Sgrinio Cyn Geni Cymru
Antenatal Screening Wales

Antenatal Screening Wales Policy, Standards and Protocols 2015

GIG CYMRU NHS WALES
Iechyd Cyhoeddus Cymru
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Thanks are given to the Antenatal Screening Wales (ASW) sub groups and the ASW Quality and Clinical Governance Group for their assistance and advice in the preparation of this document.

An equality impact assessment has been carried out for this document and is available from ASW.

To be reviewed 2018

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1.0 Introduction

The Health Board maternity services in Wales provide antenatal screening tests to pregnant women as part of their antenatal care. Antenatal screening tests are provided for different reasons, and this makes antenatal screening a complex programme with a number of different purposes and unique ethical considerations and implications.

The agreed purpose of the antenatal screening programme in Wales is:

> *• to detect defined serious conditions present in either the mother or baby that are likely to have an adverse effect on the health of either, and for which an effective intervention is available and warranted.*

For some conditions, preventive treatment is available during the antenatal period or after delivery to improve the baby's health.

For others, the condition can be identified during the antenatal period but no preventive treatment is available. With high quality counselling women can make an informed choice about whether they wish to continue the pregnancy. Appropriate support, in line with the woman's choice, can be arranged.

Antenatal Screening Wales (ASW) was asked by the Welsh Assembly Government to establish policies, standards and a performance management framework for antenatal screening delivered by maternity services in Wales. ASW is part of Public Health Wales, Screening Division, who have extensive expertise in the management and provision of population based screening programmes. ASW sits within Maternal and Child Screening. Governance for the work is provided by the Quality and Clinical Governance Group and the Sub Groups. ASW does not provide or directly manage any antenatal screening services.

ASW published the initial standards and protocols in 2005 and then revised them in 2010. All Health Boards in Wales have adopted these policies, standards and protocols for antenatal screening. This enables women across Wales to have access to services that are working to best practice. The Antenatal Screening Coordinators, Antenatal and Newborn Screening Governance Leads and Superintendent Sonographers work closely with Antenatal Screening Wales to implement and maintain Antenatal Screening Wales standards in their Health Boards.

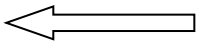
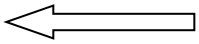
A bi-annual performance monitoring assessment known as performance indicators is undertaken by ASW in collaboration with Health Boards. This gives information about performance to Health Boards about compliance with ASW standards and provides the information on which action plans for improvement can be developed in the Health Boards.

There are a number of important United Kingdom (UK) documents which support antenatal screening which have been referred to during the 2015 review of the policy, standards and protocols. The recommendations of the UK National Screening Committee (UK NSC), National Institute for Health and Clinical Excellence (NICE), specific laboratory national standards, the advice of Royal Colleges and good practice models have been considered in this revision. These programme standards and protocols should be considered with due regard to the recommendations contained in supporting literature, e.g. guidance of Professional Bodies, Royal Colleges and Welsh Risk Pool Standards.

1.1 Document Design

The document highlights the standards for antenatal screening in Wales in purple shading. They are followed by the recommended supporting protocols as per the example shown below.

The letters in superscript at the end of a sentence ([a]) refer to a footnote which can be found at the bottom of the page. The numbers in superscript at the end of a sentence ([1]) refer to an endnote and these can be found on page 74 of the document. Hovering over these letters and numbers with the mouse on the screen will allow the notes to appear in a box next to the small letter or number as per the example below on protocol 3.

Standard C10	**Numbered Standard Statement**
The sample must be taken before 13 weeks of pregnancy (if the woman presents for care before this gestation). Target 95%	
1) If the woman is more than 23 completed weeks pregnant when the sample is taken, the sample should be marked urgent. 2) If the woman is more than 36 weeks pregnant when the sample is taken, the sample should be marked urgent and the laboratory contacted 3) If the woman is in labour or is postnatal when the sample is taken, the health professional should contact the consultant microbiologist/consultant virologist to ask for a risk assessment and to establish the urgency of testing and management of the woman whilst the results are awaited.[a]	**List of protocols to support the full implementation of the standard by:** • **giving additional information to the health professional on how to fulfil the standard** • **requirement for additional action** • **exclusions** • **inclusions** • **documentation requirements** • **management and risk management requirements** • **referral requirements** 

The numbers in superscript that refer to endnotes can be clicked on and this will take you to the end notes page. If you then click onto the number at the beginning of the endnote it will return you to the relevant page in the document.

[a] This is an example of how the footnotes work

2.0 Programme Governance Arrangements

2.1 Service Governance

The liability for antenatal screening provision rests with the Health Board providing care. Similarly the responsibility for providing antenatal screening to meet the proposed standards rests with the Health Board.

As part of the Health Board governance framework for antenatal screening it is recommended that:

- All clinical incidents should be reported via the Health Board clinical incident reporting system, including those on the ASW trigger list.

- If, following identification and preliminary investigation by the Health Board, an antenatal screening clinical incident is found to be caused by a system failure which the service judges could be present in other services in Wales, the Antenatal Screening Coordinator, Governance Lead or Health Board Risk Manager should notify ASW as soon as possible. This will enable ASW to consider if action or additional guidance is required to reduce the identified programme risk recurring in other services.

2.2 Screening Pathways

Antenatal screening should be supported by locally developed care pathways which describe the Health Boards arrangements for:

- giving pre test information and offering the test
- requesting and providing the test
- the results handling process for each test
- providing support services for women with screen positive results
- meeting agreed timescales and monitoring arrangements
- necessary antenatal and immediate postnatal management
- referral to other agencies if required.

3.0 Management Arrangements

The effective management of the antenatal screening programme is essential. The Health Boards antenatal screening programme should be supported by the following management arrangements.

3.1 Programme Coordination

Standard M 1

Health Boards should have a designated obstetric, sonographer, laboratory and midwifery lead responsible for the discrete aspects of the programme.

Target 100%

Standard M 2

Health Boards should establish an antenatal screening forum or have antenatal screening as a standing agenda item on an established multiprofessional forum.

Target 100%

Standard M 3

Health Boards should identify named Antenatal Screening Coordinators who are responsible for overall programme management.

Target 100%

The named Antenatal Screening Coordinator will have responsibility for:

(1) Coordinating the provision of antenatal screening services to enable an effective, timely and appropriate service.

(2) Implementation of the ASW policy, standards, protocols and pathways.

(3) Leading the audit of antenatal screening services and performance management reporting to ASW.

(4) Managing the results reporting process including the introduction of risk reduction processes.

(5) Developing a relevant service within maternity departments for discussing results with women who have problems detected by antenatal screening.

(6) Planning and providing a multiprofessional in-service education programme for health professionals involved in antenatal screening.

(7) Reporting activity in an annual antenatal screening report to the Health Board.

(8) Coordinating the supply of information for women to health professionals providing care.

(9) Developing and auditing a pathway to enable the structured re-offer of antenatal syphilis, HIV and hepatitis B screening to women who initially decline.

(10) Compiling and maintaining a list of contacts and contact numbers for the laboratories to enable effective and timely communication of urgent results from the laboratory to the maternity service.

(11) Raising awareness of new standards, protocols or guidance e.g. communicable diseases re-offer.

(12) Providing support, information and relevant resources to other healthcare professionals regarding antenatal screening.

(13) Coordinating the Health Board antenatal screening forum.

Standard M 4

There must be a process in place to deal with known request card errors.
Target 100%

(1) Down's, Edwards' and Patau's syndromes request card errors should not exceed 2%. Blood group and antibody request card errors should be 0%.

(2) For Down's, Edwards' and Patau's syndromes screening errors there must be a pathway for returning correct information to the laboratory within one working day of notification of mistake.

(3) There must be a risk management pathway in place to reduce numbers of errors.

Standard M 5

Health Boards should identify a named Governance Lead for Maternal and Child Screening who manages the strategic governance role of these programmes.
Target 100%

Within the antenatal screening programme, the named Governance Lead will have responsibility for:

(1) Acting as Governance Lead for the Health Board in matters relating to the newborn hearing, newborn bloodspot and antenatal screening programmes.

(2) Acting as liaison between the Health Board and Maternal and Child Screening programmes.

(3) Lead on the implementation of the antenatal standards, protocols, and pathways in the Health Board.

(4) Lead the Health Board in facilitating the provision of information for audit and feedback for the programmes to ensure quality assurance.

(5) The Governance Lead is expected to work one day a week for Maternal and Child Screening.

(6) To work alongside the obstetric, sonographer, laboratory and midwifery leads.

(7) To ensure action plans for the performance indicators and Down's syndrome Quality Assurance Support Service (DQASS) reports are developed where required and acted upon in a timely manner.

3.2 Information for Women

Standard M 6

Health Boards must make arrangements for women to receive the Antenatal Screening Wales Information for Women pack in early pregnancy.[b]

Target 100%

(1) Where women have a different language or communication need, Health Boards should ensure the provision of accurate information in a format that is accessible to each individual woman. This is essential to obtain informed consent. This may include for example British Sign Language, or an approved interpreter service.

3.3 Record Keeping

Standard M 7

Maternity services must use the All Wales Hand Held Maternity Record which contains a structured antenatal screening record section to facilitate the capture of all key information.

Target 100%

(1) A contemporaneous, dated and signed record must be made. This information must include:

- the name of the professional who provided information to the woman about the screening test
- the date the screening test was offered
- the woman's decision whether to accept or decline the screening test
- the date the blood test or ultrasound scan was performed
- the test result
- the date the result was discussed with the woman
- any follow-up care planned.

[b] Written information for women is available from ASW in hard copy and as `e-leaflets´ on *http://www.antenatalscreening.wales.nhs.uk/public/antenatal-screening-tests*.

4.0 Antenatal Screening for HIV, Hepatitis B and Syphilis

Policy Statement

All women resident in Wales should be offered antenatal screening in every pregnancy for:

• HIV (National Assembly for Wales 2000; NICE 2008)

• hepatitis B (WHC 1998 (36), NICE 2008)

• syphilis (NICE 2008)

HIV (Human Immunodeficiency Virus)

HIV is a retrovirus that attacks and destroys T-lymphocytes, resulting in immune-suppression that eventually leads to acquired immune deficiency syndrome (AIDS). Vertical transmission of the virus from mother to fetus or baby can occur during pregnancy, at delivery or postnatally through breastfeeding.

Rationale for Antenatal HIV Screening

To identify women who have an established HIV infection so that treatment and care can be offered to reduce the risk of mother to baby transmission of the virus from about 25% to around 1%. The identification and treatment of HIV also has considerable health benefits for the woman. A system of clear referral pathways is required in each unit or department so that pregnant women who are diagnosed with an HIV infection are managed and treated by the appropriate specialist teams (NICE 2008).

Programme Limitations

The screening programme will not detect infections contracted recently or infections contracted after the antenatal screening test has been taken. Women who are at higher risk of contracting HIV, hepatitis B, syphilis or other sexually transmitted infections will require specific individual advice on the advisability of additional testing in pregnancy, preferably from the sexual health services.

Anticipated Outcome

Mother to baby transmission of HIV can be significantly reduced with appropriate pregnancy, delivery and postnatal care management.

Hepatitis B

Hepatitis B is an infectious disease of the liver caused by the hepatitis B virus (HBV), resulting in both acute and chronic infection and is spread by direct contact with an infected person's blood. An infected mother can transmit the infection to her baby at the time of delivery. The virus can also be detected in other body fluids such as semen and saliva. Most adults infected with hepatitis B recover fully from the infection but some adults develop a chronic form of the disease.

Vertical transmission at or around the time of delivery from an infected mother to her baby is an important cause of the continued high prevalence of this infection in some parts of the world. Neonates infected in this way are very likely (approximately 90%) to become infected and become chronic carriers of the hepatitis B virus.

From September/ October 2017 all babies in Wales will be offered Infanrix hexa® (DTaP/IPV/Hib/HepB) at the ages of 8, 12 and 16 weeks as part of the routine childhood immunisation schedule. This does not remove the need for existing screening programmes for hepatitis B in pregnancy in Wales or the administration of hepatitis B vaccine (with immunoglobulin where required). There will be a change to the vaccination schedule following the first dose at birth (WHC (022) 2017).

Rationale for Hepatitis B Screening
To enable the identification of women who are infected with hepatitis B and are pregnant whose infants will be at significant risk of contracting hepatitis B at or around the time of delivery. This will enable the offer of post-exposure prophylaxis to the neonate.

Programme Limitations
The screening programme aims to detect women with established hepatitis B infection and not infections contracted in the weeks before the screening test is taken or infections contracted after the antenatal screening test. Women who are at higher risk of contracting HIV, hepatitis B, syphilis or other sexually transmitted infections because of their lifestyle will require specific individual advice on the advisability of additional testing in pregnancy, preferably from the sexual health services.

Anticipated Outcomes
The rate of mother to baby transmission of hepatitis B will be significantly reduced by the identification of at risk babies and the provision of an appropriate vaccination programme.

Syphilis
Syphilis results from infection by the spirochete bacterium, treponema pallidum. Humans are the only host, and transmission can occur through sexual contact (adult syphilis) or following transmission across the placenta during pregnancy from an infected mother to her fetus (congenital syphilis).

Rationale for Syphilis Screening
To identify women who have syphilis in early pregnancy and offer appropriate treatment to substantially reduce the risks of the fetus contracting congenital syphilis. The identification and treatment of this communicable disease also has potential health benefits for the mother.

Programme Limitations
The screening programme will not detect infections contracted recently or infections contracted after the antenatal screening test has been taken. Women who are at higher risk of contracting HIV, hepatitis B, syphilis or other sexually transmitted infections will require specific individual advice on the advisability of additional testing in pregnancy, preferably from the sexual health services.

If the screening test result is suggestive of current or previous infection, the result must be considered in conjunction with the woman's clinical and social history before a diagnosis can be made. This should be undertaken by a physician who is experienced in the laboratory diagnosis and management of this infection.

Anticipated Outcomes
With early diagnosis and treatment of the mother if required, the risk of a fetus contracting congenital syphilis is substantially reduced.

Cessation of Rubella Screening in Wales

A review of antenatal screening for rubella susceptibility, held in 2012, by the UK National Screening Committee (UK NSC) found that rubella susceptibility screening in pregnancy no longer met the UK NSC criteria for a screening programme because of the effectiveness of the measles, mumps and rubella (MMR) immunisation programme: legacy.screening.nhs.uk/rubellasusceptibility

The Wales Screening Committee considered the UK NSC's recommendation and endorsed the decision for Wales. England ceased screening in April 2016 and Scotland ceased in June 2016. The offer of antenatal screening for rubella susceptibility stopped for pregnant women in Wales whose booking bloods were taken on or after **3 October 2016.**

Due to the high uptake of the MMR vaccination, the epidemiology of rubella has changed, providing the rationale to end screening for susceptibility in pregnancy:

- Rubella infection levels in the UK are at a level defined as eliminated by the World Health Organization. The last case of laboratory confirmed rubella in Wales was in 2005.
- Screening for rubella susceptibility in pregnancy does not give any protection to the unborn baby in the current pregnancy.
- The test may falsely reassure some women that they are not susceptible to rubella infection in the current pregnancy.
- Being fully immunised before becoming pregnant is the most effective way to protect women against rubella in pregnancy. Two doses of MMR vaccine are recommended.
- Stopping antenatal screening is unlikely to result in increased rates of congenital rubella. There were 12 cases of congenital rubella reported in the UK between 2005 and 2015, but none of these could have been prevented by the screening programme as they were in women born overseas. There have been no cases of congenital rubella in Wales in the last 10 years. We will continue to monitor cases following the cessation of screening.
- Women who have not previously had two doses of a vaccine containing rubella should ask their GP to arrange for two doses of MMR a month apart and should avoid becoming pregnant for at least a month after the second dose. The vaccine cannot be given during pregnancy.

Also see Frequently Asked Questions for more information.

4.1 General Standards and Protocols for HIV, Hepatitis B and Syphilis Screening

4.1.1 Pre Test Information

Standard C 1

The woman must be given the ASW Information for Women pack about infections in pregnancy and a record of the information provided made in the All Wales Maternity Record.[c]

Target 100%

(1) A copy of the ASW Information for Women pack should be provided before the woman is asked to consent to this test.

(2) The midwife should make a record of written information given to the woman.

Standard C 2

The midwife must have a verbal discussion with the woman about the infections in pregnancy prior to consenting for the test and a record of the discussion must be made in the All Wales Maternity Record.

Target 100%

(1) The purpose, implications, limitations and benefits of these screening tests must be explained to the woman by the midwife.[d]

(2) For women who require more information, counselling or support, this service is available from Integrated Sexual Health.

4.1.2 Screening Offer

Standard C 3

All women must be offered antenatal screening for HIV, hepatitis B and syphilis before 10 completed weeks of pregnancy (if the woman presents before that time). A record of the offer must be made in the All Wales Maternity Record.

Target 100%

(1) Women who attend for antenatal care after 10 completed weeks of pregnancy should be offered screening for HIV, hepatitis B and syphilis at the first opportunity.

(2) Women who decline screening should be re-offered these screening tests during pregnancy, preferably at the 28 week antenatal appointment.

[c] Written information for women is available from ASW in hard copy and as `e-leaflets on http://www.antenatalscreening.wales.nhs.uk.

[d] Where women have a different language or communication need, Health Boards should ensure the provision of accurate information in a format that is accessible to each individual woman. This may include for example British Sign Language, or an approved interpreter service.

Standard C 4

Women who do not attend for antenatal care during the pregnancy and present during labour, should be offered screening for HIV, hepatitis B and syphilis at the most appropriate time and within four hours of delivery. The midwife or doctor should contact the consultant microbiologist to ask for a risk assessment and to establish the urgency of testing and management whilst results are awaited.

Target 100%

4.1.3 Consent

Standard C 5

The woman's informed verbal consent is required for these tests and this must be recorded in the All Wales Maternity Record.

Target 100%

(1) If the woman declines screening for HIV, hepatitis B or syphilis, the midwife should ensure the woman has received accurate information on which to base her decision.

Standard C 6

Women who decline screening for HIV, hepatitis B or syphilis should be given a further opportunity to consent to these screening tests during pregnancy, preferably at the 28 week antenatal appointment and this must be recorded in the All Wales Maternity Record.

Target 100%

4.1.4 Test Requesting

Standard C 7

The laboratory request form must be identified as 'Antenatal Screening' and requires the name of the lead clinician or identified as obstetric led care if the named obstetrician is not known at this stage.

Target 100%

Standard C 8

All mandatory fields on the laboratory request must be completed.

Target 100%

Standard C 9

The health professional requesting the test must complete and sign the request form.[e]

Target 100%

(1) Electronic requesting must enable a clear audit trail to identify the requester.

(2) If a single request form is used for multiple screening tests, there must be a clear indication of the screening tests to which the woman has given consent and those that are declined.

[e] By signing the laboratory or ultrasound request form, the requesting health professional is confirming that written and/or verbal information about the purpose of the test or scan has been given to the woman and that she has given informed consent for the test.

4.1.5 Test Procedure

Standard C 10

The sample must be taken before 13 weeks of pregnancy (if the woman presents for care before this gestation).

Target 95%

(1) If the woman is more than 23 completed weeks pregnant when the sample is taken, the sample should be marked urgent.

(2) If the woman is more than 36 weeks pregnant when the sample is taken, the sample should be marked urgent and the laboratory contacted.

(3) If the woman is in labour or is postnatal when the sample is taken, the health professional should contact the consultant microbiologist/consultant virologist to ask for a risk assessment and to establish the urgency of testing and management of the woman whilst the results are awaited.

Standard C 11

The person taking the sample must make a signed and dated record of the sample being taken in the All Wales Maternity Record.

Target 100%

(1) The woman's privacy must be respected. The discussion and blood test must be performed in a place where the woman's privacy can be assured.

(2) The person taking the sample must ask the woman to state her name, date of birth and address and these must be identical to the information on the request form and the sample.

4.1.6 Laboratory Services

Standard C 12

The laboratory must be appropriately accredited in accordance with United Kingdom Accreditation Service, and working toward ISO standard 15189. The laboratory must be able to demonstrate satisfactory performance.

Target 100%

Standard C 13

The sample must be received by the local laboratory within one working day of the sample being taken.

Target 95%

Standard C 14

If the sample is forwarded to another laboratory, the sample must be received by the testing laboratory within two working days of the sample being taken.

Target 100%

Standard C 15

The testing laboratory must aim to achieve a five working day turnaround from sample receipt to result reporting for non urgent samples.

Target 95%

Standard C 16

Samples marked `urgent´ must be processed and reported within one working day.
Target 95%

(1) Samples from a woman who has booked for maternity care after 23 completed weeks of pregnancy should be marked as urgent.

Standard C 17

Laboratory reports must contain a clinical comment to aid interpretation of results.
Target 100%

(1) The clinical comment should be given verbally when results are telephoned from the laboratory.

4.1.7 Results Handling

Standard C 18

If the sample has not been tested at the local laboratory, the result must be returned to the local laboratory within one working day of the result being signed out by the testing laboratory.
Target 95%

Standard C 19

The result must be available to the maternity service within one working day of the result being reported by, or to, the local laboratory.
Target 95%

(1) Results should be issued to the clinical team taking care of the woman during her pregnancy. Laboratories should not normally give results to health professionals following a telephone enquiry unless there is a clear indication of clinical need that affects immediate management of care.

Standard C 20

Positive results must only be reported for HIV, hepatitis B and syphilis following confirmation of the initial screening result using a different method to the original test.
Target 100%

Standard C 21

There must be a written and agreed failsafe process in place to identify and follow up results not received by the maternity service.
Target 100%

Standard C 22

There must be a written and agreed process in place to identify and follow up where an additional sample or additional information is required by the laboratory.
Target 100%

Standard C 23

Where no problem is found, women should be informed of the results of all the tests she has consented to by the maternity service at the 16 week antenatal visit. Where sampling has occurred later in pregnancy results should be given within 3 weeks of the sample being taken.

Target 100%

(1) If any of these results are not available, the local pathway as identified in Standard C 21 should be followed.

Standard C 24

The result must be recorded in the All Wales Maternity Record the next time the woman is reviewed by a health professional.

Target 100%

(1) A dated and signed record that the result has been discussed with the woman must be made in the maternity notes.

(2) Any actions relating to the result should also be documented.

4.2 Specific Standards and Protocols for Antenatal HIV Screening

4.2.1 Previous Infection

Standard C 25

If the woman indicates that she has been previously diagnosed with HIV, she must be offered re-screening to confirm the diagnosis and the relevant information should be included on the request form with the woman's consent.

Target 100%

Standard C 26

Women who are aware they are HIV positive must be offered a referral to Integrated Sexual Health within 2 working days to enable the development of a joint care plan.

Target 100%

4.2.2 HIV Reactive Results

Standard C 27

The antenatal screening coordinator (or named deputy) must be informed of HIV reactive test results within one working day by the laboratory.

Target 100%

(1) The relevant Antenatal Screening Wales pathway should be followed depending on the result of the test.

(2) Written information for women is available from Antenatal Screening Wales to inform the discussion with the woman.

Standard C 28

A dated and signed record must be made in the hospital maternity notes of actions undertaken and planned in response to a HIV reactive result.

Target 100%

(1) A record of the reactive result should be recorded appropriately in the hospital maternity notes and the confidentiality of the information ensured by Health Board confidentiality policies.

4.2.3 HIV Positive Results

Standard C 29

The antenatal screening coordinator (or named deputy) must be informed of HIV positive test results within one working day by the laboratory.

Target 100%

Standard C 30

The result must be given to the woman within five working days of the result being available.

Target 95%

(1) Arrangements should be made for pregnant women to return to the antenatal clinic to be given her HIV positive result as soon as possible and when the necessary healthcare professionals are available.

(2) Interpreter services should be arranged if required.

(3) HIV is a relatively rare infection in Wales; only named health professionals with suitable skills and knowledge, as agreed by the Health Board should give the result to the woman. Support should be sought from a member of the HIV specialist team.

(4) Sensitive results, including communicable disease positive results, should be given in a clinic setting (not in the woman's home) as the health professional will have more control over the confidentiality of the environment.

(5) To maintain confidentiality, the woman should be given the result in person, without other relatives or friends being present.

(6) Unless the General Practitioner requested the test and is providing the woman with the result, the General Practitioner should not be informed of the result before the woman has given her consent for the General Practitioner to be informed.

(7) A copy of the ASW information for women leaflet should be provided to the woman.[f]

Standard C 31

For complete confirmation of sample identity, a second sample will be required.

Target 100%

4.2.4 Record Keeping

Standard C 32

A dated and signed record must be made in the maternity notes of actions undertaken and planned in response to HIV positive results.

Target 100%

(1) HIV positive screening results should not be recorded in the woman's All Wales Maternity Record without her consent.

(2) A record of the confirmed positive test should be recorded on the maternity information system with the woman's informed consent.

(3) A record of the confirmed positive test should be recorded appropriately in the hospital maternity notes and the confidentiality of the information ensured by Health Board confidentiality policies.

[f] Written information for women is available from ASW in hard copy and as `e-leaflets' on *http://www.antenatalscreening.wales.nhs.uk/public/leaflets*.

4.2.5 Care Plan

Standard C 33

An urgent appointment within 10 working days to Integrated Sexual Health is required so that suitable treatment can be commenced promptly.

Target 95%

(1) Sexual contacts require the offer of screening for HIV via the Integrated Sexual Health.

Standard C 34

An appropriate integrated care plan must be developed by the maternity services in collaboration with Integrated Sexual Health and this must be documented in the hospital notes.

Target 100%

(1) This should be developed in accordance with BHIVA (2014) guidance and must be developed in discussion with the woman and with the advice of a multidisciplinary team. This may take a number of visits and discussions. The woman will require adequate time to consider her diagnosis before the care planning process can start. The type of care required will depend on the woman's viral load and other factors and must be managed by a specialist HIV team.

(2) Paediatric referral should be made by the maternity services within 10 working days of the woman receiving the result because the baby will require specific follow up usually including antiretroviral drug treatment.

(3) The woman will require ongoing support from a named midwife and all maternity care arrangements should be coordinated by the antenatal screening coordinator.

(4) Interpreter services should be arranged for every antenatal clinic visit if required.

(5) The result should not be given by the maternity staff to the woman's partner or relatives without the woman's consent. The result should not be given to the General Practitioner or Health Visitor without the woman's consent. Discussing these issues should form part of a comprehensive care plan developed with the specialist HIV team.

(6) Breastfeeding should be discouraged as the HIV virus can be transmitted in breast milk (free formula milk is available to HIV positive women in Wales).

4.2.6 Postnatal Care

Standard C 35

The baby must be referred to a paediatrician as soon as possible after delivery and within 4 hours of birth.

Target 100%

(1) The baby will require specific follow up usually including antiretroviral drug treatment coordinated by the paediatrician.

4.3 Specific Standards and Protocols for Antenatal Hepatitis B Screening

4.3.1 Previous Infection

Standard C 36

If the woman indicates that she has been previously diagnosed with a hepatitis B infection, or has a current hepatitis B infection, she should be re-screened to confirm the diagnosis and the relevant information should be included on the request form with the woman's consent.

Target 100%

(1) In cases where the diagnosis is already known, a sample for hepatitis B DNA should be taken, with verbal consent, at the same time as the antenatal screening tests and that a copy of the result is sent to the health board's consultant gastroenterologist/hepatologist to whom the woman has been referred.

(2) The woman should be advised that if the infection is ongoing the baby will require vaccination and may require immunoglobulin.

(3) The woman should be reviewed by a hepatology/gastroenterology team within 6 weeks of confirmation to assess viral load and consider treatment to reduce the woman's viral load.

4.3.2 Hepatitis B Reactive Results

Standard C 37

The antenatal screening coordinator (or named deputy) must be informed of hepatitis B reactive test results within one working day by the laboratory.

Target 100%

(1) The relevant Antenatal Screening Wales pathway should be followed depending on the result of the test.

(2) Written information for women is available from Antenatal Screening Wales to inform the discussion with the woman.

Standard C 38

A dated and signed record must be made in the hospital maternity notes of actions undertaken and planned in response to a hepatitis B reactive result.

Target 100%

(1) A record of the reactive result should be recorded appropriately in the hospital maternity notes and the confidentiality of the information ensured by Health Board confidentiality policies.

4.3.3 Hepatitis B Positive Results

Standard C 39

The antenatal screening coordinator (or named deputy) should be informed of confirmed hepatitis B positive test results within one working day by the laboratory.

Target 100%

Standard C 40

Arrangements must be made for the woman to return to the antenatal clinic to be given her hepatitis B positive results.

Target 100%

(1) Interpreter services should be arranged if required.

(2) Hepatitis B is a relatively rare infection in Wales; only named health professionals with suitable skills and knowledge as agreed by the Health Board should give the result to the woman. Support should be sought from a member of the hepatology/gastroenterology specialist team.

(3) Unless the woman is known to be in labour or more than 24 weeks pregnant, there is no immediate urgency to give this result. Suitable arrangements should be made for the woman to return to the antenatal clinic usually within a week to receive the result.

(4) Sensitive results, including communicable disease results, should be given in a clinic setting (not in the woman's home) as the health professional will have more control over the confidentiality of the environment.

(5) To maintain confidentiality, the woman should be given the result in person, without other relatives or friends being present.

(6) Unless the General Practitioner requested the test and is providing the woman with the result, the General Practitioner should not be informed of the result before the woman has given her consent for the General Practitioner to be informed. This should prevent screening of other family members inadvertently being instigated by the General Practitioner prior to the woman first being informed of her result.

(7) A copy of the ASW information for women leaflet should be provided to the woman.[g]

Standard C 41

For complete confirmation of sample identity, a second sample will be required.

Target 100%

(1) It is recommended, in order to expedite the management of women who have been newly diagnosed with hepatitis B that a sample for hepatitis B DNA is taken, with verbal consent, at the time as the confirmatory sample. A copy of the result is sent to the health board's consultant gastroenterologist/ hepatologist to whom the woman has been referred.

(2) The laboratory should inform the Health Protection Team of the confirmed positive result to enable care planning to commence.

[g] Written information for women is available from ASW in hard copy and as `e-leaflets´ on *http://www.antenatalscreening.wales.nhs.uk/public/hepatitis-b*.

Standard C 42

A dated and signed record must be made in the maternity notes of actions undertaken and planned in response to hepatitis B positive results.

Target 100%

(1) Hepatitis B positive screening results should not be recorded in the woman's All Wales Maternity Record without her consent.

(2) A record of the confirmed positive test should be recorded on the maternity information system with the woman's informed consent.

(3) A record of the confirmed positive test should be recorded appropriately in the hospital maternity notes and the confidentiality of the information ensured by Health Board confidentiality policies.

4.3.4 Care Plan

Standard C 43

All women diagnosed with a positive hepatitis B infection must be reviewed by a hepatology/ gastroenterology specialist team within 6 weeks of diagnosis.

Target 100%

(1) The woman should be reviewed by a hepatology/gastroenterology team within 6 weeks of diagnosis to assess viral load and consider treatment to reduce the woman's viral load.

(2) A joint care plan should be written and may require discussion with the obstetrician, paediatrician, hepatologist/gastroenterologist and virologist.

(3) Paediatric referral should be made by the maternity services within 10 working days of the woman receiving the result because arrangements must be made for infants of women who are hepatitis B positive to receive appropriate treatment rapidly after birth.

(4) The woman will require ongoing support from a named midwife and all maternity care arrangements should be coordinated by the antenatal screening coordinator.

(5) Interpreter services should be arranged for every antenatal clinic visit if required.

(6) The result should not be given by the maternity staff to the woman's partner or relatives without the woman's consent. The result should not be given to the General Practitioner or Health Visitor without the woman's consent. Discussing these issues should form part of a comprehensive care plan developed with the hepatology/gastroenterology specialist team.

Standard C 44

Arrangements must be made in the antenatal period for infants of women who are hepatitis B positive to receive appropriate treatment rapidly after birth.[1]

Target 100%

(1) Maternal consent should be obtained at a suitable time during the antenatal period for the baby to receive appropriate immunisation in the very early postnatal period.

(2) Hepatitis B specific immunoglobulin (HBIG), to provide short term passive immunity (or protection), for those babies born to the most infectious mothers should be ordered from the Health Protection Team for babies of named mothers ensuring availability from when the woman is 32–34 weeks pregnant.

(3) The Health Protection Team must arrange for household contacts to receive counselling and the offer of screening for hepatitis B (WHC 1998 (36).

4.3.5 Postnatal Care

Standard C 45

Arrangements must be in place for the baby to receive the 1st vaccination (and HBIG if the baby is deemed to be high risk of hepatitis B), within 24 hours of birth.[2]

Target 100%

(1) Babies born to women who are hepatitis B positive will require (with maternal consent) immunisation in accordance with 'Screening of pregnant women for hepatitis B and immunisation of babies at risk' (WHC 1998 (36)).

(2) Babies born weighing less than 1500gs should receive HBIG in addition to the vaccine regardless of the antigen status of the mother (DOH 2017).

(3) An unscheduled vaccination form should be completed and sent to the Child Health Department after the vaccination has been given.

(4) The importance of the baby receiving the full course of immunisations should be explained to the mother by the community midwife.[3]

(5) The woman can be encouraged to breastfeed if the baby is immunised/vaccinated.

4.4 Specific Standards and Protocols for Antenatal Syphilis Screening

4.4.1 Previous Infection

Standard C 46

If the woman indicates that she has been previously diagnosed with a syphilis infection, or has a current syphilis infection, she must be re-screened to confirm the diagnosis and the relevant information should be included on the request form with the woman's consent.

Target 100%

4.4.2 Syphilis Reactive Results

Standard C 47

The antenatal screening coordinator (or named deputy) must be informed of syphilis reactive test results within one working day by the laboratory.

Target 100%

(1) The relevant Antenatal Screening Wales pathway should be followed depending on the result of the test.

(2) Written information for women is available from Antenatal Screening Wales to inform the discussion with the woman.

Standard C 48

A dated and signed record must be made in the hospital maternity notes of actions undertaken and planned in response to a syphilis reactive result.

Target 100%

(1) A record of the reactive result should be recorded appropriately in the hospital maternity notes and the confidentiality of the information ensured by Health Board confidentiality policies.

4.4.3 Syphilis Positive Results

Standard C 49

The antenatal screening coordinator (or named deputy) should be informed of significant syphilis positive test results within one working day by the laboratory.

Target 100%

(1) The syphilis screening test is not able to discriminate between syphilis and other non communicable diseases, e.g. yaws, pinta, bejel or a previously treated syphilis infection. The laboratory result therefore needs expert interpretation by a consultant microbiologist/virologist before the result is issued.

Standard C 50

Urgent arrangements (within 3 working days) must be made for the woman to return to the antenatal clinic for the result.

Target 100%

(1) Interpreter services should be arranged if required.

(2) Syphilis is a rare condition in the UK; only health professionals with suitable skills and knowledge as agreed by the Health Board should give the result to the woman. Support should be sought from a member of the Integrated Sexual Health specialist team.

(3) Sensitive results, including communicable disease results, should be given in a clinic setting (not in the woman's home) as the health professional will have more control over the confidentiality of the environment.

(4) To maintain confidentiality, the woman should be given the result in person, without other relatives or friends being present.

(5) Unless the General Practitioner requested the test and is providing the woman with the result, the General Practitioner should not be informed of the result before the woman has given her consent for the General Practitioner to be informed.

(6) The woman should be informed of the possible significant health risks to the baby and the need for treatment.

(7) A copy of the ASW information for women leaflet should be provided to the woman[h].

Standard C 51

For complete confirmation of sample identity, a second sample will be required.

Target 100%

4.4.4 Care Plan

Standard C 52

Women with a confirmed syphilis positive result should have an urgent appointment (within 2 working days) to Integrated Sexual Health for assessment, counselling and possible treatment.

Target 100%

(1) Treatment with antibiotics (if required) should be commenced promptly by the Integrated Sexual Health specialist to reduce the risk of fetal damage caused by maternal to fetal transmission of syphilis.

(2) Arrangements must be made (if required) by Integrated Sexual Health for any sexual contacts to receive counselling and the offer of screening for syphilis.

(3) Follow up care and management should be planned in conjunction with the consultant obstetrician and Integrated Sexual Health and a care plan should be written in the All Wales Maternity Record with the woman's consent.

[h] Written information for women is available from ASW in hard copy and as `e-leaflets on *http://www.antenatalscreening.wales.nhs.uk/public/syphilis*

(4) Referral to fetal medicine department to evaluate fetal involvement including non-immune hydrops or hepatosplenomegaly and fetal monitoring for fetal distress in the early stages of therapy is recommended after 26 weeks gestation (BASHH 2008).

Standard C 53

A dated and signed record must be made in the maternity notes of actions undertaken and planned in response to syphilis positive results.

Target 100%

(1) Syphilis positive screening results should not be recorded in the woman's All Wales Maternity Record without her consent.

(2) A record of the confirmed positive test should be recorded on the maternity information system with the woman's informed consent.

(3) A record of the confirmed positive test should be recorded appropriately in the hospital maternity notes and the confidentiality of the information ensured by Health Board confidentiality policies.

Standard C 54

The paediatrician should be informed of the confirmed maternal syphilis infection within 10 days of the woman receiving the result. This is to enable an appropriate care plan for the neonate to be developed with the woman and the maternity services and recorded in the maternity notes.

Target 100%

4.4.5 Postnatal Care

Standard C 55

Arrangements must be in place for the baby to be reviewed by the paediatrician as soon as possible after delivery and within 4 hours of birth.

Target 100%

(1) A maternal and neonatal blood sample (clotted sample) for syphilis testing should be taken just after delivery before treatment of the baby is started. The exact requirements should be discussed with the virologist before delivery.

Standard C 56

Arrangements must be in place for the neonate to receive paediatric follow up including appropriate treatment and serology testing.

Target 100%

5.0 Antenatal Blood Group and Antibody Screening

Policy Statement

All women resident in Wales should be offered antenatal screening for blood group and antibodies in pregnancy (NICE 2008).

Blood Group and Red Cell Antibodies

There are four main blood groups: group O, group A, group B and group AB. There is also another blood factor called the Rhesus (Rh) group and people have a blood group and Rh group, e.g. group O Rhesus D positive. Rh factor is a protein found in red blood cells in about 85% of people and its presence denotes a person is Rh D-positive. If it is absent, the person is RhD-negative.

Where the woman is RhD-negative and the baby is RhD-positive there is the possibility of maternal antibodies passing from the maternal bloodstream into the fetus. This can cause a rare condition called haemolytic disease of the fetus and newborn (HDN). In clinical terms, Rhesus factor antibodies is the commonest and most significant but a number of other red cell proteins (such as Kell, c, Duffy and Kidd) may also cause maternal IgG antibody production, leading to similar problems to those caused by Rhesus factor antibodies.

Rationale for Screening

Antenatal screening for blood group and antibodies should be offered to all pregnant women in early pregnancy, irrespective of previous screening results as an integrated part of their antenatal care. If any antibodies are found, particularly anti D, anti Kell, or anti c, the antibodies can be monitored and appropriate obstetric management advised. If pregnancies at risk of fetal and neonatal HDN caused by RhD incompatibility are identified, i.e. RhD-negative women, anti D prophylaxis can be offered.

Anticipated Outcome

Reduction in neonatal HDN and a reduction in pregnancy associated problems.

5.1 Pre Test Information

Standard BG 1

The woman must be given the ASW Information for Women pack and a record of the information provided made in the All Wales Maternity Record.[i]

Target 100%

(1) A copy of the ASW Information for Women pack should be provided before the woman is asked to consent to this test.

(2) The midwife should make a record of written information given to the woman.

Standard BG 2

The midwife must have a verbal discussion with the woman about blood group and antibodies in pregnancy prior to consenting for the test and a record of the discussion must be made in the All Wales Maternity Record.

Target 100%

(1) The purpose, implications, limitations and benefits of this screening test must be explained to the woman by the midwife.[j]

5.2 Screening Offer

Standard BG 3

All women must be offered antenatal screening for blood group and antibodies before 10 completed weeks of pregnancy (if the woman presents before that time). A record of the offer must be made in the All Wales Maternity Record.

Target 100%

(1) Women who attend for antenatal care after 10 weeks of pregnancy should be offered this screening at the first opportunity.

(2) All women who have previously had an infant affected by HDN should be referred before 20 weeks to a specialist unit for advice and for assessment of fetal haemolysis, irrespective of antibody level.

[i] Written information for women is available from ASW in hard copy and as `e-leaflets´ on http://www.antenatalscreening.wales.nhs.uk/public/antenatal-screening-tests.

[j] Where women have a different language or communication need, Health Boards should ensure the provision of accurate information in a format that is accessible to each individual woman. This may include for example British Sign Language, or an approved interpreter service.

5.3 Consent

Standard BG 4

The woman's informed verbal consent is required for these tests and this must be recorded in the All Wales Maternity Record.

Target 100%

(1) If the woman declines screening for blood group and antibodies the midwife should ensure the woman has received accurate information on which to base her decision.

5.4 Test Requesting

Standard BG 5

The laboratory request must be identified as `Antenatal Screening´ and either a booking or 28 week sample. It also requires the name of the lead clinician or identified as obstetric led care if the named obstetrician is not known at this stage.

Target 100%

Standard BG 6

The health professional requesting the test must complete and sign the request form.[k]

Target 100%

(1) Electronic requesting must enable a clear audit trail to identify the requester.

Standard BG 7

All mandatory fields on the laboratory request must be completed.

Target 100%

(1) If antenatal anti D prophylaxis has been administered to the woman, at any stage in the pregnancy, this information must be included on the laboratory request, as this may affect the interpretation of the results. The laboratory will require the date and dose of anti D given (BCSH 2006).

5.5 Test Procedure

Standard BG 8

The sample should be taken before 13 weeks of pregnancy (if the woman presents for care before this gestation).

Target 95%

[k] By signing the laboratory or ultrasound request form, the requesting health professional is confirming that written and/or verbal information about the purpose of the test or scan has been given to the woman and that she has given informed consent for the test.

Standard BG 9

The person taking the sample must make a signed and dated record of the sample being taken in the All Wales Maternity Record.

Target 100%

(1) The woman's privacy needs must be respected. The discussion and blood test must be performed in a place where the woman's privacy can be assured.

(2) The person taking the sample must ask the woman to state her name, date of birth and address and these must be identical to the information on the request form and the sample.

5.6 Laboratory Services

Standard BG 10

The laboratory must be appropriately accredited in accordance with United Kingdom Accreditation Service, and working towards ISO standard 15189. The laboratory must be able to demonstrate satisfactory performance.

Target 100%

Standard BG 11

Antibody screening should be undertaken using an indirect antiglobulin test and a red cell panel conforming to current UK guidelines (NICE 2008).

Target 100%

(1) The local laboratory should provide advice on the sample requirements as this will vary depending on the laboratory. The sample should be tested for blood group and atypical red cell alloantibodies.

Standard BG 12

The sample must be received by the local laboratory within one working day of the sample being taken.

Target 95%

Standard BG 13

If the sample is forwarded to another laboratory, the sample must be received by the testing laboratory within two working days of the sample being taken.

Target 100%

Standard BG 14

The testing laboratory must aim to achieve a five working day turn around from sample receipt to result reporting for non urgent samples.

Target 95%

5.7 Results Handling

Standard BG 15

If the sample has not been tested at the local laboratory, the result must be returned to the local laboratory within one working day of the result being signed out by the testing laboratory.

Target 95%

Standard BG 16

The result must be available to the maternity service within one working day of the result being reported by, or to, the local laboratory.

Target 95%

(1) Results should be issued to the clinical team taking care of the woman during her pregnancy. Laboratories should not normally give results to health professionals following a telephone enquiry unless there is a clear indication of clinical need that affects immediate management of care.

Standard BG 17

There must be a written and agreed failsafe process in place to identify and follow up results not received by the maternity service.

Target 100%

Standard BG 18

There must be a written and agreed process in place to identify and follow up where an additional sample or additional information is required by the laboratory.

Target 100%

5.8 Rhesus Positive, Antibody Negative Result

Standard BG 19

Where no problem is found, women should be informed of the results by the maternity service at the 16 week antenatal visit. Where sampling has occurred later in pregnancy results should be given within 3 weeks of the sample being taken.

Target 100%

(1) If any of these results are not available, the local pathway as identified in Standard BG 17 should be followed.

(2) The woman should be informed that she is RhD-positive and will not require anti D prophylaxis. Further screening for atypical red cell alloantibodies is advised at 28 weeks of pregnancy.

Standard BG 20

The results must be recorded in the All Wales Maternity Record the next time the woman is reviewed by a health professional.

Target 100%

(1) A dated and signed record that the results have been discussed with the woman must be made in the All Wales Maternity Record.

(2) Any actions relating to the result should also be documented.

5.9 Rhesus D Negative, Antibody Negative Results

Standard BG 21

Where no problem is found, women should be informed of the results by the maternity service at the 16 week antenatal visit, or where sampling has occurred later in pregnancy within 3 weeks of the sample being taken.

Target 100%

(1) The woman should be informed of the implications of being Rhesus D negative.

Standard BG 22

Every Health Board must have a protocol for antenatal anti D prophylaxis care and management of Rhesus D negative women.

Target 100%

(1) All women who are RhD-negative should receive verbal and written information about antenatal and postnatal anti D prophylaxis and have the opportunity to discuss this treatment with a midwife in the early antenatal period.

(2) Information for women about being RhD-negative is provided in the ASW Information for Women pack. This information pack includes information about notifying a healthcare professional if a potentially sensitising event occurs.

(3) Routine antenatal anti D prophylaxis (RAADP) should be offered to all non-sensitised pregnant women who are RhD-negative. Each maternity service should have arrangements in place for implementing the offer and administration of this antenatal anti D prophylaxis[4, 5]

(4) The Health Board should have a process in place to ensure that women who are sensitised to anti D are not inadvertently administered with prophylactic anti D.

(5) The 28 week blood group and antibody sample must be collected prior to the administration of routine anti D prophylaxis.

(6) RAADP should be regarded as a separate entity and administered regardless of, and in addition to, any anti D immunoglobulin that may have been given for a potentially sensitising event (BCSH 2014).

Standard BG 23

Health Boards should have an appropriate protocol in place for offering specific antenatal treatment following a sensitising event. [6]

Target 100%

(1) Anti D prophylaxis (250 iu if less than 20 weeks gestation and 500 iu if greater than 20 weeks gestation) should be offered and, if accepted, given as soon as possible after the sensitising event and certainly within 72 hours.

(2) Kleihauer screening should be offered following a potentially sensitising event in pregnancy after 20 weeks gestation or after birth. Additional doses of anti D prophylaxis may be required, as advised by the laboratory, following Kleihauer screening result being obtained. This is not affected by the administration of routine anti D prophylaxis.

(3) A repeat maternal sample should be taken and screened 72 hours after the total dose of anti D immunoglobulin (Ig)injection (48 hours if the anti D Ig was given intravenously) if the feto-maternal haemorrhage is greater than or equal to 4ml. This is to check for clearance of fetal cells (BCSH 2009).

5.10 Antibody Positive Results

If antibodies are detected they should be identified, and quantified by the laboratory where appropriate, to assess the likelihood of HDN.

Target 100%

Standard BG 24

(1) There are a large number of potential antibodies which can cause HDN. If significant antibodies are found the laboratory should inform the consultant obstetrician, antenatal screening coordinator, or deputy.

(2) Confirmatory testing is required at a reference laboratory prior to a fetal medicine referral.

(3) When a new case of anti D antibodies is detected this should be reported to SHOT by the blood transfusion laboratory of the referring hospital (SHOT 2012).

Standard BG 25

Arrangements should be made for the woman to return to the antenatal clinic to be given her antibody positive result.

Target 100%

(1) Interpreter services should be arranged if required.

(2) The management of the pregnancy will depend on the clinical significance and titre of the antibody detected.

Standard BG 26

Pregnant women with clinically significant atypical red cell alloantibodies should be offered referral to a fetal medicine department.

Target 100%

(1) This should include:
- all women with a pregnancy where an infant was previously affected by HDN
- all anti K - (regardless of titre, and where paternal sample has been confirmed as K+ for this pregnancy)
- all clinically significant antibodies with a titre of 32 or greater (including anti E, e, Fya, Fyb, Jka, Jkb, S, s, M)
- all anti D with a quantitation greater than 4iu/ml
- all anti c with a quantitation greater than 7.5iu/ml.

5.11 Care Plan

Standard BG 27

A contemporaneous, dated and signed record must be made in the All Wales Maternity Record of actions planned and undertaken in response to the woman's RhD-negative and antibody status.

Target 100%

(1) There should be a dated and signed care plan in the notes regarding anti D prophylaxis and administration.

5.12 Postnatal Care

Standard BG 28

A maternal sample is required between 30 minutes and 2 hours (BCSH 2014) post delivery from all RhD-negative women (and from women where the maternal Rhesus group is not known) accompanied by a cord blood sample.

Target 100%

(1) Maternal and cord blood samples are required to assess feto-maternal haemorrhage in RhD-negative women who have delivered a RhD-positive infant to establish whether the woman requires additional anti D prophylaxis.

Standard BG 29

If the baby is RhD-positive, non-sensitised women who are RhD-negative should be offered, and if accepted, given postnatal anti D prophylaxis by the maternity service, within 72 hours of delivery (BCSH 2014) and a record made in the Health Board approved record.

Target 100%

(1) Additional doses of anti D prophylaxis may be required, as advised by the laboratory, following Kleihauer screening.

6.0 Antenatal Sickle Cell and Thalassaemia Screening

Policy statement

Antenatal screening for sickle cell and thalassaemia should be offered to all pregnant women at an increased risk of having a child affected by a sickle cell disorder or thalassaemia major (WHC 2003b (127); NICE 2008).

Sickle cell and Thalassaemia

Sickle cell and thalassaemia disorders are both types of recessively inherited haemoglobin disorders, only some of which are clinically significant. They affect people whose ancestry is mainly but not exclusively African, Caribbean, Middle Eastern, Mediterranean, South Asian and South East Asian. Those with severe forms of these disorders have a lifelong dependency on hospital care.

Rationale for Screening

To identify women who have a high chance of having a fetus affected by a sickle cell disorder or thalassaemia major (as defined by the ASW family origin screening questionnaire) to enable laboratory screening and, if required, antenatal diagnostic testing. The woman then has the opportunity for reproductive choices.

There may also be health benefits to the mother in the pregnancy if she is identified as having a sickle cell disorder.

Anticipated Outcome

Women who have a high chance of having a child affected by a sickle cell disorder or thalassaemia major will have reproductive choices.

6.1 Pre Test Information

Standard SCT 1

The woman must be given the ASW Information for Women pack about sickle cell and thalassaemia screening in pregnancy and a record of the information provided made in the All Wales Maternity Record.[l]

Target 100%

(1) A copy of the ASW Information for Women pack should be provided before the woman is asked to consent to this test.

(2) The midwife should make a record of written information given to the woman.

Standard SCT 2

The midwife must have a verbal discussion with the woman about sickle cell and thalassaemia in pregnancy prior to consenting for the test and a record of the discussion must be made in the All Wales Maternity Record.

Target 100%

(1) The purpose, implications, limitations and benefits of this screening test must be explained to the woman by the midwife.[m]

(2) The potential health benefits for the woman if she is identified as having a sickle cell disorder, and the disorder is appropriately managed, should also be explained.

6.2 Screening Question

Standard SCT 3

The woman must be asked the ASW family origin screening question (ASW FOQ) for sickle cell and thalassaemia in every pregnancy and before 10 completed weeks of pregnancy (if the woman presents before that time). A record of the offer must be made in the All Wales Maternity Record.

Target 100%

(1) The ASW FOQ should be asked by the midwife to assess whether laboratory screening for sickle cell and thalassaemia should be offered.

(2) If the result of the ASW FOQ suggests that the woman has a low chance of either carrying sickle cell or thalassaemia, or having a sickle cell or thalassaemia disorder, the woman can be informed by the midwife that she has a low chance of having a baby with a sickle cell disorder or thalassaemia major and that laboratory screening is not recommended.

[l] Written information for women is available from ASW in hard copy and as `e-leaflets´ on *http://www.antenatalscreening.wales.nhs.uk/public/antenatal-screening-tests*.

[m] Where women have a different language or communication need, Health Boards should ensure the provision of accurate information in a format that is accessible to each individual woman. This may include for example British Sign Language, or an approved interpreter service.

Standard SCT 4

The woman must be offered screening for thalassaemia if the full blood count indices indicate a possible thalassaemia (i.e. mean cell haemoglobin (MCH) below 27pg). This must be documented in the All Wales Maternity Record.

Target 100%

Standard SCT 5

A record of the responses to the ASW FOQ for sickle cell and thalassaemia and the advice given must be made in the All Wales Maternity Record by the person asking the question.

Target 100%

6.2.1 If Laboratory Screening is Recommended by the ASW FOQ

Standard SCT 6

If the result of the ASW FOQ shows that testing is recommended, the woman must be offered laboratory screening for sickle cell and thalassaemia.

Target 100%

(1) The woman should be offered laboratory screening for sickle cell and thalassaemia in every pregnancy if one or more of the following applies:
- the woman or the biological father of the baby has a family history of sickle cell or thalassaemia
- the woman's family origins or those of the biological father, no matter how many generations back, are from anywhere outside of the UK or Republic of Ireland
- the woman's family origins or those of the biological father are unknown, e.g. the woman was adopted

(2) The woman should be informed that if the screening test result shows she carries sickle cell or thalassaemia or has a haemoglobin disorder, screening of the biological father is required for the most accurate pregnancy risk assessment.

6.2.2 Women Previously Diagnosed with a Haemoglobin Disorder, or are Carriers

Standard SCT 7

If the woman indicates that she has been previously diagnosed with a haemoglobin disorder or is a carrier, she must be offered re-screening and the relevant information must be included on the request form.

Target 100%

(1) If the woman knows she carries sickle cell or thalassaemia or has a haemoglobin disorder she should be advised that screening of the biological father is required for the most accurate pregnancy risk assessment.

(2) If the biological father has previously been screened, he should be offered re-screening and the relevant information about previous screening results should be included on the request card.

(3) If the woman and the biological father of the baby carry a sickle cell or thalassaemia or haemoglobin disorder there is a risk of a significant disorder being inherited by the fetus and diagnostic testing should be offered by the midwife.

(4) If diagnostic testing is accepted by the woman, an urgent appointment should be offered with the All Wales Medical Genetics Service for a fast-track appointment with a fetal medicine unit.

(5) If the biological father has not been screened and paternal consent is obtained, arrangements must be made for the biological father's sample to be taken by maternity services as soon as possible and within three working days.

Standard SCT 8

Women known to have haemoglobin disorders must be referred for joint haematology/ obstetric care within 6 weeks of confirmation of result.

Target 100%

6.3 Consent

Standard SCT 9

The woman's informed verbal consent is required for these tests and this must be recorded in the All Wales Maternity Record.

Target 100%

(1) If the woman declines to answer the ASW FOQ for sickle cell and thalassaemia, 'declined to answer screening question' should be recorded in All Wales Maternity Record.

(2) If the woman declines screening for sickle cell and thalassaemia the midwife should ensure that the woman has received accurate information on which to base her decision.

(3) The full blood count test offered to women in pregnancy to diagnose and monitor anaemia includes an estimation of the mean cell haemoglobin (MCH). Women should be asked if they consent to screening for sickle cell and thalassaemia if suggested by this laboratory result.

6.4 Test Requesting

Standard SCT 10

The laboratory request form must be identified as 'Antenatal Screening' and requires the name of the lead clinician or identified as obstetric led care if the named obstetrician is not known at this stage.

Target 100%

Standard SCT 11

The health professional requesting the test must complete and sign the request form.[n]

Target 100%

(1) Electronic requesting must enable a clear audit trail to identify the requester.

[n] By signing the laboratory or ultrasound request form, the requesting health professional is confirming that written and/or verbal information about the purpose of the test or scan has been given to the woman and that she has given informed consent for the test.

Standard SCT 12

All mandatory fields for the laboratory request must be completed.

Target 100%

(1) The laboratory request card must identify which test has been consented to:
- full blood count only (sickle cell and thalassaemia testing declined) **or**
- sickle cell and thalassaemia screen required as identified by the ASW FOQ **or**
- full blood count and sickle and thalassaemia screen if required following a low MCH.

(2) The laboratory will require information about the woman's and the biological father's family origins to interpret the laboratory result.

6.5 Test Procedure

Standard SCT 13

The sample must be taken before 13 weeks of pregnancy (if the woman presents for care before this gestation).

Target 95%

(1) If the screening process (including screening the biological father of the fetus if required) is conducted as per standards SCT 13, SCT 28 and SCT 32, CVS rather than amniocentesis may be a preferable option for women who wish to access diagnostic testing.[7]

Standard SCT 14

The person taking the sample must make a signed and dated record of the sample being taken in the All Wales Maternity Record.

Target 100%

(1) The woman's privacy must be respected. The discussion and blood test must be performed in a place where the woman's privacy can be assured.

(2) The person taking the sample must ask the woman to state her name, date of birth and address and these must be identical to the information on the request form and the sample.

6.6 Laboratory Services

Standard SCT 15

The laboratory must be appropriately accredited in accordance with United Kingdom Accreditation Service, and working toward ISO standard 15189. The laboratory must be able to demonstrate satisfactory performance.

Target 100%

Standard SCT 16

The screening test algorithm used by the laboratory must follow the ASW modified algorithm and the NSC guidelines and algorithm for low prevalence areas (NHS Sickle Cell and Thalassaemia Screening Programme 2012).

Target 100%

(1) The laboratory should not undertake sickle cell and thalassaemia screening without the woman's consent being indicated on the request card.

(2) Initial screening for sickle cell and thalassaemia should be a full blood count (FBC) usually followed by high performance liquid chromatography (HPLC), or other UKNSC approved methods (NSC 2012).

(3) If the analysis shows an abnormality, appropriate further testing or referral to a reference laboratory to specifically identify the abnormality should be undertaken, in line with the NSC guidelines and algorithm.

Standard SCT 17

The sample must be received by the local laboratory within one working day of the sample being taken.

Target 95%

Standard SCT 18

If the sample is forwarded to another laboratory, the sample must be received by the testing laboratory within two working days of the sample being taken.

Target 95%

Standard SCT 19

The testing laboratory must aim to achieve a five working day turn around from sample receipt to result reporting.

Target 95%

(1) For every sample received at the laboratory, there should be a process in place to ensure a report is issued. Where a request for a further test is issued (including partner testing), the laboratory should have a process in place to ensure a sample is received and a report is issued.

6.7 Results Handling

Standard SCT 20

If the sample has not been tested at the local laboratory, the result must be returned to the local laboratory within one working day of the result being signed out by the testing laboratory.

Target 95%

Standard SCT 21

The result must be available to the maternity service within one working day of the result being reported by, or to, the local laboratory.

Target 95%

(1) Results should be issued to the clinical team taking care of the woman during her pregnancy. Laboratories should not normally give results to health professionals following a telephone enquiry unless there is a clear indication of clinical need that affects immediate management of care.

Standard SCT 22

If the MCH is below 27pg on the full blood count result and screening was declined, a further sickle cell and thalassaemia screen must be offered when the full blood count results are explained and this must be documented in the All Wales Maternity Record.

Target 100%

(1) If the woman accepts screening the midwife should take the sample and request the test as 'FBC and sickle cell and thalassaemia screen' on the ASW sticker on the request card. The midwife should note on the form that the 'initial MCH less than 27pg'.

Standard SCT 23

There must be a written and agreed failsafe process in place to identify and follow up results not received by the maternity service.

Target 100%

Standard SCT 24

There must be a written and agreed process in place to identify and follow up where an additional sample or additional information is required by the laboratory.

Target 100%

Standard SCT 25

Where no problem is found, women should be informed of the results by the maternity service at the 16 week antenatal visit, or where sampling has occurred later in pregnancy within 3 weeks of the sample being taken.

Target 100%

(1) If any of these results are not available, the local pathway as identified in Standard SCT 23 should be followed.

(2) The woman should be informed that the chance of her having a child affected by a sickle cell disorder or thalassaemia major is very low.

Standard SCT 26

The result must be recorded in the All Wales Maternity Record the next time the woman is reviewed by a health professional.

Target 100%

(1) A dated and signed record that the result has been discussed with the woman must be made in the All Wales Maternity Record.

(2) Any actions relating to the result should also be documented.

6.7.1 Maternal Sickle Cell or Thalassaemia Screen Positive

Standard SCT 27

The antenatal screening coordinator (or named deputy) must be informed of screen positive results within one working day by the laboratory.

Target 100%

Standard SCT 28

The result must be given to the woman within three working days of the result being available.

Target 95%

(1) Arrangements should be made for pregnant women to return to the antenatal clinic to be given her result.

(2) Interpreter services should be arranged if required.

(3) If appropriate the biological father of the baby should be asked to attend with her.

(4) If the woman is a sickle cell or thalassaemia carrier, or has a haemoglobin disorder, she should be given written[o] and verbal information about her diagnosis. She should be informed by an appropriately trained professional that the chance of her having a fetus with an inherited sickle cell disorder or thalassaemia major will depend on whether the biological father of the fetus is also a carrier of sickle cell or thalassaemia.

Standard SCT 29

If the woman has a haemoglobin disorder she must be referred for joint haematology/ obstetric care within 6 weeks.

Target 100%

[o] Antenatal information for women on specific haemoglobinopathies are available from Antenatal Screening Wales via the laboratory, medical genetics or screening coordinators.

Standard SCT 30

If the woman wishes to know the risk to the baby, with the woman's consent, the maternity services must offer the biological father of the fetus, sickle cell and thalassaemia screening. This offer must be documented in the All Wales Maternity Record.

Target 100%

(1) If the woman knows she has a haemoglobin disorder she should be advised that screening of the biological father is required for the most accurate pregnancy risk assessment.

(2) If the biological father has previously been screened, he should be offered re-screening and the relevant information about previous screen results should be included on the request card.

Standard SCT 31

If the biological father of the fetus is not available, declines to be tested, or the woman does not consent to him being contacted, a risk assessment must be offered. This must be undertaken by the Health Board haematologist or All Wales Medical Genetics Service within three working days, to advise the maternity service of the risk to the fetus. This assessment must be based on the ethnicity of the woman and that of the biological father.

Target 100%

(1) Neonatal sickle cell and thalassaemia testing should be offered as per Standard SCT 35.

Standard SCT 32

If paternal consent is obtained, arrangements must be made for the biological father's sample to be taken by maternity services as soon as possible and within three working days.

Target 100%

(1) The antenatal screening coordinator or sickle cell and thalassaemia counsellor, should coordinate the linking of results and provide the necessary information for the laboratory to ensure that the biological father's result is available to be considered with the woman's result.

(2) The sample should clearly be marked `urgent´ and the laboratory informed that the sample should be expected.

(3) If the biological father is screened and the result shows that he is a sickle cell or thalassaemia carrier or has a haemoglobin disorder, the risks to the fetus will depend on the potential interaction between the specific haemoglobin variants of the parents.

(4) If the biological father is screened and does not carry sickle cell or thalassaemia, the woman can be informed by an appropriately trained professional that the chance of her having a child affected by a sickle cell disorder or thalassaemia major in this pregnancy is very low and antenatal diagnostic testing is not recommended.

(5) The woman should also be advised that the risk in any future pregnancy should be reassessed pre-conceptually or as soon as she is aware of the pregnancy if she has a different partner. This can be performed via a sickle cell and thalassaemia centre or her General Practitioner.

Standard SCT 33

If both the mother and the biological father of the baby are sickle cell or thalassaemia carriers or have haemoglobin disorders they should be referred to the All Wales Medical Genetics Service within 5 working days of the result being received by the maternity services.

Target 100%

(1) The All Wales Medical Genetics Service will assess the risk to the fetus.

(2) Where appropriate the woman will be offered antenatal diagnostic testing by the All Wales Medical Genetics Service.

(3) If antenatal diagnostic testing is declined, neonatal sickle cell and thalassaemia testing should be offered as per Standard SCT 35.

Standard SCT 34

Where antenatal diagnostic testing is accepted this must be offered as soon as possible and within 5 working days if the woman has reached the gestation for her preferred diagnostic test.

Target 100%

(1) To assist in interpreting the results, antenatal CVS or amniocentesis diagnostic samples for haemoglobinopathies must be accompanied by a 10ml blood sample in an EDTA bottle taken on the day of the procedure from the mother.

(2) A sample is also required from the biological father of the baby if he is available.

(3) If an amniocentesis procedure is performed, 20ml of amniotic fluid is required by the laboratory.

6.7.2 Postnatal Care

Standard SCT 35

If the baby has been identified as having a high chance of inheriting a sickle cell or other significant haemoglobin disorder, arrangements must be in place for the baby to be reviewed by a paediatrician within 24 hours of birth.

Target 100%

(1) This will include when a carrier or disorder is identified in the mother but no result for the biological father of the baby or where both the mother and the biological father of the baby are either carriers or have a haemoglobinopathy disorder.

Standard SCT 36

Neonatal testing must be offered if the baby has a high chance of inheriting a sickle cell or other significant haemoglobin disorder or to confirm an antenatal fetal sickle cell and thalassaemia diagnostic test.

Target 100%

(1) All Health Boards must have a policy regarding which babies should be offered neonatal testing for sickle cell and thalassaemia disorders and a pathway for management of these babies.

(2) Cord blood is not suitable for this test, and the required sample is 0.3-1ml of blood, in a paediatric EDTA bottle.

(3) This blood test should be performed before and in addition to routine newborn bloodspot screening.

7.0 Antenatal Screening for Down's, Edwards' and Patau's syndromes

Policy Statement

Antenatal screening for Down's, Edwards' and Patau's syndromes should be offered to all pregnant women to identify women who have a pregnancy affected by one of these syndromes (NSC 2016; NICE 2008; WHC 2003b (127)).

Down's Syndrome

Down's syndrome is the most common chromosomal anomaly and is caused by abnormalities involving the presence of additional genetic material associated with chromosome pair 21. Overall this condition usually occurs approximately once in every 415 pregnancies in Wales. The prevalence increases with maternal age.

Edwards' Syndrome

Edwards' syndrome is caused by abnormalities involving the presence of additional genetic material associated with chromosome pair 18. This condition occurs approximately once in every 1656 pregnancies in Wales. The prevalence increases with maternal age. Edwards' syndrome is life limiting.

Patau's Syndrome

Patau's syndrome is caused by abnormalities involving the presence of additional genetic material associated with chromosome pair 13. This condition occurs approximately once in every 4201 pregnancies in Wales. The prevalence increases with maternal age. Patau's syndrome is life limiting.

Rationale for Screening

If the fetus is affected by Down's, Edwards' or Patau's syndrome, the woman can make an informed decision about whether to continue with the pregnancy. If the pregnancy is continuing, appropriate identification of additional structural problems, e.g. cardiac anomalies should be made and suitable care and support offered.

Anticipated Outcomes

Women who have a pregnancy affected by Down's, Edwards' or Patau's syndrome will have reproductive choices.

Screening Test Options

The screening test available for Down's, Edward's and Patau's syndromes involve the use of ultrasound measurements of the fetus and a blood test for biochemical markers to contribute towards calculating the chance of either Down's, or Edwards'/Patau's syndromes in the pregnancy. This combined test uses an ultrasound measurement to assess the gestation and a measurement of the fetal neck (the nuchal translucency or NT) with the results from the biochemical markers to give the woman the result for Down's and Edwards'/Patau's syndrome in singleton and twin pregnancies in early pregnancy.

Women with a singleton pregnancy can use this result to decide whether they wish to accept the offer of a further screening test called non invasive prenatal testing (NIPT), which is a more accurate screening test, or alternatively an invasive test (CVS or amniocentesis) to enable invasive testing.

The screening test which is recommended in the second trimester is the quadruple test. This test uses an ultrasound measurement to assess the gestation with the results from biochemical markers to give the woman a result for Down's syndrome only in singleton pregnancies up to 18 weeks gestation.

(1) First trimester screening (the combined test) can only be undertaken when the CRL measurement is between 45.0mm and 84.0mm (approximately 11 weeks and 2 days to 14 weeks and 1 day) in singleton and twin pregnancies. This will give a result for Down's syndrome and for Edwards'/Patau's syndromes.

(2) Second trimester screening (the quadruple test) can only be undertaken on samples between 15 weeks and 3 days and 18 weeks and 0 days of pregnancy by the Cardiff biochemistry laboratory. This can only be performed in singleton pregnancies and will give a result for Down's syndrome only.

(3) Following a higher chance result from the above tests, women with a singleton pregnancy can be offered a further, more accurate, screening test called NIPT as an alternative choice to invasive testing.

(4) An invasive procedure is required for a definitive diagnosis..

7.1 Pre Test Information

Standard DEP 1

The woman must be given the ASW Information for Women pack about screening for Down', Edwards' and Patau's syndromes in pregnancy and a record of the information provided made in the All Wales Maternity Record.[p]

Target 100%

(1) A copy of the ASW Information for Women pack should be provided before the woman is asked to consent to this test.

(2) The woman should be advised to view the ASW film clip which provides information on screening for Down's, Edwards' and Patau's syndromes prior to the verbal discussion with the midwife.

(3) The midwife should make a record of written information given to the woman and whether the woman has watched the ASW film clip.

Standard DEP 2

The midwife must have a verbal discussion with the woman prior to consenting for the test and a record of the discussion must be made in the All Wales Maternity Record.

Target 100%

(1) The purpose, implications, limitations and benefits of this screening must be explained to the woman by the midwife.[q]

(2) The midwife should explain to the woman that Down's syndrome is a lifelong genetic condition and that some people with Down's syndrome will have associated abnormalities. People with Down's syndrome can have a good quality of life. Some people with Down's syndrome can live semi-independently while others will require full time care.

(3) The midwife must explain to the woman that people with Edwards' and Patau's syndromes will have a range of problems, including brain abnormalities, heart defects, cleft lip and palate as well as feeding and breathing difficulties. Both of these conditions are life limiting.

(4) The woman must be informed that if the combined or quadruple test result places her in a 'higher chance' group she will be offered NIPT or invasive testing.

(5) The woman should be informed that if the NIPT is low chance she will not be offered further testing but if the NIPT result is high chance she will be offered an invasive test.

(6) The risks of miscarriage associated with antenatal invasive testing should be explained.

(7) If the woman has a family member with either Down's, Edwards' or Patau's syndrome, enquiries should be made into whether the type of syndrome is known, as a familial translocation will increase the chance of inheriting either Down's, Edwards' or Patau's syndrome. Referral to the All Wales Medical Genetics Service may be advised. Parental karyotyping should be considered on advice from the All Wales Medical Genetics Service.

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[p] Written information for women is available from ASW in hard copy and as `e-leaflets´ on *http://www.antenatalscreening.wales.nhs.uk/public/antenatal-screening-tests*.

[q] Where women have a different language or communication need, Health Boards should ensure the provision of accurate information in a format that is accessible to each individual woman. This may include for example British Sign Language, or an approved interpreter service.

7.2 Screening Offer

Standard DEP 3

All women with singleton or twin pregnancies must be offered antenatal screening for Down's, Edwards' or Patau's syndromes before 10 completed weeks of pregnancy (if the woman presents before that time). A record of the offer must be made in the All Wales Maternity Record.

Target 100%

(1) Women should be offered screening for Down's, Edwards' and Patau's syndromes. The woman should be informed that if she is within the gestational parameters for a combined test this will be reported by the sonographer at her early pregnancy dating appointment. If the woman is outside of the parameters for a combined test (CRL greater than 84.0mm on the day of the scan) and has a singleton pregnancy she will be offered a quadruple test to screen for Down's syndrome only. This will also apply if CRL or NT measurement (s) cannot be obtained.

(2) Women who have previously had a pregnancy affected by Down's, Edwards' or Patau's syndromes should be offered a discussion with a consultant obstetrician, antenatal screening coordinator or geneticist prior to any screening. This is because the screening test result would be less reliable.

(3) Women who have a twin pregnancy should have a discussion with the Health Board nominated professional for screening in twin pregnancies prior to sending the blood sample for the combined test.

(4) The combined screening test can be offered in a twin pregnancy if only one NT measurement has been measured. The accuracy of the screening test will be reduced in this case and the woman should be informed of this before she consents to the screening test.

Standard DEP 4

The Health Board must have a pathway for women who consent to screening for Down's, Edwards' and Patau's syndromes and are then diagnosed as having a twin pregnancy during their early pregnancy dating scan

Target 100%

(1) If a woman consents to screening for Down's, Edwards' and Patau's syndromes and is then diagnosed as having a twin pregnancy during her early pregnancy scan, the health board will have a pathway for:

(a) arranging an appointment with the nominated health board professional for screening in twin pregnancies
(b) taking the NT measurements before 14 weeks and 1 day and
(c) collecting the blood sample for screening before 14 weeks and 1 day.

(2) The pre-test counselling for screening in twins should include information on:

(a) Whether the twins are monochorionic or dichorionic as this will affect the screening result
(b) If only one NT measurement is obtained that the result will be less accurate than if both twins were measured
(c) The quadruple test will not be offered in twin pregnancies if neither of the NT measurements are obtained
(d) Where the twins have individual placentas there is a possibility that one twin may be affected and one unaffected
(e) NIPT will not be offered in a twin pregnancies
(f) The risk of miscarriage from an invasive test in twin pregnancy is approximately doubled that of a singleton pregnancy
(g) Invasive procedures need to be carried out in a centre where the selective termination will be carried out if this is the choice of the woman

(h) Selective termination of one of the twins in a pregnancy is complicated and carries risks of miscarriage and morbidity to the other twin
(i) Screening is not offered for triplets or higher multiple pregnancies.

7.3 Consent

Standard DEP 5

The woman's informed verbal consent is required for these tests and this must be recorded in the All Wales Maternity Record.

Target 100%

7.4 Test Requesting

Standard DEP 6

Where screening for Down's, Edwards' and Patau's syndromes is accepted, the woman's consent must also be recorded on the ultrasound request card.

Target 100%

(1) If the woman presents in a timely manner, the early pregnancy scan should be arranged for around 12 week's gestation.

Standard DEP 7

The laboratory request form for Down's, Edwards' and Patau's screening must be identified as 'Antenatal Screening' and requires the name of the lead clinician or identified as obstetric led care if the named obstetrician is not known at this stage.

Target 100%

Standard DEP 8

All mandatory fields for the Down's, Edwards' and Patau's syndromes screening laboratory request card must be completed.

Target 100%

(1) The gestation must have been confirmed by ultrasound scan and the required ultrasound measurements must be included on the request card. CRL and NT measurements are required for combined testing and either a CRL or HC measurement for quadruple testing.

(2) If the woman has had IVF treatment this information is required by the laboratory. If the pregnancy is from a donor egg, the age of the donor is also required.

(3) An accurate maternal weight is required, preferably on the day of the sample being taken, but not more than one week before.

(4) The maternal family origin (1st and 2nd generation), history of maternal diabetes and insulin therapy, and smoking status should be recorded on the request form as this will affect the accuracy of the result.

(5) In a twin pregnancy, whether the pregnancy is monochorionic, dichorionic or unknown should be recorded as this will be adjusted for within the chance calculation.

(6) The combined screening test can be offered in a twin pregnancy if only one NT has been measured. This should be noted on the request card.

(7) The DQASS number of the sonographer undertaking the NT measurement for combined screening should be provided on the Down's, Edwards' and Patau's syndromes screening request card.

Standard DEP 9

The health professional requesting the test must complete and sign the request forms.[r]
Target 100%

(1) Electronic requesting must enable a clear audit trail to identify the requester.

7.5 Blood Test Procedure

Standard DEP 10

The person taking the sample must make a signed and dated record of the sample being taken in the All Wales Maternity Record.
Target 100%

(1) The woman's privacy must be respected. The discussion and blood test must be performed in a place where the woman's privacy can be assured.

(2) The person taking the sample must ask the woman to state her name, date of birth and address and these must be identical to the information on the request form and the sample.

(3) First trimester screening (the combined test) can only be undertaken when the CRL measurement is between 45.0mm and 84.0mm (approximately 11 weeks and 2 days to 14 weeks and 1 day).

(4) In a twin pregnancy, both twins CRL must be between 45.0mm and 84.0mm (approximately 11 weeks and 2 days and 14 weeks and 1 day), for combined screening.

(5) Second trimester screening (the quadruple test) can only be undertaken on singleton pregnancies and on samples between 15 weeks and 3 days and 18 weeks and 0 days of pregnancy by the Cardiff biochemistry laboratory.

(6) For samples being processed at the Cardiff biochemistry laboratory, 3mls of venous blood in a serum separator tube (SST) is required for this test and if taking more than one blood sample at a time, the Down's, Edwards' and Patau's syndromes screening sample must be taken first as contamination from the EDTA in other blood vacutainers can affect the result.

(7) If second trimester screening is offered and there is a history of vaginal bleeding during pregnancy this may affect the AFP level. If timescales allow, it is preferable to delay taking the sample for one week after the bleeding has stopped as the presumed effect of the bleeding cannot be adjusted for by the laboratory.

7.6 Laboratory Services

Standard DEP 11

The laboratory must be appropriately accredited in accordance with United Kingdom Accreditation Service, and working toward ISO standard 15189. The laboratory must be able to demonstrate satisfactory performance.
Target 100%

[r] By signing the laboratory or ultrasound request form, the requesting health professional is confirming that written and/or verbal information about the purpose of the test or scan has been given to the woman and that she has given informed consent for the test.

Standard DEP 12

The laboratory must submit screening data to DQASS at least twice a year.

Target 100%

Standard DEP 13

There must be a designated senior member of the laboratory staff at consultant level (either clinical scientist or chemical pathologist) with relevant experience in screening, taking overall responsibility for all laboratory aspects of the Down's, Edwards' and Patau's syndromes screening service.

Target 100%

Standard DEP 14

The laboratory must participate in an audit of the screening service and provide information, as required, to Antenatal Screening Wales.

Target 100%

Standard DEP 15

The detection rate and false positive rate for the Down's, Edwards' and Patau's syndromes screening programmes must be monitored. A quadruple test must be used which can achieve a minimum standard of a 75% detection rate for a 3% screen positive rate, and a combined test with a detection rate of 85% for a screen positive rate of 2.7% aiming towards a detection rate of 90% for a 2.7% screen positive rate.

Target 100%

Standard DEP 16

The sample must be received by the local laboratory within one working day of the sample being taken.

Target 95%

(1) Sample preparation and transportation should follow the Standard Operating Procedures recommended by the Cardiff laboratory.

Standard DEP 17

If the sample is forwarded to another laboratory, the sample must be received by the testing laboratory within two working days of the sample being taken.

Target 100%

Standard DEP 18

The testing laboratory must aim to achieve a three working day turnaround from when the sample is received.

Target 95%

7.7 Results Handling

Standard DEP 19

The screening result of for Down's, Edwards' and Patau's syndromes must be available to the maternity service within three working days of the sample reaching the testing laboratory.

Target 95%

(1) The antenatal screening coordinator or deputy should coordinate the results handling process as they are received via email.

Standard DEP 20

There must be a written and agreed failsafe process in place to identify and follow up results not received by the maternity service within 3 working days.

Target 100%

(1) If the sample is taken at the correct time but the laboratory is unable to report a result, the woman should be offered a discussion to consider the alternative options. The Health Board responsible for the error must complete a DATIX report and has a responsibility to provide an alternative test for the woman at their expense. If the chosen test is a NIPT to be processed in the Cardiff laboratory the person taking the sample must telephone the laboratory to inform them that a "private" sample is expected.

Standard DEP 21

There must be a written and agreed process in place to identify and follow up where an additional sample or additional information is required by the laboratory.

Target 100%

7.7.1 Lower Chance of Down's, Edwards' and Patau's Syndromes Results (a chance of 151 or lower)

Standard DEP 22

If the result of the combined or quadruple screening is lower chance women should be informed of the results by the maternity service at the 16 week antenatal visit, or where sampling has occurred later in pregnancy within 3 weeks of the sample being taken.

Target 100%

(1) The woman should be informed that she has a lower chance of having a baby with Down's, Edwards' or Patau's syndromes and that no further testing is recommended. The actual serum screen result (expressed as a risk of 1 in XXX for Down's syndrome and a risk of 1 in xxx for Edwards'/Patau's syndromes) can be given to the woman if the woman requests the information.

Standard DEP 23

The result must be recorded in the All Wales Maternity Record the next time the woman is reviewed by a health professional.

Target 100%

(1) A dated and signed record that the result has been discussed with the woman must be made in the All Wales Maternity Record.

(2) Any actions relating to the result should also be documented.

7.7.2 Higher Chance of Down's, or Edwards'/Patau's Syndromes (a chance of 1:5 to 1:150)

Standard DEP 24

Women who have a higher chance combined or quadruple screening result must be informed of the result by the maternity service within five working days of the sample being taken.

Target 90%

(1) The woman should be informed by letter or telephone call (according to local arrangements and/or the woman's preference) that she has been identified as being in the group of women who are in the higher chance group and offered a NIPT or an invasive test.

(2) The result should not usually be given during the weekend or on Friday afternoon unless the woman has access to a health professional who can discuss the result and give accurate information about NIPT, CVS/ amniocentesis.

Standard DEP 25

An appointment must be made for the woman to discuss the result with the antenatal screening coordinator, or other health professional with suitable skills and knowledge within 24 hours of the result being given.

Target 100%

(1) Interpreter services should be arranged if required.

(2) Where the higher chance result is in association with a NT of 3.5mm and above an invasive test should be offered. If the woman declines an invasive test an NIPT can be offered but the woman should be informed that the NIPT will only give a result for Down's, Edwards' and Patau's syndromes whereas the invasive procedure will result in an array CGH test providing more information on genetic conditions.

(3) The health professional should discuss the short and long term, medical and social implications of Down's, or Edwards' and Patau's syndromes.

(4) The woman should be informed that she has a choice of a NIPT or CVS/amniocentesis or no further testing and that she will be supported whatever decision she makes.

(5) The woman should be informed that if the NIPT result is low chance she will not be offered further testing but if the NIPT result is high chance she will be offered an invasive test.

(6) NIPT cannot be offered if:

- There was at any point in this pregnancy a 2nd sac or fetus (vanished or vanishing twin pregnancy)

- There is a maternal malignancy
- The woman has chromosomal changes that include chromosomes 13, 18 and 21
- The woman has had a blood transfusion in the last four months
- The woman has had a transplant

(7) Women with a twin pregnancy who have a higher chance combined screening result should be referred to the Health Board nominated health professional to discuss the options for invasive testing in twin pregnancies.

   a. If the woman requests an invasive procedure, an appointment should be made in a unit where a selective termination of pregnancy can be carried out if the result shows an affected baby and the woman chooses not to continue with the pregnancy.

(8) A copy of the ASW **'Information for women offered further tests for suspected chromosomal conditions'** leaflet should always be given to the woman at this visit.[s] This literature includes contact information for the Down's Syndrome Association (DSA), Support Organisation for Trisomy 13 and Trisomy 18 (SOFT UK) and Antenatal Results and Choices (ARC).

7.8 NIPT

7.8.1 Consent for NIPT

Standard DEP 26

The woman's informed verbal consent is required for NIPT and this must be documented in the All Wales Maternity Record

Target 100%

Before consent the woman should be:

(1) Informed of the purpose, implications, limitations and benefits of the NIPT
(2) Informed that if the NIPT is low chance she will not be offered further testing but if the NIPT result is high chance she will be offered an invasive test.
(3) Informed that NIPT is not performed following a higher chance screening result after 20 weeks and 0 days of pregnancy.

7.8.2 Test Requesting

Standard DEP 27

All mandatory fields for the NIPT screening laboratory request must be completed.

Target 100%

(1) If the combined or quadruple test has been reported from anywhere other than the Cardiff Biochemistry laboratory, a copy of the laboratory report must be included with this request card.

[s] Written information for women is available from ASW in hard copy and as `e-leaflets on *http://www.antenatalscreening.wales.nhs.uk/public/down-s-edwards-and-patau-s-syndromes*

Standard DEP 28

The health professional requesting the test must complete and sign the request form.

Target 100%

7.8.3 NIPT Blood Test Procedure

Standard DEP 29

The person taking the sample must make a signed and dated record of the sample being taken in the All Wales Maternity Record.

Target 100%

(1) The woman's privacy must be respected. The discussion and blood test must be performed in a place where the woman's privacy can be assured.

(2) The person taking the sample must ask the woman to state her name, date of birth and address and these must be identical to the information on the request form and the sample.

(3) The NIPT sample must contain at least 10mls of blood. It must be collected in a specialist cell stabilising tube (Streck). If the first bottle fails to fill, another can be used and both sent to the laboratory together. Once the sample has been collected the bottle(s) must be inverted 8-10 times to maintain the stability of the blood.

(4) The NIPT sample is not to be placed in a fridge or freezer. The sample should not be centrifuged.

(5) The sample and completed request form should be sent to the All Wales Genetic Laboratory preferably on the day that the sample is taken.

(6) The person taking the sample should telephone the All Wales Genetic Laboratory to inform them that the sample is on its way to the laboratory.

(7) Where samples are being transported directly from maternity services to the All Wales Genetic Laboratory they should fulfil the requirements of UN packaging instructions P650.

7.8.4 Sample Handling

Standard DEP 30

The sample must be received by the All Wales Genetic Laboratory within five days of the sample being taken.

Target 95%

(1) Wherever possible the sample should arrive in the testing laboratory within one day of the sample being taken to minimise the risk of a failed test due to a breakdown of fetal DNA in the sample

(2) Sample preparation and transportation should follow the Standard Operating Procedures recommended by the All Wales Genetic Laboratory.

Standard DEP 31

The laboratory must be appropriately accredited in accordance with United Kingdom Accreditation Service, and working toward ISO standard 15189. The laboratory must be able to demonstrate satisfactory performance.

Target 100%

Standard DEP 32

There must be a designated senior member of the laboratory staff at consultant level with relevant experience in screening, taking overall responsibility for all laboratory aspects of the NIPT screening service.

Target 100%

Standard DEP 33

The laboratory must participate in an audit of the screening service and provide information, as required, to Antenatal Screening Wales.

Target 100%

(1) The laboratory is required to submit all agreed data to CARIS.

Standard DEP 34

The All Wales Genetic Laboratory must aim to achieve a ten working day turnaround from when the sample is received in the laboratory to results reporting to the Health Board.

Target 100%

(1) The laboratory should send the results of the NIPT via email to the agreed Health Board recipients.

7.8.5 Results Handling

Standard DEP 35

There must be a written and agreed failsafe process in place to identify and follow up results not received by the maternity service

Target 100%

(1) The antenatal screening coordinator or deputy should coordinate the results handling process as they are received via email.

Standard DEP 36

There must be a written and agreed process in place to identify and follow up where additional information is required by the laboratory.

Target 100%

(1) Around 2% of women who will not get a result from the NIPT and these are slightly more likely to have an affected baby. The health board must have a process in place to ensure that women who do not get a result will be offered an invasive test.

7.8.6 Low Chance NIPT Results

Standard DEP 37

Women who have a low chance NIPT result for Down's, Edwards' and Patau's syndromes should be informed of the results by the maternity service within 1 working day of the result being available to the maternity services

Target 100%

(1) Women should be informed that a low chance NIPT result for Down's, Edwards' and Patau's syndromes means that it is very unlikely that the baby will be affected

(2) The woman should be informed that no further testing will be offered.

Standard DEP 38

The result must be recorded in the All Wales Maternity Record the next time the woman is reviewed by a health professional.

Target 100%

7.8.7 High Chance NIPT Results

Standard DEP 39

Women who have a high chance NIPT result for either Down's, Edwards' or Patau's syndromes must be informed of the result by the maternity service within 2 working days of the result being received by the maternity service.

Target 90%

(1) The woman should be informed by telephone (or her preference) that she has been identified as being in a group of women who are offered an invasive test

(2) The result should not usually be given during the weekend or on Friday afternoon unless the woman has access to health professionals who can discuss the result and give accurate information about CVS and amniocentesis.

Standard DEP 40

An appointment must be made for the woman to discuss the result with the antenatal screening coordinator, or other health professional with suitable skills and knowledge within 24 hours of the result being given.

Target 100%

(1) Interpreter services should be arranged if required.

(2) The woman should be informed that a high chance result is not a diagnostic test and for confirmation of the result an amniocentesis should be offered

(3) The health professional should discuss the short and long term, medical and social implications of the syndrome that is high chance on the result

(4) A copy of the ASW 'Information for women offered further tests for suspected chromosomal conditions' leaflet should always be given to the woman at this visit.[t] This literature includes contact information for the Down's Syndrome Association (DSA), Support for Trisomy 13 and 18 (SOFT) and Antenatal Results and Choices (ARC).

Standard DEP 41

All women who have a high chance screening result following NIPT must be offered an invasive test.

Target 100%

(1) The discussion should include information about:
   (a) invasive procedures
   (b) the risk of miscarriage associated with invasive test
   (c) QF-PCR and the information which this result will provide
   (d) any other information requested by the woman to enable her to make an informed decision regarding antenatal invasive testing.

(2) The midwife should also discuss pregnancy choices following invasive testing if the result shows that the baby has one of these syndromes.

(3) Termination of pregnancy should be discussed. If gestation is more than 21 weeks and 6 days feticide should be included in this discussion (RCOG 2011).

(4) The woman should have sufficient time in order to feel comfortable about making a decision (usually at least 24 hours) regarding whether to accept or decline antenatal invasive testing.

(5) A copy of the ASW 'Information for women offered further tests for suspected chromosomal conditions' leaflet should always be given to the woman at this visit.[t] This literature includes contact information for the Down's Syndrome Association (DSA), Support Organisation for Trisomy 13 and Trisomy 18 (SOFT UK) and Antenatal Results and Choices (ARC).

[t] Written information for women is available from ASW in hard copy and as `e-leaflets on *http://www.antenatalscreening.wales.nhs.uk/public/down-s-edwards-and-patau-s-syndromes*

Standard DEP 42

A contemporaneous, dated and signed record must be made in the All Wales Maternity Record of actions planned and undertaken in response to the high chance NIPT result.
Target 100%

(1) Where the woman decides to continue with the pregnancy after a high chance NIPT she an should be offered the opportunity to be involved in planning her care for the pregnancy which may include relevant specialities E.g. Paediatricians, voluntary organisations.

7.9 Invasive testing

Standard DEP 43

Where invasive testing is accepted this must be offered as soon as possible and within 5 working days if the woman has reached the gestation for her preferred choice.
Target 100%

Standard DEP 44

A contemporaneous, dated and signed record must be made in the All Wales Maternity Record of actions planned and undertaken for women with a high chance of having a baby with Down's, Edwards' or Patau's syndromes.
Target 100%

(1) Where the woman decides to continue with the pregnancy after a diagnosis of Down's, Edwards' or Patau's syndromes the woman should be offered the opportunity to be involved in planning her care for the pregnancy which should include relevant specialities E.g. paediatricians, breast feeding specialist midwives, surgical teams, voluntary organisations etc

8.0 Ultrasound Screening in Pregnancy

Policy Statement

All women resident in Wales should be offered an early pregnancy ultrasound scan (WHC 2003b; NICE 2008) and a fetal anomaly ultrasound scan (NICE 2008).

Early Pregnancy Scan

Rationale for Screening

The early pregnancy ultrasound scan is offered to determine viability, the gestational age and to detect multiple pregnancies (fetal number and chorionicity/amnionicity). Some major fetal anomalies may be detected, but this is not the primary purpose of this scan. Measurements to determine the gestational age are required for the Down's, Edwards' and Patau's syndromes screening programme and also an additional measurement if the scan is before 14 weeks and 1 day of pregnancy (maximum CRL 84mm). Using ultrasound derived gestation reduces the need for post term induction of labour (NICE 2008). Where first trimester screening for Down's, Edwards' and Patau's syndromes is provided the woman will receive an earlier screening test result.

Anticipated Outcome

Confirmation of viability, accurate calculation of gestational age and identification of multiple pregnancies to support pregnancy management and the screening programme for Down's, Edwards' and Patau's syndromes

Fetal Anomaly Ultrasound Scan

Rationale for Screening

The purpose of the fetal anomaly ultrasound scan is to detect significant structural fetal anomalies that are likely to have an adverse effect on the health of the mother or baby and for which an effective intervention is available and warranted at 18 weeks and 0 days to 20 weeks and 6 days of pregnancy.

For some conditions, preventive treatment is available during the antenatal period or after delivery to improve the baby's health. For others, the condition can be identified by ultrasound scanning but no preventive treatment is available. Women can make an informed decision about whether they wish to continue the pregnancy.

Anticipated Outcome

Detection of significant structural abnormalities in the baby to enable appropriate interventions as required.

8.1 General Standards for Early Pregnancy and Fetal Anomaly Scans

8.1.1 Pre Test Information

Standard US 1

The woman must be given the ASW Information for Women pack and a record of the information provided made in the All Wales Maternity Record. [u]

Target 100%

(1) A copy of the ASW `Information for Women´ pack should be provided before the woman is asked to consent to this ultrasound scan.

(2) The midwife should make a record of written information given to the woman.

Standard US 2

The midwife must have a verbal discussion with the woman prior to consenting for the test and a record of the discussion must be made in the All Wales Maternity Record.

Target 100%

(1) The purpose, implications, limitations and benefits of this ultrasound scan must be explained to the woman by the midwife.[v]

(2) Women who wish to have an early pregnancy or fetal anomaly ultrasound scan, but do not wish to be informed if abnormalities are found should be advised that all findings seen on the scan will be reported.

(3) Where first trimester screening for Down's, Edwards' and Patau's syndromes is provided, the standards and protocols in section 7 of this document should also be met.

8.1.2 Offer of Ultrasound Scans

Standard US 3

All women must be offered an early pregnancy ultrasound scan at around 12 weeks and before14 weeks and 1 day of pregnancy and a fetal anomaly ultrasound scan at between 18 weeks and 0 days to 20 weeks and 6 days of pregnancy (if the woman presents for maternity care before that gestation). A record of the offer must be made in the All Wales Maternity Record.

Target 100%

(1) Women who attend for antenatal care later in pregnancy should be offered a scan appropriate to their presumed gestation when they first attend.

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[u] Written information for women is available from ASW in hard copy and as `e-leaflets´ on *http://www.antenatalscreening.wales.nhs.uk/public/antenatal-screening-tests*.

[v] Where women have a different language or communication need, Health Boards should ensure the provision of accurate information in a format that is accessible to each individual woman. This may include for example British Sign Language, or an approved interpreter service.

8.1.3 Consent

Standard US 4

The woman's informed verbal consent is required for these ultrasound scans and this must be recorded in the All Wales Maternity Record.

Target 100%

(1) Where first trimester screening for Down's, Edwards' and Patau's syndromes are offered the woman must additionally be asked to consent to or decline screening for Down's, Edwards and Patau's syndromes and a record of her decision must be made in the All Wales Maternity Record and on the ultrasound request card.

8.1.4 Test Requesting

Standard US 5

The scan request form must be identified as 'Antenatal Screening' and requires the name of the lead clinician or identified as obstetric led care if the named obstetrician is not known at this stage.

Target 100%

Standard US 6

Accurate demographic and relevant clinical information must be included on the ultrasound request form or electronic request.

Target 100%

(1) Scan requests should include information on relevant obstetric, medical and social issues which can affect fetal wellbeing.

(2) These should include information on:
- previous pregnancies affected by abnormalities, e.g. neural tube defects and cardiac anomalies
- a family history of congenital abnormalities
- maternal diabetes
- epilepsy (and medication if taken)
- high BMI
- other relevant factors.

(3) The scan request card should indicate whether the woman consents to:
- early pregnancy scan
- screening for Down's, Edwards' and Patau's syndromes and
- fetal anomaly scan.

Standard US 7

The health professional requesting the test must complete and sign the request form.[w]

Target 100%

(1) Electronic requesting must enable a clear audit trail to identify the requester.

[w] By signing the ultrasound request form, the requesting health professional is confirming that written and/or verbal information about the purpose of the scan has been given to the woman and that she has given informed consent for the scan.

8.1.5 Ultrasound Services

Standard US 8

Only an appropriately trained sonographer, or sonographer who is in training under the supervision of a sonographer, should perform ultrasound scans.[8]

Target 100%

(1) Sonographers taking part in antenatal screening must be currently registered with/regulated by their professional body/regulatory bodies e.g. NMC/HCPC.

Standard US 9

The sonographer must have passed an assessment in Wales to participate in combined screening. Sonographers must be registered with the Down's syndrome Quality Assurance Support Service (DQASS) and take part in ongoing assessment with their health board NT lead or ASW ultrasound coordinator.

Target 100%

(1) Each sonographer must complete a satisfactory biannual assessment of at least 3 sets of paired CRL and NT images with their named NT lead.

(2) Each sonographer must complete the E-LfH NT resource and the ASW Down's, Edwards' and Patau's syndromes e-learning resource annually and compliance must be verified by the Health Board NT lead.

(3) The six monthly DQASS report for each sonographer has to show a flag status of green or amber for that sonographer to continue to practice.

(4) If a sonographer has less than 25 paired measurements on the 6 monthly DQASS report that sonographer can continue to practice. If that sonographer achieves less than 25 paired measurements in the consecutive 6 month period that sonographer will be deemed a red flag and must be reassessed and an action plan put in place by the NT lead.

(5) The name and DQASS number of the sonographer undertaking the NT measurement(s) must be provided on the ultrasound report. The screening for Down's, Edwards' and Patau's syndromes request card requires the sonographer's DQASS number.

Standard US 10

If the DQASS report shows a red flag for a sonographer, that sonographer must only perform ultrasound for combined screening under supervision until reassessed. An action plan must be devised and implemented by the Health Board NT lead, in conjunction with the ASW ultrasound coordinator.

Target 100%

Standard US 11

All ultrasound equipment to be used in maternity services must be of a standard that meets the ASW/NHS Wales Shared Services Partnership (NWSSP) machine specification.

Target 100%

Standard US 12

A full record of the findings must be made on the ultrasound reporting module and images must be stored on the Health Board electronic image storage (PACS).

Target 100%

(1) The RadIS2 obstetric reporting module or other Health Board approved radiology electronic reporting module should be used to report all early pregnancy and fetal anomaly ultrasound scans.[9]

(2) A clear and concise ultrasound report should be produced and authorised by the person performing the ultrasound examination as an integral part of the examination.

(3) The scan report is a legal document and part of the medical record. The scan report and associated images and/or cine loops required for a record of the scan should be stored electronically. They must be stored for 25 years.

(4) Adequate identifiers to include the date and time of the examination should be entered on all images relevant to that woman.

8.1.6 Test Procedure

Standard US 13

The early pregnancy scan must be performed between 11 weeks and 2 days (CRL 45.0mm) and 14 weeks and 1 day (CRL 84.0mm) of pregnancy. The fetal anomaly scan must be performed between 18 weeks and 0 days and 20 weeks and 6 days of pregnancy.

Target 85%

(1) The woman's privacy needs must be respected. The discussion and ultrasound scan must be performed in a room where privacy can be assured.

(2) The sonographer should confirm with the woman her identity, her awareness of the purpose of the ultrasound scan and that she has given consent.

8.1.7 Results Handling

Standard US 14

If the scan findings appear normal following the early pregnancy or fetal anomaly scan, the woman must be informed and given the relevant ASW information leaflet by the sonographer to explain the ultrasound scan findings and result.

Target 100%

(1) There are different leaflets available to accompany the verbal result. Three leaflets for early pregnancy scans and one leaflet for fetal anomaly scans.

Standard US 15

A record that the ultrasound scan has been performed and the result must be included in the All Wales Maternity Record.

Target 100%

(1) A copy of the scan report must be printed and included in the woman's All Wales Maternity Record at the time of the scan.

8.2 Specific Standards and Protocols for Early Pregnancy Scans

8.2.1 Test Procedure

Standard US 16

The scan must be arranged and performed between 11 weeks and 2 days and 14 weeks and 1 day of pregnancy, ideally at 12 weeks (if the woman presents for antenatal care before 12 weeks gestation).

Target 100%

(1) The early pregnancy scan should be performed transabdominally.

(2) If indicated a TV scan may be appropriate, local policies and pathways should be followed including those for probe decontamination. This must follow Welsh Government guidance and probe manufacturer's recommendations. (NWSSP 2014)

(3) If there are no clinical indications, a further routine appointment for an early pregnancy scan is not required if the scan is inadvertently performed after 8 weeks and 4 days (CRL greater than 20.0mm) of pregnancy and before 11 weeks and 1 day (CRL less than 45.0mm) of pregnancy, unless Down's, Edwards' and Patau's syndrome screening has been offered and accepted.

Standard US 17

The gestation must be calculated using the crown rump length (CRL) measurement up to 84.0mm. Where CRL is over 84.0mm the head circumference (HC) measurement must be used to calculate the gestation (Loughna 2009).

Target 95%

(1) If an adequate CRL cannot be obtained and the HC is over 88.0mm, the HC should be used to date the pregnancy (Loughna 2009).

Standard US 18

As a minimum standard, the sonographer should report:

- whether pregnancy is intrauterine
- presence or absence of a fetus
- viability (i.e. presence of heart pulsation)
- CRL (up to 84.0mm) or HC as appropriate'
- NT measurement(s) where screening for Down's, Edwards' and Patau's syndrome is requested
- fetal number and in multiple pregnancies the chorionicity and amnionicity
- any gross fetal abnormality which is seen.

Target 100%

(1) The Health Board must have a policy for dealing with non-viable pregnancies and this must be followed for all non-viable pregnancies found on the early pregnancy scan (NICE 2012).

(2) If the woman has requested screening for Down's, Edwards' and Patau's syndromes and the process for obtaining NT measurements is unsuccessful or the CRL is greater than 84.0mm the woman must be offered second trimester screening (quadruple test) for Down's syndrome only. The quadruple test is not available for Edwards' and Patau's syndromes and is only available in a singleton pregnancy. A repeat scan appointment is not offered in order to obtain an accurate NT measurement. There must be a local pathway for offering women quadruple test appointments.

Standard US 19

The Health Board must have a pathway for women who consent to screening for Down's, Edwards' and Patau's syndromes and are then diagnosed as having a twin pregnancy during their early pregnancy dating scan.

Target 100%

(1) Women known to have a twin pregnancy prior to their early pregnancy scan, should have had specific counselling for screening in twin pregnancies and consented to that screening prior to their scan. The sonographer should check that the woman has consented.

(2) If a woman consents to screening for Down's, Edwards' and Patau's syndromes and is then diagnosed as having a twin pregnancy during her early pregnancy scan, the health board will have a pathway for:
   (a) arranging an appointment with the nominated health board professional for screening in twin pregnancies
   (b) taking the NT measurements before 14 weeks and 1 day and
   (c) collecting the blood sample for screening before 14 weeks and 1 day.

(3) The quadruple test is not available for twin pregnancies.

(4) If the woman has requested screening for Down's, Edwards' and Patau's syndromes and no NT measurements are obtained or either CRL is greater than 84.0mm, the woman must be informed that screening cannot be offered.

(5) If only one NT measurement can be obtained combined screening can be offered but the result will be less accurate.

(6) If either CRL is below 45.0mm a further scan appointment should be offered.

(7) Antenatal Screening Wales have provided information on offering combined screening and NIPT when there is a second pregnancy sac.

8.2.3 Abnormal Early Pregnancy Scans

Standard US 20

If the pregnancy is ongoing and an abnormality is identified, the sonographer must arrange for an appropriately trained midwife or obstetrician to discuss the finding with the woman within 24 hours.

Target 100%

(1) Where a problem has been identified, verbal information that there may be a problem should initially be provided by the sonographer. The sonographer must place a report within the woman's All Wales Maternity Record at the time of this appointment.

(2) Verbal information should then be provided by the antenatal screening coordinator (or deputy) or obstetrician and a record of the discussion documented in the All Wales Maternity Record.

(3) Where appropriate services are not available locally, women must be offered an appointment in a fetal medicine department within an appropriate timescale for the condition found.

(4) Where the woman has not consented to screening for Down's, Edwards' and Patau's syndromes, the nuchal translucency (NT) assessment or measurement is not part of the early pregnancy scan. Where during the scan the NT is visualised and appears enlarged a measurement should be taken and reported.

(5) If a cystic hygroma is present or if the nuchal translucency is 3.5mm and above, this is a significant ultrasound finding and the woman should be informed and referred to a health care professional with

appropriate skills and knowledge for further information and management. In this circumstance the electronic image should be made available with the referral correspondence, if the woman wishes to be referred for further assessment.

(6) If the NT is 3.5mm and above, screening for Down's, Edwards' and Patau's syndromes should be completed if consent for the test has been given.

(7) In circumstances where there is no live fetus identified during the early pregnancy scan the local Health Board policy for dealing with non-viable pregnancies should be followed.

(8) Any suspected congenital anomaly should be reported to Congenital Anomaly Register and Information Service (CARIS) via the RadIS2 reporting module. It is the sonographer's responsibility to ensure that reporting to CARIS has been completed. If the RadIS2 reporting module is not available, a 'CARIS notification card' for a suspected congenital anomaly should be completed and sent to the CARIS coordinator/office.[10]

(9) The woman's explicit consent is not required for reporting to CARIS. Information about the purpose of CARIS and the woman's right not to have information about herself used by CARIS is provided in the ASW Information for Women pack.

Standard US 21

A contemporaneous, dated and signed record must be made in the All Wales Maternity Record of actions planned and taken in response to any abnormal finding(s).

Target 100%

8.3 Specific Standards and Protocols for Fetal Anomaly Ultrasound Scans

8.3.1 Test Procedure

Standard US 22

The fetal anomaly ultrasound scan must be offered and an appointment made between 18 weeks and 0 days and 20 weeks and 6 days of pregnancy (if the woman presents for antenatal care before this gestation).

Target 100%

(1) Women who attend for antenatal care later in pregnancy should be offered an ultrasound scan appropriate to their presumed gestation. The routine anomaly scan reporting module in RadIS2 cannot be used for these scans as the estimation of normal measurements may not be accurate with increased gestational age.

Standard US 23

The minimum standard for reporting the 18 weeks and 0 days to 20 weeks and 6 days fetal anomaly ultrasound scan, as set out in the 'Antenatal Screening Wales agreed all Wales fetal anomaly screening scan standard check list' April 2018 must be achieved.[11]

Target 100%

(1) Where the first examination is suboptimal or checklist incomplete and the sonographer is suspicious of a possible fetal abnormality, a second opinion should be sought as soon as possible.

(2) If appropriate images cannot be obtained to allow the standard checklist to be completed the woman should be offered one further ultrasound scan. The woman should be informed that there are a number of reasons why it is sometimes not possible to complete the scan checklist. Examples of why it may not be possible to complete the checklist are maternal considerations such as maternal habitus or body mass index, uterine fibroids, abdominal scarring and/ or by fetal considerations such as a suboptimal fetal position.

(3) This second examination should be performed before 23 completed weeks of pregnancy. The routine anomaly scan reporting module in RadIS2 cannot be used for scans after 20 weeks and 6 days as the estimation of normal measurements may not be accurate with increased gestational age.

(4) Where it is not possible for the sonographer to complete the standard checklist on the second scan, the woman should be informed that it was not possible to complete the checklist.

(5) Written information for women is available from ASW on incomplete fetal anomaly scans.

Standard US 24

The following specific ultrasound findings must be referred for further assessment:
- ventriculomegaly
- echogenic bowel
- renal pelvic dilatation.

Target 100%

8.3.2 Abnormal Fetal Anomaly Scans

Standard US 25

Where a fetal anomaly is identified, the sonographer must arrange for an appropriately trained midwife or obstetrician to discuss the findings with the woman within 24 hours.

Target 100%

(1) Where a problem has been identified, verbal information that there may be a problem should initially be provided by the sonographer. The sonographer must place a report within the woman's All Wales Maternity Record at the time of this appointment.

(2) Antenatal Screening Wales has provided guidance on short femur lengths.

(3) Verbal information should then be provided by the antenatal screening coordinator (or deputy) or obstetrician and a record of the discussion documented in the All Wales Maternity Record.

(4) Advice on relevant serological investigation on maternal serum can be found in the infections in pregnancy document.

(5) Where appropriate services are not available locally, women must be offered an appointment in a fetal medicine department within an appropriate timescale for the condition found.

(6) Any suspected congenital anomaly should be reported to CARIS via the RadIS2 reporting module. It is the sonographer's responsibility to ensure that reporting to CARIS has been completed. If the RadIS2 reporting module is not available, a `CARIS notification card´ for a suspected congenital anomaly should be completed and sent to the CARIS coordinator/office.

(7) The woman's explicit consent is not required for reporting to CARIS. Information about the purpose of CARIS and the woman's right not to have information about her used by CARIS is provided in the ASW Information for Women pack.

Standard US 26

Following a suspected fetal cardiac anomaly, the woman must be reviewed within three working days by a fetal cardiologist.

Target 90%

Standard US 27

A contemporaneous, dated and signed record must be made in the All Wales Maternity Record of actions planned and taken in response to any abnormal finding(s).

Target 100%

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End Notes

[1] As soon as possible after delivery and with parental consent, vaccination of term babies is recommended according to the hepatitis B status of the mother as recommended in the Green Book (DOH 2017)

[2] Hepatitis B vaccine should be given to term babies weighing more than 1500gms when the mother is HBsAG positive and anti-HBe positive and with a maternal HBV DNA level < $1x10^6$iu/ml in an antenatal sample. All other babies will require both hepatitis B vaccine and HBIG.

[3] Further doses of hepatitis B vaccine are required at one, two, three, four and twelve months of age. A blood test should be undertaken at 12 months of age to check immunity.

[4] NICE (2008) indicates; `In the case where a woman is Rhesus D-negative, consideration should also be given to offering partner testing because, if the biological father of the baby is negative as well, anti-D prophylaxis, which is a blood product will not need to be administered´.

[5] NICE (2008) also indicates; `Other situations where anti-D prophylaxis may not be necessary include cases where a woman has opted to be sterilised after the birth of the baby or, when a woman is otherwise certain that she will not have another child after the current pregnancy´.

[6] Potentially sensitising events in pregnancy:

- amniocentesis, chorionic villus biopsy and cordocentesis
- antepartum haemorrhage/ uterine (PV) bleeding in pregnancy
- external cephalic version
- abdominal trauma (sharp/blunt, open/closed)
- ectopic pregnancy
- evacuation of molar pregnancy
- intrauterine death and stillbirth
- *in-utero* therapeutic interventions (transfusion, surgery, insertion of
- shunts, laser)
- miscarriage, threatened miscarriage
- therapeutic termination of pregnancy
- delivery – normal, instrumental or caesarean section
- intra-operative cell salvage

[7] The woman should be offered sickle cell and thalassaemia screening as early as possible in the pregnancy so that if invasive testing is offered CVS can be an option. Although CVS can be performed on a gestation greater than 13 weeks (RCOG 2005), CVS is usually performed between 11 and 13+6 weeks.

[8] A `sonographer´ is a healthcare professional qualified in ultrasound who carries out ultrasound examinations. There is currently no regulatory control on performing obstetric ultrasound scans but any sonographer performing obstetric screening scans in Wales must hold a relevant diploma of medical ultrasound qualification in obstetrics, or a post graduate certificate or diploma in medical ultrasound imaging which is case accredited. Taking into account the recommendations of relevant professional bodies, Health Boards should agree which health professionals have the skills and competencies to undertake early pregnancy and fetal anomaly ultrasound scans.

[9] The RadIS2 obstetric reporting module has been developed to assist sonographers in the reporting of the early pregnancy and fetal anomaly scans by using a structured reporting format and structured printing of the report. The implementation of this module is progressing during 2015. Where the module is available within the Health Board it must be used to report these scans. Where the module is not yet available the existing ultrasound reporting arrangements should continue.

[10] CARIS has Section 60 support. Section 60 of the Health and Social Care Act 2001 provides a power to ensure that patient identifiable information needed to support essential NHS activity can be used without the consent of patients. The power can only be used to support medical purposes that are in the interests of the patient or the wider public, where consent is not a practicable alternative, and where anonymised data will not suffice.

[11] Fetal anomaly ultrasound scans are only able to detect a proportion of structural abnormalities due to the limitations of the test. It is important to note that a 'completed fetal anomaly scan' does not mean that all the structures are necessarily normal or that there are no abnormalities, but only means that the scan has been completed to the required standard.