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The Efficacy of Pediatric Pain Management Techniques for Infants During Inoculation Procedures

Kimberly K. Wisdorf-Houtkooper

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THE EFFICACY OF PEDIATRIC PAIN MANAGEMENT TECHNIQUES
FOR INFANTS DURING INOCULATION PROCEDURES

by

Kimberly K. Wisdorf-Houtkooper

A Dissertation
Submitted to the
Faculty of The Graduate College
in partial fulfillment of the
requirements for the
Degree of Doctor of Philosophy
Department of Psychology

Western Michigan University
Kalamazoo, Michigan
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In this study four different pre-immunization interventions were compared with respect to their effects on modifying arousal level before an immunization and their effects on the level and duration of distress after the immunization. In addition, the study evaluated whether the infants' pre-inoculation behavioral state affected their response to a painful stimulus. Data consisting of facial expression, presence or absence of cry, cry duration, and behavioral state were collected prior to, during, and after the inoculation. Forty-two subjects were randomly assigned to one of four soothing conditions. These included: rocking, swaddling, sucking on a pacifier, and a control group.

An analysis of variance across dependent measures revealed that there were no significant differences between groups during the baseline phase. Repeated measures ANOVA on each dependent variable with phases as the within factor were then conducted. Facial characteristics measured by the Neonatal Facial Coding System (NFCS) were not significantly different across groups, but were significant during the post-immunization phase. This further validated facial features as an index of pain.

As expected, there was a significant difference between the presence or absence of cry during the baseline, experimental phase, and post-immunization phase. Duration of cry was not significant between groups but was significant during both the experimental phase and post immunization phase. Only 10 subjects failed to soothe
within the 2 minute post-immunization phase (swaddle group = 4, rocking group = 2, pacifier group = 1, control group = 3).

Infant State was not significantly different across groups but again was significant during the post-immunization phase. A Kruskal-Wallis one-way analysis of variance on state during the post-immunization phase indicated no significant differences between groups. One-way analysis of variance revealed that infants in an "active awake" state exhibited significantly more facial characteristics associated with pain. The results are discussed in light of past research.
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Kimberly K. Wisdorf-Houtkooper
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CHAPTER I

INTRODUCTION

Until recently, research on the management of pain in the medical population was largely focused on adult populations (Harbeck & Peterson, 1992; Ross & Ross, 1984; Varni, Walco & Katz, 1989). Although there is a rising tide of research on the effects of psychological interventions and combinations of pharmacological and psychological interventions for managing pain in school aged children, (Fanurick, Zeltzer, Roberts, & Blount, 1993; Jay, Elliot, Woody, & Siegal, 1991; Kuttner, 1989; LaBaw, Holton, Tewell, & Eccles, 1975; Lyles, Burish, Krozely, & Oldham, 1982; McGrath & Craig, 1989; Patterson, Everett, Burns, & Marvin, 1992; Schechter, 1989; Zeltzer & Zeltzer, 1989) the application and investigation of these procedures with younger children, (i.e., birth to three years) has not occurred (McGrath & Craig, 1989; Owens, 1984; Zeltzer, 1994). With advances in the treatment and management of a number of chronic and life threatening medical disorders in childhood, (e.g., pediatric oncology) children are surviving at an increased rate and many may experience medical interventions which are sometimes highly invasive and painful (Jay & Elliot, 1984; Miser et al., 1987; Varni & Katz, 1987). The management of pain related to medical disorders or treatments in very young children has not kept pace with such extraordinary medical advances (Miser et al., 1987). Although very young children may have different pain management needs and or respond to different types of pain management interventions, there have been few efforts to assess or reduce pain in young medical patients to date (Berman, Duncan, & Zeltzer, 1992; Miser et al., 1987; Schechter, 1985 & 1989).
Pharmacological Limitations

Practical limits on the use of pharmacological agents have certainly been an impetus for development of psychological interventions for pain management in medical populations. Many strong analgesics have sedative or physiological depressive effects. These side effects can be particularly severe with neonatal patients. For example, in neonates analgesics of various types can cause problems with feeding, sleeping, state control, constipation, drug tolerance, and respiratory suppression (Schechter, 1989), increased drug absorption through the skin, increased sensitivity to the depressive effects of these drugs, and differences in pharmacokinetics in infants in comparison to adults due to immature liver and kidney function (Reitz, Harris, & Yeh, 1991). In addition to these medical limits on the use of pharmacological agents for pain management (especially in very young children), social concerns continue to suppress the use of narcotic analgesics in all medical populations (Schechter, 1989). Despite extensive evidence to the contrary, physicians frequently under medicate patients, out of fear that they will induce a drug use or abuse problem (Marks & Sachar, 1978 as cited in Schechter, 1985).

The Under-treatment of Pain

It has been widely documented that children's pain is less aggressively treated than are similar levels of pain in adults (Beyer, DeGood, Ashley, & Russell, 1983; Johnston & Strada, 1986; Schechter, 1989; Sutters & Miaskowski, 1992). An exemplary display of this differentiation is the absence of administration of analgesics or anesthesia to young children during invasive medical procedures such as lumbar punctures, debridement, and circumcisions, as well as the lack of research and inadequate pain relief for postoperative pain in children (Beyer & Bournaki, 1989;
the administration of postoperative narcotics following cardiac surgery to fifty children
(ages two weeks to fourteen years), and fifty adults. Twenty-four percent of the
children did not receive any analgesics after open heart surgery. Of all the analgesics
administered in the study children received 30%, whereas adults received 70% . Those
who did not receive medication ranged in age from two weeks to four years. Likewise,
in a survey of United States burn centers conducted by Perry and Heidrich (1982) it
was reported that seventeen percent of the centers did not recommend the use of
anesthesia or analgesics during debridement procedures.

Beyond the obvious ethical and social concerns regarding the withholding of
pain management procedures for young children, and beyond medical concerns
discussed above, there is considerable evidence that untreated pain may impair feeding
and weight gain, cause respiratory distress or suppression, lead to emotional
withdrawal or agitation (Schechter, 1985, 1989), and a range of other emotional and
psychological difficulties (McGrath & Craig, 1989). There is wide agreement that pain
in medical populations is under treated and that the under treatment of pain has a variety
of physical and psychological affects as noted above. Less well documented are
emotional and psychological effects of untreated pain. For example, Schechter (1989)
suggested that irritability may be demonstrated by young children following painful
medical procedures, which may effect parents responses to children, establishing a
cycle of parent child interaction with potentially deleterious effects on the child.

In addition to practical, social, and ethical issues, there has been an underlying
theme in the literature concerning pain management, that pre-verbal children do not
experience pain or do not experience it in the same way that verbal children do. Pain is
a complex process involving biological, psychological, and social interactions
(McGrath & McAlpine, 1993; Schechter, 1985; Varni, Walco, & Katz, 1989; Zeltzer in
Bearison & Mulhem, 1994) which may effect the experience, expression, and management of pain. For example, it has been suggested that children have no memory for pain so therefore there is no need for pain management (Fletcher, 1988, and Merskey, 1970 as cited in McGrath & Craig, 1989). Neurological immaturity of pain receptors due to incomplete myelination of the nerve fibers in very young children might mediate the perception of pain sensation in young children (Volpe, 1987 as cited in Holditch Davis & Calhoon, 1989). However, the relationship between myelination of nociceptive fibers and the experience of pain is debatable (Anand, Phil, & Carr, 1989; McGrath & Craig, 1989; Schechter, 1989). Additionally, we have other evidence that higher velocity of neuro-impulses in adults is offset in infants due to the shorter pathway with which the impulse needs to travel. Anand, Phil, and Carr (1989) identifies literature by Giles, Shankle, & Dooling (1983) that nerve tracts associated with nociceptive impulses are fully myelinated by 30 weeks gestation. Regardless of the debate over the perception of pain due to the degree of myelination, there are numerous behavioral and physiological measures which indicate that children do experience pain.

Physiological measurement of pain is often considered in the context of regular monitoring of vital signs for infants in a neonatal care unit (Johnston, 1989). In particular, heart rate, respiratory rate, arterial blood pressure, skin color and temperature are considered to be affected by stress (Berman, Duncan, & Zeltzer, 1992; Franck & Gregory, 1995). More complex investigations of physiological responses to painful stimuli are associated with neurochemical and neurohormonal concentrations, and palmar sweating (Franck & Gregory, 1995; Johnston, 1989; Porter, 1995). For a more detailed discussion of the neuroendocrine responses to pain see Gunnar (1986, 1992). Porter (1995) indicated that “these parameters have been selected for study because they have been found to accompany verbally reported pain in adults” (p.91).
However, such measurements are rarely taken for routine acute pain procedures such as immunizations, and more invasive procedures such as spinal taps unless some form of sedation is used.

Behavioral measures have been used both independently and in conjunction with physiological measurement of pain responses. Like the physiological responses, the initial study of pain responses of infants was based on responses exhibited by adults who could verbally describe their pain. Behavioral assessment of infant pain most commonly includes the evaluation of the infants facial expression (Grunau & Craig, 1987; Hadjistavropoulos, Craig, Grunau, & Johnston, 1994; Izard, Hembree, Dougherty, & Spizzirri, 1983; Johnston, 1989; Johnston, Stevens, Craig, & Grunau, 1993; Johnston & Strada, 1986) crying (Hadjistavropoulos, Craig, Grunau, & Johnston, 1994; Johnston, 1989; Johnston, Stevens, Craig, & Grunau, 1993; Franck & Gregory, 1995; Grunau & Craig, 1987) and body movement (Berman, Duncan, & Zeltzer, 1992; Craig et al., 1984; Franck, 1986; Johnston & Strada, 1986). These behavioral measures have high face validity and social value but are unsuitable as exclusive criteria for the experience of pain.

Behavioral Interventions

A class of interventions that has been shown to affect responses of infants to external stimuli involves providing rhythmic or prolonged stimulation, (e.g., pacifier, rocking, rubbing the skin) (Franck, 1987; Johnston, 1989; Kuttner, 1989). These procedures may also affect responding by reducing arousal. For example, rapid rocking of neonates at a rate of fifty-seven beats/minute appears to reduce respiration and induce soothing (Elliott, Fisher, & Ames, 1988). However, another mechanism by which rhythmic stimulation might affect responding to other external stimuli is through response competition or attentional factors. Thus, pain responses may be mediated by
reinforcement of alternative behaviors, such as sucking on a pacifier, or by diverting ones attention away from one stimulus to another, such as rhythmic rocking. A similar effect has been noted in the developmental disabilities literature, where participation in or demonstration of a stereotyped behavior seems to decrease attention to important environmental stimuli (e.g., interfering with important learning tasks) (Guess & Carr, 1991).

Rhythmic stimulation and distraction have been suggested as interventions for attenuating infants response to pain. For example, Kuttner (1989) suggested kinesthetic methods such as rocking and patting the back as well as behavioral distraction with bubbles and pop-up books. Likewise, Campos (1989) suggested the use of techniques such as swaddling and pacifiers to reduce stress in infants after PKU tests and immunization inoculations. Field & Goldson (1984) found that non-nutritive sucking appeared to decrease the amount of fussing and crying in infants following heel stick procedures. In a study by Campos (1989) of two-week old infants undergoing heel-stick procedures and two-month old infants receiving immunization injections pain elicited distress was soothed with the use of pacifiers and swaddling. Pacifiers tended to impede crying and reduce heart rate rapidly in two-week old infants, whereas swaddling reduced heart rate but not crying. Two-month old infants responded equivocally to both pacifiers and swaddling.

Sucrose solutions as a possible pain-reducing substance has been studied during heel lance procedures and immunizations (Barr et al., 1995; Blass & Shah, 1995). Blass and Shah (1995) demonstrated a relationship between the administration of sucrose at various concentrations and a reduction in pain elicited crying. In addition, sucrose appeared to have an increased efficiency in moderating the experience of pain based on the time between its administration and the onset of the noxious stimulus. It appeared as though sucrose was more efficient in modifying the pain response after a 2
minute delay between the sucrose administration and the onset of the procedure. The authors suggested that the increased efficiency may be accounted for by the time necessary for the “endogenous opiates that may be released by taste stimulation to occupy the available receptor sites in the periventricular region that manages pain responsivity” (p.33). Barr, Young, Wright, Cassidy, Hendricks, Bedard, Yaremko, Leduc, and Treherne (1995) found that despite the fact that previous studies had found sucrose to be effective in reducing distress associated with noxious stimuli in newborns it had more limited effects on older infants.

Rosa (1993) found that among the strategies employed spontaneously by mothers, a combination of sensory intervention (e.g., rub, cradle, rock, bounce) and social reassurance (kiss, hug, verbal interaction) was most effective in soothing 15-18 month old infants after an immunization.

In summary, a small number of interventions which can be provided to young infants have been shown to be effective in reducing a distress response “after” a painful event, but there has been little attention paid to the effects of such techniques that occur “before” painful events. Researchers studying interventions for young infants have tended to cite arousal level or state as a mediating variable between a standard painful stimulus and a behavioral response such as crying, increased heart rate, etc. It has been suggested that infants who are sleeping at the onset of an aversive stimulus will respond with less distress than infants who are awake or previously agitated (Grunau & Craig, 1987). Likewise, infants who are awake but not agitated respond with lesser intensity than do those infants already experiencing distress before the presentation of the noxious stimuli. Although their are theoretical problems with using state as an explanatory mechanism, there are reliable observational-based methods for detecting “behavioral states” (e.g., facial characteristics, intensity and duration of cry, body gestures). Careful consideration should be taken in the interpretation of the observation
of behaviors as a "measurement of state" due to multiple stimuli which may elicit such responses. In addition, what has not been examined are the use of these techniques before painful procedures.

Response Measures

Behavioral measures of pain responses rely on the observation of overt behaviors such as motor activity, facial activity and cry. Facial coding systems have been developed (Grunau & Craig, 1987) and identify particular facial patterns characteristic of pain. Motor activity has been measured with behavior rating scales of the amount and intensity of the response (Craig, McMahon, Morrison, Zaskow, 1984; Franck, 1986; Mills, 1989). Cry as a specific indicator of pain has been identified by its intensity (i.e., pitch and tone), duration, and latency.

The assessment of behavioral states has been modified in various studies (Campos, 1989; Giacoman, 1971; Grunau & Craig, 1987; Prechtel, 1974; Stevens, Johnston, & Horton, 1994; Thoman, 1975) based on different definitions of the particular state being measured. These studies have found that facial activity (Grunau & Craig, 1987; Stevens, Johnston, & Horton, 1994) and cry (Grunau & Craig, 1987) during painful procedures were affected by the infants behavioral state prior to the procedure rather than solely reflecting tissue damage.

It appears that infants in sleep states show smaller changes in facial activity in response to painful stimuli. However, infants who are in an active awake state show a greater proportion of all facial actions before the presentation of a noxious stimuli thus making their facial response less discriminating than infants in other states. Changes from quiet or alert behavioral states to intense crying with high motor activity are universally recognized as indicators of a pain experience in infants (Porter, 1995). However, it may be inappropriate to expect pain to elicit consistent behavioral state
changes in all infants. In fact, the type of motor activity may vary with the child’s age. McGraw in Johnston (1995) studied the motor responses of 0-4 year old children receiving pin pricks. She reported that younger children (0-3 months) displayed more diffuse, unlocalized movement and did not appear to have any anticipatory fear when a needle entered the visual field. By 6 months of age infants exhibited more directed movements of avoidance as well as apparent fear when a needle entered the visual field. Craig et al. (1994) reported that 18 month old toddlers actively avoided or pulled away a limb upon seeing a needle. Mills (1989) in an observational study of infants with surgical wounds, fractures, and burns, reported that infants 6 months of age resisted being turned over, and by 9 months actively pushed away the nurses hands when they approached the child. Older infants were more specific in their avoidance behaviors. Franck (1986) reported that newborns swiped at the leg which was lanced with the unaffected leg as though trying to rub it.

Facial expression is described as one of the most reliable and consistent measures of the pain response in infants. Infants have the ability to move the muscles of their face at birth and adults have been able to identify such responses as early as a half an hour after birth (Johnston & Strada, 1989). The notion that particular forms of facial activity are indicative of particular emotions was first described and studied by Charles Darwin. Izard (1977, 1983) suggested that these characteristics are also present in infants. Invasive procedures have been shown to instigate a pattern of facial activity (Craig et al. 1993; Grunau & Craig, 1987; Grunau, Johnston, & Craig, 1990; Johnston, Stevens, Craig, & Grunau, 1993; Scott, et al., 1994) demonstrating the construct validity of this measure.

Facial expression is one of the most widely accepted signs of pain in infants (Johnston, 1989; Johnston, 1995; Porter, 1995). Studies using facial coding systems (Grunau & Craig, 1987; Izard et al., 1983; Johnston, 1995; and Johnston & Strada,
1986) have demonstrated that adults can reliably identify emotional states in infants and that certain facial characteristics have shown consistency as an indicator of pain across many infants. The Neonatal Facial Coding System (NFCS) designed by Grunau and Craig (1987) assesses the presence or absence of ten facial characteristics. Of those ten actions a cluster of four facial movements have consistently been found to be associated with heel lance for blood collection, and with injection. These were brow lowering, eyes squeezed shut, deepening of the nasolabial furrow, and open lips. Two additional actions, vertical stretch mouth and taut cupped tongue, also show high frequency of occurrence during these procedures. Tongue protrusion is elicited when pain is not present.

The sudden onset, high pitch, long expiratory phrases accompanied by breath holding have exemplified the pain cry of an infant (Johnston, 1989; Porter, 1995). Adults sometimes have difficulty distinguishing pain cries from other types of cries. The meaning of the cry and the caregivers response to the cry depend on the characteristics of the cry eliciting conditions, the arousal level of the infant, and particular patterns of interactions negotiated between the infant and caregiver. Audio mechanisms and computerized spectrographic analysis have been used to carefully assess the components of infants cry (Campos 1989, 1994; Craig, & Grunau, 1993; Grunau & Craig, 1987; Johnston & Strada, 1986; Stevens, Johnston, & Horton, 1994). Such analyses examine characteristics such as: cry frequency, duration, harmonic structure, spectral energy, and latency to cry. Hadjistavropoulos, Craig, Grunau, & Johnston (1994) explored the facial and cry characteristics that adults use when assessing an infants pain. Their results suggest that although the shrill qualities of an infant’s cry demand the initial response of an adult, it was the facial characteristics that accompanied the cry that appeared to determine the adults judgment of whether the infant was experiencing pain.
Caution is needed when using any single indicator of pain, whether it be a behavioral or physiological measure. The principle limitations of using either behavioral or physiological variables is their lack of specificity for pain. Several other stressors such as anxiety and fear can elicit similar changes (Wong, 1992). In essence, the validity of such measures may further be supported when concurrent measures are utilized. Likewise, it is imperative to examine the context in which the response occurs to identify any possible variables that may influence the responses being measured.

A Context for Which to Study Pain

McGrath, Ritchie, and Unruh (1993) suggest that, “the best evidence for reliability and validity of behavioral measures is for short, sharp pain such as that from needle procedures” (p.104). Acute pain is generally defined by a rapid onset, short duration (Hunter, 1993) and “is produced by a well-defined noxious or tissue damaging stimulus” (McGrath & Hillier, 1989, p.9) such as an injection, cut, animal bite, bone fracture, etc... Acute pain is said to serve as a warning signal that something is wrong, and may induce escape or avoidance of the harmful stimuli (McGrath & Hillier, 1989; Vami, Jay, Masek, Thompson, 1986). Acute pain is usually more intense than chronic pain and is often associated with strong anxiety responses (Varni et al., 1986). McGrath & Hillier (1989) cite that common referrals to a pain clinic “were for acute pain related to medical procedures (cancer treatments, diabetic blood sampling and injections, growth hormone injections, and surgical procedures); and acute pain associated with injury or disease (burns, phantom limb pain, and fractures)” (p.9). Since acute pain often occurs in the context of planned medical intervention it lends itself to possibly being effectively managed through behavioral measures. In fact, the application of psychological techniques to pain management that has been done with children has focused largely on chronic illness but acute pain (Schechter, 1985, 1989).
A standard context in which to study infant responses to pain is the routine inoculation visit. There are several benefits for using this context:

1. Inoculation provides a context in which to study behavioral response to a standard painful stimulus. Experimenters do not have to make interpretations about how the infant got into a distressed state because it is induced in the session.

2. The immunization serves as an experimental analog to other acutely painful medical procedures, to be used for developing procedures for more clinically relevant situations (e.g., dressing changes, blood draws, insulin injections).

3. It is also useful for inoculation procedures per se due to the fact that immunizations and heel sticks are the most common form of medically induced pain experienced by almost all young children (McGrath & Unruh, 1987) and fear/avoidance responses (classical conditioning) are observed as early as 6 months (Craig, et al., 1984; McGrath & Craig, 1989).

Problem Statement

There has been an increasing awareness of the experience of pain in infants and young children who are unable to verbalize their experience or utilize assessment tools which require higher cognitive functioning. However, there are still barriers which impede the effective management of pain for infants, such as the maintenance of belief’s of whether infants can experience pain the way adults do; whether they remember painful experiences; and the effects of pharmacological agents. In addition, the difficulty in documenting and evaluating pain in infants due to their inability to verbally communicate their experience leaves them susceptible to treatment based solely on the observation and understanding of pain from the caretaker’s (nurse, physician, parent) perspective.
Ideally, pain should be approached from a preventative point of view. Preventing and/or minimizing painful experiences from the earliest time in life could possibly have the potential to influence the process of respondent conditioning that has been observed in infants behaviors during inoculation procedures as young as 6 months of age (McGraw in Johnston, 1995). The responses that result from this process may lead to the avoidance of much needed medical care (e.g., chemotherapy) as well as routine procedures such as immunizations. There are several techniques (e.g., swaddling, pacifiers, rocking) that have been identified as having soothing effects on infants following painful procedures such as inoculations and heel lances (Campos, 1989; Field & Goldson, 1984; Franck, 1987; Johnston, 1989). However, the systematic study of these soothing techniques administered prior to painful situations is limited. Therefore several techniques that have been identified as having “soothing” effects on infants after an inoculation or heel lance were utilized in this study for infants but they were received before standard immunizations.

The assessment of pain in infants is based largely on behavioral characteristics. Although physiological measures can be utilized they are infrequently used for standard acute pain management. Therefore, further validation of such assessment tools, particularly in situations for which the experience of pain may be minimized because of its acute nature, may further the documentation of the pain experience during these procedures. This study may benefit the literature not only by clarifying the possible role of behavioral state in mediating responses to pain, but also by identifying techniques that appear to moderate an infants response to painful stimuli.

In this study three different pre-immunization interventions were examined with respect to their ability to modify arousal level before an immunization and their ability to decrease the level and duration of distress after the immunization. There were no known medical risks for participating in this research study. Participation in the study
did not impede on the delivery of medical procedures or withhold any routine procedures.

The current study assessed whether infants behavioral state effected their response to a painful stimulus and whether certain soothing techniques would moderate the infants response to a painful stimulus. Data were collected prior to, during, and after an inoculation. It was hypothesized that the application of certain soothing techniques and observation of behavioral states would serve several functions. First, behavioral observations of state may serve to validate previous theories that suggest that an infants state prior to a painful stimulus moderates their response. Second, the application of certain soothing strategies may identify their effectiveness or ineffectiveness in reducing behavioral distress responses and whether such techniques can successfully alter the behavioral response of infants after exposure to an acute pain event. The intent of this study was to determine the following: (a) if a child’s state is affected by these soothing techniques, (b) if one technique appears to soothe better than others, (c) whether the child’s behavior/affect prior to the intervention would affect the results of the soothing technique, and (d) whether the technique influences the duration of distress after an inoculation exhibited by the infant as measured by their facial reaction and cry. Most importantly, it is the goal of this study to identify a strategy that will attenuate the pain response from inoculation procedures by implementing soothing strategies prior to the immunization.

Benefits of participating in such procedures may have exposed caretakers to alternative soothing strategies. If such procedures show a degree of effectiveness with the infant the caretaker may be inclined to use these strategies for future clinic visits which involve needle pricks.
CHAPTER II

METHOD

Subjects

Recruitment

Subjects were recruited from two primary pediatric outpatient clinics. Criteria for inclusion were: (a) no acute illnesses based on the scheduled reason for the clinic appointment and the physician's or nurses report following examination; (b) no current physical trauma (e.g., broken bones, burns, abrasions), or a history of intensive/repeated medical procedures; (c) the infant has a history of pacifier use; (d) visit to the clinic is within one month of the date of the 4 month immunization, and (e) the infant has not received medication (e.g. Tylenol) as a form of analgesic prior to the immunization. Subjects were recruited by contacting the Pediatric Clinic each week or month to receive a list of any appointments scheduled for a 4 month well baby check. Of the 95 potential subjects 53 were excluded for various reasons (see Table 1).

Characteristics

The sample included 42 infants, 18 males and 24 females, and one set of twins, who were between 3 and 5 months old, presenting for a routine 4 month immunization and well baby check-up. Data from an additional 9 subjects were excluded due to procedural error (e.g., camera problems, not enough time in the condition, or interruption of the experimental procedure). This sample was selected from a total pool of 95 subjects.
Table 1
Number of Subjects Excluded

<table>
<thead>
<tr>
<th>Reason for Exclusion</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute illness</td>
<td>4</td>
</tr>
<tr>
<td>Current physical trauma or a history of intensive/repeated medical procedures</td>
<td>1</td>
</tr>
<tr>
<td>Infant does not use a pacifier</td>
<td>2</td>
</tr>
<tr>
<td>Child was not between 3-5 months of age</td>
<td>3</td>
</tr>
<tr>
<td>Infant had received medication (e.g., Tylenol) prior to the immunization</td>
<td>12</td>
</tr>
<tr>
<td>Refused to participate</td>
<td>3</td>
</tr>
<tr>
<td>Did not speak/understand English</td>
<td>2</td>
</tr>
<tr>
<td>Received their shots at the Health Department</td>
<td>16</td>
</tr>
<tr>
<td>Infant accompanied by someone other than the legal guardian.</td>
<td>1</td>
</tr>
<tr>
<td>Procedure error (e.g., camera problems, not enough time in the condition, or interruption of the experimental procedure)</td>
<td>9</td>
</tr>
</tbody>
</table>

Settings

Parents of the subjects were approached once they were placed in the treatment room. Depending on the health professionals schedule they either conducted their initial exam before or after the introduction. If they conducted their exam first, the physician would inform the parent about the study. Likewise, nursing staff routinely asked if the child would be receiving their shots during the visit and/or if the child had
received any Tylenol the day of the visit. Parents appeared to be more enthusiastic about participating when the study was briefly introduced by their physician. The parent was informed that inoculation procedures do not generally include analgesic administration, therefore routine procedures would not be withheld or disrupted in any way. They were informed of the procedures of the study (see Appendix A), and a written informed consent (see Appendix B) was then obtained from the parent/guardian for their infants voluntary participation. The parents were given a copy of the consent form to keep for their own records.

All observations of infant response and state were conducted by the author in the clinic examination room prior to, during, and immediately following the immunization. Detailed observational data were collected from the videotapes in the Infant and Child Behavior Laboratory (room 308, West Hall, WMU) after completion of the clinic visit.

Materials

Videotaped observations of the immunization were collected using a Panasonic AF Piezo Cam corder (model number AG-180) and Kodak High Standard video cassette tapes (series T-120). Videotapes were played on a standard video deck and a 27-inch screen television (Mitsubishi, Model number CS-2724R). Each experimental condition included the use of a Graco Converta Cradle III, Model number 1530. In addition to the Graco Cradle, each experimental condition included one of the following: (a) the Graco Cradle with quiet wind mechanism swinging at a rate of 73 swings per minute, (b) the infants own pacifier or a Gerber Nuk Pacifier, or (c) a Baby Dreams by Bibb, X*Y 100% cotton fleece receiving blanket with velcro adhesive.

The Neonatal Facial Coding System (NFCS) designed by Grunau and Craig (1990) was used to assess the facial characteristics of the infants throughout all of the
phases in the study (Appendix C). It assesses 11 different facial actions, which are scored (1 = present, 0 = absent) based on the proportion of time each is present during a given time period (Appendix D). Because of the similarity between eye squeeze and eye slit the categories were combined for this study. A variety of studies (Dale, 1986, 1989; Johnston & Strada, 1986; Marvin & Pomeitto, 1991) have indicated that facial expression is the most consistent response to pain across babies. The NFCS characterization of facial activity during pain similar to comprehensive coding with the baby-adapted Facial Acting Coding System (FACS) has demonstrated convergent validity of the shorter, more readily applied system (Craig, Hadjistavropoulos, Grunau, & Whitfield, 1994). The facial actions of the NFCS resemble facial activity during pain of older children and adults, with differences understandable considering the anatomical structure, learning history, and coping mechanisms (Craig, Prkachin, & Grunau, 1992).

Concurrent validity of the NFCS has been demonstrated when the presence of body movements and physiological changes associated with infant pain, but not unique to pain, occur with invasive events concurrently with facial display (Craig, Whitfield, Grunau, Linton, & Hadjistavropoulos, 1993). Invasive procedures have been shown to instigate a pattern of facial activity (Craig et al. 1993; Grunau & Craig, 1987; Grunau, Johnston, & Craig, 1990; Johnston, Stevens, Craig, & Grunau, 1993; Scott, et al., 1994) demonstrating the construct validity of this measure. Of the ten actions in the NFCS, a cluster of four facial movements have consistently been found to be associated with heel lance for blood collection, and with injection. These are brow lowering, eyes squeezed shut, deepening of the nasolabial furrow, and open lips. Two additional actions, vertical stretch mouth and taut cupped tongue, also show high frequency of occurrence during these procedures. Tongue protrusion is elicited when pain is not present.
There are several factors that have been identified as having an influence on facial display which may effect the utility of this measure. Pharmacological intervention reduces facial display. Scott et al. (1994) determined that the NFCS discriminated pre-term infants on morphine versus no morphine during heel-lance. In addition, facial activity appears to vary depending on the child’s sleep/waking state (Grunau & Craig, 1987). Facial activity changes with maturation and is valuable as a nonverbal indicator of pain in humans from infancy to adulthood (Craig, Prkachin & Grunau, 1992; Johnston et al. 1993). Finally, adults identify pain in neonates using facial pattern. Social validation of the NFCS as signifying pain in neonates has been established in judgment studies (Craig, Grunau & Aquan-Assee, 1988; Jadjistravopoulos et al, 1994).

An adaptation of Prechtl’s (1974) observational rating system was used to assess infants state during each segment of the procedure. This system has been used in several studies of infants behavioral responses to painful stimuli (Grunau & Craig, 1987; Stevens, Johnston, & Horton, 1994). The categories of "states" utilized in this study included: (a) Active Awake, which consisted of the child being awake with the eyes open and actively moving his/her arms or legs, and/or engaging in vocalizations, either babbling or crying; (b) Quite Awake, is when the infant is awake with the eyes open with minimal body movement and no vocalization; (c) Active Asleep, was present when the infant's eyes were closed but there was movement of the extremities; and (d) Quite Asleep, was present when an infant's eyes were closed and there was no movement of the extremities.

Cry was measured as a continuous variable for which it was recorded in 1second intervals during each 10 second sample as well as an overall duration during each phase of the study.

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Procedure

Design

A two factor repeated measure design with one between factor and one within factor was used. The between factor consisted of four levels of soothing and the within factor consisted of 3 levels/phases of assessment. The effects of swaddling, pacifier, and rhythmic stimulation compared to control subjects were measured in healthy infants as a preliminary study of the effects of interventions prior to a painful medical procedure. The independent variables included: swaddling in a blanket, sucking on a pacifier, and rhythmic stimulation by rocking in a bassinet. The dependent variables included: behavioral state, absence or presence of cry, duration of cry, and facial action.

Facial expression (Appendix C), behavioral state (Appendix E) and cry were examined during the baseline, experimental procedure and immediately after the inoculation. The relative effectiveness of swaddling, pacifier, and rhythmic stimulation were measured by the degree of change between the 4 different states induced by each intervention, absence or presence of cry and the duration of cry; and facial characteristics frequently associated with pain/distress (Grunau & Craig, 1987; Grunau et al., 1994).

Experimental Sessions

After informed consent was obtained, each subject was randomly assigned to one of four soothing techniques. The author joined the mother/father and infant in the examining room and prepared to begin taping. During this interval, the infant's care giver was be instructed by the author how to implement the procedure assigned to their child and answered any questions the parent may have had regarding the study.
procedures. The parent was instructed that they could talk/sing to the infant, and remain in visual contact with their child when they were placed in the experimental condition. Likewise, they were instructed not to give their child a pacifier or a bottle during the 2 minute post intervention/inoculation phase. However, they were allowed to pat the infant on the back, sway, or use distraction to calm the infant if they were in an agitated state during this time. The parents were told that after the two minute post inoculation phase was complete, they could implement any technique that they felt would be beneficial in soothing their child. Refer to Appendix F for a guideline of all procedures.

Baseline

Continuous video recording occurred from the onset of baseline until the final post-experimental phase was completed. The infant's state was judged immediately upon completion of the instructions by the author when the caregiver was implementing their own strategies or methods of interacting with the infant. The infant's state must have been within a range of "quiet awake" and "active awake", with the absence of crying and/or agitated bodily gestures (e.g., flailing of the arms or legs, rigid torso) for two consecutive 5 second intervals. If this criterion was met on the basis of the observer's judgment, the subject was placed in the assigned experimental condition. If the infant did not meet this criteria, observation continued until the behavioral criteria were met or when the nurse was ready to begin the immunization procedure. Beginning the procedure despite meeting criteria allowed for data to be obtained from infants who were in an agitated state prior to being placed in an experimental condition, thus possibly representing the influence of the soothing technique and/or the child's later response to the inoculation. The average time spent in baseline for all subjects was 52 seconds ranging from 20 seconds to 171 seconds.
**Experimental Condition**

This baseline phase was followed by an experimental condition which consisted of being placed in one of four conditions for two minutes immediately before the oral polio and inoculation. The infant was placed in a supine position in an infant bassinet for one of the four conditions, which included, (1) Swaddling: wrapped snugly in a swaddling blanket confining the arms, legs, and torso within the blanket; (2) The pacifier condition consisted of placing the infant's own pacifier in his/her mouth and placing it back in the mouth if it fell out, or holding the pacifier in place with the experimenter or parents' fingers; and (3) the rocking condition consisted of the child rocking at a steady rate of approximately 73 swings per minute. In the control condition, the infant was placed in the stationary bassinet with no additional manipulated intervention. Parents were allowed to maintain visual and auditory contact with their child during all of the phases. If the infant's behavioral state changed to an agitated level of crying the parent was instructed to lean over the child and talk/sing but not touch the infant. If the infant did not return to the criterion state within the 2 minute experimental phase, the immunization proceeded. As soon as the nurse was finished, the parent was instructed to pick up the infant (while removing the pacifier or blanket).

**Post Experimental Condition/Post Inoculation**

A post experimental phase was conducted for two minutes after the child received the inoculation to measure the child's response to the painful stimulus. As many of the parents held the child facing them, nestled against the chest, they were requested to turn their bodies to orient the infant's face toward the camera. The parent was instructed not to give their child a pacifier or a bottle during this 2 minute post intervention/inoculation phase. However, they were allowed to pat the infant on the
back, sway, or use distraction to calm the infant if they were in an agitated state during this time. If a child had not calmed at the end of this two minute period, monitoring continued in order to evaluate techniques that parents initiated to soothe their children.

Scoring and Analysis

Training and Reliability

Rater’s were 5 undergraduate students recruited from a Child Psychology course. All five were trained to use the Neonatal Facial Coding System developed by Grunau & Craig (1990) by the principal investigator over four 3 hour training sessions. Definitions of behaviors to be measured from the video samples (Appendix C) were defined and reviewed. Tape segments from the subjects who were excluded from the study sample were used for practice. All trainees and the experimenter coded these segments simultaneously and compared the results to determine everyone’s preliminary understanding of the dependent measures. When there were discrepancies between viewers, the segment was reviewed and discussion ensued regarding the definition and reasons for disagreement. Of the five individuals trained, one volunteered to serve as the reliability checker. By the fourth week of training all trainees coded a segment of tape independently yet simultaneously with the reliability checker. The criterion coding for a number of video clips was 70% to pass the proficiency and begin coding study subjects. When this level of reliability was not met, the trainee was further instructed on the area of difficulty, and began coding study subjects. A further reliability check of these individuals met the 70% criteria. Reliability was calculated with the following formula:

\[
\% \text{ Agreement} = \frac{\text{Number of observations on which Coder 1 and Coder 2 agreed}}{\text{Agreements} + \text{Disagreements}}
\]
Response Measures

By examining the video samples the infants state was measured by facial expression, state, and cry before the intervention, during the intervention, and after the inoculation.

The raw facial, state, and cry data were subjected to coding and/or data reduction. A video cassette recorder with remote control and super still advance playback and color monitor were used by trained coder's for the second-to-second analysis of the facial activity. Real time observations of the recordings provided data for the cry and behavioral state measures.

Each facial action was scored as present, absent, or unobservable from a 10 second sample divided into 1 second intervals. These 1 second intervals were obtained from the start and end points of the baseline phase; and from a standardized start, mid, and end point of the experimental and post inoculation 2 minute periods. Therefore, a total of 30 seconds of each 2 minute section was analyzed for facial characteristics and behavioral state. Cry recorded in seconds was documented for each of the 1 second intervals as well as a total duration of cry for the full 2 minute phase. Behavioral state was recorded for each 1 second interval.
CHAPTER III

RESULTS

Preliminary Analysis

Forty-two subjects between 3-5 months old receiving their 4 month immunization participated in the study. Subjects were randomly assigned to one of four interventions (pacifier = 11, rocking = 11, swaddle = 10, control = 10). Video tape recordings of the procedures allowed for detailed analysis of the dependent measures. Inter-rater reliability was coded for 23% of the infants across all of the dependent variables. The overall mean percentage reliability for the NFCS was 97.9% (alpha = .9389). An adaptation of Prechtl's (1974) observational system was used to assess behavioral state during all phases of the experiment. Infants were classified as being in quiet sleep, active sleep, quiet awake, or active awake. Inter-rater agreement of 92.8% was obtained. In addition, inter-rater agreement for the cry variable was 100%.

Although all subjects were in the experimental and post immunization phases for a standardized 2 minutes, the time spent in baseline was variable with an average of 56 seconds (minimum = 20 seconds, maximum = 171 seconds). There was a total of 11 subject's who did not soothe during the post-immunization phase. Observation of the soothing techniques used by these parents when the limitations posed during the post-immunization phase were lifted indicated that fifty-percent of the parent's continued holding and talking to the infant. The other fifty-percent were soothed by means of either a pacifier or a bottle. Analysis of variance indicated that, for each dependent measure, there were no significant differences between the groups at
baseline. Therefore, any differences detected by further analysis should be attributed to either the experimental condition, responses to a painful stimuli in the post-experimental phase, or error.

Primary Analysis

A two factor repeated measures analysis of variance was conducted for each of the baseline, experimental, and post-immunization measures (state, NFCS, and cry duration). A Friedman's Ranks Test on cry by phase and group was used to analyze the presence, absence, or intermittence of infant cry. For each one of the measures, the data will be presented first graphically in figures for visual inspection. Then the appropriate statistical analysis will be described and displayed in table form.

State

Initial comparison of frequencies of the four states across phases suggests that the majority of infants were considered "active awake" throughout the study (see Figure 1). Infant state appeared to be altered the most during the post immunization phase.

![Figure 1. Number of Subjects in Each “State” Across Phases.](image-url)
The two factor repeated measures analysis of variance on state (4 soothing techniques X 3 phases) showed no significant main effect for treatment groups (p > .05), a significant main effect for the repeated measure (p < .05), and no significant group by phase interaction (p > .05) (Table 2). Measure of state during the post-immunization phase was significantly different (p < .05) than during either the baseline or experimental phase (Table 3).

Table 2

Two Factor Repeated Measures ANOVA
State: Phase and Group

<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>SS</th>
<th>DF</th>
<th>MS</th>
<th>F</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group (A)</td>
<td>2.04</td>
<td>3</td>
<td>.68</td>
<td>.51</td>
<td>.681</td>
</tr>
<tr>
<td>Within + Residual</td>
<td>9.08</td>
<td>76</td>
<td>.12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase (B)</td>
<td>3.63</td>
<td>2</td>
<td>1.81</td>
<td>15.18</td>
<td>.000*</td>
</tr>
<tr>
<td>Group by Phase</td>
<td>1.38</td>
<td>6</td>
<td>.23</td>
<td>1.93</td>
<td>.087</td>
</tr>
</tbody>
</table>

Table 3

Univariate F-tests With (3, 38) Degrees of Freedom

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hypoth.SS</th>
<th>Error SS</th>
<th>Hypoth.MS</th>
<th>Error MS</th>
<th>F</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-Immunization</td>
<td>3.23</td>
<td>4.90</td>
<td>3.23</td>
<td>.129</td>
<td>25.00</td>
<td>.000</td>
</tr>
</tbody>
</table>
Cry

Cry Duration

Duration of cry was measured in seconds as a continuous variable. Cry duration increased across phases with the maximum duration in the post-immunization phase (Baseline Mean = 5.05 seconds, Experimental Mean = 16.07 seconds, and Post-Immunization = 67.55 seconds). Figure 2 displays the change in group means across the phases for each of the interventions. Upon visual inspection, all of the groups demonstrate an increase for duration of cry during the post immunization phase. Although the visual display suggests that infants in the control group spent considerably less time crying after the immunization, the statistical analysis does not support a significant difference.

![Figure 2. Duration of Crying by Group Across Phases.](image)

The two factor repeated measures analysis of variance on cry duration showed no significant main effect of the treatment groups (p > .05), a significant effect for the repeated measure (p < .05), and no significant intervention by phase interaction (p >
Once again, there was a significant effect on cry duration by phase for both the experimental ($p < .05$) and post-immunization ($p < .05$) segment (Table 5).

Further analysis of the significant effect of state across phases is depicted in Table 5.

### Table 4

**Two Factor Repeated Measures ANOVA**

<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>SS</th>
<th>DF</th>
<th>MS</th>
<th>F</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group (A)</td>
<td>7663.80</td>
<td>3</td>
<td>2554.60</td>
<td>1.62</td>
<td>.200</td>
</tr>
<tr>
<td>Within + Residual</td>
<td>72937.93</td>
<td>76</td>
<td>959.71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase (B)</td>
<td>92002.66</td>
<td>2</td>
<td>46001.33</td>
<td>47.93</td>
<td>.000 *</td>
</tr>
<tr>
<td>Group by Phase</td>
<td>7911.39</td>
<td>6</td>
<td>1318.57</td>
<td>1.37</td>
<td>.236</td>
</tr>
</tbody>
</table>

### Table 5

**Univariate F-tests With (1, 38) Degrees of Freedom**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hypoth.SS</th>
<th>Error SS</th>
<th>Hypoth.MS</th>
<th>Error MS</th>
<th>F</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental</td>
<td>2606.98</td>
<td>23509.09</td>
<td>2606.98</td>
<td>618.66</td>
<td>4.21</td>
<td>.047 *</td>
</tr>
<tr>
<td>Post-Immunization</td>
<td>89395.69</td>
<td>49428.84</td>
<td>89395.69</td>
<td>1300.76</td>
<td>68.73</td>
<td>.000 *</td>
</tr>
</tbody>
</table>
Cry as Categorical Data (Present, Absent, Intermittent)

Comparison of the frequency of each cry variable is shown in Figure 3. Visual inspection shows that there was virtually no crying during the baseline phase with a dramatic increase during the post-immunization phase. Because of the non-parametric categorical nature of this data, a Friedman two-way ANOVA was used for the analysis. As one would expect phase had a significant effect on cry for the post-immunization phase ($p < .05$) (Table 6). One might predict that in the majority of cases crying is more likely to occur after an inoculation.

![Figure 3. Frequency of Cry Across Phases.](image)

Facial Action

Relative to previous studies using the NFCS there was an expected difference of facial characteristics in response to a painful stimulus, indicated by the significant difference of facial characteristics (mean = 30.84) during the post experimental phase from all other phases (baseline mean = 4.51) and (experimental mean = 7.10) (Figure 4). The facial characteristics with the highest frequency across subjects in response to
the painful stimulus were brow bulge, naso-labial furrow, eye squeeze, and lip push. As with state a repeated measures ANOVA revealed that there was a significant effect of facial characteristic by phase. However, there were no significant effect for group by phase (p > .05) or between groups (p > .05) (Table 7). Further analysis of the significant effect of facial characteristics across phases is depicted in Table 8.

Table 6
Friedman Two-Way ANOVA on Cry

<table>
<thead>
<tr>
<th>Mean Rank</th>
<th>Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.35</td>
<td>Cry Phase 1</td>
</tr>
<tr>
<td></td>
<td>Cry Phase 2</td>
</tr>
<tr>
<td>1.27</td>
<td>Cry Phase 2</td>
</tr>
<tr>
<td></td>
<td>Cry Phase 3</td>
</tr>
<tr>
<td>2.38</td>
<td>Cry Phase 3</td>
</tr>
<tr>
<td></td>
<td>Cry Phase 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cases</th>
<th>Chi-Square</th>
<th>D.F.</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>42</td>
<td>46.5500</td>
<td>2</td>
<td>.0000</td>
</tr>
</tbody>
</table>

State was considered as an independent variable in order to address the question of whether state has an effect on an infant's behavioral response (i.e., facial characteristics) to a painful stimulus. There was a significant effect for facial characteristics (p < .05) (Table 9). The Fisher LSD on paired comparisons showed a significant difference between infants in an active awake state and quiet awake state, as well as between active awake and quiet sleep states. There were no subjects identified as being in the "active sleep" state. These data suggest that infants who were in an "active awake" state exhibited more NFCS facial characteristics than infants in any other state.
Figure 4. Facial Action by Group Across Phases.

Table 7

Two Factor Repeated Measures ANOVA
Facial: Phase and Group

<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>SS</th>
<th>DF</th>
<th>MS</th>
<th>F</th>
<th>P-value</th>
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<tbody>
<tr>
<td>Group (A)</td>
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<td>1269.56</td>
<td>.54</td>
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<td>Within + Residual</td>
<td>90435.01</td>
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<td>1189.93</td>
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<tr>
<td>Phase (B)</td>
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<td>85767.53</td>
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<td>.000 *</td>
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<tr>
<td>Group by Phase</td>
<td>11946.35</td>
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<td>1991.06</td>
<td>1.67</td>
<td>.139</td>
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</table>
Table 8
Univariate F-tests With (1, 38) Degrees of Freedom

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hypoth. SS</th>
<th>Error SS</th>
<th>Hypoth. MS</th>
<th>Error MS</th>
<th>F</th>
<th>P-value</th>
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<tr>
<td>Post-Immunization</td>
<td>168034.85</td>
<td>48137.2</td>
<td>168034.85</td>
<td>1266.77</td>
<td>132.65</td>
<td>.000 *</td>
</tr>
</tbody>
</table>

Table 9
One-Way Analysis of Variance
State and Facial Characteristics

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<tr>
<th>Source</th>
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<th>Mean of Squares</th>
<th>F Ratio</th>
<th>P-value</th>
</tr>
</thead>
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<td>18674.48</td>
<td>9337.24</td>
<td>18.12</td>
<td>.0000</td>
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<tr>
<td>Within Groups</td>
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<td>183953.64</td>
<td>515.28</td>
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The majority of subjects were considered to be “active awake” throughout the study which was defined as the child being awake with the eyes open and actively moving his/her arms or legs, and/or engaging in vocalizations, either babbling or crying. There were no significant differences between groups that could be accounted for by the technique they received.
CHAPTER IV

DISCUSSION

In this study four different pre-immunization interventions were compared with respect to their effects on modifying arousal level before an immunization and their effects on the level and duration of distress after the immunization. In addition, the study evaluated whether the infants pre-inoculation behavioral state affected their response to a painful stimulus. There were no significant differences between groups across response measures during baseline, thus leading us to suspect that any effects thereafter were due to either the experimental condition, painful stimulus, or some confounding variable.

Comparison With Previous Research

Consideration of the Main Hypotheses

It has been suggested that an infant's state prior to the presentation of a painful stimulus has an effect on the infants response after delivery of that stimulus (Grunau & Craig, 1987; Steven, Johnston, & Horton, 1994). In particular, infants who are sleeping appear to have a less intense response to pain as measured by their facial characteristics and cry. In this study, infant state prior to the immunization did not appear to have an effect on the infants response. This finding may be somewhat overzealous, in that the majority of the infants were in a similar state (active awake) prior to the immunization. Therefore, there were no group differences to compare. In particular, the quiet asleep state which has been reported to have a significant effect on an infants response to heel-lance procedures (Grunau & Craig, 1987) was exhibited

34
among only two infants in this study. The majority of the subjects were considered to be “active awake” which was defined as the child being awake with the eyes open and actively moving his/her arms or legs, and/or engaging in vocalizations, either babbling or crying.

Previous attempts to assess the efficacy of techniques such as swaddling, rocking, and sucking on pacifiers (Campos, 1989; Field & Goldson, 1984; Franck, 1987; Johnston, 1989; Rosa, 1993) were not directed toward an examination of their utility or effectiveness prior to a painful event. Hence, this study served to advance the clinical research on the use of soothing techniques during painful procedures. However, there were no significant differences between groups that could be accounted for by the technique they received. Rather, as one might expect the differences amongst the measures occurred across phases with a significant effect for the post-immunization phase. This finding is accounted for by the introduction of a painful stimulus (shot) at the beginning of this phase. On a case by case level, there were mixed reactions to the interventions. There were occasions when a baby that was upset (crying or restless) prior to the intervention soothed when placed in one of the conditions and others who were calm but became upset when placed in the intervention.

With regard to the effects of the different interventions on the duration of distress exhibited after the inoculation there were no significant differences. In general, the majority of infants soothed with a clear decrease of facial characteristics and cry within 2 minutes after the inoculation. Although this amount of time may seem endless for parents who want to limit their child’s suffering or whose perceptions are influenced by their own learning experiences, it is in actuality relatively brief. Observations were made of the techniques parent’s used to soothe their infant if they did not stop crying during the 2 minute post immunization phase. Such techniques included giving the baby a bottle, pacifier, or continuation of holding and talking to the
infant. Further details regarding subject characteristics may have provided added information and possible hypotheses for why some infants continued to exhibit distress for longer than 2 minutes. For example, a number of parent's provided spontaneous information about their infant's state or behavior which was recorded. Ten parents reported that their infant was hungry, 2 reported that the baby was tired, and 1 child was teething. Seven parents indicated that their infant had coped well during their 2 month immunizations and 4 parents suggested that their infant's response was better during this procedure.

Consideration of the Outcome Measures

Indices that characterize an infant's response to pain include cry, facial characteristics, and body movements. The inspection of these characteristics in this study served to further support previous evidence that the type of cry (present, absent, intermittent), duration of cry (Campos 1989, 1994; Craig, & Grunau, 1993; Grunau & Craig, 1987; Johnston & Strada, 1986; Stevens, Johnston, & Horton, 1994), and facial movements (Craig et al. 1993; Grunau & Craig, 1987; Grunau, Johnston, & Craig, 1990; Johnston, Stevens, Craig, & Grunau, 1993; Scott, et al., 1994), are a good index of pain for infants when measured concurrently.

The NFCS appeared to demonstrate the ability to discriminate a pain response from general distress. Specifically, even when infants were crying prior to the immunization phase, the number of characteristics increased at the onset of the painful stimulus. The increase in overall mean of total facial actions in response to the immunization was significant, with a positive correlation between the presence of cry and facial characteristics.

State was coded across four categories consisting of active awake, quiet awake, active asleep, and quiet asleep. The division of the active awake category into one
which included cry and one without cry may have served to better differentiate the affect of the subjects during all phases of this experiment. This was obvious when one considered that a child who appeared content and happy, moving his/her legs and arms and cooing was ranked the same as infants who were moving their arms and legs but were crying at some level.

The analysis of cry was limited to the observation of whether it was present, absent, or intermittent and its duration. Although it may lack the sophistication of technical devices such as spectrograph analysis from audio samples, these measures are likely to be more useful in a clinic setting. Likewise, as reported in Hadjistavropoulos et al. (1994) although it is the shrill quality of a cry that gains immediate attention by a caregiver, the interpretation of its meaning is based largely on the context in which it occurs and the additive effects of other characteristics (e.g., facial characteristics).

Limitations of the Study

Limitations of this study and the absence of many significant results may be reflective of the sample size, state prior to the immunization, as well as variation on parent interactions with infants after the immunization. Samples in previous studies in the area (Campos, 1989; Craig et al., 1994; Field & Goldson, 1984; Giacoman, 1971; Grunau & Craig, 1987; Izard et al., 1983; Johnston & Strada, 1986; Johnston et al., 1993; Stevens, Johnston, & Horton, 1994) average 77 subjects with a minimum of 14 and maximum of 144. Due to ethical concerns, parents were allowed to hold their infant immediately following the shot. It was deemed somewhat cruel to expect them to have to observe their child in distress without intervening for 2 minutes. Hence, the effects or lack of effects of the conditions may have been influenced by that variable. Spontaneous explanations provided by parents for some of the infants' behavior, besides the inoculation, suggest that additional information regarding such factors as
infants temperament, time since last feeding, time since last bowel movement, and sleep schedules, may require further investigation as to whether any of these conditions affect infant’s response during invasive procedures.

The fact that the techniques used in this study have been found to be useful in reducing pain responses for infants following immunizations is reason enough to continue to test their influence for infants who are in a distressed state prior to a painful procedure. The importance of minimizing arousal is particularly important for groups such as premature infants, when distress may result in detrimental physiological changes and intraventricular hemorrhage. Likewise, a technique that has a soothing effect on a child under any circumstance is likely to decrease parent distress as well as influence the interaction pattern between the child and parent.

Because some of the infants became increasingly agitated when separated from their parent when placed in the experimental condition, this suggests that separation from the parent during painful procedures is distressing in and of itself. Therefore the response to a painful stimulus may be influenced by a “stranger effect” rather than or in addition to pain. Hence, consideration should be given to whether parents should be allowed to hold their infant during immunizations as a possible means of minimizing the distress of the experience.

Therefore, in the future a similar study of this nature should look at such factors as temperament, feeding and sleeping schedules, as well as previous exposure to the soothing techniques as possible variables that could effect the infants response to an inoculation.
Appendix A

Subject Recruitment Script
Recruitment

Hello my name is Kim Wisdorf-Houtkooper a doctoral psychology student conducting my dissertation research at MSU/KCMS or Rambling Road Pediatrics about how to change babies reactions to pain that they feel during inoculations. This experiment is testing whether providing infants with procedures such as wrapping in a snug blanket, pacifier, or rocking in a bassinet before a shot will reduce the distress they exhibit after the shot (for example, how strongly he/she cries, expression).

The Study includes 4 conditions involving either rocking, a pacifier, a snug blanket, or no special procedures as a way to prepare him/her for the inoculation. If he/she is assigned to no special procedure, he/she will just be in a regular bassinet before the shot. The study would require you to place your child in one of these conditions, which is assigned by the researcher, prior to his/her inoculation. Each condition involves the child being placed in the bassinet where the inoculation will occur. Prior to the shot, you may talk, sing, look at, etc.. to your child when he or she is in the bassinet. You will be allowed to pick up your child after the inoculation and asked to intervene in only the following manner for 2 minutes: hold the infant, pat the child on the back, and/or sway. After 2 minutes you will be allowed to use any soothing technique you prefer, (e.g., pacifier, bottle, etc.)

Your child and you will be videotaped so that the researchers can later analyze the infants response to inoculation (for example, by watching his/her expression and recording how strongly he cries). In addition, the tapes will allow the researchers to observe how you try to soothe your child after the shot. Completing such procedures will not interfere with any of the standard procedures performed during the immunization visit. If you decide to participate in the study you may end your participation at any time.
Before having you review the consent form I need to ask several questions which are inclusion criteria for this study.

1. No acute illnesses (e.g., ear infection) based on the scheduled reason for the clinic appointment and the physician’s or nurses report following examination;

2. No current physical trauma (e.g., broken bones, burns, abrasions), or a history of intensive/repeated medical procedures;

3. The infant uses a pacifier.

4. Visit to the clinic is within one month of the date of the 4 month immunization (the child is between 3-5 months old).

5. The infant has not received medication (e.g. Tylenol) prior to the immunization.

Please read the informed consent form carefully, if you have any question please ask. I will read it to you if you like.
Appendix B

Informed Consent Form
RESEARCH PARTICIPATION INFORMED CONSENT FORM

Western Michigan University, Department of Psychology

"The Efficacy of Pediatric Pain Management Procedures for Infants During Inoculation Procedures"

Principal Investigator: Patricia M. Meinhold, Ph.D.
Associate Investigator: Kim Wisdorf-Houtkooper, M.A.

I, ______________________________(parent/guardian) have freely consented to take part in a research study about how to change baby's reactions to pain that they feel during inoculations. I understand that this study is being conducted by Kim Wisdorf-Houtkooper, a doctoral Clinical Psychology student from Western Michigan University or a trained graduate student and supervised by Dr. Patricia M. Meinhold, a psychologist and faculty member in the department of Psychology at Western Michigan University. I further understand that the purpose of this project is to fulfill Kim Wisdorf-Houtkooper's dissertation requirement. Additionally, I give my consent for my child, ______________________________and myself__________________________ to participate in this research study.

The study has been explained to me and I understand the explanation that has been given and what the participation will mean for myself and my child. I understand that my child will be experience either rocking, a pacifier, a snug blanket, or no special procedures as a way to prepare him/her for the inoculation. I understand that if he/she is assigned to no special procedure, that he/she will just be in a regular bassinet before and during the shot. I understand that my child and I will be videotaped so that the researchers can later analyze my infants response to inoculation (for example, by
watching his/her expression and recording how strongly he cries). I understand that
the tapes will also allow the researchers to observe how I try to soothe my child after
the shot. I understand that completing such procedures will not interfere with any of
the standard procedures performed during the immunization visit.

I understand that my participation is voluntary and that I am free to discontinue
my participation as well as my child’s participation at any time without penalty. In
addition, I understand that I will not be compensated for my participation, including
any fee changes for the pediatric visit. I am also aware that the my involvement or lack
of involvement will not affect our access to clinic services in any way.

I understand that the results of the study will be treated in strict confidence, that
our participation and the resulting videotapes will remain confidential while stored in a
locked drawer within the Infant and Child Behavior Laboratory at Western Michigan
University, that no use of the video tapes will be made outside of research, and that the
video tapes will be destroyed in 5 years. I understand that Mrs. Wisdorf-Houtkooper,
Dr. Meinhold, and research assistants within the Infant and Child Behavior Laboratory
will be the only individuals viewing the videotapes. I understand that as a means for
confidentiality the child’s name will be omitted from the label of the tape and a code
number will be assigned. A separate list of all youngster’s names and corresponding
codes will be kept in a locked file.

I understand that general results of the research may appear in medical and/or
psychological science literature and may be presented at professional meetings, but my
and my child’s name will never be used.

I understand that my child’s participation or my participation in the study does
not involve any anticipated risks nor does it guarantee any beneficial results to us or to
the members of our family.
I understand that participation in this research study will only require videotaping and handling of my child prior to and after placing him/her in a bassinet. However, in the event that physical injury or illness resulting from the research procedures, I understand that Western Michigan University, Rambling Road Pediatrics, MSU/KCMS Pediatrics and/or the investigator, Kim Wisdorf-Houtkooper will provide or arrange to provide for all necessary medical care to help me/or my child recover, but they do not commit themselves to pay for such care, or to provide any additional compensation.

I understand that I may direct any questions or concerns I have about the research study to Mrs. Kim Wisdorf-Houtkooper and/or Dr. Patricia M. Meinhold, Psychology Department, Western Michigan University, Kalamazoo, MI 49008; (616) 387-8326 and/or Western Michigan University HSIRB (616) 387-8293 or the Vice President for Research (616) 387-9298.

“I acknowledge that I have read and understand the above information, and that I agree to allow myself and my child to participate in this research study. I have received a copy of this document for my own records.”

Signed:

____________________________________  _______________________
Parent/Guardian                      Date

“I have witnessed that the information in this Research Participation Informed Consent Form was adequately explained to the patient.”

____________________________________  _______________________
Signature of Witness                  Date

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Appendix C

Neonatal Facial Coding System
Neonatal Facial Coding System
(NFCS)

<table>
<thead>
<tr>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brow Bulge</td>
<td>Bulging, creasing and vertical furrows above and between brows occurring as a result of lowering and drawing together of the eyebrows.</td>
</tr>
<tr>
<td>Eye Squeeze</td>
<td>Identified by the squeezing or bulging of the eyelids. Bulging of the fatty pads about the infant’s eyes is pronounced.</td>
</tr>
<tr>
<td>Eye Slit</td>
<td>Squeeze of muscles around eyes, but eyes open and appear as slits.</td>
</tr>
<tr>
<td>Naso-Labial Furrow</td>
<td>Primarily evidenced by the pulling upwards and deepening of the naso-labial furrow (a line or wrinkle which begins adjacent to the nostril wings and runs down and outwards beyond the lip corners).</td>
</tr>
<tr>
<td>Mouth Open</td>
<td>Mouth open more than relaxed lips apart. Many babies lips are apart even when their face is relaxed. Comparison is the individual baby’s usual relaxed face. Jaw drop may be visible as a cue.</td>
</tr>
<tr>
<td>Vertical Mouth Stretch</td>
<td>Characterized by a tautness at the lip corners coupled with a pronounced downward pull on the jaw. Often stretch mouth is seen when an already wide open mouth is opened a fraction further by an extra pull at the jaw.</td>
</tr>
<tr>
<td>Horizontal Mouth</td>
<td>This appears as a distinct horizontal stretch pull at the corners of the mouth.</td>
</tr>
<tr>
<td>Lip Push</td>
<td>Upward movement of the lower lip. When the mouth is closed the lower lip may protrude. When the mouth is open you may see a “horseshoe” shape mouth.</td>
</tr>
<tr>
<td>Taut Tongue</td>
<td>Characterized by a raised, cupped tongue with sharp tensed edges. The first occurrence of taut tongue is usually easy to see, often occurring with a wide open mouth. After this first occurrence, the mouth may close slightly. Taut tongue is still scorable on the basis of the still visible tongue edges.</td>
</tr>
<tr>
<td>Chin Quiver</td>
<td>An obvious high frequency up-down motion of the lower jaw.</td>
</tr>
<tr>
<td>Tongue Protrusion</td>
<td>Tongue visible and extended beyond the lips.</td>
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Appendix D

NFCS Coding Form
## CODING SHEET

**BABY #:**

**STUDY:**

**CODER:**

**DATE:**

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<th>Eyes</th>
<th>Naso</th>
<th>Lips</th>
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<th>Horiz.</th>
<th>Purse</th>
<th>Taut</th>
<th>Chin</th>
<th>Protru</th>
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Appendix E

Behavioral State Categories
<table>
<thead>
<tr>
<th>State</th>
<th>Description</th>
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<tbody>
<tr>
<td>Active Awake</td>
<td>Child awake with the eyes open and actively moving his/her arms or legs, and/or engaging in vocalizations, either babbling or crying.</td>
</tr>
<tr>
<td>Quite Awake</td>
<td>Infant awake with the eyes open with minimal body movement and no vocalization.</td>
</tr>
<tr>
<td>Active Asleep</td>
<td>Infant’s eyes closed with some movement of the extremities.</td>
</tr>
<tr>
<td>Quite Asleep</td>
<td>Infant’s eyes closed and no movement of the extremities.</td>
</tr>
</tbody>
</table>
Appendix F

Guidelines for All Study Procedures
<table>
<thead>
<tr>
<th>Condition</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swaddling</td>
<td>Place child in center of AxB blanket.</td>
</tr>
<tr>
<td></td>
<td>Take right tip and wrap over the right arm and left arm until reaching the anterior side of the infant.</td>
</tr>
<tr>
<td></td>
<td>Extend the bottom tip up to the center of the infant's torso.</td>
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<tr>
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<td>Followed by pulling the left tip firmly across the chest/front of the child and fastening with velcro tabs at a point in which the infant is wrapped snugly and unable to move freely.</td>
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<tr>
<td></td>
<td>Place the child on their back in the stationary bassinet.</td>
</tr>
<tr>
<td>Pacifier</td>
<td>Place a pacifier in the infant's mouth when he/she is put in the stationary bassinet. If the child should project the pacifier out of his/her mouth the pacifier will be immediately placed back into the child's mouth (repeatedly if necessary) until the child sucks or the procedure has ended.</td>
</tr>
<tr>
<td>Rhythmic</td>
<td></td>
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<tr>
<td>Stimulation</td>
<td>Child placed on their back in a cradle that rocks at 70 swings per minute.</td>
</tr>
<tr>
<td>Control</td>
<td>Child is placed in a stationary bassinet on their back.</td>
</tr>
</tbody>
</table>
Part 2
Procedures

Subjects b/w 3-5 months ______________ Excluded as possible
appt. for 4 month NO subjects
immunization

YES

Explanation to parent______NO______ Did not sign consent ____ Excluded
& written informed
consent

YES (signed consent)

Meet all inclusion criteria ______ NO_______ Exclude (record data on consent
& reason for exclusion)

YES

Assign to 1 of 4 Tx
conditions/or control

Parent instructed how to either:
1. Put pacifier in mouth & keep
   putting it in the child's mouth
   even if infant spits it out.
2. Swaddle; wrap in blanket.
   (provide model with doll)
4. Observe 2 minutes on stop watch

Answer questions ________________ At any time parent may choose not to
participate.
**BASELINE**

Observe state ______ Meet criteria for 2 consecutive 5 second intervals

__________ NO ______

Observations continue for 5 second intervals until criteria state is met

YES

YES

NO

continue to proceed with the intervention if nurse is ready.

**INTERVENTION (2 minutes)**

Begin Intervention (e.g., pacifier, swaddle, rock, or laid supine in a bassinet).

Infant behavioral state within ______ NO ______ criteria range 5 seconds prior to immunization.

Parent instructed to lean over cradle, talk, sing, but do not touch infant.

( Parent allowed 2 minutes).

YES

Return to criteria state.

YES/NO

Oral Polio/Immunization
**POST INTERVENTION**

Timer started for 2-minute post immunization phase.

Parent instructed to pick up infant from the bassinet, and remove the blanket or pacifier if necessary.

Parent instructed to hold infant for 2 minutes limiting their soothing attempts to patting on the back, and/or swaying.

Child Soothes

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Care giver initiate their own strategies.

Experimental session complete.
Thank participant.
Appendix G

Human Subjects Institutional Review Board Approval
Date: April 13, 1995
To: Wisdorf, Kimberly K.
From: Richard Wright, Interim Chair
Re: HSIRB Project Number 95-03-05

This letter will serve as confirmation that your research project entitled "The efficacy of pediatric pain management procedures for infants during inoculation procedures" has been approved under the full category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note that you must seek specific approval for any changes in this design. You must also seek reapproval if the project extends beyond the termination date. In addition if there are any unanticipated adverse or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: Apr 13, 1996

xc: Meinhold, Patricia M., PSY
April 17, 1996

Richard Wright
HSIRB
Western Michigan University
Kalamazoo, MI 49008-3899

Dear Dr. Wright,

I am currently working with Kim Wisdorf-Houtkooper on her dissertation entitled, "The efficacy of pediatric pain management procedures for infant's during inoculation procedures." While Kim completes her pre-doctoral internship at the Children's Hospital Medical Center in Cincinnati, Ohio, I have been assisting with data collection and subject recruitment. As her research assistant, I received a letter of approval from Rambling Road Pediatrics. If you have any questions regarding the letter of site approval, please contact me at (616) 375-7671.

Thank you.

Sincerely,

Cristy Sullivan, M.A.

Cristy Sullivan, M.A.
April 8, 1996

Cristy Sullivan  
Doctoral Psychology Student  
Western Michigan University  
College of Arts and Sciences  
Department of Psychology  
Kalamazoo, MI 49008-5052

Dear Cristy:

I enjoyed our recent meeting at Rambling Road Pediatrics and feel we share a mutual interest in pediatric research.

Rambling Road Pediatrics agrees to provide access to four month old patients for your study on infant reaction to pain during immunizations. You have our permission to recruit and run subjects using pre-established informed consent methods, beginning Monday May 6th.

I look forward to working with you on this project.

Respectfully,

Mark A. Sloane, D.O.

MAS/tlh
To: Patricia M. Meinhold  
   Kimberly K. Wisdor-Houtkooper

From: Richard A. Wright, Chair  
   Human Subjects Institutional Review Board

Subject: HSIRB Project # 95-03-05

Date: May 20, 1996

This letter will serve as confirmation that the modifications of your research project “The Efficacy of Pediatric Pain Management Procedures for Infant’s During Inoculation Procedures,” requested in your memo, have been approved by the Human Subjects Institutional Review Board.

Your project is approved for a period of one year from the above date. If you should revise any procedures relative to human subjects or materials, you must resubmit those changes for review in order to retain approval. Should any untoward incidents or unanticipated adverse reactions occur with the subjects in the process of this study, you must suspend the study and notify me immediately. The HSIRB will then determine whether or not the study may continue.

Please be reminded that all research involving human subjects must be accomplished in full accord with the policies and procedures of Western Michigan University, as well as all applicable local, state, and federal laws and regulations. Any deviation from those policies, procedures, laws or regulations may cause immediate termination of approval for this project.

Thank you for your cooperation. If you have any questions, please do not hesitate to contact me.

Project Expiration Date: May 20, 1997
BMH1006 The Efficacy of Pediatric Pain Management Procedures for Infants During Inoculation Procedures (KKWisdorf)

At the March 7, 1995 Meeting of the Expedited Review Committee, BMH1006 and the informed consent were approved as submitted.

1. The BMH Human Use Committee determined the continuing review interval for this study to be set at 12 months.

2. Before this protocol can be implemented i.e., prior to a drug being given or a procedure undertaken, all changes must be made and a corrected signed copy of the protocol and informed consent filed with the BMH Human Use Committee Chairman (or designee). The clinical investigator is required to receive approval from the BMH Human Use Committee prior to initiating any changes in approved research during the period for which BMH Human Use Committee approval has been given.

Robert H. Hume, M.D., Chairman
Bronson Methodist Hospital
Human Use Committee
252 East Lovell Street
Kalamazoo, MI 49007
(616) 341-7988

cc: KKWisdorf
At the March 14, 1996 Meeting of the Bronson Methodist Hospital Human Use Committee, the following annual review reports and final review reports for the following protocols were accepted as submitted:


At the March 14, 1996 Meeting of the Bronson Methodist Hospital Human Use Committee, the continuation of all ongoing protocols, and termination of all protocols for which annual/final reports were received were approved as submitted. The reporting intervals remain the same as previously approved.

Robert H. Hume, M.D., Chairman
Bronson Methodist Hospital
Human Use Committee
252 East Lovell Street
Kalamazoo, MI 49007
(616) 341-7988
At the March 13, 1997 Meeting of the Bronson Methodist Hospital Human Use Committee, the following annual review reports and final review reports for the following protocols were accepted as submitted:


At the March 13, 1997 meeting of the Bronson Methodist Hospital Human Use Committee, the continuation of all ongoing protocols, and termination of all protocols for which annual/final reports were received were approved as submitted. The reporting intervals remain the same as previously approved.

Robert H. Humé, M.D., Chairperson
Bronson Methodist Hospital Human Use Committee
252 East Lovell Street
Kalamazoo, MI 49007
(616) 341-7988

Date
13 Mar 97
Appendix H

Copyright Approval
Dear Ms. Wiedorf-Houtkooper:

Permission is granted to include the Infant Facial Coding System from

Grunau RVE & Craig KD, "Facial activity as a measure of neonatal pain expression,"

in your dissertation, using the standard format and footnotes suggested in the UNIVERSITY OF CHICAGO STYLE MANUAL or those required by your university.

However, if the dissertation is selected for commercial publication and a contractual agreement has been signed, then you should submit your formal permission request to this office.

This course of action must be taken since many times representation of the copyrighted material may change between the time a thesis is submitted and the date that a contractual arrangement for publication has been secured.

Congratulations as you complete your advanced studies, and with very best wishes for your future work.

Sincerely,

Tobias Wechsler
Permissions Assistant, Journals
BIBLIOGRAPHY


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