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Tutorial

Implementation Science: Increasing the Public Health Impact of Audiology Research

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ABSTRACT

Purpose: Implementation science aims to facilitate the use of evidence-based programs, practices, and policies in routine care settings. In audiology, as in other health disciplines, there is a persistent research-to-practice gap. Improving the adoption, reach, implementation, and sustainment of effective interventions in audiology would increase their public health impact, ensuring that all individuals needing hearing health care services could benefit from innovations and evidence-based best practices. This tutorial provides an introductory overview of implementation science relevant to the field of audiology, including Internet-based practices and interventions.
Method: Major concepts and themes of implementation science are presented, including implementation outcomes, implementation science frameworks, implementation strategies, current topics in implementation science, and study design considerations. Recent publications in audiology are highlighted to illustrate implementation science concepts and themes. The relevance of each topic to the use of evidence-based programs, practices, and policies in audiology is highlighted with reference to recent research in the field.
Conclusions: Challenges in the widespread delivery of evidence-based audiological practices and interventions limit their public health impact. The application of implementation science principles and methods in audiology research, as demonstrated in other areas of health research, can increase our focus on ensuring that effective practices are widely available, accessible, equitable, and sustainable to improve the lives of those who need them.

The potential contributions of audiology to quality of life are wide-ranging, and exciting advances and innovations in audiological care continue to multiply. Efficacy, effectiveness, and health services research in audiology have led to important developments in screening, assessment, telemedicine, hearing aid technologies, and more. Substantial time and resources are required for such discoveries and progress, and the ultimate goal of these investments is to have widespread, meaningful impact on the quality of life of consumers of hearing health care.

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As in other areas of health care, however, the time and resources dedicated to developing advances in audiology often do not translate into meaningful public health impact (Bernstein et al., 2018; Boisvert et al., 2017), even when research evidence of efficacy and effectiveness is clear. To have public health impact, an evidence-based program, practice, or policy must be used at scale in routine care to effect desired change at a broad population level—rather than influencing only small pockets of recipients in isolated settings. Studies in health care, broadly defined, estimate that the time required for translation of research evidence into usual practice is 17 years (Balas & Boren, 2000; Grant et al., 2003; Morris et al., 2011)—and that only half of such evidence is ever used in routine care in clinical settings. This is an unacceptable delay, particularly when resources, time, and expertise have been poured into the development and testing of practices and interventions that could benefit so many. Reasons for inadequate translation of evidence to practice in audiology are multifaceted and

complex (Moodie et al., 2011) but can be characterized as barriers to implementation that exist at multiple ecologic levels: the patient level, the provider level, the organizational level, and the broader outside context, including barriers in terms of policy and payment.

This tutorial provides an introductory overview of the field of implementation science, with an emphasis on the relevance of implementation science principles, frameworks, and methods to audiology. Throughout, examples from the audiology literature are highlighted to illustrate how implementation science can be used to strengthen the impact of evidence-based programs, practices, and policies in audiology and related fields (see Table 1 for a list).

Implementation Science and Audiology

The interdisciplinary field of implementation science developed in response to the need to speed the translation of evidence into practice (Westfall et al., 2007). Implementation science is defined as "the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practice into routine practice and, hence, to improve the quality and effectiveness of health services" (Eccles & Mittman, 2006). Everett Rogers' (1962) diffusion of innovations theory, describing the process and determinants of the spread of innovations in health care, industry, and agriculture, marked the early origins of the field and serves as the basis for several current and widely used implementation science frameworks. The integration of expertise in behavioral science, medicine, public health, global health, health economics, health policy, health communication, organizational psychology, systems science, and other fields to understand and increase the adoption, implementation, and sustained use of research evidence in clinical care is a defining feature of implementation science.

Table 1. Cited articles illustrating implementation science concepts in audiology research.

Implementation science concept	Article citation(s)
Implementation outcomes	
Acceptability	Saunders, G. H., & Roughley, A. (2021). Audiology in the time of COVID-19: Practices and opinions of audiologists in the U.K. *International Journal of Audiology, 60*(4), 255–262.
Adoption	Glista, D., O'Hagan, R., Moodie, S., & Scollie, S. (2020). An examination of clinical uptake factors for remote hearing aid support: A concept mapping study with audiologists. *International Journal of Audiology, 60*, S13–S22.
Costs	Ramkumar, V., John, K. R., Selvakumar, K., Vanaja, C. S., Nagarajan, R., & Hall, J. W. (2018). Cost and outcome of a community-based paediatric hearing screening programme in rural India with application of tele-audiology for follow-up diagnostic hearing assessment. *International Journal of Audiology, 57*(6), 407–414.
Feasibility	Amlani, A. M., Smaldino, J., Hayes, D., Taylor, B., & Gessling, E. (2019). Feasibility of using a smartphone-based hearing aid application to improve attitudes toward amplification and hearing impairment. *American Journal of Audiology, 28*(1), 125–136. Ferguson, M. A., Maidment, D. W., Gomez, R., Coulson, N., & Wharrad, H. (2020). The feasibility of an m-health educational programme (m2Hear) to improve outcomes in first-time hearing aid users. *International Journal of Audiology, 60*, S30–S41.
Sustainability	Nalley, C. (2020). Navigating patient care, teleaudiology during the COVID-19 pandemic. *The Hearing Journal, 73*(7), 24–27.
Frameworks and models	Tuepker, A., Elnitsky, C., Newell, S., Zaugg, T., & Henry, J. A. (2018). A qualitative study of implementation and adaptations to Progressive Tinnitus Management (PTM) delivery. *PLOS ONE, 13*(5), e0196105.
Implementation strategies	Ekberg, K., Timmer, B., Schuetz, S., & Hickson, L. (2021). Use of the behaviour change wheel to design an intervention to improve the implementation of family-centred care in adult audiology services. *International Journal of Audiology, 60*, 20–29.
Context	Konrad-Martin, D., Poling, G. L., Garinis, A. C., Ortiz, C. E., Hopper, J., O'Connell Bennett, K., & Dille, M. F. (2018). Applying U.S. national guidelines for ototoxicity monitoring in adult patients: Perspectives on patient populations, service gaps, barriers and solutions. *International Journal of Audiology, 57*(Suppl. 4), S3–S18.
Adaptations	Tuepker, A., Elnitsky, C., Newell, S., Zaugg, T., & Henry, J. A. (2018). A qualitative study of implementation and adaptations to Progressive Tinnitus Management (PTM) delivery. *PLOS ONE*, 13(5), e0196105. https://doi.org/10.1371/journal.pone.0196105
Stakeholder engagement	Marrone, N., Ingram, M., Somoza, M., Jacob, D. S., Sanchez, A., Adamovich, S., & Harris, F. P. (2017). Interventional audiology to address hearing health care disparities: *Oyendo Bien* pilot study. *Seminars in Hearing, 38*(2), 198–211.
Health equity	Mulwafu, W., Kuper, H., Viste, A., & Goplen, F. K. (2017). Feasibility and acceptability of training community health workers in ear and hearing care in Malawi: A cluster randomised controlled trial. *BMJ Open, 7*(10), e016457.
Designing for dissemination	Sanchez, V. A., Arnold, M. L., Reed, N. S., Oree, P. H., Matthews, C. R., Eddins, A. C., Lin, F. R., & Chisolm, T. H. (2020). The Hearing Intervention for the Aging and Cognitive Health Evaluation in Elders randomized control trial: Manualization and feasibility study. *Ear and Hearing, 41*(5), 1333–1348.

For implementation science to contribute to meaningful advances in the delivery of evidence-based care within a given field, it is essential that researchers, providers, and leaders in that field prioritize the goal of moving evidence into practice. Recognition of the research-to-practice gap in audiology is not new. A decade ago, the case for overcoming barriers to the use of evidence-based practices, programs, and policies in audiology was made by Moodie et al. (2011), with an extensive discussion of the rationale for systematic efforts toward translating research into practice. Since then, several organizations and researchers in audiology and related disciplines have recognized and contributed vital efforts to increase the use of evidence-based practices to benefit consumers of hearing health care (American Speech-Language-Hearing Association [ASHA], n.d.-b; Bernstein et al., 2018; Douglas et al., 2015; Moodie et al., 2011; Olswang & Prelock, 2015; Palmer & American Academy of Audiology [AAA], n.d.). This tutorial is intended to reinforce this important progress by introducing some of the concepts and principles of implementation science to a broad audience in audiology, highlighting the need for more implementation science research in this field to close the research-to-practice gap. Increased interest in and conduct of implementation research could significantly strengthen the public health impact of evidence-based audiology practices, policies, and programs.

Implementation Outcomes Versus Traditional Audiology Outcomes

Implementation science is by nature broad and concerned with many questions about the uptake, delivery, and reach of evidence-based programs, practices, and policies. To answer these questions, implementation science focuses on a different set of outcomes than traditional health research and health services research (Proctor et al., 2011). Traditional health research is concerned with patient-level symptoms, satisfaction, function, and quality of life, whereas health services research often addresses the safety, efficiency, equity, patient-centeredness, and timeliness of services (Institute of Medicine, 2001; Proctor et al., 2011). In audiology research, outcomes typically include objective and subjective measures of auditory function, including audiological measures (e.g., thresholds and speech recognition scores), patient-reported outcomes (e.g., problem situations and perceived benefit), and correlates of these indicators of patients' hearing. In contrast, implementation science outcomes include those related to the uptake, use, and sustainment of evidence-based practices. Implementation outcomes such as reach, adoption, acceptability, appropriateness, feasibility, penetration, costs, fidelity, and maintenance reveal important facets of whether, how, and why an evidence-based program, practice, or policy is used and sustained in a clinical or community setting (Glasgow et al., 2019; Proctor et al., 2011). See Table 2 for definitions of implementation outcomes and the types of questions that implementation research in audiology could answer.

Examples in Audiology

Though not necessarily framed as implementation science research, numerous studies in audiology consider implementation science outcomes. Examples of studies addressing the adoption (e.g., Glista et al., 2020), acceptability (e.g., Saunders & Roughley, 2021), feasibility (e.g., Amlani et al., 2019; Ferguson et al., 2020), and costs (e.g., Hatton et al., 2019; Manus et al., 2021) of specific programs and practices are readily available and illustrate how implementation science can increase understanding of whether and why an evidence-based program, practice, or policy may be implemented. Other implementation outcomes—particularly reach and maintenance—are rarely addressed, even in audiology research addressing health services and public health perspectives. Increased attention to (a) who benefits from hearing health care interventions and who does not and (b) how effective practices and programs are sustained over time would offer higher level perspectives on the impact of audiology care beyond that demonstrated in clinical research applications.

Frameworks and Models in Implementation Science

Given the broad range of questions implementation science seeks to answer; the diversity in fields facing implementation challenges; and the complex, multilevel factors involved in implementation processes, the use of organizing frameworks and models is vital for selecting implementation outcomes and planning, conducting, and evaluating implementation research (Damschroder, 2020; Moullin et al., 2020). There is no shortage of relevant frameworks and models in implementation science; in fact, there are so many that selecting among them can be a daunting task without guidance (e.g., Dissemination & Implementation Models in Health Research & Practice, n.d.). What these frameworks and models have in common is that each seeks to systematically describe and organize sets of implementation outcomes, factors influencing implementation, and/or processes important in implementation, often with attention to how these outcomes, factors, and processes interact (Nilsen, 2015). Examples of frequently used frameworks include the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework (Glasgow et al., 2019) and the Practical, Robust Implementation and Sustainability Model (PRISM; Feldstein & Glasgow, 2008), which are connected; the Consolidated Framework for Implementation Research (CFIR; Damschroder et al., 2009); the Exploration, Preparation, Implementation, Sustainment (EPIS)

Table 2. Two implementation science frameworks: outcomes and questions for audiology.

Framework	Outcome	Definition	Sample questions for audiology
Proctor's Taxonomy of Implementation Outcomes (Proctor et al., 2011)			
	Acceptability	Satisfaction with an intervention/program	Is this audiology intervention acceptable to patients, providers, and administrators?
	Adoption	Uptake/initial implementation by a provider/clinician or organization	Has this audiology intervention been adopted in a particular setting? What are the barriers to its use?
	Appropriateness	Perceived fit, relevance, compatibility, and suitability of an intervention/program	What do key stakeholders think about the appropriateness of this audiology practice in their setting?
	Feasibility	Actual fit, suitability, and practicability of an intervention/program	Can this audiology program be implemented in a particular setting?
	Fidelity	The degree to which an intervention/program is delivered as intended	How well is this evidence-based intervention delivered?
	Cost	Costs of implementing an intervention/program	What are the costs associated with implementing this audiology intervention?
	Penetration	Level of spread or institutionalization of an intervention/program within an organization	To what extent has this audiology intervention become part of this setting's usual practice?
	Sustainability	The degree to which an intervention/program can be continued over time	What are the barriers and facilitators to the continued use of this audiology intervention?
Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM; Glasgow et al., 2019)			
	Reach	Proportion and representativeness of those who could benefit who actually receive an intervention/program	Of those who could benefit from this audiology intervention, what proportion receive it? How representative are they of all of those who could benefit? How can access be increased and equitable?
	Effectiveness	The impact of an intervention on important outcomes, including potential negative effects, quality of life, and economic outcomes	What are the patient-level effects of this audiology intervention? What unintended effects result from it?
	Adoption	(a) Proportion and representativeness of organizations that adopt an intervention/program (b) Proportion and representativeness of providers/clinicians who adopt an intervention/program	Of those organizations and providers who could adopt this audiology intervention, how many do? How representative are they of all who could use it?
	Implementation	Fidelity, adaptations, and costs of delivering an intervention/program	How consistently is this audiology intervention delivered? What adaptations were made (or could be made) to improve its fit in this setting? What are the costs of implementing it from multiple perspectives?
	Maintenance	(a) An organization's continued provision of an intervention/program over time (b) Continued effects of the intervention/program on those who receive it over time	How can we ensure that this audiology intervention continues to be delivered over time? Do the patient-level effects of the intervention last? Are the continued delivery and effects of the intervention equitable?

framework (Aarons et al., 2011); and the Promoting Action on Research Implementation in Health Services (PARIHS) framework (Harvey & Kitson, 2016), among many others.

The choice of an implementation science framework or model depends on multiple considerations, such as the question(s) of interest, the phase of investigation, the scope and resources of a project, and the ecological levels that must be included (e.g., patients, providers, administrators, organizations, and/or the broader outside context; Moullin et al., 2020). Some frameworks (e.g., RE-AIM and Proctor's Taxonomy of Implementation Outcomes) focus primarily on implementation outcomes. Others (e.g., CFIR and PRISM) specify multilevel contextual factors that may serve as barriers of or facilitators to implementation of an evidence-based program, practice, or policy. Use of multiple frameworks or models is sometimes necessary throughout phases of research or within a single project to adequately address the specific goals.

Examples in Audiology

To date, few studies in audiology have incorporated implementation science frameworks. A noteworthy exception is work conducted by Tuepker et al. (2018) in the U.S. Veterans Health Administration (VHA) system. This qualitative study explored the perceptions and experiences of audiologists, psychologists, and service chiefs for audiology and mental health regarding Progressive Tinnitus Management (PTM; Henry et al., 2010), an evidence-based stepped-care approach to tinnitus clinical services (Henry et al., 2017). The authors sought to identify

barriers and facilitators to implementation of PTM in audiology and mental health clinics and to understand adaptations to PTM that had been made during implementation. Two implementation science frameworks guided the study's data collection and qualitative analyses, CFIR (Damschroder et al., 2009) and PARIHS (Harvey & Kitson, 2016), facilitating a systematic assessment of the challenges and successes of PTM implementation to inform future scale-up of the practice within the VHA system.

Implementation Strategies

Once factors impeding or facilitating implementation of evidence-based practices are identified, implementation strategies can be selected to reduce or enhance those factors. Implementation strategies are the methods or techniques intended to effect change and improve one or more implementation outcomes for a given evidence-based program, practice, or policy (Proctor et al., 2013). For example, implementation strategies have been developed to improve provider knowledge; reinforce desired practices; disincentivize ineffective practices; restructure payment practices and policies; adapt evidence-based practices to specific contexts; develop opinion leaders and influencers; increase patient buy-in; and more (Powell et al., 2015). Just as context and stakeholder engagement encompass multiple levels, implementation strategies can target barriers and facilitators to implementation at multiple levels. The Expert Recommendations for Implementing Change project (Powell et al., 2015) sought to review and categorize the full range of implementation strategies reported in the literature across fields, resulting in nine overarching groups: implementation strategies that use iterative evaluation and feedback, provide interactive assistance, adapt and tailor to context, develop stakeholder interrelationships, train and educate stakeholders, support providers, engage consumers, utilize financial strategies, and change infrastructure. Within and across these groups, implementation strategies can target each level of the socioecological framework: patients, patients' families, providers and staff, organizations and leadership, communities, and policy and financial structures.

Ongoing work in the implementation science field seeks to inform and guide the matching of implementation strategies to specific barriers, facilitators, contexts, and goals (Waltz et al., 2019). Systematic processes (e.g., implementation mapping [Fernandez et al., 2019] and others) have been developed to identify multilevel barriers and facilitators to implementation; engage stakeholders at each level; and select relevant multilevel implementation strategies to increase implementation of evidence-based programs, practices, and policies (Michie et al., 2011; Powell et al., 2017; Waltz et al., 2019). More recent work has addressed not only the matching of implementation strategies (and de-implementation strategies) to specific barriers, facilitators, context, and goals (e.g., Perry et al., 2019) but also testing the effects of these strategies (Pantoja et al., 2017; Rietbergen et al., 2020), including the mechanisms through which they may work (Lewis et al., 2020; Williams, 2016).

Examples in Audiology

Illustrating audiology research on implementation strategies, Ekberg et al. (2021) describe a systematic process of selecting implementation strategies to improve the delivery of the family-centered care (FCC) model in an adult audiology practice setting. Research supports the positive effects of the FCC (Hickson et al., 2014; Singh et al., 2015), but implementation of this model is limited in practice (Ekberg et al., 2014; Grenness et al., 2015). Using the behavior change wheel (Michie et al., 2011), a systematic approach to designing behavior change interventions targeting health professionals, Ekberg et al. assessed and prioritized potential provider-level behavioral changes needed to improve implementation of the FCC. Strategies that addressed identified barriers and were supported by practice administrators included provider education, training, and environmental restructuring. These implementation strategies were operationalized in two face-to-face interactive workshops including all clinic staff, the development of scripted and customizable cue cards to cue targeted behaviors, follow-up individual coaching with all involved staff, and incentivizing participation in the implementation strategies using a voucher system.

Current Topics in Implementation Science

With the overarching goal of increasing the adoption and sustained use of evidence-based programs, practices, and policies in routine practice, the broad scope of implementation science includes recent emphasis on several specific topics in the field. The themes that follow are not all-inclusive but provide a broad sampling of current implementation science topics that are highly relevant to implementation science in audiology.

Context

The context in which implementation happens (or does not happen) is a fundamental consideration in implementation science. Context—sometimes defined as "everything but the intervention"—is not merely the setting or site in which a program, practice, or policy may be implemented. Rather, context is multilevel, with multiple domains that interact with each other and change over time (May et al., 2016). One relatively simple way to conceptualize context is by applying ecological models (Richard et al., 2011), depicting multiple nested levels of influence on health and health behaviors, for example,

individual level, interpersonal level, organizational and institutional level, community level, and policy/systems level. Multilevel contextual factors are not ignorable in implementation science and are, in fact, a primary focus. Planning, implementing, and sustaining evidence-based practices all require consideration of the dynamic influences of factors such as patient characteristics, provider beliefs, organizational culture, leadership engagement, community norms, and health care policies, just to name a few. Implementation science frameworks incorporating contextual factors (e.g., CFIR, EPIS, and PRISM) are particularly useful in identifying, prioritizing, and assessing multilevel determinants of implementation (Aarons et al., 2011; Damschroder et al., 2009; Feldstein & Glasgow, 2008; Nilsen & Bernhardsson, 2019).

Examples in audiology. Konrad-Martin et al. (2018) described contextual factors serving as barriers and facilitators to the implementation of effective ototoxicity monitoring programs in the United States. Despite national audiology guidelines promoting such programs (AAA, 2009; ASHA, 1994), monitoring ototoxicity during drug treatment is inconsistent. Although they did not formally apply an implementation science contextual framework, the authors explored the implementation of ototoxicity monitoring programs in five distinct institutions using semistructured interviews and questionnaires administered to key informants in each setting. Variation in implementation of monitoring programs was attributed to several multilevel contextual factors, including referral processes, logistical considerations (e.g., scheduling, staffing, equipment, and location), patient costs, characteristics of the health system and setting, characteristics of the patient population, and perceptions of the quality of evidence for recommendations. Based on this exploratory research, Konrad-Martin et al. suggested targets for strategies aimed at reducing barriers to the implementation of existing U.S. national guidelines for ototoxicity monitoring in adult patients.

Adaptations

Closely related to context is the issue of adaptation. When an evidence-based program or practice is implemented outside the setting in which it was developed and tested, adaptations are typically made—either reactively, in response to implementation challenges encountered along the way, or proactively, to increase the "fit" of the practice or program in its new setting (Stirman et al., 2019). Examples of changes in context that may necessitate adaptations to a program or practice include differences between the original and new settings in patient populations, access to resources, staffing, leadership engagement, and policies. Although adaptations to evidence-based programs or practices in traditional health research have been either underreported or critiqued as weakening fidelity (Chambers & Norton, 2016), in implementation science, modifications are usually accepted as necessary to support implementation and sustainment (Chambers et al., 2013)—and important to understand. Multiple systematic approaches to proactive, planned adaptation have been described (Escoffery et al., 2019), and comprehensive methods for tracking and classifying adaptations to both interventions and implementation strategies are available (Miller et al., 2021; Stirman et al., 2019). Understanding the effects of adaptations and their role in achieving positive implementation outcomes is a focal area in implementation science.

Examples in audiology. Tuepker et al.'s (2018) qualitative study of barriers and facilitators to implementation of PTM in the VHA also exemplifies the focus on adaptations in implementation science. One goal of this project was to identify and understand adaptations to the original intervention that had been made during implementation. Through their qualitative interviews, the authors identified numerous adaptations to PTM, the effects of which were not known. Identified adaptations included having an audiologist deliver PTM with no mental health provider collaboration, delivering tinnitus management education in an individual rather than group modality, offering education remotely rather than in person, changing the number and length of education sessions, and changing the therapeutic approach used by the mental health provider from cognitive behavioral therapy (CBT; Hofmann et al., 2012) to acceptance and commitment therapy (ACT; Hayes et al., 2006), among others. The rationale for adaptations was generally to improve the fit and feasibility of PTM for specific clinics and providers. However, the authors noted that, until their study, no systematic efforts had been made to track or understand adaptations and that it was unclear whether any of the adaptations may have changed the "core components" of PTM (e.g., eliminating the group sessions, which foster social support; changing the therapeutic modality from CBT, supported in the literature as an effective intervention for tinnitus, to ACT). This study highlights implementation science's focus on adaptations of evidence-based practices, specifically in considering how they may improve or compromise intervention implementation and effectiveness.

Stakeholder Engagement

The importance of engaging stakeholders at multiple levels and in multiple sectors cannot be overemphasized in implementation science. Drawing from decades of work in participatory research, the engagement of stakeholders in planning, implementing, and evaluating implementation of evidence-based programs, practices, and policies is essential (Forsythe et al., 2016). Stakeholders are "individuals, organizations or communities that have a direct interest in the process and outcomes of a project, research or policy endeavor" (Deverka et al., 2012), and engagement of stakeholders takes many forms (Goodman

& Thompson, 2017)—these include, but are not limited to, community–academic research partnerships in developing and conducting implementation projects, priority setting, facilitating engagement of populations and settings, defining outcomes of interest, sharing perspectives and insights to guide and inform implementation efforts, and disseminating findings back to relevant communities (including target populations, organizations, and policy-makers). The forms that such engagement can take include formal partnerships (Drahota et al., 2016), inclusion in advisory boards (Oldfield et al., 2019), involvement in user-centered design processes (Dopp et al., 2020), participation in focus groups or key informant interviews (Concannon et al., 2014), contributions to consensus methods (McMillan et al., 2016), and others (Goodman & Thompson, 2017). Stakeholders are ideally identified and engaged based on their vested interests in a specific topic (e.g., expanding Internet-based audiology services to a broad population). The multilevel context within which an implementation effort exists offers guidance regarding whom these stakeholders may be (Norris et al., 2017): patients, family members, clinicians, staff, administrators, representatives of payers, and policy-makers, for example.

With such diversity in the forms and types of stakeholder engagement used in implementation science research, as well as variability in who is identified as a stakeholder and to what degree they are engaged, an important developing area in implementation science is understanding of the effects of stakeholder engagement on implementation outcomes and public health impact (Goodman & Thompson, 2017). Recent work has highlighted major design principles for stakeholder engagement in implementation research, including organizational facilitation of stakeholder engagement; the importance of shared commitment among all partners to stakeholder engagement; and intentional efforts to ensure ongoing, meaningful, and systematic prioritization and incorporation of stakeholder input (Boaz et al., 2018). With evidence that multilevel stakeholders are still inadequately integrated into many implementation efforts, this topic is of key interest in the field (Knoepke et al., 2019).

Examples in audiology. The benefits of stakeholder engagement in audiology research are well described by Marrone et al. (2017). This team aimed to increase community engagement on hearing and to develop *Oyendo Bien* (hearing wellness), a hearing health education outreach program for Hispanic/Latino older adults in a rural U.S.–Mexico border region of Arizona (Ingram et al., 2016). Academic researchers in audiology and public health partnered with a federally qualified health center to design and conduct a community needs assessment, exploring the needs, resources, and concerns in the community related to hearing loss, as well as to identify community strengths and barriers related to accessing care. Collaboration between the researchers and community partners led to development and pilot testing of *Oyendo Bien*, an interventional audiology program delivered by community health workers. The authors note that their intentional stakeholder engagement methods helped align the intervention to the perspectives and needs of the community.

Health Equity

Inequities in health care and health outcomes are well documented and undeniable across the globe. Researchers have assessed and documented health disparities for decades (Braveman, 2006), and health care disparities researchers have increased understanding of the etiology and maintenance of inequities in the delivery of health care. In light of recent events and movements underscoring the persistent and destructive consequences of social forces (e.g., racism) that marginalize populations and communities, both domestically and worldwide, researchers in implementation science have elevated health equity as a prominent focal point in the field (Brownson et al., 2021). Health equity as a goal can inform all topics, phases, and methods of implementation science research (Baumann & Cabassa, 2020), and the development and integration of implementation science frameworks incorporating the principles, determinants, and outcomes of health equity are progressing (Shelton et al., 2020; Woodward et al., 2019, 2021). Accordingly, growth in the number of publications and projects addressing the intersection of health equity and implementation science has been exponential in recent years.

Social determinants of health (Braveman & Gottlieb, 2014)—including the effects of structural racism and massive economic inequalities—are "upstream" factors that influence all aspects of health, including hearing loss (Reavis et al., 2016), but have not traditionally been the focus of health interventions. As implementation science seeks to increase the widespread adoption and sustained use of evidence-based programs, practices, and policies, care is needed to ensure that existing inequities are not inadvertently exacerbated and that those benefiting from improved implementation are representative of the full diversity of all who could—and should—benefit (Baumann & Cabassa, 2020; Brownson et al., 2021; Shelton et al., 2020, 2021). Similarly, from an organizational and service delivery perspective, interventions and implementation strategies must be feasible, acceptable, and sustainable in communities and settings with few resources and many barriers (Maaløe et al., 2021). Designing interventions and implementation strategies with true stakeholder engagement and valuing of community needs, preferences, and capacity building is required to progress toward the goal of health equity.

Examples in audiology. Mulwafu et al.'s (2017) study of the feasibility and acceptability of an intervention tasking community health workers with identifying and referring community members to hearing health care services illustrates the importance and challenges of

implementation research focused on health equity. The setting for this project was Malawi, where access to hearing health care is extremely limited, including access to basic primary-level ear and hearing care for simple conditions. Community health workers were trained using the basic and intermediate manuals of the World Health Organization (WHO) Primary Ear and Hearing Care Training Resources (WHO, 2006) and then given 1 month to identify community members with possible ear and hearing disorders. Those identified were referred to community screening events held at heath centers. The 29 trained community health workers identified > 1,700 individuals with suspected hearing loss, ranging in age from 2 months to 90 years; of these, approximately half attended a screening event, and half of these were subsequently diagnosed with hearing impairment. Social, cultural, and community-level factors were identified that either facilitated or impeded the community health workers' efforts, highlighting the importance of recognizing the impact of social determinants of health. Acceptability of the intervention was high among community health workers and varied among communities, and the high number of individuals identified through the project suggested that similar approaches could be valuable in reducing the burden of ear and hearing disorders in other low- and middle-income countries.

Designing for Dissemination, Implementation, and Sustainment

The goal of designing for dissemination (D4D)—expanded to designing for implementation and sustainment—moves the focus on implementation earlier in the intervention development process (Chambers, 2020; Kwan et al., 2022). Although implementation strategies are generally used to increase the implementation and sustainment of evidence-based programs, practices, and policies in routine care, many practices and innovations are developed and tested with no consideration of whether they could ever be implemented outside research settings (Brownson et al., 2013). The traditional intervention research focus on internal validity and efficacy means that newly developed interventions are often highly regimented; depend on strict fidelity; are delivered in settings with unusual levels of training, resources, and staff; and are tested with participants who meet very specific inclusion and exclusion criteria. These characteristics of intervention development are often not compatible with the contexts in which they would need to be used to benefit broadly representative populations of patients. Additionally, many evidence-based programs or practices are so resource-intensive or complex that they are not viable options for settings outside of academic medicine.

The implementation science principle of D4D aims to prevent such incompatibility by keeping implementation, sustainability, and dissemination in mind from the earliest stages of intervention development (Kwan et al., 2022). Incorporating knowledge about where, by whom, and for whom a practice or program would be implemented may avert design decisions that later pose insurmountable challenges to adoption and use in routine care settings and contexts. Involving diverse and multilevel stakeholders early in the process to identify barriers and facilitators to implementation and sustainment can inform intervention development and testing, as well as contribute to future dissemination and sustainment planning.

Examples in audiology. An example of the D4D principle in practice is Sanchez et al.'s (2020) development of the Aging and Cognitive Health Evaluation in Elders (ACHIEVE)–Hearing Intervention, a manualized intervention protocol providing a "patient-centered, yet standardized, step-by-step process for comprehensive audiological assessment, goal setting, and treatment through the use of hearing aids, other hearing assistive technologies, counseling, and education aimed at supporting self-management of hearing loss" (p. 1333). Prior to testing the efficacy of the ACHIEVE–Hearing Intervention on rates of cognitive decline in older adults, its developers sought to formally assess the feasibility and acceptability of the intervention among members of the target population, their communication partners, and the audiologist delivering the intervention in a feasibility trial. They describe an iterative process of intervention development and refinement based in part upon considerations of future implementation and dissemination, illustrating the value of D4D in intervention design.

Costs of Implementation

The costs associated with evidence-based programs, practices, and policies are rarely assessed in traditional intervention research but are important determinants of their ultimate adoption, implementation, and sustainment (Cidav et al., 2020; Dopp et al., 2019; Gold et al., 2022). The fields of health services research and health economics bring expertise in understanding costs from multiple perspectives to implementation science. Collecting and analyzing costs data offer insights on the resources needed for implementation of an evidence-based program or practice, including start-up or initiation costs, maintenance costs, site-specific costs, and central or higher level costs (Hinde et al., 2020); research-related costs are typically excluded from cost analyses. Implementation costs have been underemphasized in implementation science until relatively recently, but multiple sets of recommendations for incorporating costs data into implementation research are now available, emphasizing pragmatic approaches useful at all stages of implementation (Cidav et al., 2020; Dopp et al., 2019; Gold et al., 2022).

Examples in audiology. A compelling example of the assessment of costs in audiology research was recently published by Ramkumar et al. (2018). A community-based

pediatric hearing screening program was implemented in the state of Tamil Nadu, India, using a two-stage screening protocol conducted by trained village health workers. Children in need of further evaluation were referred to an audiologist for diagnostic auditory brainstem response (ABR) assessment, which over the course of the study shifted from delivery in a mobile televan using satellite connectivity to remote delivery via broadband Internet access. This study addresses multiple themes in implementation science, including context, adaptations, and health equity—but highlighted here is its focus on cost assessment and analyses. Using capital cost estimates (i.e., equipment and training), recurrent direct costs (i.e., medical supplies, personnel, repair and maintenance, and travel), and patient-borne costs (i.e., wages lost and travel), results revealed lower costs for remote broadband Internet-based ABR compared to ABR completed in mobile televans, offering vital information to complement more traditional outcome measures (number of children screened, followed up, and confirmed with hearing loss). Costs data such as these can provide vital information informing decisions about implementation, scale-up, and sustainment of evidence-based programs, practices, and policies.

Sustainment

Like costs, sustainment is an implementation outcome that has recently garnered increased attention. Sustainment, or maintenance, of an evidence-based program or practice involves the continued use of program components over time, with the intensity and fidelity required to achieve their intended patient-level and population-level health benefits (Shelton & Lee, 2019). Without planning for and supporting sustained use of effective interventions, their public health impact is reduced, and the time, resources, and relationships invested in their development and implementation are wasted (Shelton & Lee, 2019). Recent research suggests that multilevel factors including available resources and funding, organizational buy-in and infrastructure, and workforce commitment and stability are associated with sustained implementation of evidence-based programs and practices, pointing to the need for specific implementation strategies targeting maintenance of implementation beyond initial adoption (e.g., Bond et al., 2014; Singh et al., 2017). Research on sustainment not only addresses understanding, predicting, and promoting the ongoing use of effective programs and practices but also recognizes the relevance of adaptations, changing context, new evidence, and de-implementation in determining how and whether a program or practice should be sustained (Birken et al., 2020).

Examples in audiology. There are currently few examples in audiology research addressing the sustainment of evidence-based programs, practices, and policies in routine care. A particularly timely topic related to sustainment is the future of tele-audiology services launched during COVID-19 restrictions (Nalley, 2020). In light of increased numbers of audiologists using tele-audiology (Parmar et al., 2021), attention to the factors potentially influencing sustainment of tele-audiology services is warranted; these may include its evidence base, patient and provider preferences, staffing and workflows, patient and provider access to resources (e.g., technology, equipment, and broadband Internet), and policies and financial structures (e.g., the Health Insurance Portability and Accountability Act, licensing, and reimbursement requirements).

Study Design Considerations in Implementation Science

Just as implementation science addresses different outcomes than traditional health research, its questions can be answered with a range of study designs, not limited to "gold-standard" randomized controlled trials (RCTs; Brown et al., 2017; Mazzucca et al., 2018). The evidence base for effective practices and programs is typically composed of RCTs, systematic reviews, and meta-analyses of interventions conducted in high-resourced settings with narrow, unrepresentative populations. Internal validity is prioritized in the studies providing this evidence base (Schwartz & Lellouch, 2009). Questions of implementation, however, require attention to generalizability. What works in an academic medical setting with procedures and participants selected to minimize variability and maximize effects is unlikely to work equally well in other settings with diverse patient populations, limited resources, and other contextual differences.

Design considerations for implementation research include the need for pragmatic approaches appropriate for usual care settings; the use of brief and low-burden measures whenever possible; assessment of implementation outcomes and context at multiple levels of the socioecological framework; attention to unintended consequences (both positive and negative) of implementation efforts; and reliance on intervention delivery by personnel who are representative of (and ideally embedded in) those in the target settings for implementation, rather than highly trained and supervised research staff. Although RCTs are appropriate for some questions in implementation research, for others, rigorous quasi-experimental designs are better suited (e.g., pre–post designs with nonequivalent control groups, interrupted time series, stepped wedge, sequential multiple assignment trials [SMART], and others; Hull et al., 2019; Miller et al., 2020; Schliep et al., 2017). Cross-cutting design considerations in implementation science include the importance of pragmatic trials, mixed methods, and hybrid designs.

Pragmatic Trials

In contrast with the tightly controlled explanatory trials favored in traditional intervention research, pragmatic trials are conducted in ways that maximize external validity (Holtrop & Glasgow, 2020; Loudon et al., 2015; Schwartz & Lellouch, 2009). Consistent with the goals of implementation science, pragmatic trials aim to improve implementation at multiple levels, including providers' practices and policy decisions at the organizational or systems level (Gaglio et al., 2014; Maclure, 2009). Rather than tightly controlling research conditions and comparing interventions to placebo, pragmatic trials may test interventions or implementation strategies in comparison to usual care or other existing effective practices. Flexibility to meet the needs of local settings, rather than rigid adherence to protocolized fidelity, is also incorporated in these types of trials (Glasgow, 2013). Process data, documenting how interventions or implementation strategies were delivered, are valuable in understanding how and why results are achieved (or not achieved). By using pragmatic designs, implementation researchers seek to demonstrate not whether an intervention is efficacious or effective in ideal circumstances but whether it actually works in routine care contexts and settings (Schwartz & Lellouch, 2009). Apart from trials of interventions or implementation strategies, pragmatic research approaches in implementation science also include natural experiments, case studies and multiple case studies, and observational studies of multilevel contextual factors influencing the process and outcomes of implementation.

Qualitative and Mixed Methods

It is unsurprising that qualitative and mixed methods are integral to implementation science research. Many of the questions posed in implementation studies require in-depth exploration of stakeholder perspectives, particularly regarding the feasibility, acceptability, and appropriateness of proposed evidence-based programs and practices, as well of implementation strategies (National Cancer Institute QUALRIS Workgroup, 2018). Assessment of contextual factors often relies on qualitative approaches, because some aspects of context are not easily measurable and appropriate quantitative measures may not exist (National Cancer Institute QUALRIS Workgroup, 2018). The "hows and whys" of implementation processes and outcomes can be assessed with qualitative approaches (Hamilton & Finley, 2019), offering actionable insights on priorities, what went well, and where efforts faltered, providing real-time insights regarding the effectiveness of implementation strategies, guiding adaptations, and informing decisions about dissemination and taking implementation to scale. Qualitative methods commonly used in implementation science include individual interviews, focus groups, observation (including ethnographic approaches), and archival analysis, among others (Hamilton & Finley, 2019).

Mixed methods, in which qualitative and quantitative approaches are intentionally integrated (Creswell & Plano Clark, 2017), are very common in implementation science. Use of mixed methods benefits implementation research in multiple ways: generating hypotheses based on qualitative findings that can be tested quantitatively, triangulating data from multiple sources and methods, and interrogating quantitative findings through qualitative methods, just to name a few (Palinkas et al., 2011). Approaches to integrating qualitative and quantitative data are well defined and rigorous, and examples of mixed-methods implementation research are plentiful (Palinkas et al., 2011).

Hybrid Designs

With the goal of speeding the translation of research evidence into usual practice, the traditional intervention research progression from basic science investigations to efficacy trials to effectiveness trials—eventually leading to systematic reviews, meta-analyses, and the generation of practice guidelines—is unacceptably slow (Westfall et al., 2007). To address this issue, hybrid effectiveness–implementation designs, originally proposed by Curran et al. (2012), have been widely adopted in the implementation science field. This shift involves moving away from a linear, staged approach toward a more overlapping, recursive integration of implementation and effectiveness research. Consistent with the D4D principle, hybrid designs can be applied in even earlier stages in the research-to-practice progression, including efficacy–implementation trials and investigating factors important to future implementation in the initial stages of intervention development.

Three types of hybrid designs have been defined (Curran et al., 2012): (a) Type 1 hybrid trials, which focus primarily on effectiveness outcomes but include secondary implementation-related outcomes (e.g., feasibility, acceptability, identification of barriers and facilitators to implementation); (b) Type 2 hybrid trials, which give equal weight to effectiveness and implementation (e.g., examining implementation strategies for interventions in need of more evidence of effectiveness); and (c) Type 3 hybrid trials, which compare implementation strategies' effects on implementation outcomes but include evaluation of patient-level effectiveness outcomes. Although the three types of hybrid designs differ regarding primary and secondary emphases in trials incorporating both effectiveness and implementation, what they have in common is the concurrent collection and examination of both types of data.

Conclusions

This tutorial provides an introductory overview to the field of implementation science, highlighting its potential applications in audiology. As in other health

disciplines, many evidence-based practices, programs, and policies in audiology are not implemented at broad scale, and challenges to adoption, implementation, and sustainment limit their potential public health impact. Implementation science offers perspectives, frameworks, and methods that are highly relevant to the shared mission of audiology and related fields: to deliver the best hearing health care possible to all who need it, contributing to patients' improved function and quality of life and to population health. By promoting evidence-based practice, engaging stakeholders, and prioritizing health equity, implementation science is also complementary to the mission of ASHA to support its members in advancing science, settings standards, fostering practice excellence, and advocating for providers and patients (ASHA, n.d.-a) and to the core values of the AAA, specifically valuing the provision of accessible, individualized, understandable, cost-effective care based on evidence, quality, and research innovations (AAA, n.d.). Implementation research necessitates multidisciplinary teams and crossing traditional boundaries in research collaborations, and audiologists can build their capacity to conduct this type of research by partnering with behavioral scientists, qualitative methodologists, health economists, health services researchers, and others. Interest in and funding for implementation science research has grown significantly over the past decade, including the development of resources and release of funding announcements at the National Institutes of Health (Kilbourne et al., 2020), including R01 (PAR-22-105), R21, (PAR-22-109), and R03 (PAR-22-106) announcements in which the National Institute on Deafness and Other Communication Disorders participates. Future implementation science research in audiology could benefit patients, providers, organizations, and communities invested in high-quality hearing health care for all.

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