Royal Cornwall Hospitals
NHS Trust

Visual Reinforcement Audiometry (VRA) Standard Operating Procedure

V1.0

January 2024

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Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

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1. Introduction

1.1. The Royal Cornwall Hospitals NHS Trust Audiology Service provides a wide range of diagnostic and rehabilitation services. Audiology patients range from newborn to the very elderly.

1.2. This document supports the British Society of Audiology (BSA) Recommended Procedure for Visual Reinforcement Audiometry (VRA) 2014, with local amendments documented for the Treliske hospital site and uncertainty of measurement detailed.

2. Purpose of this Standard Operating Procedure

2.1. This document provides a procedure and guidance for all clinical staff who perform VRA to ensure accuracy and quality of assessment and interpretation.

2.2. This document in part relates to local amendments to BSA Recommended Procedure for VRA, 2014, sections 5.1, 5.6 and 5.7.

3. Ownership and Responsibilities

3.1. VRA clinics are shared care between the responsible paediatric Audiology clinical staff e.g., the Clinical Lead and paediatric Audiologists.

3.2. Role of the Service Manager and the Clinical Lead

The Service Manager and the Clinical Lead are responsible for:

- Cascading this Standard Operating Procedure (SOP) to the Audiology paediatric team.
- Ensuring the SOP is followed by all Audiology paediatric staff and find resolution where compliance is not met.
- To be the point of escalation in regard to this subject.
- To ensure an up-to-date copy of the SOP is available at all times on the document library.

3.3. Role of Individual Staff

The Audiology paediatric team members are responsible for:

- Understanding and adhering to the SOP and to escalate to the Audiology Service Manager or Clinical Lead where these standards are not met.

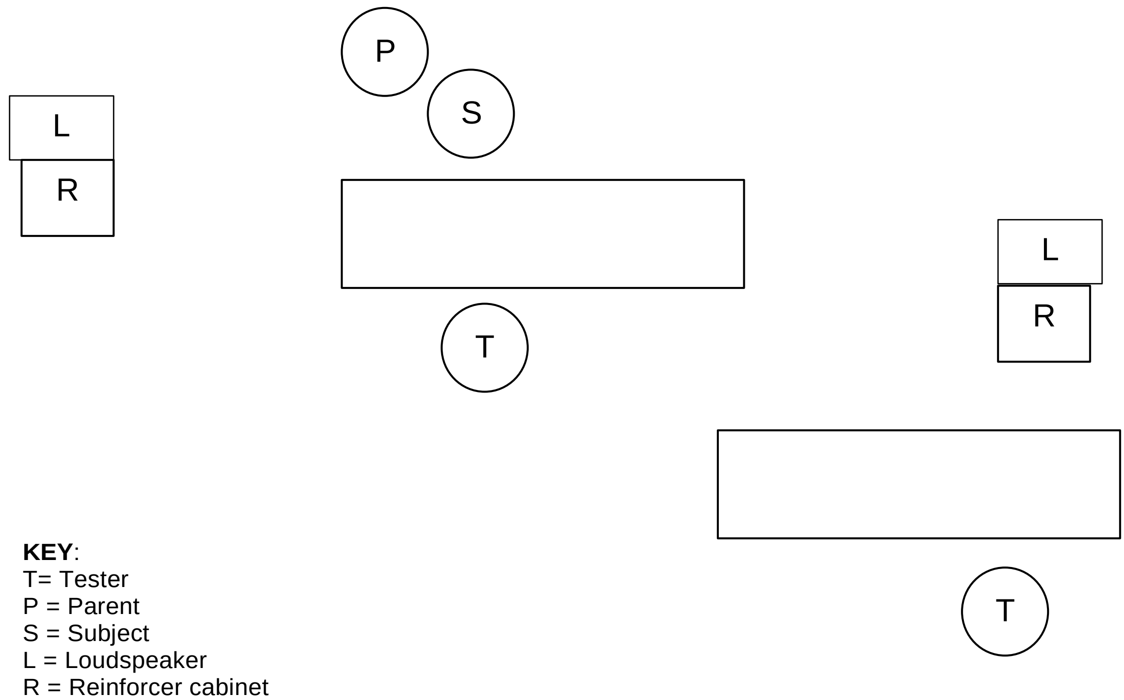
4. Standards and Practice

4.1. The BSA Recommended Procedure for VRA, 2014, should be followed in every aspect other than the local amendments highlighted below:

4.2. 5.1 of the BSA Recommended Procedure for VRA:

Test environment, set-up, and equipment. The local amendment relates only to the tester 1 and tester 2 locations during testing. The equipment set-up using 2 speakers and 2 reinforcers is maintained as is the positions required for optimum testing. Tester 2 remains directly in front of the child with a low table and a range of toys to engage the child. Tester 1 is located in the same room behind tester 2 and to the side, to ensure they have easy access to the audiometer to control the stimuli, and to be able to easily operate the reward and record the child's responses. Tester 1 should be mindful of visual distraction and cues which the child may detect during the test to ensure the child responds purely to the auditory stimulus.

4.3. Example of room layout at Treliske hospital site.



4.4. 5.6 of the BSA Recommended Procedure for VRA, 2014. As tester 2 is in the room 5.6 is not required.

4.5. 5.7 of the BSA Recommended Procedure for VRA. Tester 2 is in the room therefore 5.7 is not required.

4.6. Local procedure:

- VRA assessment procedure will follow BSA recommended procedure, 2014, but with some local policy to include:

- Testing in the soundfield initially down to 25dBHL across the main speech frequency range (at 1, 4, 0.5 and 2 kHz) as per BSA recommended procedure for VRA, 2014. If it is felt that the child will perform well with insert earphones, then testing in the soundfield at all frequencies is not necessary.

- Insert earphones will then be used to obtain ear specific information. 2kHz will be tested first, so that if further frequencies are not possible to record, then we have some ear specific data.

- Discharge levels for soundfield are 25dBHL and for inserts 20dBHL.
- If tympanograms are normal but the child will not condition or perform for VRA then Transient Evoked OtoAcousticEmission's (TEOAE's) may be attempted
- OAE's may also be recorded in the case of a normal tympanogram where insert VRA cannot be performed, and ear specific information is needed.
- The child may be discharged if OAE's and tympanometry are normal UNLESS:
  - There are strong concerns from parents that hearing is not normal.
  - The child has very delayed or no speech.
  - The child is not observed to be responding to sound appropriately in clinic.

In these cases, a test of the whole hearing pathway, which may include an Auditory Brainstem Response assessment must be carried out to rule out an Auditory Neuropathy Spectrum Disorder (ANSD) hearing loss.

If a child is discharged, their referral will be kept open for a period of 6 months post discharge (added to Patient Initiated Follow Up (PIFU) on Patient Administration System (PAS) for date reference). After this time period, a new referral will be required.

If the child has come through the Newborn hearing screen (NHS) the Clinician will update Smart 4 Hearing (S4H) with the results from VRA assessment.

The NICE guidelines for managing Otitis Media with Effusion (OME) will be followed, that is the persistence of bilateral Otitis Media with Effusion (OME) and hearing loss (25 to 30dBHL or worse averaged at 0.5, 1, 2 and 4kHz) should be confirmed over a period of 3 months before a referral to ENT is considered. The child's hearing should be re-tested at the end of this time.

The appropriate Local Clinical pathway (seschare/Audiology Speciality Services/Childrens Hearing Services/pathways) will be followed.

4.7. Uncertainty of measurement:

Whilst all efforts will be taken to ensure as high a degree of accuracy in the VRA assessment as possible, it is acknowledged that there is some uncertainty in the test.

This could include the test environment, or the equipment used, not meeting the appropriate standards for testing. For example, soundfield testing due to extraneous noise being beyond the control of the testers. This may lead to the inability to accurately test minimal response levels (MRL), which may in turn lead to an inaccurate indication of a hearing loss. To ensure as accurate test conditions as possible, a sound level meter will be used to measure the noise floor of the test environment prior to beginning the assessment to ensure it does not exceed 25dB(A) as documented in BSA Practice Guidance 'The Acoustics of sound field Audiometry in Clinical Audiological Applications', 2019.This will be documented in the clinical notes. Daily calibration (Stage A checks; BS EN ISO 8253-2:2009) on the equipment to be used will be performed and documented in the services Team’s spreadsheet. Annual calibration (Stage B checks; BS EN ISO 8253-2:2009) of the equipment and sound field be carried out and documented for traceability and accuracy in the Calibration folder on the Audiology shared drive.

There could also be an uncertainty of measurement if the child is not cooperative or if there is tester bias. An example of this is where the tester/s incorrectly decide the child’s response to the presented sound is a true one, when it is in fact a false positive response. This could lead to a hearing loss being misdiagnosed or missed. Equally, the child may be deemed to not hear the sound as they fail to turn in response, when in fact they are choosing not to turn (a false negative) – and would thus perhaps be better suited to a different type of assessment. This could lead to raised MRL’s inaccurately indicating a hearing loss. As the BSA recommended procedure for VRA, 2014, notes: ‘The desired response is a clear head-turn to view the reinforcer. In a child who will not turn their head but will respond by a prolonged turn in their gaze toward the reinforcer, this shall be interpreted with more caution and reported as such. Due to the risk of misinterpretation, other responses such as eye glances / flicks, small movements and stilling shall not be deemed a response.’ To mitigate the risk of misinterpretation of response, comments on how the child responds (and reliability) will be documented in the clinical notes. To ensure as accurate a test as possible, 2 out of 3 rules (documented on a tick sheet) will be implemented and no sound trials presented and documented in the clinical notes. At the end of the test, the first frequency will be returned to, and a sound presented at 5dBHL above the obtained MCL, to ensure repeatability and reliability of the assessment.

Whilst the Clinicians performing the VRA assessment are highly skilled in their work, there is a possibility that they inadvertently cue the child to a response. This may lead to the child giving a MRL at a lower intensity than they are truly hearing, thus a hearing loss being missed or misdiagnosed. To mitigate this risk of inaccuracy, communication between the testers (and sometimes the parent/carer) is essential for agreement of responses. Regular peer review (at least once a year) will be carried out to ensure consistency and accuracy of test technique. This will be documented in the ‘Competency’ spreadsheet on the shared drive.

There may be uncertainty around the interpretation of the data obtained. It is widely acknowledged that there is an acceptance that normally hearing infants (<12 months) have a mean threshold +- 10dB compared to adult thresholds in the frequencies used for VRA. It is acknowledged that this general acceptance has led to this +-10dB value being applied to the infants MRL but that there is an uncertainty about this value due to lack of evidence. Thus, we test down to a MRL of 25dBHL in the soundfield rather than 30dBHL, to allow for this uncertainty and thus ensuring the infants MRL is within the normal range of hearing rather than at the limit of normal. The use of insert earphones is encouraged in order to obtain ear specific hearing data. It is acknowledged that there is uncertainty around the differences between an infant’s MRL’s obtained by VRA and adult normative data. Although there are correction factors for this which are used at RCHT, it is acknowledged that there is a need for further research into this area and that this may influence practice in future.

5. Dissemination and Implementation

This document will be disseminated through the Audiology paediatric team immediately following agreement and will be stored on the shared drive/Operational delivery/policies procedures protocols/ SOPs/Paed SOP's.

6. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	All of the policy to be monitored.
Lead	Audiology Clinical Lead.
Tool	Audit and review tool to assess compliance with assessment and discharge criteria; Audit of daily calibration checks on Teams; Audit of annual calibration logs.
Frequency	Monitoring will be an ongoing practice with quarterly audits on assessment and discharge criteria; weekly audits of daily calibration checks.
Reporting arrangements	Any concerns regarding the ongoing implementation of this procedure should be reported back to the Audiology Clinical Lead wo will investigate and report back to the Audiology staff.
Acting on recommendations and Lead(s)	Any recommendations/changes to this procedure will be reported at the Audiology team monthly meetings and appropriate changes implemented.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within 6 weeks. The Clinical Lead will take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders.

7. Updating and Review

This procedure will be reviewed every 3 years or with a significant change of practice recommended by the BSA.

8. Equality and Diversity

8.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

8.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Visual Reinforcement Audiometry (VRA) Standard Operating Procedure V1.0
This document replaces (exact title of previous version):	New document
Date Issued / Approved:	May 2023
Date Valid From:	January 2024
Date Valid To:	January 2027
Author / Owner:	Demelza Wake, Audiology Clinical Lead
Contact details:	01872 254907
Brief summary of contents:	Local policy for VRA assessment and interpretation.
Suggested Keywords:	VRA, NICE, measurement of uncertainty.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Care Group Governance Meeting. Information Governance Group.
Manager confirming approval processes:	Roz Davies
Name of Governance Lead confirming consultation and ratification:	Maria Lane
Links to key external standards:	https://www.thebsa.org.uk/wp-content/uploads/2014/06/OD104-37-Recommended-Procedure-Visual-Reinforcement-Audiometry-2014-1.pdf
Related Documents:	NICE 2022 Otitis Media with effusion in under 12's

Information Category	Detailed Information
Training Need Identified:	Yes – refresh on VRA technique – training to be led by Clinical Lead; refresh on discharge criteria and PIFU timeframe.
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Audiology

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
11 May 2023	V1.0	Initial issue	Demelza Wake, Audiology Clinical Lead

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Visual Reinforcement Audiometry (VRA) Standard Operating Procedure V1.0
Department and Service Area:	Audiology, Specialist Services and Surgery
Is this a new or existing document?	New
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Demelza Wake, Audiology Clinical Lead
Contact details:	01872 254907

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	Clinical staff who assess paediatric patients in the Audiology department.
2. Policy Objectives	To clarify assessment, discharge criteria, PIFU and uncertainty of measurement of VRA.
3. Policy Intended Outcomes	Clear and consistent process and criteria of discharge for VRA appointments.
4. How will you measure each outcome?	Audit of clinical caseload and calibration.
5. Who is intended to benefit from the policy?	Patients and their families who are assessed using VRA.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: Yes • Local groups/ system partners: Yes • External organisations: Yes • Other: Yes
6b. Please list the individuals/groups who have been consulted about this policy.	Paediatric Audiology clinical staff, local CHSWG members.
6c. What was the outcome of the consultation?	Approved
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	
Marriage and civil partnership	No	

Protected Characteristic	(Yes or No)	Rationale
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Demelza Wake, Audiology Clinical Lead.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis