

Revised **Policy, Standards and Protocols**

**to Support
the Provision
of Antenatal
Screening
in Wales**



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Antenatal Screening Wales is grateful to the Antenatal Screening Wales (ASW) sub groups and Local Multiprofessional Management Groups (LMMG) for their assistance and advice in the preparation of this document.

Public consultation on these standards and protocols was held between April 2009 and June 2009.

ASW are extremely grateful to those who responded to the consultation. All of the consultation responses have been reviewed by the All Wales Multiprofessional Management Group (AWMMG) and changes recommended by the AWMMG have been incorporated in this document.

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Foreword

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

The agreed purpose of Antenatal Screening in Wales is:

- *Antenatal screening is undertaken to detect defined serious conditions present in either the mother or baby that are likely to have an adverse effect on the health of either, and for which an effective intervention is available and warranted.*
- *For some conditions, preventive treatment is available during the antenatal period or after delivery to improve the baby's health.*
- *For others, the condition can be identified during the antenatal period but no preventive treatment is available. With high quality counselling women can make an informed choice about whether they wish to continue the pregnancy and appropriate support, depending on their ultimate choice, can be arranged (Choices, Velindre NHS Trust 2002).*

In April 2003 the Minister for Health and Social Services agreed that a Managed Clinical Network for antenatal screening should be established in Wales, based on the principles described in the Antenatal Screening Project Report Choices – Recommendations for the Provision and Management of Antenatal Screening in Wales (Velindre NHS Trust 2002). The network is known as Antenatal Screening Wales (ASW) and is hosted by Public Health Wales as part of Screening Services.

As part of its initial work, ASW was asked by the Welsh Assembly Government to establish policies, standards and a performance management framework for antenatal screening to support demonstrable improvements in the quality of antenatal screening offered to women. Standards and protocols for antenatal screening were first published by ASW in December 2005 and these have been reviewed in 2009.

Public consultation on these standards and protocols was held between April 2009 and June 2009 and 17 organisational and 11 individual responses were received. The All Wales Multiprofessional Management Group (AWMMG) has reviewed all the consultation responses and this has led to a number of significant revisions to the consultation document.

The implementation of service changes to meet the expectations in the original standards has been monitored by the ASW balanced scorecard, which will continue to be reported every 6 months. An audit framework has been developed to facilitate record keeping and process audits in Health Boards providing services. These documents will now be updated to reflect the changes required to meet the new standards.

Standard C4

The woman's informed verbal consent is required for these tests.

- (1) Written consent is not required but a record of the woman's verbal consent must be made by the midwife in the maternity notes.
- (2) If the woman declines screening for HIV, hepatitis B or syphilis, the midwife should ensure the woman has received accurate information on which to base her decision.
- (3) Women who decline screening for HIV, hepatitis B or syphilis should be given a further written or verbal opportunity to consent to these screening tests during pregnancy, preferably at the 28 week antenatal appointment.

Numbered Standard Statement



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*



1.0 Introduction

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

The publication of agreed all Wales antenatal screening standards and protocols in 2005 by ASW and the supporting clinical framework provided by the ASW network, has enabled close working with stakeholders, and resulted in improvements in the antenatal screening programme. Antenatal screening services have improved for pregnant women who book early for their pregnancy care. They are now much more likely to receive timely verbal and written information about antenatal screening tests to inform their decision on accepting or declining antenatal screening. There is more timely access to screening tests and systems are in place for women to receive their screening test results in a timely manner.

A review of antenatal screening services was undertaken in the summer of 2008 by the All Wales Programme Coordinator and Regional Coordinators. A semi-structured questionnaire and site visits were used to assess progress with meeting the existing standards and explore areas where additional standards would be helpful to improve care. The information gained from this review combined with advice from the three ASW Local Multiprofessional Management Groups (LMMGs) and three ASW AWMMG Sub Groups, and balanced scorecard information have been used to consult on and agree these standards and protocols.

Standards and protocols were developed and published in April 2008 to support amniocentesis and chorionic villus sampling (CVS). These are invasive tests which may be required if a problem is identified by antenatal screening and the woman accepts diagnostic testing. These standards and protocols are available on the ASW website: www.antenatalscreening.org

Pathways to support the antenatal screening programme in Wales are being developed by ASW and will be available on: www.mapofmedicine.com.

Document Design

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

The numbers in brackets following a standard or protocol refer to an explanatory note. These are available on pages 62 and 63.

2.0 Programme Governance Arrangements

2.1 Background

The importance of appropriate governance arrangements for screening programmes has been emphasised by the Welsh Assembly Government and the 2008–09 All Wales Operating Framework (WHC 2007, 086) states:

3.24 Screening

In 2008/2009, Trusts must be able to evidence that clear clinical governance measures are in place to ensure that the safety of the patient is paramount.

ASW does not provide or directly manage any antenatal screening services. Governance for the work of ASW is provided by the AWMMG and the three Sub Groups. The work of ASW is supported and assisted by Screening Services, which are part of Public Health Wales, and which have extensive expertise in the management and provision of population-based screening programmes.

2.2 Service Governance

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

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

- The Health Board should aim to provide services to meet the standards and protocols recommended by ASW, including the standards and protocols relating to the provision of amniocentesis and chorionic villus sampling (CVS) which have been published separately.¹
- All clinical incidents should be reported to the Health Board clinical incident reporting system.
- If, following identification and preliminary investigation by the provider service, an antenatal screening clinical incident is found to be caused by a system failure which the service judges could be present in other services in Wales, the antenatal screening coordinator 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.

2.3 Screening Pathways

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

- giving pre test information and offering the test
- requesting and providing the test
- the results handling process for each test
- antenatal screening counselling and support services
- meeting agreed timescales and monitoring arrangements
- necessary antenatal and immediate postnatal care and follow-up
- referral to other agencies if required.

¹ Amniocentesis and Chorionic Villus Sampling – Policy, Standards and Protocols (2008). Available on www.antenatalscreeningwales.org

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

Standard M 2

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

Standard M 3

Health Boards should identify named antenatal screening coordinators who are responsible for overall programme management and who should 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 an information and counselling service within the maternity service for women who have problems detected by antenatal screening
- (6) planning and providing a multiprofessional in-service education programme for health professionals involved in antenatal screening
- (7) reporting activity in an annual antenatal screening report to the Health Board
- (8) coordinating the supply of patient information to health professionals providing care
- (9) developing and auditing a pathway to enable the structured re-offer of antenatal syphilis, HIV and hepatitis B screening to women who initially decline
- (10) compiling and maintaining a list of contacts and contact numbers for the laboratories to enable effective and timely communication of urgent results from the laboratory to the maternity service.

3.2 Information for Women²

Standard M 4

Health Boards should make arrangements for women to receive written antenatal screening information in early pregnancy.

Standard M 5

If the woman does not understand English or requires sign language interpretation, Health Boards should use an approved interpreter service to enable the provision of accurate information and to obtain informed consent. ASW provides information leaflets in a number of languages to support this process, and a DVD is available with explanations in British Sign Language.

3.3 Record Keeping

Standard M 6

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

A contemporaneous, dated and signed record must be made in the maternity notes. This information must include:

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

² ASW has developed, printed and supplied written information for women on antenatal screening tests. A list of the information available and copies are available on: www.antenatalscreening.org

4.0 Antenatal Screening for HIV, Hepatitis B, Syphilis and Rubella Susceptibility

Policy Statement

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

- HIV (National Assembly for Wales 2000; NICE 2008)
- hepatitis B (WHC 1998 (36), NICE 2008)
- syphilis (NICE 2008)
- rubella susceptibility (NICE 2008).

HIV (Human Immunodeficiency Virus)

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

Rationale for Antenatal HIV Screening

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

Programme Limitations

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

Anticipated Outcome

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

Hepatitis B

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

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

Rationale for Hepatitis B Screening

To enable the identification of maternal hepatitis B carriers whose infants will be at significant risk of contracting hepatitis B at or around the time of delivery and enable the offer of post-exposure prophylaxis to the neonate.

Programme Limitations

The screening programme aims to detect women with established hepatitis B infection and not infections contracted in the weeks before the screening test is taken or infections contracted after the antenatal screening test 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 the sexual health services.

Anticipated Outcomes

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

Syphilis

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

Rationale for Syphilis Screening

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

Programme Limitations

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

If the screening test result shows suspicion of an infection, the result must be considered by the virologist in conjunction with the woman's clinical and social history before a diagnosis can be made.

Anticipated Outcomes

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

Rubella

Rubella (or German measles) is a mild infectious disease, most common in unimmunised populations among children aged 4 to 9 years. It causes a transient erythematous rash, lymphadenopathy and occasional arthralgia. For those infected after birth, there are no long-term problems. Maternal rubella in the first 8–10 weeks of pregnancy results in severe fetal damage in up to 90% of infants. The risk of defects declines to 10–20% for infection at 16 weeks gestation and, after this stage, fetal damage is rare.

Rationale for Rubella Susceptibility Screening

To enable the identification of maternal rubella susceptibility (i.e. antibodies less than 10 IU/ml). If identified by screening, these women can be given appropriate advice regarding immunisation with measles, mumps and rubella vaccine (MMR) following completion of the pregnancy. Women who are rubella susceptible should be offered and provided MMR vaccination by the maternity service after completion of the pregnancy.

Programme Limitations

Screening is to assess antenatal rubella susceptibility but does not enable vaccination in the pregnancy. The screening does not identify rubella infection in the mother or prevent the baby contracting congenital rubella in the current pregnancy.

Anticipated Outcomes

With appropriate post-pregnancy vaccination, the risk of the woman contracting rubella in subsequent pregnancies is reduced.

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

4.1.1 Pre Test Information

Standard C 1

The woman must be given verbal and written pre test information about infections in pregnancy and a record of the information provided made in the maternity notes.

- (1) A copy of the ASW 'Information for Women' pack (in an appropriate language and format, if available) should be provided before the woman is asked to consent to this test. (1)
- (2) The purpose, implications, limitations and benefits of these screening tests must be explained to the woman by the midwife. (2)
- (3) The midwife should make a record of written information given to the woman, including a record of any information given in other media, e.g. DVD or audio CD. (3)
- (4) For women who require more information, counselling or support, this service is available from the GUM/Sexual Health Service.

4.1.2 Screening Offer

Standard C 2

All women resident in Wales should be offered antenatal screening for HIV, hepatitis B, syphilis and rubella susceptibility.

- (1) Women who attend for antenatal care after 13 weeks of pregnancy should be offered screening for HIV, hepatitis B, syphilis and rubella susceptibility at the first opportunity.
- (2) Women who decline screening should be given a further written or verbal opportunity to have this screening test during pregnancy, preferably at the 28 week antenatal appointment.
- (3) Women who do not attend for antenatal care during the pregnancy and present during labour, should be offered screening for HIV, hepatitis B and syphilis on admission to the delivery suite. The midwife or doctor should contact the consultant microbiologist to ask for a risk assessment and to establish the urgency of testing and management whilst results awaited.

Standard C 3

Women who have not been offered screening for HIV, hepatitis B or syphilis in the antenatal period or intrapartum period must be offered these tests in the immediate postnatal period (within 4 hours of delivery) by the midwife caring for her.

4.1.3 Consent

Standard C 4

The woman's informed verbal consent is required for these tests.

- (1) Written consent is not required but a record of the woman's verbal consent must be made by the midwife in the maternity notes.
- (2) If the woman declines screening for HIV, hepatitis B or syphilis, the midwife should ensure the woman has received accurate information on which to base her decision.
- (3) Women who decline screening for HIV, hepatitis B or syphilis should be given a further written or verbal opportunity to consent to these screening tests during pregnancy, preferably at the 28 week antenatal appointment.

4.1.4 Test Requesting

Standard C 5

The laboratory request form must require the name and signature of the requester. Electronic requesting must enable a clear audit trail to identify the requester. (4)

Standard C 6

The health professional requesting the test must complete and sign the request form. (4)

Standard C 7

The test request must be identified as 'antenatal screening'.

Standard C 8

All mandatory fields on the laboratory request must be completed.

Standard C 9

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

- (1) If the woman is more than 24 weeks pregnant when the sample is taken, the sample should be marked urgent. This sample should then be processed by the laboratory as soon as possible.
- (2) If the woman is in labour or is postnatal when the sample is taken, the midwife should contact the consultant microbiologist to ask for a risk assessment and to establish the urgency of testing and management of the woman whilst the results are awaited.

4.1.5 Test Procedure

Standard C 10

Whenever possible, the sample should be taken before 13 weeks of pregnancy.

Standard C 11

The person taking the sample must make a signed and dated record of the sample being taken in the maternity notes.

- (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) This screening test can be performed most cost effectively on one laboratory sample for antenatal screening tests for HIV, hepatitis B, syphilis and rubella susceptibility. Any combination of these screening tests can be performed on one 5ml plain tube sample.

Standard C 12

Maternity services must develop a clear system for confirmation of the sample identity.

- (1) This process must include asking the woman to state her name, date of birth and address and these must be identical to the information on the request form and the sample.

4.1.6 Laboratory Services

Standard C 13

The laboratory must be appropriately accredited in accordance with CPA (Clinical Pathology Accreditation), now part of UKAS (United Kingdom Accreditation Service) and able to demonstrate satisfactory performance.

Standard C 14

The sample should be received by the local laboratory within one working day of the sample being taken. *Minimum standard 90%*

Standard C 15

If the sample is forwarded to another laboratory, the sample should be received by the testing laboratory within two working days of the sample being taken. *Developmental minimum standard 90%*

Standard C 16

The testing laboratory should aim to achieve a five working day turn-around from sample receipt to result reporting for non urgent samples. *Developmental minimum standard 90%*

Standard C 17

Samples marked 'urgent' should be processed and reported as soon as possible.

Standard C 18

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

4.1.7 Results

Standard C 19

The Health Board should ensure that the results of HIV, hepatitis B or syphilis antenatal screening are not electronically transferred from the laboratory to the maternity or other services unless appropriate security arrangements are in place to ensure the result can only be accessed by agreed named individuals.

Standard C 20

If the sample has not been tested at the local laboratory, the result should be returned to the local laboratory within one working day of the result being signed out by the testing laboratory. *Developmental minimum standard 90%*

Standard C 21

The result should be available to the maternity service within one working day of the result being reported by, or to, the local laboratory. *Developmental minimum standard 90%*

- (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 22

The antenatal screening coordinator must compile and maintain a list of contacts and contact numbers to enable effective and timely communication of urgent results.

Standard C 23

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

Standard C 24

There must be a written and agreed process in place to identify and follow up results not received by the maternity service and where an additional sample is required by the laboratory.

Standard C 25

Where no problem is found, women should be informed of the results by the maternity service within 15 working days of the sample being taken. *Minimum standard 90%*

Standard C 26

The result must be recorded in the maternity notes.

- (1) A dated and signed record that the result has been discussed with the woman must be made in the maternity notes.
- (2) The woman should be reminded of how to protect herself from infection in the future.

4.2 Specific Standards and Protocols for Antenatal HIV Screening

4.2.1 Previous Infection

Standard C 27

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

Standard C 28

Women who are aware they are HIV positive should be referred to the GUM/Sexual Health Service to enable the development of a joint care plan.

4.2.2 HIV Positive Results

Standard C 29

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

Standard C 30

The result must be given to the woman within five working days whenever possible.

- (1) Arrangements should be made for pregnant women to return to the antenatal clinic to be given her HIV positive result as soon as possible and when the necessary healthcare professionals are available.
- (2) Interpreter services should be arranged if required.
- (3) HIV is a relatively rare infection in Wales; only named health professionals with suitable skills and knowledge as agreed by the Health Board (i.e. a consultant obstetrician or antenatal screening coordinator with support from a member of the HIV specialist team) should give the result to the woman.
- (4) Sensitive results, including communicable disease positive results, should be given in a clinic setting (not in the woman's home) as the health professional will have more control over the confidentiality of the environment.

- (5) To maintain confidentiality, the woman should be given the result in person, without other relatives or friends being present.
- (6) Unless the General Practitioner requested the test and is providing the woman with the result, the General Practitioner should not be informed of the result before the woman has given her consent for the General Practitioner to be informed.
- (7) For complete confirmation of sample identity, a second sample will be required.
- (8) Written information (in an appropriate language if available) should be given to the woman. A suitable information leaflet is available from ASW.

4.2.3 Record Keeping

Standard C 31

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

- (1) HIV positive screening results should not be recorded in the woman's hand held notes without her consent.
- (2) A record of the confirmed positive test result should be recorded on the maternity information system with the woman's informed consent.
- (3) A record of the confirmed positive test result should be recorded appropriately in the hospital maternity notes and the confidentiality of the information ensured by Health Board confidentiality policies.

4.2.4 Care Plan

Standard C 32

An urgent referral to the GUM/Sexual Health Service (or Infectious Disease Consultant) is required so that suitable treatment can be commenced promptly.

- (1) Sexual contacts require the offer of screening for HIV via the GUM/Sexual Health Service.
- (2) An appropriate integrated care plan should be developed in accordance with BHIVA guidance and must be developed in discussion with the woman and with the advice of a multidisciplinary team. This may take a number of visits and discussions. The woman will require adequate time to consider her diagnosis before the care planning process can start. The type of care required will depend on the woman's viral load and other factors and must be managed by a specialist HIV team.
- (3) Paediatric referral should be made at an appropriate time during the antenatal period.
- (4) The woman will require ongoing support from a named midwife and all maternity care arrangements should be coordinated by the antenatal screening coordinator.
- (5) Interpreter services should be arranged for every antenatal clinic visit if required.
- (6) The result should not be given by the maternity staff to the woman's partner or relatives without the woman's consent. The result should not be given to the General Practitioner or Health Visitor without the woman's consent. Discussing these issues should form part of a comprehensive care plan developed with the HIV Specialist Team.

4.2.5 Postnatal Care

Standard C 33

Breastfeeding should be discouraged as the HIV virus can be transmitted in breast milk.

- (1) Free formula milk is available to HIV positive women in Wales.
- (2) The baby will require specific follow up usually including treatment with antiretroviral drug treatment coordinated by the paediatrician.

4.2.6 Postnatal Offer of HIV Screening

Standard C 34

Women who have not been offered screening for HIV, hepatitis B, syphilis in the antenatal or intrapartum period must be offered these tests in the immediate postnatal period (within 4 hours of delivery) by the midwife caring for her.

- (1) The midwife or doctor should contact the consultant microbiologist to ask for a risk assessment and to establish the urgency of testing and management of the mother and baby whilst the results are awaited.

4.3 Specific Standards and Protocols for Antenatal Hepatitis B Screening

4.3.1 Previous Infection

Standard C 35

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

- (1) The woman should be advised that if the infection is ongoing the baby will require vaccination and may require immunoglobulins.
- (2) The Health Protection Team should be informed the woman is pregnant to enable care planning to commence.

4.3.2 Hepatitis B Positive Results

Standard C 36

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

Standard C 37

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

- (1) Interpreter services should be arranged if required.
- (2) Hepatitis B is a relatively rare infection in Wales; only named health professionals with suitable skills and knowledge as agreed by the Health Board (i.e. a consultant obstetrician or antenatal screening coordinator), should give the result to the woman.
- (3) Unless the woman is known to be in labour or more than 24 weeks pregnant, there is no immediate urgency to give this result, and suitable arrangements should be made for the woman to return to the antenatal clinic usually within a week to receive the result.
- (4) Sensitive results, including communicable disease results, should be given in a clinic setting (not in the woman's home) as the health professional will have more control over the confidentiality of the environment.
- (5) To maintain confidentiality, the woman should be given the result in person, without other relatives or friends being present.
- (6) Unless the General Practitioner requested the test and is providing the woman with the result, the General Practitioner should not be informed of the result before the woman has given her consent for the General Practitioner to be informed.
- (7) For complete confirmation of sample identity, a second sample will be required.
- (8) Written information (in an appropriate language if available) should be given to the woman. A suitable information leaflet is available from ASW.

Standard C 38

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

- (1) Hepatitis B positive screening results should not be written in the woman's hand held notes without her consent.
- (2) A record of the confirmed positive test result should be recorded on the maternity information system with the woman's informed consent.
- (3) A record of the confirmed positive test result should be recorded appropriately in the hospital maternity notes and the confidentiality of the information ensured by Health Board confidentiality policies.

4.3.3 Care Plan

Standard C 39

Arrangements should be made in the antenatal period for infants of women who are hepatitis B positive to receive appropriate treatment rapidly after birth. (5)

- (1) Maternal consent should be obtained at a suitable time during the antenatal period for the baby to receive appropriate immunisation in the very early postnatal period.
- (2) The General Practitioner should not be informed before the woman has been given the result, as screening of other family members may inadvertently be instigated by the General Practitioner prior to the woman first being informed of her result.

- (3) Hepatitis B specific immunoglobulin (HBIG), to provide short term passive immunity (or protection), for those babies born to the most infectious mothers should be ordered from the Health Protection Team for babies of named mothers ensuring availability from when the woman is 32–34 weeks pregnant. (5)
- (4) Women with chronic hepatitis B infection should be referred, by the lead professional, during the antenatal period for further assessment by a gastroenterologist, hepatologist or infectious disease specialist (dependent on availability of local services).
- (5) The care plan may require discussion with the paediatrician and virologist.
- (6) The Health Protection Team must arrange for household contacts to receive counselling and the offer of screening for hepatitis B (WHC 1998 (36)).

4.3.4 Postnatal Care

Standard C 40

Arrangements should be in place for the baby to receive the accelerated immunisation schedule recommended for post exposure prophylaxis. (5)

- (1) Babies born to women who are hepatitis B positive will require (with maternal consent) immunisation in accordance with 'Screening of pregnant women for hepatitis B and immunisation of babies at risk' (WHC 1998 (36)).
- (2) An unscheduled vaccination form should be completed and sent to the Child Health Department after the vaccination has been given.
- (3) The importance of the baby receiving the full course of immunisations should be explained to the mother by the community midwife.
- (4) The woman can be encouraged to breastfeed if the baby is immunised/vaccinated.

4.3.5 Postnatal Offer of Hepatitis B Screening

Standard C 41

Women who have not been offered a hepatitis B screening test in the antenatal period must be offered the test in the immediate postnatal period (within 4 hours of delivery) by the midwife caring for her.

- (1) The midwife or paediatrician should contact the consultant microbiologist to ask for a risk assessment and to establish the urgency of testing and management whilst results are awaited.

4.4 Specific Standards and Protocols for Antenatal Syphilis Screening

4.4.1 Previous Infection

Standard C 42

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

4.4.2 Syphilis Positive Results

Standard C 43

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

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

Standard C 44

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

- (1) Interpreter services should be arranged if required.
- (2) Syphilis is a rare condition in the UK; only health professionals with suitable skills and knowledge as agreed by the Health Board (i.e. a consultant obstetrician or antenatal screening coordinator with support from a member of the GUM/Sexual Health Service) should give the result to the woman.
- (3) Sensitive results, including communicable disease results, should be given in a clinic setting (not in the woman's home) as the health professional will have more control over the confidentiality of the environment.
- (4) To maintain confidentiality, the woman should be given the result in person, without other relatives or friends being present.
- (5) Unless the General Practitioner requested the test and is providing the woman with the result, the General Practitioner should not be informed of the result before the woman has given her consent for the General Practitioner to be informed.
- (6) For complete confirmation of sample identity, a second sample will be required.
- (7) The woman should be informed of the possible significant health risks to the baby and the need for treatment.
- (8) Written information (in an appropriate language if available) should be given to the woman. A suitable information leaflet is available from ASW.

4.4.3 Care Plan

Standard C 45

Women with a confirmed syphilis positive result should have an urgent referral to a specialist in GUM/Sexual Health Service for assessment, counselling and possible treatment.

- (1) Treatment with antibiotics (if required) should be commenced promptly by the GUM/Sexual Health Service specialist to reduce the risk of fetal damage caused by maternal to fetal transmission of syphilis.
- (2) Arrangements must be made by the GUM/Sexual Health Service for any sexual contacts to receive counselling and the offer of screening for syphilis.
- (3) Follow-up care and management should be planned in conjunction with the consultant obstetrician and the GUM/Sexual Health Service and a care plan should be written in the hand held notes.
- (4) Referral to fetal medicine department for ultrasound to evaluate fetal involvement including non-immune hydrops or hepatosplenomegaly and fetal monitoring for fetal distress in the early stages of therapy is recommended after 26 weeks gestation (BASHH 2008).

Standard C 46

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

- (1) Syphilis positive screening results should not be written in the woman's hand held notes without her consent.
- (2) A record of the confirmed positive test result should be recorded on the maternity information system with the woman's informed consent.
- (3) A record of the confirmed positive test result should be recorded appropriately in the hospital maternity notes and the confidentiality of the information ensured by Health Board confidentiality policies.

Standard C 47

The paediatrician should be informed of the maternal syphilis infection in the antenatal period to enable an appropriate care plan to be developed with the woman and the maternity services for the neonate.

4.4.4 Postnatal Care

- (1) Maternal and neonatal bloods should be taken just after delivery before treatment of the baby is started. The exact requirements should be discussed with the virologist before delivery.
- (2) Arrangements must be made for the neonate to receive paediatric follow-up including appropriate treatment and serology testing (BASHH 2008).

4.4.5 Postnatal Offer of Syphilis Screening

Standard C 48

Women who have not been offered a syphilis screening test in the antenatal period must be offered the test in the immediate postnatal period (within 4 hours of delivery) by the midwife caring for her.

- (1) The midwife or paediatrician should contact the consultant microbiologist to ask for a risk assessment and to establish the urgency of testing and management whilst results awaited.

4.5 Specific Standards and Protocols for Antenatal Rubella Susceptibility Screening

4.5.1 Pre Test Information and Diagnostic Testing

- (1) The woman must be informed that rubella susceptibility screening cannot identify current or recent rubella infection in the woman, or prevent congenital rubella infection in the fetus.
- (2) Screening for rubella susceptibility only enables the identification of women who are susceptible to rubella. These should then be offered post pregnancy immunisation with MMR (WHC 2003a (94)).

Standard C 49

Women who present in early pregnancy with a rash, or recent history of a rash, should be offered screening for rubella susceptibility and should also be offered a diagnostic test for rubella, parvovirus and measles as soon as possible.

- (1) Women who have had recent contact with a confirmed case of rubella and who have not had rubella specific IgG antibodies of 10 IU/ml or greater confirmed by laboratory testing on two previous occasions should be offered diagnostic testing for a primary rubella infection.
- (2) Advice on this testing is available from the local Health Protection Team.
- (3) The midwife should use the laboratory request form determined by the Health Board and give full clinical details, including dates of contact, to enable accurate laboratory reporting.

4.5.2 Results

Standard C 50

The rubella susceptibility screening result should be reported by the laboratory and should indicate whether postnatal vaccination with MMR is advised.

- (1) If the rubella antibody level is 10 IU/ml or more, the woman should be informed that she is likely to be protected against rubella.
- (2) If the woman is rubella susceptible (i.e. rubella antibody level less than 10 IU/ml), she should be informed she will be offered postnatal MMR.

- (3) Verbal and written information about rubella susceptibility (in an appropriate language if available) should be given to women who are rubella susceptible. A suitable information leaflet is available from ASW.
- (4) The woman should be advised to report to her midwife or General Practitioner any suspected contact with a person who has rubella or any rubella like rash before 20 weeks of pregnancy. With advice from the Health Protection Team and the woman's consent, testing for viral studies can be arranged.
- (5) If rubella is contracted in early pregnancy there is a significant risk of the fetus developing congenital rubella syndrome and further management of the pregnancy should be based on an informed risk assessment by an obstetrician with advice from the Health Protection Team.
- (6) Immunisation of women with MMR in pregnancy should be avoided. In the case of inadvertent immunisation in early pregnancy a termination is not advised due to the low risk of MMR vaccine causing congenital rubella syndrome (NICE 2008).

Standard C 51

A contemporaneous, dated and signed record must be made in the maternity notes of actions undertaken and planned in response to a rubella susceptible result.

4.5.3 Postnatal Care

Standard C 52

When the pregnancy is completed, the first immunisation with MMR must be offered and provided by the maternity service to women who are rubella susceptible.

Standard C 53

A contemporaneous, dated and signed record must be made in the maternity notes of:

- the date MMR vaccine is offered to women who are susceptible to rubella
- whether the vaccination is accepted or declined
- the date MMR vaccine is given and by whom and the batch number.

- (1) If the woman has hospital care, this immunisation should be offered before the woman is transferred home.
- (2) The woman should be advised to avoid conception for at least one month after the vaccination (British National Formulary 2009).
- (3) Information that the vaccination has been given should be provided to the General Practitioner in the hospital discharge letter.
- (4) MMR vaccine may be given in the postnatal period simultaneously with anti-D immunoglobulin (Ig) injection, provided that separate syringes are used and the products are administered into different limbs.
- (5) The woman should be informed by the midwife that she requires a second MMR vaccination at her General Practitioner's surgery in 4 weeks. This information needs to be documented on the discharge letter (Department of Health 2006, p. 350).

5.0 Antenatal Sickle Cell and Thalassaemia Screening

Policy Statement

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

Sickle cell and Thalassaemia

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

Rationale for Screening

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

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

Anticipated Outcome

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

5.1 Pre Test Information

Standard SCT 1

The woman must be given verbal and written pre test information and a record of the information provided made in the maternity notes.

- (1) A copy of the ASW 'Information for Women' pack (in an appropriate language and format, if available) should be provided before the woman is asked to consent to this test. (1)
- (2) The purpose, implications, limitations and benefits of this screening test must be explained to the woman by the midwife. (2)
- (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.
- (4) The midwife should make a record of written information given to the woman, including a record of any information given in other media, e.g. DVD or audio CD. (3)

5.2 Screening Question

Standard SCT 2

The woman should be asked the ASW family origin screening question (ASW FOQ) for sickle cell and thalassaemia in every pregnancy.

- (1) The ASW FOQ should be asked by the midwife to assess whether laboratory screening for sickle cell and thalassaemia should be offered.
- (2) If the result of the ASW FOQ suggests that the woman has a low chance of having sickle cell or thalassaemia, the woman can be informed by the midwife that she has a low chance of having a baby with a sickle cell disorder or thalassaemia major and that laboratory screening is not recommended.
- (3) The woman should be informed that as part of her full blood count estimation for anaemia, thalassaemia can sometimes be identified or suspected.

Standard SCT 3

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

5.2.1 If Laboratory Screening is Recommended by the ASW FOQ

Standard SCT 4

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

- (1) The woman should be offered laboratory screening for sickle cell and thalassaemia in every pregnancy if one or more of the following applies:
 - the woman or the biological father of the baby has a family history of sickle cell or thalassaemia
 - the woman's family origins or those of the biological father, no matter how many generations back, are from anywhere outside of the UK or Republic of Ireland
 - the woman's family origins or those of the biological father are unknown, e.g. the woman was adopted
 - the woman has a history of unexplained anaemia.
- (2) The woman should be informed that if the screening test result shows she carries sickle cell or thalassaemia or has a haemoglobin disorder, screening of the biological father is required for the most accurate pregnancy risk assessment.

5.2.2 Women Previously Diagnosed with a Haemoglobin Disorder, or who are Carriers, or if the Biological Father of the Baby has a Haemoglobin Disorder or is a Carrier

Standard SCT 5

If the woman indicates that she has been previously diagnosed with a haemoglobin disorder, she should be re-screened and the relevant information should be included on the request form.

Standard SCT 6

Women known to have haemoglobin disorders should be referred for joint haematology/obstetric care.

- (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, confirmation of the result should be obtained either from the haemoglobinopathy card, from the laboratory, or he should be offered re-screening.
- (3) If the woman and the biological father of the baby carry a sickle cell or thalassaemia or haemoglobin disorder there is a risk of a significant disorder being inherited by the fetus and diagnostic testing should be offered by the midwife.
- (4) If diagnostic testing is accepted by the woman, an urgent appointment should be offered with the All Wales Medical Genetics Service for a fast-track appointment with a fetal medicine unit.

5.3 Consent

Standard SCT 7

The woman's informed verbal consent is required for this test.

- (1) Written consent is not required, but a record of the woman's verbal consent must be made in the maternity notes.
- (2) If the woman declines to answer the ASW FOQ for sickle cell and thalassaemia, 'declined to answer screening question' should be recorded in the maternity notes.
- (3) The full blood count test offered to women in pregnancy to diagnose and monitor anaemia includes an estimation of the mean cell haemoglobin (MCH). Women should be asked if they consent to screening for sickle cell and thalassaemia if suggested by this laboratory result.

5.4 Test Requesting

Standard SCT 8

The laboratory request form must require the name and signature of the requester. Electronic requesting must enable a clear audit trail to identify the requester.

Standard SCT 9

The health professional requesting the test must complete and sign the request form. (4)

Standard SCT 10

All requests must be identified as 'antenatal screening'.

Standard SCT 11

All mandatory fields for the laboratory request must be completed.

- (1) The laboratory will require information about the woman's and the biological father's family origins to interpret the laboratory result.
- (2) If the woman has consented to further testing if indicated by the full blood count result, this consent should be documented on the request card.

5.5 Test Procedure

Standard SCT 12

Whenever possible, the screening test should be offered and the sample taken in early pregnancy (NICE 2008).

- (1) If the screening process (including screening the biological father of the fetus if required) is conducted in a timely manner, CVS rather than amniocentesis may be a preferable option for women who wish to access diagnostic testing. (6)

Standard SCT 13

The person taking the sample must make a signed and dated record of the sample being taken in the maternity notes.

- (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.

Standard SCT 14

The maternity services must develop a clear system for confirmation of the sample identity.

- (1) This process must include asking the woman to state her name, date of birth and address and these must be identical to the information on the request form and the sample.

5.6 Laboratory Services

Standard SCT 15

The laboratory must be appropriately accredited in accordance with CPA (Clinical Pathology Accreditation), now part of UKAS (United Kingdom Accreditation Service) and able to demonstrate satisfactory performance.

Standard SCT 16

As a minimum requirement, the screening test algorithm used by the laboratory should follow the NSC guidelines and algorithm for low prevalence areas (NHS Sickle Cell and Thalassaemia Screening Programme 2009).

- (1) The laboratory must not undertake sickle cell and thalassaemia screening without the woman's consent being indicated on the request card.
- (2) Initial screening for sickle cell and thalassaemia should be a full blood count (FBC) usually followed by high performance liquid chromatography (HPLC)(NICE 2008).

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

Standard SCT 17

The sample should be received by the local laboratory within one working day of the sample being taken. *Developmental minimum standard 90%*

Standard SCT 18

If the sample is forwarded to another laboratory, the sample should be received by the testing laboratory within two working days of the sample being taken. *Developmental minimum standard 90%*

Standard SCT 19

The testing laboratory should aim to achieve a five working day turn-around from sample receipt to result reporting. *Developmental minimum standard 90%*

5.7 Results Handling

Standard SCT 20

If the sample has not been tested at the local laboratory, the result should be returned to the local laboratory within one working day of the result being signed out by the testing laboratory. *Developmental minimum standard 90%*

Standard SCT 21

The result should be available to the maternity service within one working day of the result being reported by, or to, the local laboratory. *Developmental minimum standard 90%*

- (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 the immediate management of care.
- (2) If the MCH is 27pg or below on the full blood count result and screening was declined, a further opportunity should be offered for screening when the full blood count results are explained.

Standard SCT 22

There must be a written and agreed process in place to identify and follow up screening test results not received.

Standard SCT 23

The result must be recorded in the maternity notes.

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

5.7.1 Result with no Evidence of Sickle Cell or Thalassaemia

Standard SCT 24

Women should be informed that there is no evidence of sickle cell or thalassaemia by the maternity service within 15 working days of the sample being taken. *Minimum standard 90%*

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

5.7.2 Maternal Sickle Cell or Thalassaemia Screen Positive

Standard SCT 25

The consultant obstetrician and antenatal screening coordinator (or named deputy) or sickle cell and thalassaemia counsellor should be informed of the screen positive result within one working day by the laboratory.

Standard SCT 26

Arrangements should be made for the woman to return to the antenatal clinic to be given her result within three working days.

- (1) Interpreter services should be arranged if required.
- (2) If the woman is a sickle cell or thalassaemia carrier or has a haemoglobin disorder, she should be given written and verbal information about her diagnosis. She should be informed by an appropriately trained professional that the chance of her having a fetus with an inherited sickle cell disorder or thalassaemia major will depend on whether the biological father of the fetus is also a carrier of sickle cell or thalassaemia.
- (3) If the woman has a haemoglobin disorder she should be referred for joint haematology/obstetric care.

Standard SCT 27

If the woman wishes to know the risk to the baby, with the woman's consent, the maternity services should offer the biological father of the fetus, sickle cell and thalassaemia screening.

- (1) If the biological father has previously been screened, confirmation of the result should be obtained either from the haemoglobinopathy card, from the laboratory, or he should be offered re-screening.

Standard SCT 28

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

- (1) The antenatal screening coordinator or sickle cell and thalassaemia counsellor, should coordinate the linking of results and provide the necessary information for the laboratory to ensure that the biological father's result is available to be considered with the woman's result.
- (2) The sample should clearly be marked 'urgent' and the laboratory informed that the sample should be expected.
- (3) If the biological father is screened and the result shows that he is a sickle cell or thalassaemia carrier or has a haemoglobin disorder, the risks to the fetus will depend on the potential interaction between the specific haemoglobin variants of the parents.
- (4) Expert advice and a risk assessment is required from a haematologist with appropriate knowledge and skills to assess the risk to the fetus. The woman may be offered antenatal diagnostic testing after the risk to the fetus has been established by a haematologist.
- (5) If the biological father is screened and does not carry sickle cell or thalassaemia, the woman can be informed by an appropriately trained professional that the chance of her having a child affected by a sickle cell disorder or thalassaemia major is very low and antenatal diagnostic testing is not recommended.

- (6) The woman should also be advised that the risk in any future pregnancy should be reassessed pre-conceptually or as soon as she is aware of the pregnancy if she has a different partner. This can be performed via a sickle cell and thalassaemia centre or her General Practitioner.
- (7) If the biological father of the fetus is not available, declines to be tested, or the woman does not consent to him being contacted, a risk assessment should be undertaken by the Health Board haematologist to advise the maternity service of the risk to the fetus. This assessment should be based on the ethnicity of the woman and that of the biological father. An amniocentesis or CVS should be offered as appropriate.
- (8) If antenatal diagnostic testing is declined, neonatal sickle cell testing should be recommended.

Standard SCT 29

Where antenatal diagnostic invasive testing is accepted, the policy, standards and protocols for amniocentesis and chorionic villus sampling should be followed.

- (1) To assist in interpreting the results, antenatal CVS or amniocentesis diagnostic samples for haemoglobinopathies must be accompanied by a 10ml blood sample in an EDTA bottle taken on the day of the procedure from the mother.
- (2) A sample is also required from the biological father of the baby if he is available.
- (3) If an amniocentesis procedure is performed, 20ml of amniotic fluid is required by the laboratory.

5.7.3 Postnatal Care

Standard SCT 30

Neonatal testing for sickle cell disorders should be offered if the baby has a high chance of inheriting a sickle cell or other significant haemoglobin disorder.

- (1) All Health Boards must have a policy regarding which babies should be offered neonatal testing for sickle cell disorders.
- (2) Cord blood is not suitable for this test, and the required sample is 0.3-1ml of blood, in a paediatric EDTA bottle.

6.0 Antenatal Down's Syndrome Screening

Policy Statement

Antenatal screening for Down's syndrome should be offered to all pregnant women (NICE 2008; WHC 2003b (127)).

Down's Syndrome

Down's syndrome is the most common chromosomal anomaly and is caused by abnormalities involving the presence of additional genetic material associated with chromosome pair 21. Overall this condition usually occurs approximately once in every 500 to 600 pregnancies with the prevalence increasing with maternal age.

Rationale for Screening

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

Anticipated Outcomes

Women who have a pregnancy affected by Down's syndrome will have reproductive choices.

Screening Test Options

The screening tests commonly available for Down's syndrome screening both involve the use of ultrasound measurements of the fetus and a blood test for biochemical markers to contribute towards calculating the chance of Down's syndrome in the pregnancy. Women can use this risk assessment result to decide whether they wish to accept the offer of an invasive test (CVS or amniocentesis) to enable cytogenetic diagnostic testing.

The UK NSC (2008) and NICE (2008) have recommended that the screening test should be able to demonstrate a detection rate of 75% for a screen positive rate of less than 3%. The second trimester triple test is not able to meet this standard.

The screening test which is recommended in the first trimester (up to 13 weeks and 6 days of pregnancy) is the 'combined test'. This test uses an ultrasound measurement to assess the gestation and a measurement of the fetal neck (the nuchal translucency or NT) with the results from the biochemical markers to give the woman the result in early pregnancy.

The UK NSC and NICE have both recommended that this first trimester test should be available to pregnant women who first attend for care in early pregnancy.

The screening test which is recommended in the second trimester (from 15 to 20 weeks of pregnancy) is the 'quadruple test'. These tests use an ultrasound measurement to assess the gestation with the results from biochemical markers to give the woman the result in mid pregnancy.

The UK NSC and NICE have both recommended that a second trimester test should be available to pregnant women who do not attend for care in time to be offered the first trimester Down's syndrome screening test.

6.1 Pre Test Information

Standard DS 1

The woman must be given verbal and written pre test information and a record of the information provided made in the maternity notes.

- (1) A copy of the ASW 'Information for Women' pack (in an appropriate language and format, if available) should be provided before the woman is asked to consent to this test. (1)
- (2) The purpose, implications, limitations and benefits of this screening test must be explained to the woman by the midwife. (2)
- (3) The midwife should explain to the woman that Down's syndrome is a lifelong genetic condition and that some people with Down's syndrome will have associated abnormalities. People with Down's syndrome can have a good quality of life. Some people with Down's syndrome can live semi-independently while others will require full time care.
- (4) The midwife should make a record of written information given to the woman, including a record of any information given in other media, e.g. DVD or audio CD. (3)
- (5) The woman must be informed that if the test result places her in a 'higher chance' group she will be offered antenatal diagnostic testing.
- (6) The risks of miscarriage associated with antenatal diagnostic testing should be explained.

6.2 Screening Test Offer

Standard DS 2

Antenatal screening for Down's syndrome should be offered to all pregnant women.

- (1) If the sample is taken at the correct time but the laboratory is unable to report a result, the woman should be offered a discussion to consider whether alternative options are available. This may include offering an amniocentesis based on maternal age or screening by a laboratory able to provide testing in pregnancies up to 20 weeks of pregnancy.
- (2) If the woman has a family member with Down's syndrome, enquiries should be made into whether the type of Down's syndrome is known, as a familial translocation will increase the chance of inheriting Down's syndrome. Referral to the genetic services may be advised. Parental karyotyping should be considered on advice from the genetic services.
- (3) Women who have previously had a pregnancy affected by Down's syndrome should be offered a discussion with a consultant obstetrician, antenatal screening coordinator or geneticist prior to any screening. This is because the screening test result would be less reliable.
- (4) The Cardiff laboratory is not currently able to give a risk assessment for Down's syndrome in multiple pregnancies.

Standard DS 3

First trimester screening for Down's syndrome provided by Health Boards must meet the NSC standards and guidance (NSC 2007).

6.3 Consent

Standard DS 4

The woman's informed verbal consent is required for this test.

- (1) Written consent is not required, but a record of the woman's verbal consent must be made by the midwife in the maternity notes.

6.4 Test Requesting

Standard DS 5

The laboratory request form must require the name and signature of the requester. Electronic requesting must enable a clear audit trail to identify the requester.

Standard DS 6

The health professional requesting the test must complete and sign the request form. (4) (9)

Standard DS 7

All mandatory fields on the laboratory request must be completed.

- (1) The gestation must have been confirmed by ultrasound scan and the required ultrasound measurements must be included on the request card.
- (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.

Standard DS 8

Where first trimester screening for Down's syndrome is offered, the woman's consent to Down's syndrome screening must additionally be included on the early pregnancy ultrasound request card.

- (1) The name of the sonographer undertaking the NT measurement should be provided on the Down's syndrome screening request card.

6.5 Test Procedure

Standard DS 9

The person taking the sample must make a signed and dated record of the sample being taken in the maternity notes.

- (1) The woman's privacy must be respected. The discussion and tests must be performed in a place where the woman's privacy can be assured.
- (2) First trimester screening (the combined test) can only be undertaken between 11 weeks and 0 days and 13 weeks and 6 days gestation.
- (3) Second trimester screening can only be undertaken on samples between 15 weeks and 3 days and 18 weeks and 0 days of pregnancy by the Cardiff biochemistry laboratory.
- (4) For samples being processed at the Cardiff biochemistry laboratory, 3mls of venous blood in a serum separator tube (SST) is required for this test and if taking more than one blood sample at a time, the Down's syndrome screening sample must be taken first as contamination from the EDTA in other blood vacutainers can affect the result.
- (5) If second trimester screening is offered and there is a history of vaginal bleeding during pregnancy this may affect the AFP level. If timescales allow, it is preferable to delay taking the sample for one week after the bleeding has stopped as the presumed effect of the bleeding cannot be adjusted for by the laboratory.

Standard DS 10

Maternity services must develop a clear system for confirmation of the sample identity.

- (1) This process must include asking the woman to state her name, date of birth and address and these must be identical to the information on the request form and the sample.

Standard DS 11

There must be a written and agreed process in place to identify and follow up results not received.

6.6 Laboratory Services

Standard DS 12

The laboratory must be appropriately accredited in accordance with CPA (Clinical Pathology Accreditation, now part of UKAS (United Kingdom Accreditation Service) and able to demonstrate satisfactory performance.

Standard DS 13

There must be a 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 screening service.

Standard DS 14

The laboratory must submit screening data to Down's Syndrome Quality Advisory Service (DQASS) at least twice a year.

Standard DS 15

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

Standard DS 16

Developmental minimum standard to be achieved by September 2010.

The detection rate and false positive rate for the Down's syndrome screening programme must be monitored and a test used which can achieve a minimum standard of a 75% detection rate for a screen positive rate of less than 3%.

Standard DS 17

The sample should be received by the local laboratory within one working day of the sample being taken. *Developmental minimum standard 90%*

Standard DS 18

If the sample is forwarded to another laboratory, the sample should be received by the testing laboratory within two working days of the sample being taken. *Developmental minimum standard 90%*

Standard DS 19

The testing laboratory should aim to achieve a three working day turn-around from when the sample is received. *Minimum standard 90%*

6.7 Results Handling

Standard DS 20

The result of Down's syndrome serum screening should be available to the maternity service within three working days of the sample reaching the testing laboratory. *Minimum standard 95%*

- (1) The antenatal screening coordinator or deputy should coordinate the results handling process.

6.7.1 Lower Chance of Down's Syndrome Results

Standard DS 21

Women with a lower chance Down's syndrome screening result should be informed of the result by the maternity service within 10 working days of the sample being taken.

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

Standard DS 22

The result must be recorded in the maternity notes.

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

6.7.2 Higher Chance of Down's Syndrome (a chance of 1:2 to 1:150)

Standard DS 23

Women who have a higher chance Down's syndrome screening result should be informed of the result by the maternity service within five working days of the sample being taken.

- (1) The woman should be informed by letter or telephone call (according to local arrangements and/or the woman's preference) that she has been identified as being in the group of women who are offered a diagnostic test.
- (2) The result should not usually be given during the weekend or on Friday afternoon unless the woman has access to health professionals who can discuss the result and give accurate information about CVS and/or amniocentesis.

Standard DS 24

An appointment should 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.

- (1) Interpreter services should be arranged if required.
- (2) An additional or early fetal anomaly ultrasound scan or 'marker' scan is not recommended and should not be used to modify the result.
- (3) The midwife should discuss the short and long term, medical and social implications of Down's syndrome.
- (4) Whenever possible, a copy of the ASW 'Information for women who have a higher chance of Down's syndrome' leaflet should be given to the woman at this visit. This literature includes contact information for the Down's Syndrome Association and Antenatal Results and Choices (ARC).

Standard DS 25

The woman should be offered a diagnostic test (i.e. CVS or amniocentesis) appropriate to her gestation.

- (1) The discussion should include information about:
 - the diagnostic tests available (amniocentesis or CVS)
 - the risk of miscarriage associated with diagnostic testing
 - PCR and karyotyping and the information which these diagnostic tests can give
 - any other information requested by the woman to enable her to make an informed decision regarding antenatal diagnostic testing.

- (2) The midwife should also discuss pregnancy choices following an 'abnormal' result if diagnostic testing is accepted.
- (3) Termination of pregnancy should be discussed including that feticide is recommended if the gestation is more than 21 weeks and 6 days.
- (4) The woman should have sufficient time in order to feel comfortable about making a decision (usually at least 24 hours) regarding whether to accept or decline antenatal diagnostic testing.
- (5) Whenever possible, a copy of the ASW 'Amniocentesis' and 'CVS' leaflet should be given to the woman at this visit. This literature includes contact information for the Down's Syndrome Association and Antenatal Results and Choices (ARC).

Standard DS 26

A contemporaneous, dated and signed record must be made in the maternity notes of actions planned and undertaken for women with a higher chance of having a baby with Down's syndrome.

7.0 Ultrasound Screening in Pregnancy

Policy Statement

All women resident in Wales should be offered an early pregnancy ultrasound scan before 13 weeks and 6 days of pregnancy (WHC 2003b; NICE 2008) and a fetal anomaly ultrasound scan at 18 weeks and 0 days to 20 weeks and 6 days of pregnancy (RCOG 2000; NICE 2008).

Early Pregnancy Scan

Rationale for Screening

The early pregnancy ultrasound scan is offered to determine viability, the gestational age and to detect multiple pregnancies (fetal number and chorionicity/amnionicity). Measurements to determine the gestational age are required for the Down's syndrome screening programme and using ultrasound derived gestation reduces the need for post term induction of labour (NICE 2008). Some major fetal anomalies may be detected, but this is not the primary purpose of this scan. Where first trimester screening for Down's syndrome 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 Down's syndrome screening programme.

Fetal Anomaly Ultrasound Scan

Rationale for Screening

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

For some conditions, preventive treatment is available during the antenatal period or after delivery to improve the baby's health. For others, the condition can be identified by ultrasound scanning but no preventive treatment is available. Women can make an informed decision about whether they wish to continue the pregnancy (Choices, Velindre NHS Trust 2002).

Anticipated Outcome

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

7.1 General Standards for Early Pregnancy and Fetal Anomaly Scans

7.1.1 Pre Test Information

Standard US 1

The woman must be given verbal and written pre test information and a record of the information provided made in the maternity notes.

- (1) A copy of the ASW 'Information for Women' pack (in an appropriate language and format, if available) should be provided before the woman is asked to consent to this ultrasound scan. (1)

- (2) The purpose, implications, limitations and benefits of this ultrasound scan must be explained to the woman by the midwife. (2)
- (3) The midwife should make a record of written information given to the woman, including a record of any information given in other media, e.g. DVD or audio CD. (3)
- (4) Women who wish to have an early pregnancy or fetal anomaly ultrasound scan, but do not wish to be informed if abnormalities are found should be advised that all significant findings seen on the scan will be reported and they should consider not having the ultrasound scan.
- (5) Where first trimester Down's syndrome screening is provided, the standards and protocols in section 6 should also be met.

7.1.2 Offer of Ultrasound Scans

Standard US 2

All women should be offered an early pregnancy ultrasound scan before 13 weeks and 0 days of pregnancy and a fetal anomaly ultrasound scan at 18 weeks and 0 days to 20 weeks and 6 days of pregnancy.

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

7.1.3 Consent

Standard US 3

The woman's informed verbal consent is required for this ultrasound scan.

- (1) Written consent is not required, but a record of the woman's verbal consent must be made in the maternity notes and on the ultrasound request card.
- (2) Where first trimester screening for Down's syndrome is offered the woman must additionally be asked to consent to or decline Down's syndrome screening and a record of her decision must be made in the maternity notes and on the ultrasound request card.

7.1.4 Test Requesting

Standard US 4

The scan request form must require the name and signature of the requester. Electronic requesting must enable a clear audit trail to identify the requester.

Standard US 5

The health professional requesting the test must complete and sign the request form. (4)

Standard US 6

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

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

- (2) These should include information on:
- previous pregnancies affected by abnormalities, e.g. neural tube defects and cardiac anomalies
 - maternal diabetes
 - epilepsy (and medication if taken)
 - other prescribed and non-prescribed drugs
 - excess alcohol intake
 - maternal BMI.
- (3) The early pregnancy scan request should indicate whether Down's syndrome screening is required.

7.1.5 Ultrasound Services

Standard US 7

Only an appropriately trained sonographer, or sonographer who is in training under the supervision of a sonographer, should perform ultrasound scans. (10)

Standard US 8

All ultrasound equipment used in maternity services must be of an appropriate standard as outlined in RCOG (2000) and NICE (2008).

- (1) Ultrasound equipment should be replaced in-line with recommendations from the NHS Purchasing and Supply Agency (NHS PASA and HE1 98 Regulations).

Standard US 9

A full record of the findings must be made on the ultrasound reporting module.

- (1) The RadIS2 obstetric reporting module should be used to report all early pregnancy and fetal anomaly ultrasound dating scans.⁵
- (2) The ultrasound report should be produced or authorised by the person performing the ultrasound examination as an integral part of the examination.
- (3) A clear and concise ultrasound report should be produced as soon as possible after the examination has been completed.
- (4) The scan report is a legal document and part of the medical record, together with any hard copy images, computer stored images and/or video recordings which may accompany it. They must be stored for 25 years. Where images are recorded they may be used to support, or refute, the content of the report.
- (5) Adequate identifiers to include the date and time of the examination should be entered on all images relevant to that woman.
- (6) A full record of the ultrasound findings should be maintained in an electronic format.

⁵ The RadIS2 obstetric reporting module has been developed to assist sonographers in the reporting of the early pregnancy and fetal anomaly scans by using a structured reporting format and structured printing of the report. The implementation of this module is progressing during 2010/11. Where the module is available within the Health Board it should be used to report these scans. Where the module is not yet available the existing ultrasound reporting arrangements should continue.

7.1.6 Test Procedure

- (1) The woman's privacy needs must be respected, the discussion and ultrasound scan must be performed in a room where privacy can be assured.
- (2) The sonographer should confirm with the woman her identity, her awareness of the purpose of the ultrasound scan and that she has given consent.

7.1.7 Results Handling

Standard US 10

If an abnormality is not identified, the woman should be informed and given a written information leaflet by the sonographer to explain the ultrasound scan result.

Standard US 11

A record that the ultrasound scan has been performed and the result should be made in the maternity notes.

- (1) A copy of the scan report should normally be printed and included in the woman's maternity notes at the time of the scan.
- (2) A record that the result has been discussed with the woman must be made in the maternity notes.

7.2 Specific Standards and Protocols for Early Pregnancy Scans

7.2.1 Test Procedure

Standard US 12

The scan should ideally be arranged and performed between 11 weeks and 0 days and 13 weeks and 6 days of pregnancy.

- (1) If there are no clinical indications, a further routine appointment for an early pregnancy scan is not required if the scan is inadvertently performed after 8 weeks and 4 days of pregnancy and before 11 weeks and 0 days of pregnancy, unless Down's syndrome screening using the combined test has been offered.
- (2) This ultrasound scan should be performed transabdominally. If an appropriate image cannot be obtained, the woman should be offered a transvaginal ultrasound scan or a further appointment for a repeat transabdominal ultrasound scan.
- (3) If the woman is offered a transvaginal scan by the sonographer, verbal consent should be obtained, and a record of her consent made on the radiology reporting module and if possible in the woman's maternity notes.
- (4) Women who attend for antenatal care later in pregnancy should be offered an ultrasound scan appropriate to their presumed gestation.

Standard US 13

The gestation should be calculated using the crown rump length (CRL) measurement up to 12 weeks and 6 days of pregnancy (i.e. 66mm or less) and biparietal diameter (BPD) after 13 weeks and 0 days of pregnancy (i.e. if the CRL is greater than 66mm).

Note: Head circumference (HC) measurement (98–150mm) rather than BPD measurements will be required and implemented in Wales in the near future. When the HC measurement is implemented in clinical practice in Wales, the upper limit of the CRL measurement will increase to 80mm (NHS FASP 2008⁶, Loughna et al 2009⁷).

- (1) If Down's syndrome screening is requested the reported biometry measurements must be within the limits used by the Biochemistry Laboratory.⁸

Standard US 14

As a minimum standard, the sonographer should report:

- whether pregnancy is intrauterine
- presence or absence of a fetus
- viability (i.e. presence of heart pulsation)
- CRL (up to 66mm) or BPD as appropriate
- fetal number and in multiple pregnancies the chorionicity and amnionicity
- any gross fetal abnormality which is seen.

7.2.2 First Trimester Screening

Standard US 15

Where first trimester screening for Down's syndrome is offered, the woman's consent to Down's syndrome screening must additionally be included on the early pregnancy ultrasound request card.

Standard US 16

The sonographer must be trained to take the NT measurement and be able to demonstrate satisfactory competence.

- (1) The name of the sonographer undertaking the NT measurement should be provided on the ultrasound report and Down's syndrome screening request card.
- (2) If the process for obtaining NT measurements is unsuccessful or the woman is more than 13 weeks and 6 days, the woman should be offered second trimester Down's Syndrome screening.
- (3) If the NT is equal to or greater than 3.5mm this is an abnormal clinical finding and the woman should be referred to an obstetrician or radiologist with specialist skills in ultrasound for further management as set out in section 7.2.3. An image of the NT/cystic hygroma should be included with the referral correspondence.

⁶ NHS Fetal Anomaly Screening Programme (2008) Statement for the CRL conversion measurement and the algorithm to be used for Down's Syndrome screening risk calculation. Available at <http://fetalanomaly.screening.nhs.uk/programmestatements> (Accessed on 29th September 2009).

⁷ Loughna, P., Chitty, L., Evans, T, Chudleigh, T. (2009) Fetal size and dating: charts recommended for clinical obstetric practice, *Ultrasound*, 17 (13), pp. 161–167.

⁸ The limits of the measurements that can be used are dependent on the biochemistry computer software. As these limits can vary according to the software, they have therefore not been specified in this document but are available from Antenatal Screening Wales.

7.2.3 Abnormal Early Pregnancy Scans

Standard US 17

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

- (1) Where a problem has been identified, verbal information that there may be a problem should initially be provided by the sonographer and a record of the discussion documented in the woman's maternity notes.
- (2) Verbal information should then be provided by the antenatal screening coordinator (or deputy) or obstetrician and a record of the discussion documented in the woman's maternity notes.
- (3) Where Health Boards or services do not offer combined screening for Down's syndrome, the nuchal translucency (NT) assessment or measurement is not part of the early pregnancy scan.
- (4) If a cystic hygroma is present or if on incidental visualisation the nuchal translucency appears very enlarged, this is a clinical finding and the woman should be informed and referred to an obstetrician or radiologist with specialist skills in ultrasound for further information and management.
- (5) In this circumstance a hard copy image of the NT/cystic hygroma should be included with the referral correspondence, if the woman wishes to be referred for further assessment.

Standard US 18

A contemporaneous, dated and signed record must be made in the maternity notes of actions planned and taken in response to any abnormal finding(s) on the early pregnancy scan.

Standard US 19

Following an abnormal early pregnancy ultrasound scan and where appropriate services are not available locally, women should be offered an appointment and seen in a fetal medicine department within three working days.

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

The woman's explicit consent is not required for reporting to CARIS. Information about the purpose of CARIS and the woman's right not to have information about herself used by CARIS is provided in the ASW 'Information for Women' pack. (11)

7.3 Specific Standards and Protocols for Fetal Anomaly Ultrasound Scans

7.3.1 Test Procedure

Standard US 20

The fetal anomaly ultrasound scan should usually be performed between 18 weeks and 0 days and 20 weeks and 6 days of pregnancy.

Standard US 21

The minimum standard for reporting the 18 weeks and 0 days to 20 weeks and 6 days fetal anomaly ultrasound scan, as set out by the RCOG (2000) and NICE (2008), should be achieved if possible.

Note: this standard will be reviewed and revised following publication by the NSC Fetal Anomaly Screening Programme of their recommended menu in 2010.

Standard US 22

The sonographer should complete the agreed all Wales standard screening scan checklist if possible.¹⁰

- (1) The reporting of cardiac outflow tracts should be incorporated into the fetal anomaly scan as soon as possible and by September 2010.¹¹
- (2) Where the first examination is sub-optimal or checklist incomplete and the sonographer is suspicious of a possible fetal abnormality, a second opinion should be sought as soon as possible.
- (3) If appropriate images cannot be obtained to allow the standard checklist to be completed the woman should be offered one further ultrasound scan. The woman should be informed that there are a number of reasons why it is sometimes not possible to complete the scan checklist.

Examples of why it may not be possible to complete the checklist are maternal considerations such as maternal habitus or body mass index, uterine fibroids, abdominal scarring and/or by fetal considerations such as a suboptimal fetal position.

- (4) This second examination should be performed before 23 completed weeks of pregnancy.
- (5) Where it is not possible for the sonographer to complete the standard checklist on the second scan, the woman should be informed that it was not possible to complete the checklist.
- (6) Written patient information is available from ASW on incomplete fetal anomaly scans.

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 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 Where the cardiac outflow tracts are visualised by the sonographer, they should be reported on the radiology reporting module. This will enable Health Boards and ASW to audit the potential service impact of incorporating these measurements into the standard checklist of the fetal anomaly scan and any training requirements.

Standard US 23

The following specific ultrasound findings should continue to be referred for further assessment:

- Nuchal fold
- Ventriculomegaly
- Echogenic bowel
- Renal pelvic dilatation.

ASW (2004) has provided guidance on the reporting of specific ultrasound findings (ultrasound markers). This guidance will be revised when the outcome of the Welsh Study of Mothers and Babies is available.

7.3.2 Abnormal Fetal Anomaly Scans

Standard US 24

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

Standard US 25

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

- (1) Where a problem has been identified, verbal information that there may be a problem should initially be provided by the sonographer and a record of the discussion documented in the woman's maternity notes.
- (2) Verbal information should also be provided by the antenatal screening coordinator (or deputy) or obstetrician and a record of the discussion documented in the woman's maternity notes.

Standard US 26

Following an abnormal fetal anomaly ultrasound scan and where appropriate services are not available locally, women should be offered an appointment and seen in a fetal medicine department within three working days.

Standard US 27

Following a confirmed fetal cardiac anomaly, the woman should be seen within three working days by a fetal cardiologist. *Minimum standard 90%*

- (1) Any suspected congenital anomaly should be reported to CARIS via the RadIS2 reporting module. It is the sonographer's responsibility to ensure that reporting to CARIS has been completed. If the RadIS2 reporting module is not available, a 'CARIS notification card' for a suspected congenital anomaly should be completed and sent to the CARIS coordinator/office.
- (2) The woman's explicit consent is not required for reporting to CARIS. Information about the purpose of CARIS and the woman's right not to have information about herself used by CARIS is provided in the ASW 'Information for Women' pack. (11)

8.0 Antenatal Blood Group and Antibody Screening

Policy Statement

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

Blood Group and Red Cell Antibodies

There are four main blood groups: group O, group A, group B and group AB. There is also another blood factor called the Rhesus (Rh) group and people have a blood group and Rh group, e.g. group O Rhesus 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. If it is absent, the person is RhD-negative.

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

Rationale for Screening

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

Anticipated Outcome

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

8.1 Pre Test Information

Standard BG 1

The woman must be given verbal and written pre test information and a record of the information provided made in the maternity notes.

- (1) A copy of the ASW 'Information for Women' pack (in an appropriate language and format, if available) should be provided before the woman is asked to consent to this test. (1)
- (2) The purpose, implications, limitations and benefits of this screening test must be explained to the woman by the midwife. (2)
- (3) The midwife should make a record of written information given to the woman, including a record of any information given in other media, e.g. DVD or audio CD. (3)

8.2 Screening Test Offer

Standard BG 2

The screening test should be offered and the sample taken before 13 weeks of pregnancy and once again at around 28 weeks of pregnancy regardless of RhD status (British Committee for Standards in Haematology (BCSH) 2008; NICE 2008).

- (1) Women who attend for antenatal care after 13 weeks of pregnancy should be offered this screening at the first opportunity.

8.3 Consent

Standard BG 3

The woman's informed verbal consent is required for this test.

- (1) Written consent is not required, but a record of the woman's verbal consent must be made in the maternity notes.

8.4 Test Requesting

Standard BG 4

The laboratory request form must require the name and signature of the requester. Electronic requesting must enable a clear audit trail to identify the requester.

Standard BG 5

The health professional requesting the test must complete and sign the request form. (4)

Standard BG 6

All requests must be identified as 'antenatal screening' and it must be identified as either a booking or 28 weeks sample.

Standard BG 7

All mandatory fields on the laboratory request must be completed.

- (1) If antenatal anti-D prophylaxis has been administered to the woman, this information must be included on the laboratory request, as this may affect the interpretation of the results.

8.5 Test Procedure

Standard BG 8

The person taking the sample must make a signed and dated record of the sample being taken in the maternity notes.

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

Standard BG 9

The maternity services must develop a clear system for confirmation of the sample identity.

- (1) This process must include asking the woman to state her name, date of birth and address and these must be identical to the information on the request form and the handwritten details on the sample.

8.6 Laboratory Services

Standard BG 10

The laboratory must be appropriately accredited in accordance with CPA (Clinical Pathology Accreditation), now part of UKAS (United Kingdom Accreditation Service) and able to demonstrate satisfactory performance.

Standard BG 11

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

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

Standard BG 12

The sample should be received by the local laboratory within one working day of the sample being taken. *Developmental minimum standard 90%*

Standard BG 13

If the sample is forwarded to another laboratory, the sample should be received by the testing laboratory within two working days of the sample being taken. *Developmental minimum standard 90%*

Standard BG 14

The testing laboratory should aim to achieve a five working day turn-around from sample receipt to result reporting for non-urgent samples. *Developmental minimum standard 90%*

8.7 Results Handling

Standard BG 15

If the sample has not been tested at the local laboratory, the result should be returned to the local laboratory within one working day of the result being signed out by the testing laboratory. *Developmental minimum standard 90%*

Standard BG 16

The result should be available to the maternity service within one working day of the result being reported by, or to, the local laboratory. *Developmental minimum standard 90%*

- (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 the immediate management of care.

8.8 Rhesus Positive, Antibody Negative Result

Standard BG 17

Women should be informed of the result by the maternity service within 15 working days of the sample being taken. *Minimum standard 90%*

- (1) The woman should be informed that she is RhD-positive and will not require anti-D prophylaxis. Further screening for atypical red cell alloantibodies is advised at 28 weeks of pregnancy (BCSH 2008; NICE 2008).

Standard BG 18

There must be a written and agreed process in place to identify and follow up results not received.

Standard BG 19

The result must be recorded in the maternity notes.

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

8.9 Rhesus D Negative, Antibody Negative Results

Standard BG 20

Women should be informed of the result by the maternity service within 15 working days of the sample being taken. *Minimum standard 90%*

Standard BG 21

The woman should be informed of the implications of being Rhesus negative.

Standard BG 22

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

- (1) Information for women about being RhD-negative is provided in the ASW 'Information for Women pack'. This information pack includes information about notifying a healthcare professional if a potentially sensitising event occurs.
- (2) NICE (2008) has recommended that routine antenatal anti-D prophylaxis is offered to all non-sensitised pregnant women who are RhD-negative. Each maternity service should have arrangements in place for implementing the offer and administration of this antenatal anti-D prophylaxis. (7) (8)
- (3) Health Boards should have an appropriate protocol in place for offering specific antenatal treatment following a sensitising event and for postnatal anti-D prophylaxis. In the event of such an occurrence, anti-D prophylaxis (250 IU if less than 20 weeks gestation and 500 IU if greater than 20 weeks gestation) should be offered and, if accepted, given as soon as possible after the sensitising event and certainly within 72 hours (RCOG 2002b).
- (4) Kleihauer screening should be offered following a potentially sensitising event in pregnancy after 20 weeks gestation or after birth. Additional doses of anti-D prophylaxis may be required, as advised by the laboratory, following Kleihauer screening.

8.10 Antibody Positive Results

Standard BG 23

If antibodies are detected they should be identified and if necessary quantified by the laboratory to assess the likelihood of HDN.

- (1) There are a large number of potential antibodies which can cause HDN. If significant antibodies are found the laboratory should inform the consultant obstetrician, antenatal screening coordinator, or deputy.
- (2) Confirmatory testing is required at a reference laboratory prior to a fetal medicine referral.

Standard BG 24

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

- (1) Interpreter services should be arranged if required.
- (2) The management of the pregnancy will depend on the clinical significance and titre of the antibody detected.
- (3) Pregnant women with clinically significant atypical red cell alloantibodies should be offered referral to a specialist centre.

8.11 Care Plan

Standard BG 25

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

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

8.12 Postnatal Care

Standard BG 26

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

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

Standard BG 27

If the baby is RhD-positive, non-sensitised women who are RhD-negative should be offered postnatal anti-D prophylaxis by the maternity service, within 72 hours of delivery (RCOG 2002b).

List of Respondents to the Consultation

Individuals

Carol Evans – Deputy Head of Medical Biochemistry & Immunology Laboratory Service, University Hospital of Wales
Jo Sperduti – Trust Antenatal Screening Coordinator, Royal Gwent Hospital
Julie Richards – Head of Midwifery and Sexual Health, Powys Local Health Board
Liz Boxall – Consultant Clinical Scientist, Health Protection Agency, Heart of England Foundation Trust
Lynne Francis – Superintendent Sonographer, Royal Glamorgan Hospital
Mandy Staffer – Trust Antenatal Screening Coordinator, Wrexham Maelor Hospital
Pat Tookey – Senior Lecturer, MRC Centre of Epidemiology for Child Health, UCL Institute of Child Health
Samantha Ray – Health Protection Nurse, National Public Health Service for Wales
Selwyn Roberts – Head of Cytogenetics Laboratory, Deputy Director Laboratory Genetics Service for Wales, Institute of Medical Genetics, University Hospital of Wales
Fran Rushworth – Consultant Obstetrician and Gynaecologist, Princess of Wales Hospital
Wendy Williams – Superintendent Radiographer, Llandough Hospital

Organisations

Abertawe Bro Morgannwg University NHS Trust, Women and Child Health Directorate
All Wales Senior Nurse, Integrated Sexual & Reproductive Health, Professional Advisory Group
British Association of Sexual Health and HIV - Wales
Cardiff and Vale NHS Trust
Down's Syndrome Association
Gwent Local Health Board, Nurse Directors
NHS Fetal Anomaly Screening Programme
North West Wales NHS Trust
Society and College of Radiographers
The Board of Community Health Councils in Wales
The Royal College of Midwives
The Royal College of Radiologists
Tiny Tickers Charity
University Hospital of Wales, Children's Heart Unit for Wales
University Hospital of Wales, Virology Department
Welsh Nursing and Midwifery Committee
Welsh Scientific Advisory Committees

References

Antenatal Screening Wales (2004) Specific Antenatal Ultrasound Findings Guidelines for Health Professionals in Wales. Cardiff: Velindre NHS Trust.

British Association for Sexual Health and HIV (BASHH) (2008) UK National Guidelines on the Management of Syphilis. International Journal of STD & AIDS. Volume 19, 729-740.

British Committee for Standards in Haematology (2008) Available from: www.bcsghguidelines.com (Accessed on 14/01/09).

British National Formulary (2009) BNF 57 2009. London: Pharmaceutical Press.

Choices – Recommendations for the Provision and Management of Antenatal Screening in Wales (2002) Cardiff: Velindre NHS Trust. Available on: www.antenatalscreening.org.

Clinical Pathology Accreditation UK. Available from: www.cpa-uk.co.uk. (Accessed on 23/03/09).

Department of Health (2006) Immunisation Against Infectious Diseases – ‘The Green Book’ Available from www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/Greenbook/DH_4097254. (Accessed on 24/09/09).

Department of Health (2009) Immunisation Against Infectious Diseases – ‘The Green Book’ : Download Updates to Chapter 18. Available from www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/Greenbook/DH_4097254. (Accessed on 24/09/09).

Down's Syndrome Screening Quality Assurance Support Service. Available from: www.fetalanomaly.screening.nhs.uk/dqass. (Accessed on 15/03/10).

Loughna, P., Chitty, L., Evans, T. and Chudleigh, T. (2009) Fetal size and dating: charts recommended for clinical obstetric practice. Ultrasound. Volume 17, Number 3. Pages 151–167.

National Assembly for Wales (2000) Antenatal Screening to Reduce Mother to Baby Transmission of HIV. Cardiff: National Assembly for Wales.

NHS Fetal Anomaly Screening Programme (FASP) (2008) NHS Fetal Anomaly Screening Programme – Screening for Down's syndrome: UK NSC Policy Recommendations 2007-2010: Model of Best Practice. Exeter: NSC.

NHS Purchasing and Supply Agency. Available from: www.pasa.nhs.uk. (Accessed on 23/03/09).

NHS Sickle Cell and Thalassaemia Screening Programme (2009) Sickle Cell and Thalassaemia Handbook for Laboratories. London: Oakdean Commercial Design and Print.

NICE (2008) CG62. Antenatal Care: Routine Care for the Healthy Pregnant Woman. London: RCOG Press.

NSC (2007) Antenatal Screening – Working Standards for Down's Syndrome Screening 2007. Exeter: NSC.

NSC (2008) NHS Fetal Anomaly Screening Programme – Screening for Down's Syndrome: UK NSC Policy Recommendations 2007-2010: Model of Best Practice. Exeter: DH.

Royal College of Obstetricians and Gynaecologists (RCOG) (2000) Routine Ultrasound Screening in Pregnancy, Protocols, Standards and Training. Supplement to Ultrasound Screening for Fetal Abnormalities. Report of the RCOG working party. London: RCOG Press.

Royal College of Obstetricians and Gynaecologists (2002a) Advice on Planning Services in Obstetrics and Gynaecology. London: RCOG Press.

Royal College of Obstetricians and Gynaecologists (2002b) Use of Anti-D Immunoglobulin for Rh Prophylaxis (22). London: RCOG Press.

Royal College of Obstetricians and Gynaecologists (2005) Amniocentesis and Chorionic Villus Sampling (8). London: RCOG Press.

United Kingdom National External Quality Assessment Service. Available from: www.ukneqas.org.uk. (Accessed on 23/03/09).

Welsh Health Circular (1998) Number 36. Screening Of Pregnant Women For Hepatitis B and Immunisation Of Babies At Risk. Cardiff: Welsh Office.

Welsh Health Circular (2003a) Number 94. Protecting Women and Healthcare Workers Against Rubella: Switch from Single Rubella Vaccine to MMR. Cardiff: Welsh Assembly Government.

Welsh Health Circular (2003b) Number 127. Annual Priorities and Planning Guidance for the Service and Financial Framework 2004-05. Cardiff: Welsh Assembly Government.

Other resources which assisted the preparation of this document

Antenatal and Newborn Screening Programme (2006) Sickle Cell and Thalassaemia Handbook For Laboratories. London: NHS Sickle Cell and Thalassaemia Screening Programme.

Department of Health (2003) Screening for Infectious Diseases in Pregnancy. Standards to Support the UK Antenatal Screening Programme. London.

Fetal Anomaly Screening Programme Available from: www.fetalanomaly.screening.nhs.uk. (Accessed on 15/03/10).

Royal Pharmaceutical Society of Great Britain (2008) British National Formulary, 56. London.

Welsh Health Circular (2008) Number 36. Good Practice in Consent Implementation Guide: Consent to Examination or Treatment. Welsh Assembly Government. Cardiff.

Explanatory Notes

1. Written information for women is available from ASW in hard copy and as 'e-leaflets' in a number of languages on www.antenatalscreeningwales.org. Other suitable written information may be available from internet sites and voluntary organisations, but the content should be reviewed by the health professional prior to this information being recommended.
2. Verbal information must be given to the woman in a language she understands with the support of a trained interpreter if necessary.
3. Some information is available from ASW in an audio CD format or as a DVD/video with British Sign Language and subtitles.
4. By signing the laboratory or ultrasound request form, the requesting health professional is confirming that written and/or verbal information about the purpose of the test or scan has been given to the woman and that she has given informed consent for the test.
5. 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 set out in the table below. (See 'Green Book' for information on premature infants). The midwife should liaise with the paediatrician to ensure that this takes place as early as possible, and always within 24 hours of birth.

Hepatitis B status of mother	Baby should receive	
	Hepatitis B vaccine	HBIG
Mother is HBsAg positive and HBeAg positive	Yes	Yes
Mother is HBsAg positive, HBeAg negative and anti-HBe negative	Yes	Yes
Mother is HBsAg positive where e-markers have not been determined	Yes	Yes
Mother had acute hepatitis B during pregnancy	Yes	Yes
Mother is HBsAg positive and anti-HBe positive	Yes	No
A woman who is HBsAg sero-positive and known to have an HBV DNA level equal or above 1×10^6 IU/ml in an antenatal sample*.	Yes	Yes

* Where viral load testing has been performed to inform the management of the mother. (Adapted from DoH 2009).

Further doses of vaccine are required at one, two and twelve months of age. A blood test should be undertaken at 15 months of age to check immunity.

6. The woman should be offered sickle cell and thalassaemia screening as early as possible in the pregnancy so that if invasive testing is offered CVS can be an option. Although CVS can be performed on a gestation greater than 13 weeks (RCOG 2005), CVS is usually performed between 10 and 13 weeks.

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

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

9. Specific guidance for health professionals on completing the request form is available from ASW.

10. A 'sonographer' is a healthcare professional qualified in ultrasound who carries out ultrasound examinations. There is currently no regulatory control on performing ultrasound scans.

Taking into account the recommendations of relevant professional bodies, Health Boards should agree which health professionals have the skills and competencies to undertake early pregnancy and fetal anomaly ultrasound scans.

Antenatal Screening Wales will explore the possibility of Health Boards maintaining a list of sonographers who the Health Board authorises to undertake early pregnancy and fetal anomaly scans by using the RadIS2 reporting module log on information.

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.

