Antenatal Screening Wales, Policy Standards and Procedures

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Author:	Governance Screening Lead	
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The latest approved version of this document is online.
If the review date has passed please contact the Author for advice.

Version Control

Version	Summary of Changes/Amendments	Issue Date
1	Initial Issue	July 2019
2	Review to ensure website link works and add additional Powys detail	June 2025

ENGAGEMENT & CONSULTATION

Key Individuals/Groups Involved in Developing this Document

Role / Designation
Governance screening lead

Circulated to the following for Consultation

Date	Role / Designation
27/4/25	Powys Midwives
27/4/25	Powys Midwifery Leadership and Management team
27/4/25	Women and Children's guidelines group
27/4/25	Safeguarding

Groups approved at

Date	Group
14/10/2025	Maternity Guidelines Group
21/10/2025	Women and Children's guidelines group

Evidence Base
Please list any National Guidelines, Legislation or Health and Care Standards relating to this subject area? Antenatal screening Wales standards, policies and procedures

Detail:

The midwives in Powys follow the Antenatal Screening Wales (ASW) Programmes.

The ASW Programmes offered are: -

- Blood Group D group and Antibodies
  Cell free DNA (cffDNA) (for D neg
  blood group)
- HIV screening
- Hepatitis B screening
- Syphilis Screening
- Down Syndrome, Edwards Syndrome and Patau's Syndrome screening.
- Sickle cell and Thalassemia screening
- Early pregnancy dating scan
- Fetal Anomaly Ultrasound Scan.

Information on all the tests offered can be found on the following link
The link below contains all the relevant documents relating to antenatal screening:
Standards and Protocols 2023 English amends April 2025.pdf - See Appendix 1

All women are provided with a QR code at booking detailing all the screening tests that are available – the details of which can be found on the website above.

Please ensure that records of which screening tests are offered, consented to, declined and are obtained are recorded in the digital maternity record.

Powys Caveats

HIV/Hepatitis B/ Syphilis

- Pregnant women that are diagnosed with Hepatitis B, HIV or Syphilis should be referred and advised to deliver in a District General Hospital (DGH). DGH will ensure appropriate care by seeking advice from sexual Health, obstetrician, hepatologist if appropriate. Medication if required to be commenced in a timely manner and neonatal management is planned in a timely manner.
- Arrangements must be made in the antenatal period for neonates of women who are Hepatitis B Pos, HIV Pos or syphilis to receive appropriate treatment, rapidly after birth in their chosen DGH and clear evidence developed by the multi-disciplinary team of the management plan should be documented in the All-Wales maternity notes.
- Please complete below surveillance screening

  V1 Pathway for surveillance of pregnant women with a positive antenatal screening test result for syphilis or HIV.docx - See Appendix 2

Blood Group, D Group and Antibodies.

Antibody Positive result

- Women with positive antibodies should be offered a referral to a fetal medicine Department. The results should be Clearly documented in the digital maternity record.

V1 cffDNA screening test A Guide for Health Professionals – See appendix 3

Sickle cell and Thalassemia

Women previously diagnosed with a haemoglobin disorder or are carriers

- If diagnostic testing is accepted by the woman an urgent appointment should be offered with the All-Wales medical Genomics Services for fast track to medicine. Please seek advice from Powys genomics lead and clearly document in digital maternity record what actions have been taken.

Down's Syndrome, Edwards Syndrome and Patau's Syndrome

- All women who have a high chance screening result following NIPT must be offered, as part of ongoing management an invasive test in the DGH/Fetal medicine.
- If there is an abnormal early pregnancy dating scan or anomaly scan the woman is referred to a Fetal medicine for ongoing management and the offer of Chronic villi sampling (CVS) or amniocentesis.
  Document in hand-held records/tracer what actions have been taken.
  If women have had a previous high chance result for Down syndrome, Edward Syndrome or Patau Syndrome please see pathway.
  Pathway NIPT for previous trisomy on HP template.pdf

Safeguarding

If any safeguarding concerns or significant risk factors are identified for a unborn child or young person/vulnerable adult practitioners must follow Wales Safeguarding Procedures (2019) and SGP036 Safeguarding Policy Policies & Written Control Documents - SGP 036 Safeguarding Policy.pdf (sharepoint.com) . Advice and support concerning any safeguarding issue can be sought from PTHB Safeguarding Team via the Safeguarding Hub on 01686 252806 or email PowysTHB.Safeguarding@wales.nhs.uk (Monday-Friday 09:00-17:00, excluding Bank Holidays). Outside of office hours, Local Authority can be contacted on 0345 0544 847 or contact Silver on Call.
All registered practitioners should access appropriate safeguarding supervision and training as per guidance. Safeguarding Supervision (sharepoint.com)

Equality Statement

Powys Teaching Health Board Maternity Services are committed to:
• The elimination of unlawful and unfair discrimination
• The active promotion of equal opportunities for women and their families and our workforce
• The protection of the human rights of women and their families and our workforce

• The promotion of inclusive relationships between groups who share protected characteristics and those who don't
• The valuing of the diversity inherent in the communities we serve and in our workforce.

The words 'woman' and 'women' have been used throughout this document as this is the way that the majority of those who are pregnant and having a baby will identify. For the purpose of this document, this term includes girls. It also includes people whose gender identity does not correspond with their birth sex or who may have a non-binary identity. Similarly, where the term 'parents' is used, this should be taken to include anyone who has main responsibility for caring for a baby. It is recognised that there are many different family arrangements.

When translation services are required, there is the expectation that a face-to-face translator or digital interpretation services will be provided.

The Language Line App is available to all maternity staff to use for this purpose. Consideration is required with written documents and leaflets to be provided in a woman's preferred or 1st language.

For further support and advice contact PTHB Equality Team:
powys.equalityandwelsh@wales.nhs.uk

References

Antenatal Screening Wales. (2023). Antenatal Screening Wales Policy, Standards and Protocols 2023.

Public Health Wales. (2023). Antenatal Screening Wales Policy, Standards and Protocols. https://publichealthwales.nhs.wales/services-and-teams/screening/antenatal-screening-wales/programme-reports/antenatal-screening-wales-policy-standards-and-protocols-v7/

Appendix 1- Antenatal Screening Wales Policy, Standards and Protocols 2023

Sgrinio Cyn Geni Cymru
Antenatal Screening Wales

Antenatal Screening Wales Policy, Standards and Protocols 2023

GIG | Iechyd Cyhoeddus

Thanks are given to the Antenatal Screening Wales (ASW) advisory 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.

Summary of change			
Date	**Section**	**Page**	**Comments**
May 2024	Following the introduction of cell free fetal DNA, the section on blood group, D status and antibodies has been updated.	34-47	To include cffDNA
March 2025	7.0 Antenatal Screening for Down's syndrome, Edwards' syndrome and Patau's syndrome	64	ASW film clip removed from ASW website - protocol deleted
March 2025	7.0 Antenatal Screening for Down's syndrome, Edwards' syndrome and Patau's syndrome	65	To include offer of Primary NIPT by midwifery services for past history of T13, T18, T21
March 2025	8.0 Antenatal ScreeningUltrasound	80	ASW film clip removed from ASW website - protocol deleted
March 2025	Endnotes	94	Recommendations for sonographers without CASE accredited qualification

Contents

1.0 Introduction

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. Governance for the work is provided by the Quality and Clinical Governance Group and programme specific advisory groups. ASW does not provide or directly manage any antenatal screening services.

The health board maternity services in Wales offer antenatal screening tests to pregnant women as part of their antenatal care. Antenatal screening tests are offered for different reasons, and this makes antenatal screening a complex programme with a number of different purposes and unique ethical considerations and implications. Supporting individuals to make personal informed decisions about their antenatal screening choices is important during pregnancy. Health professionals must ensure that individuals have the information and understanding they need to make decisions and to give informed consent.

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

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

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

For others, the condition can be identified during the antenatal period but no treatment is available. With high quality counselling, women can make a personal informed choice about whether they wish to continue the pregnancy or plan their care for the pregnancy including referral to relevant specialities. Appropriate support will be offered whichever choice is made.

ASW published the initial policy, standards and protocols in 2005. The policy, standards and protocols are reviewed every three years. All health boards in Wales have adopted the policy, standards and protocols for antenatal screening. This enables individuals across Wales to have equal access to quality assured screening services during pregnancy. The antenatal screening coordinators, maternal and child screening governance leads, obstetric lead sonographers, ultrasound nuchal translucency (NT) leads and ultrasound fetal cardiac leads work closely with ASW to implement and maintain ASW standards in their health boards.

A biannual performance monitoring assessment known as performance indicators is undertaken by ASW in collaboration with health boards. This provides health boards with information about the performance and compliance with ASW policy, standards and protocols. Where ASW policy, standards and protocols are not being met, action plans for improvement should be developed between key health professionals in the health boards.

The recommendations of: UK National Screening Committee (UK NSC), National Institute for Health and Clinical Excellence (NICE), British Society for Haematology (BSH), British HIV Association (BHIVA), British Association for Sexual Health and HIV (BASHH), NHS England Sickle Cell and Thalassaemia Screening Programme Handbook for antenatal laboratories, Down's Syndrome Screening Quality Assurance Support Service (DQASS), Royal College of Obstetricians and Gynaecologists (RCOG) and The British Medical Ultrasound Society (BMUS) and good practice models e.g. Supporting women and their partners through prenatal screening for Down's syndrome, Edwards' syndrome and Patau's syndrome | RCOG have been considered in this revision.

These programme policy, standards and protocols should be considered with due regard to the recommendations contained in supporting literature, e.g. guidance of Professional Bodies and Royal Colleges.

ASW have developed educational resources to support health professionals delivering antenatal screening and provided further guidance for health professionals in the following publications: Infections and Rashes in Pregnancy: A Guide for Health Professionals, Midwives Handbook and Obstetric Ultrasound Handbook for Sonographers.

This document will be updated online in between publications. All updates will be outlined at the beginning of the document. To ensure that the version in use is the most up to date it is advised that users view the document online and do not print.

1.1 Terminology

ASW acknowledges the challenges that gender identity can have on pregnancy and recognise the importance of health professionals providing personal, inclusive and respectful care during pregnancy and childbirth. For the purpose of this professional document, the programme policy, standards and protocols use the terms 'woman', ‘women’ or 'mother' throughout. These should be taken to include pregnant people who do not identify as women but present for antenatal care.

These programme policy, standards and protocols use the terms ‘must’ and ‘should’ throughout. The use of ‘must’ indicates a requirement and the use of ‘should’ indicates a recommendation.

These programme policy, standards and protocols use the terms ‘calendar days’ and ‘working days’ throughout. Calendar days mean consecutive days, inclusive of Saturdays, Sundays and public/bank holidays in Wales. Working days mean any day other than a Saturday, Sunday or public/bank holiday in Wales.

1.2 Document Design

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

Standard C 28	**Numbered Standard Statement**
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 laboratory will email the result to the relevant generic email box in the health board unless the laboratory need to discuss the result with the antenatal screening coordinator or named deputy. (2) The relevant ASW pathway should be followed depending on the result of the test. (3) ASW written information must be used to inform the discussion between the woman and the health professional.[1]	**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 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 89 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 on this page.

The numbers in superscript that refer to endnotes can be clicked on and this will take you to the endnotes 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.

Key documents will be hyperlinked throughout these policy, standards and protocols. To access these, click on the hyperlink (highlighted in Protocol 3 in the table above) and the document will open in a separate webpage.

2.0 Programme Governance Arrangements

2.1 Service Governance

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

The liability for antenatal screening provision rests with the health board providing care. Similarly, the responsibility for operational delivery of the antenatal screening pathway, which meets the agreed standards, rests with the health board.

As part of the health board governance framework for antenatal screening it is recommended that:

- all antenatal screening incidents should be reported via the health board clinical incident reporting system

- if, following identification and preliminary investigation by the health board, an antenatal screening 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, maternal and child 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 Health Board Governance Lead for Maternal and Child Screening

Standard G 1

Health boards must identify a named governance lead for maternal and child screening who manages the strategic governance role of these programmes.

Target 100%

As part of the long term agreement between health boards and the screening division of Public Health Wales there is a requirement that a governance lead will be identified within each health board for maternal and child screening. The person must be sufficiently senior and have adequate time to be effective in this role. The identity of individual(s) undertaking the role must be made known to ASW to ensure effective communication and ASW made aware of any changes/movement of personnel.

Within the antenatal screening programme, the named governance lead will ensure provision of high quality antenatal screening within their own health board area.

- Provide regular updates on performance and service quality to appropriate health board forums and staff groups, to support monitoring and provide opportunities to identify areas of service improvement.
- Feed issues, concerns and learning from incidents up to the relevant health board forums (e.g. directorate quality groups), maintaining oversight of any resultant actions to ensure full resolution or appropriate further escalation.
- Liaise with the relevant directorate clinical governance lead (e.g. maternity, obstetric, neonatal, etc.) to maintain service quality and address local issues impacting on delivery.
- Ensure action plans are developed and followed through with the relevant people and groups for:
    - Down's syndrome Screening Quality Assurance Support Service (DQASS) ultrasound reports ○ performance indicators
    - training needs analysis ○ audits and monitoring issues.
- Undertake incident reviews in liaison with directorate governance lead, sharing lessons and themes to embed improvements.
- Facilitate the provision of information for audit to support quality assurance and benchmarking against national performance.
- Ensure sufficient resources are available to support ASW service delivery through the development and management of relevant processes for resource provision (e.g. test consumables, information resources), and troubleshooting with the antenatal screening coordinator where supply issues occur.
- Develop and maintain contacts and working alongside relevant individuals in other directorates (e.g. ultrasound leads, neonatal unit leads and health visitors) to manage service quality and service improvements.
- Ensure effective and consistent implementation of antenatal screening policies, standards and protocols within own health board area.
- Actively participate in the development and review of policy, standards and protocols to support high quality, evidence-based screening provision.
- Develop education plans and communication pathways to disseminate changes to standards or protocols.
- Develop action plans to deal with non-compliance issues and follow through to ensure compliance.

- Ensure appropriate communication networks and mechanisms are in place to rapidly and safely disseminate standards and protocol changes to health board colleagues in the event of business continuity disruption.
- Attending and participating at:
    - All Wales Governance Leads Meetings (six-monthly full day meeting) to share practice, contribute to programme development and ensure awareness of local issues impacting on service delivery
    - nominated ASW programme meetings (e.g. Quality & Clinical Governance, programme advisory group) as a governance lead representative.[2]
- Attending routine meetings with the national programme/ASW teams to discuss quality and performance issues.
- Liaising between the national programme/ASW team(s) and the health board to report incidents, which may indicate system failure.
    - Liaising between the national programme/ASW team(s) and the health board regarding performance indicator and audit action plans.
    - Liaising between the national programme/ASW team(s) and the health board regarding training needs analysis results.
    - Liaising between the national programme/ASW team(s) and the health board regarding education plans and training.
- Undertake agreed actions in the event of business continuity disruption, particularly to disseminate information about required changes to normal process to affected health board staff and feedback issues/concerns to the national programme/ASW team(s).

2.3 Screening Pathways

Antenatal screening should be supported by locally developed care pathways which describe the health board's arrangements for:

- giving pre-test information and offering the test
- recording the individual's decision whether to accept or decline the screening test
- requesting and providing the test
- the results handling process for each test

[2] Membership of these groups is shared across maternal and child governance leads.

- providing support services for women with results that prompt further management
- 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 board's antenatal screening programme should be supported by the following management arrangements.

3.1 Programme Coordination

Standard M 1

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 2

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 and auditing a relevant service within maternity departments for discussing results with women that prompt further management detected by antenatal screening

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

(7) developing a plan within the health board to ensure that all midwives who deliver the antenatal screening programmes have successfully completed the ASW elearning resources within the required frequency

(8) coordinating the supply of public information resources to health professionals providing care

(9) developing and auditing a pathway to enable the structured reoffer 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

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

(13) coordinating the health board antenatal screening forum.

Standard M 3

Health boards should identify a named ultrasound obstetric lead for antenatal screening who manages the ultrasound antenatal screening programme.

Target 100%

The named ultrasound obstetric lead will:

(1) be an experienced sonographer who has participated in the ultrasound aspect of antenatal screening

(2) act as liaison between the health board and ASW

(3) implement the ASW policy, standards, protocols and pathways in relation to the early pregnancy dating scan, the fetal anomaly ultrasound scan and some aspects of the

Down's syndrome, Edwards' syndrome and Patau's syndrome screening programme

(4) attend the biannual ASW joint ultrasound leads meeting

(5) performance manage the antenatal ultrasound screening programmes and deal with high level programme risk issues

(6) work alongside the nuchal translucency (NT) lead and fetal cardiac lead to implement strategies for any required service changes

(7) lead the health board, working alongside the NT lead and fetal cardiac lead, to ensure that all ASW audits, as part of the performance management framework, are completed and forwarded to ASW in a timely manner

(8) lead in the coordination of the supply of public information resources to sonographers providing care

(9) lead on the development of educational activities and education resources for health professionals

(10) develop a plan within the health board to ensure that all sonographers who deliver the antenatal screening programmes have successfully completed the relevant ASW e-learning resources within the required frequency

(11) ensure partnership working with the maternal and child governance lead to ensure action plans for the performance indicators, audit results and DQASS ultrasound results are developed where required and acted upon in a timely manner.

Standard M 4

Health boards should identify a named nuchal translucency (NT) lead for antenatal screening who leads the combined screening aspect of the ultrasound antenatal screening programme.

Target 100%

The named NT lead will:

(1) be an experienced sonographer who has participated in the ultrasound aspect of antenatal screening

(2) act as liaison between the health board and ASW

(3) lead the quality assurance of the ultrasound element of the combined Down's syndrome, Edwards' syndrome and Patau's syndrome screening programme within their health board in line with ASW standards and protocols

(4) attend the biannual ASW joint ultrasound leads meeting.

The NT lead will be expected to:

(1) assess three randomly selected paired images per sonographer to ensure compliance with the required standards and feed back to sonographer

(2) comply with ASW required standards by maintaining a personal NT diagnostic plot and submitting three of their randomly selected paired images for audit biannually

(3) ensure sonographers maintain a personal NT diagnostic plot for internal quality control assurance

(4) regularly monitor NT diagnostic plots for each sonographer to ensure compliance with DQASS requirements

(5) liaise with ASW regarding the biannual DQASS ultrasound reports received

(6) communicate with sonographers, antenatal screening coordinators, maternal and child governance leads, radiology service managers and ASW programme coordinators with regards to standards achieved and monitoring the programme

(7) ensure that all sonographers who deliver the antenatal screening programmes have successfully completed the relevant ASW e-learning resources within the required frequency

(8) oversee and ensure sonographers maintain a record of initial training and ongoing e-learning

(9) produce and implement action plans following the DQASS report where necessary

(10) provide practical training and support in relation to image production

(11) liaise with the ultrasound applications specialist to ensure optimum image settings/parameters.

Standard M 5

Health boards should identify a named fetal cardiac ultrasound lead for antenatal screening who leads the fetal cardiac aspect of the antenatal screening programme.

Target 100%

The named fetal cardiac ultrasound lead will:

(1) act as liaison between the health board, ASW and regional/tertiary fetal medicine centres and fetal cardiology centres

(2) attend the biannual ASW joint ultrasound leads meeting

(3) carry out audits for ASW and feed back results to the health board

(4) provide education, training and support in fetal cardiology for their colleagues

(5) ensure that all sonographers who deliver the antenatal screening programmes have successfully completed the relevant ASW e-learning resources within the required frequency

(6) train student sonographers in the cardiac views and any new sonographers to the health board until they reach the competency required

(7) attend fetal medicine cardiac clinics once/twice a year to further their knowledge.

Standard M 6

Health boards must have a designated laboratory lead responsible for the discrete aspects of the antenatal screening programme.

Target 100%

Standard M 7

Health boards must have a process in place to ensure that every pregnant woman is offered and has access to the ASW Antenatal Screening Tests literature in Welsh or English and a record of the offer made.

Target 100%

(1) Welsh language must not be treated less favourably than English language in line with Welsh Language Standards.

(2) The midwife must ensure women receive verbal and digital information about the antenatal screening tests.

(3) The midwife must ensure women who are unable to access the digital version of the ASW Antenatal Screening Tests literature are given a hard copy.

(4) Where women have a different language or communication need, the midwife must ensure that the information is provided in the appropriate format, i.e. in hard copy, large print, easy read, Braille, audio, British Sign Language or an approved interpreter service may be appropriate.

Standard M 8

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

Target 100%

(1) Down's syndrome, Edwards' syndrome, Patau's syndrome and sickle cell and thalassaemia request card errors should not exceed 2%. Blood group and antibody request card and cell free fetal DNA (cffDNA) errors must be 0%.

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

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

3.2 Record Keeping

Standard M 9

Maternity services must use the All Wales 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 about the screening test
- the date the screening test was discussed and 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
- any follow-up care planned.

4.0 Antenatal Screening for HIV, Hepatitis B and Syphilis

Policy Statement

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

- HIV (National Assembly for Wales 2000; NICE 2021)
- hepatitis B (Welsh Health Circular 1998; NICE 2021)
- syphilis (UK National Screening Committee 1998; NICE 2021).

HIV (Human Immunodeficiency Virus)

HIV is a retrovirus that attacks and destroys T-lymphocytes, resulting in immunesuppression 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 in early pregnancy who have an established HIV infection so that treatment and care can be offered to reduce the risk of vertical transmission of the virus from about 25% to around 0.3% (ISOSS 2023). The identification and treatment of HIV also has considerable health benefits for the woman living with HIV. 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 (BHIVA 2018).

Programme Limitations
The screening programme will not detect infections contracted within eight weeks 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 sexual health.

Anticipated Outcome
Vertical 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, resulting in both acute and chronic infection, and is spread by direct contact with the blood of a person who has hepatitis B. A mother who has hepatitis B can transmit the virus to her baby at the time of delivery. The virus can also be detected in other bodily fluids such as semen and saliva. Most adults 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 a mother with hepatitis B to her baby is an important cause of the continued high prevalence of this infection in some parts of the world. Neonates who acquire the virus in this way are very likely (approximately 90%) to contract hepatitis B and become chronic carriers of the hepatitis B virus (DOH 2022).

All babies in Wales are offered Infanrix hexa® (DTaP/IPV/Hib/Hep B) 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 (Welsh Health Circular 2017).

Rationale for Hepatitis B Screening
To enable the identification of pregnant women in early pregnancy who have hepatitis B and 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. The identification and treatment of this communicable disease also has potential health benefits for the mother.

Programme Limitations
The screening programme may not detect infections contracted within 12 weeks 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 because of their lifestyle will require specific individual advice on the advisability of additional testing in pregnancy, preferably from sexual health.

Anticipated Outcome
The rate of vertical transmission of hepatitis B will be significantly reduced by the identification of at risk babies and the provision of an appropriate vaccination programme and also has potential health benefits for the mother.

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 a mother who has syphilis 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 may not detect infections contracted within 12 weeks 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 sexual health.

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

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

4.1.1 Pre-test Information

Standard C 1

Every pregnant woman must be offered and directed to the ASW Antenatal Screening Tests literature available on the ASW website. Target 100%

(1) The midwife must ensure women receive verbal and digital information about the antenatal screening tests.

(2) The midwife must ensure women who are unable to access the digital version of the ASW Antenatal Screening Tests literature are given a hard copy.

(3) Where women have a different language or communication need, the midwife must ensure that the information is provided in the correct format, i.e. in large print, easy read, Braille, audio, British Sign Language or an approved interpreter service may be appropriate.

(4) The midwife must make a record of the format in which the information is given to the woman.

Standard C 2

The midwife must have a verbal discussion with the woman about HIV, syphilis and hepatitis B infections in pregnancy prior to asking her to make a personal informed choice whether she wants the test and a record of the discussion must be made in the All Wales Maternity Record.

Target 100%

(1) Where the woman has a different language or communication need, the midwife must ensure the provision of accurate information in a format that is accessible. Primarily this should be in digital format, but after assessing the woman's needs, hard copy, British Sign Language, easy read, audio or an approved interpreter service may be appropriate. This is essential to obtain informed consent.

(2) The purpose, implications, limitations and benefits of these screening tests must be explained to the woman by the midwife. This is essential to obtain informed consent.

(3) For women who require more information, counselling or support, this service is available from sexual health.

4.1.2 Screening Offer

Standard C 3

Every pregnant woman must be offered antenatal screening for HIV, hepatitis B and syphilis before 10^{+0} weeks of pregnancy if the woman presents for antenatal care before this gestation. A record of the offer must be made in the All Wales Maternity Record.

Target 100%

(1) Women who attend for antenatal care from 10^{+1} weeks of pregnancy must be offered screening for HIV, hepatitis B and syphilis at the first opportunity.

(2) Women who decline screening for one or more of the communicable diseases must be formally reoffered these screening tests by 20^{+6} weeks of pregnancy.

(3) Women who choose to have private antenatal screening are still eligible to access, and must be offered, NHS Wales antenatal screening tests.

Standard C 4

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

Target 100%

4.1.3 Consent

Standard C 5

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

Target 100%

(1) Prior to performing the test, the midwife must ensure that the woman:

- understands the screening test she has consented to
- does not require further information about the screening test
- gives her informed verbal consent to proceed with the screening test she has consented to.

(2) If the woman declines screening for HIV, hepatitis B or syphilis, the midwife must 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 must be formally reoffered these screening tests by 20^{+6} weeks of pregnancy as

part of the antenatal care pathway and this must be recorded in the All Wales Maternity Record.

Target 100%

(1) The midwife must ensure women receive verbal and digital information about the antenatal screening tests.

(2) The midwife must ensure women who are unable to access the digital version of the ASW Antenatal Screening Tests literature are given a hard copy.

(3) Where women have a different language or communication need, the midwife must ensure that the information is provided in the correct format, i.e. in large print, easy read, Braille, audio, British Sign Language or an approved interpreter service may be appropriate. This is essential to obtain informed consent.

(4) The midwife must make a record of the format in which the information is given to the woman.

4.1.4 Test Requesting

Standard C 7

The laboratory request[3] 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.[4]

Target 100%

[3] The request for the test may be hard copy request card or electronic.

[4] By signing the laboratory or ultrasound request, the requesting health professional is confirming that verbal and digital (or other appropriate format) 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.

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

(2) If a single request card 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.

4.1.5 Test Procedure

Standard C 10

The sample must be taken before 12^{+6} weeks of pregnancy if the woman presents for antenatal care before this gestation.

Target 80%

(1) Women who attend for antenatal care after 13^{+0} weeks of pregnancy should have this screening at the first opportunity.

(2) 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.

(3) 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 and the sample.

Standard C 11

If the woman is more than 23^{+6} weeks pregnant when the sample is taken, the laboratory must be contacted to inform them of the sample.

Target 100%

(1) If the woman is more than 23^{+6} weeks pregnant when the sample is taken, the sample should be marked 'rapid result'.

(2) If the woman is more than 36^{+6} weeks pregnant when the sample is taken, the sample should be marked 'urgent'.

(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 while the results are awaited.

Standard C 12

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%

4.1.6 Laboratory Services

Standard C 13

The laboratory must be appropriately accredited, or working towards accreditation, in accordance with the United Kingdom Accreditation Service, and compliant with ISO standard 15189 for antenatal HIV, hepatitis B and syphilis screening tests.

Target 100%

Standard C 14

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

Target 95%

Standard C 15

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 16

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 17

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 36^{+6} weeks of pregnancy should be marked as 'urgent'.

Standard C 18

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

Target 100%

4.1.7 Results Handling

Standard C 19

If the sample has not been tested at the local laboratory, the result must be available to the local laboratory within one working day of the final report being authorised by the testing laboratory.

Target 95%

Standard C 20

The result must be available to the maternity service within one working day of the report being released 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 21

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 22

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

Target 100%

Standard C 23

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 24

Women must be informed of the negative results by the maternity service at the 16week antenatal appointment. The results must be recorded in the All Wales Maternity Record.

Target 100%

(1) If any of these results are not available, the local health board pathway as identified in Standard C 22 should be followed.

(2) If the woman has had a miscarriage between sample collection and results being given, the results should be given to the woman as per the local health board pathway.

(3) The results discussion should have an emphasis on 'negative now', and that a repeat test should be taken if the woman feels that she has put herself at risk during the pregnancy.

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

(5) If this antenatal appointment is not face to face, a dated and signed record that the individual results have been discussed with the woman must be made in the maternity notes/health board IT system. The results must be documented in the All Wales Maternity Record the next time the midwife has a face-to-face appointment with the woman.

(6) Any actions relating to the results should also be documented.

Standard C 25

Where sampling has occurred later in pregnancy, results must be given within three weeks of the sample being taken. 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 result has been discussed with the woman must be made in the All Wales Maternity Record/health board IT system.

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

(3) If any of these results are not available, the local health board pathway as identified in Standard C 22 should be followed.

4.2 Specific Standards and Protocols for Antenatal HIV Screening

4.2.1 Known HIV Infection

Standard C 26

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

Target 100%

Standard C 27

Women who are aware they are HIV positive must be offered a referral to sexual health within two working days to enable the development of a joint care plan.

Target 100%

(1) Antenatal clinic to liaise with sexual health to ensure that the woman is assessed on an individual basis and provided with an appointment with sexual health appropriate to her needs.

4.2.2 HIV Reactive Results

Standard C 28

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 laboratory will email the result to the relevant generic email box in the health board unless the laboratory need to discuss the result with the antenatal screening coordinator or named deputy.

(2) The relevant ASW pathway should be followed depending on the result of the test.

(3) ASW written information must be used to inform the discussion between the woman and the health professional.

Standard C 29

A dated and signed record must be made in the hospital maternity notes/IT system 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/IT system and the confidentiality of the information ensured by health board confidentiality policies.

(2) The reactive result, management and follow-up results must be documented in the All Wales Maternity Record the next time the woman has a face-to-face appointment with the midwife.

4.2.3 HIV Positive Results

Standard C 30

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

Target 100%

(1) The laboratory must email the result to the relevant generic email box in the health board unless the laboratory need to discuss the result with the antenatal screening coordinator or named deputy.

Standard C 31

The result must be given to the woman within five working days of the result being available if the woman is less than 36^{+0} weeks pregnant.

Target 95%

(1) Arrangements should be made for pregnant women to return to the antenatal clinic to be given their HIV positive result as

soon as possible and when the necessary healthcare professionals are available.

(2) Interpreter services must 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 HIV specialist services.

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

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

(8) ASW written information must be used to inform the discussion between the woman and the health professional.

Standard C 32

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

Target 100%

(1) Arrangements should be made for the confirmatory sample to be taken when the woman returns to the antenatal clinic to be given her HIV positive result.

4.2.4 Record Keeping

Standard C 33

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

Target 100%

(1) HIV positive screening results should be recorded in the woman's All Wales Maternity Record with 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.

4.2.5 Care Plan

Standard C 34

The woman must be referred to local HIV specialist services, or the service who already manages the woman's care, within five days of a positive HIV result. The HIV service will manage the pregnant woman as per British HIV Association (BHIVA) guidance.

Target 95%

(1) Sexual contacts require the offer of screening for HIV via sexual health.

Standard C 35

An appropriate care plan must be developed by the multidisciplinary team and this must be documented in the hospital notes/IT system and All Wales Maternity Record with the woman's consent.

Target 100%

(1) This should be developed with reference to BHIVA (2018) guidance and must be developed in discussion with the woman and within the multidisciplinary team meeting. Paediatric referral must be made by the maternity services within 10 working days of the woman receiving the positive result to enable a birth plan to be developed.

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

(3) Interpreter services should be arranged for every antenatal clinic appointment if required.

(4) The result must not be given by the maternity staff to the woman's partner or relatives without the woman's consent. New positive HIV results may be shared with the GP with the woman's consent. Discussing these issues should form part of a comprehensive care plan developed with the HIV multidisciplinary team.

4.2.6 Postnatal Care

Standard C 36

The baby must be referred to a paediatrician as soon as possible after delivery and within four hours of birth. Target 100%

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

Standard C 37

The woman must be referred back to a named member of the HIV specialist team after delivery (BHIVA 2018). Target 100%

(1) All women should be reviewed in the postnatal period by a named member of the multidisciplinary team within 4–6 weeks to discuss medical and social issues.

4.3 Specific Standards and Protocols for Antenatal Hepatitis B Screening

4.3.1 Previous Infection

Standard C 38

If the woman indicates that she has been previously diagnosed with a hepatitis B infection, or has a current hepatitis B infection, she must be rescreened to confirm the diagnosis and to ensure that she follows the correct pathway. The relevant information must be included on the request card 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 six 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 39

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 laboratory will email the results to the relevant generic email box in the health board unless the laboratory need to discuss the result with the antenatal screening coordinator or named deputy.

(2) The relevant ASW pathway should be followed depending on the result of the test.

(3) ASW written information must be used to inform the discussion between the woman and the health professional.

Standard C 40

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

Target 100%

(1) A record of the reactive result must be recorded appropriately in the hospital maternity notes/IT system and the confidentiality of the information ensured by health board confidentiality policies.

(2) The reactive result, management and follow up results must be documented in the All Wales Maternity Record the next time the woman has a face-to-face appointment with the midwife.

4.3.3 Hepatitis B Positive Results

Standard C 41

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

Target 100%

(1) The laboratory must email the result to the relevant generic email box in the health board unless the laboratory need to discuss the result with the antenatal screening coordinator or named deputy.

Standard C 42

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 must 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 23^{+6} 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 GP requested the test, and is providing the woman with the result, the GP should not be informed of the result before the woman has given her consent for the GP to be informed. This should prevent screening of other family members inadvertently being instigated by the GP prior to the woman first being informed of her result.

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

(8) ASW written information must be used to inform the discussion between the woman and the health professional.

Standard C 43

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

Target 100%

(1) Arrangements should be made for the confirmatory sample to be taken when the woman returns to the antenatal clinic to be given her hepatitis B positive result.

(2) 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 same 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.

(3) The laboratory should inform the health protection team of the confirmed positive result to enable care planning to commence.

4.3.4 Record Keeping

Standard C 44

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

Target 100%

(1) Hepatitis B positive screening results should be recorded in the woman's All Wales Maternity Record with her consent.

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

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

4.3.5 Care Plan

Standard C 45

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

Target 100%

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

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

(3) Paediatric referral must be made by the maternity services within 10 working days of the woman receiving the positive

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 must not be given by the maternity staff to the woman's partner or relatives without the woman's consent. The result must not be given to the GP 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 46

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 must 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 must be ordered from virology department (according to local health board policy) for babies of named mothers ensuring availability from when the woman is 32–34 weeks pregnant.

(3) Hepatology/gastroenterology team must arrange for household contacts to receive counselling and the offer of screening for hepatitis B.

4.3.6 Postnatal Care

Standard C 47

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 Immunisation Against Infectious Diseases – Hepatitis B: 'The Green Book' (DOH 2022).

(2) Babies born weighing less than 1500g should receive HBIG in addition to the vaccine regardless of the antigen status of the mother (DOH 2022).

(3) An unscheduled vaccination form must 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]

4.4 Specific Standards and Protocols for Antenatal Syphilis Screening

4.4.1 Previous Infection

Standard C 48

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 to ensure that she follows the correct pathway. The relevant information must be included on the request card with the woman's consent.

Target 100%

4.4.2 Syphilis Reactive Results

Standard C 49

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 laboratory must email the result to the relevant generic email box in the health board unless the laboratory need to discuss the result with the antenatal screening coordinator or named deputy.

(2) The relevant ASW pathway must be followed depending on the result of the test.

(3) ASW written information must be used to inform the discussion between the women and the health professional.

Standard C 50

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

Target 100%

(1) A record of the reactive result must be recorded appropriately in the hospital maternity notes/IT system and the confidentiality of the information ensured by health board confidentiality policies.

(2) The reactive result, management and follow up results must be documented in the All Wales Maternity Record the next time the woman has a face-to-face appointment with the midwife.

4.4.3 Syphilis Positive Results

Standard C 51

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

Target 100%

(1) The laboratory must email the result to the relevant generic email box in the health board unless the laboratory need to discuss the result with the antenatal screening coordinator or named deputy.

(2) 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 is result issued and continues with a clinical assessment when the woman is reviewed by sexual health.

Standard C 52

The result must be given to the woman within three working days of the result being available. Target 100%

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

(2) Interpreter services must be arranged if required.

(3) Syphilis is a relatively 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 sexual health specialist team.

(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 GP requested the test and is providing the woman with the result, the GP must not be informed of the result before the woman has given her consent for the GP to be informed.

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

(8) ASW written information must be used to inform the discussion between the woman and the health professional.[5]

[5] Written information for women is available from ASW in hard copy and in digital format.

Standard C 53

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

Target 100%

(1) Arrangements should be made for the confirmatory sample to be taken when the woman returns to the antenatal clinic to be given her syphilis positive result.

4.4.4 Record Keeping

Standard C 54

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 must be recorded in the woman's All Wales Maternity Record with her consent.

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

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

4.4.5 Care Plan

Standard C 55

An urgent appointment within two working days to sexual health is required for assessment, counselling and so that possible treatment can be commenced promptly.

Target 100%

(1) Sexual contacts require the offer of screening for syphilis via sexual health.

Standard C 56

An appropriate care plan must be developed by the maternity services in collaboration with sexual health and this must be documented in the

hospital notes/IT system and All Wales Maternity Record with the woman's consent.

Target 100%

(1) This must be developed with reference to British Association for Sexual Health and HIV (BASHH 2015) guidance and must be developed in discussion with the woman and with the advice of a multidisciplinary team. The woman's care must be managed by the multidisciplinary team in accordance with BASHH guidelines and led by sexual health. The multidisciplinary team must include obstetrics, paediatrics, sexual health and microbiology.

(2) Treatment with antibiotics (if required) should be commenced promptly by the sexual health specialist to reduce the risk of fetal damage caused by vertical transmission of syphilis.

(3) Paediatric referral must be made by the maternity services within 10 working days of the woman receiving the positive result. This is to facilitate liaison between the obstetrician and paediatrician in the management of the baby.

(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 appointment if required.

(6) The result must not be given by the maternity staff to the woman's partner or relatives without the woman's consent. The result must not be given to the GP or health visitor without the woman's consent. Discussing these issues should form part of a comprehensive care plan developed with the multidisciplinary team.

(7) Maternal referral to fetal medicine is recommended in cases of maternal syphilis treated after 26 weeks gestation.

4.4.6 Postnatal Care

Standard C 57

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

Target 100%

(1) A paired maternal and neonatal blood sample (clotted sample) for syphilis testing should be taken just after delivery before treatment of the baby is started (Syphilis Birth Plan 2016). The exact requirements should be discussed with the virologist before delivery.

Standard C 58

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

Target 100%

5.0 Antenatal Screening for Blood Group, Rhesus (Rh) D group and Antibodies

Policy Statement

All pregnant women resident in Wales must be offered antenatal screening for blood group, RhD status and antibodies in pregnancy (NICE 2021).

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 RhD group; people have a blood group and Rh group, e.g. group O RhD positive. Rh factor is a protein found in red blood cells in about 85% of people and its presence denotes a person is RhD positive, which is a more common blood group within the UK. If it is absent, the person is RhD negative, which is less common.

During pregnancy there is the possibility of maternal antibodies passing from the maternal bloodstream, crossing the placenta into the fetal circulation. This can cause a rare condition called haemolytic disease of the fetus and newborn (HDFN). This most commonly occurs when the woman is RhD negative and the baby is RhD positive, although a number of other red cell proteins (such as Kell,

c, Duffy and Kidd) may also cause maternal IgG antibody production, leading to HDFN.

Rationale for Screening

Antenatal screening for blood group, RhD status 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 HDFN caused by RhD incompatibility are identified, i.e. RhD negative women, further screening by cell free fetal DNA (cffDNA), can be offered to women who are RhD negative which can predict the fetal RhD group, allowing women to make a personal informed choice about the care and treatment they receive.

Anticipated Outcome

Reduction in HDFN and pregnancy associated problems. Offering cffDNA to women who are RhD negative, will allow women to make a personal informed choice, reduce the number of women receiving blood products unnecessarily, and conserve the supply of antiD to women who require it.

Screening Test Options

The screening test available for blood group, RhD status and antibodies will determine if the woman is RhD positive or RhD negative.

Women who are RhD negative, who are pregnant with a singleton or twin pregnancy and are non-sensitised to anti-D or anti-G antibodies, therefore, do not have maternal antibodies can use this result to decide whether they wish to accept or decline the offer of a further screening test called cffDNA. Women who are RhD negative and present for care at $\geq 26^{+1}$ weeks of pregnancy or greater, will be offered anti-D immunoglobulin.

5.1 Pre-test Information

Standard BG 1

Every pregnant woman must be offered and directed to the ASW Antenatal Screening Tests literature available on the ASW website.
Target 100%

(1) The midwife must ensure women receive verbal and digital information about the antenatal screening tests.

(2) The midwife must ensure women who are unable to access the digital version of the ASW Antenatal Screening Tests literature are given a hard copy.

(3) Where women have a different language or communication need, the midwife must ensure that the information is provided in the correct format, i.e. in large print, easy read, Braille, audio, British Sign Language or an approved interpreter service may be appropriate.

(4) The midwife must make a record of the format in which the information is given to the woman.

Standard BG 2

The midwife must have a verbal discussion with the woman about blood group, RhD group and antibodies in pregnancy prior to asking her to make a personal informed choice whether she wants the test, and a record of the discussion must be made in the All Wales Maternity Record.
Target 100%

(1) Where the woman has a different language or communication need, the midwife must ensure the provision of accurate information in a format that is accessible. Primarily this should be in digital format, but after assessing the woman's needs, hard copy, British Sign Language, easy read, audio, or an approved interpreter service may be appropriate. This is essential to obtain informed consent.

(2) The purpose, implications, limitations, and benefits of this screening test must be explained to the woman by the midwife. This is essential to obtain informed consent.

(3) The woman should be informed that if the results show she is RhD negative and non-sensitised to anti-D or anti-G antibodies she will be offered the option of cffDNA screening.

5.2 Screening Offer

Standard BG 3

Every pregnant woman must be offered antenatal screening for blood group, RhD group and antibodies before 10^{+0} weeks of pregnancy if the woman presents for antenatal care before this gestation. 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^{+1} weeks of pregnancy must be offered this screening at the first opportunity.

(2) Women must be informed that if their results show they are RhD negative and non-sensitised to anti-D or anti-G antibodies, they will be offered cffDNA screening which can predict the fetal D group.

(3) All women who have previously had an infant affected by HDFN must be offered a referral and reviewed by 19^{+6} weeks gestation in a specialist unit for advice and for assessment of fetal haemolysis, irrespective of antibody level (BSH 2016).

(4) Women who choose to have private antenatal screening are still eligible to access, and must be offered, NHS Wales antenatal screening.

Standard BG 4

Women who do not attend for antenatal care during the pregnancy and present during labour, must be offered screening for blood group, RhD group and antibodies as a matter of urgency. When the sample is taken, the local laboratory must be contacted to inform them of the sample.

Target 100%

5.3 Consent

Standard BG 5

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

Target 100%

(1) Prior to performing the test, the midwife must ensure that the woman:

- understands the screening test she has consented to
- does not require further information about the screening test
- gives her informed verbal consent to proceed with the screening test she has consented to.

(2) If the woman declines screening for blood group, RhD status and antibodies, the midwife must ensure the woman has received accurate information on which to base her decision.

5.4 Test Requesting

Standard BG 6

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%

(1) If the woman is RhD negative and non-sensitised to anti-D or anti-G antibodies, she must be offered cffDNA screening which can predict the fetal genotype (see Standard 23).

Standard BG 7

The health professional requesting the test must complete and sign the request.[6]
Target 100%

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

[6] By signing the laboratory or ultrasound request card, the requesting health professional is confirming that verbal and digital (or other appropriate format) 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 8

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.

5.5 Test Procedure

Standard BG 9

The sample must be taken before 12^{+6} weeks of pregnancy if the woman presents for antenatal care before this gestation.
Target 100%

Standard BG 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) Women who attend for antenatal care after 13^{+0} weeks of pregnancy should have this screening at the first opportunity.

(2) 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.

(3) 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 and the sample.

5.6 Laboratory Services

Standard BG 11

The laboratory must be appropriately accredited, or working towards accreditation, in accordance with the United Kingdom Accreditation Service and compliant with ISO standard 15189 for antenatal blood group and antibody screening tests.
Target 100%

Standard BG 12

Antibody screening must be undertaken using an indirect antiglobulin test and a red cell panel conforming to current UK guidelines (Transfusion Handbook).
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 13

The sample must be received by the local laboratory within one working day of the sample being taken.
Target 95%

Standard BG 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 BG 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%

(1) Where significant antibodies are identified, the laboratory must email the result to the relevant generic email box in the health board within one working day of reporting.

5.7 Results Handling

Standard BG 16

If the sample has not been tested at the local laboratory, the result must be available to the local laboratory within two working days of the final report being authorised by the testing laboratory.
Target 95%

Standard BG 17

The result must be available to the maternity service within one working day of the report being released 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 18

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 19

The maternity service must have 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 BG 20

Women must be informed of the results by the maternity service at the 16 week appointment. The results must be recorded in the All Wales Maternity Record.

Target 100%

(1) If any of these results are not available, the local health board pathway as identified in Standard BG 18 should be followed.

(2) If the woman has had a miscarriage between sample collection and results being given, the results should be given to the woman as per the local health board pathway.

(3) Further screening for atypical red cell alloantibodies is advised at 28 weeks of pregnancy.

(4) If the woman is RhD negative and non-sensitised to anti-D or anti-G antibodies, she must be offered cffDNA screening which can predict the fetal D group (See Standard 23).

(5) If the woman is RhD positive she should be informed that she will not require anti-D prophylaxis.

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

(7) If this antenatal appointment is not face to face, a dated and signed record that the individual results have been discussed with the woman must be made in the maternity notes/health board IT system.

(8) Any actions relating to the results should also be documented.

Standard BG 21

Where sampling has occurred later in pregnancy, results must be given within two weeks of the sample being taken. 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) If any of these results are not available, the local health board pathway as identified in Standard BG 18 should be followed.

(2) Further screening for atypical red cell alloantibodies is advised at 28 weeks of pregnancy.

(3) If the woman is RhD positive she must be informed that she will not require antiD prophylaxis.

(4) If the woman is RhD negative, non-sensitised to anti-D or anti-G antibodies and ≤26^{+0}weeks gestation she must be offered cffDNA screening. If the woman is RhD negative and ≥ 26^{+1} weeks gestation, she will be recommended prophylactic antiD immunoglobulin as cffDNA will not be available.

(5) A dated and signed record that the results have been discussed with the woman must be made in the All Wales Maternity Record/health board IT system.

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

5.8 RhD Negative, Antibody Negative Results

Standard BG 22

The woman must be informed of the implications of being RhD negative. Target 100%

(1) The woman must be informed by either letter, antenatal clinic appointment or telephone call (according to local health board arrangements and/or the woman's preference), that she has been identified as being RhD negative. The woman must be offered an appointment to discuss the result. This must be discussed and offered prior to 16 weeks gestation if the woman presents for care before this gestation.

(2) Information about being RhD negative in pregnancy is provided in the ASW Antenatal Screening Tests literature available on the ASW website and in other formats if required. It includes information about notifying a healthcare professional if a potentially sensitising event occurs.

(3) Interpreter services must be arranged if required.

Standard BG 23

All women who are RhD negative should receive information about cffDNA screening to predict the fetal D group and must have the opportunity to discuss this test with a midwife by 16 weeks of pregnancy [7]if the woman presents for care before this gestation.

Target 100%

(1) The health professional must give up-to-date accurate information about cffDNA and what the results would predict and what management would be recommended.

(2) ASW written information must be used to inform the discussion between the woman and the health professional.

(3) Interpreter services must be arranged if required.

(4) The woman must be informed that she has a choice of cffDNA which is a further screening test, and she will be supported whatever decision she makes.

(5) If the woman declines cffDNA or cffDNA cannot be offered, or cffDNA has predicted the fetus to be RhD positive, and has a potentially sensitising event, prophylactic anti-D immunoglobulin must be offered antenatally.

(6) CffDNA cannot be offered it:

- At any point in this pregnancy if there was a triplet or higher multiple pregnancy
- There are anti-D or anti-G antibodies present,
- The woman's gestation is ≥ 26^{+1} weeks gestation,
- If there has been a triplet or greater pregnancy initially, where there is a vanishing/vanished twin.

(7) All women who are RhD negative and pregnant with a fetus predicted to be RhD positive or have declined cffDNA screening, should receive verbal and digital information about antenatal and postnatal anti-D prophylaxis and have the opportunity to discuss this treatment with a midwife in the early antenatal period.

[7] (14 to 18 weeks) appointment www.nice.org.uk/guidance/ng201

(8) Routine antenatal anti-D prophylaxis (RAADP) must be offered and recommended to all non-sensitised pregnant women who are RhD negative if cffDNA has predicted a fetus to be RhD positive or returned and inconclusive result, or, if cffDNA screening was declined.

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

(10) RAADP must 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, for women if cffDNA has predicted a fetus to be RhD positive or returned and inconclusive result, or, if cffDNA screening was declined.

Standard BG 24

Every health board must have a protocol for antenatal anti-D prophylaxis care and management of RhD negative women.

Target 100%

(1) Each maternity service should have arrangements in place for implementing the offer and administration of antenatal anti-D prophylaxis.

(2) The health board must have a process in place to ensure that women who are sensitised to anti-D are not inadvertently administered with prophylactic anti-D.

Standard BG 25

Health boards must have an appropriate protocol in place for offering specific antenatal treatment following a sensitising event to women whose fetus is predicted to be RhD positive or the fetal D group is unknown.[4]

Target 100%

(1) Anti-D prophylaxis must be offered and, if accepted, given as soon as possible after the sensitising event and certainly within 72 hours.

(2) Kleihauer screening must be offered following a potentially sensitising event in pregnancy after 20^{+0} weeks gestation or after birth. Additional doses of anti-D prophylaxis may be

required, as advised by the laboratory, following the Kleihauer screening result being obtained. This is not affected by the administration of routine anti-D prophylaxis.

(3) A repeat maternal sample must 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 2014).

5.9 cffDNA

5.9.1 Consent for cffDNA

Standard BG 26

The woman's informed verbal consent is required for cffDNA screening and this must be documented in the All Wales Maternity Record. Target 100%

(1) Women who are RhD negative, non-sensitised to anti-D or anti-G antibodies, ≤ 26^{+0} weeks gestation with a singleton or twin pregnancy can:

(2) Choose to have cffDNA screening where the fetal RhD genotype can be predicted.

(3) Choose not to have cffDNA screening.

(4) The health professional with suitable skills and knowledge must have a verbal discussion about cffDNA screening with the woman prior to asking her to make a personal informed choice about whether she wants the test. The woman should be:

- informed of the purpose, implications, limitations, and benefits of cffDNA screening
- informed that if the cffDNA predicts the fetus to be D negative prophylactic anti-D immunoglobin **will not** be recommended.
- informed that if the cffDNA predicts the fetus to be D positive, or if the test result is inconclusive, prophylactic anti-D immunoglobin **will be** recommended.

- informed that cffDNA is not available after ≥26^{+1} weeks of pregnancy. In such cases, anti-D immunoglobulin will be recommended.

(5) The normal antenatal screening pathway for cffDNA screening will enable women whose pregnancies have progressed to ≥16^{+0} weeks gestation. Samples must not be collected prior to ≤11^{+2} weeks gestation.

(6) The cffDNA test can be performed from 11+2 weeks gestation, therefore screening will be available to some women who are attending Fetal Medicine Unit at an earlier gestation.

(7) Samples must not be collected after ≥26^{+1} weeks.

(8) ASW written information must be used to inform the discussion between the woman and the health professional.

5.9.2 Test Requesting

Standard BG 27

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

Target 100%

Standard BG 28

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

Target 100%

5.9.3 cffDNA Blood Test Procedure

Standard BG 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 and the sample.

(3) The cffDNA sample must contain at least 10mls of blood. It must be collected in a purple top EDTA bottle. Only one sample is to be sent. Once the sample has been collected the bottle must be inverted 8–10 times to maintain the stability of the blood.

5.9.4 Sample Handling

Standard BG 30

The sample must be received by the Welsh Blood Service within five calendar days of the sample being taken. Target 100%

(1) Sample preparation and transportation must follow the Standard Operating Procedures recommended by Welsh Blood Service.

(2) NHS number is a mandatory requirement, however for those women who are waiting for an NHS number, contact with WBS must be made prior to the sample being obtained.

(3) The cffDNA sample is not to be placed in a fridge or freezer. The sample must not be centrifuged.

(4) The sample and completed request card must be sent to the Welsh Blood Service laboratory preferably on the day that the sample is taken. This will minimise the risk of a failed test due to a breakdown of fetal DNA in the sample.

(5) Where samples are being transported directly from maternity services to the Welsh Blood Service Laboratory they must fulfil the requirements of UN packaging instructions P650.

5.9.5 Laboratory Services

Standard BG 31

The laboratory must be appropriately accredited or working towards accreditation in accordance with United Kingdom Accreditation Service,

and compliant with ISO standard 15189 for antenatal blood group, antibodies and cffDNA screening tests.

Target 100%

Standard BG 32

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

Target 100%

Standard BG 33

The Welsh Blood Service must aim for to achieve a 10 working day turnaround from when the sample is received in the laboratory to results reporting to the health board.

Target 100%

(1) The laboratory must email the list of samples received to the relevant generic email box in the health board on a weekly basis. It is the responsibility of the health board antenatal clinic midwives to check the results.

(2) Any samples that have been rejected will be included in the weekly spread sheet/ reporting template from Welsh Blood Service with the reason for rejection.

5.9.6 Results Handling

Standard BG 34

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 named deputy should coordinate the results handling process as they are received via the relevant generic email box.

Standard BG 35

The maternity services must have a written and agreed process in place to identify and follow up where additional information is required by the laboratory.

Target 100%

5.9.7 cffDNA Antibody Positive Results

Standard BG 36

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

Target 100%

(1) There are a large number of potential antibodies which can cause HDFN. If significant antibodies are found, the laboratory must inform the consultant obstetrician, antenatal screening coordinator or named 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 must be reported to SHOT by the blood transfusion laboratory of the referring hospital (SHOT 2022).

Standard BG 37

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

Target 100%

(1) Interpreter services must be arranged if required.

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

(3) Where requested by the laboratory, the biological father of the baby must be offered testing, and this should be arranged at this visit.

Standard BG 38

Pregnant women with clinically significant atypical red cell alloantibodies must 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 HDFN
- 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.

5.10 Care Plan

Standard BG 39

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) Where women are identified as RhD negative, this should include actions planned in relation to anti-D prophylaxis.

(2) Where women are identified as RhD negative with antibodies (excluding anti-D and anti-G) and have had cffDNA screening, a dated and signed record of the fetal result has been discussed with the woman, must be made in the maternity notes/health board IT system.

(3) Women who have clinically significant antibodies (i.e. antibodies discussed in Standard BG 27, Protocol 1) should be closely observed for evidence of HDFN. A direct antiglobulin test (DAT) should be performed on a cord blood sample, and haemoglobin and bilirubin concentrations should be measured (BSH 2016).

5.11 Postnatal Care

Standard BG 40

A maternal sample is required between 30 minutes and 2 hours post-delivery from all RhD negative women (and from women where the maternal RhD group is not known) accompanied by a cord blood sample.
Target 100%

(1) A cord blood sample is required to test for fetal blood group and to confirm the cffDNA screening result, if this has been performed. A maternal blood sample is required to assess feto-maternal haemorrhage in RhD negative women who have delivered a RhD positive baby to establish whether the woman requires additional anti-D prophylaxis.

(2) In women who have clinically significant antibodies, a direct antiglobulin test (DAT) should be performed on a cord blood sample, and haemoglobin and bilirubin concentrations should be measured in the laboratory (BSH 2016).

Standard BG 41

Prior to the administration of anti-D immunoglobin all postnatal cord blood results must be checked against the antenatal cffDNA screening result (if performed) to ensure the results correlate.
Target 100%

(1) If a false negative [8]result is discovered, (i.e., cffDNA result = RhD negative, cord blood result = RhD positive) the woman should be informed of the result and advised that anti-D is recommended.

(2) If a false positive [9]result is discovered, (i.e., cffDNA result =RhD positive, cord blood result = RhD negative) the woman should be informed of the result and advised that anti-D is not recommended.

(3) The ASW Standard Operating Procedures for the management and reporting of discrepant results must be followed.

[8] False negative result indicates that the predicted fetal genotype was RhD negative, but the baby was RhD positive.

[9] False positive results indicate that the predicted fetal genotype was RhD positive but the baby is actually RhD negative.

Standard BG 44

If the baby is RhD positive, non-sensitised women who are RhD negative must 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 Screening for Sickle Cell and Thalassaemia

Policy Statement

All pregnant women resident in Wales must be offered antenatal screening for sickle cell and thalassaemia to identify women who may be at a high chance of having a baby with either a sickle cell disorder or thalassaemia major (WHC 2003; UK NSC 2017; NICE 2021).

Sickle Cell and Thalassaemia

Sickle cell and thalassaemia disorders are both types of recessively inherited haemoglobin disorders, only some of which are clinically significant. The chances of being a carrier are higher in 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 pregnant women who have a high chance of having a baby with a sickle cell disorder or thalassaemia major (as defined by the ASW family origin screening question) to enable laboratory screening and, if required, offer antenatal invasive testing. The woman can then make a personal informed choice and has the opportunity for reproductive choices including planning their care for the pregnancy and referral to relevant specialities.

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 baby with a sickle cell disorder or thalassaemia major will have personal informed choices about their pregnancy.

6.1 Pre-test Information

Standard SCT 1

Every pregnant woman must be offered and directed to the ASW Antenatal Screening Tests literature available on the ASW website. Target 100%

(1) The midwife must ensure women receive verbal and digital information about the antenatal screening tests.

(2) The midwife must ensure women who are unable to access the digital version of the ASW Antenatal Screening Tests literature are given a hard copy.

(3) Where women have a different language or communication need, the midwife must ensure that the information is provided in the correct format, i.e. in large print, easy read, Braille, audio, or British Sign Language or an approved interpreter service may be appropriate.

(4) The midwife must make a record of the format in which information is 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 asking her to make a personal informed choice whether she wants the test and a record of the discussion must be made in the All Wales Maternity Record.

Target 100%

(1) Where the woman has a different language or communication need, the midwife must ensure the provision of accurate information in a format that is accessible. Primarily this should be in digital format, but after assessing the woman's needs, hard copy, British Sign Language, easy read, audio or an approved interpreter service may be appropriate. This is essential to obtain informed consent.

(2) The purpose, implications, limitations and benefits of this screening test must be explained to the woman by the midwife. This is essential to obtain informed consent.

(3) 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 Offer

Standard SCT 3

Every pregnant woman must be offered antenatal screening for sickle cell and thalassaemia before 10^{+0} weeks of pregnancy if the woman presents

for antenatal care before this gestation. 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^{+1} weeks of pregnancy must be offered screening for sickle cell and thalassaemia at the first opportunity.

(2) Women who choose to have private antenatal screening are still eligible to access, and must be offered, NHS Wales antenatal screening.

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

Standard SCT 4

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.[10]

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 rescreening and the relevant information about previous screening results must be included on the request.

(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 baby and invasive testing should be discussed by the midwife.

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

[10] The request may be in either hard copy or electronic requesting formats.

(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 ideally at the same time as the woman is screened, or within three working days of the woman's results being reported.

(6) If invasive testing is declined, the offer of early neonatal testing should be discussed.

Standard SCT 5

Women known to have haemoglobin disorders must be referred for joint haematology/obstetric care within six weeks of confirmation of result.
Target 100%

6.4 Consent

Standard SCT 6

The woman's informed verbal consent is required for these tests and her decision must be recorded in the All Wales Maternity Record.
Target 100%

(1) Prior to performing the test, the midwife must ensure that the woman:

- understands the screening test she has consented to
- does not require further information about the screening test
- gives her informed verbal consent to proceed with the screening test she has consented to.

(2) If the woman has a family history of sickle cell, thalassaemia, any other significant haemoglobinopathy or hydrops fetalis this must be recorded in the clinical details part of the request.[h]

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

(4) If the woman is a surrogate mother or if the pregnancy has been achieved by donor egg, the woman should be offered

screening to ensure optimum maternal care. The biological father must also be offered screening.

(5) If the woman has had a bone marrow transplant, it is likely that the results obtained will reflect the bone marrow transplant donor and not accurately represent the genetic status of the baby. In these cases the biological father of the baby should be tested to ensure this is not a high risk pregnancy.

6.5 Test Requesting

Standard SCT 7

The laboratory request[11] 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%

(1) In the case of surrogacy, the surrogate mother should be tested (to ensure optimal maternal care). Her demographic details and the fact that this is a surrogate pregnancy should be recorded on the request. In cases of surrogacy/use of donor egg or donor sperm, where the fetal risk of a haemoglobinopathy disorder cannot be accurately assessed a referral to AWMGS should be offered for a prenatal risk assessment for haemoglobinopathies.[k]

(2) Where the pregnancy has been achieved using a donor egg, the woman should be screened to ensure optimal maternal care. Her demographic details, and the fact that this is a donor egg, must be recorded on the request. The biological father of the baby should be tested. A referral must be offered to AWMGS for a prenatal risk assessment if the biological father of the baby has a confirmed carrier result.

(3) Where the pregnancy has been achieved using donor sperm, the mother should be tested and it is her demographic details that should be recorded on the request. If she is screened positive, a referral should be offered to AWMGS for a prenatal risk assessment.

[11] The request may be in either hard copy or electronic requesting formats.

(4) If the mother of the baby has had a bone marrow transplant, the biological father of the baby should be tested. His demographic details should be recorded on the request[12] and the request should include the maternal details and the fact that she has received a bone marrow transplant. If the paternal sample is screened positive, expert advice should be sought from AWMGS.

Standard SCT 8

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

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

Standard SCT 9

All mandatory fields for the laboratory request[l] must be completed, including the ASW sickle cell and thalassaemia family origin screening question (FOQ) request 'sticker' when requests are made. Target 100%

(1) The health professional requesting the test must request only one test:

- full blood count and further testing if required following a low mean cell haemoglobin (MCH) (ANTHAL) **or**
- full blood count and sickle cell and thalassaemia screen (ANSCT) **or**
- FBC only (sickle cell and thalassaemia declined) (ANDEC).

(2) In order for the laboratory to interpret the result, the request for the country of origin for both the woman and the biological father should be included.[l]

[12] The request may be in either hard copy or electronic requesting formats. [m] By signing the laboratory or ultrasound request card, the requesting health professional is confirming that verbal and digital (or other appropriate format) 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.

6.6 Test Procedure

6.6.1 ASW Family Origin Screening Question (ASW FOQ)

Standard SCT 10

The woman must be asked the ASW family origin screening question (ASW FOQ) for sickle cell and thalassaemia in every pregnancy and before 10^{+0} weeks of pregnancy. This FOQ is given in Protocol 1 below. A record of the responses to the ASW FOQ for sickle cell and thalassaemia must be made in the All Wales Maternity Record by the person asking the question.

Target 100%

1) The ASW FOQ asks the following questions; the answers will determine what screening test is required.

    - does the woman or the biological father of the baby have a family history of sickle cell or thalassaemia
    - does the woman's family origins or those of the biological father of the baby have a family history of sickle cell or thalassaemia
    - does the woman's family origins or those of the biological father, no matter how many generations back, come from anywhere outside of the UK or Ireland
    - the woman's family origins or those of the biological father are unknown, e.g.

adoption, donor egg, donor sperm, including IVF or a bone marrow transplant

    - if none of the above applies, the woman should be offered screening for thalassaemia
    - the woman may choose not to disclose the family origins but still requests screening (family origins would be documented as unknown) or may also decline all testing
    - the ASW FOQ must be asked by the midwife to assess whether further laboratory testing should be offered for sickle cell and thalassaemia if one or more of the above applies (ASW FOQ)

2) If the woman answers no to all of the above questions, she can be informed by the midwife that she has a low chance of having a baby with a sickle cell disorder or thalassaemia major.

3) 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.

Standard SCT 11

If the woman answers no to all questions in the ASW FOQ she must be offered a full blood count (FBC) and further testing 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 12

The sample must be taken before 12^{+6} weeks of pregnancy if the woman presents for antenatal care before this gestation.

Target 100%

(1) Women who present for antenatal care before 12^{+6} weeks must be offered screening for sickle cell and thalassaemia and have this completed at the earliest opportunity, preferably before 10^{+0} weeks.

(2) Women who attend for antenatal care after 13^{+0} weeks of pregnancy must have this screening at the first opportunity.

(3) 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.

(4) 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 and the sample.[n]

(5) If the screening process (including screening the biological father of the baby if required) is conducted as per Standards SCT 10, SCT 26 and SCT 31, chorionic villus sampling (CVS) rather than amniocentesis may be a preferable option for women who wish to access invasive testing.[5]

Standard SCT 13

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%

6.7 Laboratory Services

Standard SCT 14

The laboratory must be appropriately accredited or working towards accreditation in accordance with the United Kingdom Accreditation Service, and compliant with ISO standard 15189 for antenatal sickle cell and thalassaemia screening tests.

Target 100%

The request may be in either hard copy or electronic requesting formats.

Standard SCT 15

The screening test used by the laboratory must follow the NHS guidelines (NHS Sickle Cell and Thalassaemia Screening Programme 2021) and the ASW algorithm for low prevalence areas.

Target 100%

(1) The laboratory must not undertake antenatal sickle cell and thalassaemia screening if the information on ASW FOQ sickle cell and thalassaemia request 'sticker' is not completed on the request.[n]

[n]

(2) Screening for sickle cell and thalassaemia must be by high performance liquid chromatography, or other UK National Screening Committee (NSC) approved methods (NHS Sickle Cell and Thalassaemia Screening Programme 2021) following a full blood count (FBC). If the analysis shows an abnormality, appropriate further testing or referral to a reference laboratory to specifically identify the abnormality must be undertaken, in line with the NSC guidelines.

Standard SCT 16

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

Target 95%

Standard SCT 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 95%

Standard SCT 18

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

Target 95%

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

The request may be in either hard copy or electronic requesting formats.

(2) Requests for the biological father to be tested must be emailed to the relevant generic email account. If testing is declined or the biological father of the baby is not available, this must be recorded on the Laboratory Information Management System (LIMS). An AWMGS risk assessment must be offered.

(3) Where there is an issue with the request and further information is required, this must be requested using the relevant generic email box in the health board.[o]

(4) All mandatory fields must be completed; this includes ASW FOQ. The test request must reflect the FOQ consent for the test requested.

6.8 Results Handling

Standard SCT 19

If the sample has not been tested at the local laboratory, the result must be available to the local laboratory within one working day of the final report being authorised by the testing laboratory.

Target 95%

[o]

Standard SCT 20

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

Target 95%

(1) Results must 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 21

If the MCH is below 27pg on the full blood result and screening was declined, a further sickle cell and thalassaemia screen must be offered when the full blood

[o] The request may be in either hard copy or electronic requesting formats.

count (FBC) results are explained as part of the antenatal care pathway and this must be recorded 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'. The midwife should document on the request that the 'initial MCH less than 27pg'.[p]

Standard SCT 22

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

Target 100%

Standard SCT 23

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 24

Women must be informed of any result that does not require further action by the maternity service at the 16 week antenatal appointment. The results must be recorded in the All Wales Maternity Record.

Target 100%

(1) If any of these results are not available, the local health board pathway as identified in Standard SCT 22 should be followed.

(2) If the woman has had a miscarriage between sample collection and results being given, the results must be given to the woman as per the local health board pathway.

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

(4) Any actions relating to the result must also be documented.

[p] The request may be in either hard copy or electronic requesting formats.

(5) The woman must be informed that the chance of her having a baby with a sickle cell disorder or thalassaemia major is very low.

(6) If the antenatal appointment is not face to face, a dated and signed record that the individual results have been discussed with the woman must be made in the maternity notes/health board IT system.

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

Standard SCT 25

Where sampling has occurred later in pregnancy, results that do not require further action must be given within three weeks of the sample being taken. 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 result has been discussed with the woman must be made in the All Wales Maternity Record.

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

6.9 Maternal Sickle Cell or Thalassaemia Screen Positive

Standard SCT 26

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

Target 100%

(1) The laboratory must email the result to the relevant generic email box in the health board within one working day of reporting.

Standard SCT 27

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 women to return to the antenatal clinic to be given their result.

(2) Interpreter services must 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 must be given written[13] and verbal information about her diagnosis. She should be informed by an appropriately trained professional that the chance of her having a baby with an inherited sickle cell disorder or thalassaemia major will depend on whether the biological father of the baby is also a carrier of sickle cell or thalassaemia.

Standard SCT 28

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

Target 100%

Standard SCT 29

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 baby 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 must 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 must be offered rescreening and the relevant information about previous screen results should be included on the request.[14]

Standard SCT 30

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

Target 100%

(1) The antenatal screening coordinator must coordinate the linking of results and provide any 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 must clearly be marked 'urgent' and the laboratory informed that the sample should be expected.

[13] Antenatal information for women on specific haemoglobinopathies if available from ASW, AWMGS or screening coordinators.

[14] The request may be in either hard copy or electronic requesting formats.

(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 risk to the baby 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 baby with a sickle cell disorder or thalassaemia major in this pregnancy is very low and antenatal invasive 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 GP.

Standard SCT 31

If the biological father of the baby is not available, declines to be tested or retested or the woman does not consent to him being contacted, a risk assessment must be offered. The risk assessment should be commenced within three working days by All Wales Medical Genomics Service and completed as soon as possible, to advise the maternity service of the risk to the baby. This assessment must be based on the family origins of the woman and that of the biological father.

Target 100%

(1) The genetic counsellor will complete a prenatal outcome form following a risk assessment. This will be returned to the referrer to update the electronic antenatal clinical record/All Wales Maternity Record and a copy is sent to the haemoglobinopathy laboratory at University Hospital of Wales

(2) Where appropriate the woman will be offered antenatal invasive testing by AWMGS. If the invasive test is negative then no further testing is necessary e.g. early neonatal testing.

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

Standard SCT 32

If both the mother and the biological father of the baby are sickle cell or thalassaemia carriers or have haemoglobin disorders they must be referred to

All Wales Medical Genomics Service (AWMGS) within five working days of the result being received by the maternity services.

Target 100%

(1) AWMGS will assess the risk to the baby and will complete a prenatal outcome form following the risk assessment for the maternity and neonatal team.

(2) Where appropriate the woman will be offered antenatal invasive testing by AWMGS.

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

Standard SCT 33

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

Target 100%

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

(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.

(4) The reporting of results following a prenatal diagnosis should be provided by AWMGS or the lead consultant in the fetal medicine unit.

(5) Following a prenatal diagnosis the woman and her partner will be supported and provided with information to make a personal informed choice in relation to the results.

6.10 Care Plan

Standard SCT 34

An appropriate care plan must be developed by the multidisciplinary team and this must be documented in the hospital notes/IT system and All Wales Maternity Record with the woman's consent.

Target 100%

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

(2) Interpreter services must be arranged for every antenatal clinic appointment if required.

6.11 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 or unknown in the mother but no result for the biological father of the baby
- to exclude results where the testing of the biological father of the baby has not been recommended, e.g. if the mother has a possible alpha thalassaemia +/- iron deficiency
- where both the mother and the biological father of the baby are either carriers or have a haemoglobinopathy disorder

- where there is no screening result available for the mother and her or the biological father's family origin are from anywhere outside of the UK or Ireland
- where there is no screening result available for the mother of the baby and her FBC shows an MCH is less than 27pg regardless of family origin and has not been tested as part of the screening pathway antenatally.

(2) A record of the result, offer of early neonatal testing and paediatric review of the baby must be recorded in the All Wales Maternity Record/IT maternity system.

(3) The neonatal pathway for the investigation and referral of haemoglobinopathy disorders in the newborn can be located in the Neonatal SharePoint.

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.
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, the required sample is 0.3-1ml of blood, in a paediatric EDTA bottle.

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

(4) Early neonatal testing is not required to confirm an antenatal invasive test result.

(5) The mother and baby who are ready to be transferred to community care should not be kept in hospital awaiting the results of these tests.

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

Policy Statement

Antenatal screening for Down's syndrome, Edwards' syndrome and Patau's syndrome should be offered to all pregnant women to identify women whose baby may have one of these conditions (UK NSC 2016; UK NSC 2019; NICE 2021; WHC 2003).

Down's Syndrome (Trisomy 21/T21)

Down's syndrome is the most common chromosomal condition and is caused by the presence of additional genetic material associated with chromosome pair 21. Overall this condition usually occurs approximately once in every 424 pregnancies in Wales.[15] The prevalence increases with maternal age.

Edwards' Syndrome (Trisomy 18/T18)

Edwards' syndrome is caused by the presence of additional genetic material associated with chromosome pair 18. This condition occurs approximately once in every 1562 pregnancies in Wales.[t] The prevalence increases with maternal age. Edwards' syndrome is life limiting.

Patau's Syndrome (Trisomy 13/T13)

Patau's syndrome is caused by the presence of additional genetic material associated with chromosome pair 13. This condition occurs approximately once in every 3803 pregnancies in Wales.[u] The prevalence increases with maternal age. Patau's syndrome is life limiting.

Rationale for Screening

If the baby has Down's syndrome, Edwards' syndrome or Patau's syndrome, the woman can make a personal informed choice about

[15] Congenital Anomaly Register and Information Service CARIS (2022) [t] Congenital Anomaly Register and Information Service CARIS (2022). [u] Congenital Anomaly Register and Information Service CARIS (2022).

whether to continue with the pregnancy. Appropriate identification of additional unexpected ultrasound findings, e.g. cardiac conditions, should be made and suitable management and support offered.

Anticipated Outcome

Women who have a baby with Down's syndrome, Edwards' syndrome or Patau's syndrome will have personal informed choices about their pregnancy.

Screening Test Options

The screening test available for Down's syndrome, Edwards' syndrome and Patau's syndrome involves 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 syndrome, or a joint result for Edwards' syndrome/Patau's syndrome in the pregnancy. This combined test uses an ultrasound measurement to assess the gestation and a measurement of the collection of fluid at the back of the fetal neck (the nuchal translucency or NT) with the results from the biochemical markers to give the woman a chance result for Down's syndrome, and joint chance result for Edwards' syndrome/Patau's syndrome in singleton and twin pregnancies in early pregnancy.

Women with a singleton or twin pregnancy can use this result to decide whether they wish to accept or decline the offer of a further screening test called non-invasive prenatal testing (NIPT), which is a more accurate screening test, or alternatively an invasive procedure (CVS or amniocentesis) to enable diagnosis of the condition that the screening test result has been higher/high chance for.

If the woman presents too late for screening in the first trimester or if the NT measurement cannot be obtained, the recommended laboratory screening test 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 chance result for Down's syndrome only in singleton pregnancies up to 18^{+0} weeks gestation.

(1) First trimester screening (the combined test) can only be undertaken when the crown rump length (CRL) measurement is between 45.0mm and 84.0mm (approximately 11^{+2} weeks to 14^{+1} weeks) in singleton and

twin pregnancies. This will give a result for Down's syndrome and a joint result for Edwards' syndrome/Patau's syndrome.

(2) Second trimester screening (the quadruple test) can only be undertaken on samples between 15^{+0} weeks and 18^{+0} weeks of pregnancy by Cardiff and Vale 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 or twin pregnancy can:

- continue with no further testing
- choose a further, more accurate, screening test called NIPT (if the NIPT result is high chance, an invasive procedure is required if the woman wishes a definitive diagnosis)
- choose an invasive procedure.

7.1 Pre-test Information

Standard DEP 1

Every pregnant woman must be offered and directed to the ASW Antenatal Screening Tests literature available on the ASW website. Target 100%

(1) The midwife must ensure women receive verbal and digital information about the antenatal screening tests.

(2) The midwife must ensure women who are unable to access the digital version of the ASW Antenatal Screening Tests literature are given a hard copy.

(3) Where women have a different language or communication need, the midwife must ensure that the information is provided in the correct format, i.e. in large print, easy read, Braille, audio, British Sign Language or an approved interpreter service may be appropriate.

(4) The midwife must make a record of the format in which information is given to the woman.

Standard DEP 2

The midwife must have a verbal discussion with the woman about Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) prior to asking her to make a personal informed choice whether she wants the test and a record of the discussion must be made in the All Wales Maternity Record.

Target 100%

(1) Where the woman has a different language or communication need, the midwife must ensure the provision of accurate information in a format that is accessible. Primarily this should be in digital format, but after assessing the woman's needs, hard copy, British Sign Language, easy read, audio or an approved interpreter service may be appropriate. This is essential to obtain informed consent.

(2) The purpose, implications, limitations and benefits of this screening must be explained to the woman by the midwife. This is essential to obtain personal informed choice.

(3) The midwife must explain to the woman that Down's syndrome (T21) is a lifelong genetic condition. People with Down's syndrome (T21) can have a good quality of life. Some people with Down's syndrome (T21) can live semi-independently while others will require higher levels of support. All people with Down's syndrome (T21) will have some level of learning disability. Some people with Down's syndrome (T21) will have health challenges.

(4) The midwife must explain to the woman that people with Edwards' syndrome (T18) and Patau's syndrome (T13) will have cognitive and developmental delay and a range of health difficulties, some of which can be extremely serious. They may have heart conditions, swallowing and feeding difficulties, seizures and breathing difficulties including apnoea. Edwards' syndrome (T18) and Patau's syndrome (T13) are life limiting. An individual with mosaic or partial forms of Edwards' syndrome (T18) and Patau's syndrome (T13) may have less serious health difficulties.

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

(6) The woman must 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 procedure.

(7) The risks of miscarriage associated with an antenatal invasive procedure must be explained.

If the woman has a family member with Down's syndrome (T21), Edwards' syndrome (T18) or Patau's syndrome (T13), enquiries should be made into whether the type of condition is known, as a familial translocation will increase the chance of inheriting Down's syndrome (T21), Edwards' syndrome (T18) or Patau's syndrome (T13). If it is unclear or there is more than one family member with the condition, referral to All Wales Medical Genomics Service (AWMGS) must be offered. Parental karyotyping or NIPT may be offered through AWMGS dependent on family history. The referral should be made using the standard All Wales Medical Genomics Service referral form.

(8) Where the woman has received a diagnosis in a previous pregnancy of Down's syndrome (T21), Edwards' syndrome (T18) or Patau's syndrome (T13), NIPT should be offered as a primary screening test. Follow the All Wales NIPT pathway for previous T21, T18, T13 management. Referral to health board hospital antenatal clinic or All Wales Medical Genomics Service (AWMGS) as early as possible during the pregnancy to enable their screening options. The referral should be made using the standard All Wales Medical Genomics Service referral form.

7.2 Screening Offer

Standard DEP 3

Every pregnant woman with singleton or twin pregnancies must be offered antenatal screening for Down's syndrome (T21), Edwards' syndrome (T18) or Patau's syndrome (T13) before 10^{+0} weeks of pregnancy if the woman presents for antenatal care before this gestation. A record of the offer must be made in the All Wales Maternity Record.

Target 100%

(1) Women must be offered screening for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13). The woman must 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 scan 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 the CRL and/or NT measurement cannot be obtained.

(2) If either the women, or the biological father of the baby previously had a pregnancy diagnosed with Down's syndrome (T21), Edwards' syndrome (T18) or Patau's syndrome (T13) they must be offered a referral to AWMGS or the hospital antenatal clinic to enable discussions on options available. Follow the All Wales NIPT pathway for previous T21, T18, T13 management. This referral form must be completed by the community midwife/antenatal clinic (as per local protocol) at the earliest opportunity to enable counselling, early scan for gestation and if NIPT is the test of choice, it can be performed around 10 weeks gestation. Antenatal clinics and AWMGS to work closely together to ensure the antenatal screening test's appointment is, where possible, arranged at a time when the NIPT result is reported as to negate the need for the woman to be offered combined screening unnecessarily.

(3) Women who have a twin pregnancy must 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 must be informed of this before she consents to the screening test.

(5) ASW have provided information on offering screening for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) and NIPT when there is a second pregnancy sac.

(6) Women who chose to have private antenatal screening are still eligible to access, and must be offered, NHS Wales antenatal screening.

Standard DEP 4

The health board must have a pathway for women who consent to screening for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) 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 syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) and is then diagnosed as having a twin pregnancy during her early pregnancy dating scan, the health board will have a pathway for:

- arranging an appointment with the nominated health board professional for screening in twin pregnancies
- taking the NT measurements before 14^{+2} weeks
- collecting the blood sample for screening before 14^{+2} weeks.

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

- whether the twins are monochorionic or dichorionic as this will affect the screening result
- an adequate CRL between 45.0mm and 84.0mm, for each fetus, must be achieved to allow combined screening to be performed
- if only one NT measurement is obtained that the result will be less accurate than if both twins were measured
- if neither NT measurements are obtained, the combined or quadruple test will not be offered in twin pregnancies, i.e. no screening will be possible
- where the twins have individual placentas there is a possibility that one twin may have one of the conditions screened for and one twin not have any of the conditions screened for

- if the combined test result is higher chance, then the options are: ○ no further testing ○ NIPT ○ invasive procedure
- the risk of miscarriage from an invasive procedure in a twin pregnancy is approximately double that of a singleton pregnancy
- 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
- selective termination of one of the twins in a pregnancy is complicated and carries risks of miscarriage and morbidity to the other twin
- 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 her decision must be recorded in the All Wales Maternity Record. Target 100%

(1) Prior to performing the early pregnancy dating scan, the sonographer must enquire if the woman:

- understands the screening test she has consented to
- requires further information
- gives her informed verbal consent to proceed with the screening test she consented to:
    - the early pregnancy dating scan if the woman has declined screening for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13), or
    - the early pregnancy dating scan including measuring the nuchal translucency (NT) and taking a maternal blood sample if the woman consents to screening for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13).

(2) If the woman does not understand or has changed her mind about the screening test or requires further information:

- the sonographer should refer the woman back to the midwife[16] to discuss her decision and to ensure that the woman has received accurate information on which to base her decision before the early pregnancy dating scan is performed.

(3) The midwife must record any further discussions and changes in decision in the All Wales Maternity Record.

7.4 Test Requesting

Standard DEP 6

Where screening for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) is suspected, the woman's consent must also be recorded on the ultrasound request.

Target 100%

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

Standard DEP 7

The laboratory request for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) 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 syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) screening laboratory request card must be completed.

Target 100%

[16] Some specialist sonographers, e.g. midwife sonographer, obstetrician, may have the skills, knowledge and time to conduct this discussion with the woman themselves.

(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 head circumference (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 must be recorded on the request card as this will affect the accuracy of the result.

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

(6) The combined screening test can be performed in a twin pregnancy if:

- an adequate CRL between 45.0mm and 84.0mm is achieved for each fetus
- only one NT has been measured
- measurements must be documented on the request card.

(7) The DQASS number of the sonographer undertaking the NT measurement for combined screening must be provided on the request card.

Standard DEP 9

The health professional requesting the test must complete and sign the request.[17] Target 100%

[17] By signing the laboratory or ultrasound request, the requesting health professional is confirming that verbal and digital (or other appropriate format) 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.

(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 card 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^{+2} weeks to 14^{+1} weeks).

(4) In a twin pregnancy, both twins CRL must be between 45.0mm and 84.0mm (approximately 11^{+2} weeks and 14^{+1} weeks) and documented on the request card, for combined screening.

(5) Second trimester screening (the quadruple test) can only be undertaken on singleton pregnancies and on samples between 15^{+0} weeks and 18^{+0} weeks of pregnancy by Cardiff and Vale Biochemistry Laboratory. If a sample is being taken between 15^{+0} weeks and 15^{+2} weeks or 17^{+5} weeks and 18^{+0} weeks please phone the laboratory to ensure that the sample will be accepted.

(6) For samples being processed at Cardiff and Vale Biochemistry Laboratory, 3mls of venous blood in a serum separator tube is required for this test. If taking more than one blood sample at a time, the Down's syndrome, Edwards' syndrome and Patau's syndrome screening sample must be taken first as

contamination from the EDTA in other blood vacutainers can affect the result.

7.6 Laboratory Services

Standard DEP 11

The laboratory must be appropriately accredited or working towards accreditation in accordance with the United Kingdom Accreditation Service, and compliant with ISO standard 15189 for antenatal combined and quadruple screening tests.
Target 100%

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 syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) screening service.
Target 100%

Standard DEP 14

The laboratory must participate in an audit of the screening service and provide information, as required, to ASW.
Target 100%

Standard DEP 15

The detection rate and false positive rate for the Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) screening programmes must be monitored. A quadruple test must be used which can achieve a minimum standard of an 80% detection rate for a 4% screen positive rate, and a combined test with a detection rate of 80% for a screen positive rate of 3%.
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 Cardiff and Vale Biochemistry 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 for combined screening from when the sample is received.
Target 95%

Standard DEP 19

The testing laboratory must aim to achieve a four working day turnaround for quadruple screening from when the sample is received.
Target 95%

7.7 Results Handling

Standard DEP 20

The result for combined screening must be available to the maternity service within three working days of the sample reaching the testing laboratory and four working days for quadruple screening.

Target 95%

(1) The laboratory must email the result to the relevant generic email box in the health board within one day of reporting.

Standard DEP 21

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

Target 100%

(1) If the sample is taken at the correct time but the laboratory is unable to report a result due to an error in following the screening pathway, the woman must 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 (there will be a cost for the health board if the alternative test is an NIPT).

- If the chosen test is a quadruple test, and the error is recognised before the woman is 20^{+0} weeks gestation, then the health board should contact the local biochemistry laboratory, who will supply details of other laboratories, who will analyse the sample and produce a report.
- If the chosen test is an NIPT to be processed in the All Wales Genomics Laboratory the person taking the sample must telephone the laboratory to inform them that a sample is expected which is 'outside of the screening pathway'.
- If the test of choice is an NIPT performed as a primary test, then the woman should be informed of the performance of NIPT as a primary test. This is different to the performance of NIPT as a contingent test. Please note: ASW does not produce information for women who are offered NIPT as a primary screening test. This discussion

should be between the woman and the health professional[18] with relevant skills and knowledge.

Standard DEP 22

The maternity services must have 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 DEP 23

Women must be informed of the lower chance results by the maternity service at the 16 week antenatal visit and the results must be recorded in the All Wales Maternity Record.

Target 100%

(1) If the result is lower chance, the woman must be informed that she has a lower chance of having a baby with Down's syndrome (T21), Edwards' syndrome (T18) or Patau's syndrome (T13) and that no further testing is recommended. The actual serum screen result (expressed as a chance of 1 in xxx for Down's syndrome (T21) and a chance of 1 in xxx for Edwards' syndrome (T18)/Patau's syndrome (T13)) can be given to the woman if the woman requests the information.

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

(3) If this antenatal appointment is not face to face, a dated and signed record that the individual results have been discussed with the woman must be made in the maternity notes/health board IT system.

(4) Any actions relating to the result must also be documented.

Standard DEP 24

Where sampling has occurred later in pregnancy, results must be given within three weeks of the sample being taken. The results must be recorded in the All Wales Maternity Record the next time the woman is reviewed by a health professional.

Target 100%

[18] A health professional with up-to-date knowledge in NIPT being offered as a primary screening test.

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

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

7.7.1 Higher Chance of Down's Syndrome (T21), or Edwards' Syndrome (T18)/Patau's Syndrome (T13) (a Chance of 1 in 2 to 1 in 150)

Standard DEP 25

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 must be informed by letter or telephone call (according to local health board 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. The woman must be offered an appointment to discuss the result as per Standard DEP 26.

(2) The result should not usually be given during the weekend or on Friday afternoon unless the woman has access to a health professional with relevant skills and knowledge.

Standard DEP 26

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) A face-to-face appointment must be offered to discuss these results.

(2) Interpreter services must be arranged if required.

(3) Where the higher chance result is in association with an NT of 3.5mm or above, an invasive procedure must be offered. If the woman declines an invasive procedure, an NIPT can be offered but the woman should be informed that the NIPT will only give a result for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) whereas the invasive procedure will result in a single nucleotide polymorphism (SNP) array test providing more information on genetic conditions.

(4) The health professional must give up-to-date accurate information about Down's syndrome (T21), or Edwards' syndrome (T18) and Patau's syndrome (T13).

(5) The woman must be informed that she has a choice of an NIPT which is a further screening test or CVS/amniocentesis which are invasive tests or no further testing and that she will be supported whatever decision she makes.

(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) The woman must 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 procedure.

(8) Women with a twin pregnancy who have a higher chance combined screening result must be referred to the health

board nominated health professional to discuss the options for NIPT or an invasive procedure in twin pregnancies.

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

(9) ASW literature 'This information is for you if you have been offered further tests for suspected chromosomal conditions' must be used to inform the discussion between the woman and the health professional.[19] 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 27

The woman's informed verbal consent is required for NIPT and this must be documented in the All Wales Maternity Record. Target 100%

(9) The health professional with suitable skills and knowledge must have a verbal discussion about NIPT with the woman prior to asking her to make a personal informed choice about whether she wants the test. The woman should be:

- informed of the purpose, implications, limitations and benefits of the NIPT
- 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 procedure
- informed that NIPT is not performed following a higher chance screening result after 20^{+0} weeks of pregnancy.

[19] Written information for women is available from ASW in hard copy and in digital format.

7.8.2 Test Requesting

Standard DEP 28

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 Cardiff and Vale Biochemistry Laboratory, a copy of the laboratory report must be included with this request.

Standard DEP 29

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

Target 100%

7.8.3 NIPT Blood Test Procedure

Standard DEP 30

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 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 person taking the sample must email the All Wales Genomics Laboratory to inform them that the sample is on its way to the laboratory.

7.8.4 Sample Handling

Standard DEP 31

The sample must be received by the All Wales Genomics Laboratory within five days of the sample being taken.
Target 95%

(1) Sample preparation and transportation must follow the Standard Operating Procedures recommended by the All Wales Genomics Laboratory.

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

(3) The sample and completed request card must be sent to the All Wales Genomics Laboratory preferably on the day that the sample is taken. This will minimise the risk of a failed test due to a breakdown of fetal DNA in the sample.

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

7.8.5 Laboratory Services

Standard DEP 32

The laboratory must be appropriately accredited or working towards accreditation in accordance with the United Kingdom Accreditation Service, and compliant with ISO standard 15189 for antenatal combined and quadruple screening tests.
Target 100%

Standard DEP 33

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 34

The laboratory must participate in an audit of the screening service and provide information, as required, to ASW and the Congenital Anomaly Register and Information Service (CARIS).
Target 100%

Standard DEP 35

The All Wales Genomics Laboratory must aim to achieve a 10 calendar day turnaround from when the sample is received in the laboratory to results reporting to the health board.
Target 100%

(3) The laboratory must email the result to the relevant generic email box in the health board within one calendar day of reporting.

7.8.6 Results Handling

Standard DEP 36

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%

(2) The antenatal screening coordinator or named deputy should coordinate the results handling process as they are received via the relevant generic email box.

Standard DEP 37

The maternity services must have a written and agreed process in place to identify and follow up where additional information is required by the laboratory.
Target 100%

7.8.7 Low Chance NIPT Results

Standard DEP 38

Women who have a low chance NIPT result for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) must be informed of the results by the maternity service within one working day of the result being available to the maternity services.
Target 100%

(1) Women must be informed that a low chance NIPT result for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) means that it is very unlikely that the baby will have the conditions being screened for.

(2) The woman must be informed that no further testing will be offered.
(3) A dated and signed record that the result has been discussed with the woman must be made in the maternity notes/health board IT system.

Standard DEP 39

The result must be recorded in the All Wales Maternity Record the next time the woman is reviewed by a health professional.
Target 100%

7.8.8 High Chance NIPT Results or No Result

Standard DEP 40

Women who have a high chance NIPT result for Down's syndrome (T21), Edwards' syndrome (T18) or Patau's syndrome (T13) must be informed of

the result by the maternity service within two working days of the result being received by the maternity service.

Target 90%

(1) The woman must be informed by telephone (or her preference) that she has a high chance result.

(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.

(3) Around 0.3% of women will not get a result from the NIPT and these are slightly more likely to have a baby with one of the conditions being screened for. The health board must have a process in place to ensure that women who do not get a result will be offered an invasive procedure.

(4) A dated and signed record that the result has been discussed with the woman must be made in the maternity notes/health board IT system if this discussion is virtual.

Standard DEP 41

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) The appointment must be offered face to face to discuss these results.

(2) Interpreter services must be arranged if required.

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

(4) The health professional must give up-to-date accurate information about the syndrome that is high chance on the result.

(5) ASW literature 'This information is for you if you have been offered further tests for suspected chromosomal conditions' must be used to inform the discussion between the woman and the health professional.[20] This literature includes contact information for the Down's Syndrome Association (DSA), Support for Trisomy 13 and 18 (SOFT UK) and Antenatal Results and Choices (ARC).

Standard DEP 42

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:

- invasive procedures
- the risk of miscarriage associated with an invasive procedure (RCOG 2021)
- Quantitative Fluorescence-Polymerase Chain Reaction (QF-PCR) and the information which this result will provide
- any other information requested by the woman to enable her to make an informed decision regarding an antenatal invasive procedure
- where the result is from a twin pregnancy:
    - which has resulted in individual placentas there is a possibility that one twin may have one of the conditions screened for and one twin may not have any of the conditions screened for
    - the risk of miscarriage from an invasive procedure in a twin pregnancy is approximately double that of a singleton pregnancy
    - 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
    - selective termination of one of the twins in a pregnancy is complicated and carries risks of miscarriage and morbidity to the other twin.

(2) The midwife should also discuss pregnancy choices following an invasive procedure if the result shows that the baby has one of these conditions. These include continuing with the

[20] Written information for women is available from ASW in hard copy and in digital format.

pregnancy or ending the pregnancy. Women must be offered support in whichever choice they make.

(3) Termination of pregnancy should be discussed. If gestation is more than 21^{+6} weeks, feticide should be included in the 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 an antenatal invasive procedure.

(5) ASW literature 'This information is for you if you have been offered further tests for suspected chromosomal conditions' must be used to inform the discussion between the woman and the health professional.[21] This literature includes contact information for the Down's Syndrome Association (DSA), Support for Trisomy 13 and 18 (SOFT UK) and Antenatal Results and Choices (ARC).

Standard DEP 43

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 have no further testing after a high chance NIPT she should be offered the opportunity to be involved in planning her care for the pregnancy which may include being offered access to relevant specialities, such as paediatricians, breast feeding specialist midwives, surgical teams, support organisations, etc.

7.9 Invasive Procedures

Standard DEP 44

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

[21] Written information for women is available from ASW in hard copy and in digital format.

Standard DEP 45

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 syndrome (T21), Edwards' syndrome (T18) or Patau's syndrome (T13).

Target 100%

(1) Where the woman decides to continue with the pregnancy after a diagnosis of Down's syndrome (T21), Edwards' syndrome (T18) or Patau's syndrome (T13) the woman should be offered the opportunity to be involved in planning her care for the pregnancy which should include relevant specialities, such as paediatricians, breast feeding specialist midwives, surgical teams, support organisations, etc.

8.0 Antenatal Screening - Ultrasound

Policy Statement

All pregnant women resident in Wales should be offered an early pregnancy dating scan and a fetal anomaly ultrasound scan (NICE 2021).

Early Pregnancy Dating Scan

Rationale for Screening

The early pregnancy dating 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 syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) screening programmes, and an additional measurement if the scan is before 14^{+2} weeks of pregnancy (maximum CRL 84mm). Where first trimester screening for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) 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 syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13).

Fetal Anomaly Ultrasound Scan

Rationale for Screening
The purpose of the fetal anomaly ultrasound scan is to screen for 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^{+0} weeks to 20^{+6} weeks of pregnancy.

For some conditions, 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 treatment is available. Women can make a personal informed choice about whether they wish to continue the pregnancy. Appropriate support will be offered whichever choice is made.

Anticipated Outcome
Detection of significant structural anomalies in the baby to enable appropriate interventions and personal informed choice and planning their care for the pregnancy and referral to relevant specialities.

8.1 General Standards for Early Pregnancy Dating Scans and Fetal Anomaly Ultrasound Scans

8.1.1 Pre-test Information

Standard US 1

Every pregnant woman must be offered and directed to the ASW Antenatal Screening Tests literature available on the ASW website. Target 100%

(1) The midwife must ensure women receive verbal and digital information about the antenatal screening tests.

(2) The midwife must ensure women who are unable to access the digital version of the ASW Antenatal Screening Tests literature are given a hard copy.

(3) Where women have a different language or communication need, the midwife must ensure that the information is provided in the correct format, i.e. in large print, easy read, Braille, audio, British Sign Language or an approved interpreter service may be appropriate.

(4) The midwife must make a record of the format in which information is given to the woman.

Standard US 2

The midwife must have a verbal discussion with the woman about the early pregnancy dating scan and the fetal anomaly ultrasound scan prior to asking her to make a personal informed choice whether she wants the test and a record of the discussion must be made in the All Wales Maternity Record.

Target 100%

(1) Where the woman has a different language or communication need, the midwife must ensure the provision of accurate information in a format that is accessible. Primarily this should be in digital format, but after assessing the woman's needs, hard copy, British Sign Language, easy read, audio or an approved interpreter service may be appropriate. This is essential to obtain informed consent.

(2) The purpose, implications, limitations and benefits of these ultrasound scans must be explained to the woman by the midwife. This is essential to obtain informed consent.

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

(4) Where first trimester screening for Down's syndrome (T21), Edwards' syndrome
(T18) and Patau's syndrome (T13) is provided, the standards and protocols in Section 7 of this document must also be met.

8.1.2 Offer of Ultrasound Scans

Standard US 3

Every pregnant woman must be offered ultrasound screening before 10^{+0} weeks of pregnancy if the women presents for antenatal care before that gestation. A record of the offer must be made in the All Wales Maternity Record.

Target 100%

(1) This offer includes the early pregnancy dating scan between 11^{+2} weeks and 14^{+1} weeks of pregnancy and a fetal anomaly ultrasound scan between 18^{+0} weeks to 20^{+6} weeks of pregnancy.

(2) Women who attend for antenatal care later in pregnancy must be offered an ultrasound scan appropriate to their presumed gestation when they first attend.

(3) Women who chose to have private antenatal screening are still eligible to access, and must be offered, NHS Wales antenatal screening.

8.1.3 Consent

Standard US 4

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

Target 100%

(1) Prior to performing the early pregnancy dating scan, the sonographer must enquire if the woman:

- understands the screening test she has consented to
- requires further information
- gives her informed verbal consent to proceed with the screening test she consented to:
    - the early pregnancy dating scan if the woman has declined screening for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13), or

- the early pregnancy dating scan including measuring the nuchal translucency (NT) and taking a maternal blood sample if the woman consents to screening for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13).

(2) If the woman does not understand or has changed her mind about the screening test or requires further information:

- the sonographer should refer the woman back to the midwife[22] to discuss her decision and to ensure that the woman has received accurate information on which to base her decision before the early pregnancy dating scan is performed.

(3) The midwife must record any further discussions and changes in decision in the All Wales Maternity Record.

8.1.4 Test Requesting

Standard US 5

The scan request 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 or electronic request.

Target 100%

(1) Ultrasound scan requests must include information on relevant obstetric, medical and social issues which can affect fetal wellbeing including:

- 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)

[22] Some specialist sonographers, e.g. midwife sonographer, obstetrician, may have the skills, knowledge and time to conduct this discussion with the woman themselves.

- high BMI
- other relevant factors.

(2) The scan request must indicate whether the woman consents to:

- early pregnancy dating scan
- screening for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13)
- fetal anomaly ultrasound scan.

Standard US 7

The health professional requesting the test must complete and sign the request.[23]

Target 100%

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

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, must perform ultrasound scans for antenatal screening.[6]

Target 100%

(1) Sonographers taking part in antenatal screening and who are currently registered with/regulated by their professional body/regulatory bodies e.g. Nursing and Midwifery Council (NMC)/Health and Care Professions Council (HCPC).

(2) For those who are currently not able to be registered with/regulated by a professional body (i.e. those who have completed a direct entry higher education ultrasound programme) they must be named on the health board's governance register and have a named governance lead for ultrasound.[7]

[23] By signing the ultrasound request, the requesting health professional is confirming that verbal and digital (or other appropriate format) information about the purpose of the scan has been given to the woman and that she has given informed consent for the scan.

Standard US 9

The sonographer must have passed an assessment to participate in combined screening. Sonographers must be registered with the Down's syndrome Screening 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, as a minimum, must complete a satisfactory biannual assessment of at least three sets of paired CRL and NT images with their named NT lead.

(2) Each sonographer must complete the ASW First Trimester Screening Resource for Sonographers and the ASW 'Down's, Edwards' and Patau's syndromes' e-learning resource every two years and compliance must be verified by the health board NT lead.

(3) The six-monthly DQASS report for each sonographer must show a flag status of green or amber for that sonographer to continue to undertake combined screening.

(4) If a sonographer has less than 25 paired measurements on the six-monthly DQASS report (white flag), that sonographer can continue to undertake combined screening. If that sonographer achieves less than 25 paired measurements in the consecutive six-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 blood test 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 programme 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 ultrasound scan findings must be made on the ultrasound reporting module and images must be stored on the health board electronic image storage Picture Archiving and Communication System (PACS).[8]

Target 100%

(1) All health boards in Wales currently use the Welsh Radiology Information System (WRIS), also known as RadIS2.

(2) RadIS2 or an agreed alternative obstetric reporting module must be used to report all early pregnancy dating and fetal anomaly ultrasound scans.

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

(4) 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 must be stored electronically. They must be stored for 25 years.

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

8.1.6 Test Procedure

Standard US 13

The early pregnancy dating scan must be performed between 11^{+2} (CRL 45.0mm) and 14^{+1} weeks (CRL 84.0mm) of pregnancy. The fetal anomaly ultrasound scan must be performed between 18^{+0} weeks and 20^{+6} weeks

of pregnancy if the woman presents for antenatal care before this gestation.

Target 100%

(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 must 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 there are no unexpected scan findings following the early pregnancy dating or fetal anomaly ultrasound 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.

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 Dating Scans

8.2.1 Test Procedure

Standard US 16

The scan must be arranged and performed between 11^{+2} weeks and 14^{+1} weeks of pregnancy, ideally at 12 weeks if the woman presents for antenatal care before this gestation.

Target 100%

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

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

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

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) In the event an adequate CRL cannot be obtained:

- If the woman has consented to screening for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) and the HC is equal to or more than 88mm, the HC should be used to date the pregnancy (Loughna 2009). This will allow for the quadruple test to be performed.
- If the woman has declined screening for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) then sonographers should refer to Loughna 2009 for guidance on how to accurately date the pregnancy.

Standard US 18

As a minimum standard, the sonographer must report:
- Whether the pregnancy is intrauterine
- presence or absence of a fetus
- viability (i.e. presence of heart pulsation)
- CRL(s) or HC(s) as appropriate
- NT measurement(s) where screening for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) is requested
- fetal number and in multiple pregnancies the chorionicity and amnionicity • any fetal abnormality which is seen.

Target 100%

(1) The health board must have a guideline for dealing with non-viable pregnancies and this must be followed for all non-viable pregnancies found on the early pregnancy dating scan (NICE 2019).

(2) If the woman has requested screening for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) and the NT measurement is not obtained 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' syndrome 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 health board 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 syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) and are then diagnosed as having a twin pregnancy during their early pregnancy dating scan. Standard DEP 4.

Target 100%

(1) Women known to have a twin pregnancy prior to their early pregnancy dating 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 syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) and is then diagnosed as having a twin pregnancy at the time of her early pregnancy dating scan, the health board will have a pathway for:

- arranging an appointment with the nominated health board professional for screening in twin pregnancies
- specific counselling for screening in twin pregnancies and consented to that screening prior to the screening
- taking the NT measurements before 14^{+2} weeks
- collecting the blood sample for screening before 14^{+2} weeks.

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

(4) Combined screening cannot be offered in twins if:

- an adequate CRL between 45.0mm and 84.0mm, for each fetus cannot be achieved
- neither NT measurements are obtained

(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) ASW has provided information on offering combined screening and NIPT when there is a second pregnancy sac.

8.2.2 Unexpected Findings at the Early Pregnancy Dating Scan

Standard US 20

If the pregnancy is ongoing and an anomaly is identified or suspected, the sonographer must arrange for a midwife or obstetrician with suitable skills and knowledge to discuss the findings with the woman within 24 hours.
Target 100%

(1) Where an unexpected finding is identified or suspected, verbal information must initially be provided to the woman 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 must then be provided by the appropriately trained midwife 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/fetal cardiology department within an appropriate timescale for the condition found.

(4) Where the woman has not consented to screening for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13), the nuchal translucency (NT) measurement is not part of the early pregnancy dating scan. If during the scan the NT is visualised and appears enlarged, a measurement should be taken and reported.

(5) If a fetal anomaly is identified and/or the NT is 3.5mm and above, the woman must be informed and (with her consent) referred to a health care professional with appropriate skills and knowledge for further information and management. The electronic image(s) must be made available with the referral correspondence.

(6) If a fetal anomaly is identified and/or the NT is 3.5mm and above, screening for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) must be completed if consent for the test has been given.

(7) If the woman has a fetal anomaly or an NT of 3.5mm and above, an invasive test should be offered. If the woman declines an invasive test, NIPT can be offered if the result from combined screening is higher chance, but the woman must be informed that the NIPT will only give a result for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) whereas the invasive procedure will result in an SNP array (single nucleotide polymorphism) test providing more information on genetic conditions.

(8) In circumstances where there is no live fetus identified during the early pregnancy dating scan, the local health board guideline for dealing with nonviable pregnancies should be followed.

(9) Any suspected congenital anomaly must 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, CARIS can be notified via the web portal or a 'CARIS notification card' should be completed and sent to the CARIS coordinator/office.[9]

(10) 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 Antenatal Screening Tests literature.

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 unexpected 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^{+0} weeks and 20^{+6} weeks of pregnancy if the woman presents for antenatal care before this gestation.

Target 100%

(1) Women who attend for antenatal care later in pregnancy must be offered an ultrasound scan appropriate to their presumed gestation. The routine anomaly scan reporting module in RadIS2 or an agreed alternative can be used for these scans with the

understanding that the estimation of normal measurements may not be accurate with increased gestational age.

Standard US 23

The minimum standard for reporting the 18^{+0} weeks to 20^{+6} weeks fetal anomaly ultrasound scan, as set out in the Antenatal Screening Wales Anomaly Scan Checklist (April 2020) must be achieved.[10]

Target 100%

(1) Where the first examination is suboptimal and the sonographer is suspicious of a possible fetal anomaly, a second opinion must be sought as soon as possible.

(2) If the standard scan checklist cannot be completed, the woman should be offered one further ultrasound scan. The woman must 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 completed before 22^{+6} weeks of pregnancy.

(4) Where it is not possible to complete the standard checklist on the second scan, the sonographer must inform the woman as to why and no further scan should be offered.

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

Standard US 24

The following specific ultrasound findings must be referred for further assessment as per the ASW ultrasound observations pathways 2018:

- ventriculomegaly
- echogenic bowel • renal pelvic dilatation.

Target 100%

8.3.2 Unexpected Findings at the Fetal Anomaly

Ultrasound Scan

Standard US 25

Where a fetal anomaly is identified or suspected, the sonographer must arrange for a midwife or obstetrician with suitable skills and knowledge to discuss the findings with the woman within 24 hours.

Target 100%

(1) Where a fetal anomaly is identified or suspected, verbal information must initially be provided to the woman by the sonographer. The sonographer must place a report within the woman's All Wales Maternity Record at the time of this appointment.

(2) ASW has provided guidance on the reporting of routine biometry which plot below the 5th centile at the time of the fetal anomaly ultrasound scan.

(3) Verbal information must then be provided by the appropriately trained midwife 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 unit within five working days of the fetal anomaly ultrasound scan.

(6) Any suspected congenital anomaly must 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, CARIS can be notified via the web portal or a 'CARIS notification card' should be completed and sent to the CARIS coordinator/office.[11]

(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 Antenatal Screening Test literature.

Standard US 26

A contemporaneous, dated and signed record must be made in the All Wales Maternity Record of actions planned and taken in response to any unexpected finding(s). Target 100%

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Welsh Language Standards (No7) Regulations 2018 Standard 38 Welsh Assembly
Government

Endnotes

[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 2022).

[2] Hepatitis B vaccine should be given to term babies weighing more than 1500g when the mother is HBsAG positive and anti-HBe positive and with a maternal hepatitis B virus DNA level $<1x10^6$iu/ml in an antenatal sample. All other babies will require both hepatitis B vaccine and HBIG (DOH 2022).

[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 (DOH 2022).

[4] Potentially sensitising events in pregnancy (BCSH 2014):

- 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.

[5] 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 2021), CVS is usually performed between 11^{+0} and 13^{+6} weeks.

[6] There is currently no regulatory control on performing obstetric ultrasound scans but any sonographer delivering obstetric

screening in Wales must hold an appropriate qualification, for example:

- Certificate or Diploma in Medical Ultrasound in obstetrics, or
- Post Graduate Certificate or Diploma in medical ultrasound accredited by the Consortium of Accreditation of Sonographic Education (CASE), including an appropriate obstetric module.

*Where a sonographer has an alternative qualification not accredited by CASE, Health Boards should consider recommendations from relevant professional bodies to agree which practitioners hold an equivalent level of qualification and the relevant skills and competencies to deliver obstetric screening in Wales.

[7] With the recent advent of direct entry higher education ultrasound programmes, some sonographers will gain an accredited qualification but will not be able to be registered with a regulatory body e.g. HCPC. 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 dating scans and fetal anomaly ultrasound scans.

[8] **Images to be stored at the early pregnancy dating scan:** The obstetric and NT lead sonographers agreed the following set of images as a minimum requirement for storage, and to provide a quality assessment of the examination. A midline sagittal section to demonstrate an intrauterine pregnancy, the CRL measurement documented in the issued report and the documented NT measurement if a woman has consented to combined screening. Any abnormality or other measurement included in the report should have an image to support the finding.

Images to be stored at the fetal anomaly ultrasound scan: The obstetric lead sonographers agreed the following set of images as a minimum requirement for storage, and to provide a quality assessment of the examination. Head circumference, nose, lips and chin, femur length, four chamber heart view, transverse section of kidneys in the abdomen, three vessel trachea view with colour, midline longitudinal section to include the internal os,

sagittal spine. Any abnormality or other measurement included in the report should have an image to support the finding.

[9] 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.

[10] 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 ultrasound 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.

[11] 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.

Appendix 2

Sgrinio Cyn Geni Cymru
Antenatal Screening Wales

GIG CYMRU NHS WALES
Iechyd Cyhoeddus Cymru
Public Health Wales

Pathway for surveillance of pregnant women with a positive antenatal screening test result for syphilis or HIV

Positive syphilis or HIV result sent to health board generic email address from virology

↓

Antenatal Screening Coordinator to complete digital notification form after initial treatment
Link to HIV notification form
Link to Syphilis notification form

↓

Antenatal Screening Coordinator to liaise with obstetrics, sexual health and neonatology to complete digital outcome form within 6 weeks of delivery
Link to HIV outcome form

↓

***CARIS to chase up cases on a quarterly basis**

↓

CARIS to liaise with Virology to ensure all cases have been reported. Annual data to be sent from CARIS to *CDSC

↓

CDSC to report on pregnancy data within All Wales report

↓

Report published on CDSC website

Appendix 3

Cell Free Fetal DNA (cffDNA) screening test: A Guide for Health Professionals

Summary

cffDNA screening test is a highly accurate test. We know that there will however be a small percentage of false positive and false negative results reported, which is a risk of any screening programme.

Who can have the fetal RhD screening test?

The test is for D-negative pregnant women who do not have anti-D or anti-G antibodies at booking.
The normal antenatal screening pathway will enable women whose pregnancies have progressed to 16^{+0} weeks gestation (samples must not be collected prior to 11+2 weeks gestation).
The cffDNA test can be performed from 11^{+2} weeks gestation, therefore screening will be available to some women who are attending Fetal Medicine Unit at an earlier gestation. If a woman requires referral to FMU, she can have cffDNA screening, however the turnaround time will be the same as the current/ normal pathway.
If the woman has had confirmation that her baby is RhD positive, or, the RhD status of the baby is inconclusive, then we should consider the baby as being RhD positive and recommend anti-D immunoglobulin.
Welsh Blood Service (WBS) should be notified if a sample is performed in these circumstances. You can contact WBS on - 01443 622186 or email: molecular.genetics@wales.nhs.uk
The latest gestation the test can be performed as per the normal antenatal screening pathway will be $\leq 26^{+0}$ weeks gestation. This will allow time for the sample to be processed and for the routine 28/40 anti-D appointment to be arranged if appropriate.

Women who are expecting twins.

We can offer the test to women pregnant with twins. A positive result in this case means at least one of the fetuses is D-positive. A negative result would mean that both fetuses are D-negative. **The test cannot be offered to women who are pregnant with higher multiple pregnancies.**

Women who have weak D or D variant.

It is difficult to differentiate between maternal and fetal DNA. Women who have been confirmed to be weak D or D variant are unlikely to benefit from the fetal RhD screening test because the maternal RhD gene will prevent prediction of fetal D phenotype and an inconclusive test result will be issued. Women who are confirmed weak D should be treated as D-positive and prophylactic anti-D is not required. Women who are confirmed D variant should be given anti-D prophylaxis in line with local policy.

Pregnant women with antibodies

We do not offer the cffDNA screening test to pregnant women who have anti-D or anti-G antibodies **due to the complexities** of these antibodies.

We **can** offer the cffDNA screening test to pregnant women who have alloantibodies other than anti-D or anti-G.

Potential Sensitising Events (PSE)

Women who have a potential sensitising event and have anti-D Immunoglobulin administered prior to the offer of cffDNA screening can still have screening performed as the anti-D Ig does not interfere with this test. However, the serological antibody test at booking, prior to the cffDNA screening must be negative for D and G antibodies.

Previous termination/miscarriage within the last 6 months

Women who are RhD negative and have had a termination of pregnancy or miscarriage within the last six months can be offered screening providing the antibody screen at booking is negative for D or G antibodies.

If the serological investigation at booking identifies an anti-D antibody (or G antibodies) -. please follow the BSH guidelines for Blood grouping and antibody testing in pregnancy [Blood Grouping and Antibody Testing in Pregnancy (b-s-h.org.uk)](b-s-h.org.uk).

Vanished Twin

CffDNA screening can be offered to a woman who has had a twin pregnancy initially, but now has a vanishing or vanished twin. However, in this group of women there is a higher chance of a false positive result if circulating cffDNA from the vanished/demised twin is still present.

Test Performance

Sensitivity of cffDNA screening

- The tests' ability to correctly identify the proportion of true positive results is ≥99.9%.
- A true positive (TP) is defined as a clinical sample with detected fetal RhD DNA that is confirmed as RhD Positive.

Specificity of cffDNA screening

- The tests' ability to correctly identify the proportion of true negative results is ≥99.8%.
- A true negative (TN) is defined as a clinical sample with no detected fetal RhD DNA that is confirmed as RhD negative.

False positive (FP) rate of cffDNA screening

- The false positive rate is 0.14%.
- For fetal blood group genotyping tests a false positive result means that cffDNA screening test has predicted a fetus to be RhD positive when the baby is found to be RhD negative at birth.

False negative (FN) rate of cffDNA screening

- The false negative rate is 0.09%.
- For fetal blood group genotyping tests, a false negative result means that cffDNA screening test has predicted a fetus to be RhD negative when the baby is found to be RhD positive at birth.

Results

The fetal RhD screening results will only be available via the Welsh Results Reporting System (WRRS). This allows health care professionals across Wales to access and view results across all health boards in Wales. The turnaround time will be 10 working days from receipt of sample.
If a result is not available 10 working days since a sample was taken, then you should contact WBS on 01443 622186 or email: molecular.genetics@wales.nhs.uk

Reports

Test Reporting (Singleton pregnancy).

The report will state if the fetus is predicted to be RhD Positive, RhD Negative or if the test was inconclusive. Examples for each scenario are shown below.

- Fetal RhD typing predicts that this fetus is RhD POSITIVE. This result only applies to the pregnancy with EDD above.
- Fetal RhD typing predicts that this fetus is RhD NEGATIVE. This result only applies to the pregnancy with EDD above.
- Fetal RhD typing was INCONCLUSIVE. Manage this pregnancy as if this fetus is RhD POSITIVE. This result only applies to the pregnancy with EDD above.

Test Reporting (Twin pregnancy).

In a twin pregnancy, a positive result means at least one of the fetuses is D-positive. A negative result would mean that both fetuses are D-negative.

- Fetal RhD typing predicts that one or both fetuses are RhD POSITIVE. This result only applies to the pregnancy with EDD above.
- Fetal RhD typing predicts that both fetuses are RhD NEGATIVE. This result only applies to the pregnancy with EDD above.
- Fetal RhD typing was INCONCLUSIVE. Manage this pregnancy as if one or both fetuses are RhD POSITIVE. This result only applies to the pregnancy with EDD above.

If a sample has been rejected this will also be noted on the report. Reasons for sample rejection will include, but are not limited to:

- 'Insufficient blood in tube' if there was insufficient plasma
- Sample grossly haemolysed therefore unable to test
- EDD not supplied
- Inadequate labelling of sample or sample not dated/signed
- There was a discrepancy between the sample and request card

Samples will need to be repeated before 26 weeks gestation.

Documentation and sample requirements

Positive patient identification procedures must be followed. There is clear guidance for sample requirements. The NHS number is mandatory as it will be the unique identifier, there must be a minimum of three points of identification that match between the sample and request card. In some cases where a woman may not initially have an NHS number, the sample may be accepted providing that there is a minimum of three points of identification. WBS will not accept samples which have incomplete mandatory

data. Rejected samples will have a report explaining why the sample has not been accepted. CffDNA Sample Taker SOP.

It is acceptable to have addressograph labels on the request card providing they do not obscure other vital details. However, the sample must be handwritten, addressograph labels are not acceptable on the samples. Any minor alterations must be initialled by the person taking the sample to be acceptable for testing.
For the fetal RhD screening test use a 10mL EDTA tube with a purple top. Fill the sample tube correctly because samples will be rejected if there is less than 9mL inside the tube.

Postnatal – maternal and cord blood sampling

Test Reporting (Singleton pregnancy).

A maternal blood sample is required from all RhD negative women who have had cffDNA screening regardless of whether the fetus is predicted to be RhD negative or RhD positive. This is to assess feto-maternal haemorrhage in RhD negative women who have delivered a RhD positive baby to establish whether the woman requires additional anti-D prophylaxis. It will also be needed if a false negative result from cffDNA screening is discovered.

A cord blood sample is required from all RhD negative women who have had cffDNA screening regardless of whether the fetus is predicted to be RhD negative or RhD positive. This is to test for the fetal RhD group and confirm the antenatal cffDNA result, if applicable.

- WBS and ASW are not currently recommending that hospitals discontinue cord blood testing.

All postnatal cord blood samples should be correlated with the antenatal cffDNA result to ensure there are no discrepant results.

Discrepant results

You must report all discrepancies to the local blood bank who will inform the WBS. A pathway for discrepant results can be located here; Management pathway for discrepant results.

False negative result

If a false negative result is discovered, the woman should be informed of the result and advised that anti-D is recommended. A

maternal antibody screen should be taken prior to the administration of anti-D and the women should be offered and recommended anti-D. This should be administered (if accepted) without delay and within 72 hours of birth.

A repeat blood group from the infant to confirm the result should be obtained.

The local laboratory should be informed and an incident should be raised as per local practices

e.g. Datix and the relevant teams (maternity risk & governance team midwives, local laboratory, WBS) informed so that appropriate actions can be taken.

The local laboratory will –

- Request a repeat blood group from the infant to confirm the result.
- Notify Welsh Blood Service. Initiate a local investigation by submitting a Datix.

NB – A false negative result is where screening has predicted the RhD group of the fetus to be negative, but the cord blood results show the infant to be RhD positive. We anticipate approximately 5 false negative results annually throughout Wales. This has been risk assesses and agreed as acceptable.

False positive result

If a false positive result is discovered, the woman should be informed of the result and advised that anti-D is not recommended.

A repeat blood group from the infant to confirm the result should be obtained.

The local laboratory should be informed. The local laboratory will –

- Request a repeat blood group from the infant to confirm the result.
- Notify Welsh Blood Service. Initiate a local investigation by submitting a Datix.

NB – A false positive result is where screening has predicted the RhD group of the fetus to be positive, but the cord blood results show the infant to be RhD negative.

- **All discrepant results will be reported to the Serious Hazards of Transfusion (SHOT) haemovigilance scheme either by the local blood bank or Welsh Blood Service.**

Explanation regarding discrepancies:

Women who have accepted cffDNA screening will be aware that this is a screening test and although very accurate, is not 100% accurate.

Women who have a false negative result will not have had anti-D at 28 weeks or for any sensitising events during the pregnancy. We estimate that this will be approximately 1 in 1000 women. These women will have been at risk of becoming sensitised during their pregnancy and birth. It's estimated that 1% of women become sensitised if they receive post-natal anti-D but do not receive antenatal anti-D at 28 weeks.

Women who have a false positive result will have had anti-D unnecessarily at 28 weeks and for any sensitising events during pregnancy. The small false positive rate when using the cffDNA, means that approximately only 1.26% of D negative women will receive antenatal prophylaxis unnecessarily, rather than 40% without using cffDNA screening.

References:

https://onlinelibrary.wiley.com/doi/full/10.1111/tme.12091

https://www.nice.org.uk/guidance/ta156/documents/pregnancy-rhesus-negative-women-routinehttps://www.nice.org.uk/guidance/ta156/documents/pregnancy-rhesus-negative-women-routine-antid-review-overview2antid-review-overview2#:~:test=The%20base%2Dcase%20sensitisation%20rate.and%20therefore%20be%20 at%20risk

High-throughput, non-invasive prenatal testing for fetal rhesus D status in RhD negative women: a systematic review and meta-analysis – PubMed (nih.gov)