

## Using Formative Research to Develop a Hospital-Based Perinatal Public Health Intervention in the United States: The Thirty Million Words Initiative Newborn Parent Education Curriculum

Eileen Graf, PhD<sup>1</sup>  
Livia Garofalo, MA<sup>2</sup>  
Alison C. Hundertmark, MA<sup>3</sup>  
Glenda L. Montague, BA<sup>4</sup>  
Nicole M. Polash, MS<sup>5</sup>  
Elizabeth Suskind, BS<sup>3</sup>  
Kristin R. Leffel, BS<sup>3</sup>  
Robert J. Webber, BA<sup>6</sup>  
Dana L. Suskind, MD<sup>3</sup>

<sup>1</sup>NORC at the University of Chicago, Academic Research Centers

<sup>2</sup>Northwestern University, Department of Anthropology

<sup>3</sup>University of Chicago Medicine, Department of Surgery, Division of Otolaryngology

<sup>4</sup>University of California, San Francisco, Department of Otolaryngology, Division of Pediatric Otolaryngology

<sup>5</sup>Erikson Institute

<sup>6</sup>University of Chicago, Department of Statistics

**Abstract:** Parents and caregivers do not exist in a vacuum and, with regard to crafting impactful interventions, it is increasingly being recognized that there are no one-size-fits-all approaches to behavior change. Implementing research to practice is a complex endeavor and requires the adaptation of basic research findings to different cultural and environmental contexts of intended beneficiaries (Sepinwall, 2002; Weisner & Hay, 2014). The practice of formative research allows for the systematic assessment of diverse implementation contexts and provides insights into responsive adaptations of content and delivery. In this study, we detail the use of formative testing to inform the development of a curriculum designed to support the Universal Newborn Hearing Screening (UNHS). The Thirty Million Words Initiative Newborn (TMW-Newborn) Parent Education Curriculum provides caregivers of newborns with information on the UNHS. The curriculum also illustrates the importance of identifying newborns who are deaf or hard of hearing (DHH) to ensure that caregivers learn how to promote early language development. The information provided could potentially reduce lost-to-follow up (LFU) rates for newborns who may be DHH. Using qualitative methods, we collected and responded to feedback obtained from caregivers of newborns and were able to gear content, messaging, and delivery of the intervention to stakeholder needs. A subsample of participants also completed a knowledge survey testing their understanding of intervention content prior to receiving the intervention, as well as the day after. The results showed that participant scores increased significantly post-intervention.

**Key Words:** Universal Newborn Hearing Screening, Newborn Screening, Formative Research, DHH, Intervention, Public Health, Language Development

**Acronyms:** ASL = American Sign Language; CDC = Centers for Disease Control and Prevention; DHH = deaf or hard of hearing; EHDI = Early Hearing Detection and Intervention; EI = early intervention; HL = hearing loss; LFU = lost-to-follow up; MBU = Mother-Baby Unit; NICU = Neonatal Intensive Care Unit, RCT = randomized controlled trial; SES = socio-economic status; TMW-Newborn = Thirty Million Words Initiative Newborn; Universal Newborn Hearing Screening (UNHS)

**Correspondence concerning this article should be address to;** Eileen Graf PhD, NORC at the Univeristy of Chicago, 1155 East 60th Street, 2nd Floor, Chicago, IL 60637. Phone: 773-256-6215 Email: graf-eileen@norc.org

### Introduction

Congenital hearing loss (HL) affects approximately 1 to 3 in 1000 newborns (Gaffney, Gamble, Costa, Holstrum, & Boyle, 2003) and has profound health and educational implications. If undetected, hearing loss can have severe effects on children's early social, emotional, and cognitive development which, in the long-term, prevents children from reaching their academic and economic potential. Children's ability to use language depends critically on early

experience (Gauthier & Genesee, 2011; Kral & Sharma, 2012; Ruben, 1999). Growing language competencies during the first 12 months predict later development (Markus, Mundy, Morales, Delgado & Yale, 2000; Ramirez-Esparza, García-Sierra, & Kuhl, 2014; Wu & Gros-Louis, 2014). Additionally, delayed identification and management of severe to profound hearing loss impedes the child's ability to succeed academically, socially, and vocationally (Moeller, 2000, 2007; Yoshinaga-Itano & Mah-rya, 1998).

With the implementation of the Early Hearing Detection and Intervention Act (EHDI) in 2010, and the subsequent nationwide adoption of Universal Newborn Hearing Screening (UNHS) in the immediate postpartum period, practitioners were able to decrease the age of HL detection on average from three years to three months for children born in the United States (Harrison, Roush, & Wallace, 2003; Hoffman & Beauchaine, 2007; White & Muñoz, 2008). According to a 2016 report on 2014 UNHS data, the Centers for Disease Control and Prevention (CDC) report that 97.9% of newborns in the United States were screened for hearing loss. Of those newborns, 98.4% were found to have normal hearing, but 1.6% ( $N = 63,341$ ) did not pass their final hearing screening, indicating that they may be DHH. After this initial screening in the hospital, caregivers must then follow up on their infants' hearing status with an audiologist to receive the next step of treatment, either rescreening or comprehensive audiologic evaluation. Of the 1.6% ( $N = 63,341$ ) of children who did not pass their hearing screening in the hospital, 57.6% ( $n = 36,472$ ) received a comprehensive follow-up evaluation with an audiologist (CDC, 2016), as initiated by their caregivers. 9.7% ( $n = 6,163$ ) of these children were diagnosed with hearing loss (of which 87.9% [ $n = 5,419$ ] were subsequently referred for early intervention [EI] services). This makes the UNHS one of the most successful public health initiatives in recent history and showcases the practicability of implementing a public health intervention at the population level.

However, the CDC reports that a sizeable number of newborns (34.4%,  $n = 21,819$ ) who did not pass the UNHS also did not receive timely further evaluation; they were reported as *Lost to Follow-Up*<sup>1</sup> (LFU). That is, their caregivers did not schedule the necessary rescreening or audiologic evaluation and therefore, put their children at risk of not acquiring language (spoken or signed), which may lead to adverse cognitive development. The causes of LFU are complex. Barriers to follow-up include issues of transportation, distance of the follow-up facility from home, insurance type/cost, multiple re-screens, whether or not the baby was in the Neonatal Intensive Care Unit (NICU), or caregiver anxiety about the screening (Beger & Loveland Cook, 1998; Bowman, 2005; Crockett, Baker, Uus, Bamford, & Marteau, 2006; Spivak, Sokol, Auerbach, & Gershkovich, 2002; Vohr, Letourneau, & McDermott, 2001).

Another substantial factor affecting follow-up rates (Cockfield, Garner, & Borders, 2012) is caregiver understanding of children's language development, specifically, the impacts of hearing loss on language and brain development. A lack of caregiver knowledge about healthy child development has been linked to caregiving/parenting behaviors such that children of caregivers with more up-to-date knowledge of child development fare better, especially in terms of language development (Rowe, 2008). With regard to the UNHS specifically, there is an added concern that parents are not provided with an adequate explanation of the use and importance of the hearing screening. For similar reasons, it is also

unclear whether caregivers understand that they are required to follow-up in the event of a negative screening. Notably, however, caregiver knowledge and behavior has been shown to be malleable, leading to increases in understanding and awareness, and subsequently, to changes in the corresponding parenting behavior (Bentley et al. 2014; Suskind et al., 2015). Up-to-date knowledge of the effects of congenital hearing loss on early language and cognitive development and the preventative role of the UNHS are fundamental in ensuring that caregivers pursue treatment for their children. To this end, we conceived of an adjunct to the UNHS: The Thirty Million Words Initiative Newborn (TMW-Newborn) Parent Education Curriculum, a short, video-based intervention presented to caregivers while their newborns receive the hearing screening.

### The Importance of Formative Research

Caregivers and parents do not exist in a vacuum, and with regard to crafting impactful interventions, it is increasingly being recognized that there are no one-size-fits-all approaches to behavior change. Implementing research to practice is a complex endeavor and requires the adaptation of basic research findings to different cultural and environmental contexts of intended beneficiaries (Sepinwall, 2002; Weisner & Hay, 2014). However, all too often evidence-based interventions are being implemented without consideration of the "cultural beliefs and 'ethnotheories' of care [and] parenting [...] that guide caregiver behavior" (Bentley et al., 2014, p. 64).

In an attempt to identify and understand the interests, behaviors, and needs that influence the decisions and actions of target populations, researchers have adopted a methodology from the social sciences: Formative research or evaluation allows for the systematic assessment of the complexities of diverse implementation contexts and provides insights into responsive adaptations of content and delivery. Stetler et al. (2006) define formative research as "a rigorous assessment process designed to identify potential and actual influences on the progress and effectiveness of implementation efforts" (p. S1).

The strength of formative research lies in its ability to identify barriers to participation, issues in intervention content, messaging and delivery, and any other unexpected factors that may be affecting outcomes. Therefore, intervention development is an iterative process and co-occurs with the use of qualitative methods as part of a participatory design (Bourgeault, Dingwall, & De Vries, 2010; Morse & Cheek, 2014; Nichter, Nichter, Thompson, Shiffman, & Moscicki, 2002; Padgett, 2012). Through the use of focus groups, informant interviews, and experiential feedback researchers can establish the greatest fit between intervention design/implementation and the cultural and environmental context of the intended beneficiary

<sup>1</sup>Per CDC data (CDC, 2016); parents of LFU patients are either unresponsive or cannot be contacted.

(Bentley et al., 2014; Danaher, Smith, Telang, & Chen, 2012; Gittelsohn et al., 2006; Neuhauser, Rothschild, Graham, Ivey, & Konishi, 2009).

Parenting and caregiving behaviors differ by cultural group and socio-economic status (SES; Connell & Prinz, 2002; Hoff, 2013; Rowe, 2008). These differences are expected to interact with content and delivery of the proposed intervention. We conducted informant interviews at each iteration throughout the development process of the parent education curriculum to be responsive to caregiver knowledge, beliefs, and needs, as well as address the needs of caregivers of newborns from diverse backgrounds and SES. After each wave of interviews, aspects of intervention design and delivery were changed based on formative participant feedback.

### **The TMW-Newborn Parent Education Curriculum**

The development of the intervention prototype began with translational research of recent findings in child development. Then, hearing technicians and pediatricians contributed expert content and helped prioritize topics. Pediatricians further reviewed the content and feasibility of the curriculum prototype (Stage 1, see Figure 1) and provided input throughout the process when appropriate (see Results, Wave 3). This prototype was then iteratively reviewed with members of the target population using qualitative methods such as key informant interviews and experiential feedback to create a relevant and appealing intervention (Stage 2). We employed this formative research process to test and evaluate messaging, presentation, and timing of the intervention. Through this process, documented in detail below, we were able to identify target population knowledge and refine intervention content and delivery according to beneficiary input. By being responsive to the ways in which caregiver beliefs, knowledge, and practices interact with intervention uptake, we have developed an intervention that is uniquely geared toward stakeholders. The research design, implementation, and findings described in this paper refer to Stage 2 of the formative research process (see Figure 1).

The intervention video sets the stage by explaining that the UNHS is a critical component of early care because language is essential to babies' brain, language, and social-emotional development. Next, the intervention illustrates the idea that intelligence is malleable, and that language is a critical component in reaching full academic potential. Caregivers have the power to enhance their infants' nascent abilities by being responsive to their children's needs. Through initiating a rich dialog with children, caregivers provide infants with a high quality language environment. Spoken or signed language and other means of care go hand in hand here since every contact with a baby is communicative.

The video introduces three simple messages, called the 3 T's, which are intended to help establish and foster a rich language environment for the baby: *Tune In!*, *Talk More!*, and *Take Turns!* *Tune In!* means responding to everything the baby communicates to build secure attachment between the baby and the caregiver. The video dispels the notion that an infant can be spoiled by too much attention. It describes how children learn the most when caregivers comment on what their child is focused on at that time, and explains the benefits of child-directed speech. *Talk More!* explains how caregivers can support their child's language learning by using descriptive language during all activities involving the infant. Importantly, this T refers to spoken as well as signed language. *Take Turns!* illustrates the benefits of engaging the child in early conversation by establishing eye contact and by waiting for them to respond in whatever early communicative way they can (e.g., cooing, babbling, eye contact) to help them learn how to communicate.

The TMW-Newborn Parent Education Curriculum uses video and animation to convey the importance of newborns' language environments and illustrate strategies parents can use to promote language learning and secure attachment in their infants. The curriculum also explains the critical importance and purpose of UNHS for the language learning process. Messaging and strategies are specifically tailored to caregivers of neonates up to six months of age, with a focus on preverbal communication and mother-child attachment. Families are strongly encouraged to follow up after the screening if their newborn is referred for further testing.

## **Method**

### **Participants**

Participants were recruited from the Mother-Baby Unit (MBU) at the University of Chicago Medicine. The participant sample consisted of a total  $N = 70$  mothers. All participants were over the age of 18, spoke English, and had given birth within the last day or two. The total sample was distributed across five waves ranging from  $n = 11$  to  $n = 22$  participants per wave. Each participant contributed to only one wave of formative research. Participants ranged in age from 18–51 years ( $M = 29.8$ ). Thirty percent ( $n = 21$ ) of the sample reported education levels equivalent to elementary school, high school degree, or GED. Thirty-three percent ( $n = 23$ ) were in possession of an Associate's degree or trade/vocational school certificate, or had taken some college classes. Another 37% ( $n = 26$ ) had a Bachelor's or Master's degree. Sixty-seven percent of the sample identified as African-American ( $n = 47$ ), 16% as White ( $n = 11$ ), 7% as Multiracial ( $n = 5$ ), 6% as Hispanic/Latino ( $n = 4$ ), 3% as Asian/Pacific Islander ( $n = 2$ ), and

**Table 1**  
*Participant Demographics Per Wave and Subsample*

		Wave 1	Wave 2	Wave 3	Wave 4	Wave 5	p-value	Test-takers only
		<i>n</i> = 12	<i>n</i> = 12	<i>n</i> = 22	<i>n</i> = 13	<i>n</i> = 11		<i>n</i> = 40
Age	Range	24-22	20-51	18-44	18-41	20-42	0.72	18-44
	Mean	32.1	29.1	27.7	29.5	30.8		29.4
Education	Elementary	0	0	2	0	0	0.07	2 (5%)
	GED	1	3	4	0	2		5 (12%)
	High School Diploma	0	0	5	3	1		7 (18%)
	Trade / Vocational School	0	0	0	1	0		1 (2%)
	Some College (No Degree)	3	2	1	5	4		10 (25%)
	Associate's Degree	1	1	2	1	2		3 (8%)
	Bachelor's Degree	3	0	3	3	2		7 (18%)
	Post-Bachelor's Degree	4	6	5	0	0		5 (12%)
Race	Asian/ Pacific Islander	1	1	0	0	0	0.16	0 (0%)
	Black / African-American	5	8	18	9	7		28 (70%)
	Hispanic / Latino	2	0	0	0	2		2 (5%)
	Multiracial	2	0	0	2	1		3 (8%)
	Other	0	0	0	1	0		1 (2%)
	White	2	3	4	1	1		6 (15%)
Health Care	Medical Card	6	5	15	7	7	0.55	23 (58%)
	No Health Insurance	0	0	0	1	0		1 (2%)
	Private Insurance	6	6	7	5	4		16 (40%)

*Note.* The balance table shows strong evidence of homogeneity between difference waves. Chi-squared tests were used for categorical data and an analysis of variance was used for age data (R Core Team, 2015, *p*-values determined by resampling), with insignificant results (*p* > .05). In the last column, test-takers are isolated from the rest of the sample.

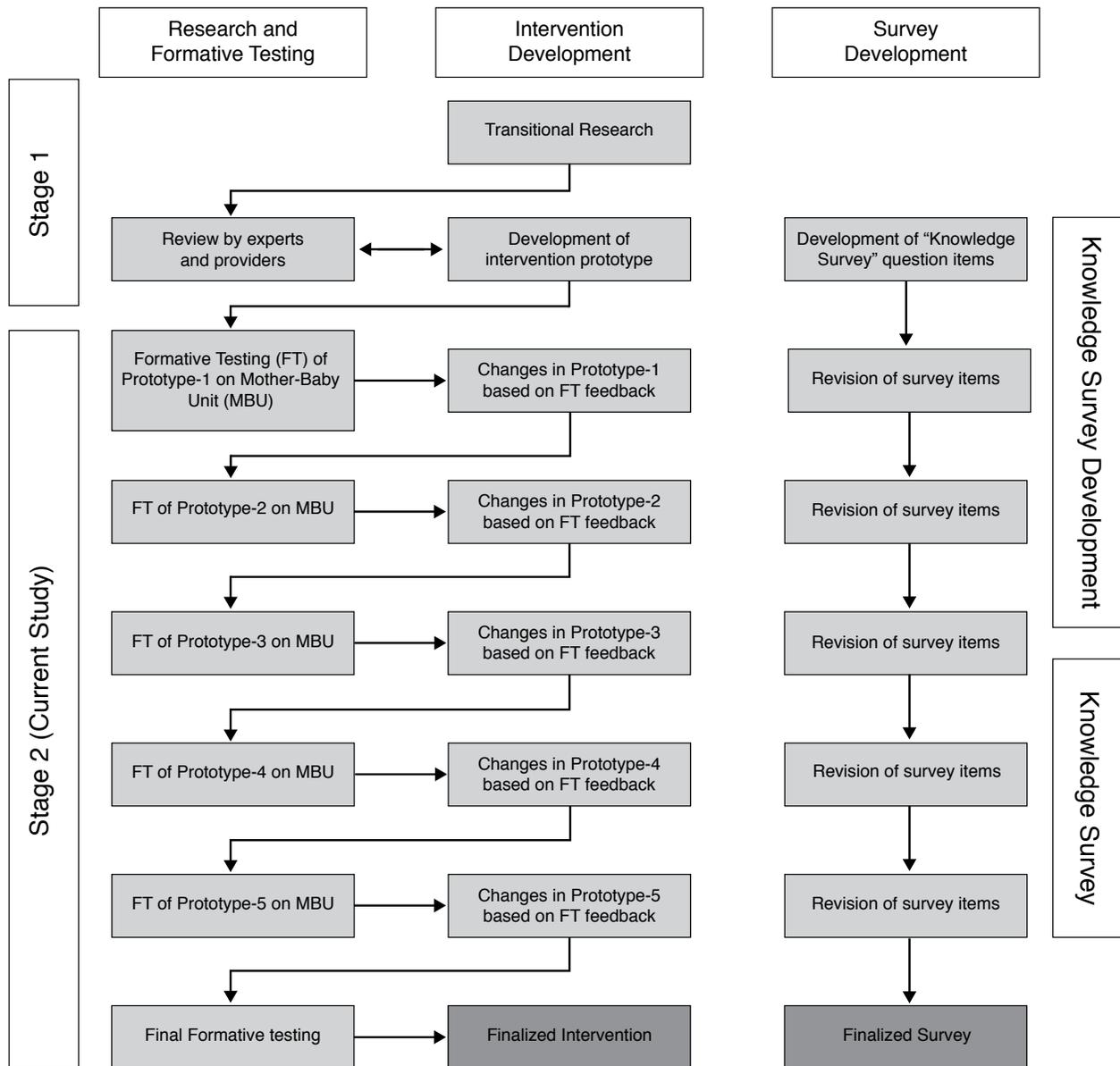
1% as Other (*n* = 1). The majority of participants (60%, *n* = 42) received Medicaid. For an overview of participant demographics, please see Table 1.

### Design

The intervention was tested in five separate waves of formative research, using informant interviews and experiential feedback from the target population. After each wave, participant feedback was coded and respective changes were made to the intervention module. Each subsequent wave was presented with a newly revised module. The number of waves was not pre-specified;

rather, the formative development process was continued until participants no longer reported actionable feedback. Figure 1 provides a schematic of the formative research process.

A subsample of *n* = 40 mothers (Waves 3, 4, & 5) was selected to complete the knowledge survey, an instrument designed to test caregiver knowledge of early child language and cognitive development as well as intervention uptake (see below). The survey was administered pre-intervention as well as 24 hours after the intervention, so as to counteract immediate recall effects.



**Figure 1. Intervention and knowledge survey development: The formative process.**  
 FT = formative testing, MBU = mother-baby unit

Mothers in this group were between the ages of 18 and 44 ( $M = 29.4$ ). Demographics regarding education, ethnicity, number of births, and health care coverage were consistent across all waves (for an overview, please see Table 1, column labeled “test-takers only”).

The knowledge survey was developed in parallel to the intervention (see Figure 1). The survey underwent iterative changes in regards to content, phrasing, format, and scoring scales based on feedback from parents, health-care providers, and experts in the fields represented in the intervention. Participants in Waves 1 and 2 completed the instrument at its corresponding stages of development and helped ensure content validity of the individual survey items through cognitive interviews. That is, they were questioned about their understanding of individual survey

items or specific terms used in questions. Participants took part in the survey pre-intervention and immediately after intervention delivery. Waves 4 and 5 completed the penultimate version of the knowledge survey that was analyzed in support of this study (see *Procedure* and *Results*). The knowledge survey was finalized after Wave 5.

### Procedure

In order to identify and approach eligible participants, research assistants accompanied UNHS technicians on their MBU rounds twice a week. The UNHS technician entered a patient’s room in order to perform the hearing screening on the infant and asked whether the mother was available and interested in reviewing a presentation with a research assistant. Upon obtaining oral consent, mothers completed a short demographic questionnaire as

<sup>2</sup>Pre-test Cronbach’s alpha is estimated at 0.43, with a confidence interval of 0.18 – 0.68. Post-test Cronbach’s alpha is estimated at 0.64, with a confidence interval of 0.49 – 0.8 (Revelle, 2016)

well as the knowledge survey probing mothers' knowledge of child language development and UNHS. Next, research assistants proceeded to view the intervention together with the participant. The intervention consisted of a series of slides with text and animations narrated by the research assistant with the explanation that the final product would be in video format and include a series of clips illustrating intervention content with real life caregivers. Mothers were encouraged to interrupt at any time with questions or remarks.

The intervention was followed by a 20-minute, semi-structured interview probing participants' thoughts and reactions. The interview guide included questions about mothers' hospital stay experience, opinions about the hearing screening, and any educational materials received during their stay. The review questions assessed logistics, aesthetics, and content of the presentation, as well as the parenting experience and child-rearing beliefs of mothers. For participants in Waves 1 and 2, the survey was administered again after the review session in order to verify and discuss uptake of the intervention messaging. During this discussion, the research assistant debriefed participants about the state of research in particular areas and topics covered in the intervention or the knowledge survey. Participants in Waves 3, 4, and 5 received the penultimate version of the instrument and completed their post-intervention survey a day after intervention administration (followed by debriefing). These participants were included in the analysis of knowledge survey outcomes (see outcome measure section below for details on survey development). All research procedures were approved by the Biological Sciences Division Institutional Review Board of the University of Chicago.

**Coding qualitative interview data.** Transcripts of five waves of interviews with participants provided the qualitative basis for iterative changes to the intervention. All interviews were recorded with participants' permission and transcribed by research assistants. The transcribed interviews were then coded using a codebook based on Saldaña (2013). The codebook permitted thematic analysis of the topics addressed in the interviews, allowing the research team to analyze reactions to the intervention in order to systematically incorporate the changes suggested by the participants. The codebook was organized in a series of families of codes and sub-codes. The coding families included the following: (a) reaction to aesthetics/logistics of the intervention; (b) caregiver beliefs in response to intervention messaging; (c) comprehension and retention of intervention materials, and (d) prior parenting experience relating to intervention. In order to determine inter-coder reliability, a first coder coded the entire data set, while a second coder re-coded 25% of the transcriptions. Reliability was assessed as number of codes in common per utterance, and the two coders agreed 90% of the time.

**Knowledge survey score.** The knowledge survey assessed changes in caregiver knowledge about UNHS

and the importance of the follow-up visit, as well as early child language and cognitive development. The survey is a 16-item self-administered instrument with Likert-like questions, with a maximum possible score of 80 points. Due to the small sample size ( $n = 40$ ), it was impossible to accurately estimate Cronbach's alpha for the pilot instrument;<sup>2</sup> however, a complete list of questions is provided in Table 2 below.

## Results

### Wave 1: Changes from Module 1 to Module 2

Overall, participants liked the tone of the presentation and found information accessible and key messaging (e.g., the 3 T's) easy to remember (e.g., "it's memorable, I remember the 3 T's and the whole concept behind it"). In order to increase the retention of the material further, an analogy between milk as food for the body, and talk as food for the brain was added after this round of participant feedback. Critical feedback revolved around the wordiness of the intervention (e.g., "informative, but long, it didn't keep me engaged"). Therefore, we shortened long descriptive elements in the presentation, but increased mention of the 3 T's to provide a unified framework and to ensure retention of information by participants. For example, the awareness of TV and technology use were integrated into "You can't tune into your baby if you are tuned into the TV/phone." Interactive parts of the intervention, where multiple choice questions were asked of participants, were removed since participants did not find these questions helpful.

### Wave 2: Changes from Module 2 to Module 3

During this wave, a central concern emerged among participants. The idea of having a conversation with a baby received strong participant push back. In an attempt to give these concerns a voice, they were built into the intervention. In module 3, cartoon parents now express participant feedback, in combination with other misconceptions or common questions, for example, "How can I have a conversation with my baby if he can't even talk yet?" These "push-back" episodes are used to introduce more information about infant development. The new intervention materials discuss specific age-appropriate ways to have conversations with children. "Your baby's first turns will be coos, gurgles, gestures, and eye contact. Since he doesn't have words yet, when your baby makes eye contact, it's a way of communicating. When you meet his gaze, you're responding."

### Wave 3: Changes from Module 3 to Module 4

During Wave 3, another critical concern arose. Participants disagreed with the notion that infants cannot be spoiled, for example, "If you pick them up and hold them all day, I feel that is spoiling them and you're not teaching them how to be independent because they've had all of their needs met. And they're just crying." Spoiling, a key misconception around infant development, was included in the intervention

<sup>2</sup>Effect size based on pooled standard deviation (5.76), since pre- and post-intervention standard deviations are comparable (5.43 and 6.07 respectively).

based on consultation with pediatricians. However, when presented with information on spoiling, participants had difficulties disconnecting their opinions on spoiling from its effects on older children, specifically toddlers. In response to this feedback, we inserted more video push-back episodes with cartoon parents stating the concerns: “So what if I can’t tell what is wrong when my baby cries?” and “My niece is so spoiled, she whines until she gets what she wants.” Based on consultation with pediatricians, we responded to the concerns around spoiling by adding information about infants’ very limited memory capacity. Specifically, in the intervention, we state, “It’s true, you can definitely spoil a child. But newborns are different! The memory part of your baby’s brain hasn’t fully developed yet. He can’t remember that you’ve responded to his needs in the past, so he doesn’t learn to expect it. All he knows is that something is wrong and that causes him stress. After six months, your baby will be able to start learning how to calm himself, so he’ll be able to remember that you’ll be there when he needs you.” By linking memory capacity to a particular developmental period in time, we were able to dissociate the positive effects of parental responsiveness from the perceived negative effects of spoiling older children, which made the concept relatable for parents.

#### Wave 4: Changes from Module 4 to Module 5

This wave of formative testing illuminated a remaining critical concern, related to spoiling. Parental responsiveness during a baby’s first year is key to developing a secure attachment between baby and caregiver. However, the terminology we used to describe the effects of secure and insecure attachment was perceived as “cold” and “clinical”. Therefore, in Module 5, these terms were changed to “forming a strong/special bond.”

#### Wave 5: Finalizing the Intervention

Module 5 interviews revealed more sources of contentment than criticism among participants. At this point, the decision was made to end the process of formative testing.

#### Knowledge Survey Analysis

Participants showed a significant increase in pre- to post-intervention scores ( $p < .001$ ). Mothers’ scores increased from 64.8 average points pre-intervention to a post-intervention average of 69.6 ( $\beta=4.72$ ,  $t(39) = 7.13$ ,  $d = 0.82$ ;<sup>3</sup> see Figure 2). If the mothers in this sample are a representative sample of the target population, then we would expect, with 95% confidence, the intervention to produce a mean increase in test scores between 3.38 and 6.07 points.

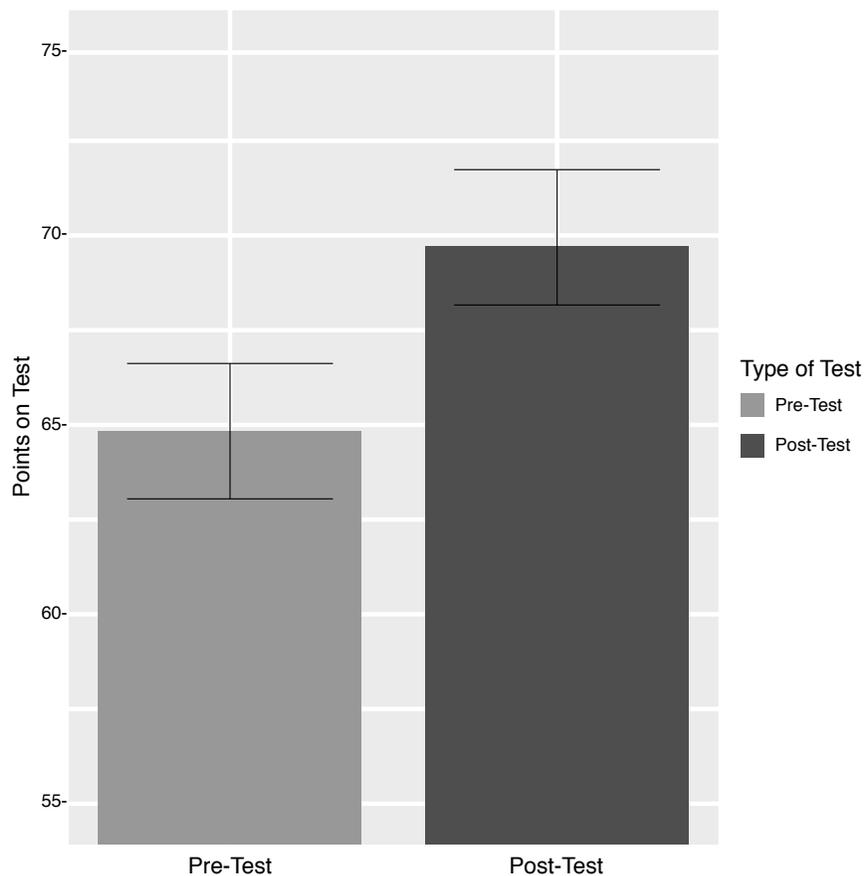


Figure 2. Knowledge survey results with 95% error bars.

**Table 2**  
**Knowledge Survey Items**

Item	Prompt	Pre-Test		Post-Test		Change		
		Mean	SD	Mean	SD	Change in Means	p- value	
1a	An infant's brain develops quite naturally without much help from his or her parents.	4.10	1.30	4.03	1.27	-0.07	0.77	
1b	When infants babble, sometimes they're actually trying to communicate something.	4.65	0.70	4.78	0.62	0.13	0.10	*
1c	Always responding to a crying infant will only end up spoiling him or her.	4.13	1.11	4.80	0.61	0.68	0.00	***
1d	Infants can typically recognize their mother's voice as soon as they are born.	4.73	0.82	4.93	0.27	0.20	0.13	
2a	It's harmful to give an infant too much attention.	4.70	0.82	4.88	0.40	0.18	0.18	
2b	Talking to an infant in a playful or exaggerated voice will help the infant's language learning.	3.50	1.38	4.53	1.13	1.03	0.00	***
2c	An infant's brain is like a sponge and is ready to learn right away.	4.68	0.83	4.90	0.63	0.23	0.02	**
2d	Getting close and making eye contact is a great way to build a connection with an infant.	4.80	0.61	4.90	0.38	0.10	0.25	
3a	Infants can understand some words even before they can speak.	4.53	0.82	4.65	0.80	0.13	0.38	
3b	Basic care, such as feeding, changing, and bathing, is the only thing an infant really needs.	4.55	0.93	4.43	1.17	-0.13	0.51	
3c	As soon as they are born, typical infants can hear just as well as adults.	3.68	1.05	4.25	0.95	0.58	0.00	***
3d	How smart an infant will be depends mostly on his or her "natural" intelligence at birth.	3.60	1.22	4.30	1.11	0.70	0.00	***
4a	Infants who get a lot of attention from their parents will grow up to be needy and dependent	4.28	1.04	4.68	0.94	0.40	0.00	***
4b	Showing infants educational TV gives them a jump-start on learning how to talk.	2.08	1.12	2.48	1.38	0.40	0.06	*
4c	Talking on the phone around infants is a great way to expose them to new words.	2.83	1.36	2.68	1.54	-0.15	0.42	
4d	Infants learn much more from watching educational TV than they do from being read to by their parents.	4.03	1.27	4.38	0.93	0.35	0.04	**

Note. One sample t-tests reveal significant changes between pre- and post-test results on 8 out of 16 questions.  
\* $p \leq 0.1$ , \*\* $p \leq 0.05$ , \*\*\* $p \leq 0.01$

## Discussion

By investigating how beneficiary knowledge, beliefs, and practices interact with participant uptake and influence behavior change, formative processes are indispensable in ensuring acceptability and viability of health interventions (Bentley, Gavin, Black, & Teti, 1999; Bentley et al., 2014; Horner et al., 2008; Linde et al. 2014; Newes-Adeyi, Helitzer, Caulfield, & Bronner, 2000). Using qualitative methods, such as key informant interviews and experiential feedback, we were able to tap into stakeholders' knowledge

of child language development and parenting beliefs, which provided us with feedback and areas of continuous quality improvement during the development of the TMW-Newborn Parent Education Curriculum.

Participant feedback showed us that the postpartum period is a time when caregivers are in need of and open to receiving information about their child's healthy development. Increased scores on the knowledge survey suggested that the TMW-Newborn Parent Education Curriculum is effective in improving knowledge in key areas

of child development related to language development and the importance of the UNHS. By impacting parental knowledge, the TMW-Newborn Parent Education Curriculum is expected to reduce LFU and lead to improved outcomes for children who are deaf or hard-of-hearing.

The formative research process supported the development of the intervention such that we were able to define and understand populations at greatest risk for LFU and create a program that is specific to the needs of those populations. We were further able to ensure that the TMW-Newborn Parent Education Curriculum is acceptable and feasible to beneficiaries before launching a large-scale efficacy study. Due to the fact that both health care professionals as well as patient populations provided key input to the curriculum, the intervention stands to positively impact the relationship between beneficiaries and care providers. The curriculum supports the work of MBU nurses and UNHS hearing technicians by providing a standardized approach for disseminating essential information. The 10-minute intervention is easily implemented in the postpartum period, since hospital rooms typically come equipped with DVD players (which are increasingly used to disseminate information, e.g., on breastfeeding). Materials can also be made accessible online, along with links providing more information about child development, hearing loss, and language development.

It is important to note that due to the location of the University birthing hospital on the South Side of Chicago, the majority of the study participants were English-speaking African-Americans. In order to be responsive to other major cultural and linguistic groups in the United States, we will be adapting the TMW-Newborn Parent Education Curriculum for use with Spanish-speaking populations. The development of this curriculum will be informed by formative testing with representatives of Spanish-speaking populations.

Additionally, due to the low incidence rate of DHH in the general population, we were not able to include DHH participants in the MBU sample. We designed the curriculum with a DHH population in mind and recruited both a parent who is deaf, as well as an educator who is deaf to participate in the video component. The curriculum includes video vignettes of both English-speaking caregivers as well as children and caregivers who are signers of American Sign Language (ASL). The messaging used in the curriculum was crafted to be inclusive of signed and spoken languages, noting that language access (and development) is all about the brain, not about the ear, e.g., “For your baby to learn, her brain must be exposed to language. That’s why having her hearing tested is so important. Without the screening, a hearing loss could go undetected until she gets older. This could affect her ability to learn and communicate with the world around her.” We are also in the process of adding closed captioning to the curriculum.

The TMW-Newborn Parent Education Curriculum will soon be ready for implementation in a large-scale randomized controlled trial (RCT) to test its efficacy. With an RCT, it will be possible to demonstrate whether or not the knowledge gain found in the current study can be replicated using an appropriately powered sample, and whether that knowledge increase can also be shown after a 4-week-period of delay. In order to answer the outstanding question of whether the intervention effectively reduces LFU, it will be necessary to gain access to a large population sample. One possible avenue is to implement the curriculum in the NICU, where the incidence of hearing loss is higher than in the general population encountered in the MBU.

## References

- Beger, D., & Loveland Cook, C. A. (1998, March). Postpartum teaching priorities: The viewpoints of nurses and mothers. *Journal of Obstetric, Gynecologic & Neonatal Nursing, 27*(2), 161–168. doi:10.1111/j.1552-6909.1998.tb02606.x
- Bentley, M., Gavin, L., Black, M. M., & Teti, L. (1999). Infant feeding practices of low-income, African-American, adolescent mothers: An ecological, multigenerational perspective. *Social Science & Medicine, 49*(8), 1085–1100. doi:10.1016/s0277-9536(99)00198-7
- Bentley, M. E., Johnson, S. L., Wasser, H., Creed-Kanashiro, H., Shroff, M., Fernandez Rao, S., & Cunningham, M. (2014). Formative research methods for designing culturally appropriate, integrated child nutrition and development interventions: An overview. *Annals of the New York Academy of Sciences, 1308*(1), 54–67. doi:10.1111/nyas.12290
- Bourgeault, I. L., Dingwall, R., & De Vries, R. (2010). *The SAGE handbook of qualitative methods in health research*. Los Angeles: SAGE.
- Bowman, K. G. (2005). Postpartum learning needs. *Journal of Obstetric, Gynecologic, and Neonatal Nursing, 34*(4), 438–443. doi:10.1177/0884217505276054
- Centers for Disease Control and Prevention. (2016). Summary of 2014 national CDC EHDI data. Retrieved from [http://www.cdc.gov/ncbddd/hearingloss/2014-data/2014\\_ehdi\\_hsfh\\_summary\\_h.pdf](http://www.cdc.gov/ncbddd/hearingloss/2014-data/2014_ehdi_hsfh_summary_h.pdf)
- Cockfield, C., Garner, G., & Borders, J. (2012). Follow-up after a failed newborn hearing screen: A quality improvement study. *ORL-head and Neck Nursing: Official Journal of the Society of Otorhinolaryngology and Head-Neck Nurses, 30*(3), 9–13. Retrieved from <http://www.ncbi.nlm.nih.gov/>
- Connell, C. M., & Prinz, R. J. (2002). The impact of childcare and parent-child interactions on school readiness and social skills development for low-income African American children. *Journal of School Psychology, 40*(2), 179–193.
- Crockett, R., Baker, H., Uus, K., Bamford, J., & Marteau, T. M. (2006). Maternal anxiety and satisfaction following infant hearing screening: A comparison of the health visitor distraction test and newborn hearing screening. *Journal of Medical Screening, 12*(2), 78–82. doi:10.1258/0969141053908320
- Danaher, B., Smith, M. D., Telang, R., & Chen, S. (2012). The effect of graduated response anti-piracy laws on music sales: Evidence from an event study in France by Brett Danaher, Michael D. Smith, Rahul Telang, Siwen Chen: SSRN. *Social Science Research Network*. doi:10.2139/ssrn.1989240
- Gaffney, M., Gamble, M., Costa, P., Holstrum, J., & Boyle, C. (2003, October 17). Infants tested for hearing loss—United States, 1999–2001. Retrieved from <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5241a1.htm>
- Gauthier, K., & Genesee, F. (2011, March 17). Language development in internationally adopted children: A special case of early second language learning. *Child Development, 82*(3), 887–901. doi:10.1111/j.1467-8624.2011.01578.x
- Gittelsohn, J., Dyckman, W., Tan, M., Boggs, M., Frick, K., Alfred, J., ... Palafox, N. (2006). Development and implementation of a food store-based intervention to improve diet in the republic of the Marshall Islands. *Health Promotion Practice, 7*(4), 396–405. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/16885512>

- Harrison, M., Roush, J., & Wallace, J. (2003). Trends in age of identification and intervention in infants with hearing loss. *Ear and Hearing, 24*(1), 89–95. doi:10.1097/01.aud.0000051749.40991.1f
- Hoff, E. (2013). Interpreting the early language trajectories of children from low-SES and language minority homes: Implications for closing achievement gaps. *Developmental Psychology, 49*(1), 4–14.
- Hoffman, J., & Beauchaine, K. (2007). Babies with hearing loss: Steps for effective intervention. *The ASHA Leader, 12*(2), 23–28. doi:10.1044/leader.FTR3.12022007.8
- Horner, J. R., Romer, D., Vanable, P. A., Salazar, L. F., Carey, M. P., Juzang, I., . . . Valois, R. F. (2008). Using culture-centered qualitative formative research to design broadcast messages for HIV prevention for African American adolescents. *Journal of Health Communication, 13*(4), 309–325. doi:10.1080/10810730802063215
- Kral, A., & Sharma, A. (2012, February). Developmental neuroplasticity after cochlear implantation. *Trends in Neurosciences, 35*(2), 111–122. doi: 10.1016/j.tins.2011.09.004
- Linde, J. A., Sevcik, S. M., Petrich, C. A., Gardner, J. K., Laska, M. N., Lozano, P., & Lytle, L. A. (2014). Translating a health behavior change intervention for delivery to 2-year college students: The importance of formative research. *Translational Behavioral Medicine, 4*(2), 160–169. <http://doi.org/10.1007/s13142-013-0243-y>
- Markus, J., Mundy, P., Morales, M., Delgado, C. E., & Yale, M. (2000, August). Individual differences in infant skills as predictors of child-caregiver joint attention and language. *Social Development, 9*(3), 302–315. doi:10.1111/1467-9507.00127
- Moeller, M. P. (2000). Early intervention and language development in children who are deaf and hard of hearing. *Pediatrics, 106*(3), e43.
- Moeller, M. P. (2007). Current state of knowledge: Psychosocial development in children with hearing impairment. *Ear and Hearing, 28*(6), 729–739. doi: 10.1097/AUD.0b013e318157f033.
- Morse, J. M., & Cheek, J. (2014, January). Making room for qualitatively-driven mixed-method research. *Qualitative Health Research, 24*(1), 3–5. doi:10.1177/1049732313513656
- Neuhauser, L., Rothschild, B., Graham, C., Ivey, S. L., & Konishi, S. (2009). Participatory design of mass health communication in three languages for seniors and people with disabilities on Medicaid. *American Journal of Public Health, 99*(12), 2188–2195. doi:10.2105/ajph.2008.155648
- Newes-Adeyi, G., Helitzer, D. L., Caulfield, L. E., & Bronner, Y. (2000). Theory and practice: Applying the ecological model to formative research for a WIC training program in New York State. *Health Education Research, 15*(3), 283–291. doi:10.1093/her/15.3.283
- Nichter, M., Nichter, M., Thompson, P. J., Shiffman, S., & Moscicki, A. (2002). Using qualitative research to inform survey development on nicotine dependence among adolescents. *Drug and Alcohol Dependence, 68*, 41–56. doi:10.1016/s0376-8716(02)00214-4
- Padgett, D. K. (2012). *Qualitative and Mixed Methods in Public Health*. Thousand Oaks, CA: Sage Publications, Inc.
- R Core Team. (2016). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. Retrieved from: <https://www.R-project.org/>
- Ramírez-Esparza, N., García-Sierra, A., & Kuhl, P. K. (2014, November 07). Look who's talking: Speech style and social context in language input to infants are linked to concurrent and future speech development. *Developmental Science, 17*(6), 880–891. doi:10.1111/desc.12172
- Revelle, W. (2016). psych: Procedures for Personality and Psychological Research, Northwestern University, Evanston, Illinois, USA, Retrieved from: <http://CRAN.R-project.org/package=psych> Version =1.6.4.
- Rowe, M. L. (2008). Child-directed speech: Relation to socioeconomic status, knowledge of child development and child vocabulary skill. *Journal of Child Language, 35*(1), 185–205. doi:10.1017/s0305000907008343
- Ruben, R. J. (1999, July). A time frame of critical/sensitive periods of language development. *Indian Journal of Otolaryngology and Head & Neck Surgery, 51*(3), 85–89. doi:10.1007/bf02996542
- Saldaña, J. (2013). *The coding manual for qualitative researchers*. Los Angeles, CA: Sage Publications.
- Sepinwall, D. R. (2002). Health and behavior: The interplay of biological, behavioral, and societal influences. *Psychosomatics, 43*(5), 431–432. doi:10.1176/appi.psy.43.5.431
- Stetler, C. B., Legro, M. W., Wallace, C. M., Bowman, C., Guihan, M., Hagedorn, H., . . . , & Smith, J. L. (2006). The role of formative evaluation in implementation research and the QUERI experience. *Journal of General Internal Medicine, 21*(S2), S1–S8.
- Spivak, L., Sokol, H., Auerbach, C., & Gershkovich, S. (2002). Newborn hearing screening follow-up: Factors affect hearing aid fitting by 6 months of age. *American Journal of Audiology, 18*(1), 24–33. doi: 10.1044/1059-0889(2008/08-0015)
- Suskind, D., Lefell, K. R., Graf, E., Hernandez, M. W., Gunderson, E. A., Sapolich, S. G., . . . Levine, S. C. (2015). A parent-directed language intervention for children of low socioeconomic status: A randomized controlled pilot study. *Journal of Child Language, 43*(2), 1–41.
- Vohr, B. R., Letourneau, K. S., & McDermott, C. (2001). Maternal worry about neonatal hearing screening. *Journal of Perinatology, 21*(1), 15.
- Weisner, T. S., & Hay, M. C. (2014). Practice to research: Integrating evidence-based practices with culture and context. *Transcultural Psychiatry, 52*(2), 222–243. doi:10.1177/1363461514557066
- White, K., & Muñoz, K. (2008). Screening for mild and unilateral hearing loss. *Seminars in Hearing, 29*(2), 149–158. doi:10.1055/s-2008-1075822
- Wu, Z., & Gros-Louis, J. (2014, February). Infants' prelinguistic communicative acts and maternal responses: Relations to linguistic development. *First Language, 34*(1), 72–90.
- Yoshinaga-Itano, C., & Mah-rya, L. A. (1998). Identification of hearing loss after age 18 months is not early enough. *American Annals of the Deaf, 143*(5), 380–387. doi: 10.1353/aad.2012.015