

**NATIONAL PROTOCOLS**

**Programme:** Communicable diseases in pregnancy screening programme

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## Foreword

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Health Department Letter HDL (2001) 34<sup>1</sup> issued in April 2001, set out the steps required to standardise screening in Scotland for Down's syndrome and neural tube defects (NTDs), communicable diseases in pregnancy (hepatitis B, syphilis, rubella, Human Immunodeficiency Virus (HIV)) and the modernisation and development of the newborn bloodspot screening programme for Phenylketonuria (PKU) and Congenital Hypothyroidism (CHT). Further advice regarding the implementation of universal screening for HIV was outlined in HDL (2002)52<sup>2</sup>. In May 2016 CMO (2016)9 was issued outlining that screening for rubella susceptibility in pregnancy should cease from 1 June 2016 in response to a recommendation from the NSC in January 2016. It should be noted that for women booking and accepting screening prior to 1<sup>st</sup> June 2016 the previous pathway and protocol should be followed.

The screening programme for communicable diseases in pregnancy is designed to offer women the opportunity for early identification of hepatitis B, HIV and syphilis thus allowing management interventions to be offered to prevent mother to child transmission.

A Scottish multidisciplinary group has agreed to mirror the revised English infectious diseases in pregnancy screening programme documentation including their protocols and laboratory handbook in this composite document wherever applicable with the kind permission of the IDPS programme centre and the NSC.

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<sup>1</sup> Scottish Executive Health Department (2001) Antenatal screening for Down's syndrome and neonatal screening for phenylketonuria and congenital hypothyroidism. HDL (2001)34

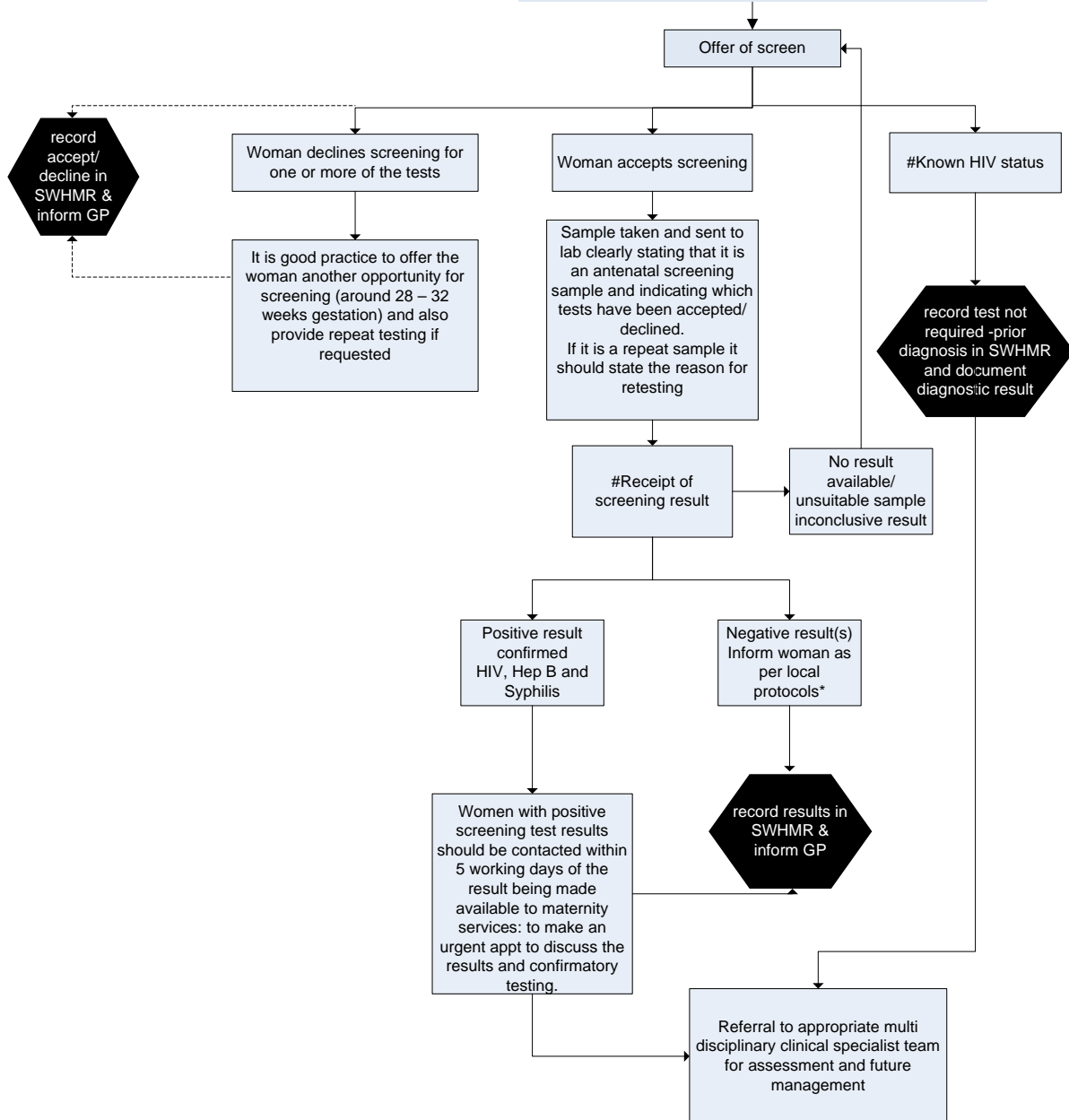
<sup>2</sup> Scottish Executive Health Department (2002) Offering HIV testing to women receiving antenatal care. HDL (2002)52

# Screening Pathway

## Patient Pathway: Screening for Communicable Diseases in Pregnancy

Screening to occur as early as possible during pregnancy, but can be done at any time, as soon as a woman arrives for care

Provide and discuss screening information, give 'your guide to screening tests during pregnancy' leaflet ideally 48 hours in advance of testing  
[www.healthscotland.com/pregnancynewborn](http://www.healthscotland.com/pregnancynewborn)



# It is the responsibility of the maternity service to have clear processes in place to ensure a result is received for each specimen sent, and that confirmation is received of prior diagnosis. These processes should detail who to contact within the laboratory service if no result is received/confirmed.

\*If the woman has disclosed ongoing risk factors it is best practice for the Health professional to offer repeat testing around 28-32 weeks gestation. Advice about risk of acquisition and avoidance of infection should be provided to women receiving negative test results. Information should also be provided on the availability of testing on request should the woman consider herself to be at risk at any point in the pregnancy.

# 1. Introduction

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This document contains standard national protocols for all healthcare professionals involved in the NHS Scotland screening programme for communicable diseases in pregnancy. In order to ensure equity of service across Scotland, NHS Boards are required to ensure that the screening service provided locally adheres to these protocols. The protocols support the ambitions of Scottish Government's Healthcare Quality Strategy for NHSScotland<sup>3</sup> of ensuring that the highest quality NHS healthcare services are delivered in Scotland by ensuring that effective screening, treatments, interventions, support and services are provided to women and their families, and ensuring that services provided are evidence based and appropriate.

Standard operating procedures and local protocols are not included in the document; these need to reflect specific local arrangements and therefore need to be produced and maintained locally.

## Hepatitis B

The aim of pregnancy screening is to contribute to the reduction of perinatal hepatitis B infection.

Hepatitis B is an infectious disease of the liver caused by the hepatitis B virus (HBV). It is transmitted through infected blood and other body fluids. Hepatitis B is transmitted through:

- Unprotected sexual activity
- Contaminated blood e.g. needle sharing
- Transmission from mother to child, which can occur in utero or during delivery.

The risk of perinatal transmission is dependent on the status of the maternal infection. About 70 - 90% of babies born to mothers who are positive for both HB surface antigen (HBsAg) and HB e-antigen will become chronically infected (without immunisation). The rate of chronic infection is less than 10% in babies born to women positive for HBsAg and antibody to e antigen (AntiHBe).

Infection can result in an acute or chronic infection. A chronic infection with HBV may result in cirrhosis of the liver and liver cancer. It is recognised that, without intervention, the earlier in life the infection occurs the greater the risk that it will lead to chronic infection, liver disease and early death.

Immunisation of the baby within 24 hours of delivery, and at 1, 2 and 12 months has been shown to be effective in preventing transmission of infection from mother to baby. In babies born to women with a higher risk of transmission, the addition of Hepatitis B Specific Immune Globulin (HBIG) can help reduce the risk further. With this strategy, transmission can be prevented in over 90% of babies exposed to maternal infection.

The objectives of the screening programme are to:

- ensure that all HBV positive women are identified
- provide counselling and support and where appropriate, testing and immunisation to the family
- refer all HBV positive women for assessment and management by an appropriate specialist (e.g. a hepatologist / gastroenterologist / infectious diseases specialist) within 6 weeks of the screening test result being received by maternity services even if the woman has already been referred previously and is being followed up/getting treatment as they may be unaware of her pregnancy and the management plan may need to be reviewed.
- ensure that the infant immunisation schedule is offered for their babies, that the first dose is administered within 24 hours of delivery and that arrangements for completion of the schedule are initiated.

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<sup>3</sup> Scottish Government (2010a) *The Healthcare Quality Strategy for NHSScotland*. Scottish Government, May 2010. Available from: <http://www.scotland.gov.uk/Publications/2010/05/10102307/8>

Assessment by an appropriate specialist provides a comprehensive evaluation of maternal infection, determines whether treatment in late pregnancy is indicated and further assesses risk of transmission and whether HBIG should be administered with the first dose of the infant immunisation schedule.

Assessment within this environment also provides an opportunity to discuss arrangements for notification of the infection and for testing family and other contacts.

A consensus statement on the management of HBV in pregnancy was developed by the British Viral Hepatitis Group (BVHG) in 2008 and this represents the first attempt to formalise practice in this area. The statement can be accessed at:

[http://www.basl.org.uk/uploaded\\_files/HBV%20in%20pregnancy.pdf](http://www.basl.org.uk/uploaded_files/HBV%20in%20pregnancy.pdf)

The European Association for the Study of the Liver have also produced guidelines which now incorporate advice on anti viral treatment in late pregnancy, 'Management of chronic hepatitis B' (2009). This can be accessed at:

[www.easl.eu/assets/application/files/b73c0da3c52fa1d\\_file.pdf](http://www.easl.eu/assets/application/files/b73c0da3c52fa1d_file.pdf)

Recommendations on the schedule and administration of the infant hepatitis B immunisation schedule can be found in the Department of Health publication 'Immunisation against infectious diseases – The Green Book' (2009). This can be accessed at:

<https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>

Regulations for notification of hepatitis B have been established in the Public Health etc (Scotland) Act 2008. This can be accessed at:

[http://www.legislation.gov.uk/asp/2008/5/pdfs/asp\\_20080005\\_en.pdf](http://www.legislation.gov.uk/asp/2008/5/pdfs/asp_20080005_en.pdf)

## **HIV**

The aim of antenatal screening is to contribute to the reduction of paediatric HIV infection.

Human Immunodeficiency Virus (HIV) is a blood borne virus. It is a retrovirus that infects and damages T-lymphocytes, resulting in immune suppression that eventually leads to acquired immune deficiency syndrome. Two forms of the virus have been identified, HIV-1 and HIV-2. The commonest and most virulent form is HIV-1 with HIV-2 being relatively uncommon in western countries.

HIV is transmitted through:

- Unprotected sexual activity
- Contaminated blood e.g. needle sharing
- Transmission from mother to child, which can occur in utero, during delivery or through breast feeding.

Pregnant women are offered screening for HIV infection so that interventions can be offered to reduce the risk of mother-to-child transmission of the virus, as well as to safeguard the woman's own health. Antiretroviral therapy, appropriate management of delivery and the avoidance of breast feeding can reduce the risk of mother-to-child transmission from 15 - 25% to 1% or less.

All pregnant women should be offered HIV screening in each pregnancy, unless they are already known to be HIV positive. The objectives of the screening programme are to:

- ensure that all HIV positive women are identified
- ensure the rapid referral of all women who are diagnosed as HIV positive for assessment and management within a multi-disciplinary team.
- provide counselling and support to the family

Guidelines for the management of HIV in pregnancy have been developed by the British HIV Association (BHIVA) and these represent best management practice. The guidelines can be accessed at <http://www.bhiva.org/cms1191540.asp>

In addition, Healthcare Improvement Scotland (HIS) has developed clinical standards for HIV services these were published in July 2011. Maternity and laboratory services must ensure they meet any applicable standards in relation to screening for HIV in pregnancy and any ongoing obstetric and neonatal care. The standards can be accessed here:

<http://www.healthcareimprovementscotland.org/his/idoc.ashx?docid=98cb70b3-3f2d-4ba2-8fb9-ba59a36f157e&version=-1>

Effective assessment and management of HIV in pregnancy, and any baby exposed to maternal HIV, should be undertaken within a multi disciplinary team (MDT) framework. This provides a comprehensive evaluation of maternal infection and determines how the pregnancy and delivery should be managed. It also provides an opportunity to reinforce health promotion advice and to discuss arrangements for partner notification and testing of previous children. The Scottish HIV testing algorithm can be accessed here:

<http://www.documents.hps.scot.nhs.uk/labs/bbv/scottish-hiv-testing-algorithm-referral-labs-2009.pdf>

## Syphilis

The aim of pregnancy screening is to contribute to the reduction of congenital syphilis infection.

Syphilis is an infectious disease caused by the *Treponema pallidum* bacterium. Syphilis is transmitted through:

- Unprotected sexual activity
- Transmission from mother to child, which can occur in utero or during delivery.

Acquired and congenital syphilis infection is staged according to the time from acquisition of the primary infection. The risk of transmission from mother to baby declines as maternal syphilis infection progresses. Risk ranges from 70 – 100% in primary syphilis, 40% in early latent syphilis and 10% in late latent syphilis.

Maternal syphilis infection can result in a range of adverse pregnancy and neonatal outcomes. These include late miscarriage, stillbirth, hydrops and low birth weight. If left untreated, congenital syphilis can result in physical and neurological impairments affecting the child's bones, teeth, vision and hearing. Congenital syphilis is a preventable condition but this depends on correct diagnosis and adequate treatment of the mother.

All pregnant women should be offered screening for syphilis early in each pregnancy regardless of the results of syphilis screening tests in previous pregnancies.

The objectives of the screening programme are to:

- identify all women with positive syphilis screening test results early in pregnancy,
- ensure women who are diagnosed with syphilis receive rapid assessment by an appropriate specialist, e.g. a Genitourinary Medicine (GUM) within a multi-disciplinary environment.
- provide counselling and support to the family

Assessment within an appropriate clinical environment provides a diagnostic evaluation of maternal infection and determines whether treatment and follow up are required. It also provides an opportunity to discuss arrangements for partner notification and management.

Guidelines for the assessment and management of syphilis in pregnancy and infancy have recently been developed by British Association for Sexual Health and HIV (BASHH) and these represent best management practice. The guidelines can be accessed at [www.bashh.org/guidelines](http://www.bashh.org/guidelines)

Effective assessment and management of syphilis in pregnancy, and that of the baby, should be undertaken within a multi disciplinary framework. This involves joint management by midwives obstetricians, specialist physicians (e.g. GUM physicians), and paediatric infectious disease specialists.

## 2. Offer of Screening

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The aim of offering screening in pregnancy is to offer women the opportunity for early identification of HBV, HIV, and syphilis, thus allowing management interventions to be offered to prevent mother to child transmission of HBV, HIV and syphilis. It is strongly recommended that screening be offered regardless of what gestation the women first presents, including in labour and postnatally, as there are still management options that can improve the wellbeing of the woman and baby if a positive diagnosis is made even late in pregnancy or in the postnatal period.

### 2.1 Responsibilities

NHS Scotland is responsible for ensuring that all pregnant women known to the service are provided with clear information in an appropriate format to help them make an informed choice about whether to take up any offer of screening. This should include the provision of an appropriate interpreter and written translated information where appropriate. In order for the woman to make an informed choice, the midwife should provide information on the following points:

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

Women should be informed that they will be contacted directly if the HBV, HIV or syphilis test is positive or needs to be repeated for any reason (e.g. insufficient sample, unclear result).

There are some responsibilities which rest with the woman herself including: the registration of pregnancy in time to access pregnancy screening and testing; making the decision whether to undergo screening and testing; provide accurate clinical information required for the accurate interpretation of the results; notifying the NHS if no result is provided within the agreed timeframe; and where offered, attending appointments for onward care.

Each Board should have in place a *Multi-Disciplinary Clinical Steering Group* to oversee the clinical management, governance and quality of the Boards pregnancy and newborn screening programmes.

The Multi-Disciplinary Steering Group should set out a comprehensive strategic plan for improving quality in accordance with the NHS Board's overall service developments; develop policies aimed at managing and reducing clinical risk and ensure inter-agency arrangements are in place to support women/couples through the screening and diagnostic pathways.

The group also has a responsibility for:

- Contributing to the development and implementation of screening and diagnostic care pathways in line with national standards and policies
- Ensuring that all care pathways are regularly reviewed and modified in line with the national programme's changing standards and policy
- Ensuring arrangements are in place for the audit of the pregnancy communicable diseases screening programmes and linking to an agreed quality assurance framework
- Providing a supportive framework for women who are identified as having a communicable disease through pregnancy screening
- Advising and supporting staff on pregnancy screening and diagnostic issues
- Communicating with primary care services



- Providing an ongoing education and training programme for staff offering screening and diagnostic testing to improve awareness and skills and reduce risk of serious untoward incidences
- Providing an annual screening report which reflects the national minimum audit criteria for the pregnancy communicable diseases screening programmes

## **2.2 Process**

All pregnant women attending an antenatal booking clinic, or being seen in the community, should be given sufficient information on the screening tests available in time to seek more information and make a decision whether to undergo testing. All women and their partners must be given the opportunity to discuss communicable diseases screening options with an appropriately trained professional. This should include the provision of an appropriate interpreter and written translated information where appropriate.

All women should be offered communicable disease screening regardless of their gestation, acknowledging that those being screened later in pregnancy may have fewer management options available than those booking at an earlier gestation. If the woman declines testing it is good practice to offer a further opportunity to undergo screening at around 28-32 weeks gestation. Additionally repeat testing should be offered to any woman at continuing risk of infection or any woman requesting a second or subsequent test at other points in the pregnancy.

The specimen should be clearly identified as a pregnancy screening sample. It is necessary to indicate which tests are being requested and, if relevant, which have been declined. All mandatory fields on the request form should be completed. The requester's identity should be clear. For example, where paper forms are used the requester's name should be printed and the form should be also signed by the requester.

NHS Boards should identify a designated senior midwife who is responsible for ensuring that:

- Every eligible woman is given the opportunity to be screened.
- Both a primary and failsafe mechanism is in place to ensure that a result is received for all women screened.
- Women have the opportunity to receive the results in writing with the offer of appropriate counselling and onward care into diagnostic pathways.

The host NHS Board of the antenatal clinic/community maternity service is responsible for the clinical governance of the service and for ensuring that:

- Every health professional involved in offering/performing a screening test is suitably qualified and trained.
- Every woman who presents for maternity care is offered screening for communicable diseases in pregnancy.
- Information on the offer made, whether or not it is accepted and the results of the screen and any diagnostic testing is recorded in SWHMR or equivalent and relevant maternity systems.

It should be noted that the maternity service should also have clear processes in place to ensure a result is received for each specimen sent, these processes should detail who to contact within the laboratory service if no result is received.

### **2.2.1 Women booking late for antenatal care**

For women booking at 24 weeks gestation or later blood samples should be marked 'urgent' and drawn to the attention of the testing laboratory as urgent by phone call or other method as agreed locally to undergo rapid analysis.

HIV test results should normally be received by the next working day of receipt of the specimen by the laboratory, or urgently if in labour. If positive, the woman should be referred immediately to the relevant specialist service for further assessment.

Short intervals between treatment and delivery are associated with an increased risk of mother to child transmission of HIV and syphilis despite the initiation of treatment of the maternal infection. There is a clinical need to ensure that women who require treatment receive it as promptly as possible and, consequently, to ensure that a clinical evaluation is not delayed.

### **2.2.2 Women presenting in labour who are not already booked for antenatal care**

Tests for the conditions are recommended for women arriving in labour who are not already booked for antenatal care.; Local arrangements for this should be clear and specified in the screening policy and pathways. The approach to offering the tests should be based on a case by case assessment. Considerations should include the stage of labour and risk factors specific to these infectious diseases.

For HIV refer to the British HIV Association guideline:

<http://www.bhiva.org/PregnantWomen2008.aspx>

For HBV refer to the Department of Health publication 'Immunisation against infectious diseases – The DH Green Book:

<https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>

Point of care tests should **not** be used for routine screening purposes, although there may be a place for such testing in the delivery suite for instances such as those above. Points of care tests should only be carried out with the approval and support of the local laboratory with respect to quality control and QA monitoring. The training and quality assurance procedures needed to ensure accurate results from point of care tests preclude their use for routine screening at the moment. A system should be in place to ensure that tests have been performed and that, where this has not happened, screening for all conditions is offered prior to discharge from maternity services.

### **2.3 Women already known to be HIV positive**

Where a prior positive diagnosis of HIV is documented and known to the healthcare professional this should be recorded and arrangements for prompt clinical evaluation made. It is essential that the current status of the infection is promptly assessed by an appropriate specialist to evaluate its implications for the care of the woman, the onward management of the pregnancy and care of the baby. If a woman presents for antenatal care with a previously diagnosed HIV infection, other screening tests should be offered as normal.

The midwife should ensure the woman is being managed within an appropriate multidisciplinary environment and that the team is aware of the pregnancy. Where this is not the case appropriate arrangements for referral should be made immediately. Discussion with the woman should cover the same issues as those at appointments to discuss positive screening test results.

These circumstances should be recorded as screening 'test not required – prior diagnoses' rather than 'declined'. The woman's infection status should be appropriately recorded as per NHS Board confidentiality guidelines.

### **2.4 Women already known to be HBV positive**

Even if the woman is known to be HBV positive and under appropriate clinical care, they should still be screened to allow for the current status of the infection in these women to be fully assessed by an appropriate specialist to enable the correct management of the pregnancy and the baby.

### 3. Consent for Screening

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Information should be made available taking into account of the woman's physical, cultural, ethical, educational and mental health needs at least 48 hours in advance of the screening tests, unless precluded by late presentation. This should include the provision of an appropriate interpreter and written translated information where appropriate.

Women and their partners should be provided with information about the implications of the screening tests. For communicable diseases screening in pregnancy, this should include: implications of receiving a positive result; information about the need to confirm positive results, the techniques involved and risks that may be associated with any diagnostic tests and also information about the conditions themselves. The potential implications of not being tested should also be presented to the woman.

Screening systems should be discussed as 'an option' rather than an inevitable aspect of routine maternity care, but it should be emphasised that they are strongly recommended. Women must be given sufficient time to make decisions whenever options are presented.

Where samples are being obtained, there should be information available about their storage and disposal. Should there be an interest in studying any excess material there should be a process for the woman to decline to give consent.

It is the responsibility of the health professional to ensure that the correct information is entered into all fields when completing a screening request form.

If a woman declines a screening or diagnostic test, this should also be recorded in the notes by healthcare professional responsible for her care. A protocol should be in place to allow women who have opted out of screening or diagnostic testing to change their mind and still undergo gestationally appropriate screening or testing at a later date.

Supplementary information, including relevant informative/supportive websites or details of support organisations, should be offered to all women receiving a positive screening or diagnostic test result, the patient information leaflet has a list of support organisations / additional sources of information. [www.healthscotland.com/pregnancynewborn](http://www.healthscotland.com/pregnancynewborn)

Professionals involved in screening for communicable diseases in pregnancy should work collaboratively with primary care and appropriate agencies such as: social services, voluntary sector support groups, religious bodies and bereavement services; in order to provide a comprehensive support network that is centred on the woman's needs and requests.

## 4. Screening for communicable diseases in pregnancy

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### 4.1 Organisational requirements

#### 4.1.1 Laboratory organisation

There must be an agreed local written policy which adheres to national standards to define the purpose of laboratory based assessment of risk of a communicable disease. The laboratory must have a standard operating procedure describing the process of laboratory testing from initial receipt of the specimen until dispatching of the report. There must be a documented risk management policy for the laboratory aspects of the service. This should describe the steps in the testing protocol where mistakes could occur and the procedures that have been implemented to minimise the risk of the mistake occurring.

Screening laboratories must be fully or conditionally accredited with a nationally approved accreditation scheme, such as United Kingdom Accreditation Service (UKAS), whose standards are based on an international standard (ISO 15189). There must be a named senior member of staff at medical consultant or clinical scientist consultant level accountable for the infectious diseases screening service, with defined levels of authority and clear lines of responsibility for all laboratory aspects of the service.

The Department of Health document 'Screening for infectious diseases in pregnancy - Standards to support the UK antenatal screening programme', updated in 2012, recommend that laboratories undertaking screening should perform a minimum of 1000 tests per year (per infection screened). Where small numbers affect the timeliness of reporting, centralisation may be an option. Laboratories that detect few screen positive cases should link with centres of expertise that can provide diagnostic support for presumed positive cases.

The initial screening test for all three infectious diseases should be performed in a single laboratory or within a single multidisciplinary pathology department. Positive results should only be reported on the initial screening specimen for HIV, HBV and syphilis following confirmation of the result using appropriate analytical methods by a competent laboratory with relevant expertise. Specimens for confirmatory tests may be sent to a reference laboratory or performed by the screening laboratory as long as quality and turnaround times are maintained. Interpretation of screen positive results and management advice should be available from laboratory staff with the required level of experience and competency.

The initial antenatal screening specimen for infectious diseases and the request form should be clearly identifiable from other types of requests. This is to ensure that work associated with the antenatal screening programme is not confused with work performed for other purposes.

If a screening specimen is confirmed as screen positive for HIV, HBV or syphilis, a second specimen should be taken to confirm the initial results and the woman's identity, and to perform additional diagnostic tests as agreed with the appropriate clinical speciality. A second specimen taken purely to confirm the original screening results prior to referral to clinical services is not considered necessary. Local policies should be in force to specify exactly how the woman will be referred to the appropriate clinical service and the mechanism for obtaining the second specimen. This second specimen could be taken in the maternity setting if there is a written protocol agreed with those specialist clinicians regarding which tests are required, or it could be taken in the specialist clinical area if there is an agreed referral pathway for the woman after the initial screening result is obtained. The results from the initial screening specimen and the confirmatory specimen should both be available to the specialist clinical services to avoid delays in treatment.

There should be clear processes in place in the laboratory to identify any outstanding tests on screening specimens that have been received by the laboratory and also to identify outstanding requests for repeat or confirmatory specimens. Although it is not the primary responsibility of the

laboratory to ensure that repeat or confirmatory specimens are taken, there should be local written policies in force describing the follow-up action to be taken if such a specimen has not been received in the laboratory within 10 working days of the request. Responsibility for collecting the repeat specimen would rest with the maternity service but the laboratory would provide a failsafe if the specimen was not forthcoming. The maternity service should also have clear processes in place to ensure a result is received for each specimen sent, these processes should detail who to contact within the laboratory service if no result is received. The number of unsatisfactory specimens and the reasons for them being unsatisfactory should be recorded and regularly audited and fed back to maternity services.

The laboratory must have standard operating procedures for the screening service, describing the process of laboratory testing from initial receipt of the specimen until dispatch of the report. These should form part of a set of local protocols and standard operating procedures for the whole of the screening pathway, including the pre-analytical, analytical and post-analytical phases. These should be developed collaboratively and should cross-refer to Board level protocols and pathways as appropriate. There must be a documented risk management policy for the laboratory aspects of the screening programme, describing the steps in the testing pathway where errors could occur and the procedures that have been taken to minimise the risk of the error occurring. This policy should be part of an overall risk management policy for the infectious disease screening programme in pregnancy.

The laboratory must agree to collect a minimum dataset of information for monitoring purposes. The laboratory must participate in audit of the screening service at local and national level and provide an annual report, or the necessary data for the preparation of an annual report. In the absence of universal or standardised maternity information systems, the laboratory information management system will be used as a repository of national aggregated data on the screening programme.

#### **4.1.2 Analytical Processes**

The screening laboratory must participate in an accredited External Quality Assessment Scheme (EQAS) appropriate for each of the screening tests and be able to demonstrate satisfactory performance as defined by the criteria specified by the EQA scheme organisers. The laboratory must use assays for screening that are CE marked, or comply with the UK standards for Microbiology Investigations – European Directive on In Vitro Diagnostic Medical Devices (98/79/EC)<sup>4</sup> in the case of the use of in-house reagents. Appropriate internal quality control procedures must be implemented when using any assay for screening purposes.

Samples and forms should be given a number and the details on the form entered into the screening database. The assigned number should be used to link sample, patient details and analytical results and appear on the final report.

The request form must contain fields which conform to the minimum dataset including:

- Patient identifying details (name, date of birth, Community Health Index (CHI) number)
- Hospital attended or other referral source.
- The date the sample was taken.
- Information on the pregnancy needed to interpret the screening results

The clinical meaning of the test results should be clearly stated on laboratory reports issued to maternity units.

After testing, any left over serum is stored in numbered tubes in a freezer bank to allow repeat analysis in the event of an analytical problem (these stored samples may also be used for quality control).

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<sup>4</sup> [http://www.hpa.org.uk/webc/HPAwebFile/HPAweb\\_C/1317131676211](http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317131676211)

Screening for the three infectious diseases should be undertaken using the nationally agreed screening protocols. Further details are given in the disease specific sections but in summary these are:-

**Hepatitis B (HBV)** - the initial screening test should have an analytical sensitivity of at least 0.05IU/ml HBsAg with a cut-off defining a diagnostic sensitivity of greater than 99.9% and a diagnostic specificity of greater than 99.5%. Confirmation of a positive result on the initial screening specimen should be performed by a neutralisation assay or a different HBsAg assay of equivalent analytical sensitivity. Initial assessment of infectivity should also be performed on the positive screening specimen. These tests should be undertaken in a laboratory competent at performing these specialist assays. A second specimen, taken within a specialist clinical environment is needed to confirm the initial results and the woman's identity, and complete the clinical evaluation of the woman.

**Human Immunodeficiency Virus (HIV)** - fourth generation screening assays which detect HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen should be used as these assays are now the standard of care in the UK. Confirmation of a positive result on the screening specimen should be performed using two further independent assays to confirm that the reactivity is specific for HIV. This should be done in a laboratory competent to perform HIV confirmatory testing. Confirmatory assays need to discriminate between HIV-1 and HIV-2 infections and be able to detect p24 antigen and thus identify acute infection.

**Syphilis** - the recommended method for the initial screening test is an enzyme immunoassay (EIA) for *Treponema pallidum*, which should be repeated on any positive specimen, (to check reproducibility), and confirmed using a *Treponema pallidum* particle agglutination (TPPA) or *Treponema pallidum* haemagglutination (TPHA) assay. Confirmation of a positive result on the screening specimen should be performed in a laboratory competent to perform confirmatory testing for syphilis.

#### 4.1.3 Confirmatory testing

For HBV, HIV and syphilis there is a requirement for appropriate confirmatory testing on the initial screen-positive screening specimen before the laboratory issues a report recommending maternity services recall a woman. Different approaches to confirmation are available, however it is recognised that sending specimens to referral laboratories involves delays with transporting specimens and receiving reports. It is recommended that if confirmatory tests need to be sent away, efficient transport systems and rapid reporting mechanisms are in place to ensure compliance with the turnaround times for results. A failsafe system should be in place by the laboratory to track samples sent to referral laboratories and to ensure all results are received. Turnaround times should be specified in any contracts between the referring and referral laboratories. Consideration should be given to centralising screening work in laboratories that have the necessary expertise and repertoire of tests (including confirmatory tests), and can analyse specimens sufficiently frequently to comply with the turnaround times for reporting.

#### 4.1.4 Specimen requirements

Ideally, a single specimen tube should be sent from the pregnant mother for all antenatal screening tests for communicable diseases in pregnancy, although some screening services may require more than one tube. The specimen of choice is serum obtained from a clotted blood sample. If clotting agents or gel separators are used their use should be validated for each of the analytical methods being used. The assay suppliers should be able to provide a list of the specimens suitable for use in their assays. If gel separators are not used, the serum should be removed from the clot by centrifugation as soon as practically possible and preferably within 24 hrs of the specimen being taken.

A 5-10ml blood specimen is typically required to allow for confirmatory testing and other diagnostic tests where necessary, however please see local protocol for sample requirements in your area.

Consideration should be given to the use of specimen tubes that can be used to allow primary sample handling on laboratory analysers, thus minimising the risk of an identification error. Storage of the blood without separation of the red cells and serum may result in haemolysis, which can interfere with the assays. Some assays are able to utilise plasma, as detailed in the product insert, but this is not normally recommended for routine screening specimens.

All specimens should be clearly marked with at least three identifiers e.g. the patient's full name, date of birth and CHI number, plus date and ideally the time that the specimen was taken. The specimen should be accompanied by a completed screening request form (or electronic request) clearly indicating that it is a pregnancy sample with the same patient identity and clear indications of which tests the mother has consented for, gestation at time sample taken and with the test requester's identity clearly indicated. There have been some difficulties in the past identifying screening specimens as opposed to routine, non-screening specimens. The use of a specific pregnancy screening request form would overcome that problem. Local policies must be in force giving details of the action to be undertaken by the laboratory if it is unclear whether consent to testing has been given, ensuring that any woman that has requested screening has the opportunity to have this carried out. The request form should also indicate the source of the request, e.g. hospital or clinic, and the location and contact telephone number to which results should be reported. Local protocols must also be in force for reporting positive and negative results and for obtaining repeat specimens where the initial specimen was unacceptable. It is also helpful to know the gestational age of the woman and who took the blood specimen, indicated on the request form or on the blood specimen itself. Screening specimens received after 24 weeks should be marked as urgent and drawn to the attention of the testing laboratory as urgent by phone call or other method as agreed locally and a result should be available to the requester by the next working day, or urgently if in labour. To audit the effectiveness of screening, the information should be recorded in a computerised format and be amenable to database searches.

## **4.2 Training and Education**

The NHS contribution to reducing health inequalities is highly dependant on effectively reaching and engaging with women as early as possible, particularly those women in high risk groups. Pregnancy screening supports early engagement and offers the opportunity to concurrently raise issues around the use of tobacco, drugs and alcohol and poor nutrition supporting women to have as healthy a pregnancy as possible as early as possible.

All those directly involved in the provision of pregnancy screening information or services should have a suitable induction to the programme and undertake regular updating in line with continuing professional development guidance for their profession including access to learning opportunities which support the knowledge skills and values necessary in the delivery of assets based and behavioural change approaches to care.

Additional training for more specific aspects of the programme such as specialist counselling for 'couples at higher chance' of an affected pregnancy should be made available if required.

## **4.3 Laboratory reports**

The report issued from the laboratory must contain information which conforms to the minimum data set which should include:

- The patient (name, date of birth, CHI number)
- Hospital or other referral source
- The date the sample was taken
- The report should also comment that the interpretation of the results is only correct provided the relevant information is correct.

Computer generated reports conforming to the agreed minimum dataset should be issued by each laboratory. If the initial screening tests and subsequent confirmatory testing are performed in the



same laboratory, the analytical service should be configured to enable a report, whether a screen negative or confirmed screen positive, to be dispatched from the laboratory (or to be available on electronic reporting systems) within 5 working days of receipt of the specimen. If confirmatory testing has to be referred to another laboratory, the time for reporting screen positive specimens may be extended to 8 working days to take account of the time taken to transport the specimen and receive the referral laboratory report. Over 95% of results should be available within 5 working days of receipt of the sample by the laboratory.

It is good laboratory practice to repeat the analysis on any specimens that have a positive screening result. This lessens the possibility of a laboratory error and increases the confidence that the result is correct. If repeating the test would hinder the turnaround time for reporting results or critically deplete the volume of specimen, (especially if it has to be sent away for further confirmatory tests), repeat testing may be omitted if the referral laboratory is prepared to analyse a specimen that has only been tested once.

All reports should be communicated to the referrer/deputy and on receipt; the details on the report should be checked. If any information is inaccurate, the laboratory should be contacted as soon as possible with the correct information before the woman is notified. The laboratory must comply with the relevant statutory regulations regarding the notification of infectious diseases.

All women should have the opportunity to receive the result in writing and for the report to be filed in the hand held notes. For those women who are identified as having a communicable disease the results should be given priority and telephoned or securely emailed to the referrer depending on prior arrangement between referrer and screening laboratory. There should be a robust system in place so that any results arriving at the agreed referral point can be identified immediately on their receipt. This will usually involve a phone call from the laboratory to the referrer/deputy indicating that a written/electronic report is on its way. E-mail systems should be secure and only accessible to the relevant staff.

Women who have undergone screening should have previously indicated how they would like to receive any higher chance result and had their preference documented in the hospital notes. The result should be communicated to the patient within 3 working days of it being received and an opportunity to attend for a diagnostic appointment given within a further 2 working days.

All reports should be retained in electronic format by each laboratory. It should be possible for information and results relating to individual pregnancies held on the laboratories' screening database to be accessed by telephone enquiry from an identifiable and verifiable source.

All laboratory documentation should be retained for appropriate periods of time and then disposed of as specified in the laboratory Standard Operating Procedure.

#### **4.4 Failsafe**

The screening offer and whether screening has been accepted, declined or whether known to be HIV/Hep B positive should be documented for all the conditions; this should be checked at the next contact with the mother. Screening should be re-offered to all women who decline the initial offer, ideally by 28 weeks gestation. Again documentation that the re-offer has been made should be checked at the next contact with the mother. There should be processes in place to ensure the blood samples are taken and safely and timeously transported to the lab, the use of an IT system to track this is preferable. There should be processes in place for regular checks of antenatal samples to cross check with maternity information. If the sample is not fit for purpose or does not clearly identify the requirements to screen there should be a standard operating procedure in place detailing actions between the lab and the maternity services with named healthcare professionals responsible to ensure appropriate screens are undertaken. All results should be sent by the screening laboratory to the referral source unless indicated otherwise. There should be a system in place to identify and follow-up results that have not been received within 10 working days, and specifically in preparation for the next antenatal visit. If no result has been received within the timeframe agreed with the screening laboratory, the laboratory should be contacted and should



provide a report as soon as possible. If no sample or request was received at the laboratory a repeat sample should be taken and sent to the laboratory as soon as possible. Additionally there should be two way cross-check processes in place to ensure that lab requests for repeat samples are identified and followed up. For women with a positive screening result there should be clear documentation of the date of receipt of the result, the date of the referral and the date of when the woman was seen by the relevant health professional. For negative results these should be reported back before or at the next antenatal visit according to local protocol, the date of the receipt of each condition tested for should be clearly documented. For women identified through screening or already known to be positive for Hepatitis B, the offer of vaccination for the baby and whether this has been accepted should be documented. If vaccination is accepted the first dose of the vaccine should be administered and documented and communication made to the primary care team responsible for ensuring the completion of the remaining vaccination schedule likely to be the paediatrician or ANNP who would give the immunisation and ensure child health are notified. The Child Health Record Department should also be informed. The importance of completing the full vaccination schedule should be emphasised to the mother. Where a mother has declined immunisation this should be communicated to the primary care team for follow up.

## **4.5 Organisational condition specific guidance**

### **4.5.1 Hepatitis B**

Even if the woman is known to be HBV positive and under appropriate clinical care, they should still be promptly referred to be fully assessed by an appropriate specialist to enable the correct management of the pregnancy and the baby.

The recommended screening test for hepatitis B is an immunoassay to detect hepatitis B surface antigen (HBsAg). This should have an analytical sensitivity of at least 0.05IU/ml and a cut off defining a diagnostic sensitivity of greater than 99.9% and a diagnostic specificity of greater than 99.5%. Screening assays that detect common escape mutations are to be preferred to minimise false negative results. The screening test is designed to detect women who have acute or chronic infection with HBV. Tests for HBsAg are very sensitive and may detect women who are in the early incubation phase of an infection. The further tests used to assess infectivity will identify such cases. No report should be issued until the confirmatory tests outlined below have been performed and a conclusion reached about the complete set of screening results. Interim reports and presumptive reports should not be issued as they can cause confusion and mislead recipients.

- **Confirmation of a positive screening test result**

All specimens that are positive for the HBsAg screening test should be confirmed using a neutralisation assay or an alternative HBsAg test of equivalent analytical sensitivity.

- **Assessment of infectivity**

Confirmed positive screening tests should be followed with an assessment of HBV infectivity on the initial specimen. This is the first step in a more comprehensive clinical evaluation of the pregnant woman which also determines whether the baby requires postnatal HBIG. At present this should be undertaken on the initial screening specimen as the pattern of referral to specialist services is uncertain in some areas. The screening programme will work with stakeholders to embed robust referral patterns into routine clinical practice.

Tests for the following markers should be performed on the initial screening specimen:

- AntiHBc (total)
- AntiHBc IgM
- HBeAg
- AntiHBe

AntiHBc (antibody to hepatitis B core antigen) is a marker of current or resolved HBV infection and can therefore 'support' though not necessarily 'confirm' the presence of HBsAg. AntiHBc IgM assays are used to give an indication whether the infection is acute or chronic.

In patients with chronic infection the presence of HBeAg (in addition to HBsAg) is a good predictor of the presence of a high level virus in the blood and hence the increased risk of passing on the infection to others. It also a predictor of a higher risk of developing the life threatening long term complications of hepatitis B, such as primary hepatocellular carcinoma. In patients with chronic hepatitis B AntiHBe indicates the presence of antibodies to the HBe antigen that have been produced in response to an infection. Those who are HBsAg positive and HBeAg negative (usually anti-HBe positive) are infectious but generally of lower infectivity. Recent evidence suggests that a proportion of chronically infected people who are HBeAg negative will have high levels of the virus in the blood, and may be more infectious.

AntiHBs (antibody to hepatitis B surface antigen) is a marker of immunity and not usually included in the repertoire of tests for assessment of infectivity after a positive screening test result. Its presence indicates an immune response to HBV infection; an immune response to vaccination, or the presence of passively acquired antibody.

The definitive test used to assess the level of virus in the blood is the hepatitis B virus DNA test (HBV DNA). This is a specialised test available in few screening laboratories. This may be performed on the screening test sample but will often require a separate sample of blood taken into EDTA containers (the same containers as used for full blood counts). The HBV DNA test is an essential part of the assessment of chronic hepatitis B infection. It gives the specialist detailed information on the patient's current infectivity and current risk of developing complications. In patients taking antivirals to manage their infection, HBV DNA testing is used to monitor the effectiveness of treatment. Levels fall during successful treatment and rise back up if the virus is becoming resistant to the antiviral medication. In the pregnant woman with chronic hepatitis B and both HBsAg and antiHBe in her blood the level of HBV DNA is often low. If it is above  $1 \times 10^6$  IU/ml in an antenatal sample then an injection of HBIG is indicated for the baby after birth, in addition to immunisation.

Tests to assess markers of infectivity should be performed in a competent laboratory with sufficient expertise to interpret and report the results. A rapid service for testing for markers of infectivity should be provided to avoid delays in reporting and to meet the standards for turnaround times.

A second specimen taken purely to confirm the initial results prior to referral to clinical services is not considered necessary, however, two positive results from separate specimens are required to establish positive HBV status and appropriate circumspection should be used when informing the woman of positive results from the initial screening specimen. The screening tests should be repeated on the second specimen but further tests as determined by the clinical specialists will also be required on this specimen to enable a complete assessment of the woman.

- **Reporting and standard comments**

A report should be issued for every screening specimen received by the laboratory. A report should be issued when the infectivity marker results are available to prompt maternity services to recall the woman. This is to discuss the test results, arrange referral to an appropriate specialist to complete the clinical evaluation of maternal infection and prompt maternity services to initiate arrangements for the postnatal infant immunisation.

Local policies for the reporting of screen positive results and robust communication systems must be in place so that referral to the most appropriate clinical services and the collection of a second specimen can be initiated promptly and in a sensitive manner. Mechanisms should be in place to ensure that results from the screening specimen are available to the specialist clinic so that delays in treatment are avoided. It is recommended that standardised comments are appended to reports, including the action required, to improve communication with the requester. Positive results must be reported to the local Health Protection Unit/team.

- **Completion of clinical evaluation**

An appropriate specialist (e.g. a hepatologist, gastroenterologist or infectious diseases specialist) who will be advising on the management of the woman during her pregnancy should be instrumental in deciding the tests required on the second specimen. This specimen may be taken prior to the woman being seen in the specialist clinic, as long as the tests required and the mechanisms for reporting the results have been agreed. The clinical evaluation is completed when the woman is assessed by an appropriate specialist. The British Viral hepatitis Group (BVHG) has outlined the tests which should be performed and these include HBV DNA viral load, liver function tests, etc.

<http://www.basl.org.uk/microsites/bvhg/resources.cfm>

HBV DNA viral load is an increasingly important feature of diagnostic practice and is recommended by BVHG to guide clinical decision making on treatment options for pregnant women. The HPA and JCVI also advise that, where it is used for this purpose, it may also guide decision making on the prescription and administration of postnatal HBIG to supplement the infant immunisation schedule. As part of a complex clinical assessment it is recommended that tests to measure DNA viral load should be performed following referral to an appropriate specialist rather than within maternity services as part of the screening programme.

<https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>

Systems should be developed locally to ensure that tests on the second specimen can be linked to the results of the screening specimen. Management of the woman within a multidisciplinary team could facilitate this.

#### **4.5.2 HIV**

The recommended screening tests are 'fourth generation' assays which detect HIV-1 antibodies, HIV-1 p24 antigen and HIV-2 antibodies. Screening using a fourth generation assay is now established as the standard of care in the UK. Assays must have a high sensitivity (> 99.9%) and specificity (> 99.5%) and be able to detect all the major subtypes of HIV-1 and HIV-2.

Nucleic acid amplification tests are not recommended for screening purposes as they can give false positive results. Such tests provide only a minimal advantage, compared with fourth generation assays, in terms of detecting recent infection and they may not detect all HIV subtypes.

No report should be issued until the confirmatory tests outlined below have been performed and a conclusion reached about the complete set of screening results. Interim reports and presumptive positive reports should be avoided as they can cause confusion and mislead recipients. The Scottish testing algorithm can be accessed here

<http://www.documents.hps.scot.nhs.uk/labs/bbv/scottish-hiv-testing-algorithm-referral-labs-2009.pdf>

- **Confirmation of the screening test results**

All results considered to be positive in the screening assay must be confirmed on the initial specimen by two further independent assays that use different methodologies. This is to confirm that the reactivity is specific for HIV and reduce the possibility of non-specific reactions causing a false positive result to be reported.

Confirmatory assays need to discriminate between HIV-1 and HIV-2 infections and be able to detect p24 antigen and thus identify acute infection.

Confirmatory testing should be performed in a laboratory competent to perform these tests and with sufficient expertise to interpret and report the results. A rapid service for confirmatory testing should be provided to avoid delays in reporting and to meet the standards for turnaround times.

If a positive result in the screening assay is not confirmed by confirmatory tests the results are discordant. The sample should be sent to a Reference Laboratory for further investigation before a confirmed screening test result is issued.

A second specimen taken purely to confirm the initial results prior to referral to clinical services is not considered necessary. However, two positive results from separate specimens are required to establish positive HIV status and appropriate circumspection should be used when informing the woman of positive results from the initial screening specimen. The second specimen should be taken at the time of clinical referral.

- **Reporting and standard comments**

A report should be issued after confirmatory testing to prompt maternity services to recall the woman. This is to discuss the test results and arrange referral for assessment within a multi-disciplinary team.

A report should be issued for every screening specimen received by the laboratory. The report must indicate whether the infection is with HIV-1, HIV-2 or is a dual infection. It is recommended that standardised comments are appended to reports, including the action required, to improve communication with the requester.

Local policies for the reporting of screen positive results must be in place so that referral to the most appropriate clinical services and the collection of a second specimen can be initiated promptly and in a sensitive manner. Mechanisms should be in place to ensure that results from the screening specimen are available to the specialist clinic so that delays in treatment are avoided. Laboratories should ensure that the appropriate notification systems are in place for positive results.

- **Clinical evaluation of maternal HIV**

Two positive results from separate specimens are required to establish positive HIV status. The second specimen should be taken within a multi-disciplinary environment. This will confirm the woman's identity and enable additional tests to be performed to determine the care of the woman and the onward management of the pregnancy. Further tests will include CD4 monitoring and HIV viral load testing. <http://www.bhiva.org/ClinicalGuidelines.aspx>

Local policies should be in force to specify exactly how the woman will be referred to the multi-disciplinary team and the mechanism for obtaining the second specimen and exactly how the woman will be referred to the multi-disciplinary team responsible for her care.

Systems should be developed locally to ensure that tests on the second specimen can be linked to the results on the screening specimen.

#### **4.5.3 Syphilis**

The recommended screening test for syphilis is an enzyme immunoassay (EIA) that detects antibodies to *Treponema pallidum*, or an alternative immunoassay of equivalent analytical sensitivity. A total EIA, that can detect both treponemal IgG and IgM antibodies, is recommended because of the test's high diagnostic sensitivity. A cut-off value should be chosen for the assay to differentiate between the negative and positive specimens as defined using the manufacturer's instructions.

These first line serological screening tests rely on a woman having mounted an antibody response to their infection and therefore they may be insensitive in very early treponemal infection. Some laboratories introduce 'equivocal' ranges around the cut off value. The screening programme does not recommend this practice but, if it is used, equivocal results should be processed in the same way as EIA positive results.

- **Confirmation of screening test results**

All EIA positive, or equivocal, specimens should be confirmed using the same assay to confirm reproducibility. Repeating the assay may be omitted if other confirmatory assays are to be performed in the same laboratory.

A Treponema Pallidum Particle Agglutination (TPPA) or Treponema Pallidum Haemagglutination (TPHA) assay should be performed as a confirmatory test on the same screening specimen. These assays are sensitive and specific and a combination of a positive result with both EIA and TPPA/TPHA gives a strong likelihood for past or current treponemal infection.

A positive or equivocal result with EIA but negative with TPPA/TPHA are discordant and needs further investigation in a competent and experienced laboratory before a confirmed screening test result is issued. False positive results on the initial screening test may be caused by cross-reacting antibodies in the woman's blood. If, after further analysis, the results are still inconclusive a repeat specimen is required to rule out the presence of cross reacting antibodies. A conclusive positive result on the repeat specimen requires immediate referral.

Confirmatory testing should be performed in a laboratory competent to perform these tests and with sufficient expertise to interpret and report the results. Samples being sent to a referral laboratory should be clearly labelled as antenatal screening samples for confirmation, so that appropriate tests and comments can be made. A rapid service for confirmatory testing should be provided to avoid delays in reporting and to meet the standards for turnaround times.

A second specimen taken purely to confirm the original screen positive result prior to referral to clinical services is not considered necessary, however, two positive results from separate specimens are required to establish positive syphilis status. The screening test should be repeated on the second specimen but further tests as determined by the clinical specialist will also be required on this specimen to complete the assessment of the woman.

- **Reporting results**

A report should be issued after confirmatory testing to prompt maternity services to recall the woman. This is to discuss the test results and arrange referral for clinical assessment. A report should be issued for every screening specimen received by the laboratory.

Specimens which are equivocal on the EIA but positive on TPPA/TPHA should be reported as screen positive. Specimens which are equivocal on both the EIA and TPPA/TPHA assays should be reported as screen positive.

It is recommended that standardised comments are appended to reports, including the action required, to improve communication with the requester.

Local policies for the reporting of screen positive results must be in place so that referral to clinical services and the collection of a second specimen can be initiated promptly and in a sensitive manner. Mechanisms should be in place to ensure that results from the screening specimen are available to the specialist clinic so that delays in treatment are avoided. Positive results must be reported to the local Health Protection Unit or equivalent body.

- **Additional testing**

Once there is an indication that treponemal infection is present in a pregnant woman, a Rapid Plasma Reagin (RPR – sometimes (erroneously) called the VDRL test) is usually also performed depending on local protocols. This test contributes to the diagnostic pathway by providing a baseline quantification of titre against which subsequent tests within a specialist environment can be referenced. The result of the RPR test provides useful information for the diagnostic process but does not affect the urgency of referral to specialist services. As such this test should not be performed at the expense of meeting the recommended turnaround time.

- **Diagnostic process**

Diagnosis of syphilis infection, its staging and treatment requirements, is informed by laboratory test results combined with clinical examination and sexual history. Towards this end guidance has been developed by the British Association of Sexual Health & HIV (BASHH).  
[www.bashh.org/guidelines](http://www.bashh.org/guidelines)

A second specimen should be taken within a specialist clinical environment to perform additional tests required for the diagnostic process and to confirm the woman's identity. Local policies should be in force to specify exactly how the woman will be referred to the appropriate clinical service and the mechanism for obtaining the second specimens.

Systems should be developed locally to ensure that the outcome of the diagnostic process, including test results from the second specimen can be linked to the initial screening results. Management of the woman within a multidisciplinary team could facilitate this.

## 5. Management of screening results

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### 5.1 Positive screening results

#### HIV, hepatitis B and syphilis

Women with positive screening test results should be contacted and advised about the results, at an appointment made for that purpose, within 5 working days of the result being made available to maternity services. The purpose of the appointment is to discuss the screening test result and to arrange for referral to a relevant specialist service for clinical assessment. 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.

Contact should be made by an appropriate professional/s, trained to communicate positive results as information of this kind is likely to have a significant emotional impact. Efforts must be made to ensure that women whose first language is not English understand the significance of the screening test result and the need for specialist assessment. The use of interpreters is recommended where appropriate.

The appointment should not normally be on Friday afternoons or immediately prior to a public holiday unless appropriate support mechanisms are in place during these periods.

#### Confidentiality

Screening test results should be made available to the healthcare professionals responsible for the care of the woman and her baby without compromising the woman's right to confidentiality.

Information relevant to the care of the mother and baby should be documented in the woman's central hospital record. There should be 24 hour access for those professionals who need to be aware of the requirements of the woman and her baby during the antenatal, intrapartum and postnatal period. There should be strict access controls to protect patient confidentiality.

Positive results should only be recorded in non-secure sites, for example handheld records, following discussion and with the consent of the woman.

Health professionals who are engaged with the woman's care in contexts other than antenatal care should be informed of positive results. Positive results should be transferred and recorded securely, for example by direct communication to the GP for inclusion in their records. Women should be informed that this action has been undertaken.

#### Legislation

Sexually transmitted diseases are covered by the

- NHS (Venereal Diseases) Regulations 1974 and 1991 s.2;
- NHS (**Scotland**) Act 1978

Every NHS Board shall take all necessary steps to secure that any information capable of identifying an individual obtained by any of their members or employees with respect to persons examined or treated for any sexually transmitted disease (including HIV and AIDS) shall not be disclosed except:

(a) for the purpose of communicating that information to a medical practitioner, or to a person employed under the direction of a medical practitioner in connection with the treatment of persons suffering from such disease or the prevention of the spread thereof, and

(b) for the purpose of such treatment or prevention.

## **Notifiable diseases**

Laboratory diagnosed HBV is included in Public Health etc (Scotland) Act 2008. This states that diagnostic laboratories must notify the health protection team within the health board in whose area the diagnostic laboratory is situated and Health Protection Scotland. The details of the Act can be accessed at [http://www.legislation.gov.uk/asp/2008/5/pdfs/asp\\_20080005\\_en.pdf](http://www.legislation.gov.uk/asp/2008/5/pdfs/asp_20080005_en.pdf)

## **5.2 Negative screening results**

Negative screening test results should be reported back to women before or at the next antenatal visit, according to local protocol. If the woman has disclosed ongoing risk factors it is best practice for the Health professional to offer repeat testing around 28-32 weeks gestation.

Advice about risk of acquisition and avoidance of infection should be provided to women receiving negative test results. Information should also be provided on the availability of testing on request should the woman consider herself to be at risk at any point in the pregnancy.

If negative results are reported by letter, this information should be included.

The process for providing negative results should be explained when screening is offered.

Results should be recorded in maternity notes and if utilised the electronic patient record on receipt of the information.

## **5.3 Management of positive results condition specific guidance**

### **5.3.1 Hepatitis B**

#### **Appointments to discuss positive results and referral**

Arrangements should be made for an appointment with an appropriate specialist (eg a hepatologist, gastroenterologist or infectious diseases specialist) within 6 weeks of the screening test result being issued to maternity services. Even if the woman has already been referred previously and is being followed up/getting treatment they should be re-referred as they may be unaware of her pregnancy and the management plan may need to be reviewed.

Women booking late, after 24 weeks, for antenatal care should be referred immediately for a clinical evaluation. The following should be discussed with the woman:

- the significance of HBV infection for her own health, the pregnancy and the baby's health. Discussions should also include the health and wellbeing of other family members where appropriate.
- the need for further tests for confirmation of identity and evaluation of maternal management requirements
- the potential benefits of specialist management for the pregnancy, the woman's health and that of the baby
- practical arrangements for further assessment eg date options for appointments with specialist services

Robust mechanisms are required to ensure that HBV positive women are managed within a multidisciplinary environment. The composition of the multi-disciplinary team may vary locally. Different models of service delivery may be appropriate.

Local arrangements should be made to support consultant and/or midwife to consultant referral. Non attendance at the specialist appointment should be reviewed within a multidisciplinary framework and a management / action plan developed.



Maternal consent for the baby to be vaccinated in accordance with the Department of Health publication 'Immunisation against infectious diseases – The Green Book<sup>5</sup> schedule should be sought and action taken to facilitate this. The following should be discussed with the woman:

- the benefits to the baby of completion of the infant immunisation schedule
- the importance of specialist assessment in determining the maternal infection status, risk of transmission and the requirement for HBIG.

Arrangements should be made to prescribe, order, store and have access to the vaccine including out of hours (+/- HBIG as required) in advance of the estimated delivery date.

The following should be informed of all confirmed positive screening results:

- the specialist responsible for clinical assessment and management of the woman,
- the health care professional responsible for arranging testing of other older siblings, partner and other household contacts if different from the above specialist,
- the GP, health visitor and / or practice nurse,
- Health Protection Scotland (HPS).
- the NHS Board Immunisation Lead should be informed from an early stage
- The NHS Board health protection team

### **Care during pregnancy**

Local protocols should be in place to ensure multidisciplinary links and close working relationships between maternity services and specialist services (eg hepatology, gastroenterology, infectious diseases) are established and function well. This will support the flow of information on:

- non attendance at appointments for assessment
- confirmation of the mother's identity
- results of clinical evaluation as it relates to the infant immunisation schedule
- maternal management / treatment plan
- discussions relating to the place of birth
- issues relating to prenatal invasive tests eg amniocentesis and CVS should these be relevant

This information is needed for management in the antenatal period and to ensure immunisation of the infant.

Future antenatal appointments should be used to ensure the management plan is progressing appropriately.

### **Considerations for intrapartum care**

It is essential that the relevant information is available to the delivery team. This should include:

- maternal disease status
- confirmation of the neonatal immunisation requirements
- the need to avoid both fetal blood sampling and use of a fetal scalp electrode in most circumstances.

The health care professional responsible for administering the vaccine should be informed that the woman is in labour and that the infant will require immunisation.

### **Infant immunisation schedule**

Details of the infant immunisation schedule and whether the baby requires HBIG are available in the Department of Health publication 'Immunisation against infectious diseases – The Green Book (2006).

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<sup>5</sup> Green book: *Immunisation against infectious disease*. Department of Health 2006, <http://www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/Greenbook/DH4097254>

### **Postnatal dose of the infant immunisation schedule**

The first dose of the vaccine (+/- HBIG) should be administered within 24 hours of birth. If there is doubt about the schedule, expert advice should be sought immediately. The midwife/responsible health professional administering the vaccine (+/- HBIG) should inform the Health Protection team that the first dose of vaccine has been given and what the arrangements are for further vaccines.

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

### **Arrangements for completion of the immunisation schedule**

In the majority of cases, the mother and baby are transferred to primary care for completion of the immunisation schedule. However other models of care are available. Making arrangements for completion of the immunisation schedule is a critical point in the pathway. It is important that the midwife responsible for this action undertakes the following prior to discharge:

- informing the local Child Health Records Department of the mother's HBV status, that the first dose of vaccine (+/- HBIG) has been administered and the need for subsequent vaccines
- discussion with the mother regarding the baby's immunisation schedule and importance of completion
- completion of relevant immunisation forms (Form 13a from [www.immunisation.nhs.uk](http://www.immunisation.nhs.uk)) or local equivalent
- recording of the woman's HBV status and the baby's immunisation schedule on the postnatal discharge letter as well as the Personal Child Health Record (PCHR)
- confirmation that a process is in place for arranging further follow up appointments
- notification to the GP and health visitor of the mother's HBV status and that the infant needs to complete a hepatitis B immunisation course
- informing the Health Protection Team (HPT) hepatitis lead or NHS Board equivalent regarding follow up with GP

It is of vital importance that the woman's discharge address is accurate as follow up will be compromised if the health visitor is not able to contact the woman. Transfer of contact details such as a mobile phone number is helpful.

### **Subsequent doses of the infant immunisation schedule**

The subsequent doses of the immunisation schedule are administered over a lengthy period, usually within primary care. These take place at four weeks and eight weeks with a booster dose given at 12 months.

The final dose should be accompanied by a blood sample taken for HBsAg testing to rule out infection, taking this specimen may require paediatric input. A paediatric out-patient appointment should either be made prior to discharge or the discharge letter to GP should specify the need for this to be done.

It is important that processes are in place to ensure the mother is aware of the immunisation schedule.

A process to arrange appointments, issue prompts and identify missed appointments at each stage should be in place to facilitate completion of the schedule. This may require an IT process through the Child Health Records Departments.

### **5.3.2 HIV**

Arrangements should be made for urgent referral to the MDT responsible for co-ordinating the woman's HIV care in accordance with the BHIVA Guidelines.

The following should be discussed with the woman:

- the significance of HIV infection for her own health, the pregnancy and the baby's health. Discussions should also include the health and wellbeing of other family members where appropriate.
- need to attend specialist appointment for further tests to confirm identity and evaluate maternal treatment needs
- the potential benefits of multi-disciplinary management for the pregnancy, the woman's health and that of the baby
- practical arrangements for further assessment eg date options for appointments with the multi-disciplinary team

Robust mechanisms are required to ensure that HIV positive women are managed within a multidisciplinary environment.

Non attendance at the specialist appointment should be reviewed by the multidisciplinary team and a management / action plan agreed.

### **Multi-Disciplinary management in the antenatal period**

Women with screen positive results are most effectively managed by a multi-disciplinary team. Multi-disciplinary links and close working relationships will help ensure the flow of information on:

- non attendance at appointments for further tests and management
- confirmation of the mother's identity
- maternal care plan
- issues relating to prenatal invasive tests eg amniocentesis and CVS should these be relevant
- recommended mode of delivery
- care plan for management of the baby in the neonatal period

Future antenatal appointments should be used to ensure the management plan is progressing appropriately.

### **Considerations for the intrapartum period**

It is essential that the relevant information is available to the delivery team. This should include:

- maternal infection status
- maternal treatment history
- requirement for paediatric assessment and management
- confirmation that paediatric treatment has been ordered and is available where necessary

The paediatric or neonatal team should be informed during delivery to ensure prompt transfer of care.

### **Postnatal management**

Postnatal management of the mother and baby should be undertaken in accordance with the BHIVA guideline. <http://www.bhiva.org/cms1191540.asp>

### **5.3.3 Syphilis**

Arrangements should be made for urgent referral for assessment by an appropriate specialist in accordance with the BASHH guideline. [www.bashh.org/guidelines](http://www.bashh.org/guidelines)

The following should be discussed with the woman:

- need for further assessment to provide a diagnostic evaluation, confirm identity and evaluate maternal treatment needs
- the significance of syphilis infection for maternal health, the pregnancy and the baby's health, discussions should also include the health and wellbeing of other family members where appropriate.
- the potential benefits of multi-disciplinary management for the pregnancy, the woman's health

and that of the baby

- practical arrangements for further assessment eg date options appointments

Robust mechanisms are required to facilitate rapid assessment of women with screen positive results within a multi-disciplinary environment. Different models of service delivery may be appropriate in this area.

The urgency to complete the assessment is because:

- not all positive screening test results will be confirmed as a syphilis diagnosis or as an infection requiring treatment,
- treatment, when indicated, needs to be instituted as early as possible to avoid adverse outcomes of pregnancy.

Non attendance for assessment should be reviewed by a multidisciplinary team and a management / action plan agreed.

## **Multi-Disciplinary management in the antenatal period**

### **i. Information flow between services**

Women with screen positive results will be most effectively managed in a multi-disciplinary context and close working relationships should be established between maternity services, specialist syphilis services (eg GUM) and paediatrics to ensure the flow of information on:

- non attendance at appointments for assessment
- confirmation of the mother's identity from tests on a second sample
- results of diagnostic evaluation and disease staging,
- maternal treatment
- follow up test results

This information is needed for management in the antenatal period and for surveillance purposes.

Future antenatal appointments should be used to ensure the management plan is progressing appropriately.

### **ii Reporting categories**

The results of diagnostic evaluation should be reported to maternity services using the following broad criteria:

- current syphilis infection – treatment required
- syphilis infection at some time with inadequate history of treatment - treatment required
- syphilis infection at some time with history of adequate treatment - treatment not required
- false positive screening test – treatment not required
- mother incorrectly identified on screening test – urgently review screening test results.

Reports should specify which babies need following up. Babies born to the false positive screening test mothers do not require follow up.

### **iii Antenatal management of diagnosed syphilis**

Following diagnosis and the identification of a treatment schedule, the following issues should be considered by the multi-disciplinary team:

- informing the paediatrician
- clearly recording the requirement for postnatal tests for mother and baby
- ordering and storing paediatric treatment detailed in the BASHH guideline which should be available at the time of delivery
- partner notification and testing

## **Considerations for the intrapartum period**

It is essential that the relevant information is available to the delivery team. This should include:

- final diagnosis and staging of maternal disease if known
- maternal treatment history
- maternal treatment outcome / titre of final follow up blood test if known at delivery
- fetal medicine assessment if relevant
- requirement for postnatal tests for mother and baby
- requirement for paediatric assessment
- confirmation that paediatric treatment has been ordered and is available.

The paediatrician should be informed during delivery to ensure prompt transfer of care.

### **Neonatal management**

Postnatal management of the mother and baby should be undertaken in accordance with the BASHH guideline. Preparations for this should be made in the antenatal period and are outlined above.

## **6. Evaluation of the communicable diseases in pregnancy screening programme**

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Audit and monitoring of the screening programme should be performance managed at all health service levels (national and local).

All screening programmes are expected to have the appropriate tools to support the minimum criteria for the audit process. This must include clerical support, information technology (IT) equipment/software and networks that link with appropriate data collection systems within the Board.

All abnormal findings subsequently proved to be normal should be kept on a database for the purposes of quality control; confirmed diagnosis should be recorded on/in the:

- i. Board's clinical information system
- ii. Woman's maternity hand held notes
- iii. Woman's hospital notes

A high standard of feedback to the laboratory departments are an essential element for a screening service.

### **6.1 Quality control**

Laboratory services must be able to provide (as a minimum) from the proportion of the pregnant population that had screening,

- Screen positive rate (SPR)

All Board areas are expected to return data in regard to the nationally agreed quality indicators in relation to screening for communicable diseases and to be meeting any applicable HIS clinical standards. In addition each NHS Board should aim to carry out an exploratory survey of user views and experiences annually.

## 7. Adverse Incidents

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As with any screening programme, there is potential for significant adverse incidents. All adverse incidents should be managed appropriately to minimise the risks to, and effects on the patient and participating Boards.

An adverse incident can be any of the following:

### ***Administrative***

- Failsafe procedures not instigated
- Woman/ GP not notified of result

### ***Laboratory***

- Assay errors
- Interpretation errors
- Failure to analyse sample

### ***Clinical***

- Misdiagnosis
- Long waiting times through process; from positive screening test to confirmed diagnosis

### 7.1 Procedure

Any healthcare professional involved in the NHS Scotland pregnancy screening programme who becomes aware of a suspected problem should follow agreed local NHS Board clinical governance procedures.

Local clinical governance procedures may vary from one Board to another but commonly involve an initial period of local investigation and establishment of extent of problem followed by external independent peer review when appropriate.

In all cases associated with the screening programme, there will be a thorough investigation and National Services Division (NSD) will be notified early in the process – at the time of internal investigation. In view of the sensitivities of national screening programmes and the public interest in them, NSD may require an external peer review even if local Board management decide not to invoke this.

If necessary NSD and the Board will meet to discuss and agree what action, if any, is required.

NSD will notify the Scottish Government Health and Social Care Directorates (SGHSC) and decide if action is needed in other NHS Board areas.

Note:

These protocols are to be used in addition to, and do not replace, the Boards' Clinical / Adverse Incident Reporting Procedures.

## 8. Confidentiality

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Professional staff involved in the screening programme will comply with the provisions of the Caldicott Report. In particular, patient-identifiable information will only be used in clearly defined and monitored circumstances, only when absolutely necessary and should entail the use of the minimum necessary patient-identifiable information.

Access to patient identifiable information will be on a strict need to know basis, everyone in the organisation will be aware of their responsibilities with respect to patient confidentiality and the organisation will ensure that its use of patient-identifiable information is lawful.

NHS National Services Scotland (ISD and NSD) does not require aggregated information returns on the performance of the screening programme to include patient-identifiable information; information on clinical activity for national data sets and monitoring must be submitted in anonymised format.



## Abbreviations

AntiHBc	Antibody to Hepatitis B core antigen
BASHH	British Association for Sexual Health and HIV
BHIVA	British HIV Association
BSH	British Society of Haematology
BVHG	British Viral Hepatitis Group
CEL	Chief Executive Letter
CHI	Community Health Index
CI	Confidence Interval
CPA UK (Ltd)	Clinical Pathology Accreditation United Kingdom Limited
CPD	Continuous Professional Development
CVS	Chorionic villus sampling
EDD	Estimated Date of Delivery
EIA	Enzyme Immunoassay
EU	European Union
GMC	General Medical Council
GUM	Genitourinary Medicine
HBIG	Hepatitis B Specific Immune Globulin
HBV	Hepatitis B virus
HBeAg	Hepatitis B e-antigen
HBsAg	Hepatitis B surface antigen
HDL	Health Department Letter
HIE	Higher Institute of Education
HIS	Healthcare Improvement Scotland (formerly NHS QIS)
HIV	Human Immunodeficiency Virus
HPA	Health Protection Agency
HPC	Health Professional Council
HTA	Health Technology Assessment
IDPS	Infectious Diseases in Pregnancy Screening
ISD	Information Services Division
IT	Information Technology
KPI	Key Performance Indicator
MDT	Multi Disciplinary Team
MMR	Measles, Mumps and Rubella
MoM	Multiples of the Median
NHS QIS	National Health Service Quality Improvement Scotland
NICE	National Institute for Clinical Excellence
NMC	Nursing and Midwifery Council
NSD	National Services Division
NTD	Neural Tube Defect
PCHR	Personal Child Health Record
PKU	Phenylketonuria
NSS	National Services Scotland
PND	Prenatal Diagnosis
QC	Quality Control
RCOG	Royal College of Obstetricians and Gynaecologists
SGHD	Scottish Government Health Directorates
SPR	Screen Positive Rate
SWHMR	Scottish Woman Held Maternity Record
TPHA	Treponema pallidum haemagglutination
TPPA	Treponema pallidum particle agglutination
UKAS	United Kingdom Accreditation Service
UK NEQAS	United Kingdom National External Quality Assessment Service
UK NSC	United Kingdom, National Screening Committee

## Glossary

Affected pregnancies	Pregnancies in which the fetus has the target condition.
Antenatal	The period from conception to birth.
Confirmed result	The results of initial screening tests are not usually 100% certain, and are often called presumptive results. The results of screening tests are NOT confirmed results. They are often confirmed later, with further diagnostic tests
Congenital	Present at or shortly after birth.
Coverage	This is the proportion of people in the eligible group who actually undergo the screening.
Diagnostic test	Refers to the analytical process involved in obtaining a result.
Effectiveness	The extent to which intervention results in the desired outcomes under everyday conditions.
False-negative result	Screening tests divide people into lower and higher risk groups. Some people with a negative screening test result do actually have the condition being screened for. These people are said to have a 'false-negative' result.
False-positive result	Screening tests divide people into lower and higher risk groups. Some people with a positive screening test result do not actually have the condition being screened for. These people are said to have a 'false-positive' result.
Fetus	In humans, the unborn child after the end of the eighth week of pregnancy to the moment of birth.
Gestational age	The duration of an ongoing or completed pregnancy, measured from the first day of the last menstrual period (usually about two weeks longer than that measured from conception). Gestational age is usually measured in completed weeks.
Incidence	The number of new instances of a specific condition occurring during a certain period in a specified population.
Miscarriage	Loss of a fetus before the 24th week of pregnancy.
Prevalence	The proportion of people in a population who have a given disease or attribute.
Quality assurance	A system for monitoring and maintaining high standards in every aspect of a screening programme.
Risk	Risk is usually taken to mean the chance of an event happening. It can be expressed in a number of ways.
Screening	Screening is a process of identifying apparently healthy people who may be at increased risk of a disease or condition. They can then be offered information, further tests and appropriate treatment to reduce their risk and/or any complications arising from the disease or condition.
Screening programme	The whole system of activities needed to deliver high quality screening. It ranges from identifying and informing those to be offered screening through to the treatment and follow up of those found to have abnormality, and support for those who develop disease despite screening.
Screening test	A test or inquiry used on people who do not have or have not recognised the signs or symptoms of the condition being tested for. It divides people into low and higher risk groups.
Screen Positive Rate	The screen positive rate is the chance that a test will be above the screen cut-off and the result will be reported as screen positive. This rate includes both false positives and true positives.
Sensitivity	This is a measure of test performance. High sensitivity means that the test 'catches' as many people with the condition as

	possible. It is measured as the proportion of those with the condition, who have a positive test result. It is the same as the detection rate.
Specificity	This is a measure of test performance. High specificity means the test has as few false positives as possible. It is measured as the proportion of those without the condition, who have a negative test result.
Surveillance	Ongoing observation of the health of individuals or populations.
Target condition	The condition that a screening programme is aiming to find, in order to reduce risk of adverse effects from that condition.
Termination of pregnancy	The medical expulsion or extraction from the uterus of a fetus in the first, second or third trimester of pregnancy.
Threshold	On the basis of research, the group at “higher risk” has been defined as “above the threshold of”.
Uptake	Is the proportion of people, who when offered a test, take it up.