Public Health England

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NHS public health functions agreement 2019-20

Service specification No.15
NHS Infectious Diseases in Pregnancy Screening Programme

NHS England and NHS Improvement

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Promoting equality and addressing health inequalities are at the heart of NHS England and NHS Improvement 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 and those who do not share it (as required under the Equality Act 2010); and
- Given due 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 (in accordance with the duties under sections 13G and 13N of the NHS Act 2006, as amended).

Contents

Service specification No.15

This is a service specification to accompany the ‘NHS public health functions agreement 2019-20 (the ‘2019-20 agreement’).

This service specification is to be applied by NHS England and NHS Improvement in accordance with the 2019-20 agreement. 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 2019-20 agreement was made between the Secretary of State and NHS England and NHS Improvement Board, unless otherwise specified. Any changes in other published documents or standards may have effect for the purposes of the 2019-20 agreement in accordance with the procedures described in Chapter 3 of the 2019-20 agreement.

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

The 2019-20 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

A common national service specification must be used to provide, monitor and govern the NHS Infectious Diseases in Pregnancy Screening Programme (IDPS) Programme. This enables a consistent and equitable approach across England.

The purpose of the service specification for the IDPS Programme is to outline the service and quality indicators expected by NHS England and NHS Improvement 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.

The role of PHE Screening

The national screening team in Public Health England (PHE Screening) provides expert advice and support to the NHS Screening Programme. It does those things which make sense to do once rather than by each individual screening service. This includes:

- developing and monitoring standards
- producing public information leaflets
- quality assurance of local screening services
- enabling accessible training and education

Providers should subscribe to the PHE Screening blog for the latest national news and updates. National documentation and guidance is published on GOV.UK.

This specification should be read in conjunction with:

- NHS Infectious diseases in pregnancy (IDPS) screening standards
- Antenatal and newborn screening key performance indicators (KPIs)
- IDPS programme laboratory handbook
- IDPS programme handbook
- Managing Safety Incidents in the NHS Screening Programmes
- IDPS: Checks and audits to improve quality and reduce risks
- PHE Immunisation against Infectious Disease Hepatitis B: the green book, chapter 18
- Guidance on the PHE Hepatitis B Antenatal Screening and Neonatal Immunisation Pathway
- PHE Guidance on viral rash in pregnancy
- PHE Pregnancy: How to protect you and your baby

- PHE Protecting your baby against hepatitis B leaflet
- 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. 2017update
- British Association for the Study of the Liver (BASL) British Viral Hepatitis Group (BVHG) Consensus Statement – UK guidelines for the management of babies born to women who are HBsAg positive 2008
- British HIV Association (BHIVA) guidelines for the management of HIV infection in pregnant women
- UK national guidelines on the management of syphilis 2015 (British Association of Sexual Health and HIV – BASHH)

1.2 Aims

The NHS Infectious Diseases in Pregnancy Screening Programme requires all pregnant women are offered AND recommended screening for hepatitis B, HIV and syphilis.

1.3 Objectives

- to reduce vertical (mother-to-child) transmission of hepatitis B, HIV and syphilis
- to make sure women with hepatitis B, HIV and syphilis are identified early in pregnancy to facilitate appropriate assessment and management of their health
- to facilitate appropriate neonatal referral and management

1.4 Expected health outcome

To reduce the vertical (mother-to-child) transmission of HIV, hepatitis B and syphilis by early detection, intervention and treatment to safeguard the health of the baby and the woman's own health.

1.5 Principles

- individuals will be treated with courtesy, respect and an understanding of their needs
- those participating in the IDPS Programme will have adequate information on the benefits and limitations to enable a personal 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 and accountability between the different providers of services in screening centres, primary care and secondary care

1.6 Personal informed choice

All screening is an individual choice. The UK NSC has published guidance for screening programmes in the 4 UK countries to follow. Everyone must be given the opportunity to make an informed choice about whether or not to be screened. The decision should be based on an understanding of:

- why they are being offered screening
- what happens during the test
- the benefits and risks of screening
- the potential outcomes (including types of result, further tests and treatment)
- what happens to their screening records

If someone is provided with the above information about the programme and chooses not to have screening, then this is a valid choice and must be respected.

1.7 Addressing inequalities and ensuring equal access to screening

Screening is inherently equitable because it is offered to all individuals within the eligible population. One of the objectives of the NHS Screening Programmes is to help reduce health inequalities. The PHE Screening inequalities strategy has more information.

Delivery of the screening programme contributes to reducing health inequalities and should include the following deliverables:

- screening should be delivered in a way which addresses local health inequalities, tailoring and targeting interventions when necessary
- a Health Equity Audit, or other appropriate public health tools, should be used to assess and address screening inequalities as part of both the commissioning and review of this screening programme 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 equality, health inequality and screening guidance when making such decisions

The provider will demonstrate they have systems in place to address health inequalities and make sure there is equity of access to screening, subsequent diagnostic testing and outcomes. This will include, for example, how the services are designed to make sure 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

Sharing personal information

Under the 2010 Equality Act, screening services are required to anticipate and prevent discrimination against people with learning disabilities.

The duty of care to share information can be as important as the duty to protect patient confidentiality. GPs and other health professionals should have the confidence to share relevant information with screening services in the best interests of their patients. For example, a GP may know that an individual with a learning disability requires accessible information about screening in easy read format or needs a longer than normal appointment slot.

See NHS England's information sharing policy for more detailed guidance.

PHE Screening's privacy notice has more information about how screening data is shared within the legal requirements, including those of the General Data Protection Regulation (GDPR).

Reasonable adjustments

Under the 2010 Equality Act, screening providers have a legal duty to make reasonable adjustments to make sure services are accessible to disabled people as well as everybody else.

Screening providers must follow the Accessible Information Standard by law. The standard aims to make sure that people who have a disability, impairment or sensory loss are provided with information they can easily read or understand with support, so they can communicate effectively with health and social care services.

As part of the Accessible Information Standard, screening providers must do 5 things.

1 Ask people if they have any information or communication needs, and find out how to meet their needs.

2 Record those needs clearly and in a set way.

3 Highlight or flag the person's file or notes so it is clear that they have information or communication needs and how to meet those needs.

4 Share information about people's information and communication needs with other providers of NHS and adult social care, when they have consent or permission to do so.

5 Take steps to ensure that people receive information which they can access and understand, and receive communication support if they need it.

National accessible information materials

PHE Screening has published national easy read versions of screening information leaflets and screening appointment letter templates.

Local screening providers should use these national materials when inviting individuals for screening who have been identified as needing information in an easy read format.

Large print and audio (MP3) versions of standard information leaflets are also available to download from GOV.UK for people with sight loss.

Local screening providers should send any individual requests for hard copy Braille versions of PHE Screening leaflets to the screening helpdesk.

Section 2: Scope of Screening Programme

2.1 Description of screening programme

The local provider is expected to follow guidance from the national screening programme. To make sure there is national consistency the provider should:

- work to national screening standards
- provide data and reports against programme standards and key performance indicators (KPIs) and other measures as requested by the national screening programme
- provide data on screening outcomes as required by the national screening programme
- make sure appropriate governance structures are in place
- take part in quality assurance (QA) processes and implement changes recommended by quality assurance including urgent suspension of services if required
- implement and monitor failsafe procedures and drive continuous quality improvement
- work with NHS England and NHS Improvement and the screening quality assurance service (SQAS) in reporting, investigating and managing screening safety incidents
- respond to national action/lessons, for example change of software, equipment or equipment supplier or new technologies
- make sure all health care professionals access appropriate training to maintain continuous professional development and competency
- use materials provided by the national screening programme, for example leaflets, e-learning resources and operational guidance
- implement and support national IT developments

Screening for HIV, hepatitis B and syphilis is part of the NHS Infectious Diseases in Pregnancy Screening (IDPS) Programme.

HIV:

- vertical transmission of HIV is now rare in the UK following the widespread implementation of antenatal screening, antiretroviral treatment in pregnancy and avoidance of breastfeeding
- the risk of vertical HIV transmission in an untreated woman in pregnancy is around 25%. However, with early diagnosis, effective treatment and subsequent viral suppression, the risk of transmission is now very low (under 0.5%)

Hepatitis B:

- babies born to mothers with hepatitis B are at higher chance of acquiring HBV

infection, particularly if the mother has a high level of HBV DNA (viral load)

- the risk of transmission depends on the status of the maternal infection
- without intervention, 70 to 90% of mothers who have higher infectivity will pass the infection to their baby compared to a 10% risk for mothers who have lower infectivity
- perinatal transmission can result in an acute or chronic infection, but babies have a much higher chance of being chronically infected
- without vaccination, 95% will have a sub-clinical infection (rather than acute hepatitis) and many become chronic carriers for life
- the development of chronic infection after perinatal transmission can be prevented in over 90% of cases by timely vaccination (hepatitis B vaccine +/- hepatitis B immunoglobulin (HBIG)).

Syphilis:

- may be transmitted transplacentally at any stage of pregnancy and may result in miscarriage, pre-term labour, stillbirth, and congenital syphilis (CS)
- untreated CS can result in physical and neurological impairments affecting the child's bones, teeth, vision and hearing
- CS can be prevented with early diagnosis and treatment of the mother
- all women who screen positive need a comprehensive sexual health assessment and examination by the genitourinary medicine (GUM) team

2.2 Screening pathway

Providers must be familiar with the screening pathway and the timeframes in which to refer women (Figure 1).

The screening pathway consists of the following:

Identify population- the eligible population is all pregnant women identified through maternity antenatal care services. All providers should have a process in place in all departments, such as maternity assessment units, gynaecology wards and delivery suites to manage women who book late or present with no reliable documentation of their screening result from a laboratory accredited by the UK Accreditation Service (UKAS)

- **Inform -** during the first contact or booking visit with the midwife, verbal and written information about screening should be given to the woman using the Public Health England(PHE) booklet 'Screening Tests for You and Your Baby' to enable her to make a personal informed choice
- **Offer -** all eligible women should be offered AND recommended screening separately for EACH of the three infections, HIV, hepatitis B and syphilis in every pregnancy, irrespective of any previous results.
- If the woman changes care provider during the pregnancy it is not necessary to repeat the screening tests if the results are from a laboratory accredited by the UK Accreditation Service (UKAS)

- The offer and recommendation of screening and subsequent acceptance or decline for each of the individual screening tests must be documented in the patient held record / maternity notes (paper or electronic) and on the laboratory request (paper and/or electronic)
- **women who accept screening for all three infections -** a blood sample should be taken as soon as possible in line with local protocols and sent to the laboratory with a completed request form (paper and/ or electronic) for analyses (in line with the testing algorithms in the IDPS Laboratory Handbook). Taking of the sample must not be delayed to coincide with other appointments or scan visits as this can delay potential treatment and care that could significantly impact on vertical transmission of infection from the mother to the child.
- **management of women who decline one or more screening tests -** there should be a local protocol in place to notify the screening coordinator/team directly if a woman declines any of the three infections offered to facilitate prompt follow up. This notification must be acknowledged on receipt.
- the midwife who offered the initial screen should inform the woman that she will be contacted by the screening coordinator/team as soon as possible to discuss their decision further (in line with the IDPS Screening Programme Handbook)
- the midwife should make sure a blood sample is taken for the test(s) accepted and sent to the laboratory with a complete request form, paper and/or electronic, clearly identifying the tests she has declined screening for a process should be in place for the Screening Coordinator/team to contact the woman as soon as possible after receipt of a decline notification to facilitate the formal reoffer of screening to the woman by 20 weeks gestation (or within 2 weeks if ≥24 weeks gestation)
- the purpose of the reoffer is to:
    - enable a discussion with a specialist health professional to facilitate an informed decision and not to coerce women to accept screening
    - discuss her decision to decline and ensure that she is fully apprised of the benefits of screening for her, her baby and her partner and other children
    - reoffer the screening test(s) and if accepted arrange testing and follow up of the result
- if the woman declines the second formal reoffer of screening the local multidisciplinary team clinicians will be responsible for further management in line with local protocols
- **known positive women (Hepatitis B or HIV) -** women should be offered and recommended screening in every pregnancy, irrespective of their previous result. This is to:
    - ensure there is a current result on the providers laboratory and maternity IT systems
    - reduce the risk of missed entry into the care pathway

    - ensure the woman receives updated information on her condition, current care and treatment options and support services and resources available
- if the woman declines screening she should be referred directly to the Screening Coordinator/team and receipt of notification acknowledged. She should be seen for assessment by the Screening Coordinator/team within 10 working days of the known status being reported to maternity services (in line with IDPS screening standard 5 and the Programme and Laboratory Handbooks)
- 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 testing algorithms)
- all women should be offered screening for syphilis in every pregnancy regardless of previous testing and/or treatment
- **Sexual health and prevention of infections in pregnancy -** women should be advised on the availability of sexual health testing at any stage of pregnancy and to report any symptoms of genitourinal infection as soon as possible.
    - repeat tests should be recommended if women change their sexual partner, inject recreational drugs, are a sex worker, have a partner that is known to be bisexual, have a partner that is known to have HIV or hepatitis, or if either partner is diagnosed with an STI or requests a test
    - there should be a local protocol in place to ensure midwives utilise the PHE leaflet on vaccinations in pregnancy 'Pregnancy: How to protect you and your baby'.
    - at the booking visit midwives should discuss and promote vaccinations for pertussis and influenza and advise women to ensure they check their MMR status post-delivery.
    - midwives should advise women to report any rash or rash-like illness to their midwife or GP as soon as possible to facilitate appropriate management of viral rash in pregnancy as per PHE guidance. The woman should be advised to avoid any clinic setting or other pregnant women until she has been assessed
- **women who present in labour**
    - there should be a system in place to ensure that screening for HIV, hepatitis B and syphilis are offered, recommended and performed for all women who present in labour with no reliable laboratory evidence of screening results from a laboratory accredited by the UK Accreditation Service (UKAS)
    - the midwives on the delivery suite or in-patient department offering screening should ensure women are able to understand the rationale for the offer and recommendation of screening for infections and are in a position to exercise their personal informed choice

    - where this is not possible, screening should be offered and recommended to the woman prior to discharge from maternity services
    - the maternity service should liaise directly with the laboratory to ensure the laboratory has the clinical information required to prompt analyses 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 screening purposes
    - there should be robust processes in place to ensure all results are managed appropriately in a timely manner to expedite care and treatment for the mother and baby if required
    - the Screening Coordinator/team should be informed of any woman admitted to delivery suite/postnatal wards/in-patient services who were offered screening to support appropriate tracking and follow-up of results and care.
- **Test -** Laboratories should comply with the testing algorithms in 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
    - local failsafe protocols 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: incorrect or incomplete information on the request form so that all required identifiers and information to support timely analyses can be provided
    - requests for repeat samples- either inadequate or short samples or those requiring a two week repeat second sample to exclude recent infection
    - identified declines for one or more screening tests
- analysis should be undertaken in line with testing algorithms in the IDPS Laboratory Handbook
    - provisional results should not be reported to maternity services before the full confirmatory testing has been undertaken
    - all confirmed screening test results should be issued by the laboratory and received by maternity services within specified timescales as per IDPS Standards (Standard 4- laboratory turnaround time)
    - processes should be in place locally to identify and follow-up results that have not been received within the specified time period

    - a result should be issued for each screening sample received by the laboratory
    - the format of the laboratory report (whether written or verbal) should clearly specify whether the result is ‘positive’; ‘negative’; known positive or decline (see IDPS Laboratory Handbook)
    - local protocols should be in place between the laboratory and maternity provider to ensure results are communicated within nationally set timescales/ standards. Processes should be in place to check these local protocols, as they are critical to ensure adequate and timely follow up of results and entry into treatment and care services
- **Management of results**
- **Negative results:**
    - all women should be notified of their screening test result as soon as possible / before or at the next antenatal visit, according to local protocol. The result should be documented in the health records
    - the healthcare professional notifying the woman of her negative result should inform the woman that she was negative at the time of testing and give the woman sexual health advice to protect herself from infections in pregnancy and report any symptoms or risk factors as soon as possible. She should be informed that repeat tests are recommended if women change their sexual partner, inject recreational drugs, are a sex worker, have a partner that is known to be bisexual, have a partner that is known to have HIV or hepatitis, or if either partner is diagnosed with an STI or requests a test (see IDPS Programme Handbook)
- **Positive results:**
    - results should not be communicated to the maternity service, either written or electronic, until confirmatory tests are completed on the screening sample (see IDPS Laboratory Handbook)
    - the laboratory should directly inform the designated lead within the IDPS Screening Team (e.g. Screening Coordinator / Specialist Midwife) of the positive result
    - a local protocol should be in place between the laboratory and maternity service to log notification and receipt of positive results
- **Inconclusive results**:
    - There should be an agreed process in place between the laboratory and screening coordinator/team to directly alert them to an inconclusive result and the need for a repeat sample within 2 weeks after the initial sample was taken to exclude recent infection (see Laboratory and Programme Handbooks)
- **Women who miscarry or terminate their pregnancy following screening -** There should be a local protocol in place to ensure that all women who miscarry or

terminate their pregnancy after screening receive their results and are followed up as required:

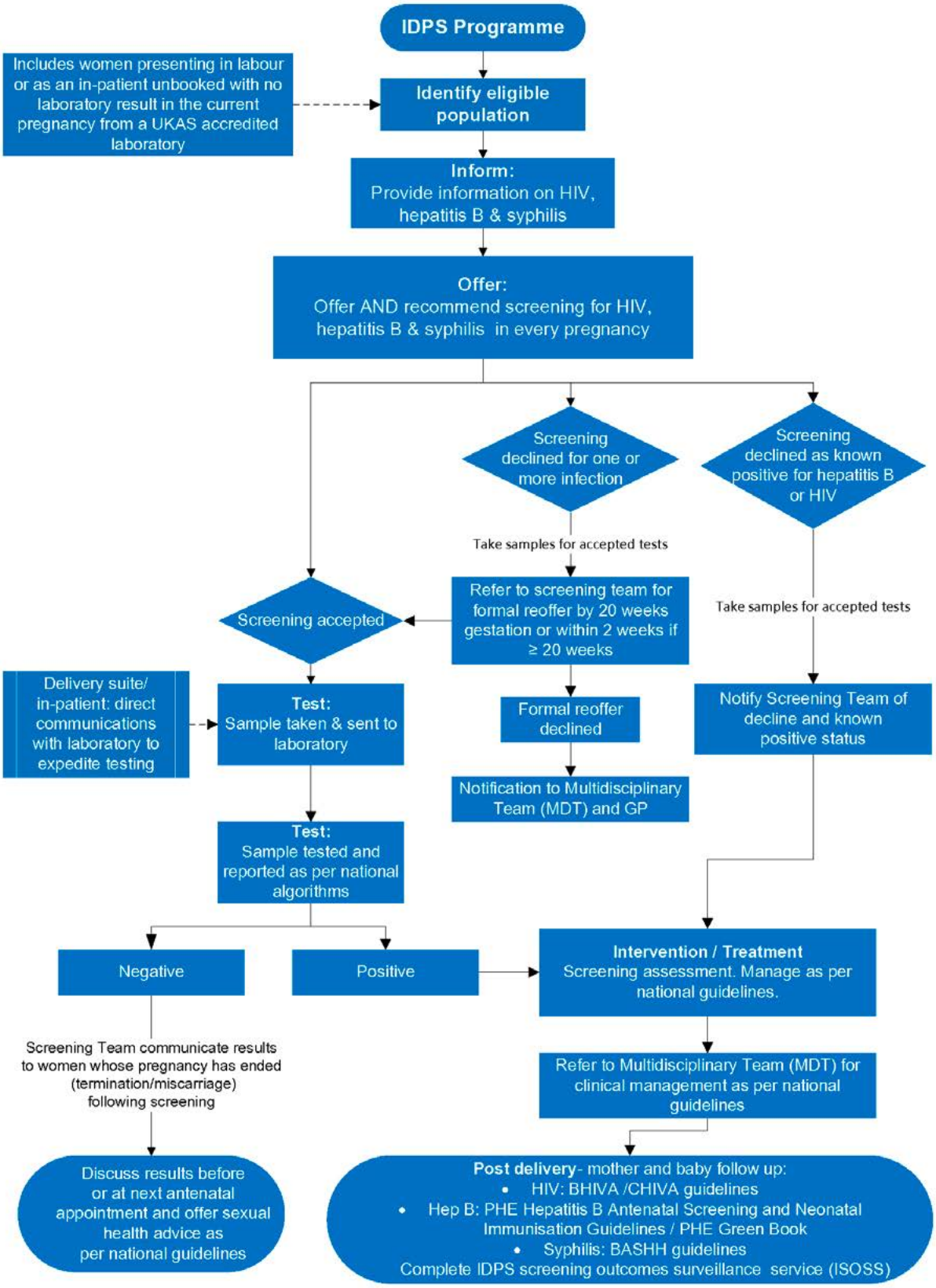
  - positive- the Screening Coordinator/team should liaise with the woman within 10 working days of the positive result to facilitate appropriate onward referral into specialist services and close the maternity care episode
  - negative- arrangements should be in place to notify the woman of her result by maternity services and close the maternity care episode (see Programme Handbook). A letter template is available for providers to use to support this process.

- **Intervention / Treatment**
- **Generic -** for the three infections
- women who have a positive result for any of the three infections should be invited to attend for screening assessment within 10 working days of the positive report being received from the laboratory (IDPS Standard 4)
- the purpose of this visit is to ensure the woman is seen by a specialist health professional to ensure she has a comprehensive assessment of her needs and is apprised on the current care and treatments for her condition and her baby and family
- 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 the Screening Coordinator / team (can include a Specialist Midwife or Clinical Nurse Specialist working to agreed local protocols), at an appointment made for that purpose within agreed timescales
- all women should have a full assessment of their needs including social circumstances and status of possible co-infections to ensure continuity of care and appropriate onward referral and appropriate involvement of clinical expertise and other support agencies
- non-attendance at the screening assessment 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 (see IDPS Programme Handbook)
- **HIV -** appropriate referral to the specialist team coordinating the woman's HIV care in accordance with the BHIVA Guidelines
- **hepatitis B -**
  - Protocols should be in place to ensure management of the woman, her partner and her family in accordance with PHE Hepatitis B Antenatal Screening and Neonatal Immunisation Pathway Guidelines, PHE Green Book and BASL British Viral Hepatitis Group (BVHG) clinical guidelines

- **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.
- **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 - to ensure there is a neonatal alert and plan in place for babies born to women with hepatitis B in line with PHE Hepatitis B Antenatal Screening and Neonatal Immunisation Pathway Guidelines and PHE Green Book
    - Syphilis - to ensure there is a neonatal alert and plan in place for 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 Screening Quality Assurance Service, and NHS England and NHS Improvement 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 Roles and accountability throughout the 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/health protection teams, Child Health Record Departments, specialist services, Children's universal public health services and professional bodies who set guidance for management of infectious diseases in pregnancy.

NHS England and NHS Improvement is expected to ensure that the whole pathway is robust. The provider is expected to make sure 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:

- providing robust screening coordination
- making sure 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
- operating an escalation process for screening incidents
- agreeing joint checks and audit mechanisms where required to ensure safe and timely processes across the whole screening pathway
- contributing to any NHS England and NHS Improvement and Public Health England 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

2.4 Commissioning arrangements

HIV, hepatitis B and syphilis screening services are commissioned by NHS England and NHS Improvement, alongside specialised services where appropriate. Commissioning of the screening service involves commissioning at different levels which may include NHS England and NHS Improvement public health commissioning, CCGs, specialist commissioning and directly by maternity services.

2.5 Links between screening programme and national programme expertise

PHE, through the national screening programmes, is responsible for defining high-quality, uniform screening, 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 is 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 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 and NHS Improvement should meet at regular intervals to monitor and review the local screening pathway. It is recommended that the meetings should include representatives from programme coordination, clinical services, laboratory services, service management and governance leads.

3.3 Governance and leadership

The provider will:

- cooperate with and have representation on local oversight arrangements as agreed with NHS England and NHS Improvement commissioners
- identify a trust director who is responsible for the screening programme
- ensure internal clinical oversight and governance by an identified clinical lead and a programme manager. The clinical lead has overall clinical responsibility and professional accountability for the programme across the pathway.
- provide documented evidence of clinical governance that includes:
    - compliance with NHS Trust and NHS England and NHS Improvement information governance/records management
    - user involvement, experience and complaints
    - failsafe procedures
    - risks and mitigation plans
- ensure that there is regular monitoring and audit of the screening programme, and as part of the organisation's clinical governance arrangements, the board is assured of the quality and integrity of the screening programme
- produce an annual report of screening services, which is signed off by the board

- ensure the programme is delivered by trained workforce that meet national requirements

3.4 Definition, identification and invitation of cohort/eligibility

The target population is all pregnant women identified through maternity antenatal care services - see Section 2.2.

3.5 Location(s) of programme delivery

The provider will make sure there is 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.

Providers must ensure there are local systems in place to support laboratory testing 24 hours a day, 7 days a week particularly for women presenting on delivery suite (see IDPS Laboratory Handbook)

3.7 Entry into the screening programme

All women are 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 Teams, Children's universal public health services 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 is expected to fully contribute to ensuring that cross organisational systems are in place to maintain the quality of the entire screening pathway.

3.9 Information on test/screening programme

Prior to any screening offer, the midwife will provide verbal and written information regarding screening utilising the PHE booklet 'Screening Tests for You and Your Baby' as a guide for discussion.

Where there are specific communication requirements, for example, English is not the woman's first language or she has a 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 accept or decline the offer and recommendation of screening should be recorded.

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

See Section 4. National standards, risks and quality assurance for further detail.

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 and IT system.

See section 2.2 Care Pathway for further detail.

3.12 Transfer of and discharge from care obligations

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

- when the screening result is negative for HIV, hepatitis B and syphilis
- when the woman has a 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

PHE Screening uses published best practice processes to develop public information leaflets. It also works with NHS Digital to ensure that information on the NHS.UK website for the public is accurate.

Providers must:

- use the public information leaflets from PHE Screening at all stages of the screening pathway
- involve PHE in the development of any local awareness campaigns
- not duplicate clinical information on local websites

- involve PHE if they want to move from providing printed leaflets to online sources of information

Using the leaflets provided by PHE ensures accurate messages about the risks and benefits of screening and any subsequent surveillance or treatment are provided. PHE Screening must be consulted and involved before developing any other supporting materials.

Providers must involve PHE 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 so that the national screening helpdesk is not over.

Local provider websites must not duplicate clinical information about screening but should be restricted to contact and logistical information. Links should be provided to the national information on NHS.UK (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.

Ordering leaflets

Providers can order leaflets developed by PHE Screening for free for core screening purposes.

Leaflets are regularly updated so providers should not order more than 3 months' supply, or stockpile leaflets, as they could become out of date and need to be destroyed. Leaflets for non-core activities, such as local health promotion purposes, can be bought from the national print provider.

PHE can only provide one leaflet per person per screening episode. A screening episode is defined as an invitation (with any subsequent reminders) for a particular screening test. People who are referred for further assessment following a screen should get a single copy of the appropriate follow-up leaflet.

Antenatal and newborn screening is treated as a single episode, so women should get a single copy of Screening Tests For You and Your Baby to last the entire antenatal and newborn period. (include this text for the ANNB programmes)

This means that duplicate copies should not be provided with reminder letters or if people lose or forget their leaflet. They should be signposted to electronic sources of information instead.

3.14 Exclusion criteria

All pregnant women should be offered and recommended screening for the three infections in every pregnancy regardless of any previous testing.

3.15 Staffing, education and training

PHE screening provides a variety of education and training for NHS screening staff. Evidence based, up-to-date e-learning resources, study days and courses can be

accessed here https://www.gov.uk/guidance/nhs-population-screening-education-and-training.

In addition, each screening programme will have specific guidance for the initial training and ongoing learning for screeners. This learning should be facilitated, supported and monitored by local screening providers. In line with professional regulations individuals have a responsibility to ensure their practice is up-to-date and evidence based. Local programmes can use the national programme training guidance and resources to support this.

Providers will have in place a dedicated screening coordinator/screening midwife (with appropriate deputy and administrative support arrangements to ensure continual cover) to oversee the implementation, delivery and monitoring of the screening programme in the antenatal, intrapartum and postnatal settings. These staff are also responsible for ensuring there is an on-going educational programme for health professionals involved in screening.

Providers are responsible for funding minimum training requirements to maintain an effective screening workforce including CPD where necessary. Training requirements are detailed in the IDPS Programme Handbook

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

3.16 User involvement

The provider(s) should:

- 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 and NHS Improvement 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 and 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 2015/16 NHS Standard Contract.

Section 4: National standards, risks and quality assurance

The provider will:

- meet the acceptable national screening standards and work towards attaining and maintaining the achievable standards
- adhere to specific professional standards and guidance
- maintain a register of risks, working with NHS England and NHS Improvement and quality assurance teams within Public Health England to identify areas of risk in the screening pathway, and make sure these points are reviewed in contracting and peer review processes
- participate fully in national quality assurance (QA) processes which includes:
    - submitting agreed minimum data sets and reports from external quality assurance schemes
    - undertaking audits and reviews as requested
    - completing self-assessment questionnaires / tools and associated evidence
    - responding to SQAS recommendations within agreed timescales providing specified evidence
    - producing with agreement of commissioners of the service an action plan to address areas for improvement that are identified in recommendations
- operate and evidence
    - check points that track individuals through the screening pathway
    - identify, as early as possible, individuals that may have missed screening, where screening results are incomplete or where referral has not happened
    - have process in place to mitigate against weakness in the pathway
- have arrangements in place to refer individuals to appropriate treatment services in a timely manner and these should meet national screening standards
- demonstrate that there are audited procedures, policies and protocols in place to make sure the screening programme consistently meets programme requirements
- comply with guidance on managing safety incidents in national screening programmes and NHS England and NHS Improvement serious incident framework
- make sure business continuity plans are in place where required
- make sure sub-contracts and/or service level agreements with other providers meet national standards and guidance
- all screening laboratories must
    - be accredited by the UK Accreditation Service (UKAS) to ISO. ‘Medical laboratories – Requirements for quality and competence (ISO 15189)’

- participate in EQA schemes accredited to ISO. ‘Conformity assessment. General requirements for proficiency testing schemes (ISO 17043)’
- meet the screening programme quality assurance requirements mapped to ISO 15189
- and use ISO 15189 accredited reference laboratories

The UK Accreditation Service (UKAS) will look at both ISO 15189 and the screening requirements on behalf of PHE Screening Quality Assurance Services and the national screening programme

Service improvement:

The provider will develop and agree with commissioners a Continual Service Improvement Plan (CSIP) in cases where national recommendations and/or screening standards are not fully met. The CSIP will include the following:

- action plans specifying changes and improvements that will be made during the contracting period
- defined timescales for actions
- roles and responsibilities for actions
- performance issues highlighted by the commissioners
- concerns raised by service users

New technologies:

New technologies should not be used for screening unless approved by the UK National Screening Committee.

Section 5: Data and Intelligence

The collection, analysis and comparison of good quality data is critical for the all NHS screening programmes in England.

PHE Screening aims to develop a consistent approach to data collection and reporting across all screening programmes and is committed to making sure that stakeholders have access to:

- reliable and timely information about the quality of the screening programme
- data at local, regional and national level
- quality measures across the screening pathway without gaps or duplications

Performance thresholds are selected to align with existing screening standards and service objectives; 1 or 2 thresholds are specified.

The acceptable threshold is the lowest level of performance which screening services are expected to attain to assure patient safety and service effectiveness. All screening services should exceed the acceptable threshold and agree service improvement plans to meet the achievable threshold. Screening services not meeting the acceptable threshold are expected to put in place recovery plans to deliver rapid and sustained improvement.

The achievable threshold represents the level at which the screening service is likely to be running optimally. All screening services should aspire to attain and maintain performance at or above this level.

5.1 Key performance indicators (KPIs) and screening standards

The provider should adhere to the requirements as specified on following web pages:

- KPIs: “Reporting data definitions” at https://www.gov.uk/topic/population-screening-programmes/population-screening-data-key-performance-indicators
- Screening standards: https://www.gov.uk/government/collections/nhs-population-screening-programme-standards

Please note that indictor definitions are updated regularly and you should always obtain the most recent version available.

5.2 Data collection, monitoring and reporting

Data must be shared with the IDPS Integrated Screening Outcomes Surveillance Service (ISOSS) on screening outcomes for HIV, hepatitis B and syphilis and congenital infections, including congenital syphilis and congenital rubella.

5.3 Public Health Outcomes Framework (PHOF)

PHE Screening contributes to “PHOF indicator 2.20 – National Screening Programmes”. Each screening programme reports on one or more sub-indicators.

IDPS screening contributes to PHOF with “HIV coverage”

Key performance indicators

The provider shall adhere to the requirements specified in the document 'PHE screening key performance indicators'. Please refer to http://www.gov.uk/government/collections/nhs-screening-programmes-national-data-reporting for further details, guidance and updates on these indicators.