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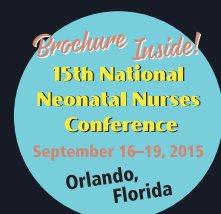
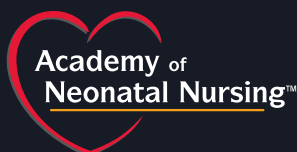
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Probiotics for Preterm Infants

Development of Home Educational Materials

Pressure Ulcer Prevention



# Establishing Intervention Fidelity of an Oral Motor Intervention for Preterm Infants

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## Disclosure

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## ABSTRACT

**Purpose:** To establish intervention fidelity of the premature infant oral motor intervention (PIOMI)

**Design and sample:** A rating tool was developed and tested for interrater reliability before being used to test the fidelity of intervention behaviors. A purposeful convenience sample of three users was recruited to perform the intervention under direct observation.

**Main outcome variables:** Three types of reliabilities were calculated: (1) interrater reliability to test the rating tool, followed by (2) interuser reliability, and (3) test-retest reliabilities to test the intervention behaviors of several registered nurses (RNs) over repeated performances of the intervention.

**Results:** The rating tool demonstrated a high interrater reliability (97.57 percent), indicating its accuracy for systematically rating the specific intervention behaviors. Subsequently, the rating tool was used to determine interuser and test-retest performances of the PIOMI and resulted in high reliabilities (97.59 percent and 97.58 percent, respectively). This demonstrates that the intervention can be reliably delivered as prescribed, supporting intervention fidelity.

**Keywords:** intervention fidelity; intervention reliability; treatment fidelity; premature infant; premature infant oral motor intervention (PIOMI); oral motor; neonatal; oral stimulation; preterm infant

FIDELITY OF NURSING INTERVENTIONS IS needed to assure quality and safety in the clinical setting. Intervention fidelity is defined in the literature as the competent and reliable delivery of an intervention/treatment.<sup>1,2</sup> The internal validity of an outcome study is dependent on the systematic and reliable delivery of the independent treatment variable.<sup>3</sup> The process of establishing reliable delivery of the intervention is vital to the integrity of any research. An instrument to measure intervention fidelity must first be developed and tested in order for any conclusions about the intervention's effect on an outcome to be sound.

This study describes the development of an instrument to measure intervention fidelity

of an oral motor intervention on preterm infants. Once the interrater reliability of the new instrument was determined, it could be used to test for consistent delivery of the intervention among several users across cases (intervention fidelity). The development of a valid and reliable rating tool involves several steps, including the identification of observable behaviors specific to the intervention.<sup>1</sup> To understand this process, background on the intervention is first provided.

## BACKGROUND ON THE INTERVENTION

In 2013, 11.5 percent of live births were babies born prematurely.<sup>4</sup> The feeding

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difficulties of preterm infants have been well established in the literature. Oral feeding difficulties are caused by underdeveloped oral-motor skills and the lack of coordination between sucking, swallowing, and breathing.<sup>5-10</sup> Preterm infants are required to consume all of their feedings per bottle/breast before being discharged from the NICU.<sup>11</sup> Poor oral feeding is one of the primary reasons for the delay in hospital discharge of healthy preterm infants.<sup>12</sup>

Recent research to improve feeding skills in preterm infants has focused on various oral motor interventions<sup>6,13-18</sup> and crosses the disciplines of nursing, occupational therapy, and speech language pathology (SLP). Studies using various types of oral motor programs have shown positive effects on both feeding progression and length of hospital stay.<sup>19-22</sup> Several researchers<sup>18,23-25</sup> used a more targeted oral motor intervention based on the principals of the Beckman oral motor intervention (BOMI) and have shown improved feeding and decreased length of stay.<sup>26</sup> However, there is no reliability testing in the literature on the use of these interventions to know if they can be consistently performed by the wide range of persons (including parents) who may implement them. Without assuring consistent performance of the intervention, outcome data lack validity.

A new intervention (the premature infant oral motor intervention [PIOMI]) was recently developed specifically for preterm infants as young as 29 weeks postmenstrual age (PMA).<sup>18</sup> The PIOMI (Figure 1) was adapted from the BOMI and modified for use in preterm infants as a prefeeding intervention performed prior to any attempt to oral feed. The BOMI does not require the cognitive cooperation of the patient nor demand a response to verbal direction; therefore, it lent itself perfectly to be modified for the preterm infant population. The original 15-minute BOMI was designed for all ages from infancy to elderly but was not suitable for preterm infants and needed to be redesigned specifically to accommodate the smaller oral cavity and to reduce the time frame so that it was physiologically safe and tolerable for infants as young as 29 weeks PMA. The PIOMI was therefore developed with eight modified steps done in a five-minute time frame. It provides assisted movement to activate muscle contraction and provides movement against resistance to build strength in the oral cavity. The intervention addresses target areas in and around the mouth including the cheeks, lips, gums, tongue, and palate.

A randomized triple-blind pilot study demonstrated that the PIOMI improved the preterm infant's oral feeding success rate by reducing the number of days to reach full oral feeds by five days when compared with controls.<sup>18</sup> This translated into the intervention group being discharged almost three days earlier than the control group. This finding has the potential for an estimated savings of more than \$2 billion annually.<sup>4</sup> The pilot also demonstrated the efficacy of the PIOMI on ten preterm infants as young as 29 weeks PMA. The study was replicated in Iran with double the sample size and similar positive results, with the additional outcome of earlier

feeding readiness.<sup>24</sup> Since the initial publication and professional presentations, the researcher has had many requests to train interdisciplinary staff on how to implement the PIOMI in their NICUs and/or conduct their own clinical trial on the intervention. Therefore, the need existed to establish the fidelity of the intervention before further dissemination of the PIOMI. A clinical trial is dependent on the systematic and reliable delivery of the independent treatment variable,<sup>3</sup> and, therefore, "methods to establish reliable delivery of the treatment intervention objectively are central to the integrity of any randomized trial."<sup>1</sup>


## DEVELOPMENT OF AN INTERVENTION FIDELITY INSTRUMENT

Although the efficacy and safety of the PIOMI was established in the pilot study, intervention fidelity was not measured. In the pilot, the persons performing the PIOMI received training from the researcher using a written instruction sheet describing the steps and observed one another performing the intervention to test each other to criterion before the study began. However, there was no objective instrument developed that operationalized specific criteria or behaviors to observe for adherence or competence (the two core components of intervention fidelity<sup>2,27</sup>) in delivery of the intervention.

Nursing research has historically been very limited in assessing intervention fidelity,<sup>2,27</sup> and most studies establishing fidelity of interventions come from the mental health sciences.<sup>28</sup> Stein and colleagues identified steps that they found were essential to the development of a valid and reliable measure of intervention fidelity in nursing clinical trials.<sup>1</sup> These steps include identification of essential elements or behaviors specific to the intervention, construction of rating scales for each element, specification of rater qualifications and training of the raters using the instrument, and pilot testing of the instrument by determining its interrater reliability. *Interrater reliability* is defined as the consistency in which more than one observer rates persons using a specified rating tool.<sup>29,30</sup> Once the instrument has been tested for interrater reliability, it can then be used to test fidelity of the intervention.

Therefore, the first step in this study was to develop a PIOMI reliability rating tool (Figure 2) that contains meaningful categorization and quantification of the specific intervention behaviors.<sup>1</sup> The essential elements/behaviors were identified by the research team through an iterative review of the instructions and by viewing the intervention on videotape. Three essential elements emerged as specific, concrete, and observable behaviors: (1) performing the eight steps in the *correct order*, (2) performing each step using the *correct technique*, and (3) performing each step for the *correct amount of time*. Next, scales for rating each element were determined. It was decided to avoid a simple dichotomous rating of each behavior as either "occurred" or "not occurred" and instead create Likert scales to capture more differentiation

**FIGURE 1 ■ Premature infant oral motor intervention tool.**



PREMATURE INFANT ORAL MOTOR INTERVENTION

8 Steps	Technique	Purpose	Frequency	Duration
Cheek C - Stretch	<ol style="list-style-type: none"> <li>1. Place a finger inside the cheek, and one on the outer cheek. Slide and stretch front to back (toward the ear), then down, then back to front (C pattern).</li> <li>2. Repeat for other side.</li> </ol>	Improve range of motion and strength of cheeks, and improve lip seal.	2X each cheek	30 sec
Lip Roll	<ol style="list-style-type: none"> <li>1. Place a finger on the inside and thumb on outside of upper lip.</li> <li>2. Move finger in horizontal direction while moving thumb in opposite direction (rolling lip between fingers).</li> <li>3. Do on the left side of lip, then repeat on right side (2 placements).</li> <li>4. Repeat on lower lip.</li> </ol>	Improve lip range of motion and seal.	1X each lip	30 sec
Lip Curl or Lip Stretch	<ol style="list-style-type: none"> <li>1. Place a finger on outside of upper lip, and one on the inside.</li> <li>2. Gently compress lip, and stretch downward towards midline, moving across lips.</li> <li>3. Repeat on lower lip, stretching upward.</li> </ol> <p><b>Or</b> (if lips are too small to grab for Lip Curl, replace with this Lip Stretch:)</p> <ol style="list-style-type: none"> <li>1. Lay finger across upper lip, slightly compressing tissue.</li> <li>2. Move tissue horizontally, stretching to one side, then the other.</li> <li>3. Repeat for bottom lip.</li> </ol>	Improve lip strength, range of motion, and seal.	1X each lip	30 sec
Gum Massage	<ol style="list-style-type: none"> <li>1. Place finger on left side of the upper gum, with firm sustained pressure slowly move across the gum to the other side.</li> <li>2. Move down the lower gum (to continue a circle), with firm sustained pressure slowly move across to other side.</li> </ol>	Improve range of motion of tongue, stimulate swallow, and improve suck.	2X	30 sec
Lateral Borders of Tongue/ Cheek	<ol style="list-style-type: none"> <li>1. Place finger at the level of the molar between the side blade of the tongue and the lower gum.</li> <li>2. Move the finger toward midline, pushing the tongue towards the midline.</li> <li>3. Then move the finger back and all the way into the cheek, stretching it.</li> </ol>	Improve tongue range of motion and strength.	1X each side	15 sec
Midblade of Tongue/ Palate	<ol style="list-style-type: none"> <li>1. Place finger at center of the mouth, give sustained pressure into the hard palate for 3 seconds.</li> <li>2. Move the finger down to contact center blade of the tongue.</li> <li>3. Displace the tongue downward with a firm pressure.</li> <li>4. Move the finger back up to the center of the hard palate.</li> </ol>	Improved tongue range of motion and strength, and Improve suck.	2X	30 sec
Elicit a Suck	<ol style="list-style-type: none"> <li>1. Place finger at the midline, center of the pallet, gently stroke the palate to elicit a suck.</li> </ol>	Improve suck, and soft palate activation.	N/A	15 sec
Support for Non- Nutritive Sucking	<ol style="list-style-type: none"> <li>1. Leave finger/pacifier in mouth (or place pacifier in mouth) and allow sucking.</li> </ol>	Improve suck, and soft palate activation.	N/A	2 min

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**FIGURE 2 ■ Reliability rating tool**


PREMATURE INFANT ORAL MOTOR INTERVENTION

## Reliability Rating Tool

<p style="font-size: 0.8em; margin: 0;">Write TIME in seconds: See Likert Scale below</p> <div style="border: 1px solid black; width: 40px; height: 40px; margin: 5px auto;"></div> <div style="border: 1px solid black; width: 40px; height: 40px; margin: 5px auto;"></div> <div style="border: 1px solid black; width: 40px; height: 40px; margin: 5px auto;"></div> <div style="border: 1px solid black; width: 40px; height: 40px; margin: 5px auto;"></div> <div style="border: 1px solid black; width: 40px; height: 40px; margin: 5px auto;"></div> <div style="border: 1px solid black; width: 40px; height: 40px; margin: 5px auto;"></div> <div style="border: 1px solid black; width: 40px; height: 40px; margin: 5px auto;"></div> <div style="border: 1px solid black; width: 40px; height: 40px; margin: 5px auto;"></div>	<p><b>Cheek C-Stretch (2x each cheek) 30 sec</b></p> <p>0- No attempt made at all  1- Only one cheek stretched.  2- Cheek stretch only done with one finger (either inside or outside)  3- Completed exactly as described</p> <p><b>Lip Roll (1X each lip) 30 sec</b></p> <p>0- No attempt made at all  1- Only one lip rolled  2- Lip roll only done with one finger (either inside or outside)  3- Completed exactly as described</p> <p><b>Lip Curl OR Lip Stretch (1X each lip) 30 sec</b></p> <p>0- No attempt made at all  1- Only one lip done  2- Lip curl/stretch only done with one finger (either inside or outside)  3- Completed exactly as described</p> <p><b>Gum Massage (upper and lower, 2X around) 30 sec</b></p> <p>0- No attempt made at all  1- Only one gum massaged  2- Wrong repetitions  3- Completed exactly as described</p> <p><b>Lateral Borders of Tongue/Cheek (1X each side) 15 sec</b></p> <p>0- No attempt made at all  1- Only one side of the tongue is moved  2- Wrong repetitions or Cheek is not stretched  3- Completed exactly as described</p> <p><b>Midblade of Tongue/Palate (2X) 30 sec</b></p> <p>0- No attempt made at all  1- Wrong repetitions (should be 2)  2- Hard palate not touched  3- Completed exactly as described</p> <p><b>Elicit a Suck (finger or pacifier) up to 15 seconds</b></p> <p>0- No attempt made at all  1- Finger not placed at midline  2- Does not stroke the palate  3- Completed exactly as described</p> <p><b>Support of Non-Nutritive Sucking 2 minutes</b></p> <p>0- No attempt made at all  1- Finger/pacifier in mouth, but no sucking prompted  2- Finger/pacifier in mouth with sucking prompted part of the time  3- Completed exactly as described</p>
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<p>Steps done in order:</p> <p>0 - 5 out of 8  1 - 6 out of 8  2 - 7 out of 8  3 - All</p>	<p>Time of each step:</p> <p>0 - took &lt; 75% of time  1 - took &lt; 50% of time  2 - took &gt; allotted time  3 - correct time (+/- 5 sec)</p>	
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of behaviors,<sup>1</sup> thus decreasing variability in interventionist effects and increasing the rigor of the fidelity measure. The two researchers practiced rating several videotaped PIOMI performances, discussed areas where the methods for rating were ambiguous, and modified the instrument.

The three elements are all rated on one page of the rating instrument for ease of use. The left column is the area to rate the element of *time*. The exact time in seconds that it took to perform each step was documented on the rating tool during the performance and then transcribed into the Likert scale using the legend at the bottom of the tool. Because the time frames were as discreet as 15–30 seconds, it is acceptable to allow a reasonable amount of tolerance in rating time.<sup>31,32</sup> A margin of error of  $\pm 5$  seconds was given when the standard in a step was 30 seconds, and a margin of error of  $\pm 3$  seconds was given when the standard in a step was 15 seconds. The total time to perform all eight steps should be five minutes (tolerance for 29-week PMA infants) and was also documented. Time was measured using an analog clock hanging on the wall or a wristwatch.

The center section of the tool is for rating *technique*. All eight steps are listed with the descriptions for each step operationalized underneath. A four-point Likert scale was again developed to allow a higher degree of specificity than a binary choice of *correct* or *not correct*. For example, each rating for technique specifically described what variation and/or omission in technique would result in a rating of 0, 1, or 2, with 3 indicating that step was perfectly done (no variation). The observer circled the rating that most closely described the user's technique for each step. This ability to determine specifically how a step was done incorrectly would help to identify what areas of the PIOMI were more difficult to perform and/or may require more clarification in the training phase.

Finally, the level of correctness for *order* of the eight steps was recorded at the bottom of the tool using a four-point Likert scale, with all eight steps done in the correct order receiving the highest possible score of 3. In addition to rating the three elements, there is also a column for annotations if needed.

Ten scores can be recorded on the instrument: eight for the element of technique representing each of the eight steps, one for time, and one for order. The final score on the instrument can be used two ways: for training and for reliability testing. For training, an *overall* raw score and/or raw scores on each of the elements can test a single individual on his or her adherence and competence in performing the PIOMI. For reliability testing, more than one score can be compared and calculated as a percent agreement among the scores, such as when testing the test–retest reliability (the consistency of one user performing more than once over time)<sup>29</sup> and when establishing inter-user reliability (comparing performance among more than one user to determine if it can be reproduced consistently across users).<sup>29</sup> With the breakdown of the instrument into the three specific elements, the percent agreements can be calculated for

each of the individual elements, providing an opportunity to test competence and adherence to more focused behaviors. In addition, the overall percent agreements can be calculated to determine general performance of the intervention.

## PURPOSE

This study was designed to establish intervention fidelity of the PIOMI. First, interrater reliability was tested on the new reliability rating tool. Second, if interrater reliability was sufficient, the reliability rating tool was then used to test the interuser and test–retest reliability of performing the specific behaviors of the PIOMI.

## METHODS

Institutional review board (IRB) approval was granted by the research teams' affiliate university, as well as the community and hospital IRBs where the research was conducted.

### Setting and Sample


This study took place at a 45-bed Level III NICU at a large midwestern teaching hospital. A purposeful convenience sample consisted of three NICU registered nurses (RNs), with varying levels of experience performing oral motor therapy (20–100 times) on preterm infants and varying levels of NICU experience ranging from 7 to 34 years. Two RNs were past participants in the pilot study and thus had a basic level of training and experience specifically on the PIOMI. The third RN was chosen because she had no exposure to the PIOMI prior to this study. Informed consent was obtained from the three RNs to be tested for this study. The PIOMI was already standard of care in the NICU, so no additional consent for the infants was needed.

### Procedures

A standardized training program was created for this study to first train the raters testing the new instrument and then to train the three RNs being tested to establish intervention fidelity. In the review by Stein and colleagues,<sup>1</sup> the training of interventionists was found to be critical, and those methods need to be defined. Training typically requires a written manual, didactic training, and practice opportunities with the goal of the interventionist reaching the same level of adherence and competence as the researcher.<sup>1</sup>

In this study, a single two-hour training session was provided on site by the researchers. The three RNs were trained simultaneously to ensure consistency of training. The program included a didactic portion using written instructions with detailed explanations of each behavior required to perform the intervention, a basic training video demonstrating the techniques, and a hands-on group training session with the researchers to practice and get feedback. Along with the written instructions, a "quick reference" card

FIGURE 3 ■ Quick reference.



PREMATURE INFANT ORAL MOTOR INTERVENTION

## Quick Reference

Technique	Repetitions	Time
Cheek C - Stretch	2X each cheek	30 seconds
Lip Roll	1X each lip	30 seconds
Lip Curl	1X each lip	30 seconds
Gum Massage	2X	30 seconds
Lateral Tongue	1X	15 seconds
Midblade Tongue	2X	30 seconds
Elicit a Suck	N/A	<15 seconds
Support of Non-Nutritive Sucking	N/A	2 minutes

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(Figure 3) was provided to tape onto the incubator while performing the PIOMI. This quick reference showed the order of the steps, an abbreviated technique description including the correct number of repetitions, and the correct time for each step. In the video, the researcher performed the PIOMI on a full-term infant (rather than preterm) so that the larger oral cavity would allow better visualization of each step and did not require filming through an incubator. After viewing the video, a practice session was done on a model. The model was the user's own dominant hand performing the PIOMI steps on the nondominant hand in the closed fist position, with the thumb loosely mimicking a movable mouth and the opening of the fist mimicking the soft tissues of the perioral area. It also mimicked the proper placement of both of the user's hands, allowing only the dominant hand available to deliver the techniques while the other hand remains at the head. This model also allowed multiple practice sessions, which would not be feasible if done on an actual preterm infant. It was important that the specific methods of the intervention training program be standardized and evaluated so adjustments could be made if the training did not result in sufficient reliabilities to ensure intervention fidelity.<sup>1,2,27</sup>

### Statistical Analysis

Percent agreement is the statistic most consistently reported for interrater reliability.<sup>33–35</sup> Percent agreement is the only measure of variability appropriate for use with nominal data.<sup>29</sup> Continuous or interval data would require correlation coefficients. On the reliability rating tool, each item on the Likert scale was nominally operationalized into a specific behavior or category to lend itself best to percent agreement for all reliabilities, including interuser and test-retest. Although percent agreement is the most widely used measure for reliability,<sup>36</sup> it does not take into account the amount of agreement due solely to chance.<sup>29,37,38</sup> Therefore, percent agreement may overestimate true reliability. However, this overestimation is most pronounced when the ratings are dichotomous (the raters have a 50 percent chance of agreeing on chance alone)<sup>29,39</sup> and is one of the primary reasons for designing an expanded Likert scale for each of the elements on the instrument in this study. A common alternative is the kappa statistic; however, there is wide disagreement as to whether kappa is “chance-corrected” when used as a measure of agreement. Kappa may be very low even when there is a very high level of agreement.<sup>39</sup> A desirable percent agreement

is considered to be at least 70 percent on a new instrument, with 90 percent being the goal.<sup>29,40</sup>

### Determining Interrater Reliability to Test the Instrument

The two researchers observed three RNs performing the PIOMI twice each and rated all six performances using the reliability rating tool. This resulted in 12 performances being rated. Each RN had 48 behaviors within the three elements of time, order, and technique. Percent agreement was calculated for time, order, and technique within each of the eight individual steps and was then averaged for an overall interrater reliability.

### Determining Interuser Reliability

Interuser reliability for all three elements (order, technique, and time) was calculated by rating all three RNs performing the PIOMI and comparing their scores for percent agreement. This was repeated during each RN's second performance, doubling the number of performances to sample. The scores from each RN's two performances were averaged and compared with two other RNs' scores for percent agreement among three different users.

### Determining Test–Retest Reliability

Test–retest reliability for all three elements was calculated by rating each RN's first and second performances and comparing those for percent agreement. The total time between the first and second performances purposely ranged from 20 minutes to 24 hours to capture possible differences and was always done on a different infant, as would be the case in the clinical setting.

## RESULTS

Microsoft Office Excel 2004 version 11.5.8 was used for data entry. The results were analyzed using IBM SPSS Statistics 19 to calculate percent agreement for interrater, interuser, and test–retest reliability.

The interrater reliability on the new instrument resulted in high overall percent agreement of 98 percent between the two researchers (Table 1). Percent agreement broken down for each of the three elements (order, time, and technique) ranged from 95.5 to 100 percent. The high interrater reliability of >90 percent surpassed the sufficient level expected for a new instrument.<sup>29</sup> Therefore, the instrument was found to be sound to use for testing both interuser and test–retest reliabilities on the intervention, with the goal of establishing intervention fidelity.

The interuser and test–retest reliabilities were also high (see Table 1). First, all three users delivered the intervention with >90 percent agreement with each other, with the interuser agreements ranging from 96.3 to 98.5 percent. The interuser percent agreements within the three individual elements ranged from 93.3 to 100 percent, with the element of *correct time* having the lowest agreement, and *correct order*

**TABLE 1 ■ Reliability**

	Correct Order*	Correct Technique*	Correct Time*	Total Reliability*
<b>Interrater</b>	100.00%	97.20%	95.52%	<b>97.57%</b>
<b>Interuser</b>				<b>97.59%</b>
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%
<b>Test–retest</b>				<b>97.58%</b>
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%

Abbreviation: RN = registered nurse.

\*Percent agreement.

reaching total agreement between all three RNs. The test–retest reliability also resulted in 96–99 percent agreement between each RN's first and second overall performance. When examining each element, that of *correct order* and *correct technique* were delivered with total agreement between all three RNs' repeated performance, whereas *correct time* had the lowest agreement at 87 percent between only one RN's repeated performance.

Even though the >90 percent overall agreement is a more than sufficient reliability, it is valuable to identify the weakest areas to determine if they may require a modification in the training program. The elements of time and technique did not reach 100 percent agreement for interrater, interuser, or test–retest reliabilities. Therefore, those two elements were further broken down for a more detailed analysis to determine which of the elements resulted in the lowest percent agreements. Finally, the percent agreements were compared on the eight individual steps separately to determine if any specific steps had weaker reliabilities. Three of the eight steps resulted in slightly lower percent agreements (Table 2): the cheek C-stretch, lip curl, and midblade of tongue/palate.

When the element of *correct time* was evaluated separately from the other elements, it had the most significant and variable dip in percent agreements. One interuser pair had only a 66.7 percent agreement on time, even though another pair attained 100 percent agreement. One RN delivered the test–retest at 60 percent agreement for time between her two performances, whereas another RN attained 100 percent agreement.

## DISCUSSION

Our results indicate that the reliability rating tool can demonstrate high interrater reliability, and thus it was established as a sound measure to test for intervention fidelity. The high



**TABLE 2 ■ Element with Weakest Reliabilities**

	Interrater Reliability*	Interuser Reliability*	Test-Retest Reliability*
<b>Correct technique</b>			
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%
<b>Correct time</b>	86.67%–100.00%	66.67%–100.00%	60.00%–100.00%

\*Percent agreement.

interuser and test–retest percent agreements on the intervention indicate that the intervention can be delivered consistently among different users with variations in experience, on different infants, and by the same user more than once.

Despite high percent agreements for overall *technique*, there were three steps (cheek C-stretch, lip curl, and midblade of tongue/palate) that consistently resulted in lower technique scores than the other five steps. Each RN performed cheek C-stretch slightly differently, recorded in the anecdotal notes by the raters. For example, 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. When a variation in technique is identified, the description of those steps needs to be reevaluated for ambiguity. These three techniques may require improved explanation and reinforcement on how they are to be done in a revised training program.


The least reliable element was the *time* taken to perform each step. When measuring such a specific variable in seconds, variations in adhering to the exact time are understandable. The small sample size also increases the impact of one subject's variance. A larger sample size would provide a better picture of accurate adherence to time. From a practical standpoint, the lower reliabilities on time may have been because of either the inability of the users to accurately monitor time while performing the intervention and/or the rater's ability to accurately rate the time because of its specificity in seconds. In the future, digital forward-count timers are recommended to allow both the user and the observer to more accurately monitor time. Videotaping the performance would also allow for manual pauses to accurately monitor time as well as allow more than two raters to rate the performance and allow multiple ratings of each performance. Evaluating videotapes for interventionist behaviors is considered the gold standard test of treatment fidelity.<sup>1</sup> It may also be beneficial to have the users practice rating each other during the training session so they become more accustomed to the timing. Time may not be a crucial element if each step

only requires initial muscle activation. However, if allowing time for repetition provides an opportunity to further train the afferent neural pathways in the preterm infant brain for oral–motor skills related to feeding, it follows that time may indeed be a crucial element<sup>41</sup> and needs further exploration.








In response to this study, revisions were made to the training program to increase intervention fidelity in the weaker areas. First, a new training video was professionally produced by a media team. This video added a didactic introduction on oral motor development in preterm infants. It also improved the demonstration by filming each step performed on a real preterm infant in the actual NICU setting so that accurate behaviors could be seen related to technique, order, and time. Graphically designed illustrations of each step were also created and included on the video. To enhance the practice section of the training program, an uninterrupted real-time demonstration was filmed for “follow-along practice” that can be paused and replayed as necessary for learners to practice along with the researcher. The method of using a fist with the thumb as a movable mouth is also demonstrated so learners can practice without a live infant. Proper positioning of the infant is also included in the new training video. Preterm infants have poor head/neck control, and positioning may play a role in muscle activation in and around the oral cavity.<sup>42</sup> 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 semiflexed position. Although the flexed position was properly demonstrated on the original training video, that infant was a term infant with increased muscle development and head/neck control and much larger in size than the 29-week PMA infant. Contact information of the researcher who developed the PIOMI was also provided at the end of the video for users to consult as they train.

Because intervention fidelity was achieved with professional staff in this study, the researcher has since developed a “parent version” of the PIOMI tool with simplified language and the addition of illustrations for each step (Figure 4). In the climate of family-centered care, parents delivering the intervention may add to their satisfaction by having an increased role in their infant's outcomes, which may result in an earlier discharge home. A developmental clinic that does preterm infant

**FIGURE 4 ■** Premature infant oral motor intervention illustrated tool.



PREMATURE INFANT  
**ORAL MOTOR INTERVENTION**

8 Steps	Technique	
<b>Cheek C - Stretch</b>  <b>(30 Sec.)</b>	One finger in the cheek and one outside cheek. Slide and stretch tissue front to back toward the ear, & back to front. Move slowly. Do both cheeks twice.	
<b>Lip Roll</b>  <b>(30 Sec.)</b>	Gently roll the lip between your thumb and finger (like rolling a pea). Roll both sides of upper lip once. Roll both sides of lower lip once.	
<b>Lip Curl or Lip Stretch</b>  <b>(30 Sec.)</b>	Compress lip between thumb and finger, and curl downward. Curl both sides of upper lip once, and both sides of lower lip once.  If lip is too small to grip for the curl, do the Lip Stretch: Lay finger across upper lip, gently compress and stretch side to side. Repeat on lower lip.	
<b>Gum Massage</b>  <b>(30 Sec.)</b>	Use finger to put gentle pressure on outside of upper gum. Move finger slowly around upper gum to other side of mouth. (Be sure to touch outer gum surface, not biting surface.) Repeat on lower gum.	
<b>Lateral Borders of Tongue/ Cheek</b>  <b>(15 Sec.)</b>	Put finger beside tongue and push to the middle. Then move finger back into cheek, stretching it. Repeat on the other side of tongue/cheek.	
<b>Midblade of Tongue/ Palate</b>  <b>(30 Sec.)</b>	Use finger to put pressure on roof of mouth for 3 seconds. Move finger down to tongue and gently press tongue down. Move finger back up to hard palate. Repeat these movements twice.	
<b>Elicit a Suck</b>  <b>(15 Sec.)</b>	Put finger or pacifier on tongue and gently stroke to allow sucking.	
<b>Support for Non- Nutritive Sucking</b>  <b>(2 Min.)</b>	Allow sucking on finger or pacifier for 2 minutes.	

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follow-up visits requested the simplified version of the tool to use along with the video to teach parents of infants who have been discharged from the NICU and instructed to use it at home. This is a modification of the training program; therefore, use of this illustrated version should also be evaluated.

Initial intervention fidelity has been established in this pilot study. Fidelity studies should be continued on the PIOMI using a larger sample size and incorporated into future outcome studies. For example, the frequency, intensity, and duration of the intervention to achieve optimal outcomes needs further testing. With infant-directed feeding becoming standard practice, it will be important to determine if the PIOMI has an effect on feeding readiness scores. It is important to note, however, that, because the 29-week preterm infants studied are fairly homogeneous in oral motor sensitivity and response, the PIOMI may be a safe and effective program to start with but may need modification as the infant progresses in development. As neurodevelopment and subsequent feeding skills become increasingly varied among infants as they grow, oral motor therapy needs to include increased evaluation by a trained therapist as these steps are used so the need for any variation in treatment can be assessed and implemented.

Testing the fidelity of a new intervention is essential to build evidence that an intervention can be properly taught and consistently performed before translating evidence-based interventions into practice. The high overall reliability in performing the PIOMI is encouraging and points to solid intervention fidelity. Fidelity measures are valuable when a clinical trial yields significant treatment outcomes. In future outcome studies, establishing fidelity of the intervention provides confirmation that the manipulation of the independent variable occurred as planned, thus supporting the internal validity of the research.<sup>1</sup> In addition to increasing the confidence in the study's internal validity, the fidelity measures provide a road map for replication.<sup>27</sup> Also, ongoing fidelity monitoring is important over the course of a study, especially over multiyear studies,<sup>27</sup> to ensure that the treatment continues to be delivered as assigned. Existence of good fidelity measures also make it easier for researchers to describe their interventions in the literature and for other researchers to synthesize research when doing literature reviews.<sup>27</sup>

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