Telemedicine for people with cochlear implants in the UK: empowering patients to manage their own hearing healthcare

Short title: CHOICE - cochlear implant home care

Protocol version 1.9

Previous versions:

1.1	15 June 2018	Submitted to University of Southampton Research Integrity and Governance team for review
1.2	11 October 2018	Approved by IRAS and HRA
1.3	5 June 2019	updated to reflect no cost extension – only change is dates
1.4	24 September 2019	Wales site removed. They withdrew 16/9/19 due to local capacity issues
1.5	21 October 2019	Clarified evaluation use of Dictaphone and storage of consents, removed previous Project Manager name
1.6	26 March 2020	COVID-19 modification. Included all UK adult CI centres.
1.7	11 June 2020	COVID-19 modification. Added Sheffield Hearing Implant Programme
1.8	15 September 2020	Updated to include participants aged 16 and 17 years old in addition to the existing 18 years and over
1.9	17 December 2020	Removed all reference to hearing check

A.1 Research reference numbers

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A.2 **SIGNATURE PAGE**

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the project in compliance with the approved protocol and will adhere to all regulatory requirements.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the project publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the project will be given; and that any discrepancies and serious breaches of GCP from the project as planned in this protocol will be explained.

For and on behalf of the Sponsor:
Signature:
..... Date: ...../...../.....
Name (please print):
.....
Position: .....

Chief Investigator: 
Signature: .....Date: ..11..../..08..../..2020....
Name: (please print):
.....Helen Cullington.....

A.3 KEY PROJECT CONTACTS

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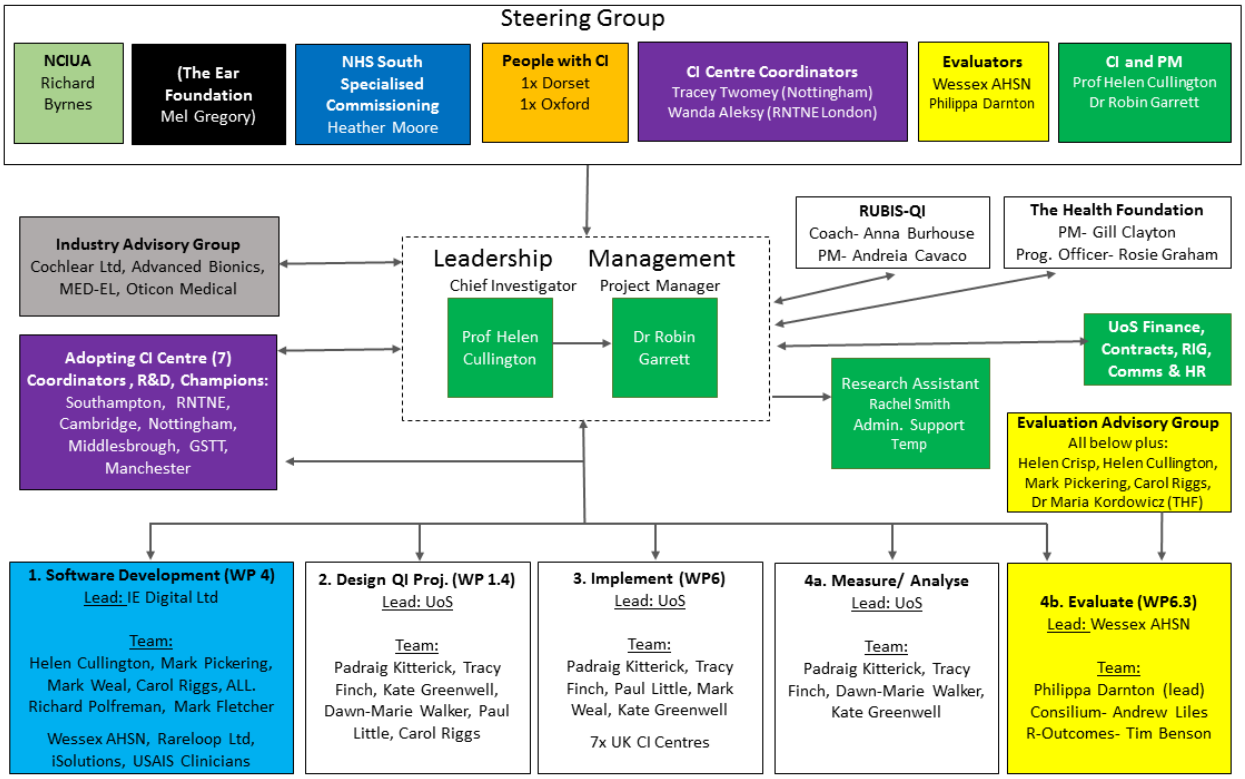
B. ROLES AND RESPONSIBILITIES OF PROJECT MANAGEMENT COMMITTEES AND GROUPS

B.1 Project Organogram:



B.2 Steering Group:

The CHOICE project is primarily guided by a Steering Group (SG) including representatives of all key UK stakeholders. The SG meets on a 4 monthly frequency across the 30 month project at the University of Southampton Auditory Implant Service. It comprises the CHOICE Chief Investigator (CI) and Project Manager (PM), two service users (patients), coordinators of two other cochlear implant centres, the lead of the independent evaluation team, and senior representatives of NHS Specialist Commissioning, The Ear Foundation and the National Cochlear Implant Users Association (NCIUA). The purpose of the Steering Group is to advise and guide the CHOICE Leadership Team by reflecting differing stakeholder needs to maximise the success and ensure long term sustainability of the project. The SG acts as sounding

board to the project, particularly in relation to key project risks (including: time, cost, quality, commercial, legal and ethical). The SG also deals with safety monitoring, adverse events, data monitoring, and deviations and breaches of protocol and major changes in the project. The CI remains the project Executive and the final decision maker. The Project is reportable financially to the project funder- The Health Foundation, however the SG may be asked to advise on significant matters. The PM will provide a board level update to the SG at each meeting. The meeting chair will rotate and will not include either the CI or PM.

B.3 Evaluation Advisory Group:

The Evaluation Advisory Group (EAG) is a requirement of the project funder and the scope of its remit is specifically in relation to the independent evaluation of the CHOICE Quality Improvement Programme. The EAG meets on a quarterly frequency at Chilworth Science Park hosted and convened by Wessex AHSN as the independent evaluator. It is comprised of the Wessex AHSN's Director of Insight (chair), Associate Director of Insight (evaluation lead), Programme Manager, Data Analyst; at least one member of the CHOICE Leadership Team (CI or PM); a Strategic Advisor from Consilium Partners Ltd; the Director of R-Outcomes Ltd; the RUBIS.Qi Evaluation Lead (coaching organisation provided by the funder) and a service user (patient). The CI or PM will update the EAG on the progress of the project in order that it can monitor and mitigate risks to the delivery of the evaluation. It also facilitates a regular interaction with the CHOICE Leadership Team without compromising the independence of the evaluation. The CHOICE Leadership Team do not take decisions on the evaluation but collaborate and provide input as required. The EAG also provides a forum to reflect on the findings of evaluation during the course of the project and enable improvements in the scaling up of CHOICE via this formative learning.

B.4 Industry Advisory Group:

The Industry Advisory Group (IAG) has been formed to ensure two way dialogue with the device manufacturers of cochlear implants is maintained throughout the project. This stakeholder group is purposefully separate from the SG in order that CHOICE continues its ethos of being patient centric, charity funded and agnostic of individual industry parties. The IAG meets on a 6 monthly frequency at the University of Southampton Auditory Implant Service. It comprises the CI and PM (chair) and one representative from each of the major UK (also global) cochlear implant Companies: Advanced Bionics UK Ltd, Cochlear Europe Ltd, MED-EL UK Ltd and Oticon Medical Ltd. This meeting (as with the SG)

is undertaken under Non-Disclosure Agreement between University of Southampton and the four other parties and compliance with competition law is ensured.

B.5 Leadership/Management Team:

The Leadership/Management Team (LMT) take overall responsibility for the CHOICE project and connects the Steering Group, Evaluation Advisory Group and Industry Advisory Group bringing this input to bear on all aspects of the project. The LMT meets on a weekly basis to discuss the day to day management of the project as well as more significant matters requiring attention. It comprises the CHOICE CI Dr Helen Cullington and the CHOICE PM. Broadly the LMT roles are allocated as follows, with both contributing to the roles of the other. The CI is the Project Executive with ultimate responsibility for project and leads particularly on matters of a clinical and ethical nature, vision, ethos and study design. The PM is responsible to the CI for project delivery in line with their vision and leads particularly on matters of scheduling, finance, contracts, commercialisation, managing the team and contractors, and meetings. The CI and PM share responsibilities around Intellectual Property, compliance with the funder/ethical requirements and managing project risks, with the CI holding overall responsibility. The LMT also engage with the array of charity, industry, clinical and public stakeholders.

B.6 CHOICE Team:

CONTENTS

C. ABSTRACT

Introduction

Cochlear implants provide hearing to around 600,000 people with deafness worldwide; they require lifelong follow-up. Care in the UK occurs at one of 18 centres, which may be far from the patient's home. In a previous RCT funded by the Health Foundation, we successfully introduced person-centred care. We designed, implemented and evaluated a remote care pathway: a personalised online support tool, home hearing check, self device adjustment, and upgrading of sound processors at home rather than in clinic.

The remote care group had a significant increase in empowerment after using the tools; patients and clinicians were keen to continue. We would now like to scale up these improvements as a choice to the more than 9,000 UK patients aged 16 and over using implants; we will provide an evaluation of this intervention and roll out to establish if it achieves its aims. This is a unique opportunity to scale up and offer a successful intervention to all people with a condition across the nation. We would like to generate and share evidence and learning, both within the field of deafness and beyond.

Expected improvements:

- more empowered and confident patients
- more accessible and equitable care
- more efficient, person-centred and scalable service
- more satisfied and engaged patients and clinicians

Methods and analysis

This project will scale up and evaluate a person-centred long-term follow-up pathway for people using cochlear implants incorporating a personalised webapp, self-adjustment of device, and home sound processor upgrades.

D. INTRODUCTION

Cochlear implants are the most successful of all neural prostheses (Wilson & Dorman, 2008); they can provide hearing to people with severe to profound deafness. Approximately 1,200 people receive a cochlear implant in the United Kingdom (UK) each year (BCIG, 2015). The total number of people with implants is approximately 14,000 in the UK and 600,000 worldwide (Ear Foundation, 2016). Numbers are likely to increase rapidly: only approximately 5% of eligible people in the UK have received an implant (Ear Foundation, 2016), and the number of people of retirement age is projected to increase by 28% by 2035 (Office for National Statistics, 2011) meaning a further increase in the number of people with hearing impairment. Cochlear implant care in the UK is provided at one of 18 tertiary centres involving assessment, surgery, and a resource-intensive acute phase of device adjustment and rehabilitation. These centres may be several hours away from the patient's home necessitating travel expense, time off work or school and family disruption. Currently UK implant centres review patients on a clinic-led schedule; this means that review appointments that provide little benefit to the patient can occur. Conversely, when some patients attend a routine appointment, there is hearing deterioration which the patient had not noticed. This is often remedied by replacing equipment that the patient could have done at home. Making this care pathway patient-centred instead may provide a more efficient and effective service and allow more timely identification of issues.

When a patient attends a long-term follow-up appointment, the following tasks may be done: speech recognition testing, device adjustment, rehabilitation, equipment check and troubleshooting, and provision of replacement or upgraded equipment. Results of our previous Randomised Controlled Trial suggested that some of these tasks can be done by the patient themselves at home and enabling patients to do so increases their empowerment (Cullington, Kitterick, Weal, & Margol-Gromada, 2018). People using cochlear implants could therefore only attend the clinic when there is clinical need (no more routine appointments). Potential benefits for the patient are:

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- better hearing (ability to fine tune when away from clinic)
- convenience of not travelling to routine appointments
- reduction of travel cost and time, time off work/school and disruption to family life
- increased confidence to manage own hearing
- greater equality in service delivery (same level of service regardless of distance from clinic)

It may also mean that the clinic has greater resources (time, money, space) to see patients with more complex needs and the expanding population of new patients. People using cochlear implants and their

families would generally like to take a more active role in their care and welcome the use of technology to assist self-care.(Cullington, 2013; Tsay, 2013) The NHS has a strong commitment to supporting self-care for people with long-term conditions (NHS, 2014) with 'the vision of a citizen-centred, digitally-enabled, health and social care system' (National Information Board, 2015). Evidence shows a significant improvement in outcomes when patients use self-management tools (Panagioti et al., 2014) and those who are activated and involved in their care tend to have better health outcomes (Hibbard, Greene, Shi, Mittler, & Scanlon, 2015; Mosen et al., 2007).

We ran a 6 month clinical trial with 60 people randomised to either the remote care pathway or a control group who followed their usual appointment schedule (Cullington et al., 2016). The main outcome evaluated was patient empowerment; this has been shown to be strongly linked to better outcomes in people with long-term conditions. We found that only the remote care group had a significant increase in their cochlear implant empowerment after using the remote care tools (Cullington et al., 2018). Quality of life remained unchanged in the two groups. The hearing check result in clinic had improved in the remote care group, although they had not noticed a change. The control group, however, felt their hearing had become slightly worse. This may suggest that the remote care group were more able to take action to keep their hearing stable during the trial, or perhaps that the control group felt they were missing out on a desirable opportunity to take a more active role in their hearing healthcare.

D.1 The standard clinical care pathway

D.1.1 Speech recognition testing

The main speech recognition measure used in UK clinics is Bamford-Kowal-Bench (BKB) sentences (Bench, Kowal, & Bamford, 1979) in quiet and noise; these are usually performed in a sound-treated room in the clinic by experienced clinicians, although there are some reports of testing remotely using an assistant at a remote location and video conferencing facilities (Goehring et al., 2012; Hughes et al., 2012). Speech perception in noise testing using spoken digits (e.g. 'one') has been developed (Smits, Kapteyn, & Houtgast, 2004); digits are highly familiar stimuli and are usually known by people with even limited language skills. Digit testing requires a closed set response and thus is suitable for self-testing over the telephone or internet (Smits & Houtgast, 2005; Smits, Merkus, & Houtgast, 2006) and has a minimal learning effect (Smits, Theo Goverts, & Festen, 2013). The test correlates well with speech recognition in noise with sentences in people using cochlear implants (Agyemang-Prempeh, 2012; Aidi, 2015; Kaandorp, Smits, Merkus, Goverts, & Festen, 2015; Mahafzah, 2013). A digit test in English is

freely available online at the Action on Hearing Loss website (Action on Hearing Loss, 2015) and also as an application for mobile devices (Action on Hearing Loss Hearing Check).

D.1.2 Device adjustment

In order to provide benefit to a hearing-impaired person, the levels of electrical stimulation need to be individually adjusted for both soft and loud sounds on up to 22 electrode contacts in the cochlea. The levels can change as the person using a cochlear implant becomes more accustomed to listening, more experienced at doing the task and as physiological changes occur. Most cochlear implant centres offer frequent appointments in the first few months following implantation and annual adjustment appointments thereafter (Vaerenberg et al., 2014). Device adjustment usually occurs in the clinic in a sound-treated room, led by an experienced clinician. Several centres are now offering remote device programming (Eikelboom, Jayakody, Swanepoel, Chang, & Atlas, 2014; Hughes et al., 2012; Kuzovkov et al., 2014; McElveen et al., 2010; Ramos et al., 2009; Rodriguez et al., 2010; Samuel, Goffi-Gomez, Bittencourt, Tsuji, & Brito, 2014; Wasowski et al., 2010; Wesarg et al., 2010). However, these reports continue to use a clinician-centred model involving the patient attending a centre closer to their home where an assistant is present, and the cochlear implant centre clinician leading the session using video conferencing and remote desktop connection.

People using cochlear implants have commented that they would like to be able to adjust their device parameters in their own home or work environment, rather than just in the sound-treated clinic room (Cullington, 2013). The company Cochlear® have introduced a self-fitting paradigm (Remote Assistant Fitting) using the speech processor remote control that patients already have. This allows adjustment of programming to be done by the patient at any time and anywhere with equivalent hearing outcomes to audiologist-led sessions (Botros, Banna, & Maruthurkkara, 2013).

D.1.3 Rehabilitation

Many clinical resources are devoted to rehabilitation after people receive a cochlear implant; the new sound can be difficult to get used to. Rehabilitation appointments are frequent in the first year and may be offered annually thereafter (Muller & Raine, 2013). Computer-based auditory training completed by the patient at home can significantly improve their speech recognition (Fu, Galvin, Wang, & Nogaki, 2004) but is not offered and supported widely in the UK as part of routine rehabilitation.

D.1.4 Equipment troubleshooting/repairs/spares provision/upgrades

Cochlear implant speech processors are complex; some parts need regular replacement in order to keep the device in optimum condition (Cochlear.com, accessed 01/03/2016). No reminder is given on the device. Many NHS cochlear implant centres offer an upgraded speech processor approximately every 5 years, requiring a clinic visit (Muller & Raine, 2013).

D.2 The new care pathway choice

This project introduces a new care pathway choice to patients aged 16 and over using cochlear implants: cochlear implant home care. The patients choosing this pathway will be given access to the new personalized CHOICE webapp.

Clinicians at each participating cochlear implant centre will be encouraged and supported to provide:

- Self-mapping (if appropriate)
- Upgraded sound processor at home

The patient's own clinician at their cochlear implant centre will have access to their results and activity in the CHOICE app including alerting when results fall outside specified tolerances, or when the patient has not interacted with the tools for 3 months. Cochlear implant centre clinic appointments will be given if required, requested or indicated by the outputs of the remote care tools. Otherwise the patients on this pathway will continue with home care. Participants may access the tools as often as they wish and can use them wherever they wish (at home, at a friend's house, at the library etc.).

We are rolling out this care pathway initially to 8 of the 18 cochlear implant centres in the UK. We are commissioning Wessex Academic Health Science Network (Wessex AHSN) to perform an independent evaluation of the roll out. The initial adopting centres will commit to comply with the evaluation.

D.2.1 Personalised CHOICE webapp

IE Digital have built a personalised scalable responsive webapp based on our previously-trialled CIRCA (Cochlear Implant Remote Care) website (built in LifeGuide (Yardley et al., 2009). It incorporates personalised reminders (e.g. change microphone cover), rehabilitation exercises (listening in noise and music and telephone practice), uploading a photo of cochlear implant surgery site (behind the ear) for review by their clinical care team, information and training, logging how many hours they use their device if they want to (self-reported only), evaluation measures, stock ordering, emotional support resources, and questionnaires. The patient will sign up for the app using their email address and NHS number. They will consent for data to be shared with the relevant parties (see Figure 1: Data flow diagram for CHOICE app).

Clinicians at each cochlear implant centre have a dashboard to view their own patients' results and interactions with the tools. There are alerts when results or interactions fall outside specified tolerances.

Automated flagging will be the cornerstone of the remote care pathway. This will ensure that patient problems are not missed and will provide most efficient use of clinician time. Some flagging situations are:

- if patients haven't interacted with the app at all for 3 months
- patients who indicate that they need help on their long-term questionnaire
- each time a photo is uploaded, clinicians will need to review it
- patients requiring replacement stock items
- a patient reporting on the long-term questionnaire that they are using their sound processor for less hours than they used to
- a patient requesting to leave the remote care pathway

Extensive within CHOICE Southampton team validation has verified the flagging process.
Patients will be responsible for entering their own personal data; if NHS number does not match a patient in their centre, a centre clinician can query it with the patient. We will have access to the app to amend any information that becomes out of date. If a patient changes email address (their login), they will contact us (UoS) to amend this information (right to rectification). Other info (sound processor make and model, mobile phone number for reminders) – they will be able to amend themselves. We have access to an admin portal of the CHOICE app – from this we can download all results and verify flagging scenarios.

Careful monitoring and reporting of patient activity is recommended by the national standard (BCIG, 2018). This webapp therefore has the capacity to improve clinical care without requiring any additional clinical resource.

Patients will receive reminders (in the app and by email or text message) to perform routine equipment maintenance (e.g. change microphone cover), complete any questionnaires required for their clinical care or the evaluation, and if new features of the app become available.

D.2.2 Self-mapping

The ability to self-adjust the programming parameters of one's own cochlear implant is currently only available for some cochlear implant devices. Clinicians at participating cochlear implant centres will be encouraged to offer this choice to their patients. It has been shown that patients can use self-mapping appropriately, gaining improvements in their perceived sound quality without compromising auditory performance (Vroegop, Dingemanse, van der Schroeff, Metselaar, & Goedegebure, 2017).

D.2.3 Upgraded processor sent to home

When patients are eligible for upgraded sound processors, they can be offered the choice to have the new processor sent to them at home with their own settings pre-loaded. They could then attend for a review in 4 weeks (and return the old processor) when they have had a chance to find out what they like or don't like, and what they need help with. We feel patients would be under less pressure and would feel less anxious because they can try the new processor before having to hand back the old processor. Clinicians at participating centres will be encouraged to offer this choice where appropriate.

E. METHODS AND ANALYSIS

E.1 Project design

This is a Quality Improvement (QI) project to roll out and evaluate a new person-centred clinical care pathway. We will be evaluating this rollout until the end of January 2021 to establish if it meets its aims. If successful, we hope this will become a standard clinical care pathway option.

This project comprises two phases which will run concurrently:

- Rolling out the new care pathway
- Evaluating the new care pathway

E.2 Setting and participants

The project is led by University of Southampton Auditory Implant Service (USAIS): a tertiary treatment centre mostly funded by NHS referrals. Other stakeholders are:

- Patients (people using cochlear implants in the UK)
- Clinicians at UK cochlear implant centres
- University of Southampton collaborators
- University of Nottingham (collaborator)
- Northumbria University (collaborator)
- Wessex Academic Health Science Network (evaluation partner)
- The Health Foundation (funder)
- IE Digital (designer of web app)
- The Ear Foundation (charity)
- National Cochlear Implant Users Association (national patient group)
- RealSpeech creators (listening in noise task)
- Creators of EQ-5D (questionnaire)
- NHS England (providing licence of PAM questionnaire)

E.3 Proposed sample size

CHOICE may be offered at the following centres:

1. St Thomas' Hospital Hearing Implant Centre
2. University of Southampton Auditory Implant Service
3. Royal National Throat Nose and Ear Hospital
4. Nottingham Auditory Implant Programme
5. North East Regional Cochlear Implant Programme
6. The Richard Ramsden Centre for Hearing Implants, Manchester
7. Emmeline Centre, Cambridge
8. South Wales Cochlear Implant Programme, Bridgend
9. Auditory Implant Centre, Belfast
10. The Midlands Hearing Implant Programme
11. The Oxford Cochlear Implant Programme
12. St George's Hospital Auditory Implant Service
13. Yorkshire Auditory Implant Service
14. Cardiff Adult Cochlear Implant Programme
15. North Wales Cochlear Implant Programme
16. Portland Hospital Cochlear Implant Programme
17. West of England Hearing Implant Programme
18. Scottish Cochlear Implant Programme
19. Sheffield Hearing Implant Programme

We do not yet know what proportion of patients will choose to follow this pathway, as the previous work was a single-centre Randomised Controlled Trial that involved a limited number of patients. If we assume eight centres offer a remote care pathway, we may roughly assume that these centres care for approximately half of the approximately 11,000 adults with cochlear implants in the UK. If we estimate that 40% of patients enrol for a home care pathway, this may involve around 2200 patients. Due to increased demand from centres due to Covid-19, we have been asked if persons aged 16-17 may also use CHOICE; we estimate 100 of this age group may enroll. If eight centres participate, we may assume

approx ten members of staff per site are involved so 80 clinicians at cochlear implant centres. As a mixed methods approach will be taken by the independent evaluation team to assess the impact and success of the care pathway on changing services, clinicians and patients, and the aim of the project is not to formally test a hypothesis, a sample size calculation has not been conducted.

E.4 Rolling out the new care pathway

E.4.1 Who decides who should be on the remote care pathway?

We recommend shared decision making. This means that the patient and their families, and the clinician will jointly decide (Elwyn et al., 2012). Shared decision making has 3 steps:

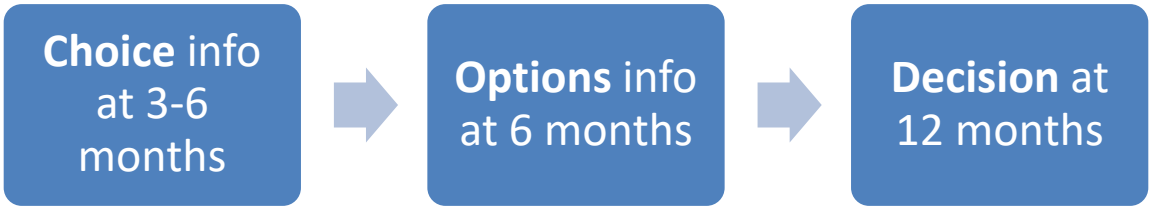
1. Introduce choice
2. Describing options
3. Helping patient explore preference and make decision

E.4.2 How is the care pathway decision made?

The patient and clinician will establish together which pathway is most appropriate. The clinician will not make assumptions about the patient's abilities and motivations; there will be an open discussion taking into account the patient's care needs, routine maintenance of equipment and access to technology. Support will be matched to the patient's needs (Coulter, Roberts, & Dixon, 2013). It may be helpful for the patient and clinician to together also consider the patient's mobility, literacy, dexterity, any comorbidities e.g. visual impairment and other factors such as do they live alone, do they have transport etc. Training of local project teams will include guidance on issues to consider.

E.4.3 When is the decision made?

Patients need time to consider and discuss with others outside the clinic if and when they might be ready to opt for remote care. We recommend the following as a guideline although of course this will be very personal to the patient and the clinician will make a case by case decision. These time intervals represent the earliest point that we recommend; clinicians and patients may choose any appropriate time point:



Choice: tell patients there is a choice in care

Options: at 6 months post-implantation onwards– going through the options with the patient, eliciting what they already know and giving them high quality information to enable them to make an informed choice

Decision: jointly making the decision about which care path is best and making it clear that this can be changed at any time if needed. This is likely to be done some time after the choice and options talk so that the patient has time to consider their options and talk it through with their family/carers (e.g. at 12 months but can be later)

E.4.4 Risks of new care pathway

Risk to whom	Nature of risk	Mitigation
Patient	Lost to follow-up. Patient does not attend centre again but does not engage with remote care tools either.	The webapp will flag patients who do not interact with the tools for at least 3 months. These can then be followed up and moved to a clinic-based pathway if needed.
Patient	Missed medical issue	The webapp will direct the patient to their own clinical care centre for information about ear infections and other medical

		issues. A questionnaire asks questions about implant comfort, and implant site health. There will also be the ability to upload a photo of the implant site which the clinician will need to review.
Patient and clinic	Data protection breach	We have performed a Data Protection Impact Assessment (DPIA) of the CHOICE app, and have appropriate measures in place
Clinic	Patients interact with and attend clinic more (difficulty with remote tools, concern with remote tools results, more empowered and therefore wanting more support)	This will be monitored by the evaluation. It is possible that it may occur initially and then settle down.
Patients and staff	Potential for participants to feel discomfort, distress, intrusion or inconvenience from being asked about their experience of using the new care pathway. Not experienced in previous evaluations using the same methods but evaluators aware of this potential.	Participant information makes it clear to participants that they may withdraw from the intervention and project at any time without giving a reason. Interviews will be conducted by a highly experienced qualitative researcher from Wessex AHSN. All interviews will be arranged to accommodate participants' preferences as far as possible within the evaluation schedule.

E.4.5 How does a patient change pathway?

Patients' circumstances and abilities change. We recommend service delivery flexibility, with easy transfer to a clinic-based care model. Minimal or no interactions with the webapp may indicate to clinicians that a patient is having difficulties using them and contact may be required. We anticipate a cycle of self-care: self-care can be exited at any point to trigger a clinic visit (Figure 2). Certain outcomes will trigger a clinic visit.

We recommend that centres use an Individual Care Plan (ICP) to document which care pathway patients are on; this complies with the national quality standard (BCIG, 2018). We recommend that at each contact with the patient, a reminder of the flexibility of care pathways will be given; the patient will be encouraged to let the centre know if their circumstances change. Centre clinicians can inform the patient's GP about the Individual Care Plan and also encourage them to let the centre know if the patient's circumstances change.

E.4.6 Medical matters

It is vital that patients remain vigilant to prevent medical issues related to their cochlear implant. This mainly involves appropriate action with ear infections (following the centre's protocol) and checking the site of the implant and skin under the coil magnet. The patient will be advised to contact their centre with any medical concerns.

E.4.6.1 Implant site photo

The webapp has the functionality to upload and store photos of the patient's implant site (behind their ear). We recommend the baseline photo being taken at an early stage to provide comparison for later images.

The following guidance is given to the patient:

- Several photos should be taken from different angles, including the skin under the coil and the incision behind the ear
- One photo should be included with the coil in place, so it is clear exactly where the coil sits
- Hair should be parted around the implant site, perhaps with clips
- It is very difficult to take the photos oneself – a friend, relative or other person needs to be involved

- For data protection reasons, patients will be advised not to upload photos showing a face (the tool will include a cropping tool so the patient can crop out their face) although photographs will only be seen by members of their clinical care team

The CHOICE app advises the patient to contact their clinical care centre for other medical matters.

E.4.7 Change management

Research on telehealth implementation remains in its infancy (Davies & Newman, 2010), however a few studies have identified a number of barriers to successful implementation. These include frontline staff acceptance of new technologies (Brewster, Mountain, Wessels, Kelly, & Hawley, 2014), the implementation process (Mair et al., 2002), the need for stakeholder buy-in (Forducey, Glueckauf, Bergquist, Maheu, & Yutsis, 2012) and additional workload (Sharma, Barnett, & Clarke, 2010). We recognise that change is difficult for all stakeholders. In order to ease the change, we will ensure all stakeholders are fully informed at all stages. Our aim is to put in place conditions which will maximise the chance of success, recognising change from a more processual perspective (Pettigrew, Ferlie, & McKee, 1992). A large part of this will be provision of information at all stages to all stakeholders. An example of a concern is that audiologists may feel that they will be seeing less patients and thus may not meet the minimum requirements in order to maintain their skill set (BCIG, 2018). We can reassure people that they will still be seeing all patients up until at least the 12 month interval, and many more beyond. In addition, care for children is currently unchanged.

E.4.8 Training

E.4.8.1 Patients

Patients may need to receive training in remote care e.g. how to do the Triple Digit Test. Those patients not yet at the 12 month interval can receive help and information during their clinic visits. The CHOICE user manual will include detailed instructions, but the app has been designed to be simple and self explanatory.

There is a large group of patients in the UK who are already past the 12 month interval and may not be attending the clinic for a while. Each centre can choose how to offer the new care pathway choice to these patients. One suggestion is a 1 hour group information and training session, plus the user manual.

E.4.8.2 Clinicians

Once the new tools are ready for roll out, the project team will offer virtual training using a webinar, and also site visits if necessary. We want clinicians to feel confident to offer remote care as a pathway choice.

E.4.9 Patient inclusion criteria

- Person using cochlear implant (any device, unilateral or bilateral)
- Living in the UK
- Aged 16 years or more
- Able to give informed consent to data sharing
- Access to a computer or device with internet access
- Willing and able to comply with a cochlear implant home care pathway
- Willing and able to comply with the pathway evaluation

E.4.10 Patient exclusion criteria

- Those that do not fulfil the inclusion criteria plus any medical condition or known disability that would limit their capacity to use the remote care tools or to consent

E.4.11 Health professional inclusion criteria

- Staff at participating cochlear implant centre

E.5 Outcome measures and evaluation

We have evidence of the efficacy of these remote care tools in a small number of research participants (Cullington et al., 2018). Now we are rolling out the tools to a much wider population through many different clinical care centres, we would like to monitor that the tools produce the desired effect in more real world situations.

Our outcome measures set out to explore if a remote care pathway choice provides the following:

- more empowered and confident patients
- more accessible and equitable care

- more efficient, person-centred and scalable service
- more satisfied and engaged patients and clinicians

We have commissioned an independent evaluation from Wessex Academic Health Science Network (Wessex AHSN). The evaluation will seek to understand the extent to which the programme has been rolled out, the impact of the new pathway on users (staff and people using the care programme) and the factors which enable or hinder the roll out of the programme. It will employ a range of evaluation methods to do this, including the analysis of quantitative data and qualitative data collected from multiple sources over the course of the evaluation. The evaluation will draw conclusions at the end of the study. Interim findings will also be shared with the investigators during the course of the rollout to inform the quality improvement approach that is adopted at each site. The learning from this study will be used to inform further rollout and the sustainability of the new pathway of care.

Our research team will also measure the intended effects of the care pathway on the patients', empowerment, and quality of life that were identified by the previous RCT.

The participant will enter the following information on enrolment to the app:

- email address (this is for the login and to receive project information)
- NHS number (to ensure correct patient identification – this is the minimum data that will uniquely identify them)
- main sound processor(s)
- own cochlear implant centre (e.g. Manchester, Southampton etc.)
- date microphone cover and other equipment parts were changed (if appropriate)
- age in 10 year band
- gender
- highest qualification achieved (based on categories used in the Office for National Statistics 2011 census)
- month and year of first cochlear implant surgery
- postcode (last letter will not be saved)
- mobile phone number (optional, to receive reminders)

E.5.1 Primary questions

Evaluation team: What is the impact of the roll out of the new care pathway on users of the programme (staff and people with cochlear implants)?
Research team: Does the new care pathway increase empowerment for people with cochlear implants while having no detrimental effect on their quality of life?

E.5.2 Secondary Questions

1) What is the extent of spread of the new care pathway?
    a) What has facilitated adoption of the new care pathway?
    b) What has hindered adoption of the new care pathway?
2) Does the new care model improve patients' confidence to self-manage their cochlear implant as measured by patient-reported outcomes of health confidence, health status and personal wellbeing?
    a) Do patients initiate review appointments with the service rather than rely on or wait for appointments scheduled by the service?
3) Does the new care model improve patients' experience of follow up care?
    a) Do patients engage with the technology as measured by patient reported outcomes of digital confidence and perceived value of the tool?
4) Does the new care model improve equity of access to follow up care?
5) Does the new model of care improve the experience of staff working in the service as measured by staff reported outcomes of job confidence and work wellbeing.
    a) Do staff have confidence in the new care model as measured by staff reported outcomes of digital confidence and perceived value of the tool?
    b) Do they recommend it?
6) Does the new care model improve use of resources through reducing the need for follow up appointments and enabling the service to be delivered by a different skill mix?
7) What lessons can be learned from the implementation process that will benefit spread and adoption of this model?

E.5.3 Evaluation design

The design of the evaluation is derived from the evaluation questions and the programme logic model (Figure 3). Early findings will be fed back to the Steering Group and investigators to enable any changes

to the quality improvement approach that will facilitate the rollout. The evaluation programme is made up of the elements described below. These do not sit alone and much of the work will follow a combined or mixed methods approach to triangulate the findings. In particular, triangulation of quantitative and qualitative data will enable us to answer important questions relating to how the technology is adopted and used, and its impact on equity of access to post-implantation care.

E.5.3.1 Qualitative evaluation

The qualitative analysis is central to this evaluation. It will capture the views of patients, staff and stakeholders by investigating how the new model actually works, its feasibility and acceptability – and will include review work with individuals and groups. The design of the qualitative evaluation responds to the outcomes and impacts described in the logic model related to desired changes in knowledge, awareness and attitude and changes in behaviour of those involved. The qualitative fieldwork will be undertaken at a single site visit to each participating site. Each visit will take place over two days, comprising one focus group with staff, one focus group with patients, and face to face patient interviews (for those who are unable to attend the focus group or who would prefer an individual interview).

Patient participation: The primary method will be focus groups. However, if patients are unable to attend the focus group or would prefer a one to one interview, these will be offered. A purposeful and consecutive sample of patients for focus groups or interview will be obtained by asking staff / key contact at the site to invite experienced patients to participate until the desired number - up to 20 patients per site – is obtained. Undertaking a purposeful sample ensures we recruit patients who have had experience with the intervention, are motivated to feedback their experience, and able to attend a focus group. A random sample would be no guarantee of achieving this situation and the success of the focus group. Staff / key contact at the site will be supported by the research team to obtain a representative / characteristically appropriate sample for the focus group by considering demographics, clinical characteristics, and motivation of potential patients. The structure of the focus group discussion and the patient interview questions will be derived from the logic model and evaluation questions.

Staff participation: The primary method will be focus groups. However, if staff are unable to attend the focus group, a telephone interview will be scheduled at a separate time. It is expected that up to 10 staff per site will be involved in either the focus group or interviews. This component of the evaluation will

help to deepen understanding of the emerging issues around implementation, including enablers and barriers.

Case studies will be collected by staff at each site (around 10 per site) to further inform the experience of service users. Staff would be asked to describe a case study of someone they have worked with using a simple template – Appendix 1. They would not include any personal details and it would not be shared in the evaluation report, other than to use anonymous quotes. We will analyse them for themes, which often corroborate other themes that emerge from interviews or focus groups.

The above measures will occur after introduction of the remote care tool as the qualitative work will discuss its impact and any barriers to roll out. Wessex AHSN will schedule the visits with the sites to align with their implementation timescales, and will provide as much advance notice as possible to assist with scheduling.

E.5.3.2 Quantitative evaluation

The collection and analysis of data over time will be critical to measuring the scale of change of the new care model and its impact in terms of quantifiable evidence for patients, providers and commissioners. Much of the data will be routinely collected local activity data. Quantitative information will also include patient and staff reported outcomes of their experience of the new service using R-Outcomes (see more detail below). Quantitative data (in the form of dashboards) will be regularly used by the project group and front-line teams to understand and inform their progress and impact. Service level activity captured in appointment schedules, staff contact logs and data provided through the CHOICE app and clinician portal will be examined to investigate the following:

- change in use of outpatient appointments as a consequence of using the remote care pathway, including numbers and types of clinic attendances and other contacts, and numbers of self-initiated versus service-initiated (scheduled) appointments, and reasons for clinic attendance/type of appointment
- numbers of patients registered to use the new care model (as an indicator of staff uptake/confidence in the system)
- number of staff registered on clinician portal
- numbers of patients using the new care model (as an indication of patient uptake)
- actions arising from use of the remote care package, e.g. orders for replacement parts

- mapping of activity by truncated postcodes or distance from the clinic (to understand whether distance from the clinic is a factor influencing uptake of the remote care tool and contributes to improving equity of access)
- patient travel cost, time, hours off work or school, childcare (including accompanying person)
- Did Not Attend rate
- number of logins and time spent on CHOICE app, uses of self device adjustment (if appropriate), to understand which elements of the CHOICE offer are used most frequently and patterns of use over time
- number of errors in online resources, adverse events, missed issues

The specification for this data is included at Appendix 2.

Balancing measures

- contacts from patients having difficulty with remote tools
- additional appointments to train in remote care
- additional appointments for patients concerned about results from remote tools
- clinician caseload ratio (patients with problems: straightforward patients)
- number of patients who register to use the tool but do not log in subsequently

Spread measures

- number of patients changing back to clinic pathway
- clinics wanting to stop offering remote pathway
- patients wanting to continue remote care after the end of the evaluation
- % clinics wanting to participate
- patients using the remote care pathway, as a percentage of the total clinic caseload

Quantitative data will be collected at all sites, with a view to obtaining data on all clinic patients to maximise the sample size. A cohort of patients for comparison will be identified. This will comprise patients registered with the clinics but who have not yet been offered the new care model. We will look at aggregated clinical activity pre introduction of the tool and after (e.g. numbers of out-patient appointments, DNAs etc. in the inclusion group – i.e. 1 year post implant). There will not be a control

group of patients undergoing the same measures as the intervention group. We will also analyse centres' previously-collected service level data to evaluate current pathway.

For the purposes of this analysis, aggregated data provided by each of the services will be used. The evaluation team will work with the service providers (NHS Trust in most circumstances) to develop a specification for the data fields required from the clinic information systems to capture all of the above measures (see Appendix 2 as the foundation for this).

E.5.3.2.1 R-Outcomes

Quantitative data about the use of the remote care programme from patients and staff will be collected using the R-Outcomes survey tool (Benson et al., 2010). Wessex AHSN has used R-Outcomes in several evaluations to provide the tools required for health and care systems to measure their impact on service users in terms of health status, wellbeing, confidence to self-manage or experience.

R-Outcomes tools and methods are generic, applicable to all types of patient and care models, irrespective of types of conditions and treatments. A generic approach allows comparisons to be made between different innovations using common metrics. Surveys provide quantitative data, which is also combined with qualitative results from free text comment boxes; all R-Outcomes measures include a free text box. The measures share a common framework with 4 items and 4 responses suitable for use on a mobile device. The tools are validated, short and have a lower reading age than other measures. R-Outcomes typically use a before and after approach, collecting data on referral to the service and at agreed intervals thereafter. Ideally, individual patients are tracked over time, to measure individual change. As an alternative, to obtain faster results, we can use a snapshot approach where we compare new referrals with existing patients who are already receiving the service. Patient R-Outcomes are incorporated into the CHOICE app and patients will be consented for patient level tracking of their results.

Evaluation of impact on patients

The five domains of the NHS Outcomes Framework (NHS, 2018) focus on the impact on patients. Domain 2 focusses on enhancing quality of life for people with long-term conditions. Key aspects of this vision are met by R-Outcomes measures. R-Outcomes has developed, validated and tested a unique, coherent family of patient-reported outcome measures covering health status, personal wellbeing and happiness, health confidence (patient activation) and patient experience which can be used in combination or independently to monitor patients' own perceptions of how they are faring.

The *Health Confidence Score* (HCS) measures people's capability to look after their own health, with dimensions for confidence about knowledge, self-management, ability to get help and shared decision-making (Benson, Potts, & Bowman, 2016).

Health status score (HowRu) is a short generic health status (health-related quality of life) measure, with four dimensions for pain and discomfort, mental distress, disability and dependence, each rated on four levels. HowRu has been validated against SF-12 and EQ-5D-5L and at the individual patient level (Benson, Potts, Whatling, & Patterson, 2013; Benson et al., 2010; Hendriks et al., 2015).

The *Personal Wellbeing Score* (PWS) covers satisfaction, worthwhileness, happiness and anxiety, based on the ONS-4 Personal Wellbeing standard, used in the Annual Population Survey for Great Britain (Office for National Statistics, 2015).

Evaluation of impact on staff

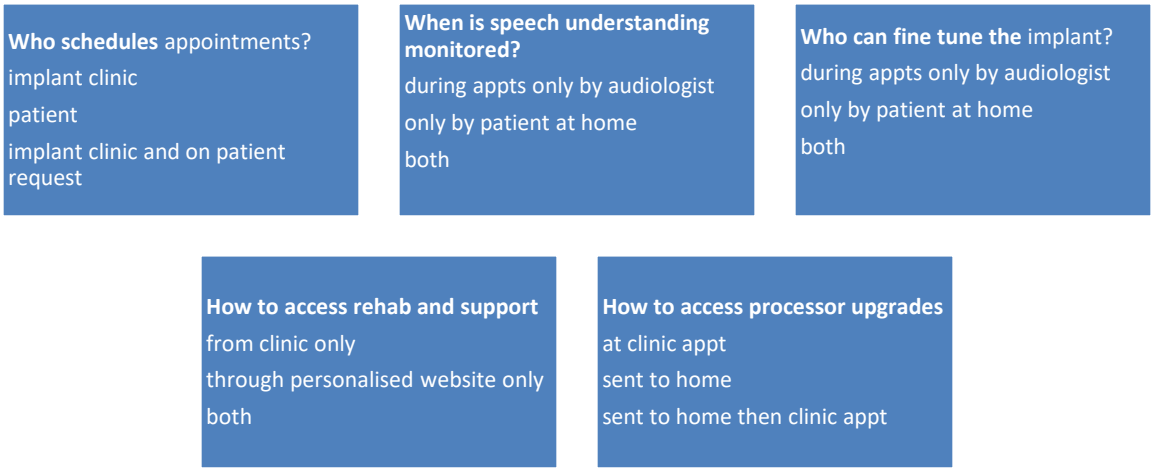
The Work Wellbeing Score (WWS) measures happiness at work and the Job Confidence Score (JCS) measures staff confidence that they have the knowledge, self-efficacy, support and involvement needed to do their job as well as possible. Staff measures will be collected through the CHOICE app (at baseline and six monthly thereafter, and at the site visit).

In addition to the R-Outcomes measures described above, the research team will collect clinical outcome measures in order to compare with results from the previous project, we will also use the Patient Activation Measures® (PAM®), the Cochlear Implant Empowerment Scale (CI-EMP), the EuroQoL EQ-5D-5L, the Health Utilities Index Mark 3 (HUI3), a global change rating, and a Discrete Choice Experiment (DCE). The PAM® is a well-validated generic measure of patient activation that evaluates the knowledge, skills, beliefs and behaviours that patients have for self-management of their long-term condition (Hibbard, Mahoney, Stockard, & Tusler, 2005; Hibbard, Stockard, Mahoney, & Tusler, 2004). It is a one-page questionnaire comprising 13 statements about health. The subject is asked to indicate how much they agree or disagree with each statement on a 4-point Likert-type scale (Hibbard et al., 2005). CI-EMP is a questionnaire specifically designed to measure how empowered people are to manage their own cochlear implant care (Kitterick, Fackrell, & Cullington, 2016).

The EQ-5D-5L is a standardised health outcome measure; it comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The HUI Mark 3 (HUI3) is a multi-attribute health status classification system evaluating eight domains of vision, hearing, speech, ambulation, dexterity, emotion, cognition and pain.(Feeny, Furlong, Boyle, & Torrance, 1995) Participants' responses were used to derive 'utility values' for their health states based on the preferences of a sample of the Canadian public (Feeny et al., 2002).

Global rating of change scales will be used to capture whether patients perceive that there has been a change in their hearing, empowerment and quality of life. The change scales simply ask the patient to rate whether their hearing, empowerment, and quality of life have improved, got worse, or stayed the same since starting on the new care pathway on 7-point Likert scales that range from 'Much worse' to 'Much improved'. These change ratings are used to determine whether any changes observed on the PAM, CI-EMP, HUI3 or EQ-5D-5L are meaningful; i.e. whether they were perceived by patients. At baseline, these measures capture the perceived severity of a patient's hearing problems on their empowerment and quality of life.

The Discrete Choice Experiment (DCE) will ask the patients to choose between different possible care pathways including one or more elements of remote care. Five elements were chosen, each having three levels:



Patients will be asked to choose between 9 pairs of pathways: 'implant service A', 'implant service B', or neither A or B if they don't like either. To analyse the data, we need choices from 18 pairs of pathways generated from the various attributes and levels, but that may be too many choices for patients to make. Therefore, there are two 'blocks' of choices, each with 9 pairs. Patients will be randomly assigned to complete either block 1 or block 2.

A summary of all the measures collected from patients and staff is provided below:

Measures	**Patients**	**Staff**	**Done at entry**	**Done continually**	**Done at end**
R-Outcomes measures:					
User experience (what do you think of this product?)	✓	✓	✓	✓	✓
Digital Innovation (questions about digital confidence and readiness for innovation)	✓	✓	✓	✓	✓
Health confidence (how do you feel about caring for your health?)	✓	✓	✓	✓	✓
Health status (how are you today?)	✓	✓	✓	✓	✓
Personal wellbeing (how are you feeling in general?)	✓	✓	✓	✓	✓
Innovation adoption measures, derived from Normalisation Process Theory		✓ (follow up only)		✓	
Job confidence (how do you feel about doing your job?)		✓	✓	✓	✓
Work wellbeing (what do you think about your job?)		✓	✓	✓	✓
Clinical outcome measures:					

Patient Activation Measure® (PAM®)	✓		✓		✓
Cochlear implant Empowerment Scale (CI-EMP)	✓		✓		✓
DCE	✓		✓		✓
Global rating of change in hearing, empowerment and quality of life	✓		✓		✓
Health Utilities Index Mark 3 (HUI3)	✓		✓		✓
EuroQoL EQ-5D-5L	✓		✓		✓
Other measures:					
NHS Friends and Family Test	✓	✓		✓	
NOMAD questionnaire		✓	✓		✓
Economic evaluation	✓				✓

The timelines for survey presentation are described below:

For patients:

1. Patient surveys (using R-Outcomes tool) - At registration for the online tool (compulsory as part of registration process) and at every six months thereafter relative to their registration date. Some participants may choose to complete an optional shorter questions set more often.
2. Patient survey about their use of follow up care (consequences for travel times, convenience etc.) – optional at focus group, or during telephone interview if not attending focus group. Completed only ONCE.
3. Initial R-Outcomes survey will normally have been completed before participation in the focus group or interview.

For staff:

4. Staff surveys (using R-Outcomes tool) - Staff will be asked to complete this at baseline (on registration) and every six months following their registration date. This will be completed via the clinician portal on the CHOICE app.
5. NOMAD questionnaire (Normalization Process Theory based-survey of staff to assess the extent to which CHOICE becomes embedded at each site www.normalizationprocess.org) (staff) - To be completed twice. At site focus group/or by email (for staff not attending the focus group) and by email request towards the end of the evaluation.
6. Initial R-Outcomes survey will normally have been completed before participation in the focus group or interview.

For both:

7. NHS Friends and Family Test – this is incorporated into the R-Outcomes questionnaires for patients and staff so will be presented at the intervals described above for R-Outcomes

Process Evaluation

This part of the evaluation is particularly important to the scaling up programme. What lessons can be learned from the implementation process and what 'key ingredients' are replicable to other clinic settings? It is proposed that this evaluation is comprised of the following elements:

Evaluation of the behaviours of staff involved in the implementation of the new model of care: The evaluation design is informed by Normalisation Process Theory (NPT) which provides a pragmatic framework for collecting and analysing what staff do in response to changes in the model of care. This will enable us to understand what factors facilitate or inhibit the embedding of CHOICE in the care pathway. The NPT framework will inform the design of the staff focus groups and staff interviews. In addition, the NoMAD questionnaire will be administered with staff early on in the roll out (at the site visit) and later (by email at end of data collection period).

Evaluation of the factors which have facilitated of hindered the adoption of CHOICE: An analysis of findings from the qualitative data sources will be compared to factors known to be important for spread and adoption (Greenhalgh et al., 2017).

***Assessment of resource utilisation and workforce*:** As this model is scaled up, it will offer important learning for how it can be delivered most efficiently and whether the anticipated changes in clinic activity and type (as a consequence of remote care options) have any implications for the clinic workforce. For example, if the reason for clinic attendance is known in advance because it is requested by the patient, the patient may not need to be seen by a senior audiologist. Data about the workforce at each site, and any changes during the project, will be collected and analysed.

Economic evaluation

A key question for the evaluation is whether the introduction of CHOICE improves use of resources through reducing the need for follow up appointments and enabling the service to be delivered by a different skill mix. This component of the evaluation will examine the impact on clinic activity of implementing the new care model. We will also apply predictive modelling to understand the impact of scaling up the model beyond the target cohort of several thousand patients. The costs associated with the delivery of follow-up activity will be sourced from each site to understand the impact of uptake of remote care. Patient participants will also be invited to complete a short survey about the cost implications of switching to remote care (e.g. impact on travel costs, need for child care etc.)

E.5.4 Details of evaluation activities and participant engagement (patient in blue, staff in green)

The intervention i.e. evaluation activity	Number of times received by each participant	Part of routine care Yes/No	Average participation time	Who is conducting the intervention and where
Staff surveys (using R-Outcomes tool)	Staff will be asked to complete this at baseline (on registration) and every six months following their registration date. This will be completed via the clinician portal on the CHOICE app.	N/A	10 minutes per questionnaire	Staff who use the clinician portal in the CHOICE app
NOMAD questionnaire (staff)	To be completed twice. At site focus group/or by email (for staff not attending the focus group) and by email request towards the end of the evaluation.	N/A	15 minutes per questionnaire	Staff at the participating sites. To be conducted at the focus group or sent by email

Patient surveys (using R-Outcomes tool)	At registration for the online tool (compulsory as part of registration process) and at every six months thereafter relative to their registration date. Some participants may choose to complete an optional shorter questions set more often.	No	5 minutes per questionnaire	Patients using the CHOICE app, done via the app
Survey about their use of follow up care (consequences for travel times, convenience etc.) (patients)	Once at patient focus group or interview	No	15 minutes per survey	Evaluation team led by experienced researcher in qualitative research At the clinic site
Focus groups (patients)	Once i.e. one focus group per site	No	2 hours	Evaluation team led by experienced researcher in qualitative research At the clinic site
Focus groups (staff)	Once i.e. one focus group per site	N/A	2 hours	Evaluation team led by experienced researcher in qualitative research At the clinic site
One to one interviews (patients)	Once. Interviews will be arranged during the site visit for those patients who would prefer one-to-one interviews, or for those who are unable to attend the focus group.	No	Up to 1 hour	Experienced qualitative researcher To be conducted during the site visit.
One to one interviews (staff)	Once for key staff who are not available for the on-site focus group. To be offered a telephone interview at another time	No	Up to 1 hour	Experienced qualitative researcher By telephone if unavailable during the on-site visit
Case Studies completed by staff about patients of the online care pathway (staff)	Each site will be encouraged to complete a minimum of 10 case studies. A single member of staff could complete all of these, or more likely, these would be shared out between staff.	N/A	Up to 15 minutes per case study	Completed by staff At the clinic site
PAM questionnaire (patients)	Twice (immediately after registering for remote care and after using remote care for 6 months or the end of the project, whichever comes sooner)	No	10 minutes	Research team will undertake, either on paper or online
CI-EMP questionnaire (patients)	Twice (immediately after registering for remote care and after using remote care for 6 months or the end of the project, whichever comes sooner)	No	15 minutes	Research team will undertake, either on paper or online
HUI3 questionnaire (patients)	Twice (immediately after registering for remote care and after using remote care for 6 months or the end of the project, whichever comes sooner)	No	10 minutes	Research team will undertake, either on paper or online
EQ-5D-5L questionnaire (patients)	Twice (immediately after registering for remote care and after using remote care for 6 months or the end of the project, whichever comes sooner)	No	5 minutes	Research team will undertake, either on paper or online

Global ratings of change questionnaire (patients)	Twice (immediately after registering for remote care and after using remote care for 6 months or the end of the project, whichever comes sooner)	No	5 minutes	Research team will undertake, either on paper or online
Discrete Choice Experiment (DCE) questionnaire (patients)	Twice (immediately after registering for remote care and after using remote care for 6 months or the end of the project, whichever comes sooner)	No	15 minutes	Research team will undertake, either on paper or online
NHS Friends and Family Test (patients and staff)	Minimum of 2 times (before registering for remote care and after using remote care for several months)	Yes	2 minutes	Completed on paper or online.

Please note the participation times above do not include travel time if the participant is expected to attend clinic.

E.5.5 Evaluation risks

Risk or challenge	**Mitigating Actions**
Engagement of participating sites in the collection of activity data and qualitative data (e.g. R-Outcomes)	We have found that staff engage most successfully with evaluation if they are involved from the outset by being provided with good information about the project, regular updates and feedback at regular intervals throughout the project. A briefing pack about the evaluation has been provided to all sites.
Obtaining consent from participating patients and staff	Patients and staff will be provided with all necessary information to meet the organisations' ethics procedures. It will be clear that patients and staff have the option not to participate and how they can withdraw at any time.
Difficulties recruiting patients to the new care model (and impact on effect sizes)	Findings from the evaluation will offer insights into any barriers affecting the implementation of the remote care programme e.g. through staff focus groups. These findings will be shared with the project team to inform their approach to recruitment of patients onto the new care pathway.

Unexpected delays to Ethics Approval or Information Governance permissions	Different providers of NHS care have different arrangements in place to satisfy their own ethics and Information Governance requirements at a local level. Mitigation of delays requires sufficient lead-in times to be incorporated into the planning process. The project team has sought expert advice on ways to expedite these processes.

E.6 Data management

A data sharing agreement will be signed by all partners, collaborators and Wessex AHSN. Data will be collected by team members, patients, participating clinicians and the evaluation team (Wessex AHSN). The Chief Investigator (Cullington) holds ultimate responsibility for data collection, storage and dissemination.

Research data: Data will be managed according to the University of Southampton Research Data Management Policy (RDMP). Staff from University of Southampton Research Data Management Service will assist with data storage, curation and sharing, under the guidance of Isobel Stark, Research Data Development Manager. The research assistant will clean data and enter paper data into electronic format. An individual study Data Management Plan is stored on the University network and shared with the team. In line with good research practice, we will have regular reviews of the data collected to make sure that its quality and integrity are maintained and to keep the Data Management Plan up to date by incorporating details of agreed protocols and procedures for cleaning data, file-naming, version control, documentation, metadata collection, backup etc. Data will be in standard file formats: .xlsx, SPSS data files, csv, paper, jpegs, standard audio files. The University provides secure storage for all active research data up to 1TB (http://library.soton.ac.uk/researchdata/unistorage). The data are regularly backed up and a copy of the back up is regularly off-sited to a secure location for disaster recovery purposes. De-identified data will be kept at University of Southampton for at least 10 years in line with University of Southampton research data policy. We also have a Data Protection Impact Assessment (DPIA) which details compliance with GDPR requirements.

Clinical data: In line with the Records Management Code of Practice for Health and Social Care (Information Governance Alliance, 2016), data related to a long-term condition (deafness) should be retained for 30 years from discharge/ patient last seen or 8 years after the patient has died. Individual cochlear implant centres will retain their own clinical patient data and their own Trust/centre policies may vary.

Evaluation data: Only de-identified data will be provided to the independent evaluator who will handle and store this in accordance with the agreements that are put in place with each site. There will be a contract for the evaluation programme in place. Wessex AHSN will ensure that data are handled in line with the NHS Standards including Data Collection, Code of Practice, and Information Governance.
All Wessex AHSN staff are employed on University Hospital Southampton Foundation Trust (UHSFT) contracts of employment. They are required to adhere to UHSFT terms and conditions and have received mandatory training on Information Governance and data protection. The UHSFT Information Governance Policy can be provided upon request. The ASHN computer network is a private, cloud based system which is compliant to ISO27001 and approved under the NHS IG Toolkit. The cloud servers are based in the UK. Only AHSN Evaluation Team members are able to access the folders where data in relation to this project is saved – access is controlled by user profiles.
The retention schedule for data collected by Wessex AHSN is as follows:

1. Audio recordings will be kept until publication of the evaluation report (July 2021) and then destroyed. This will be undertaken by the AHSN's IT provider, and written confirmation of the deletion will be requested.

2. All other data, including transcriptions of the audio recordings, will be kept until 12 months after publication of the evaluation report (July 2022) and then securely transferred to University of Southampton (under the control of the Chief Investigator) to retain until 10 years after the conclusion of the study, as required. If not required by the University of Southampton Chief Investigator, this will be destroyed.

E.7 Monitoring

Please see section “Roles and responsibilities of project management committees and groups” for project governance details. We have not established an independent Data Monitoring Committee as this is not a

clinical trial and it is not a requirement of the funder. The funder (The Health Foundation) may observe, monitor and inspect delivery of the project and reserves the right to externally evaluate any aspects of the project and its outputs. The funder also requires regular reports – both financial and about the project progress, and may need to allow members of The Health Foundation Research Directorate to inspect all records and data including recordings and transcripts of interviews with patients and others. However in correspondence on 17 April 2018, The Health Foundation stated that they would not expect raw data and would expect records to be anonymised where applicable to protect personal data.

Safety monitoring and reporting of adverse events will occur according to requirements of the local and national ethics committees. Details for the HRA are given here https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/. Safety monitoring, adverse events, data monitoring, and deviations and breaches of protocol are standing items on the Steering Group agenda.

The Chief Investigator (Cullington) retains GCP training and uses the NHS Delegation and Training Decision Aid (https://sites.google.com/a/nihr.ac.uk/dandtda/) to decide who else needs to be trained.

Responsibilities for maintaining the operational usage of the app are split between University of Southampton iSolutions, IE Digital and the CHOICE Leadership and Management Team.

E.8 Notification of Serious Breaches to GCP and/or the protocol

A "serious breach" is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the project; or

(b) the scientific value of the project

The sponsor (University of Southampton) will be notified immediately of any case where the above definition applies during the project.

E.9 Public and patient involvement, PPI

The project team has a strong commitment to PPI; a member of the project team is a service user (Riggs). Two additional service users are on the project Steering Group. Local and national publicity (website, twitter, presentation to National Cochlear Implant Users' Association, newsletter articles, letters, emails, Yahoo group) have already invited help in designing the project. Several people using cochlear implants

have trialled the CHOICE app and the hearing check before its release and given feedback in writing and in focus groups.

E.10 Ethics

This is a Quality Improvement (QI) project. We are rolling out and evaluating a new care pathway choice. We are performing systematic data-guided activities designed to bring about immediate, positive changes in the delivery of healthcare. We will use quantitative and qualitative data to identify problems in the delivery of care and their causes and act to achieve improvement. In order to safeguard patients, this requires ethical oversight (Healthcare Quality Improvement Partnership, 2017). Using the HRA decision tool (Medical Research Council), the project is defined as research and requires NHS REC ethical review because 'the study protocol demands changing treatment/care/services from accepted standards' and 'participants identified from, or because of their past or present use of services (adult and children's healthcare within the NHS and adult social care), for which the UK health departments are responsible'.

Ethical implications

- Risk breaching patient confidentiality or privacy through use of the webapp
- Patient and clinician burden of taking part in evaluation process
- Involves departure from usual clinical care pathway

Patients are free to withdraw from remote care at any point without giving a reason; they will then move back to a clinic-based care pathway. If patients decide to stop using the CHOICE app, we will keep the information we have collected so far, unless participants request it is deleted. It will not be possible to delete data if it has already been anonymised . Data already collected will be retained by their cochlear implant clinic (for clinical care reasons). It may not be possible to delete data from focus groups.

The CHOICE app conforms to the following specifications:

Risk management	ISO 14971:2007
Software lifecycle	BS EN 62304:2006

and complies with the requirements of the EU directive:

93/42/ECC for medical devices

It has achieved CE marking and is registered with the MHRA as a Class I medical device.

The CHOICE Chief Investigator and Project Manager will review that CHOICE is being used for its registered purpose and that any changes are within the scope of its described use. This will be reviewed quarterly (and as required in interim periods) with the Senior Quality Assurance manager Professor Carl Verschuur, Director of University of Southampton Auditory Implant Service (agreed as CE Mark Qualty Assurance person with Letitia Baldock, Head of Contracts).

We have completed a Data Protection Impact Assessment of the CHOICE app.

E.11 Confidentiality

Personal and sensitive personal data will be entered by the patient into the webapp. The patient will consent to data sharing as shown in Figure 1. Data will be encrypted before transfer. At the close of the project or before, data will be de-identified (personal data removed). We cannot guarantee anonymity because patients with cochlear implants are still rare in the general population (approximately 0.01% of the UK population, or approximately 1 in 10,000 people). This makes anonymity more challenging.

Focus groups and interviews (with staff and patients) will be audio-recorded with an encrypted dictaphone and transcribed. Any names used will be removed after transcription. Participants will be advised that given the nature of focus groups, confidentiality cannot be guaranteed. All participants will be asked to respect the privacy of what is said in group discussions and not repeat what is said outside the discussion. A recogised and widely used approach to thematic analysis will be used for both patient and staff qualitative findings (Braun & Clarke, 2006). Thematic findings from all focus groups and interviews will be 'member checked' with a random sample of participants and other research staff to ensure the reliability/trustworthiness of the thematic framework/table(s) of themes developed by the primary qualitative researcher. Paper consent forms for qualitative evaluation will be transported (car or public transport) from the site to store securely in a locked cabinet in the Wessex AHSN offices, separately to the interview notes. Where paper notes are made (e.g. at the focus groups), these will be scanned and uploaded to the AHSN's secure IT network, and the paper copies will be shredded.

Data relating to individuals will not be linked together i.e. individual interview and individual R-Outcomes data will not be linked. Findings will be linked through the synthesis process at an aggregate level.

E.12 Dissemination

Results will be presented locally, nationally and internationally. Dissemination will include but not be limited to peer-reviewed publications both online and in print, conference and meeting presentations, posters, newsletter articles, website reports, and social media. In order to inform people with cochlear implants of the results, information will be sent to the National Cochlear Implant Users' Association and other patient groups, and the USAIS patient newsletter. We have budgeted for our clinical results academic publication to be gold open access. The results of the evaluation will be published as a report by Wessex AHSN. The final evaluation report will be shared with the project team, The Health Foundation, and the sponsor (University of Southampton).

F. ACKNOWLEDGEMENTS

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H. FUNDING STATEMENT

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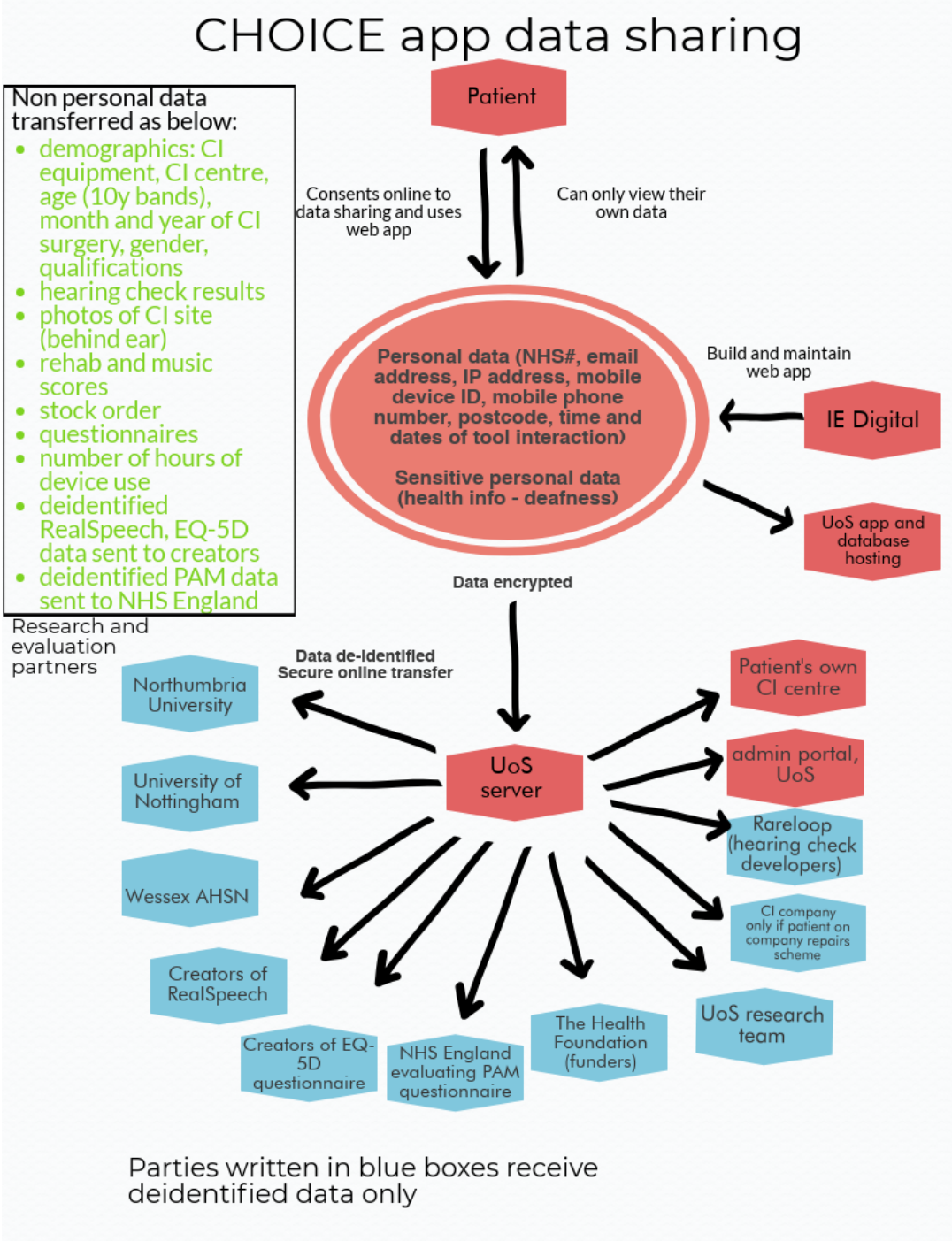
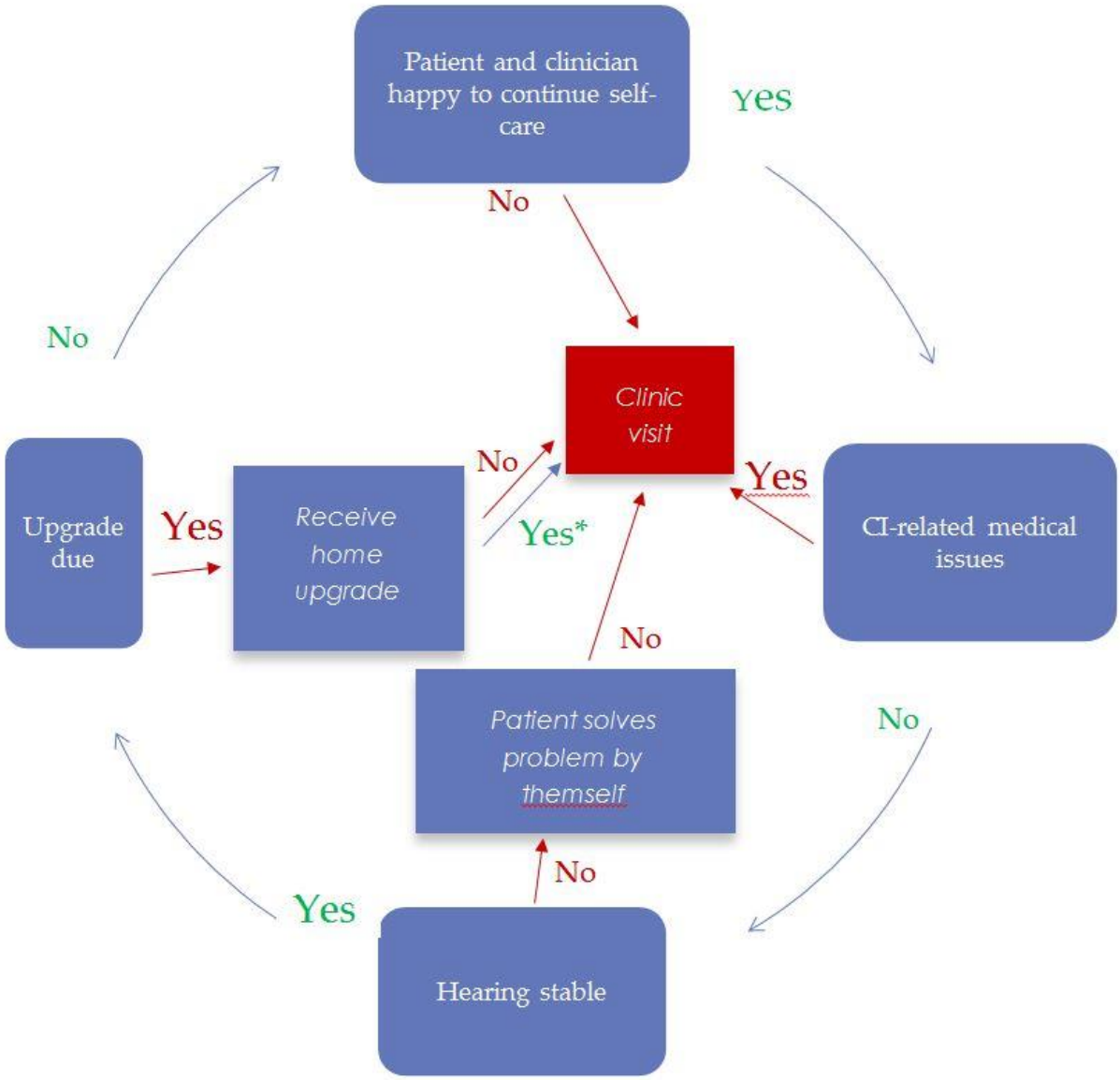
I. FIGURES

I.1 Figure 1. Data flow diagram for the CHOICE app. This figure refers only to data sharing within the CHOICE app. Please refer to Confidentiality section too

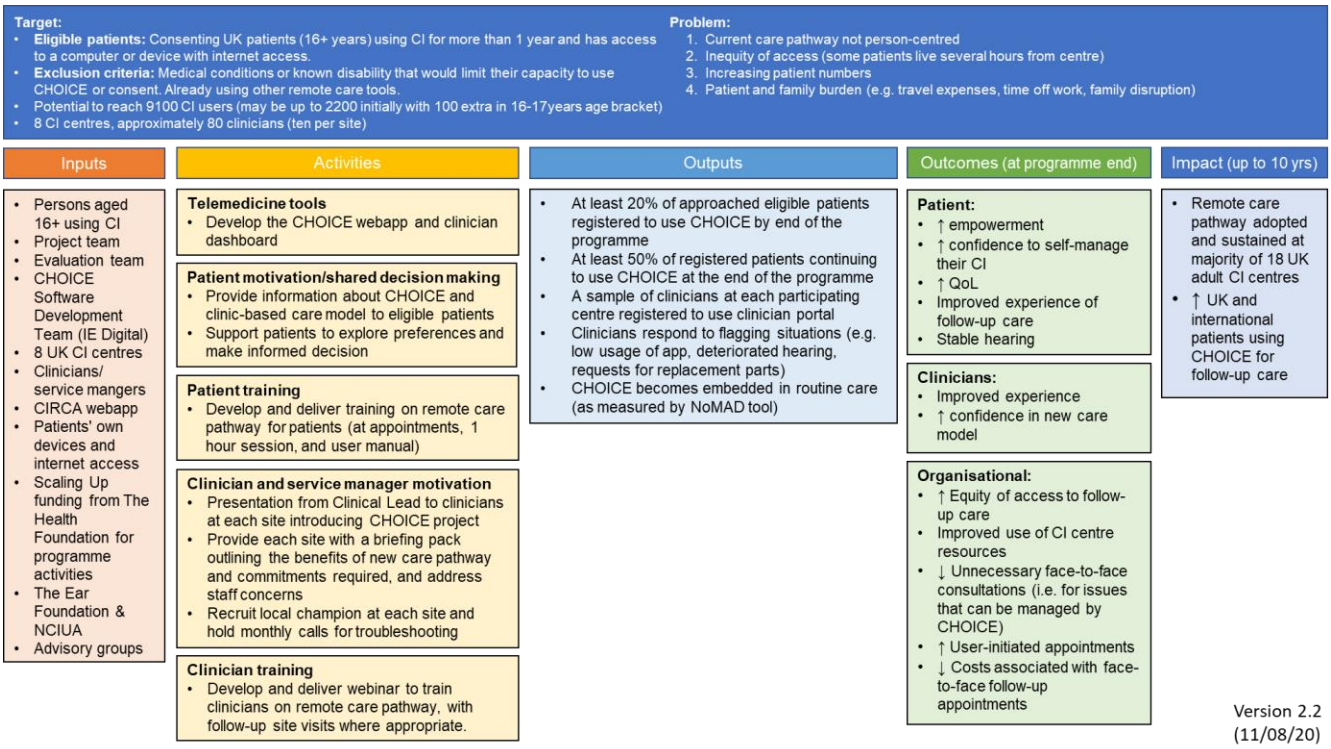


I.2 Figure 2. Cycle of self care



*** Centres may initially want to follow up all patients who receive a home upgrade**

I.3 Figure 3. Project logic model



J. APPENDICES

J.1 Appendix 1. Case study template

Please use this template to document case studies from your clinic

Please ensure these are anonymous.

Situation *Give a brief description of the presenting situation*	*(e.g. 40 year old male, limited family support, working as..)* • •
Obstacles Challenges *What were the obstacles and challenges you needed to overcome / resolve?*	*(e.g. the individual challenges faced by this person)* • •
Action *What did you do? What was the*	*(e.g. referred onto remote care pathway, other types of support offered.)* • •

intervention you made?	
Result *What were the positive outcomes of your intervention?*	*(e.g. person is more confident, has returned to work, confident to self-manage)* • •

J.2 Appendix 2. Draft specification for activity information and source of data

CHOICE Evaluation: Draft specification for activity information and source of data

Dataset	Expected outcome	Detail	Measures	Source of data	Frequency of data supply (to AHSN)
1	Change in use of out-patient appointments Reduction in number of out-patient appointments (additional to pre-planned review appointments, and after one year post implant), following implementation of the tool	It is expected that post-implementation of the remote care tool, out-patient appointments will be offered on a request basis according to need rather than on a pre-planned basis. We will need to understand the activity of each clinic before implementation of the remote care option and afterwards (what happens to the numbers of out-patient appointments, who initiates them and what for) The out-patient appointment may be provided by a different member of staff (e.g. technician rather than clinician) if the reason for the appointment is known in advance through using the tool.	For each cochlear implant clinic: - Total number of outpatient appointments completed by the clinic, by month, and by care pathway (either remote care or traditional pathway) for 36 months before rolling out the remote care system, and until the end of Jan 2021. Outpatient activity associated with care of a patient in their first year of having a cochlear implant should be excluded. Data to also include type of appointment to be provided if available (e.g. routine check, problem (urgent/emergency appointment), technical appointment (e.g. upgrade) For each user recommended and taking up care using the remote care pathway: - date registered on the on-line tool - number of clinic appointments by month for past 36 months (or maximum period of time if user has had their implant less than 36 months)and end of January 2021 Appointments associated with the user's first year of care should be excluded. - Field to show clinic initiated or user initiated appointments (and which staff type if clinic initiated) - reason for out-patient appointment	Clinic / Trust PAS system	At start of evaluation, and then every 6 months beginning 3 months after CHOICE launch

			- Role of professional who saw the person (e.g. technician, clinician, etc.)		
2	Equity of access	It is hoped that more people with cochlear implants will access follow up care if they are given a remote care option. This may particularly apply to those who live a long distance from the clinic. Geo-mapping will enable us to locate all clinic attendees – to maintain anonymity, a patients partial postcode will be supplied to the AHSN.	cochlear implant sites are to provide: - Postcodes (shortened to outgoing postcode only, E.g. SO16 2AP will be shortened to SO16) of all those on the clinic caseload (A row listing per patient is recommended), with supporting fields to indicate: o A person care pathway (either remote care or traditional pathway) o Date of CHOICE uptake - For all outpatient appointments 36 months before launch of CHOICE and until January 2021, the patients outgoing postcode (e.g. SO16), the clinic outcome (attended/DNA/cancelled) and the reason for not attending clinic appointments (e.g. declined).	Clinic / Trust PAS system	At start of evaluation, and then every 6 months, beginning 3 months after CHOICE launch
3	Remote care tool is embedded in routine practice	We would expect to see the percentage of total caseload recommended for remote care increasing over the duration of the project.	Total caseload of cochlear implant users (one year or more post-implant), by quarter Number of users recommended to register on on-line tool, by quarter Number of patients changing back to old pathway, by quarter Number of users registered on on-line tool, by quarter Number of staff registered on the portal, by quarter	Clinic / Trust PAS system Online system registration data	At start of evaluation, and then every 6 months, beginning 3 months after CHOICE launch
4	Improved use of resources	What is the costing model for remote care during the project?	- Included as part of the data in dataset 1	Clinic / Trust PAS system	At start of evaluation, and then every 6 months beginning

		Aggregate data on number of out-patient appointments pre- and post implementation of remote care pathway at each site should show a reduction in out-patient appointments (excluding those that are required as part of routine care)			3 months after CHOICE launch
5	Possible workforce changes	This detail may be revealed in the qualitative work but should be quantified where possible	Staffing complement (WTE) and job roles at time of implementing remote care pathway. To be updated by the clinic manager throughout the project to note any changes that respond to implementation of the pathway. A template is suggested, below.	Clinic / Trust PAS system	At start of evaluation, and then every 6 months, beginning 3 months after CHOICE launch

Sample Workforce every 6 months return template

Date of return	

Role description	**Staff grade (e.g. AfC band 6)**	**Number of WTE**	**Have the responsibilities of this role changes in the past quarter, as a result of CHOICE?**