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NHS public health functions agreement 2015-16

Service specification no.15

NHS Infectious Diseases in Pregnancy Screening Programme

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NHS public health functions agreement 2015-16

Service specification no.15

NHS Infectious Diseases in Pregnancy Screening Programme

Prepared by Public Health England

Contents

Service specification No.15

This is a service specification within Annex C of the ‘NHS public health functions agreement 2015-16 (the ‘2015-16 agreement’) published in December 2014.

This service specification is to be applied by NHS England in accordance with the 2015-16 agreement. This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

Where a specification refers to any other published document or standard, it refers to the document or standard as it existed at the date when the 2015-16 agreement was made between the Secretary of State and NHS England Board. Any changes in other published documents or standards may have effect for the purposes of the 2015-16 agreement in accordance with the procedures described in Chapter 3 of the 2015-16 agreement

Service specifications should be downloaded in order to ensure that commissioners and providers refer to the latest document that is in effect.

The 2015-16 agreement including all service specifications within Annex 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 Infectious Diseases in Pregnancy Screening as part 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 the population for whom it is responsible and which meets the policies, recommendations and standards of the UK National Screening Committee (UK NSC).

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 specification should be read in conjunction with:

- Current NHS IDPS 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 .
- Any separate service specifications for the screening laboratory used by the provider for antenatal screening services
- Managing Serious Incidents in the English NHS National Screening Programmes http://www.screening.nhs.uk/incidents
- Failsafe Processes http://www.screening.nhs.uk/failsafe
- Guidance and updates on Key Performance Indicators (KPIs): http://www.screening.nhs.uk/kpi
- DH Immunisation against Infectious Disease – the Green Book (Chapter 18 on Hepatitis B – updated 2009 and Chapter 28 on rubella susceptibility – updated 2010) https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

- 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 http://infectiousdiseases.screening.nhs.uk/standards#fileid10844
- British HIV Association guidelines for the management of HIV infection in pregnant women 2012 (BHIVA) http://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
- National Institute for Health and Clinical Excellence (NICE) Clinical guideline 62 Antenatal care June 2010 http://www.nice.org.uk/Guidance/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. Aims

The NHS Infectious Diseases in Pregnancy Screening Programme advocates that all pregnant women are offered and recommended 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 to facilitate appropriate assessment and management for their health
- to reduce the risk of mother-to-child transmission of these conditions
- to facilitate appropriate neonatal referral and management
- to identify women who are susceptible to rubella, for whom postnatal MMR vaccination could protect future pregnancies

1.4. Expected health outcomes

The following are expected in accordance to the programmes overall aims and objectives:

- safeguard the woman's own health and reduce the risk of a mother-to-child transmission of HIV from 25% to less than 1%
- safeguard the woman's own health and reduce the risk of mother-to-child transmission of hepatitis B
- safeguard the woman's own health and reduce the risk of mother-to-child transmission of syphilis
- reduce the risk of congenital rubella in future pregnancies, by identifying and offering rubella susceptible women postnatal MMR vaccination

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 with clear lines of communication between the different providers of services in screening centres, primary care and secondary care

1.6. Equality

The provider will be able to demonstrate what systems are in place to ensure equity of access to screening and subsequent confirmatory testing. This will include, for example, how the services are designed to ensure that there are no obstacles to access on the grounds of race, culture, sexual preference, physical or learning disabilities.

The provider will have procedures in place to identify and support those women who are considered vulnerable including, but not exclusive to, asylum seekers, women in prison, women with drug or alcohol harm issues, women with disabilities, women experiencing domestic abuse, with physical disabilities or women with communication difficulties. The provider will comply with safeguarding policies and good practice recommendations for such women.

Providers are expected to meet the public sector Equality Duty which means that public bodies have to consider all individuals when carrying out their day-to-day work – in shaping policy, in delivering services and in relation to their own employees. https://www.gov.uk/equality-act-2010-guidance

It also requires that public bodies:

- have due regard to the need to eliminate discrimination
- advance equality of opportunity
- foster good relations between different people when carrying out their activities

Section 2: Scope of Screening Programme

2.1. Description of screening programme

The UK NSC policy for IDPS is that all eligible pregnant women in England should be offered screening for:

- hepatitis B
- Human Immunodeficiency Virus (HIV)
- syphilis
- rubella susceptibility

In delivering a national screening programme and to ensure national consistency the local provider is expected to fulfil the following, in conjunction with guidance from the National Screening programme where appropriate and as detailed in the standards and policies available on http://infectiousdiseases.screening.nhs.uk/standards and http://www.screening.nhs.uk/policydb.php

- 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
- work with NHS England in reporting, investigating and resolving screening incidents
- provide data and reports against programme standards, key performance indicators (KPIs), and quality indicators as required by the national 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
- ensure appropriate governance structures are in place

2.2. Care pathway

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

A full description of the screening pathway can be found on the Map of Medicine http://healthguides.mapofmedicine.com/choices/map/infectious_diseases_in_pregnancy_screening1.html

The IDPS Programme pathway consists of the following:

- the eligible population is identified through maternity antenatal care services. All women should be offered and recommended screening for hepatitis B, HIV, syphilis and susceptibility to rubella early in pregnancy. This is to enable early referral, diagnosis, 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
- during the first contact or booking visit with the midwife, verbal and written information about the four infections is given to the woman (using UK NSC booklet 'Screening Tests for You and Your Baby') to enable her to make an informed choice
- screening for each of the four infections should be offered and recommended and acceptance or decline for each of the individual screening tests 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, transportation to the laboratory and receipt of sample, should be defined by local protocol and are the responsibility of the provider
- the laboratory should receive a fit for purpose antenatal blood sample within one working day of the sample being taken
- the specimen should be clearly identified as an antenatal screening sample. It is necessary to indicate the tests being requested and, if relevant, those declined

- a local failsafe protocol must be in place to ensure that all women who accept screening complete the testing pathway 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 log receipt of a 'fit for purpose' sample, 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 ensure early identification of screen positive women and all requests should be tracked until completed
- repeat specimens should be sent to the laboratory within 10 working days of the request being received by the maternity unit. Analysis and testing should be undertaken in line with nationally agreed screening standards and timescales
- for hepatitis B, HIV and syphilis, appropriate confirmatory testing **must** be undertaken on the initial screen positive specimen before the laboratory issues a report to maternity services
  - local protocols should be in place between the laboratory and maternity services to ensure results are communicated within nationally set timescales/standards. NHS England should check these local protocols as they are critical to ensure adequate and timely follow up of results
  - all confirmed screening test results should be issued by the laboratory and received by maternity services within 10 working days of the screening specimen being taken. Processes should be in place locally to identify and follow-up results that have not been received within this time period
- a report should be issued for every screening specimen received by the laboratory. 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

In addition:

- screening should be formally re-offered to all women who decline the initial offer of screening at around 28 weeks gestation, and if accepted managed in line with IDP Standards
- testing should be available on request at any stage of pregnancy 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. Screening samples received after 24 weeks gestation should be fast-tracked through the analytical process and a result reported within 48 hours

- women presenting in labour who have not been screened or whose screening results are not available should be offered screening for the four infections. Blood samples should be tested urgently by the laboratory and an initial screening result dispatched as soon as possible. Point of care tests should not be used for routine screening purposes. A system should be in place to ensure that tests have been performed and that, where this has not happened, screening for all four conditions is offered prior to discharge from maternity services

Management of results

Screen negative results:

- all women should be notified of their screening test result before or at the next antenatal visit, according to local protocol. The result should be recorded in the health records
- The healthcare professional should inform the woman that she can request screening at any stage in her pregnancy if she deems herself at risk or changes her sexual partner

Screen positive results:

HIV, syphilis and hepatitis B results:

- results should not be communicated to the maternity service until appropriate confirmatory tests are completed on the initial screening sample
- the laboratory directly informs the designated lead within the maternity service (e.g. Screening Coordinator) of the screen positive result
- a local protocol should be in place between the laboratory and maternity service to log receipt of screen positive results
- the woman is informed of the result at a face-to-face discussion with an appropriate specialist midwife at an appointment made for that purpose within 10 working days of the result being made available to maternity services. However, the time between initial contact with the woman and the appointment should be as short as possible to minimise the duration of any anxiety she is likely to experience
- arrangements should be made for referral to:
  - the multi-disciplinary team responsible for co-ordinating the woman's HIV care in accordance with the BHIVA Guidelines
  - an appropriate specialist (e.g. a hepatologist, gastroenterologist or infectious diseases specialist) within 6 weeks of the screening test result being issued to

maternity services. Local arrangements should be made to support consultant and/or midwife to consultant referral.

  - an appropriate specialist, e.g. a GUM physician in accordance with the BASHH guideline

- women booking late for antenatal care, after 24 weeks, should be referred immediately for a clinical evaluation
- maternity services should ensure the referral has taken place and the woman has been seen by specialist services in a timely manner
- non-attendance at the specialist appointment should be reviewed within a multidisciplinary framework and a management / action plan developed
- 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 multidisciplinary links and close working relationships between maternity services and specialist services are established and function well
- local arrangements should be in place to inform the Health Protection Unit (HPU) of screen positive results in line with 'Green Book' requirements

Rubella susceptible women:

- women should be informed about the test results and requirement for postnatal vaccination before or at their next antenatal visit, according to local protocol. They must be advised to report any contact with 'rash-like' illness in pregnancy

Postnatal maternity services are responsible for:

- hepatitis B
  - ensuring arrangements are in place to prescribe, order and store the vaccine (+/- HBIG as required) in advance of the estimated delivery date
  - offering and administering the immunoglobulin/ vaccine as required to the baby within 24 hours of delivery and recorded in the specific Hep B page of the PCHR
  - ensuring a mechanism is in place to inform Child Health Record Departments (CHRD) of the administration of the initial vaccine/immunoglobulin and the need to schedule further vaccinations/serology in line with Green Book guidance

  - ensuring processes are in place to ensure the mother is aware of the immunisation schedule. A process to arrange appointments, issue prompts and identify missed appointments at each stage should be in place to facilitate completion of the schedule. This may require an IT process through the Child Health Records Departments

  - arrangements for the mother to be seen by an appropriate specialist (e.g. a hepatologist, gastroenterologist, infectious diseases specialist) should be made if this has not already been done during pregnancy

- rubella
  - offering and recommending postnatal MMR vaccination prior to discharge from maternity services
  - ensuring a mechanism is in place to inform the woman and primary care of the need to administer the second dose of MMR

Women who miscarry or terminate their pregnancy:

- all women should be notified of their results once they have been tested. There should be a mechanism in place to ensure that women who subsequently miscarry or terminate their pregnancy receive their results to allow appropriate management of their condition
- screen positive for HIV; hepatitis B or syphilis- maternity services should coordinate the process to ensure timely entry into specialist services
- rubella susceptible women- maternity services should notify the woman and GP and advocate vaccination to protect future pregnancies

All providers are expected to review and risk assess local care 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.

A full description of the screening pathway can be found on the Map of Medicine at http://healthguides.mapofmedicine.com

A pathway for IDPS screening with identification of failsafe points is shown in Figure 1.

2.3. Failsafe Procedures

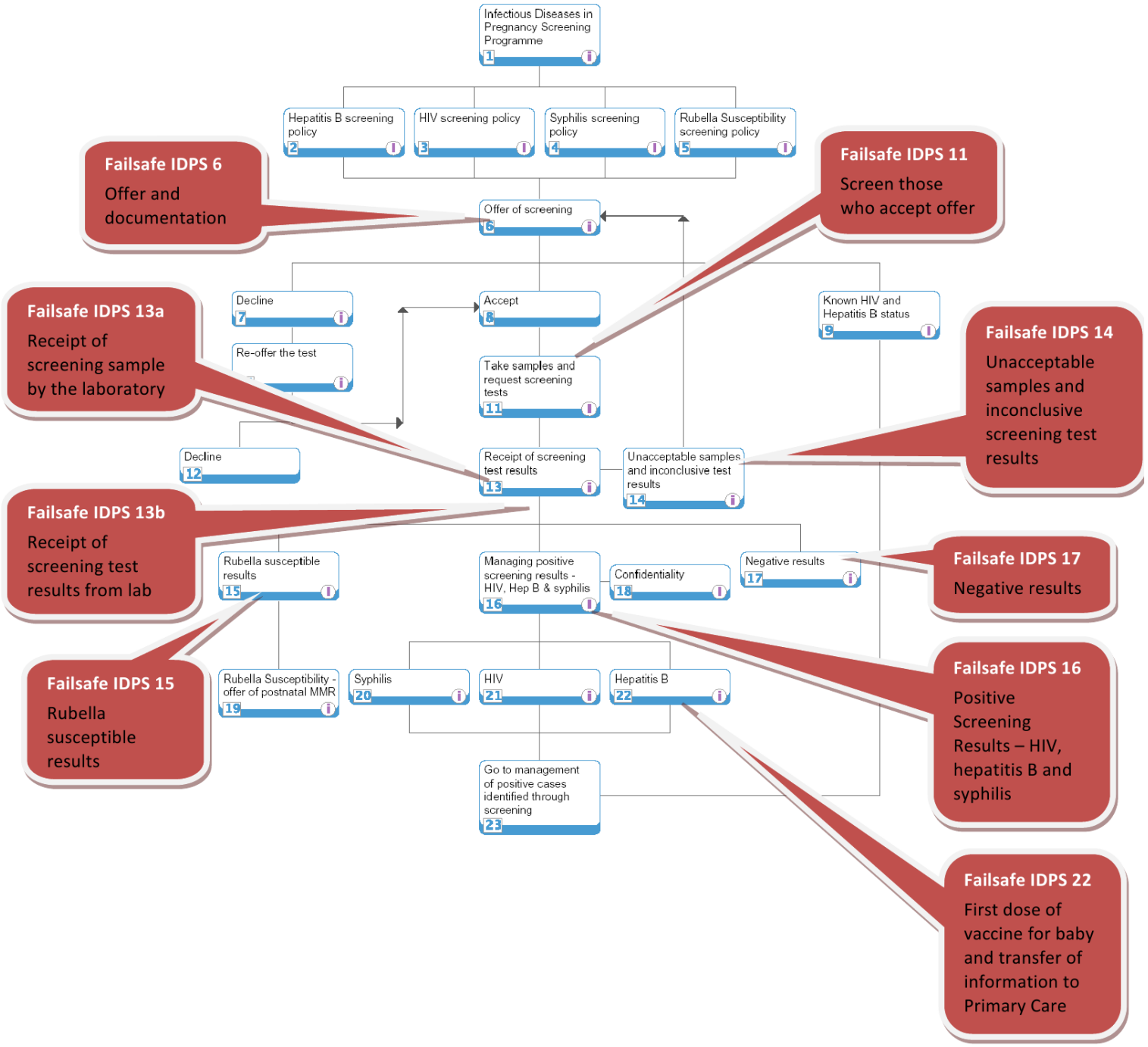
Quality Assurance within the screening pathway is managed by including failsafe processes. Failsafe is a back-up mechanism, in addition to usual care, which ensures if something goes wrong in the screening pathway, processes are in place to identify (i) what is going wrong and (ii) what action follows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

The provider is expected to:

- have and evidence 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
- 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

Figure 1 Map of Medicine screening pathway for IDPS with failsafe points

http://www.screening.nhs.uk/failsafe



2.4. Roles and accountabilities through the screening pathway

The IDPS programme is dependent on systematic specified relationships between stakeholders. Stakeholders include maternity services, the screening laboratory/reference laboratory, 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 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 and organisational boundaries 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.

For further specific staffing requirements refer to Section 3.15.

2.5. Commissioning Arrangements

Infectious Diseases in Pregnancy screening services will be commissioned by NHS England alongside specialised services where appropriate. Commissioning the IDPS screening pathway involves commissioning at different levels which may include Area Teams, CCGs, and directly by maternity services. Refer to ‘Maternity Pathway Payments: Who pays for what’

http://www.england.nhs.uk/wp-content/uploads/2014/01/who-pays-for-what-fin.pdf

2.6. Links between screening programme and national programme expertise

PHE, through the national screening programmes, is responsible for defining high-quality, uniform screening, and providing accessible information to both the public and health care professionals, and developing and monitoring standards. It is also responsible for the delivery of national quality assurance, based at regional level, and for ensuring training and education for all those providing screening is developed, commissioned and delivered through appropriate partner organisations.

Section 3: Delivery of Screening Programme

3.1. Service model summary

The model of delivery for the screening programme is primarily through maternity services care.

See section 2.2 Care Pathway above for further details.

3.2. Programme co-ordination

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 ensure that they have a Screening Midwife/Coordinator (and deputies) in place to oversee the screening programme, 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 NHS England should meet at regular intervals to monitor and review the local screening pathway. The meetings should include representatives from programme coordination, clinical services, laboratory services and service management.

3.3. Clinical and corporate governance

The provider will:

- ensure co-operation with and representation on the local screening oversight arrangements/ structures, e.g. screening programme boards/groups
- ensure that responsibility for the screening programme lies at Director-level
- 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 designation of a clinical lead, a programme coordinator/manager and the establishment of a multidisciplinary steering group /programme board including NHS England representation and has terms of reference and record of meetings

- 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 screening 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 is all pregnant women, irrespective if they have been screened in previous pregnancies.

There may be no need to screen for an existing condition where the woman is already known to be hepatitis B or HIV positive. This should be appropriately evidenced and documented. In these circumstances arrangements should be made for prompt clinical referral and assessment.

3.5. Location(s) of programme delivery

The provider will ensure appropriate accessible service provision for the population whilst assuring that all locations where IDPS screening occurs fully comply with the policies, standards and guidelines referenced in this service specification.

3.6. Days/Hours of operation

The days and hours of operation are to be determined locally and must ensure sufficient resources are in place to meet screening demand within required timescales without

compromising relevant standards and guidelines. However, timeliness is essential and is a key criterion of quality along all parts of the screening pathway.

3.7. Entry into the screening programme

All women will be identified through maternity services. While there is nothing specific in the general practitioner (GP) contract regarding the IDPS screening programme, GPs have a key role in ensuring that pregnant women presenting to them are referred on as soon as possible to midwifery services. Providers will ensure timely access for women to all aspects of the screening programme.

3.8. Working across interfaces between departments and organisations

The screening programme is dependent on strong functioning working relationships, both formal and informal, between primary care, the hospital trust (maternity services), the screening and referral laboratories, specialist Genitourinary Medicine (GUM); Hepatology and HIV specialities; paediatrics, Health Protection Units and PHE Centres and laboratories and other appropriate 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 be expected to fully contribute to ensuring that cross organisational systems are in place to maintain the quality of the entire screening pathway. This will include, but is not limited to:

- work to nationally agree programme standards, policies and guidance
- ensuring that midwives are supported to facilitate early booking for maternity care within primary and community care settings
- provide strong clinical leadership and clear lines of accountability
- agree and document roles and responsibilities relating to all elements of the screening pathway across organisations to assure appropriate handover arrangements are in place between services
- develop joint audit and monitoring processes
- agree jointly on the failsafe mechanisms required to ensure safe and timely processes across the whole screening pathway
- develop an escalation process for screening incidents (SIs)

- contribute to any NHS England initiatives in screening pathway development in line with UKNSC expectations
- facilitate education and training both inside and outside the provider organisation

3.9. Information on Test/ Screening Programme

Prior to any screening offer, the midwife will provide verbal and written information regarding screening utilising the approved UK NSC booklet 'Screening Tests for You and Your Baby' as a guide for discussion. Where there are specific communication requirements (e.g. English is not the woman's first language, visual/hearing impairment) appropriate interpretation services should be used during the booking appointment and appropriate information provided. All women, including those with special requirements, will be fully informed of the choices regarding all antenatal screening programmes.

The information should be impartially presented and should include an explanation of the limitations of the screening test. The decision to consent to screening or to decline should be recorded appropriately.

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

All IDPS laboratories are required to:

- follow the guidance set out in the IDPS laboratory handbook
- comply with the IDPS programme standards
- be CPA accredited and participate in external quality assurance schemes (i.e. NEQAS)

3.11. Results giving, reporting and recording

Screening results should be explained to women by appropriately trained staff and recorded in the woman's health records/IT systems.

See section 2.2 for further detail.

3.12. Transfer of and discharge from care obligations

Active inclusion in the screening programme ends at three points depending on the woman's result:

- when the screening result is negative for HIV, hepatitis B and syphilis, and non-susceptible for rubella
- when the woman has a screen positive result for HIV, hepatitis B or syphilis and arrangements have been made for referral to an appropriate specialist and they have been seen. Non-attendance at the specialist appointment should be reviewed within a multi-disciplinary framework and a management/action plan developed
- when the woman has a rubella-susceptible result and is offered post-natal MMR to protect future pregnancies

3.13. Public information

Providers must always use the nationally-developed public information leaflets at all stages of the screening pathway to ensure accurate messages about the risks and benefits of screening and any subsequent surveillance or treatment are provided and should involve the national screening team before developing any other materials.

Providers must involve the national screening team in the development of local publicity campaigns to ensure accurate and consistent messaging, particularly around informed choice, and to access nationally-developed resources.

3.14. Exclusion criteria

All pregnant women should be offered screening for the four infections.

There may be no need to screen for an existing condition where the woman is already known to be hepatitis B or HIV positive. This should be appropriately evidenced and documented. In these circumstances arrangements should be made for prompt clinical referral and assessment.

3.15. Staffing

The provider will ensure that they have a Screening Midwife/Coordinator (and deputies) in place to oversee the screening programme, supported by appropriate administrative support to ensure timely reporting and response to requests for information.

Providers are responsible for funding minimum training requirements to maintain an effective screening workforce including CPD where necessary. Training standards are detailed at http://infectiousdiseases.screening.nhs.uk/

Providers should ensure training has been completed satisfactorily and recorded and that there is a system in place to assess on-going competency.

The provider will ensure that there are adequate numbers of appropriately trained staff in place to deliver the screening programme in line with best practice guidelines.

3.16. User involvement

The provider(s) will be expected to:

- demonstrate that they regularly seek out the views of service users, families and others in respect of planning, implementing and delivering services
- demonstrate how those views will influence service delivery for the purposes of raising standards
- make results of any user surveys/questionnaires available to NHS England on request

3.17. Premises and equipment

The provider will:

- ensure that suitable premises and equipment are provided for the screening programme
- have appropriate polices in place for equipment calibration and electronic safety checks, maintenance, repair and replacement in accordance with manufacturer specification to ensure programme sustainability
- ensure that equipment meets the European Council Directive, enforced by the Medicines and Healthcare Regulatory Agency, to ensure that it is safe and effective to use

3.18. 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/nhs-standard-contract/

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 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 mechanisms are in place to regularly audit implementation of risk reduction measures and report incidents
- ensure that risks are reported through internal governance arrangements, such as risk registers
- 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

High scoring risks will be identified and agreed between the provider and the commissioners and plans put in place to mitigate against them.

4.3. Quality assurance

Providers will participate fully in national Quality Assurance processes, co-operate in undertaking ad-hoc audits and reviews as requested by QA teams and respond in a timely manner to their recommendations. This will include the submission to QA teams and commissioners of:

- agreed data and reports from external quality assurance schemes
- minimum data sets as required

- self-assessment questionnaires / tools and associated evidence

Laboratories undertaking screening should:

- be accredited by UKAS / CPA or equivalent and list the screening tests in their repertoire of services (http://www.UKAS.co.uk/)
- participate in an accredited external quality assurance scheme for IDP screening. e.g. UKNEQAS scheme and respond within agreed timescales
- Make available timely data and reports from external quality assurance programmes and accreditation services to QA, national screening programmes and commissioners within agreed timescales
- All providers should operate failsafe systems that can identify, as early as possible, women and babies that may have been missed or where screening results are incomplete

Providers will respond to QA recommendations within agreed timescales. They will produce with agreement of commissioners of the service an action plan to address areas for improvement that have been identified in recommendations. Where QA believe there is a significant risk of harm to the population, they can recommend to commissioners to suspend a service.

4.4. Safety concerns, safety incidents and serious incidents

Providers will comply with the national guidance for the management of safety concerns and incidents in screening programmes and NHS England guidance for the management of serious incidents (http://www.screening.nhs.uk/incidents).

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. 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.

Section 5: Data Monitoring

5.1. Key performance indicators

The provider shall adhere to the requirements specified in the document 'Key Performance Indicators for Screening'. Please refer to http://www.screening.nhs.uk/kpi or further details, guidance and updates on these indicators.

5.2. Data collection monitoring

Providers should:

- ensure that appropriate systems are in place to support programme delivery including audit and monitoring functions
- continually monitor and collect data regarding its delivery of the service
- comply with the timely data requirements of the national screening programmes and regional Quality Assurance teams. This will include the production of annual reports. The most up to date dataset can be accessed from the national screening programme website

For quality and monitoring, information should be shared with:

- UK NSC commissioned national screening audits e.g. :
  - National Study of HIV in Pregnancy and Childhood (NSHPC) www.ucl.ac.uk/nshpc
  - UK NSC National Hepatitis B in Pregnancy Audit http://infectiousdiseases.screening.nhs.uk/hepbaudit
  - British Paediatric Surveillance Unit http://www.rcpch.ac.uk/what-we-do/british-paediatric-surveillance-unit/british-paediatric-surveillance-unit
- the National Congenital Anomaly and Rare Disease Registration Service
- the PHE National Antenatal Infection Screening Monitoring (NAISM) Programme

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

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.

5.3. Public Health Outcomes Framework Indicators

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.

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 ≥ 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)

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/256502/nhs_public_health_functions_agreement_2014-15.pdf