A Protocol for a Horizon Scan of Current and Future Technologies for Audiology Testing Services

Identification: This is a protocol for a horizon scanning review.

Registration: This review protocol is registered with Open Science Framework (<u>https://osf.io/7xdjq</u>).

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AB conceived and designed the review, drafted the protocol and will oversee the review process as the guarantor.

Amendments: Amendments to this protocol will be documented with corresponding dates and rationale. **(Version 1.0 13/04/2024)**

Support

This review is undertaken by the Sheffield Evidence Synthesis Group (EnSygN – Sheffield) under contract to the UK National Institute for Health and Care Research (NIHR) Evidence Synthesis Programme on behalf of NHS England. The protocol was developed independently by the EnSygN – Sheffield team in response to a brief from NHS England.

Introduction:

Audiology services encompass diverse activities, including hearing assessments, diagnosis, treatment planning, hearing aid fitting and counselling (Criter et al, 2023). These services are essential for early identification and management of hearing impairments, which can have profound impacts on communication, cognitive function, and overall well-being. Despite their critical importance, audiology services have faced significant challenges relating to access, efficiency, and patient experience. Many individuals, especially those in underserved communities or remote areas (De Wet Swanepoel et al, 2010), face barriers to obtaining timely and quality audiology care. Audiology practices may be time-consuming, resource-intensive, and may not always provide an optimal patient experience (D'Onofrio et al, 2022).

Recent technological advancements offer the potential to reconfigure audiology services, offering innovative solutions. Emerging technologies, encompassing novel diagnostic tools, hearing aids, telehealth platforms and mobile applications, have the capacity to transform how audiology services are delivered and experienced by patients (De Wet Swanepoelet al, 2023).

The role of Audiology Testing Services

Potential surrounds new testing technologies to enhance the accuracy, efficiency, and accessibility of audiological evaluations (Wasmann et al, 2022). Technologies may include advanced imaging techniques, automated testing platforms, or portable devices to enable remote or self-administered assessments (Wassman et al, 2021).

Genetic approaches also hold significant potential. Genetic testing can be incorporated into newborn hearing screening programs to identify infants at risk for hearing loss due to specific genetic mutations (Satterfield-Nash et al, 2020). This allows for earlier intervention and management. Alternatively, where there is a family history of hearing loss, targeted genetic testing can look for specific mutations. While genetic testing alone may not identify all cases of hearing loss, given the role of environmental factors and other non-genetic causes, it offers particular potential when used in conjunction with other screening methods (D'Aguillo et al, 2019).

As audiology continues to evolve, it is crucial to critically evaluate the landscape of current technologies and anticipate future innovations that could shape the delivery and design of audiology testing services (D'Onofrio et al, 2022). A comprehensive understanding of these technologies, their potential benefits, and their implications for patient care is essential for informing decision-making, resource allocation, and the adoption of evidence-based practices in audiology (Muñoz et al, 2021).

This horizon scan aims to provide a comprehensive synthesis of the current and future technologies that could influence audiology testing services and their design, with a focus on both paediatric and adult populations.

Rationale:

Audiology testing services play a crucial role in the identification, diagnosis, and management of hearing and balance disorders across the lifespan. However, services have historically faced challenges in terms of access, efficiency, and patient experience. Technological advancements have the potential to revolutionize audiology services, offering innovative solutions for testing, treatment, and service delivery. To optimize the adoption and implementation of these technologies, a comprehensive understanding of the current landscape and future possibilities is essential.

Objectives:

This horizon scan aims to identify and synthesize evidence on current and emerging technologies that could influence audiology testing services and their design, for both paediatric and adult populations. The review will address the following questions:

- What are the currently available technologies for audiology testing services?
- What future technologies or innovations (currently phase II or phase III or beyond) are on the horizon that could impact audiology testing services?
- How could these technologies influence the design and delivery of audiology testing services?

Methods:

Eligibility Criteria:

We will include studies and reports that describe, evaluate, or discuss technologies related to audiology testing services, for both current and future/emerging applications. Studies will be included regardless of design. Only technologies intended to be used in a high income context will be included. Conference proceedings and technical reports will be considered, to reflect the focus of

the topic, but other grey literature will be excluded. Given a focus on current and future technologies date restrictions will be applied from 2017 (when a horizon scan of New and emerging technologies for hearing loss was published by the UK Horizon Scanning Research & Intelligence Centre [March 2017]).

Filter criterion	Inclusion criteria	Exclusion criteria
Conditions	 Hearing loss (all ages, types and grades) Deafness (all ages) Associated conditions 	
Clinical setting	 Hearing Assessment and Diagnosis (newborn hearing screening; paediatric hearing evaluations; adult hearing assessments; diagnostic audiometric testing, auditory processing disorder (APD) assessments) Hearing Aid Services (Hearing aid selection, fitting, programming and adjustments, repairs, maintenance, counseling and rehabilitation) Cochlear Implant Services (Candidacy evaluation, implant mapping and programming, rehabilitation and support; Tinnitus Management (Tinnitus assessment and counselling, sound therapy and treatment strategies); Balance and Vestibular Assessment (Vestibular function testing, diagnosis and management of balance disorders); 	Surgical interventions; Medical management of hearing loss (e.g. medications or treatments for conditions e.g. sudden sensorineural hearing loss, Ménière's disease, or medical disorders that may cause hearing impairment); Congenital or genetic hearing disorders (beyond initial assessment and diagnosis e.g. medical management and genetic counselling); Auditory nerve and central auditory pathway disorders (that require referral to specialised centres or multidisciplinary teams). Forensic audiology Specialized research and advanced diagnostic techniques for use in an experimental non- clinical context. (e.g. electrophysiological testing or imaging studies)
Place in the Pathway	 Screening, diagnosis and assessment New patient group for currently available technology 	Prevention
	 Impacts directly on design of hearing testing services 	
Technology type	All current and emerging technology types for hearing testing, diagnosis, assessment or monitoring including Technologies in use in some other countries but not yet in general use in the UK NHS	DrugsSurgical interventions

https://www.researchgate.net/publication/315669789_New_and_emerging_technologies_for_heari ng_loss

	 Existing technologies adopting. new approach, modification representing a stepwise advancement or innovation 	 Technologies already in widespread use in the UK National Health Service
		 Technologies used in low-middle income countries
Stage in development	Current Phase II and III clinical trials (or trials updated in the last 2 years) Pre-registration	 Pre-clinical – lab or animal studies Early trials – phase 0 or phase I
	Devices Pre-CE (conformity assessment) marking Just received CE (conformity assessment)marking Not yet launched Launched but poorly diffused	 Phase II and III clinical trials with no updating information within the last 2 years Late trials – phase IV
	Programmes Not widely implemented	

Information Sources:

We will search electronic databases (e.g., Medline, Embase, Scopus, IEEE Xplore, Compendex) from January 2017 to April 2024. We will also search clinical trial registries, organizational websites, and reference lists of included studies.

Source	Website		
Horizon scanning websites & databases			
NIHR Innovation	https://www.io.nihr.ac.uk/		
Observatory			
HealthPACT (formerly	http://www.health.qld.gov.au/healthpact/html/tech-evaluated.asp		
Australia and New Zealand			
Horizon Scanning Network			
[ANZHSN])			
EuroScan International	www.euroscan.org Restricted access for non-members		
Network			
CADTH	https://www.cadth.ca		
Agency for Healthcare	http://www.effectivehealthcare.ahrq.gov		
Research and Quality			
(AHRQ)			
MedTech industry news sites			
Medical News Today	http://www.medicalnewstoday.com/		
Clinical trial registries			
ClinicalTrials.gov	http://clinicaltrials.gov/		
WHO International Clinical	http://apps.who.int/trialsearch/AdvSearch.aspx		
Trials registry platform			
(ICRTP)			

Bibliographic databases	
MEDLINE In-process &	
Other Non-indexed	
Citations; MEDLINE;	
EMBASE (OVID)	
IEEE Xplore, Compendex)	
SCOPUS	
SPIE digital library	https://www-spiedigitallibrary-org.sheffield.idm.oclc.org/
Licensing bodies	
US Food and Drug	http://www.fda.gov/medicaldevices/productsandmedicalprocedures/
Administration	
General internet	Google with domain searching

Additionally, we will contact experts in the field to identify any unpublished or ongoing studies.

Search Strategy:

Draft search strategy for Medline:

Population	Children or adults with hearing loss	Exp Hearing loss/[MeSH] OR hearing impair* OR deaf OR Deafness [MeSH] deafness OR Exp Auditory Diseases, Central [MeSH] OR auditory disorder* OR Hearing disorders [MeSH]
Intervention	Novel innovations OR Hearing screening OR Specific novel innovations name	Future OR innovation*OR horizon OR emerging OR breakthrough* OR "new technology" audiology OR Hearing/[MeSH] OR "hearing test*" OR "hearing screening" OR audiologic* Electrocochleography OR ECoG OR Auditory brainstem response OR ABR OR Distortion product otoacoustic emission* OR DPOAE OR DPOAEs OR brainstem evoked response audiometry OR BERA OR Transient evoked otoacoustic emissions (TEOAEs) OR genetic test* OR Cytomegalovirus test* OR Artificial intelligence OR AI OR Machine learning OR smartphone* OR smartwatch* OR Wearable device* OR app OR apps OR ((Auditory evoked potential* OR AEP OR AEPS) AND Sleep) "wearable device*" OR "assistive device*" OR "digital signal processing" OR "machine learning" OR "artificial intelligence" OR "nanotechnology" OR genetic OR "Hearing Aid*" OR "Cochlear Implant*" OR teleaudiology OR "smart hearing aid*" OR "hearing technolog*"

Comparison	? Current or Past technology	[Non-Searchable] Current or Past	
	or No comparator	Technology	
Outcome	?Speech and language	We wouldn't search for outcome terms	
	impact	to keep the search broad and ensure all	
	Test accuracy	relevant evidence is retrieved	
	Timeliness		
	Cost		
	Technology impact?		
	The primary outcomes of		
	interest are impacts on the		
	design and delivery of		
	audiology testing services,		
	including accuracy,		
	efficiency, accessibility, and		
	patient experience.		
	Secondary outcomes may		
	include cost-effectiveness,		
	implementation		
	considerations, and		
	stakeholder perspectives.		
Population		OR "hearing test*" OR "hearing	
	screening" OR audiologic*		
Intervention	"wearable device*" OR "assisti		
	processing" OR "machine learning" OR "artificial intelligence" OR		
	"nanotechnology" OR genetic		
Population/Intervention			
	hearing aid*" OR "hearing technolog*"		
Comparison	[Non-Searchable] Current or Past Technology		
Outcome	Hearing loss/ [MeSH]		
Timing	Future OR innovation*OR horizon OR emerging OR breakthrough* OR		
	"new technology"		

Limit search:

Publication date range 2017-2024. English only. Journal articles, technical reports and conference proceedings.

Study Records:

All references will be managed using EndNote reference management software. Two pairs of reviewers will independently screen titles/abstracts and full texts, with disagreements resolved through discussion or consultation with a third reviewer. Data from included studies will be extracted independently by a single reviewer using a standardized Google Form. Discrepancies will be resolved through discussion or consultation with a third reviewer.

Data Items:

Extracted data will include study characteristics (e.g., design, setting, population), description and details of the purpose of the audiology technology (e.g., type), its stage of development), technical specification outcomes related to testing services (e.g., accuracy, efficiency, patient experience), and other relevant information.

1.	Description and purpose of the technology:	Detail of technology and how it works; Specific audiology application(s) or use case(s) it is designed for (e.g. hearing testing, hearing aid fitting, etc.); intended target patient population(s) (e.g. paediatrics, adults, etc.)
2.	Stage of development	Current stage (conceptual, prototype, pilot testing, etc.); Development timeline and projected availability/launch; Regulatory requirements and approval process needed
3.	Technical specifications and performance:	Key technical features and capabilities; Results from any testing or evaluation studies on accuracy, reliability, validity; Comparisons to existing audiology technologies in terms of performance metrics
4.	Advantages and improvements:	Potential benefits over current audiology practices/technologies; Aspects that may enhance testing efficiency, accessibility, patient experience; Opportunities to overcome limitations of existing approaches
5.	Implementation considerations:	Infrastructure or training requirements for adoption; Compatibility with existing systems/workflows; Potential barriers or challenges to real-world implementation
6.	Cost and economic factors:	Projected development and manufacturing costs; Anticipated costs for healthcare providers/systems to adopt; Potential for long-term cost savings or economic benefits
7.	Stakeholder perspectives:	Feedback from audiologists, hearing specialists, patients on perceived value; Opinions from experts in the field on the technology's potential impact; Alignment with current priorities and areas of need in audiology

Outcomes:

The primary outcomes of interest are impacts on the design and delivery of audiology testing services, including accuracy, efficiency, accessibility, and patient experience. Secondary outcomes may include cost-effectiveness, implementation considerations, and stakeholder perspectives.

Risk of Bias:

Risk of bias will not be assessed for individual studies. The unit of analysis will be the technology, not the study. All reports contributing to a particular technology will be identified and then a summary of supporting evidence based on the set of reports, its component study designs and breadth and quality of coverage will be produced for each technology. Assessments of supporting evidence will be assessed by a single reviewer and then checked by a second reviewer, with disagreements resolved through discussion or consultation with a third reviewer.

Data Synthesis:

Study data will be synthesized quantitatively if appropriate and feasible based on the nature and heterogeneity of the included studies. The following qualitative data will be collected and synthesised.

- i. degree of innovation of the technologies (Varela-Lema et al, 2014)
- ii. foreseeable clinical impact (Varela-Lema et al, 2014)
- iii. ease of implementation and integration
- iv. patient acceptance and usability
- v. cost-effectiveness and economic considerations
- vi. scalability and sustainability

- vii. ethical and legal considerations
- viii. summary of the evidence base
- ix. stakeholder perspectives and acceptance
- x. overall assessment

Findings will be presented in a narrative synthesis of the findings, structured around the review objectives and the key criteria as identified previously.

Meta-biases:

Publication bias will be mitigated by searching both published and unpublished sources. Technologies that are only supported by manufacturer claims (with no independent perspective or peer review) will be listed but not evaluated.

References

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Appendix of Impact Criteria

- i. degree of innovation of the technologies (Varela-Lema et al, 2014)
- Entirely new or improvement over existing solutions
- Leveraging cutting-edge or emerging technologies (e.g., artificial intelligence, machine learning, nanotechnology, etc.)
- Potential to disrupt/transform current practices/industry norms?
 - ii. foreseeable clinical impact (Varela-Lema et al, 2014)
- Improved clinical outcomes/efficacy compared to current standards. Potential for better diagnosis, treatment, or management of conditions
- Improved safety and potential for reducing risks, adverse events, or complications;
- Accessibility and reach to underserved populations
- Potential to optimize resource utilization/reduce healthcare costs and to deliver improved workflow efficiency or productivity
- Impact on or transformation of current clinical practice and care delivery practices
- Potential for new diagnostic/therapeutic approaches
- iii. Ease of implementation and integration:
- Compatibility with existing workflows, systems, and infrastructure
- Complexity of training and skill requirements for end-users (clinicians, patients, etc.)
- Potential barriers to adoption (e.g., cost, regulatory hurdles, user resistance)
- iv. Patient acceptance and usability:
- User-friendliness and intuitive design for patients
- Potential to improve patient experience, satisfaction, and engagement
- Alignment with patient preferences and needs
- Enhancement of patient experience, satisfaction, or quality of life
- Addresses unmet needs or provides new solutions for patient populations
 - v. Cost-effectiveness and economic considerations:
- Upfront and ongoing costs of development, implementation, and maintenance
- Potential for long-term cost savings or improved efficiency
- vi. Scalability and sustainability:
- Ability to scale up and roll out the technology across different settings and populations
- Long-term viability and potential for continuous improvement or upgrades
- Availability of technical support and resources for maintenance

vii. Ethical and legal considerations:

- Privacy and data security implications
- Adherence to relevant regulations and standards
- Potential for unintended consequences or ethical concerns
- viii. Evidence base:

- Availability of high-quality research and clinical evidence supporting the technology
- Rigor of evaluation studies assessing safety, efficacy, and performance
- Comparison to existing standard practices or technologies
- ix. Stakeholder perspectives and acceptance:
- Perspectives and buy-in from clinicians, patients, caregivers, and other stakeholders
- Alignment with professional guidelines and recommendations
- Potential impact on clinician workload, job satisfaction, and workflow
- Interoperability and data integration
 - x. Overall assessment summary of the above

Breakdown of resource estimation

EnSygN: Horizon Scan of Current and Future Technologies for Audiology Testing Services April 2024 – September 2024

Project task	Total	Total PWD
	PWD FY2	
Scoping and protocol development	34	34
Creation of Reviews Database by Intervention	5	5
Supplementary Literature searches	15	15
Screening and study selection	44	44
Data extraction and study assessment	50	50
Report/paper writing and internal review	54	54
Dissemination planning and activities	13	13
PPI	13	13
Meetings with client	2	2
Regular team meetings	13	13
General project management/administration	12	12
	242	242

PWD = Person working days

Preliminary Timetable:

Review stage	Started	Completed
Preliminary searches	14/04/2024	23/04/2024
Registration of protocol	w/b 06/05/2024	

Piloting of the study selection process	06/05/2024	08/05/2024	
Formal screening of search results against eligibility criteria (reviews)	08/05/2024	31/05/2024	
Data extraction and quality assessment (reviews)	01/06/2024	22/06/2024	
PPI (Initial Findings)	w/b 15/06/2	w/b 15/06/2024	
Supplementary literature searches (technical reports and conference proceedings)	01/06/2024	22/06/2024	
Formal screening of search results against eligibility criteria ((technical reports and conference proceedings)	08/06/2024	28/06/2024	
Data extraction and study assessment (technical reports and conference proceedings)	15/07/2024	23/08/2024	
Data analysis	23/07/2024	23/08/2024	
Report/paper writing and internal review	26/08/2024	06/09/2024	
Report to NHS England	13/09/2024		
Report to NIHR	26/09/2024		
PPI (Dissemination)	w/b 13/09	w/b 13/09/2024	