

Establishing Intervention Fidelity in Neonatal Practice: Lead the Way

*Dr. Brenda S. Lessen, PhD, RN
Associate Professor of Nursing
Illinois Wesleyan University*

13th National
Advanced Practice
Neonatal Nurses Conference



Sheraton Hotel and Marina
San Diego, California

Objectives

- Define Intervention Fidelity
- Discuss the importance of establishing intervention fidelity in nursing research
- Identify the essential steps in creating a tool to measure intervention fidelity
- Describe how to test Intervention Fidelity

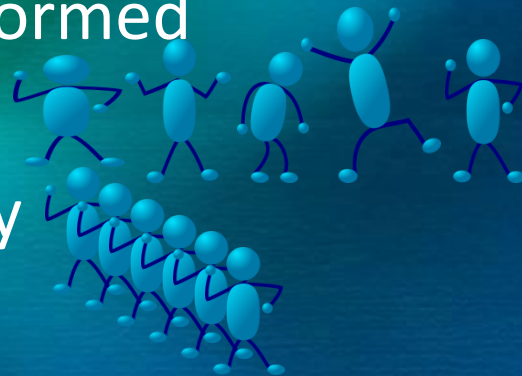


What is Intervention Fidelity?

- The competent and reliable delivery of an intervention or treatment by the interventionist .^{1,2}

It means that...

- ✓ An intervention can be clearly and accurately taught
- ✓ It can be consistently performed
 - Interuser reliability
 - Test-retest reliability
- ✓ We can believe it's effect in a RCT



Importance of Fidelity

- Fidelity of the intervention is foundational to the internal validity of an outcome study¹⁻³
- Integral to both the interpretation and generalization of research findings (internal & external validity)
- VITAL before translating “evidence” into practice

***Intervention
(cause)***

Delivery

***Outcome
(effect)***

“EVIDENCE”? → PRACTICE?



Implications for Internal Validity

The internal validity of an outcome study is dependent on the systematic and reliable delivery of the independent treatment variable. ^{3,5}

Significant Results



May be due to an effective treatment
or

unknown variables added to the treatment?

Non-significant Results



May be due to an ineffective treatment
or



a treatment that was inadequately administered?

Without fidelity of the intervention used...

we can't know!



Implications for Internal Validity

- Ensure that treatment “dose” (treatment intensity-measured by number, frequency, length of contact) **is the same for each subject** within a particular treatment condition
- Ensure that treatment “dose” **is the same across interventions** that include multiple behaviors and across treatment and control/comparison groups
- Lack of standardization within and between providers, and variation in treatment intensity and content across participants  inflates error variance  decreases power

Implications for External Validity

- Benefits of High Fidelity
 - Standardized training program established
 - Replication of treatment in other studies
 - Generalization of treatment to applied settings
 - Dissemination
- Costs of Low Fidelity
 - Rejection of effective interventions
 - Acceptance of ineffective interventions

Lead the Way.....

- Establishing fidelity is a KEY methodological strategy to enhance validity and reliability of behavioral interventions
- Nursing literature has historically been very limited in assessing intervention fidelity^{2,4}
- There is very little guidance on how fidelity of an intervention or treatment should be established
- Advanced Practice RNs are at the frontline of accessing, critiquing and applying research findings
- Neonatal interventions should be assessed for fidelity before evidence of their efficacy can be translated to practice

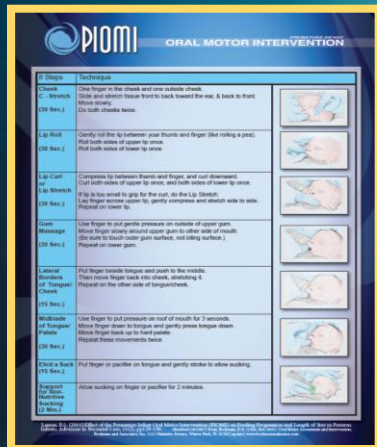


How to Test for Intervention Fidelity

Case Example

The Premature Infant Oral Motor Intervention (PIOMI) ⁵

- A 5 minute oral motor intervention to provide assisted movement to activate muscle contraction and provide movement against resistance to build strength
- Cheeks, lips, gums, tongue and palate are stimulated per specific protocol with finger stroking for 3 minutes
- Ends with non-nutritive sucking for 2 minutes
- **OUTCOME:** improves feeding (shorter transition from tube to bottle)



How to Test for Intervention Fidelity

Training Tool

- Standardize the **training** for the intervention
- Design a **tool** to measure key elements/behaviors of the intervention
- Test the tool for its own reliability before it is used to rate the behaviors
- Use the tool to establish reliable delivery of the intervention
 - Interuser and test-retest reliabilities

Training is Critical

- Providers must be properly trained to deliver the intervention
- **Standardized** Training Program:
 - Time frame – single 2 hour session
 - Didactic
 - Written instructions
 - Video demonstration
 - Hands-on practice
 - Return demonstration
 - Evaluate the training



Developing a Tool to Test Fidelity

- Scoring rubrics are often used when testing behaviors
- Stein and colleagues¹ identified steps in creating a tool to test an intervention:
 1. Identify essential, observable behaviors specific to the intervention
 2. Construct a rating scale for each behavior
 3. Train raters to use the tool
 4. Pilot test the tool
 - a) Determining its *interrater* reliability
 - b) If raters reliabilities are good, raters can use the tool to rate others

The image shows a sample of the PIOMI Reliability Rating Tool, a scoring rubric for premature infant oral motor interventions. The tool is a form with a header that reads "PIOMI PREMATURE INFANT ORAL MOTOR INTERVENTION Reliability Rating Tool". It contains a list of interventions, each with a corresponding rating scale and a time limit. The interventions listed are: Cheek C-Stretch (2x each cheek) 30 sec, Lip Roll (1x each lip) 30 sec, Lip Curl OR Lip Stretch (1x each lip) 30 sec, Gum Massage (upper and lower, 2x around) 30 sec, Lateral Borders of Tongue/Cheek (1x each side) 15 sec, Middle of Tongue/Palate (2x) 30 sec, Elicit a Suck (finger or pacifier) up to 15 seconds, and Support of Non-Nutritive Sucking 2 minutes. Each intervention has a rating scale with three options: 0 - No attempt made at all, 1 - Only one [behavior] made at all, and 2 - Completed exactly as described. The form also includes a section for "Steps done in order" and a "Time of each step" section.

Intervention	Rating Scale	Time
Cheek C-Stretch (2x each cheek)	0 - No attempt made at all 1 - Only one cheek stretched 2 - Completed exactly as described	30 sec
Lip Roll (1x each lip)	0 - No attempt made at all 1 - Only one lip rolled 2 - Completed exactly as described	30 sec
Lip Curl OR Lip Stretch (1x each lip)	0 - No attempt made at all 1 - Only one lip done 2 - Completed exactly as described	30 sec
Gum Massage (upper and lower, 2x around)	0 - No attempt made at all 1 - Only one gum massaged 2 - Completed exactly as described	30 sec
Lateral Borders of Tongue/Cheek (1x each side)	0 - No attempt made at all 1 - Only one side of the tongue is moved 2 - Completed exactly as described	15 sec
Middle of Tongue/Palate (2x)	0 - No attempt made at all 1 - Wrong repetitions (should be 2) 2 - Completed exactly as described	30 sec
Elicit a Suck (finger or pacifier) up to 15 seconds	0 - No attempt made at all 1 - Finger not placed at midline 2 - Does not stroke the palate 3 - Completed exactly as described	up to 15 seconds
Support of Non-Nutritive Sucking 2 minutes	0 - No attempt made at all 1 - Finger/pacifier in mouth, but no sucking prompted 2 - Finger/pacifier in mouth with sucking prompted 3 - Completed exactly as described	2 minutes

Steps done in order: 0 - 5 out of 8, 1 - 6 out of 8, 2 - 7 out of 8, 3 - All

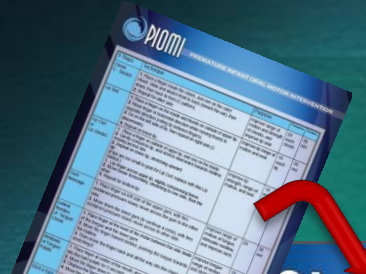
Time of each step: 0 - took < 75% of time, 1 - took < 50% of time, 2 - took > 50% of time, 3 - correct time (~ 5 sec)

3 Essential Behaviors

- Performing the 8 steps in the correct **ORDER**
- Performing each step using correct **TECHNIQUE**
- Performing each step for the correct amount of **TIME**

Rating Scale for Each One

- Dichotomous too vague
- Likert Scale 0-3
 - Increases specificity
 - Decreases variability
- Score the tool
 - Each behavior
 - Overall score



PIOMI PREMATURE INFANT ORAL MOTOR INTERVENTION

Reliability Rating Tool

Write TIME in seconds: See Likert Scale below

<input type="checkbox"/>	Cheek C-Stretch (2x each cheek) 30 sec 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
<input type="checkbox"/>	Lip Roll (1X each lip) 30 sec 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
<input type="checkbox"/>	Lip Curl OR Lip Stretch (1X each lip) 30 sec 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
<input type="checkbox"/>	Gum Massage (upper and lower, 2X around) 30 sec 0- No attempt made at all 1- Only one gum massaged 2- Wrong repetitions 3- Completed exactly as described
<input type="checkbox"/>	Lateral Borders of Tongue/Cheek (1X each side) 15 sec 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
<input type="checkbox"/>	Midblade of Tongue/Palate (2X) 30 sec 0- No attempt made at all 1- Wrong repetitions (should be 2) 2- Hard palate not touched 3- Completed exactly as described
<input type="checkbox"/>	Elicit a Suck (finger or pacifier) up to 15 seconds 0- No attempt made at all 1- Finger not placed at midline 2- Does not stroke the palate 3- Completed exactly as described
<input type="checkbox"/>	Support of Non-Nutritive Sucking 2 minutes 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

Steps done in order:	0 - 5 out of 8 1 - 6 out of 8 2 - 7 out of 8 3 - All	Time of each step:	0 - took < 75% of time 1 - took < 50% of time 2 - took > allotted time 3 - correct time (+/- 5 sec)
----------------------	---	--------------------	--

Train the Raters

- We trained two raters, and tested interrater reliability on the tool
- Percent Agreement: most widely used statistic for interrater reliability⁶⁻⁸
- Percent agreement used for nominal data
- Standard desirable percent agreement is:
 - 70% for new instrument
 - 90% the goal

The tool demonstrated a 98% interrater reliability



A sound measure to test for intervention fidelity

Test Intervention Fidelity

- Determining **interuser reliability**
 - Rating multiple users performing the PIOMI (on different infants) over two separate performances
 - Average scores from the two performances for each user
 - Compare averaged scores among all users for percent agreement
- Determining **test-retest reliability**
 - Rating of the same user performing the PIOMI (on different infants) over two separate performances
 - Compare scores between that users two performances for percent agreement



Results

Table 1

Reliability

	Correct Order <input type="checkbox"/>	Correct Technique <input type="checkbox"/>	Correct Time <input type="checkbox"/>	Total Reliability <input type="checkbox"/>
<u>Interrater</u>	100.00%	97.20%	95.52%	97.57%
<u>Interuser</u>				97.59%
<i>RN A and RN B</i>	100.00%	95.83%	93.33%	96.39%
<i>RN A and RN C</i>	100.00%	97.87%	97.87%	98.58%
<i>RN B and RN C</i>	100.00%	97.92%	95.45%	97.79%
Test-retest				97.58%
<i>RN A</i>	100.00%	100.00%	95.65%	98.55%
<i>RN B</i>	100.00%	100.00%	95.35%	98.45%
<i>RN C</i>	100.00%	100.00%	87.23%	95.74%

☐ Percent agreement

- Exceeded the 70% standard, and the 90% goal
- With the stated training, the intervention can be systematically and reliably delivered
- The PIOMI has established intervention fidelity

Using scores to revise training

- Calculations were also done on the 8 individual steps
- Areas with the weaker reliabilities prompted me to adjust the training on those areas
 - New training DVD professionally produced
 - Filmed a real preterm infant to demonstrate each step
 - Included a “practice” segment to practice along with me
 - Demonstration of the “fisted hand” for practice

Table 2

Elements with Weakest Reliabilities

	<u>Interrater</u> Reliability□	<u>Interuser</u> Reliability□	Test-retest Reliability□
Correct Technique			
<i>Cheek C-Stretch</i>	94.44%	91.67%-100.00%	83.33%-100.00%
<i>Lip Curl</i>	94.12%	75.00%-100.00%	80.00%-100.00%
<i>Midblade of Tongue</i>	88.89%	83.33%-100.00%	100.00%
Correct Time	86.67%-100.00%	66.67%-100.00%	60.00%-100.00%

□Percent agreement

Implications for Research and Practice

- Evidence is built for this intervention's fidelity
 - Continue testing it in future studies
- Increases integrity of the research on the PIOMI
- A good fidelity measurement tool makes it easier to accurately and specifically describe the intervention in the literature for further studies
- The tool can also be used for initial training
- And then periodically to assess maintenance of the skill over time

Implications for Research and Practice

- Provides confirmation that the manipulation of the independent variable in the study occurred as planned
 - So we can believe that the “effects” were the result of the “cause” the way we described it



Hooray!

“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.”⁵

Primary References

1. Stein KF, Sargent JT, Rafaels N. Intervention research: establishing fidelity of the independent variable in nursing clinical trials. *Nurs Res*. 2007;56(1):54-62.
2. Santacroce SJ, Maccarelli LM, Grey, M. Intervention fidelity. *Nurs Res*. 2004;53(1):63-66.
3. Calsyn RJ. A checklist for critiquing treatment fidelity studies. *Ment Health Serv Res*. 2000; 2(2):107-113.
4. Bond GR, Evans L, Salyers M, Williams J, Hea-Won K. Measurement of fidelity in psychiatric rehabilitation. *Ment Health Serv Res*. 2000; 2(2):75-87.
5. Lessen BS, Morello CA, Williams, LJ. Establishing intervention fidelity of an oral motor intervention for preterm infants. *Neo Network*. 2015;34(2):72-82.
6. Daving Y, Andrén E, Grimby G. Inter-rater agreement using the instrumental activity measure. *Scand J Occup Ther*. 2000; 7(1):33-38.
7. Gardner SE, Frantz RA, Park H, Scherubel M. The inter-rater reliability of the Clinical Signs and Symptoms Checklist in diabetic foot ulcers. *Ostomy Wound Manage*. 2007; 53(1):46-51.
8. To T, Estrabillo E, Wang C, Cicutto L. Examining intra-rater and inter-rater response agreement: A medical chart abstraction study of a community-based asthma care program. *BMC Med Res Methodol*. 2008; 8:29.

Contact Information

Brenda S. Lessen, PhD, RN
Associate Professor of Nursing
Illinois Wesleyan University
PO Box 2900
Bloomington, IL 61702
blesen@iwu.edu
309-212-0544(c)
309-556-3279(w)



For PIOMI Training/Information, contact blesen@iwu.edu
PIOMI Training Bundle or On-Site Training