



Commissioning Board

Public health functions to be exercised by the NHS Commissioning Board

Service specification No.15

NHS Infectious Diseases in Pregnancy Screening Programme

November 2012

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NHS Infectious Diseases in Pregnancy Screening Programme

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Service specification No.15

This is a service specification within Part C of the agreement “Public health functions to be exercised by the NHS Commissioning Board” dated November 2012 (the “2013-14 agreement”).

The 2013-14 agreement is made between the Secretary of State for Health and the National Health Service Commissioning Board (“NHS CB”) under section 7A of the National Health Service Act 2006 (“the 2006 Act”) as amended by the Health and Social Care Act 2012.

This service specification is to be applied by the NHS CB in accordance with the 2013-14 agreement. An update to this service specification may take effect on an agreed date as a variation made in accordance with the 2013-14 agreement.

This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

The 2013-14 agreement including all service specifications within Part C is available at www.dh.gov.uk/publications

Section 1: Purpose of Screening Programme

1.1 Purpose of the Specification

To ensure a consistent and equitable approach across England a common national service specification must be used to govern the provision and monitoring of the NHS Infectious Diseases in Pregnancy Screening (IDPS) Programme.

The purpose of the service specification for the IDPS Programme is to outline the service and quality indicators expected by the NHS Commissioning Board (NHS CB) for the NHS CB's responsible population and which meets the policies, recommendations and standards of the UK National Screening Committee (UK NSC).

The IDPS Programme is in the process of revising and updating its Programme and Laboratory Standards by early 2013, and will be looking to follow a similar model to the Abdominal Aortic Aneurysm (AAA) and Diabetic Retinopathy Screening (DRS) Standards. As an interim, the standards and expectations in relation to the delivery of the programme locally (that are derived from the Programme Standards) are listed below. The NHS CB should agree a pace of change with providers to deliver a service that meets the national service specification.

The service specification is not designed to replicate, duplicate or supersede any relevant legislative provisions which may apply, e.g. the Health and Social Care Act 2008 or the work undertaken by the Care Quality Commission. The specification will be reviewed and amended in line with any new guidance as quickly as possible.

This document provides details of the specification required to commission the IDPS Programme in England.

This specification needs to be read in conjunction with:

- IDPS Programme Standards (2010) and the IDPS Laboratory Handbook (2010) <http://infectiousdiseases.screening.nhs.uk/standards>
- "Handbook for Laboratories" (2010) which can be found at: <http://infectiousdiseases.screening.nhs.uk/standards>.
- Managing Serious Incidents in the English NHS National Screening Programmes <http://www.screening.nhs.uk/quality-assurance#fileid9902>
- DH *Immunisation against Infectious Disease – the Green Book* (Chapter 18 on Hepatitis B – updated 2009 and Chapter 28 on rubella susceptibility – updated 2010) http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917

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- British Viral Hepatitis Group (BVHG) consensus statement on the management of hepatitis B positive women www.basl.org.uk/media/uploads/BVHGPregnancy.pdf
- Guidelines for the management of HIV in pregnancy (British HIV Association – BHIVA) <http://www.bhiva.org/PregnantWomen2008.aspx>
- Guidelines for the assessment and management of syphilis in pregnancy and infancy (British Association of Sexual Health and HIV – BASHH) www.bashh.org/guidelines.
- Guidance and updates on KPIs: <http://www.screening.nhs.uk/kpi>
- UK NSC Guidance, Managing Serious Incidents in the English NHS National Screening Programmes <http://www.screening.nhs.uk/quality-assurance#fileid9902>

1.2 Aim

The IDPS Programme in England is responsible for ensuring that all pregnant women are routinely offered screening for hepatitis B, HIV, syphilis and susceptibility to rubella infection.

1.3 Objectives

- To ensure that women with hepatitis B, HIV and syphilis are identified early in pregnancy, and that strategies are put in place to prevent mother-to-child transmission of these conditions; and
- To identify women who are susceptible to rubella, for whom postnatal MMR vaccination could protect future pregnancies.

1.4 Health outcomes

The IDPS Programme, if coordinated and delivered well in practice, can offer real benefits for women and their children and has the potential to:

- reduce the risk of a mother-to-child transmission of HIV from 25% to less than 1%, as well as safeguard the woman's own health, using a range of interventions such as antiretroviral drugs, appropriate management of delivery and avoidance of breastfeeding;
- reduce transmission of hepatitis B from mother-to-child, with vaccination of the baby within 24 hours of delivery, and at 1, 2 and 12 months;
- reduce the risk of congenital syphilis with appropriate treatment of the mother;
- reduce the risk of congenital rubella in future pregnancies, by identifying and offering rubella susceptible women postnatal MMR vaccination.

The IDPS Programme contributes to the Public Health Outcomes Framework indicator on the uptake of screening for national screening programmes. Indicator 2.21v Access to non cancer screening programmes: infectious diseases in pregnancy screening.

1.5 Principles

- All individuals will be treated with courtesy, respect and an understanding of their needs,
- All those participating in the IDPS Programme will have adequate information on the benefits and risks to allow an informed decision to be made before participating,
- The target population will have equitable access to screening
- Screening will be effectively integrated across a pathway including between the different providers, screening centres, primary care and secondary care.

Section 2: Scope of Screening Programme

2.1 Description of screening programme

The IDPS Programme in England is responsible for ensuring that all pregnant women are routinely offered screening for hepatitis B, HIV, syphilis and susceptibility to rubella. The IDPS Programme, if coordinated well at service level, can help to prevent the transmission of infection from mother to child, as well as safeguard the wellbeing of women identified as positive through screening.

In delivering a national programme the local provider is expected to meet the following, in conjunction with the National Screening programme where appropriate:

- Work to nationally agreed common standards and policies
- Be required to implement and support national IT developments
- Use materials provided by the National Screening programme, e.g. leaflets, and protocols for their use
- Be required to respond to national action/lessons such as change of software, equipment supplier, techniques
- The provider is responsible for identifying, reporting on and resolving serious incidents
- Provide data and reports against programme standards, key performance indicators (KPIs), and quality indicators as required by the Screening programme on behalf of the UK NSC
- Take part in quality assurance processes and implement changes recommended by Quality Assurance (QA) including urgent suspension of services if required
- Implement and monitor failsafe procedures and continuously ensure quality
- Work with bordering providers to ensure that handover of results or patients is smooth and robust
- Participate in evaluation of the screening programme

Documents referred to above are available from the National Screening programme website.

2.2 Care pathway

A description of the IDPS Programme pathway is given below, along with a diagram of the pathways showing failsafe processes (**Diagram 1**) identified by the IDPS Programme.

A full description of the screening pathways can be found on the Map of Medicine at:

http://eng.mapofmedicine.com/evidence/map/infectious_diseases_in_pregnancy_screening1.html

IDPS Programme Pathway

The IDPS Programme consists of the following:

- The eligible population is identified through routine midwifery-led antenatal care. All women should be offered screening for hepatitis B, HIV, syphilis and susceptibility to rubella early in pregnancy. Ideally this should be early in pregnancy (around booking) in order that treatment where appropriate can be managed. However it is possible (and useful) to screen women even very late in pregnancy.
- Women should be provided with written information and also have the key information about screening for the four infections explained to them.
- Screening for each of the four infections should be offered and accept/declines should be documented. Blood samples are taken and sent to the laboratory with completed request form. Arrangements for the collection of specimens, for example volume of blood required, container for collecting the sample and transportation to the laboratory, should be defined by local protocol and are the responsibility of the provider
- Laboratory receives sample.
- The specimen is processed to ensure that the tests requested are undertaken. Local protocols should be in place to deal with incomplete information on the request form, or any unacceptable samples that require repeat specimens. This should be done as soon as practicable to enable treatment where appropriate.
- Analysis and testing should be undertaken in line with nationally agreed screening protocols. For hepatitis B, HIV and syphilis, appropriate confirmatory testing is undertaken on the initial screen positive specimen before the laboratory issues a report to maternity services.
- Once results are available, within nationally set standards, they should be dispatched by the laboratory to the requestor, with a clear indication of any action that needs to be taken, using the recommended reporting comments set out in the Laboratory Handbook (2010).
- Management of results:
 - Women with positive screening test results for HIV, syphilis and hepatitis B should be contacted and advised about the results at an appointment made for that purpose and then arrangements should be made for referral to a relevant specialist service for clinical assessment. Maternity services should ensure the referral has taken place and the woman has been seen by specialist services.
 - Women who are susceptible to rubella infection should be informed about the test results at their next antenatal visit.
 - Negative screening test results should be reported back to women before or at the next antenatal visit, according to local protocol. The NHS CB will want to check these local protocols as they are critical to ensure adequate follow up and timely results

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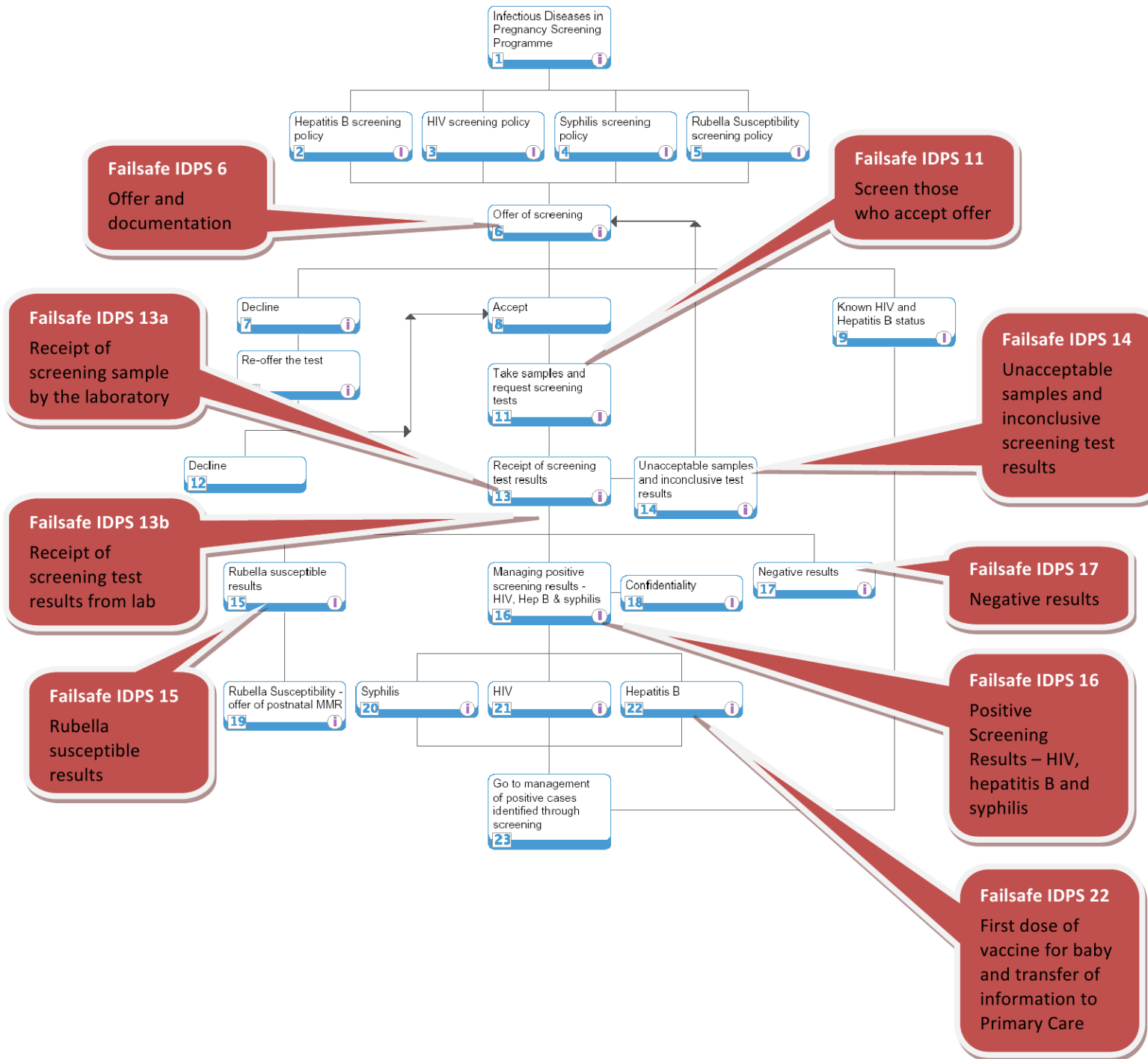
- Following referral for positive syphilis, HIV or hepatitis B results, information should be shared between the specialist team and maternity services to ensure appropriate management/delivery of the baby, and post-partum care. Local protocols should be in place to ensure multi-disciplinary links and close working relationships between maternity services and specialist services are established and function well.
- Postnatal maternity screening responsibilities:
For hepatitis B this includes - offering and ordering the vaccine and giving the vaccine to the baby within 24 hours of delivery. Vaccine delivery should be communicated to the Child Health Record Departments (CHRD) via the PCHR in time to ensure that the one month hepatitis B vaccine can be given;
For postnatal MMR vaccination this includes - offering and ordering the vaccine and giving the vaccine to women prior to discharge from maternity services, as well as making arrangements made for the notification of the primary care regarding second dose.

Failsafe arrangements will be in place across the whole screening pathway at national, sub-national and local levels. The NHS CB is expected to oversee the implementation and functioning of national failsafe guidance incorporated within the service specification.

All providers are expected to review and risk assess local pathways in the light of national IDPS Programme guidance and work with the NHS CB, Quality Assurance teams, and sub-regional teams in the new NHS architecture to develop, implement and maintain appropriate risk reduction measures. This should involve mechanisms to audit implementation, report incidents, ensure routine staff training and development, and have appropriate links with internal governance arrangements.

Further details about the failsafe processes for the IDPS Programme can be found at <http://infectiousdiseases.screening.nhs.uk/qualityassurance> including failsafe points

Diagram 1: Infectious Diseases in Pregnancy Screening Programme Pathway



2.3 Failsafe Procedures

QA within the screening pathway is managed by including failsafe processes. Failsafe is a back-up mechanism, in addition to usual care, which ensures if something goes wrong in the screening pathway, processes are in place to identify (i) what is going wrong and (ii) what action follows to ensure a safe outcome.

The provider is expected to:

- have appropriate failsafe mechanisms in place across the whole screening pathway.
- review and risk assess local screening pathways in the light of guidance offered by Quality Assurance processes or the National Screening programme
- work with the NHS CB and Quality Assurance Teams to develop, implement, and maintain appropriate risk reduction measures see section 2.4
- ensure that mechanisms are in place to regularly audit implementation of risk reduction measures and report incidents
- ensure that appropriate links are made with internal governance arrangements, such as risk registers
- ensure routine staff training and development

2.4 Roles and accountability throughout the pathway

The IDPS Programme is dependent on systematic specified relationships between stakeholders. Stakeholders include maternity units, the screening laboratory/reference laboratories, primary care/GPs/immunisation teams, CHRDs, specialist services, and professional bodies who set guidance for management of diseases in pregnancy.

The NHS CB will be expected to ensure that the whole pathway is robust with safe hand offs commissioned throughout. The provider will be expected to fully contribute to ensuring that systems are in place to maintain the quality of the whole screening pathway in their organisation. This will include, but is not limited to:

- provision of robust screening coordination which links with all elements of the screening pathway
- ensuring that community midwifery services are supported to facilitate early booking for maternity care within primary and community care settings
- agreeing and documenting roles and responsibilities relating to all elements of the screening pathway across organisations
- developing joint audit and monitoring processes
- agreeing joint failsafe mechanisms where required to ensure safe and timely processes across the whole screening pathway
- contributing to any NHS CB and public health screening lead initiatives in screening pathway development in line with UK NSC expectations

- providing or seeking to provide robust electronic links with relevant organisations
- links with primary care
- the need for robust IT systems across the screening pathway.

2.5 Commissioning Arrangements

Pathway	Provider	Possible level of commissioning	Possible level of contracting	Rationale and other comments
Antenatal				
Identify cohort in a timely manner	Maternity services / primary care	LAT	CCG	The eligible population is identified through routine midwifery-led antenatal care or via primary care (GPs and pharmacy).
Inform the cohort and maximize uptake of screening in a timely manner	Maternity services / primary care	LAT	CCG	Informing the cohort and maximizing uptake in a timely manner takes place during routine midwifery-led antenatal care and also sometimes in primary care.
Screening test - sample taking	Maternity services / primary care	LAT	CCG	Mostly carried out through routine midwifery care - midwives take the blood sample.
Screening test - analysis	Antenatal labs	LAT	CCG	There are currently between 130 and 140 laboratories carrying out antenatal blood tests for the IDP screening programme. This work is perceived to be part of the

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				maternity tariff in many areas. Some parts of the country have centralized this work. Level of commissioning needs to be above that of individual CCGs to allow centralisation of these services and to improve quality and efficiency as per direction of the pathology modernization agenda. (Carter Review of NHS Pathology Services (2006, 2008) made the case for consolidating pathology nationally to improve quality, patient safety and efficiency)
Results reporting	Maternity services	LAT	CCG	Midwives report negative and positive screen results back to the woman as part of routine midwifery care. In addition, for positive results they will make arrangements for referral to appropriate specialists and ensure that these referrals have taken place; share information with appropriate specialist teams; offer, order and

				<p>deliver hepatitis B vaccine to the newborn baby and make arrangements for the completion of the vaccination schedule and transfer this information to CHRDs.</p>
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The commissioning of the IDPS Programme pathway involves commissioning at different levels. The IDPS services will be commissioned by the NHS CB alongside specialised services where appropriate.

2.6 Links between screening programme and national programme centre expertise

Public Health England (PHE) will be responsible for delivery of the essential elements of screening programmes best done once at national level.

These include:

- developing, piloting and roll-out to agreed national service specifications of all extensions to existing screening programmes and new screening programmes;
- setting QA standards;
- setting and reviewing programme standards;
- setting and reviewing national service specifications and advising on section 7A agreements (under the direction of DH requirements);
- developing education and training strategies;
- providing patient information;
- determining data sets and management of data, for example to ensure KPIs are collected;
- setting clear specifications for equipment, IT and data;
- procurement of equipment and IT where appropriate; (Procurement may undertaken by NHS CB but will need advice from PHE screening expertise and related clinical experts);
- collect, collate and quality assure data for cancer and non-cancer screening programmes;
- monitor and analyse implementation of NHS commissioned screening services;
- provide advice to DH on priorities and outcomes for the NHS CB mandate and section 7A agreement, and to lead on detailed provisions, in particular the 7A agreement on screening;
- advise the NHS CB how to increase uptake of screening.

PHE will also be responsible for

- providing the quality assurance functions for screening programmes;
- providing Public Health expertise and advice on screening at all levels of the system, including specialist Public Health expertise being available as part of NHS CB screening commissioning teams;
- ensuring action is taken to optimise access to screening programmes, e.g. among socio-economically disadvantaged groups;
- ensuring reports on important aspects of screening are available at various geographies (e.g. local authority) to enable population based oversight.

Section 3: Delivery of Screening Programme

3.1 Service model summary

The IDPS Programme consists of:

- (i) screening offered to all pregnant women early in pregnancy to identify women with hepatitis B, HIV and syphilis so that strategies are put in place to reduce the risk of mother-to-child transmission of these infections and ensure women are offered appropriate assessment and management for their own health;
- (ii) identifying women who are susceptible to rubella, for whom postnatal MMR vaccination could protect future pregnancies.

As with all screening programmes there are key points about this programme which make it different, and also are relevant to effective commissioning. The key points for the IDPS Programme are:

- interface between maternity, laboratories and specialist services
- linkage with primary care/CHRDs, regarding immunisation for babies at risk of hepatitis B and for rubella-susceptible women
- re-offer of screening to those who initially decline, offer for all women who book late for antenatal care, or present in labour who have not already booked for antenatal care
- that testing should be available at any stage during the pregnancy, should a woman consider herself to be at risk
- importance of urgent referral of syphilis and HIV screen-positive women into specialist care, and for hepatitis B positive women within six weeks, to assess the current status of infection, evaluate its implications for care of the woman and the onward management of the pregnancy and care of the baby – the links between the end of screening and enrolment in care should be explicit if the benefits that can be delivered by a screening programme are to be achieved and optimal outcomes delivered
- the way a woman with positive screening results for syphilis, HIV and hepatitis B are notified and communicated about the results and the skills required to communicate positive results
- alignment with clinical guidance on the management of people with HIV, syphilis or hepatitis B.

3.2 Programme co-ordination

In accordance with UK NSC standards and protocols the provider will be responsible for ensuring that the part of the programme they deliver is coordinated and interfaces seamlessly with other parts of the programme with which they collaborate, in relation to timeliness and data sharing.

The provider will provide one or more named individuals who will be responsible for the coordination of the delivery of the programme within the provider trust and provider contribution to planning supported by appropriate administrative support to ensure timely reporting and response to requests for information. Where there is only one named coordinator, the provider will ensure that there are adequate cover arrangements in place to ensure sustainability and consistency of programme.

The provider and the NHS CB will meet at regular intervals (at least annually). The meetings will include representatives from programme coordination, clinical services, laboratory services and service management.

3.3 Clinical and corporate governance

In accordance with UK NSC standards and protocols the provider will:

- ensure co-operation with and representation on the local screening oversight arrangements/ structures.
- ensure that responsibility for the screening programme lies at Director-level, (or delegated responsibility).
- ensure that there is appropriate internal clinical oversight of the programme and have its own management and internal governance of the services provided with the appointment of a Clinical Lead, a Programme Manager and the establishment of a multidisciplinary steering group (that meets quarterly) as a minimum.
- ensure that there is regular monitoring and audit of the screening programme, and that, as part of organisation's Clinical Governance arrangements, the organisation's Board is assured of the quality and integrity of the screening programme.
- comply with the UK NSC guidance on managing serious incidents.
- have appropriate and timely arrangements in place for referral into treatment services that meet the screening programme standards found on the National Screening programme Website.
- be able to provide documented evidence of clinical governance and effectiveness arrangements on request.
- ensure that an annual report of screening services is produced which is signed off by the organisation's Board.
- have a sound governance framework in place covering the following areas:
 - information governance/records management
 - equality and diversity
 - user involvement, experience and complaints
 - failsafe procedures
 - failsafe procedures.

3.4 Definition, identification and invitation of cohort/eligibility

The target population to be offered screening is all pregnant women, irrespective if they have been screened in previous pregnancies. Although, there may be no need for initial screening if a woman is known to be hepatitis

B or HIV positive, and this is documented and known to the healthcare professional. In this instance, this should be documented and arrangements made for prompt clinical evaluation.

3.5 Location(s) of programme delivery

The physical location of the offer of screening, and taking of the blood sample, is to be locally determined. Antenatal laboratory tests is to be provided by laboratories meeting required standards, as set out in the IDPS Programme Laboratory Handbook (2010).

3.6 Days/Hours of operation

To be locally determined. However, timeliness is essential and is a key criteria of quality along all parts of the screening pathway.

3.7 Entry into the screening programme

All women will be identified through the maternity service.

3.8 Working across interfaces between departments and organisations

The screening programme is dependent on strong working relationships (both formal and informal) between the midwifery services, laboratories and specialist clinical services. Accurate and timely communication and handover across these interfaces is essential to reduce the potential for errors and ensure a seamless pathway for service users. It is essential that there remains clear named clinical responsibility at all times and at handover of care the clinical responsibility is clarified. The Provider will ensure that appropriate systems are in place to support an interagency approach to the quality of the interface between these services. This will include, but is not limited to:

- agreeing and documenting roles and responsibilities relating to all elements of the screening pathway across organisations.
- providing strong clinical leadership and clear lines of accountability.
- developing joint audit and monitoring processes.
- working to nationally agreed Programme standards and policies.
- agreeing jointly on what failsafe mechanisms are required to ensure safe and timely processes across the whole screening pathway.
- contributing to any NHS CB Screening Lead's initiatives in screening pathway development in line with UK NSC expectations.
- meeting the IDPS Programme standards covering managing interfaces.

Interfaces

- Midwife to send blood sample to antenatal screening laboratory with request form.
- Screening laboratories may send samples to reference laboratories for confirmatory testing.

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- Antenatal screening laboratory to send results to requestor/midwife and may ask for repeat samples.
- Women with positive screening results for syphilis, hepatitis B or HIV referred to appropriate specialist service by maternity services.
- Maternity unit and specialist services, such as GUM.
- Maternity unit and primary care (GP/immunisation team/Health visitor/CHRD).

Interaction of laboratory and maternity services

Clarity on the interaction between laboratory and maternity services is necessary to ensure that a high volume of specimens are processed efficiently. To address this, the IDPS Programme Laboratory Handbook establishes recommended laboratory test turnaround times for all screening test results. This is to strengthen referral arrangements for the diagnosis and management of syphilis, HIV and hepatitis B.

It is important that maternity services are able to account for all screening test results. This is to ensure that all positive tests have been identified, that no specimens have been lost and that other problems are identified in sufficient time to rectify the situation.

Interaction of maternity services and specialist clinical services

A relatively small number of women will require assessment and management within a specialist environment. Different approaches to this might be available but referral to the HIV multi-disciplinary team provides a model for developing the hepatitis B and syphilis pathways.

3.9 Information on Test/ Screening Programme

In line with the IDPS Programme Standards (2010), the provider will ensure women have seen the written information *Screening tests for you and your baby* or had access to it in a format appropriate.

The provider will discuss the screening programme, and in order for women to make an informed choice, the following points should be discussed:

- the four infections, their routes of transmission and the implications of a positive test,
- the benefits, to both mother and baby, to be gained from the identification and management of those with positive results,
- the results procedure, including the feedback of results and the possibility of a false negative or false positive result,
- that all pregnant women should be advised that if they develop, or are exposed to, a rash during the pregnancy they should seek professional advice.

The screening test offered to women in the antenatal period for the HIV, syphilis, hepatitis B and rubella susceptibility is a blood test.

If the initial offer is declined this should be documented.

Screening should be re-offered to all women who decline the initial offer of screening, and if accepted marked “urgent”. Testing should be available on request at any stage should a woman consider herself to be at risk of infection. Screening for the four infections should be offered all women who book late for antenatal care, or present in labour who have not already booked for antenatal care.

3.10 Testing (laboratory service, performance of test by individuals)

Laboratories are expected to follow the standards laid out in the IDPS Programme.

The standards include:

- minimum standards for laboratories undertaking antenatal screening for infections in pregnancy, such as: organisation of services; analytical processes; performance standards and audit;
- specimen requirements, including: container, volume of specimen; identifiers marked on the specimen and a clear indication of which tests the woman has consented to;
- laboratory workloads; confirmatory tests in initial screening specimen; and arrangements for women who book late; and
- clinical condition specific guidance.

A process should be in place to ensure that. Repeat specimens, for example in response to laboratory requests when the first specimen is unacceptable or the screening test result is inconclusive, should be sent to the laboratory within 10 working days of the request being received by the maternity unit

Laboratories should be able to process “urgent” samples, for example women booking after 24 weeks gestation or presenting in labour unbooked for antenatal care, within 24 hours.

For hepatitis B, HIV and syphilis there is a requirement for appropriate confirmatory testing on the initial screen-positive specimen before the laboratory issues a report recommending maternity services recalls a woman.

3.11 Results giving, reporting and recording

All confirmed screening test results should be issued by the laboratory and received by the maternity service within ten working days of the screening sample being taken. Processes should be in place locally to identify and follow-up results that have not been received within this time period.

The format of the laboratory reporting (whether written or verbal) should clearly specify whether the result is “screen positive” or “screen negative” and whether referral to the relevant specialist service is necessary.

A report should be issued for every screening specimen received by the laboratory. The standardised reporting comments, included in the Handbook

for Laboratories, should be used to make clear the results and actions required, and to improve communication with the requester of the results.

The results should be documented in the woman's notes and electronic record (if applicable).

Results giving

The IDPS Programme Standards (2010) provides guidance about the management of screening results for which the provider will be responsible for meeting. These are summarised here:

- Women with positive screening results should be contacted and advised about the results, at a specific appointment made for that purpose, within ten working days of the result being available. The purpose of the appointment is to discuss the screening result and to arrange for referral to a relevant specialist service for clinical assessment. The time between initial contact and the appointment should be as short as possible to minimise any anxiety. An appropriate professional/s, trained to communicate positive results should participate in this appointment and the use of interpreters is recommended where appropriate.

3.12 Transfer of and discharge from care obligations

Screening ends when the following conditions are met:

- The maternity service has received a negative screen result from the laboratory for HIV, hepatitis B and syphilis, and rubella immune results, and these have been communicated back to the women (either before or at the next antenatal visit, according to local protocol).
- The maternity service has received a positive screening result for HIV, hepatitis B and syphilis, has communicated the screen-positive result to the woman (in a face-to-face appt) and arrangements have been made for referral to an appropriate specialist, in accordance with clinical guidelines. For hepatitis B the woman has been informed about the need for postnatal vaccination of baby within 24 hours of birth and the vaccine has been ordered. Maternity services should ensure the referral has taken place and the woman has been seen by specialist services. Non-attendance at the specialist appt should be reviewed within a multi-disciplinary framework and a management/action plan developed.
- The maternity service has received a rubella-susceptible result, has communicated the result with the woman (at the next antenatal appt or according to local protocol) and informed her about the need for post-natal MMR to protect future pregnancies.
- Following referral for positive syphilis, HIV or hepatitis B results, information should be shared between the specialist team and maternity services regarding to ensure appropriate management/delivery of the baby, and post-partum care of the baby. Local protocols should be in place to ensure multi-disciplinary links and

close working relationships between maternity services and specialist services are established and function well.

- The maternity service in which the woman delivered is responsible for:
 - For hepatitis B this includes - offering and ordering the vaccine and giving the vaccine to the baby within 24 hours of delivery, as well as making arrangements for the completion of the vaccination schedule with primary care and transferring this information to primary care/CHRD/information systems;
 - For postnatal MMR vaccination this includes - offering and ordering the vaccine and giving the vaccine to women prior to discharge from maternity services, as well as making arrangements for the notification of primary care re second dose.

3.13 Self-care/patient information

Information on managing conditions can be found on the National Screening programme website.

3.14 Exclusion criteria

All pregnant women should be offered screening for the four infections. However, there may be no need for initial screening if the woman is known to be hepatitis B or HIV positive and is under appropriate clinical care and her status for all four infections is already known.

3.15 Staffing

Providers will ensure that there are adequate numbers of appropriately trained staff in place to deliver the screening programme in line with the IDPS Programme Standards and Laboratory Handbook and other relevant best practice guidelines.

3.16 User involvement

All Provider(s) will be required to:

- demonstrate that they have collected (or have plans in place to collect) the views of service users, families and others in respect of the services they provide
- demonstrate how those views will influence service design and delivery for the purposes of raising standards
- show that all families are given information about how to provide feedback about services they receive, including about the complaints procedure.

Collection of the views of service users/families will often be via surveys or questionnaires. It is expected that such surveys will take place on a regular (rather than ad hoc) basis and that the results will be made available to the NHS CB on request.

Section 4: Service Standards, Risks and Quality Assurance

4.1 Key criteria and standards

The key criteria for the IDPS Programme are:

- The standards for the programme are set out in the IDPS Programme Standards and Laboratory Handbook (<http://infectiousdiseases.screening.nhs.uk/standards>)

Providers will contribute to national surveillance data collection where required and will provide the Key Performance Indicator data detailed in 5.1.

4.2 Risk assessment of the pathway

Providers are expected to have an internal quality assurance process that assures the NHS CB of its ability to manage the risks of running a screening programme. Providers may use the Failures Modes and Effects Analysis (FMEA) method which is recommended by the NHS National Patient Safety Agency's risk assessment programme. Risks should be defined in the standard NHS format (*likelihood and severity multiplied to give a RAG score*)

Providers are expected to maintain a register of risks and work with the NHS CB and QA staff to identify key areas of risk in the screening pathway to ensure that these points are reviewed in contracting and peer review processes. On a quarterly basis high scoring risks will be identified and agreed between the provider and the NHS CB, and plans put in place to mitigate against them.

4.3 Quality assurance

The NHS CB will suspend a service on recommendation from QA.

The Provider will:

- meet national programme standards, or have plans in place to meet them where this is not the case
- participate fully in national Quality Assurance processes and respond in a timely manner to recommendations made
- make available data from external quality assurance programmes to screening programmes, national team and the NHS CB
- collect and submit minimum data sets as required to assure the NHS CB and the Quality Assurance Team in Public Health England of the safety and quality of the services provided

- complete and submit the annual self-assessment tool with or without (as requested) an annual report of services to the Quality Assurance team and respond to identified areas for improvement

4.4 Serious incidents

A serious incident (SI) for screening programmes is defined as an actual or possible failure at any stage in the pathway of the screening service which exposes the programme to unknown levels of risk that screening or assessment have been inadequate, and hence there are possible serious consequences for the clinical management of patients. The level of risk to an individual may be low or high, but because of the large numbers involved the corporate risk may be very high. Complex screening pathways often involve multidisciplinary teams working across several NHS organisations in both primary and secondary care, and inappropriate actions within one area, or communication failures between providers, can result in serious incidents.

Potential serious incidents or serious near misses in screening programmes should be investigated with the same level of priority as for actual serious incidents.

In accordance with UK NSC standards and protocols the provider will:

- have a serious incident policy for screening programmes in place and ensure that all staff are aware of it and of their responsibilities within it
- inform the NHS CB within 24 hours in the event of a serious adverse event and provide all reasonable assistance to the NHS CB in investigating and dealing with the incident. Where appropriate, such incidents should also be reported to the National Screening programme to assist in the development of a national picture of risk identification and management
- comply with appropriate statutory regulations (e.g. Data Protection Act, COSHH Regulations etc) to ensure a safe working environment
- comply with the UK NSC guidance
- review their procedures and processes against the standards for the Infectious Diseases in Pregnancy screening programme to reduce the likelihood of incidents occurring
- have a robust system in place whereby families, other professionals and the public can raise concerns about the quality of care and where there are adequate arrangements for the investigations of such concerns.

4.5 Continual service improvement

Where national recommendations and core and/or developmental standards are not currently fully implemented the provider will be expected to indicate in service plans what changes and improvements will be made over the course of the contract period.

Public health functions to be exercised by the NHS Commissioning Board

The Provider shall develop a CSIP (continual service improvement plan) in line with the KPIs and the results of internal and external quality assurance checks. The CSIP will respond and any performance issues highlighted by the NHS CB, having regard to any concerns raised via any service user feedback. The CSIP will contain action plans with defined timescales and responsibilities, and will be agreed with the NHS CB.

Section 5: Data and Monitoring

5.1 Data collection, monitoring and reporting

Activity, performance and KPI data will be collected by providers and shared with the NHS CB to allow benchmarking between areas within the eligible screening programme population (Guidance and updates on KPIs: <http://www.screening.nhs.uk/kpi>).

For the IDPS Programme, there are two domains of data collection and monitoring which include:

- surveillance data through the PHE National Antenatal Infection Screening Monitoring (NAISM) Programme¹
- collection and monitoring of screening Key Performance Indicators relating to HIV coverage and referral of hepatitis B positive women into specialist care.

5.2 Surveillance data through the Health Protection agency

Since 2004, the Health Protection Agency's National Antenatal Infection Screening Monitoring (NAISM) Programme has had a formal role in centrally collating, analysing and publishing IDPS data. The NAISM Programme monitors the uptake of antenatal screening and the proportion of screened women that test positive for hepatitis B, HIV and syphilis and susceptible to rubella.

As part of this surveillance collection, information is requested at maternity unit or trust level on the number of pregnant women booked for antenatal care, the number screened for each of the four infections, and the results of the screening tests. This information is recorded on a standard proforma and supplied quarterly to the HPA Regional Epidemiologist and/or the Regional Antenatal and Child Health Screening Teams. The data are then cleaned and forwarded to the NAISM Programme where they are analysed and published annually.

In future this will be managed through PHE.

¹

http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1245581538007