, nose wrinkle, nasolabial furrow, cheek raiser, upper lip raise, lip corner pull, vertical mouth stretch, horizontal mouth stretch, blink, flared nostril, open lips.	Used to assess other emotions associated with facial expression. Used in infants, provides a system for judging brow, eye and mouth movement. The "pain expression" associated with it consists of brows lowered and drawn together, forehead in vertical furrows or bulge between brows, nasal root broadened and bulged; eye fissure scrounged, eyes tightly closed; mouth angular, squarish and open, or open and tense.
Source	Craig et al, 2001; Craig et al, 1994; Lilley, Craig & Grunau, 1997; Patrick, Craig & Prkachin, 1986; Prkachin, 1992; Prkachin & Mercer, 1989; Williams, 2002.	Barr et al, 1992; Craig et al, 1994; Grunau & Craig, 1987; Grunau, Johnston & Craig, 1990; Grunau et al, 1998; Grunau et al, 2006; Johnston et al, 1993; Morison et al, 2003; Ogawa et al, 2005.	Breau et al, 2001; Cassidy et al, 2002; Gilbert et al 1999; Goodman & McGrath, 2003; Hadden & von Baeyer, 2005	Izard, 1983; Izard & Abe, 2004; Izard, Hembree & Huebner, 1987; Mercer & Glenn, 2004; Sullivan & Lewis, 2003.

<sup>\*</sup>FACS = Facial Action Coding System. NFCS = Neonatal Facial Coding System.

CFCS = Child Facial Coding System. MAX = Maximally Discriminate Facial Movement Coding System.

# Table 2: Subject Criteria

- Quota sample of 40 subjects
  - 10 each by major race/ethnic background: White/Caucasian (non-Hispanic), African

American (non-Hispanic), Hispanic/Latino, and Asian.

- Each racial/ethnic group equally divided by sex (5 males/5 females)
- Term infant: 38-42 weeks gestation
- Vaginal delivery
- No history of present maternal pregnancy complications
- No history/evidence of genetic or congenital disorders
- No evidence of birth distress (apgar scores at one and five minutes >6)
- No history of substance abuse during pregnancy

Table 3: Methods & Software

## **Video Recording**

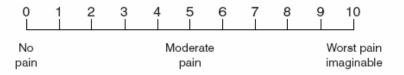
A digital camera will be the primary source of data collection. Video editing software included with the hardware should suffice as long as slow motion capture and viewing is possible. In addition, a "measurement tool" is needed to analyze facial movement involved in the expression. "Video Toolbox" by Zarbecco LLC, appears to suffice this need (<a href="http://www.zarbeco.com/video\_toolbox\_la.htm">http://www.zarbeco.com/video\_toolbox\_la.htm</a>). Finally, two techniques are being considered for PFP reconstruction. A sampling of software to both methodologies is listed below.

Photograph Editing Software	<b>Modeling and Animation Software</b>
Face Filter Studio:	Poser:
http://www.reallusion.com/facefilter/default.asp	http://www.e-frontier.com/go/poser hpl
FantaMorph: <a href="http://www.fantamorph.com/">http://www.fantamorph.com/</a>	FaceGen: <a href="http://www.facegen.com/">http://www.facegen.com/</a>

# Appendixes

- 1. Numeric, Verbal and Visual Analog Scales
- 2. Facial Pain Scales
- 3. Glossary of Terminology
- 4. Forms
- 5. Measures for Protection of Human Participants
- 6. References

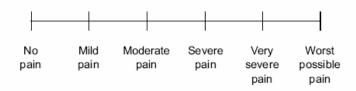
# 0-10 Numeric Pain Intensity Scale\*



# 0-10 Numeric Pain Distress Scale\*



# Simple Descriptive Pain Intensity Scale\*



\*If used as a graphic rating scale, a 10-cm baseline is recommended.

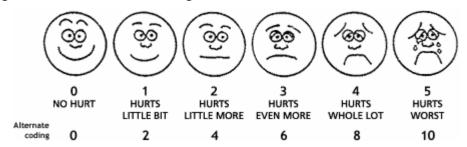
From: Acute Pain Management: Operative or Medical Procedures and Trauma, Clinical Practice Guideline No. 1. AHCPR Publication No. 92-0032; February 1992. Agency for Healthcare Research & Quality, Rockville, MD; pages 116-117.

Visual Analog	Scale (VAS)*			
No pain	Pain as bad as it could possibly be			
*A 10-cm baseline is recommended for VAS scales. From: Acute Pain Management: Operative or Medical Procedures and Trauma, Clinical Practice Guideline No. 1. AHCPR Publication No. 92-0032; February 1992. Agency for Healthcare Research & Quality, Rockville, MD; pages 116-117.				
Visual Analog Scale				
NOPAIN	WORST PAIN			
Directions: Ask the patient to indicate on the line extremes. Measure from the left hand side to the m				
From Stration Hill C. Guidelines for Treatment of Cancer Pain: The F Council's Workgroup on Pain Control in Cancer Patients, 2nd Editio Reprinted with permission. www.texascancercouncil.org.				

Memorial Pain A	ssessment Card
4 Mood Scale	2 Pain Description Scale
Worst Best mood mood  Put a mark on the line to show your mood.	Moderate Just noticeable  Strong No pain  Mild  Exerciating Severe  Weak  Circle the word that describes your pain.
•	•
1 Pain Scale	3 Relief Scale
Least Worst possible possible pain pain  Put a mark on the line to show how much pain there is.	No relief Complete of pain relief of pain pain  Put a mark on the line to show how much relief you get.
Fold page along broken line so that each measure is presented to the patient separately in the numbered order.	Reprinted by permission. Memorial Steen-Kettering Cencer Center Pain Assessment Cerd. A7012A5-9

## Appendix 2: Facial Pain Scales

### Wong-Baker FACES Pain Rating Scale



Source: Wong, D., & Baker, C. (1988). Pain in children: Comparison of assessment scales. Pediatric Nursing, 14(1), 9-17.

### **Faces Pain Scale Revised**



Source: Hicks, C. L., von Baeyer, C. L., Spafford, P. A., van Korlaar, I., & Goodenough, B. (2001). The Faces Pain Scale-Revised: toward a common metric in pediatric pain measurement. Pain, 93(2), 173-183.

## **Oucher Scale (Caucasian Version)**

**OUCHER** 

Source: Beyer, J. E., Denyes, M. J., & Villarruel, A. M. (1992). The creation, validation, and continuing development of the Oucher: a measure of pain intensity in children

#### LeBaron & Zeltzer



Source: LeBaron, S., & Zeltzer, L. (1984). Assessment of acute pain and anxiety in children and adolescents by self-reports, observer reports, and a behavior checklist. Journal of consulting and clinical psychology, 52(5), 729-738

### Manuksela et al



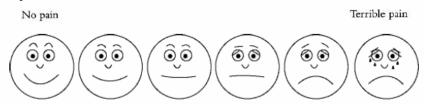
Source: Maunuksela, E. L., Olkkola, K. T., & Korpela, R. (1987). Measurement of pain in children with self-reporting and behavioral assessment. Clinical pharmacology and therapeutics, 42(2), 137-141.

#### McGrath et al



Source: McGrath, P., deVeber, L. L., & Hearn, M. J. (Eds.). (1985). Multidimensional pain assessment in children (Vol. 9). New York: Raven Press.

### **McCaffery & Pasero**



Source: McCaffery, M. & Pasero, C. (1998). Pain: Clinical manual. Mosby.

Appendix 3: Glossary of Terminology

**CFCS** *Child Facial Coding System*. A facial coding system derived from both the FACS and NFCS to detect pain in toddlers and school-aged children, and consists of 13 FAs.

**Ethnicity** A social or cultural variable, derived not biologically but by experience and exposure.

**FA** Facial Actions. Discreet unit of muscle measurement in facial coding systems.

**FACS** Facial Action Coding System. Most widely used system for measuring and describing facial expressions. Developed by Ekman and Friesen.

**FPS** *Facial Pain Scales*. Measurement tools to assess pain in school-aged children; generally cartoon or line drawings depicting pain intervals. See Appendix 4 for examples.

**MAX** *Maximally Discriminative Facial Movement Coding System*. A facial coding system used with infants which focuses in three anatomical areas: forehead and brows, eyes and nose, and mouth and chin.

**NFCS** *Neonatal Facial Coding System*. A facial coding system adapted for neonates from the FACS.

**PFP** *Primal Face of Pain.* Proposed here to be a communicative adaptation, phylogenic and universal in nature, with the protective function of enlisting aid by expressing distress. The PFP

is present and least modified in newborns, and it is the internal reference used by children in self-

assessing pain and responsible for the success of FPSs in this group.

**Phylogenic** From an evolutionary origin, genealogically developed.

**Proxy Rater** An observer, usually a clinician, evaluating patient pain based on their assessment

of patient facial expression; not a self-report.

Race See Ethnicity.

**Sex** Biologically derived variable: Male or female.

VAS Visual Analog Scale. A measurement tool generally used in adults consisting of a line

indicating extremes at either end. A standard ruler (i.e. 10 cm) is set behind the line to indicate a

ratio level measurement. See Appendix 3 for examples.

99

### Appendix 4: Forms

Research process forms follow. All other institutional Forms to be submitted with IRB process.

### PFP RESEARCH

### Control Form

	Yes
• Participant number	
• Informed consent?	
• Photo consent?	
Demographic data collected?	
Video data collected?	
Anthropometric data collected?	
<ul> <li>Parent debriefing</li> </ul>	
- Turent deorioring	
Notes:	

### PFP RESEARCH

### Inclusion/Exclusion Form

Criteria	Yes
• Date of birth	
• Time of birth	
• Race/ethnicity	
• Vaginal delivery?	
• Term pregnancy? (weeks)	
• No history of pregnancy complications?	
• No history/evidence of genetic or congenital disorders?	
• No history of substance abuse during pregnancy?	
• Apgar scores at one and five minutes >6	
Assigned Participant Number	

Notes:

### PFP RESEARCH

### Data Collection Form

	Data collection time
	Infant age (hours):
	Infant race/ethnicity (circle): 1 2 3 4
Length _	Weight (Kg)
_	
	Length _

#### Appendix 5: Measures for Protection of Human Participants

Both University and Agency institutional review board (IRB) will be sought according to standard operating requirements. Subject parents' will be approached for informed consent as to their participation and willingness for the study shortly after infant delivery (24-48 hours). This strategy will ensure prior access to medical history and assessment of inclusion/exclusion criteria, as well as to a time measurement for ideal data collection. There will be no monetary compensation offered for participation.

The heel stick used as a painful stimulus in the study will be the "standard of care" at the institution. There is little intrusiveness in our research outside of the video recording of this "standard" painful experience for the newborn. There are no risks identified to the parents or the child in this study. There is perhaps the potential inconvenience of being approached for participation after the significantly exhaustive event of giving birth. This will be attempted to be minimized by thoughtful and timely approach by researcher. Potential benefits include the personal knowledge and satisfaction by the parents of their involvement and advancement in this significant field of pain research in children.

Identifying participant information will include participant gestational age, gender and race/ethnicity. Any and all potential identifiers will be replaced with number codes during the informed consent stage. Confidentiality will be ensured with these codes in all data collected. Parents will be informed of video recording and all other measurement intents prior to agreement with the study. Both photo consent and inform will be obtained.

Data, including inclusion criteria and all related information (i.e. demographics) will be digitally recorded. Privacy and confidentiality for this and all subsequently collected findings will be ensured by keeping all data-implicated systems password protected. Additionally, any

and all paper documents collected (i.e. signed informed consent forms) will be kept private and separate under principal researcher's care in a locked office. Finally, any and all participant families wishing to know results, and/or study findings will be offered the opportunity to be informed of our work findings following data analysis.

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- Wolf, K., Raedler, T., Henke, K., Kiefer, F., Mass, R., Quante, M., et al. (2005). The face of pain--a pilot study to validate the measurement of facial pain expression with an improved electromyogram method. *Pain research & management : the journal of the Canadian Pain Society = journal de la societe canadienne pour le traitement de la douleur, 10*(1), 15-19.

### APPENDIX B: LETTERS OF IRB APPROVAL

1414 Kuhl Avenue • Orlando, Florida 32806-2093 • 407 841-5111

### When it matters most.

February 12, 2007

Martin Schiavenato, RN,MS 9806 Heaton Court Orlando, FL 32817

Dear Mr. Schiavenato:

Concerning the following Study:

Our Study # 0702803

Protocol Title: Evaluating Newborn Infant Facial Pain Expression: Is there a Primal Face of Pain?

Under federal guidelines for expedited review, I have reviewed and approved the fact sheet, informed consent, and protocol for your project stated above. The study is approved under 21CFR 56.110 (b) (1) for this project since it presents no more than minimal risk. The Chair has approved this study at all ORHS facilities and your office. The Institutional Review Board review process is in compliance with GCP's and included review of potential risks to subjects, risk benefit ratio, subject selection criteria and safety, content of the informed consent, confidentiality and appropriate safeguards. The project was reviewed in detail on 2/9/07. It will be sent to the 3/1/07 Institutional Review Board meeting and be reviewed in the minutes by a majority of membership with quorum present.

Subjects may be enrolled in your project from the date of this letter through 2/11/08. For approval to be extended after that date, a continuing review report must be submitted to the Institutional Review Board meeting prior to the deadline date. A form for continuing review is available on the IRB website (click "Our Services") at <a href="https://www.orhs.org">www.orhs.org</a>. If you wish to terminate your project before the expiration date, please notify the IRB office at 321-841-5895.

Institutional Review Board approval is contingent upon:

- Per the guidelines for expedited review and approval, you may begin enrollment as of the date of this letter. However, enrollment may not continue after the expiration date. This expedited information will be submitted to the Institutional Review Board for final review.
- Modifications to protocol must be approved prior to implementation unless they reduce immediate danger to subject.
- All protocol deviations must be reported to Institutional Review Board within 5 working days.
- 4. FDA requires you to notify the IRB of any change of Investigator or site location, amendment or changes in the protocol, significant protocol deviations, or termination of the study. Please note that you must submit all protocol amendments to the Chairman, prior to implementing the amendment.

If you have any questions, please feel free to contact the IRB Office at 321-841-5895.

Sincerely,

Richard Hornick, M.D.

Chairman of Institutional Review Board

Juhantthmuk mi)



February 12, 2007

Martin Schiavenato 9806 Heaton Court Orlando, FL 32817

Dear Mr. Schiavenato:

With reference to your protocol #07-4183 entitled, "Evaluating Newborn Infant Facial Pain Expression: Is there a Primal Face of Pain?," I am enclosing for your records the approved, expedited document of the UCFIRB Form you had submitted to our office.

This study was approved on 02/09/2007. The expiration date for this study will be 02/08/2008. Per IRB chair approval, you must make certain that you do not include those infants whose parents have only limited English-reading ability. Should there be a need to extend this study, a Continuing Review form must be submitted to the IRB Office for review by the Chairman or full IRB at least one month prior to the expiration date. This is the responsibility of the investigator.

Please be advised that this approval is given for one year. Should there be any addendums or administrative changes to the already approved protocol, they must also be submitted to the Board through use of the Addendum/Modification Request form. Changes should not be initiated until written IRB approval is received. Adverse events should be reported to the IRB as they occur.

Should you have any questions, please do not hesitate to call me at 407-823-2901.

Please accept our best wishes for the success of your endeavors.

Cordially,

Joanne Muratori

(FWA00000351 Exp. 5/13/07, IRB00001138)

Copies: IRB File

Jacqueline Byers, Ph.D.

JM:jm

### **APPENDIX C: INFORMED CONSENT FORM**

APPROVED INFORMED CONSENT Orlando Regional Healthcare System Institutional Review Board ORHS# 0702803 Original Version: Revised and Amended Version: February 12, 2007

#### INFORMED CONSENT FORM

Evaluating Newborn Infant Facial Pain Expression: Is there a Primal Face of Pain?

Good medical care includes obtaining informed consent before beginning any experimental procedure. The patient or subject should be told the nature, purpose, alternative and possible side effects of the therapy. This experimental research study is being conducted by Martin Schlavenato, RN, Doctoral Candidate.

Principal Investigator(s): Martin Schiavenato, RN, Doctoral Candidate

Sub-Investigator(s): Jacqueline Byers, PhD, RN, CNAA, CPHQ, FAAN

Sponsor: College of Nursing, University of Central Florida

Investigational Site(s): Winnie Palmer Hospital for Women and Babies

This consent form gives detailed information about the research study. The Principal Investigator will discuss this information with you. Once you understand the study, you will be asked to sign this form if you wish to participate.

- <u>PURPOSE OF RESEARCH STUDY</u>: The purpose of the research study is to evaluate the facial
  expression of newborns in response to pain. It is my goel to video record this facial expression and to measure
  the movement or grimace on the face of your child. This work will help lay the foundation for developing better
  methods to recognize pain in children.
- EXPECTED DURATION: The total time for video recording will not exceed two minutes. There will be no additional steps or "follow ups" to our study.
- 3. PROCEDURES TO BE FOLLOWED: Your child will be video recorded while blood is drawn from the heel for the "PKU screening." PKU (phenylketonuria) screening is performed in all newborns in the State of Florida to ensure that they process phenylalankine, an enzyme found in milk. It is important to test your beby for PKU soon after birth to prevent brain damage. Hospital staff will perform this test according to their established protocols which include puncturing the heel and collecting several drops of blood for testing. All bables in the State of Florida are required to have this test. We are asking you to let us record your baby's face expression to this test.
- 4. <u>IDENTIFICATION OF EXPERIMENTAL PROCEDURES:</u> There are no experimental procedures or variations to the care your child will receive. The only difference occurring with our study is that we will be video recording your infant's facial expressions during the PKU procedure.
- 5. <u>POTENTIAL RISKS AND DISCOMFORTS</u>: There are no direct physical risks anticipated by this study as the PKU test is the standard of care applied by the staff during a normal newborn stay. There will be no changes in this process other than the presence of a video recorder.
- 6. <u>POTENTIAL BENEFIT TO SUBJECT OR OTHERS:</u> Your baby's participation in this study will help to expand our understanding of pain expression in children. Additionally, if you would like, we can mail you a photograph of your child which we will print from the video as a memento.
- 7. ALTERNATIVE PROCEDURES OR TREATMENTS: The alternative to participating in this study is to not have the PKU test video recorded.

  APPROVED BY

Orlando Regional Healthcare System Institutional Review Board

APPROVED INFORMED CONSENT
Orlando Regional Healthcare System
Institutional Review Board
ORHS#

Original Version:	
Revised and Amended Version:	

#### INFORMED CONSENT FORM

Evaluating Newborn Infant Facial Pain Expression: Is there a Primal Face of Pain?

Good medical care includes obtaining informed consent before beginning any experimental procedure. The patient or subject should be told the nature, purpose, alternative and possible side effects of the therapy. This experimental research study is being conducted by Martin Schiavenato, RN, Doctoral Candidate.

Principal Investigator(s): Martin Schiavenato, RN, Doctoral Candidate

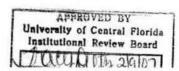
Sub-Investigator(s): Jacqueline Byers, PhD, RN, CNAA, CPHQ, FAAN

Sponsor: College of Nursing, University of Central Florida

Investigational Site(s): Winnie Palmer Hospital for Women and Babies

This consent form gives detailed information about the research study. The Principal Investigator will discuss this information with you. Once you understand the study, you will be asked to sign this form if you wish to participate.

- PURPOSE OF RESEARCH STUDY: The purpose of the research study is to evaluate the facial
  expression of newborns in response to pain. It is my goal to video record this facial expression and to measure
  the movement or grimace on the face of your child. This work will help lay the foundation for developing better
  methods to recognize pain in children.
- 2. <u>EXPECTED DURATION</u>: The total time for video recording will not exceed two minutes. There will be no additional steps or "follow ups" to our study.
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  changes in this process other than the presence of a video recorder.
- 6. <u>POTENTIAL BENEFIT TO SUBJECT OR OTHERS:</u> Your baby's participation in this study will help to expand our understanding of pain expression in children. Additionally, if you would like, we can mail you a photograph of your child which we will print from the video as a memento.
- ALTERNATIVE PROCEDURES OR TREATMENTS: The alternative to participating in this study is to not have the PKU test video recorded.



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APPROVED INFORMED CONSENT Orlendo Regional Mealthcare System Institutional Review Board ORHS# 0702803 Original Version: Revised and Amended Version: February 12, 2007

Sa. <u>CONFIDENTIALITY OF RECORDS</u>: All data will be collected according to HIPAA regulations and treated confidentially. You will be issued a unique identification number to maintain confidentiality. Your name and personal identifying information will be kept separate from the forms that we use to record research information. Your name and personal identifying information will not appear on video images. All personal identifying information will be kept in a locked cabinet, separate from the data collection forms. All digital data including recorded videos will be kept in a locked cabinet and/or under computer password protection. You and your child will not be personally identified in any presentation or publication of study findings. Paper data will be maintained for three years. With your consent, we may keep the digital videos without any personal identifying information and use them for educational purposes. Otherwise, the digital videos will be destroyed/deleted as soon as the data are analyzed.

8b. <u>AUTHORIZATION TO USE OR DISCLOSE PROTECTED HEALTH INFORMAITON (PHI) FOR RESEARCH:</u> The Federal Privacy Regulations explain how your personal health information will be used and to whom it will be disclosed (given to) for this research study. You will be provided with a copy of the Notice of Privacy Practices, which describes the Orlando Regional Healthcare System, Inc. privacy practices. Your protected health information may be used or disclosed for research purposes.

What protected health information is collected in the study?

The following protected health information will be collected during this study: Name, medical history related to the pregnancy, infant/mother demographic information (age, sex, and ethnic beckground), infant delivery and medical history, diagnosis, therapies and procedures, and current medications.

Who may Use or Disclose your Protected Health Information?

The following Individuals/organizations may use or disclose your protected health information for this research study:

Principal Investigator: Martin Schiavenato, RN, Doctoral Candidate Orlando Regional Healthcare Institutional Review Board University of Central Florida Institutional Review Board

To whom may your Protected Health Information be Disclosed?

As part of the study, the study Principal Investigator: Martin Schiavenato, RN, Doctoral Candidate may disclose the results of study-related tests and procedures that may identify you to the following:

Orlando Regional Healthcare Institutional Review Board University of Central Florida Institutional Review Board Office for Human Research Protection (OHRP)

In addition to the list of individuals and organizations to whom your Protected Health Information may be disclosed, others may receive the information that are not currently known. If information from your records is given to any of these people, they might give it to someone else. If this happens, the information will no longer be protected. If Orlando Regional Healthcare gives the information to someone, it is supposed to protect it, but Orlando Regional Healthcare cannot always keep that person from giving it to someone else. Your PHI may no longer be protected by the Federal Privacy Rule once it is disclosed by the study investigator to these other parties.

By agreeing to participate in this research study and signing this informed consent, you are authorizing Orlando Regional Healthcare System, Inc, Winnie Palmer Hospital for Women and Babies, and Mertin Schiavenato RN, Doctoral Candidate (Principal Investigator) to use and disclose your protected health information for the purpose of research related to this study. Only the smallest amount of protected health information necessary will be used. There is no expiration date for the use of your health information for this research study. It may be used until all follow-up procedures and all research/data collection has been completed. Your health information may be used in future additional re-checking of data accuracy (correctness). At the time that your records no longer need to be checked including video images, the University of Central Florida, College of Nursing, and Orlando Regional Healthcare will destroy/delete your research records. With you consent, your video images without any identifiable information, may be kept indefinitely and used in the future for educational purposes.

Orlando Regional Healthcare System Institutional Review Board APPROVED INFORMED CONSENT Orlando Regional Healthcare System Institutional Review Board ORHS# 0702803 Original Version: Revised and Amended Version: February 12, 2007

Additional information about confidentiality of and access to your protected health information while you participate in this research study:

- If the Principal Investigator (Martin Schlaveneto, RN, Doctoral Candidate) wishes to use your identifiable information for any other reason than this research study, he/she must get your permission for that purpose.
- You may withdraw your permission to use your protected health information by talking with the Principal Investigator and making a request in writing. Use and release of information that was already gathered may continue when necessary in checking and reporting important events, such as accounting for your withdrawal from the study, adverse events reported to the FDA to monitor safety of participants, or federal regulatory agency audits (reviews).
- If you withdraw your permission to use your health information, neither Orlando Regional Healthcare System, Inc. nor your Martin Schiaveneto RN, Doctoral Candidate will release information collected after your withdrawal to the University of Central Florida, College of Nursing or any other third party.
- If you withdraw your permission to use and release your health information, you will no longer be able to participate in the study. However, if you decide to withdraw from the study, you will not be penalized or lose benefits to which you are otherwise entitled.
- Your doctor may discuss other research projects with you if he/she thinks the other projects relate to your condition. However, your health information cannot be given to another doctor or sponsor for the reason of asking you to enroll in another research study.
- COMPENSATION: You will not receive any money for participating in the study. As a token of our
  gratitude, you may choose to have a photograph of your baby printed from the video and mailed to you. There
  will be no costs to you for this.
- 10a. <u>RESEARCH RELATED INJURY:</u> In the unlikely event that injury occurs as a result of this research, treatment will be available. However, you will not be reimbursed by Orlando Regional Healthcare System Inc., the University of Central Florida, or the investigator for these costs. For more information about your rights as a research subject, you may call the ORHS Institutional Review Board Office, at (321) 841-5895, or the University of Central Florida Institutional Review Board Office, at (407) 823-2901. You are free to ask the Principal Investigator Martin Schiavenato RN, Doctoral Candidate at (407) 823-2744 any questions concerning this research study that you have now or in the future.
- 10b. <u>LIMITED LIABILITY:</u> If you believe you have been injured during participation in this research project, you may file a claim with UCF Environmental Health & Safety, Risk and Insurance Office, P.O. Box 163500, Orlando, FL 32816-3500 (407) 823-6300. The University of Central Florida is an agency of the State of Florida for purposes of sovereign immunity and the university's and the state's liability for personal injury or property damage is extremely limited under Florida Law. Accordingly, the university's and the state's ability to compensate you for any personal injury or property damage suffered during this research project is very limited.
- 11. <u>VOLUNTARY PARTICIPATION</u>: You are free to refuse or stop participation in this research study at any time without penalty. If you do not take part in or withdraw from the study, you and your child may continue to receive care for which you will be financially responsible.
- ADDITIONAL RISKS: Participation in this study may involve risks to the subject which are currently unforeseeable.
- 13. <u>INVOLUNTARY TERMINATION:</u> Your participation in this study may be stopped by the investigator or sponsor under the following circumstances: not following protocol, or administrative reasons.
- 14. PROCEDURES FOR WITHDRAWAL: You may request to stop participating in this study any time without impecting your health care in any way.
- 15. NEW FINDINGS: Significant new findings developed during the course of the research which may relate to your willingness to continue your participation will be provided to you.

  Orlando Regional Healthcare System institutional Review Board

APPROVED INFORMED CONSENT Orlando Regional Healthcare System Institutional Review Board ORHS# 0702803 Original Version: Revised and Amended Version: February 12, 2007

 NUMBER OF PARTICIPANTS: The approximate number of patients involved in the study at this site will be 80.

- 17. ADDITIONAL COST: There are no foreseeable additional costs that may arise from this study.
- 18. <u>FINANCIAL DISCLOSURE</u>; This clinical research study is sponsored by the University of Central Florida, College of Nursing, and it is financially unfunded by any institution or third parties.

APPROVED INFORMED CONSENT
Oriendo Regional Healthcare System
Institutional Review Board
ORHS# 0702803

Original Version: Revised and Amended Version: February 12, 2007

### Evaluating Newborn Infant Facial Pain Expression: Is there a Primal Face of Pain?

(name the co addition	19. <u>SIGNATURES:</u> My signature indicates that I consent and authorize Martin Schiavenato RN, Doctoral Candidate and whomever he may designate as his assistant(s) to perform upon me(name of patient or "myself") and my child the research described above. If any unforeseen conditions arise in the course of the research calling in Martin Schiavenato RN, Doctoral Candidate's judgment for procedures in addition to or different from those planned, I (we) further request and authorize the him to do whatever he deems advisable.			
IN THE	MAKING A DECISION WHETHER OR NOT TO PARTICIPATE A IIS STUDY. I HAVE READ, OR HAD READ TO ME IN A LANGU ABOVE, ASKED QUESTIONS, RECEIVED ANSWERS CONCER ERSTAND, AND WILLINGLY GIVE MY CONSENT TO PARTICIP ING THIS FORM I WILL BE GIVEN A COPY.	AGE THAT I UNDERSTAND, ALL O NING AREAS I DID NOT		
	I consent to you keeping the video images without identifying in purposes.	formation indefinitely for educational		
	I would like a photograph of my child made from the video mail	ed or emailed to me. My address is:		
Addre	ess			
Signa	ture of Subject, Parent or Legal Representative	Date		
Signa	sture of Witness	Date		
	e explained and defined in detail the research procedure in wi ented to participate.	hich the patient has		
Inves	tigator's Signature	Date		
Trans	slator/Interpreter			
Name	Phones Phones			
Addre	oss			
For S	signatures by Parent, Guardian, or Legal Representative, please de articipant below:	escribe the authority to act on behalf o		
_		APPROVED BY		

# APPENDIX D: CERTIFICATE OF HUMAN PROTECTION CONTINUING EDUCATION



### **Completion Certificate**

This is to certify that

#### Martin Schiavenato

has completed the Human Participants Protection Education for Research Teams online course, sponsored by the National Institutes of Health (NIH), on 09/14/2004.

This course included the following:

- key historical events and current issues that impact guidelines and legislation on human participant protection in research.
- ethical principles and guidelines that should assist in resolving the ethical issues inherent in the conduct of research with human participants.
- the use of key ethical principles and federal regulations to protect human participants at various stages in the research process.
- a description of guidelines for the protection of special populations in research.
- a definition of informed consent and components necessary for a valid consent.
- a description of the role of the IRB in the research process.
- the roles, responsibilities, and interactions of federal agencies, institutions, and researchers in conducting research with human participants.

National Institutes of Health http://www.nih.gov

### **APPENDIX E: CURRICULUM VITAE**

### Martin Schiavenato, Doctoral Candidate

University of Central Florida College of	Home:
Nursing:	
P.O. Box 162210	9806 Heaton CT
Orlando, FL 32816-2210	Orlando, FL 32817
(407) 823-2744Office	(407) 574-5015
(407) 823-5675Fax	schiavenato@yahoo.com

### I. <u>EDUCATION</u>

Year	Degre e	Institution	Clinical Major	Role Preparation
2007 anticipated	PhD	University of Central Florida, Orlando, FL	Nursing Innovative Tech	Research/Advanc ed Practice
1998		Valdosta State University, Valdosta, GA	NP Track	Advanced Practice
1997	MS	Florida State University, Tallahassee, FL	Sociology/De mo	Research
1996	BSN	Florida State University, Tallahassee, FL	Nursing	
1992	BS	Florida State University, Tallahassee, FL	Sociology	
1992	ADN	University of the State of New York, Albany, NY	Nursing	

### II. <u>LICENSURE/CERTIFICATION</u>

RN Florida, 2691612

### III. <u>EMPLOYMENT</u>

## ACADEMIC APPOINTMENTS:

08/04-Present	Graduate leaching/Research Assistant, University of Central Florida
	School of Nursing, Orlando, FL.
08/98-08/04	Editor in Chief, Bandido Books, Orlando, FL.
01/97-12/97	Research Associate, Florida State University, Tallahassee, FL.

#### **CLINICAL APPOINTMENTS:**

08/04-Present	Clinical/Laboratory Instructor, University of Central Florida School of
	Nursing, Orlando, FL. Bachelor and Master student clinical training and
	supervision in pediatric and adult settings.
08/99-08/00	Staff Nurse, (Home Health Nursing), Pediatric "High Tech Care",
	Children First Home Health, Orlando, FL.
08/97-08/00	Military Reserve Nurse, Clinician and manager in a variety of clinical
	settings including field hospital/acute care, and critical care/flight
	nursing.
01/92-01/97	Staff Nurse, Newborn Intensive Care (NICU) and other critical care
	settings, Tallahassee Memorial Hospital, Tallahassee, FL.

#### IV. PUBLICATIONS

#### REFEREED NATIONAL/INTERNATIONAL JOURNALS:

**Schiavenato, M**. (2007). Facial expression and pain assessment in the pediatric patient: The Primal Face of Pain. *Journal for Specialists in Pediatric Nursing,* forthcoming.

Schiavenato, M. (2006). Technology Brief: Digital Pen and Paper: A review of the technology and its potential application in healthcare. Online Journal of Nursing Informatics (OJNI), 10, (1).

Schiavenato, M. (1997). The Hispanic Elderly: Implications for nursing care. *Journal of Gerontological Nursing*, 23 (6).

**Schiavenato, M**. (1995). The Gray: Thoughts on social inquiry. *Journal of Creative Social Discourse*. Issue 1.

#### NON-REFEREED NATIONAL/INTERNATIONAL:

Schiavenato, M. (2005). Bedside Nursing: Adapting to emerging technologies. *Nursing* 2005, Supp (35).

Schiavenato, M. (2001). The Anthrax Threat: What Every Nurse Must Know. [previously available at www.bandidobooks.com/anthrax].

#### NON-REFEREED REGIONAL/STATE:

Schiavenato, M. (2003). A Moment in the NICU: Memoirs of a male nurse. Vital Signs, June.

#### **TEXTBOOKS:**

Schiavenato, M. and Jackson, R. (2004). Martin's Quick-E Charting: Documentation & Medical Terminology. Orlando Bandido Books.

**Schiavenato, M**. (2003). *Martin's Quick-E Peds: Pediatric Nursing Clinical Reference*. 2<sup>nd</sup> Ed. Orlando Bandido Books.

**Schiavenato, M**. (2003). *Martin's Quick-E Spanish Guide: Clinical Nursing Reference*. 2<sup>nd</sup> Ed. Orlando Bandido Books.

**Schiavenato, M**. (2002). *Martin's Quick-E Critical Care: Clinical Nursing Reference*. 2<sup>nd</sup> Ed. Orlando Bandido Books.

- **Schiavenato, M**. (2002). *Martin's Quick-E E.R.:Emergency Nursing Clinical Reference*. 2<sup>nd</sup> Ed. Orlando Bandido Books.
- **Schiavenato, M**. (2002). *Martin's Quick-E Med-Surg: Clinical Nursing Reference*. 2<sup>nd</sup> Ed. Orlando Bandido Books.
- **Schiavenato, M**. (2000). *Martin's Quick-E O.B.: Obstetric Clinical Nursing Reference*. Orlando Bandido Books.
- **Schiavenato, M**. (2000). *Martin's Quick-E I.V.: Intravenous Clinical Nursing Reference*. Orlando Bandido Books.

#### MANUSCRIPTS UNDER REVIEW:

Schiavenato, M., & Holcomb, Lygia. (2007). The Patient Encounter Continuum: A model for classifying simulation techniques in healthcare education. Simulaton in Healthcare.

#### MANUSCRIPTS IN PREPARATION::

- Schiavenato, M. Pain Assessment as a Transaction: Beyond the "Gold Standard."
- **Schiavenato, M**. Evaluating Newborn Infant Facial Pain Expression: Is there a Primal Face of Pain?

### V. <u>PRESENTATIONS</u>

#### REFEREED NATIONAL/INTERNATIONAL:

08/07	Is there a Primal Face of Pain? A methodology answer. 29th IEEE EMBS Annual International Conference, Lyon, France.
05/07	Synopsis of research on the Primal Face of Pain. 8 <sup>th</sup> Pain in Child Health Institute, Quebec, Canada.

Validity evaluation of the Oucher scale: Hispanic and African-American versions. Abstracts from the Souther Nursing Research Society 2006 Conference, Memphis, TN.

Marriage and Pregnancy Outcome: Race/Ethnic Differentials (with I. Eberstein). Paper presented at the annual meeting of the Southern Demographic Association, Orl, FL.

#### LOCAL/REGIONAL:

11/06 Measuring Facial Expression of Pain in the Newborn Infant. Graduate Seminar Series in Computer Science. Harris Center, UCF, Orlando, FL.

### VI. AWARDS/HONORS

2007 Mayday Fellow, International Trainee in the Pain in Child Health, PICH,

Training Initiative, from the Canadian Institutes of Health Research.

2005 Book of the Year Award, American Journal of Nursing. Publisher and Editor

of The Art of Becoming a Nurse Healer by Beverly Hall PhD, RN, FAAN.

2004 Graduate Merit Fellowship, University of Central Florida. Orlando, FL.

#### VII. PROFESSIONAL ACTIVITIES

#### PROFESSIONAL ORGANIZATIONS:

American Society for Pain Management Nursing, 2005-Present. International Association for the Study of Pain, 2005-Present.

SIG: Pain in Childhood, IASP, 2005-Present.

Society for Simulation in Healthcare, 2005-Present.

Southern Nursing Research Society, 2005-Present.

Council for the Advancement of Nursing Science, 2007.

### VIII. RESEARCH/TEACHING INTERESTS

**Pain:** Assessment and measurement techniques; pediatric pain interventions;

communication and pain; gender, culture and pain.

**Technology:** Development of a computer-based pediatric pain scale. Modeling and

simulation in nursing education.

**Teaching:** Instructor of Record: NUR 4945 Nursing Practicum; NUR 3065L Health

(recent courses) Assessment Lab.

Teaching Assistant: NGR 5638 Health Promotion; NGR 5004L Advanced

Health Assessment Lab; NUR 3616 Promoting Healthy Families.

### IX. COMMUNITY SERVICE

**Graduate Resource Network.** Volunteer nursing student advisor (ADN and BSN levels) for Excelsior College (formerly Regents College) Distance Degree Program.

**GEM-Nursing Mentor.** Volunteer mentor for web-based program sponsored by the *US Department of Labor* and the *University of Michigan* with the goal of introducing High School Students and other young adults to nursing as a career.

**Junior Achievement.** 2006, 2007. Volunteer discussions and lab demonstrations related to the profession of nursing with Middle School students. Program sponsed by the *Burnetter Honors College, University of Central Florida*.

#### X. **OTHER SKILLS**

Dedicated software packages such as WebCT. Also worked developing Web-Based Teaching:

online video integration and two-way demonstration/simulation of

advanced health assessment techiniques.

Facial Coding: Certified, Neonatal Facial Coding System (NFCS).

Languages: Spanish, fluent; Italian, working.