



Our Mission: To advance access to the gift of hearing provided by cochlear implantation through research, advocacy and awareness.

August 30, 2023

Jeffrey Shuren MD, JD
Director of the Center for Devices and Radiological Health (CDRH)
Food and Drug Administration
10903 New Hampshire Avenue
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Dear Dr. Shuren:

Thank you for the opportunity to provide comments to the FDA relative to the topic of patient access to digital health technologies in non-clinical settings. These comments were prepared by the American Cochlear Implant Alliance (ACI Alliance) and are focused on patients with hearing loss who face pervasive disparities in access to care which impact clinical outcomes and quality of life.^{1,2}

The ACI Alliance is a non-profit organization with the mission to address barriers to cochlear implantation by sponsoring research, driving heightened awareness, and advocating for improved access to cochlear implants (CI) for patients of all ages across the United States. ACI Alliance members are hearing care clinicians working in cochlear implantation including surgeons, audiologists, speech-language pathologists (SLPs) as well as scientists, educators, adults with hearing loss, and family members.

The primary digital health technology utilized by patients with hearing loss include hearing aids, implantable hearing devices, and CI. These devices provide essential access to sound for patients yet require regular interaction with specialists in hearing healthcare to optimize performance of the devices and clinical outcomes. Unfortunately, access to hearing healthcare providers is critically limited³ and there is a pressing need to expand delivery of care using novel models and involving non-clinical settings. Based on a growing body of evidence⁴ and the experience of our CI community, access to care in non-clinical settings through telehealth services would provide a critical expansion to hearing healthcare and advance health equity. The following comments address the burden of disease of hearing loss, the pervasive health inequities in hearing healthcare, the role of care delivery in non-clinical settings, and specific topics raised for public comment.

Hearing Loss is a Public Health Problem Involving Technology Access and Specialist Care

An estimated 1.5 billion people worldwide have hearing loss, representing approximately one in five people globally.⁵ Undiagnosed and untreated hearing loss causes a measurable impact on health and social, occupational, and emotional well-being of those affected.¹ Access to specialty hearing healthcare also plays a crucial role in timely identification and treatment of hearing loss to maximize hearing and communication abilities.¹ These hearing healthcare services could include hearing screenings, diagnostic testing and evaluation, surgical or medical treatment delivery, fitting and programming of hearing technology (hearing aids, CI, or implantable hearing devices), auditory rehabilitation, counseling, or even speech therapy.⁶

Hearing Health Inequities Persist Due to Limited Access to Care

Patients throughout the world in need of those services do not have access to them or have difficulty accessing them in a timely manner.⁷ The barriers to high-quality hearing healthcare access are significant and have been linked to many factors, including lack of providers, lack of access to affordable technology, and sociodemographic factors.^{1,8} Location of residence has an impact on access to, utilization of, and quality of care. Rural children and adults are delayed in access to cochlear implantation due to distance from and limited access to specialists who can program their devices, provide speech therapy, and optimize outcomes.⁸⁻¹⁵ The utilization of hearing healthcare care in the United States differs based on race and ethnicity as Black, Indigenous, and Persons of Color (BIPOC) patients with hearing loss are less likely to receive hearing technology and are delayed in receiving hearing healthcare.¹⁶⁻¹⁸ The COVID-19 public health emergency (PHE) further deepened long lasting disparities in healthcare access and utilization experienced by patients hearing loss.¹⁹

Real Families Face Significant Challenges to Overcome Access Difficulty

Because cochlear implantation involves multiple visits, being at distance from a CI center is a barrier to care. Barbara Mellert, a parent advocate interviewed for these comments, lives in rural west-central New Hampshire near Dartmouth College Health. In the case of her family, her two (now adult) sons both received CI at Dartmouth, which has a comprehensive health facility with an excellent CI program. Currently in their 20s, both of her sons no longer live near their childhood CI center. One of Ms. Mellert's sons lives two hours from the nearest CI center; his CI appointments entail a four-hour roundtrip (not including the appointment itself), which means he misses most of a day of work for routine CI mapping.

Ms. Mellert is an Administrator of the Parents of Children with Cochlear Implants Facebook Group. She hears often from families that are challenged by living at distance from a pediatric CI program. Not only do visits involve the parent and the child with a CI but may also involve finding care for other children in the family, taking the child with a CI out of school, and the parent missing work. Single parents (typically mothers) and those of lower educational attainment are especially impacted by living at distance from a center. Ms. Mellert notes that remote mapping would provide significant benefit for families who live at a distance from a CI center and wish to pursue cochlear implantation for their child.

Delivery of Hearing Care Through Telehealth Can Increase Access and Advance Equity

Cochlear implantation requires multiple appointments by various providers (e.g., audiologists, ENT surgeons, speech-language pathologists, psychologists) over the lifetime of the patient. The age of the CI recipient impacts on the type and frequency of needed services; for example, young children will typically receive the services of a speech-language pathologist for several years post CI surgery—often once per week for the first few years. Consistently attending those appointments can be challenging for some individuals or families. Telehealth is the transmission of health-related services and information by means of telecommunication technology and has been recognized as a valid and useful tool to deliver care for underserved populations.²⁰ The use of telehealth in hearing care includes patient education, otoscopy, audiometric testing,^{21,22} and electrophysiological testing,²³ and CI candidacy evaluations.²⁴ This technology has also been used to program hearing aids and CI thereby increasing the access to rehabilitation services.^{4, 25-}

³⁰ The studies involving programming CI remotely have reported a variety of outcomes that include amount of time required for programming, audiologist and patient satisfaction with remote programming, and objective hearing outcomes following programming methods. One study demonstrated that patients could have their CI activated remotely from hundreds of miles away

without experiencing adverse events.³¹ Another study demonstrated that patients located in different countries can have their CI device activated safely with a high level of satisfaction with care.³² Prospective research studies comparing remote and in-person programming of CI devices have demonstrated that some challenges in the lack of a soundproof environment; however, the programming parameters of devices were similar, and patients valued the close proximity of remote care.^{33,34} Telehealth speech therapy is another example of a medical service provided as part of CI after-care that has been effectively provided for a number of years. At-home therapy for children encourages (and facilitates) compliance and family participation. Additional general benefits for at-home use of medical care include: 1) Overcomes the challenges of distance from a medical center or provider(s), 2) Provides equal access for individuals with mobility concerns, which can be particularly problematic for older adults, 3) Provision of services to individuals in an institutional setting (such as an assisted living or skilled nursing facility) could be arranged—particularly in a larger institution, 4) Reduces time away from the workplace for those who find it challenging to make appointments given work responsibilities, 5) Possibility to reach more patients with virtual options for candidacy evaluation and continuing care. Embracing care delivery in non-clinical settings is health policy priority as the June 2016 report of The National Academy of Sciences, Engineering, and Medicine has recommended the evaluation and implementation of innovative models of hearing healthcare delivery that improve access, with special focus on underserved populations.³⁵

Hearing Care Telehealth Delivery Faces Significant Challenges

The implementation of telehealth hearing care delivery is complicated by several factors. Licensure and reimbursement variations represent barriers to the practical delivery of telehealth.⁴ Licensure to provide services remotely differs widely within different regions and across international borders. Licensure is complicated within the United States and may restrict the region of delivery of telehealth services. Recent legislation within the US seeks to expand licensure to other states while providing telehealth care within federal healthcare systems.^{36,37} Currently there is variability in insurance reimbursement for non-clinical setting delivery of services related to cochlear implantation. Some clinicians note that they are utilizing teletherapy (specifically speech services) and being reimbursed from Medicare and private insurers as a continuance of the PHE rules. There are sometimes challenges with specific policies rather than overall providers (i.e., the company covers but not for a specific person's plan). In some situations, patients have a decreased co-pay if they choose telehealth over in-person services. CI counseling represents a billable service for physicians but not for audiologists. Implementation of telehealth in hearing care has been progressive in the United States Veterans Affairs systems, which has served as a model to other health systems. There is also a lack of evidence of cost-effectiveness data for telehealth hearing care.³⁸ Technological factors also limit telehealth hearing care delivery due to challenges with the cost, set-up and troubleshooting of the technology in the remote sites. Furthermore, the lack of remote site assistant expertise in CI programming may limit some of the activities that can be performed remotely. Some CI centers have overcome remote technology limitations by shipping computers with installed mapping software; however, this comes with significant cost, set-up, and risk for the equipment and does not represent a sustainable solution.

Recent Legislation Promotes Telehealth Delivery of Care

Interest in telehealth for CI services was heightened by the COVID-19 pandemic, which shut down “non-essential” in-person medical services at most hospitals. At the time that occurred, the leadership of ACI Alliance recognized the potential opportunity that the forced shutdown of in-person services could offer the field in terms of investigating expanded access to care mechanisms. ACI Alliance encouraged our community to explore how we might test various telehealth options that could, longer term, expand CI access. Telehealth services were allowed under Medicare during the PHE but are currently due to expire in 2024 unless extended by The Center for Medicare and Medicaid Services.

This interest was also occurring in other areas of medicine, demonstrated by the introduction of Federal legislation intended to encourage use of telehealth. In the first eight months of the 2023-2024 Congress, 18 bills were introduced with “telehealth” in the title or subject matter—all support telehealth in various ways. A few illustrative examples that demonstrate the breadth of interest include:

HR 3875 – Expanded Telehealth Access Act³⁹

- Would make permanent the temporary expansion of allowing SLPs, audiologists, OTs, and PTS provide telehealth services as practitioners. The Consolidated Act of 2022 only did so through 2024.

HR 3440/S. 1636 – Protecting Rural Telehealth Access Act⁴⁰

- Expands most flexibilities and removes hinderances for accessing telehealth.

HR 3432 – Telemental Health Care Access Act of 2023⁴¹

- Makes permeant coverage of mental and behavioral health services furnished through telehealth.

HR 1843 S 1001 – Telehealth Expansion Act of 2023⁴²

- Permanently exempts high deductible health plans from the requirement of a deductible for telehealth and other remote care services.

HR 1144 – Department of Veterans Affairs Telehealth Strategy Act⁴³

- Requires the Department of Veterans Affairs (VA) to submit a strategy to Congress for the telehealth services furnished by the Veterans Health Administration. Additionally, the VA must report on the utilization of end-user devices provided to veterans by the VA to facilitate telehealth during FY2023 and FY2024.

HR 197 – Rural Telehealth Expansion Act⁴⁴

- Expands coverage of telehealth services under Medicare to include store-and-forward technologies (in which information is sent to providers and reviewed at a later time, rather than through a real-time interaction). Current coverage is limited to federal demonstration programs in Alaska and Hawaii.

S 731 – TELEHEALTH HSA Act of 2023⁴⁵

- Makes permanent the preferred treatment of telehealth and other remote care services for purposes of health savings accounts.

HR 134 – Amendment of Social Security Act of 2023⁴⁶

- Permanently allows any site to serve as an originating site (i.e., the location of the beneficiary) for purposes of Medicare telehealth services, including a beneficiary's home.

Technological Needs from CI Centers to Expand Availability of Remote Services

The need for regular programming (or mapping) of the sound processor provided by a specially trained audiologist presents challenges to CI care for people of many different demographics including but are not limited to those who live at distance from a CI center. Individuals with mobility or health limitations, older adults who have difficulty attending appointments without support, those who don't have a car, people who rely upon public transportation, and working age adults who don't want to miss work may all find the need for regular mapping appointments to be a deterrent in going forward with CI and/or receiving regular care and appropriate care after obtaining a CI.

At present, remote mapping is not widely available though it is possible with certain devices if the clinic is willing to ship equipment. One clinic in Colorado has been using remote programming for some years with experienced patients. The programming pod and pad is shipped via FEDEX to the patient, who then hooks themselves up for an Internet-based appointment. When completed, the patient sends the equipment back. Patients have rated the remote mapping experience highly.⁴⁷

Remote mapping is currently used by the VA in a limited number of VHA CI Centers (e.g., West Haven CT, Seattle, and Pittsburgh). Patients who were implanted at those clinics but live at distance can be programmed at a remote telehealth site. This is accomplished by the VHA CI Center by providing mapping technology to remote sites and having an individual trained in connecting the patient up to the computer with installed software. The remote professional serves as a facilitator for the patient, allowing Veterans to meet remotely with a mapping audiologist. The service has been popular with Veterans and has served to expand access to cochlear implantation.⁴⁸ It is an example of what conceivably could be used in the private health care system.

A physician at a large, innovative CI center noted that his clinic is not currently engaged in remote mapping due to IT and billing issues though it has been done in the past under research protocols. He noted "We all agree that this something that needs technological development to improve patient access and efficiency."

Telehealth Facilitates Monitoring Patient Progress Remotely

One CI manufacturer (Cochlear) introduced a clinical evaluation tool called Remote Check as a means of utilizing a clinician-enabled tool that allows CI recipients with certain sound processors to complete a series of hearing tests using a compatible Apple OS device (iPhone, iPod touch or iPad). The tool allows a recipient's clinic to complete a series of hearing tests using the Nucleus Smart App and then review the results. Remote Check is viewed positively by clinicians and patients who have used it as it allows a review of patient data for troubleshooting and a means of avoiding an unnecessary trip to the clinic. The tool allows prioritization for treatment and frees up clinic time for patients who do need an in-person appointment.

A study of one site involving a total of 32 patients who had utilized Remote Check found that it was easy to use by most patients. There were no significant differences in testing scores between the clinic and at-home administered test. Use of the Remote Check tool is currently not reimbursed by insurance.⁴⁹

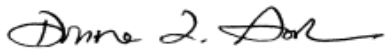
Development and Dissemination of Telehealth Care Delivery Requires Rigorous Research and Transdisciplinary Communication

Multiple factors need to be considered to effectively develop and disseminate digital health technology to promote equitable home-based care. Specific to the delivery of CI care, these factors include, but are not limited to, the following: delivery location, ease of use, cost of care, type of patient technology in remote site and clinician technology in clinical site (i.e. - computer, tablet, mobile phone, connection cables, headphones/audio equipment, and audiometer), additional equipment or personnel needed to connect patient to equipment, software interface between patient and clinician, timing of information exchange or care deliver (synchronous versus asynchronous), internet bandwidth, sound environment status of remote site, safety controls of technology, patient information protection. Furthermore, the social determinants of health (SDH) domains are important factors that need to be considered in the development and dissemination of technology to promote equitable hearing health.¹ The SDH are much more than just sociodemographic data as each of the domains has core areas that influence every aspect of health, healthcare, and health-related research. Aspects of SDH can and should be considered during every phase of research and development of technology spanning from descriptive analytical studies to interventional clinical trials. There is much work to be done in hearing-related research to understand these complex interactions and develop and implement innovative solutions to bridge disparity gaps in hearing health.

In developing and disseminating technologies and diagnostics to support patient with hearing loss in non-clinical settings, we encourage the FDA to continue to dialogue with the ACI Alliance. It is essential to consider the knowledge, attitudes, and behaviors of patients, the adaptability and feasibility of technology modifications from hearing health industry leaders, and the clinical expertise and the pragmatic research capacity of hearing healthcare professionals. The ACI Alliance represents an organization that facilitates communication and collaboration between patients, industry leaders, clinicians, and researchers to inform the FDA on types of equipment, settings for care delivery, and necessary research to conduct to advance health equity through telehealth hearing care delivery. The FDA could advance the use of telehealth for cochlear implant care by prioritizing review of submissions by cochlear implant manufacturers that would advance the availability CI care in additional locations such as in-home or non-clinical settings.

Thank you for your consideration of our comments. Please contact our executive director, Donna Sorkin at dsorkin@acialliance.org if you wish to continue discussion of any aspect of our comments.

Sincerely,



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