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What are the requirements for developing a successful national registry of auditory implants? A qualitative study

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ABSTRACT

Objective

Hearing loss is an area of unmet need and industry is targeting this field with a growing range of surgically-implanted hearing devices. Currently, there is no comprehensive United Kingdom (UK)-registry capturing data on these devices; in its absence, it is difficult to monitor clinical and cost-effectiveness and develop national policy. Recognising that developing and maintaining such a registry faces considerable challenges, it is important to gather opinions from stakeholders and patients. This paper builds upon a systematic review on surgical registry development and aims to identify the specific requirements for developing a successful national registry of auditory implants.

Methods

Data were collected in two ways: (1) Semi-structured interviews with UK professional stakeholders; and (2) Focus groups with patients with hearing loss. The interview and focus group schedules were informed by a systematic review on registry development. Data were analysed using directed content analysis. Judges mapped the themes obtained against a conceptual framework developed from the systematic review on registry development. The conceptual framework consisted of 5 categories for successful registry development: 1) Planning; 2) Registry governance; 3) Registry dataset; 4) Anticipating challenges; 5) Implementing solutions.

Results

Twenty-seven themes emerged from 40 semi-structured interviews with professional

stakeholders and 18 themes emerged from 3 patient focus groups. The most important factor for registry success was high rates of data completion. Benefits of developing a successful registry of auditory implants include: strengthening the evidence base and regulation of auditory implants, driving quality and safety improvements, increased transparency, facilitating patient decision making, and informing policy and guidelines development.

Conclusions

This study identifies the requirements for developing a successful national registry of auditory implants, benefitting from the involvement of numerous professional stakeholder groups, as well as patients with hearing loss. Our approach may be used internationally to inform successful registry development.

Strengths and limitations of this study

- This study adopted an inclusive and robust approach, involving multiple professional stakeholder groups as well as patients with hearing loss.
- Our findings built upon a conceptual framework on successful surgical registry development, that was developed following a systematic review and narrative synthesis.
- The interview schedules were informed by a published systematic literature review and were piloted and updated before data collection.
- Interview and focus group data were extracted and analysed by two independent data judges, with further verification by a data auditor.
- We recognise that the use of purposive sampling for identifying professional stakeholders may have been prone to researcher bias.

INTRODUCTION:

Hearing loss has been identified as a key public priority by the Department of Health (DOH) and UK policy makers.[1-3] In the UK, 10 million people suffer from hearing loss, with an estimated annual cost to the economy of £30 billion.[1,4] Hearing loss affects people's ability to communicate and has a major impact on social functioning.[1,5-7] The impact of hearing loss is set to increase with our ageing population - by 2031 approximately 1 in 5 people in the UK will suffer from hearing loss.[8,9] Importantly, hearing loss has been associated with dementia, with the hazard ratio for developing dementia increasing two, three, and five times with mild, moderate, and severe losses in hearing, respectively.[7,10,11]

Policymakers, guideline developers, clinicians, researchers and industry have realised that hearing loss is an area of unmet need.[1,7] This has resulted in increased focus and rising investment in the development of novel hearing loss strategies, including a range of surgically-implanted hearing devices. These auditory implants include cochlear implants (CIs) and bone conducting hearing implants (BCHIs).

Whilst auditory implants have been widely adopted, UK registry data on patients with auditory implants is lacking.[2,12,13] The current UK initiatives to collect hearing data on auditory implants are fragmented and incomplete.[2,14] Scandals around other surgical implants such as the "Poly Implant Prostheses (PIP)" breast implant and the "metal-on-metal (MOM)" hip implant highlight the dangers of not collecting such information.[15,16] The quality of evidence on auditory implants is also an area of concern, with recent systematic

reviews and policy documents emphasising the low quality of available evidence.[17-20] Hearing stakeholders, policymakers and patients have recognised that, in the absence of registry data, it is difficult to regulate the provision of auditory implants, monitor clinical and cost-effectiveness, and ultimately develop appropriate guidelines and policy.[2]

A potential solution is to develop a national registry of auditory implants.[2] Recognising that developing and maintaining such a registry faces considerable challenges, it is important to gather opinions from relevant stakeholders and patients with hearing loss.[21] This paper builds upon a recent systematic review[22] on successful surgical registry development and aims to identify the specific requirements for developing a successful national registry of auditory implants.

MATERIALS AND METHODS

Ethical considerations

Ethical approval was granted by UCL Research Ethics Committee 9031/001. Information sheets were provided to participants before taking part, and informed consent was sought from all stakeholders and patients. To facilitate patient attendance, travel expenses were remunerated and gift vouchers were given to patients taking part in the focus group.

Data collection

Data were collected in two ways: (1) Semi-structured interviews with professional stakeholders; and (2) Focus groups with patients with hearing loss. The methodological orientation underpinning the study was content analysis[23] and the study protocol was designed in accordance with the consolidated criteria for reporting qualitative studies (COREQ).[24]

Semi-structured interviews with professional stakeholders

Participants

We adopted a purposive sampling strategy to identify and select groups of individuals that are especially knowledgeable about hearing loss and auditory implants.[25] Stakeholders were initially identified from a network of professionals known to the authors and their collaborators. The list of stakeholders was cross-checked by two independent individuals from separate institutions. At the end of each interview, interviewees were asked to provide names and contact details of stakeholders with significant experience relevant to our study. These individuals were selected based on their added expertise to those already identified. Stakeholders were approached via email invitation, which included a study information sheet. Provisional data analysis commenced after completion of the first interview. Stakeholders were recruited and interviewed until data saturation was reached in our analysis. Professional stakeholder groups were located across the United Kingdom and included: ENT surgeons, audiologists, commissioners, policy experts, health economics experts, national guidelines experts, industry representatives, patient charity representatives, representatives from national hearing bodies, existing ENT registry leads,

national surgical registry leads, and DoH representatives. Information on stakeholder group frequency can be seen in Table 1.

A total of 40 stakeholders were interviewed. This sampling approach led to a response rate of 89% (40 out of 45 stakeholders). Reasons for non-participation included: unable to schedule suitable time (n=2) and nonresponse to invitation (n=3).

Procedures

Individual interviews lasted a mean of 24 minutes (range 14 - 34) and were digitally recorded and transcribed. Participation was voluntary and transcripts were anonymised. Participants were interviewed between March 2015 and December 2016, either in person at the University College London (UCL) Ear Institute or via telephone. The semi-structured interviews followed an interview schedule comprising 13 questions, each of which contained specific probes (see Appendix 1). The interview schedule was developed following a narrative systematic review on UK surgical registry development, conducted by the research team.[22] The interviewer (primary investigator) was an ENT Academic Clinical Trainee with expertise in the field of auditory implants and health policy research. The interview schedule focused on (1) opinions on existing auditory implant registries, (2) the requirements of a successful registry, and (3) the strategic challenges of establishing a future national registry of auditory implants and potential solutions.

The interview schedule was piloted on two clinical professionals and updated following their feedback before conducting the semi-structured interviews.

Focus groups with patients with hearing loss

Participants

Adult patients with hearing loss and their family members were interviewed in three focus groups, each comprising 6 to 7 participants. Participants were identified from a UCL Ear Institute database of patients who had given their consent to be contacted to take part in clinical research. Participants were approached via email invitation and information about the study was included in the invitation. A total of nineteen participants were included. Characteristics of participants, are shown in Table 2. Ten patients refused to participate; reasons for non-participation were: lack of time (n=3), caring commitments (n=3) and difficulty in travelling (n=4).

Procedures

The focus groups explored a schedule of 10 questions, each containing specific probes about a future national registry of auditory implants (see Appendix 2). The questions were developed from the same systematic review on UK surgical registry development.[22] Focus groups took place in July 2016 at the UCL Ear Institute and were facilitated by the primary investigator and a patient and public involvement expert.

The focus group discussions lasted between 90 and 105 minutes. The discussions were recorded using a digital recorder and professionally transcribed. Field notes were also taken

during the interviews. Transcripts were anonymised. The focus group schedule was trialled on two patients with hearing loss who provided feedback on the wording of the questions and probes. Their feedback was used to update the schedule before carrying out the focus groups.

Analysis

Data analyses were performed in 2 stages. *Stage 1:* Two data judges (RM and CT) qualitatively analysed the interviews and focus group discussions using directed content analysis.[23] Stakeholder interviews and focus group transcripts were analysed separately and data were extracted into two separate data extraction tables. The framework of the data extraction tables reflected the structure of the interview and focus group schedules. Data judges independently read through the interview and focus group transcripts and extracted data from the transcripts manually onto the data extraction tables. The data judges independently made notes of themes and met regularly to compare their analyses. Discrepancies in extracted data and themes were discussed and resolved. Amending the themes list was repeated until no new themes emerged from the data and until no further changes needed to be made to accommodate both judges' suggestions (coding saturation). The data judges met periodically with the data auditor (AS) to discuss the analysis and check the analysis process for rigor.

Stage 2: Judges independently mapped the themes obtained from the stakeholder interviews and focus group responses against a conceptual framework developed from the systematic review on successful registry development.[22] The conceptual framework

consisted of 5 fundamental categories for successful registry development: 1) Planning; 2) Registry governance; 3) Registry dataset; 4) Anticipating challenges; 5) Implementing solutions.[22] Judges compared their findings and discrepancies were discussed and resolved.

RESULTS

Semi-structured interviews with professional stakeholders

The themes identified from the extracted data are presented below for each interview question.

Professional stakeholder (PS) Question (Q)1. What are your thoughts on the existing auditory implant registries available?

1a. Existing registries include

Stakeholders were aware of the following UK otology registries: The Ear Foundation Bone Anchored Hearing Aid (BAHA) registry, The Ear Foundation BCHI registry, Pochia CI registry, Bawtry Database, Auditbase, National Audit of Bilateral CIs, Auditbase, Otology Web Based database, Cochlear Paediatric Implanted Recipient Observational Study (Cochlear™ P-IROS registry). Some implant centres and device manufactures have their own registries.

1b. Existing registries are limited

Whilst it should be commended that registries have been established, existing registries are limited. Limitations include: poor rates of data completion; not user-friendly; difficult to navigate and enter data; overly basic or complex datasets; inappropriate outcome measures; too clinician-focused with inadequate representation from patients and other stakeholders; and inappropriate datasets. *"The registries are just not useful – they are incomplete, so there's no value in me entering data" (Consultant implant surgeon).* Owing to these shortcomings, existing registries are limited in their ability to inform clinical practice, commissioning or guidelines development.

PS Q2. Do you think a national registry of auditory implants will be of benefit?

2a. Improve safety and quality of care

A successful registry would be able to monitor national practices, identify safety concerns early and facilitate implant recall. *"A registry could help prevent a PIP breast implant scandal" (Audiologist).* The registry would also promote (inter)national comparison of practices, communication between centres and a culture of learning, resulting in improved quality of care. Poorly performing centres could be identified and supported. Registry leads noted that their registries were associated with increased adherence to clinical standards, shorter waiting times, reductions in length of stay, as well as reductions in morbidity and mortality. The registry would facilitate comparison between different implants, assisting clinicians in their decision making – *"by understanding the treatments more, we can improve the care we provide" (Consultant implant surgeon).*

2b. Promote research and innovation

A registry would provide essential data for clinical and cost-effectiveness research. *"It's essential to have a national registry – I fear that increasing numbers of implants are coming into practice with insufficient evidence" (Consultant implant surgeon).* It would also facilitate research collaborations, provide data with external validity, refine indications for implantation, promote epidemiological research and drive device improvements as well as new innovations.

2c. Facilitate commissioning and guideline development

A registry would enable monitoring of national clinical activity, facilitating efficient implant procurement, fair distribution of resources and equitable access to care. The registry would also provide valuable information for policy and guidelines development as well as commissioning of new services. *"Our registry has made the commissioning process easier, by proving that the treatment is effective, safe and that we have met our targets" – (Non-ENT surgical registry lead).*

2d. Help patient decision making

A national registry could empower patients, providing them with information on procedure effectiveness and risks, and help patients to make informed decisions about their care.

PS Q3. What do you think the main purpose or goal of the registry should be?

3a. To improve the quality and safety of care

The main purpose of the registry should be to improve the quality and safety of care provided whilst promoting transparency and patient choice. The registry should also aim to monitor practices, identify and compare device effectiveness, drive clinical research and innovation as well as assist in the development of national guidelines and policy.

PS Q4. How should the registry be led/who should make the decisions?

4a. Steering committee

The registry should be led by an independent steering committee, with representation from the following stakeholder groups: audiologists, an ENT UK representative, implant surgeons, commissioners, policy experts, a health economist, guideline developers, patients and a lay-member. This would ensure that the registry remains valuable to all stakeholders, promoting engagement. Subcommittees would be responsible for separate areas, including funding, data collection, data verification and governance.

PS Q5. How should the registry be managed/maintained?

5a. Dedicated management team

The registry should be managed by a dedicated and funded management team, responsible for: collecting data centrally, maximising data completion and verifying data. An external validator could perform 'spot data-accuracy checks' on individual centres. The management team should have experience in data governance, and each hospital should have its own data manager, responsible for unit-level data collection and accuracy.

5b. Robust IT systems to verify data

Robust IT systems should be in place, to verify and clean data, thereby increasing data accuracy. Registry data can be verified by comparing it with data from other platforms including Hospital Episode Statistics (HES).

PS Q6. Broadly speaking, what do you think should be included in the dataset?

6a. Registry dataset

Table 3 summarises the pre-, intra- and post-operative data items on which consensus was reached. A consensus meeting would be required to establish the specifics of the dataset. The dataset should be simple. "*The key is trying to collect data that reflects the normal patient pathway – as this is what would be collected normally" (Surgical registry lead).*

6b. Quality of life (QoL) data

QoL data is valuable in providing meaningful outcomes, particularly for patients and commissioners, and facilitates health economic analyses. However, there are difficulties in reaching consensus on which QoL outcomes to use. QoL data collection is time consuming and demanding and may result in reduced data completion rates. Therefore, QoL data collection should be introduced when the registry is well-established. *"QOL data is ideal, but not essential and is initially very hard to do – it's best to wait until the registry is embedded" (Surgical registry lead).*

PS Q7. What are the main challenges of establishing a registry?

7a. 'Buy-in' and data completion

The biggest challenge would be achieving long-term 'buy-in' and data completion. *"The biggest barrier is getting people to enter and share their data" (Consultant implant surgeon).* Reaching agreement on the registry dataset would also be challenging. "*If people don't agree with the dataset – they're not going to enter the data" (Commissioner).*

7b. Resource heavy

The registry would require considerable financial, human and time resources for initial set-up, data entry as well as registry maintenance. *"Surgeons are already so busy, they're not going to have the time to enter the data unless they are given the resources to do so" (Commissioner).*

7c. Registry governance

Data governance and legal factors are other challenges. These include compliance with data protection and information governance laws, maintaining data security, policing data access, appointing a steering committee, identifying data ownership, and acquiring informed patient consent. Another key challenge is ensuring data accuracy and quality. This would require robust and expensive data processing systems.

PS Q8. How can we overcome these challenges?

8a. Engage with opinion leaders

Having key opinion leaders as registry advocates would help increase registry awareness. Seeking early collaboration and support from influential organisations such as DoH, NICE and Commissioning Groups, would help maximise registry relevance and funding.

8b. Registry development and design

All stakeholder groups should be involved in registry development and design and the registry must be simple, electronic, and adaptable to maximise data completion and promote longevity. *"You need a minimal dataset, that's under 1-page, takes less than 3 minutes to complete, and has no free-text data entry – data entry needs to become routine, like a step in the operation" (Surgical registry lead).* The registry should be managed in a transparent and inclusive manner and legal, governance and IT experts should be consulted

from the outset, with data verification systems in place to maximise data quality. A pilot registry, run in selective centres would help identify issues, obtain user-feedback and facilitate registry improvement before national launch.

8c. Compulsory

The most effective way to maximise data completion would be by making the registry compulsory for revalidation and commissioning. *"Clinicians need to show during their revalidation that they have entered their data into the registry, and hospitals should be paid based on the data that is submitted" (Commissioner).* Financial incentives could be applied to hospitals and data completion rates could be published to promote data entry. Data-entry could be a prerequisite for membership to professional societies and awards could be issued to hospitals and clinicians with high levels of data completion.

8d. Make it clearly useful

Making the registry useful for stakeholders would increase 'buy-in' and data completion. *"You need to make the registry invaluable for things like publications, audits, revalidation and hospital funding" (Guidelines expert).* The registry should be advertised through its steering committee, influential stakeholders as well as via a launch event and annual meetings, where registry achievements could be showcased, increasing registry awareness.

PS Q9. Should patients be involved in the registry and if so how?

Patients should be involved in the registry in three different capacities.

9a. Leadership and development

Patients should be involved during registry development, with a patient representative on the steering committee. This would help make the registry meaningful to patients and policymakers. Patient representatives will help make steering groups more efficient, accountable and professional.

9b. Accessing the registry

Patients should be given access to the registry, particularly to their own data. "*It's their information after all and they would want to know about the benefits and risks" (Consultant implant surgeon).* Patient access would encourage data completion since *"patients will demand that their data is up-to-date and complete" (Guidelines expert).* Safeguards would be needed to comply with data-protection and patient confidentiality. Integrating patient access would be complex and expensive, and should therefore be implemented later, once the registry is already well-established.

9c. Entering data

It would be helpful and efficient for patients to enter their own data, particularly QoL data that is otherwise difficult to collect. However, data verification systems would be needed.

Patients would likely achieve high rates of data-input since *"patients have the biggest vested interest in ensuring the data is complete" (Commissioner).*

PS Q10. Who should own the data of the registry?

10a. Independent national body

The registry should be owned by an independent national body. Suggestions included: NHS England, DoH, the Secretary of State for Health, Public Health England, and the NHS. These bodies would provide longevity, impartiality, fair access and experience. Other national bodies were suggested including ENT UK, British Society of Audiology (BSA), The Ear Foundation and The British Academy of Audiology. However, these organisations may not be perceived by all stakeholder groups as impartial.

PS Q11. How should we fund the registry?

11a. Multiple sources

Funding should be requested from all stakeholder groups with an interest in the registry. Multiple income streams would provide financial security and increase engagement. *"If all the stakeholder groups pay for the registry, it's in their interest for it to succeed, so they will engage with it" (Policy expert).* Suggested funders included: ENT UK, DoH, patient charities, research grants (National Institute for Health Research [NIHR], Medical Research Council [MRC], Action on Hearing Loss [AoHL], healthcare providers, hospitals, industry, The Ear

Foundation, British Society of Audiology and The British Academy of Audiology. Whilst it is important to raise funding for registry development, it is essential to establish funding for long-term registry maintenance.

11b. Levy on all implants used

A fee, applied to each implant used, would be a helpful source of income. The fee would be paid for by industry and the purchasing hospital.

PS Q12. Should we publish data on specific surgeons and hospitals?

12a. Wait until the registry is established

There is a growing trend towards publishing this data. Potential benefits include: increased patient choice, trust, transparency, and promoting a culture of learning. Negatives include: data being misleading if unadjusted for case mix, data poorly reflecting that outcomes are dependent on the entire healthcare team, reporting bias, risk-averse practices, and reduced rates of data completion. Due to these risks, this data should be reported once the registry is well-established, with robust mechanisms for adjusted reporting. The data should be available to the registry steering committee, who could capture safety concerns and feedback to individual surgeons and centres.

PS Q13. Overall what do you think is the most important factor for making a registry successful?

13a. Data completeness

High levels of data completion and accuracy are essential. To achieve this, the most important factors include: involving stakeholders and patients during registry development; compulsory data entry; making the registry useful for all groups; and having robust data processing systems.

Focus groups with patients with hearing loss

The themes identified from the extracted data are presented below in italics, under each focus group question.

Focus Group (FG) Q1. What are your thoughts on developing a registry of patients that have surgically implanted hearing devices?

1a. Improve quality and safety of care

A registry would provide a record of implanted patients, identify implant problems early and permit recall in the event of safety concerns *"I can't believe there isn't anything already, that's quite dangerous - there should at least be something that tells you who has an implant" (BCHI user); "Its essential for safety - if things go wrong with one of the implants, you'll have no way of contacting those patients" (CI user).* The registry would help implant manufacturers evaluate their products, improve safety and effectiveness and encourage

competition. It would identify underperforming centres, enable national comparison of outcomes and promote an environment of learning. Existing research is overly influenced by industry with potential publication bias and concerns around transparency. A registry would promote robust and transparent research and publication.

1b. Help develop national guidelines and policy

Auditory implant practices including indications for treatment, type of implants used and patient follow-up, appear to vary amongst clinicians and hospitals. A national registry would help develop guidance and policy that would reduce this variation. *"The registry can help produce guidelines that standardise practices around the country and help reduce the post-code lottery that we have now" (BCHI user).* Registry data could help commissioners plan services better, including implant procurement. *"The information from the registry will help hospitals buy the implants for the best price" (CI user).*

1c. Facilitate patient decision making

It is difficult for patients to make decisions on their care. *"There are so many different companies and implants available, with not enough information, so you just can't make an educated decision." (BCHI user) "I chose an implant based on the way it looked, rather than how effective it was, because I just didn't have the information" (BCHI user).* A national registry would help patients make decisions, by providing accurate information on implant effectiveness, risks as well as new developments.

1d. Challenges to registry development

Professionals may not input data regularly, resulting in poor rates of data completion. "*It will be hard to get professionals to enter the information, especially in the long-term" (Family member).* It would be challenging to reach agreement on the registry dataset as well as registry ownership. *"You need to be careful about who owns the registry – if people disagree, they won't enter the information" (patient with hearing loss).*

FG Q2. How do you think patients could be involved in developing, leading or managing such a registry?

2a. Formal patient representation

Patients should be involved in registry development and leadership, with formal patient representation on the registry steering committee. This would make the registry more relevant and useful for patients. *"This is really our information, so we need to have a say on how the registry is developed and run" (CI user). "It's important to gain a balance – whilst you clearly need to have professional experts, you need to have patients too, so that the registry stays relevant and useful for patients" (Patient with hearing loss).*

FG Q3. What type of information do you think should be recorded in the registry?

3a. Registry dataset and easy-to-understand outcome measure

It is important for the registry dataset to reach a balance between comprehensibility and simplicity: comprehensive datasets would be too time consuming to complete, whilst basic datasets would provide limited value. Table 4 summarises the pre, intra and post-operative data-items on which consensus was reached. The registry should include an outcome measure that is easily understandable by patients. This could consist of a free-text field, in which patients could write a review about their experiences, the effectiveness of the procedure and impact on day-to-day life.

FG Q4. Would you want to be able to access and add information into the registry?

4a. Benefits of patient access

All participants thought that patient-access would be beneficial. It would make the registry more patient focused and help patients make decisions on their care. *"Having access to the registry would give me important information that would help me make choices about my treatment and make me feel like I have more power over my care" (patient with hearing loss).*

4b. Patients entering data

Patients were keen to contribute to data entry. *"It's essential that we enter our own data, because this is the information that other patients want to know" (CI user).* It would be easier for patients to enter data online, using 'apps' on mobile phones or tablets. Paper-based entry could be used for patients not familiar with online platforms.

FG Q5. How can we help get patients to input their data and be involved in the registry?

5a. Make the registry useful for patients

Making the registry useful for patients would increase patient involvement. This could be achieved by involving patients in registry leadership and by having a patient section that highlighted registry achievements and contained information that patients wanted to know. *"Basically, you need to make it worthwhile for patients, so that the registry helps them make decisions and cope with their treatment" (BCHI user).*

5b. Make the registry simple and use technology

The registry should be simple and easy to use. "*It shouldn't be overly technical – the key is to keep it simple so patients can use it easily and enter information easily" (family member).* This could be facilitated by using technology including 'apps' and text message alerts to remind patients to enter data.

5c. Inbuilt patient discussion forum

A patient discussion forum built into the registry, would help engage patients. This forum would enable patients to learn from one-another and share experiences. *"I always find it hard to meet people who can give me advice – having a forum in the registry would be really helpful and I would use it regularly" (CI user).*

FG Q6. Would you like the registry to contain information on results of named surgeons or hospitals?

6a. No – inaccurate reflection of practices

Publishing this information may result in inaccurate reflection of practices. Centres and surgeons with complex cases may necessarily have higher risk complications. Publication may result in surgeons becoming more risk-averse, leading to reduced innovation and fewer operations on high-risk patients. *"It's dangerous to focus on surgeon-specific information, because the ones that are cutting edge may unfairly look bad" (CI patient).* Publishing this data would poorly reflect that outcomes are dependent on the entire healthcare team. Rather, an independent committee should have access to this data and provide feedback and support where necessary, thereby promoting a blame-free, learning culture.

6b. Yes – increase patient choice

This information would help increase patient choice. *"There is supposed to be patient choice – but how can we choose without knowing how hospitals are performing?"* The information would also increase transparency and patient trust, whilst giving surgeons and hospitals incentive to improve practices.

FG Q7. How do you think the data should be protected and kept confidential? Who should be allowed to access your data?

7a. Data governance

Data should be anonymous, with patients identifiable only via a patient number. The registry must comply with government data regulations and patient consent should be obtained for data collection. Registry access should be password protected.

7b. Data protection committee

The registry should have a data protection committee, with a patient representative member, that would be responsible for data security and for permitting access to registry data. All NHS healthcare professionals should be able to access the registry if necessary for patient care and data should not be used for marketing purposes.

FG Q8. Who should own the data of the registry?

8a. Independent organisation

The registry should be owned by an independent body. Registry ownership by a single hospital, academic group or implant company could lead to conflicts of interest, publication bias or data manipulation and therefore reduced confidence in the registry. *"The registry needs to be owned by a body that is independent, with no vested interests" (CI user).* Ownership by an independent body may also attract more diverse funding in the long-term.

FG Q9. Registries are expensive to set up and maintain. How should the registry be paid for?

9a. Multiple sources

Funding should be obtained from a mixture of sources, to avoid over-reliance on a single funder. All parties that benefit from the registry should contribute towards it, including: industry, the government, ENT and audiology professional bodies, hospitals, and patient charities. A fee should be charged for accessing registry data for research or industry purposes.

FG Q10. Overall what do you think is the most important factor for making a registry successful?

10a. Data completeness

The most important factor for registry success is securing high-levels of data completion. The key to achieving this would be by involving patients and professional groups during the development and running of the registry. This would make the registry useful and relevant, securing 'buy-in'.

Organisation of themes into a conceptual framework

The themes obtained from the interviews and focus groups were mapped against a conceptual framework, consisting of 5 fundamental categories for successful registry

development[22] (Figure 1): 1) *Planning* includes setting registry objectives, appointing a steering committee, establishing registry management systems, acquiring long-term funding and defining registry ownership. 2) *Registry governance* involves appointing a data protection committee and incorporating patient access and surgeon specific data reporting once appropriate registry systems are in place. 3) *Registry dataset* includes selecting the fundamental data-items, having a free-text field, holding a dataset consensus meeting and implementing QoL data collection once the registry is well established. 4) *Anticipating challenges* consists of being aware of core challenges including: data completion; reaching consensus on registry dataset, resource requirements, data governance and legal factors. 5) *Implementing solutions* involves putting in place the following strategies to maximise registry success: compulsory data-input, advertise registry benefits, engage with influential groups, involve stakeholders and patients, make the registry user-friendly, have early input from legal, IT and governance experts.

DISCUSSION

Summary of findings

Professional stakeholders and patients highlighted the urgent need for a national registry of auditory implants. Existing UK auditory implant registries are incomplete with limitations in their ability to inform clinical practice, policy and guidelines. Figure 1 summarises the key requirements for developing a successful national registry of auditory implants.

Relevance to existing research

The call for surgical registries extends beyond auditory implants, with a UK and European-wide drive to establish registries for all surgical implants.[26] Across the EU and UK, new implants can enter surgical practice on the basis of similarity to an existing implant, rather than on the basis of its own clinical effectiveness.[26,27] Concerns over the evidence base for surgical implants have been raised by several bodies including the IDEAL collaborative and the House of Commons Science and Technology committee.[26,27] Whilst there is a clear need for high quality research on surgical implants, it is important to consider the barriers to high quality research in this field, particularly randomised controlled trials (RCTs).

RCTs are expensive and due to their considerable costs and the growing numbers of implants, it is not feasible for RCTs to be performed for all implants.[28] Conflicts of interest are another area of concern. A large number of RCTs are industry funded [29] and evidence supports associations between industry funding and statistically significant pro-industry findings.[30,31] RCTs take considerable amounts of time to perform and, given the rapidly advancing surgical landscape, the implant assessed may become outdated. Another key limitation is external validity. RCTs by nature are strictly controlled which limits the generalisability of their findings.[28] For operations it is often impossible to blind treatment arms, thereby introducing bias.[32]

Registries represent a more pragmatic approach to address concerns over the evidence base and regulation of surgical implants. When compared to trials, registries require fewer resources, collect data from a broader population base and provide a more accurate reflection of current practices.[33] Moreover, unlike conventional clinical studies, registries

can answer the fundamental questions required for policy and guideline development, namely: 1) Does it work? 2) Will it work here? 3) Is it worth it?[34] Owing to these factors, the IDEAL collaborative, the DOH, the National Institute of Health and Care Excellence (NICE), policy makers and commissioning groups have called for surgical registries to improve our evidence base, drive quality and safety improvements, and inform policy and guidelines development.[1,13,18,26,27]

Strengths and Limitations

A key strength of this study is its inclusive and robust approach, involving multiple professional stakeholder groups as well as patients with hearing loss. Moreover, our findings built upon a conceptual framework on successful surgical registry development, that was developed following a systematic review and narrative synthesis.[22] The approach enabled the collection of a rich dataset in a field where there is a paucity of empirical evidence and a high level of uncertainty. The interview schedules were informed by a published systematic literature review and were piloted and updated before data collection. Focus groups and interviews were facilitated by individuals with expertise in qualitative interviewing, and patient and public involvement. Interview and focus group data were extracted and analysed by two independent data judges, with further verification by a data auditor. At the end of all interview and focus group sessions, participants were given an opportunity to discuss any other areas of registry development, not already covered by the questions and follow-ups.

Two limitations may restrict the generalisability of our findings. First, patients were selected from a UCL database of patients, with focus groups taking place at the UCL Ear Institute. This resulted in the majority of patients being located in or near London. Replication of the study in other geographical areas would strengthen the findings. Second, the use of purposive sampling for identifying professional stakeholders may have been prone to researcher bias. However, we attempted to mitigate this limitation by cross-checking the sample with independent experts from external institutions, and by giving all interviewees the opportunity to suggest stakeholders for subsequent interviews.

Implications

This paper identifies the requirements for developing a successful national registry of auditory implants. Its approach and findings can be adopted on an international level to inform successful registry development in other countries.

A successful registry of auditory implants would help develop robust national policy and guidelines. It would also help develop (inter)national research collaborations, identify the most effective implants, and drive implant innovations and improvements. From a patient perspective, the registry would help patients make decisions about their care and promote patient choice, trust and transparency. Other implications include facilitating inter(national) comparison of practices and personal audit, resulting in a culture of learning. The registry would help drive healthcare quality improvement, inform clinician decision making, improve patient safety, identify and support underperforming centres and detect faulty implants early. From a commissioning perspective, the registry would enable monitoring of trends in

practice, facilitating fair distribution of resources, equitable access to care, as well as efficient procurement of implants. Registry data would also provide the information required for the commissioning of new implant centres.

CONCLUSION

This study identifies the requirements for developing a successful national registry of auditory implants, benefitting from the involvement of numerous professional stakeholder groups, as well as patients with hearing loss. Our approach may be used internationally to inform successful registry development.

Contributors: RM, AK, AC, CT, EM, PL and AS made substantial contributions to the conception and design of the work. R.M collected the data. R.M, C.T, and A.S analysed the data. RM, AK, AC, CT drafted the work. RM, AK, AC, CT, EM, PL and AS revised the work critically and made final approval of the version to be published. All authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Table 1: Stakeholder group frequency

Stakeholder group	n =
Audiologists	6
ENT Surgeons	9
Non-ENT Surgical Registry Representatives	7
ENT Registry Leads	3
Industry	4
Registry experts	3
Commissioners	2
Patient charity representatives	2
National guidelines experts	3
Policy experts	3
Health economics experts	2
Department of Health Representatives	3
National hearing body representatives	4

Table 2: Characteristics of participants in focus groups

Patient number	Characteristic	Location
1	Family member of patient with bilateral hearing aids	Birmingham
2	Unilateral CI user	London
3	Family member of patient with unilateral CI	London
4	Unilateral CI and unilateral hearing aid user	Manchester
5	Family member of patient with bilateral hearing aids	Birmingham
6	Bilateral hearing aid user	Leeds
7	Unilateral BAHA user	London
8	Unilateral CI user	Sheffield
9	Bilateral CI user	Oxford
10	Bilateral CI user	Oxford
11	Member of patient group of patients with hearing loss	London
12	Unilateral BAHA user	Leicester
13	Unilateral CI user	Norwich
14	Unilateral CI user and works in a hearing loss charity	London
15	Unilateral CI and unilateral hearing aid user	London
16	Bilateral BAHA user	London
17	Unilateral BAHA and unilateral hearing aid	Brighton
18	Unilateral CI and unilateral BAHA	Reading
19	Bilateral CI user	Swindon

CI: Cochlear Implant, BAHA: Bone Anchored Hearing Aid

Table 3: Stakeholder suggested data-items

Pre-operative	Operative	Post-operative
NHS number / patient identifier (linkable to HES)	Name of hospital	Length of stay
Patient demographic details	Name of operation	Hearing test result at each follow-up
Patient diagnosis	Date of surgery	Complications at each follow-up
Indication	Grade of surgeon	Employment status
Primary or revision	Side of surgery	
Cost of implant	Surgery start time	
Hearing test result	Surgical approach	
Co-morbidities	Name, make and model of implant	
MDT outcome	Implant serial number	
Employment status	Intra-operative complication(s)	
Date of decision to operate	Surgery end time	
	Cost of implant	

Table 4: Patient focus group suggested data-items

Pre-operative	**Operative**	**Post-operative**
Patient demographics	Name of hospital	Levels of hearing
Occupation	Grade of surgeon	QoL
Co-morbidities	Date of surgery	Complications
Pre-operative QoL	Indications for surgery	Implant problems
Levels of hearing	Name of implant	Dates of follow-up appointments
Duration of hearing loss	Implant serial number	Details on assistive listening devices
Type of hearing loss	Implant manufacturer	Measure of cognitive status (for elderly patients)
Current hearing devices being used	Duration of surgery	Outcome measure understandable by patients
Information on previous hearing treatments	Intra-operative complication(s)	
Measure of cognitive status (for elderly patients)		

Qol: Quality of life

FIGURE LEGENDS

Figure 1: The requirements for developing a successful national registry of auditory implants

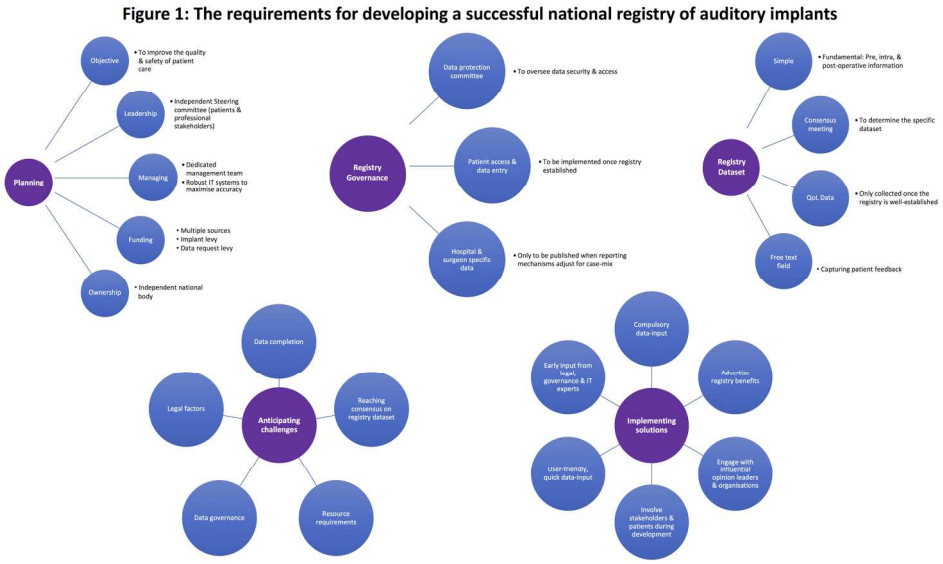

Figure 1: The requirements for developing a successful national registry of auditory implants

178x100mm (300 x 300 DPI)

APPENDIX 1:

Semi-structured interview schedule with professional stakeholders

There is a European and UK drive to establish registries for all surgical implants including for surgically implanted hearing devices. These auditory implants include Bone Conduction Hearing Devices and Cochlear Implants. The current initiatives to collect hearing data on these implants are fragmented and incomplete. In the absence of a national registry of auditory implants it is difficult to regulate the provision of auditory implants and monitor their clinical and cost-effectiveness.

Establishing a registry faces several challenges. We are conducting a series of interviews with professionals and patients through which we can explore the requirements for establishing a successful national registry of auditory implants. You have been identified as an expert on this topic and we would like to schedule a 15-minute telephone interview with you to gain your input. Results will be discussed at a future consensus conference to inform the development of a national registry of auditory implants.

Who we are?

evidENT is a research team based at the Ear Institute at University College London (UCL). We are dedicated to developing the best research to test and evaluate new and current treatments in ENT hearing and balance.

I am an ENT Academic Clinical Fellow and NICE Scholar

Opening questions

Please introduce yourselves including your relevant experience/expertise.

1. What are your thoughts on the existing auditory implant registries available? – what are their gaps/problems

a. National registry for Bone Conduction Hearing Implants (Ear foundation)

b. National Paediatric Bilateral Cochlear Implant Audit

c. Cochlear paediatric implanted recipient observational study (Cochlear™ P-IROS).

2. Do you think a national registry of auditory implants will be of benefit/do you think registries are beneficial - if so why?

3. What do you think the main purpose or goal of the registry should be?

a. For example: Improve patient care, monitoring interventions, drive research etc.

4. How should the registry be led/who should make the decisions?

a. Should patients be involved in registry leadership?

5. How should the registry be managed and maintained?

a. In terms of the day-to-day functioning.

b. Ensuring data is being collected and checking accuracy.

6. Broadly speaking, what do you think should be included in the dataset

a. Should we collect quality of life data and please explain your answer?

7. What do you think are the main challenges/barriers of establishing such a registry?

8. How can we overcome these challenges and increase registry participation/ buy-in?

9. Should patients be involved in the registry and if so how?

a. How should patients be involved (for example leadership/steering committee; registry design; registry management; registry reports/publications?

b. Should patients be able to access their own data and input their own data? Please explain you answer.

10. Who should own the data of the registry?

11. How should we fund the registry, taking into account costs for initial set-up and long term maintenance?

a. Should government pay?

b. Should Industry pay?

c. Should contributing hospital pay?

d. Should professional societies pay (ENT UK)?

e. Should we try and get funding from patient charities?

f. Should private individuals/organisations pay when requesting information?

12. Should we publish data on specific surgeons and hospitals?

13. Overall what do you think are the key factors for making a registry successful?

Is there anything else you would like to discuss about a national registry of auditory implants that we haven't already covered so far?

APPENDIX 2:

Focus groups interview schedule

Who we are?

evidENT is a research team based at the Ear Institute at University College London (UCL). We are dedicated to developing the best research to test and evaluate new and current treatments in ENT hearing and balance.

Introduction

There is growing interest in the development of a national UK registry of patients that have surgically implanted hearing devices. These devices include Cochlear Implants and Bone Conduction Hearing Implants that work to improve peoples' hearing. A registry is a collection of specific information about a treatment. Registries have been used in other surgical specialties to collect information on who has received treatment, which treatments are best, how patients are faring, if there are any safety concerns and so on.

We are running small discussion groups with patients and their family members to gather opinions and ideas on how to develop this registry. In parallel we have also discussed this with hearing loss professionals. The questions we are asking are based on a review of all the information known on developing surgical registries.

This is an opportunity for you to help shape this future national registry.

Opening questions

Introduce yourselves and tell us a bit about your hearing loss

Main questions

1. From what we've said, what are your thoughts on developing a registry of patients that have surgically implanted hearing devices.

a. What are the potential benefits for patients of the registry and why?
b. What are the potential risks/problems of developing a registry and why?

2. How do you think patients could be involved in developing, leading or managing such a registry?
   For example: being involved in setting the aims and direction of the registry, being involved in deciding what information to collection, allocating resources within the registry, being involved in writing the reports.

3. What type of information do you think should be recorded in the registry?
   a. Do you want information about changes in peoples' quality of life to be collected?

4. Would you want to be able to access and add your own information into the registry?
   a. What kind of information would you like to access/add?
   b. How would you like to access the information?

5. How can we help get patients to input their data and be involved in the registry?

6. Would you like the registry to contain information on results of named surgeons or hospitals? For example a named consultant's/hospital's complication rates following cochlear implantation.

7. How do you think the data should be protected and kept confidential?
   a. Who should be allowed to access your data?

8. Do you have any ideas on who should own the data of the registry?
   a. For example some registries are owned by their professional body. Others are owned by the government, hospitals, private industry, charities.

9. Registries are expensive to set up and maintain. How should the registry be paid for?

a. For example: The government, hospitals, private industry, professional organisations in ENT.

10. If you could the choose the one thing that's most important to be included/thought about for the registry – what would it be?

Is there anything else you would like to discuss about a national registry of auditory implants that we haven't already covered so far?

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	7 & 8
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	1
Occupation	3	What was their occupation at the time of the study?	1
Gender	4	Was the researcher male or female?	1
Experience and training	5	What experience or training did the researcher have?	7
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	6 & 8
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	6 & 8
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	7
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	9
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	6 & 8
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	6 & 8
Sample size	12	How many participants were in the study?	7 & 8
Non-participation	13	How many people refused to participate or dropped out? Reasons?	7 & 8
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	7 & 8
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	8
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	7 & 8
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	7 - 9
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	7
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	7 & 8
Field notes	20	Were field notes made during and/or after the inter view or focus group?	8 & 9
Duration	21	What was the duration of the inter views or focus group?	7 & 8
Data saturation	22	Was data saturation discussed?	9
Transcripts returned	23	Were transcripts returned to participants for comment and/or	9

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	9
Description of the coding tree	25	Did authors provide a description of the coding tree?	9
Derivation of themes	26	Were themes identified in advance or derived from the data?	9
Software	27	What software, if applicable, was used to manage the data?	9
Participant checking	28	Did participants provide feedback on the findings?	9
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	10 - 29
Data and findings consistent	30	Was there consistency between the data presented and the findings?	31
Clarity of major themes	31	Were major themes clearly presented in the findings?	29
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	10 - 29

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

BMJ Open

What are the requirements for developing a successful national registry of auditory implants? A qualitative study

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What are the requirements for developing a successful national registry of auditory implants? A qualitative study

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ABSTRACT

Objectives: Hearing loss is an area of unmet need and industry is targeting this field with a growing range of surgically-implanted hearing devices. Currently, there is no comprehensive United Kingdom (UK)-registry capturing data on these devices; in its absence, it is difficult to monitor clinical and cost-effectiveness and develop national policy. Recognising that developing such a registry faces considerable challenges, it is important to gather opinions from stakeholders and patients. This paper builds upon our systematic review on surgical registry development and aims to identify the specific requirements for developing a successful national registry of auditory implants.

Design: Qualitative study

Participants: Data were collected in two ways: (1) Semi-structured interviews with UK professional stakeholders; and (2) Focus groups with patients with hearing loss. The interview and focus group schedules were informed by our systematic review on registry development. Data were analysed using directed content analysis. Judges mapped the themes obtained against a conceptual framework developed from our systematic review on registry development. The conceptual framework consisted of 5 categories for successful registry development: 1) Planning; 2) Registry governance; 3) Registry dataset; 4) Anticipating challenges; 5) Implementing solutions.

Results: Twenty-seven themes emerged from 40 semi-structured interviews with professional stakeholders and 18 themes emerged from 3 patient focus groups. The most

important factor for registry success was high rates of data completion. Benefits of developing a successful registry of auditory implants include: strengthening the evidence base and regulation of auditory implants, driving quality and safety improvements, increased transparency, facilitating patient decision making, and informing policy and guidelines development.

Conclusions: This study identifies the requirements for developing a successful national registry of auditory implants, benefitting from the involvement of numerous professional stakeholder groups, as well as patients with hearing loss. Our approach may be used internationally to inform successful registry development.

Strengths and limitations of this study

- This study adopted an inclusive and robust approach, involving multiple professional stakeholder groups as well as patients with hearing loss.
- Our findings built upon a conceptual framework on successful surgical registry development, that was developed following our systematic review and narrative synthesis.
- The interview schedules were informed by our published systematic literature review and were piloted and updated before data collection.
- Interview and focus group data were extracted and analysed by two independent data judges, with further verification by a data auditor.
- We recognise that the use of purposive sampling for identifying professional stakeholders may have been prone to researcher bias.

INTRODUCTION:

Hearing loss has been identified as a key public priority by the Department of Health (DOH) and UK policy makers.[1-3] In the UK, 10 million people suffer from hearing loss, with an estimated annual cost to the economy of £30 billion.[1,4] Hearing loss has a major impact on social functioning and is associated with an increased risk of dementia.[1,5-11] Importantly the impacts of hearing loss are set to increase with our ageing population.[8,9]

Policymakers, guideline developers, clinicians, researchers and industry have realised that hearing loss is an area of unmet need.[1,7] This has resulted in increased investment in the development of surgically-implanted hearing devices including cochlear implants (CIs), Bone Conducting Hearing Devices (BCHDs) and Middle Ear Implants (MEIs).

Whilst auditory implants have been widely adopted, UK registry data on patients with auditory implants are lacking.[2,12-14] Safety incidents around other surgical implants such as the "Poly Implant Prostheses (PIP)" breast implant and the "metal-on-metal (MOM)" hip implant highlight the dangers of not collecting such information.[15-17] Conversely successful registry initiatives such as the National Hip Fracture Database (NHFD), the National Joint Registry (NJR) and the National Audit Cardiac Surgery (NACSA) registry highlight the benefits of registry data.[18-20] Hearing stakeholders, policymakers and patients have recognised that, in the absence of registry data, it is difficult to regulate auditory implants, monitor clinical and cost-effectiveness, and ultimately develop appropriate guidelines and policy.[2]

A potential solution is to develop a national registry of all auditory implants.[2] Recognising that developing such a registry faces considerable challenges, it is important to gather opinions from relevant stakeholders and patients with hearing loss.[21] This paper builds upon our recent systematic review[22] on successful surgical registry development and aims to identify the specific requirements for developing a successful national registry of auditory implants.

MATERIALS AND METHODS

Ethical considerations

Ethical approval was granted by UCL Research Ethics Committee 9031/001. Informed consent was sought from all stakeholders and patients. To facilitate patient attendance, travel expenses were remunerated and gift vouchers were provided.

Data collection

Data were collected in two ways: (1) Semi-structured interviews with professional stakeholders; and (2) Focus groups with patients with hearing loss. The methodological orientation underpinning the study was content analysis[23] and the study protocol was designed in accordance with the COREQ criteria.[24]

Semi-structured interviews with professional stakeholders

Participants

We adopted a purposive sampling strategy to identify individuals that are especially knowledgeable about hearing loss and implants.[25] Stakeholders were identified from a network of professionals known to the authors and their collaborators. The list of stakeholders was cross-checked by two independent individuals from separate institutions. At the end of each interview, interviewees were asked to provide contact details of stakeholders with relevant experience to our study. Stakeholders were approached via email invitation. Data analysis commenced after completion of the first interview. Stakeholders were recruited and interviewed until data saturation was reached. Professional stakeholder groups were located across the UK. Information on stakeholder groups can be seen in Table 1.

A total of 40 stakeholders were interviewed. This sampling approach led to a response rate of 89%. Reasons for non-participation included: unable to schedule suitable time (n=2) and nonresponse to invitation (n=3).

Procedures

Individual interviews lasted between 14 and 34 minutes and were digitally recorded and transcribed. Participation was voluntary and transcripts were anonymised. Participants were interviewed between March 2015 and December 2016, either in person at the University College London (UCL) Ear Institute or via telephone. The semi-structured interviews followed an interview schedule comprising 13 questions, each of which contained specific

probes (see Appendix 1). The interview schedule was developed following our narrative systematic review on UK surgical registry development.[22] The interviewer was an ENT Academic Clinical Trainee with expertise in health policy research. The interview schedule focused on (1) opinions on existing auditory implant registries, (2) the requirements of a successful registry, and (3) the challenges of establishing a national registry of auditory implants and potential solutions.

The interview schedule was piloted on two professionals and updated following their feedback.

Focus groups with patients with hearing loss

Participants

Adult patients with hearing loss and their family members were interviewed in three focus groups, each comprising 6 to 7 participants. Participants were identified from a UCL Ear Institute database of patients who had given their consent to take part in clinical research. Participants were approached via email invitation. A total of 19 participants were included. Characteristics of participants, are shown in Table 2. Ten patients refused to participate due to: lack of time (n=3), caring commitments (n=3) and difficulty in travelling (n=4).

Procedures

The focus groups explored 10 questions, each containing specific probes about a future national registry of auditory implants (see Appendix 2). The questions were developed from the same systematic review on UK surgical registry development.[22] Focus groups took place in July 2016 at the UCL Ear Institute and were facilitated by the primary investigator and a patient and public involvement expert.

The focus group discussions lasted between 90 and 105 minutes. The discussions were recorded using a digital recorder and professionally transcribed. Transcripts were anonymised. The focus group schedule was trialled on two patients and updated following their feedback.

Analysis

Data analyses were performed in 2 stages. *Stage 1:* Two data judges (RM and CT) qualitatively analysed the interview and focus group transcripts separately using directed content analysis.[23] Data judges independently read through the interview and focus group transcripts and extracted data from the transcripts manually onto separate data extraction tables. The framework of the data extraction tables reflected the structure of the interview and focus group schedules. The data judges independently made notes of themes arising from the extracted data and compared their analyses. Discrepancies were discussed and resolved. Amending the themes list was repeated until no new themes emerged. The data judges met periodically with the data auditor (AS) to discuss the analysis.

Stage 2: Judges independently mapped the themes obtained from the stakeholder interviews and focus group responses against a conceptual framework developed from our systematic review on registry development.[22] The conceptual framework consisted of 5 fundamental categories for successful registry development: 1) Planning; 2) Registry governance; 3) Registry dataset; 4) Anticipating challenges; 5) Implementing solutions.[22] Judges compared their findings and discrepancies were discussed and resolved.

Patient involvement

- Patients with hearing loss helped inform the research question during previous focus groups held at the UCL institute.
- Patients gave feedback on the wording of the focus group schedule. Their feedback was used to update the schedule before carrying out the focus group discussions.
- Patients were able to suggest the inclusion of their family members in the focus groups.
- Results will be disseminated back to study participants during a consensus conference held at the UCL Ear Institute.

RESULTS

Semi-structured interviews with professional stakeholders

All themes identified are presented below in italics under each interview question. A summary of the extracted data giving rise each theme is provided. Table 3 summarises all themes identified.

Professional stakeholder (PS) Question (Q)1. What are your thoughts on the existing auditory implant registries available?

Theme (T)1a. Existing registries available

Stakeholders were aware of the following UK auditory registries: The Ear Foundation Bone Anchored Hearing Aid (BAHA) registry, The Ear Foundation BCHI registry, Pochia CI registry, Bawtry Database, Auditbase, National Audit of Bilateral CIs, Auditbase, Otology Web Based database, Cochlear Paediatric Implanted Recipient Observational Study (Cochlear™ P-IROS registry). Some implant centres and device manufactures have their own registries.

T1b. Existing registries are limited

Limitations of existing registries include: poor rates of data completion; not user-friendly; difficult to navigate and enter data; overly basic or complex datasets; inappropriate outcome measures; too clinician-focused; unable to sufficiently inform clinical practice, commissioning or guidelines development.

PS Q2. Do you think a national registry of auditory implants will be of benefit?

T2a. Improve safety and quality of care

A successful registry would be able to monitor national practices, improve quality of care, identify safety concerns, and facilitate implant recall. The registry would also facilitate (inter)national comparison of practices and comparison between implants. Poorly performing centres could be identified and supported. Registry leads noted that their registries were associated with improved clinical standards, shorter waiting times and length of stay, as well as reductions in morbidity and mortality.

T2b. Promote research and innovation

A registry would provide essential data to assess the clinical and cost-effectiveness of auditory implants. It would also facilitate research collaborations, provide data with external validity, refine indications for implantation and drive device improvements and innovations.

T2c. Facilitate commissioning and guideline development

A registry would enable monitoring of national clinical activity, facilitating efficient implant procurement, fair distribution of resources and equitable access to care. The registry would also provide valuable information for guidelines and policy development.

T2d. Help patient decision making

A national registry would help patients make informed decisions by providing them with information on procedure effectiveness and risks.

PS Q3. What do you think the main purpose or goal of the registry should be?

T3a. To improve the quality and safety of care

The main purpose of the registry should be to improve the quality and safety of care provided whilst promoting transparency and patient choice. The registry should also aim to monitor practices and device effectiveness, drive clinical research as well as assist in the development of policy.

PS Q4. How should the registry be led/who should make the decisions?

T4a. Have a Steering committee

The registry should be led by an independent steering committee, with representation from: audiologists, an ENT UK representative, implant surgeons, commissioners, policy experts, a health economist, guideline developers, patients and a lay-member. Subcommittees would be responsible for separate areas, including funding, data collection, data verification and governance.

PS Q5. How should the registry be managed/maintained?

T5a. Dedicated management team

The registry should be managed by a dedicated management team, responsible for: collecting data centrally, maximising data completion and verifying data. Each hospital should have its own data manager.

T5b. Robust IT systems to verify data

Robust IT systems should be in place, to verify and clean data. Registry data can be verified by comparing it with Hospital Episode Statistics (HES) data.

PS Q6. Broadly speaking, what do you think should be included in the dataset?

T6a. Registry dataset

Table 4 summarises the pre-, intra- and post-operative data items on which consensus was reached. A consensus meeting would be required to establish the specifics of the dataset.

T6b. Quality of life (QoL) data

QoL data helps provide meaningful outcomes and facilitates health economic analyses. However, it is challenging to reach consensus on QoL outcome measures and QoL data collection is time consuming and may result in reduced data completion. Therefore, QoL data collection should be introduced when the registry is well-established.

PS Q7. What are the main challenges of establishing a registry?

T7a. 'Buy-in' and data completion

The main challenge would be achieving long-term 'buy-in' and data completion. Reaching agreement on the registry dataset would also be a key challenge.

T7b. Resource heavy

The registry would require considerable financial, human and time resources for initial set-up, data entry as well as registry maintenance.

T7c. Registry governance

Data governance and legal factors are other challenges. These include compliance with data protection and information governance laws, maintaining data security, policing data access, appointing a steering committee, identifying data ownership, acquiring patient consent and ensuring data accuracy and quality.

PS Q8. How can we overcome these challenges?

T8a. Engage with opinion leaders

Having opinion leaders as registry advocates would increase registry awareness. Support from influential organisations such as DoH, the National Institute for Health and Care

Excellence (NICE) and Commissioning Groups, would help maximise registry relevance and funding.

T8b. Registry development and design

All stakeholder groups should be involved in registry development and the registry must be simple, electronic, and adaptable to maximise data completion and promote longevity. A minimal dataset should be employed that is quick to complete, with no free-text data entry. Legal, governance and IT experts should be consulted from the outset, with data verification systems in place. A pilot registry, would provide user-feedback and facilitate registry improvement before national launch.

T8c. Make it Compulsory

The most effective way to maximise data completion would be by making the registry compulsory for clinician revalidation and for commissioning. Financial incentives could be applied to hospitals and data completion rates could be published.

T8d. Make it clearly useful

Making the registry useful for stakeholders for publications, audits, revalidation, implant procurement and policy development would increase 'buy-in' and data completion. Registry achievements should be disseminated to increase registry awareness.

PS Q9. Should patients be involved in the registry and if so how?

Patients should be involved in the registry in three different capacities.

T9a. Leadership and development

A patient representative should be on the steering committee. This would help make the registry more accountable and meaningful.

T9b. Accessing the registry

Patients should be given access to the registry, particularly to their own data. This would encourage data accuracy and completion. Safeguards would be needed to comply with data-protection and patient confidentiality.

T9c. Entering data

It would be helpful and efficient for patients to enter their own data, particularly QoL data. However, data verification systems would be needed and patient data entry would be complex and expensive; and should therefore be implemented once the registry is already well-established.

PS Q10. Who should own the data of the registry?

T10a. Independent national body

The registry should be owned by an independent national body such as : NHS England, DoH, the Secretary of State for Health and Public Health England. These bodies would provide longevity, impartiality, fair access and experience.

PS Q11. How should we fund the registry?

T11a. Multiple sources

Funding should be requested from all stakeholder groups. Multiple income streams would provide financial security and increase engagement. Suggested funders included: ENT UK, DoH, patient charities, research grants, National Institute for Health Research (NIHR), Medical Research Council (MRC), Action on Hearing Loss (AoHL), healthcare providers, industry, The Ear Foundation, British Society of Audiology and The British Academy of Audiology.

T11b. Levy on all implants used

A fee, applied to each implant used, would be a helpful source of income. The fee would be paid for by industry and the purchasing hospital.

PS Q12. Should we publish data on specific surgeons and hospitals?

T12a. Wait until the registry is established

Potential benefits include: increased patient choice, trust, transparency, and promoting a culture of learning. Negatives include: data being misleading if unadjusted for case mix, data poorly reflecting that outcomes are dependent on the entire healthcare team, reporting bias, risk-averse practices, and reduced rates of data completion. Due to these risks, data should be reported once the registry is well-established, with robust mechanisms for adjusted reporting.

PS Q13. Overall what do you think is the most important factor for making a registry successful?

T13a. Data completeness

High levels of data completion and accuracy are essential. To achieve this, the most important factors include: involving stakeholders and patients during registry development; compulsory data entry; making the registry useful for all groups; and having robust data processing systems.

Focus groups with patients with hearing loss

All themes identified are presented below in italics under each interview question. A summary of the extracted data giving rise each theme is provided. Table 3 summarises all themes identified.

Focus Group (FG) Q1. What are your thoughts on developing a registry of patients that have surgically implanted hearing devices?

T1a. Improve quality and safety of care

A registry would identify implant problems early, permit recall in the event of safety concerns and allow manufacturers to evaluate their products and improve effectiveness whilst encouraging competition. It would enable national comparison of outcomes and promote research.

T1b. Help develop national guidelines and policy

A national registry would help develop guidance and policy that would reduce variation between centres. It would also help commissioners plan services better, including efficient implant procurement.

T1c. Facilitate patient decision making

By providing accurate information on implant effectiveness, risks as well as new developments, a registry would help patients make decisions on their care.

T1d. Challenges to registry development

Professionals may not input data, resulting in poor rates of data completion and it would be challenging to reach agreement on the registry dataset as well as data ownership.

FG Q2. How do you think patients could be involved in developing, leading or managing such a registry?

T2a. Formal patient representation

Patients should be formally involved in registry development and leadership. This would make the registry more relevant and useful for patients.

FG Q3. What type of information do you think should be recorded in the registry?

T3a. Registry dataset and easy-to-understand outcome measure

There should be a balance between comprehensibility and simplicity: comprehensive datasets would be too time consuming, whilst basic datasets would provide limited value. Table 5 summarises the data-items on which consensus was reached. The registry should include an outcome measure that is easily understandable by patients.

FG Q4. Would you want to be able to access and add information into the registry?

T4a. Benefits of patient access

Patient-access would make the registry more patient focused and help patients make decisions on their care.

T4b. Patients entering data

Patients were keen to contribute to data entry via 'apps'. Paper-based entry could be used for patients not familiar with online platforms.

FG Q5. How can we help get patients to input their data and be involved in the registry?

T5a. Make the registry useful for patients

Making the registry useful for patients would increase patient involvement. This could be achieved by having a patient section containing relevant information for patients.

T5b. Make the registry simple and use technology

The registry should be simple and easy to use. This could be facilitated by using technology including 'apps' and text message alerts to remind patients to enter data.

T5c. Inbuilt patient discussion forum

A patient discussion forum within the registry would help engage patients. This forum would enable patients to learn from one-another and share experiences.

FG Q6. Would you like the registry to contain information on results of named surgeons or hospitals?

T6a. Inaccurate reflection of practices

Publishing this information may result in inaccurate reflection of practices. Surgeons with complex cases may have a higher risk of complications. Publication may result in surgeons becoming more risk-averse and this data would not reflect that outcomes are dependent on the entire healthcare team. An independent committee should have access to this data and provide feedback and support where necessary.

T6b. Increase patient choice

This information would help increase patient choice as well as transparency and trust, whilst giving surgeons incentive to improve practices.

FG Q7. How do you think the data should be protected and kept confidential? Who should be allowed to access your data?

T7a. Data governance

Data should be anonymous, with patients identifiable only via a patient number. Patient consent should be obtained for data collection and registry access should be password protected.

T7b. Data protection committee

The registry should have a committee for data protection, with a patient representative. All healthcare professionals should be able to access the registry if necessary for patient care.

FG Q8. Who should own the data of the registry?

T8a. Independent organisation

The registry should be owned by an independent body. Registry ownership by a single hospital, academic group or implant company could lead to conflicts of interest, or data manipulation and therefore reduced confidence in the registry.

FG Q9. Registries are expensive to set up and maintain. How should the registry be paid for?

T9a. Multiple sources

Funding should be obtained from a mixture of sources, to avoid over-reliance on a single funder. All parties that benefit from the registry should contribute towards it. A fee should be charged for accessing registry data for research or industry purposes.

FG Q10. Overall what do you think is the most important factor for making a registry successful?

T10a. Data completeness

There was consensus amongst patients that the most important factor for registry success is high-levels of data completion. To achieve this, patients and professional groups must be involved during the development and running of the registry.

Organisation of themes into a conceptual framework

The themes obtained from the interviews and focus groups were mapped against a conceptual framework, consisting of 5 fundamental categories for successful registry development[22] (Figure 1): 1) *Planning* includes setting registry objectives, appointing a steering committee, establishing registry management systems, acquiring long-term funding and defining registry ownership. 2) *Registry governance* involves appointing a data protection committee and incorporating patient access and surgeon specific data reporting once appropriate registry systems are in place. 3) *Registry dataset* includes selecting the fundamental data-items, having a free-text field, holding a dataset consensus meeting and implementing QoL data collection once the registry is well established. 4) *Anticipating challenges* consists of being aware of core challenges including: data completion; reaching consensus on registry dataset, resource requirements, data governance and legal factors. 5) *Implementing solutions* involves putting in place the following strategies to maximise

registry success: compulsory data-input, advertise registry benefits, engage with influential groups, involve stakeholders and patients, make the registry user-friendly, have early input from legal, IT and governance experts.

DISCUSSION

Summary of findings

Figure 1 summarises the key requirements for developing a successful national registry of auditory implants.

Relevance to existing research

The call for surgical registries extends beyond auditory implants, with a UK and European-wide drive to establish registries for all surgical implants.[26] Across the EU and UK, new implants can enter surgical practice on the basis of similarity to an existing implant, rather than on the basis of its own clinical effectiveness.[26,27] Concerns over the evidence base for surgical implants have been raised by several bodies including the IDEAL collaborative, the EU and the House of Commons Science and Technology committee.[26,27] Registries represent a pragmatic approach to address these concerns.[28-33] Unlike conventional clinical studies, registries can answer the fundamental questions required for policy and guideline development, namely: 1) Does it work? 2) Will it work here? 3) Is it worth it?[34] Owing to these factors, the IDEAL collaborative, the DOH, NICE, policy makers and commissioning

groups have called for surgical registries to improve our evidence base, drive quality and safety improvements, and inform policy and guidelines development.[1,13,18,26,27]

Strengths and Limitations

A key strength of this study is its inclusive and robust approach, involving multiple stakeholder groups as well as patients with hearing loss. Moreover, our findings built upon a conceptual framework on successful surgical registry development, developed following our systematic review.[22] The approach enabled the collection of a rich dataset in a field where there is a paucity of empirical evidence and a high level of uncertainty. The interview schedules were informed by our published systematic literature review and were piloted before data collection. Focus groups and interviews were facilitated by individuals with expertise in qualitative interviewing, and patient and public involvement. Data were extracted and analysed by two independent data judges, with further verification by a data auditor. Participants were given an opportunity to discuss any other areas of registry development, not already covered by the questions and follow-ups.

Two limitations may restrict the generalisability of our findings. First, patients were selected from a UCL database of patients, with focus groups taking place at the UCL Ear Institute. This resulted in the majority of patients being located in or near London. Second, the use of purposive sampling for identifying professional stakeholders may have been prone to researcher bias. However, we attempted to mitigate this limitation by cross-checking the sample with independent experts from external institutions, and by giving all interviewees the opportunity to suggest stakeholders for subsequent interviews.

Implications

This paper identifies the requirements for developing a successful national registry of auditory implants. Its approach and findings can be adopted on an international level to inform successful registry development in other countries.

A successful registry of auditory implants would help develop robust national policy and guidelines. It would also help promote research and innovation, improve healthcare quality and safety and help patients make decisions about their care. From a commissioning perspective, the registry would facilitate equitable access to care and efficient procurement of implants.

CONCLUSION

This study identifies the requirements for developing a successful national registry of auditory implants, benefitting from the involvement of numerous professional stakeholder groups, as well as patients with hearing loss. Our approach may be used internationally to inform successful registry development.

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published. R.M, A.K, A.C, C.T, E.M, P.L and A.S agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Table 1: Stakeholder group frequency

Stakeholder group	n =
Audiologists	6
ENT Surgeons	9
Non-ENT Surgical Registry Representatives	7
ENT Registry Leads	3
Industry	4
Registry experts	3
Commissioners	2
Patient charity representatives	2
National guidelines experts	3
Policy experts	3
Health economics experts	2
Department of Health Representatives	3
National hearing body representatives	4

Table 2: Characteristics of participants in focus groups

Patient number	Characteristic	Location
1	Family member of patient with bilateral hearing aids	Birmingham
2	Unilateral CI user	London
3	Family member of patient with unilateral CI	London
4	Unilateral CI and unilateral hearing aid user	Manchester
5	Family member of patient with bilateral hearing aids	Birmingham
6	Bilateral hearing aid user	Leeds
7	Unilateral BAHA user	London
8	Unilateral CI user	Sheffield
9	Bilateral CI user	Oxford
10	Bilateral CI user	Oxford
11	Member of patient group of patients with hearing loss	London
12	Unilateral BAHA user	Leicester
13	Unilateral CI user	Norwich
14	Unilateral CI user and works in a hearing loss charity	London
15	Unilateral CI and unilateral hearing aid user	London
16	Bilateral BAHA user	London
17	Unilateral BAHA and unilateral hearing aid	Brighton
18	Unilateral CI and unilateral BAHA	Reading
19	Bilateral CI user	Swindon

CI: Cochlear Implant, BAHA: Bone Anchored Hearing Aid

Table 3: Themes identified from stakeholder interviews and patient focus groups

Semi-structured interviews with professional stakeholders

PS Q1. What are your thoughts on the existing auditory implant registries available?	*T1a. Existing registries available*	*T1b. Existing registries are limited*		
PS Q2. Do you think a national registry of auditory implants will be of benefit?	*T2a. Improve safety and quality of care*	*T2b. Promote research and innovation*	*T2c. Facilitate commissioning and guideline development*	*T2d. Help patient decision making*
PS Q3. What do you think the main purpose or goal of the registry should be?	*T3a. To improve the quality and safety of care*			
PS Q4. How should the registry be led/who should make the decisions?	*T4a. Have Steering committee*			
PS Q5. How should the registry be managed/maintained?	*T5a. Dedicated management team*	*T5b. Robust IT systems to verify data*		
PS Q6. Broadly speaking, what do you think should be included in the dataset?	*T6a. Registry dataset*	*T6b. Quality of life (QoL) data*		
PS Q7. What are the main challenges of establishing a registry?	*T7a. 'Buy-in' and data completion*	*T7b. Resource heavy*	*T7c. Registry governance*	
PS Q8. How can we overcome these challenges?	*T8a. Engage with opinion leaders*	*T8b. Registry development and design*	*T8c. Make it compulsory*	*T8d. Make it clearly useful*
PS Q9. Should patients be involved in the registry and if so how?	*T9a. Leadership and development*	*T9b. Accessing the registry*	*T9c. Entering data*	
PS Q10. Who should own the data of the registry?	*T10a. Independent national body*			
PS Q11. How should we fund the registry?	*T11a. Multiple sources*	*T11b. Levy on all implants used*		
PS Q12. Should we publish data on specific surgeons and hospitals?	*T12a. Wait until the registry is established*			
PS Q13. Overall what do you think is the most important factor for making a registry successful?	*T13a. Data completeness*			

Focus groups with patients with hearing loss

FG Q1. What are your thoughts on developing a registry of patients that have surgically implanted hearing devices?	*T1a. Improve quality and safety of care*	*T1b. Help develop national guidelines and policy*	*T1c. Facilitate patient decision making*	*T1d. Challenges to registry development*
FG Q2. How do you think patients could be involved in developing, leading or managing such a registry?	*T2a. Formal patient representation*			
FG Q3. What type of information do you think should be recorded in the registry?	*T3a. Registry dataset and easy-to-understand outcome measure*			
FG Q4. Would you want to be able to access and add information into the registry?	*T4a. Benefits of patient access*	*T4b. Patients entering data*		
FG Q5. How can we help get patients to input their data and be involved in the registry?	*T5a. Make the registry useful for patients*	*T5b. Make the registry simple and use technology*	*T5c. Inbuilt patient discussion forum*	
FG Q6. Would you like the registry to contain information on results of named surgeons or hospitals?	*T6a. Inaccurate reflection of practices*	*T6b. Increase patient choice*		
FG Q7. How do you think the data should be protected and kept confidential? Who should be allowed to access your data?	*T7a. Data governance*	*T7b. Data protection committee*		
FG Q8. Who should own the data of the registry?	*T8a. Independent organisation*			
FG Q9. Registries are expensive to set up and maintain. How should the registry be paid for?	*T9a. Multiple sources*			
FG Q10. Overall what do you think is the most important factor for making a registry successful?	*T10a. Data completeness*			

PS: Professional Stakeholder; Q: Questions; T: Theme

Table 4: Stakeholder suggested data-items

Pre-operative	**Operative**	**Post-operative**
NHS number / patient identifier (linkable to HES)	Name of hospital	Length of stay
Patient demographic details	Name of operation	Hearing test result at each follow-up
Patient diagnosis	Date of surgery	Complications at each follow-up
Indication	Grade of surgeon	Employment status
Primary or revision	Side of surgery	
Cost of implant	Surgery start time	
Hearing test result	Surgical approach	
Co-morbidities	Name, make and model of implant	
MDT outcome	Implant serial number	
Employment status	Intra-operative complication(s)	
Date of decision to operate	Surgery end time	
	Cost of implant	

Table 5: Patient focus group suggested data-items

Pre-operative	Operative	Post-operative
Patient demographics	Name of hospital	Levels of hearing
Occupation	Grade of surgeon	QoL
Co-morbidities	Date of surgery	Complications
Pre-operative QoL	Indications for surgery	Implant problems
Levels of hearing	Name of implant	Dates of follow-up appointments
Duration of hearing loss	Implant serial number	Details on assistive listening devices
Type of hearing loss	Implant manufacturer	Measure of cognitive status (for elderly patients)
Current hearing devices being used	Duration of surgery	Outcome measure understandable by patients
Information on previous hearing treatments	Intra-operative complication(s)	
Measure of cognitive status (for elderly patients)		

Qol: Quality of life

FIGURE LEGENDS

Figure 1: The requirements for developing a successful national registry of auditory implants

Figure 1: The requirements for developing a successful national registry of auditory implants

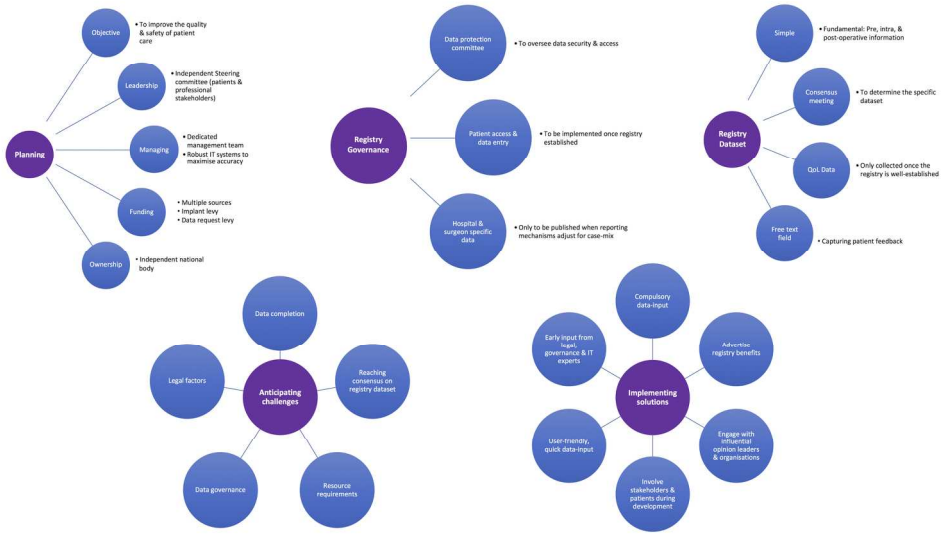

Figure 1: The requirements for developing a successful national registry of auditory implants

178x100mm (300 x 300 DPI)

APPENDIX 1:

Semi-structured interview schedule with professional stakeholders

There is a European and UK drive to establish registries for all surgical implants including for surgically implanted hearing devices. These auditory implants include Bone Conduction Hearing Devices and Cochlear Implants. The current initiatives to collect hearing data on these implants are fragmented and incomplete. In the absence of a national registry of auditory implants it is difficult to regulate the provision of auditory implants and monitor their clinical and cost-effectiveness.

Establishing a registry faces several challenges. We are conducting a series of interviews with professionals and patients through which we can explore the requirements for establishing a successful national registry of auditory implants. You have been identified as an expert on this topic and we would like to schedule a 15-minute telephone interview with you to gain your input. Results will be discussed at a future consensus conference to inform the development of a national registry of auditory implants.

Who we are?

evidENT is a research team based at the Ear Institute at University College London (UCL). We are dedicated to developing the best research to test and evaluate new and current treatments in ENT hearing and balance.

I am an ENT Academic Clinical Fellow and NICE Scholar

Opening questions

Please introduce yourselves including your relevant experience/expertise.

1. What are your thoughts on the existing auditory implant registries available? – what are their gaps/problems

a. National registry for Bone Conduction Hearing Implants (Ear foundation)

b. National Paediatric Bilateral Cochlear Implant Audit

c. Cochlear paediatric implanted recipient observational study (Cochlear™ P-IROS).

2. Do you think a national registry of auditory implants will be of benefit/do you think registries are beneficial - if so why?

3. What do you think the main purpose or goal of the registry should be?

a. For example: Improve patient care, monitoring interventions, drive research etc.

4. How should the registry be led/who should make the decisions?

a. Should patients be involved in registry leadership?

5. How should the registry be managed and maintained?

a. In terms of the day-to-day functioning.

b. Ensuring data is being collected and checking accuracy.

6. Broadly speaking, what do you think should be included in the dataset

a. Should we collect quality of life data and please explain your answer?

7. What do you think are the main challenges/barriers of establishing such a registry?

8. How can we overcome these challenges and increase registry participation/ buy-in?

9. Should patients be involved in the registry and if so how?

a. How should patients be involved (for example leadership/steering committee; registry design; registry management; registry reports/publications?

b. Should patients be able to access their own data and input their own data? Please explain you answer.

10. Who should own the data of the registry?

11. How should we fund the registry, taking into account costs for initial set-up and long term maintenance?

a. Should government pay?

b. Should Industry pay?

c. Should contributing hospital pay?

d. Should professional societies pay (ENT UK)?

e. Should we try and get funding from patient charities?

f. Should private individuals/organisations pay when requesting information?

12. Should we publish data on specific surgeons and hospitals?

13. Overall what do you think are the key factors for making a registry successful?

Is there anything else you would like to discuss about a national registry of auditory implants that we haven't already covered so far?

APPENDIX 2:

Focus groups interview schedule

Who we are?

evidENT is a research team based at the Ear Institute at University College London (UCL). We are dedicated to developing the best research to test and evaluate new and current treatments in ENT hearing and balance.

Introduction

There is growing interest in the development of a national UK registry of patients that have surgically implanted hearing devices. These devices include Cochlear Implants and Bone Conduction Hearing Implants that work to improve peoples' hearing. A registry is a collection of specific information about a treatment. Registries have been used in other surgical specialties to collect information on who has received treatment, which treatments are best, how patients are faring, if there are any safety concerns and so on.

We are running small discussion groups with patients and their family members to gather opinions and ideas on how to develop this registry. In parallel we have also discussed this with hearing loss professionals. The questions we are asking are based on a review of all the information known on developing surgical registries.

This is an opportunity for you to help shape this future national registry.

Opening questions

Introduce yourselves and tell us a bit about your hearing loss

Main questions

1. From what we've said, what are your thoughts on developing a registry of patients that have surgically implanted hearing devices.

a. What are the potential benefits for patients of the registry and why?
b. What are the potential risks/problems of developing a registry and why?

2. How do you think patients could be involved in developing, leading or managing such a registry?
   For example: being involved in setting the aims and direction of the registry, being involved in deciding what information to collection, allocating resources within the registry, being involved in writing the reports.

3. What type of information do you think should be recorded in the registry?
   a. Do you want information about changes in peoples' quality of life to be collected?

4. Would you want to be able to access and add your own information into the registry?
   a. What kind of information would you like to access/add?
   b. How would you like to access the information?

5. How can we help get patients to input their data and be involved in the registry?

6. Would you like the registry to contain information on results of named surgeons or hospitals? For example a named consultant's/hospital's complication rates following cochlear implantation.

7. How do you think the data should be protected and kept confidential?
   a. Who should be allowed to access your data?

8. Do you have any ideas on who should own the data of the registry?
   a. For example some registries are owned by their professional body. Others are owned by the government, hospitals, private industry, charities.

9. Registries are expensive to set up and maintain. How should the registry be paid for?

a. For example: The government, hospitals, private industry, professional organisations in ENT.

10. If you could the choose the one thing that's most important to be included/thought about for the registry – what would it be?

Is there anything else you would like to discuss about a national registry of auditory implants that we haven't already covered so far?

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	7 & 8
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	1
Occupation	3	What was their occupation at the time of the study?	1
Gender	4	Was the researcher male or female?	1
Experience and training	5	What experience or training did the researcher have?	7
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	6 & 8
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	6 & 8
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	7
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	9
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	6 & 8
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	6 & 8
Sample size	12	How many participants were in the study?	7 & 8
Non-participation	13	How many people refused to participate or dropped out? Reasons?	7 & 8
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	7 & 8
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	8
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	7 & 8
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	7 - 9
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	7
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	7 & 8
Field notes	20	Were field notes made during and/or after the inter view or focus group?	8 & 9
Duration	21	What was the duration of the inter views or focus group?	7 & 8
Data saturation	22	Was data saturation discussed?	9
Transcripts returned	23	Were transcripts returned to participants for comment and/or	9

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	9
Description of the coding tree	25	Did authors provide a description of the coding tree?	9
Derivation of themes	26	Were themes identified in advance or derived from the data?	9
Software	27	What software, if applicable, was used to manage the data?	9
Participant checking	28	Did participants provide feedback on the findings?	9
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	10 - 29
Data and findings consistent	30	Was there consistency between the data presented and the findings?	31
Clarity of major themes	31	Were major themes clearly presented in the findings?	29
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	10 - 29

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.