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UK Bone Conduction Hearing Device Consensus Workshop: Narrative Summary

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On behalf of the Bone Conduction Hearing Device Workshop

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We would like to thank the participation from all stakeholders and patient representatives.

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Professor Jaydip Ray is the Clinical Director and Research Lead of the Sheffield Clinical Research Office. His research interest is in Neurotology, including complex hearing and balance disorders as well as the use of novel diagnostic and therapeutic strategies in their management.

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Abstract

Objectives: To identify United Kingdom (UK)-specific research priorities in the field of Bone Conduction Hearing Devices (BCHDs).

Method: Narrative summary of the discussions and outcomes of a UK BCHD research workshop. The workshop was organised on 8th September 2016 under the auspices of the National Institute for Health Research (NIHR) Clinical Research Network (CRN) ENT Specialty group and Royal College of Surgeons (RCS) Clinical Research Initiative.

Representatives from a wide range of patient and professional groups from the UK and abroad were invited to attend. Main outcome measures were: Research priorities and approaches in the field of BCHDs.

Results: Key research questions in the field of BCHDs are: 1) What are the existing national BCHD practices? 2) What are the patient information and support needs on BCHDs? 3) Which outcomes should be measured across clinical studies in the field of BCHDs? The workshop suggested the following approaches to address these priorities: 1) A service evaluation of current UK BCHD practice; development of a national registry of BCHDs; 2) Qualitative research to understand patient information and support needs; development of patient decision support tools 3) Development of core outcome sets (COSs) for BCHDs.

Discussion: Building upon the framework of the recent UK Research Agenda for ENT, Hearing and Balance, patients and professionals defined key UK-specific research priorities and approaches in the field of BCHDs. This approach promotes engagement, buy-in, national collaboration and thereby value of future BCHD research.

Keywords: Research priorities; Research agenda; Bone Conduction Hearing Devices; Hearing; Hearing implants; Consensus.

Introduction

The recent 2016 Bone Conduction Hearing Device (BCHD) commissioning policy (NHS England, 2016) sets the criteria for BCHD service delivery in England and as such determines the care received by patients with hearing loss within the NHS. In creating this policy, NHS England reviewed the evidence for BCHDs including whether they represent an efficient use of NHS resources. Whilst criteria were set, the commissioning policy (NHS England, 2016) highlights the lack of high-quality research on clinical and cost-effectiveness of BCHDs. Such research is key to developing the evidence base on BCHDs so that future commissioning policies can make informed decisions, based on strong evidence and help deliver the best care for patients within the available resources. With high quality research calling upon (competitive) funding as well as (limited) capacity, it is important to prioritise future research around BCHDs.

The 2015 UK Research Agenda for ENT, Hearing and Balance care identified hearing loss as one of the next decade's key research priorities (GENERATE, 2015; Bohm *et al.*, 2016). Recognising that this broad topic needed further refinement, taking into context current policy and research activity, the National Institute for Health Research (NIHR) Clinical Research Network (CRN) ENT Specialty group organised a workshop with representatives from a wide range of patient and professional groups active in the field of BCHDs. This workshop aimed to identify UK-specific research priorities in the field of Bone Conduction Hearing Devices (BCHDs). This paper reports on the discussions of this workshop and the research priorities and approaches identified.

Method

Study design

Narrative summary of the BCHD research workshop discussion.

Setting

The workshop was held on the 8th September 2016, under the auspices of NIHR CRN ENT Specialty Group (NIHR, 2016a) and the Royal College of Surgeons (RCS) Clinical Research Initiative (RCS, 2016).

Participants

Using purposive sampling a broad representation of UK professionals active in the field of BCHDs, international experts and patient representatives from a BCHD interest group were invited to attend the workshop. Participants were invited via email invitation and telephone. For the discussions participants were allocated to four groups, aiming at equal representation from the range of stakeholders.

Workshop

The workshop started with four presentations: 1) Objectives of the workshop; 2) Summary of the 2016 BCHD commissioning policy and a review and quality assessment of the existing evidence on BCHDs; 3) An international perspective on BCHD research; and 4) How to facilitate the group discussions.

Each group was then encouraged to consider and discuss two main areas:

- 1) What are the key questions in the field of BCHDs that need to be addressed by research?
- 2) How should these questions be addressed?

Finally, a representative from each group presented a summary of their groups' discussion to all participants, who were encouraged to ask questions and stimulate further discussion.

Notes were taken on a flip chart stand, in real time, visible to all attendees. The workshop lasted 2 hours 30 minutes (Figure 1).



Figure 1: Bone Conduction Hearing Device (BCHD) research workshop held at the Royal College of Surgeons (RCS)

Analysis and write-up

Notes taken during the meeting were summarised by 2 authors (RM and PD) and synthesised into a structured narrative. This narrative was reviewed and commented upon by all other authors, with any discrepancies being resolved by discussion and consensus.

Ethics

For the involvement of patients and professionals in planning or advising on research, ethical approval and formal consent is not required and was therefore not sought (NIHR, 2016b; NIHR, 2015).

Results

Eighteen UK and two international professionals and two patient representatives, took part in the workshop. They represented all relevant UK stakeholder groups in BCHD (Table 1).

Name	Role	Region
Danny Hind	Assistant director, Clinical Trials Research Unit	Sheffield
Munyia Dimairo	Medical Statistician, Clinical Trials Research Unit	Sheffield
Sue Jowett	Senior Lecturer Health Economics	Birmingham
Kevin Peters	Commissioner	Yorkshire and Humber
Sue Archibold	Chief Executive, The Ear Foundation	National
Melanie Gregory	Appointed Chief Executive, The Ear Foundation	National
Rupan Banga	ENT Consultant	Birmingham
Panagiotis Dimitriadis	ENT Academic Clinical Fellow	Sheffield
Rishi Mandavia	ENT Academic Clinical Fellow, NICE Scholar, Policy expert	London
Caroline Mitchell	General Practitioner	Sheffield
Anand Kasbekar	ENT Senior Fellow	Cambridge
Padraig Kitterick	Senior Research Fellow	Nottingham
Myrthe Hol	International expert on BCHDs, Chair of the Dutch BCHD guideline and	Nijmegen, Netherlands
Gerard O'Donoghue	Professor of ENT	Nottingham
Ivo Kruyt	PhD Student, ENT Trainee	Nijmegen, Netherlands
Peter Monksfield	ENT Consultant	Birmingham
Jaydip Ray	Professor of ENT	Sheffield
Anne Schilder	Professor of ENT	London
Penny Hill-Feltham	Audiologist	Manchester
Amanda Hall	Audiologist	Birmingham
Rowena Egan	Patient representative	London
Anne Sargent	Patient representative	London

Table 1: Stakeholder list, including role(s) and location

Key research questions in the field of BCHDs

a) What are the existing national BCHD practices?

Participants noted that although an estimated 7,000 UK patients have been implanted with BCHDs (The Ear Foundation, 2015) data are lacking on: the current patient pathway, numbers and types of BCHDs implanted across UK regions, patient demographics, outcomes including long term safety and costs. It was felt that collecting such information is essential for: evaluating clinical and cost-effectiveness of BCHDs, comparing outcomes of different devices, early detection of risks and faulty implants, establishing appropriate patient selection and priority patient populations. Giving patients access to this information would help

empower them and involve them in making decisions about their treatment. From a policy and commissioning perspective, identifying national practices would also help recognise variations in service provision and variations in patient pathways, including patient follow-up. Information on costs and patient outcomes would be critical for cost-effectiveness analyses, which are valued by policy makers and guideline developers, including the National Institute for Health and Care Excellence (NICE).

b) What are the patient information and support needs on BCHDs?

Participants highlighted that non-specialist professionals often lack knowledge about hearing loss and BCHDs so it can be difficult for potential patients to access information about treatment options. There was felt to be a need for improved patient information pre-implantation on the risks and benefits of BCHDs, and post-implantation on the practical aspects of BCHDs and managing hearing loss, to obtain maximum benefit from devices. Information provision and access to support was felt to be patchy across the country and different models of patient support, such as peer support groups, websites and expert patients, were discussed. It was felt that further research is required to determine the optimal model for providing information and supporting patients.

c) Which outcomes should be measured across clinical studies in the field of BCHDs?

Currently, there is no consistency across UK and international centres or in the scientific literature, in the outcomes assessed following BCHD implantation nor in the instruments used to measure these outcomes. This lack of standardisation in reporting outcomes in BCHDs impacts on clinicians' ability to make shared decisions with their patients, as it makes it very difficult to inform patients about the likely outcomes of treatment based upon previous experiences. This research need was also highlighted in the 2015 UK Research

Agenda for ENT, Hearing and Balance care (GENERATE, 2015). Regarding the instruments to measure these outcomes, it was felt that there is a paucity of validated instruments appropriate for measuring Quality of Life (QoL) in patients implanted with a BCHD. Generic QoL instruments such as the SF-36 or EQ-5D, were considered not sensitive enough to capture the subtler effects of hearing problems and treatments on QoL. The two QoL questionnaires that are currently used in patients with a BCHD are the Glasgow Benefit Inventory (GBI) and disease-specific Abbreviated Profile of Hearing Aid Benefit (APHAB). These lack data related to comfort, ear discharge, pain and hours of use.

How these questions can be addressed

- a) *A service evaluation of current UK BCHD practice; development of a national registry of BCHDs*

There was consensus among participants that an evaluation of current BCHD practices and services delivered nationally (and internationally) would provide important information on patient selection and models of service delivery. A qualitative analysis of the factors, individual and contextual, that influence decision making and strategies chosen by professionals involved in BCHD provision will provide key insight as to why practice may vary. This will also inform the development of a prospective (inter)national registry of BCHDs, which was considered by participants the best tool for future mapping and evaluating outcomes of existing practices. Through the registry, data can be collected on: patients (e.g. demographics, otological and audiological history, indications), devices, and outcomes (e.g. audiological, comfort, complications, cost, QoL). It was emphasised that finding the optimum dataset size would be essential: too large will hamper data completion and too small will limit its usefulness. Enabling patients to access and input data into the registry would facilitate data collection and shared decision-making. Participants were aware

of existing registries upon which an (inter)national registry could build, such as the Ear Foundation Bone Conducting Hearing Implant Registry (The Ear Foundation, 2015) and those set up by device companies (AuditBase, 2016). It was also suggested that a future registry could be linked to Hospital Episode Statistics (HES) data, for data validation. As sources of funding for initial registry development, charities, professional organisations, industry and industry were proposed, with research programmes and projects utilising registry data and funded by larger grants from major funders (e.g. NIHR, MRC, EU Horizon 2020) providing resources to sustain the registry. Participants recognised that the development of a registry would face challenges, and therefore it would be important to engage with all stakeholders including patients from its inception. Piloting a registry in select centres providing a valuable learning experience prior to national roll-out was considered important. Participants felt that randomised controlled trials comparing BCHD approaches and devices may currently not be the most cost-effective method to answer fundamental questions in BCHDs; rather conducting future trials within a national registry would provide value.

b) *Qualitative research to understand patient information and support needs; development of patient decision support tools*

Participants felt that an initial step could involve a systematic review with a qualitative meta-synthesis looking at the existing research around patient information needs on BCHDs pre and post implantation, and identifying gaps in knowledge. It was reported that some qualitative research is ongoing to identify patient information and decision needs on BCHDs, such as that being carried out by the Ear Foundation (The Ear Foundation, 2016). This and further qualitative work, focused on specific questions raised from the meta-synthesis, could inform the development of patient decision aids for BCHDs. These should follow

international Patient Decision Aids Standards (Elwyn *et al.*, 2006) with involvement of patients and clinicians and should be tested in practice. To map patient needs and preferences for post-implant support, and develop and test support models it was felt that a collaborative approach with patients was important.

c) *Development of core outcome sets (COSs) for BCHDs*

A solution to the lack of consistency in outcome measurement in patients with BCHDs would be standardisation through the development of ‘core outcome sets’ (COSs) for BCHD, a minimum set of outcomes agreed by patients, carers and professionals that should be measured and reported in all clinical research. COSs could be embedded within a national registry of BCHDs facilitating research including trials within the registry. Participants raised that research has already been initiated around COS in this area (Tysome *et al.*, 2015), and in the first instance a careful literature review would be necessary. The development of COSs for BCHDs would require a structured process involving various stakeholders to define ‘what’ should be measured and ‘how’ and ‘when’ - that is the appropriate methods and timing to quantify these outcomes. It was also emphasised that the COSs and corresponding instruments should be validated across different BCHD patient groups and receive patient input during development. Proposed UK initiatives providing guidance in this process were the University of Oxford Innovation Clinical Outcomes Assessments (Oxford University Innovation, 2016) and COMET (COMET Initiative, 2016).

Discussion and conclusion

This workshop represents a unique approach, building upon the 2015 UK Research Agenda for ENT, Hearing and Balance care, bringing together BCHD stakeholders and patients to refine UK-specific research priorities in BCHD research. Importantly, this inclusive approach

will promote stakeholder engagement, buy-in, and (inter)national collaboration, producing BCHD research that can have an impact on patient care and (inter)national policy.

This approach can be used to refine research priorities in other areas of ENT, Hearing and Balance research.

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