

The quality assurance process

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)

Antenatal and newborn (ANNB) screening programmes

- Infectious diseases in pregnancy (IDPS)
- Sickle cell and thalassaemia (SCT)
- Fetal anomaly screening programme (FASP)
- Newborn and infant physical examination (NIPE)
- Newborn hearing screening programme (NHSP)
- Newborn blood spot screening programme (NBS)

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
Service provision and population served	<p>Describes the scope of service and interface amongst providers along the screening pathway</p> <p>Sets context of the service using internal information, data and intelligence and where relevant intelligence from other external bodies</p> <p>Checks the provider understands the section 7a service specification requirements</p> <p>Checks that provider understands local population health needs and their duties as defined within the Equality Act</p>	<p>Summary within the provider's annual report (or alternative), including:</p> <ul style="list-style-type: none"> • geographic distribution and location of all sites belonging to and used by the maternity provider • geographic location of all child health information services (CHIS) and NHSP services used by the provider • details of any cross-border issues • details of outsourcing of services to private providers or services that the provider delivers on behalf of other ANNB screening services • information on recent or planned mergers, outsourcing of services (contracts/networks with other providers) with description of any impact on screening service • evidence that commissioners and/or providers have undertaken a health equity audit or similar activity to understand the population need within the last 3 years (or as part of a procurement process or sooner if substantial population change)- this should 	<p>Provider annual report (if available)</p> <p>Local reports including health equity audits and action plans</p> <p>Other information /soft intelligence</p>	3,4,5,6	<p>Public health national service specifications (section 7a) numbers 15,16,17,18,19,20,21, 28</p> <p>15 - IDPS 16 - FASP (T21/T18/T13) 17 - FASP (ultrasound) 18 - SCT 19 - NBS 20 - NHSP 21 - NIPE 28 - CHIS</p>

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
		<p>include an action plan that is monitored</p> <ul style="list-style-type: none"> • how service meets the screening needs of vulnerable groups, including people with serious mental illness and/or in mental care settings, prisoners, people with learning disability and homeless (and other groups as specified) • other available information and/or soft intelligence • feedback on 3 areas of achievements and 3 areas for improvement 			
Governance and leadership	<p>Programme management accountability</p> <p>Checks arrangements are in place for co-ordinating screening</p> <p>Outlines organisation processes for the oversight and governance of screening within the provider and to commissioners</p> <p>Checks processes, interface and governance for NHSP (if relevant),</p>	<p>Provider led screening steering group, including:</p> <ul style="list-style-type: none"> • terms of reference (TOR), membership, attendance list with participation from all screening programme services (Foe example, maternity, clinical leads for each programme where relevant, sonography, labs, NHSP, CHIS, specialist ID, SCT, neonatal intensive care unit (NICU) • agenda and minutes for 	<p>Documentation from providers</p> <p><u>data security protection toolkit</u></p>	3,4,5,6	<p>Public health national service specifications (section 7a) numbers 15,16,17,18,19, 20, 21, 28</p>

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
	<p>CHIS and other providers including private services (if relevant)</p> <p>Checks that the provider meets information governance requirements</p>	<p>previous 3 meetings (within the preceding 12 to 18 months)</p> <ul style="list-style-type: none"> • health inequalities is a standing agenda item at the provider screening steering group and referenced in terms of reference • action or work plans / regular monitoring tools or reports • TOR and minutes of internal CHIS, NHSP, other providers governance meetings (within the preceding 12 months) • CHIS, NHSP, other providers management or structure chart, including lines of accountability to internal and external governance groups • risk register • relationship to other governance groups, such as, risk management, patient safety, clinical governance committee • escalation to the 			

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
		<p>organisation board and commissioners</p> <ul style="list-style-type: none"> • data security protection toolkit completed and returned in the last 12 months 			
Governance and leadership	<p>Commissioning accountability</p> <p>Outlines commissioner landscape both within and outside of maternity and specialised commissioning arrangements</p> <p>Checks commissioner governance arrangements including strategic screening programme board and escalation processes between different commissioning elements</p> <p>Checks that relevant provider to provider arrangements (including interfaces with private providers), such as contracts with service level agreements (SLAs) are in place</p> <p>Includes contract monitoring and gap analysis against section 7a service specification</p>	<p>Commissioner led screening programme board including:</p> <ul style="list-style-type: none"> • TOR, membership, attendance list with participation from the 6 screening programmes • agenda and minutes for previous 3 meetings (within the preceding 12 to 18 months) • health inequalities is a standing agenda item at programme board and referenced in TOR • action or work plans / regular monitoring tools or reports • risk register • relationship to other commissioner governance groups, such as CCG, specialised commissioning • discipline or area specific subgroups – national health screening programmes (NHSP) should participate in their local Children Hearing Services Working Group (CHSWG) 	Documentation from commissioners	3,4,5,6	Public health national service specifications (section 7a) numbers 15,16,17,18,19,20,21, 28

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
	<p>Checks that the commissioners understand local population health needs and their duties as defined within the Equality Act</p> <p>Checks informal and formal communication mechanisms including regular reports</p>	<ul style="list-style-type: none"> • links to wider groups including health and well-being • evidence that commissioners and/or providers have undertaken a health equity audit or similar activity to understand the population need within the last 3 years (or as part of procurement process or sooner if substantial population change) - this should include an action plan that is monitored <p>Completed commissioning questionnaire, including:</p> <ul style="list-style-type: none"> • copies of any contracts which are outside of standard maternity and specialised commissioning arrangements and contract monitoring • gap analysis against section 7a specifications and actions taken • description of arrangements for public health support for clinical commissioning groups (CCGs), specialist and screening commissioning and local authority (LA) public health (PH) commissioning 			

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
		<ul style="list-style-type: none"> • escalation processes for NHS England/Improvement 			
Governance and leadership	<p>Escalation, risk management and incidents</p> <p>Reviews systems/oversight for handling and escalating risks (see programme management and commissioning sections above), quality concerns and incidents, including interface with commissioners</p> <p>Checks approach to risk management</p> <p>Checks approaches to resilience and business continuity</p> <p>Checks on how screening safety incidents are reported and investigated</p>	<ul style="list-style-type: none"> • risk management policy with evidence of use of reporting arrangements within the governance structure • local incident policy including reference to national screening incident guidance • list of screening incidents for the 2 years prior to submission date (For example, April 14 to March 16 for evidence submitted April 16) including incidents from CHIS, NHSP, maternity providers, laboratories, relevant specialist screening services • business continuity arrangements 	Documentation from providers	1,2,3,4,5,6	<p>Public health national service specifications (section 7a) numbers 15,16, 17, 18, 19, 20, 21, 28</p> <p>Managing incidents in NHS screening programmes</p>
Governance and leadership	<p>Policies and guidelines</p> <p>Checks local policies, guidelines and standard operating procedures</p>	<p>Policies and SOPs in current use and processes for review and ratification of policies, the documents provided should include:</p>	Documentation from providers- policies, guidelines	4,5,6	<p>Public health national service specifications (section 7a) numbers 01,15,16,17,18, 19, 20,</p>

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
	<p>(SOPs) align with section 7a service specifications, NHS screening programmes guidance and screening standards</p> <p>Checks clinical audit reports demonstrate conformity to local screening policies</p>	<ul style="list-style-type: none"> • first trimester dating scan and second trimester fetal anomaly ultrasound scan (including storage and archiving of images, referrals for suspected or confirmed fetal anomalies) • Down's syndrome, Edwards' syndrome and Patau's syndrome (including referrals of women with higher chance results) • hepatitis B (including referral into hepatology, paediatrics and CHIS for administering and scheduling neonatal vaccination) • human immunodeficiency virus (HIV) (including links with genitourinary medicine (GUM) and specialist service) • syphilis (including links with GUM and specialist service) • SCT (including father testing and referral to sickle cell and thalassaemia specialist services and linked neonatal services) • NIPE (including effective use of NIPE national IT system entering all screening results, screening positive referrals and outcomes) - this requires daily failsafe checks and 			<p>21, 28</p> <p>01 - neonatal hepatitis B immunisation</p>

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
		<p>use of weekly and monthly data reports to ensure completion of the screening pathway for all newborn babies and recording of accurate performance data</p> <ul style="list-style-type: none"> • NBS (including babies up to 1 year old and movers in and referrals of babies with screen positive results) and CHIS/health visiting process for inviting movers in for screening • NHSP (including babies < 3 months and the process for referrals of babies with screen positive results to audiology services and receiving and recording outcomes) • NICU policies covering newborn screening and hepatitis B vaccination • CHIS SOP for NBS, NHSP, NIPE and hepatitis B linked antenatal screening neonatal vaccination programme • did not attend (DNA) policy (mothers and babies-was not brought) • booking/early access policy • late bookers/un-booked women-policy for the offer, completion and management of screening and 			

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
		<p>screening results</p> <ul style="list-style-type: none"> • policies covering re-offer of screening where relevant for example, IDPS • process for repeat testing/samples where required • process for newborn screening programmes dealing with deceased babies (NHSP, NIPE, NBS) including communication links with CHIS, NICU, and maternity units • results checking policy (for SCT maternal results are matched to the baby's father in the current pregnancy) • process for communicating positive and negative results to women/parents for each screening programme • failsafe policy/SOP on cohort tracking for the screening pathway including a lab tracking SOP and process for communicating positive results 			
Governance and leadership	<p>Audit</p> <p>Checks for a culture of audit including a screening related audit schedule</p>	<p>Audit schedule examples include:</p> <ul style="list-style-type: none"> • participation in relevant Public Health England (PHE) national audits and development of action plans where required 	<p>Audit examples</p> <p>Participation in national audits where relevant</p>	2,4,5	Public health national service specifications (section 7a) numbers 15,16,17,18,19,20,21, 28

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
	with reports and action plans demonstrating progress	<ul style="list-style-type: none"> • NHSP-S03 referral rate • NIPE-S03 (KPI-NP2) • failsafe audits as outlined in 'checks and audits to improve quality and reduce risks' • Minutes from local clinical audit meetings demonstrating inclusion of ANNB screening related topics 			
Governance and leadership	<p>User feedback</p> <p>Checks user feedback is used in service evaluation and development</p>	<ul style="list-style-type: none"> • evidence of the service making changes based on service user feedback • evidence of user satisfaction with screening, complaints and compliments 	User satisfaction survey	4,5	Public health national service specifications (section 7a) numbers 15,16,17,18,19,20,21,28
Infrastructure	<p>Workforce</p> <p>Checks relevant staff are in place to deliver screening functions in a timely manner and screening functions are included in job descriptions/roles</p>	<ul style="list-style-type: none"> • provider annual report where available • staffing levels, vacancies, use of agency staff • structure of screening team(s) <p>Job description and job roles for specific functions outlined in the service specifications – Screening Quality Assurance Service (SQAS) will look at a sample of these on the day of the visit unless requested in advance where SQAS has concerns</p> <p>Roles/functions/JDs may include:</p>	<p>Provider annual report</p> <p>Organisation structure</p> <p>Job descriptions</p> <p>Business continuity plan includes staffing contingency arrangements</p>	3,4,5	Public health national service specifications (section 7a) numbers 15,16,17,18,19,20,21,28

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
		<ul style="list-style-type: none"> • screening co-ordinator and deputy • NHSP local manager and team leader • infectious diseases screening specialist if relevant (may be midwife, specialist nurse or medical clinician with responsibility for IDPS) • Sickle cell and thalassaemia specialist counsellor if relevant • screening support sonographer • NIPE lead • CHIS manager, co-ordinator, team leader or any other staff with a significant role in delivery of screening and failsafe in child health • failsafe officer/administrator 			
Infrastructure	<p>Equipment and IT</p> <p>Checks IT systems including contingency arrangements</p> <p>Checks that there is sufficient capacity for storage of ultrasound images and that images are accessible for audit</p> <p>Checks paper or electronic family origin questionnaire (FOQ) conforms to the latest national version</p>	<ul style="list-style-type: none"> • adequacy of IT support for delivery, development, storage of data/information, data reporting and audit of the screening programmes • risk assessment completed if relevant for example, if no information technology (IT) system/contingency is in place • working with software suppliers to make sure software for calculating results for Down's syndrome, Edwards' syndrome and Patau's syndrome screening conforms to 	Local policies including ultrasound equipment maintenance procedure NHSP data set and log sheets for equipment quality assurance checks FOQ	4,5	Public health national service specifications (section 7a) numbers 15,16,17,18,19,20,21,28

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
	<p>Checks specific NHSP equipment requirements - checks that appropriate quality assurance checks of the NHSP equipment are completed prior to screening</p> <p>Checks software for calculating results for Down's syndrome, Edwards' syndrome and Patau's syndrome screening conforms to FASP software specification</p>	<p>FASP software specification</p> <ul style="list-style-type: none"> • data fields of paper or electronic FOQ against latest national version • have a review and maintenance process in place, as per Royal College of Radiologists guidance, providing an ultrasound service • the provider must only use newborn hearing screening equipment (with recommended QA checks and use of log sheets to record equipment quality assurance checks or testing using unchecked equipment identified from national reports) and consumables that meet the NHSP technical specification as determined within the NHS supply chain framework agreement 			
Infrastructure	<p>Education and training</p> <p>Checks process for training and assessing competency of staff delivering screening activity (including agency staff where applicable) - this includes that the provider has in place a process for checking appropriate qualifications of staff, monitoring on-going training and continuous personal development (CPD)</p>	<ul style="list-style-type: none"> • policy for induction, education and training for all staff involved in screening which lists all staff groups covered (including maternity, neonatal staff, NHSP, CHIS and sonography) • process in place to assess competency of agency staff before they embark on delivering screening for example, sonographer's image review 	Local policies, SOP, training logs	1,4,5,6	Public health national service specifications (section 7a) numbers 15,16,17,18,19,20,21,28

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
	requirements, learning from screening safety incidents and access to PHE screening e-learning resources	<ul style="list-style-type: none"> • process in place for training and induction of new screening staff including newly appointed NHSP local managers - new NHSP screeners must register and complete the level 3 diploma for health screeners • ongoing educational programme for staff performing NIPE to assess ongoing competency • genetic risk assessment course for SCT screening where applicable • 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 performing NHSP screens • evidence of how training is monitored including training needs, training needs analysis, training reports, training log • resources used: NHS screening programmes e-learning and audit facility and other resources and/or in-house training resources 			
Antenatal: identifying and	Checks that failsafe processes are in place and that failsafe databases used regularly (weekly) and there is	Antenatal cohort tracking Example of complete cohort tracking system from offer of screening to	Documentation from the provider/SOPs	1,2,3,4,5,6	Public health national service specifications

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
tracking cohort	<p>adequate cover for annual leave/sickness, SOP in place</p> <p>Checks that the failsafe processes cover end to end pathway tracking from identification of eligible population to giving results with onward referral where relevant and must include receipt into referral/specialist service (including relevant re-offer, repeat tests and transportation of samples to screening laboratories) or closure of the maternity episode</p> <p>Checks that there are robust processes in place to establish the denominator including exclusions for example, transfers in and out, miscarriages and termination of pregnancies (TOPs) and can account for declines</p> <p>Checks that there is a clear process in place for timely follow up of any missed screens identified where relevant</p> <p>FASP - checks failsafe process for</p>	<p>the eligible population to notification of results for antenatal population and associated operating procedures using anonymised database and/or screen shots - this evidence should demonstrate:</p> <ul style="list-style-type: none"> • evidence of failsafe systems in place with identification of the eligible cohort including data flows into the system(s) for booked cohort • screening offer (and re-offer for IDPS) 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) • capture of transfers in and out, late bookers, terminations and miscarriages • clarity of roles and responsibility for failsafe checks and evidence of implementation 	<p>and policies</p> <p>Relevant screening safety incidents</p>		<p>(section 7a) numbers 15,16,17,18</p>

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
	women who transfer from first to second trimester T21/T18/T13 screening				
Newborn: identifying and tracking cohort	<p>Checks there is a system to make sure birth notifications, personal demographics service/birth notification application (PDS/BNA) are completed promptly prior to newborn screening to identify the eligible cohort with backup systems in place for manual checks should there be any IT system failure</p> <p>Checks that national systems in place are used for identifying and tracking the newborn cohort (NIPE, NHSP, newborn blood spot screening failsafe solution (NBSFS)) and they are used regularly, there is adequate cover for annual leave/sickness, SOP in place</p> <p>Checks that tracking/failsafe processes includes movers in and out, repeat tests where relevant and transportation of samples (NBS) to screening laboratories</p> <p>Checks that processes are robust for babies who are on NICU and PICUs</p>	<ul style="list-style-type: none"> • use of national IT systems for NIPE, NHSP and NBSFS • 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 and given • evidence of clarity of roles and responsibilities for failsafe checks including exception reports and evidence of implementation • Paediatric Intensive Care Units (PICUs) use of NBSFS (developmental) 	<p>Documentation from the provider/SOPs and policies</p> <p>Relevant screening safety incidents</p>	1,2,3,4,5,6	Public health national service specifications (section 7a) numbers 19,20,21, 28

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
	<p>with processes to deal with transfers in and out for all babies to another area or another acute or primary care</p> <p>Checks process for monitoring declines and whether the provider understands the reasons for declines for example, any inequalities</p> <p>Checks that there is a clear process in place for timely follow up of any missed screens identified where relevant</p> <p>Ensure process is in place to identify and communicate information about babies who die</p>				
Coverage	<p>Checks that the provider submits coverage KPI data, and the data is cohort data</p> <p>Checks for evidence of initiatives to increase/understand uptake/coverage where appropriate</p> <p>Collect information on initiatives to improve access to vulnerable groups, people with serious mental illness, late bookers, black minority ethnic</p>	<p>Coverage standards and KPI data</p> <p>Health equity audits related to access</p> <p>Postnatal discharge processes</p>	<p>Screening standards/KPIs -coverage</p> <p>Health equity audits</p>	1,2,3,4,5,6	<p>FASP-S01 (FA3), FASP-S02 (FA2)</p> <p>IDPS-S01 (ID1), IDPS-S02 (ID3), IDPS-S03 (ID4)</p> <p>SCT-S01 (ST1)</p> <p>NBS-S01a (NB1), NBS-S01b (NB4), NBS-S02</p> <p>NHSP-S01 (NH1)</p> <p>NIPE-S01 (NP1)</p>

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
	<p>(BME) groups and others, such as health equity audits</p> <p>Checks process in place for postnatal discharges to enable safe handover of responsibility</p> <p>Check links with CHIS and health visiting services</p>				
Invite and inform	<p>Checks there are robust processes in place for timely access to maternity care and screening</p> <p>Checks maternity booking process is timely to support personal informed choice and screening at the optimal time including a short time lag from referral to booking appointment</p> <p>Checks screening information on provider's website and apps to promote early access</p> <p>Checks use of national materials including translated versions, easy read screening tests for you and your baby (STFYAYB) and processes to revisit information prior to newborn</p>	<p>Provider's understanding of birth population demographics of language, ethnicity, age, birth rate for last financial year</p> <p>Audits - DNA (did not attend)/was not brought, documented evidence of STFYAYB, SCT leaflet for dads and carriers, NICU leaflet, screening information on provider's website and apps</p> <p>Where NHSP screening is performed as an out-patient - it is family friendly and that uptake is not adversely affected</p>	<p>Local audits</p> <p>Local guidelines (as above)</p> <p>Provider website</p>	1,4,5,6	Public health national service specifications (Section 7A) numbers 15,16,17,18,19,20,21,28

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
	<p>screening, use of NICU leaflet, SCT leaflet for dads and carriers</p> <p>Checks access and use of interpreters/other translation services</p> <p>Checks did not attend (DNA) process/was not brought for follow up and any audits undertaken to understand rates</p> <p>Checks processes for inviting babies under 1 year old especially movers in for NBS screening and babies < 3 months for NHSP</p> <p>Check interface with other providers including private and/or independent midwifery/ultrasound services where applicable</p> <p>Checks SCT pathway including processes for inviting and informing fathers (mothers who are carriers or who have a SCT condition)</p>				
Test (non-laboratory)	Checks performance of test/test elements against national screening standards, for example ensuring the test is taken at the right time with the right identifiers	<ul style="list-style-type: none"> • national screening standards • process for dealing with data quality reports issued by NHSP, NIPE, NBSFS 	National screening standards NHSP data set	1,2,3,4,5,6	SCT-S02 (ST2), SCT-03 (ST3) NHSP-S02, NHSP-S03 NBS-S03, NBS-S04, NBS-S06 (NB2)

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
	<p>Checks that the ultrasound department has a process in place for Nuchal Translucency and Crown Rump Length NT/CRL image review as per FASP guidance</p> <p>Checks participation in DQASS (specific checks to include processes are in place for (1) feedback from the screening support sonographer (SSS) to individual practitioners, individual practitioners must receive their DQASS plots, (2) review any outstanding action plans for USS red flags) and (3) the SSS checks the list of practitioners and DQASS codes regularly and informs the DQASS team of any changes) - this includes agency sonographers</p>	<p>including outstanding action plan from last report if applicable</p> <ul style="list-style-type: none"> • Down's syndrome screening quality assurance support service (DQASS) - ultrasound reports and internal SSS feedback process to all ultrasound practitioners, departmental image review of NT/CRL • where SCT-S02 (ST2) thresholds are not met - recommend (see standard recommendation) completion of checklist and develops an action plan • where NBS-S06 (KPI NB2) thresholds are not met - recommend (see standard recommendation) completion of checklist and develops an action plan 			<p>NBS-S07a, S07b, S07c (developmental) DQASS USS reports</p>
Test (laboratory)	Checks performance of laboratory test elements against national screening standards and components of section 7a national service specifications and laboratory handbooks aligned with ISO 15189 standards for example,	United Kingdom accreditation service (UKAS) reports of screening requirements (undertaken 4 yearly at full visit or at annual surveillance	National screening, ISO 15189, incidents	1, 6, 3, 4 SQAS visits on exception basis as per	FASP-S03a, FASP-S03b, FASP-S05, FASP-S06 (FA1), FASP-S09a, FASP-S09b, FASP-S09c, FASP-S09d IDPS-S04a, IDPS-S04b,

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
	<p>accreditation and status regarding non-conformities</p> <p>Checks interfaces between laboratory, maternity services and child health information service</p> <p>Undertake assessment visits to laboratories on an exception basis</p>	<p>visits)</p> <p>Use of laboratory requirements document as the assessment tool for any SQAS visits to laboratories</p> <p>Other – DQASS laboratory reports</p> <p>Contributes to national congenital anomaly and rare disease registration service (NCARDRS) for FASP to enable calculation of national detection rates</p>	<p>National screening standards</p> <p>UKAS reports</p> <p>DQASS laboratory reports</p>	operational framework	<p>IDPS-S04c</p> <p>SCT-S04</p> <p>NBS-05, NBS-S09</p> <p>DQASS laboratory reports</p>
Giving results	<p>Checks process for giving negative results for each condition including timeliness and evidence of audit</p> <p>Checks there are robust processes in place to send negative NBS screening results letters to parents</p> <p>Checks process for giving higher chance/screen positive results for each condition- check that national leaflets are used where available (FASP, IDPS, SCT, NBS, NHSP)</p>	<ul style="list-style-type: none"> 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 and IDPS before or at the next AN appointment) anonymised examples of NBS, NHSP screen negative letters, FASP result letters- 	<p>Local guidelines</p> <p>National screening standards</p> <p>National and/or local audits</p>	1,2,4,5	<p>IDPS-S05a, IDPS-S05b, IDPS-S05c</p> <p>FASP-S07</p> <p>SCT-S08</p> <p>NBS-S12a, NBS-S12b</p>

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
	<p>Checks process for giving positive results including timeliness - see national standards</p> <p>Checks process for giving results includes women who were screened antenatally but subsequently miscarry or have a termination</p>	<p>check terminology for example, use of chance and not risk, use of national template letter for women who miscarry</p> <ul style="list-style-type: none"> • performance against national screening standards for higher chance/screen positive screening results • check participation in national audits where standards are not met (IDPS-S05 and FASP-S07 national audits in 2019/20) 			
Referral following a positive screening result	<p>Checks that timely referral processes are in place with feedback to enable monitoring of outcomes</p> <p>Checks process is in place to follow up did not attend (DNAs)/was not brought</p> <p>Triangulate information on relationships, particularly required for external referrals for example, sickle cell counsellors, metabolic services, specialist fetal medicine, ultrasound</p>	<p>Performance against national screening standards:</p> <ul style="list-style-type: none"> • SCT: Pre-natal diagnosis (PND) offered by 12 +0 weeks and communication of PND result within 5 days of diagnostic test (SCT-S05a, b and SCT-S07) • IDPS: timely assessment of women with hepatitis B (IDPS-S06) • FASP: time to intervention (FASP-S08a, FASP-S08b) • NHSP: time from screening outcome to offered and attendance 	National screening standards	1,2,3,4,5,6	<p>SCT-S05a (ST4a), SCT-S05b (ST4b), SCT-06, SCT-07</p> <p>IDPS-S06 (ID2)</p> <p>FASP-S08a, FASP-S08b</p> <p>NHSP-S04, NHSP-S05</p> <p>NIPE-S02, NIPE-S03 (NP2), NIPE-S04, NIPE-S05</p> <p>NBS-S11</p>

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
	<p>services, referral for USS for hips for all screen positive including those referred for risk factors (NIPE) that may be at another provider</p> <p>Check process is in place to identify where standards are not met including any issues impacting on the ability to refer/ be seen in a timely manner, such as access to prenatal diagnosis, potential capacity issues in diagnostic service and participation in any relevant national audits</p> <p>Checks that referral for prenatal invasive procedure includes a comprehensive review of all screening results for example, referral for T21/T18/T13 checks sickle and thalassaemia, HIV screening results</p> <p>Checks that there is a NHSP referral pathway into an UKAS improving quality in physiological services (IQIPs) accredited audiology service</p>	<p>at appointment for diagnostic audiological assessment (NHSP-S04, NHSP-S05)</p> <ul style="list-style-type: none"> • NHSP: completion of NHSP-S05 (KPI NH2) checklist and development of an action plan as recommended in NHSP guidance: Sharing best practice in newborn hearing screening to ensure early assessment of babies (see standard recommendation) • NIPE: timeliness of intervention (NIPE-S02, NIPE-S03, NIPE-S04, NIPE-S05) • NBS: timely entry into clinical care (NBS-S11) • Evidence of recording maternal Hepatitis B status and administration of first neonatal hepatitis B vaccination +/- immunoglobulin to enable scheduling of subsequent neonatal vaccination and serology at 1 year of age 			Public health national service specifications (Section 7A) number 01
Outcomes	Clinical reviews of babies with unexpected outcomes at birth - review of the screening pathway for the	Minutes of clinical review meeting and/or shared learning	National screening standards	1,4,5,6	IDPS-S07a, IDPS-S07b FASP-S04 SCT-S09

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
	<p>individual, take appropriate action and apply any relevant learning</p> <p>Checks process in place to contribute to national registers to enable monitoring of outcomes for example, NCARDRS, Integrated Screening Outcomes Surveillance Service (ISOSS)</p> <p>Checks an alert system is in place to inform newborn laboratories of SCT at risk couples (process in place for matching antenatal and newborn results where appropriate)</p> <p>Completion of PND outcome forms- short and long term (SCT), FASP - as requested by genomics (cytogenetics) laboratories</p>	<p>Performance against relevant screening standards/contribution to national data systems</p> <p>NHSP data set - yield</p> <p>NCARDRS fetal anomaly detection rate report (front sheet only) - the provider should develop an action plan where relevant to make improvements outlined in the NCARDRS report</p>	<p>Local reports/ screening safety incidents</p> <p>NHSP data set</p>		
Diabetic eye screening in pregnancy	<p>Checks that the maternity provider has a process in place for identifying pregnant women with existing type 1 and type 2 diabetes</p> <p>Checks that there is a written guideline that specifies the population that will be offered screening – eligibility, exclusions and when</p>	<p>Guidelines</p> <p>Database if available</p> <p>SOP between the maternity services and the local DESP</p> <p>Attendance or papers from the local DES programme at the</p>	<p>Documentation from providers</p>	4,5	<p>Public health national service specifications (section 7a) number 22</p>

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
	<p>screening should be offered. The guideline should be developed by the maternity provider but agreed with the diabetic eye screening (DES) programme local to the maternity provider</p> <p>Checks that STFAYB is used as information for pregnant women with diabetes</p> <p>For development over the next 12 months:</p> <ul style="list-style-type: none"> • each maternity provider should develop communication links with their local DES programme (including informing the local DES programme when a pregnant woman with existing diabetes books for maternity care) - this may mean that a local DES programme may have links with more than one maternity provider • the local DES programme will take responsibility for communicating to the DES programme the woman belongs to - this is because a DES programme is allocated to a woman based on her GP, and may 	<p>provider's screening steering group meeting</p>			

Pathway	SQAS activity	Evidence SQAS will examine	Source of data/evidence	Frequency	Mapped to standards/ KPIs/service specification
	<p>not be the same DES programme local to the maternity provider</p> <p>Maternity providers and commissioners should agree how and how often DES in pregnancy will be on the programme board agenda with representation from local DESP (we suggest minimum of 12 months)</p>				