

Pregnancy and Newborn Screening: General Standards

January 2019

We are committed to equality and diversity. These standards are intended to support improvements in healthcare for everyone, regardless of their age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, sexual orientation, socio-economic status or any other status. Suggested aspects to consider and recommended practice throughout the standards should be interpreted as being inclusive of everyone living in Scotland. We have assessed these standards for likely impact on the nine equality protected characteristics as stated in the Equality Act 2010. A copy of the impact assessment is available upon request from the Healthcare Improvement Scotland Equality and Diversity Advisor.

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Introduction

Background to the pregnancy and newborn screening standards

Screening is offered to groups of the population to identify people who may be at an increased chance of a particular condition. Pregnancy screening is offered to help women make informed choices about their health and the health of their unborn baby during pregnancy. Newborn screening is offered to facilitate parents and carers to make informed choices about the health of their newborn baby. It is important that informed decisions are made in partnership with healthcare professionals at the respective stage of the screening programme.¹ Information on pregnancy and newborn screening, including national information produced by NHS Health Scotland, is provided to women throughout their pregnancy and following the birth of the baby.

Policy context

National Services Division (NSD) has an ongoing role in the national multidisciplinary groups which monitor and evaluate the pregnancy and newborn screening programmes. Healthcare Improvement Scotland supports NHSScotland's screening programmes through developing new and, where appropriate, revising existing standards. A request to revise the *Clinical Standards for Pregnancy and Newborn Screening* (October 2005) was received from the Scottish Government and NSD in summer 2016.

NSD has developed and published a set of Key Performance Indicators (KPIs)² to document progress in areas that have been identified within the pregnancy and newborn screening programme as requiring additional support.

These standards should be read alongside other relevant legislation, standards and guidance such as the KPIs mentioned above.

Scope of the general standards

These general standards apply to the services providing pregnancy and newborn screening within NHSScotland and cover the following areas:

- leadership and governance, and
- information and support.

The general standards should be read alongside Healthcare Improvement Scotland's suite of service-specific pregnancy and newborn screening standards:

- **Fetal Anomaly**
- **Haemoglobinopathies in Pregnancy**
- **Infectious Diseases in Pregnancy**
- **Newborn Bloodspot**
- **Newborn Hearing**

The full suite of standards is available on the Healthcare Improvement Scotland website (www.healthcareimprovementscotland.org).

Newborn and infant physical examination (Public Health England, [Newborn and Infant Physical Examination Screening Programme Handbook 2016/2017](#))³ is not covered in the suite of Scottish pregnancy and newborn screening standards.

Revising Healthcare Improvement Scotland's *Pregnancy and Newborn Screening Indicators* (November 2013) and developing KPIs are outwith the remit of this project.⁴

More information about the development of the standards is set out in Appendix 1.

Format of the standards

All our standards follow the same format. Each standard includes:

- a statement of the level of performance to be achieved
- a rationale providing reasons why the standard is considered important
- a list of criteria describing the required structures, processes and outcomes
- what to expect if you are a person receiving care
- what to expect if you are a member of staff, and
- what the standards mean for organisations, including examples of evidence of achievement.

Within the standards, all criteria are considered 'essential' or 'required' in order to demonstrate the standard has been met.

Terminology

Wherever possible, we have incorporated generic terminology which can be applied across all health and social care settings.

The terms 'woman', 'women' and 'individual' are used within the standards to refer to all individuals with a female Community Health Index (CHI) number.

The term 'eligible women' refers to women who are invited for pregnancy screening.

The term 'parents and carers' is used within the standards to refer to the parent, caregiver or guardian who assumes legal parental responsibility for the newborn.

The first antenatal contact can be defined as the first appointment with the midwife or hospital.

Quality of care approach

The pregnancy and newborn screening standards are a key component in supporting the pregnancy and newborn screening programme in quality assurance of its services. Monitoring and improving performance against these standards, at a local and national level, aims to improve the quality of the pregnancy and newborn screening programme.

External quality assurance (EQA) of screening programmes is delivered using Healthcare Improvement Scotland's quality of care approach and the Quality Framework.⁵ This approach specifies how Healthcare Improvement Scotland will design and deliver EQA activity to support improvement in healthcare.

The quality of care approach emphasises the importance of regular open and honest self-evaluation using the Quality Framework as a basis, combined with other relevant data and intelligence including the performance against these standards. Any outcomes from the quality assurance activity will be risk based and set in the context of the programme capacity for improvement. Further information on this approach is available on the Healthcare Improvement Scotland website (www.healthcareimprovementscotland.org).

Implementation

Healthcare Improvement Scotland develops and publishes national standards to support organisations and health professionals in providing a high quality pregnancy and newborn screening programme. The implementation of these standards is for local determination.

Summary of standards

Standard 1: NHS boards can demonstrate effective leadership and governance of its pregnancy and newborn screening services.

Standard 2: Information and support is available for individuals to facilitate informed choice throughout pregnancy and newborn screening.

Pregnancy and newborn screening: general standards

Standard 1: Leadership and governance

Standard statement

NHS boards can demonstrate effective leadership and governance of its pregnancy and newborn screening services.

Rationale

NHSScotland territorial boards are accountable to the Scottish Screening Committee and are responsible for the availability and delivery of pregnancy and newborn screening services for people living in that area. Screening co-ordinators within NHSScotland territorial boards are responsible for overseeing the delivery, quality and effectiveness of the Scottish pregnancy and newborn screening programmes (SPNBSP).⁶⁻¹¹

Effective governance arrangements, including accountability, adverse events management and data monitoring, are critical for the delivery and assurance of a pregnancy and newborn screening service.⁶⁻¹¹

A number of specialties are involved in the delivery and assurance of the Scottish pregnancy and newborn screening programmes, including sonographers, midwives, obstetricians, clinical scientists, biomedical scientists and newborn hearing screeners. Staff are provided with regular training that is relevant to their roles and responsibilities, and have access to continued professional development.

Criteria

- 1.1 NHS boards have systems and processes in place to demonstrate the implementation and monitoring of:
 - multidisciplinary input to pregnancy and newborn screening, including assessment and referral for treatment
 - education and training programmes for healthcare professionals involved in pregnancy and newborn screening
 - regular data collection against quality outcomes for national benchmarking, and
 - ongoing quality assurance and improvement of the Scottish pregnancy and newborn screening programmes, including offering people the opportunity to feedback on their experience.
- 1.2 NHS boards have:
 - a public health lead acting as the pregnancy and newborn screening co-ordinator, and
 - a named healthcare professional or professionals at operational level co-ordinating the provision of pregnancy and newborn screening.

- 1.3** NHS boards have a clear and structured adverse events process, which includes¹²:
- accountability and responsibility arrangements for reporting any adverse events within the programmes
 - a consistent approach to reporting, and
 - a documented escalation process for adverse events in the Scottish pregnancy and newborn screening programmes.
- 1.4** Staff involved in the ongoing delivery of the Scottish pregnancy and newborn screening programmes:
- participate in regular audit and quality assurance
 - are suitably trained relevant to their role and screening service
 - maintain their continued professional development, and
 - adhere to guidance for the Scottish pregnancy and newborn screening programmes.
- 1.5** NHS boards use IT systems to enable the collection of standardised national data to support the governance of the Scottish pregnancy and newborn screening programmes.
- 1.6** NHS boards have locally agreed pathways and processes to ensure:
- timely management options
 - communication and transfer of information, shared appropriately between public health and screening departments, primary care, secondary care, and laboratories
 - timely screening, communication of all screening results, and onward referral for diagnosis, management and support as necessary
 - provision of access to screening, referral and management which reflects, where possible, individual need, and
 - women and parents and carers are supported through the screening pathway and signposted to additional areas of support, including the third sector, where appropriate.
- 1.7** NHS boards demonstrate a commitment to addressing health inequalities in pregnancy and newborn screening through:
- identifying and engaging with women who may experience barriers in attending screening, and
 - engaging with people more likely to experience barriers to participation, including developing action plans to increase equality of access.

1.8 NHS boards have systems in place to ensure the following actions are undertaken for all equipment and peripherals used in the provision of pregnancy and newborn screening:

- planned preventative maintenance
- quality assurance, and
- rolling replacement schedules.

1.9 Laboratories providing pregnancy and newborn screening services:

- meet recognised professional standards
- are accredited by the appropriate national bodies
- have clearly defined processes and pathways between the services and the laboratory
- ensure their predicted annual workload meets the national recommended throughput, and
- ensure nationally recommended throughput is monitored and reviewed with action plans developed if required.

What does the standard mean for the individual participating in pregnancy and newborn screening?

- All individuals will be supported to:
 - access relevant screening services, including further referral or management according to their individual needs
 - make informed choices and have those choices supported and respected, and
 - make contact with support groups where required/appropriate.
- All individuals can be confident that local pregnancy and newborn screening services have effective leadership and governance, and are committed to quality improvement.
- All individuals will be given the opportunity to feedback their experiences to the pregnancy and newborn screening services.

What does the standard mean for staff?

- Staff can demonstrate:
 - knowledge, skills and competencies relevant to their role and responsibilities
 - an understanding of, and access to, care pathways, standards and guidance
 - an awareness of their role within the multidisciplinary team, and
 - how to report and escalate adverse events, and how to support pregnant women and parents and carers to reach informed decisions, in partnership with the appropriate healthcare professionals

What does the standard mean for the NHS board?

- The NHS board:
 - has governance arrangements in place to determine roles, responsibilities and lines of accountability, including adverse event management
 - ensures co-ordinated person-centred pathways for access and delivery of pregnancy and newborn screening services are developed and implemented
 - has failsafe processes for monitoring pregnancy and newborn screening services
 - will monitor workload to ensure nationally recommended throughputs (where these have not been met, this will be reviewed and an action plan implemented)
 - ensures barriers to access and delivery are understood and action plans are in place to minimise barriers
 - records and monitors data and undertakes quality improvement and assurance activities to ensure performance against standards and outcomes
 - ensures staff are provided with suitable training and continued professional development, and this is monitored, and
 - has planned preventative maintenance, quality assurance checks and a rolling replacement schedule in place for all screening equipment and peripherals.

Practical examples of evidence of achievement *(NOTE: this list is not exhaustive)*

- Documentation describing, for example, lines of accountability, roles and responsibilities, and escalation of adverse event reporting.
- Care pathways, local and national standard operating procedures demonstrating multidisciplinary working.
- Documentation demonstrating evidence of staff and team performance, for example audit activity.
- Demonstration of engagement with hard to reach groups, including action plans to increase equality of access.
- Improvement work, including action plans, data collection and review of data, including feedback from service users, national benchmarking and evidence of achieving the timeliness of processes.
- Documentation evidencing preventative maintenance, quality assurance checks and rolling replacement schedules for screening equipment and peripherals.
- A management system for reporting, reviewing and learning from all types of adverse events.¹²

Standard 2: Information and support

Standard statement

Information and support is available for individuals to facilitate informed choice throughout pregnancy and newborn screening.

Rationale

It is important that there is good communication between healthcare professionals and individuals throughout the pregnancy and newborn screening programme. Good communication and provision of information enables informed choices to be made and is integral to providing person-centred care and supported decision-making.¹³ It also reduces anxiety and concerns about the health and wellbeing of all individuals being screened.¹

Communication should be non-directive and supported by evidence-based information tailored to the individual's needs. Information provided should be culturally appropriate and accessible depending on the individual's needs.¹

Person-centred information should be made available in advance of offering any of the screening tests, including provision of pregnancy screening information 48 hours in advance of the screening test.^{14, 15}

Although screening is time limited for some programmes, opportunities should be made available to discuss gestationally-appropriate screening options at a later date if the individual changes their mind after initially deciding not to participate in screening.

Once a decision has been made about whether to participate in screening, or to opt out further down the line, this should be respected, regardless of the personal views of the healthcare professional.^{1, 6-11}

Note: In this standard, the term 'all individuals' refers to:

- pregnant women for pregnancy screening, and
- parents and carers for newborn screening.

Criteria

- 2.1 Information on pregnancy screening is provided in advance of the screening test and in a language and format that is appropriate to the woman's needs, to facilitate informed choice.
- 2.2 Information on newborn screening is provided in advance of the screening test and in a language and format that is appropriate to the individual's needs, to facilitate informed choice.

- 2.3** Information on pregnancy and newborn screening conforms to national guidelines and includes:
- an explanation that the tests are optional
 - information on the condition being screened for
 - information about the screening test and the test method
 - an explanation of the limitations of screening tests
 - the meaning and potential consequences of screening results
 - the options available following results, and
 - how to access further information and support.
- 2.4** An opportunity is provided to all individuals to discuss any aspect of screening before they make a decision about screening.
- 2.5** Shared decision-making for pregnancy and newborn screening is carried out in advance of the screening test.
- 2.6** The individual's decision to accept or decline screening and/or referral for further assessment is recorded and shared appropriately.
- 2.7** All individuals are treated with sensitivity, dignity and respect, with their personal wishes and preferences sought and acted on where possible.
- 2.8** All individuals have access to appropriately trained staff to discuss results, management options and/or further testing.
- 2.9** All individuals are supported to access appropriate information and further support.
- 2.10** All individuals, who initially decide not to participate in any aspect of the screening programme, are made aware of the process enabling to opt back into screening if they reconsider their decision, and if clinically possible.
- 2.11** All individuals are aware of the process that allows them to opt out of screening, where appropriate.

What does the standard mean for the individual participating in pregnancy and newborn screening?

- All individuals will have:
 - opportunities to discuss the different elements of pregnancy and newborn screening with an appropriate healthcare professional, and
 - time to consider their options and make an informed choice about each element of the screening process and this will be respected.
- Information is provided:
 - in a format and style that is appropriate to individual needs, and

<ul style="list-style-type: none">- to enable anyone who has initially decided not to participate in screening to re-engage with the screening process if they reconsider their decision, and if clinically possible.• All individuals will:<ul style="list-style-type: none">- feel supported when making an informed choice about all aspects of the screening process and the choices available- be made aware of support groups available, and- have their individual wishes and preferences captured and shared appropriately.
What does the standard mean for staff?
<ul style="list-style-type: none">• Staff can offer:<ul style="list-style-type: none">- a responsive and person-centred service and information for all individuals participating in pregnancy and newborn screening, and- the relevant support to individuals to reach informed decisions, in partnership with the appropriate healthcare professionals.
What does the standard mean for the NHS board?
<ul style="list-style-type: none">• The NHS board will:<ul style="list-style-type: none">- have information on pregnancy and newborn screening in a range of formats- record the decisions made by individuals to accept or decline any aspect of the screening process, and- ensure individuals are treated with sensitivity, dignity and respect, with their personal wishes and preferences sought and acted on.
Practical examples of evidence of achievement <i>(NOTE: this list is not exhaustive)</i>
<ul style="list-style-type: none">• Examples of relevant information booklets in a range of formats.• Evidence that all decisions reached by individuals are recorded.• Evidence of multidisciplinary working, including involvement of professionals, care pathways, and local and national standard operating procedures.

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Appendix 1: Development of the pregnancy and newborn screening standards

The pregnancy and newborn screening standards have been informed by current evidence, best practice recommendations and developed by group consensus.

Development activities

To ensure each standard is underpinned with the views and expectations of both health and social care staff, third sector representatives, individuals and the public in relation to pregnancy and newborn screening, information has been gathered from a number of sources, including:

- a scoping meeting in September 2016 with a subset of development group members
- a scope engagement exercise in October 2016
- literature review and equality impact assessment
- three standards development group meetings between September 2017 and February 2018
- three consultation events during the 8-week consultation period, and
- a finalisation meeting in October 2018.

A project group, chaired by Dr Surindra Maharaj, Consultant Obstetrician, NHS Lanarkshire, was convened in September 2017 to consider the evidence and to help identify key themes for standards development.

Membership of the project group is set out in Appendix 2.

Consultation feedback and finalisation of standards

Following consultation, the project group reconvened to review all comments received and to make final decisions and changes relating to the standards content. More information can be found in the consultation feedback report which is available on the Healthcare Improvement Scotland website [www.healthcareimprovementscotland.org/our_work/reproductive, maternal_child/pr_ogramme_resources/pregnancy_screening_standards.aspx](http://www.healthcareimprovementscotland.org/our_work/reproductive,_maternal_child/pr_ogramme_resources/pregnancy_screening_standards.aspx).

Quality assurance

All project group members were responsible for advising on the professional aspects of the standards. Clinical members of the project group were also responsible for advising on clinical aspects of the work. The chair was assigned lead responsibility for providing formal clinical assurance and sign-off on the technical and professional validity and acceptability of any reports or recommendations from the group.

All project group members made a declaration of interest at the beginning stages of the project. They also reviewed and agreed to the project group's Terms of Reference. More details are available on request from: hcis.standardsandindicators@nhs.net

Healthcare Improvement Scotland also reviewed the standards document as a final quality assurance check. This ensures that:

- the standards are developed according to agreed Healthcare Improvement Scotland methodologies
- the standards document addresses the areas to be covered within the agreed scope, and
- any risk of bias in the standards development process as a whole is minimised.

For more information about Healthcare Improvement Scotland's role, direction and priorities, please visit:

www.healthcareimprovementscotland.org/drivingimprovement.aspx

Appendix 2: Membership of the pregnancy and newborn screening standards project group

Name	Position	Organisation
Dr Surindra Maharaj (Chair)	Consultant Obstetrician	NHS Lanarkshire
Karen Boyle	Newborn Hearing Screening Manager in Glasgow	NHS Greater Glasgow and Clyde
Susan Campbell	Newborn Hearing Screening Manager	NHS Tayside
Dr Theresa Carswell	Screening Coordinator	NHS Ayrshire & Arran
Dr Alison Cozens	Consultant in Paediatric Inherited Metabolic Medicine	NHS Lothian
Dr Peter Fowlie	Consultant Paediatrician	NHS Tayside
Elaine Gardiner	Programme Lead MSc Medical Ultrasound / Diagnostic Imaging Lecturer	Glasgow Caledonian University
Jo Hughes (from June 2018)	Family Support Service Manager	Down's Syndrome Scotland
Lyn Hutchison	Senior Programme Manager	National Specialist and Screening Services Directorate (NSD)
Linda Kerr	Child Health Systems Manager	NHS Lothian
Rachel Le Noan (to May 2018)	Policy Officer	Down's Syndrome Scotland
Morag Liddell	Neonatal Nurse Specialist	NHS Greater Glasgow and Clyde
Kelly Macdonald	Programme Manager, Standards and Indicators Team	Healthcare Improvement Scotland
Dr Ann MacKinnon	Associate Specialist (Paediatric Audiology)/National Clinical Lead for Newborn Hearing Screening	NHS Tayside
Wendy McDougall	Project Officer, Standards and Indicators Team	Healthcare Improvement Scotland
Dr Louisa McIlwaine	Consultant Haematologist	NHS Greater Glasgow and Clyde
Karen McIntosh	Scottish Co-ordinator	Antenatal Results & Choices
Paul McIntyre	Consultant Virologist	NHS Tayside

Name	Position	Organisation
Sarah Manson	Senior Policy Manager, National Screening Programmes	Scottish Government
Fiona Mundell	Lead Midwife, Fetal Medicine & Antenatal Screening	NHS Highland
Paula O'Brien (to September 2018)	Administrative Officer, Standards and Indicators Team	Healthcare Improvement Scotland
Fiona Paton	Senior Health Visitor	NHS Dumfries & Galloway
Elaine Pirrie	Fetal Services & Early Pregnancy Lead Midwife	NHS Ayrshire & Arran
Dr Andrew Powls	Consultant Neonatologist	NHS Greater Glasgow and Clyde
Catherine Shearing	Principal Grade Clinical Scientist Laboratory	NHS Lothian
Sarah Smith	Principal Healthcare Scientist Laboratory	NHS Greater Glasgow and Clyde
Tasmin Sommerfield	Consultant in Public Health Medicine/Screening Coordinator	NHS Lanarkshire
David Steel	Programme Associate Director	National Specialist and Screening Services Directorate (NSD)
Rev Hugh M Stewart	Patient representative/public partner	Healthcare Improvement Scotland
Margaretha van Mourik	Consultant/Lead Genetic Counsellor	NHS Greater Glasgow and Clyde
Stuart Waugh (from October 2018)	Administrative Officer, Standards and Indicators Team	Healthcare Improvement Scotland

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