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Promotion of Early Pediatric Hearing Detection Through Patient Navigation

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PROMOTION OF EARLY PEDIATRIC HEARING DETECTION THROUGH PATIENT NAVIGATION

DISSERTATION

A dissertation submitted in partial fulfillment of the
requirements for the degree of Doctor of Philosophy in the
College of Medicine
at the University of Kentucky

By
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2017

ABSTRACT OF DISSERTATION

PROMOTION OF EARLY PEDIATRIC HEARING DETECTION THROUGH PATIENT NAVIGATION

Congenital hearing loss is the most common neonatal sensory disorder and it is crucial to diagnose hearing loss as soon as possible after birth in order to facilitate rapid treatment. Universal standards of infant hearing healthcare dictate that infant hearing screening should be completed by one month of age and abnormal screening tests should be followed with definitive audiological testing by three months of age. Obtaining diagnostic testing can be complicated by limited access to care in rural areas, breakdowns in communication, lack of parental support, and poor coordination of care. There is no established method to address appointment non-adherence in newborn hearing testing. Patient navigation (PN), which uses trained healthcare workers to educate patients and facilitate adherence to healthcare, is an evidence-based approach that has had widespread success in facilitating timely care in other healthcare settings but has not been studied in infant hearing testing. The objective of this dissertation is to 1) assess the effect of patient navigation on care delivery in healthcare inequity settings, 2) assess the efficacy of a PN intervention to decrease non-adherence to recommended infant audiological testing after failed newborn hearing screening, and 3) develop a method to implement patient navigation into the state hearing screening program.

The original concept and development of PN stems from the findings of the American Cancer Society National Hearings on Cancer in the Poor in 1989, which revealed a host of barriers that underserved populations face in receiving timely and appropriate, care. Cancer treatment centers have utilized patient navigators (PNs) to address these barriers in the delivery of cancer care. In order to consider the potential of applying patient navigation in promoting timely infant hearing healthcare, a systematic review was performed to systematically assess the efficacy of patient navigation to improve diagnosis and treatment of diseases affecting medically underserved populations. Specific outcomes assessed in the review included the effect of PN on timing of definitive diagnosis and effect on initiation of treatment. The search strategy produced 1,428 articles and 16 were included for review. In the Oncology field, timing of initial contact with a patient navigator after diagnostic or screening testing was correlated to the effectiveness of the navigator intervention. The majority of the studies reported significantly shorter time intervals to diagnosis and to treatment with patient navigation. This review provided evidence to justify a PN efficacy trial in infant hearing healthcare.

To investigate the efficacy of PN to decrease non-adherence to recommended infant audiological testing after failed newborn hearing screening, a randomized controlled trial was conducted in sixty-one guardian-infant dyads. All infants had abnormal newborn hearing screening and were recruited within the first week after birth. Dyads were randomized into a PN study arm or standard of care arm. PN was found to be efficacious as the percentage of participants with follow-up non-adherence was significantly lower in the PN arm compared with the standard of care arm (7.4% versus 38.2%, p=0.005). The timing of initial follow-up was significantly lower in the PN arm compared with the standard of care arm (67.9 days versus 105.9 days, p=0.010). Based on this efficacy data, the next objective of the research was to scale up PN to maximize public health impact by combining an effectiveness trial with implementation research. A hybrid effectiveness/implementation study was designed to investigate patient navigation within the state-funded EHDI (early hearing detection and intervention) system. Using a stepped wedge design this trial investigates the 1) effectiveness of PN to decrease non-adherence to hearing testing, 2) implementation factors using the Consolidated Framework of Implementation Research (CFIR), and 3) cost-effectiveness and sustainability of a PN program within a state-supported EHDI system.

KEYWORDS: Hearing Loss, Patient Navigation, Healthcare Disparity

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PROMOTION OF EARLY PEDIATRIC HEARING DETECTION THROUGH PATIENT NAVIGATION

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1.1 PEDIATRIC HEARING LOSS: A PUBLIC HEALTH CONCERN

As the most common neonatal sensory disorder in the United States, infant hearing loss occurs in 1.6 per 1000 births.[1] The sense of hearing is vital and early childhood hearing loss can result in lifelong learning delay and disability. The consequences of delayed infant hearing loss diagnosis and intervention include significant delays in language, cognitive, and social development[2] with profound effects on education and employment.[3] The economic costs of hearing loss are substantial and, according to the Centers for Disease Control, the overall lifetime medical, educational, and occupational costs due to deafness for children born in 2000 is estimated to be $2.1 billion.[4]

1.2 DIAGNOSTIC DELAYS IN PEDIATRIC HEARING LOSS

The United States Preventive Services Task Force recognizes that early diagnosis of hearing loss leads to decreases in language development problems, social and emotional challenges, and learning and behavioral disorders.[5] Intervention for hearing loss prior to 6 months of age has profound effects on language expressive measures and social adjustment.[6,7] To promote early diagnosis and treatment, all infants should be screened no later than 1 month after birth, diagnosis of hearing loss should occur before 3 months of age, and hearing loss treatment should occur before 6 months of age (1-3-6 rule).[8-11] The Joint Committee on Infant Hearing (JCIH) gold standard is that no more than 10% of infants would be non-adherent to diagnostic testing by 3 months of age;[12] however, this standard is not being met. In 2014, 58.9% of U.S. infants failed to obtain a diagnosis within 3 months after abnormal screening.[1] In spite of efforts to closely

document follow-up and promote adherence to timely testing in Kentucky, the state's non-adherence rate is still 25.9%, nearly 3 times the JCIH goal.[1] In addition, children from underserved rural regions such as Appalachia are consistently delayed in diagnosis and treatment of hearing loss.[13-15]

1.3 FACTORS LEADING TO DIAGNOSTIC DELAYS

Timely adherence to infant diagnostic testing and hearing loss treatment is a complex process and parents face many barriers. Early infant hearing detection and intervention (EHDI) programs are coordinated by each state and the diagnostic and treatment process is complex. Despite multiple streamlining initiatives, many parents find the diagnostic process and treatment difficult to navigate.[16] Risk of non-adherence is higher in families with greater travel distances, low levels of parental education, low socioeconomic status, and public insurance.[17-20] Families of children with hearing loss report that they lack confidence and resources needed for healthcare decision-making for their child.[21] Many parents lack role models who have been through the complex process of hearing loss diagnosis and intervention[22] because more than 90% of deaf children have hearing parents.[23] Consistent with the tenets of Social Cognitive Theory (SCT),[24-27] a complex interaction of personal, interpersonal, and environmental factors influences hearing healthcare adherence and access.

1.4 LACK OF EVIDENCE-BASED APPROACHES TO DECREASE INFANT HEARING DIAGNOSTIC NON-ADHERENCE

There are no existing evidence-based approaches to decrease non-adherence to infant hearing testing and treatment. Tele-audiology may expand access but requires significant resources, and insufficient data are available to support widespread use of this strategy.[28] Prenatal educational modules[29] and social worker counseling[30] have not

demonstrated significant benefit in promoting rescreening after failed infant hearing screening; however, parental contact after postnatal hospital discharge may promote rescreening.[31] Parent-to-parent programs, such as *Guide By Your Side*,[32] are available in many states and may reduce parental isolation and boost parental acceptance of the child's condition.[22] However, despite promising data from nearly 2 decades ago, these programs are not consistently integrated into state-funded EHDI services and diagnostic centers, and when provided they are under-utilized. Additionally, these programs typically require the parents to make initial contact to establish services, and they often are not utilized until ***after*** a diagnosis of hearing loss is made. Evidence regarding the effects and optimal implementation of these programs is lacking; in fact, a recent meta-analysis found ***no literature addressing the effectiveness or cost of initiatives designed to decrease non-adherence in follow-up*** after failed newborn hearing screening.[33]

1.5 THE POTENTIAL OF PATIENT NAVIGATION TO PROMOTE INFANT HEARING ADHERENCE

PN programs can increase healthcare adherence and improve access to care, especially in underserved rural populations. PNs are trained healthcare workers who assess and mitigate personal, interpersonal, and environmental barriers to healthcare adherence and access, consistent with SCT-based approaches to promote healthy behaviors.[24-27] PNs educate patients on health conditions and healthcare systems while facilitating adherence to healthcare recommendations.[34] Primarily implemented and studied in the cancer field, PN reduces medical non-adherence and hastens diagnosis and treatment.[35-37] PN programs have been especially effective in assisting patients from traditionally underserved backgrounds, including rural Appalachia.[38-45] The positive patient-level effects of PN (i.e., improved adherence with medical diagnostic testing[46-48] and timely diagnosis and treatment[39,46,49]) can resulted in significant healthcare cost

savings.[45] In order to consider the potential for patient navigation in promoting timely infant hearing healthcare, it is necessary to obtain a deeper understanding of the role that patient navigation has played in healthcare promotion in underserved populations.

1.6 PATIENT NAVIGATION IN THE MEDICALLY UNDERSERVED: A SYSTEMATIC REVIEW

1.6.1 Introduction

Patient adherence to physician recommended follow-up and treatment plans is often a challenge. Martin et al reported in 2005 that up to 40% of patients did not comply with their recommended treatment plans. When a patient's treatment plan is more complex or requires active lifestyle changes, that percentage of non-adherence can rise to as high as 70%. Such lack of patient compliance can lead to significant complications in the patient's healthcare as well as increased medical expenses.[50] Reported factors that lead to non-adherence include misunderstanding the recommended follow-up or treatment plan, lack of consistency in the patient's medical care, cultural or health beliefs that conflict with the plan, socioeconomic status, mistrust of the healthcare system, and a lack of social support for the patient.[51] All of these factors serve as potential barriers that doctors, nurses, and other providers must assist the patient in overcoming.

Patient navigation is an evidence-based intervention created to address non-adherence and help patients maneuver through personal and systematic barriers in order to achieve timely follow-up care for health conditions.[52] The role of a patient navigator is to assist patients in overcoming challenges that prevent adherence to their healthcare plan, allowing them to timely and adequate treatment. The original concept and development of this intervention stems from the findings of the American Cancer Society National

Hearings on Cancer in the Poor in 1989. These hearings revealed a host of difficulties that underserved populations face in receiving timely and appropriate care. Based on these findings, Dr. Harold Freeman initiated the first patient navigation program in 1990 to promote timely cancer treatment in Harlem, New York.[53] Since that pilot program, treatment centers worldwide have been using patient navigators to improve the quality and timeliness of therapy in a multitude of cancer types. The purpose of this research is to systematically evaluate the efficacy of patient navigation in improving timely and appropriate diagnosis and treatment of disease in medically underserved populations. We hypothesize that patient navigation is effective in improving timely, appropriate follow-up care for diagnosis and treatment of chronic illness within underserved populations.

1.6.2 Methods

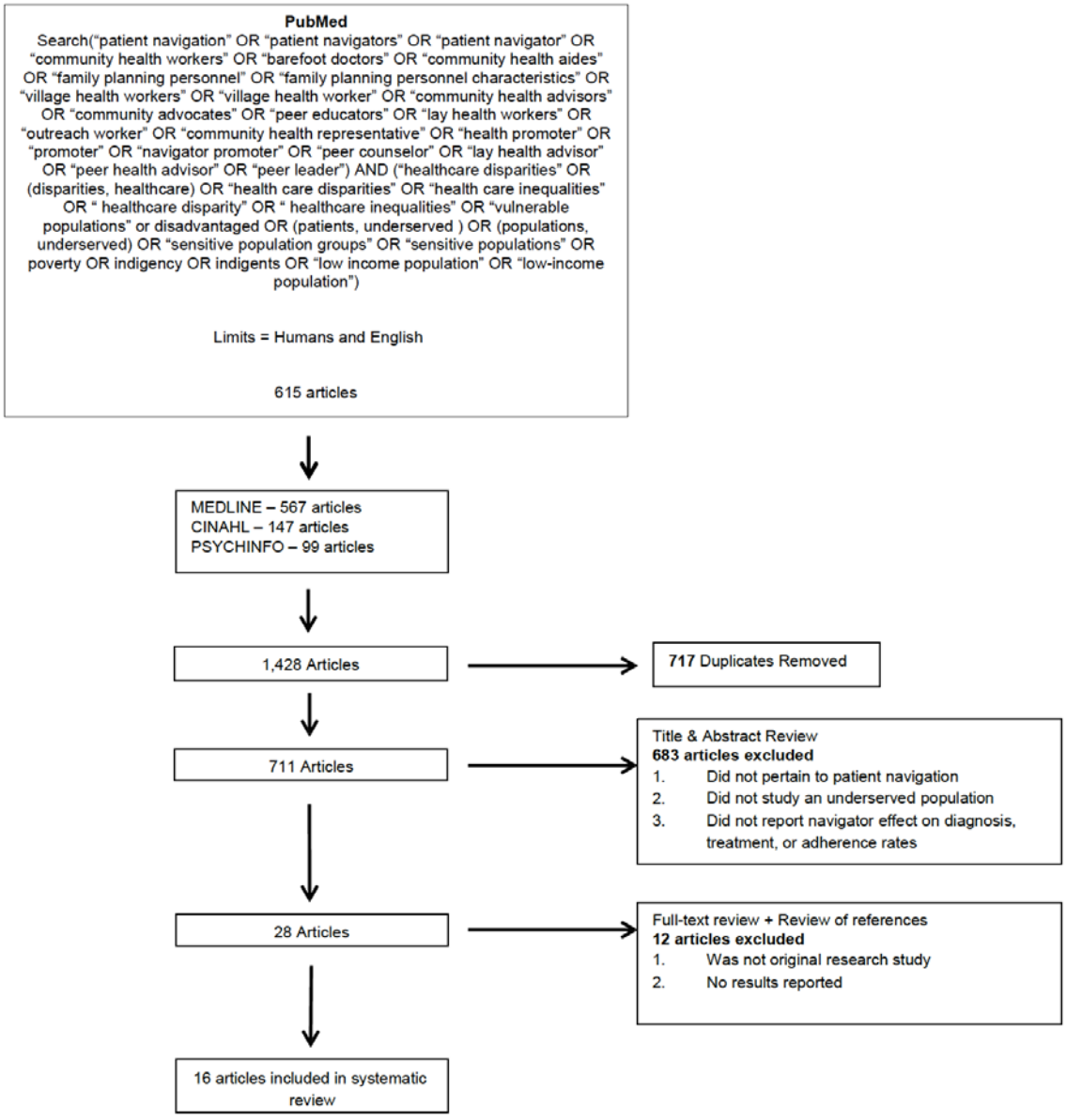
This study was exempt from Institutional Review Board approval. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis[54] checklist was used to guide this systematic review. A specific outcome measure was not required for inclusion in this review. The specific inclusion criteria included: 1) articles pertaining to patient navigation in the healthcare setting, 2) articles reporting on the effect of navigation on definitive diagnosis, and 3) articles reporting on the effect of navigation on timely initiation of treatment, and 4) articles studying patient population designated as underserved. Exclusion criteria included: 1) single case reports or non-original research and 2) language other than English.

Search Strategy: To perform a systematic literature review of patient navigation in the underserved, a search string was developed to include patient navigation or similar programs used in populations that are medically underserved. A search string was designed to include studies that addressed both (1) patient navigation and (2) medically underserved populations. See **FIGURE 1.1** for the complete search string. A search

strategy was developed using The National Library of Medicine's (NLM) medical subject heading (MeSH) browser in expanded concept view to identify MeSH indexed search terms (http://www.nlm.nih.gov/ mesh/MBrowser.html). In an attempt to capture articles pertaining to the study objective, MeSH terms associated with "patient navigation" were used to ensure that pertinent navigation studies were not excluded based on the title of the program. These included barefoot doctors, community health workers, community health aides, and health promoter. To identify all relevant articles related to "health disparity" the following words were also included: inequality, low-income, poverty, and indigent. An initial search was performed in PubMed. [All Fields] was selected to ensure that articles that mentioned the pertinent terms in any form would be captured. The search was confined to English only papers. The same search string was then used to search MEDLINE, PsychINFO, Web of Science, and CINAHL, with duplicates from the four searches being removed. Title and abstract reviews were conducted to select articles that dealt with human participants and any form of patient navigation and health disparity, eliminating case studies, literature reviews, or studies with no reported timing to diagnosis or treatment outcomes. The search was performed in August 2015. **FIGURE 1.1** lists terms utilized in the search string as well as the algorithm for inclusion/exclusion.

Data Extraction: Article titles and abstracts were reviewed independently by 2 reviewers and were selected or removed based on the inclusion and exclusion criteria. In the event of disagreement over inclusion, the article was included for full text review to be more inclusive. A full-text review of all eligible articles was completed independently by the reviewers and the bibliographies of these articles were examined to identify additional articles. The two reviewers independently analyzed the articles and results were then organized into two tables focusing on the outcomes of (1) effect of navigation on obtaining a definitive diagnosis following screening test and (2) effect of navigation on obtaining

FIGURE 1.1 – Preferred reporting items for systematic review and meta-analysis algorithm



treatment following diagnosis. The level of evidence of each article was also assessed according to the Oxford Centre for Evidence-based Medicine guidelines.[55]

Bias Assessment: Articles were reviewed independently and scored based on accepted bias assessment tools. Randomized controlled studies were analyzed using the National Institute of Health Quality Assessment Tool for Controlled Intervention Studies. A score was obtained based on the 14-point questionnaire. The authors agreed on a score of 10 or above for a low risk of bias, 6-9 for a moderate risk of bias and 5 or less for high risk of bias. Retrospective studies were assessed using the Newcastle – Ottawa Scale.[56] The authors agreed on a score of greater than 8 as a low risk for bias, 5-8 for moderate risk and less than 5 as high risk of bias. Studies that did not conform to these bias scales were not assessed.

1.6.3 Results

Search Results: The initial search of all 4 databases yielded 1,428 articles. After the duplicates were removed, 711 articles remained. The titles and abstracts of these articles were scanned to determine if they met the study objectives; 683 articles were removed through this process. A full text review and scan of the references of the remaining twenty-eight articles were performed. Of the twenty-eight, sixteen met the inclusion criteria and were eligible for the systematic review. All studies were from the field of Oncology. Of these studies, seven used a randomized trial design, five used a non-randomized design, two were observational, and two included multiple study sites that use different methods. There was a lack in consistency in outcome reporting and intervention conditions, thus a meta-analysis was not performed. The type of navigator in each study differed; seven of the studies recruited lay people to be trained in the role of a navigator, three employed nurses with oncology experience, and six studies used a team approach consisting of a lay person and a nurse or an individual with a master's in social

work (MSW). The studies were conducted from 1998-2011, and all were based in the United States. The participants in the studies included uninsured, non-English speaking, and underserved residents from urban or rural locations. The reported efficacy of navigation on diagnosis and treatment are recorded in **TABLE 1.1** and **TABLE 1.2**, respectively, along with description of the study sample.

Studies with Time to Diagnosis as the Primary Outcome: Fifteen of the articles included in the review assessed the effect of patient navigation on timely diagnostic resolution following an abnormal cancer screening. The studies varied regarding the cancer type included in the trial; six of the articles addressed only patients with abnormal breast cancer screenings, one involved cervical cancer, one involved colorectal cancer, and the remaining seven included multiple types of cancer including breast, cervical, colorectal, and prostate cancers. Diagnostic resolution was defined as a patient obtaining follow-up testing that resulted in either a definitive diagnosis of cancer or no cancer.[57,58] A majority of the studies measured time to diagnosis as the date of the abnormal screening to the date diagnostic testing was complete.[51,52,57,59-63] Three of the studies placed more emphasis on adherence to follow-up appointments; however, these appointments usually resulted in diagnostic resolution as well.[59,64,65]

As mentioned previously, the qualifications and characteristics of the navigators varied between studies. Some utilized lay navigators who had personal experience with the disease and represented the population they were serving (e.g. Hispanic women serving as navigators in an area where majority of the patients were also Hispanic). Others reported hiring professional health care workers or MSWs to perform navigation activities. Some studies included one or more navigators who were bilingual, commonly speaking English and Spanish. The structure of navigation also varied across studies. While some used a highly structured guide or assessment tool for each patient encounter,

TABLE 1.1: Effect of Patient Navigation on Diagnosis as Primary Outcome

Author/Year	Level of Evidence	Sample	Cancer Type	Type of Navigator	Navigation Effective?	Bias Score and Risk Assessment	Time to Diagnosis
Percac-Lima (2015)	IIb.	369 women who were nonwhite, non-English speaking or had Medicaid or no insurance	**1**	--	Yes	9 - Low	Not Reported
Lee (2014)	IIb.	193 racial & ethnic minority participants	**2**	--	Yes	10 Low	Not Reported
Freund (2014)	IIb.	10,521 mainly racial & ethnic minority and uninsured/publicly insured participants	**1, 2, 3, 4**	--	Yes	Unable to Assess	Not Reported
Bensink (2014)	IIb.	4330 racial & ethnic minority/ low income participants	**1, 2, 3, 4**	-- +	Yes	Unable to Assess	Mean: 110 days PN vs 109 days control
Lee (2013)	IIb.	1,039 mainly low- income, non-English speaking, Hispanic women	**1**	--	Yes	11- Low	Median: 6.2 months PN vs 12 months control
Battaglia (2012)	IIb.	3,041 women mainly from racial & ethnic minority groups	**1, 3**	+	Yes	8 - Low	Not Reported
Dudley(2012)	IIb.	461 mainly low income women with lower education level	**1**	-- +	Yes	8 - Low	Mean (Hispanic): 36.65 days PN vs 52.96 days control Mean (other minorities): 37.68 days PN vs 70 days control
Markossian (2012)	IIb.	897 low-income, racial & ethnic minority women	**1, 3**	-- **	Yes	9 - Low	Not Reported
Paskett (2012)	IIb.	862 participants from clinics serving mainly minority, low-income, and elderly patients.	**1, 2, 3**	+	Yes	10 - Low	Not Reported
Raich (2012)	IIb.	993 mainly racial & ethnic minority and uninsured/publicly insured participants	**1, 2, 4**	--	Yes	10 - Low	Not Reported
Wells (2012)	IIb.	1,267 mainly racial & ethnic minority and uninsured/publicly insured participants	**1, 2**	--	No	11- Low	Mean: 61 days PN vs 42 days control
Ferrante (2008)	IIb.	105 non-English speaking Hispanic women	**1**	+	Yes	11 - Low	Mean: 25.0 days PN vs 42.7 days control
Ell (2007)	IIb.	204 Hispanic women with low incomes and non-English speaking	**1**	-- **	Yes	10 - Low	Not Reported
Ell (2002)	IIb.	196 Hispanic women with low incomes	**3**	-- **	Yes	5 - Moderate	Not Reported
Ell(2002)	IIb.	605 culturally diverse women with low incomes	**1**	-- **	Yes	8 - Low	Not reported

Table 1: Description of patient navigator effect on diagnosis. Lay navigator (--), professional health care workers (+), & MSW (**). Breast Cancer (1), Colorectal (2), Cervical (3), & Prostate (4).

TABLE 1.2 – Effect of Patient Navigation on Treatment as Primary Outcome

Author/Year	Level of Evidence	Sample	Cancer Type	Navigator Type	Navigation Effective?	Bias Score and Risk Assessment	Average Time to Treatment
Ramirez (2014)	IIb.	109 Hispanic women with public or no insurance	**1**	**--**	Yes	8 - Low	Mean: 22.22 days PN vs 48.30 control
Freund (2014)	IIb.	10,521 mainly racial & ethnic minority and uninsured/publicly	**1, 2, 3, 4**	**--**	Yes	Unable to Assess	Not Reported
Dudley (2012)	IIb.	461 mainly low income women with lower education level	**1**	**+**	Yes	8 - Low	Mean: 57 days PN vs 74 days control
Ell (2002)	IIb.	605 culturally diverse women with low incomes	**1**	**--** **	Yes	8 - Low	Median: 24 days PN vs 29 days control

Table 2: Description of patient navigator effect on treatment. Lay navigator (**--**), professional health care workers (**+**), & MSW (**). Breast Cancer (1), Colorectal (2), Cervical (3), &

others used a simple logging system to record barriers or problems addressed during a conversation with the patient. Though the execution of navigation differed between the articles, the basic services provided and challenges addressed were consistent. The articles cited obstacles such as transportation difficulty, lack of insurance, poor coordination of healthcare appointments, language barriers, and general misunderstanding of the follow-up process as difficulties that navigators helped patients overcome.

Fourteen of the articles reported significant improvement in obtaining diagnostic resolution when a navigator was utilized.[51,52,57-67] The remaining article did not find the use of a patient navigator to be effective in improving the time from screening to diagnosis.[68] This outlying study reported a significant gap between the screening test and contact with the patient navigator. Over one-third of the patients in that study were not contacted by the navigator within the first month following the abnormal screening test.[68] This suggests that timeliness of initial contact by the navigator may influence the efficacy of such a program. Another study reported earlier diagnostic resolution with navigation; however, there was no significant difference in cancer stage at time of diagnosis between the navigator group and the control group in those patients that were actually diagnosed with cancer.[67]

Studies with Time to Treatment as Primary Outcome: Four of the sixteen articles included in this review assessed the effect of a patient navigator on time from definitive diagnosis to initiation of appropriate treatment. Three of these studies only included patients diagnosed with breast cancer; the remaining study included patients who had been diagnosed with breast, cervical, colorectal, and prostate cancers. Two of the studies utilized a non-randomized design, one used an observational design, and one utilized multiple designs to accommodate the needs to each site in their study. These articles

also had the same variation in the characteristics and qualifications of their navigators as the studies that focused on time to diagnosis, ranging from laypersons to nurses or MSWs. Each of the studies defined time to treatment initiation as the time from date of definitive diagnosis to the date that treatment was first received.[59,60,69,70] Types of treatment that were included were radiation, chemotherapy, hormone therapy, and surgery.[69] All four articles saw a significant decrease in time to treatment initiation or improvement of adherence in the navigated patients over the standard of care.

1.6.3 Discussion

Patient compliance to care is a factor that limits the efficacy of all aspects of medicine. Within the medically underserved, groups that have limited access to healthcare, this is an even larger problem. Patient navigation programs are designed to assist patients, specifically ones from underserved populations, in receiving and maintaining timely and adequate health care. The studies in this review assessed the efficacy of patient navigation in assisting the medically underserved in overcoming barriers to their care. All reports came from the field of Oncology. Review of these articles yielded themes as to what makes a successful navigation program and which patients may benefit most from such programs. First, timeliness of navigation initiation plays a role in the success of a program. The non-efficacious program consistently took longer to enroll patients into the treatment arm of the study. This suggests that future navigation programs would benefit their patients by beginning to navigate those patients as soon after an abnormal screening test as possible. These authors suggest that this would make the patient-to-navigator relationship more meaningful, and increase the likelihood that the patient will receive diagnostic resolution and treatment within the necessary timeframe.[68]

The risk of malignant disease on screening testing may have an inverse

relationship with patient navigation efficacy. When screening-testing results revealed a high risk for cancer patient navigation was less effective as it is likely that key providers of care play an active role in expediting diagnostic evaluation. However, patients with low or moderate risk of a cancerous lesion on screening testing yielded the highest efficacy when navigated versus the control group.[62,63] This is proposed to be due to the perceived importance of definitive diagnostic evaluation.[62,63] A navigator may be able to emphasize the importance of definitive diagnostic evaluation in spite of low to moderate risk of disease, increasing their rates of adherence to care over control groups. While all patients from diverse backgrounds benefit from navigation compared with control groups in these studies, programs with limited resources may see the highest efficacy when targeting resources towards this specific patient group.

This review found that patient navigation is an efficacious intervention to improve adherence to receive timely medical care. This is an important issue within Oncology, as decreasing time to diagnosis and time to treatment has been shown to decrease mortality. Huo et al. found that delays in diagnosis among breast cancer patients correlated to increased likelihood of cancer metastasis and lower rates of disease-free survival.[70] Redaniel et al. describe that the patients receiving colorectal cancer screening sooner after diagnosis have higher survival rates.[71] Similarly, Dolly et al. found that a delay between diagnosis and treatment in endometrial cancer patients was correlated with higher disease mortality.[72] Although disease survival and treatment outcomes were not consistently reported in the studies within this review, patient navigation expedites diagnosis and treatment in oncology patients and has the potential to impact survival in the treatment of cancer. The cost of navigation was underreported in the studies reviewed and this issue remains a concern when considering wide implementation of such interventions. In spite of demonstrating more expeditious diagnostic resolution following

cancer screening with navigation, Bensink et al reported an increased cost of $275 per patient with patient navigation compared with control. The overall value and cost savings in patient navigation is likely understated as this study did note patient navigation contributed to significantly higher diagnostic resolution and probability of ever having diagnostic resolution.[66]

There are limitations of this review as well as the articles included in the review. In spite of thorough search criteria, it is possible that relevant articles were excluded from this review. Publication bias is also a limitation as equivocal findings in intervention studies may not be reported or published. Outcome reporting bias is also a limitation of this review but using a protocol such that our hypothesis and methods were determined *a priori* to the knowledge of the results reduced this. Potential biases were reduced in our interpretation of the data by employing a systematic approach to our search strategy outlined above. Conclusions drawn from this systematic review are limited given that a meta-analysis could not be performed.

Patient navigation is useful in assisting in care delivery for the underserved. This review supports the use of navigation as an effective tool in increasing adherence to care in these populations. While certain populations may benefit more from navigation, it has been shown to work in diverse groups. In the future, it may be beneficial to investigate different delivery methods for patient navigation, the timing of intervention, and factors associated with successful patient navigators (i.e. the training and background of patient navigators). Further research into the use of navigation in the medically underserved will give more insight into potential uses.

CHAPTER TWO: PROMOTION OF EARLY PEDIATRIC HEARING DETECTION THROUGH PATIENT NAVIGATION: A RANDOMIZED CONTROLLED CLINICAL TRIAL

2.1 ABSTRACT

2.1.1 Objectives/Hypothesis

Congenital hearing loss is the most common neonatal sensory disorder and it is crucial to diagnose hearing loss as soon as possible after birth in order to facilitate rapid treatment. Universal standards of infant hearing healthcare dictate that infant hearing screening should be completed by one month of age and abnormal screening tests should be followed with definitive audiological testing by three months of age. Obtaining diagnostic testing can be complicated by breakdowns in communication, lack of parental support, and poor coordination of care. There is no established method to effectively educate parents, promote sound decision-making, and assist in coordinating care following failed newborn hearing screening testing. Patient navigation, which uses trained healthcare workers to educate patients and facilitate adherence to healthcare, is an evidence-based approach that has had widespread success in facilitating timely care in other healthcare settings but has not been studied in infant hearing testing. The objective of this research was to decrease non-adherence (lost to follow-up rates) to recommended infant audiological testing after failed newborn hearing screening. We aimed to assess the efficacy of a patient navigator intervention to achieve this objective and we hypothesized that the utilization of a patient navigator would decrease non-adherence to obtain audiological testing following failed screening, compared to those receiving the standard of care.

2.1.2 Study Design

The study design was a randomized controlled clinical study. Guardian-infant dyads, in which the infants had abnormal newborn hearing screening, were recruited

within the first week after birth. All participants were referred for definitive audiological diagnostic testing at either a University-based audiology practice or a state-funded audiology clinic. Dyads were randomized into a patient navigator study arm or standard of care arm. The primary outcome was the percentage of patients with follow-up non-adherence to obtain diagnostic testing. The participant follow up adherence was monitored for 6 months after enrollment and the non-adherence rates and timing of diagnostic testing were compared between groups. Secondary outcomes were parental knowledge of infant hearing testing recommendations and barriers in obtaining follow-up testing, which were obtained at enrollment and at the conclusion of the study through entrance and exit questionnaires.

2.1.3 Results

Sixty-one dyads were enrolled in the study (patient navigator arm=27, standard of care arm=34). PN was found to be efficacious, as the percentage of participants non-adherent to diagnostic follow-up during the first 6 months after birth was significantly lower in the patient navigator arm compared with the standard of care arm (7.4% versus 38.2%) based on chi-squared test analysis (p=0.005). The timing of initial follow-up was significantly lower in the navigator arm compared with the standard of care arm (67.9 days after birth versus 105.9 days, p=0.010). Patient navigation increased baseline knowledge regarding infant hearing loss diagnosis recommendations compared with the standard of care (p=0.004). High satisfaction was reported with the patient navigation intervention.

2.1.5 Conclusions

Patient navigation decreases non-adherence rates following abnormal infant hearing screening and improves knowledge of follow-up recommendations. This intervention has the potential to improve the timeliness of delivery of infant hearing

healthcare and future research is needed to assess the cost and feasibility of larger scale implementation.

2.2 MATERIALS AND METHODS

2.2.1 Regulatory and Registration Data

Institutional review board approval of the protocol was obtained prior to initiating the study (protocol 12-1059-P1H). The protocol was registered with ClinicalTrials.gov prior to initiating the study (NCT01917747).

2.2.2 Participants

We carried out a prospective randomized trial involving a parent or guardian and their infant who failed infant hearing screening and were referred for outpatient audiological evaluation. Within this population, the majority of primary caregivers are mothers and were, thus, the primary candidates for recruitment into this study. The parent and their child (the dyad) who were referred for testing were eligible for participation in this study if they met enrollment criteria including being a: 1) Parent with an infant less than 2 weeks old and born after 34 weeks gestation, 2) Parent whose infant failed hearing screening (either automated auditory brainstem response test or otoacoustic emission test) in one or both ears in the newborn nursery, 3) Parents with a working phone willing to be contacted over the phone by a patient navigator during the first year after birth. Exclusion criteria include: 1) Parents whose infant was hospitalized more than 2 weeks after birth, 2) Parents whose infant was born prior to 34 weeks gestation, 3) Parents of an infant in neonatal intensive care unit, 4) Infants with outpatient audiological follow-up less than 2 weeks from the time of enrollment, or 5) Infants who are wards of the state and cases of adoption.

2.2.3 Sample Size Calculation and Recruitment

The national non-adherence rate following failed infant hearing screening is 25%[1] and we proposed that the navigator intervention would decrease the non-adherence rate to 12%. A power analysis was performed and in order to have 80% power to detect this difference (at the 0.05 significance level) a sample size of 60 patients was selected. All potential participant dyads were referred for outpatient definitive audiological testing prior to discharge from the birthing hospital. Potential participants were identified and recruited from 3 primary areas: the newborn nursery of a tertiary University-based medical center (children born within the University system and referred to the University audiology practice), the same University-based audiology practice (children born outside of the University but referred to the University audiology practice), and a state-funded audiology clinic (for children born outside and referred outside the University system). The recruitment team contacted these areas on a daily basis and verified eligibility. Potential participants within the University were contacted in person prior to discharge and those outside the University were contacted by phone within 2 weeks after hospital discharge. The study was discussed with participants and informed consent was obtained.

2.2.4 Randomization and Study Protocol

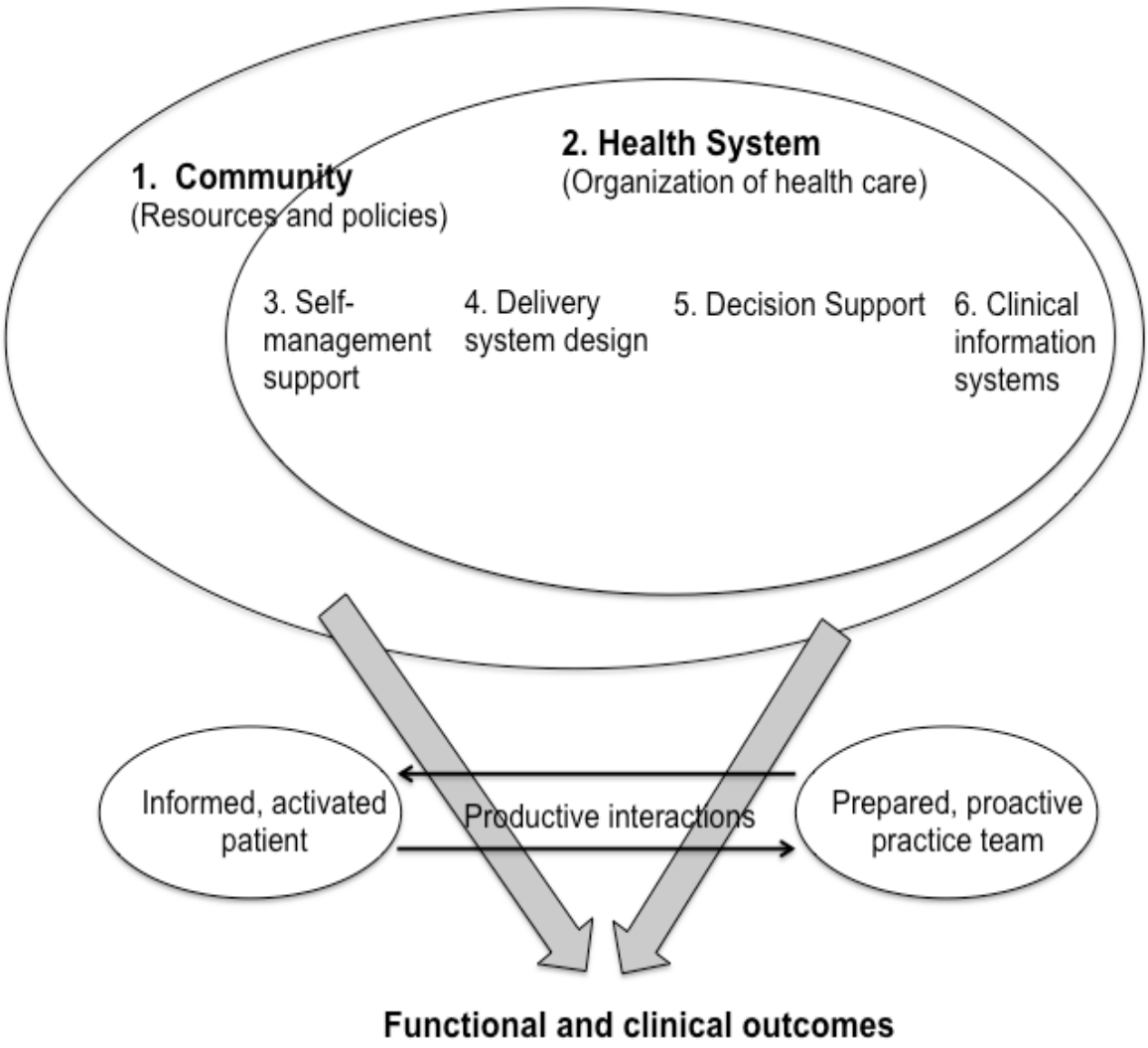
All eligible and enrolled participants were given follow-up appointment dates and time prior to enrollment, typically one month after birth but no later than 3 months after birth. In describing the study to eligible candidates, the parent or guardian was told that their child had referred on a newborn hearing screening for further hearing testing. All participants were told that they would be obtaining an outpatient appointment with the ability to contact the referral clinic at any time with questions or concerns. Participants were told that those agreeing to be involved in the study would be randomized into either a group that will proceed with their appointment as scheduled without further contact from the research staff or they would be placed in a group that would be contacted by a

patient navigator before their appointment. At the time of enrollment and informed consent, participants completed a previously tested 26-item entrance questionnaire[17] (**APPENDIX 1**) assessing knowledge of infant hearing testing recommendations and barriers in obtaining follow-up testing. Similar questions regarding knowledge and barriers were asked at the end of the study for all participants in a 24-item exit questionnaire[17] (**APPENDIX 2**). These questionnaires have been used previously to assess parental knowledge, attitudes, and behaviors regarding the EHDI system and audiological assessment. Following enrollment, the participant dyad was assigned a study number and was randomized (using block randomization with varying block sizes to assign participants into either the navigator or standard of care arms). Blocked randomization of individuals with variable block sizes (differing numbers of participants per block) ensured equal probabilities of group assignment. A biostatistician created the computer-generated randomization scheme.

2.2.5 Patient Navigation Intervention

Patient navigation was selected as the intervention for this study because it is widely effective in other complex healthcare fields, it is extremely useful and appropriate among rural and low socioeconomic populations, and there is a lack of evidence to support other methods of improving EHDI non-adherence. The Chronic Care Model[39] has guided the development and implementation of many patient navigator interventions and this program incorporates key components of this model (**FIGURE 2.1**). Based on this model, navigators have the potential to assist patient in the identification and recruitment of community resources along with health system resources to facilitate delivery of care. The patient navigator program (PNP) focused on elimination of breakdowns in communication, parent decisional support, and coordination of care through the complex EHDI system. An interview guide using semi-structured and open-ended questions was developed for this study and was piloted tested with parents of children who have gone

Figure 2.1: Chronic Care Model Constructs for Patient Navigation[73]



through the EHDI diagnostic process **(APPENDIX 3)**. Participants randomized to the PNP group were assigned to a navigator who contacted the participant by phone within 5 days following the assignment with expected interview duration between 10-30 minutes. Through the initial interview, the navigator used the interview guide to assess the participants' fears and concerns regarding infant hearing testing, barriers to appointment adherence, and potential connections to community and healthcare system support services. Additionally, during the initial interview, the navigator discussed the 1-3-6 EDHI hearing testing and treatment guidelines. Participants were contacted by phone weekly (text and email were also offered as alternative communication methods) after the initial interview to address key discussion points: 1) the status of the newborn/family and whether newborn hearing testing had occurred, 2) family fears and reservations regarding the infant's hearing, and 3) the parent's knowledge of the recommended testing/treatment and the timing of appointments as well as perceived/real barriers to obtaining testing/treatment. During the follow-up interviews, the navigator provided education on the standard recommendations of infant hearing diagnostic testing/treatment and the importance of timely adherence to recommended testing/treatment. The timing of the appointment and the directions to the testing center were discussed. The weekly phone sessions occurred during the first six months after the birth of the child concluding when the diagnostic testing was performed. Participants were given the opportunity to contact the navigator outside of scheduled interviews based on their needs, concerns, and questions.

Navigators identified specific barriers to care and then assisted participants by taking actions tailored to the specific needs of the individual. Social support was provided by supportive listening, providing educational materials, and assisting with referrals for psychological assistance, if needed. Navigators provided instrumental assistance by helping participants with making appointments, resolving child-care

problems, and helping with transportation issues. At the participant level, navigators educated participants on the 1-3-6 EDHI recommendations for hearing evaluation and treatment and counseled them on the importance of adherence to follow-up appointments.

Navigators were selected and trained in accordance with a widely accepted model established by the National Cancer Institute Patient Navigator Research Program and the American Cancer Society Patient Navigation Program.[74] Patient navigators for this study included a parent of a child with hearing loss and an adult layperson with hearing loss. A bilingual (Spanish-English) navigator was also utilized in this study. The navigators were paid hourly by the primary university conducting the study and they completed onsite training using multiple modalities that included traditional lectures, interactive formats, and role-play with case scenarios. They were trained in the complexity of the EHDI hearing healthcare system and in helping patients navigate through the process in a timely manner. The navigator's training involved: 1) rural context training, 2) EHDI system and audiological testing training with university audiologists and state EHDI coordinators, 3) medical training with an otolaryngologist, 4) medical center patient services training with clinical support staff to equip the navigator with education regarding logistical problems with obtaining appointments, and 5) navigator telephone training. Following the American Cancer Society patient navigator model, the navigators contacted participants by telephone.[74] Adherence to outpatient testing was monitored on a weekly basis. Additional appointment variables were also recorded (number of scheduled appointments, number of attended appointments, number of rescheduled or "no-show" visits). At the conclusion of the study, participants completed the Patient Satisfaction with Navigation questionnaire to assess patient satisfaction with the intervention.[75]

2.2.6 Control Group (Standard of Care)

According to EHDI standards, all parents of children who fail infant hearing screening are given printed educational materials and may view an educational video regarding infant hearing loss and EHDI services while in the hospital. All participants of the standard of care group were given their outpatient follow-up appointment prior to discharge. Once the participant was discharged from the hospital and/or enrolled in the study he or she did not have any further contact with the research staff. The parent participant had access to discuss any questions or concerns with the office or audiology staff, as is the standard of care practice, but this was parent-initiated contact. There was an automated appointment reminder phone call (which is a medical center standard of care) that occurred 48 hours prior to the appointment, which requested confirmation of the planned adherence to the clinical appointment. The research staff monitored adherence to follow-up of study participants.

2.2.7 Measures

The primary outcome was a dichotomous variable based on whether the child received the outpatient audiological testing during the first six months after birth. Adherence was recorded when the participant presented for the audiological testing in the audiology clinic. Adherence and timing of follow-up was confirmed by cross-referencing with the EHDI state data registry. We also recorded process variables of the navigator intervention including number of telephone sessions, number of missed or terminated navigator sessions, reasons for missed sessions, length of the sessions, and Patient Satisfaction with Navigation questionnaire scores (**APPENDIX 4**).[75] The secondary outcome of interest assessed was the time interval from birth to the attended initial outpatient ABR appointment during the first 6 months after birth. The time interval from birth to final diagnosis was also recorded. Number of no-show office visits and rescheduled visits were also recorded. Failure to obtain a follow-up within 6 months after

birth was considered as follow-up non-adherence (lost to follow-up) and 180 days was designated for these participants in time analyses.

2.2.8 Analysis

Data were managed using the REDCap data collection system and was exported into an Excel spreadsheet (Microsoft, Redmond, WA, USA), and statistical analysis was performed with STATA (StataCorp, College Station, TX, USA). Continuous variables were summarized with descriptive statistics (n, mean, standard deviation) and categorical variables were described with counts and percentages. A p-value < 0.05 was considered statistically significant. The effect of sociodemographic variables on the primary outcome was assessed with multivariate logistic regression analysis. Differences of follow-up adherence between patient navigator and the standard of care arms were assessed with chi square analysis and odds ratios were calculated. Process variables were analyzed in a similar way. Regression analyses (Cox proportional hazard) were used to detect differences among navigator group and the standard of care group for the time of diagnostic testing. We used a log-rank test to examine differences in the distributions of time to first ABR for each group. Corresponding Kaplan-Meier curves were used to visualize these distributional differences. Comparison of entrance and exit paired data for the study arms was performed with McNemar's test as well as the Generalized Estimating Equation procedure. The data regarding participant knowledge of hearing loss involved descriptive statistics (means, standard deviations, frequencies, and ranges) and correlational quantitative methods to compare differences between study arms.

2.3 RESULTS

A total of 260 dyads were assessed for eligibility between 2014-2016. The Consolidated Standards of Reporting Trials (CONSORT) flow diagram[76] demonstrates

the subject recruitment enrollment, allocation, follow-up, and analysis (**FIGURE 2.2**). Of those assessed for eligibility, 197 were unable to enrolled and consented for study participation (41 not meeting inclusion criteria, 68 declined to participate, and 88 could not be reached by telephone). A total of 63 dyads were enrolled and two participant dyads withdrew from the study. A total of 61 dyads were included in the final analysis (patient navigator arm = 27 and standard of care arm = 34). The majority of infants were born in the University medical center and referred to the University audiology practice (n=34) with smaller numbers born outside the University system and referred to the University audiology practice (n=15) or born outside the University system and referred to a state-funded audiology practice (n=12). The demographic information of parental participants is presented in **TABLE 2.1**. There was a difference in the educational and insurance status between the two study arms; however, subgroup analysis within these areas revealed no significant difference. There was no significant differences in race, age, socioeconomic status, or other demographic factors between the patient navigator arm and the standard of care arm. Approximately 28% of the participants reside in rural counties and the travel distance to the hearing diagnostic center was significantly greater for those participants than those living in urban/suburban counties (61.8 minutes versus 20.4 minutes, $p > 0.001$).

During the first 6 months following birth, adherence to audiological follow-up was monitored in all 61 participants and cross-referenced with the EHDI state data registry. A significantly lower percentage of participants in the patient navigation arm were non-adherent to follow up compared to the standard of care arm (7.4% versus 38.2%, $p=0.005$) (**FIGURE 2.3**); thereby, confirming the hypothesis of this study. According to the state registry, those that were non-adherent to follow up in this study did not receive any audiological diagnostic care at any facility within the state. Of those from rural counties (n=17), none of navigated participants were non-adherent to follow up while

FIGURE 2.2: The CONSORT (CONsolidated Standards of Reporting Trials) flow diagram for this study

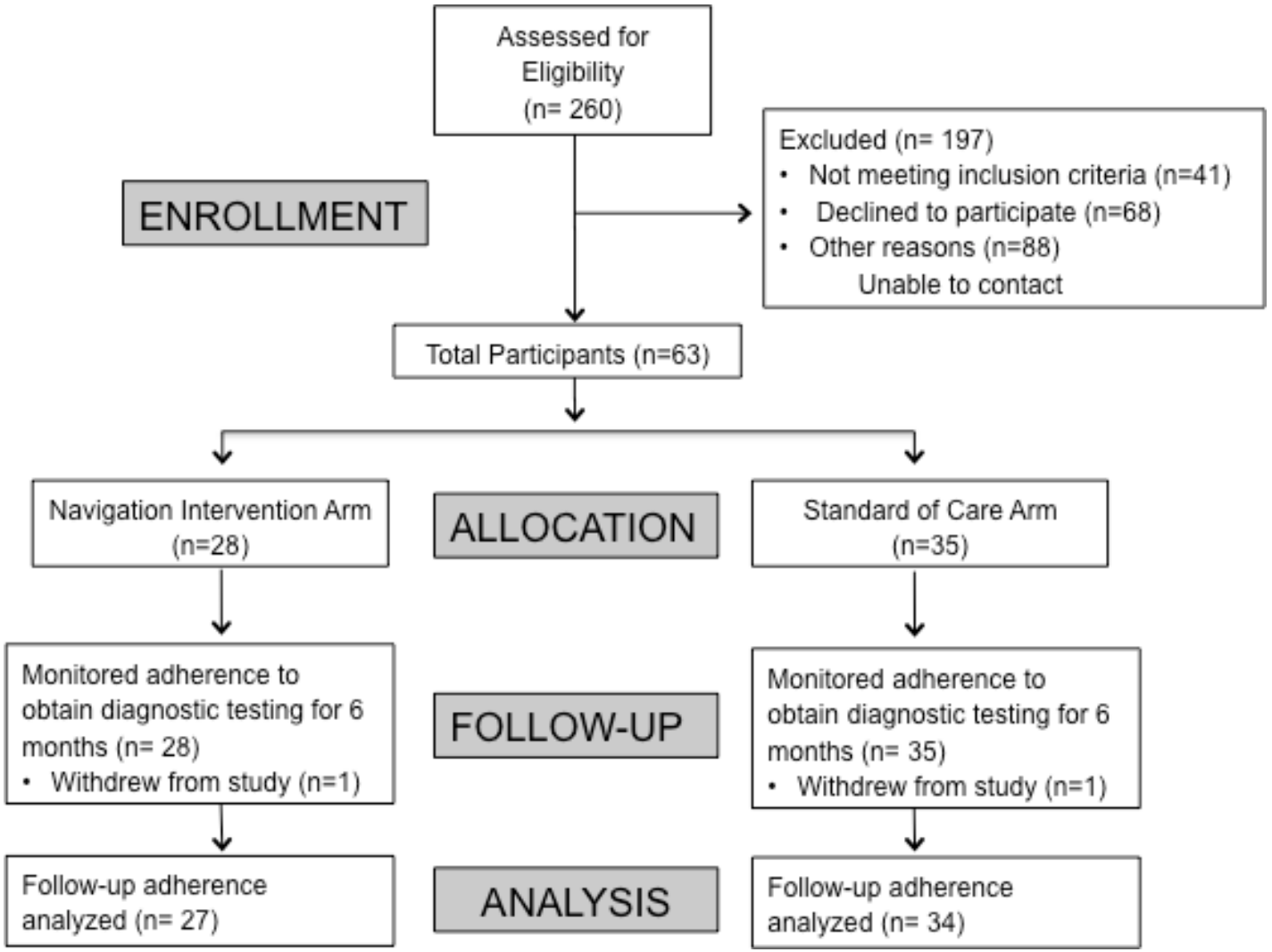
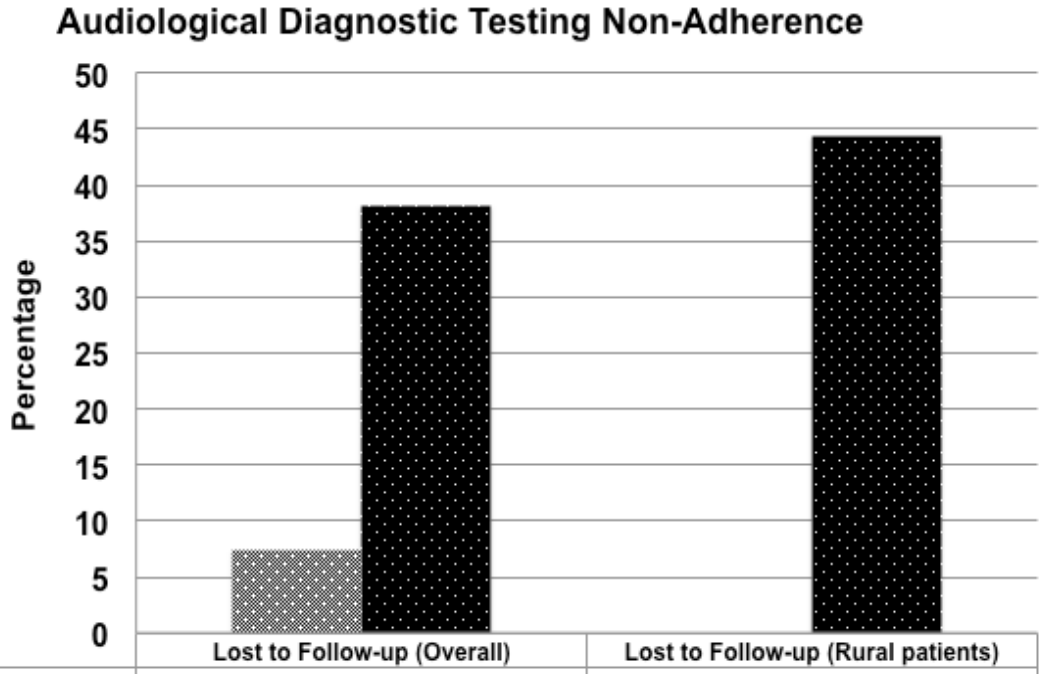


TABLE 2.1 Patient Navigator RCT Study Parental Participant Demographical Data

	Response	Navigation Arm	Standard Arm	Total	*p value*
Sample Size (%)		27 (44)	34 (56)	61 (100)	
Rural Residence (%)					0.78
	Yes	8 (13)	9 (15)	17 (28)	
	No	19 (31)	25 (41)	44 (72)	
Distance to Diagnostic Care (%)					0.35
	Near (0-29 min)	15 (25)	18 (30)	33 (54)	
	Moderate (30-59 min)	10 (16)	10 (16)	20 (33)	
	Far (60+ min)	1(2)	5 (8)	6 (10)	
	Not reported	1 (2)	1 (2)	2 (3)	
Method of Transport (%)					0.70
	Personal Vehicle	19 (31)	18 (30)	37 (60)	
	Friend/Family	3 (5)	5 (8)	8 (13)	
	Public Transport	1 (2)	0 (0)	1 (2)	
	Not reported	4 (7)	11 (18)	15 (25)	
Race (%)					1.00
	White/Caucasian	15 (25)	19 (31)	34 (56)	
	Black/African American	4 (7)	6 (10)	10 (16)	
	Hispanic/Latino	5 (8)	5 (8)	10 (16)	
	Asian/Pacific Islander	0 (0)	0 (0)	0 (0)	
	Native American	0 (0)	0 (0)	0 (0)	
	Other	1 (2)	1 (2)	2 (3)	
	Not reported	2 (3)	3 (5)	5 (8)	
Language (%)					0.39
	English	23 (38)	32 (52)	55 (90)	
	Spanish	4 (7)	2 (3)	6 (10)	
Age (%)					0.40
	18-25	9 (15)	14 (23)	23 (38)	
	26-29	5 (8)	5 (8)	10 (16)	
	30-34	11 (18)	9 (15)	20 (33)	
	35-39	0	3 (5)	3 (5)	
	40+	0	2 (3)	2 (3)	
	Not reported	2 (3)	1 (2)	3 (5)	
Education (%)					0.04
	Less than Middle School	2 (3)	0	2 (3)	
	Some High School	1 (2)	8 (13)	9 (15)	
	High School/GED degree	7 (11)	4 (7)	11 (18)	
	Some College	6 (10)	9 (15)	15 (25)	
	Completed College	7 (11)	12 (20)	19 (31)	
	Graduate Degree	2 (3)	0	2 (3)	
	Not reported	2 (3)	1 (2)	3 (5)	
Income (%)					0.16
	<%10,000	4 (7)	10 (16)	14 (23)	
	$10,000-$20,000	8 (13)	5 (8)	13 (21)	
	$20,000-$30,000	2 (3)	7 (11)	9 (15)	
	$30,000-$60,000	5 (8)	2 (3)	7 (11)	
	>$60,000	6 (10)	8 (13)	14 (23)	
	Not reported	2 (3)	2 (3)	4 (7)	
Marital Status (%)					0.27
	Single/Never Married	7 (11)	15 (25)	22 (36)	
	Married/Domestic Partner	18(30)	18 (30)	36 (59)	
	Widowed	0 (0)	0 (0)	0	
	Divorced/Separated	0 (0)	0 (0)	0	
	Not reported	2 (3)	1 (2)	3 (5)	
Child Insurance (%)					0.048
	Medicaid	8 (13)	19 (31)	27 (44)	
	Private or HMO/PPO	10 (16)	11 (18)	21 (34)	
	None	1 (2)	2 (3)	3 (5)	
	Other	6 (9)	1 (2)	7 (11)	
	Not reported	2 (3)	1 (2)	3 (5)	
Family Hearing Loss History (%)					0.86
	Yes	6 (9)	5 (8)	11 (18)	
	No	14 (23)	17 (28)	31 (50)	
	Unsure	0	1 (2)	1 (2)	
	Not reported	7 (11)	11 (18)	18 (30)	
Tobacco Use During Pregnancy (%)					1.00
	Yes	2 (3)	3 (5)	5 (8)	
	No	23 (38)	28 (46)	51 (84)	
	Not reported	2 (3)	3 (5)	5 (8)	
Alcohol Use During Pregnancy (%)					0.45
	Yes	1 (2)	0	1 (2)	
	No	24 (39)	31 (51)	55 (90)	
	Not reported	2 (3)	3 (5)	5 (8)	
Drug Use During Pregnancy (%)					
	Yes	0	0	0	1.00
	No	25 (41)	31 (51)	56 (92)	
	Not Reported	2 (3)	3 (5)	5 (8)	

FIGURE 2.3. Non-adherence to audiological diagnostic testing



	Lost to Follow-up (Overall)	Lost to Follow-up (Rural patients)
Patient Navigation	7.4	0
Standard of Care	38.2	44.4

44% of those in the standard of care arm were non-adherent to follow up (p=0.03) (**FIGURE 2.3**). The timing of the diagnostic appointment was 67.9 days (range 10 – 180 days) after birth for the navigated participants versus 105.9 days (range 29 - 234 days) after birth for the standard of care participants. The distribution of this time interval differed significantly between study arms (p=0.01) (**FIGURE 2.4**). According to the state EHDI registry, one participant in the navigation arm was non-adherent with the University audiology practice follow-up, but had follow-up at another audiology practice outside of the study sites 10 days after birth. We assessed the effect of variables on non-adherence, which included rural residence, distance to diagnostic center, number of children in family, race, language, caregiver age, caregiver educational level, household income, marital status, child insurance type, family history of hearing loss, tobacco/alcohol/illicit drug use during pregnancy. Univariate analysis revealed that marital status was the only variable affecting non-adherence with 41% of unmarried caregivers non-adherent to follow-up compared with 14% of married caregivers (p=0.02). Multivariate logistic regression analysis was then conducted based on this finding and when controlling for maternal marital status, participants receiving the patient navigation intervention had 83% lower odds of non-adherence than standard of care participants (p=0.04).

During the diagnostic evaluation multiple appointments may be required for a variety of reasons (i.e. – rescheduling, failure to follow-up, failure of child to sleep through ABR testing, middle ear fluid present) and appointment variables were assessed (**TABLE 2.2**). Navigated participants had a higher average number of attended appointments compared with the standard of care participants (p=0.01). Diagnostic testing was completed within 3 months in 52% of the entire sample (56% in the navigation arm and 48% in the standard of care arm, p=0.57). The timing of a final diagnosis was 96.8 days (range 10-236 days) after birth for the

FIGURE 2.4. Kaplan-Meier analysis of time (days after birth) to outpatient audiological diagnostic testing following failed newborn hearing screening (p=0.010).

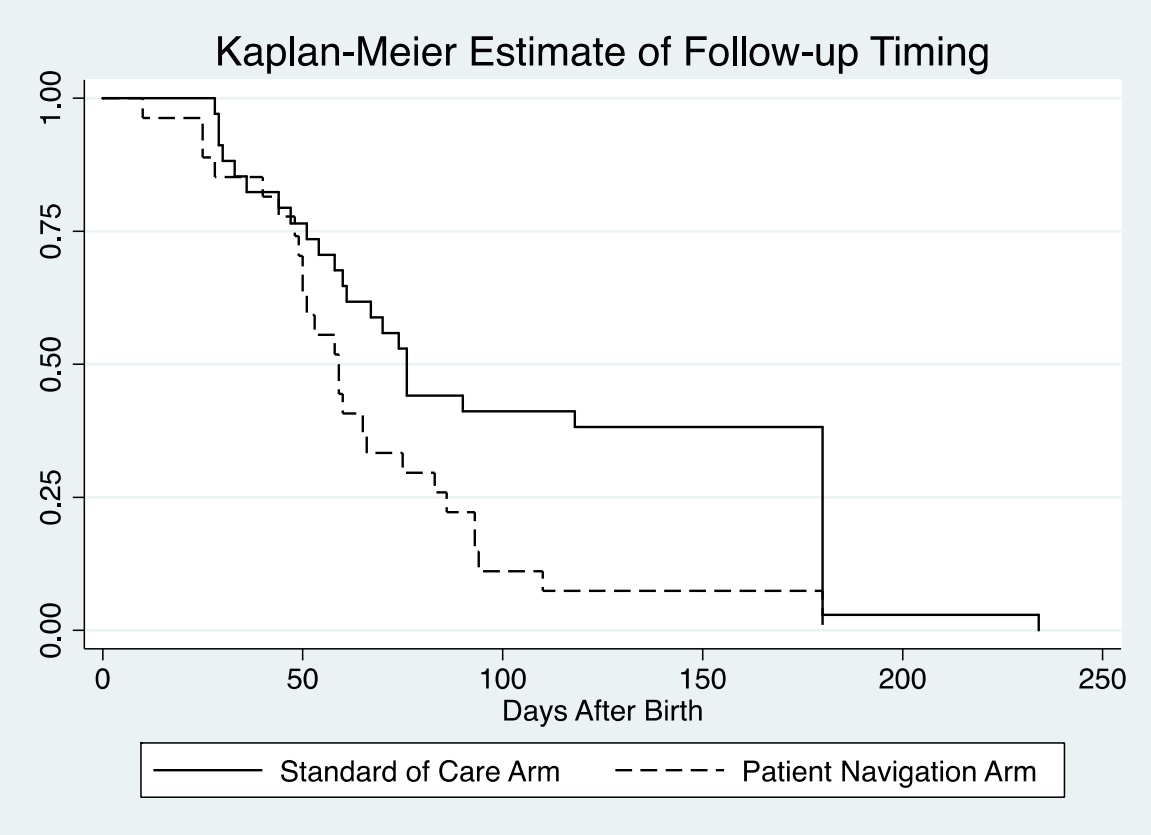


TABLE 2.2. Appointment variables of study participants

	Navigation Arm	Standard Arm	Total	*p value*
Appointments Scheduled	1.8 (1-5)	1.72 (1-4)	1.75 (1-5)	0.95
Appointments Attended	1.32 (0-4)	0.79 (0-2)	1.02 (0-4)	***0.01***
Non-compliant Appointments (Reschedule or No-show)	0.48 (0-2)	0.94 (0-4)	0.74 (0-4)	0.17

navigated participants versus 114.7 days (range 29-234 days) after birth for the standard of care participants. Four children in the study were diagnosed with congenital hearing loss (2 from the navigation arm and 2 from the standard of care arm). These children sought care outside the primary institution following diagnosis and no further outcome data is available.

The entrance and exit questionnaire data was available for 43 participants and revealed their experiences with the infant hearing assessment process as well as their knowledge of recommendations and perception of barriers regarding infant hearing healthcare. Approximately 16% of parents did not understand why their child had a hearing-screening test in the hospital; however, at the entrance of the study, 98% of participants agreed that obtaining follow-up for their child's hearing was important. Regarding outpatient testing, 66% of participants reported that they did not know what to expect and 52% reported that they were not knowledgeable regarding the testing process. In assessing knowledge of infant hearing loss and treatment, 33% did not know the recommended time for infant hearing diagnosis (within 3 months of birth). The participants in the patient navigation arm increased in their knowledge of the recommendations on outpatient audiological follow up during the course of the study (54% correct on entrance versus 78% correct on exit) compared with those in the standard of care arm (76% correct on entrance versus 52% correct on exit) ($p=0.004$) (**FIGURE 2.5**). Overall, the participants reported a high level of confidence with obtaining follow-up (97%) at the beginning of the study, which was also reflected on the exit questionnaire (100%). At the conclusion of the study, 74% reported that they would be comfortable talking about their child's hearing with others and 98% were willing to provide information regarding the hearing testing process to other parents. Multiple barriers to obtain follow-up testing were assessed in the entrance and exit questionnaires (**FIGURE 2.6**).

FIGURE 2.5. Assessment of participant knowledge of EHDI recommendations regarding timing of audiological diagnostic testing and treatment of hearing loss (diagnosis by 3 months and treatment by 6 months of age) at the time of study enrollment and exit.

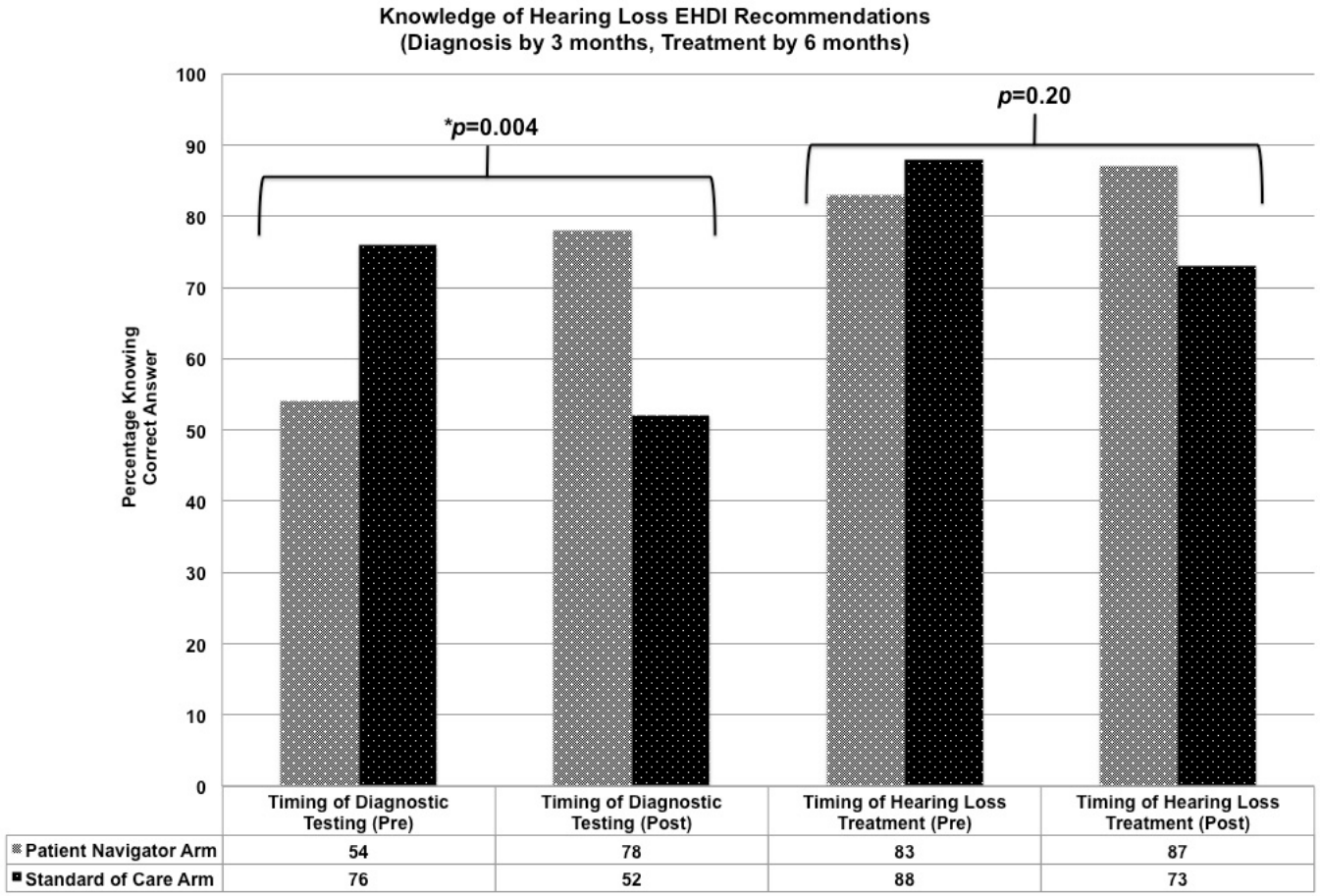
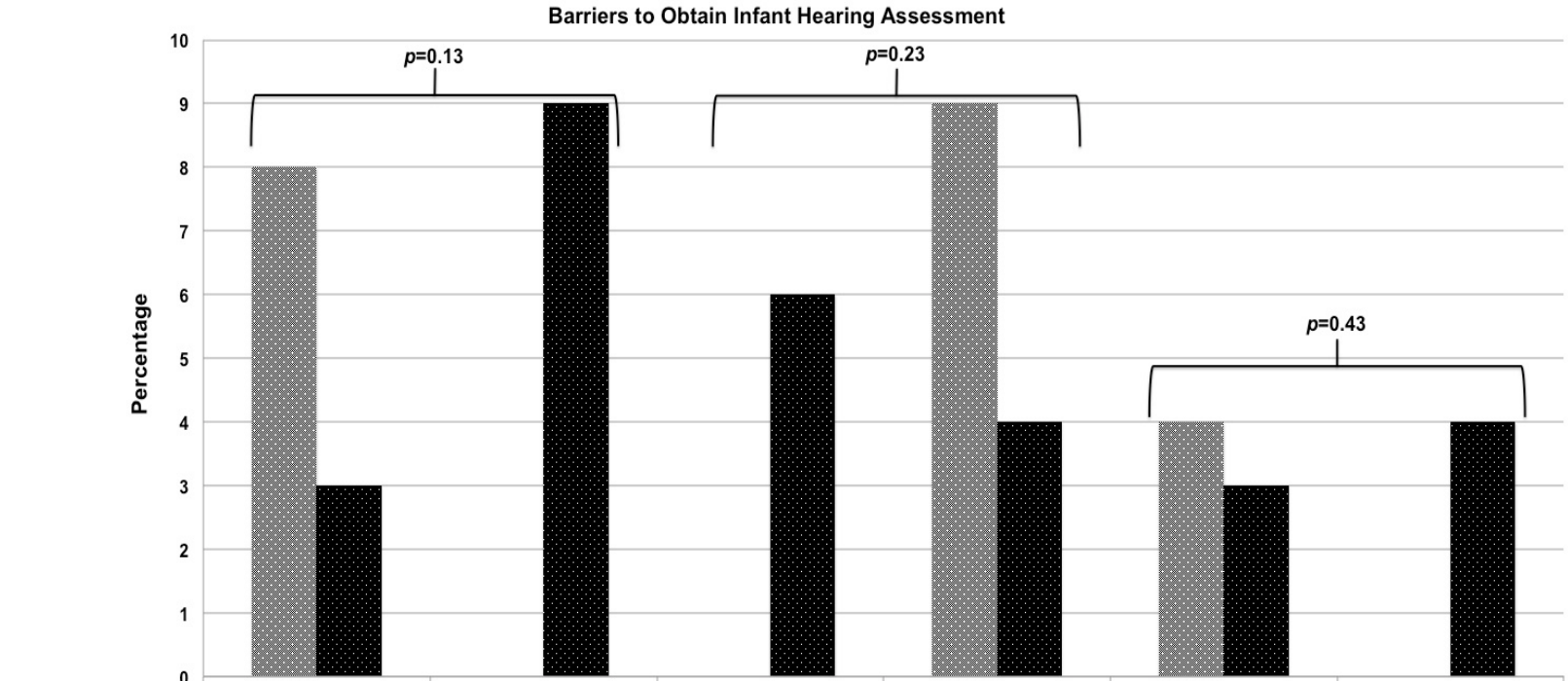


FIGURE 2.6. Assessment of participant barriers to obtain hearing assessment at the time of study enrollment and exit.



Data from the patient navigation intervention were analyzed in 25 of the 27 participants receiving the intervention and results were compared between rural residents and urban residents (**TABLE 2.3**). Data regarding navigation variables was incomplete with 2 participants and this was not included in the analysis. The navigator contact with participants occurred primarily over telephone calls, but some communication occurred through mobile phone texting. Contact with patient navigation participants was complicated by inactive mobile phone service (monthly minutes cellular phone plans) or disconnected numbers. Patient navigation satisfaction was also assessed at the conclusion of the study and the intervention was rated highly (**TABLE 2.4**).

TABLE 2.3. Patient navigation intervention variables

	Rural Participants	Urban Participants	Total
Total Participants	7	18	25
Average Number of Attempted Phone Calls	9.3 (1-20)	5.7 (1-15)	6.7
Average Number of Phone Navigator Sessions	3 (1-8)	3 (0-13)	3
Average Number of Voicemail Messages	2.6 (0-9)	1.6 (0-4)	1.9
Average Number of Phone Call to the Navigator from Participants	0.14 (0-1)	0.33 (0-3)	0.28
Average Number of Text Conversations	3.6 (0-13)	1.94 (0-9)	2.4

TABLE 2.4. Patient navigation satisfaction data

Question	Rural Participants	Urban Participants	Overall
My navigator gives me enough time (%)			
Agree	6 (86)	15 (83)	21 (84)
Disagree	0	0	0
Not Reported	1 (14)	3 (17)	4 (16)
My navigator makes me feel comfortable (%)			
Agree	6 (86)	15 (83)	21 (84)
Disagree	0	0	0
Not Reported	1 (14)	3 (17)	4 (16)
My navigator is dependable (%)			
Agree	6 (86)	15 (83)	21 (84)
Disagree	0	0	0
Not Reported	1 (14)	3 (17)	4 (16)
My navigator is courteous and respectful to me (%)			
Agree	6 (86)	15 (83)	21 (84)
Disagree	0	0	0
Not Reported	1 (14)	3 (17)	4 (16)
My navigator listens to my problems (%)			
Agree	6 (86)	14 (78)	20 (80)
Disagree	0	1 (5)	1 (4)
Not Reported	1 (14)	3 (17)	4 (16)
My navigator is easy to talk to (%)			
Agree	6 (86)	14 (78)	20 (80)
Disagree	0	1 (5)	1 (4)
Not reported	1 (14)	3 (17)	4 (16)
My navigator cares about me personally (%)			
Agree	6 (86)	14 (78)	20 (80)
Disagree	0	1 (5)	1 (4)
Not Reported	1 (14)	3 (17)	4 (16)
My navigator figures out the important issues is my healthcare (%)			
Agree	6 (86)	13 (72)	19 (76)
Disagree	0	1 (5)	1 (4)
Not Reported	1 (14)	4 (22)	5 (20)

2.4 DISCUSSION

Pediatric hearing loss constitutes a major public health problem and delayed diagnosis can lead to life-long communication deficits. Early identification and treatment of infant hearing loss is essential but unfortunately delayed in many children.[13-15] This research addresses a significant gap in the field of early hearing diagnosis and intervention research. There is no literature that addresses the efficacy of initiatives designed to decrease non-adherence in follow-up after infant screening for diagnosis or hearing loss intervention. Contact with parents after infant hearing screening may influence follow-up.[31] Parent-to-parent programs, such as Guide By Your Side,[32] are available in many states and may reduce parental isolation and boost parental acceptance of the child's condition.[22] Current programs typically require the parents to make initial contact to establish services and often are not utilized until a diagnosis of hearing loss is made. No previous studies have examined the use of a patient navigator following infant hearing screening; however, navigation is an intervention model that is well suited to address non-adherence. The original concept and development of this intervention stems from the findings of the American Cancer Society National Hearings on Cancer in the Poor in 1989 and the subsequent work of Dr. Harold Freeman to develop the first patient navigation program to promote timely cancer treatment in the inner city of New York.[53] Since that pilot program, many cancer centers have been using patient navigators to improve the quality and timeliness of care This study demonstrated a decrease in the lost to follow-up rates in participants that received the patient navigation intervention after discharge from the hospital compared with the standard of care arm of the study. In spite of a small sample of rural participants, the intervention was similarly efficacious in rural residents. Randomization in study arm allocation helps to strengthen the validity of the findings.

Many efforts are underway in EHDI programs nationwide to improve infant hearing testing. Screening tests such as automated ABR and OAE have many false-positive results that lead to medical staff and parents dismiss and devalue the screening results and the importance of definitive adherence of infant.[17] Double screening while in the newborn nursery is currently being investigated to decrease the false positive rate. Further efforts to improve adherence include hospital scheduling of outpatient testing and more effective communication with primary care physicians. Better communication between EHDI programs and primary care physicians may also improve adherence rate. This will provide additional opportunities to educate providers on the importance of timely infant hearing assessment. Many factors and barriers complicate timely access to healthcare. Misinformation, inconsistent care, cultural or health beliefs, socioeconomic status, mistrust of the healthcare system, and lack of social support influence non-adherence within healthcare.[51] Within the EHDI field, factors complicating access to care include poor communication of hearing screening results, difficulty in obtaining outpatient testing, inconsistencies in healthcare information from primary care providers, lack of local resources, insurance-related healthcare delays, and conflict with family and work responsibilities.[77] Addressing these barriers to care is complicated and may require multiple approaches. Families of children with hearing loss report that they lack confidence and resources needed for healthcare decision-making for their child.[22] Parents of children with hearing loss also lack role models who have been through the complex process of hearing loss diagnosis and intervention.[22] In previous research, prenatal educational modules[29] and social worker counseling[30] have not demonstrated significant benefit in promoting rescreening after a failed infant hearing screening. The personalized patient support and continuity of education and assistance may differentiate patient navigation from other care coordination models. This method of educating patients through patient navigation may be a potential mechanism for

improved adherence with testing in this population, as there was evidence in this study of an improved knowledge base in navigated participants regarding EHDI hearing assessment and treatment recommendations. Navigation also has the potential to address multiple personal and external barriers that prevent adherence and access to care. A small percentage of the participants in this study reported on barriers to obtain infant hearing assessment; however, there was a trend toward a decrease in insurance barriers and home responsibilities barriers in the navigated patients at the conclusion of the study. A sampling bias is present in barrier assessment in this study as there is a lack of data from those that were lost to follow up and the responses of those participants would likely be informative. Further research is needed to capture data regarding barriers on those lost to follow up which may employ participant interviews to identify barriers to care.

Patient navigation has been successfully implemented within the oncology field to improve access to care in underserved populations and overcoming barriers to their care. A variety of types of navigators has been reported and may include lay people who have had personal experience with the disease and represent the population they were serving.[62] Others have reported using professional health care workers[66] or social workers[64] to perform navigation activities. Bilingual navigators may further improve adherence with non-English speakers.[68] The structure of a navigation intervention may involve a highly structured guide or assessment tool or an informal discussion of barriers to care.[59,64-67] Within the field of oncology, navigators have assisted patients in overcoming obstacles such as lack of transportation, lack of insurance, poor coordination of healthcare appointments, language barriers, and limited healthcare literacy.[59,64,67] The timing of navigation is also associated with the success of such a program[67] as navigation is more effective if it is initiated shortly after an abnormal screening test and may increase adherence with obtaining definitive diagnostic testing.

The implementation and sustainability of patient navigation within infant hearing healthcare is dependent on cost. There is a lack of cost assessment of patient navigation within established oncology navigation programs; however, one such program reported an increase in cost of $275 per patient with patient navigation compared with the control group during the course of screening testing leading to diagnostic testing.[66] The cost of a patient navigation program within EHDI programs is unknown and deserves further study. Method of intervention delivery also deserves further attention, as it may be possible to deliver patient navigation through remote access or telehealth link. Telemedicine may also allow connection of patients to providers; however, consistent delivery of infant hearing diagnostic testing can be complicated by cost and fidelity of testing. Telemedicine may also be a means to education caregivers and audiologists in remote areas to improve efficiency and accuracy of infant diagnostic hearing testing. Further research is needed on cost assessment and cost effectiveness of telemedicine interventions and other interventions developed to expand access to care.

This study was complicated by difficulty in recruiting all eligible study participants. When evaluating potential participation into the study, 68 parents did not wish to participate, primarily due to concerns with randomization in study arm allocation. Most of these parents expressed concern and did not wish to be randomized into the control group as they wished to receive every possible resource to aid in their child's hearing testing follow-up. Others expressed concern over being enrolled in a research study, as they perceived they might receive substandard care. In spite of careful explanation of the study, these 68 did not wish to participate. A concerning number of participants (N=88) were potentially eligible for the study; however, they could not be contacted by phone. Most of these potential participants had provided mobile cell numbers; however, when research staff attempted to contact these individuals their phone usage minutes had

been maximized or the number was no longer in service. Most participants did not provide alternative numbers; therefore, we were unable to contact them. Some of these patients may have been discharged from the primary University recruitment site during evenings or weekends and were not visited by study staff while in the hospital. Adjustments were made to recruiting methods to prevent the loss of these participants. Most of the 88 parents were referred to a facility outside the main university and there was no direct contact between that clinic, the university, or the research staff. This group of parents is an important subset of patients that need further research and attention. Parents that leave a small birthing hospital and are not given follow-up appointments and cannot be contacted by phone are at a significant risk for non-adherence. Additional uncontrolled variables and design limitations to this study may limit the generalizability of the findings. Since these participants were never contacted, informed consent was not obtained and we are unable to investigate the status of follow-up or outcomes of this group. It may be possible to increase recruitment among participants such as these by sending study information documents to the home address of these participants. By partnering with state EHDI system, it may be also possible to increase recruitment by sending study information to the primary care physician caring for that newborn. Connecting with the parents who were not enrolled initially into the study could provide valuable information regarding knowledge, attitudes, and behaviors regarding infant hearing testing adherence. Increased efforts to contact the parents prior to discharge may also bear fruit.

Attention bias is a potential limitation of this study as the intervention group may have had improved adherence to follow-up due to increased contact alone while the standard of care group had less contact and thus had poorer adherence. While this was not directly controlled for in this efficacy study, other studies that have had increased contact with parents through prenatal educational modules[32] and social worker

counseling[30] has not demonstrated significant benefit in promoting rescreening after a failed infant hearing screening when compared with control groups. The mechanism behind the efficacy of navigation delivery is unknown and further research, through mixed quantitative and qualitative methods, is needed. Another potential limitation includes selection bias with differences in the demographics of the study samples. These differences could influence the results (i.e. overall educational level and insurance status); however, subgroup analyses within these areas reveal no significant differences and household income is similar between the two study arms. An additional factor that could influence the outcomes of this study involves the type of education and level of communication provided in different birthing hospitals (prior to enrollment). Randomization in the study design may decrease the influence of this factor; however, there remains significant variability in the teaching provided directly by healthcare staff (or lack thereof), as well as, the educational resources provided to parents of infants who fail newborn screening. An additional limitation includes a lack of long-term follow up and assessment of the effect of patient navigation on timing of treatment for those diagnosed with hearing loss in this study. Finally, this study was limited in that a single parent or caregiver was targeted for the intervention; however, other caregivers (grandparents or other family members) may be vital targets for navigation and further research is needed to assess the role of other care providers in adherence to outpatient diagnostic testing.

Patient navigation is a promising intervention to promote adherence to infant hearing assessment following failed screening. Further work is needed in this field to assess, through multivariate analysis, key factors that influence non-adherence with testing. By identification of the key factors in non-adherence, navigation may be modified and customized to target those factors to maximize appointment adherence. The method of navigation intervention delivery is an area for future research as well. The lack of consistent phone service in lower socioeconomic groups is a significant barrier to

communication in healthcare, which also complicated patient navigation in this study. In-person delivery of navigation could help address this communication gap. Home visits with participants would be a potential method to increase the strength of the patient-navigator relationship. Development and implementation of a community-based navigation program that will monitor long-term hearing outcomes may have greater reach into remote areas to educate and support these patients. Further research is needed to investigate the effectiveness of patient navigation on a larger statewide level and investigate that implementation factors that enable patients to successfully navigation the hearing healthcare system. Additionally, assessment of the cost of patient navigation may influence the likelihood of integrating it into state EHDI programs. Performing cost-benefit analysis of patient navigation in the future will require long-term assessment of speech and language outcomes along with costs associated with rehabilitation and education of children with hearing loss.

CHAPTER THREE: *HELPING INFANTS GET HEARING RESOURCES*: THE HIGHER PATIENT NAVIGATOR TRIAL

3.1 SPECIFIC AIMS

As the most common neonatal sensory disorder, infant hearing loss has an incidence of at least 1.6 per 1000 births.[1] Early childhood hearing loss that is not identified and treated appropriately usually results in significant delays in language, cognitive, and social development,[2] with profound later effects on education and employment.[3] The economic costs of hearing loss are substantial; the overall lifetime medical, educational, and occupational costs due to deafness are estimated to be $2.1 billion.[4] The U.S. Preventive Services Task Force (USPSTF) reported that early detection and intervention of infant hearing loss decreases speech impairment, social/emotional challenges, and learning/behavioral disorders.[5-7] The Joint Committee on Infant Hearing (JCIH) recommends that all infants be screened before 1 month of age, diagnosed before 3 months of age, and initiate treatment before 6 months of age (often referred to as the "1-3-6 rule").[12]

Early infant hearing detection and intervention (EHDI) programs are coordinated on a state level; however, non-adherence to diagnostic testing after failed newborn screening is a national problem. EHDI programs aim to have 90% of U.S. infants with failed infant hearing screens tested and diagnosed within 3 months of failed screening, but fall unacceptably short: only 41.1% meet that standard.[1] Heightening the concern for life-long complications due to delayed diagnosis following a failed newborn screening, the outpatient diagnostic and hearing loss treatment process is complex and difficult for parents to navigate.[16] Families of children with hearing loss are often uninformed regarding the EHDI process and lack peer support in obtaining care for their child.[21,22]

Similar problems in cancer care have been addressed with patient navigation (PN) programs, leading to improved adherence to recommended diagnostic testing after abnormal screening and resulting in improved patient care and healthcare system cost savings.[45,50,64] Patient navigators (PNs) are trained healthcare workers who assess and mitigate personal and environmental barriers to promote healthcare adherence and improve access to care.[34]

We have recently conducted a randomized controlled efficacy trial of PN in collaboration with the Kentucky EHDI program and have demonstrated significantly decreased infant hearing diagnostic testing non-adherence (7%) compared to the standard of care (38%)(p=0.005). However, PN has yet to be tested or systematically implemented within state EHDI programs. Further, there is a major gap in the hearing healthcare field regarding effectiveness and implementation research on interventions designed to decrease infant hearing diagnostic non-adherence.[33] **To address this significant gap in research and practice, an effectiveness trial of PN coupled with implementation research would inform its potential scale-up to maximize public health impact.** The proposed research is a type 2 hybrid effectiveness-implementation trial[78] of a PN intervention aimed at decreasing infant hearing diagnosis non-adherence after failed newborn hearing screening, delivered in 10 state-funded EHDI program clinics. This design allows for simultaneous assessment of the effectiveness of a clinical intervention, while comparing implementation methods. Using a stepped wedge design, we will:

<u>Specific Aim 1</u>: Test the overall effectiveness of PN to decrease non-adherence to receipt of infant hearing diagnosis within 3 months after birth. *Hypothesis: PN will decrease non-adherence to obtaining infant hearing diagnosis within 3 months after birth compared to the standard of care.* In Aim 1, effectiveness of PN to decrease clinic-level

non-adherence rates will be tested via comparison to non-adherence rates during the standard of care condition.

<u>Specific Aim 2</u>: Explore associations among implementation factors, implementation outcomes,[79] and effectiveness outcomes. *Research questions:* (a) *What are the associations of inner clinic setting characteristics (I.e. - clinic resources, clinics' need for change, clinic culture, clinic readiness for implementation), outer clinic setting characteristics (patient needs and resources, external policy and incentives), and PN characteristics with adoption, recruitment/retention, reach/penetration, and sustainability?* (b) *How does PN modality—local or centralized—affect clinic-level non-adherence rates?* Aim 2 will employ mixed methods to provide valuable information regarding key factors associated with implementation and effectiveness outcomes.

<u>Specific Aim 3</u>: Determine the cost-effectiveness of PN from the perspective of third party payers. *Hypotheses:* (a) *PN via either local or centralized delivery will be cost-effective compared to the standard of care from the perspective of third-party payers;* (b) *Centralized PN will be as or more cost-effective as local PN.* In Aim 3, net costs and net effectiveness of PN will be compared with standard of care.

This study is *significant* because it aims to reduce non-adherence to timely infant diagnostic hearing testing to prevent life-long negative consequences. It harnesses our research team's *existing collaborations and expertise* in addressing hearing healthcare disparities with culturally appropriate interventions. This research is *innovative* in testing an intervention not previously assessed in hearing healthcare within a state-funded EHDI program, and in integrating implementation research and cost-effectiveness methods with our effectiveness aim. Our results will *impact* the field by informing

potential scale-up of this and other innovative patient supportive interventions to create efficient and effective EHDI programs and maximize public health impact.

3.2. SIGNIFICANCE

3.2.1: The Importance of Assessing PN Effectiveness and Implementation Factors

For PN to be scaled up to maximize public health impact, effectiveness trials must be coupled with implementation research. A key challenge in implementing any evidence-based program is understanding and addressing the multilevel factors influencing the success (or lack thereof) of whether and how an intervention is delivered. There is no research or clinical standard in hearing healthcare to guide the development, scope, or delivery of programs to reduce non-adherence. However, state-funded EHDI programs provide infrastructure within each state to assess and track hearing in young children, providing an ideal platform for the delivery of PN targeting infant hearing testing and treatment. EHDI programs have the capacity to target the most vulnerable patient populations (e.g., low levels of parental education, low socioeconomic status, public insurance), who are also at highest risk for non-adherence with recommended diagnostic testing.[15,17-20] In Kentucky, audiology clinics serving EHDI patients are administered by the Kentucky Commission for Children with Special Health Care Needs (CCSHCN). By partnering with EHDI and CCSHCN to conduct this research, we can assess not only effectiveness of PN, but also implementation factors, outcomes, and costs expended/averted in the settings intended to reach the most vulnerable patient populations in our state.

3.2.2: The Project Goal

The overarching goal of the proposed research is to conduct a type 2 hybrid effectiveness-implementation trial[78] of a PN intervention aimed at decreasing infant hearing diagnosis non-adherence after failed newborn hearing

screening, delivered in state-funded EHDI clinics. Hybrid designs in implementation science offer rigorous and efficient approaches to simultaneously assess the effectiveness and implementation of interventions and programs delivered in community settings and thus are ideal for the proposed project.[78] Type 2 hybrids directly blend clinical effectiveness and implementation research aims toward more rapid translation to practice. Effectiveness, implementation outcomes, implementation factors, and cost-effectiveness of PN will be assessed.

3.2.2: Summary of Significance

The ***scientific premise*** of the proposed study is based on our own and others' research showing that: 1) delayed diagnosis of pediatric hearing loss has profound life-long negative effects, yet non-adherence rates for diagnostic testing are unacceptably high; 2) there is a pressing need for a scale-able evidence-based approach to address this public health problem; 3) PN is efficacious to reduce non-adherence to infant hearing diagnostic testing, but lacks effectiveness evidence; and 4) understanding of implementation factors and cost-effectiveness of PN are critical to potential scale-up of this intervention. Our findings will directly inform state-level policy and services impacting children with hearing loss and set the stage for a national multi-site implementation trial and potential scale-up to maximize public health impact.

3.3 INNOVATION

3.3.1: Investigating PN delivered within state-funded clinics is a novel step forward in developing efficient, effective, and scale-able EHDI programs.

PN is an ideal intervention model to implement in the field of hearing loss because it is evidence-based and distinct from existing programs in hearing healthcare and EHDI settings. As demonstrated in the cancer field, PN can be effectively delivered and scaled-up to a broader level. EHDI programs do not have an evidenced-based

standardized program that addresses non-adherence to diagnostic testing in infants; PN has the potential to fill this gap and could become a national standard in EHDI programs.

3.3.2: An evidence-based preventive intervention targeted to parents/caregivers of infants immediately after abnormal screening is a novel strategy to improve EHDI system efficiency.

This intervention differs from other EHDI parent support programs (i.e., Guide by Your Side) because it is integrated into the referral to the EHDI program and support is provided **before** the scheduled diagnostic testing appointment. Other programs (i.e., Guide by Your Side and tele-audiology) require families to voluntarily seek support and typically occur **after** the diagnosis of hearing loss, which may be delayed. Delivery of PN shortly after abnormal screening, rather than at the time of follow-up/diagnosis, could improve the efficiency of EHDI and expedite pediatric hearing loss diagnosis and treatment.

3.3.3: The utilization of a type 2 hybrid effectiveness-implementation study using a stepped wedge trial design is innovative in this field.

This study allows for multilevel intervention and analysis of clinical effectiveness and implementation outcomes at the clinic level and the patient level. Given the positive results of our preliminary efficacy trial, the pragmatic stepped wedge design is preferred to a randomized controlled trial design due to ethical and feasibility concerns,[80] while still allowing rigorous design and robust evaluation. This study design is unique in the field of pediatric hearing loss and would significantly advance the field.

3.3.4: The delivery of preventive interventions to high risk and underserved communities is often overlooked but is an essential component of this research.

Disparities in underserved populations are a NIDCD priority area.[81] However, no intervention studies have targeted rural pediatric hearing loss and hearing healthcare disparities. This proposal is responsive to and innovatively addresses the NIDCD

Strategic Plan Priority Area 4, focused on increasing access to health care and enhancing delivery of care.[81]

3.3.5: The cost analysis component of this study will use a novel simulation modeling approach that accounts for multi-site variation at both the individual patient level and programmatic level.

This will allow us to provide cost-estimates of PN, and more importantly, provide evidence about the economic feasibility of implementing PN on a larger scale.

3.4 APPROACH

3.4.1 Overview

We propose a rigorous, type 2 hybrid effectiveness-implementation trial testing a PN intervention to reduce infant hearing diagnosis non-adherence after failed newborn hearing screening. Using a stepped wedge trial design, PN will be implemented sequentially in each of 10 state-funded Kentucky CCSHCN clinics randomized to cross from usual care to PN in steps of 6-month intervals over the project period **(Aim 1)**. Prior to initiation of PN at each clinic, the control condition will be the standard of care. The overall effectiveness of PN will be tested by comparing non-adherence rates during the PN condition to those during the standard of care condition. We will also assess key factors associated with implementation outcomes at each clinic **(Aim 2)**, including potential effects of using centralized versus local PNs. Finally, we will determine the cost-effectiveness of PN from the perspective of third party payers, using a novel simulation modeling approach accounting for multi-site variation at both the individual patient level and programmatic level **(Aim 3).** Successful completion of our aims will inform EHDI programming to (1) reduce infant hearing diagnosis non-adherence, (2) facilitate development of a multi-state implementation trial of PN to further support scale-up, and (3) contribute to the developing field of implementation science. Our highly

collaborative interdisciplinary research team has collective expertise in hearing healthcare disparities, behavioral clinical trials, community-engaged research, implementation science, and health economics/health policy. We are uniquely positioned to conduct this project with our existing collaborations, the support and engagement of strong research partnerships with Kentucky's CCSHCN and its EHDI program, our network of audiologists and hearing healthcare providers across the state, and outstanding consultants providing support for each aim.

3.4.2 Pilot Studies

1. **The complexities of the EHDI system influence timing and access to care in largely rural states.** This transdisciplinary research team has recently completed a series of studies documenting:
   a. ***Delayed treatment results from infant hearing testing non-adherence following newborn hearing screening in rural communities***: In a retrospective review of 2009-2011 state EHDI data, we have found that infant hearing loss occurs in 1.7 of 1000 live births in Kentucky.[13] Of those with failed newborn hearing screening, 27% of children born in rural regions were non-adherent to obtain diagnostic testing.[13] Children from rural areas were also delayed in intervention.[14,15]
   b. ***Primary care physicians face barriers to promote EHDI initiatives:*** In a cross-sectional survey of 93 rural physicians, many providers reported that they do not receive newborn hearing screening results consistently and they lack confidence in counseling parents through the EHDI process.[82]
   c. ***Lack of parental knowledge and support to navigate the EHDI system***: In quantitative and qualitative studies investigating parental knowledge, attitudes, and behaviors regarding the EHDI system, more than 20% of parents found the process of newborn hearing testing difficult, and many were unaware of the screening

results and need for follow-up at the time of hospital discharge.[17] Misinformation from providers and difficulty coordinating appointments were prominent barriers to infant hearing testing.[77]

Importantly, the state EHDI program is the ***only*** entity to follow up on outpatient testing; thus, successful collaboration with the EHDI program and CCSHCN clinics is essential. In each of the above studies, close collaboration with our state EHDI program was crucial. **These studies demonstrate the expertise and history of collaboration among the PI, co-investigators, and the EHDI program and CCSHCN clinics in investigations of the causes and effects of infant diagnostic hearing testing non-adherence.**

2. ***PN is Efficacious in Promoting Timely Infant Hearing Healthcare.*** We have recently conducted a randomized controlled clinical trial (N = 63) with parents of infants with abnormal newborn hearing screening. Dyads who were referred for audiological diagnostic testing were recruited from an academic hospital birthing center within the first week after birth and randomized to PN or standard of care. Receipt of diagnostic testing was monitored for 6 months after enrollment and the non-adherence rates and timing of diagnostic testing were compared between groups. Significantly fewer participants in the PN arm were non-adherent to follow-up testing compared to standard of care (7.4% vs 38.2% overall, p=.005; 0% vs 44% among rural participants, p=.03). Timing of the diagnostic appointment was 67.9 days (range 10-180 days) after birth for PN participants versus 105.9 days (range 29-234 days) for standard of care (p=0.01). PN participants increased knowledge of diagnostic testing recommendations (54% correct on entrance versus 78% correct on exit) compared with those in the standard of care arm (76% correct on entrance versus 52% correct on exit) (p=0.004). **This study was conducted in collaboration between UK and several CCSHCN clinics, and demonstrates (a) the expertise of**

the investigative team in conducting clinical trials involving PN in this population; (b) justification for studying effectiveness and implementation of PN; (c) feasibility of the proposed project; and (d) successful collaboration with our state and community partners.

3. ***PN Procedures are Feasible and Acceptable but Require Flexibility.*** Analyses of process data from the PN arm revealed that while PN contact with participants occurred primarily over telephone calls, some communication occurred through mobile phone texting. Contact was sometimes complicated by inactive mobile phone service or disconnected numbers, suggesting that facilitating multiple modes of contact (including in-person) could increase uptake of the program. Patient satisfaction with PN was also assessed at the conclusion of the study and the intervention was rated highly by parents. **This study demonstrates the expertise of the investigative team in assessing PN feasibility/acceptability and lays the groundwork to assess different implementation strategies in this population**.

3.4.3. The PN Intervention

PN is widely effective in other complex healthcare fields, as well as accepted and effective among rural and low socioeconomic status populations. PNs are trained individuals who assess and mitigate personal, interpersonal, and environmental barriers to healthcare adherence, consistent with the tenets of SCT[24-27] toward promoting healthy behaviors. Our PNs will work with participants to identify and address specific barriers to obtaining follow-up diagnostic hearing testing for their infants, provide social support via supportive listening, provide educational materials, and provide referrals for additional assistance, if needed.[75] PNs will provide instrumental assistance by helping participants make appointments, resolve child-care problems, and address transportation issues.83

PN selection criteria and training will be in accordance with a widely accepted

model established by the National Cancer Institute Patient Navigator Research Program and the American Cancer Society Patient Navigation Program.[74] Potential PNs will be identified from an existing pool of parents/patients who have requested to be involved in hearing healthcare research and patient advocacy maintained by Kentucky's CCSHCN (see C.6.a for details). At least one bilingual (Spanish-English) PN will be recruited for each site. All PNs will complete a 3-week curriculum involving:

1) **Standardized PN Training:** PNs will complete the training and fidelity standards set by a National Patient Navigator training program.[74] It is important to establish that there is currently no subject-specific standard protocol for PN for families in the EHDI system; thus, our PN efficacy trial guided content development of our training protocol. The positive results of our efficacy trial support our PN curriculum.
2) **Audiology/EHDI System Training**: PNs' audiological training will be directed by Dr. Shinn, who serves as the co-chair of the Kentucky EHDI advisory committee and has extensive knowledge of audiological resources across the state. Initial audiological training will involve three hours of ***formal lecture*** covering the process of diagnosing and treating infants with congenital hearing loss. These will be supplemented by appropriate and relevant ***readings*** (i.e., JCIH 2007 Position Statement[12]), adjusted to a sixth grade reading level. Our consultant Dr. White serves as the director of the National Center for Hearing Assessment and Management (NCHAM) and will provide further resources for PNs from the NCHAM website (www.infanthearing.org).[84] Finally, PNs will participate in 8 hours of ***experiential training*** in which they will observe live patient encounters, testing equipment/procedures, and clinic procedures, including scheduling.
3) **Patient Communication Strategies and Resource Development:** Using resources from a national PN collaborative (http://patientnavigatortraining.org),[85] PNs will be trained in communication strategies, developing community resource maps,

interviewing skills, conflict resolution, and professional boundaries.

Navigator intervention delivery will follow the American Cancer Society PN model.[74] Navigation will be delivered through either local PNs (parents from the same geographic region as the clinic) or centralized PNs (parents at the PI's institution; see C.4 and C.6 for details). PNs will seek to identify parent needs, connect parents to community and social support services, facilitate interaction and communication with healthcare staff and providers, and provide health education, all toward the goal of obtaining diagnostic hearing testing for their infant. PNs will contact parents by telephone for an initial interview, building rapport and assessing needs and resources. PNs will then contact parents weekly using the parent's preferred method (phone or text – local and centralized PNs; in-person visits – local PNs only). Weekly PN contacts will continue until the diagnostic test has been obtained (verified by EHDI data) or until 12 weeks since birth have elapsed, whichever occurs first.

3.4.4 Overall Study Design

We propose a rigorous stepped wedge randomized prospective trial to achieve our 3 aims investigating the (1) effectiveness, (2) implementation, and (3) cost-effectiveness of PN versus standard of care in reducing infant hearing diagnosis non-adherence after failed newborn hearing screening.

The state-level EHDI and CCSHCN are our partners in this research, and we have existing collaborations with audiologists and staff at all of their clinic sites. CCSHCN has agreed to engage 10 of their 11 clinics in this study. (The number of infants referred annually to the 11th clinic is <16, making it inappropriate for this study.) The Kentucky EHDI Advisory Board has also fully supported this study.

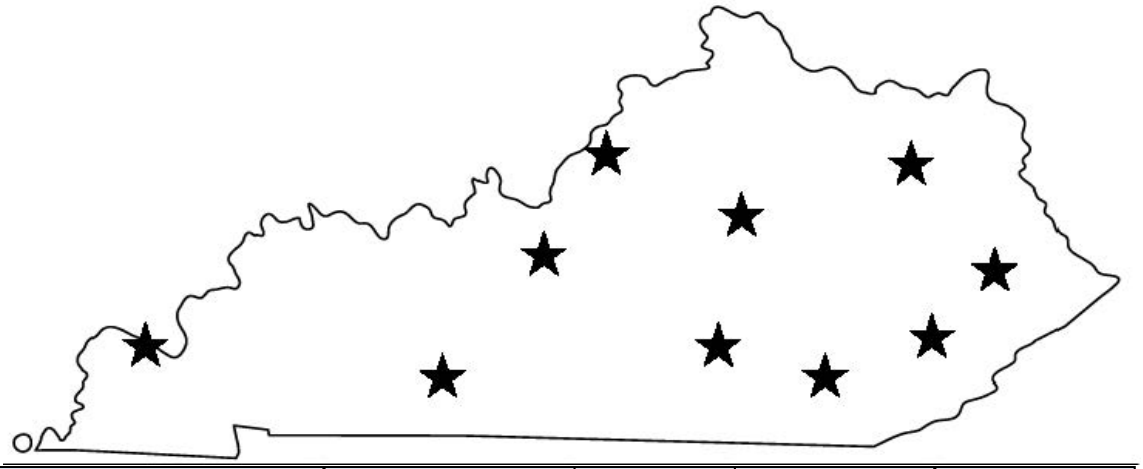
The 10 participating clinics represent a cross-section of the Kentucky population

with urban and rural settings and are located in Knox, Warren, Hardin, Perry, Fayette, Rowan, McCracken, Floyd, Pulaski and Jefferson counties (**FIGURE 3.1**). These clinics provide 500-600 diagnostic hearing tests per year following failed newborn nursery screening, but not all meet the 1-3-6 rule. An additional ~100 referrals are made to each clinic each year that do not result in diagnostic testing. Overall, of all referred infants, 25.9% are non-adherent to diagnostic follow-up testing within 3 months of birth.

Under a sequential rollout in steps of 6-month intervals, the 10 clinics will be randomly allocated to implement PN over the project period **(FIGURE 3.2)**. Randomization will be stratified by clinic patient population size and conducted by our study biostatistician, Dr. Westgate. The highly pragmatic stepped wedge trial design will allow all clinics to contribute control group data as well as intervention data. Note that during the first 6 months of the project, all 10 clinics will be in the control condition. The first clinic will cross to the intervention condition following month 6 of Y1, and the 10^{th} clinic will do so following month 6 of Y4 of the project period. PN delivery will continue through the first half of Y5.

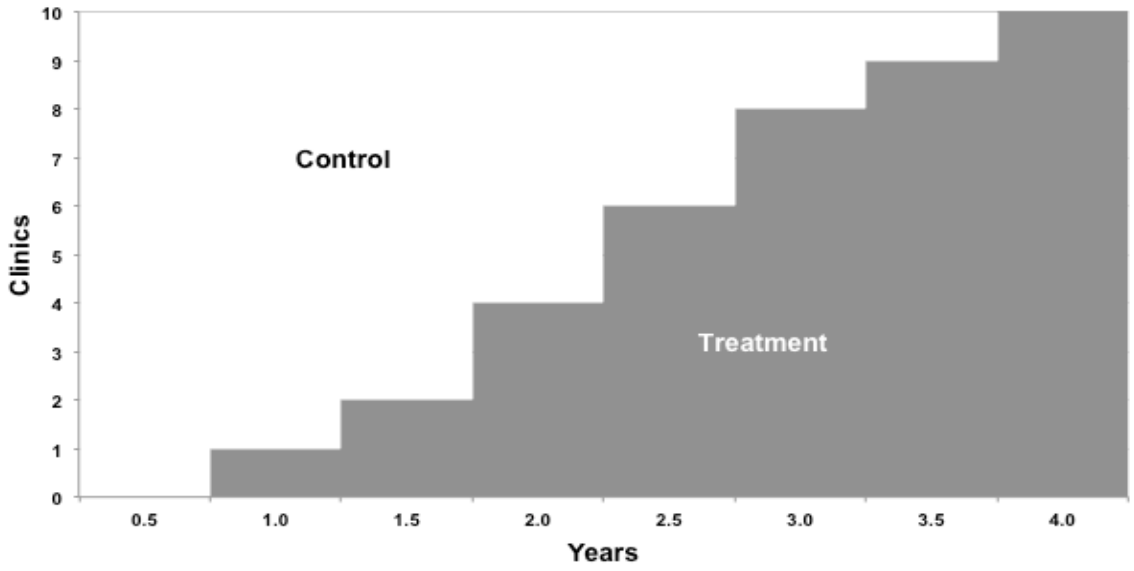
Additionally, clinics will be randomly allocated to either local or centralized PN by Dr. Westgate. Based on our preliminary feasibility and acceptability results (see pilot study (c) under C.2), combined with our previous work in cultural adaptions and delivery of parent-focused interventions in rural Appalachian communities,[86] local PNs may be more acceptable to parents than centralized PNs. Including two intervention modality conditions will allow investigation of this implementation factor in Aim 2.

FIGURE 3.1 : Number of Unique Infant Hearing Diagnostic Tests per CCSHCN Clinic



Commission Clinic	County	2013	2014	2015
Barbourville	Knox	20	25	24
Bowling Green	Warren	106	121	120
Elizabethtown	Hardin	65	79	70
Hazard	Perry	48	67	55
Lexington	Fayette	131	232	172
Louisville	Jefferson	24	34	27
Morehead	Rowan	21	22	25
Paducah	McCracken	22	11	27
Prestonsburg	Floyd	27	27	35
Somerset	Pulaski	16	21	30
Grand Total		**490**	**660**	**586**

FIGURE 3.2: Stepped Wedge Trial Design



3.4.5. Aim 1 Methods: *Test the effectiveness of PN to decrease non-adherence to receipt of infant hearing diagnosis within 3 months after birth compared to standard of care.*

Aim 1 Study Sample and Recruitment

Clinics: The 10 participating clinics are described above under 3.4.4.

Parent-Infant Dyads: Given the referral data described in 3.4.4, we anticipate ~1700 referrals to the 10 clinics during their time in the PN intervention condition (i.e., an average of 68 referrals per year per clinic, with clinics randomized to receive PN for periods spanning 1 to 4 years). In our efficacy trial, 84% of all referred dyads were eligible. Thus, we anticipate ~1400 eligible infant referrals to the clinics while in the PN condition, and we aim to enroll 80% of all eligible dyads (N=1120 dyads). *Inclusion criteria* include: 1) Parents whose infants fail hearing screening in one or both ears before postnatal hospital discharge, 2) whose infants are referred for follow-up diagnostic testing at one of the 10 participating CCSHCN clinics, and 3) who are ages 18 and older. *Exclusion criteria* include: 1) Infants hospitalized past 30 days after birth, 2) parents who live outside Kentucky or will be moving out of state within the infant's first 3 months of life, or 3) infants who are wards of the state.

Once a clinic crosses from standard of care to PN in the stepped wedge design, recruitment of all eligible parent-infant dyads in that clinic will begin. Prior to postnatal hospital discharge, parents whose infants fail their newborn hearing screening test are referred to university-based, private, or CCSHCN hearing centers for follow-up testing. The referral and contact information for these parents is collected and maintained by the state EHDI program. Within one week of postnatal hospital discharge, research personnel will contact by phone each parent referred to a clinic in the PN condition to describe the study, screen the parent-infant dyad for eligibility, and invite eligible dyads to enroll in the study. Informed consent will be obtained over the phone and will include permission from parents to access their infant's hearing data from EHDI.

Aim 1 Procedures

Clinics: All data collected on non-adherence to follow-up within 3 months after birth will be at the clinic level. The primary effectiveness outcome is the proportion of non-adherent referrals for diagnostic testing at each clinic during each month of the trial. Clinic-level data will be compiled on a monthly basis by CCSHCN co-investigator Cathy Lester. The effectiveness of PN (regardless of local versus centralized) to decrease non-adherence rates will be compared to the standard of care condition.

Parent-Infant Dyads: Within one week of study enrollment, a trained research assistant will administer by phone baseline measures of knowledge of hearing loss, self-efficacy for obtaining follow-up testing, and real and perceived barriers in obtaining follow-up testing. In the event of an non-operational phone, the participant will be mailed the baseline measurement questionnaire which will be returned in a stamped return envelope. Following completion of baseline measures, parents will be contacted by the PN to initiate intervention delivery as described in C.3.b above. Post-test measures will be administered by phone by a research assistant 16 weeks after birth; the research assistant will not have access to data regarding parents' follow-up with diagnostic testing. Parent participants will be compensated $20 for each set of completed measures (i.e., at baseline and at post-test assessment).

Measures: Secondary effectiveness outcomes include parent participants' knowledge, self-efficacy, and barriers regarding obtaining follow-up diagnostic testing for their infant. **Parent knowledge** will be assessed using 4 multiple-choice items on diagnostic testing purpose and recommendations. These items were developed in our preliminary RCT and yield knowledge scores from 0-4. **Parent self-efficacy** to obtain diagnostic testing for their infant will be measured using a 10-item self-efficacy scale adapted from an existing measure examining self-efficacy to obtain cancer screening.[87] Each item uses a 5-point Likert-type response scale and addresses one step associated with the process

of obtaining testing (e.g., making an appointment, transportation, payment, proceeding when worried, and others). Scores range from 10 (low self-efficacy) to 50 (high self-efficacy). **Parent-identified barriers** will be measured using five items with 5-point Likert-type response options. The items tap barriers to obtaining diagnostic testing identified by parents in our preliminary studies,[17,77] and scores range from 5 (minimal) to 25 (many). We will obtain EHDI clinic data for all enrolled infants until their one-year birthday (or until data collection ends) to determine the **time from birth to initial completed outpatient hearing assessment**, **number of no-show appointments,** and **number of rescheduled appointments**.

Aim 1 Analyses

All tests will be two-sided and will use a 5% statistical significance level. Analyses will be conducted in SAS version 9.4 (SAS Institute, Cary, NC). Secondary analyses will utilize adjusted significance levels or p-values to control for Type I errors due to multiple testing using the method of Benjamini and Hochberg[88] to control the false discovery rate, which is an alternative to, and more powerful than, the conservative Bonferroni correction. **The primary effectiveness outcome is non-adherence rate**, obtained with clinic-level data. Analysis methods must account for any clustering within clinics (i.e., statistical correlation among the binary non-adherence outcomes from patients within the same clinic). Therefore, the primary intent-to-treat data analysis will utilize generalized estimating equations (GEE) with corrected empirical standard errors in order to maintain valid inference.[89] We will fit the commonly utilized logistic regression model for the analysis of binary outcomes arising from a stepped wedge design with clinics.[90] Specifically, fixed effects for trial condition (primary interest) and time (nuisance covariates needed to ensure a valid model) will be included in the model. Due to the use of a stepped wedge design, clinics serve as their own controls, thus reducing the

possibility of having a lack in balance between trial arms. For all analyses, recommended statistical approaches will be utilized in the presence of missing data (e.g., multiple imputation at the cluster level). Sensitivity analyses will be considered and dictated by the type(s) of missing data.

Consistent with NIH requirements for **rigor and transparency**, secondary analyses will include important sociodemographic variables (including sex of parents and infants, parental age, parental educational attainment, household income, rural residence) as covariates within the above model. Regarding additional secondary outcomes of interest, we will explore associations among parent knowledge, self-efficacy, and barriers as related to (a) non-adherence, (b) time interval from birth to the initial completed outpatient ABR, (c) number of no-show office visits, and (d) number of rescheduled visits. Each of these analyses will utilize the same general GEE approach to account for clustering of outcomes from participants in the same clinic. Depending on the outcome type, a marginal (population average interpretation) generalized linear model will be fit (i.e., a linear model for a continuous outcome and logistic model for a binary outcome).

Aim 1 Power and Sample Size Calculations

The trial follows a stepped wedge design consisting of data collection from 10 clinics over a 4.5 year period (see **Figure 3** and **Time Table** in C.9). To optimize power while also ensuring an adequate number of participants within each clinic for each time period, steps will consist of 6-month periods. The number of clinics receiving PN will accumulate over time as shown in **Figure 3**. Based on this design, using a two-sided test and a 5% significance level, we will have greater than 90% power to detect a difference between PN and standard of care conditions, assuming a clinically meaningful effect of PN in reducing non-adherence rates from 25.9% to the CDC benchmark of 10%. This power

calculation accounts for any clustering within clinics (i.e., statistical correlation among the binary non-adherence outcomes from participants within the same cluster, as measured by the coefficient of variation). With an extremely conservative estimate of 10 referred infants per clinic each period, and conducting a power calculation for the usual range of coefficients of variation from 0.15 to 0.4,[90] statistical power ranged from 0.91 to 0.96. Furthermore, with slightly larger cluster sizes of 15 referred infants per clinic each period, power was at least 0.98 under all scenarios. With 500-600 newborns with failed hearing screens referred to these clinics each year (see **Figure 2** in C.4), we expect actual power to be higher.

Aim 1 Potential Limitations and Alternatives

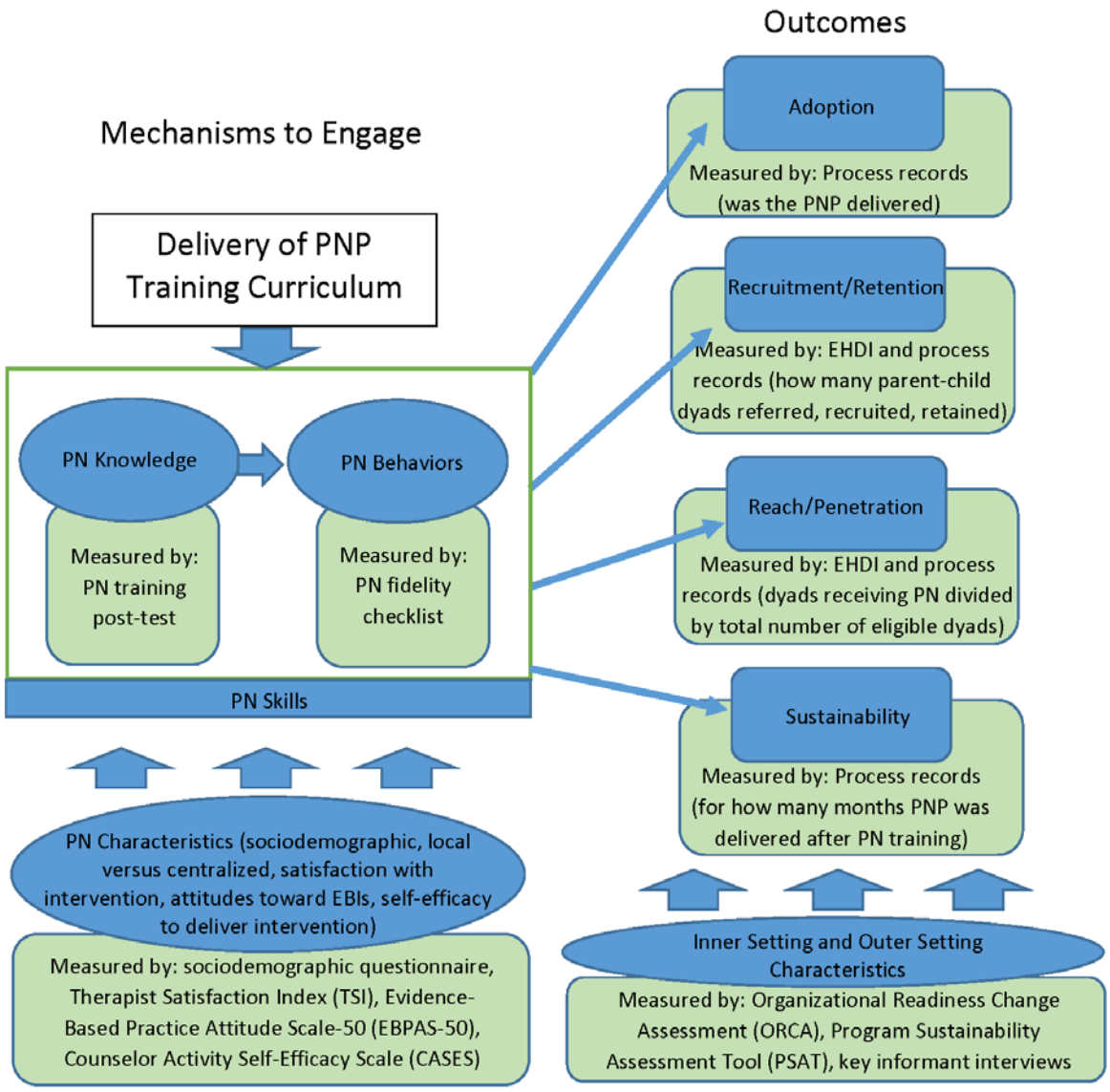
Recruitment: The volume of referrals for infant hearing may fluctuate and the timing of such referrals may vary, which may impact recruitment. We will monitor this closely and work with CCSHCN clinics' scheduling staff to efficiently and effectively enroll all eligible participants. ***Loss to Follow-up:*** Those who are non-adherent and lost to follow-up may have been tested at another institution. Our intent-to-treat analyses will maintain those participants in the study and we will assess their adherence using the EHDI database and individual follow-up attempts for data collection purposes. ***Control Group:*** Due to the study design, prior to rollout of PN, each clinic will be in a control condition and no individual-level data will be collected. If further individual-level data is needed from the control condition, we will consider recruiting participants from some of the clinics during standard of care. ***Turnover of PNs:*** Each clinic will be assigned 3 PNs. These navigators are not employed full-time in this study, thus, having a pool of navigators will allow for flexibility in delivery of the navigation intervention based on the availability of the navigator. Reimbursement of the navigators will be based on the number of participants navigated during the study. In the case of turnover, we will seek to

continually identify new candidates to serve as PNs within each clinic. If we are unable to recruit or maintain a PN in a particular clinic then we will utilize the centralized PNs for that clinic, regardless of randomized condition. We will pay the PNs per dyad navigated to improve retention of PNs. ***Alternate Study Designs:*** Each design considered for this project has limitations. For example, an RCT with individual randomization would add significant complexity, increase the likelihood of contamination, and require additional personnel and resources to identify and train PNs simultaneously in all ten clinics; a traditional cluster-randomized trial would have many of the same practical and complexity concerns. A typical crossover design would pose logistical and ethical challenges because (1) PN would be rolled out to 5 clinics at the same time, and (2) reverting to the control condition may be unacceptable. The stepped wedge design lends itself well to the goals of hybrid effectiveness-implementation studies and allows adequate time at multiple geographically dispersed clinics to identify and train PNs. Finally, this design is ideal because all clinics eventually cross to the PN condition, consistent with the preferences of our CCSHCN partners.

3.4.6. Aim 2 Methods: *Explore associations among implementation factors, implementation outcomes, and effectiveness outcomes.*

Specific Aim 2 will investigate factors associated with implementation and effectiveness outcomes across the 10 clinic sites. This aim is guided by the Consolidated Framework for Implementation Research (CFIR),[79] using implementation constructs and outcomes recommended by Proctor et al.[91] Sources of data for this aim will include process records of PNs, clinic administrators, staff, and providers, and parent participants. The rationale for the procedures and measures proposed in this aim is illustrated in **FIGURE 3.3. To prepare for potential scale-up of PN, we must understand the implementation-related factors and outcomes that will maximize its public health impact.** Consistent with CFIR, we will assess PN skill (knowledge and behaviors)

FIGURE 3.3: Implementation Logic Model



following completion of the PN curriculum, including intervention fidelity; PN characteristics (including local vs. centralized); inner and outer setting clinic characteristics; and four key implementation outcomes: adoption, recruitment/retention, reach/penetration, and sustainability.

Aim 2 Study Sample & Recruitment

Patient Navigators: The PNs (N = 23: 3 PNs serving 5 clinics in the centralized PN condition; 15 serving 5 clinics in the local PN condition; 5 back-ups) will be enrolled as study participants as well to collect implementation data. PNs will be identified from an existing pool of parents/patients who have requested to be involved in hearing healthcare research and patient advocacy, maintained by the CCSHCN. During the selection process, potential PNs will be informed by trained research staff of the purpose of the study and will provide written informed consent to participate in study procedures. *Inclusion criteria* include: 1) age 21 years or older, 2) able to speak and read English, and 3) willing to complete the PN training curriculum and deliver PN. Local PNs will be required to reside within 50 miles of their CCSHCN clinic; the centralized PN will be required to reside within 50 miles of the University of Kentucky campus. At least one PN per clinic must be bilingual (Spanish-English).

Clinic Administrators, Staff, and Providers: At each clinic, one administrator, one staff member, and one hearing healthcare provider (N=30) will be invited to participate in Aim 2. *Inclusion criteria* include: 1) age 18 years or older, 2) able to speak/read English.

Parent Participants: All parent participants recruited in Aim 1 (N=1120) will also provide Aim 2 data during their baseline and post-test assessments. A subset of approximately 20 (dependent on saturation) parent participants will be recruited through purposive sampling and invited to also complete qualitative key informant interviews during their post-test assessment, after providing written informed consent. These parents will

represent a combination of urban vs. rural communities, non-adherent vs. adherent results, and receiving centralized vs. local PN.

Aim 2 Procedures

Patient Navigators: It is necessary to collect data regarding PN skill (knowledge and behaviors) to assess factors that influence successful implementation. There 2 types of navigators that are used during this study: 1) local navigators that live in close proximity to the clinic where they are assisting patients, and 2) central navigators that are located at the primary institution of the PI. The data to be collected will include measures of the PN knowledge regarding infant hearing loss diagnosis and treatment recommendations, PN behaviors in the intervention delivery, and PN characteristics (sociodemographic, local versus central navigator, attitudes toward evidence-based interventions). Baseline data collection from PNs will occur immediately following study enrollment and before PN training, comprising both quantitative and qualitative measures administered by a trained interviewer. At the conclusion of PN training, PNs will take an examination to ensure comprehension of critical principles necessary for successful navigation. A score >80% will be required to pass the training. PNs with less than a passing score will be allowed to repeat relevant training elements and retake the examination one time; if the examination is not passed on the second round, the PN will not be employed in this study and a new PN will be identified. PN skill is a key implementation factor, thus, for those who pass the examination and proceed to intervention delivery, this outcomes will be assessed by measuring the following: PNs will (1) audio-record 10% of PN sessions (with parent permission) to allow assessment of fidelity, (2) complete a PN fidelity checklist[59] following each PN session, and (3) maintain process logs detailing time, travel, attendance, frequency and modes of contact with families, and other activities and expenses associated with PN delivery. Approximately 6 months after completing PN

training, PNs will be interviewed and complete post-test assessments, again administered by a trained interviewer. PNs will be compensated $25 at baseline and post-test for completing the battery of assessments. In each clinic, the PN intervention will continue after the 6-month assessment time point until the end of the 2nd quarter of year 5.

Clinic Administrators, Staff, and Providers: Approximately 6 months after crossing to the PN condition, administrators, staff, and providers from each clinic will participate in qualitative interviews and complete quantitative measures administered by a trained interviewer. For key informant interviews, we develop and utilize a semi-structured open question interview script using a CFIR interview guide tool, (http://www.cfirguide.org/guide/app/index.html#/)[92] for inner and outer settings for the Commission clinics. These constructs will include patient needs and resources, cosmopolitanism, peer pressure, external policy and incentives, structural characteristics, networks and communications, culture, implementation climate, compatibility, relative priority, organizational incentives and rewards, goals and feedback, learning climate, readiness for implementation, leadership engagement, available resources, access to knowledge and information (http://cfirguide.org/constructs.html).[93] Research staff will contact all study candidates and informed consent will be obtained. A trained interviewer will conduct these interviews in-person with participants. Initial questions will be open-ended, and follow-up probes will be used to prompt clarification and elaboration of answers. Interviewers also will take field notes during and after each interview. These notes will focus on the tenor of the discussion and the participants' non-verbal presentation. These participants will be compensated $25.

Parent Participants: At the Aim 1 post-test assessment (16 weeks post-birth), parents will complete a PN satisfaction measure.[75] Parents completing post-test measures will

be compensated $20 under Aim 1. ***:*** At the Aim 1 post-test assessment (16 weeks post-birth), parents will complete a PN satisfaction measure.[75] Selected parents (N = approximately 20) will also complete a 1-hour semi-structured key informant interview with a trained interviewer exploring parents' experiences with the PN intervention. We develop and utilize a semi-structured open question interview script using a CFIR interview guide tool[92] for characteristics of individuals. Related to patient navigation, these constructs will include knowledge and beliefs about the intervention, self-efficacy, individual stages of change, individual identification with organization, and other personal attributes.[93] Research staff will contact all study candidates and informed consent will be obtained. A trained interviewer will conduct these interviews in-person with participants. Initial questions will be open-ended, and follow-up probes will be used to prompt clarification and elaboration of answers. Interviewers also will take field notes during and after each interview. These notes will focus on the tenor of the discussion and the participants' non-verbal presentation. Parents completing post-test measures will be compensated $20 under Aim 1, and parents also completing key informant interviews will be compensated an additional $25.

Aim 2 Measures

All instruments and interviews will be administered in person by trained interviewers. **Implementation outcomes** of interest for this study include adoption, recruitment/retention, reach/penetration, and sustainability, as depicted in **Figure 3.3**. **Adoption** per clinic will be measured using a binary indicator of whether the PN intervention was delivered even once at each CCSHCN clinic; this variable will be measured using PN process records. **Recruitment/retention** per clinic will be measured using data from EHDI and PN process records: the number of parent-infant dyads contacted, screened for eligibility, and enrolled will be tracked, as well as numbers of

dyads lost to follow-up, with reasons recorded when known. Number of PN contacts with each dyad will also be recorded. **Reach/penetration** per clinic will be measured with the ratio of parent-infant dyads receiving any dose of the PN intervention to the number of all potential parent-child dyads referred; the numerator will be obtained from PN process records, while the denominator will be obtained from EHDI records. **Sustainability** per clinic will be measured by assessing PN activity each month and recording how many consecutive months (out of all months in which referrals for infant diagnostic testing occurred following the 6-month assessment time point) the PN intervention is delivered.

Measures of CFIR **implementation factors** will include **PN characteristics**: knowledge (post-training examination score); fidelity (fidelity checklist and research staff-rated transcripts of PN audiotapes); sociodemographic characteristics (age, sex, education, and previous related professional experience); attitude toward evidence-based interventions (Evidence-Based Practice Attitude Scale-50 (EBPAS-50)[94]); self-efficacy to deliver the PN intervention (Counselor Activity Self-Efficacy Scale (CASES)[95]); and PN modality (centralized versus local). Other factors include **inner setting characteristics**: number of full time employees employed at the clinic; clinic patient population size; clinic staff/adminstrator/provider-completed measures of communication, organizational culture, capacity, environmental supports and resources (Organizational Readiness to Change Assessment (ORCA)[96] and Program Sustainability Assessment Tool (PSAT)[97]); and inner setting themes identified in key informant interviews of clinic staff/administrators/providers. Finally, measures of **outer setting characteristics** include: county population size; designation as Appalachian versus non-Appalachian county; rural versus urban; and number of competing service providers in the county. All outer setting characteristics will be collected from existing data sources (e.g., state and Census data, provider referral lists from referring hospitals). Outer setting themes will also be identified in key informant interviews of clinic

staff/administrators/providers. **Parent satisfaction** with the PN intervention will also be measured as an implementation factor, using the Patient Navigation Satisfaction Inventory[75] administered at the post-test assessment. Measures for Aim 2 are based on up-to-date reviews of available instrument repositories (Seattle Implementation Research Collaborative (SIRC) and Grid-Enabled Measures-Dissemination & Implementation (GEM-D&I)); however, measurement of implementation constructs is a rapidly evolving field, and consensus on recommended quantitative measures for many of these constructs is still in development.[91,98] Characteristics of individuals are also key implementation factors and these constructs will be assessed from parent interviews regarding patient navigation.

Aim 2 Analyses

Because this is a type 2 hybrid effectiveness-implementation trial, most Aim 2 analyses are exploratory in nature and intended to inform potential scale-up and multi-state evaluation of implementation of PN (if found to be effective in this trial). Aim 2 employs a convergent mixed-methods approach to interpret quantitative and qualitative findings simultaneously.[99] For all quantitative measures, we will obtain descriptive statistics and conduct exploratory comparisons among the 10 clinics, with particular attention to PN, inner, and outer setting characteristics that seem to be associated with effectiveness and implementation outcomes. As in Aim 1, exploratory analyses of the quantitative data described in C.6.c above will use marginal (population average interpretation) generalized linear models (i.e., a linear model will be utilized for a continuous outcome and a logistic model for a binary outcome). Analyses comparing patient-level data between clinics will utilize the same general GEE approach described in Aim 1 to account for clustering of outcomes in the same clinic.

Additionally, we will examine the effects of the implementation factor of PN

modality (centralized versus local) on clinic-level non-adherence rates. We will use the same modeling strategy described for the primary effectiveness outcome in Aim 1 (see C.5.c), but the fixed effects for trial condition will be extended to account for three conditions (standard of care, centralized PN, local PN) in this exploratory analysis.

For key informant interviews, CFIR constructs of interest, as described above, will be used to categorize themes generated by the key informants regarding individual characteristics of parents, inner clinic setting, and outer clinic setting factors affecting implementation of the PN intervention in CCSHCN clinics across Kentucky. Digital recordings of key informant interviews will be transcribed in full. Transcripts will be compared to interview notes by the interviewer the PI. Facilitated by use of Atlas.ti,[100] transcripts will be coded line-by-line. The qualitative research team will co-code the text, develop an initial codebook for each CFIR theme (i.e., individual characteristics, inner setting, and outer setting), and use concordant and discordant codes to refine and develop final codebook versions. After both raters re-code the first transcripts, the results will be analyzed for inter-rater reliability. If reliability does not reach or exceed 0.85, the raters will re-examine concordant and discordant coding and revise codes and definitions accordingly until consensus is achieved.[101]

After achieving adequate inter-rater reliability, the coding process will continue for the rest of the transcriptions. Four randomly selected transcripts will be identified for double-coding and evaluation of inter-rater reliability, followed by any needed modifications and recoding to achieve adequate inter-rater reliability. Once initial topical coding has been completed, 10% of the sample (i.e., 2 parents and 3 clinic staff/administrators/ providers) will be invited to participate in a member-checking process to determine whether additional data collection is necessary and to ensure valid inferences are made through coding procedures.[102] Participants involved in member-checking will receive an additional $25 compensation for their time and effort. Following

the member-checking process and any needed corrections to the codebooks and coding, the investigative team will meet to review the results of the topical coding process and develop a summative grid of themes emerging from the interviews.

The summative grid of themes will be considered with the quantitative results describing implementation factors and outcomes in a series of investigator meetings designed to integrate these findings. Interpretations will be discussed with all co-investigators, and differences will be resolved through discussion and revisiting of primary data. As recommended by Creswell and colleagues,[99] the convergent mixed-methods design of Aim 2 will allow us to simultaneously consider quantitative and qualitative data from multiple perspectives to contextualize and gain a more complete understanding of key implementation factors linked with the effectiveness and implementation outcomes of PN.

Aim 2 Power and Sample Size Calculations

Because Aim 2 is primarily exploratory, the sample sizes for this study are based on power calculations for the primary effectiveness outcome in Aim 1. With only 10 clinics participating, we may not have adequate power to detect significant associations among implementation factors and outcomes (e.g., adoption, sustainability). However, we will have sufficient power to detect differences in the primary effectiveness outcome (clinic-level non-adherence rate) by local vs. centralized PN compared to the standard of care condition. Specifically, using a two-sided test, a 5% significance level, and assumed non-adherence of 10% in either PN condition and 25.9% in standard of care, our conservative power calculations suggest that with 5 clinics per PN condition we will have statistical power ranging from 0.80 to 0.87 to compare local PN to control and centralized PN to control. This particular implementation factor is modifiable and results will inform both scale-up and future implementation studies. For our qualitative analyses,

the numbers of parents, clinic staff, administrators, and providers planned for key informant interviews are based on previous work and expectations regarding the number of participants needed to attain saturation.[103]

Aim 2 Potential Limitations and Alternatives

As described under Aim 1, potential Aim 2 limitations include difficulties with recruitment, loss to follow-up, and turnover of PNs. Our strategies to overcome these roadblocks are the same as described under Aim 1. In Aim 2, however, each of these roadblocks also relates directly to the implementation factors and outcomes under investigation; thus, encountering these problems and exploring their causes (e.g., low self-efficacy of PNs leading to turnover; low satisfaction of parents with PN leading to drop-out) will actually inform our Aim 2 analyses and conclusions and allow us to identify strategies to improve implementation of PN.

3.4.7. Aim 3 Methods: Determine cost-effectiveness of PN from the perspective of third party payers

Specific Aim 3 involves incremental cost-effectiveness analyses in which net costs and net effectiveness of the intervention will be compared with that of standard of care for patients referred to CCSHCN clinics after a failed newborn hearing screen. *Hypotheses:* (a) *PN of either kind after a failed newborn hearing screen will be cost effective compared to the standard of care from the perspective of third-party payers;* (b) *Centralized PN will be as or more cost-effective than local PN.* We will compare net costs and effectiveness of each PN modality–centralized versus local–compared to standard of care. Results will be expressed as a ratio of differences in observed costs to differences observed outcomes. The perspective of this evaluation will be third party payers.

Aim 3 Measures

Costs: Both direct and indirect costs associated with PN will be included. Costs associated with the initial newborn hearing screen will be excluded from analyses since these costs are incurred for all infants regardless of outcomes. ***Direct costs*** include the cost of: PN establishment (PN recruitment and training costs), program implementation (office space, PN time, PN travel and tools, PN materials, staff turnover), parent time and travel (travel to seek diagnostic or PN services, time spent receiving diagnostic services), treatment costs (costs of a rescreen or diagnostic audiology appointment), and non-adherence costs for the clinics (no-show appointments). Research activity costs (e.g., data collection, human subject protection training of PNs) are not included. ***Indirect costs*** include opportunity costs of time (e.g. loss of productivity/wages) for the parent(s). Cost data will be collected and monitored annually throughout the study period, for both the intervention and standard of care conditions. Unit program costs will be documented as Aims 1 and 2 are implemented and sustained over the study period. Unit costs of PN and parent participant travel will be estimated using the distance between patient and clinic address/zip code multiplied by the standard GSA standard mileage rate and adding any lodging expenses (if applicable). Unit costs of PN time will be estimated using logs maintained by the PNs and applying the hourly PN pay rate. Parent participant time will be estimated using the average wage rate for Kentucky (estimated using average wage data from the Bureau of Labor Statistics (BLS)). Unit treatment costs will be estimated using charge data from the CCSHCN, aggregated at the clinic level. Unit costs of non-adherence will be based on costs of PN time not used but spent (which may vary if services are centralized versus local) and staff costs associated with rescheduling. Loss of productivity will be estimated using an estimate of time away from work (calculated using driving distance) and lost wages for one parent, using BLS average wage statistics.

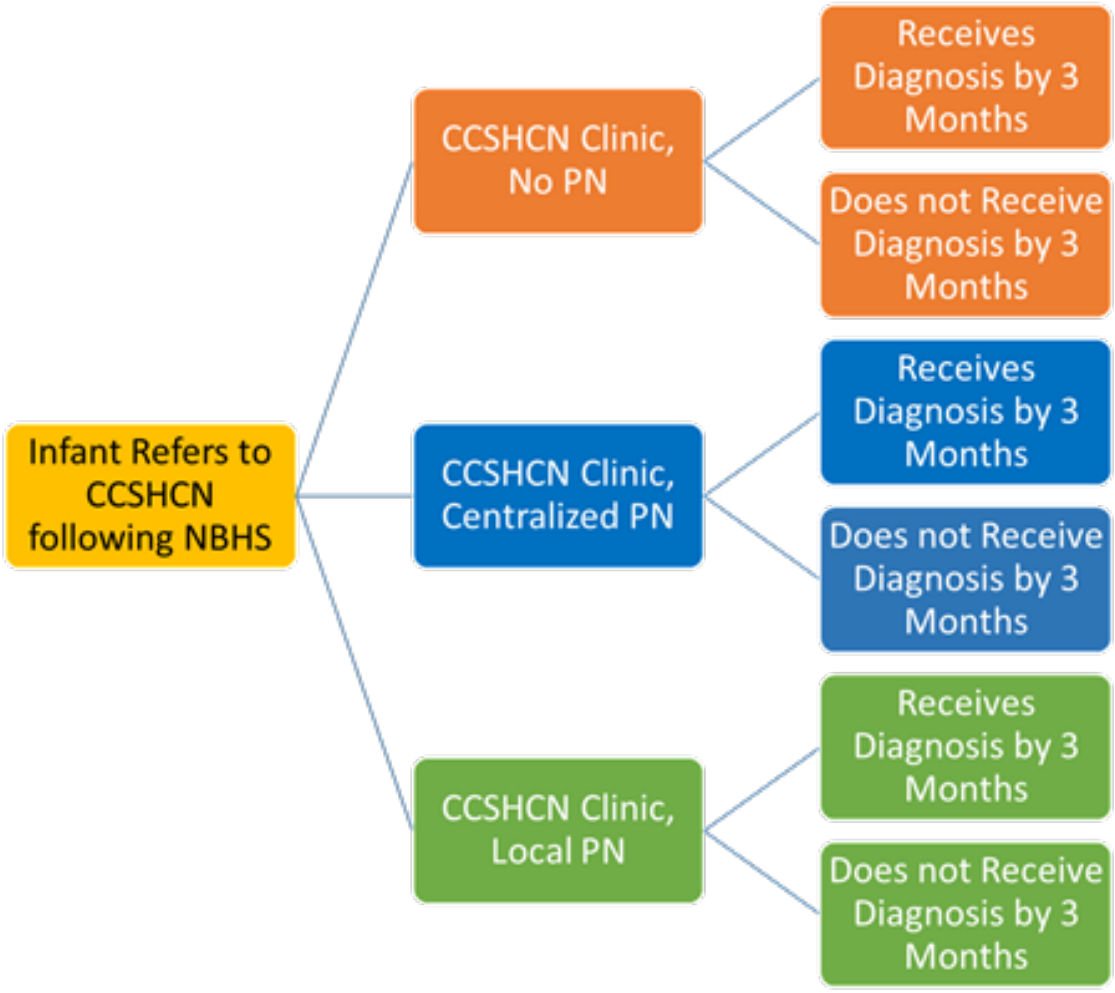
Effectiveness: The ***measured outcome of effectiveness*** to which costs will be compared is the proportion of individuals in each group who achieve diagnosis by 3 months of age. We will derive these outcome data using clinic-level non-adherence rates reported monthly by EHDI, collected in Aim 1.

Aim 3 Analyses

The cost-effectiveness analysis will follow analytic procedures outlined by Muennig and Bounthavong.[104] We will estimate costs associated with an incremental change (measured as an increase or decrease in percentage points) in effectiveness for each PN modality compared to standard of care (prior to a clinic crossing to the PN condition). **FIGURE 3.4** illustrates the anticipated flow of events in the PN. Using effectiveness and implementation data from Aims 1 and 2, we will apply probabilities and costs to each terminal event outlined to model estimated cost-effectiveness for each outcome. The analyses will be performed using TreeAge Pro software.[105] Results will be reported as a ratio of incremental cost to incremental effectiveness for each terminal event, comparing costs and outcomes of each PN group to the standard of care group, and, separately. An incremental cost effectiveness ratio (ICER) will be calculated for each alternative to determine the relative difference in costs associated with a percentage change in effectiveness for each alternative. The general ICER equation is: ICER = $\frac{(C1-C0)}{(E1-E0)}$, where: C_1 = Costs associated with PN, PN centralized, PN local; C_0 = Costs associated with standard of care; E_1 = Effectiveness (outcomes) associated with PN, PN centralized, PN local; and E_0 = Effectiveness (outcomes) associated with standard of care. For any alternative with positive incremental cost but negative incremental effectiveness, an ICER is not meaningful and thus will not be calculated.

The calculated ICERs can be used to determine which alternative may produce

FIGURE 3.4. Flowchart of Possible Events



the best outcome without exceeding stakeholders' threshold of willingness-to-pay. As this threshold is generally unknown, results will be presented for alternative thresholds and reported using cost-effectiveness acceptability curves to plot the probability of each alternative being cost-effective in relation to different values of willingness-to-pay, presented in dollars.[106] In addition, we will use one-way sensitivity analyses to account for uncertainty in our parameter estimates, including the number of participating families, costs of implementation, and PN effectiveness. For each key parameter, the sensitivity analysis will estimate the expected value of PN given changes in each parameter, using the estimate derived from study data plus or minus 20 percent. The results of the analysis will be prepared as technical documents for presentation to the Kentucky Medicaid program and other third-party payers that make policy decisions regarding covered services. The results of the sensitivity analyses will further assist payers in determining interest and ability to reimburse for PN services.

Aim 3 Potential Limitations and Alternatives

If aim 1 does not demonstrate effectiveness of patient navigation to reduce non-adherence, then this could serve as a challenge for this cost-effectivenss aim. Even if the intervention is not effective in the primary outcomes, this aim will still provide valuable information because, according to a national taskforce for EHDI programs, all states must develop and implement family support interventions.[10] An assessment of cost-effectiveness of PN will be useful to further develop more effective interventions. If PN under either modality does not demonstrate cost-effectiveness, the study results remain useful in terms of identifying target areas for potential cost reduction and as guidance for others considering implementation of similar PN programs. Another potential challenge in Aim 3 is accurate measurement of costs. The study requires reliable data on PN implementation and treatment costs, and necessitates detailed

monitoring throughout the study period. Despite the challenge of collecting these data, all stakeholders in this PN program have committed to providing the cost data outlined.

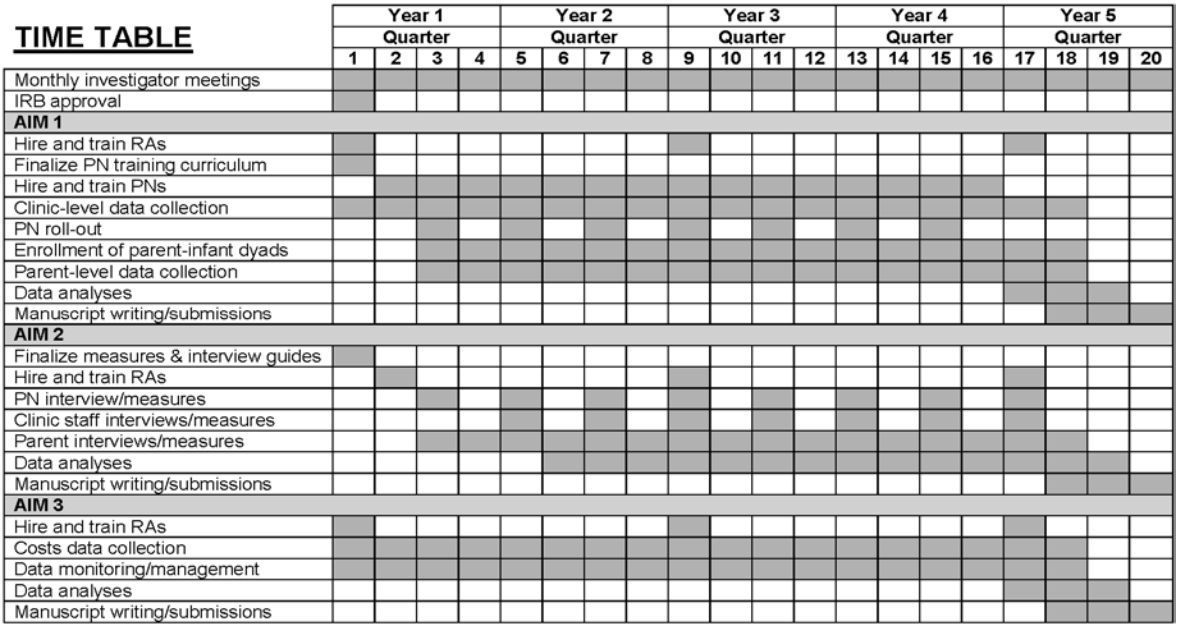
3.5. RIGOR AND REPRODUCIBILITY

As described in the Significance section, no interventions have been shown to reduce non-adherence to diagnostic testing in this population. Our preliminary data, based on a well-designed RCT, suggests that the PN intervention could be very effective in reducing non-adherence, but a larger effectiveness study is needed. Our selection of the pragmatic stepped wedge design maximizes feasibility and will achieve robust and unbiased results. The biological variable of sex of parents and infants is included in Aim 1 effectiveness analyses; sex of PNs will be assessed in Aim 2 assessment of PN characteristics as implementation factors. To address reproducibility and transparency, we will also publish our study protocol and provide detailed methods and results. We will also share study data and systematically disseminate our results to stakeholders, researchers, and practitioners, as described in the Resource Sharing Plan section.

3.6. IMPLICATIONS AND FUTURE DIRECTIONS

We seek to follow the time timeline outlined in **FIGURE 3.5**. This study is critical to assess the effectiveness, implementation factors, and cost of PN to improve delivery of infant hearing healthcare within a larger state-funded clinic environment. These data will be used to inform health policy on state and national levels. If PN is found to be effective in these settings, future research will investigate the implementation of PN into multiple practice types (university-based, private, state-funded) in a multi-state trial. Other directions include testing effects of PN on adherence to hearing healthcare treatment. This research is the first of its kind in hearing healthcare, will be rapidly translatable to practice, and will contribute to implementation science.

FIGURE 3.5. Study Time Table



TIME TABLE	Year 1				Year 2				Year 3				Year 4				Year 5			
	Quarter				Quarter				Quarter				Quarter				Quarter			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Monthly investigator meetings																				
IRB approval																				
AIM 1																				
Hire and train RAs																				
Finalize PN training curriculum																				
Hire and train PNs																				
Clinic-level data collection																				
PN roll-out																				
Enrollment of parent-infant dyads																				
Parent-level data collection																				
Data analyses																				
Manuscript writing/submissions																				
AIM 2																				
Finalize measures & interview guides																				
Hire and train RAs																				
PN interview/measures																				
Clinic staff interviews/measures																				
Parent interviews/measures																				
Data analyses																				
Manuscript writing/submissions																				
AIM 3																				
Hire and train RAs																				
Costs data collection																				
Data monitoring/management																				
Data analyses																				
Manuscript writing/submissions																				

APPENDIX 1

Newborn Hearing Parent Questionnaire (Entrance)

Please read each of the below questions and mark the box or boxes next to your response. Your name and your child's name will not be attached to any of your responses. We ask the same parent to fill out this questionnaire each time.

*Study ID:*_____

*Date:*_____

Contact phone:_____

Consent Form signed ☐ Date: _____

1. Which county do you live in? _____

2. How long does it take you to drive to the University of Kentucky?

_____hour(s) _____minutes

3. What is your gender?

☐ Male ☐ Female

4. How are you related to this child? (Please check one.)

☐ Mother

☐ Father

☐ Relative

☐ Friend

☐ Other (Please explain: _____)

5. What is your ethnicity?

☐ White/Caucasian

☐ Black/African American

☐ Hispanic /Latino

☐ Asian /Pacific Islander

☐ Native American/American Indian

☐ Other

6. When is your birthday? _____ (mm/dd/yyyy)

7. What is your marital status?

- ☐ Single, never married
- ☐ Married/domestic partnership
- ☐ Widowed
- ☐ Divorced/Separated

8. How many children do you have? _____

9. How many years of education have you completed?

- ☐ Less than Middle School
- ☐ Some High School
- ☐ Completed High School/GED
- ☐ Some college
- ☐ College
- ☐ Graduate Degree

10. What is your annual household income?

- ☐ >$10,000
- ☐ $10,000-20,000
- ☐ $20,000-30,000
- ☐ $30,000-60,000
- ☐ >$60,000

11. What is your current employment status?

- ☐ Employed for wages
- ☐ Self-employed
- ☐ Out of work and looking for work
- ☐ Out of work but not currently looking for work
- ☐ A homemaker
- ☐ A student
- ☐ Military
- ☐ Retired
- ☐ Unable to work/Disabled

12.

	Yes	No
Did you smoke or use tobacco while pregnant?	☐	☐
Did you use alcohol while pregnant?	☐	☐
Did you use any illicit drugs or prescription drugs not prescribed to you while pregnant?	☐	☐

The following questions are about your child who did not pass the hearing screening test given right after birth at the hospital.

13. What kind of health insurance does your child have? (Please check as many as apply.)

- ☐ Medicaid
- ☐ K-Chip
- ☐ Private or HMO/PPO
- ☐ None
- ☐ Other (Please explain: _____)

14.

	Yes	No
Does your child have an established primary doctor (Doctor, Nurse Practitioner, or Physician Assistant)?	☐	☐
Did someone in the hospital tell you that your baby had a newborn hearing screening test?	☐	☐
Were you told the results of your child's newborn hearing screening test?	☐	☐
Do you understand why your child had a newborn hearing screening test?	☐	☐

15. When were you told the results of the hearing screening test?

☐ Right after the screening test was finished

☐ Some time after the screening test was conducted, but before leaving the hospital

☐ I was not told the results

☐ Other (Please explain: _____)

16. What were you told when you were given the results of the newborn hearing screening test?

(Please write your answer below):

17. Your child was recommended to have follow-up testing on the:

☐ Right ear

☐ Left ear

☐ Both ears

☐ I do not know

18. How important do you think it is to follow up for more testing of your child's hearing? (Please check one.)

☐	☐	☐	☐
Not at all Important	A little important	Pretty important	Extremely important

19. Do you have anyone in your family with hearing loss?

☐ Yes ☐ No ☐ I do not know

Tell us which family members have hearing loss (Father, mother, brothers, sisters…)

_____

20. Please read the following items and check the box for each one that shows how much you agree or disagree with that statement.

	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
My child's health insurance will make it hard to follow-up for hearing testing.	☐	☐	☐	☐	☐
The distance to the clinic will make it hard to follow-up for my child's hearing testing.	☐	☐	☐	☐	☐
Difficulty getting appointments will make it hard to follow-up for my child's hearing testing.	☐	☐	☐	☐	☐
My home responsibilities will make it hard to follow-up for my child's hearing testing.	☐	☐	☐	☐	☐
My job responsibilities will make it hard to follow-up for my child's hearing testing.	☐	☐	☐	☐	☐

Please write down any other things that might make it difficult to follow-up for your child's hearing testing in the space below:

21.	Yes	No	I do not know
Do you believe that newborn hearing screening is important?	☐	☐	☐
Do you believe that the newborn hearing screening results are accurate?	☐	☐	☐
Would you like help in attending follow-up appointments for your child's hearing from UK Healthcare?	☐	☐	☐

22. Please describe in what ways UK Healthcare could make this hearing testing process easier for you. (Please answer in the space below):

23. Please read the following items and check the box for each one that shows how much you agree or disagree with that statement.

	Strongly disagree	Disagree	Undecided	Agree	Strongly Agree
I would like to talk with my child's primary doctor about the hearing test results.	☐	☐	☐	☐	☐
I feel that there are doctors in my area who can test my child's hearing	☐	☐	☐	☐	☐
I feel my family will accept and support my child, regardless of the hearing tests results.	☐	☐	☐	☐	☐
I feel uncomfortable talking about my child's hearing to others.	☐	☐	☐	☐	☐
I feel confident about the steps that need to be taken to check my child's hearing	☐	☐	☐	☐	☐
I'm afraid about what the future hearing testing may show about my child	☐	☐	☐	☐	☐
I do not know what to expect with regard to future hearing testing	☐	☐	☐	☐	☐

24. The latest a child born with hearing loss should be diagnosed with hearing loss is:

- ☐ 3 months after birth
- ☐ 6 months after birth
- ☐ 9 months after birth
- ☐ 12 months after birth

25. A child born with hearing loss should have started treatment no later than:

- ☐ 3 months after birth
- ☐ 6 months after birth

☐ 9 months after birth

☐ 12 months after birth

26. Please read the following items and check the box for each one that shows how much you agree or disagree with that statement.

	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
I am knowledgeable about the testing process for newborn hearing health.	☐	☐	☐	☐	☐
Finding out my child's hearing test result was upsetting. (Leave blank if you did not receive the results)	☐	☐	☐	☐	☐
Hearing is important for a child's social relationships.	☐	☐	☐	☐	☐
Hearing is important for a child's school performance.	☐	☐	☐	☐	☐
Early intervention services can help families with children who have hearing loss.	☐	☐	☐	☐	☐
There is no health treatment for newborn hearing impairment.	☐	☐	☐	☐	☐

Thank you for the time you have spent answering these questions. If there is anything else that you would like to share with us— comments, complaints, compliments, concerns, or questions— please use this page to do so.

APPENDIX 2

Newborn Hearing Parent Questionnaire (Exit Interview)

Please read each of the below questions and mark the box or boxes next to your response. Your name and your child's name will not be attached to any of your responses. We ask the same parent to fill out this questionnaire each time.

*Study ID:*_____

*Date:*_____

Contact phone:_____

1. Which county do you live in? _____

2. What is your sex?

☐ Male ☐ Female

3. When is your birthday? _____ (mm/dd/yyyy)

4. What is your current employment status?

☐ Employed for wages
☐ Self-employed
☐ Out of work and looking for work
☐ Out of work but not currently looking for work
☐ A homemaker
☐ A student
☐ Military
☐ Retired
☐ Unable to work/Disabled

5. How long does it take you to drive to the University of Kentucky?

_____hour(s) _____minutes

6. How do you normally travel to doctor appointments?

☐ Personal vehicle
☐ Family/Friends bring me
☐ Public transportation

The following questions are about your child who did not pass the hearing screening given right after birth at the hospital.

7. What kind of health insurance does your child have? (Please check as many as apply.)

- ☐ Medicaid
- ☐ K-Chip
- ☐ Private or HMO/PPO
- ☐ None
- ☐ Other (Please explain: _____)

8. How are you related to this child? (Please check one.)

- ☐ Mother
- ☐ Father
- ☐ Relative
- ☐ Friend
- ☐ Other (Please explain: _____)

9. Did you understand why your child had a hearing screening in the newborn nursery?

☐ Yes ☐ No

10. Did someone in the hospital tell you about your appointment today?

☐ Yes ☐ No

11. Do you understand why you child has a hearing test today?

☐ Yes ☐ No

12. What were you told regarding the reasons for this appointment? (Please write your answer below):

13.	Not at all Important	A little Important	Pretty Important	Extremely Important
How important was the hearing screening test that your child received in the newborn nursery?	☐	☐	☐	☐
How important do you feel it was to follow up today for testing of your child's hearing?	☐	☐	☐	☐

14. Do you have anyone in your family with hearing loss?

☐ Yes

☐ No

☐ I do not know

Tell us which family members have hearing loss (Father, mother, brothers, sisters…) _____

15. Please read the following items and check the box for each one that shows how much you agree or disagree with that statement.

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
My child's health insurance made it hard to follow-up for hearing.	☐	☐	☐	☐	☐
The distance to the clinic made it hard to follow-up for my child's hearing.	☐	☐	☐	☐	☐
Difficulty getting appointments made it hard to follow-up for my child's hearing.	☐	☐	☐	☐	☐
My home responsibilities made it hard to follow-up for my child's hearing.	☐	☐	☐	☐	☐
My job responsibilities will make it hard to follow-up for my child's hearing.	☐	☐	☐	☐	☐

Please write down any other things that made it difficult to follow-up for your child's hearing in the space below:

16. Please read the following items and check the box for each one that shows how much you agree or disagree with that statement.

	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
I have talked with my child's primary doctor about the hearing screening done in the newborn nursery.	☐	☐	☐	☐	☐
My child's primary doctor recommend follow-up testing of my child's hearing.	☐	☐	☐	☐	☐
I feel that there are doctors in my area who can test for and treat hearing loss	☐	☐	☐	☐	☐
I feel my family has been supportive in the getting my child's hearing tested	☐	☐	☐	☐	☐
I have talked with friends and family about the hearing screening done in the newborn nursery.	☐	☐	☐	☐	☐
I feel confident about the steps that need to be taken to check my child's hearing	☐	☐	☐	☐	☐
I feel uncomfortable talking about my child's hearing testing to others.	☐	☐	☐	☐	☐

17. Please tell us how difficult it would be to obtain the following services:

	Extremely difficult	Slightly difficult	Not difficult	Readily accessible	I don't Know
Audiologist (someone who checks hearing)	☐	☐	☐	☐	☐
Speech therapist	☐	☐	☐	☐	☐
Primary doctor (Doctor, Nurse Practitioner, or Physician Assistant)	☐	☐	☐	☐	☐
Ear, Nose, and Throat doctor	☐	☐	☐	☐	☐

18. The latest a child born with hearing loss should be diagnosed with hearing loss is:

- ☐ 3 months after birth
- ☐ 6 months after birth
- ☐ 9 months after birth
- ☐ 12 months after birth

19. A child born with hearing loss should have started treatment no later than:

- ☐ 3 months after birth
- ☐ 6 months after birth
- ☐ 9 months after birth
- ☐ 12 months after birth

20. Please read the following items and check the box for each one that shows how much you agree or disagree with that statement.

	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
Hearing is important for a child's social relationships.	☐	☐	☐	☐	☐
Hearing is important for a child's school performance.	☐	☐	☐	☐	☐
Early intervention services can help families with children with hearing loss.	☐	☐	☐	☐	☐

21. Would you like more help to attend follow-up appointments for your child's hearing?

☐ Yes ☐ No ☐ Unsure

22. Please answer the following questions regarding your experience

	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
I am more knowledgeable about the testing process for newborn hearing health since I left the hospital	☐	☐	☐	☐	☐
I understand how to proceed with my infant's hearing care	☐	☐	☐	☐	☐
I have been provided adequate information and resources regarding newborn hearing loss	☐	☐	☐	☐	☐
I am an integral part of my child's hearing healthcare team	☐	☐	☐	☐	☐
Finding out my child's hearing test result was upsetting.	☐	☐	☐	☐	☐
The help I received from the UK Healthcare to get my child's hearing tested was adequate	☐	☐	☐	☐	☐
I feel comfortable providing information to other parents about newborn hearing loss and the hearing testing	☐	☐	☐	☐	☐
I would be interested in helping other parents learn about hearing loss and the hearing screening process.	☐	☐	☐	☐	☐

23. Please describe in what way UK Healthcare could have made this hearing process easier for you. (Please answer in the space below):

24. How difficult was the process of having your child's hearing loss diagnosed? (Please check one.)

☐	☐	☐	☐
Not at all difficult	A little difficult	Pretty difficult	Extremely difficult

Thank you for the time you have spent answering these questions.
If there is anything else that you would like to share with us— comments, complaints, compliments, concerns, or questions. Please use the rest of this page to do so.

APPENDIX 3

Patient Navigator Interview Guide:

<u>Phone Contact 1 (initially after discharge)</u>
Let the participant know that we do record the phone conversation for review to assess discussion and find better ways of helping families through navigation.

Greetings and Building Trust – Remind participant of the study and the definition of a patient navigator and rapport building through asking about the participant and newborn.

a. Study purpose: We would like to see if the support and educational tools from a patient navigator are helpful in reducing barriers to hearing health for your child. You were randomized to the patient navigator, so you will have weekly to every other week phone calls until you come in for your child's hearing test by an audiologist, or hearing professional.
b. Patient navigator: A person who has interest in pediatric hearing health or has been trained to provide support and give resources to parents of children who fail the newborn hearing screening or who have hearing loss. This person will provide guidance and follow up with you to answer any questions regarding your child's condition.

2. Building rapport through asking about the participant and newborn

a. Tell me a little about yourself and your family.
b. How is your family adjusting to the newborn?
c. What are you fears or concerns about your infant's hearing? the follow-up hearing testing?

3. Has the baby seen the pediatrician? Did you speak to the doctor about the newborn hearing screening? What were you told about the results?

4. Inquiry about the hearing test date and any questions related about expectations for the visit
a. Give the participant the test date/time and let her/him know that she/he will be contacted by the Audiology Department a day or two before the appointment. If he/she has any additional questions related to the visit, she/he can contact Audiology directly or contact the navigator.
b. Does the participant have an understanding of what to expect at the ABR (Auditory Brainstem Response) test?
- Stickers that detect how well a baby is hearing are placed on the baby's forehead and behind the ears
- We hope that the baby will sleep during the test. If he or she does not sleep, you may have to return for a follow up visit to get an accurate test. We do not perform sedated ABRs. The baby can have a bottle or pacifier before the test, but once the test has begun, those items will cause noise on the test and cannot be used.
- During the test the baby stays asleep in a parent's lap and testing is done for about 20-30 minutes. If the baby wakes up, there will be a few minutes to try to get the baby back to sleep.
- After the test, the audiologist will let you know the results of the test and whether or not your baby needs to return for additional testing. Sometimes your baby may need to

grow further to get an accurate test, so he or she may have to come back for further testing.

4. Navigator reviews the standard of care recommendations: 1, 3, 6, 12 month steps

a. Newborn Hearing Screening completed by 1 month (already completed!)
b. Diagnosis by 3 months by an hearing test called an ABR (Auditory Brainstem Response) completed by an hearing professional called an audiologist. Primary care doctors do not have the specialized equipment or the training to do this test in his or her office.
c. If a child is diagnosed with hearing loss, he or she will have to have another ABR by a different audiologist to determine a diagnosis. There is available assistance, but a child should have hearing aids if needed or any beginning therapy starting before 6 months old.
d. If a child needs a cochlear implant, this should be done at about 12 months old.

5. Are there any community or UK resources that relate to your child health care that we can provide to you at either follow up phone calls or give to you in person when we see you in the Audiology Clinic?

<u>Phone Contact 2 (follow up from first phone contact) at Week 2 or Week 3</u>

Participant reminded that phone conversation will be recorded to assess the discussion

1. Greetings and any questions that were discussed from the first phone call

2. Make sure the participant knows where to park and the clinic location

3. Review information from the last phone conversation and answer any questions the parent may have since that last phone call.

4. Has the baby seen the pediatrician? Did you speak to the doctor about the newborn hearing screening? What were you told about the results?

4. Inquiry about the hearing test date and any questions related about expectations for the visit

a. Give the participant the test date/time and let her/him know that she/he will be contacted by the Audiology Department a day or two before the appointment. If he/she has any additional questions related to the visit, she/he can contact Audiology directly or contact the navigator.
b. Does the participant have an understanding of what to expect at the ABR (Auditory Brainstem Response) test?
- Stickers that detect how well a baby is hearing are placed on the baby's forehead and behind the ears
- We hope that the baby will sleep during the test. If he or she does not sleep, you may have to return for a follow up visit to get an accurate test. We do not perform sedated ABRs. The baby can have a bottle or pacifier before the test, but once the test has begun, those items will cause noise on the test and cannot be used.

- During the test the baby stays asleep in a parent's lap and testing is done for about 20-30 minutes. If the baby wakes up, there will be a few minutes to try to get the baby back to sleep.

- After the test, the audiologist will let you know the results of the test and whether or not your baby needs to return for additional testing. Sometimes your baby may need to grow further to get an accurate test, so he or she may have to come back for further testing.

5. Give sleep deprivation instructions

APPENDIX 4

Patient Navigator Satisfaction Questionnaire

Please read each of the below questions and mark the box or boxes next to your response. Your name and your child's name will not be attached to any of your responses. We ask the same parent to fill out this questionnaire each time.

	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
My navigator gives me enough time	☐	☐	☐	☐	☐
My navigator makes me feel comfortable	☐	☐	☐	☐	☐
My navigator is dependable	☐	☐	☐	☐	☐
My navigator is courteous and respectful to me	☐	☐	☐	☐	☐
My navigator listens to my problems	☐	☐	☐	☐	☐
My navigator is easy to talk to	☐	☐	☐	☐	☐
My navigator cares about me personally	☐	☐	☐	☐	☐
My navigator figures out the important issues in my healthcare	☐	☐	☐	☐	☐
My navigator is easy to contact	☐	☐	☐	☐	☐

Thank you for the time you have spent answering these questions.

If there is anything else that you would like to share with us about your experience with the patient navigator, please use the back of this page to do so. Comments, complaints, compliments, concerns, or questions are welcome.

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efficacy of patient navigation in improving quality of diagnostic care for patients with breast or colorectal cancer abnormalities. Cancer Epidemiol Biomarkers Prev. 2012; 21(10): 1664- 1672.
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98. Chaudoir SR, Dugan AG, Barr CH. Measuring factors affecting implementation of health innovations: a systematic review of structural, organizational, provider, patient, and innovation level measures. Implement Sci. 2013;8:22.
99. Creswell J, Klassen A, Plano Clark V, Smith KC for the Office of Behavioral and Social Sciences Research. Best practices for mixed methods research in the health sciences. National Institutes of Health; August 2011
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106. Briggs AH, Weinstein MC, Fenwick EA, Karnon J, Sculpher MJ, Paltiel AD, ISPOR-SMDM Modeling Good Research Practices Task Force. Model parameter estimation and uncertainty: a report of the ISPOR-SMDM Modeling Good Research Practices Task Force-6. Value in Health, 2012;15(6):835-842.

VITA

MATTHEW L. BUSH, M.D., FACS

Department of Otolaryngology – Head and Neck Surgery
University of Kentucky Chandler Medical Center

EDUCATION

08/2012 – current **University of Kentucky Graduate School**, Lexington, KY
Ph.D. candidate, Clinical and Translational Science
08/1999 – 05/2003 **Marshall University School of Medicine,** Huntington, WV
M.D., 2003
08/1995 – 05/1999 **Bob Jones University,** Greenville, SC
B.S., Premedicine, *Magna Cum Laude*
05/1995 **Cross Lanes Christian High School**, Cross Lanes, WV
Valedictorian

POST-GRADUATE TRAINING

07/2009 – 06/2011 **The Ohio State University Medical Center**, Columbus, OH
Fellowship – Neurotology and Cranial Base Surgery
07/2008 – 06/2009 **The Ohio State University Medical Center and Nationwide Children's Hospital Research Institute**, Columbus, OH
Research Fellowship (D. Bradley Welling, M.D., Ph.D. – Mentor)
07/2004 – 06/2008 **University of Kentucky Medical Center,** Lexington, KY
Residency – Otolaryngology – Head and Neck Surgery
07/2003 – 06/2004 **University of Kentucky Medical Center**, Lexington, KY
Internship – General Surgery

ACADEMIC AND PROFESSIONAL POSITIONS

2016 – Present **Honorary Lecturer**
Department of Surgery (Otorhinolaryngology)
University of Nairobi, Nairobi, Kenya
2016 – Present **Associate Professor** *with Tenure*
Department of Otolaryngology-Head and Neck Surgery
University of Kentucky, Lexington, KY
2016 – Present **Board member,** Kentucky Board of Speech Language Pathology and Audiology, Frankfort, KY
2015 – Present **Kentucky Early Hearing Detection and Intervention Program Advisory Board**, Kentucky Cabinet for Health and Family Services, Commission for Children with Special Healthcare Needs
2014 – Present **Medical Advisory Committee**
Kentucky Cabinet for Health and Family Services
Commission for Children with Special Healthcare Needs
2011 – 2016 **Assistant Professor**
Department of Otolaryngology-Head and Neck Surgery
University of Kentucky, Lexington, KY
2011- Present **Division Chief**
Otolaryngology – Head and Neck Surgery
Veterans Affairs Medical Center, Lexington, KY

2011 – 2015 **Medical Director**
Otology, Neurotology, and Cranial Base Surgery
The Heuser Hearing Institute, Louisville, KY

2012 – 2013 **President,** Kentucky Society of Otolaryngology

2011 – 2012 **President elect** – Kentucky Society of Otolaryngology

2000 – 2001 **Gross Anatomy Lab Assistant**
Mentor: Sasha Zill, Ph.D.
Marshall University School of Medicine
Department of Anatomy and Cell and Molecular Biology

MEDICAL CREDENTIALS AND CERTIFICATION

Hospital Privileges:

The University of Kentucky Chandler Medical Center and Children's Hospital
800 Rose Street
Lexington, KY 40536

Veteran's Affairs Medical Center
1101 Veterans Drive,
Lexington, KY 40502

University of Kentucky Good Samaritan Hospital,
310 S. Limestone
Lexington, KY 40508

Specialty Training: **University of Kentucky Executive Healthcare Leadership Program,** University of Kentucky Gatton College of Business and Economics
December 2015 – May 2016

Principles and Practice of Gamma Knife Radiosurgery: Special Emphasis on Perfexion Training, Center of Image-Guided Neurosurgery, University of Pittsburgh, September 27 – October 1, 2010.

***Gamma Knife Radiosurgery Training*.** Mentor – John McGregor, M.D., Department of Neurosurgery, The Ohio State University Medical Center, Columbus, OH. 2010-2011.

***Mentee*, Lessons for Success**
American Speech-Language-Hearing Association
Gaithersburg, MD, April 28-30, 2014.

***Fellow*, Summer Institute On Randomized Behavioral Clinical Trials**
National Institutes of Health/National Heart, Lung, and Blood Institute
Airlie Conference Center, Warrenton, VA. July 20 – August 1, 2014

***Fellow*, Training Institute for Dissemination and Implementation Research in Health**
National Institutes of Health
Westin Pasadena, Pasadena, CA. July 27 – 31, 2015

Certification: NBME: USMLE Step 1 (2001), 2 (2002), and 3 (2004).
American Board of Otolaryngology:

Otolaryngology (2009)
Neurotology (2012)

LICENSE

Ohio – Current, Expires July 1, 2019
Kentucky – December 17, 2010 – March 1, 2018 (Active)

ASSOCIATIONS

American College of Surgeons, *Fellow*
North American Skull Base Society, Member
Society of University Otolaryngologists
The Triological Society, Member
American Neurotology Society, *Fellow*
American Academy of Otolaryngology–Head and Neck Surgery, Member
Kentucky Medical Association
Lexington Medical Association
Greater Louisville Medical Society
Kentucky Society of Otolaryngology

HONORS & AWARDS

2014 **Phi Kappa Phi,** University of Kentucky Chapter
2014 **Songs for Sound Success Award**
2014 **Triological Society Career Development Award**
2013 **Scholars Abstract Award, Translational Science 2013**
Diagnostic Disparities of Pediatric Congenital Hearing Loss in Appalachia
2013 **Outstanding Poster Award (Cross-cultural Focus), Early Hearing Detection and Intervention Annual Meeting**
Bridging the Gap: Assessment of Hearing Healthcare Barriers in Appalachia
2012 **University of Kentucky KL2/Physician Scientist Career Development Award**
Bridging the Gaps: Assessment of Pediatric Hearing Loss in Appalachia
2011 **American Neurotology Society Fellow Research Award**
Treatment of Vestibular Schwannoma Cells with ErbB Inhibitors
2009 **American Hearing Research Foundation Research Award**
1-year $25,000 CORE grant offered through the AAO-HNS: *"In vitro and in vivo effects of HDAC inhibitors on vestibular schwannomas."*
2008 **Kentucky State Otolaryngology Resident Research Award**
Test-Retest Reliability of VEMPS
2008 **The G. Slaughter Fitz-Hugh First Place Resident Research Award**
Long-term Hearing Results in Gamma Knife Radiosurgery for Acoustic Neuromas
2007 **University of Kentucky Department of Surgery Teaching Award**
Given by medical students for excellence in teaching
2007 **University of Kentucky Temporal Bone Lab Resident Award**
Given for excellence in resident temporal bone dissection
2006 **Kentucky State Otolaryngology Resident Research Award**
ABR and Behavioral Testing in Acoustic Neuroma Detection
2005 **University of Kentucky Temporal Bone Lab Resident Award**

Given for excellence in resident temporal bone dissection

2002 **Alpha Omega Alpha**
Beta of West Virginia, Marshall University School of Medicine

2001 **MS-II Academic Achievement Award**
Given to the second year medical student with the highest GPA

2001 **Joan C. Edwards Scholarship**
Financial award given for academic excellence in medical school

2000 **MS-I Academic Achievement Award**
Given to the first year medical student with the highest GPA

UNIVERSITY SERVICE

2016-Present University of Kentucky IRB Member

2016 University of Kentucky Associate Chief Medical Officer (Perioperative Services) Search Committee

2015-Present University of Kentucky Department of Otolaryngology Grand Rounds, **Course Director**

2015 University of Kentucky CCTS KL2 Grant Review Committee

2014-2015 University of Kentucky CCTS TL1 Grant Review Committee

2014-Present University of Kentucky Department of Otolaryngology Residency Research Committee

2013-Present University of Kentucky Department of Otolaryngology Bi-Monthly Audiology and Otology Conference, **Director**

PROFESSIONAL ACTIVITY

2016 **Visiting Professor**, University of Nairobi, Division of Otolaryngology, Nairobi, Kenya, October 9-16, 2016. Lectures given:
1. *Otologic Anatomy and Physiology*
2. *Diagnosis and management of chronic otitis media*
3. *Neuroradiology for the Otologist*
4. *Examination of the Dizzy Patient*
5. *Benign Pathology of the Lateral Skull Base*
6. *Research Design 101 for the Otolaryngologist*

2016 – Present AAO-HNS Board of Governors, Socioeconomic and Grassroots Efforts Representative, Kentucky.

2016 – 2018 Hearing Committee Member,
American Academy of Otolaryngology – Head and Neck Surgery

2016 – 2018 International Otolaryngology Committee Member,
American Academy of Otolaryngology – Head and Neck Surgery

2016 – 2021 Socioeconomic Committee, American Neurotology Society

2016 **Session Moderator**, CI2016 International Cochlear Implant Meeting, Toronto, Ontario, Canada, May 13, 2016.

2016 **Visiting Professor**, University of Nairobi, Division of Otolaryngology, Nairobi, Kenya, March 12-21, 2016. Lectures given:
1. *Otologic Anatomy and Physiology*
2. *Clinical Evaluation of the Otological Patient*
3. *Cholesteatoma and Chronic Otitis Media*
4. *Neuroradiology for the Otologist*

5. Otology Oral Exam
6. Dealing with Suffering and Complications: A Moral Crisis for Clinicians
7. Advancing Your Career and Expanding Your Practice Through Health Disparities Research

2015 *American Journal of Public Health*, Ad hoc reviewer

2015 **Visiting Professor**, University of Nairobi, Division of Otolaryngology, Nairobi, Kenya, October 2 – October 12. Lecture given:
Mastoidectomy and Tympanoplasty with OCR

2015-Present *Ear and Hearing*, Ad hoc reviewer

2015 **Visiting Professor**, University of Nairobi, Division of Otolaryngology, Nairobi, Kenya, March 14 – March 22. Lectures given:
1. *Auditory Anatomy and Physiology*
2. *Vestibular Anatomy and Physiology*
3. *Differential Diagnosis of the Dizzy Patient*
4. *Complications of Otitis Media*
5. *Tympanoplasty and Ossicular Chain Reconstruction*
6. *Radiographic Characteristics of Temporal Bone Lesions*
7. *Surgical Approaches in Chronic Otitis Media*

Kenyan ENT Society Meeting: *Work Life Balance: Is that even possible?*
University of Nairobi Department of Surgery Grand Rounds: *The Deaf Will Hear The Words: The Art of Cochlear Implantation*

2014-2016 American Academy of Otolaryngology – Head and Neck Surgery, Consultant for the Humanitarian Efforts Committee

2014 Visiting Professor, University of Nairobi, Division of Otolaryngology, Nairobi, Kenya, October 6-10, 2014. Lecture given:
Research Design 101: An Otolaryngologists Intro to Clinical Research

2014-present Surgical Advisory Board, Med El Corporation

2014 **Visiting Professor**, University of Nairobi, Division of Otolaryngology, Nairobi, Kenya, January 18-Feb 3, 2014. Lectures given:
1. *Auditory Anatomy, Embryology, and Physiology*
2. *The Vestibular System – Anatomy, Physiology, and Testing*
3. *Diagnosis and Management of Chronic Otitis Media*
4. *Cholesteatoma and the Art of Mastoidectomy*
5. *Temporal Bone Trauma and Associated Complications*
6. *Lesions of the Lateral Skull Base*
7. *Facial Nerve: Pathology and Management*
8. *Neuroradiology for the Hearing Specialist*

Kenyan ENT Society Meeting: *Cartilage Tympanoplasty: The Science and the Art*

2014-Present *Annals of Otology, Rhinology, and Laryngology*, Ad hoc reviewer

2013-Present *American Journal of Emergency Medicine,* Ad hoc reviewer

2013-Present *Otology & Neurotology* Journal, Ad hoc reviewer

2013 **Visiting Professor**, University of Nairobi, Division of Otolaryngology, Nairobi, Kenya, January 25-Feb 3, 2013. Lectures given:
1. *Mastoidectomy: Pearls and Pitfalls*
2. *Tympanoplasty: The Science and the Art*
3. *Management of Complications of Chronic Otitis Media*
4. *Management of Lateral Skull Base CSF Leaks*

Kenyan ENT Society Meeting: *Training Tomorrow's Cranial Base Surgeon*

2012-Present *Laryngoscope* Journal, Ad hoc reviewer

2012 **Visiting Professor**, University of Nairobi, Division of Otolaryngology, Nairobi, Kenya, January 21-30, 2012. Lectures given:
1. *Neuroradiology of the Lateral Skull Base*
2. *Vestibular Physiology and Testing*
3. *Approaches to the Lateral Skull Base*
4 *Temporal Bone Trauma*.
Kenyan ENT Society Meeting*: Vestibular Schwannomas: An Update and Future Options*

2011-Present **Board member**, Lexington Hearing and Speech Center, Lexington, KY

2010-Present *Clinical Anatomy*, Ad hoc reviewer

2008-Present *Otolaryngology – Head and Neck Surgery* Journal, Ad hoc reviewer

2007-2012 American Academy of Otolaryngology – Head and Neck Surgery, Member of the Credentials and Membership Committee

2007-2009 American Academy of Otolaryngology – Head and Neck Surgery, Member of the Hearing Aid Subcommittee

October 2008 Project Ear Inc., Team Member, Provided otologic surgical care on mission trips to the Dominican Republic

January 2007 Project Ear Inc., Team Member, Provided otologic surgical care on mission trips to the Dominican Republic

ORAL PRESENTATIONS

2016 **Bush M,** Noblitt B, Adkins M. Rehabilitation Barriers for Rural Pediatric Cochlear Implant Recipients. 14th International Conference on Cochlear Implants. Toronto, CA. May 13, 2016.

2016 Hixon B, Chan S, Shinn J, **Bush M**. Assessment of Rural Adult Hearing Health Disparities--Access to Care in Cochlear Implantation. 14th International Conference on Cochlear Implants. Toronto, CA. May 13, 2016.

2015 **Bush M**. Family Perceptions and Experiences with the Early Hearing Detection and Intervention System in Rural Communities. National EHDI Conference. March 10, 2015.

2014 **Bush M**. Surgical Survey on the Usability and Applicability of the HiFocus Mid Scala Electrode. 14th Annual Cochlear Implants in Children Conference. Nashville, TN. December 11, 2014.

2014Elpers J, **Bush M**. Family Perceptions and Experiences with the Early Hearing Detection and Intervention System in Rural Communities. 14th Annual Cochlear Implants in Children Conference. Nashville, TN. December 13, 2014.

2014 **Bush M.** Targeting Regional Pediatric Congenital Hearing Loss Using a Spatial Scan Statistic. 14th Annual Cochlear Implants in Children Conference. Nashville, TN. December 13, 2014.

2014 Bush M, Hardin B, Rayle C, Lester C, Studts C, Shinn J. Rural Barriers to Early Diagnosis and Treatment of Infant Hearing Loss in Appalachia. American Otological Society Annual Meeting - COSM. May 17, 2014.

2013 **Bush M**, Pediatric Congenital Hearing Loss in Appalachia: Assessing and Addressing Diagnostic Delays. Kentucky Society of Otolaryngology Annual Meeting, University of Kentucky, Lexington, Kentucky. April 20, 2013.

2013 **Bush M**, Pediatric Congenital Hearing Loss in Appalachia: Assessing and Addressing Diagnostic Delays. 8th Annual CCTS Spring Conference University of Kentucky Center for Clinical and Translational Science, Lexington Convention

Center, Lexington, Kentucky. April 8, 2013.

2013 Osetinsky M, Shinn J, Fardo, Gal TJ, Schoenberg N, **Bush M**. Congenital Sensorineural Hearing Loss in Appalachia. AOA Groves Memorial MD/PhD Program Student Research Symposium, University of Kentucky, Lexington, Kentucky. February 20, 2013.

2012 **Bush M**, Bridging the Gaps: Assessment of Appalachian Pediatric Hearing Loss. Twentieth Annual Department of Otolaryngology Saunders Symposium. The Ohio State University, Columbus, OH. June 22, 2012.

2012 Cipolla M, Iyer P, Dome C, Welling DB, **Bush M**. ***Paul Holinger, MD Resident Research Award (Middle Section).*** Modification and Comparison of Minimally Invasive Cochleostomy Techniques: A Pilot Study. The Triological Society Combined Sections Meeting, Miami, FL. January 26, 2012.

2011 **Bush M**, AR42, A Novel Histone Deacetylase Inhibitor, as a Potential Therapy for Vestibular Schwannomas and Meningiomas. Nineteenth Annual Department of Otolaryngology Alumni Symposium. The Ohio State University, Columbus, OH. June 24, 2011.

2011 Burns S, Akhmametyeva E, Oblinger J, **Bush M**, Huang J, Senner V, Giovannini M, Chen CS, Jacob A, Welling DB, Chang LS. AR-42 and AR-12 Potently Inhibit the Growth of NF2-deficient Human Meningiomas. Childrens Tumor Foundation NF Conference. Jackson Hole, WY. June 14, 2011.

2011 **Bush M,** Oblinger J, Davletova S, Burns S, Chang LS, Welling DB, Jacob A. Treatment of Vestibular Schwannoma Cells with ErbB Inhibitors. Combined Otolaryngology Society Meeting (American Neurotology Society). Chicago, IL. April 30, 2011.

2010 Oblinger J, Lee T, Packer M, Huang J, **Bush M,** Kulp S, Chen CS, Giovannini M, Welling DB, Jacob A, Chang LS. HDAC42 and OSU-03012, Novel Small-Molecule Inhibitors for the Treatment of Vestibular Schwannomas. Children's Tumor Foundation NF Conference. Baltimore, MD. June 8, 2010.

2009 **Bush M**, Oblinger J, Kulp S, Chen CS, Jacob A, Chang LS, Welling DB. Novel Inhibitors of Vestibular Schwannomas and Meningiomas. American Acadcemy of Otolaryngology – Head and Neck Surgery Annual Meeting. San Diego, CA. October 6, 2009.

2009 Oblinger J, **Bush M**, Kulp S, Chen CS, Jacob A, Chang LS, Welling DB. Radiosensitization of Vestibular Schwannomas by HDAC42. American Acadcemy of Otolaryngology – Head and Neck Surgery Annual Meeting. San Diego, CA. October 6, 2009.

2008 **Bush M**, Jones R, Shinn J. Test-Retest Reliability of VEMPS. Kentucky Society of Otolaryngology Annual Meeting. Harrodsburg, KY April 18, 2008.

2008 **Bush M**, Shinn J, Young B, Jones R. Long-term Hearing Results in Gamma Knife Radiosurgery for Acoustic Neuromas. The Triological Society Southern Section Meeting, Naples, FL. January 10-12, 2008.

2007 **Bush M**, Shinn J, Young B, Jones R. Long-term Hearing Results in Gamma Knife Radiosurgery for Acoustic Neuromas. Kentucky Society of Otolaryngology Annual Meeting, Louisville, KY. May 18-19, 2007.

2006 **Bush M**, Jones R, Musiek F & Shinn J. Auditory Brainstem Response and Behavioral Testing in Acoustic Neuroma Detection, Kentucky Society of Otolaryngology Annual Meeting, Dale Hollow Lake Resort, KY. May 19-20, 2006

2006 Shinn J, **Bush M**. Current Trends in Electrophysiology. University of Connecticut 1st Annual Symposium on (C)APD. Storrs, CT.

POSTER PRESENTATIONS

2016 Ritchie R, Alfonso K, Cheriyan M, **Bush M**, Jones R, Weihing J, Shinn J. Effect of Noise on Anesthesiologist Auditory Processing in the Operating Room. International Anesthesia Research Society Annual Meeting and International Science Symposium. San Francisco, CA. May 21-24, 2016.

2016 Chan S, Hixon B, Shinn J, **Bush M**. Hearing Loss in Rural Adults: A Geographic Comparison of Access to Care in Hearing Aid Recipients. American Otological Society Annual Meeting (COSM). Chicago, IL. May 20-21, 2016.

2016 Taylor Z, Anderson S, **Bush M**. Addressing Pediatric Hearing Loss Educational and Practice Gaps in Primary Care Providers. World Congress on Continuing Professional Development. San Diego, CA. March 17-19, 2016.

2016 Noblitt B, **Bush M**. Barriers and Outcomes of Cochlear Implantation Rehabilitation in Rural Appalachia. 15th Annual Early Hearing Detection and Intervention Meeting. San Diego, CA. March 13-15, 2016.

2016 Hixon B, Chan S, Shinn J, **Bush M**. ***John E. Bordley, MD Resident Research Award (Southern Section).*** Assessment of Rural Adult Hearing Health Disparities--Access to Care in Cochlear Implantation. Triological Society Combined Section Meeting. Miami, FL. January 22-24, 2016.

2015 **Bush M,** Christian J, Bianchi K, Lester C, Schoenberg N. Targeting Regional Pediatric Congenital Hearing Loss Using a Spatial Scan Statistic. National EHDI Meeting. Louisville, KY. March 9, 2015.

2014 Alexander D, Noblitt B, Lester C, Shinn J, **Bush M**. Rural Primary Care Provider Knowledge and Practice Patterns of Congenital Hearing Loss. Triological Society Annual Meeting - COSM. May 15-17, 2014.

2014 Noblitt B, Alexander D, Lester C, Shinn J, **Bush M**. Rural Primary Care Provider Knowledge and Practice Patterns of Congenital Hearing Loss. 9th Annual CCTS Spring Conference University of Kentucky Center for Clinical and Translational Science, Lexington Convention Center, Lexington, Kentucky. March 27, 2014.

2014 **Bush M**, Hardin B, Rayle C, Lester C, Studts C, Shinn J. Rural Barriers to Early Diagnosis and Treatment of Infant Hearing Loss in Appalachia. 9th Annual CCTS Spring Conference University of Kentucky Center for Clinical and Translational Science, Lexington Convention Center, Lexington, Kentucky. March 27, 2014.

2013 **Bush M**, Bianchi K, Lester C, Shinn J, Gal TJ, Fardo D, Schoenberg N. Diagnostic Disparities of Pediatric Congenital Hearing Loss in Appalachia. Translational Science 2013, Washington, DC. April 18, 2013.

2013 **Bush M**, Bianchi K, Osetinsky M, Shinn J. Bridging the Gap: Assessment of Hearing Healthcare Barriers in Appalachia. Early Detection Hearing and Intervention Annual Meeting, Glendale, AZ. April 15, 2013.

2013 Roberts D, **Bush M,** Jones R. Adult Progressive Sensorineural Hearing Loss: Is pre-operative imaging necessary prior to cochlear implantation. American Neurotology Society Annual Meeting – COSM. Orlando, FL. April 12, 2013

2013 **Bush M**, Bianchi K, Osetinsky M, Shinn J. Rural Pediatric Hearing Healthcare Disparity: Factors in Delayed Congenital Hearing Loss Diagnosis and Intervention. Triological Society Annual Meeting – COSM. Orlando, FL. April 12, 2013.

2013 **Bush M**, Burton M, Loan A, Shinn J. Timing Discrepancies of Early Intervention Hearing Services in Urban and Rural Cochlear Implant Recipients. American Otological Society Annual Meeting – COSM. Orlando, FL. April 12, 2013.

2013 Osetinsky M, Shinn J, Fardo, Gal TJ, Schoenberg N, **Bush M**. Congenital Sensorineural Hearing Loss in Appalachia. AOA Groves Memorial MD/PhD

Program Student Research Symposium, University of Kentucky, Lexington, Kentucky. February 20, 2013.

2012 Burns S, Akhmametyeva E, Oblinger J, **Bush M**, Huang J, Qian A, Senner V, Chen CS, Jacob A, Welling DB, Chang LS. AR-42, a Novel Histone Deacetylase Inhibitor, Differentially Affects Cell-Cycle Progression of Meningeal and Meningioma Cells and Potently Inhibits Tumor Growth in a Quantifiable NF2-deficient Benign Meningioma Model. The 2012 NF Conference, New Orleans, LA.

2012 Chang E, Bingcang C, Fornwalt B, **Bush M**, Gal T, Jones R, Shinn J. The Utility of Monothermal Caloric Testing in Screening for Vestibular Dysfunction. American Auditory Society Annual Meeting. March 2012. Scottsdale, AZ.

2012 Burns S, Akhmametyeva E, Oblinger Huang J, **Bush M**, Senner V, Chen CS, Jacob A, Welling DB, Chang LS. AR-42, a Novel Histone Deacetylase Inhibitor, Causes G2 Arrest in Meningioma Cells while Arresting Normal Meningeal Cells at G1 and Potently Inhibits Tumor Growth in a Quantifiable NF2-deficient Benign Meningioma Model. The 14th Ohio State University Comprehensive Cancer Center Annual Scientific Meeting, Columbus, OH.

2012 Burns S, Akhmametyeva E, Oblinger J, Huang J, **Bush M**, Senner V, Chen CS, Jacob A, Welling DB, Chang LS. AR-42, a Novel Histone Deacetylase Inhibitor, Causes G2 Arrest in Meningioma Cells while Arresting Normal Meningeal Cells at G1 and Potently Inhibits Tumor Growth in a Quantifiable NF2-deficient Benign Meningioma Model. The Research Institute at Nationwide Children's Hospital 2012 Research Week, Columbus, OH. The 2012 3rd Semi-Annual ONOC Meeting, Columbus, OH.

2012 Burns, S.S., E.A. Akhmametyeva, J.L. Oblinger, **M.L. Bush**, J. Huang, A. Qian, V. Senner, C.-S. Chen, A. Jacob, D.B. Welling, L.-S. Chang. 2012. AR-42, a Novel Histone Deacetylase Inhibitor, Differentially Affects Cell-Cycle Progression of Meningeal and Meningioma Cells and Potently Inhibits Tumor Growth in a Quantifiable NF2-deficient Benign Meningioma Model. The Research Institute at Nationwide Children's Hospital 2012 Research Week, Columbus, OH

2011 Walz P, **Bush M**, Robinett Z, Kirsch C, Welling DB. 3D Volumetric Conformal Analysis of Vestibular Schwannomas: Comparison of volumetric and linear measurements for estimation of sporadic vestibular schwannoma growth. American Academy of Otolaryngology – Head and Neck Surgery Annual Meeting, San Francisco, CA. September 11-14, 2011.

2011 **Bush M**, Bratasz A, Brendel V, Manning A, Oblinger J, Chang LS, Welling DB, Jacob A, Powell K. The Use of Magnetic Resonance Spectroscopy (MRS) in Monitoring Vestibular Schwannoma Growth and Treatment Effect. Childrens Tumor Foundation NF Conference. Jackson Hole, WY. June 11-14, 2011.

2011 **Bush M**, Oblinger J, Brendel V, Santarelli G, Huang J, Akhmametyeva E, Burns S, Wheeler, Davis J, Yates C, Chaudhury A, Kulp S, Chen C, Chang L, Welling D, Jacob A. AR42, A Novel Histone Deacetylase Inhibitor, as a Potential Therapy for Vestibular Schwannomas and Meningiomas. Childrens Tumor Foundation NF Conference. Jackson Hole, WY. June 11-14, 2011.

2011 **Bush M**, Oblinger J, Brendel V, Santarelli G, Huang J, Akhmametyeva E, Burns S, Wheeler, Davis J, Yates C, Chaudhury A, Kulp S, Chen C, Chang L, Welling D, Jacob A. AR42, A Novel Histone Deacetylase Inhibitor, as a Potential Therapy for Vestibular Schwannomas and Meningiomas. The Ohio State University Annual Research Day, Columbus, OH. April 7, 2011.

2011 **Bush M,** Oblinger J, Davletova S, Burns S, Chang LS, Welling DB, Jacob A. Treatment of Vestibular Schwannoma Cells with ErbB Inhibitors. The Ohio State University Annual Research Day, Columbus, OH. April 7, 2011.

2011 **Bush, M**, Oblinger J, Brendel V, Santarelli G, Huang J, Akhmametyeva E, Burns S, Wheeler, Davis J, Yates C, Chaudhury A, Kulp S, Chen C, Chang L, Welling D, Jacob A. AR42, A Novel Histone Deacetylase Inhibitor, as a Potential Therapy for Vestibular Schwannomas and Meningiomas. Nationwide Children's Hospital Research Institute Research Week Spring 2011.

2011 Burns S, Akhmametyeva E, Oblinger J, **Bush M**, Huang J, Senner V, Giovannini M, Chen CS, Jacob A, Welling DB, Chang LS. AR-42 and AR-12 Potently Inhibit the Growth of NF2-deficient Human Meningiomas. Nationwide Children's Hospital Research Institute Research Week. April 4-8, 2011.

2011 Burns S, Akhmametyeva E, Oblinger J, **Bush M**, Huang J, Senner V, Giovannini M, Chen CS, Jacob A, Welling DB, Chang LS. AR-42 and AR-12 Potently Inhibit the Growth of NF2-deficient Human Meningiomas. The Ohio State University Comprehensive Cancer Center Annual Conference. Columbus, Ohio. February 18, 2011.

2010 Hull B, **Bush M**, Yates C, Miles-Markley B, Chang LS, Welling DB. Assessment of Color Vision and Developmental Anomalies in Neurofibromatosis type 2 Patients. The Ohio State University Annual Research Day, Columbus, OH. April 8, 2010.

2010 Davis J, Burns S, **Bush M**, Welling DB, Chang LS. Establishment of Benign and Malignant *NF2*-Deficient Meningioma Mouse Models. The Ohio State University Annual Research Day, Columbus, OH. April 8, 2010.

2010 Oblinger J, Lee T, Packer M, Huang J, **Bush M,** Kulp S, Chen CS, Giovannini M, Welling DB, Jacob A, Chang LS. HDAC42 and OSU-03012, Novel Small-Molecule Inhibitors for the Treatment of Vestibular Schwannomas. The Ohio State University Comprehensive Cancer Center Annual Conference. Columbus, Ohio. February 19, 2010.

2010 Burns S, **Bush M,** Davis J, Welling DB, Chang LS. Intracranial Xenograft Models for Benign and Malignant *NF2*-Deficient Meningiomas. The Ohio State University Comprehensive Cancer Center Annual Conference. Columbus, Ohio. February 19, 2010.

2010 Oblinger J, Lee T, Packer M, Huang J, **Bush M,** Kulp S, Chen CS, Giovannini M, Welling DB, Jacob A, Chang LS. HDAC42 and OSU-03012, Novel Small-Molecule Inhibitors for the Treatment of Vestibular Schwannomas. Nationwide Children's Hospital Research Institute Research Week. Columbus, Ohio. April 7, 2010.

2010 Burns S, **Bush M,** Davis J, Welling DB, Chang LS. Intracranial Xenograft Models for Benign and Malignant *NF2*-Deficient Meningiomas. Nationwide Children's Hospital Research Institute Research Week. Columbus, Ohio. April 5, 2010.

2009 **Bush M**, Oblinger J, Burns S, Kulp S, Chen CS, Senner V, Jacob A, Welling DB, Chang LS. Preclinical Evaluation of HDAC Inhibitors and an EGFR Inhibitor on Vestibular Schwannoma and Meningioma. Childrens Tumor Foundation NF Conference. Portland, OR. June 13-16, 2009.

2009 **Bush M**, Burns S, Kulp S, Chen CS, Jacob A, Welling DB, Chang LS. Mutation Analysis and *In Vitro* HDAC Inhibitor Treatment of Benign Human Meningioma Cells. The Ohio State University Medical Center Research Day, Columbus, OH. April 3, 2009.

2007 **Bush M**, Jones R, Shinn J. Test-Retest Reliability of VEMPS. American Auditory Society Meeting, Scottsdale, AZ. March 4-7, 2007

2006 **Bush M**, Jones R, Musiek F & Shinn J. Auditory Brainstem Response and Behavioral Testing in Acoustic Neuroma Detection. American Auditory Society Meeting, Scottsdale, AZ. March 5-7, 2006

INVITED LECTURES

2016 **Bush M**, Barry P, Thomlinson B. "'But He Wears Hearing Aids!' – A Primer on Meeting the Holistic Needs of Children who are Hard of Hearing." Systems of Care Academy. Lexington, KY. June 8, 2016. (Panel Discussion)

2016 Studts T, **Bush M.** Interdisciplinary Research with Children: Examples from Biomedical and Behavioral Studies. University of Kentucky CCTS Clinical Research Update. Lexington, KY. May 10, 2016.

2016 **Bush M.** Bridging the Gaps: Assessing and Addressing Hearing Health Disparities. Johns Hopkins University Center for Hearing and Balance Seminar Series. Baltimore, MD. April 7, 2016.

2015 **Bush M.** Hearing Loss and Cochlear Implantation. Kentucky Academy of Physicians Assistants. Lexington, KY. November 5, 2015.

2015 **Bush M.** Hearing Preservation in Cochlear Implantation. Hearing Loss Association of America, Kentucky Chapter Annual Meeting, Louisville, KY. September 12, 2015.

2015 **Bush M.** Diseases of Balance and Equilibrium. Hearing Loss Association of America, Kentucky Chapter Annual Meeting, Louisville, KY. September 12, 2015.

2015 **Bush M.** Family Perceptions and Experiences with the Early Hearing Detection and Intervention System in Rural Communities. National Center for Hearing Assessment and Management Webinar. August 11, 2015. http://www.infanthearing.org/resources_home/events/family-perceptions.html

2015 **Bush M.** Bridging the Gaps: Assessing and Addressing Pediatric Rural Hearing Healthcare Disparities. Kentucky Academy of Audiology Annual Meeting, Lexington, KY. July 25, 2015.

2015 **Bush M.** Not a Second to Lose! The Race for Auditory Development. Lexington Hearing and Speech Center Little Peeps Symposium, Lexington, KY. April 18, 2015.

2015 **Bush M.** Resident Quiz Bowl. Kentucky Society of Otolaryngology Annual Meeting. Lexington, KY. April 18, 2015.

2015 **Bush M.** Hearing Preservation in Cochlear Implantation. Kentucky Speech and Hearing Association Annual Meeting, Lexington, KY. February 26, 2015.

2015 **Bush M.** Bridging the Gaps: Assessment of Rural Pediatric Hearing Health Disparities. American Academy of Audiology eAudiology session, February 11, 2015.

2014 **Bush M.** An Update On Infant Hearing Loss And Diagnostic Testing. Family Medicine Review, Lexington, KY. May 12, 2014.

2014 **Bush M.** Why Can't I Hear? An Overview of Hearing Loss Causes. Hearing Loss Association of Kentucky, Lexington Chapter, May 8, 2014.

2014 **Bush M.** Bridging the Gaps: Assessing and Addressing Rural Pediatric Hearing Health Disparities. Indiana University DeVault Research Symposium Keynote Speaker. March 12, 2014.

2013 **Bush M.** An Update On Infant Hearing Loss And Diagnostic Testing. Family Medicine Review, Lexington, KY. November 4, 2013.

2013 **Bush M.** An Expanding Gap: Addressing Rural Hearing Healthcare Disparities and Delays. University of Kentucky Department of Otolaryngology 25th Anniversary Alumni Symposium. October 19, 2013.

2013 **Bush M.** Hearing Preservation in Cochlear Implantation. Hearing Loss Association of America, Kentucky Chapter Annual Meeting, Louisville, KY. July 19, 2013.

2013 **Bush M.** Pediatric Congenital Hearing Loss in Appalachia: Assessing and Addressing Diagnostic Delays. Hearing Loss Association of America, Kentucky Chapter Annual Meeting, Louisville, KY. July 19, 2013.

2013 **Bush M.** A Pediatrician's Guide to Healthy Ears. Contemporary Pediatrics Conference. Marriott Griffin Gate Resort, Lexington, KY. May 18, 2013.

2013 **Bush M.** Hearing Preservation in Cochlear Implantation. Featured Session at the American Academy of Audiology AudiologyNOW! Annual Meeting, Anaheim, CA. April 6, 2013.

2013 **Bush M.** Hearing Preservation in Cochlear Implantation. American Academy of Audiology eAudiology Session. April 6, 2013.

2013 **Bush M.** Diagnostic and Therapeutic Inequities in Appalachian Pediatric Congenital Hearing Loss. Kentucky Speech and Hearing Association Annual Meeting, Lexington, KY. February 28, 2013.

2013 **Bush M.** Neuroradiology and Related Neuroanatomy for the Audiologist. American Academy of Audiology eAudiology session, February 12, 2013.

2012 **Bush M.** Breaking the Silence: An Overview of Cochlear Implantation. Hearing Loss Association of America, Kentucky (Bardstown) Chapter, October 22, 2012.

2012 **Bush M.** Evaluation of Dizziness in the Primary Care Setting. Kentucky Association of Physician Assistants Annual Meeting. Lexington, KY October 21, 2012.

2012 **Bush M.** Horizon of Hope: Addressing Audiologic Barriers in East Africa. Heuser Hearing Institute Grand Rounds, Louisville, KY. June 27, 2012.

2012 **Bush M.** Breaking the Silence: An Overview of Cochlear Implantation. Hearing Loss Association of Kentuckiana, Louisville Chapter, May 8, 2012.

2012 **Bush M.** ENT Through the Lifespan: Caring for the Ear from Cradle to Grave. The Kentucky Coalition of Nurse Practitioners and Nurse Widwives 24th Annual Conference. Louisville, KY. April 18, 2012.

2012 **Bush M.** Breaking the Silence: An Overview of Cochlear Implantation. Hearing Loss Association of America, Kentucky (Lexington) Chapter, March 1, 2012.

2012 **Bush M.** Neuroradiology and Related Neuroanatomy for the Audiologist. University of Louisville Division of Audiology Grand Rounds, February 20, 2012.

2011 **Bush M.** Pediatric Neuroradiology and Clinical Implications for the Pediatric Hearing Specialist. Ohio School Speech Pathology Educational Audiology Coalition Fall Conference, Columbus, OH. October 23, 2011.

2011 **Bush M.** Neuroradiology and Related 3D Neuroanatomy for the Audiologist. Alabama Academy of Audiology Annual Meeting, Sandestin, FL. October 1, 2011.

2011 **Bush M.** Pediatric Neuroradiology and Neuroanatomy for the Hearing Specialist. Heuser Hearing Institute Grand Rounds, Louisville, KY. September 14, 2011.

2011 **Bush M.** AR42, A Novel Histone Deacetylase Inhibitor, as a Potential Therapy for Vestibular Schwannomas and Meningiomas. The Ohio State University Annual Saunders Symposium, Columbus, OH. June 24, 2011.

2011 **Bush M.** Vestibular Schwannoma: Update on Current Therapies and Potential Future Options. Kentucky Society of Otolaryngology Annual Meeting, Lexington, KY, May 21, 2011.

2011 **Bush M**, Musiek F. Neuroradiology and Related 3D Neuroanatomy for the Audiologist. Featured Session at the American Academy of Audiology Annual Meeting, Chicago, IL. April 9, 2011.

2011 **Bush M**. Neuroradiology and Related Neuroanatomy for the Audiologist. Ohio Academy of Audiology Annual Meeting, Columbus, OH. February 19, 2011.
2010 **Bush M**, Musiek F. Neuroradiology and Related 3D Neuroanatomy for the Audiologist. Featured Session at the American Academy of Audiology Annual Meeting, San Diego, CA. April 16, 2010.
2009 **Bush M**, Musiek F. Neuroradiology and Related 3D Neuroanatomy for the Audiologist. Learning Lab at the American Academy of Audiology Annual Meeting, Dallas, TX. April 1, 2009.

UNIVERSITY CURRICULUM/LECTURES

2016 **Bush M**. Med 815 Introduction to Clinical Medicine. *Advancing Your Career and Expanding Your Practice through Health Disparities Research.* February 15, 2016.
2015 **Bush M.** Evaluation of Dizziness in the Primary Care Setting. University of Kentucky Department of Internal Medicine Resident Lecture Series. October 20, 2015.
2015 **Bush M, Course Director**. University of Kentucky Department of Otolaryngology – Head and Neck Surgery Grand Rounds Series. Ongoing lecture series given every 4th Wednesday of the Month.
2015 **Bush M**. Med 815 Introduction to Clinical Medicine. *Advancing Your Career and Expanding Your Practice through Health Disparities Research.* July 15, 2015.
2015 **Bush M**. Online Center for Hearing Health. CME modules for provider education. http://www.cecentral.com/node/1169
2015 **Bush M**. Med 815 Introduction to Clinical Medicine. *Advancing Your Career and Expanding Your Practice through Health Disparities Research.* April 6, 2015.
2015 **Bush M, Co-Course Director.** Resident Core Curriculum: *Otology, Neurotology and Cranial Base Surgery.* University of Kentucky, Lexington, KY. March, 2015.
2015 **Bush M.** Physiology of Equilibrium and Hearing. University of Kentucky Department of Neurology Resident Lecture Series. February 2, 2015.
2014 **Bush M**. *Work-Life Balance: Is that even possible?* Department of Otolaryngology Professionalism Lecture Series. University of Kentucky, Lexington, KY. November 5, 2014.
2014 **Bush M, Course Director.** Resident Core Curriculum: *Otolaryngologic Manifestations of Systemic Disease.* University of Kentucky, Lexington, KY
2014 **Bush M** and Valentino J. Congenital Hearing Loss. 1st year medical student Neuroanatomy/Neurophysiology Course. University of Kentucky, Lexington, KY. April 14-15, 2014.
2014 **Bush M**. *Research Design 102: Statistics for the Mathematically Challenged*. Department of Otolaryngology Lecture Series. University of Kentucky, Lexington, KY. March 5, 2014.
2014 **Bush M**. *Research Design 101: A Dummies Guide to Clinical Research*. Department of Otolaryngology Lecture Series. University of Kentucky, Lexington, KY. February 5, 2014.
2013-14 **Bush M**, *Clinical Otology: The Diagnosis and Management of Ear Disease*. 3rd year medical student lecture. University of Kentucky, Lexington, KY.
2013 **Bush M** and Valentino J. *Evaluation of the Vestibular Patient*. 1st year medical student Neuroanatomy/Neurophysiology Course. University of Kentucky, Lexington, KY. April 8, 2013.

2013 **Bush M.** Resident Core Curriculum: *Neurotology and Cranial Base Surgery: The Facial Nerve: The Mother of All Cranial Nerves.* University of Kentucky, Lexington, KY. March 27, 2013.

2013 **Bush M.** Resident Core Curriculum: *Neurotology and Cranial Base Surgery: Lesions of the Lateral Skull Base.* University of Kentucky, Lexington, KY. March 20, 2013.

2013 **Bush M.** Resident Core Curriculum: *Neurotology and Cranial Base Surgery: Cochlear Implantation.* University of Kentucky, Lexington, KY. March 13, 2013.

2013 **Bush M.** Resident Core Curriculum: *Neurotology and Cranial Base Surgery: Approaches to the Skull Base.* University of Kentucky, Lexington, KY. March 6, 2013.

2013 **Bush M, Course Director.** Resident Core Curriculum: *Neurotology and Cranial Base Surgery.* University of Kentucky, Lexington, KY. March, 2013.

2013 **Bush M.** Resident Core Curriculum: *Otology: Vestibular physiology and clinical evaluation and management of dizzy patients.* University of Kentucky, Lexington, KY January 9, 2013.

2012-13 **Bush M**, *Clinical Otology: The Diagnosis and Management of Ear Disease*. 3rd year medical student lecture. University of Kentucky, Lexington, KY.

2012 **Bush M.** *Management of Hearing Loss and Facial Nerve Injury in the Trauma Patient.* Inter-Disciplinary Trauma Conference, November 27, 2012.

2012 **Bush M, Course Director.** Resident Core Curriculum: *Oral Board Preparation.* University of Kentucky, Lexington, KY

2012 **Bush M.** *Neuroradiology and Clinical Implications for the Audiologist.* University of Louisville Division of Audiology Grand Rounds, Louisville, KY. February 20, 2012.

2011 **Bush M.** *Neuroradiology of the Temporal Bone*. University of Kentucky Department of Otolaryngology. Lexington, KY. February 17, 2012.

2011-12 **Bush M**, *Clinical Otology: The Diagnosis and Management of Ear Disease*. 3rd year medical student lecture. University of Kentucky, Lexington, KY.

2011 **Bush M, Course Director.** Resident Core Curriculum: *Otolaryngologic Manifestations of Systemic Disease.* University of Kentucky, Lexington, KY

2011 **Bush M**. *Otology/Neurology Resident Core Curriculum: Facial Nerve: Anatomy and Pathology.* Resident lecture. The Ohio State University, Columbus, OH.

2011 **Bush M**. *Clinical Otology: The Diagnosis and Management of Ear Disease*. 3rd year medical student lecture. The Ohio State University, Columbus, OH.

2010 **Bush M**. *Otology/Neurology Resident Core Curriculum: Otosclerosis.* Resident lecture. The Ohio State University, Columbus, OH.

2010 **Bush M**. *Otology/Neurology Resident Core Curriculum: Surgical Approaches to the Skull Base*. Resident lecture. The Ohio State University, Columbus, OH.

2010 **Bush M**. *Clinical Otology: The Diagnosis and Management of Ear Disease*. 3rd year medical student lecture. The Ohio State University, Columbus, OH.

2009 **Bush M**. *Clinical Otology: The Diagnosis and Management of Ear Disease*. 3rd year medical student lecture. The Ohio State University, Columbus, OH.

2009 **Bush M**. *Otology/Neurology Resident Core Curriculum: Temporal Bone Trauma.* Resident lecture. The Ohio State University, Columbus, OH.

2009 **Bush M**. *Basics of Temporal Bone Anatomy and Dissection*. Annual Resident Temporal Bone Course. The Ohio State University, Columbus, OH.

REGIONAL/NATIONAL COURSES

2013 Stryker Resident Temporal Bone Surgical Dissection Course. University of Cincinnati, March 9, 2013. Co-Course Directors: Ravi Samy and **Matthew Bush.**

RESEARCH MENTORSHIP

Medical Students:

Anita Shanker 2016-present

- ***H**elping **I**nfants **G**et **HE**aring **R**esources*: The **HIGHER** Patient Navigator Trial

Whitney Powell 2016-present

- Understanding Adult Perspectives Regarding Hearing Healthcare

Tianshi ("Mike") Liu 2016-present

- Systematic review of the Effects of Cochlear Implants and adjunctive rehabilitation therapy on language perception and performance among Infants with Congenital CMV infection

Diana Bigler 2016-present

- Assessment of disruptive behavioral problems in children with hearing loss
- Systematic Review of Disruptive Behavioral Problems Among Hearing Impaired Children

Kayla Williams 2016-present

- Understanding Adult Perspectives Regarding Hearing Healthcare

Julie Johnson 2015-present

- Current Trends in Evaluation and Management of Acoustic Neuromas

Kristen Burke 2015-present

- Systematic Review of Disruptive Behavioral Problems Among Hearing Impaired Children
- Validation of Remote Cochlear Implantation Candidacy Evaluations

Taylor Shackleford 2015-present

- Systematic review of Patient Navigation for underserved and minority populations
- Promoting Early Diagnosis of Congenital Hearing Loss with Patient Navigation
- **Primary mentor on Physician Scientist Mentored Research Fellowship**

Vania Rashidi 2015-present

- Assessment of disruptive behavioral problems in children with hearing loss
- **Primary mentor on Physician Scientist Mentored Research Fellowship**

Stevie Maxwell 2015-present

- Assessment of long term outcomes for glomus jugulare patients tumors treated with gamma knife radiation

Stephen Chan 2014-2015

- Hearing health and healthcare disparities in adult patients
- **Primary mentor on Physician Scientist Mentored Research Fellowship**

Bryce Noblitt 2013-2015

- Analysis of cochlear implant rehabilitation barriers for rural pediatric cochlear implant recipients
- Physician attitudes regarding pediatric hearing loss in rural Kentucky
- Promoting Early Diagnosis of Congenital Hearing Loss with Patient Navigation
- **Primary mentor on Physician Scientist Mentored Research Fellowship**

Julia Elpers 2013-2014

- Parental attitudes and experiences regarding pediatric hearing loss in rural Kentucky
- **Primary mentor on Physician Scientist Mentored Research Fellowship**

David Alexander (MS3-4) 2012 – 2013

- Physician attitudes regarding pediatric hearing loss in rural Kentucky

Mariel Osetinsky (MS2-4) 2011 – 2013

- Investigation of delay of hearing healthcare for children with cochlear implants in Appalachia
- **Primary mentor on Physician Scientist Mentored Research Fellowship**

Kristin Bianchi (MS2-4) 2011 – 2013

- Investigation of diagnostic challenges for children with severe hearing loss in rural Kentucky
- Geospatial Scan Statistical Analysis of Patterns of Pediatric Hearing Loss in Kentucky

Ashley Loan (MS2-4) 2012-2013

- Investigation of hearing healthcare and rehabilitative services for children in Central Kentucky

William Dougherty (MS3-4) 2012-2013

- Assessment of vestibular rehabilitation practice patterns and availability of care
- A case-series review of pediatric autoimmune inner ear disease

Ashleigh Long (MS2-4) 2011-2013

- The clinical utility of magnetic spectroscopy in cerebellopontine angle tumors
- The range of subjective symptoms in patients with normal pure tone audiometry
- The Effect Operating Room Noise on Auditory Processing

Undergraduate Students:
Nicholas Laureano 2016

- Systematic Review of Disruptive Behavioral Problems Among Hearing Impaired Children

Residents:
Christopher Bingcang (PGY4-5) 2011-2012

- The utility of monothermal caloric testing in screening for vestibular dysfunction

Joshua Dixon (PGY3-5) 2011-2014

- The effect of middle ear effusion on cochlear implant function

German Fikhmann (PGY2-5) 2012 – 2015

- Preservation of low-frequency hearing in cochlear implantation

Justin Way (PGY4-5) 2012-2013

- Investigation of the effect of operating room noise on auditory processing

Deann Roberts (PGY4-5) 2012-2013

- The clinical utility and cost-effectiveness of pre-operative imaging studies in cochlear implantation

Brian Hixon (PGY3-4) 2014-Present

- Assessment of rural adult hearing healthcare disparities
- Systematic review of barriers to hearing healthcare

Caitlin Fiorillo (PGY2-3) 2014-Present

- Assessing and addressing disruptive behavioral problems in children with hearing loss

Kyle Fletcher (PGY2) 2015-Present

- Validation of Remote Cochlear Implantation Candidacy Evaluations
- Systematic review of the Effects of Cochlear Implants and adjunctive rehabilitation therapy on language perception and performance among Infants with Congenital CMV infection

Mark Ringstrom (PGY3-4) 2014-Present

- MRI spectroscopy in the evaluation of cranial base tumors

Andrew Ebelhar (PGY3-4) 2014-Present

- Preoperative Assessment of Round Window Anatomy for Cochlear Implantation with Intention of Hearing Preservation via Round Window Insertion

Mitch Dobberpuhl (PGY3) 2015-Present

- Multidisciplinary Assessment of Clinical Symptoms and Treatment of Vestibular Migraines
- Current Trends in Evaluation and Management of Acoustic Neuromas

Mike Kaufman 2016-present

- Validation of Remote Cochlear Implantation Candidacy Evaluations
- Systematic review of Patient Navigation for underserved and minority populations

Audiology Doctoral Students:
Margaret Barnett (2015-2016)

- Perspectives of Primary Care Medical Providers Regarding Adult Hearing Healthcare in the Rural Context

JOURNAL PUBLICATIONS

1. Chan S, Hixon B, Adkins M, Shinn J, **Bush M**. Rurality and Determinants of Hearing Healthcare in Adult Hearing Aid Recipients. *Laryngoscope*. 2017. (epub)
2. **Bush M**, Thompson R, Irungu C, Ayugi J. The Role of Telemedicine in Auditory Rehabilitation: A Systematic Review. *Otology & Neurotology*. 2016. 37(10): 1466-1474.
3. Barnett M, Hixon B, Okwiri N, Irungu C, Ayugi J, Thompson R, Shinn J, **Bush M**. Factors Involved in Access and Utilization of Adult Hearing Healthcare: A Systematic Review. *Laryngoscope*. 2016. Aug 22. Epub.
4. Hixon B, Chan S, Adkins M, Shinn J, **Bush M**. Timing and Impact of Hearing 5.Healthcare in Adult Cochlear Implant Recipients: A Rural-Urban Comparison. *Otology & Neurotology*. 2016. 37(9):1320-4.
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Bush M, Welling DB. *Cerebellopontine Angle Tumors*, in Head and Neck Surgery – Otolaryngology, 5th Johnson JT and Rosen CA, eds. Philadelphia: Lippincott Williams & Wilkins. 2013. ISBN: 9781609136020.

Bush M, Welling DB. *Neurofibromatosis Type 2*, in The Five Minute Neurology Consult, 2nd ed. Lynn DJ, Newton HB, Rae-Grant AD, eds. Philadelphia: Lippincott Williams & Wilkins. 2012. ISBN: 9781451100129

Bush M. *Diseases of the external and middle ear,* in Disorders of the Auditory System, Musiek F, Baran J, Shinn J, Jones R, eds. San Diego: Plural Pub. 2012.

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CURRENT RESEARCH FUNDING

2/2016 – 2/2018 **Advanced Bionics Sponsored Clinical Trial**
Title: Implantation of the HiRes90K™ Advantage Cochlear Implant with HiFocus™ Mid-Scala and Development of a Combined Electric and Acoustic Stimulation Technology in Adults with Partial Deafness ($97,939)
Role: PI

3/2015 – 3/2018 **NIH/NIDCD Career Development Award (1 K23 DC014074-01)**
"Promoting Early Diagnosis of Congenital Hearing Loss through Patient Navigation" ($685,149)
Role: PI

7/2011 – 7/2017 **University of Kentucky College of Medicine Start-up Funds ($225,000)**

COMPLETED RESEARCH FUNDING

2/2015 – 8/2016 **University of Kentucky CCTS Junior Investigator Pilot Award (UL1TR000117)**
"Assessing and Addressing Disruptive Behavioral Problems in Children with Hearing Loss" ($25,000)
Role: Co-PI

8/2014 – 7/2016 **AAO-HNSF: Triological Society Career Development Award**
"Promoting Early Diagnosis of Congenital Hearing Loss through Patient Navigation" ($40,000)

Role: PI

11/2012 – 11/2015 **NIH/NIDCD (1U24-DC012079-01) Resources for Mentorship of Clinician Scientists in Hearing and Balance Disorders**
Mentored research grant to support career development of early clinician scientists

7/2012 – 2/2015 **NIH KL2 Award (8 KL2 TR000116-02)**
"Bridging the Gaps: Assessment of Pediatric Hearing Loss in Appalachia"

10/2012 – 10/2014 **NIH Health Disparities Loan Repayment Award**
"Pediatric Hearing Loss in Rural Appalachia: Assessment of Successful Identification and Timely Intervention."

7/2009 – 12/2010 **American Hearing Research Foundation Wiley H. Harrison Grant AAO-HNS CORE grant, Principal Investigator**
"*In vitro* and *in vivo* response to HDAC inhibitors by vestibular schwannomas" ($25,000).

INTERNATIONAL HUMANITARIAN EFFORTS

Development of the *Sikiza Society*, an international academic collaboration between the University of Kentucky and the University of Nairobi: http://www.entnet.org/content/humanitarian-efforts-map

- Call of Duty: Personal, Professional Merits of Humanitarian Work. ENTtoday. June 5, 2016. http://www.enttoday.org/article/call-duty-personal-professional-merits-humanitarian-work/?elq_mid=10215&elq_cid=3437612

CURRENT RESEARCH INTERESTS

- Rural Hearing Health Disparities
- Disruptive behavioral problems in Children with Hearing Loss
- Hearing Preservation in Cochlear Implantation
- MRI spectroscopy in cranial base tumors

CURRENT CLINICAL INTERESTS

- Adult and Pediatric Hearing Loss
- Cochlear implantation
- Tumors of the lateral cranial base and stereotactic radiosurgery

MEDIA RELEASES

"Rural children face delays in diagnosis of congenital hearing loss." Reuters Health News. November 21, 2013. http://www.thedoctorschannel.com/view/rural-children-face-delays-in-diagnosis-of-congenital-hearing-loss/

"Prescribing Patterns for Otitis Media in Children." Eastern Kentucky University Morning Edition, Radio Interview. February 26, 2013.

"Too Much Background Noise in the Operating Room Can Impair Communication Among Surgical Team Members." American College of Surgeons Press Release. May 10, 2013. http://www.eurekalert.org/pub_releases/2013-05/acos-bni051013.php

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"Ear, nose, and throat doctor at UK aims to reduce state's high rate of hearing loss among children." Lane Report, April 15, 2014
http://www.lanereport.com/30997/2014/04/ear-nose-and-throat-doctor-at-uk-aims-to-reduce-states-high-rate-of-hearing-loss-among-children/?utm_source=Faster%20Lane%20Newsletter&utm_medium=Email&utm_campaign=april-15-2014

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UK physician's patient navigator program ensures follow-up hearing tests for infants. UK OnCall Magazine. Issue 6, November 2015.

UK's Collaborative Research Environment. http://research.med.uky.edu/news/uk's-collaborative-research-environment

Rural Access to Care and Telemedicine
https://www.youtube.com/watch?v=fDQpJtnl96g&index=14&list=PLT_--N4wea5DIAN-7ePL477QMS_AYQ6Wd

Call of Duty: Personal, Professional Merits of Humanitarian Work. ENTtoday. June 5, 2016. http://www.enttoday.org/article/call-duty-personal-professional-merits-humanitarian-work/?elq_mid=10215&elq_cid=3437612

UK Surgeon-Researcher Works to Extend Cochlear Implant Program to Appalachia. UKNow University of Kentucky News. July 14, 2016. http://uknow.uky.edu/content/uk-surgeon-researcher-works-extend-cochlear-implant-program-appalachia

Giving the Gift of Hearing, Here and Around the World. http://ukhealthcare.net/blog/making-the-rounds-with-dr-matthew-bush/

Songs for Sound event benefits UK Cochlear Implant Program. http://ukhealthcare.net/blog/songs-for-sound-event-cochlear-implant/