

NHS public health functions agreement 2016-17

Service specification no.15

NHS Infectious Diseases in Pregnancy Screening
Programme

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Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

NHS public health functions agreement 2016-17

Service specification no.15

NHS Infectious Diseases in Pregnancy Screening Programme

Prepared by Public Health England

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This is a service specification to accompany the 'NHS public health functions agreement 2016-17 (the '2016-17 agreement') published in December 2015.

This service specification is to be applied by NHS England in accordance with the 2016-17 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 2016-17 agreement was made between the Secretary of State and NHS England Board, unless otherwise specified. Any changes in other published documents or standards may have effect for the purposes of the 2016-17 agreement in accordance with the procedures described in Chapter 3 of the 2016-17 agreement

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

The 2016-17 agreement is available at www.gov.uk (search for 'commissioning public health').

All current service specifications are available at www.england.nhs.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 NHS Screening Programmes.

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 Infectious diseases in pregnancy screening programme standards <https://www.gov.uk/government/publications/infectious-diseases-in-pregnancy-screening-programme-standards>
- IDPS Programme Handbook for Laboratories and Programme Handbook
- <https://www.gov.uk/topic/population-screening-programmes/infectious-diseases-in-pregnancy-screening-providing-services> Managing Serious Incidents in the English NHS National Screening Programmes
<http://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes>
- Infectious diseases in pregnancy screening programme: failsafe procedures <https://www.gov.uk/government/publications/infectious-diseases-in-pregnancy-screening-programme-failsafe-procedures>
- Guidance and updates on Key Performance Indicators (KPIs)
<http://www.gov.uk/government/collections/nhs-screening-programmes-national-data-reporting>
- DH Immunisation against Infectious Disease – the Green Book <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>
- Who pays for what?- Aspects of the Maternity Pathway Payment for the Screening and Immunisation Programmes June 2015
<https://www.england.nhs.uk/expo/wp-content/uploads/sites/18/2015/06/who-pays-mpp-upd-06-2015.pdf>

- 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
<https://www.nice.org.uk/guidance/cg165> British Viral Hepatitis Group (BVHG) Consensus Statement – UK guidelines for the management of babies born to women who are HBsAg positive
<http://www.basl.org.uk/microsites/bvhg/resources.cfm>
- British HIV Association (BHIVA) guidelines for the management of HIV infection in pregnant women 2012 (2014 interim review)
<http://bhiva.org/pregnancy-guidelines.aspx>
- UK National Guidelines on the Management of Syphilis 2008 (British Association of Sexual Health and HIV – BASHH)
<http://www.bashh.org/BASHH/Guidelines/Guidelines/BASHH/Guidelines/Guidelines.aspx?hkey=072c83ed-0e9b-44b2-a989-7c84e4fbd9de>
- National Institute for Health and Clinical Excellence (NICE) Clinical guideline 62 Antenatal care March 2008 <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 July 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 and syphilis.

From April 2016 antenatal screening for susceptibility to rubella infection should not be offered to women at antenatal booking.

<https://www.gov.uk/guidance/evidence-and-recommendations-nhs-population-screening>

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

1.4. Expected health outcomes

To reduce the risk of a mother-to-child transmission of HIV, hepatitis B and syphilis and to safeguard the woman's own health.

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 objectives of the screening programme should include:

Help reduce health inequalities through the delivery of the programme

Key deliverables:

- Screening should be delivered in a way which addresses local health inequalities, tailoring and targeting interventions when necessary
- A Health Equity Impact Assessment should be undertaken as part of both the commissioning and review of this screening programme, including equality characteristics, socio-economic factors and local vulnerable populations
- The service should be delivered in a culturally sensitive way to meet the needs of local diverse populations
- User involvement should include representation from service users with equality characteristics reflecting the local community including those with protected characteristics
- Providers should exercise high levels of diligence when considering excluding people with protected characteristics in their population from the programme and follow both equality, health inequality and screening guidance when making such decisions

The provider will be able to demonstrate what systems are in place to address health inequalities and ensure equity of access to screening, subsequent diagnostic testing and outcomes. This will include, for example, how the services are designed to ensure that there are no obstacles to access on the grounds of the nine protected characteristics as defined in the Equality Act 2010.

The provider will have procedures in place to identify and support those persons who are considered vulnerable/ hard-to-reach, including but not exclusive to, those who are not registered with a GP; homeless people and rough sleepers, asylum seekers, gypsy traveller groups and sex workers; those in prison; those with mental health problems; those with drug or alcohol harm issues; those with learning disabilities, physical disabilities or communications difficulties. The provider will comply with safeguarding policies and good practice recommendations for such persons.

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

Screening for HIV, hepatitis B and syphilis is part of the NHS Infectious Diseases in Pregnancy Screening (IDPS) Programme. In delivering a national screening programme and to ensure national consistency the local provider is expected to fulfill the following, in conjunction with guidance from the National Screening programme where appropriate and as detailed in the standards and policies available on

<https://www.gov.uk/government/collections/nhs-population-screening-programme-standards> and <https://www.gov.uk/guidance/evidence-and-recommendations-nhs-population-screening>

- 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
- provide data on screening outcomes as required by the national screening programme
- 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 women/babies 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

The pathways for each screening programme illustrate how the screening processes work, from contacting a person for screening onward (Figure 1).

<https://www.gov.uk/government/collections/nhs-population-screening-care-pathways>

The screening pathway correlates with the key themes of the Programme Standards:

- **Identify population-** the eligible population is all pregnant women identified through maternity antenatal care services. Women presenting after 20 weeks gestation; unbooked in labour or with no record of screening results should be included
- **Inform-** during the first antenatal contact or booking visit with the midwife, verbal and written information about the three infections and the benefits of screening for the woman and her unborn baby should be given to the woman (using NHS Screening Programmes booklet 'Screening Tests for You and Your Baby') to enable her to make an informed choice
- **Offer-** all women booking for antenatal care should be offered AND recommended screening for EACH of the three infections. The screening tests should not be offered as a suite of tests. Acceptance or decline for each of the individual screening tests should be documented in the patient held record / maternity notes (paper or electronic) and on the laboratory request form
 - **women who accept screening for all infections-** a blood sample should be taken in line with local protocols and sent to the laboratory with completed request form (paper or electronic) for analyses (in line with IDPS Laboratory Handbook and screening algorithms)
 - **women who decline screening for one or more infections-**
 - a blood sample should be taken for the screening tests accepted and sent to the laboratory with completed request form (paper or electronic) for analyses (in line with IDPS Laboratory Handbook and screening algorithms)
 - the laboratory request form must clearly identify the specific infection(s) declined or decline of all the three infections
 - **known positive women (Hepatitis B or HIV)-**
 - women who disclose that they are positive for HIV or hepatitis B should be referred directly to the Multidisciplinary Team (MDT) as per locally agreed protocols
 - screening should be offered for the other infections and a blood sample taken if accepted and sent to the laboratory with completed request form (paper or electronic) for analyses (in line with IDPS Laboratory Handbook and screening algorithms)
 - some trusts may have an agreed local protocol to retest all known positive women as a failsafe process. If so, this must be recorded as

'positive status known' on the laboratory request form and reported accordingly to ensure timely referral to the MDT.

- all women should be offered screening for syphilis in every pregnancy regardless of previous testing and/or treatment

- screening can be offered and requested at any stage of pregnancy especially if the woman deems herself to be at risk; changes her sexual partner or identifies risk factors
- women who present in labour who have not been screened, or whose screening results are not available should be offered screening for the three infections and if accepted
 - a system should be in place to ensure that tests have been performed and that, where this has not happened, screening is offered prior to discharge from maternity services
 - blood samples should be tested urgently by the laboratory and an initial screening result dispatched as soon as possible to inform clinical care (see laboratory handbook)
 - point of care tests should not be used for routine screening purposes.
 - there should be robust processes in place to ensure all results are obtained, reported and managed appropriately
 - the Screening Coordinator / Specialist Midwives should be made aware of any woman screened on delivery suite/postnatal wards to ensure appropriate tracking and follow-up.

- **Test-** Laboratories should comply with British Standards Institution EN ISO 15189:2012 and the IDPS Screening Laboratory Handbook. Screening laboratories must be able to identify antenatal samples as distinct from other samples they receive and should be able to match these samples to a specific maternity service
 - the specimen should be clearly identified as an antenatal screening sample
 - the request form or electronic data fields should be compliant to the minimum dataset as indicated in the IDPS Laboratory Handbook.
 - a local failsafe protocol must be in place to ensure that all women who accept screening complete the testing pathway
 - local protocols should be in place between the laboratory and maternity service to facilitate communications and management of
 - incomplete information on the request form
 - requests for repeat samples- either inadequate samples or those requiring a two week repeat second sample to exclude recent infection
 - identified declines for one or more screening tests
 - known positive status women with HIV and hepatitis B.

- analysis should be undertaken in line with nationally agreed screening protocols and testing algorithms
- confirmatory testing **must** be undertaken on the screen positive specimen before the laboratory issues a report to maternity services. Indeterminate results should not be reported to maternity services.
- all confirmed screening test results should be issued by the laboratory and received by maternity services within specified timescales as per IDPS Standards.
- processes should be in place locally to identify and follow-up results that have not been received within the specified time period
- a report should be issued for every screening request form received by the laboratory
- the format of the laboratory report (whether written or verbal) should clearly specify whether the result is 'screen positive'; 'screen negative' ; known positive or decline
- 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

- **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 notifying the woman of her negative result should offer the woman sexual health advice and inform her 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:**
 - results should not be communicated to the maternity service until confirmatory tests are completed on the screening sample
 - the laboratory should directly inform the designated lead within the IDPS Multidisciplinary Team (e.g. Screening Coordinator / Specialist Midwife) 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
- **Women who miscarry or terminate their pregnancy following screening-** There should be a mechanism in place to ensure that all

Section 2: Scope of Screening Programme
women who miscarry or terminate their pregnancy after screening
receive their results, whether negative or positive:

- screen positive- the laboratory should notify the Screening Coordinator/team to facilitate appropriate onward referral into specialist services and close the maternity care episode
- screen negative- arrangements should be in place to notify the woman of her result by maternity services (see Screening Handbook)

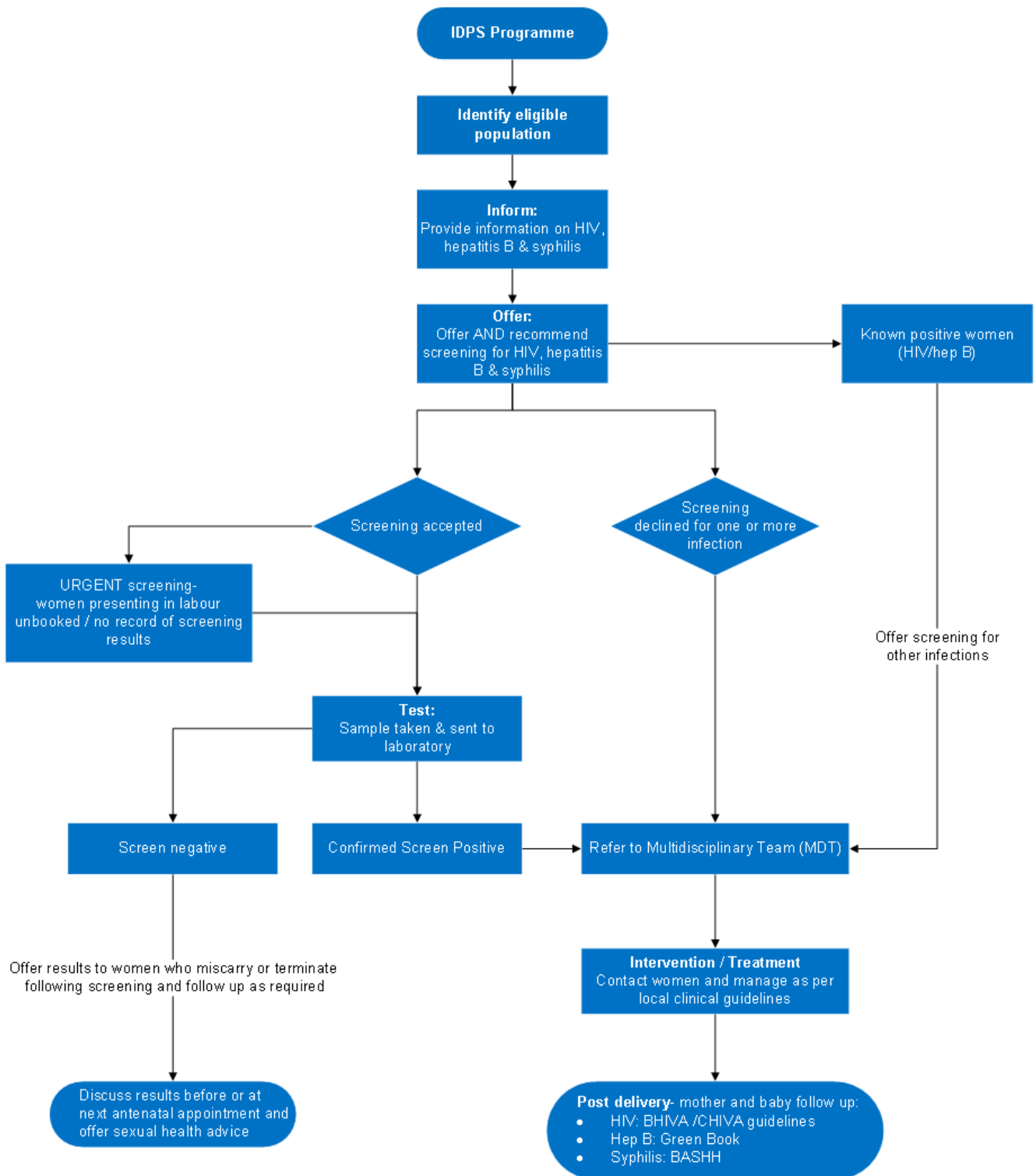
- **Intervention /Treatment**
 - **Generic-** for the three infections
 - women who are known positive (HIV or hepatitis B) or who have screened positive for any of the three infections should be contacted by the IDPS Multidisciplinary Team (MDT)
 - the time between initial contact with the woman and the appointment should be as short as possible to minimise the duration of any anxiety she is likely to experience
 - results should be discussed at a face-to-face consultation with a member of the MDT (Screening Coordinator or Clinical Nurse Specialist) at an appointment made for that purpose within agreed timescales (see IDPS standards)
 - a full assessment of the history of care for known positive women should be taken to ensure continuity of care and appropriate onward referral.
 - all women should have a full assessment of their needs including social circumstances and status of possible co-infections to ensure appropriate involvement of clinical expertise and other support agencies
 - non-attendance at the MDT appointment should be reviewed within a multidisciplinary framework and a management / action plan developed
 - **Condition specific-**a triage process should be in place in line with national clinical guidelines and locally agreed multidisciplinary protocols and pathways
 - HIV- appropriate referral to the specialist team coordinating the woman's HIV care in accordance with the BHIVA Guidelines
 - Hep B- further tests should be taken to assess hepatitis status according to local MDT protocol and determine appropriate referral to a hepatitis specialist
 - local arrangements should be in place to inform the Proper Officer (Health Protection Team [HPT]) of all screen positive results in line with 'Green Book' requirements. The woman must be informed of this statutory notification.

- ordering of the immunoglobulin, if required, should be coordinated by the MDT in line with local protocols. The immunoglobulin should be stored appropriately as a blood product, and be accessible and available when the woman is in labour to ensure administration to the neonate within 24 hours of birth (see IDPS standards). Administration or non-use of immunoglobulin should be recorded in the woman's records and notified to the MDT and the supplying laboratory at PHE Colindale.
- Syphilis- further tests may be undertaken by the MDT according to local protocols prior to referral to the GUM team for clinical assessment and review of test results to determine true syphilis status and requirement for treatment in accordance with BASHH Guidelines.
- **Management of women who decline one or more screening tests**
 - when a woman declines the screening test(s) the midwife who offered the initial screen should inform them that they will be contacted by a specialist midwife to discuss their choices
 - the woman should be contacted by the MDT (Screening Coordinator or Specialist Nurse) as soon as possible and ideally before 20 weeks gestation to:
 - discuss their decision to decline and ensure that they are fully apprised of the benefits of screening for IDPS for them and their baby
 - reoffer the screening test and arrange testing and follow up of result
 - if the woman declines the second formal reoffer of screening for one or more infections there should be a locally agreed protocol for management
 - the onus of the reoffer is to facilitate an informed choice and not to coerce women to accept
- **Postnatal / Newborn Care-** the neonate should be followed up in line with clinical guidelines and as highlighted in agreed MDT paediatric alerts and care plans
 - HIV- see BHIVA and CHIVA guidelines regarding follow up procedures
 - Hepatitis B

- ensure the vaccine (+/- HBIG) has been given within 24 hours of delivery and recorded in the specific Hep B page of the Parent Child Health record (PCHR)
 - ensure 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
 - ensure there is a process in place to notify the GP/Primary Care Team of the administration of the initial hepatitis B vaccine/immunoglobulin and the need to schedule further vaccinations/serology in line with Green Book guidance (see Screening Handbook)
 - ensure the mother is aware of the importance of the immunisation schedule
- Syphilis- to ensure paediatric assessment for babies born to women treated for syphilis in pregnancy before discharge from hospital in line with BASHH guidelines and that a follow up care pathway is in place.

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

Figure 1. NHS IDPS Screening Pathway



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 appropriate failsafe mechanisms in place across the whole screening pathway
- review and risk assess local screening pathways in the light of national IDPS programme guidance
- 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 routine staff training and development to maintain competencies

2.4. Roles and accountabilities through the screening pathway

The NHS IDPS programme is dependent on systematic specified relationships between stakeholders. Stakeholders include maternity services, the screening laboratory, reference laboratory, primary care/GPs/immunisation teams, Child Health Record Department, specialist services, and professional bodies who set guidance for management of infectious 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

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processes across the whole screening pathway

- contributing to any NHS England and public health screening lead initiatives in screening pathway development in line with NHS Screening Programmes expectations
- providing or seeking to provide robust electronic links with relevant organisations
- links with primary, secondary and tertiary care
- the need for robust IT systems across the screening pathway.

All Providers should have the following posts in place:

- a screening midwife/coordinator (and deputy) to oversee the screening programme and act as a link between other members of the IDPS Multidisciplinary Team.
- 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 Screening and Immunisation Teams; CCGs, and directly by maternity services.

Refer to 'Who pays for what? Aspects of Maternity Pathway Payment for the Screening and Immunisation Programmes'

<https://www.england.nhs.uk/expo/wp-content/uploads/sites/18/2015/06/who-pays-mpp-upd-06-2015.pdf>

2.6. Links between screening programme and national programme expertise

PHE, through the national screening programmes, is responsible for leading 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.

PHE will be responsible for delivery of the essential elements of screening programmes best done once at a national level. These include setting clear specifications for equipment, IT and data.

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 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 there is one or more named individuals responsible for the coordination of the delivery and planning of the programme, with 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 the organisation's clinical governance arrangements, the organisation's board is assured of the quality and integrity of the screening programme
- comply with the NHS Screening Programmes 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.

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 specialties; 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 UK NSC 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 NHS Screening programmes '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 (UKASS and UK 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
- 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 by the specialist team. Non-attendance at the specialist appointment should be reviewed within a multi-disciplinary framework and a management/action plan developed

3.13. Public information

- Providers must always use the patient information leaflets from PHE Screening 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. PHE Screening should be consulted and involved before developing any other supporting materials.
- Providers must involve PHE Screening and PHE Communications in the development of local publicity campaigns to ensure accurate and consistent messaging, particularly around informed choice, and to access nationally-developed resources. For local awareness campaigns, local contact details must be used.
- Providers must not develop their own information about screening for local NHS websites but should always link through to the national information on NHS Choices (<http://www.nhs.uk/Livewell/Screening/Pages/screening.aspx> or the relevant programme page) and GOV.UK (<https://www.gov.uk/topic/population-screening-programmes> or the relevant programme page).
- To support PHE Screening to carry out regular reviews of the national screening public information leaflets and online content, providers are encouraged to send PHE Screening the results of any local patient surveys which contain feedback on these national resources.

3.14. Exclusion criteria

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

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 must facilitate screener training in line with programme requirements/standards as detailed in each NHS screening programme specification. Providers should ensure training has been completed satisfactorily and recorded and that they have a system in place to assess on-going competency.

Providers must allow appropriate annual CPD in line with programme and requirements, for example a screening study day or completion of national NHS Screening Programme e-learning.

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 policies 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

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 population screening website.

<https://www.gov.uk/government/collections/nhs-population-screening-programme-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 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 Screening Quality Assurance Service (SQAS) 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 SQAS teams and respond in a timely manner to their recommendations. This will include the submission to SQAS 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 must:

- be accredited by United Kingdom Accreditation Service
- participate in accredited external quality assurance scheme for programme screening, e.g. UKNEQAS and respond within agreed timescales
- make available timely data and reports from external quality assurance programmes and accreditation services to SQAS, national screening programmes and commissioners
- operate failsafe systems that can identify, as early as possible, women and babies that may have been missed or where screening results are incomplete
- be able to identify antenatal samples as distinct from other samples they receive and should be able to match these samples to a specific maternity service.

Providers will respond to SQAS 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 SQAS 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 <https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes>

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

Section 4: Service Standards, Risks and Quality Assurance

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.gov.uk/government/collections/nhs-screening-programmes-national-data-reporting> for 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:

- NHS IDPS Programme commissioned national screening audits e.g. :
 - National Study of HIV in Pregnancy and Childhood (NSHPC) www.ucl.ac.uk/nshpc
 - National Hepatitis B in Pregnancy Audit <https://www.gov.uk/guidance/infectious-diseases-in-pregnancy-screening-programme-overview>
 - 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 Programme <https://www.gov.uk/guidance/infectious-diseases-during-pregnancy-screening-vaccination-and-treatment>

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 $\geq 90\%$
- 2012-13 national baseline is 98.1%

The 2003 Standards set an initial coverage target of 90% for HIV that was carried over into the 2010 standards. This has been amended based on 2013 NAISM data to reflect uptake of $\geq 95\%$ as a reference point for all infectious diseases screened in pregnancy (HIV, hepatitis B and syphilis).

- Acceptable level: $\geq 90.0\%$
- Achievable level: $\geq 95.0\%$

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