Programme Specific Operating Model for Quality Assurance of Antenatal and Newborn Screening Programmes

Public Health England leads the NHS Screening Programmes
About Public Health England

Public Health England (PHE) exists to protect and improve the nation’s health and wellbeing, and reduce health inequalities. We do this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health, and are a distinct delivery organisation with operational autonomy to advise and support government, local authorities and the NHS in a professionally independent manner.

Public Health England, Wellington House, 133-155 Waterloo Road, London SE1 8UG
Tel: 020 7654 8000 www.gov.uk/phe
Twitter: @PHE_uk Facebook: www.facebook.com/PublicHealthEngland

About PHE screening

Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or better informed decisions. National population screening programmes are implemented in the NHS on the advice of the UK National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the four UK countries. The Screening Quality Assurance Service ensures programmes are safe and effective by checking that national standards are met. PHE leads the NHS Screening Programmes and hosts the UK NSC secretariat.

www.gov.uk/topic/population-screening-programmes
Twitter: @PHE_Screening Blog: phescreening.blog.gov.uk
Prepared by: Screening Quality Assurance Service
For queries relating to this document, please contact: phe.screeninghelpdesk@nhs.net

© Crown copyright 2017
You may re-use this information (excluding logos) free of charge in any format or medium, under the terms of the Open Government Licence v3.0. To view this licence, visit OGL or email psi@nationalarchives.gsi.gov.uk. Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

Published July 2017
PHE publications gateway number: 2017185

PHE supports the UN Sustainable Development Goals
# Contents

About Public Health England .................................................. 2
About PHE screening .............................................................. 2

1. Introduction ............................................................................ 4
   Background ............................................................................. 4
   Programme description ....................................................... 4
   Purpose and scope ................................................................ 5
   The quality assurance process .............................................. 5

2. Quality assurance activities ................................................ 6
   Service engagement ............................................................ 6
   Systematic and routine collection and analysis of data .......... 6
   Networking and support ....................................................... 10

3. Data and intelligence for quality assurance ........................... 11
   Data sources ......................................................................... 11
   Data analysis ........................................................................ 12
   Data reporting ...................................................................... 12
   Data sharing ........................................................................ 15

4. The QA visit ........................................................................... 17
   Objectives ............................................................................. 17
   Requirements ........................................................................ 17
   Preparation for a QA visit .................................................... 20
   Components of the QA visit ................................................. 23

5. Training and development ................................................... 29
   Continuous improvement ...................................................... 29

Appendix A: The quality assurance process ............................ 30
Appendix B: Timescales in the QA visit process ...................... 51
1. **Introduction**

1.1 This document sets out the programme specific operating model (PSOM) for quality assurance (QA) of the NHS antenatal and newborn screening programmes and should be read in conjunction with the ‘Operating Model for PHE Screening Quality Assurance Service: 2015/16 to 2017/18’ and the relevant screening quality assurance service (SQAS) generic standard operating procedures documents.

**Background**

1.2 The QA of NHS screening programmes consists of 2 elements:

- an assurance process - measuring the quality of screening services against a set of agreed standards
- quality improvement activities - to support screening programmes to increase the quality of their services

1.3 SQAS undertake a number of activities to assure and improve the quality of screening services. These include but are not limited to:

- peer review (QA) visits carried out every 3 to 5 years
- production of data reports (monthly/quarterly/annually)
- incident advice and support for investigations
- expert advice and support through regular attendance at screening programme board meetings
- network and educational meetings
- targeted support to providers

1.4 This PSOM has been developed by a working group led by the national portfolio leads for antenatal and newborn (ANNB) screening and consisting of members from the SQAS teams and external stakeholders. It sets out how SQAS will work with, support and quality assure local antenatal and newborn screening services.

1.5 All associated processes and documentation have been approved by the SQAS Quality Assurance Executive Group and the Screening Division Strategy Management Group.

**Programme description**

1.6 Antenatal and newborn screening QA begins with the identification of eligible women and babies and relevant tests as per each screening programme. It includes acknowledgement of the referral by treatment or diagnostic services for
individuals or families with screen-positive results, or the completion of the screening pathway.

Purpose and scope

1.7 The purpose of this operating model is to outline the agreed QA process for antenatal and newborn screening programmes which should be adhered to by all SQAS staff and any professional and clinical advisors (PCAs) supporting the SQAS team. This will ensure consistency of approach across all screening providers.

The quality assurance process

1.8 The quality assurance process for the SQAS is provided in Appendix A and details:

- the relevant section of the screening pathway to be addressed
- specific activities to be conducted by SQAS staff and PCAs
- the evidence used to inform the QA process
- data and information sources that will be used for quality assurance
- the required frequency at which the QA activities should be carried out
- mapping of the QA activity to standards, key performance indicators (KPIs) or service specifications that detail the requirement
2. Quality assurance activities

Service engagement

2.1 A senior quality assurance advisor (SQAA) / quality assurance advisor (QAA) or deputy will attend programme steering or oversight boards to:

- identify new issues
- monitor progress against recommendations
- monitor other known issues
- support service improvement

Systematic and routine collection and analysis of data

2.2 SQAS will collect and/or review statistics and data on a monthly, quarterly or annual basis. This is described further in chapter 3.

2.3 Services will be benchmarked using national data sets.

2.4 SQAS and PCAs (where appropriate) will perform an annual review of data and intelligence at a regional or sub regional level. This data set will also be used to complete the prioritisation matrix for SQAS activities.

2.5 Further information and intelligence may be collected via forms, submission of an annual questionnaire or attendance at programme steering/oversight boards. This will be supplemented by intelligence gained by SQAS staff in the course of their routine activities and interactions with services and national screening programmes.

2.6 Laboratories will be considered using summary reports from UKAS accreditation and surveillance or outstanding actions. Summary reports received by SQAS will be followed up on an exceptional basis. SQAS will look at the interface with other services in the screening pathway.

Visits and reviews

QA visits

2.7 The frequency of QA visits starting in April 2017 will be based on findings from the prioritisation exercise. In most cases it will lie between 3 and 5 years. The maximum interval for a full visit for all services will be 5 years. This approach of
targeting QA resources and visits to services which require support will be kept under review.

2.8 Visit schedules and other QA activities will be decided by assessment against an agreed set of criteria each year. This new approach is designed to align SQAS resource according to services’ needs. SQAS will evaluate this approach and consider the impact on the average visit interval, findings at QA visits and SQAS capacity.

2.9 SQAS may undertake a focussed visit or assessment of any individual discipline or group of disciplines of the screening programme that require more detailed investigation or intervention outside the routine QA visit process. The level of intervention and most appropriate approach will be informed by the prioritisation assessment. A set of principles will be devised linked to a set of QA interventions, to support consistency of this approach. A review of the number, rationale and outcome of non-routine visit interventions will be undertaken as part of the evaluation of QA visit activities.

2.10 SQAS will share learning internally and with other relevant local services and commissioners where risks in service delivery are identified that are applicable to more than one service. This is to ensure that information can reach the front line in a rapid manner.

2.11 The QA visit process will include all providers delivering the full or part of the screening pathway. This includes private providers commissioned to deliver NHS screening programmes.

2.12 The QA visit and review of screening services will cover:

- programme management and governance
- the screening pathway
- referral to relevant diagnostic or treatment services
- links and interfaces with laboratories and checking progress with outstanding actions identified during UKAS accreditation visit or annual surveillance
- links and interfaces with other external departments such as child health services

2.13 The screening programmes covered are:

- Fetal Anomaly (FASP)
- Sickle Cell and Thalassaemia (SCT)
- Infectious Diseases in Pregnancy (IDPS)
- Newborn Blood Spot (NBS)
- Newborn Hearing (NHSP)
- Newborn and Infant Physical Examination (NIPE)

2.14 QA of public health system leadership and commissioning has been developed and will be rolled out across all programmes from July 2017.

2.15 The visit and review process will be informed by:

- identified datasets by programme
- core evidence submitted and the completed context grid (where applicable)
- ad hoc data identified as required
- specified job descriptions
- specified protocols
- walkthrough of the patient journey where applicable

**QA visit reports**

2.16 All reports will be addressed to the provider and commissioner(s). The provider may be an NHS trust or private sector organisation.

2.17 The Head of Midwifery is the point of contact for liaising with the provider with respect to the factual accuracy check of the QA reports. They will be responsible for circulating the report to other service leads.

2.18 Recommendations for subcontracted services will be included in the reports for the lead provider.

**Executive summary publication on GOV.UK**

2.19 The chief executive of each organisation involved and the NHS England Director of Commissioning Operations (DCO) or their representative will be asked for their consent to publish the executive summary on GOV.UK. If SQAS do not receive a response, it will be assumed that consent is granted.

2.20 Executive summaries will be published online in accordance with national guidance.

**Reviews**

2.21 Any QA interventions due to ad hoc events such as incidents, identification of poor performance, and so on, may be managed with formal recommendations or an action plan, similar to those for a QA visit.
Follow-up against recommendations

2.22 Recommendations designed to improve the quality of the service will be made at QA visits.

2.23 The wording of the recommendations will give the context to enable all reviewers, provider management and commissioners to understand the rationale for the recommendation.

2.24 The recommendations will have an associated timescale.

2.25 The provider is responsible for developing an action plan in collaboration with the commissioners to address the recommendations made within the available timeframe.

2.26 The commissioners require assurance that timely action is being taken to address the issues raised. Progress against the action plan should be an agenda item at the Programme Steering or Oversight Board meetings.

2.27 SQAS makes recommendations and states what evidence is required to close the recommendation. The Screening and Immunisation Lead (SIL) is responsible for ensuring that action is taken. It is the responsibility of the provider to send the evidence to the SIL and SQAS to review. SQAS will advise the provider and SIL if the evidence submitted provides assurance that the recommendation has been met.

2.28 SQAS will work with commissioners to monitor activity and progress in response to recommendations. This is for a period of 12 months following the issuing of the final report. This will allow adequate time for at least one response to all recommendations. A letter will then be sent to the provider chief executive and commissioners summarising the progress made and asking for their direct intervention to address any remaining issues.

2.29 Escalation to chief executives and commissioners will occur earlier if serious concerns are identified.

Support with screening safety incidents and serious incidents

2.30 The activity of the SQAS is outlined in PHE’s guidance ‘Managing safety incidents in NHS screening programmes (October 2015)’ and is detailed in PHE Screening Division’s ‘Managing safety incidents in NHS screening programmes standard operating procedure (March 2016)’. 
2.31 The national and regional portfolio leads will work together to develop greater consistency in the handling of suspected or confirmed safety incidents and serious incidents.

2.32 SQAS regional teams are to track and record their advice from the reporting of each incident through to closure. SQAS records of active incidents will be reviewed regularly by each regional portfolio lead.

2.33 The national portfolio leads will contribute to producing quarterly detailed thematic reports. They will agree lessons to be shared and national actions with the programme managers. Lessons to be shared will be done in a timely manner appropriate to the incident.

Networking and support

2.34 There are a wide variety of approaches to professional networking support across SQAS. These have received good feedback, showing evidence of value to both SQAS and service representatives.

2.35 Professional meetings are an important forum for SQAS to share information relating to new standards, guidance and programme developments with the relevant professionals. They provide an opportunity to share data, discuss support needs, and enable feedback on products and plans. They help identify quality issues or potential risks which could inform future QA activity.

2.36 The forums are also important to the professionals working within local screening services. They can share issues, identify possible solutions, develop networks that foster resilience and share out tasks such as development of protocols.

2.37 The meetings can also be educational events with input from external speakers or the sharing of local audit information. SQAS will work in conjunction with the national screening programme where applicable to develop joint agenda for these meetings.

2.38 The frequency of these meetings will vary by professional group. There will be a minimum of 3 per year per sub region. These will cover staff groups depending on prioritisation and current issues.
3. Data and intelligence for quality assurance

3.1 This chapter describes the specific data requirements for the antenatal and newborn screening programme. General information on the data requirements of the Programme Specific Operating Models can be found in the ‘Programme Specific Operating Model Data & Intelligence Overview’.

Data sources

Trust annual report

3.2 A trust annual report template was developed to enable trusts to report on key standards, guidance and other pathway related elements in the absence of an agreed data set. There are 2 versions of this template available; London has a slightly different word template compared to other regions.

3.3 Data collected in the annual report template is used to inform QA activities but is not sufficiently robust to provide comparisons against other providers, across regions or nationally. Use of this template will be reviewed in 2018/19.

Maternity and laboratory data submissions

3.4 For the four programmes FASP, IDPS, SCT and NBS data is submitted directly by maternity and laboratory providers to PHE Screening.

3.5 Standards for FASP were published in April 2015. Data completeness was variable as some maternity services do not yet have systems in place to collect all of the data. A standard operating procedure is available that outlines the data reporting process. Data submission templates for maternity services and screening laboratories are provided.

3.6 Standards for IDPS were published in April 2016. Data will be reported nationally. This incorporates the previous National Antenatal Infections Surveillance Monitoring (NAISM). A standard operating procedure is available that outlines the data reporting process. Data submission templates for maternity services and screening laboratories are provided.

3.7 Standards for SCT and NBS were published in March 2017. Data will be reported nationally. Some NBS data is reported by screening laboratories but is not at a
suitable level for use by SQAS to inform QA activities. Development work will take place in 2017 to address this. Data submission templates are provided.

**Screening Management and Reporting Tool**

3.8 Standards for NIPE were published in April 2016. NIPE standards will be reported from NIPE Screening Management and Reporting Tool (NIPE SMART) but is dependent on full implementation across England. Partial data should be available from April 2017 to March 2018. A standard operating procedure that outlines the data reporting process is being developed.

3.9 Standards for NHSP were published in April 2016. NHSP standards are reported from a well-established IT system.

**Data analysis**

3.10 The antenatal and newborn SQAS will comply with the national SQAS methodologies.

3.11 SQAS undertakes validation on the data received by SQAS staff through production of SQAS standard operating procedures and/or automated validation processes.

3.12 Data analysis is undertaken by national screening programme data analysts and the national data and information team in the case of KPIs.

**Data reporting**

3.13 Reporting and analysis will be done once, nationally where possible. Dissemination of data to local services will be done by the local SQAS team.

**Key performance indicators**

3.14 KPIs for antenatal and newborn screening are a subset of screening standards and are identified as part of the section 7a service specification. They focus on areas where important improvements in quality can be made. Once a KPI consistently reaches the achievable level, the KPI is either withdrawn as a KPI and remains as a standard, allowing entry of another KPI or the KPI thresholds are reviewed to promote continuous improvement.

3.15 KPIs are collated and reported quarterly. If numbers are small, aggregate data is reported annually. There are 2 to 3 KPIs per ANNB screening programme.
3.16 Two versions of KPI data reports currently exist:

- confidential version made available to all screening staff on the shared PHE drive
- published version available on GOV.UK pages

3.17 SQAS has access to a QA provider level KPI tool to help monitor performance and trends.

3.18 Coverage KPIs are also included in Public Health Outcomes Framework (PHOF) which focuses on high level outcomes and associated baseline figures are used in the Section 7A agreement.

**Screening pathway reporting**

3.19 The current list of outline reports is given in the table below.

<table>
<thead>
<tr>
<th>Report title</th>
<th>Geography</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trust annual report</td>
<td>Maternity service</td>
<td>Annual</td>
</tr>
<tr>
<td>KPI confidential data file</td>
<td>Varies as per KPI</td>
<td>Quarterly</td>
</tr>
<tr>
<td>NHSP EQA funnel plots (contains 2 KPIs)</td>
<td>NHSP site</td>
<td>Quarterly</td>
</tr>
<tr>
<td>FASP standards</td>
<td>Varies for individual standards</td>
<td>Annual</td>
</tr>
<tr>
<td>IDPS standards</td>
<td>Varies for individual standards</td>
<td>Annual</td>
</tr>
<tr>
<td>NIPE standards</td>
<td>Varies for individual standards</td>
<td>Annual</td>
</tr>
<tr>
<td>NHSP standards</td>
<td>Varies for individual standards</td>
<td>Annual</td>
</tr>
<tr>
<td>SCT standards / data</td>
<td>Varies for individual standards</td>
<td>Annual</td>
</tr>
<tr>
<td>NBS standards / data</td>
<td>Varies for individual standards</td>
<td>Annual</td>
</tr>
<tr>
<td>DQASS laboratory summary report</td>
<td>Screening laboratory</td>
<td>6 monthly</td>
</tr>
<tr>
<td>DQASS USS department and individual practitioner report (red flags)</td>
<td>USS department</td>
<td>6 monthly</td>
</tr>
<tr>
<td></td>
<td>USS practitioner</td>
<td></td>
</tr>
</tbody>
</table>

* Under development  

* To be developed

**Screening pathway reporting - national reporting systems**

3.20 There are a small number of standards that are reported at a national level. Data is usually collected and reported by other bodies such as the Association for Clinical Genetic Science, the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) and the Institute of Child Health (ICH) to PHE screening.
3.21 Six-monthly reports are also produced by the Down's syndrome screening quality assurance support service (DQASS) for laboratory and ultrasound practitioners.

3.22 Laboratory summary report includes information on:

- screening test utilised
- laboratory throughput for each screening strategy
- modelled screening performance (detection rate and screen positive rate)
- any comments made by DQASS
- actions agreed and recommended
- compliance of sonographer’s ID code.

3.23 DQASS produces ultrasound reports for each ultrasound department in the cycle. There are detailed plots with individuals’ nuchal translucency (NT) / crown rump length (CRL) measurements and a summary report per ultrasound department. DQASS assigns each data set with a flag status for bias and throughput as outlined in the ultrasound scan (USS) practitioner’s handbook.

**Screening pathway reporting – thresholds and outliers**

3.24 It has not been possible to achieve a comprehensive cyclic reporting system due to the variable stages of standards development, but work is planned in April 2017 to March 2018.

3.25 Standards generally have 2 thresholds: acceptable and achievable.

3.26 The threshold is the lowest level of performance which programmes are expected to attain to ensure patient safety and programme effectiveness. All programmes are expected to exceed the acceptable threshold and to agree service improvement plans that develop performance towards an achievable level. Programmes not meeting the acceptable threshold are expected to implement recovery plans to ensure rapid and sustained improvement.

3.27 Achievable threshold represents the level at which the programme is likely to be running optimally; screening programmes should aspire towards attaining and maintaining performance at this level.

3.28 Providers or local services are reported as either meeting the acceptable and achievable thresholds or not.

3.29 Funnel plots using a 95% and 99.8% confidence interval are also used for the NHSP data set produced specifically for SQAS.
3.30 DQASS provides ultrasound practitioners with information on their individual paired NT and CRL distributions in relation to the Fetal Medicine Foundation (FMF) reference curve.

3.31 Bias describes the number of measurements above and below the FMF reference curve.

3.32 The bias is either negative in terms of undermeasurement (below the FMF reference curve) or positive which refers to over-measurement (above the FMF reference curve).

3.33 The evidence used to develop the flag status was derived from the impact on screening performance.

3.34 For positive biases greater than 0.40mm, the standardised screen positive rate (SPR) exceeds 5% and increases the number of pregnancies exposed to the potential risks and anxieties associated with a screen positive result which may lead to invasive diagnostic procedures.

3.35 There is a loss of 5% or more in the detection rate (DR) for negative biases with magnitudes of 0.40mm or greater.

3.36 Ultrasound practitioners who submit fewer than 25 paired NT/CRL measurements over 4 cycles are issued a red flag for throughput.

Data sharing

3.37 Routine data sharing activities between PHE Screening and Chief Knowledge Officer directorates are covered by a data sharing agreement, ODR_2014_220b.

3.38 Routine data sharing between PHE Screening and NHS England for all 11 screening programmes is underpinned by the Memorandum of Understanding (MoU) signed by both organisations. This MoU extends to any onward sharing to any third party, for example, PHE Centre Directors, providers of screening services, local authority, clinical commissioning groups (CCGs), voluntary organisations and other health professionals using screening data to improve and monitor services. This is for the purpose of improving quality of screening services. The set of data items covered by the MoU is shared prior to publication and for management purposes only. Data flows, schedules and the list of data items shared are managed by the national data and information team.
3.39 Non routine data requests from commissioners and service providers should be discussed with regional SQAS who will consider requests in line with data release principles including, but not limited to, the following questions:

- has the data already been shared via the MoU or available in the public domain?
- is the data likely to support population health improvement?
- is the data likely to improve the quality of screening services?
- what is the level of anonymisation required (open government licence to potentially identifiable and identifiable information)?
- what are the resources and costs required to extract, collate, quality assure and release the data set?

3.40 Regional SQAS will, if necessary, involve programme managers and the national data and information team in the initial discussion of non-routine data requests and seek advice from research committees where appropriate. All requests for personal confidential information will be discussed with the PHE Office for Data Release.

3.41 All data requests and releases will be centrally logged and tracked.
4. The QA visit

Objectives

4.1 The objectives of the QA visit are to:

- examine the performance of the local screening service
- verify achievement of national standards, identify variance from these standards and support professionals working in the local screening service to maintain and improve standards
- gain knowledge and expertise of areas for shared learning and disseminate this to all screening services
- share experiences and understanding of current problems or concerns in NHS antenatal and newborn screening services and contribute to national development

Requirements

Frequency of visits

4.2 The frequency of QA visits starting in April 2017 will be based on findings from the prioritisation exercise and in most cases will lie between 3 and 5 years. The maximum interval for a full visit for all services will be 5 years. This approach of targeting QA resources and visits to services which require support will be kept under review.

4.3 Visit schedules and other QA activities will be decided each year by an assessment against an agreed set of criteria. This new approach is designed to align SQAS resource according to services’ need. SQAS will evaluate this approach and consider impact on the average visit interval, findings at QA visits and SQAS capacity.

4.4 PHE, NHS England and provider organisations will be informed of the proposed schedule of visits.

Membership of visiting team

4.5 The visiting team will be selected by the SQAS.

4.6 The visiting team will be led by the visit chair.
4.7 Members of the team may include the following PCAs:

- public health and commissioning
- head of midwifery
- local screening coordinator
- laboratory lead
- hearing screening local manager / team leader
- screening support sonographer
- child health

4.8 Members of SQAS:

- senior quality assurance advisor
- and/or
- quality assurance advisor / quality assurance facilitator (QAF)

4.9 Visiting team members will be asked to declare conflicts of interest before the visit. If this raises concerns about the use of a PCA for a visit, SQAS will take advice within PHE.

4.10 A maximum of 2 observers may also be present at a QA visit, for training and education purposes. The observers will only act in an observational capacity: they will not be involved with providing feedback nor will they have any input into the interviews or decision making processes.

Role of the QA visit chair and QA advisor in QA visits

4.11 The visit chair will normally lead all QA visits with the support of a SQAA or QAA.

4.12 For antenatal and newborn screening, the visit chair will either be the regional head of quality assurance (RHQA) or head of quality assurance (HQA) who holds the antenatal and newborn screening portfolio or a PCA who has undergone additional training in order to undertake this role. Where the visit chair is a PCA, this will be their sole role during the visit. They will not be acting in the capacity of a PCA, except in exceptional circumstances agreed in advance.

4.13 The visit chair is responsible for:

- chairing and directing the conduct of the QA visit
- providing considered, consistent feedback on the visit findings
- managing sensitively and appropriately any serious issues or concerns raised prior to or on the day of the QA visit
- facilitating the exchange of knowledge and ideas and encouraging productive networking in order to foster developments in quality
4.14 The SQAA/QAA supporting the visit chair is responsible for:

- ensuring that the local screening services are fully aware of what is required in preparation for the visit
- acting as a point of contact for any queries regarding organising and coordinating the visit
- assembling and managing the visiting QA review team who will be accountable to the visit chair during each visit (up to and including production of the final report)
- ensuring that all PCAs selected have undergone appropriate training
- ensuring collection of evidence to support the visit and that any required observational pre-visits have been completed
- ensuring that adequate preparatory work is undertaken
- supporting the visit chair to assemble feedback during the visit
- ensuring that an accurate, considered report of the visit is issued within an agreed timescale and disseminated to provider chief executives and NHS England / SILs
- ensuring that all agreed recommendations are followed up and monitored or escalated where necessary, within an agreed timescale
- arranging any preliminary meetings between the SQAS and the local screening service as necessary (flexible depending on regional variation)

Skills and experience of visiting QA team

4.15 Members of the visiting QA team will need to demonstrate the following generic skills and training:

- PCAs / QA training course
- report writing
- interview techniques
- public health aspects of screening
- have an understanding of incident identification and management
- analytical skills
- ideally will have observed a QA visit

4.16 Specialist skills required of the individual PCAs are documented in the antenatal and newborn screening PCA person specification / job description.

Locations to be visited

4.17 The QA visit will assess the entire local screening service. It may not be possible to visit all screening sites on the same day if a service has sites located away
from the main provider unit. The SQAA/QAA will therefore liaise with the local screening service to arrange visits to the other sites before the day of the main QA visit.

Local screening service personnel attendance

4.18 The personnel from the local screening service who should attend during the visit, depending on service configuration, are:

- public health / commissioner
- head of midwifery
- local screening coordinator

Sources of evidence considered as part of QA visits

4.19 The QA report will be built up from a number of sources of evidence. These will be:

- response of the local screening service to the pre-visit questionnaires, where applicable
- supporting evidence and documents submitted to the SQAS for review
- interviews undertaken during the QA visit
- observational visits, where applicable
- case reviews, where applicable
- analysis of annual report data and routine data for the preceding 12 month period
- analysis of audit reports
- the commissioning grid completed by commissioners

Preparation for a QA visit

4.20 The SQAS will liaise with the local screening service and commissioners to make arrangements for the visit at least 6 months prior to the visit date. A mutually convenient date within a set timeframe will be agreed and a named contact within the local service for visit preparation should be identified. This named contact will be responsible for ensuring that members of the local screening service team are invited and able to attend the visit. The date will not be changed once it is agreed, except in exceptional circumstances, and only with the agreement of both parties.

4.21 The chief executive of the host trust, stakeholding trusts, commissioners, providers of any associated services and treatment providers will be informed by the SQAS that a visit is taking place. They will be invited to attend or send a suitable representative to the summary of the visit feedback session and
subsequent discussions as appropriate. For timescales in the QA visit process see Appendix B.

Preliminary meeting between Screening QA Service and the local screening service

4.22 A preliminary meeting between the SQAS and providers or commissioners may take place where applicable. This will vary by programme, for example, SQAS might request to attend the first scheduled local screening programme board meeting or operational group meeting after notification of the visit is made.

4.23 If a local screening programme board or other appropriate meeting has not been set between notification and the day of the visit, the SQAS might ask for one to be organised approximately 3 months before the visit date.

4.24 A member of the SQAS will attend this meeting to inform the local screening service about arrangements for the visit. This will include arrangements for any observational visits, an outline of the agenda and answering any questions that the local screening service and its stakeholders may have. This will also give the local screening service an opportunity to comment on current progress.

Information to be provided by local screening service

4.25 Local screening services will be asked to provide the following information in preparation for a QA visit:

- action plans from previous QA recommendations (where not already available to SQAS)
- action plans from pre-visit questionnaire or desk top review (where applicable)
- completed pre-visit questionnaire (where applicable)
- supporting documents and protocols as outlined in the pre-visit questionnaire or documentation
- performance reports as requested
- information on any incidents that have occurred in the last 12 to 24 months
- information on venue organisation – where the visit will be held and what rooms have been booked for interviews and feedback sessions
- other relevant information requested by the SQAS

4.26 This information should be provided to the SQAS at least 10 weeks prior to the visit date. There will be no flexibility on extending deadlines for evidence submission unless it enables a reduction in burden for the SQAS. Such cases will be agreed by the visit chair and SQAA/QAA responsible for the visit.
4.27 Evidence provided which is out of date, for example policies or guidelines, will not be assessed but will be used to inform decisions relating to local screening service governance.

4.28 Any request for clarification of evidence or for further evidence from providers should be coordinated by the SQAA/QAA responsible for the visit.

4.29 Any evidence transfer must conform to information governance rules. It must not contain patient identifiable or sensitive information and should be transferred to the SQAS following SQAS information governance protocols.

Review of evidence to inform the visit

4.30 The lead SQAA/QAA will complete the context grid (summary document) where applicable and review the evidence with the visit chair to determine key lines of enquiry (KLOE). At this stage the visit chair and SQAA/QAA will decide which PCAs are required for the visit with support from the RHQA / HQA if necessary.

Standing down of PCAs

4.31 PCAs will be notified at least 6 weeks before the visit date if they are not required to attend the visit. PCAs may be asked to carry out a variety of tasks, including scrutiny of specific elements of evidence, development of KLOEs and telephone interviews.

4.32 The minimum visit team will consist of the visit chair and SQAA/QAA who will meet with the head of midwifery and lead commissioner. A full QA visit will take place where necessary. The lead SQAA/QAA will inform PCAs of any required actions.

Information for the QA visit team

4.33 The SQAS will provide an information pack, usually in electronic format, for the visiting QA team which will include:

- contact details of visiting PCAs
- list of local screening service personnel
- agenda for the visit day (including details of venue and rooms booked)
- overview of the local screening service (context grid where applicable)
- copy of last QA visit report (where applicable)
- all documents submitted by the local screening service
- outcome of the observation of clinical practice and premises (where applicable)
- outcome of the observation of administration practice (where applicable)
• data relating to performance of the local screening service
• results of annual prioritisation exercise

4.34 The information pack will be sent to the PCAs at least 2 weeks before the date of the visit.

Format of a QA visit

4.35 In some instances, a pre-visit may take place or a case notes, slide and imaging review may be undertaken.

Components of the QA visit

Briefing for visit chair, PCAs and SQAA/QAAAs

4.36 The visiting team will either meet before the day of the QA visit or just before the visit commences. The aims of the briefing meeting are to:

• introduce all members of the QA visit team
• enable the SQAS to provide PCAs with an accurate overview of the core elements of the local screening service prior to the QA visit
• initiate discussions and enable any potential areas of concern to be highlighted prior to the QA visit
• enable triangulation of initial findings from pre-visit evidence review such as KLOEs generated by the PCAs and SQAS
• ensure that all members of the visiting QA team are aware of their roles and responsibilities for the QA visit

Introductions between the visiting team and the local screening service staff

4.37 Members of the visiting QA team and SQAS representatives will introduce themselves to the local screening service on the day of the visit.

A short presentation from the local screening coordinator about the local screening service’s achievements

4.38 The local screening coordinator or designated representative will be asked to give a short 10-15 minute presentation giving a brief overview or description of the service, including:

• changes since the last visit
• activity
Programme Specific Operating Model for Quality Assurance of Antenatal and Newborn Screening Programmes

- achievements
- any challenges or particular issues

Individual interviews between each PCA and the local screening service representative for that profession

4.39 Each PCA member of the visiting QA team will ideally meet their professional counterpart(s) in the local screening service. This will be a structured interview to assess adherence to national minimum standards, professional performance and the relationship between the different components of the local screening service.

4.40 The PCA should summarise the discussion, feedback main issues and check for mutual understanding at the end of the interview.

Discussion by the visiting QA team of findings and preparation of feedback session

4.41 The visiting QA team will meet to discuss outcomes of individual interviews and amalgamate their findings. They will focus on areas of risk, recommendations and shared learning. Findings will be summarised and this may take the form of a presentation.

Feedback session

4.42 The feedback on the day will be given in 2 sessions.

4.43 The visit chair and SQAA/QAA will meet with the provider chief executives and NHS England DCO team representative, for example, SIL, to give a verbal summary of risks, high level findings and recommendations. This session may also be used to raise concerns regarding performance of an individual, or concerns for patient safety where it would not be appropriate to report these findings to a wide audience.

4.44 This session will usually, but not always, take place prior to the main feedback session and it is anticipated that this will last no longer than 15 minutes.

4.45 The main feedback session will consist of a short presentation by the visit chair of the main findings and recommendations to all local screening service staff and some stakeholders. All those interviewed should be invited to the main feedback session.

4.46 Senior management representatives of the provider trust, chief executives, CCG representatives (where applicable), NHS England DCO team representatives and other stakeholders identified by the local screening service will also be invited to
attend this session. Directors of public health or their nominated representative can be invited to attend by the DCO team.

4.47 The feedback session will highlight:

- areas for shared learning
- risks
- recommendations
- intention to publish the report executive summary on an external facing website 8 weeks following the production of the final QA report

4.48 It is anticipated that this feedback session will take no longer than 30 minutes.

4.49 Where immediate concerns related to safety are raised, a letter from the RHQA or HQA outlining the main concerns and corresponding remedial actions will be sent to the chief executive of the provider organisation and the lead commissioner within 2 working days. The letter will be copied to the RHQA (where applicable) and to the National Lead, Screening QA Service. The national programme managers will be informed where applicable.

**Feedback from local screening service provider on QA visit**

4.50 Local screening services will be asked to complete a feedback questionnaire after the QA visit in order to evaluate the visit process and provide feedback for the SQAS as part of its ongoing review process.

**Written report and follow-up**

4.51 Each member of the visiting QA team will submit to the SQAA/QAA a summary of their findings. It is expected that these summaries will be available to the SQAA/QAA within 1 week of the visit (or earlier as agreed). It is the responsibility of the lead SQAA/QAA to produce a draft report for factual accuracy checking by the local screening service and commissioners within 20 working days of the visit. Day 1 is the first working day after the visit takes place.

4.52 The final report will be completed within 8 weeks of the visit.

4.53 The QA visit report will:

- be completed using the agreed report template and associated headings
- use plain, clear English in line with the PHE style guide
- include summary descriptions of local screening service organisation and leadership arrangements
• comment on the adequacy of resource, accommodation, and equipment to meet national standards
• identify areas of shared learning
• identify variance from national standards as a centre and within specialties
• identify strengths and weaknesses within the local screening service
• make structured recommendations to address issues identified

Circulation of the report

4.54 A copy of the report will be sent to:

• provider chief executive(s)
• NHS England DCO team representative, for example SIL and the Head of Public Health Commissioning (HOPHC)

4.55 The report will be sent via email and will be copied to the Head of Midwifery.

4.56 The chief executive and SIL will be asked to disseminate to relevant colleagues including those in the local health economy with a responsibility for screening services and relevant colleagues in public health centres. Details of where the executive summary will be published will be included in the correspondence.

4.57 The executive summary of the QA report will be published on the GOV.UK website 8 weeks after the final report is issued (16 weeks after the visits) with consent from the local screening service provider and NHS England commissioners. The provider may choose to submit an action plan with progress at this time and if so, details of where the action plan can be found will be provided.

4.58 Where consent is not given by the provider, the provider’s name and the date of the visit will be published instead with an acknowledgement that a visit took place and consent to publish the executive summary was declined. A similar note will be placed on the website if NHS England commissioners declined publication.

4.59 Provider and commissioning organisations should note that the full report can be requested by a member of the public using a Freedom of Information request and may be released by PHE if requested.

Development of the action plan

4.60 SQAS will support the providers and commissioner through the action planning process. Each provider and NHS England DCO team will have a named SQAA/QAA.
4.61 The QA process should identify whether providers have met the nationally agreed programme standards and any statutory guidance or guidelines and should state the evidence used to assess how the judgement about quality was made.

4.62 The SQAS will write recommendations from which action plans can be developed. The evidence required to show that an action has been completed will be stated as part of the recommendations.

4.63 A criteria for closure will be included detailing exactly what action or documentation is required to show that an action has been satisfactorily implemented.

4.64 Timescales for the recommendations should be specific, with dates for completion clearly stipulated.

4.65 It is the responsibility of the NHS England DCO team’s SIL (the commissioner) to ensure that the recommendations made in the QA visit report are implemented. This will be done in conjunction with the provider.

4.66 An action plan should be developed by the local screening service within 4 weeks of receiving the final report, which is agreed with the SIL or HOPHC. It is good practice for this to be submitted to the next local screening programme board or equivalent governance structure within 3 months of the visit.

4.67 The SIL will ensure that progress against the action plan is maintained using relevant commissioner oversight mechanisms and levers, with SQAS kept informed via local programme / oversight boards and direct contact with the providers and commissioners.

4.68 SQAS will work with commissioners to monitor activity and progress in response to recommendations. This is for a period of 12 months following the issuing of the final report. This will allow adequate time for at least one response to all recommendations. A letter will then be sent to the provider chief executive and commissioners summarising the progress made and asking for their direct intervention to address any remaining issues.

**Escalation process**

4.69 Failure to undertake recommended actions will necessitate appropriate escalation by SQAS if progress is not being made. This will initially be through the local screening programme board or equivalent governance structure and NHS England DCO team.
5. Training and development

5.1 All staff taking part in QA activity should undertake training related to the role. The training requirements for professional and clinical advisors are set out in the relevant job descriptions / role outlines which are available from the SQAS team.

Continuous improvement

5.2 We are committed to improving our processes and measuring the impact of QA and as such we request feedback from local screening services and providers on all aspects of the QA process and visit. Any feedback received will be shared as appropriate in relevant forums, or individually where applicable, to improve the QA process.
Appendix A: The quality assurance process

Details of the process described below are in development and will be reviewed.

SQAS activity key:

- Black: provider function reviewed by SQAS
- Pink: public health system leadership and commissioning function (please refer to pre visit questionnaire for complete list of functions for peer review)
- Green: under development

Frequency key:

- 1 - incident monitoring
- 2 - performance data monitoring (monthly, quarterly, annually)
- 3 - annual risk assessment/ prioritisation
- 4 - pre visit evidence review
- 5 - at visit
- 6 - real time triggers (including soft intelligence from programmes)
<table>
<thead>
<tr>
<th>Pathway</th>
<th>SQAS activity (click title to see key)</th>
<th>Evidence SQAS will examine</th>
<th>Source of data / evidence (click title to see key)</th>
<th>Frequency (click title to see key)</th>
<th>Mapped to standards / KPIs / service specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service provider and population served</td>
<td>1. Describes scope of service and interface between providers across the whole screening pathway 2. Sets context of service using internal information, data and intelligence and where relevant intelligence from other external bodies 3. Checks provider feedback on their understanding of current position</td>
<td>Summary within trust annual report (or alternative summary) including: 1. Geographic distribution and location of all sites belonging and used by the provider 2. Geographic location of all CHRDs and NHSP services used by the provider 3. Details of any cross border issues 4. Information on recent or planned mergers with description of any impact on screening service 5. Other available information and/or soft intelligence on service provider 6. Feedback on 3 key achievements and 3 areas for improvement</td>
<td>1. Trust annual report (if available) 2. Local reports 3. Other information or soft intelligence</td>
<td>3, 4, 5, 6</td>
<td></td>
</tr>
<tr>
<td>Governance and leadership</td>
<td>Programme management and accountability 1. Checks arrangements in place for screening programme co-ordination 2. Outlines internal trust processes for the oversight and governance of screening and escalation process to commissioners 3. Checks processes, interface and</td>
<td>Trust Screening Steering Group, including: 1. terms of reference, membership or attendance list with participation from all screening programme services (e.g. maternity, sonography, labs, NHSP, CHRD, specialist ID, SCT) 2. agenda and minutes for previous 3 meetings (within the preceding 12 to 18 months) 3. action or work plans / regular monitoring tools or reports</td>
<td>Documentation from provider trusts</td>
<td>4, 5, 6</td>
<td>Public health national service specifications (Section 7A) numbers 15, 16, 17, 18, 19, 20, 21, 28</td>
</tr>
<tr>
<td>Pathway</td>
<td>SQAS activity (click title to see key)</td>
<td>Evidence SQAS will examine</td>
<td>Source of data / evidence (click title to see key)</td>
<td>Frequency (click title to see key)</td>
<td>Mapped to standards / KPIs / service specification</td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------</td>
<td>-----------------------------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>Governance and leadership</td>
<td><strong>Commissioning and accountability</strong>&lt;br&gt;1. Outlines commissioner landscape both within and outside of maternity and specialised commissioning arrangements&lt;br&gt;2. Checks commissioner governance arrangements including strategic screening programme board and escalation processes between different commissioning</td>
<td>Commissioner led screening programme board including:&lt;br&gt;1. terms of reference, membership or attendance list with participation from all screening programme services&lt;br&gt;2. agenda and minutes for previous 3 meetings (within the preceding 12 to 18 months)&lt;br&gt;3. action or work plans / regular monitoring tools or reports&lt;br&gt;4. risk register&lt;br&gt;5. relationship to other commissioner</td>
<td>Documentation from commissioners&lt;br&gt;4, 5, 6</td>
<td>Public health national service specifications (Section 7A) numbers 15, 16, 17, 18, 19, 20, 21, 28</td>
<td></td>
</tr>
<tr>
<td>Pathway</td>
<td>SQAS activity</td>
<td>Evidence SQAS will examine</td>
<td>Source of data / evidence</td>
<td>Frequency</td>
<td>Mapped to standards / KPIs / service specification</td>
</tr>
<tr>
<td>---------</td>
<td>---------------</td>
<td>---------------------------</td>
<td>---------------------------</td>
<td>-----------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>governance groups, e.g., CCG, specialised commissioning</td>
<td>Documentation from provider Trusts</td>
<td>1, 2, 3, 4, 5, 6</td>
<td>1. Public health national service specifications</td>
</tr>
<tr>
<td></td>
<td></td>
<td>discipline or area specific subgroups - NHSP programmes should participate in their local Children Hearing Services Working Group (CHSWG)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>links to wider groups including Health and Wellbeing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Completed commissioning grid, including:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. copies of any contracts which are outside of standard maternity and specialised commissioning arrangements and contracting monitoring</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. gap analysis against section 7a specifications and actions taken</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. description of arrangements for public health support for CCGs, specialist and screening commissioning and LA PH commissioning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. escalation processes for NHSE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Governance and leadership</td>
<td>• Escalation, risk management and incidents</td>
<td>Risk management policy with evidence of use of reporting arrangements within the governance structure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pathway</td>
<td>SQAS activity (click title to see key)</td>
<td>Evidence SQAS will examine</td>
<td>Source of data / evidence (click title to see key)</td>
<td>Frequency (click title to see key)</td>
<td>Mapped to standards / KPIs / service specification</td>
</tr>
<tr>
<td>---------</td>
<td>----------------------------------------</td>
<td>-----------------------------</td>
<td>-----------------------------------------------</td>
<td>--------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
</tbody>
</table>
| 1.      | Reviews systems and oversight for handling and escalating risks (see programme management and commissioning sections above), quality concerns and incidents, including interface with commissioners | 2. Local incident policy including reference to national guidance  
3. List of screening incidents for the 2 years prior to submission date (e.g. April 2014 to March 2016 for evidence submitted April 2016) including from CHRDs, NHSP, maternity providers, laboratories, relevant specialist screening services  
4. Example of a screening incident root cause analysis report from the previous 2 years including an action plan with progress recorded which demonstrates that recommendations were acted on  
5. Business continuity arrangements  
6. Trust safety improvement plan related to ‘Sign up to Safety’ campaign where available |  (Section 7A) numbers 15, 16, 17, 18, 19, 20, 21, 28 | 2. Managing incidents in NHS screening programmes |
| 2.      | Checks approach to risk management |                             |                                              |                                |                                               |
| 3.      | Checks approaches to resilience and business continuity |                             |                                              |                                |                                               |
| Governance and leadership | Policies and guidelines | Policies and SOPs in current use, the documents provided should cover:  
1. Nuchal translucency and fetal anomaly ultrasound scans  
2. Down's, Edwards' and Patau’s syndromes  
3. Hepatitis B (including referral into hepatology and paediatrics and CHRDs for administering and scheduling neonatal vaccination) | Documentation from provider trusts | 4, 5 | Public health national service specifications (Section 7A) numbers 15, 16, 17, 18, 19, 20, 21, 28 |
<p>| 1.      | Checks local policies, guidelines and SOPs align with the national NHS screening programmes guidance and standards |                             |                                              |                                |                                               |
| 2.      | Checks clinical audit reports demonstrate conformity to local screening policies |                             |                                              |                                |                                               |</p>
<table>
<thead>
<tr>
<th>Pathway</th>
<th>SQAS activity (click title to see key)</th>
<th>Evidence SQAS will examine</th>
<th>Source of data / evidence (click title to see key)</th>
<th>Frequency (click title to see key)</th>
<th>Mapped to standards / KPIs / service specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.</td>
<td>HIV (including links with GUM and other specialist service)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Syphilis (including links with GUM and other specialist service)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>SCT (including referral to sickle cell and thalassaemia specialist services and linked neonatal service)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>NIPE including the process for referrals for screen positive and receiving and recording outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>NBS including referrals for screen positive</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>NHSP including the process for referrals for screen positive to audiology services and receiving and recording outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>NICU policies covering newborn screening</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>CHRD SOP for NBS, NHSP, NIPE and hepatitis B linked antenatal screening neonatal vaccination programme</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>DNA policy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>Booking / early access policy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td>Policies covering re-offers of screening where relevant, e.g., IDPS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15.</td>
<td>Process for repeat testing / samples where required</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16.</td>
<td>Process for newborn screening programmes dealing with deceased babies (NHSP, NIPE,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Programme Specific Operating Model for Quality Assurance of Antenatal and Newborn Screening Programmes
<table>
<thead>
<tr>
<th>Pathway</th>
<th>SQAS activity (click title to see key)</th>
<th>Evidence SQAS will examine</th>
<th>Source of data / evidence (click title to see key)</th>
<th>Frequency (click title to see key)</th>
<th>Mapped to standards / KPIs / service specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Governance and leadership</td>
<td>• Audit</td>
<td>NBS) including communication links with CHRD, NICU, and maternity units 17. Results checking policy (for SCT ensure maternal results are matched to the baby’s father in the current pregnancy) 18. Process for communicating positive and negative results to women / parents for each screening programme 19. Failsafe policy / SOP on cohort tracking for the whole pathway including a lab tracking SOP and their process for communicating positive results 20. Policy around user satisfaction monitoring for screening and examples of surveys/action plans if completed</td>
<td>Audit schedule examples: 1. sonography departmental image review for NT/CRL 2. IDPS, SCT, T21/T18/T13 and laboratory audits 3. NBBS avoidable repeats audits 4. NHSP referral rate 5. policy compliance audits 6. failsafe audits 7. audit on referral to treatment/management</td>
<td>Audit examples</td>
<td>4, 5</td>
</tr>
<tr>
<td>Pathway</td>
<td>SQAS activity (click title to see key)</td>
<td>Evidence SQAS will examine</td>
<td>Source of data / evidence (click title to see key)</td>
<td>Frequency (click title to see key)</td>
<td>Mapped to standards / KPIs / service specification</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>----------------------------------------</td>
<td>----------------------------</td>
<td>-----------------------------------------------</td>
<td>----------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Governance and leadership</td>
<td>• Communication with commissioners and relationship with programme board</td>
<td>times</td>
<td>8. audit of complaints related to screening, notes audit covering screening</td>
<td>4, 5</td>
<td>1. IDPS Standard 5 1. FASP Standard</td>
</tr>
<tr>
<td></td>
<td>• Checks informal and formal communication mechanisms including regular reports</td>
<td>9. audits of compliance with screening standards</td>
<td>10. contributes to national audits</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Checks informal and formal communication mechanisms including regular reports</td>
<td>11. minutes from local clinical audit meetings demonstrating inclusion of ANNB screening related topics</td>
<td>12. audit action plans</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Governance and leadership</td>
<td>• Communication and patient feedback</td>
<td>See commissioning and accountability evidence listed above</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Checks inclusion of patient and user feedback into service development</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infrastructure</td>
<td>• Workforce</td>
<td>• Evidence of patient/user satisfaction with screening if applicable, complaints and compliments</td>
<td>Patient / user satisfaction survey</td>
<td>4, 5</td>
<td>Public health national service specifications (Section 7A) numbers 15, 16, 17, 18, 19, 20, 21, 28</td>
</tr>
<tr>
<td></td>
<td>• Checks relevant staff are in place</td>
<td>• Trust annual report</td>
<td>1. Trust annual report</td>
<td>4, 5</td>
<td>1. IDPS Standard 5 1. FASP Standard</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. staffing levels, vacancies, use of agency staff</td>
<td>2. Job descriptions</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Programme Specific Operating Model for Quality Assurance of Antenatal and Newborn Screening Programmes

<table>
<thead>
<tr>
<th>Pathway</th>
<th>SQAS activity (click title to see key)</th>
<th>Evidence SQAS will examine</th>
<th>Source of data / evidence (click title to see key)</th>
<th>Frequency (click title to see key)</th>
<th>Mapped to standards / KPIs / service specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Programme Specific Operating Model for Quality Assurance of Antenatal and Newborn Screening Programmes</td>
<td>to ensure screening functions are delivered in a timely manner and included in job descriptions/roles</td>
<td>2. structure of screening team(s) 1. screening coordinator and deputy 2. NHSP local manager and team leader 3. infectious diseases screening specialist, if relevant (may be midwife, specialist nurse or medical clinician with responsibility for ID screening) 4. Sickle Cell and Thalassaemia specialist counsellor, if relevant 5. screening support sonographer 6. NIPE lead 7. child health record department manager, coordinator, team leader or any other staff with a significant role in delivery of screening and failsafe in child health 8. failsafe officer / administrator</td>
<td>3. Business continuity plan</td>
<td></td>
<td>7 3. NBS Standard 9 4. NBS Standard 12</td>
</tr>
<tr>
<td>Infrastructure</td>
<td>Equipment and IT 1. Checks IT systems including contingency arrangements, including specific NHSP</td>
<td>1. Adequacy of IT support for development, audit and troubleshooting / risk assessment completed if relevant / contingency if no IT system in place 2. The provider must only use newborn hearing</td>
<td>Local trust policy</td>
<td>4, 5</td>
<td>Public health national service specifications (Section 7A) numbers 15, 16, 17,</td>
</tr>
<tr>
<td>Pathway</td>
<td>SQAS activity (click title to see key)</td>
<td>Evidence SQAS will examine</td>
<td>Source of data / evidence (click title to see key)</td>
<td>Frequency (click title to see key)</td>
<td>Mapped to standards / KPIs / service specification</td>
</tr>
<tr>
<td>------------------</td>
<td>----------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------</td>
<td>-----------------------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td></td>
<td>requirements</td>
<td>screening equipment and consumables that meet the NHSP technical specification as determined within the NHS Supply Chain framework agreement. Ensure the latest software version is installed (which will vary by equipment type) and ensure that the trust are using an up to date version of Internet Explorer which meets the requirements of the screening national IT system</td>
<td></td>
<td></td>
<td>18, 19, 20, 21, 28</td>
</tr>
</tbody>
</table>
| Infrastructure    | Education and training                  | 1. Policy for induction, education and training for all staff involved in screening which lists all staff groups covered (including maternity, neonatal staff, NHSP, CHRD and sonography)  
2. Evidence of how training is monitored, including training needs, e.g. training needs analysis, training reports, example training log  
3. Resources used: NHS screening programmes e-learning and audit facility and other resources and/or in-house  
4. Genetic risk assessment course for SCT screening where applicable  
5. Process in place for 2 yearly competency assessment for health visitors (HV) and registered nurses (RN) plus 1 yearly competency assessments for non-HV/RN | Local trust policy | 1, 5, 6                           | Public health national service specifications (Section 7A) numbers 15, 16, 17, 18, 19, 20, 21, 28 |
<table>
<thead>
<tr>
<th>Pathway</th>
<th>SQAS activity (click title to see key)</th>
<th>Evidence SQAS will examine</th>
<th>Source of data / evidence (click title to see key)</th>
<th>Frequency (click title to see key)</th>
<th>Mapped to standards / KPIs / service specification</th>
</tr>
</thead>
</table>
| Antenatal: identifying and tracking cohort | 1. Checks there are robust processes in place for timely access to maternity care and screening | performing NHSP screens  
6. Process in place for training/induction and follow up of new screening staff including newly appointed Local Managers and Local Learning Mentors for NHSP  
7. Process in place to assess competency of agency staff before they embark on delivering screening, e.g., sonographer’s image review  
8. Ongoing educational programme for staff performing NIPE to assess ongoing competency | 1. Booking data by 10+0 (and 12+6 where data is not available for 10+0)  
2. Provider’s website - information on website regarding local mechanisms to improve early access and screening  
3. Demographics of birth population, language, ethnicity, age, birth rate, for last financial year | 1, 2, 3, 4, 5, 6 | SCT AP1 (KPI) |
| Antenatal: identifying and tracking cohort | 1. Checks that failsafe processes are in place i.e. failsafe databases used regularly i.e. weekly and not quarterly, there is adequate cover for annual leave/sickness, SOP in place | Antenatal cohort tracking.  
Example of complete cohort tracking system (from offer of screening to notification of results) for antenatal population and associated operating procedures using anonymised database and/or | 1. National KPI data (published)  
2. National standards (published from 2016) or trust | 1, 2, 3, 4, 5, 6 | 1. FASP Standard 1  
2. FASP Standard 2 (KPI)  
3. IDPS Standard 1 (KPI) |
<table>
<thead>
<tr>
<th>Pathway</th>
<th>SQAS activity (click title to see key)</th>
<th>Evidence SQAS will examine</th>
<th>Source of data / evidence (click title to see key)</th>
<th>Frequency (click title to see key)</th>
<th>Mapped to standards / KPIs / service specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>Checks that the failsafe processes cover end to end pathway tracking from identification of eligibility to results (including relevant reoffer, repeat tests and transportation of samples to screening laboratories) or closure of the maternity episode</td>
<td>screen shots. This evidence should demonstrate: 1. evidence of failsafe systems in place with identification of the eligible cohort including data flows into the system(s) for booked cohort 2. screening accepted, declined, tested, including, inconclusive and repeat tests where required; results available including, results of baby's biological father where relevant, results given (and where applicable reasons for declines) 3. capture of transfers in and out, late bookers, terminations and miscarriages 4. clarity of roles and responsibility for failsafe checks and evidence of implementation</td>
<td>annual report where this is not yet available 3. Documentation from the provider/SOPs and policies</td>
<td>4. IDPS Standard 2 5. IDPS Standard 3 6. SCT AO1aii (KPI)</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Checks that provider submits coverage KPI data, that the data is cohort data</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Checks that there are robust processes in place to establish the denominator including exclusions, e.g., transfers in and out, miscarriages and TOPs and can account for declines</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Checks that there is a clear process in place for timely follow up of missed screens identified</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>FASP- checks failsafe process for women who need to transfer from first to second trimester T21/T18/T13 screening</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Newborn: identifying and</td>
<td>Checks there is a system to ensure birth notifications (PDS/BNA) are 1. Coverage standards and KPI data 2. Use of NIPE SMART, NHSP and NBSFS</td>
<td>1. National KPI data (published)</td>
<td>1, 2, 3, 4, 5, 6</td>
<td>1. NIPE Standard 1 (KPI)</td>
<td></td>
</tr>
<tr>
<td>Pathway</td>
<td>SQAS activity (click title to see key)</td>
<td>Evidence SQAS will examine</td>
<td>Source of data / evidence (click title to see key)</td>
<td>Frequency (click title to see key)</td>
<td>Mapped to standards / KPIs / service specification</td>
</tr>
<tr>
<td>---------</td>
<td>---------------------------------------</td>
<td>-----------------------------</td>
<td>-----------------------------------------------</td>
<td>---------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>tracking cohort</td>
<td>completed promptly prior to NB screening (in order to identify the eligible cohort with backup systems in place for manual checks should there be any IT system failure)</td>
<td>3. Evidence for full cohort tracking including capture of screening accepted, declined (and where applicable reasons for declines), movers in and out, tested, including inconclusive and repeat tests where required, results available, results given</td>
<td>2. Documentation from the provider/SOPs and policies</td>
<td>2. NHSP Standard 1 (KPI)</td>
<td>2. NBS Standard 1 (KPIs X2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3. NBS Standard 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4. NBS Standard 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5. Checks process for monitoring declines and whether providers</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5. Avoidable repeat KPI for NBS- NB2</td>
</tr>
<tr>
<td>Pathway</td>
<td>SQAS activity</td>
<td>Evidence SQAS will examine</td>
<td>Source of data / evidence</td>
<td>Frequency</td>
<td>Mapped to standards / KPIs / service specification</td>
</tr>
<tr>
<td>---------</td>
<td>---------------</td>
<td>-----------------------------</td>
<td>---------------------------</td>
<td>-----------</td>
<td>-----------------------------------------------</td>
</tr>
</tbody>
</table>
| Antenatal and Newborn: coverage | 1. Checks for evidence of initiatives to increase uptake/coverage where appropriate  
2. Collect information on initiatives to improve access to vulnerable groups, late bookers, BME groups and others, e.g., health equity audits  
3. Seeks assurance that provider & SIT understand and respond to local demographic profile including hard to reach, military and prison populations  
4. Checks process in place for postnatal discharges to enable safe handover of responsibility  
5. Check links with CHRDS and | 1. Coverage standards and KPI data  
2. Health equity audits with linkage to intelligence within Joint Strategic Needs Assessment (if available) and associated action plan including evidence to demonstrate change | 1. National KPI data (published)  
2. National standards (published from 2016) or trust annual report where this is not yet available  
3. Health equity audits/ action plans (where available)  
4. Uptake not currently measured as no way to capture | • 1, 2, 3, 4, 5, 6 | 1. FASP Standard 1  
2. FASP Standard 2 (KPI)  
3. IDPS Standard 1 (KPI)  
4. IDPS Standard 2  
5. IDPS Standard 3  
6. SCT AO1aii (KPI)  
7. NIPE Standard 1 (KPI)  
8. NHSP Standard 1 (KPI)  
9. NBS Standard 1 |
## Programme Specific Operating Model for Quality Assurance of Antenatal and Newborn Screening Programmes

<table>
<thead>
<tr>
<th>Pathway</th>
<th>SQAS activity (click title to see key)</th>
<th>Evidence SQAS will examine</th>
<th>Source of data / evidence (click title to see key)</th>
<th>Frequency (click title to see key)</th>
<th>Mapped to standards / KPIs / service specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Invite and inform</td>
<td>health visiting services</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Checks maternity booking process is timely to support informed choice (pathway for consent to screening) and screening at the optimal time-short time lag from referral to booking appointment, fast track booking process for women booking after 10 weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Checks use of national materials including translated versions-STFYAYB including processes in place to revisit information prior to newborn screening (as STFYAYB is given out antenatally), use of NICU leaflet, SCT leaflet for dads and carriers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Checks access and use of interpreters / other translation services</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Checks did not attend (DNA) process for follow up and any audits undertaken to understand rate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Local audits including notes audit if available</td>
<td></td>
<td></td>
<td>offer - MCDS awaited</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Audits - DNA (did not attend), documented evidence of STFYAYB, SCT leaflet for dads and carriers, NICU leaflet</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. NBS guideline includes babies up to 1 year old and movers in</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. NHSP guideline includes babies &lt; 3 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. SCT guideline includes father testing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Where NHSP screening is performed as an outpatient - it is family friendly and that uptake is not adversely affected</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Pre visit evidence</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Local audits</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Local guidelines</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>[1, 4, 5, 6]</td>
<td></td>
<td>[Covered in Section 7a service specifications]</td>
</tr>
</tbody>
</table>
### Programme Specific Operating Model for Quality Assurance of Antenatal and Newborn Screening Programmes

<table>
<thead>
<tr>
<th>Pathway</th>
<th>SQAS activity (click title to see key)</th>
<th>Evidence SQAS will examine</th>
<th>Source of data / evidence (click title to see key)</th>
<th>Frequency (click title to see key)</th>
<th>Mapped to standards / KPIs / service specification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test (non laboratory)</strong></td>
<td>5. Checks processes for inviting babies under 1 year old especially movers in for NBS screening and babies &lt; 3 months for NHSP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>6. Check interface with private and/or independent midwifery services where applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>7. Checks SCT pathway includes processes for inviting and informing fathers (carrier and affected mothers)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Checks that the ultrasound department has a process in place for NT/CRL image review</td>
<td>2. Process for dealing with monthly data quality reports issued by NHSP, including, outstanding action plan from last report, if applicable (NHSP QA data set - referral rates)</td>
<td>2. NHSP data set</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Checks participation in DQASS (review any outstanding action plans for USS red flags)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test (laboratory)</strong></td>
<td>1. Checks performance of laboratory test elements against national standards and components of service specifications and laboratory handbooks aligned with</td>
<td>1. UKAS reports of assessments of performance undertaken 4 yearly and exception reports of annual surveillance visits</td>
<td>1. National standards</td>
<td>1. Mapped to standards/KPIs, ISO</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Use of laboratory requirements document as the assessment tool for any SQAS visits to</td>
<td>2. KPIs</td>
<td>2. IDPS Standard 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3. ISO standards</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4. Incidents</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1, 2, 3, 4, 5, 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3 &amp; 4 SQAS visits on exception basis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pathway</td>
<td>SQAS activity (click title to see key)</td>
<td>Evidence SQAS will examine</td>
<td>Source of data / evidence (click title to see key)</td>
<td>Frequency (click title to see key)</td>
<td>Mapped to standards / KPIs / service specification</td>
</tr>
<tr>
<td>---------</td>
<td>--------------------------------------</td>
<td>-----------------------------</td>
<td>-----------------------------------------------</td>
<td>------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
</tbody>
</table>
|         | ISO standards, e.g., accreditation and status regarding non conformities  
2. Checks interfaces between laboratory, maternity services and child health records departments  
3. Undertake assessment visits to laboratories on an exception basis | laboratories  
3. Other – DQASS laboratory reports | as per operational framework | 3. FASP Standard 3, 5, 6, 9  
4. SCT AO1aii (KPI), AO2a (part 2)  
5. NBS Standard 5  
6. NBS Standard 6 (KPI)  
7. NBS Standards 8, 9, 10 | |
| Giving results | 1. Checks process for giving negative results for each condition including timeliness and evidence of audit  
2. Checks there are robust processes in place to send negative screening NBS results letters to parents  
3. Checks process for giving positive results for each condition- check that national leaflets are used where available (IDPS, SCT, NBS, NHSP)  
4. Checks process for giving positive results including timeliness - see national standards  
5. Checks process in place for | 1. Local audits to demonstrate robust and timely processes for giving negative results (NHSP, NIPE and FASP - USS results given at time of screening, NBS 6 weeks of age, FASP - T21/T18/T13 - 2 weeks after screening, SCT & IDPS before or at the next AN appointment)  
2. Anonymised examples of NBS, NHSP screen negative letters  
3. Performance against national standards for positive screening results – NHSP, NIPE & FASP - USS results given at time of screening, FASP - T21/T18/T13, IDPS - 10 working days of results, NBS - see standard 9 for condition specific timeframes) | 1. Pre visit evidence  
2. Local audits and guidelines  
3. National standards | 1, 2, 4, 5 | 1. IDPS Standard 5  
2. FASP Standard 7  
3. NBS Standard 9  
4. NBS Standard 12 |
<table>
<thead>
<tr>
<th>Pathway</th>
<th>SQAS activity (click title to see key)</th>
<th>Evidence SQAS will examine</th>
<th>Source of data / evidence (click title to see key)</th>
<th>Frequency (click title to see key)</th>
<th>Mapped to standards / KPIs / service specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referral following a positive screening result</td>
<td>matching antenatal and newborn results where appropriate (SCT) 6. Checks process for giving results includes women who were screened antenatally but subsequently miscarry or have a termination</td>
<td>Performance against national standards: 1. SCT: communication of PND result within 5 days of diagnostic test 2. IDPS: standard 6- timely assessment of women with hepatitis B 3. FASP: standard 8a, 8b - time to intervention 4. NHSP: standards 4, 5 - time from screening outcome to offered and attendance at appointment for diagnostic audiological assessment 5. NIPE: standards 2, 3, 4 and 5- timeliness of intervention 6. NBS: standard 11 for condition specific timeframes 7. Evidence of recording maternal Hepatitis B status and administration of first neonatal hepatitis B vaccination +/- immunoglobulin to</td>
<td>National standards</td>
<td>1, 2, 3, 4, 5, 6</td>
<td>1. SCT AO1b 2. SCT AP3 3. IDPS Standard 6 (KPI) 4. FASP Standard 8 5. NHSP Standard 4 6. NHSP Standard 5 7. NIPE Standard 2 8. NIPE Standard 3 (KPI) NIPE Standard 4 9. NIPE Standard 5 10. NBS Standard 11</td>
</tr>
<tr>
<td>Pathway</td>
<td>SQAS activity (click title to see key)</td>
<td>Evidence SQAS will examine</td>
<td>Source of data / evidence (click title to see key)</td>
<td>Frequency (click title to see key)</td>
<td>Mapped to standards / KPIs / service specification</td>
</tr>
<tr>
<td>---------</td>
<td>----------------------------------------</td>
<td>----------------------------</td>
<td>---------------------------------------------------</td>
<td>-----------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>timely manner, e.g. access to prenatal diagnosis, potential capacity issues in diagnostic service</td>
<td>enable scheduling of subsequent neonatal vaccination and serology at 1 year of age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Checks process in place to identify and communicate information about babies who die</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Checks that referral for prenatal invasive procedure includes a comprehensive review of all screening results, e.g., referral for T21/T18/T13 checks sickle and thalassaemia, HIV screening results</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Outcomes| 1. Case reviews of any unexpected affected results - review of the screening pathway for the individual, take appropriate action and apply any relevant learning | 1. Review of unexpected affected cases and applying learning where relevant  
2. IDPS standard 7  
3. NHSP data set - yield | 1. Local reports/ screening safety incidents  
2. NHSP data set | 1, 4, 5, 6 | 1. IDPS Standard 7  
2. FASP Standard 4  
3. SCT LO2 (part 2) |
<p>|         | 2. Checks process in place to contribute to national registers to enable monitoring of outcomes, e.g. NCARDRS, Perinatal HIV outcome (ICH) | | | | |
|         | 3. Checks an alert system is in place to inform newborn laboratories of | | | | |</p>
<table>
<thead>
<tr>
<th>Pathway</th>
<th>SQAS activity (click title to see key)</th>
<th>Evidence SQAS will examine</th>
<th>Source of data / evidence (click title to see key)</th>
<th>Frequency (click title to see key)</th>
<th>Mapped to standards / KPIs / service specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic eye screening in pregnancy</td>
<td>1. Checks that the provider has a process in place for identifying women with existing diabetes</td>
<td>1. Guidelines</td>
<td>Documentation from provider trusts</td>
<td>4, 5</td>
<td>National policy</td>
</tr>
<tr>
<td></td>
<td>2. Checks that there is a guideline that specifies the population that will be offered screening -eligibility and exclusions</td>
<td>2. Database, if available</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Checks that the guideline is clear about when screening is offered</td>
<td>3. Example of results letter</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Checks that STFYAYB is used as information for diabetic women</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. Checks that there is a process for communicating results to women within 6 weeks recommended timescales</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pathway</td>
<td>SQAS activity (click title to see key)</td>
<td>Evidence SQAS will examine</td>
<td>Source of data / evidence (click title to see key)</td>
<td>Frequency (click title to see key)</td>
<td>Mapped to standards / KPIs / service specification</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------</td>
<td>-----------------------------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td></td>
<td>SCT at risk couples</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Completion of PND outcome forms - short and long term (SCT)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. Checks process in place to ensure babies born to hepatitis B positive mothers receive first dose of vaccination +/- immunoglobulin and information to enable scheduling of subsequent doses is communicated to the CHRD</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Programme Specific Operating Model for Quality Assurance of Antenatal and Newborn Screening Programmes
### Appendix B: Timescales in the QA visit process

**Key:**
- **Red text:** Visit process milestones

<table>
<thead>
<tr>
<th>Time (weeks)</th>
<th>SQAS team</th>
<th>Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>annual</td>
<td>Decide QA schedule and lead SQAA/QAA</td>
<td>R/HQA</td>
</tr>
<tr>
<td>-26</td>
<td>Negotiate date of visit with provider and commissioner</td>
<td>QAA</td>
</tr>
<tr>
<td>-26</td>
<td>Identify QA visit team to be on standby (lab, commissioner, hearing, sonography, screening coordinator, head of midwifery)</td>
<td>QAA</td>
</tr>
<tr>
<td>-26</td>
<td>Inform stakeholders:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• letter(s)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• QA guidance document</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• evidence list</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• commissioning grid</td>
<td></td>
</tr>
<tr>
<td>-26 to -15</td>
<td>Lead QAA attends local screening programme board or bespoke meeting to explain process to stakeholders using standard slide set</td>
<td>QAA</td>
</tr>
<tr>
<td>-12</td>
<td>Reminder to stakeholders of evidence deadline</td>
<td>Admin</td>
</tr>
<tr>
<td>-10</td>
<td>Stakeholders submit evidence</td>
<td>HoM</td>
</tr>
<tr>
<td>-9</td>
<td>QAA writes context grid</td>
<td>QAA</td>
</tr>
<tr>
<td>-8</td>
<td>QAA and VC examine context grid and evidence to determine preliminary KLOEs</td>
<td>QAA</td>
</tr>
<tr>
<td>-6</td>
<td>QAA, HQA and VC utilise any professional / clinical advisors (PCAs) required to define visit agenda</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• PCAs may not be needed and therefore stood down</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• PCAs may be asked to scrutinise specific elements of evidence</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• PCAs may support refinement of KLOEs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• PCAs may conduct telephone interviews to clarify areas</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• further evidence may be requested where not clear (1 week turnaround only) PCAs informed of requirements</td>
<td></td>
</tr>
<tr>
<td>-6 to -2</td>
<td>Information pack sent to PCAs</td>
<td>QAA</td>
</tr>
<tr>
<td>Time (weeks)</td>
<td>SQAS team</td>
<td>Lead</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>------</td>
</tr>
<tr>
<td>-6</td>
<td>Stakeholders sent visit agenda</td>
<td>Admin</td>
</tr>
<tr>
<td></td>
<td>Minimum – QAA and VC meet with screening coordinator, HoM and lead commissioner</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maximum – full QA visit</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>VISIT including verbal feedback on key QA findings</td>
<td></td>
</tr>
<tr>
<td>+1</td>
<td>Visit team submit notes to QAA</td>
<td>QAA</td>
</tr>
<tr>
<td>+2</td>
<td>QAA writes draft report using template,</td>
<td>QAA</td>
</tr>
<tr>
<td></td>
<td>HQA checks prior to issue</td>
<td>HQA</td>
</tr>
<tr>
<td>+3</td>
<td>Draft report sent to stakeholders for factual accuracy check Confirm consent to publish obtained</td>
<td>Admin</td>
</tr>
<tr>
<td></td>
<td>Stakeholder feedback survey sent</td>
<td></td>
</tr>
<tr>
<td>+5</td>
<td>Comments on draft report and stakeholder feedback returned to QAA</td>
<td>HoM</td>
</tr>
<tr>
<td>+7</td>
<td>QAA completes final report for HQA sign off</td>
<td>QAA</td>
</tr>
<tr>
<td>+8</td>
<td>Final report sent to stakeholders with template letter</td>
<td>HQA</td>
</tr>
<tr>
<td>+16</td>
<td>Final report published on GOV.UK website</td>
<td>Admin</td>
</tr>
<tr>
<td>Bi-annual</td>
<td>SQAS analyse feedback for trends and actions which are communicated to national team</td>
<td>HQA</td>
</tr>
</tbody>
</table>