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Implementation Strategy for Highly-Coordinated Cochlear Implant Care With Remote Programming: The Complete Cochlear Implant Care Model

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Objective: To introduce and discuss implementation strategy for the Complete Cochlear Implant Care (CCIC) model, a highly-coordinated cochlear implant (CI) care delivery model requiring a single on-site visit for preoperative workup, surgery, and postoperative programming.
Study Design: Prospective, nonrandomized, two-arm clinical trial.
Setting: Tertiary referral CI center.
Patients: Adults who meet audiologic criteria for cochlear implantation.
Interventions: Cochlear implantation, coordinated care delivery, including remote programming.
Main outcome measures: Care delivery model feasibility and process implementation.
Results: Patients determined to be likely CI candidates based on routine audiometry are eligible for enrollment. The CCIC model uses telemedicine and electronic educational materials to prepare patients for same-day on-site consultation with CI surgery, same or next-day activation, and postoperative remote programming for 12 months. Implementation challenges include overcoming inertia related to the implementation of a new clinical workflow, whereas scalability of the CCIC model is limited by current hardware requirements for remote programming technology. A dedicated CCIC process coordinator is critical for overcoming obstacles in implementation and process improvement through feedback and iterative changes. Team and patient-facing materials are included and should be tailored to fit each unique CI program looking to implement CCIC.
Conclusion: The CCIC model has the potential to dramatically streamline hearing healthcare delivery. Implementation requires an adaptive approach, as obstacles may vary according to institutional infrastructure and policies.
Key Words: Cochlear implant—Coordinated care—Healthcare delivery—Patient-centered care—Remote programming—Telehealth—Telemedicine.

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INTRODUCTION

Despite increased recognition of the health and socioeconomic consequences of untreated or undertreated hearing loss, hearing rehabilitation remains persistently low in the United States (1,2). Specifically, estimates of cochlear implant (CI) utilization among adult audiologic candidates range from 2% to 13% despite readily available technology (2–7). Although the barriers to care for CI candidates are numerous and span individual to systemic issues, one barrier, namely the healthcare delivery model for CI care, can be directly addressed by otolaryngologists and audiologists presently. At its current state in most practices, the CI care delivery model is a protracted and arduous process for patients, requiring up to 10 appointments from initial consultation to 1-year follow-up CI programming (8). Considering that many patients, particularly those living in rural areas, travel great distances for CI care, patients may experience overwhelming barriers directly associated with receiving care, resulting in delayed or forgone treatment (9–12). Challenges around access to relatively scarce high-volume CI centers and a growing population of eligible CI candidates additionally stress the need for coordinated, convenient care that expedites treatment and minimizes obstacles for patients (13,14).

Recent technological advancements and demands for remote care accelerated by the COVID-19 pandemic have set the stage for the implementation of healthcare delivery models that leverage highly-coordinated care and telemedicine to minimize unnecessary in-person appointments. Until now, telemedicine options for patients have been limited. Since the onset of the COVID-19 pandemic, telemedicine infrastructure and appointments have not only increased, but both patients and healthcare workers have reported increased satisfaction with this modality (15,16). Although automated CI programming is still in development, previous studies have demonstrated the efficacy of remote programming when performed by an audiologist in real-time (17–20). Taken together, the implementation of telemedicine and coordinated in-person appointments may reduce the required number of trips to the institution for CI care.

With expanding CI knowledge and awareness, the CI care delivery model needs to emphasize the patient experience, as many patients perceive value from convenience and engagement in their healthcare (21,22). The Complete Cochlear Implant Care (CCIC) model, a novel CI healthcare delivery model, was developed to address barriers to care for patients who perceive benefit from reduced travel, associated costs, and the use of technology. In addition to leveraging electronic education materials and coordinating a single trip for in-person evaluation, surgery, and activation, this model uses telemedicine for CI programming postoperatively to minimize travel burden for patients. This study introduces the CCIC model and implementation strategy, which can be used to replicate this model across CI programs.

METHODS

The CCIC model (Figs. 1 and 2) was developed as an extension of previous work (8). In contrast to previous iterations, the CCIC model incorporates same or next-day CI activation and subsequent remote programming. The CCIC feasibility study is a prospective, nonrandomized, two-arm cohort study (institutional board review 20-008144). The two study cohorts include patients undergoing CI care through the CCIC model and the standard care pathway. Although this feasibility study is actively enrolling patients, the CCIC model and implementation strategy will be discussed in this article in an effort to disseminate this information earlier for CI programs, practices, and institutions interested in implementing a similarly streamlined care delivery model. Final outcome data for the CCIC trial will be published upon the completion of the study.

Ideal candidates for the CCIC model include adults who are interested in pursuing cochlear implantation and likely to meet audiologic criteria based on a routine clinical audiogram (Table 1). Importantly, patients must reside within clinical licensing jurisdiction of the institution, have access to WiFi Internet (preferably at home), and should be capable of participating in telemedicine video appointments. Patients who are uncomfortable with telecommunication technology may enlist the help of available family members; however, a family member must be present at each appointment in this case. Exclusion criteria include comorbidities or cognitive deficits that prevent participation in the telemedicine component of the care model or a preference for in-person appointments. At the time of study conception, a single CI manufacturer (Cochlear Ltd., Sydney, Australia) had remote programming software available for use, although the CCIC model may be implemented with any device with available remote programming software.

The CCIC model uses preexisting technology to provide patients with highly-coordinated CI care. Educational materials and videos are assigned to patients via the institutional patient portal, which can also track task completion. Telemedicine visits for the CCIC model use the institution's HIPAA compliant videoconferencing software (Zoom Cloud Meetings, Zoom Video Communications Inc., San Jose, CA) in the same manner used for routine medical care. At the time of initial activation, each patient is provided with a remote programming tablet with preinstalled Custom Sound Pro and Custom Sound EP software (Cochlear Americas, Lone Tree, CO), USB cable, programming pod, and written and visual instructions for processor-tablet connection (Supplemental Figure 3, http://links.lww.com/MAO/B490). During a remote programming appointment, the audiologist uses the remote desktop control function embedded in Zoom to login into the programming tablet and connect to the patient's CI. Once the connection is established, Custom Sound Pro software is used to set and optimize electrical stimulation parameters similar to what is done during an in-person programming visit. Within 5 days of remote programming appointments, aided audiometry and speech perception testing (CNC and AzBio sentences without and with noise) are performed during in-person visits (Figs. 1 and 2). After completion of testing, results are reviewed with the CI recipient. In addition to speech perception testing, outcomes are measured via patient care experience surveys and disease-specific, validated quality of life instruments including the Cochlear Implant Quality of Life Profile and the Nijmegen Cochlear Implant Questionnaire (Fig. 3) (23,24).

RESULTS

CCIC Enrollment and Prior Written Authorization

The CCIC model uses telemedicine and electronic educational materials to prepare patients for a same-day onsite consultation and CI surgery, same or next-day activation, and postoperative remote programming for 12 months (Figs. 1 and 2). Screening for CCIC enrollment occurs in conjunction with routine audiologic triage upon referral for CI evaluation. Patients identified to meet inclusion criteria are contacted by the CCIC Coordinator via telephone to review eligibility checklist items (Table 1; Supplemental Fig. 1, http://links.lww.com/MAO/B471) and gauge interest regarding enrollment. Interested patients meet with a CI audiologist via video appointment, which serves as an informational session for patients as well as a screening process to evaluate patient comfort with the telemedicine technology required to participate in CCIC.

Two CCIC pathways were developed to accommodate variable insurance requirements. For patients with Medicare or insurances, which that do not require prior written authorization (PWA), Pathway 1 (Fig. 1) is encouraged; Pathway 2 (Fig. 2) accommodates those with PWA requirements, as well as borderline audiologic candidates that would benefit from upfront CI evaluation before surgical decision-making.

Preoperative Education, Appointments, and Outcomes

Upon enrollment, the patient is asked to review educational materials, including a video regarding CI expectations and

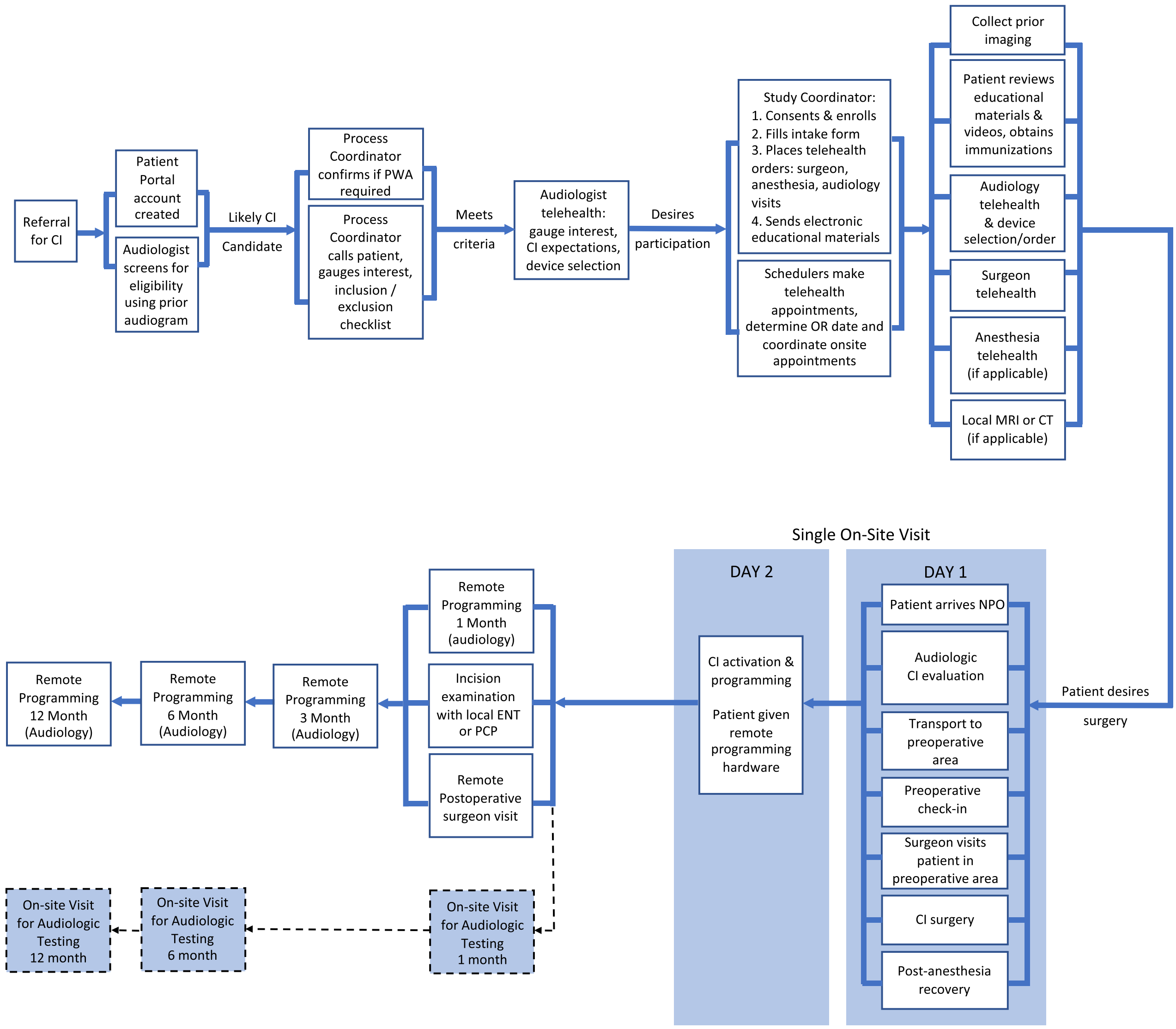

FIG. 1. The CCIC model pathway 1 combines coordinated care, upfront electronic educational materials, telemedicine appointments, and remote programming to minimize travel to the institution for cochlear implant care. Patients who do not require prior written authorization for CIs are eligible for this pathway. *Dashed boxes* represent on-site visits, which would be optional in future implementations of the model. CCIC indicates complete cochlear implant care; CI, cochlear implant.

electronic pamphlets regarding device options, the CCIC process, and postoperative remote programming (Supplemental Figs. 2, http://links.lww.com/MAO/B472 and 3, http://links.lww.com/MAO/B490). Patients without previous MRI imaging of the brain are asked to obtain one locally, after which, images are uploaded for review. Simultaneously, orders are placed for the preoperative and perioperative appointments including 1) virtual appointments with the surgeon, audiologist (device selection), and preoperative medical evaluation with the anesthesiologist, and 2) in-person same-day CI evaluation and surgery and same- or next-day device activation (Supplemental Fig. 4, http://links.lww.com/MAO/B474). The virtual anesthesia preoperative evaluation entails a screening medical record review; patients requiring additional evaluation before surgery (e.g., electrocardiogram, laboratory testing) are asked to perform this locally when medically appropriate.

On-Site Visit and Remote Programming

On the day of surgery, Pathway 1 patients arrive for an on-site CI evaluation before CI surgery. In anticipation of surgery, patients are instructed to not have anything to eat or drink after midnight, the night before surgery. When confirmed to be a CI candidate based on audiometric and speech perception testing, the examining audiologist communicates candidacy with the surgeon, and the patient proceeds to the preoperative area where they meet with the surgeon to review results and ask additional questions. After the surgery is completed, the patient is discharged and returns to the outpatient clinic for initial activation and programming

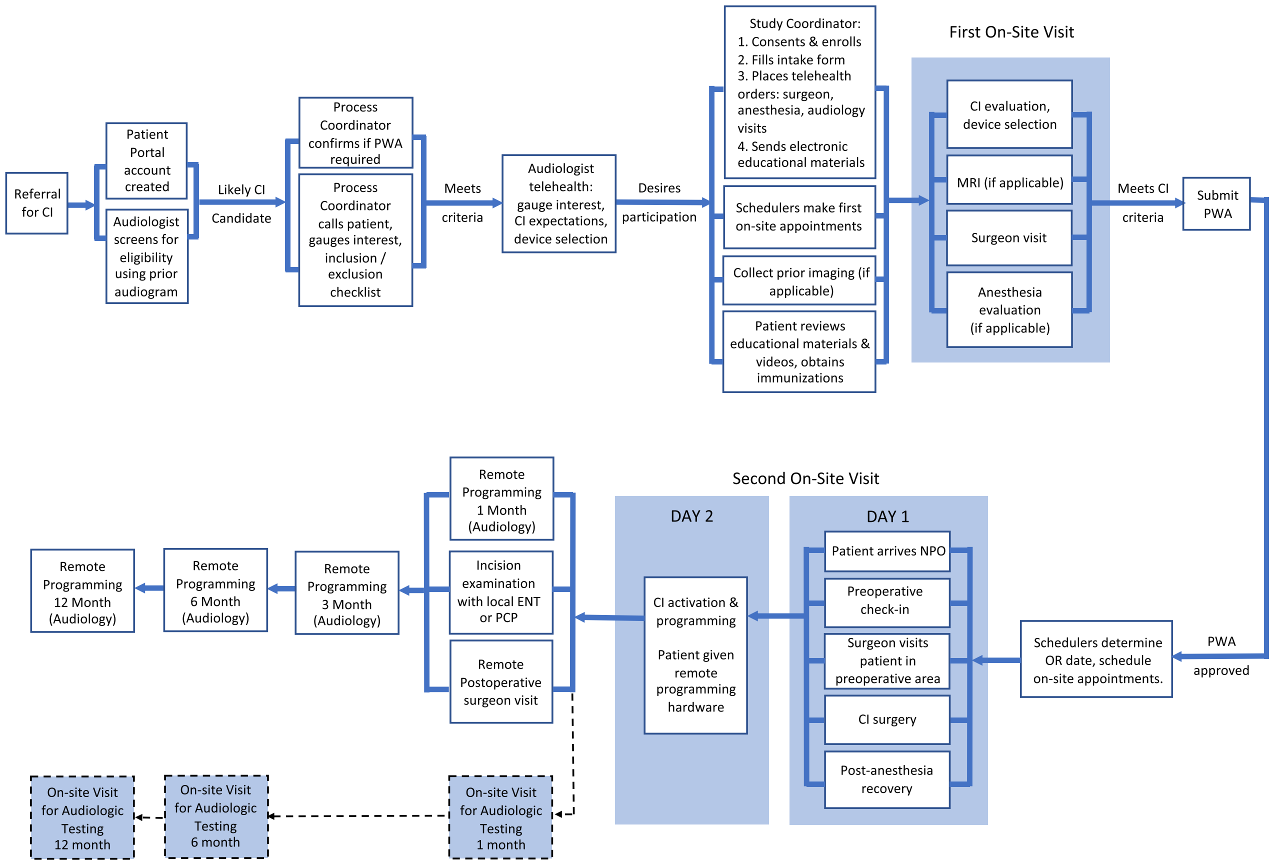

FIG. 2. The CCIC model Pathway 2 offers an alternative pathway for patients with borderline candidacy based on routine audiometry or for patients whose insurance requires PWA. In contrast with Pathway 1, Pathway 2 involves upfront CI evaluation followed by enrollment after CI candidacy and PWA have been approved. *Dashed boxes* represent on-site visits, which would be optional in future implementations of the model. CCIC indicates complete cochlear implant care; CI, cochlear implant; PWA, prior written authorization.

on the same day, or more commonly the next day, which concludes the on-site visit for the patient. Patients are provided with remote programming hardware for future appointments at the time of their activation appointment.

For the purpose of this feasibility study, patients undergo remote programming, but present for in-person testing after the remote session (dashed boxes in Fig. 2), since remote speech perception testing technology was not available at the time of this trial. Patients complete remote programming at 1, 3, 6, and 12 months postoperatively and in-person speech perception testing at 1, 6, and 12 months. As alluded to in Figures 1–3, although most postoperative remote programming sessions are supplemented with in-person testing, the 3-month visit consists of remote programming only. The purpose of this remote-only time point is to demonstrate feasibility of a remote-only session, as future iterations of this model may have most or all testing and programming performed remotely. Additional virtual or in-person appointments to address concerns are accommodated at any time point within the process.

In addition to the virtual postoperative appointment with the CI surgeon, the CCIC model includes a postoperative incision examination by a local healthcare provider; patients are asked to visit their local physician or advanced practice provider for an examination of the postauricular incision approximately 1 month after surgery. At a similar time point, patients are asked to send in a photograph of the incision through the patient portal and complete a short "Incision

TABLE 1. *CCIC process coordinator checklist*

CCIC Enrollment Checklist:
Likely to meet audiologic criteria for CI based off routine audiometry
Insurance status and PWA requirements
Residential location correlates with audiologic licensure
Access to WiFi Internet
English-speaking
Generally comfortable with telemedicine technology
Family support (if needed or applicable)
Rule out strong preference for all in-person appointments
Brief medical history checklist:
Otologic history, surgery or head trauma
Complications related to previous general anesthetic
Cardiac or pulmonary medical history
Significant cognitive deficits
Previous brain MRI or contrasted CT scan since onset of hearing loss
Contraindications to obtaining a contrasted brain MRI

During the first patient contact point, the CCIC process coordinator will go through this checklist to obtain a general overview of the patient's needs and preferences and determine eligibility for CCIC enrollment.

CCIC indicates complete cochlear implant care; CI, cochlear implant; CT, computed tomography; MRI, magnetic resonance imaging; PWA, prior written authorization.

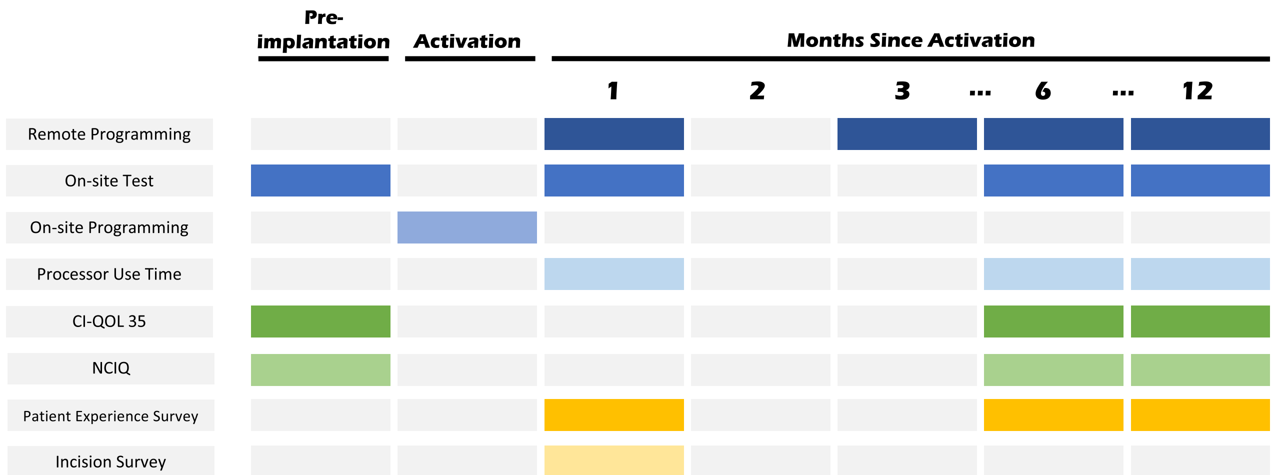

FIG. 3. CCIC programming, testing, and outcomes measurement timeline. CCIC indicates complete cochlear implant care; CI-QOL 35, Cochlear Implant Quality of Life Profile; NCIQ, Nijmegen Cochlear Implant Questionnaire.

Survey" that screens for atypical symptoms that may suggest postoperative complications. Upon study completion 12 months postoperatively, patients return the hardware used for remote programing but continue to be followed with routine clinical care.

CCIC Team

The CCIC implementation team consists of a multidisciplinary group outlined in Table 2. The CCIC process coordinator is responsible for overseeing enrollment, ensuring patient progression through the process, and encouraging team communication and collaboration. In this iteration, the CCIC process coordinator is a physician; however, an audiologist or CI care coordinator with appropriate clinical background could effectively fill this role. In addition to the traditional responsibilities of CI audiologists, the CCIC model relies on audiologists to become familiar with remote programming software and hardware management. Communication among CCIC team members occurs via email, electronic medical record, and during regular CCIC team meetings.

TABLE 2. *CCIC team roles and responsibilities*

Role	Responsibilities
CCIC process coordinator	– Initial patient conversation – Insurance check – Request previous imaging and medical records – Enrollment – Coordination of surgical date and appointments with scheduling team – Oversight of patient progression – Troubleshoot issues – Coordinate team collaboration and feedback – Implement adjustments to CCIC model based on team feedback
Study coordinator	– Consent – Appointment orders – Distribution of electronic educational materials – Monitoring survey completion – Maintaining records of hardware distribution
Audiologists	– Initial audiogram screen and referral of potential candidates to CCIC process coordinator – Initial audiology telemedicine appointment – Device selection – CI evaluation and activation – Preparing hardware and software for remote programming – Remote programming and audiologic testing appointments
Surgeons	– Preoperative and postoperative telemedicine appointments – Surgery
Schedulers	– Scheduling appointments in accordance with CCIC model
Anesthesiologists	– Triage for remote anesthesia evaluation when possible – Surgery
Patient's local physician or advanced practice provider	– Postoperative wound evaluation

DISCUSSION

The CCIC model leverages telemedicine, technology, and highly-coordinated care to improve the patient experience and minimize travel burden for prospective CI candidates. Importantly, the CCIC model does not change the method of CI evaluation and surgical treatment when compared with the traditional CI care delivery model. Although the CCIC clinical trial outcomes will be reported at the conclusion of the study, interim data and patient feedback suggest high patient satisfaction (94% likely to recommend to a friend, N = 9, 1 month postoperatively) along with noninferior clinical outcomes (64% CNC, 78% AzBio in quiet, N = 9, 1-month postoperatively). The current CCIC model, an extreme example of coordinated remote care, may not be best fit for all patients or CI programs; however, the implementation of portions of this model, such as remote care, upfront electronic educational materials, or highly-coordinated in-person visits, will likely bring value and convenience to most patients. As it is currently presented, the CCIC model functions well within a tertiary or quaternary care center that receives direct referrals for cochlear implantation. Considering that CI candidacy testing batteries and qualification criteria are interpreted differently among centers, the specificity of referrals is expected to vary (25). With some minor changes in audiogram screening processes, this model could be implemented within a practice that receives nonspecific referrals for hearing loss. In addition, this model may be implemented in a more à la carte or modular basis as elaborated above, which aids in tailoring patient-centered components to fit within varying practices. The CCIC model implementation strategy has been presented as a guide for practitioners interested in developing a more patient-centric CI care pathway within their practice, with the expectation that site-specific adjustments may be required based on institutional infrastructure and policies. When considering implementation strategy across various practices or institutions, frequent team communication, regularly scheduled touchpoints, and incorporation of feedback are key in designing and executing a model that fits within unique clinical workflows, practice patterns, available resources, and patient-specific needs.

Recommendations for Implementation

Although the implementation of new processes in any setting requires some extent of trial and error, the authors have compiled the following recommendations for successful CCIC implementation across any CI practice. Importantly, the implementation process requires a designated coordinator with dedicated time to ensure effective execution of the CCIC process, using checklists, process maps, timelines, and check points (Table 1, Figs. 1–3) along with frequent communication with the remainder of the CCIC team. With the implementation of a new clinical workflow, unanticipated challenges will arise; consequently, initial implementation requires close monitoring of processes and patient progress to ensure accurate scheduling and workflow. Along the same lines, the CCIC process coordinator maintains close communication with the team and elicits feedback with respect to each sector including audiology, otolaryngology, scheduling, and study coordination. Continuous communication, rapid feedback, and team flexibility allow for earlier opportunities to implement changes for process improvement. Finally, the CCIC process coordinator should understand the intricacies of the CCIC clinical workflows as they relate to each team member allowing for agility in altering processes to improve the experiences of not only the patients but also the staff.

Challenges in Implementation

Although the CCIC model has the potential to streamline hearing healthcare delivery, challenges and potential limitations in widespread implementation must be fully understood. The following discussion focuses on specific challenges, both expected and unexpected, encountered by the authors during the first year of CCIC implementation. One of the most consistent challenges in the implementation of any new process is overcoming the inertia of existing clinical workflow (26). Indicative of the efficacy of relationship-building in overcoming this challenge is the importance of the understanding of each team member's roles, limitations, and challenges with CCIC tasks and the willingness to incorporate feedback into newer iterations of the model. Over time, the team and system acclimate to the new clinical workflow, and barriers to change dissipate.

From a practical standpoint, several logistical challenges were encountered during the implementation of the CCIC model, particularly with remote programming. The use of any new software to conduct patient care (such as Custom Sound Pro) typically requires approval from institutional Information Technology to ensure protection of sensitive patient health information; depending on institutional regulations, the application process may require several months for review and approval. This may be a lesser hurdle for practices unaffiliated with large medical systems. Furthermore, with current remote programming technology, the patient requires access to a tablet or laptop with the appropriate software for remote programming sessions. Although it is possible to send hardware to patients for each visit, a large-scale remote programming operation would require significant coordination to ensure timely delivery of components to each patient. In our practice, this proved to be impractical, and the decision was made to send each patient home with a tablet, which would be collected at the completion of the study 1 year after surgery. Effective, large-scale implementation of remote programming will require either app-based software or stand-alone programming pods, which can be given to patients long-term, as the current practice of using tablet-based software is cost-ineffective and arduous for providers. At the time of writing, it is our understanding that such platforms will be available from several manufacturers soon. Finally, one of the major benefits of remote care is the expansion of healthcare reach; however, state licensing requirements vary and many states do not adhere to interstate reciprocity once COVID-19 emergency provisions expire (17,18,20,27). For this study, CCIC audiologists obtained medical licensure for the states with the highest CI referrals to the institution, and enrollment was limited to patients residing in those states. Reimbursements for teleaudiology vary significantly across payers; Medicare beneficiaries have limited telehealth coverage, however, expanded COVID-19 telehealth provisions allowed for coverage for CI programming services (28). As the demand for telehealth grows in the coming years, licensing and associated reimbursement policies may expand to alleviate current restrictions for practitioners seeking to improve access to care for patients (29).

Interestingly, although the authors expected significant difficulty with telemedicine visits in the CI candidate population, paradoxically, many patients seemed to fair better using the telemedicine platform compared with in person visits, likely for at least three reasons: 1) patients frequently had family members who advocated and communicated on their behalf, 2) lip reading remained effective during video appointments, which would have otherwise been lost during a masked in-person visit, and 3) patients had the option to increase the volume on the computer beyond what was typically encountered in an in-person visit. Although the authors did not have access to closed captioning for telemedicine appointments at the time of this study, this would be a welcomed addition to the CCIC model. Moreover, as CIs gain traction among the general population and patients present with greater background knowledge after having reviewed educational materials, the educational process will likely become less cumbersome for the audiologic and surgical staff.

Although the direct benefits to patients are self-evident, the CCIC model stands to positively impact hearing healthcare and CI practices on a larger scale. The relative scarcity of CI centers, particularly related to geographic heterogeneity, contributes to variability in CI utilization and accessibility across regions in the United States (14,30). Although remote programming in conjunction with coordinated care may alleviate some disparities, these strategies are not routinely implemented presently (12,14,17,18,20,30). The CCIC model offers an opportunity to reach patients who would otherwise encounter geographic barriers to CI care and, alongside other measures, may contribute to improving CI accessibility and utilization. When considering the impacts of coordinated care models such as CCIC, the financial ramifications of bundled healthcare models must be evaluated within the context of the larger healthcare system. After the launch of the Bundled Payments for Care Improvement initiative by the Center for Medicare and Medicaid Innovation, bundled surgical procedures have been demonstrated to not only improve the patient experience, but also reduce costs and treatment delays (8,31–35). As the U.S. healthcare system places priority on movement toward value-based healthcare, practices using coordinated care models ready for bundling will be poised for success from both patient satisfaction and financial standpoints.

CONCLUSION

The CCIC model has the potential to transform the healthcare experience for prospective CI candidates by using telemedicine and remote technology to minimize travel burden and coordinate in-person care. As proponents of patient-centered care, CI practices using telemedicine in a highly-coordinated CI care model may be optimally poised to reach patients who would otherwise face insurmountable barriers to care.

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