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Abstract

A study was conducted at a Level III Neonatal Intensive Care Unit (NICU) at a large Midwestern teaching medical center to determine the reliability of the Premature Infant Oral Motor Intervention (PIOMI). The PIOMI is a five minute, oral motor intervention using a gloved finger in the mouths of premature infants of at least 29 weeks post-menstrual age (PMA) developed by Dr. Brenda S. Lessen to improve feeding skills in preterm infants. The PIOMI was first introduced in a pilot study done by Dr. Lessen and the results demonstrated a decrease in the amount of time needed for premature infants to reach full bottle feedings and be discharged (Lessen, 2008). Three registered nurses (RNs) were recruited as subjects for this study and trained to perform the PIOMI on preterm infants. A training video and a reference sheet were developed and distributed during a two hour training session. A reliability rating tool was developed for this study based on a four-point Likert scale according to three criteria: order, technique, and time. Two observers rated three RNs performing the PIOMI twice on premature infants. The reliability among the observers (interobserver), the reliability among different RNs (interuser), and the reliability of the same RN performing the PIOMI twice (test-retest) were calculated. The PIOMI demonstrates high interobserver reliability (97.57%), interuser reliability (97.59%), and test-retest reliability (97.58%).

Reliability Measurement of the Premature Infant Oral Motor Intervention

In 2006, 12.8% (1 in 8) of live births were babies born prematurely. Over half a million premature infants are born annually in the United States (March of Dimes Foundation, 2007). Infants born prematurely have difficulty feeding orally by bottle, which can delay their discharge from the hospital. This increased length of hospital stay results in extraordinary expenses for the families and hospitals (March of Dimes Foundation, 2007).

The Premature Infant Oral Motor Intervention (PIOMI) (Lessen, 2008) is a new intervention that was adapted from the Beckman Oral Motor Intervention (BOMI) (Beckman, 2010; Beckman, Neal, Phirsichbaum, Stratton, Taylor, & Ratusnik, 2004) by Dr. Brenda S. Lessen in consultation with Debra Beckman, MS, CCC-SLP, a speech language pathologist who specializes in motor speech disorders. Beckman has worked in the field of communicative disorders since 1975 developing and using the BOMI in her private practice. She leads a team of speech language pathologists, speech therapists, nutritionists, and occupational therapists including those who specialize in neurodevelopmental delay and prematurity (Beckman and Associates, 2010).

The original BOMI is a 15-minute oral motor intervention for infants, children, and adults with developmental delays resulting in feeding difficulties. The intervention provides assisted movement to activate muscle contraction and provides movement against resistance to build strength in the oral cavity. The intervention addresses target areas of the mouth including the cheeks, lips, gums, tongue, and palate (Beckman, et al., 2004). The BOMI methodology is taught to therapists through a two-day training course and individual consultation. Unfortunately, there have been no studies published regarding the reliability of the BOMI.

The 15-minute BOMI needed to be redesigned specifically for use in premature infants to accommodate the smaller oral cavity and to reduce the time frame to one that is physiologically safe and tolerable (Lessen, 2008). It does not require the cognitive cooperation of the patient nor demand a response to verbal direction, and therefore lends itself for adaptation to the premature infant population. Therefore, the premature infant version of the BOMI, named the PIOMI , was developed to enhance the premature infant's ability to bottle feed either formula or breast milk, thus decreasing length of hospital stay (Lessen, 2008).

The PIOMI is a five-minute, oral motor intervention using a gloved finger in the mouths of premature infants of at least 29 weeks post-menstrual age (PMA) (Appendix A). In 2008, the PIOMI was piloted on 19 infants in a randomized experimental triple blind study in a Level III Neonatal Intensive Care Unit (NICU) at a large Midwestern teaching medical center. Results demonstrated a strong trend toward the PIOMI increasing bottle feeding success as well as decreasing length of hospital stay (Lessen, 2008). The pilot also demonstrated the safety and efficacy of the PIOMI on the premature infant population as young as 29 weeks PMA.

In performing the PIOMI, three criteria emerged as measurable entities when assessing reliability: order, technique, and time. It is not known if the intervention would be as effective in a different order, or as effective in a shorter amount of time. It is necessary, however, to limit the PIOMI to a five minute time frame in order to reduce the likelihood of a premature infant experiencing negative physiological and behavioral signs of not tolerating a more lengthy duration of stimulation (Lessen, 2008). Older infants can tolerate a longer period of stimulation, but 29 week PMA infants require caution and continued assessment of tolerance to any type of stimulation. Although it is unknown if time and order may be variable with the same effect, for

this reliability study it was necessary to operationalize the criteria to the highest level of objectivity possible so consistency among RNs and observers could be rated.

Although the safety and efficacy of the PIOMI was established in the pilot study, reliability of the intervention was assessed only informally. In the pilot, Dr. Brenda Lessen and three Research Assistants (RAs) trained together and observed one another performing the intervention to test themselves to criterion, but did not use an objective rating tool outlining those criteria. Before the replication study planned for 2010-2011, the reliability of the PIOMI needs to be more formally assessed. Therefore, an objective reliability rating tool was developed for this study, as well as a training program for the registered nurses (RNs) who served as subjects in the study. The purpose of this study was to determine the reliability of the PIOMI according to three types (interobserver, interuser, and test-retest reliability).

Background

Before investigating the reliability of the PIOMI, three topics need to be discussed: premature infants and feeding difficulties, the PIOMI itself, and reliability as it relates to an intervention (as opposed to a measurement tool). Each of these topics outlines the importance of the PIOMI and why reliability is necessary and important.

Premature Infants and Feeding Difficulties

Premature infants are infants born with a PMA of less than 37 weeks (National Center for Health Statistics, 2005). Infants born this early frequently have difficulties feeding orally (i.e. feeding per bottle/nipple) (Holditch-Davis & Thoman, 1987; Lau, Alagugurusamy, Schanler, Smith, & Shulman, 2000; Martin, Hamilton, Sutton, Ventura, Menacher, & Munson, 2005; Wolff, 1968). These oral feeding difficulties are due to underdeveloped oral-motor skills (Boiron, Da Nobrega, Roux, Henrot, & Saliba, 2007; Braun & Palmer, 1986; Bu'Lock,

Woolridge, & Baum, 1990; Hack, Estabrook, & Robertson, 1985; McGrath & Braescu, 2004) and the lack of coordination between sucking, swallowing, and breathing (Boiron, et al., 2007; Bu'Lock, et al., 1990; Lau et al., 2000; McGrath & Braescu, 2004; Wolf & Glass,1992).

The primary reason for delay in hospital discharge of premature infants is poor bottle-feeding (Institute of Medicine, 2006). Introduction of oral feeding is usually not attempted until approximately 32-33 weeks PMA. Premature infants reach the developmental ability to coordinate sucking, swallowing, and breathing at around 32 weeks PMA, which is required for nutritive sucking (Volpe, 2001). Infants less than 32 weeks PMA are fed by gavage, which is a small feeding tube passed through the nose or mouth into the stomach. The gavage allows feedings to be provided directly into the stomach avoiding the necessity of coordinating sucking, swallowing, and breathing during feeding.

Infants begin a feeding progression that starts with all feedings done per gavage until they are developed enough to attempt bottle-feeding. In the early stages of feeding progression, infants will only attempt one bottle feeding per day while receiving all other feedings via gavage. Bottle feeding takes additional calories and expends more energy than gavage feeding, so must be limited in order to ensure the infant has enough calories preserved for weight gain each day. Throughout several weeks, the number of gavage feedings is increasingly replaced by bottle feedings, until all eight feedings per day are consumed per bottle. It typically takes 15-30 days for a premature infant to complete this feeding progression and reach full bottle feedings (Lessen, 2008).

Premature infants need to be able to orally consume all of their feedings per bottle before being discharged from the NICU (American Academy of Pediatrics, 1998). An intervention that

assists premature infants in proceeding through the feeding progression faster would allow them to be discharged sooner.

PIOMI

Currently, there are no studies that describe oral motor interventions performed on premature infants *before* oral feedings are initiated. Premature infants that are less than 32 weeks PMA may receive a pacifier for non-nutritive sucking (sucking without fluids being consumed) while gavage feedings are being administered (Bernbaum, Pereira, Watkins, & Peckham, 1983; Boiron, et al., 2007; Field, Ignatoff, Stringer, Brennan, Greenberg, & Widmayer, 1982). However, non-nutritive sucking alone does not provide the targeted specific activation of muscles that an oral motor intervention provides (Beckman, 2010; Lessen, 2008). Oral motor intervention is defined as stroking and/or pressure to the structures in and around the mouth such as the lips, gums, tongue, palate, and cheeks. It is designed to improve strength of the lip, cheek and tongue, as well as improve range of motion, lip seal, stimulate swallowing, and improve suck (Beckman, 2010).

Few studies have documented the effects of oral motor interventions before oral feedings are initiated. Of these studies, none have tested these interventions on premature infants before the age of 30 weeks PMA (Fucile, Gisel, & Lau, 2002; Rocha, Moreira, Pimenta, & Lucena, 2006). The PIOMI has been designed specifically for the premature infant population based on the principles of the Beckman Oral Motor Intervention to improve bottle-feeding, thus resulting in earlier discharge (Lessen, 2008). The PIOMI is an eight step intervention that is performed for a total of five minutes by a RN on premature infants.

The pilot study demonstrated that the PIOMI improved the premature infant's bottle feeding success by reducing the number of days spent in the feeding progression when compared

to controls (Lessen, 2008). This translated into the experimental infants being discharged three days earlier than the control infants. If all the premature infants born in the US who were eligible to receive the PIOMI received it, the reduced length of hospital stay would result in an estimated savings of over 2 billion dollars annually (Lessen, 2008; March of Dimes Foundation, 2007). Due to the pilot resulting in decreased length of hospital stay and, therefore, decreased costs, a large-scale replication study is being planned. This study was designed to formally establish reliability of the PIOMI prior to the large-scale study.

Reliability

Reliability is the consistency with which an intervention can be reproduced (Polit & Beck, 2008). Reliability is also the ability of an intervention to be performed free from error and the accuracy of observed scores compared to true scores (Waltz, Strickland, & Lenz, 2005). The focus of this study was to evaluate three aspects of reliability of the PIOMI. The three types of reliability examined were interobserver reliability, interuser reliability, and test-retest reliability. Interobserver reliability is the consistency in which more than one observer can correctly rate the RNs performing the PIOMI. Interuser reliability is the consistency in which the PIOMI can be performed correctly between multiple RNs. Test-retest reliability is the ability of each RN to perform the PIOMI consistently more than once.

Utilizing a formal reliability tool that not only allows for an overall reliability score, but also provides an opportunity for examination of individual steps, will guide researchers in identifying areas within the PIOMI that are more difficult to reproduce. Developing more focused training of how to perform the PIOMI can then possibly mitigate these areas. Reliability is necessary to ensure that the results from any future studies regarding the PIOMI are indeed from a consistently performed intervention, not an intervention that contains a large degree of

variability in relation to the order in which the eight steps are performed, the specific technique used to perform each step, and the time taken for each step as well as the time taken to perform the overall intervention. Without assessing this reliability, the future results may not be accurate and incorrect interpretation of results could be made. Reliability has important implications for establishing the validity of study results (Stemler, 2004).

Methods

Sample and Setting

This study took place at a 45-bed Level III NICU at a large Midwestern teaching hospital. The convenience sample consisted of three NICU RNs who expressed an interest in the PIOMI and had varying levels of experience performing either the PIOMI or a similar type of oral stimulation on premature infants. All three RNs were Caucasian females with NICU experience ranging from 7-34 years (Table 1). All three subjects had some past experience with a similar oral stimulation protocol in the NICU that could be used on older infants (greater than 30 weeks PMA), but was not as specific as the PIOMI, nor the same amount of steps or length of time allotted for its performance. RN A and RN B were past participants in Dr. Lessen's pilot study (2008) over two years ago, thus had previous training and experience specifically on the PIOMI. RN C had no exposure to the PIOMI prior to this study. Among the three subjects, there were a total of 12 observations of the PIOMI based on six performances (each subject performing it twice) rated by two observers.

Design and Procedure

After approval by the Illinois Wesleyan University Institutional Review Board (Appendix B), Peoria Institutional Review Board (Appendix C), OSF Saint Francis Nursing Review Board (Appendix D), and OSF Clinical Research Office, a quantitative descriptive study was used to

determine the reliability of the Premature Infant Oral Motor Intervention. Both the faculty advisor (Dr. Brenda Lessen) and the Co-Investigator (CI) also completed the Collaborative Institutional Training Initiative (CITI) curriculum for biomedical researchers on Human Research.

This research was conducted over a two month period. The faculty advisor recruited the subjects. First, two RN's who had previously been in the pilot study were approached to be in this study, and both agreed. Secondly, the faculty advisor contacted the unit educator for a recommendation of a RN who was interested in research and considered an expert NICU clinician. The RN that was recommended was approached and agreed to participate as the third subject. Written consent was obtained from all subjects, and subjects were informed that there were no consequences for refusing to participate (Appendix E). Subjects were informed that the results of this study would be shared but their identity would not be linked to the data (except in the faculty advisor's locked box in a locked office).

A training video was developed to demonstrate the correct order and correct technique of each step of the PIOMI. In this video, the faculty advisor performed the PIOMI on a full-term infant with a larger oral cavity than 29 week PMA infants. This allowed viewers better visualization of each step of the PIOMI being done inside and around the oral cavity. The term infant was also not restricted to being inside an incubator, which made viewing easier. This video was not designed, however, to represent the correct number of repetitions of each movement in the steps or the correct amount of time allotted for each step. The intent was to show proper order and technique only in an abbreviated training video that would not take a full five minutes to view.

In the NICU at the study site, new protocols are commonly printed on half sheets of paper that can be taped to the infant's incubator for reference during the implementation of that protocol. For this study, a reference sheet of the PIOMI was also developed for the RNs to use while performing the PIOMI (Appendix F). This reference sheet showed the steps in the correct order, technique description, the correct time, and the correct number of repetitions. It was printed on a 4x5 inch sheet of paper, and taped to the incubator during the intervention. All three RNs utilized this reference sheet so no variation existed in resources available.

It is important when discussing reliability in performing behaviors that the approximate amount of training (in hours) required to reach the reliability level is properly reported (Lombard, Snyder-Duch, & Bracken, 2008). A single two-hour training session was provided on site conducted by the faculty advisor and CI. The three RNs were trained simultaneously to ensure consistency of teaching during this study. The training session included a detailed verbal explanation of the three criteria in the intervention (order, technique, and time), a paper copy of the PIOMI tool with written descriptions of technique, a viewing of the training video, and a practice session using a dominant hand performing the PIOMI steps on the non-dominant hand in the closed fist position with the thumb loosely mimicking a movable mouth. This training "bundle" was created to standardize training among RN's performing the PIOMI, and allow them to take the resources (including a copy of the video) home to practice to their level of comfort.

The video developed for the subjects' training was also used for training the two observers to rate the PIOMI being performed prior to rating live performances by the RNs. Each observer watched and rated the training video once independent of the other observer, then compared ratings. Training the observers to interpret the rating tool and apply the Likert scales

minimized objectivity (Stemler, 2004). The observers watched individually at different times to eliminate the opportunity for discussion or questions while rating. The training for the observers took a total of 30 minutes per observer. Ratings were then discussed to ensure that variability was minimized between observers.

After receiving training, the three RNs notified the faculty advisor and CI when a 29-30 week PMA infant was in the NICU and was scheduled to receive the intervention. Within a RN's first performance of the PIOMI and her second performance, 20 minutes to 24 hours elapsed. Each RN did not perform the PIOMI more than once on the same infant. The faculty advisor and the CI simultaneously rated each RN using the reliability rating tool (discussed below). For each observation both the faculty advisor and the CI rated the RN according to three criteria: 1) the eight steps done in the correct order, 2) each step performed in the correct amount of time, and 3) each step performed using correct technique.

Measures

The focus of this study was to assess the reliability of the PIOMI. To that end, the PIOMI Reliability Rating Tool was created. This rating tool was developed to reduce subjectivity associated with rating (Stemler, 2004). It was created specifically for this study to allow observers to rate the accuracy with which the PIOMI was performed (Appendix G). The three main criteria were rated based on a four-point Likert scale (0-3). A four-point Likert scale was chosen to allow a higher degree of specificity than a binary choice of "correct" and "not correct". For example, each rating for technique specifically described what small variation in technique would result in a rating of 0, 1, or 2 (3 was no variation-perfectly done). The ability to determine specifically how a step was done incorrectly would help to identify what areas of the PIOMI were either difficult to perform, or required more clarification in the training phase.

The reliability rating tool was originally designed as a worksheet that allowed the observer to write in a score. However, during the practice observations done by the observers on the videotaped PIOMI, it became clear that the 0-3 Likert scale definitions needed to be written onto the tool so the observers could easily and instantly reference how to rate each step.

When looking at the tool, the column on the left is the rating of the criterion of time. The exact time in seconds was written into the blanks during the performance, and then transcribed into the Likert scale rating. The center section of the tool contains all eight steps in the correct order with the Likert scale for technique operationalized for each step. The observer circled the correct rating for technique under each step. The number of steps out of order was recorded at the bottom of the tool and was transcribed into the Likert scale. The third and final column was designed for observer's comments (noting specific variations in the technique used) at each step.

The Likert scale for each criterion was operationalized as described below. First, for the criterion of order, a score of 0 indicates that 3 or more steps were done in the incorrect order. A score of 1 indicated that 2 steps were done in the incorrect order. A score of 2 indicated that 1 step was done in the incorrect order. A score of 3 indicated that all the steps were completed in the correct order.

Second, for the criterion of technique, a rating of 0 or 3 was the same for each step and a rating of 1 or 2 was defined specifically for each step. A score of 0 for any step indicated that the step was not done at all. A score of 3 indicated that the step was correctly done. A score of 1 or 2 differed slightly among the steps depending on how the technique for that step was to be performed. However, in general, a 1 indicated that the technique (movement of the fingers in or around the oral cavity) was incorrect, whereas a 2 indicated that the amount of repetitions was incorrect. For example, if the RN did the Gum Massage step only once on each gum or more

than twice but did it with the correct movements of her fingers, she would score a 2 for incorrect number of repetitions. It is important to note a score of 1 is not better or worse than a score of 2 for technique, rather it indicates what the variation was. The Likert scale is nominally defined for technique.

For the criterion of correct time, a score of 0 indicated that the step took less than 75% of the allotted time to complete. A score of 1 indicated that the step took less than 50% of the allotted time. A score of 2 indicated that the step took greater than 50% of the allotted time, but not the full time or that the step took more time than was allocated. A score of 3 indicated that the step was completed in the correct amount of time. It is acceptable to allow a reasonable amount of tolerance in measuring time frames as discreet as 15-30 seconds in interobserver reliability (MacLean, Tapp, & Johnson, 1985; Mudford, Taylor, & Martin, 2009). For this study, a margin of error of ±5 seconds was given per observer's score when determining the rating for time when the standard was 30 seconds. A margin of error of ±3 seconds was given per observer's score when determining the rating for time when the standard was 15 seconds. The overall time of the PIOMI performance should be five minutes. Time was measured using an analog clock hanging on the wall or a wristwatch. No stopwatches or timers were used.

Statistical Analysis

Microsoft Office Excel 2004 version 11.5.8 was used for data analyses. The results were analyzed to calculate percent agreement for interobserver reliability, interuser reliability, and test-retest reliability (Table 2).

Interobserver Reliability

By assessing the degree to which two observers agree, the likelihood that the data accurately represents the actual performance of the PIOMI is increased. Additionally, the

interuser reliability and test-retest reliability were calculated using the average of the two observers' scores. Interobserver reliability can be reported as percent agreement (Repp, Deitz, Boles, Deitz, & Repp, 1976). Also, it is important to calculate interobserver reliability whenever rating occurs because this type of reliability has important implications for the validity of the PIOMI (Stemler, 2004). Following are the procedures used to calculate interobserver reliability on each of the three criteria.

Percent agreement on order.

Percent agreement for the criterion of order was calculated by adding each observer's scores across all observations by that observer. The faculty advisor and CI each rated three RNs performing the PIOMI twice, which resulted in 6 scores per observer. Each observer totaled their 6 scores, and those scores were then compared for interobserver percent agreement. Based on the Likert scale, the highest attainable rating per RN on order was 3, so the highest possible score per observer across the 6 observations equals 18. To give an example of this calculation: if the CI's total score across all 6 performances was 16 and the faculty advisor's total score was 18, then 16 divided by 18 multiplied by 100 would result in an interobserver percent agreement of 88.89%.

Percent agreement on technique and time.

Percent agreement for the criterion of technique was calculated using the same methods as order. Each observer rated 6 performances, added the scores across those 6 performances, and compared the two observers' total scores for interobserver percent agreement for technique and time. However, unlike the criterion of order where only one rating was done per RN resulting in a score of 0-3 per RN, the criteria of technique and time each had 8 steps in the PIOMI to be given individual ratings of 0-3. Each RN had 16 scores across the 2 performances. There were

three RNs observed per observer, so there were 48 scores recorded by each observer. Each observer totaled their 48 scores, and those were compared for percent agreement. In addition to this overall interobserver percent agreement (Table 2), interobserver percent agreement was calculated for each of the eight individual steps for both criteria of technique and time.

Interuser Reliability

Three RNs performed the PIOMI. Interuser reliability is the consistency in which the PIOMI can be performed correctly between all three RNs (Polit & Beck, 2008). This reliability was important to study because of the potential for variations between different nurses. Even with specific directions, people may interpret the instructions differently. If the PIOMI is performed with any variation or modification then results of future studies on its effect cannot be attributed to the original PIOMI. Following are the procedures used to calculate interuser reliability on each of the three criteria.

Percent agreement on order, technique, and time.

Interuser percent agreement for all three criteria (order, technique, and time) was calculated by first adding the two observer's scores on each RN to obtain one standard score to use for comparison across the RN performances. Each RN performed the PIOMI twice; therefore the scores from both of the RN's performances were totaled and then compared to other RN's scores for interuser percent agreement.

Again, for all three criteria an overall interuser percent agreement was calculated (Table 2) and for the criteria of technique and time, an interuser percent agreement was also calculated on each of the eight steps.

Test-retest Reliability

Each of the three RNs performed the PIOMI twice. Test-retest reliability is the ability of each RN to perform the PIOMI consistently more than once (Polit & Beck, 2008). This reliability was important to study because of the potential for variations by one RN when performing the PIOMI more than once. These variations could be unknown to the RN, but would still not be the original PIOMI. Thus, to assess if variations occurred, test-retest reliability was analyzed. Following are the procedures used to calculate test-retest reliability on each of the three criteria.

Percent agreement on order, technique, and time.

Test-retest percent agreement for all three criteria was calculated by first adding the two observers' scores for each performance to obtain one standard score to use for comparison. The scores were then compared between the RN's first and second performances. For all three criteria an overall test-retest percent agreement was calculated (Table 2), and for the criteria of technique and time, a test-retest percent agreement was also calculated on each of the eight steps.

Results

Prior to assessing reliability of the PIOMI, it is important to first assess correct *performance* of the PIOMI by each RN. The same reliability rating tool was utilized with the perfect score (highest possible rating in all three criteria) being the goal. Correct performance was calculated by adding the observers' scores for each RN's performance of the PIOMI. This number was then divided by the total possible score that could have been achieved. The correct performance of the overall PIOMI was calculated, as was the correct performance of each individual step. The RNs performed the intervention with a high level of correctness with a

rating of 100% correct on the criterion of order, 96-100% correct on criterion of technique, and 85-98% correct on criterion of time (Table 3).

All three reliability statistics were calculated for each individual criterion of order, technique, and time. Both the overall percent agreement (percent agreement across all three reliability measures) was calculated as well as percent agreement for each individual step within the criteria of technique and time. The PIOMI demonstrates high interobserver reliability (97.57%), interuser reliability (97.59%), and test-retest reliability (97.58%) in this study (Table 2). When examining percent agreement for each criterion, this study demonstrated a percent agreement of 100.00% for order for each of the three reliability measures. The overall percent agreement for the criterion of technique was also consistently high (95.83%-100.00%) across the three reliability measures. The overall percent agreement for time ranged from 87.23%-97.87% across the three reliabilities. The areas with the weakest reliability include criterion of time overall, and three of the eight steps: cheek-C stretch, lip curl, and midblade of tongue/palate (Table 5). Apart from these areas with the weakest reliability, all three reliability measures for order and technique were 100%. The overall percent agreement for the criterion of correct time ranged from 87.23%-97.87% across the three reliabilities.

The total time per performance of the PIOMI was also assessed. The goal is to complete the PIOMI within a maximum five-minute time frame (based on the combined rating of both observers) that can be tolerated by 29 week PMA infants (Lessen, 2008). All three RNs improved in overall time from their first performance to their second performance (Table 4). For example, RN A's first performance was under 5 minutes by 11 seconds whereas her second performance was just over 5 minutes by 3 seconds. Although there was an improvement in each

RNs performance over the two times, it is important to note that two performances (both RN B's) were substantially over 5 minutes.

Discussion

Various degrees and methods of oral stimulation and non-nutritive sucking have been tested in the literature with positive effects on both feeding progression and length of hospital stay (Bernbaum, et al., 1983; Field, et al., 1982; Gaebler & Hanzlik, 1996; Hussey-Gardner & Famuyida, 2009; Pinelli & Symington, 2005). The more targeted oral motor interventions have also been shown to improve feeding on preterm infants greater than 30 weeks PMA (Fucile, et al., 2002; Rocha, et al., 2006). For infants at young as 29 weeks PMA, the specially designed PIOMI demonstrates a similar positive effect on feeding and length of stay (Lessen, 2008), and now has some initial reliability data to support further use.

A new reliability rating tool was developed specifically for this study. Reliability of a measurement tool is an important step in the development of any new instrument (Malmgreen, 2005; Polit & Beck, 2008). Although the interuser reliability of the PIOMI was informally tested to criterion among the four RNs performing it throughout the pilot (Lessen, 2008), there was no formal reliability rating tool utilized. More formal testing and documentation will allow other clinicians to better evaluate the tool for use in their units. This study piloted the use of this new tool and the researchers found it to be usable. However, the actual Likert scales for time and order were not printed on the tool, so had to be referenced after initial scoring. An additional column could also be added next to the time column to allow for the transcription of time in seconds into the Likert scale at each step. These changes should be incorporated into a future revision of the tool. It would also be beneficial to continue to test the reliability rating tool itself with more RNs and observers.

Study findings suggested that the performance of the five-minute PIOMI was reliable with respect to all three criteria (order, technique, and time) using percent agreement. The least reliable criterion was time for both the RNs (interuser and test-retest reliability) and the observers (interobserver reliability) (Table 5). The RNs were responsible for performing the steps, while also monitoring the timing of each step, which was a challenge. The observers also found it difficult to observe and rate each step being performed while keeping accurate track of the timing of each step.

The lowest percent agreement within the criterion of correct time was RN C in test-retest reliability at 87.23% (Table 2). RN C was the most inconsistent in regard to time. This may have been due to a difference in past experience performing the PIOMI. Both RN A and RN B had been participants in Dr. Brenda S. Lessen's pilot study of the PIOMI so those RNs had more experience performing the PIOMI. RN C was recruited as a subject just for this study so had less experience. She was rated lower on her first episode as opposed to her second episode. RN C performed the PIOMI the second time almost perfectly in relation to time, whereas the first performance was not as accurate in regards to time.

The criterion of correct time was examined for each individual step. For example, the Cheek C-stretch was to be performed within the allotted time of 30 seconds (±5 seconds). All three types of reliability were calculated using the time per step. This was important because even if a RN performed the entire PIOMI within five minutes, each individual step could have wide variations in time outside the target time.

In the future, digital forward count timers are recommended to allow the observer to more accurately record time. Another recommendation to increase accuracy of rating time for the observers is to videotape the RNs performing the PIOMI. This will allow observers to watch the

performance allowing pauses to accurately document scores, as well as allow more than two observers to rate the performance of the PIOMI. Lastly, the PIOMI training video was developed to demonstrate correct order and correct technique only. Correct time and repetitions were not adequately reflected in the training video. Thus, the training video could be revised with accurate repetitions of each step and accurate time for each step so RNs can visualize how long the intervention should take.

This study, in addition to determining the reliability of the PIOMI, also aided in planning future training of the intervention. Based on the high percent correctness among all three RNs despite variations in experience, the PIOMI was not difficult to learn. The two hour training session was sufficient to incorporate all elements of the training bundle and to answer all questions posed by the RNs. However, there were three steps (cheek C-stretch, lip curl, and midblade of tongue/palate) that consistently resulted in lower technique scores by the observers than the other five steps (Table 5). Each RN performed cheek C-stretch slightly differently, according to comments noted by the observers on the PIOMI Reliability Rating Tool. If any variations were identified, the description of that step was re-evaluated for ambiguity. For example, the instructions for cheek C-stretch were interpreted by RNs as either down the cheek and back up twice, or down the cheek twice and not back up. Lip curl required reinforcement of the instructions to do two placements per lip (rather than three). Midblade of tongue/palate required the RN to apply pressure on the hard palate, followed by pressure on the center of the tongue, and ending by moving the finger back up to the hard palate to complete the step. Some RNs were not bringing their finger back up to the hard palate. It follows that these three techniques may require improved explanation on how they are to be done. The necessary

revisions will be incorporated into the development of a formal training plan prior to the large study of the PIOMI.

Before beginning the reliability testing of the PIOMI, the faculty advisor and CI met with Debra Beckman to discuss the importance of order, technique, and time when performing the PIOMI (D. Beckman, personal communication, 2010). Time may not be a crucial element if each step only requires initial muscle activation. However, if allowing time for repetition allows for an opportunity to further train the afferent neural pathways in the preterm infant brain for oral-motor skills related to feeding then time may be a crucial element (Barlow, 2009). More study is needed on the importance and effect of time and on the necessity of repetitions.

During this study, positioning of the infant was not accounted for and may play a role in muscle activation in and around the oral cavity. Premature infants have poor head/neck control (Tecklin, 2008). Muscles that are not in a relaxed position may result in an already partially activated state. To allow proper muscle relaxation, the infant must be in a semi-flexed position. This required position could be incorporated into the PIOMI requirements and the training. Although the flexed position was already properly demonstrated on the training video, the infant in the video was a term infant with increased muscle development and head/neck control, and much larger in size than the 29 week PMA infant. Positioning of a 29 week preterm takes a different kind of skill and could be demonstrated as a supplement on the training video.

Limitations

Although percent agreement is the most widely used measure for interobserver reliability, it does not take into account the amount of agreement due solely to chance (Hunt, 1986; Polit & Beck, 2008; Lombard, et al, 2008). Therefore, percent agreement may overestimate true interobserver reliability. Percent agreement for interobserver reliability has been reported in

studies, but correlation coefficient is usually also reported (Daving, Andrén, & Grimby, 2000; Gardner, Frantz, Troia, Eastman, Macdonald, Buresh, Healy, 2001; To, Estrabillo, Wang, & Cicutto, 2008). Further analysis of the data should include a correlation coefficient. A correlation coefficient is an index that summarizes the degree of relationship between two variables, and typically ranges from +1.00 (for a perfect direct relationship) to 0.0 (for no relationship) to -1.00 (a perfect inverse relationship) (Polit & Beck, 2008). In the future, interobserver reliability will also be reported as a Pearson's correlation coefficient.

Interuser and test-retest reliability are also reported as percent agreement due to the ratings being chosen from an objective Likert scale. Unlike in most measurement tools where the Likert scale items are ranked, continuous, or interval (thus requiring correlation coefficients), this is an intervention study assessing performance of individual criterion. All three criteria were rated on a Likert scale that was not continuous or interval. Percent agreement is best used with data that is nominal (Polit & Beck, 2008). Each item on the Likert scale was nominally operationalized into a specific behavior or category, whether it was a category of time, order, or specific technique used or not used. This is not, however, the standard statistic for interuser and test-retest reliability. Most interuser and test-retest reliabilities are reported as correlation coefficients, and a further analysis of this data is needed using SPSS to report correlations.

An additional limitation in this study was the small number of research subjects performing the PIOMI. Only three RNs were observed and rated. Although only three RNs were used in the sample, the number of observations rated was 12. Even though the results obtained from this study demonstrate the reliability of the PIOMI among those 12 observations, a larger sample size would provide more definitive data on reliability.

There was also a difference in experience among the three RNs in the study. Experience with any type of oral stimulation was assessed, as was specific experience with the PIOMI (Table 1). RN A and RN B had prior experience performing the PIOMI during the pilot study, while RN C had never been exposed to it, which may have impacted the interuser reliability. In the future, all subjects should have the same experience performing the PIOMI to better assess the interuser reliability. Also, the amount of individual practice following the training session was not assessed. In the future, each RN's individual practice time and methods (i.e. watching the video or practicing on the hand method or a manikin) should be noted.

Another limitation includes the short time lapse between performances of the PIOMI, and discussions the observers had between ratings. All three RNs performed the PIOMI twice within 24 hours. The PIOMI was still at the forefront of their mind possibly allowing the second performance to be affected by the first performance. Having the RNs perform the PIOMI twice in quick succession was required due to the limited time frame allowed to complete the study. However, one possible benefit of having a short time lapse between the two performances is that it allowed less variability in the setting or within the RNs. For example, the RN's fatigue level was the same when both performances were within the same day.

Discussion among the observers between observations carries the risk of improving the interobserver reliability. The observers had two short discussions related to what to watch for during specific techniques. Although very limited, the observers should not have any discussion regarding the RNs performances or the ratings given until the conclusion of the study.

Positioning of the premature infant, as discussed earlier, may be important in allowing proper muscle relaxation in and around the oral cavity and neck. Proper positioning should be included in the training for this study, and assessed per the rating tool.

Conclusion

The PIOMI Reliability Rating Tool was determined to be usable and accurate in regards to the three criteria. The videotape used for training was well received by the subjects and found very beneficial for training on technique. This study, although small in sample size, suggests that the PIOMI can be reliably performed among different RNs (interuser) and by the same RN more than once (test-retest). The PIOMI can also be reliably rated by different observers (interobserver).

Modifications to the descriptions of techniques within the intervention as well as the training video are necessary. There is little cost to disseminating the training bundle, however the amount of one-on-one training is a factor to be considered. There is also little cost in implementing the PIOMI as the standard of care in the NICU. No special equipment is necessary to perform the PIOMI except a pair of gloves.

The literature has been fairly supportive of the effect of various methods of oral stimulation on length of hospital stay and enhanced feeding progression (Fucile et al., 2002; Gaebler & Hanzlik, 1996; Pinelli & Symington, 2005; Rocha et al., 2006). The PIOMI is a more specific oral-motor intervention developed to increase functional response to pressure and movement, range, strength, variety and control of movement for the lips, cheeks, jaw and tongue, thus enhance the premature infant's ability to bottle feed, which results in a decrease in length of hospital stay (Lessen, 2008). With the reliability of the PIOMI documented and accurate training issues identified, the original pilot study can now be replicated with a larger sample size to determine statistical significance.

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Table 1

Subject Demographics

	Age (in years)	**Gender**	**Ethnic/Racial Background**	**Experience in the NICU** (in years)	**Number of Times Performing Oral Stimulation at OSF Saint Francis Medical Center**	**Number of Times Performing the PIOMI Prior to This Study**
RN A	54	Female	Caucasian	34	>100	25
RN B	29	Female	Caucasian	7	>50	25
RN C	37	Female	Caucasian	13	20-30	0

Table 2

Reliability

	Correct Order*	**Correct Technique***	**Correct Time***	**Total Reliability***
Interobserver Reliability	100.00%	97.20%	95.52%	**97.57%**
Interuser Reliability				**97.59%**
RN A and RN B	100.00%	95.83%	93.33%	96.39%
RN A and RN C	100.00%	97.87%	97.87%	98.58%
RN B and RN C	100.00%	97.92%	95.45%	97.79%
Test-Retest Reliability				**97.58%**
RN A	100.00%	100.00%	95.65%	98.55%
RN B	100.00%	100.00%	95.35%	98.45%
RN C	100.00%	100.00%	87.23%	95.74%

* Percent agreement

Table 3

*Correct Performance**

	RN A1	**RN A2**	**RN B1**	**RN B2**	**RN C1**	**RN C2**
Correct Order	100%	100%	100%	100%	100%	100%
Correct Technique	96%	96%	100%	100%	98%	98%
Correct Time	92%	96%	85%	90%	85%	98%

*Compared to standard (highest possible score)

Table 4

Criterion of Time

	CI **Total Time**	**Faculty Advisor** **Total Time**	**Averaged** **Total Time**
RN A1	4 minutes and 42 seconds	4 minutes and 55 seconds	**4 minutes and 49 seconds**
RN A2	4 minutes and 51 seconds	5 minutes and 15 seconds	**5 minutes and 3 seconds**
RN B1	6 minutes and 13 seconds	5 minutes and 35 seconds	**6 minutes and 4 seconds**
RN B2	5 minutes and 52 seconds	5 minutes and 25 seconds	**5 minutes and 39 seconds**
RN C1	4 minutes and 13 seconds	4 minutes and 45 seconds	**4 minutes and 29 seconds**
RN C2	4 minutes and 44 seconds	4 minutes and 51 seconds	**4 minutes and 48 seconds**

Table 5

Areas with Weakest Reliabilities

	Interobserver Reliability*	**Interuser Reliability***	**Test-Retest Reliability***
Correct Technique			
Cheek C-Stretch	94.44%	91.67%-100.00%	83.33%-100.00%
Lip Curl	94.12%	75.00%-100.00%	80.00%-100.00%
Midblade of Tongue	88.89%	83.33%-100.00%	100.00%
Correct Time	86.67%-100.00%	66.67%-100.00%	60.00%-100.00%

*Percent agreement

Appendix A: The Premature Infant Oral Motor Intervention (PIOMI)

[Table removed from online deposit at author's request.
For information, contact Dr. Brenda Lessen at blessen@iwu.edu]

Appendix B: Illinois Wesleyan University Institutional Review Board Approval

Illinois Wesleyan
UNIVERSITY

February 3, 2010

Professor Brenda Lessen
School of Nursing
Illinois Wesleyan University

Dear Brenda:

We are pleased to inform you that your proposal "Reliability and Validity Measurement of the Premature Infant Oral Motor Intervention (PIOMI)" has been evaluated by the Illinois Wesleyan Institutional Review Board. This proposal has been approved under expedited review.

This approval is valid for a period of time beginning on January 26, 2010, and will expire on January 26, 2011.

The research procedures should be implemented as detailed in your approved IRB protocol. You must inform the IRB of any changes in this protocol. Likewise, the IRB must be informed immediately of any concerns that arise concerning the health or welfare of subjects.

Sincerely yours,

James P. Sikora

James P. Sikora
Professor and Chair of the IRB

JPS/pn

cc: Clare Goebel

ASSOCIATE PROVOST

Post Office Box 2900 • Bloomington, Illinois 61702-2900 • (309) 556-3255 • fax: (309) 556-3970 • www.iwu.edu

Appendix C: Peoria Institutional Review Board Approval

UNIVERSITY OF ILLINOIS
COLLEGE OF MEDICINE AT PEORIA

Institutional Review Board
One Illini Drive
Box 1649
Peoria, Illinois 61656-1649

FWA 00005172

IRB #00000688
IRB #00000689

DATE:	March 5, 2010
TO:	Brenda Lessen, Ph.D. RN
FROM:	University of Illinois College of Medicine at Peoria IRB 1
STUDY TITLE:	[154207-1] Reliability and Validity Measurement of the Premature Infant Oral Motor Intervention (PIOMI)
IRB REFERENCE #:	
SUBMISSION TYPE:	New Project
ACTION:	APPROVED
APPROVAL DATE:	March 4, 2010
EXPIRATION DATE:	February 10, 2011
REVIEW TYPE:	Expedited Review

Approval has been granted for one year pursuant to 45 CFR 46.110(a)(F)(7) "Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies."

This approval covers the consent form and protocol.

This research meets the regulatory requirements for approval as specified in 45 CFR 46.111 and 21 CFR 56.111. Specifically, the risks to subjects are minimized and reasonable in relation to anticipated benefits to subjects and the importance of the knowledge that may reasonably be expected to result, and that written informed consent and HIPAA authorization will be sought from each prospective subject or the subject's legally authorized representative.

The informed consent document meets the regulatory requirements as outlined in 45 CFR 46.116 *[and 21 CFR 50.25]*. Additionally, the authorization for the use/disclosure of PHI within the consent form document meets the regulatory requirements as outlined in 45 CFR 164.508(a)(3)(ii), (c)(1), and (c)(2).

A Continuing Review will be requested prior to the end of one year of study.

This study will expire: February 10, 2011

This study will be reviewed at the February 10, 2011 meeting of the IRB.

A completed Continuing Review Form is expected by: January 27, 2011.

The University of Illinois College of Medicine at Peoria's (UICOMP) Office of Human Research Oversight (OHRP) will no longer accept local or non-local adverse events or safety reports for IRB review that do not meet the definition of an unanticipated problem involving risks to subjects or others (UPIRSO).

Appendix D: OSF Saint Francis Medical Center Nursing Review Board Approval

February 10, 2010

Clare Goebel, BSN
210 E. Beecher Street
Magill Hall
Bloomington, Illinois 61701

Subject: Research Study – Reliability and Validity Measurement of the Premature Infant Oral Motor Intervention

Dear Clare,

The Research Committee has approved your research proposal "Reliability and Validity Measurement of the Premature Infant Oral Motor Intervention" with two changes. First, change the start date since February 1 has already passed. Secondly, remove the validity piece from the study and call it a reliability study. After you make the modification, please send a revised copy of the study to Maureen Mathews. You may then begin your study.

The committee requests an update at one year or at the completion of your study. The IRB will also request an update. You may utilize the same form for both institutions. We also request a copy of your completed research findings.

Sincerely

Maureen Mathews, RN, APN, CNP
Chair
PNC Research Committee

MM:mlb

Appendix E: Informed Consent

RESEARCH SUBJECT INFORMED CONSENT FORM

Protocol Title: **Reliability Measurement of the Premature Infant Oral Motor Intervention (PIOMI)**

Principal Investigator: **Dr. Brenda S. Lessen, PhD, RN**
Illinois Wesleyan University
Box 2900
Bloomington, IL 61701
(309)556-3279

Co-Investigators: **Clare Goebel**
210 E. Beecher Street
Bloomington, IL 61701
(630)346-1510

Emergency Contact: **Dr. Brenda S. Lessen**
309-212-0544

Why am I being invited to volunteer?

You are being invited to participate in a research study. "Research" designates an activity designed to test a hypothesis, permit conclusions to be drawn and thereby to develop or contribute to generalizable knowledge, whereas "practice of medicine" refers to interventions designed solely to enhance the well-being of an individual patient. Research subjects may or may not benefit from research procedures. Federal regulations require that you are informed of the research you are being invited to volunteer for and your signature indicating that you have been informed about the research. You are being invited to volunteer since you meet the requirements for enrollment into this study. Your participation is voluntary which means you can choose whether or not you want to participate. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. Please ask the research team about this form. If you decide to participate, you will be invited to sign this form. Your signature on this form is voluntary and does not waive any of your legal rights or make any institutions or persons involved in this research any less responsible for your well-being. Your refusal to participate in

this trial will not influence your present or future role/employment.

Who is the Principal Investigator for this Study?

Dr. Brenda S. Lessen
Illinois Wesleyan University
Box 2900
Bloomington, IL 61701
(309)556-3279

What is the purpose of this research study?

The purpose of this study is to determine the reliability of the Premature Infant Oral Motor Intervention (PIOMI). Reliability will be assessed by observing if the PIOMI is performed the same way each time among different users and the same way twice by each user on the 29-30 week infant.

How long will I be in the study?

For the length of time necessary to perform the PIOMI twice. This will take place between Feb 21, 2010 and March 30, 2010.

How many other people will be in the study?

3 people will take part in this study.

What is involved in this study?

If you agree to be in this study you agree to be observed by the Primary Investigator and the Co-Investigator while you perform the PIOMI per unit protocol two different times, either on two different infants or two times on the same infant.

What are the possible risks or discomforts?

This study has no risks or discomforts.

It is important to call the researcher when you think you are having problems, even if they are not included on the above list.

What are the possible benefits of the study?

There may be no direct benefit to you if you decide to participate in this research, other than the intrinsic value of contributing to neonatal nursing research.

What other choices do I have if I do not participate?

Instead of being in this study, you have these options:

- You could choose not to participate in this study

Will I be paid for being in this study or will I have to pay for anything?

You will receive no payment for taking part in this study.

What happens if I am injured or hurt during the study?

If you have a medical emergency during the study you may contact the Principal Investigator or Emergency contact listed on page one of this form.

In the event of any physical injury resulting from research procedures, medical treatment will be provided without cost to you, but financial compensation is not otherwise available from the University of Illinois College of Medicine at Peoria. If you have an illness or injury during this research trial that is not directly related to your participation in this study, you and/or your insurance will be responsible for the cost of the medical care of that illness or injury.

When does the Study end?

You can stop participating at any time. However, if you decide to stop participating in this study, we encourage you to talk to the researcher first. If you decide to stop participating, you may still be invited to provide the researcher with information through telephone calls or clinic visits.

This study is expected to end after all participants have completed the observed performance of the PIOMI and the brief discussion about the PIOMI, and all information has been collected. This study may also be stopped at any time by the PI and/or Co-investigator.

Who can see or use my information? How will my personal information be protected?

Your privacy and the protection of your health information are important to us. This section of the consent will cover:

- What personal health information about you will be collected in this study
- Who will use your information within the institution and why
- Who may disclose your information and to whom
- Your rights to access research information about you
- Your right to withdraw your authorization (approval) for any future use of your personal health information

1. Personal health information about you that will be collected in this study

There is no personal health information being collected in this study. The following information will be collected, used for research and may be disclosed or released during your involvement with this research study:

- Name
- Address
- Telephone number

2. Why your personal health information is being used

Your personal contact information is important for the study team to contact you during the study.

3. The personnel who may use or disclose your personal health information

The following individuals and organizations may use or disclose your contact information for this research project:

- The Principal Investigator and the Co-investigator
- The Peoria Institutional Review Boards (the committees charged with overseeing research on human subjects)
- The Office of Human Research Oversight (the office which monitors research studies)

4. Who, outside of this institution, might receive your personal health information

- In all disclosures outside of this institution's system, you will not be identified by name, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law.
- In records and information disclosed outside of this institution, you will be assigned a unique code number for this study. The Principal Investigator will ensure that the key to the code will be kept in a locked file. The key to the code will be destroyed at the end of the research study.

5. How long will this institution be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific study does not expire. This information may be maintained in a research repository (database). However, the institution may not re-use or re-disclose your personal health information collected in this study for another purpose other than the research described in this document unless you have given written permission for the Principal Investigator to do so. However, the Peoria Institutional Review Board may grant permission to the Principal Investigator or others to use your information for another purpose after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job it is to protect the safety and privacy of research subjects.

6. Access to your records

N/A

7. Changing your mind

You may withdraw from the study for any reason simply by explaining this to the Principal Investigator or a member of the study team. If you decide not to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future role/employment.

You may also withdraw your permission for the use and disclosure of any of your personal information for research, **but you must do so in writing** to the Principal Investigator at the

address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your personal information that was collected prior to your written request if that information is necessary to the study.

Who can I call about my rights as a research subject?

If you have questions regarding your participation in this research study or if you have any questions about your rights as a research subject don't hesitate to speak with the Principal Investigator listed on page one of this form. Concerning your rights as a research subject, you may also contact the Peoria Institutional Review Board by calling (309) 680-8630.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting this institution to use your personal health information collected about you for research purposes. You are also allowing this institution to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Printed Name of Subject	**Signature of Subject**
Date	
Printed Name of Person Obtaining Consent	**Signature**
Date	

Appendix F: Premature Infant Oral Motor Intervention Reference Sheet

[Table removed from online deposit at author's request.
For information, contact Dr. Brenda Lessen at blessen@iwu.edu]

Appendix G: Premature Infant Oral Motor Intervention Reliability Rating Tool

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