1 Quality System

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1 Quality System

1.0 Introduction

This section outlines NBHSW’s approach to quality and quality assurance and summarises NBHSW’s management and quality assurance structures and responsibilities.
1.1 Quality Assurance

1.1.1 Principles

Quality assurance depends on effective management to design, document, implement, maintain and review a quality system. Quality assurance relies on all staff following the requirements of the quality system; one such requirement is that any deficiencies in the system are reported and remedied.

The system is constantly improved by the feedback mechanism, and every individual has an important part to play in achieving quality.

Each individual must understand his or her contribution to quality, and must be sufficiently trained and motivated to make that contribution effectively.

The quality assurance system documented in this manual supports all NBHSW staff in meeting their responsibilities under clinical governance.

Terminology

Action

The action that is taken when limits are exceeded.

Audits and Reports

The audit(s) and/or reports that are undertaken to monitor compliance with the standard(s). All standards in sections 4, 5, and 6 are cross referenced to Section 8, Quality Audit and Reports.

Clinical Responsibility

The personal, professional responsibility for the clinical work undertaken by the individual.

Frequency

The frequency with which the quality control procedure is carried out.

Further Guidance

References to additional documents or procedures that provide further guidance on the use of the resource or the meeting of the standard(s).

Key Quality Control Checks

Where standards have been identified as of potentially high clinical risk, the quality control checks aim to minimise the risk. These checks are cross-referenced to Section 7, Quality Control and/or Section 8 Quality Audit and Reports.

Limits

Quantitative or qualitative limits of acceptability, beyond which action is taken.
Managerial Responsibility

The individual's responsibility as a manager, whether as a line manager or for a particular area of work, always includes his/her responsibility for quality. If the area of work involves key skills other than those held by the person with managerial responsibility, the additional QA advisor(s) is/are identified.

Method

The method used to ensure that the standard(s) is (are) met or that the quality control procedure and/or is carried out. This may include the selection, procurement and maintenance of resources.

Operational Staff

Identifies additional member(s) of staff, if present, who are involved in the procedure or control as part of their normal working or who contribute to the resource. All staff hold an individual responsibility for the quality of the service they provide.

Quality

The total features and characteristics of a product or service that bear upon its ability to satisfy a given need.

Quality Assurance (QA)

All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality. QA has two components:

- **quality management** which is that aspect of the overall management function which determines and implements quality policy;
- **quality control**, which is the operational techniques and activities, which are used to fulfil the requirements for quality.

QA Adviser

In the majority of cases the person holding ultimate managerial responsibility (to the Director) for a particular group of staff will also be the relevant QA Adviser. If this is not the case, it is the responsibility of the identified QA Adviser to advise the manager and the Associate Director, if appropriate, on all Quality Assurance matters relating to that standard.

Quality Manual

Full documentation of the quality system.

Quality Policy

The overall intentions and direction of an organisation with regard to quality, as formally expressed by management.

Quality Standard(s)

A specification of the quality standard(s) that must be met.

Quality System

The objectives, policies, organisation and procedures, which ensure that quality requirements are achieved.
Records

The records made during the carrying out of the quality control procedure, their distribution and filing.

Relevant Quality Standard(s)

The quality standard(s) that are checked when carrying out the quality control procedure. These standards are listed in Sections 4 to 6 of this manual.

Reports

The form and mechanism for relaying information to the Associate Director on achievement against standards

1.2 Quality Policy

In order to attain, maintain and continuously improve the quality of the service, NBHSW is committed to total quality management, whereby quality issues are integral to every aspect of the organisation.

It is accepted that there will be exceptional circumstances when clinical judgement indicates that there should be a departure from a standard and/or operational procedure, as outlined in this manual. All such departures must be documented and notified to the relevant line manager or Associate Director, so that:

- any quality and/or risk management issues may be identified
- future policy can be considered
- the documentation in this manual can be reviewed.

1.3 Management Structure

1.3.1 Organisational Status

NBHSW is a part of the screening division of Velindre NHS Trust.

1.3.2 NBHSW - An All Wales Organisation

The Welsh Assembly Government has accepted the following statement:

“… it is proposed that an All-Wales UNHS Programme is established as a managed clinical network, crossing organisational and professional boundaries, with overall responsibility for the implementation and ongoing management of the programme resting with the Director of the Screening Division of Velindre NHS Trust. …

As this is a new programme, all roles, relationships and responsibilities will need to be established prior to the first baby being screened. …

It is proposed that Velindre NHS Trust should establish a project structure that will evolve into a management structure as the programme becomes operational across Wales."

1.3.3 Director

The programme is part of screening services which is in the Division of Public Health of Velindre NHS Trust. The programme is headed by a Director, who has overall responsibility for the management, quality assurance and evaluation of all aspects of the screening programme in Wales. The Director chairs NBHSW’s All Wales Management Group.
1.3.4 **Associate Director**

The Associate Director is the professional lead of NBHSW and is responsible for the day-to-day management, evaluation and quality assurance of the screening process from the provision of antenatal information, through the screening programme and the assessment procedure. The Associate Director is also responsible for ensuring that there is satisfactory service provision across Wales for those babies identified by the screen up to the age of 2 years and for ensuring that satisfactory services are in place to complete audiological follow up or child health surveillance up to 2 years. This responsibility crosses professional and organisational boundaries.

1.3.5 **NBHSW All Wales Management Group**

The All Wales Management Group (AWMG) meets at least four times a year. It is NBHSW’s main decision-making body and deals with strategic issues at an all Wales level. The AWMG is responsible for financial monitoring and providing the director with advice in particular regarding policies, performance monitoring and equipment.

The membership of the AWMG is:
- Director (Chair)
- Associate Director
- Financial Manager
- Business Manager
- Head of Administration

1.3.6 **NBHSW Divisional Management Group**

The management of NBHSW is divided into three areas comprising
- North Wales Division
- South East Wales Division
- Mid and West Wales Division

The divisions correspond to the areas covered by the NHS Wales 'health economics'. This management group in each area is responsible for the ongoing development and management of the screening programme in a geographical area and ensuring that all babies who reside within the division are offered the full screening programme. The group consists of the following membership:
- Associate Director
- Divisional Coordinator (chair)
- Professional lead from each local group
- Programme manager
- Assistant Programme Manager
- Head of Audiology and/or Audiologist from each site

This group should meet not more than 3 monthly and not less than every 6 months.

1.3.7 **NBHSW Local Group**

Sites are based in district general hospital and are in most cases responsible for the screen within the community that accesses health care in that hospital. Following trust mergers there may be more than one site within a trust. Health care may be accessed outside Wales or cross trust boundaries, all postcodes in Wales are allocated to a site. The local management group is responsible for ensuring that the screening procedures and policies are followed and recorded for each part of the process from antenatal information through to the assessment procedure. The group should consist of the following membership:
- Divisional Coordinator
- Professional lead
- Professional providing assessment procedure (audiologist)
- Programme manager (chair)
- Screener representative
- Technical support
This group should meet not more than 3 monthly and not less than every 6 months. Other staff groups such as screeners and programme managers will meet according to local need. Liaison with Managers of Midwives, Special Care Baby Units, Child Health Systems (database) and other Managers from local Trusts is also important.

### 1.3.8 Line Management Arrangements

The organisational structure is illustrated below.

The Director of Screening Services is managerially accountable to Director of the Division of Public Health. There are line management relationships linking the Director with all directly employed staff. The Associate Director, Business Manager, Head of Information and Evaluation, are all directly managerially accountable to the Director. The Finance Manager, although directly responsible to the Trust for financial matters, is also managerially responsible to the Director.

The Associate Director is managerially responsible for the Divisional Coordinators and has administrative and contractual responsibility for all Audiologists providing the assessment procedure, Professional Leads and Technical Supports during their sessional commitment to NBHWS. This responsibility is exercised in conjunction with the employing Trusts, as appropriate.

The Divisional Coordinators are responsible for the day to day management of the screening programme in a geographical area on behalf of the Associate Director.

The Programme Managers will line manage the Assistant Programme Managers, administrative support and all screeners, but will be responsible for reporting to and taking direction from the local Divisional Coordinators.

The Director has managerial responsibility via the Head of Administration for Programme Managers.

The Screeners are line managed via the Assistant Programme Managers and/or Programme Manager although clinically responsible to the Divisional Coordinators.

The Business Manager of Screening Services will be responsible for contracts and agreements.

Information will be provided by the screening services Information Team.

The Finance Manager has managerial responsibility for his/her supporting staff.
1.3.9 Professional Responsibilities

Individual clinicians have personal professional responsibility for the clinical work they undertake. Some staff groups have professional responsibilities in parallel with the line management structure.

1.3.10 Additional Responsibilities

In addition to the responsibilities directly related to the screening programme, the Divisional Coordinators, Professional Leads and Audiologists are responsible for ensuring satisfactory services for children and families diagnosed following the screening process and for those babies requiring audiological follow up. The Divisional Coordinators are also responsible for providing information and advising Children’s Hearing Services Working Groups within the division to ensure quality screening and to work with statutory agencies to ensure a satisfactory standard of habilitation.

1.3.11 Clinical Governance

The quality system, as documented in this manual, is the main instrument by which corporate responsibility and accountability are exercised for clinical issues within NBHSW. Management arrangements for clinical governance are aligned with the quality assurance and line management structures.

1.3.12 Health and Safety

Hazards arising from Health and Safety and clinical risks have been considered throughout the NBHSW quality system. Any deviation from them (or ‘near miss’) must therefore be reported and assessed following the Trust incident and accident reporting procedures.
1.3.13 Risk Management

Risk management is coordinated through the Screening Services Risk Management Group. It is chaired by the Director of Screening Services and includes the Associate Director of NBHSW.

1.3.14 Whistleblowing Policy

NBHSW’s whistleblowing procedure relates to concerns where the interests of others, and/or those of the Trust itself are at risk and is designed to encourage staff to raise concerns about malpractice at an early stage and in the right way.

1.4 Quality Assurance Structure

1.4.1 Quality Advisory Group

The remit of the Quality Advisory Group is to provide advice regarding quality management across the programme including:

- quality assurance of services up to the age of 2 years for babies diagnosed from the screen
- ensuring satisfactory services are in place to complete audiological follow up or child health surveillance up to 2 years
- clinical and operational audit

The objectives are to:

- contribute to the policy, service specification and the delivery of screening programme
- act as a resource to provide specialist advice and expertise on hearing screening, early intervention and support
- provide a forum to share information on Quality Assurance activities between and within professions
- review the performance and effectiveness of the Quality Assurance mechanisms in the screening service
- advise on monitoring arrangements to check that the screening service is delivered to the highest levels of quality and safety
- liaise with the Screening Services Risk Management Group where concerns are identified
- provide advice on continuing professional education for staff
- recommend research
- review quality systems to promote:
  - a multidisciplinary approach to quality assurance
  - appropriate collection of data
  - timely responses to identified service deficiencies
- recommend improvements for communication with stakeholders to ensure clear lines of communication through local, regional and national level

The membership of the group is:

- Associate Director (chair)
- Divisional coordinators
- Programme manager representative
- Voluntary sector representative (NDCS)
- Audiologist
- Parent representatives
- Teacher of the Deaf
- Health Visitor
- Antenatal Screening Wales representative
- CHC representative (requested to receive minutes only)
- GP representative
- Representative National Public Health Services
- Others to be co-opted as required
1.4.2 QA Role of the Director

The Director has overall responsibility for the quality of all aspects of the new born hearing screening programme provided by NBHSW.

1.4.3 QA Role of the Associate Director and Divisional Coordinators

The Associate Director and Divisional Coordinators’ clinical and managerial roles are fully integrated with their roles in quality assurance. Responsibilities in quality assurance:

- monitoring the quality of the service, across Wales, using information and data collected and collated for the purpose.
- ensuring that standards are in place to measure quality and that relevant audits are produced for the AWMG.
- attending and providing information to the Quality Advisory Group.
- receiving advice regarding quality improvements from the Quality Advisory Group.
- bringing quality deficiencies to the attention of the Associate Director.
- recommending corrective action as necessary and verifying the outcome of any action taken.
- providing feedback on quality to the Associate Director.
- advising the Associate Director on ways of improving quality.
- encouraging the continuous professional development of colleagues.
- attending the relevant quality related group(s) within the screening division.
- representing NBHSW on relevant external groups.

1.4.4 QA Role of All Staff

All members of staff have an individual responsibility to comply with the requirements of the NBHSW quality policy and to maintain and increase the quality of the services that they provide.

1.4.5 QA Advisers

The Associate Director, Divisional Coordinators, Programme Manager representative and audiology representative advise the Quality Advisory Group on issues regarding NBHSW. The group will recommend to the AWMG commissioning further work from an expert in a particular field as the needs of the programme are identified.

1.5 Control of Documents

1.5.1 Scope

This Quality Manual is a controlled document, subject to a control procedure designed to ensure that all copies remain up to date and are identical to the master copy. The master copy is held by the Associate Director who acts as document controller.

1.5.2 Standard

All quality-critical documents are controlled, so that:
- the current version is available.
- out-of-date versions are removed.
- an archive copy of each out-of-date version is retained on the server in “Quality” for reference purposes. The dates for which each version was valid are recorded.
- changes are approved by an appropriate person prior to issue.
- the Quality Manual will be placed on the website and printed copies will be kept to a minimum.
1.5.3 Protocol

Quality-critical documents include, as a minimum, the following information:
- date of issue.
- source (e.g. name/initiais of author, or title of policy/manual).

The author of a document is responsible for ensuring that the current version is issued to all relevant staff and that out-of-date versions are removed. Depending on the nature and status of the document, the author may also need to keep a record of any changes made, with the date and reason.

Drafts or discussion documents are clearly marked as such to avoid confusion with approved documents.

Documentation is inspected as part of the audit procedure to verify that it conforms to the standard.

1.5.4 Quality Manual

The only approved printed copy of the whole Quality Manual Document is held by the Associate Director. Operational procedures (Section 6) will be strictly version controlled by version number, date and title and may be printed from the website or “Quality” on the shared drive by programme managers and divisional coordinators for training purposes. It is the responsibility of the programme manager and divisional coordinator to ensure that latest version is issued to staff. The Associate Director is responsible for updating protocols for audiology staff and ensuring that these are clearly labelled with version number, date and title. Latest versions of all documents issued must be available on the website.

The Quality Manual is a dynamic document. Changes may arise from:
- Identification of “best practice”
- Changes to NBHSW policies and procedures
- Incidents and near-misses
- Suggestions from staff for improvement of quality
- Identification of errors and omissions

Draft amendments are submitted to Associate Director who will submit to the All Wales Management Group for approval if required. Other amendments may be approved by the Associate Director. Managers will be made aware of changes to documents by the Associate Director.

All changes are implemented via the line management structure.