

Using Human-Centered Design in Personalized Anticipatory Guidance: Enriching Anticipatory Guidance on Early Cognitive and Language Development

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Abstract

In this study, we aimed to create a novel tool to assist providers at 2 Chicago-area Federally Qualified Health Centers in giving guidance on early cognitive and language development during well-child visits. We utilized a human-centered design (HCD) process to address specific barriers to providing this guidance and create a tool shaped by the needs of providers and parents. Phase I involved collaborative prototype design; phase II involved implementation, feedback gathering, and responsive iterations of the tool; and phase III involved a collective review of the HCD process. The final version of the tool was a concise, colorful, and parent-accessible “Brain Building Guide” intended for interactive provider and parent use. It featured personalized information about parental knowledge and suggested areas for guidance. It was both satisfactory to stakeholders and efficacious in improving parental knowledge immediately post-visit and 1 month out. It should be further evaluated in a randomized controlled trial.

Keywords

anticipatory guidance, human-centered design, child development, cognitive development, language development, parental knowledge

Background

A child’s early learning and language environment is an important, yet historically overlooked, social determinant of health.^{1–4} Poverty and toxic stress in early childhood are major barriers to optimal cognitive development and significant contributors to disparities in cognitive abilities and achievement later in life.^{5,6} These systemic inequities are striking; fewer than half of the children growing up in low-income families are ready for school by the age of 5 years, compared with 75% of children raised in higher-income families.¹

Within the pediatrics profession, there is a growing understanding that the early learning environment is essential to optimal brain development and school readiness.^{6,7,8–11} In fact, the American Academy of Pediatrics (AAP) Agenda for Children in 2017 designated “early brain and child development” as an integrated health priority, emphasizing the role of pediatricians on the issue.¹² Additionally, authors in the fields of both pediatrics and public health have recognized the substantial impact of poverty on early brain development and have

called for policies and programs to reduce disparities in cognitive development.^{1,6}

Research suggests that parent-directed language interventions in lower SES populations may have a positive impact on both the quality and quantity of parent-child talk.¹³ Importantly, parental knowledge of early childhood development has been shown to predict parent-child interaction and, in doing so, mediate the impact of socioeconomic status (SES) on the early language environment and subsequent cognitive development of children.^{2,14} For example, in a recent study of 173 parents from low SES backgrounds, those who had more knowledge of infant development during their child’s 1-week newborn visit were significantly more likely to exhibit behaviors known to foster social-emotional and

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cognitive growth at 9 months.¹⁵ This highlights the importance of early parental education and the potential role of anticipatory guidance on cognitive and language development during pediatric well-child visits.

Pediatric providers are uniquely well positioned to counsel parents on the importance of talk and interaction in language and brain development.¹⁶ Particularly for parents of low SES, pediatric providers are the primary source of guidance related to child rearing and developmental milestones.¹⁵ The AAP recommended well-child visits are a crucial touchpoint for providing meaningful information to parents related to cognitive development, particularly the 6 well-child visits that occur within the first 12 months.

Yet traditional anticipatory guidance given during well-child visits is focused primarily on newborn care, physical growth, and injury prevention and not early learning and language environments.¹⁷ A recent survey of parents in Chicago-area Federally Qualified Health Centers (FQHCs) revealed that only 1 in 10 providers discuss how infants learn at the 1-month well-child visit. This paucity of discussion surrounding early learning is not unique to the FQHC setting. Parents seen in private practice and hospital-based clinics report substantial unmet needs surrounding discussion of reading and vocabulary development during the well-child visit, too.¹⁷⁻¹⁹ Tight time constraints with competing priorities during visits, inadequate resources, and a limited understanding of what individual parents know about their child's cognitive development are often cited as major barriers to providing this guidance.²⁰

The human-centered design (HCD) methodology offers a useful framework for developing an intervention centered on the provider-parent relationship that could support providers in effectively educating parents about early cognitive and language development. HCD does not focus on merely solving a problem but instead encourages critical, continual examination of the ways in which context must inform design.²¹ It is centered on several core principles, including empathy with the target communities, rapid prototyping, feedback gathering processes and responsive iterations, and a tolerance for ambiguity and failure.^{22,23}

HCD has increasingly been explored in the literature over the past decade in its application to global health,^{22,24-26} but literature examining its clinical applications to promote the health of underserved populations in the United States is limited. Importantly, public health interventions that have used HCD have illustrated its efficacy in addressing health inequities because it encourages widespread participation from all stakeholders and engages with groups historically left out of the decision-making and design processes.^{27,28}

This study aimed to demonstrate how an HCD process could be used to develop a novel, effective intervention to impact parental knowledge of children's early learning environments.

Methods

Following HCD methodology, this study took place in 3 phases involving collaborative prototype design, implementation and iteration, and collective review, as displayed in Figure 1.

Phase I: Collaborative Prototype Design

After a literature review was conducted, clinician partners at each of the 2 participating FQHCs were consulted to establish need and desire for an intervention to promote parent knowledge of early learning and cognitive development. Consistent with the literature, the partners described challenges to providing anticipatory guidance on this topic, including a lack of understanding of parent baseline knowledge and time constraints within a typical well-child visit. They expressed interest in a tool that could help them better understand parent knowledge and give guidance accordingly in a time-efficient manner. The concept of a Personalized Anticipatory Guidance Tool—a clinical decision support tool that gives the provider insight into what a parent does and does not know with ready-to-use prompts for counseling during the well-child visit—emerged through these discussions.

The Survey of Parents'/Providers' Expectations and Knowledge (SPEAK) was utilized as the basis for the development of the Personalized Anticipatory Guidance Tool and to evaluate the intervention's impact. The SPEAK is a validated, self-administered questionnaire used by researchers and clinical institutions nationwide to measure parent expectations and knowledge of cognitive and language development in early childhood.²⁹ There are several validated versions of the SPEAK, including a 10-item questionnaire designed to assess knowledge pertaining to children 0 to 5 years old (Table 1). This version offered an efficient method for obtaining insight into parents' knowledge, allowing the guidance to be personalized for each parent. The 0 to 5 years age range allowed for inclusion of a diverse group of parent participants to enhance the generalizability of the study. Comparing pre-visit, immediate post-visit, and 4-week post-visit scores on the SPEAK survey provided a method for assessing the efficacy of each version of the tool in improving parents' knowledge and helped guide further iterations of the tool and its content. As the tool was refined throughout the study, performance was

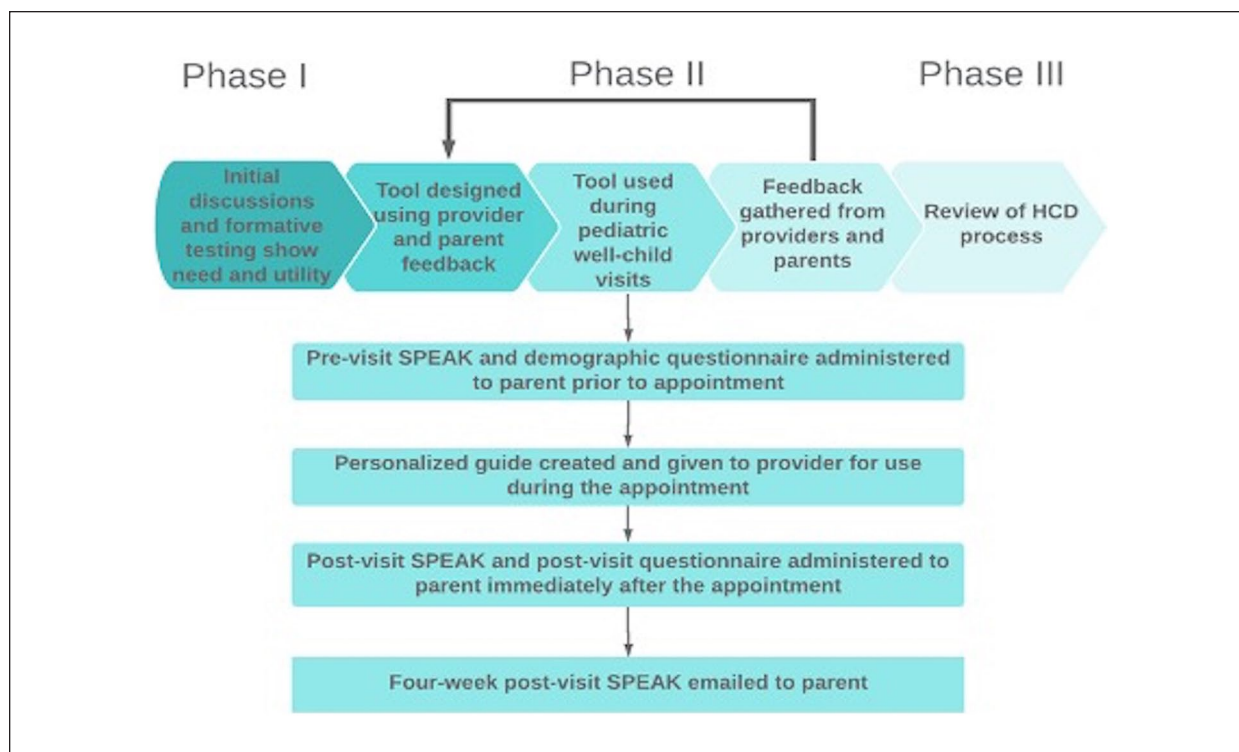


Figure 1. Methods overview.

Abbreviations: HCD, human-centered design; SPEAK, Survey of Parents'/Providers' Expectations and Knowledge.

evaluated on individual SPEAK items to identify specific guidance scripts in need of improvement, allowing the guidance to be strengthened with each iteration of the tool. Finally, the SPEAK was used to assess the overall impact of the intervention on parental knowledge by comparing previsit scores to immediate post-visit and 4-week post-visit scores.

A prototype was created that used the SPEAK to assess parental knowledge prior to a child's well-child visit and then formulated content for the Personalized Anticipatory Guidance Tool with focused topics for counseling based on the results. The 2 clinician partners were consulted throughout the design process to refine the initial prototype of the tool. They suggested that the tool contain information for counseling pertaining to 1 strength (based on the SPEAK item on which the parent scored the best) and 2 gaps in knowledge (based on the SPEAK items on which their performance was the lowest).

After conceptualizing the basic outline of the tool and mechanism for assessing its efficacy, additional prototypes were created as well as a bank of suggested scripts for delivering anticipatory guidance pertaining to each of the 10 SPEAK items and learning points. Prototypes varied in color, use of graphics, amount of

information displayed, and depth of information shared. These prototypes were reviewed with 11 additional pediatricians at The University of Chicago. Clinicians were surveyed, and semistructured individual interviews were conducted to obtain feedback on the tool's content and strategies for integrating the tool into the workflow during the well-child visit. Throughout this process, the prototype was iteratively changed in response to pediatrician feedback. The intervention was then piloted with 5 parents of pediatric patients at The University of Chicago, who were subsequently interviewed to gather feedback on their experience.

Feedback from the parents and clinicians in phase I informed iterative changes in content, phrasing for suggested guidance, and formatting of the tool, ultimately yielding what was called version I of the tool: a 1-page, provider-facing guide that synthesized a parent's results on SPEAK and offered tailored prompts for the clinician to use during the well-child visit. Through discussions with clinicians, a workflow was solidified that enabled integration of the intervention into the existing structure of well-child visits with minimal disruption. Additionally, interview responses were reviewed for themes, which were in turn used to guide feedback gathering in phase II.

Table 1. 10-Question Survey of Parents'/Providers' Expectations and Knowledge.

Question	Answer choices and points awarded (total points = 32)
When do you think a child is ready to be exposed to words?	<ul style="list-style-type: none"> • As an infant 0 to 6 months: 5 • As a baby 6 to 12 months: 4 • As a toddler 1 to 3 years: 3 • In preschool 3 to 5 years: 2 • In kindergarten 5 to 6 years: 1 • In elementary school 6 years and up: 0
How smart a baby will become depends mostly on genetics	<ul style="list-style-type: none"> • Definitely true: 0 • Probably true: 1 • Probably not true: 2 • Definitely not true: 3
Infants who get a lot of attention from their parents will grow up to be needy and dependent	<ul style="list-style-type: none"> • Definitely true: 0 • Probably true: 1 • Probably not true: 2 • Definitely not true: 3
Leaving the TV on in the background is a great way to give 0- to 2-year-olds extra chances to learn words	<ul style="list-style-type: none"> • Definitely true: 0 • Probably true: 1 • Probably not true: 2 • Definitely not true: 3
Toddlers learn more when they are told exactly what to do instead of given choices	<ul style="list-style-type: none"> • Definitely true: 0 • Probably true: 1 • Probably not true: 2 • Definitely not true: 3
Toddlers can learn more from watching educational TV than they can from being read to by their parents	<ul style="list-style-type: none"> • Definitely true: 0 • Probably true: 1 • Probably not true: 2 • Definitely not true: 3
Letting a toddler move around while listening to a story teaches the toddler bad listening skills	<ul style="list-style-type: none"> • Definitely true: 0 • Probably true: 1 • Probably not true: 2 • Definitely not true: 3
It is a bad sign when toddlers start to mix up the different languages they are learning	<ul style="list-style-type: none"> • Definitely true: 0 • Probably true: 1 • Probably not true: 2 • Definitely not true: 3
What young children learn before they go to kindergarten matters very little in the long run	<ul style="list-style-type: none"> • Definitely true: 0 • Probably true: 1 • Probably not true: 2 • Definitely not true: 3
The best place for young children to begin learning things like math is at school from their teachers	<ul style="list-style-type: none"> • Definitely true: 0 • Probably true: 1 • Probably not true: 2 • Definitely not true: 3

Phase II: Implementation, Feedback Gathering, and Responsive Iteration

Phase II of the study began with implementation of version I of the tool in well-child visits at FQHC study sites. Eight participating clinicians, including 2 who participated in phase I, were recruited from 2 Chicago-area FQHCs. These clinics were chosen because of their high volume of patients from underserved populations, the target demographic for this intervention. Clinicians at these clinics were eligible to participate if they were

pediatricians, nurse practitioners, or physician's assistants who saw patients between the ages of 0 and 5 years for well-child visits. Clinicians were recruited from a variety of training backgrounds both to ensure that the sample was representative of the diverse group of providers at the clinics and to gain access to a variety of perspectives to better shape the tool. Five pediatricians, 2 physician's assistants, and 1 nurse practitioner participated in the study.

Parents were eligible to enroll in the study if they were the primary caregivers of a child 0 to 5 years old

who was in clinic for a well-child visit with a participating clinician. Parents were only eligible to participate if they were English speaking because of limited availability of Spanish-speaking research personnel. Parents who had been involved in any previous TMW Center for Early Learning + Public Health studies were not eligible for participation because they could have participated in studies that promoted parent knowledge of similar topics through a video-based intervention and, thus, were not representative of typical parents. Parent recruitment took place in June to August of 2019. A standardized script was used to recruit potential parent subjects in the clinic waiting room or in a participating provider's exam room while they waited for their provider. To recruit a diverse group of participants, an attempt was made to approach all parents in the clinic who had children seeing a participating clinician. All recruited parents received the intervention, and there was no control group because of the relatively small scale of the study. A short demographics questionnaire and the SPEAK were administered, and a printed personalized guide was generated for the child's provider based on the parent's SPEAK results.

After the visit, parents completed a brief questionnaire to assess their satisfaction with the guidance provided to them related to early learning and language development and then repeated the SPEAK assessment. Finally, a brief one-on-one interview was conducted with each participating parent to elicit their perspectives on how the conversations with their child's provider about early learning and language development could have been improved. Parents were incentivized with \$10 and a children's book for their participation.

Four weeks after the well-child visit, participants were emailed a link to repeat the SPEAK assessment a third time. After completing the assessment, they were provided with the correct answers for each question. They received an additional \$10 gift card for completion of this step.

Version 1 was implemented with 68 parent and 8 clinician participants. The target underserved populations were well represented. The majority were Medicaid recipients (82.4%), had a monthly income of less than \$2655 (60.3%), had not obtained a 4-year college degree (85.3%), and identified as African American (80.9%) and/or Hispanic (12.0%). Recorded, semistructured interviews were conducted with the participating clinicians to gather feedback on this version of the tool. Interview questions were informed by the themes identified in phase I as well as feedback given by clinicians throughout implementation of version 1. A brief questionnaire was also administered to assess clinician satisfaction with the tool.

Survey responses from clinicians and parents were reviewed. Recordings of the clinician interviews were used by the interviewer to identify common themes that informed revisions to the tool. Themes were identified by the interviewer and included any idea or concern brought up by more than 1 clinician. These themes were shared with the research team to prioritize and determine the feasibility of addressing the concerns. Clinicians desired a tool that allowed for interactive parent-provider use. Parents and clinicians both were interested in making the tool something parents could physically review and take home following the visit, such as a printed document. Clinicians also voiced concerns about the large volume of text and lack of age specificity, expressing the need for a more concise tool tailored to the child's age.

Additionally, pre-post changes in parental knowledge were analyzed for each of the 10 survey items on the SPEAK to identify anticipatory guidance scripts associated with smaller changes in parental knowledge that therefore could benefit from revision. The tool was updated accordingly, leading to the development of version II—a concise, colorful, and parent-accessible “Brain Building Guide” intended for clinicians and parents to reference together during the visit. Further details about changes made to the tool are discussed in the Results section.

The implementation, feedback gathering, SPEAK performance analysis, and responsive iteration process was then repeated with 80 additional parents and the same 8 clinicians using version II. The demographic characteristics for these participants showed no statistically significant difference compared with the participants who were given version I.

Review of survey and interview responses showed high parent and clinician satisfaction with the updated format but a desire for more specific action items and language that addressed parents directly rather than referring to them in the third person. Performance on SPEAK items was analyzed once again to identify guidance scripts to strengthen. Version III was created based on this feedback. It retained the same format as version II with more emphasis on parent-directed language that suggested specific actions and behaviors. Version III was implemented with 72 parents and the same 8 clinicians. These parents were once again not statistically different from those given version I or version II based on demographic data. This was determined to be the final version of the tool because of constraints on personnel availability. The same feedback-gathering processes completed with versions I and II was repeated with version III to collect data on how opinions of the tool had changed over time and how this version might be changed on broader implementation.

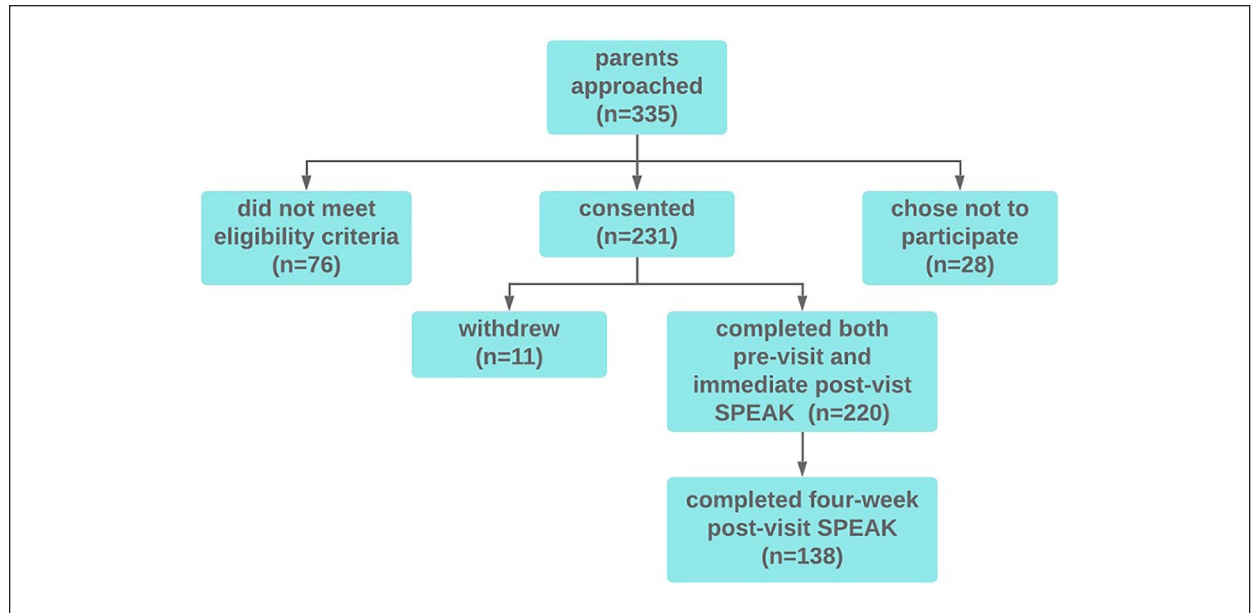


Figure 2. Matriculation of parent participants.

Abbreviation: SPEAK, Survey of Parents'/Providers' Expectations and Knowledge.

Phase III: Collective Review

At the conclusion of phase II of the study, a clinician survey was administered, and one-on-one semistructured interviews were conducted with each participating clinician with the purpose of assessing the HCD process. Specifically, the survey and interviews were used to gather feedback on clinicians' experience and assess their satisfaction with the HCD process. Interview questions were derived from clinician feedback throughout phase II. Interviews were transcribed by the research team, and these transcripts were reviewed to elucidate clinicians' attitudes toward the design process and identify areas for improvement when using a similar process in the future. Interview responses were also used to determine areas where an HCD process may be useful in future intervention design.

Results

Eight clinicians from 2 FQHCs in Chicago were recruited in April to May of 2019, including 5 pediatricians, 2 physician's assistants, and 1 nurse practitioner. Of the 8 clinicians, 6 (75%) reported that early learning and language development were addressed in their medical education. Both clinicians who reported that these topics were not addressed in their medical education were trained as pediatricians. Figure 2 shows the matriculation of participants through the study. Of the 335 parents approached, 76 individuals did not meet eligibility criteria, 28 individuals chose not to participate, and 11

participants were lost to follow-up at the end of their visit. One barrier to participation may have been concerns around privacy given the setting of a health care appointment and the sensitive nature of topics discussed in such visits. Loss to follow-up was a result of participants leaving without completion of the final survey or time constraints. A total of 220 parents enrolled and completed pre-visit and immediate post-visit SPEAK surveys. Of the 220 parent participants, 138 (63%) completed the 4-week post-visit SPEAK via email. The majority of participants were female (90.0%) and <30 years old (73%). Most participants were African American (73.6%) and/or Hispanic/Latino (19.6%). The majority of participants were Medicaid recipients (84.6%), had monthly household incomes of less than \$2655 (61.4%), and had not obtained a 4-year college degree at the time of the study (90.4%). The majority of parent participants had more than 1 child in the home (64.1%), and the average number of children in the home was 2.1. The parent participants received counseling on all children aged 5 years and less who were presenting for an appointment. The average age of these children was 1.7 years old. Demographic characteristics of parent participants are described in Table 2.

Phase I: Collaborative Prototype Design Results

The collaborative intervention design and formative testing in phase I revealed that clinicians liked the concept of

Table 2. Characteristics of Parent Participants.

	All participants (n = 220)	Completed SPEAK at 4 weeks post-visit (n = 138)	Did not complete SPEAK at 4 weeks postvisit (n = 82)
	n (%)	n (%)	n (%)
Gender			
Female	198 (90.0)	126 (91.3)	72 (87.8)
Male	21 (9.5)	12 (8.7)	9 (11.0)
Prefer not to answer	1 (0.5)	0 (0.0)	1 (1.2)
Age (years)^a			
18-24	59 (27.1)	29 (21.3)	30 (36.6)
25-29	69 (31.7)	44 (32.4)	25 (30.5)
30-34	52 (23.9)	36 (26.5)	16 (19.5)
35 Or older	38 (17.4)	27 (19.9)	11 (13.4)
Hispanic or Latinx	43 (19.6)	24 (17.4)	19 (23.2)
Race			
Black or African American	162 (73.6)	102 (74.0)	59 (72.0)
White	33 (15.5)	22 (15.9)	11 (13.4)
Native American or Alaska Native	2 (0.9)	0 (0.0)	2 (2.4)
Other	12 (5.5)	8 (5.8)	4 (4.9)
Prefer not to answer	11 (5.0)	6 (4.3)	5 (6.1)
Education level			
No or some high school (no diploma)	22 (10.0)	11 (8.0)	11 (13.4)
High school graduate or equivalent	78 (35.5)	48 (34.8)	30 (36.6)
Some college or postsecondary nondegree	77 (35.0)	46 (33.3)	31 (37.8)
Associate degree (AA, AS)	22 (10.0)	17 (12.3)	5 (6.1)
Bachelors' degree or higher	21 (9.5)	16 (11.6)	5 (6.1)
Married	34 (15.5)	24 (17.4)	10 (12.2)
Monthly household income			
Less than \$2655	135 (61.4)	86 (62.3)	49 (59.8)
\$2656 to \$3348	33 (15.0)	21 (15.2)	12 (14.6)
\$3349 to \$4402	19 (8.6)	8 (5.8)	11 (13.4)
Greater than \$4402	33 (15.0)	23 (16.7)	10 (12.2)
Insurance status^b			
Medicaid	186 (84.5)	124 (89.9)	62 (76.5)
Private	20 (9.1)	11 (8.0)	9 (11.1)
Uninsured	13 (5.9)	3 (2.1)	10 (12.4)
Employed	130 (59.1)	83 (60.1)	47 (57.3)
SNAP food benefits ^b	135 (61.4)	86 (62.3)	49 (60.5)
Women, Infants, and Children (WIC) benefits ^b	114 (51.8)	75 (54.4)	39 (48.2)

Abbreviations: SNAP, Supplemental Nutrition Assistance Program; SPEAK, Survey of Parents'/Providers' Expectations and Knowledge.

^aTwo parents were excluded because they mistakenly reported their child's age rather than their own.

^bOne parent was excluded because they did not complete items on insurance status, SNAP food benefits, or WIC.

the tool but worried that the amount of information may overwhelm parents and providers, thus limiting the tool's feasibility. Clinicians expressed desire for a tool that was not prescriptive but instead showcased a parent's SPEAK results in a straightforward, streamlined manner while affording them freedom and flexibility in counseling, however they saw fit. The parents who participated in phase I found the information displayed in the initial prototypes useful and easy to understand and

made recommendations to improve the phrasing of suggested guidance scripts.

This collaborative design and formative testing culminated in the creation of version I of the Personalized Anticipatory Guidance Tool (Table 3). Version I was developed with clinicians as the intended audience, with an individual parent's "strengths" or "gaps in knowledge" displayed to the clinician in green and red color coding, respectively. The specific SPEAK items

Table 3. Summary of Tool Design and Stakeholder Feedback.

Design phase and tool prototype	Tool description	Provider feedback	Parent feedback
Phase I: initial discussions and formative testing			
Initial discussion and prototype design with pediatric providers at FQHCs	Used the SPEAK to assess parental knowledge prior to their child's well-child visit and formulated content based on the results. Contained information for counseling pertaining to 1 "strength" and 2 "gaps in knowledge" Evolved into a 1-page, provider-facing guide that synthesized a parent's results on SPEAK and offered tailored prompts for the provider to use during the well-child visit	Providers (n = 2) expressed a need and desire for a tool to assist with providing anticipatory guidance about early learning and language development in the clinic setting. Expressed interest in a tool that reinforces topics the parent knows and introduces information on topics the parent knows less about Providers (n = 11) showed interest in the concept of the tool and indicated that the tool would be useful in clinical practice but expressed concern that the amount of information may be overwhelming to parents and providers, thus limiting the tool's feasibility. Indicated preference for a tool that was not prescriptive of what to say, but instead showcased a parent's SPEAK results in a straightforward, streamlined manner	Initial discussion and prototype design did not include parents Parents (n = 5) reported the information to be useful and easy to understand
Formative testing with University of Chicago pediatricians and parents			
Phase II: implementation at FQHCs			
Version I			
Personalized Anticipatory Guidance based on SPEAK Survey Results <i>This caregiver task was designed to measure their expectations and knowledge surrounding early language development. This form highlights their strengths and areas for improvement.</i>			
CAREGIVER'S STRENGTH: EARLY EXPOSURE TO LEARNING <i>This caregiver knows a lot about the importance of exposing young children to words!</i>	Associated SPEAK Survey Item Suggested language: • Your baby's brain is unfished at birth. • The language input that the brain receives changes the way it develops. • 85% of brain development happens in the first 3 years of life. • One of the most important ways you build your baby's brain connections is to talk and interact with him from the moment he is born.	Providers (n = 6) indicated the tool was acceptable, useful, and not disruptive to clinic workflow. Expressed challenges with the volume of text in the tool and the need to translate the text into anticipatory guidance for the parent in real time. Some providers specifically identified challenges in adapting the guidance for all age groups	Parents (n = 68) expressed high satisfaction with the guidance given to them by their provider. Some indicated desire for take-home educational materials
CAREGIVER'S GAP IN KNOWLEDGE: NATURE vs. NURTURE <i>This caregiver could benefit from guidance related to the genetic and environmental components of early learning.</i>	Associated SPEAK Survey Item Suggested language: • Babies are born smart, they're made smart. You make your baby smart by talking and interacting with her. • Your child's intelligence depends on a combination of genetics and early experiences. Genes are fixed, but early experiences – like talk and interaction – can be shaped. • When you tune in, Talk More and Take Turns with your child, every word you say builds her brain.	Providers (n = 6) indicated the tool was acceptable, useful, and not disruptive to clinic workflow. Expressed challenges with the volume of text in the tool and the need to translate the text into anticipatory guidance for the parent in real time. Some providers specifically identified challenges in adapting the guidance for all age groups	Parents (n = 68) expressed high satisfaction with the guidance given to them by their provider. Some indicated desire for take-home educational materials
CAREGIVER'S GAP IN KNOWLEDGE: MEDIA USE FOR CHILD LEARNING <i>This caregiver answered a survey item related to media use and their child's learning incorrectly.</i>	Associated SPEAK Survey Item Suggested language: • Words from television or other technology can't build your child's brain like yours can. He learns best from talking and interacting with you! • Babies learn best face to face, when they can see, interact with, and hear you. • Babies can't learn from watching screens – even when it's educational content. The only exception to this is a live video chat. The interactive nature of this experience builds connections in your child's brain just like an in-person conversation.	Providers (n = 6) indicated the tool was acceptable, useful, and not disruptive to clinic workflow. Expressed challenges with the volume of text in the tool and the need to translate the text into anticipatory guidance for the parent in real time. Some providers specifically identified challenges in adapting the guidance for all age groups	Parents (n = 68) expressed high satisfaction with the guidance given to them by their provider. Some indicated desire for take-home educational materials

(continued)

Table 3. (continued)

Design phase and tool prototype	Tool description	Provider feedback	Parent feedback
<p>Version II BRAIN BUILDING GUIDE</p> <p><i>WOW! Your survey shows that you know a lot about...</i></p> <p>Early Exposure to Learning</p> <ul style="list-style-type: none"> - Your baby's brain development is unfinished at birth. - One of the most important ways you build your baby's brain connections is to talk and interact with him from the moment he is born. <p>Based on your survey results, here are some facts that you might not know!</p> <p>A Child's Potential to Learn</p> <ul style="list-style-type: none"> - How smart a child will become does not depend mostly on genetics—early life experiences matter too! - You make your child smart by talking and interacting with her. <p>Background Noise and Language Learning</p> <ul style="list-style-type: none"> - Leaving the TV on in the background will not help very young children learn words. - Infants can't learn from watching screens. They may repeat words they hear, but their brain doesn't build connections with a screen the way that it does in person-to-person conversations. 	<p>Single page, parent-facing “Brain Building Guide.” Included graphics and age-specific information written for a parent audience. Providers were instructed to use the “Brain Building Guide” during the visit as they saw fit and send parent home with both this and an extended guide that gave information on additional topics not covered in the parent’s “Brain Building Guide.”</p>	<p>Providers (n = 8) indicated a strong preference for version II to version I and expressed satisfaction with all changes made. Some providers expressed concern that the “might not know” phrasing would be discouraging to parents. Additional consultation with design experts yielded similar feedback regarding the “might not know” phrasing as well as a suggestion to change language to directly address the parent</p>	<p>Parents (n = 80) expressed high satisfaction with the new format and graphics and reported finding the guide clear and easy to follow. Expressed that they liked having information to take home with them. Some indicated desire for clearer action steps that they could take at home</p>
<p>Version III BRAIN BUILDING GUIDE</p> <p><i>WOW! Your survey shows that you know a lot about...</i></p> <p>Early Exposure to Learning</p> <ul style="list-style-type: none"> - Your child is ready to be exposed to words as soon as they are born. - You build your child's brain connections by talking and interacting with them! - 85% of brain development happens in the first 3 years of life. <p>Based on your survey results, here are some helpful facts!</p> <p>Your Child's Potential to Learn</p> <ul style="list-style-type: none"> - How smart your child will become does not depend mostly on genetics—early life experiences matter too! - Children aren't born smart, they're made smart. - Talk and interact with your child to help them reach their full potential. <p>Background Noise and Language Learning</p> <ul style="list-style-type: none"> - Leaving the TV on in the background will not help your baby learn words. - Your baby can't learn from watching screens. They may repeat words they hear, but their brain doesn't build connections with a screen the way it does when interacting with real people. 	<p>Modeled similarly to version II with specific language changes and task-oriented suggestions for parents. The framing of parent’s “gap in knowledge” was changed from “here are some facts that you might not know” to “here are some helpful facts.” Language was changed to primarily second person to more directly address the parent (ie, “how smart a child will become” changed to “how smart your child will become.”)</p>	<p>Providers (n = 7) expressed satisfaction with the language changes and inclusion of task-oriented suggestions and indicated a slight preference for version III compared with version II</p>	<p>Parents (n = 72) reported finding the given action items useful and expressed high satisfaction overall</p>

Abbreviations: FQHC, Federally Qualified Health Center; SPEAK, Survey of Parents'/Providers' Expectations and Knowledge.

associated with each “strength” and “gap in knowledge” were included, so that clinicians had an understanding of what responses from parents yielded the displayed results. The tool included a section titled “Suggested Language,” with multiple suggested scripts for anticipatory guidance in that subject area.

Phase II: Implementation, Feedback Gathering, and Responsive Iteration Results

Version I—a 1-page, clinician-facing guide that synthesized a parent’s results on SPEAK and offered tailored prompts for the provider to use during the well-child visit—was implemented with 68 parents and 8 clinicians. Interviews with parents and clinicians were analyzed to identify themes to inform iteration of the tool. Parents expressed the desire to have educational materials to take home with them related to the topics discussed during the visit. Clinicians found the volume of text on the tool cumbersome and had difficulty utilizing it in real-time counseling of parents, particularly when the suggested guidance was not applicable to all age groups. They liked the idea of adjusting the tool for shared parent and clinician use during the visit and suggested including an extended version with detailed information for parents to take home with them. Detailed information related to tool design as well as parent and clinician feedback for each version is displayed in Table 3.

Version II of the Personalized Anticipatory Guidance Tool was created in response to the feedback from parents and clinicians described above. It was designed to be both clinician and parent facing, with the inclusion of concise, age-specific, parent-accessible information.

Additionally, clinicians were instructed to give parents their guide to take home as well as an extended guide that gave information on additional topics not covered in the parent’s personalized guide. Version II was implemented with 80 new parent participants and the same 8 clinicians. Clinician and parent satisfaction increased significantly with version II ($P < .05^*$; $P < .04^*$) when compared with version I. Parents and clinicians preferred the new format and graphics and found the guide easy to follow. Parents expressed that they liked having information to take home with them. One parent commented, “The sheets are a good idea because they are a physical thing for you to look at and remember. You could even put it up somewhere around your house. I really liked talking about the stuff on there because a lot of it nobody tells you, like how she said to let kids move around when you read. I always thought that was bad, but now I know!”

Some parents expressed interest in having more action-oriented suggestions included on the tool. Additionally,

some clinicians requested minor language changes to the header introducing a parent’s gaps in knowledge. They expressed concern that the header, which read, “Based on your survey results, here are some facts that you might not know!” may be discouraging to some parents and suggested more neutral phrasing.

Version III was developed based on this feedback, modeled similarly to version II with some specific language changes and task-oriented suggestions for parents. This version was implemented with 72 new parent participants and the same 8 clinicians. Clinicians had a slight preference for version III over version II, and parental satisfaction remained high, with many parents reporting eagerness to apply given action items to their parenting.

Throughout all 3 versions of the intervention, clinicians indicated that they liked having the Anticipatory Guidance Tool and did not find it disruptive to their clinical workflow. Pre-post measurements were used to estimate the overall efficacy of the intervention. SPEAK scores for parent participants were compared pre-visit, immediately post-visit, and 4 weeks post-visit. Versions I, II, and III of the Personalized Anticipatory Guidance Tool were compared using these comparisons as a measurement of efficacy. Means and SDs of SPEAK scores for all 220 parent participants at these 3 points in time as well as results of paired *t*-tests, are described in Table 4. Pre-visit SPEAK scores were normally distributed across the sample, with a mean of 21.8 points on a scale of 0 to 32 and SD of 5.22. Immediate post-visit SPEAK scores ($M = 23.6$; $SD = 6.05$) were significantly higher than pre-visit SPEAK scores ($P < .0001^*$), with a mean increase of 1.8 points observed. Four-week postvisit SPEAK scores remained significantly higher ($M = 24.4$; $SD = 5.47$) compared with pre-visit SPEAK scores, with a mean increase of 2.2 points ($n = 138$; $P < .0000^*$). The group that completed the 4-week post-visit SPEAK was representative of the entire group demographically and showed no significant difference from the entire group in pre-visit SPEAK scores or tool version received. All participants were included in the analysis, including those with a perfect initial SPEAK score (32/32) or nearly perfect score.

Analysis of pre-visit and post-visit SPEAK scores broken down by version of Personalized Anticipatory Guidance Tool is described in Table 4. Each version independently showed significant increases in parental knowledge immediately post-visit and at 4 weeks post-visit. Moreover, parents who were given a guide to take home (versions II and III) showed a significant increase in knowledge at 4 weeks post-visit compared with immediately post-visit ($P = .019^*$), suggesting possible continued engagement with the topics addressed in the tool after the well-child visit.

* indicates a statistically significant result ($P < .05$).

Table 4. Participant Survey of Parental Expectations and Knowledge (SPEAK) Scores at Pre-visit, Post-visit, and 4-Week Post-visit.

Personalized Anticipatory Guidance Tool	Time point	Mean SPEAK			Paired-samples T-test (compared with previsit)
		score (0-32)	SE	95% CI	
Version 1 (68)	Pre-visit	22.3	0.645	21.0-23.5	• Post: $T(df = 67) = 4.87; P < .0000^a$ • 4-Week post: $T(df = 43) = 2.09; P = .02^a$
	Post-visit	24.2	0.390	22.7-25.6	
	4-Week post-visit (n = 44)	24.3	0.808	22.7-26.0	
Version 2 (80)	Pre-visit	21.9	0.633	20.7-23.2	• Post: $T(df = 79) = 4.58; P < .0000^a$ • 4-Week post: $T(df = 46) = 4.57; P < .0000^a$
	Post-visit	23.7	0.736	22.2-25.2	
	4-Week post-visit (n = 47)	24.5	0.841	22.8-26.2	
Version 3 (72)	Pre-visit	21.3	0.544	20.2-22.4	• Post: $T(df = 71) = 4.43; P < .0000^a$ • 4-Week post: $T(df = 47) = 4.85; P < .0000^a$
	Post-visit	23.1	0.647	21.8-24.4	
	4-Week post-visit (n = 47)	24.3	0.786	22.8-25.9	

Phase III Collective Review

At the conclusion of phase II, semistructured individual interviews as well as a postintervention survey were administered to clinicians. The purpose of this collective review was to assess stakeholders' attitudes about the efficacy of HCD in the design of this intervention, gather feedback on their experience with the HCD process, and determine their beliefs about the broader efficacy of HCD for future clinical innovations.

In the semistructured interviews, clinicians largely expressed their support of the HCD process, describing their appreciation that their input was incorporated into the tool. For example, when asked about their experience participating in the design process, one person stated, "It's been really good, taking our feedback and seeing it immediately change. I think the product is so much better than how it was in the beginning."

In addition to appreciating the direct impacts of their involvement, clinicians often described possible benefits of developing a tool in the context of real patient visits. One explained, "I think it's always hard to go from medical information to practical, everyday lifestyles. And so being able to think about our patients and what would best benefit them . . . has been really helpful." Another clinician commented on the involvement of parent stakeholders, stating, "It's nice because we really feel like [the tool is] tailored well to the patient population that we see."

Through these post-intervention interviews with clinicians, feedback was also gathered on how to improve the HCD process. Some described limitations of using the SPEAK survey, finding the wording of certain items challenging for some participants. Another clinician remarked on the way feedback was gathered during phase II, suggesting that group feedback sessions with participating clinicians, in addition to individual feedback sessions, could have enhanced the generation and exchange of ideas about the tool's design.

Results of the post-intervention clinician survey were consistent with interview responses. Of the 8 participating clinicians, one did not complete the postintervention survey because of scheduling challenges. In the survey, all participants (n = 7, 100%) either agreed or strongly agreed that (1) their feedback was valued throughout the design process, (2) they enjoyed being part of the design process, and (3) the design process was an effective way to create a clinical tool. When asked if they were more likely to use the tool because their feedback was incorporated in its design, 3 clinicians (43%) agreed or strongly agreed, whereas 3 (43%) were undecided. Additionally, 6 (86%) clinicians reported that the intervention improved the quality of anticipatory guidance they gave to parents regarding early learning and language development.

Discussion

In the present study, utilizing an HCD approach allowed for the creation of a novel clinical decision support tool to assist clinicians in giving anticipatory guidance meant to increase parent knowledge of early learning and language development. By using an iterative process involving collaboration with key stakeholders, it was possible to tailor the tool to the unique needs of parents and clinicians in 2 FQHCs in Chicago. The tool was highly usable and acceptable to stakeholders, as illustrated by the high levels of parent and clinician satisfaction. What is more, use of this tool in the clinical setting yielded robust, sustained significant increases in parental knowledge, both immediately following the well-child visit and 4 weeks later. The combination of these outcomes creates a strong argument for the potential use of HCD in this realm and warrants future study.

HCD provided a means of gathering rich information about the impact of the Personalized Anticipatory Guidance Tool throughout the design process. By using multiple modalities to evaluate the tool, including

surveys, interviews, and knowledge assessments, both qualitative information about stakeholders' preferences as well as quantitative data about parental knowledge change could be gathered. This allowed the tool to be made more effective with each iteration. The findings of this study suggest that the resulting tool was efficacious in having an impact on knowledge in the study participants, fits within the context of the well-child visit with minimal workflow disruption, and was satisfactory to stakeholders. These results are encouraging and suggest potential success in broader implementation.

Prioritizing efficacy alongside acceptability and usability in the design process was critical to the creation of a clinically useful tool. Whereas many studies using HCD focus primarily on design outcomes,²⁷ this study's use of the SPEAK allowed an equal emphasis to be placed on the tool's potential to affect knowledge throughout its development. Using the quantitative data on efficacy to inform iteration of the tool added a new dimension to the HCD process. Through analysis of SPEAK scores, it was possible to demonstrate potential efficacy in affecting parental knowledge at the end of the study.

SPEAK scores also provided a means to assess trends in parental knowledge change to help elucidate the impact of revisions made to the tool. This analysis revealed that parents who were given guidance using versions II and III, which included materials for the parent to take home, showed an increase in knowledge 4 weeks postvisit compared with immediately postvisit. This suggests that incorporating feedback from study participants, such as sending educational materials home with parents, led to continued engagement with the topics discussed at the visit. This is particularly exciting because it indicates the possibility of the intervention having an impact that is sustained beyond the well-child visit and lays the groundwork for future learning.

Because parent knowledge predicts parent-child interaction, these significant and enduring increases in parent knowledge seen with the use of the tool are encouraging.¹⁵ Although evaluating parent-child interaction was beyond the scope of this study, comments from many parents in their postappointment interviews indicated an intention to change their behavior. One parent stated, "I learned that the educational TV that I thought was good wasn't actually good. We are going to stick to books." Although these findings are promising, parent-child interaction remains an essential variable to assess in future studies.

This study also demonstrated that clinicians were highly satisfied with the HCD process. They enjoyed being a part of the process and felt that their input was valued. Clinician satisfaction was further underscored

by the enthusiasm they showed for utilizing the HCD process in future intervention design. During phase III interviews, they proposed several ideas for future clinical application of HCD. Asthma education, breastfeeding, and social-emotional development were all areas of anticipatory guidance that clinicians in this study suggested could benefit from interventions designed using HCD. These findings support the idea that broader utilization of HCD in designing clinical interventions would be well received by those participating.

Limitations

Although many studies show that anticipatory guidance surrounding early learning and language development is not typically given in early pediatric well-child visits, it is important to note that because this study did not have a control group with whom to compare results, it was not possible to definitively determine a causal link between the intervention and increase in parent knowledge.^{14,17,18} Additionally, although previous studies have shown that parent knowledge predicts parent-child interaction and parent behaviors predict child outcomes, this study did not assess if the increases in parent knowledge seen here translated to these changes.^{15,30}

Several clinicians mentioned during the interview process that the HCD process used in this study was limited by the SPEAK survey, which was chosen at the outset of the study as the basis of the prompts given by clinicians and the means of parental knowledge evaluation. Although this is a validated survey, clinicians expressed concerns about the ability of this survey to accurately convey parental knowledge in the study population. In addition, because the survey used at each time point was the same brief questionnaire and no control group was utilized, it cannot be definitively concluded whether the observed changes in score show a meaningful change in knowledge or represent improvement resulting from multiple iterations of the same test. Finally, this study limited participation to English-speaking parents only, given the limited resources available for translating the study materials at the time of completion. This limitation could be rectified in future studies by translating handouts to appropriate languages for the patient population and utilizing interpreters in the clinical setting when necessary.

Future Directions

A well-designed randomized controlled trial is needed to adequately assess the efficacy of the Personalized Anticipatory Guidance Tool. Future studies may randomize parents to receive the current intervention,

widely available developmental handouts commonly used in clinical practice, or no additional change from the standard of care to further study the efficacy of this intervention. Future studies evaluating parent behaviors may also be considered to further assess this tool's impact on parent-child interaction. Additionally, this tool may be evaluated for usability and efficacy during prenatal visits because several parents suggested that this guidance would have been helpful at that time. Given that parental behaviors have been shown to affect prenatal brain development,³⁰ providing this information to parents earlier and continuing to give personalized guidance as their child grows could have an even greater impact on a child's early learning environment. Finally, modification of the SPEAK tool for use in the target population in a clinical setting will enable deeper and more precise insight into baseline parent knowledge and parental knowledge change, which may improve the impacts of the Anticipatory Guidance Tool.

Conclusion

Future studies to evaluate the efficacy of using a Personalized Anticipatory Guidance Tool to affect parental knowledge and behavior must address the aforementioned limitations of the current study, with an additional emphasis on scalability. The pre-visit knowledge assessment can be incorporated into pre-visit tasks for parents, and the creation of Personalized Anticipatory Guidance Tools can easily be completed electronically without the need for research personnel. Importantly, HCD must continue to be used to evaluate best practices for delivery mechanism and scalability, ensuring that as this intervention evolves it continues to meet the needs of target communities. In using HCD to develop this Personalized Anticipatory Guidance Tool, this study addressed the previously described barriers to providing anticipatory guidance, including a lack of time, resources, and understanding of a parent's existing knowledge and beliefs surrounding early learning.¹⁸ Previous interventions targeting the early learning environment have often been implemented without consideration of the heterogeneity among parents of low SES when it comes to knowledge, expectations, and experiences surrounding early cognitive development.^{7,31,32} Rather than using this one-size-fits-all approach, this intervention allowed for the provision of personalized information to all participants while supporting clinicians in overcoming barriers to effective counseling. This likely contributed to the observed efficacy of the tool and highlights the potential for HCD to be useful in developing interventions that address complex health inequities.

Authors' Note

Louisa Dru Brenner and Risa Brudney contributed equally to the development of this article and are recognized as co-first authors in this study.

Author Contributions

LDB: Contributed to conception and design; contributed to acquisition, analysis, and interpretation; drafted manuscript; critically revised the manuscript; gave final approval; agrees to be accountable for all aspects of work ensuring integrity and accuracy.

RB: Contributed to conception and design; contributed to acquisition, analysis, and interpretation; drafted manuscript; critically revised the manuscript; gave final approval; agrees to be accountable for all aspects of work ensuring integrity and accuracy.

JC: Contributed to conception and design; contributed to acquisition, analysis, and interpretation; drafted manuscript; critically revised the manuscript; gave final approval; agrees to be accountable for all aspects of work ensuring integrity and accuracy.

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MER: Contributed to acquisition; critically revised the manuscript; gave final approval; agrees to be accountable for all aspects of work ensuring integrity and accuracy.

KRL: Contributed to analysis; drafted manuscript; critically revised the manuscript; gave final approval; agrees to be accountable for all aspects of work ensuring integrity and accuracy.

DS: Contributed to conception and design; critically revised the manuscript; gave final approval; agrees to be accountable for all aspects of work ensuring integrity and accuracy.

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