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Real-world experience using Cochlear™ Remote Check in the United Kingdom

Overview

Cochlear implants (CIs) offer a safe, effective, and cost-effective lifelong hearing solution for individuals with severe to profound sensorineural hearing loss who do not benefit from optimally fitting hearing aids (WHO, World Report on Hearing 2021). Due to their success and the relaxation in CI indication criteria over time, the number of people with a CI (recipients) is increasing rapidly across the globe.

Data reported in 2021 by the British Cochlear Implant Group (BCIG) showed that in the United Kingdom (UK), the established adult and paediatric CI population was approximately 20,000 (BCIG Annual Data Collection Report, 2021). Each year, an additional 1,500 people receive a CI, and this number is expected to rise to 2,150 per year by 2024 (NICE 2019). Currently, the largest implant clinics support CI populations of between 1,400 - 2,000 recipients, and this is steadily growing as more CI candidates are identified and treated (BCIG Annual Data Collection Report, 2021).

CI recipients require lifelong clinical support and should continue attending regular clinic appointments to maintain optimised hearing performance. After the first 12 months post-surgery, recipients will typically transition to annual clinic visits (BCIG, 2018). Based on individual needs, patient groups such as young children or those with additional requirements for support may need to be seen more frequently in the clinic. Research has shown that for most CI recipients, hearing performance tends to stabilise within the first year or two post-surgery, while a smaller group may continue to require regular review of their progress in the clinic (Howe and Mawman, 2015).

Visits to the clinic for regular reviews may not always be sustainable or necessary for a recipient. As time after surgery increases, research has also shown that the proportion of CI recipients who do not attend an annual review appointment in the clinic tends to increase (Shapiro et al 2021). The reasons may be manyfold and are not anticipated to be specific to CI recipient aftercare. Some recipients may be satisfied with their hearing ability or do not experience issues requiring a clinic visit, while others may be unaware of changes in their hearing ability that may benefit from further care including an in-clinic appointment. Others may be aware of hearing performance or device issues but are simply unable to attend the clinic. Attendance may not be feasible for patients who need to take time off work or study, be too ill to travel to the clinic, live in distant rural areas, do not have access to transport, need to make provision for childcare, or who may find travel costs a financial burden (Public Health England, 2017, Cullington et al 2018).

As CI clinics manage ever-growing caseloads, the need for complementary care options including those with telehealth capabilities, should be considered in support of delivery of ongoing care for CI recipients during their lifetime. This is aligned with the National Health Service's (NHS) priority of digitally enabled outpatient care, enabling a more efficient use of outpatient clinic capacity as part of the NHS Long Term Plan (NHS, 2019).*

*Under NHS funding, via specialist commissioning, clinics receive annual maintenance funding per patient to cover their ongoing care costs

Cochlear™ Remote Check

Introduction

Remote Check is a Cochlear remote care monitoring solution which provides the option for a CI recipient to complete a routine hearing review at home without the need to attend the clinic. When enabled by the clinician, Remote Check becomes accessible through the Nucleus® Smart App and uses direct wireless streaming capability between the Cochlear™ Nucleus® 7 or Kanso® 2 Sound Processor and a compatible smartphone.* Clinicians can schedule a Remote Check appointment when required, selecting the desired tests for completion by the recipient remotely. The recipient then completes the scheduled hearing performance check within a two-week window, at a time and place convenient for them.

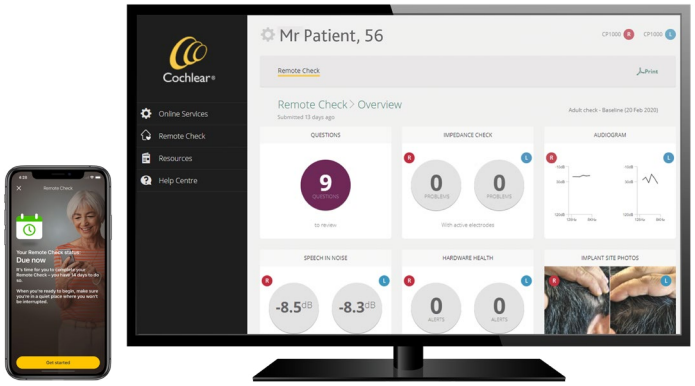
The encrypted information captured via Remote Check is uploaded and can be accessed by the clinician using a secure internet portal. The clinician then assesses the recipient's outcomes and progress, providing appropriate follow-up and intervention based on individual needs. Remote Check is a convenient way to facilitate effective patient triage, which may help minimise unnecessary in-clinic appointments and improve clinic efficiency whilst maintaining regular communication between the recipient and the clinician.

Clinical background

In 2018, Cochlear Limited (CLtd) collaborated with a number of UK CI clinics in a proof of concept study investigating use of the Remote Check assessment battery to potentially support management of a growing CI recipient base. The results from the study were leveraged to further refine the Remote Check application for commercial implementation as a digital application (Maruthurkkara et al., 2020a in press). Subsequently, Remote Check was clinically evaluated in Australia to confirm the functionality, usability, acceptability, and accuracy of commercial implementation of Remote Check as part of the Nucleus® Smart App (Maruthurkkara et al., submitted 2020b).

Flexibility to provide quality care remotely

Remote Check supports remote monitoring of both long-term experienced and newly implanted recipients. Remote Check is designed for use with recipients aged 6 years or older with compatible unilateral or bilateral cochlear implants. Using a selection of customisable, recipient-driven tasks combined with data captured automatically and directly from the recipient's sound processor, broad coverage of clinically validated hearing health metrics is available to support clinical decision making.



The modular design of Remote Check provides flexibility for the clinician to tailor assigned activities to meet an individual's needs and capabilities for self-assessment, with or without assistance from a carer. During the enrolment process, there are five tasks which can be selected by clinicians for recipients to complete during their check. Additionally, datalogging and processor diagnostics information is captured automatically during every Remote Check and is not a customisable option.

Remote Check includes the following activities:

Recipient-driven tasks

Implant photos allow the skin flap and incision site to be checked for irritation or inflammation.

An **aided audiogram test** measures thresholds across the speech frequency spectrum.

Speech-in-noise performance is assessed using a digit triplet test to determine speech recognition ability in adaptive background noise.

Questionnaires provide detailed patient feedback and include questions from the Speech, Spatial and Qualities of Hearing Scale (SSQ) self assessment tool (Noble et al., 2013; Galvin & Noble, 2013).

Data captured automatically

An **impedance check** assesses the performance of the implant electrodes.

Hardware health monitors and identifes microphone faults or processor errors.

Usage data captures information about daily device use and settings to support personalised counselling.

* For compatibility information please visit www.cochlear.com/compatability.

Clinicians can access and view the results obtained via myCochlear Professional (mCP) to evaluate the next best steps for recipient management. For some tasks, results requiring closer follow-up are visually highlighted for easy reference. Each newly enrolled recipient will be required to complete a baseline Remote Check assessment, the data from which can be used to compare with future results. The baseline Remote Check may be completed in the clinic or at home depending on the level of support required. Using the baseline and/or follow-up Remote Check results, the clinician can then determine the next actions for patient management. This may include scheduling a future remote check appointment, requesting an in-clinic visit, a combination of both, or providing a support call to a family member or carer.

Real world experience

An initial field evaluation of Remote Check in 2019* involving a small number of CI clinics in the UK, USA and New Zealand surveyed 50 clinicians and 46 CI recipients (Cochlear Limited 2020a and 2020b). A majority of the clinicians (81-84%) reported they were satisfied with using Remote Check, felt it provided clinically relevant information, was easy to use, and would be considered a valuable tool to consider for select integration into routine clinical care. Recipients using Remote Check for the first time reported the following: 80% found it was easy to use, 78% were satisfied using it, and 87% would use it again.

Following feedback from the initial field evaluation, an enhanced modular version of Remote Check was released in 2020.* In response to challenges facing implant centres during the COVID-19 pandemic, Remote Check was offered to all UK clinics from March 2020, to provide an alternative support pathway for patients using a Nucleus® 7 Sound Processor during enforced social distancing (i.e. as a low touch or no touch solution). As of the 1st March 2021, 12 clinics across the UK had enrolled over 750 recipients for a Remote Check. This evaluation has been subsequently expanded to more than 12 additional countries within Europe, Middle East and Africa and a further 16 countries globally, including Australia, New Zealand, Canada and the USA. Global enrolments of Remote Check recipients now exceed 2000.

As part of the UK field evaluation, clinicians were requested to complete a voluntary survey following each Remote Check appointment providing feedback on their learnings and experiences, as well as patient management decisions based on the data reviewed (Cochlear Limited 2021). A summary of the field experience reported by the UK NHS clinicians is provided in this paper.

Findings

Clinician reported experience with Remote Check

As at 1st March 2021, there were 101 survey responses submitted by UK clinicians from 75% (8/12) of the collaborating implant clinics (Cochlear Limited 2021). Remote Check (enabled within the Nucleus Smart App), was used across a broad age range of mostly adult CI recipients, although some school age and preschool children were also included with appropriate carer support.

The age ranges of enrolled Remote Check recipients is shown below.

Figure 1: Recipient age ranges (n=101)

Recipients were invited to complete a Remote Check by their clinician for a number of reasons and at different time intervals post implantation. In 85% of cases, the recipients had been implanted for more than 12 months at the time of enrollment, with the remaining 15% implanted for less than 12 months.

A summary of the reported reasons for requesting either an initial (baseline) or follow-up Remote Check, is shown in Figure 2. Overall, the most common reasons given for scheduling a check was as a substitute for a routine in-clinic visit or to baseline a recipient's performance, to review progress prior to scheduled appointments, to monitor newly implanted recipients, or to check hearing status following reprogramming or hardware exchanges.

* Cochlear obtained CE Mark approval for Remote Check (as part of the Nucleus Smart App) in October 2018, followed by U.S. Food and Drug Administration (FDA) approval in April 2020.

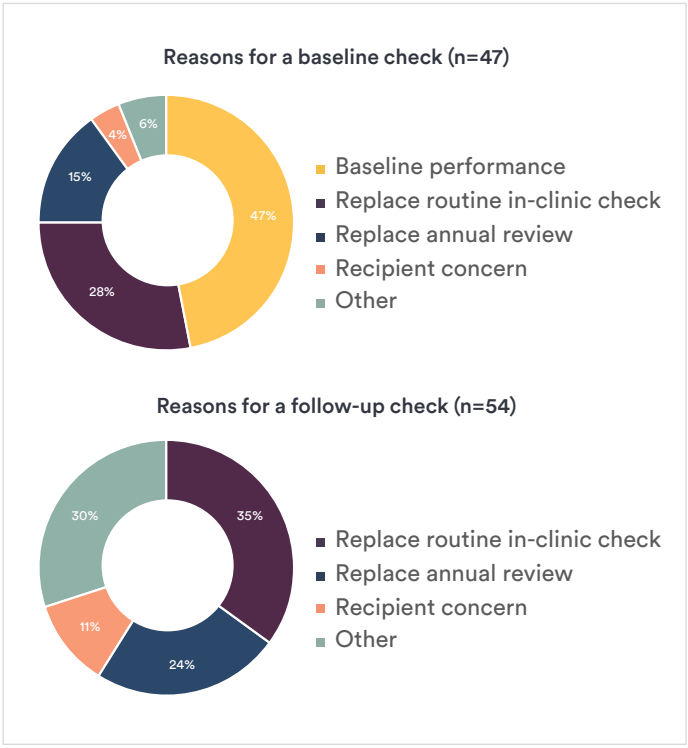


Figure 2: Clinician-reported reasons for Remote Check appointment

Clinicians assigned Remote Check tasks in a variety of ways for their recipients, in consideration of their individual hearing needs and capabilities for self-assessment. A breakdown of the selected tasks assigned by clinicians in the UK field evaluation is shown in Figure 3. Results show that all checks (100%) included a minimum of at least three of the five optional tasks, while for 83% of checks, clinicians assigned all available tasks to be completed.

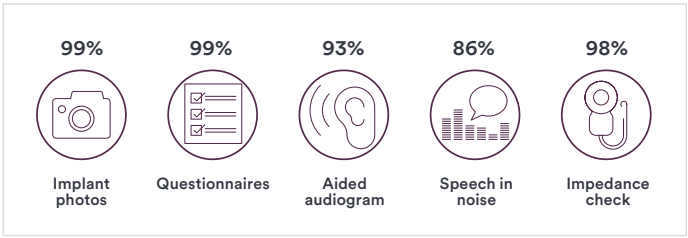


Figure 3: Percentage of Remote Checks assigned with each task

To support clinician review of check data, results are displayed on an interactive dashboard within myCochlear Professional. Review times of results obtained may also be influenced by the number of activities assigned for a check. During the UK field evaluation, clinician-reported review time of Remote Check data was captured for 96 checks.

Figure 4: Average time taken to review a Remote Check

Figure 4 shows the average time for reviewing check data was 13.5 minutes for unilateral checks and 17.5 minutes for bilateral checks. In the case of bilateral recipients, some Remote Check activities (such as photos, aided thresholds, and speech in noise), are administered and reported for each ear individually, which may lengthen the review time of results.

On completion of a Remote Check review, clinicians finalise the check and advise the recipient of the outcome including any required follow-up. Remote Check outcomes and resulting clinician actions are shown in Figure 5.

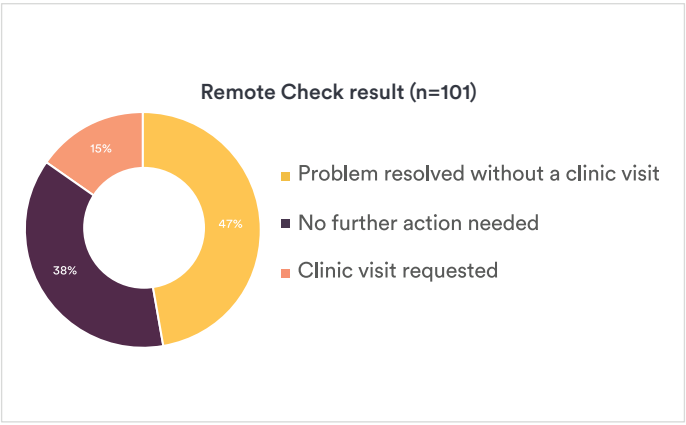


Figure 5: Clinician action following review of Remote Check

In total, 85% of completed checks did not require a follow-up in-clinic visit. Of these, clinicians identified a problem with 47% of checks which was successfully resolved remotely without bringing the recipient back to the clinic (e.g. hearing rehabilitation suggestions or equipment exchanges). For the remaining 38% of these checks, clinicians identified no issues and deemed no further action was required.

During this UK field evaluation, 15% of completed checks had an outcome resulting in a clinician request for an in-clinic visit. Clinicians were asked which Remote Check task/s acted as the trigger for the recall decision and responses are summarised below (results on more than one task may have triggered a clinic visit request):

- In 93% cases (14/15), it was a response to the Remote Check questionnaires.
- In 60% cases (9/15), it was a comment from the recipient captured in the messaging field.
- In 33% cases (5/15), it was the aided audiogram or other test results.

Summary

The demand for health care services is rapidly rising. Recent advances in CI smartphone connectivity and wireless streaming technology, together with other advances in digital health self-care, continue to transform the delivery of medical services and patient management globally. Cochlear's Remote Check solution ensures CI recipients have the option to benefit from these ongoing advances as a complement to traditional clinic based care.

Early experience with Remote Check in the Nucleus Smart App has indicated it is a clinically effective telehealth tool. Remote Check enables clinical care by enabling monitoring and evaluation of CI recipients' hearing performance and device function in the comfort of their home. Remote Check has proved to be a useful tool for monitoring of both long-term and newly implanted recipients in between or as a substitute for in-clinic visits. Clinicians reported that most recipients surveyed in the field evaluation could successfully self-administer Remote Check on their own or with the support of a family member or carer.

The modular, customisable design of Remote Check enables clinicians to tailor assessments based on the recipient's needs across all ages, to better support patient management decisions and efficient triage. Clinician time spent reviewing check results averaged under 20 minutes including those for bilateral recipients. Only 15% of Remote Checks identified issues which necessitated a clinic visit to resolve.

Further real-world experience with Remote Check will permit refinement of clinical guidelines to support adoption and integration into routine clinical care for CI recipients. As part of telehealth practices, use of Remote Check may relieve some pressure on clinical resources resulting from unnecessary clinic visits, with the potential to provide greater convenience for patients such as reduced travel time and costs.

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