



Department
of Health

NHS
England

Public health functions to be exercised by NHS England

Service specification No.15

NHS Infectious Diseases in Pregnancy Screening
Programme

November 2013

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Public health functions to be exercised by NHS England

Service specification No.15

NHS Infectious Diseases in Pregnancy Screening Programme

Prepared by –
Public Health England

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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 NHS England' dated November 2013 (the '2014-15 agreement').

The 2014-15 agreement is made between the Secretary of State for Health and NHS England 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 NHS England in accordance with the 2014-15 agreement. An update to this service specification may take effect as a variation made under section 7A of the 2006 Act. Guidance agreed under paragraph A38 of the 2014-15 agreement may inform the application of the provisions of this service specification.

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

The 2014-15 agreement including all service specifications within Part C is available at www.gov.uk (search for 'commissioning public health').

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 NHS England for its 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 2014. In the interim, the standards and expectations in relation to the delivery of the programme locally (that are derived from the Programme Standards) are listed below. NHS England 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:

- Current NHS guidance that is found on the IDPS Programme website <http://infectiousdiseases.screening.nhs.uk/>
- IDPS Programme Standards (2010) <http://infectiousdiseases.screening.nhs.uk/standards>
- IDPS Programme Handbook for Laboratories second edition (2012) <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
- National Institute for Health and Care Excellence. Hepatitis B (chronic): diagnosis and management of chronic hepatitis B in children, young people and adults. (Clinical guideline 165.) 2013. <http://guidance.nice.org.uk/CG165>.
- British Viral Hepatitis Group (BVHG) consensus statement on the management of hepatitis B positive women www.basl.org.uk/media/uploads/BVHGPregnancy.pdf
- British HIV Association guidelines for the management of HIV infection in pregnant women 2012 (BHIVA) <http://www.bhiva.org/PregnantWomen2012.aspx>
- UK National Guidelines on the Management of Syphilis 2008 (British Association of Sexual Health and HIV – BASHH) www.bashh.org/BASHH/Guidelines.
- Guidance and updates on Key Performance Indicators (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>
- National Institute for Health and Clinical Excellence (NICE) Clinical guideline 62 Antenatal care June 2010 <http://publications.nice.org.uk/antenatal-care-cg62>
- National Institute for Health and Clinical Excellence (NICE) Clinical guideline 37 Routine postnatal care of women and their babies 2006 <http://www.nice.org.uk/cg037>

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 2.21i and 2.21ii 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 the different providers of services in 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 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, training media 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, investigating 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
- Ensure all health care professionals access appropriate training to maintain continuous professional development and competency
- Be required to access the screening pathways and ensure failsafes are in place at key points
- Ensure appropriate monitoring and governance structures are in place

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 maternity antenatal care services 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 to enable early referral, management and treatment. However screening can be offered and requested at any stage of pregnancy especially if the woman deems herself to be at risk
- Women should be provided with written information and also have the key information about screening for the four infections explained to them to enable an informed choice to be made
- 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 (paper or electronic). 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 'fit for purpose' sample.
- The specimen is processed to ensure that the tests requested are undertaken. Local protocols should be in place between the laboratory and maternity service 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 and all requests should be tracked until completed.
- 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 (2012).
- 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 arrangements 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 in a timely manner.
- Women who are susceptible to rubella infection should be informed about the test results before or at their next antenatal visit, according to local protocol.
- Negative screening test results should be reported back to women before or at the next antenatal visit, according to local protocol. NHS England will want to check these local protocols as they are critical to ensure adequate follow up and timely results
- Following referral for positive syphilis, HIV or hepatitis B results, information should be shared between the specialist teams and maternity services to ensure appropriate management/delivery of the baby, and post-partum care and monitoring of screening outcomes. 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 notification to primary care regarding administration of the second dose

Failsafe arrangements will be in place across the whole screening pathway at national, sub-national and local levels. NHS England 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 Quality Assurance teams, and NHS England Screening and Immunisation Leads and 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 staff training and development and competencies, 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.

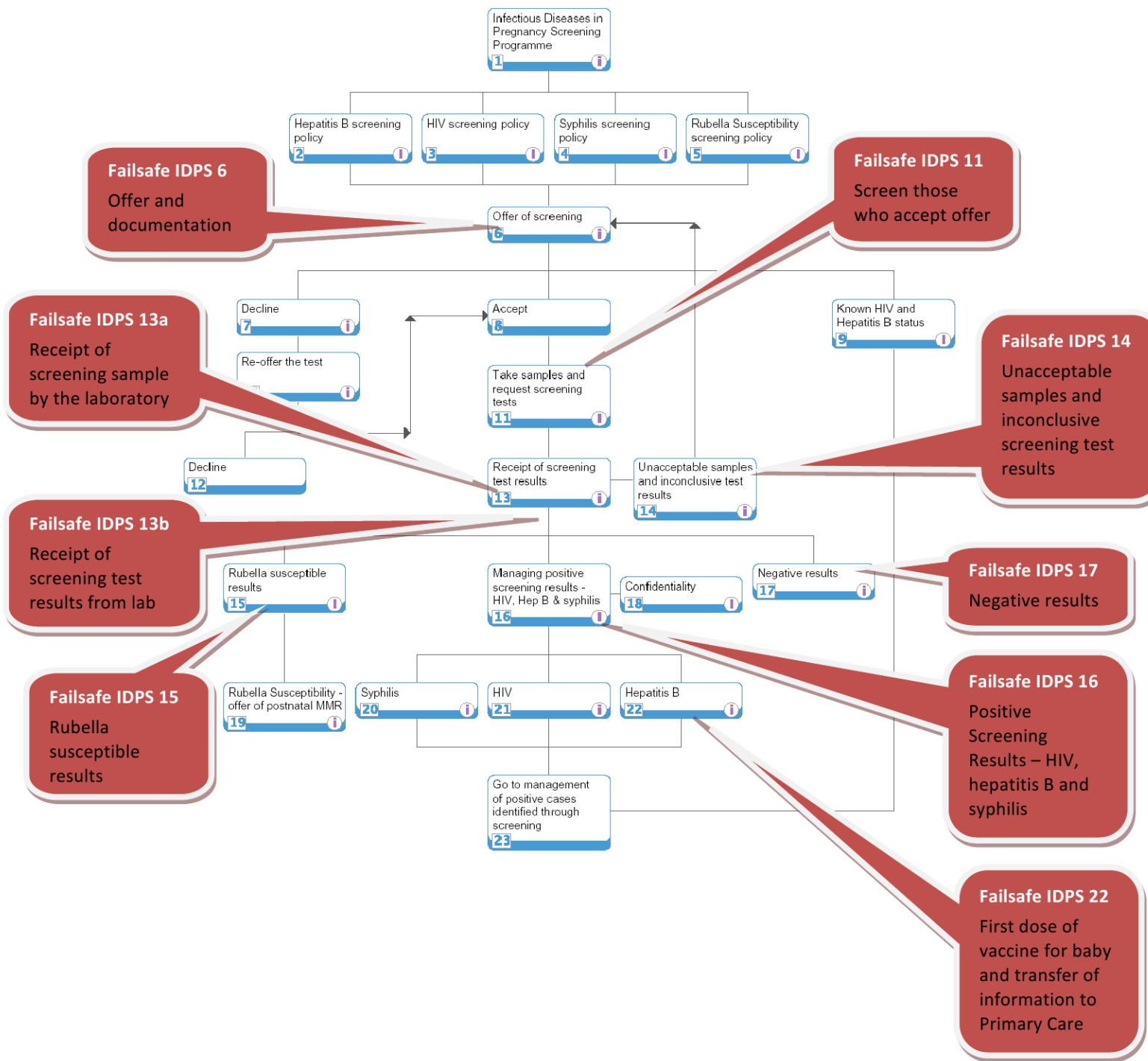


Diagram 1: Infectious Diseases in Pregnancy Screening Programme Pathway

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 NHS England 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 staff have access to appropriate training and development to maintain competencies

2.4 Roles and accountability throughout the pathway

The IDPS Programme is dependent on systematic specified relationships between stakeholders. Stakeholders include maternity services, 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.

NHS England will be expected to ensure that the whole pathway is robust. 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 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 England 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	AT	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	AT	CCG	Informing the cohort and facilitating informed choice 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	AT	CCG	Mostly carried out through maternity services, midwives or other healthcare professional take the blood sample.
Screening test - analysis	Antenatal labs	AT	CCG	There are currently between 130 and 140 laboratories carrying out antenatal blood

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				tests for the IDPS programme. This work is perceived to be part of the maternity tariff in many areas. Some parts of the country have centralised this work into pathology networks.
Results reporting	Maternity services	AT	CCG	Midwives report negative results back to the woman as part of routine midwifery care. Positive results they will be communicated by Antenatal and newborn Screening Coordinators/ Specialist Midwives are responsible for making arrangements for referral to appropriate specialists and ensuring that these referrals have taken place; share information with appropriate specialist teams; offer, order and deliver hepatitis B vaccine to the newborn baby and make arrangements for the completion of the vaccination schedule and transfer this information to CHRDs and monitor outcomes of the

				screening programme.
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The commissioning of the IDPS Programme pathway involves commissioning at different levels. The IDPS services will be commissioned by NHS England 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 changes or 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 KPIs
- setting clear specifications for equipment, IT and data;
- procurement of equipment and IT where appropriate; (Procurement may undertaken by NHS England 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 England mandate and section 7A agreement, and to lead on detailed provisions, in particular the 7A agreement on screening;
- advise NHS England how to increase uptake of screening as appropriate.

PHE will also be responsible for

- providing the quality assurance functions for screening programmes;

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- 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 England 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
- formal re-offer of screening at 28 weeks gestation to those who initially decline; offer and 'fast-track' screening 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 and full assessment within specialist services for syphilis and HIV screen-positive women 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, safety and consistency of programme.

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

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 senior 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
- 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
- risks & mitigation plans

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 appropriately evidenced and documented and known to the healthcare professional. In this instance, this should be documented and arrangements made for prompt clinical referral and 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 testing is to be provided by laboratories meeting required standards, as set out in the IDPS Programme Laboratory Handbook (2012).

3.6 Days/Hours of operation

To be determined locally. 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 England Screening Lead's initiatives in screening pathway development in line with UK NSC expectations.
- meeting the IDPS Programme standards covering managing interfaces.

Interfaces

- Midwife or healthcare professional to send blood sample to antenatal screening laboratory with request form.
- Screening laboratories may send samples to reference laboratories for confirmatory testing.
- Antenatal screening laboratory to send results to requestor/midwife and may ask for repeat samples.
- Maternity service to ensure turnaround of repeat requests to laboratory
- 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, Hepatology etc.
- 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 (2012) 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 in a timely manner. 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 tests offered to women in the antenatal period for HIV, syphilis, hepatitis B and rubella susceptibility is a blood test.

If the initial offer is declined this should be documented.

Screening should be formally re-offered to all women who decline the initial offer of screening, and if accepted managed in line with IDPS Laboratory Standards (2012). 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 to 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, as soon as possible and 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. Women who undertake screening and subsequently miscarry or terminate their pregnancy should be informed of their screening result in line with local protocols in order to close the screening pathway, commence maternal treatment if required and to inform future pregnancies.

3.15 Staffing

Providers will ensure that there are adequate numbers of competent and 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 NHS England on request.

Safety & Safeguarding

The provider should refer to and comply with the safety and safeguarding requirements as set out in the NHS Standard Contract. As an example, please see link below for 2013/14 NHS Standard Contract:

<http://www.england.nhs.uk/wp-content/uploads/2013/03/contract-service.pdf>

Section 4: Service Standards, Risks and Quality Assurance

4.1 Key criteria and standards

Programme standards are available on the programme website <http://infectiousdiseases.screening.nhs.uk/standards> . Providers will meet the acceptable and work towards the achievable programme standards. A number of resources to support providers are available on the programme website.

4.2 Risk assessment of the screening pathway

Providers are expected to have an internal quality assurance and risk management process that assures the commissioners of its ability to manage the risks of running a screening programme.

Providers will:

- ensure that appropriate failsafe mechanisms are included 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 Commissioner and Quality Assurance Teams to develop, implement, and maintain appropriate risk reduction measures
- 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 is undertaken

On a quarterly basis high scoring risks will be identified and agreed between the provider and the commissioners and plans put in place to mitigate against them. Risk identification should take into account failsafe mapping (please also see section 2.3 Failsafe Arrangements).

4.3 Quality assurance

Providers will participate fully in national Quality Assurance processes and respond in a timely manner to recommendations made. This will include the submission to QA teams and commissioners of:

- data and reports from external quality assurance schemes

- minimum data sets as required – these may be required to be submitted to national external bodies e.g. National Vascular Database etc.
- self-assessment questionnaires / tools and associated evidence
- audits or data relating to nationally agreed internal quality assurance processes

Providers will participate fully in the QA visit process where required and cooperate in undertaking ad-hoc audits and reviews as requested.

Providers will respond to QA recommendations by the submission of action plans to address identified areas for improvement and any non-conformities / deviations from recommended performance thresholds.

Where QA believe there is a significant risk of harm to the population, they will recommend to commissioners to suspend a service.

Laboratories undertaking IDPS screening should

- be accredited by CPA or equivalent and list the screening tests in their repertoire of services (<http://www.cpa-uk.co.uk/>)
- participate in and respond in a timely manner to an accredited external quality assurance scheme for IDP screening. e.g. UKNEQAS scheme
- Make available timely data and reports from external quality assurance programmes and accreditation services to screening programmes, national teams and commissioner

4.4 Serious incidents

Providers will comply with the national guidance for the management of incidents in screening programmes and NHS England guidance for the management of incidents. “Managing Incidents in England NHS National Screening Programmes Interim Guidance” and “NHS Commissioning Board. (2013) Serious Incident Framework – an update to the 2010 National Framework for Reporting and Learning from Serious Incidents Requiring Investigation. NHS Commissioning Board: London”.

4.5 Procedures and Protocols

The provider will be able to demonstrate that they have audited procedures, policies and protocols in place to ensure best practice is consistently applied for all elements of the screening programme.

4.6 Continual service improvement

Where national recommendations and acceptable/achievable 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.

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 commissioners, 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 commissioners.

4.7 Teaching and Training

The provider will ensure that:

- education, training and staff development are an integral part of the service and complies with the requirements of the screening programme
- it keeps up to date with clinical advances
- contributes to education and training of other relevant professionals where appropriate

The provider should also aspire to participate in properly conducted quality research where possible (with appropriate ethical approval).

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 NHS England to allow benchmarking between areas within the eligible screening programme population (Guidance and updates on KPIs: <http://www.screening.nhs.uk/kpi>).

5.2 Public Health Outcomes Framework Indicators / KPIs

2.21i: HIV coverage: percentage of pregnant women eligible for infectious disease screening who are tested for HIV, leading to a conclusive result

Key Deliverable: The acceptable level should be achieved as a minimum by all services

Acceptable $\geq 90\%$

2012-13 national baseline is 98.1%

2.21ii): Syphilis, hepatitis B and susceptibility to rubella uptake: The percentage of women booked for antenatal care, as reported by maternity services, who have a screening test for syphilis, hepatitis B and susceptibility to rubella leading to a conclusive result.

Key Deliverable:

Completeness: All maternity services should return complete and robust coverage and uptake data. Achievable = 100%

Uptake: 2012 national baseline is 98% for each of above three conditions (using surveillance non-cohort data)

For the IDPS Programme, there are three 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.
- Audits e.g. HIV, BPSU, etc

5.3 Surveillance data through the PHE NAISM

1

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

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 surveillance data. The NAISM Programme, now part of PHE, 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, non-cohort data 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 numbers screened positive. This information is recorded on a standard return proforma and supplied quarterly to the Field Epidemiologists as per regional arrangements. The data are then cleaned and forwarded to the NAISM Programme where they are analysed and published annually.

The IDPS Programme and NAISM team are working collaboratively to align future management of the data collation and reporting processes.