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Antenatal Screening Wales

Antenatal Screening Wales Annual Report 2022-24

Version 1

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This document is also available in Welsh.



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Key messages

Visit your midwife early to help you make the best choices for your pregnancy.

- Antenatal screening gives women important information about their and their baby's health
- Women are asked to make an appointment with a midwife as soon as they find out their pregnant.
- Women will be given information to help them make a choice about taking part in antenatal screening.
- The midwife will talk to the woman about the different tests she can have and answer her questions as part of her routine antenatal care.
- Antenatal screening tests are not 100% accurate and some conditions may be missed.
- The pregnant woman may be offered further tests or treatment after her antenatal screening.

To find out more:

Visit: phw.nhs.wales/antenatal-screening

Executive Summary

This report outlines the work undertaken by Antenatal Screening Wales (ASW) from 1 April 2022 to 31 March 2024. This summary report highlights the achievements of the team and provides an opportunity for reflection. It illustrates the wide variety of work carried out for the eight antenatal screening programmes and demonstrates collaborative working with colleagues across Wales.

Antenatal Screening Wales was formed following a request by Welsh Government to establish policies, standards and a performance management framework for antenatal screening delivered by maternity services in Wales. Health boards are responsible for delivering screening in line with the policies, standards and protocols as part of routine antenatal care.

The report covers the work streams carried out by the Team in line with the ASW Operational Plan.

All health boards in Wales have adopted ASW policies, standards and protocols for antenatal screening. This enables women in Wales access to services that are working to best practice and ensures an equitable antenatal screening service. Following the yearlong review of the Policy, Standards and Protocols, the updated version was published on the 14 August 2023. Supplementary resources were updated in line with the standards and protocols review. These include pre and post test written information for service users, Midwives Handbook, Information for women where there has been a demised twin (vanished twin) and existing e learning packages.

It details the work to scope and develop the introduction of cell free fetal DNA screening to the Blood Group and Antibodies Programme for the eligible pregnant population. This was a large project involving multidisciplinary working from colleagues in all health boards in Wales. Resources developed or amended for the implementation include:

- Amendments to Policy, Standards and Protocols
- Production of an e learning package for Blood Group and Antibodies
- Cascade training for the offer of cell free fetal DNA (cffDNA)
- Pathway for the screening test and management of discrepant results
- Amendments to health professional resources-Midwives Handbook, correct completion of the test request cards
- Amendments to service user information-pretest information, information for women who are RhD negative and offered screening, women who are offered invasive testing (eg amniocentesis, chorionic villus testing (CVS)).

Wales was the first UK nation to implement noninvasive prenatal testing (NIPT) as a three year evaluative rollout. The findings of the evaluation were published within this reporting period. Recommendations from the evaluative rollout are now incorporated into 'business as normal'.

There was development of a number of e-learning resources to support health professionals who deliver the antenatal screening programme within Wales. The resources developed included –

- Communicable Diseases
- Blood Group and Antibodies

ASW has continued to monitor performance of the Programmes by audit of:

- biannual Performance Indicator reporting
- monitoring performance of the Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T18) screening pathway in Wales with the support of Down's syndrome Quality Assurance Support Service (DQASS)
- echogenic bowel found at the anomaly scan
- management of syphilis in pregnancy, and
- re-audit the management of hepatitis B in pregnancy.

Development work is underway to scope the introduction of the abdominal circumference measurement within the anomaly scan for all Health Boards in Wales with a suggested implementation of October 2024.

The introduction of surveillance of cases of HIV and syphilis was implemented in January 2024. Collecting and reporting on screening outcome data for both the conditions in pregnancy will assess the impact of the conditions in Wales. This will lead to recommendations being made locally and nationally, strengthening policy and practice, and improving care for mothers and their children within Wales.

ASW worked in partnership with health boards to implement 'Digital First' for the provision of antenatal screening public information, with formal transition across Wales since September 2022. The implementation of Digital First proved successful. ASW continues to improve digital information for both service users and health professionals.

Working across organisational boundaries and with the dedication and support of stakeholders,

service providers including every health board in Wales, ASW have continued to ensure consistency and stability of the antenatal screening programme often in a challenging environment where there are many competing priorities.

Introduction

Background

The health board maternity services in Wales offer antenatal screening tests to pregnant women as part of their antenatal care. Antenatal screening tests are offered for different reasons, and this makes antenatal screening a complex programme with several different purposes and unique ethical considerations and implications. Supporting individuals to make personal informed decisions about their antenatal screening choices is important during pregnancy.

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

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

Antenatal Screening Wales (ASW) is funded by Welsh Government to support improvements in the standard of antenatal screening offered to women. The model of screening provision in Wales is unique to the UK. ASW is responsible for developing and supporting health boards in delivering all aspects of the antenatal screening programme, through a managed clinical network structure. This includes:

- Planning, Policy development,
- Governance structures,
- Frameworks for Quality Assurance,
- Education.

ASW has established policies, standards and a performance management framework for antenatal screening delivered by maternity services in Wales.

Current eligibility

All pregnant women resident in Wales to be offered, in every pregnancy:

- antenatal screening for HIV, hepatitis B and syphilis
- antenatal screening for blood group, RhD status and antibodies
- antenatal screening for sickle cell and thalassaemia
- an early pregnancy dating scan and a fetal anomaly scan
- antenatal screening for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13)

Timeframe for undertaking screening tests

Ideally, screening tests are to be performed in early pregnancy, by around 12 weeks of pregnancy if the woman presents for antenatal care before this gestation. Screening for HIV, syphilis, hepatitis B, sickle cell, thalassaemia, blood group and RhD status, antibodies and early pregnancy dating scan can be performed at any gestation.

The combined screening test for chance of the pregnancy having Down's syndrome, Edwards' syndrome and Patau's syndrome can be performed between 11⁺² weeks-14⁺¹ week gestation.

If the woman presents too late for screening in the first trimester or if the nuchal translucency (NT) measurement on the back of the fetal neck cannot be obtained, the recommended laboratory screening test in the second trimester is the quadruple test. This test uses an ultrasound measurement to assess the gestation with the results from biochemical markers to give the woman a chance result for Down's syndrome only in singleton pregnancies between 15⁺⁰ to 18⁺⁰ weeks gestation.

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

If the woman attends for antenatal care later in pregnancy, she must be offered an ultrasound scan appropriate to their presumed gestation. The routine anomaly scan reporting module in RadIS2 or an agreed alternative can be used for these scans with the understanding that the estimation of normal measurements may not be accurate with increased gestational age.

Managed clinical network delivery

ASW is part of Public Health Wales, Screening Division, who have extensive expertise in the management and provision of population-based screening programmes. ASW has delivered the All-Wales Managed Clinical Network for antenatal screening since 2003. The Quality and Clinical Governance Group and the programme specific advisory groups provide governance for the network. The health board providing care undertakes antenatal screening provision. ASW does not provide or directly manage any antenatal screening services.

During 2022-2024, the composition of the Antenatal Screening Wales team changed in response to workforce developments and service review changes. The ASW team consists of:

- Head of Programme (0.8wte)
- 3 Programme Coordinators – 2 midwives (1.6wte) and 1 Radiographer/Sonographer (0.8wte)

- Programme Support Manager (1.0wte) for Antenatal Screening Wales, Newborn Bloodspot Wales (NBSW) and Newborn Hearing Screening Wales (NBHSW)
- Assistant Programme Support Manager (1.0wte) for ASW, NBSW and NBHSW
- Administrative Support (1.0wte) for ASW

Professional Advisors

The ASW team and Quality and Clinical Governance Group (Q&CG) are supported by Professional Advisors who are employed through honorary contacts. The honorary contracts are for a 3 year period. As the antenatal screening programmes have become established, the professional advice, quality assurance advice, support and governance requirements need to be reviewed to ensure that the professional advisor structure and make up is what best suits the requirements of ASW and the antenatal screening programmes.

The current Professional Advisors for ASW are –

- Consultant obstetrician x2
- Consultant haematologist
- Consultant geneticist
- Consultant virologist
- Biochemist (special interest in Down's syndrome, Edwards' syndrome and Patau's syndrome screening)
- Consultant Sonographer (special interest in antenatal ultrasound/screening).

Health board maternal and child screening governance lead

Each health board has a named governance lead for Maternal and Child (MAC) Screening who manage the strategic governance of the antenatal and newborn screening programmes. These positions are funded by PHW (0.2wte).

These roles manage the strategic governance for the MAC screening programmes within each health board. The governance leads meet quarterly with ASW to discuss programme performance governance matters and provide support to each other within this role. A health board governance lead represents the group in the ASW Quality and Clinical Governance Group, advisory groups and workstream meetings.

Antenatal Screening Wales advisory groups

ASW advisory groups for the antenatal screening programmes provides a clear focus for each of the programmes, reduced the reliance on individual knowledge and skills and promoted a robust clinical governance framework to support the screening pathways. The advisory groups for the antenatal screening programmes are –

- Communicable Diseases Screening Advisory Group
- Sickle Cell & Thalassaemia/Blood Group & Antibodies screening Advisory Group
- Fetal anomaly/ Down's syndrome, Edwards' syndrome and Patau's syndrome Screening Advisory Group.

The groups' remit is to provide professional advice and consultation to the ASW Quality & Clinical Governance Group. The groups meet Biannually. The use of virtual meetings and discussions continue to promote engagement. The advisory groups have clear terms of reference and a defined membership.

Working in partnership with health boards

ASW meet regularly, and work closely with health board governance leads, antenatal screening coordinators, ultrasound obstetric leads, ultrasound fetal cardiac leads and ultrasound nuchal translucency (NT) leads to provide professional advice to the All Wales Quality and Clinical Governance Group on all aspects of the antenatal screening programmes in Wales.

Directors and Head of Midwifery Advisory Group

The purpose of this group is to discuss and develop strategic and operational work within their maternity services and to provide expert professional advice to Welsh Government. ASW Head of Programme attends this meeting and provides a summary paper to inform on work streams and provide discussions on ASW and health boards partnership working. A representative from this group is also a member of the ASW Quality and Clinical Governance Group.

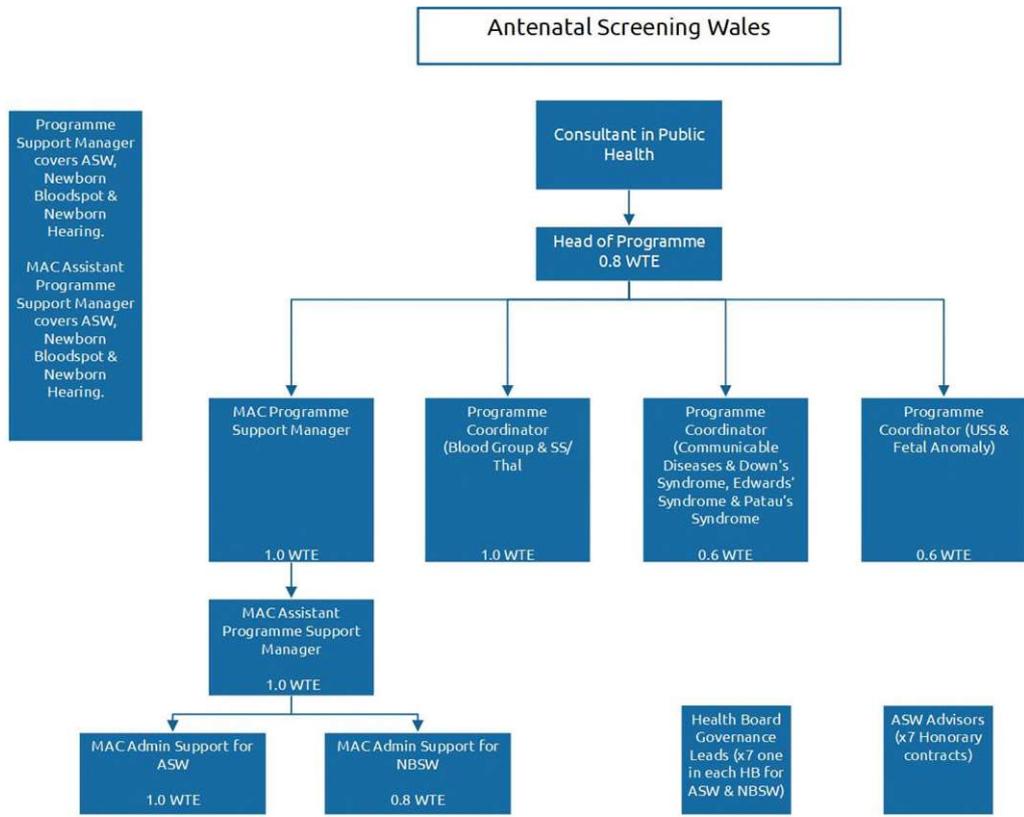


Figure 1 : ASW organogram

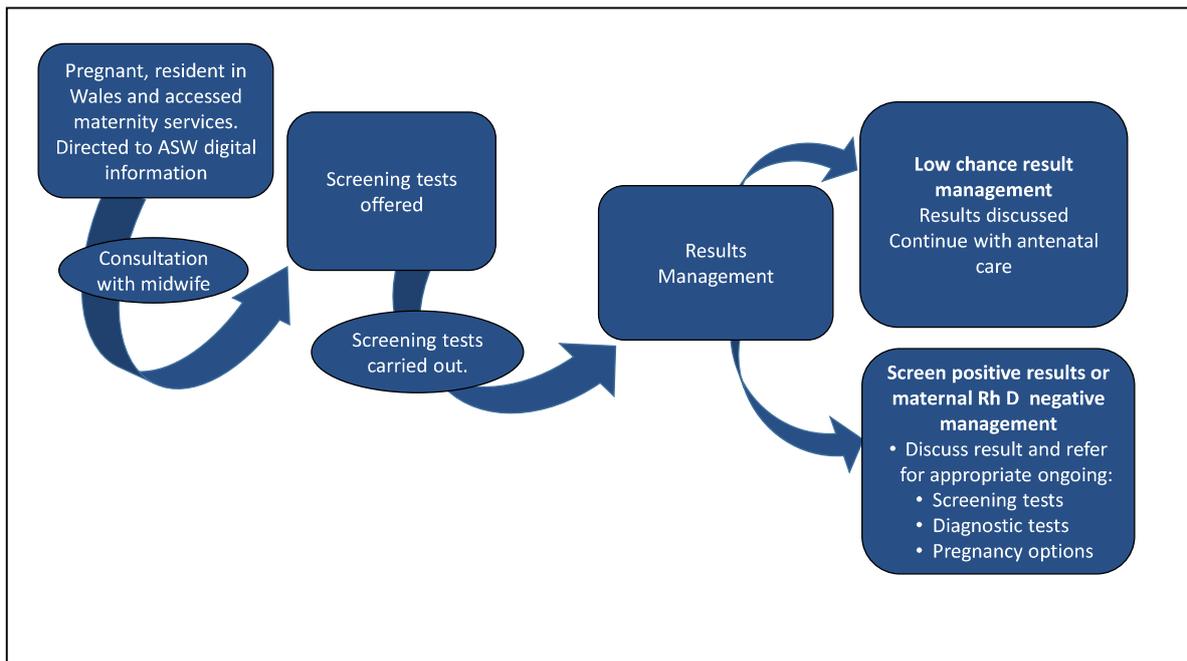


Figure 2 : Pathway for Antenatal screening



Figure 3 : Summary of activity in the reported year as per operational plan

Activity in the reported period

Antenatal Screening Wales

ASW Policy, Standards and Protocols

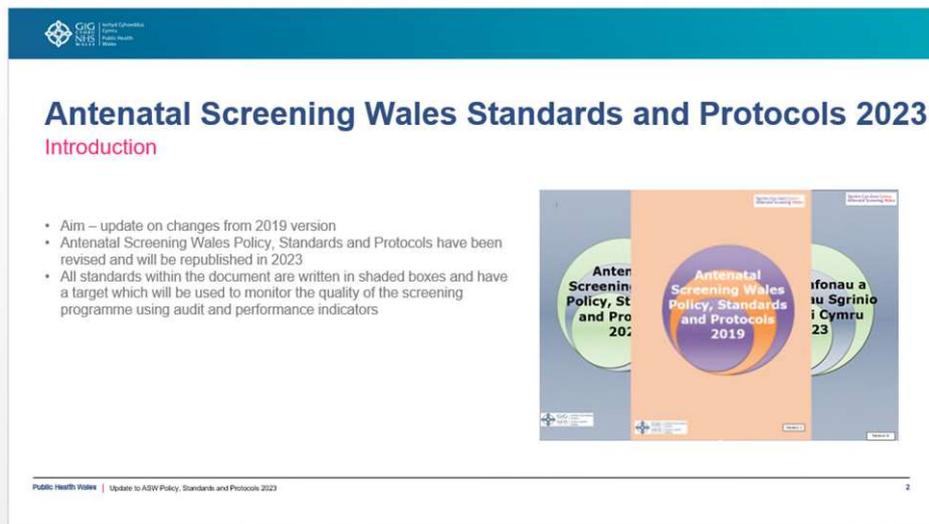
All health boards in Wales have adopted ASW policies, standards and protocols for antenatal screening. This enables women in Wales access to services that are working to best practice and ensures an equitable antenatal screening service.

Following the review of the Policy, Standards and Protocols, the updated version was published on 14 August 2023.

The stages of the review process are shown in Table 1.

Table 1: Stages of the ASW review process

Process for ASW Policy, Standards and Protocols Review		
Quality and Clinical Governance	May 2022	Process review and agreement by the group
Internal review of document	June-Sept 2022	Programme Coordinators and Head of Programme review- 8 Programmes and Management/Government Sections
Sickle Cell and thalassaemia /Blood Group and Antibodies Advisory group	Oct 2022	Sickle Cell and Thalassaemia Blood Group and Antibody review
Down's syndrome, Edwards' syndrome/Patau's syndrome/ Fetal Anomaly Advisory Group	Nov 2022	Down's syndrome, Edwards' syndrome, Patau's syndrome and ultrasound chapters
Communicable diseases advisory group	Oct 2022	HIV, hepatitis B and syphilis chapters
Lead Sonographers group	Oct 2022	Ultrasound chapter and Ultrasound Leads roles
Screening Coordinators and MAC Governance leads group	Jan 2023	Review all chapters
Consultation version sign off	Jan 2023	Quality and Clinical Governance group review and sign off
Welsh translation	Feb 2023	In line with the Welsh Language Standards
Wider Consultation	June-July 2023	Document uploaded for large stakeholder group for their review.
Ratification	August	Quality and Clinical Governance Group final review
Publication 14 August 2023		



A powerpoint presentation of the changes within the updated standards and protocols was produced and forwarded to health board colleagues to cascade within the health boards.

Figure 4 : Policy, Standards and Protocols education update.

Midwife Handbook

This resource has been developed to provide reference and guidance for midwives delivering antenatal screening for the Antenatal Screening Wales Programme. It contains pathways and clinical information for each of the programmes. For ease of accessibility, the handbook has been split into condition specific sections and published in both HTML and PDF on the ASW professional intranet site.

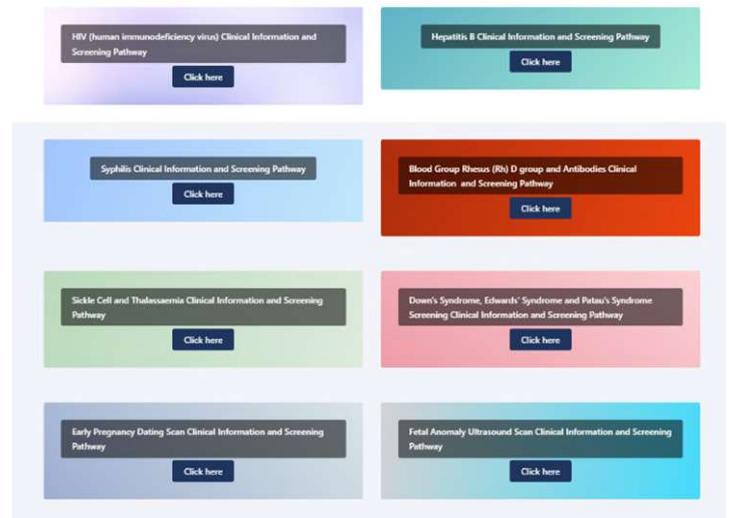


Figure 5: Midwives Handbook

Evaluation of digital first for the provision of antenatal and newborn screening pre-test information

The MAC programmes-Antenatal Screening Wales, Newborn Bloodspot Wales and Newborn Hearing Wales worked with health boards to implement 'Digital First' for the provision of antenatal and newborn screening public information, with formal transition across Wales within September 2022.

The implementation of digital first for the provision of antenatal and newborn pre-test information was a success. The approach and willingness of the health board staff and support from the national screening teams ensured that digital resources were the primary source of pre-test information across Wales by the end of September 2022.

Recommendations from the evaluation

- 1) The format of animations and videos should be designed to ensure that all viewers receive key messages. In recognition of viewing patterns, consideration should be given to the inclusion of a key message summary at the start of each video and an optimum video length.
- 2) MAC programmes should amend hard copy leaflet deliveries to 2 per annum, with the potential to reduce further should demand for paper resources decline.
- 3) In light of evidence showing the relatively low volume of participant access to pre-test information, consideration should be given to whether the current 2-year review cycle for participant resources is appropriate or a less frequent review process incorporating ad-hoc updates would be preferable.
- 4) Consideration should be given to gathering baseline data for all screening programmes about whether pre-test resources are actually read/accessed, in support of recommendation 5.

- 5) For MAC programmes, consideration should be given as to how PHW Screening can support/assure high quality practitioner pre-test conversations as a key source of trusted information and critical element to support informed choice by participants. To include:
 - a. Potential to focus greater effort on teaching for the offer rather than the current emphasis on refining written information.
 - b. Consideration of the MAC programme role as an advocate to support sufficient time for midwives to discuss screening.
 - c. Potential advocating of extension of CTM survey to gain national PREM data about practitioner conversations with health boards.
- 6) For any future digital first launch, inclusion of early project task to map out any major changes to e.g. accessibility standards, web platform that might occur part way through or shortly after implementation to avoid duplication of work.

Governance Lead Role Review

MAC Governance Leads play a vital part in supporting the continued provision of high-quality antenatal and newborn screening services across Wales during pregnancy and within the first weeks of life. These named individuals are responsible for managing the strategic governance role of the screening programmes for their Local Health Board (LHB).

Whilst Governance Leads are employed by LHBs across Wales, these roles are funded by the antenatal and newborn programmes to act as the key link between the all-Wales programmes and local screening delivery to the eligible LHB population. Within existing Long Term Agreements, PHW fund 0.2WTE at band 8a level for each LHB to deliver the Governance Lead role.

The role of the MAC Governance Lead was reviewed in 2022 and the role profile was updated. The expectation of the document will be to provide ongoing support to recruitment and to enable consistent management of these skilled professionals for this aspect of their employment. This role profile will also be appended to the Public Health Wales Screening/Individual LHB Long Term Agreement for reference.

Informal interviews were carried out in December 2023 to understand the individual role profile of the governance leads within the health board and how they manage their governance lead role in conjunction with their other roles. The findings from the interviews are being explored by the Heads of Programme to understand workload, effectiveness of the role and if any barriers impeding the strategic governance role. Recommendations will be fed back to the health boards.

Development of education for health professionals

During 2022-2024 ASW both updated and developed a number of resources to support health professionals who deliver the antenatal screening programme within Wales.

Resources updated

- Down's syndrome, Edwards' syndrome and Patau's syndrome e learning

Resources published

- Communicable Diseases - HIV, syphilis and hepatitis B e learning

Resources in development

- Sickle cell and thalassaemia e learning
- Blood group and antibodies e learning
- Cell free fetal DNA cascade training

A requirement guide was published which outlined the suggested recommended frequency each resource should be completed and by which staff group. The resources can be accessed via ESR or students or those without an ESR login they can also be accessed via Learning@Wales.

Student midwife education



Figure 6 : Student midwife virtual learning resource

Working with the University of South Wales, a virtual learning resource was created to provide students with a high-level overview of what screening is, how it differs from other healthcare interventions and explain the role of the midwife as a public health professional. The resource combines video and animation and is separated into short chapters for students to access via self-directed study. This has been shared with all 4 universities and made available at the start of the academic year. Students can now access the resource to provide helpful context in advance of placements/taught sessions. This has enabled the sessions delivered by programme staff to become more focussed on consolidating learning and sharing of experience, creating a more dynamic learning environment.

In addition, the virtual learning resource is available for students in other years to refer to, as an aid to revision and consolidating practice.

Update Sessions with Student Midwives

ASW have been providing education sessions for midwifery students in each of the Welsh universities, who provide midwifery training, since 2016. The teaching sessions cover the principles of screening and the screening pathways related to each of the antenatal screening programmes. Content of the education update has been amended to follow the screening pathway.

The emphasis that screening is not just a test – it is a programme – a test on its own is unlikely to improve health unless there is effective interventions available for the screen detected conditions.

Most teaching sessions have reverted to face to face sessions within the Universities. This allows for more interaction with the students. Future work stream for ASW is to adapt the teaching package for students dependant on where they are within their training.

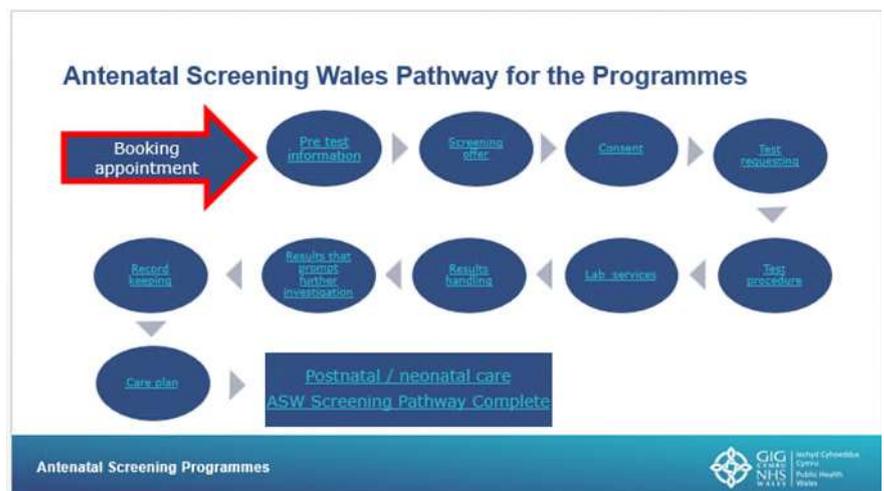


Figure 7 : Antenatal Screening Pathway

Biannual performance indicators report

Performance indicators are reported by the health boards to ASW every 6 months, in April and October. They monitor health board performance against ASW standards. Performance indicators are reported to the health board’s Director of Public Health, Director/Head of midwifery, MAC governance leads, antenatal screening coordinators and ultrasound obstetric leads for escalation within individual health boards. ASW programme coordinators meet biannually with the lead

professionals within each health board to discuss and provide support in relation to the performance indicator report.

Performance indicators are usually carried out in April and October as a way of auditing standards and protocols in health boards.

In line with the standards and protocol review, amendments were made to the Indicator for screening reoffer of HIV, syphilis and hepatitis B where the screening test for the conditions was declined in early pregnancy. The re-offer was amended from reoffer by **28⁺⁶** weeks to:

*Number of women re-offered screening by **20⁺⁶** weeks for*
HIV
Syphilis
Hepatitis B

This change would allow for earlier management and treatment if one of the conditions were diagnosed. From 2024, All Wales data will be uploaded to health board performance indicator reports to enable them to compare their performance in conjunction with All Wales.

Cross-programme work

All Wales Student midwife conference- Midwifery Past, Present and Future)

ASW were asked to present at the first Welsh University student midwife conference in May 2023, hosted by University of South Wales (USW). Around 100 student Midwives attended. The ASW programme held a stand to take the opportunity to engage with the students and discuss the screening, information for service users and the resources for health professionals. ASW also presented on the origins and advancements of antenatal screening.



Figure 8 : Welsh University Student Midwife Conference

RCM conference face to face – October 2022



ASW were delegates at the National Royal College of Midwives (RCM) 2 day conference in October 2022. This was the first face to face conference that the RCM had held since the Covid pandemic. ASW were able to engage with colleagues and update on changes within the antenatal screening programme. Short animations highlighting the pathway for antenatal screening programmes had been published and these were showcased during this event.

Figure 9 : Image from ASW stand-RCM Conference

Digital Maternity Cymru

Welsh Government has provided funding from the Digital Priorities Investment Fund to Digital Health and Care Wales (DHCW) to undertake the discovery phase of the Digital Maternity Cymru (DMC) project. ASW has engaged with DMC to scope the requirements for monitoring ASW standards within health boards in Wales within a digital solution for maternity records. The solution to have the ability to review real time screening information will allow the health boards to monitor the quality of the antenatal screening programmes, and monitor themes and issues of concern which currently may be identified and reported late due to the lack of real-time data that is supported by a digital system. ASW, in partnership with health board leads, are currently scoping future performance indicator reporting in line with real-time data.

Radiology Information System Procurement (RISP)

Following a procurement process by Digital Healthcare Wales (DHCW), Phillips were awarded the contract for the all-Wales radiology information system in 2023. Implementation of the Phillips system *Soliton* will begin in spring 2025 on an individual Health Board basis and is predicted to take two years. As part of this change obstetric reporting will move to *Viewpoint*, ASW are working collaboratively with the implementation team towards report standardisation for screening scans in-line with current practice.

Digital Health Care Wales (DHCW) and Welsh Clinical Portal (WCP)

ASW are working with DHCW for the accessibility of screening results for Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) to be uploaded to WCP. The results process for



T13,18 and 21 is managed within antenatal clinics within Wales. But the addition of uploading the results to WCP will assist clinicians to view the reports and specifically a serum marker which some health boards use within the management of small for gestational age.

Service User feedback on cffDNA information for women

As part of the cffDNA project, ASW collaboratively with PHW Screening Engagement Team (SET), reviewed and developed antenatal pretest public information as well as developing information specifically for cffDNA. This ensured information was fit for purpose and clear for service users to understand. Part of this work included visiting several health boards across Wales and service user feedback from diverse population on proposed information.

Programme specific work

Ultrasound and Fetal Anomaly

Biannual DQASS reporting

ASW commission the Down's syndrome screening quality assurance service (DQASS) to monitor and support the performance of the Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T18) screening pathway in Wales. The all-Wales Biochemistry Laboratory in Cardiff and Vale University Health Board, submit data biannually to DQASS. This consists of all paired crown-rump length (CRL) and nuchal translucency (NT) measurements for all sonographers delivering screening. Each sonographer has a unique identification code (DQASS code) which is submitted along with the measurements on the same form. DQASS produce a plot for each individual sonographer assessing bias, spread and trend against the Fetal Medicine Foundation reference curve and issue a flag status accordingly.

Sonographers are awarded a flag to record their performance.

- Green flag is where the bias for the plot is less than 0.1 and there is no evidence of substantive difference in spread or trend from the FMF reference curve
- Amber flag is where the bias is between 0.1 and 0.3 or there is a substantive difference in spread or trend from the FMF reference curve
- Red flag is where the bias is greater than 0.3. No red flags are given for spread or trend differences
- White flag is where a sonographer performs less than 25 paired measurements over a 6-month cycle, or less than 50 a year. This prevents DQASS performing a meaningful plot interpretation.

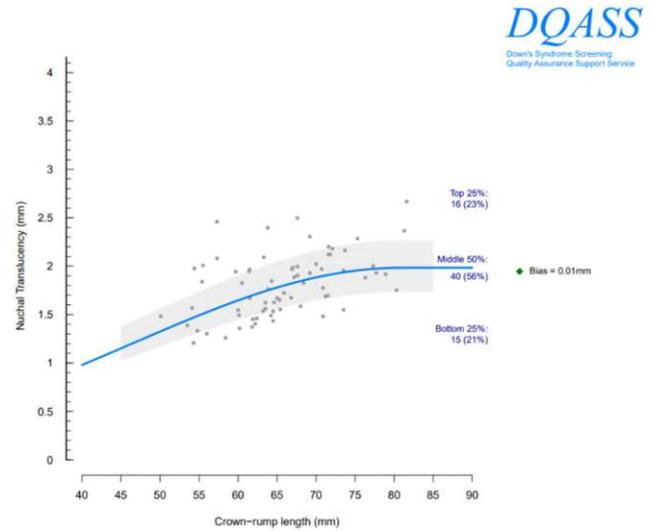


Figure 10 : Sonographer individual DQASS plot

Sonographers with a bias of >0.3 are issued with a red flag and temporarily paused from independently performing combined screening scans, as their measurements will negatively impact the performance of the screening programme.

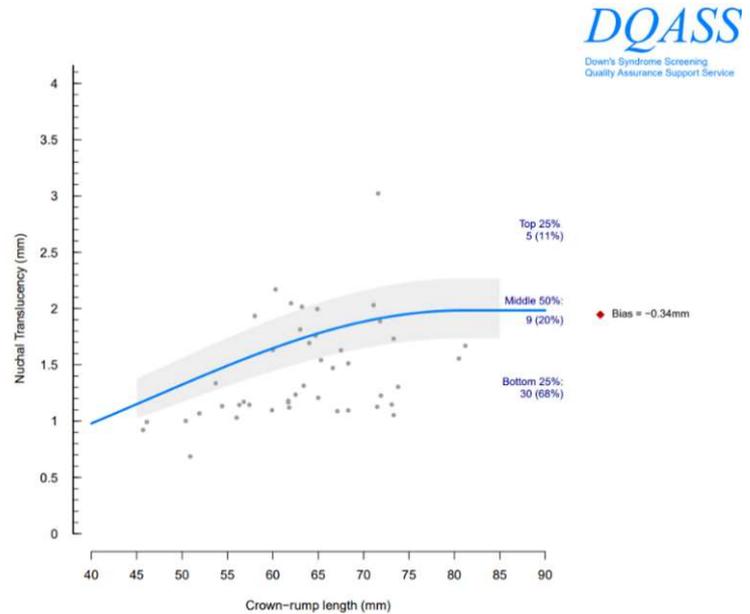


Figure 11: Sonographer individual plot demonstrating bias

Within this reporting timeframe there have been 1.4% of sonographers issued with a red flag. As a consequence of a red flag being issued, ASW work with Health Board nuchal translucency (NT) leads and MAC governance leads to agree an action plan involving supported practice and emotional support. Sonographers must submit 25 paired measurements for a new flag status to be issued prior to resuming independent practice.

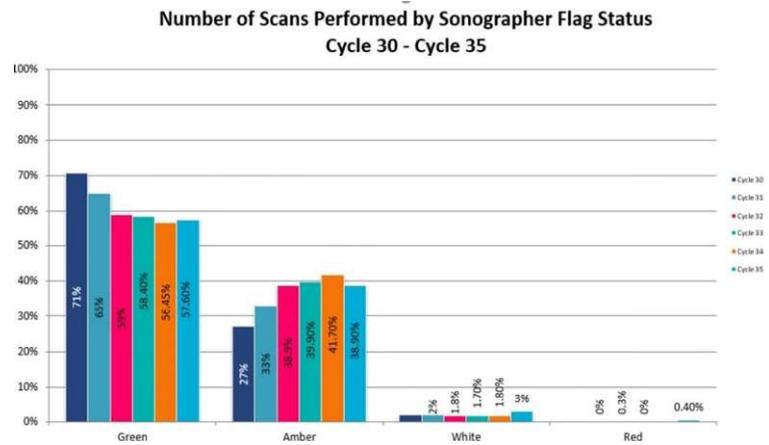


Figure 12 : Graph demonstrating sonographer flag status

The Welsh Study of Mothers and Babies (2014) found that 30% of echogenic fetal bowel cases were reclassified as normal upon expert review. In 2020, the ASW obstetric ultrasound advisor and ASW ultrasound programme coordinator audited echogenic bowel cases and found that 26.5% were reclassified as normal. Following this audit, imaging guidance was revised in 2022 with input from obstetric ultrasound Leads around Wales, with the aim of improving diagnostic confidence. This was implemented in June 2023. ASW plan to re-audit in 2024/2025 to gauge whether there has been improvement in diagnostic accuracy.



Figure 13: Image showing echogenic bowel and with gauge turned down still as bright as bone

Health board NT Leads image review by ASW

NT leads conduct paired image audits for sonographers biannually as part of the programme’s ongoing quality assurance, increased audit frequency is recommended where staff return an amber flag. NT leads are expected to submit images biannually for external assessment to the ASW programme coordinator leading for the ultrasound programme.

Sonographer summary report

DQASS

Hospital:

Cycle 35 (January 2024)

Region:
Screening laboratory:

University Hospital of Wales

Sonographer ID	Number of scans	Median CRL (mm)	Median NT (mm)	Bias (mm)*
🟢 (🟡)	180	65.6	1.8	0.02
🟢 (🟡)	164	64.0	1.7	-0.00
🟢 (🟡)	153	65.0	1.7	0.02
🟢 (🟡)	138	64.7	1.7	0.01
🟢 (🟡)	105	64.1	1.7	-0.03
🟢 (🟡)	93	63.6	1.7	0.06
🟢 (🟡)	83	65.5	1.6	-0.07
🟢 (🟡)	76	64.8	1.6	-0.14
🟢 (🟡)	71	65.0	1.8	0.01
🟢 (🟡)	65	64.4	1.6	-0.03
🟢 (🟡)	59	66.4	1.7	-0.05
🟢 (🟡)	57	63.7	1.6	-0.13
🟢 (🟡)	56	66.2	1.7	-0.04
🟢 (🟡)	42	64.2	1.7	0.14
🟢 (🟡)	27	62.1	1.8	0.09

Notes:

1. These flags are based on statistical summaries from the NT & CRL measurements supplied. They do not provide any assurance of the quality of the images on which the results are based nor on the positioning of callipers.
 2. These diagnostics should be read in conjunction with the individual sonographer outputs (which are also available as a pdf file).
 3. The flag shown in parentheses is that assigned in the previous cycle.
- * The bias above is the median deviation from the FMF reference curve.

Sonographer flag summary

Flag	Number of sonographers	Number of scans	Percentage of scans
🟢 (🟡)	12	1194	87.2
🟡 (🟠)	3	175	12.8
🟠 (🔴)	0	0	0.0
🔴 (⚪)	0	0	0.0
Total	15	1369	

Figure 14 : Sonographer summary report

DQASS feedback process

It has been 10 years since combined screening was implemented in Wales and ASW are working alongside the Health Boards NT leads to explore how Health Boards and NT leads can become more involved with the DQASS feedback process. Dissemination of all DQASS feedback is currently led by ASW but there are plans to move to a more Health Board driven approach, all reports will be checked and actioned within the health boards with performance data being fed back to ASW.

Sonographer educational Updates

Combined Screening – In February 2023, ASW hosted an online workshop delivered by DQASS. The workshop was open to all sonographers involved in delivering combined screening to women in Wales, but NT leads were asked to prioritise attendance. The workshop covered the impact of crown rump length (CRL) and NT measurements on test performance along with discussions around plot interpretations. The workshop was well-attended and gained positive feedback. A recording of the workshop was hosted on the ASW professional platform for further viewing.

Cardiac ultrasound – In November 2022 and January 2024 ASW funded 42 sonographers to attend the Welsh Fetal Cardiovascular Network meeting in the National Imaging Academy. This ensures provision of training and updates for the ultrasound programme. Fetal cardiology and ultrasound applications specialists deliver meetings that inform on common congenital cardiac anomalies and image optimisation.

Ultrasound written information for women

Information about your scan – ASW in partnership with sonographers and midwives in 2009, developed information leaflets for pregnant women following screening scans. These leaflets covered possible scan outcomes and were available for sonographers as supplementary information to provide to women at the same time as the discussion on the finding of the scan. There has been some variation in use of the hard copy outcomes and agreement that their inclusion will be considered as part of ongoing work to develop an all-Wales electronic Maternity Record.

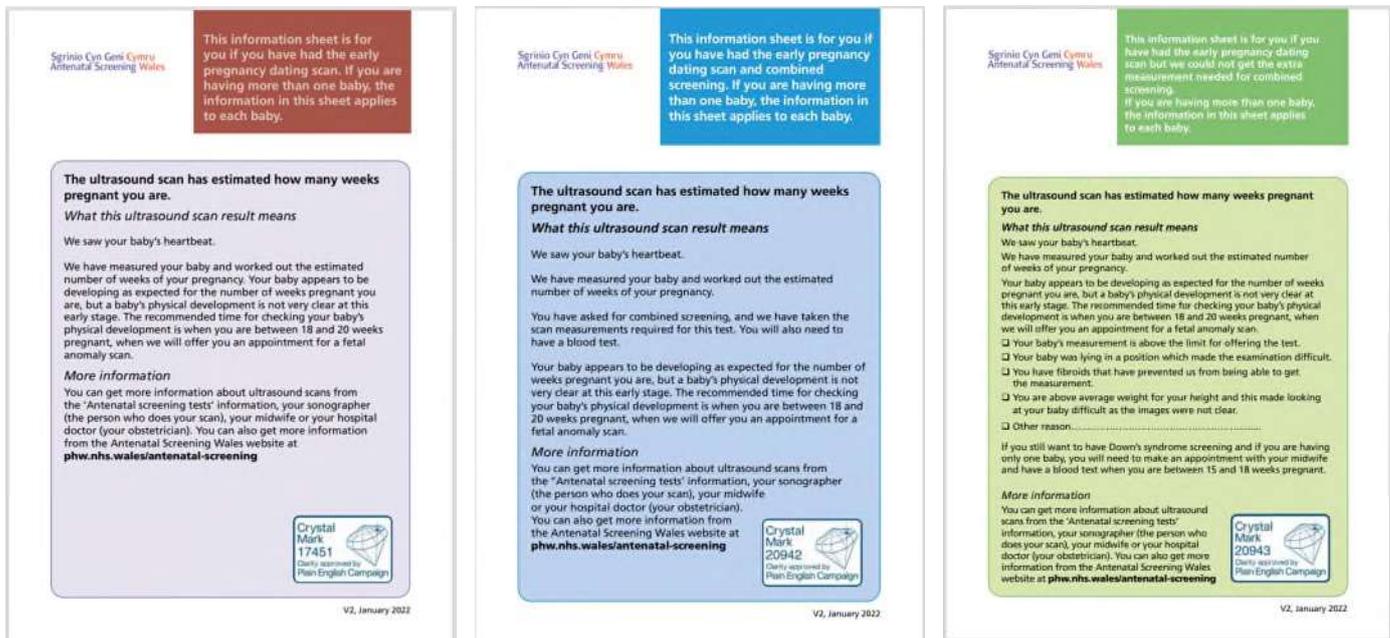


Figure 15 : Example of information leaflets following screening scans

Scoping the addition of the abdominal circumference (AC) measurement to the routine anomaly scan

In 2016, following requests from obstetric clinicians to include the abdominal circumference (AC) at all routine anomaly scans ASW commissioned a public health registrar to review available literature. The outcome of this evidence review was that there was insufficient evidence to warrant a change in practice. This was supported by ASW advisory groups, where it was felt that there would be additional training and time requirements. Following further enquiries by clinicians in 2022 ASW again discussed the additional measurement with their advisory groups. It was found that expert opinion had changed, and though there was no new available evidence, there was general support for its introduction. Wales Screening Committee (WSC) approved this programme modification in November 2023 following assurances from radiology service managers that this could be included without additional resources. ASW are leading on the implementation and has convened a task and finish group of stakeholders to plan the safe implementation of the AC to the anomaly scan and screening pathway. The implementation is scheduled for October 2024 for all Health Boards in Wales ASW will provide ongoing evaluation of the pathway.

Blood Group and Antibodies – Cell-free fetal DNA (cffDNA) Screening

ASW was asked by Welsh Government (WG) to meet with Welsh Blood Service (WBS) and scope the feasibility of introducing the offer of cell-free DNA testing for fetal RhD genotype to pregnant women who are D negative and not sensitised to D antigen.

Following discussions between ASW and WBS a briefing paper with high-level intent was presented to WSC to gain agreement to take this work stream forward. This project was approved by WSC in 2018. The project in Wales is called Cell-free fetal DNA (cffDNA) Screening. With the start of the Covid-19 global pandemic the project was suspended with discussions recommencing in January 2022. Since June 2022 the Project has undertaken many workstreams to enable implementation across the seven health boards simultaneously.

Collaborative working enabled ASW, Welsh Blood Service, Health boards, Screening Engagement Team (SET) as well as engaging with service users to aid the development of the public information to ensure the implementation of the Project on 13th May 2024. Collaborative working has enabled the objectives of the project to have been managed and met successfully.

Workstreams:

Project Board

A project board consisting of key stakeholders was agreed to inform and progress the implementation of cffDNA screening across Wales for women who are RhD negative. Part of the remit was to agree information, develop education, guidance, standards, and protocols for

implementation. It was also key to enable clear and transparent communication for the duration of the project.

Partnership working with Welsh Blood Service

It was instrumental to work collaboratively with WBS as they would be testing all the cffDNA samples for Wales. Pre validation and validation of the CE (Conformite Europeenne-European Conformity) marked kits, which would test the samples, as well as the development of the end-to-end testing pathway was managed from a laboratory perspective.

Health Board Implementation Teams

Individual health board implementation teams were developed with appropriate memberships to facilitate the management and actions needed, following agreement by the Project board.

This was to ensure:

- the health boards were able to implement the offer of cffDNA smoothly
- all relevant staff were educated with developed resources,
- the offer of cffDNA to those eligible and that women could be supported appropriately to make an informed choice.

ASW resources developed in readiness for implementation of the offer of cffDNA to RhD negative women

Information for women

- Pre-test written information and animation

All pregnant women who present for antenatal care are directed to ASW pre-test information which includes information on the screening pathway and a short animation.

- Post test information for women who are RhD negative

All eligible women would be provided with post test information which specifically explains about cffDNA screening test. This information would be in addition to the relevant discussion with the health professional.

Resources for health professionals involved in the Blood Group and Antibodies pathway in pregnancy.

Several resources have been developed to aid midwives, student midwives and other health professionals with the offer and management of care.

- cffDNA screening test: A Guide for Health Professionals. ASW and WBS have developed this resource to provide guidance for midwives completing the screening request card for cffDNA screening.
- Scenarios Resource has been developed to provide additional information for health professionals who are involved in the delivery of cffDNA screening.
- Blood group and antibodies screening Cell free fetal DNA genotyping pathway. This resource has been developed to provide additional information for health professionals who are involved in the delivery of cffDNA screening.
- cffDNA Sample taker SOP - ASW and WBS have developed this resource to provide guidance for midwives completing the screening request card for cffDNA screening.

ASW Policy, Standards and Protocols

ASW Policy, Standards and Protocols have been reviewed to include the offer and management of cffDNA. These will be published to ASW sharepoint prior to implementation which is due to commence on 13 May 2024.

E-learning update

An e-learning resource for blood group screening, RhD screening, antibody screening and the offer of cffDNA screening in pregnancy has been produced during the Project phase and will be available for health professionals from July 2024. This resource is to support health professionals who are involved in the delivery of the blood group screening, RhD screening, antibody screening and cffDNA screening programme in the NHS in Wales.

cffDNA Cascade Training

The resource has been produced by ASW and is aimed at midwives, obstetricians, nurses, and laboratory staff working in transfusion laboratories. It includes information on the management of pregnant women during their pregnancy, the birth and following birth, whose blood group is D negative. The content covered will provide information on Cell free fetal DNA (cffDNA) screening including:

- What is cffDNA?

- Why offer screening?
- Who is eligible for screening?
- Test performance

Implementation and the screening pathway

The education resource was published on 15th March 2024 and recommended that health professionals who will be offering the screening test from May 13 2024, completes the resource by the end of April 2024 to allow for up to date information to be provided to women.



Figure 16 : Education resource-Cell free fetal DNA Screening

Educational drop-in sessions

ASW are hosting educational drop in sessions from April 2024, up until December 2024 where health professionals are encouraged to attend to discuss any aspect of the pathway or any queries that they may have.

Other health professional resources, which were updated to capture the addition to the pathway, were:

- midwives handbook
- screening test request card

- invasive testing consent form and,
- invasive testing procedure form

CffDNA Screening pathway for discrepant results

cffDNA screening test is a highly accurate test. As with any screening test there will be a small percentage of false positive and false negative results reported. A pathway has been developed for health professionals to follow, where a discrepant result has been identified post-delivery. The pathway will enable health professionals to follow a simplified process in the management of these results. This will include involving the local hospital Transfusion Laboratory, Welsh Blood Service, and subsequent reporting to Serious Hazards of Transfusion (SHOT) following an investigation.

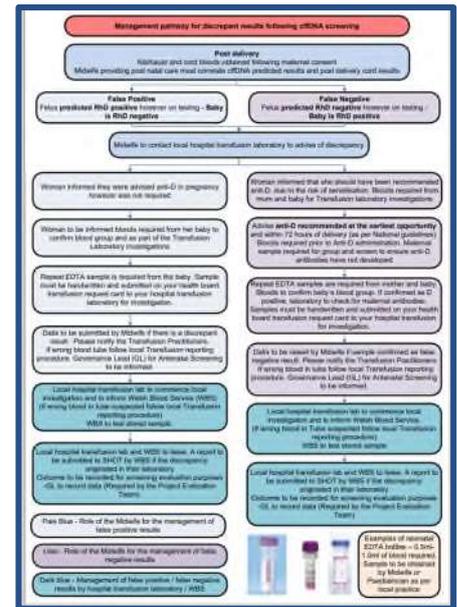


Figure 17 : Pathway for discrepant results

CffDNA - A guide for professionals' resource

This resource has been developed by the cffDNA Project Board and is available to provide additional information for health professionals who are involved in the delivery of cffDNA screening.

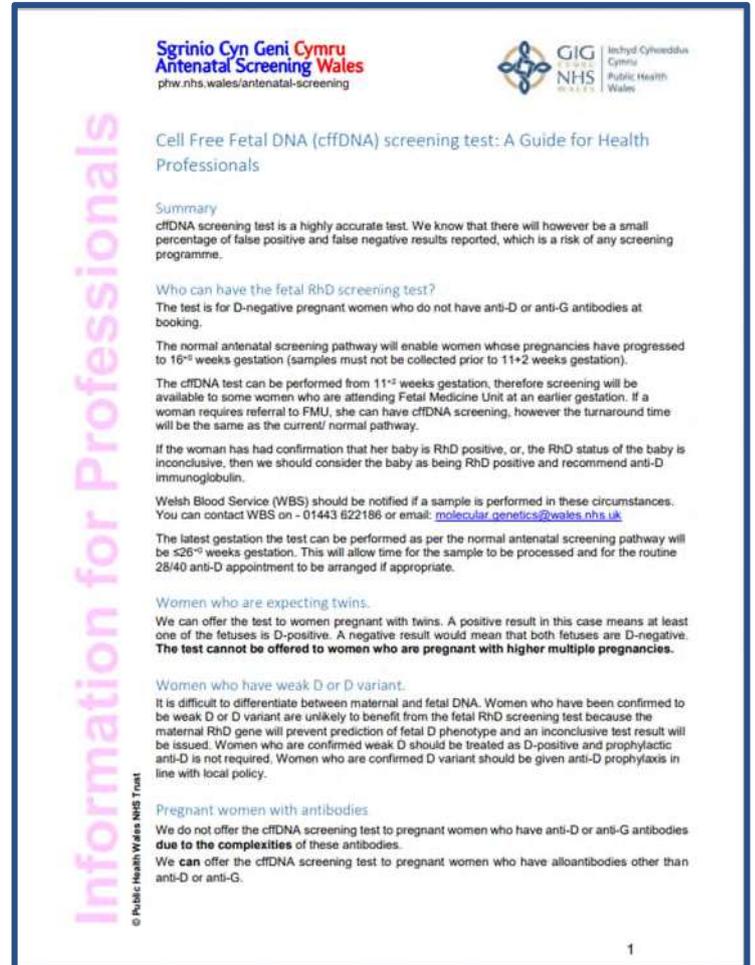


Figure 18 : Professional resource for the management of Cell free fetal DNA

Evaluation of cffDNA

There will be an evaluation of the project which will commence in July 2024 and form a one year evaluation which aims to monitor the pathway and the performance of the screening test.

Discussions are currently ongoing with regards to the evaluation aims and objectives. The evaluation board will consist of many of the key stakeholders that were part of the project board alongside some members of the Public Health Evaluation Team.



Sickle cell and thalassaemia

Review of the Neonatal pathway: Investigation and referral of haemoglobinopathy disorders in the newborn

ASW reports timeliness of referring and management of babies with suspected and diagnosed haemoglobinopathy disorders. The Performance Indicators identified that the standard was not being achieved. The pathway was reviewed in January 2023, in line with performance indicator performance and an increase in Datix had been highlighted by one of the Haemoglobinopathy Laboratories for the timeliness of referring babies. A retrospective audit was conducted with the objective to audit babies diagnosed with sickle cell disorder from newborn bloodspot screening received their first clinic appointment and prophylaxis penicillin within the recommended timeframe as per national guidelines. 18% of babies were referred as per guidance. Therefore, the pathway required a timely review.

The pathway for the neonatologists for the investigation and referral of haemoglobinopathy disorders in newborn was reviewed and updated. A multidisciplinary approach to the review proved valuable with input from ASW and:

- paediatric colleagues
- all Wales Genomics Services
- haemoglobinopathy laboratory
- Newborn bloodspot programme coordinators, and
- specialist nurses across Wales.

The neonatal pathway was shared with the antenatal screening coordinators and MAC governance leads across Wales to cascade within the neonatal departments within the Health Boards. As this was a collaborative approach to improve the pathway it has been published to ASW sharepoint and following agreement, with the Maternity and Neonatal Network website since June 2023.

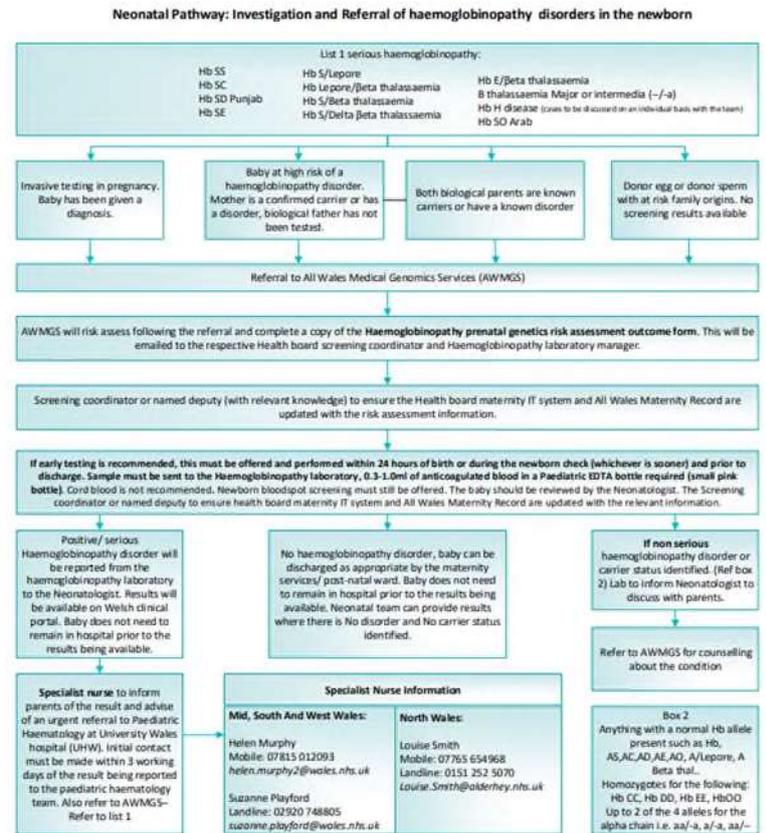
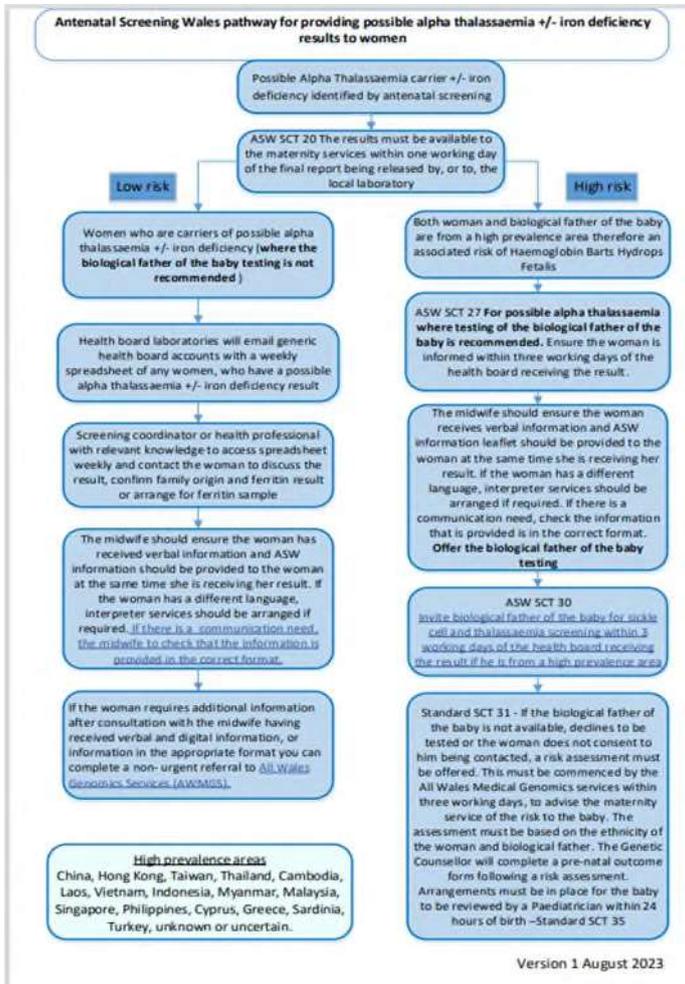


Figure 19: Pathways for management of possible alpha thalassaemia and neonatal pathway

Possible alpha thalassaemia +/- iron deficiency review

It was identified that there is variation of how health boards across Wales are interpreting and managing the results of 'possible alpha thalassaemia +/- iron deficiency' following antenatal screening.

On reviewing the evidence of this finding, it was found that this does not pose a risk to women who have a possible alpha thalassaemia +/- iron deficiency result. It is key to note these results are only for women where the baby's biological father does not need to be offered testing and where the family origin has been completed and therefore is not interpreted as a clinically significant result for this specific condition.

A pathway was devised and agreed whereby these results are managed in a timeframe acceptable to the finding. ASW information for women was amended in line with the amended pathway.

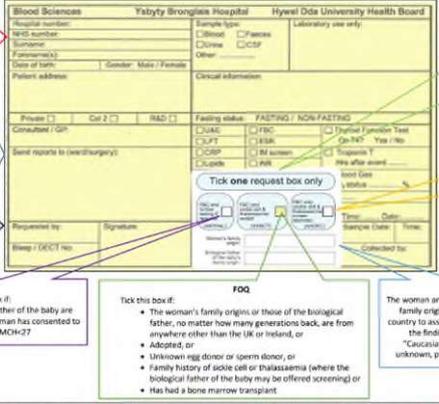
ASW worked with antenatal screening coordinators on cascading the new pathway to for community midwives to enable them to inform the woman of the result at the 16 week antenatal appointment.

Health boards agreed to produce local guidance for women who are iron deficient in pregnancy as this is outside the ASW Programme remit.

Update to teaching aids-maternal haemoglobinopathy request card and request card for biological father of the baby

ASW produce visual teaching aids to support the Programme. A review of the haemoglobinopathy teaching aid has been published and includes the linkage of maternal result with that of sample request and reporting for the biological father of the baby. This should result in the number of rejected samples following biological father of the baby. The teaching aid was published in May 2022.

Completion of maternal antenatal Sickle Cell and Thalassemia screening request card



Identification of the woman
Clear identification of the woman is required to ensure results are attributed to the correct individual.

Lead professional/ hospital
Clear details of where to send the report are required. Please state if Royal Glamorgan or Royal Gwent. RGH is not sufficient as a location.

Requester details need to be printed, if signature is required on the consent form please ensure it is legible.

FOQ
Tick this box if: The woman and biological father of the baby are from UK or Ireland and the woman has consented to further testing if MCH-27

FOQ
Tick this box if:
• The woman's family origins or those of the biological father, no matter how many generations back, are from anywhere other than the UK or Ireland, or
• Adopted, or
• Unknown egg donor or sperm donor, or
• Family history of sickle cell or thalassaemia (where the biological father of the baby may be offered screening) or
• Has had a bone marrow transplant

Family origin questionnaire (FOQ)
Only tick the correct consent box, as it is vital to determine the level of screening that is required. Ticking the incorrect consent box may lead to a potentially at risk unborn baby not being detected.

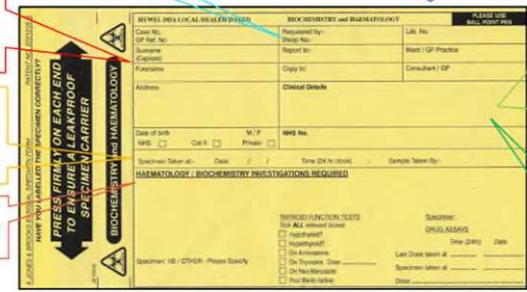
FOQ
Tick this box if the woman declines sickle cell and thalassaemia screening. A FBC only will be performed.

Date of collection
It is essential to date the sample for the laboratory to test in a timely manner.

FOQ
The woman and biological father of the baby, family origins must be documented by country to assess the possible significance of the findings. Do not use the term "Caucasian" if the family origins are unknown, please document "unknown".

This is not a universal request card so request cards will differ however the sections are all pertinent.

Completion of antenatal Sickle Cell and Thalassemia screening Request card for baby's biological father testing



Identification of the biological father
All information of the biological father will need to be hand written: name, address, date of birth, hospital number or NHS number if known

Please print requesters name clearly
(some request cards will require a signature also, again please ensure it is legible)

Lead professional/ hospital
Clear details of where to send the report is required. Please state if Royal Glamorgan or Royal Gwent. RGH is not sufficient as a location.

Clinical Details
Please **handwrite:** Woman's name, hospital number and date of birth.
Biological father's details can be linked with woman's details. Please do not add the woman's address/graph the partner request form.

Clinical details
Document if biological father of the baby has had a bone marrow transplant

Date of collection
It is essential to date the sample for the laboratory to test in a timely manner.

Test request
Haemoglobinopathy screen

This is not a universal request card so request cards will differ however the sections are all pertinent.

Figure 20: Visual Aids for correct completion of request cards

Haemoglobinopathy e learning for health professionals

ASW has produced an e learning package on sickle cell and thalassaemia screening in pregnancy. This is due to be available to health professionals after April 2024.



Figure 21 : Screenshot from sickle cell and thalassaemia e learning package

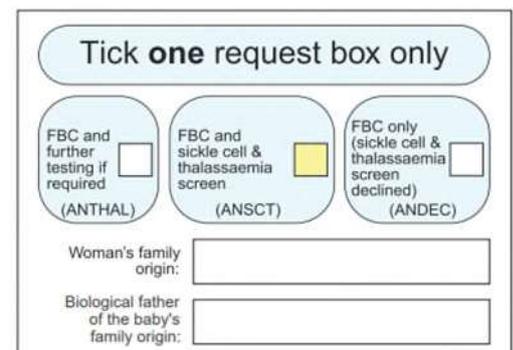
Low Prevalence Algorithm

Currently Wales is identified as a low prevalence area for sickle cell and thalassaemia (SCT) but emerging data from the All Wales Haemoglobinopathy Laboratory is indicative that this is changing and Wales may be approaching a high prevalence area. There is a planned review to be undertaken in 2024-2025 to consider next steps.

Amending acronyms within the request card

ASW has worked with the All Wales Haemoglobinopathy Laboratory to simplify acronyms used within the test request process throughout all laboratories in Wales. This will enable safer requesting and ease of laboratory auditing. There was no impact within clinical practice for the amendment. An audit of practice will take place later in 2024.

The acronyms are important as part of the consent process to identify women who are at high risk of being a haemoglobin variant carrier. The acronyms identify women who are considered to be at high or low risk based on their family origin.



The request card sticker is titled "Tick one request box only". It contains three boxes for selection:

- (ANTHAL):** FBC and further testing if required.
- (ANSCT):** FBC and sickle cell & thalassaemia screen.
- (ANDEC):** FBC only (sickle cell & thalassaemia screen declined).

Below the boxes are two text input fields:

- Woman's family origin:
- Biological father of the baby's family origin:

Figure 22 : Request card sticker showing simplified acronyms

Safe introduction of electronic test requesting (ETR)

Further work with health board colleagues and Digital Healthcare Wales (DHCW) is ongoing to ensure that there is a safe process in place within electronic test requesting (ETR) for the antenatal screening test for sickle cell and thalassaemia. Some health boards had previously implemented ETR for the screening test but some consent concerns were raised. In view of this, one health board has temporarily discontinued ETR for sickle cell and thalassaemia screening and other health boards who have introduced ETR and are aware of the concerns, are managing their processes to mitigate the issues.

Haemoglobinopathy Carrier Leaflets

ASW has undertaken a biennial review of published leaflets where a carrier status for one of the screened conditions was found. The purpose of the digital leaflets is to provide information on what it means for the woman and her family when she is diagnosed as being a carrier. The information is to complement discussions with a health professional to aid understanding. The biological father of the baby would be offered testing if the mother of the baby is a carrier to assess the risk to the current pregnancy and also any future children the couple may have together. Further work with Newborn Bloodspot Screening Wales is planned from May 2024 to streamline the information provision from antenatal care to care of the neonate.

Review of sickle cell and thalassaemia specific standards and protocols

As part of the 3-year ASW policy, standards and protocol review, specific amendments to the sickle cell and thalassaemia programme included streamlining the counselling referral pathway to All Wales Genomics Services for:

- pregnancies where a donor egg/donor sperm where the donor is known. The standard initially stated in the case of surrogacy pregnancies achieved by a donor egg or donor sperm which are unknown, where the fetal risk cannot be accurately assessed, a referral should be offered to the woman to the All Wales Medical Genomics Service (AWMGS). In circumstances where the donor egg or donor sperm is definitively known, a referral to AWMGS is not necessary.

Down's syndrome (T21), Edwards' syndrome (T18) and Patau's syndrome (T13) and Fetal Anomaly Screening Programme

Evaluative rollout of non invasive prenatal testing

The addition of NIPT as part of this change was a recommendation from the UK National Screening Committee (UKNSC) as an evaluative roll out for singleton pregnancies. The offer of non-invasive prenatal testing (NIPT) to women with a singleton pregnancy and a twin pregnancies who have with a

higher chance screening result for T21 or T18/T13 syndrome was commenced in April 2018 and June 2021 respectively. The findings from the Evaluative rollout were published in May 2022.

NIPT evaluation

The UKNSC recommended that the addition of the offer of non-invasive prenatal testing be implemented as an evaluative roll out. The evaluation of NIPT aimed to answer the following four questions:

1. What impact does NIPT have on the decisions women and their partners make?
2. What is the performance of the test for T18 and T13?
3. How often is there a “no result” from NIPT?
4. What is the time taken for women to receive NIPT results?

Following the successful implementation, ASW established an Evaluation Board to monitor the evaluative roll out of NIPT. This evaluative period included 3 years of the offer of NIPT. This included all pregnancy outcomes for women who opted for T13, T18 and T21 screening between April 2018 and November 2021. Wales Screening Committee agreed the final evaluative rollout report in July 2022.

Findings following the three year evaluative rollout.

Women were informed and supported in their choices and that they understood that they could leave the pathway at any point. This was apparent in the findings from the evaluative rollout. Findings of the first 19 months of the evaluative rollout was published in May 2022 [Prenatal Diagnosis Implementation of non-invasive prenatal testing within a national UK antenatal screening programme: Impact on women's choices - Bowden - 2022 - Prenatal Diagnosis - Wiley Online Library](#)

Implementation of non-invasive prenatal testing within a national UK antenatal screening programme: Impact on women's choices

Bethan Bowden, Sikha de Souza, Alice Puchades, Kindry Williams, Sian Morgan, Sarah Anderson, David Tucker, Sharon Hillier

Prenatal Diagnosis | Volume 42, Issue 5
First published: 12 March 2022

Abstract ^

Abstract Objective

To evaluate the implementation of non-invasive prenatal testing (NIPT) on pregnant women's choices in a national NHS antenatal screening programme for Down's syndrome, Edwards' syndrome and Patau's syndrome.

Figure 23 : Screenshot from the published paper

Womens choices

- Around 86 % of women with a higher chance combined or quadruple result chose a NIPT
- 12 % chose no further testing, and
- 2% chose an invasive test - this translated into a nearly nine-fold reduction in women undergoing an invasive test
- no difference in Down's syndrome live birth rates in Wales (2015-2020). There was the potential that adding further screening tests into the NHS screening pathway, may translate into increased terminations of pregnancy when Down's syndrome is diagnosed following screening.

Laboratory testing

- 93% low chance NIPT results
- 6% high chance results
- 1% failed NIPT results
- 84% for results of NIPT from draw to results provided to the health board within 0-5 calendar days

Performance of NIPT as a contingent test

The performance of NIPT for T13 and T18 was not answered in the evaluation period due to small numbers of Edwards' syndrome and Patau's syndrome pregnancies within the population. ASW are working with the Home Nations to monitor performance as Scotland and England are still within the countries evaluative rollout period.

Increased uptake of primary screening tests - Recommendations from the report

There was an increase in uptake of screening tests of:

- 4%-8% during the first two years of evaluation and
- 12% in the final 6 months of evaluation.

As a recommendation from the report, ASW was committed to investigate the potential reasons for the increased uptake of the initial screening test. This final six months of the evaluative rollout, was women who were pregnant during the height of the COVID pandemic, and this context needs to be taken into consideration. This work stream is currently ongoing with surveys asking women's views on screening tests that they have been offered over the past 5 years, and a survey for sonographers and

midwives on their experiences of managing women who have been offered screening for T13, T18 and T21. The results will be analysed Autumn-Winter 2024 and recommendations made from the findings.

Sharing the Findings of the Evaluative rollout

The findings of the evaluative rollout was shared with colleagues in Wales and within the UK.

- Fetal and Maternal and Child Health (May 2022)
- All Wales Maternity and Neonatal Network Network (May 2023)
- Antenatal Results and Choices (ARC) National Conference (Sept 2023)

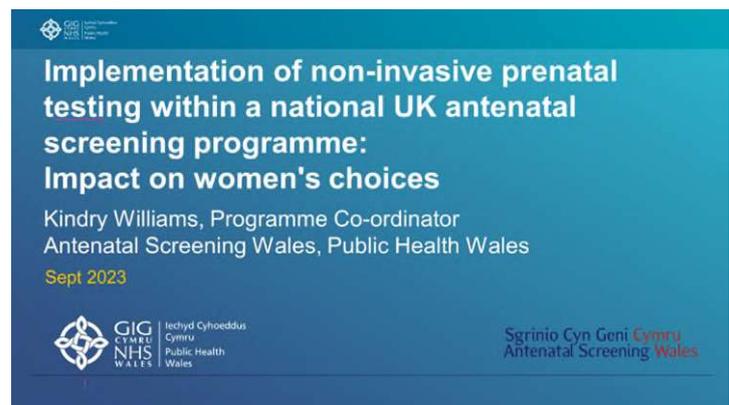


Figure 24 : Screenshot from the presentation

Business as Usual for NIPT

ASW in partnership with the All Wales Genomics Laboratory, monitors and reports NIPT performance to health boards on an annual basis following the completion of the three-year evaluative rollout. ASW work closely with NHS England and Public Health Scotland as part of 3 Nations Evaluation of NIPT. Data for April 2022-Mar 2023 continues to show similar findings as that of the evaluative roll-out period. See table below:



Table 2 : All Wales Screening and Diagnostic data annual data (2022-2023)

Data source: Diagnostic laboratory IT system					Comments
a. How many NIPT samples were performed for a higher chance combined or quadruple screening test in a singleton pregnancy	620				
b. How many NIPT samples were performed for a higher chance combined screening test in a twin pregnancy	4				
Total NIPT tests performed: (auto-completed)	624				

Data source: Diagnostic laboratory IT system					Comments
	T13	T18	T21	Total	
c. How many were high chance NIPT results in a singleton pregnancy	1.1%	1.9%	6.5%	9.5%	
d. How many were high chance NIPT results in a twin pregnancy	0.0%	0.0%	0.0%	0.0%	
Total high chance NIPT results: (auto-completed)	1.1%	1.9%	6.5%	9.5%	

Data source: Diagnostic laboratory IT system					Comments
e. How many were low chance NIPT results in a singleton pregnancy	90.5%				
f. How many were low chance NIPT results in a twin pregnancy	100.0%				
Total low chance NIPT results: (auto-completed)	90.5%				
(auto-completed)	90.5%				

Data source: Diagnostic laboratory IT system					Comments
g. How many tests did not provide a result	0.0%				

Data source: Diagnostic laboratory IT system					Comments
	7 or less calendar days	8-14 calendar days	>14 calendar days		
h. What is the NIPT test turnaround time in the laboratory	80.8%	18.8%	0.5%		

Mapping pathway for T13, 18 and T21 screening from consent to result reporting

ASW, in partnership with All Wales Biochemistry Laboratory and the health boards, undertook a mapping exercise to map the processes within the health boards from consent of the T13, T18 and T21 screening test to result reporting. This mapping exercise is currently being analysed by the All Wales Biochemistry Laboratory and will support streamlining the process for ease of clinicians and minimize errors within the pathway as well as provide information for the introduction of electronic test requesting (ETR) for the tests.

Understanding the challenges on completing combined and quadruple screening request cards- screening tests

The combined screening test is undertaken in a singleton or twin pregnancy from 11⁺²-14⁺¹ gestation and screens for T13, T18 and T21. The quadruple (quad) screening test is undertaken in a singleton pregnancy from 15⁺⁰-18⁺⁰ and screens for T21. Colleagues from the ASW Team, colleagues from a health board and the All Wales Biochemistry Laboratory participated in a Behavioural Change course, hosted by PHW. The challenge was to find out why request card errors for the Health Board for quadruple screening is approximately 30% (small numbers of samples taken, leading to high rates). The consequence of which leads to delays in women receiving results increasing anxiety, potential delays in onward management of higher chance and positive results and time consuming for laboratory staff and midwifery staff reversing the errors before the sample can be analysed.

A survey based on current behaviour was carried out and considering domains that scored highest, found that clinicians believed that:

- misconceptions around individuals errors in card completion
- unaware of the consequences of request card errors
- regarded card completion was a task and prioritized other tasks leading to more errors

Table 3: Behavioural domains and mean scores

Behavioural Domain	Mean Score
Social Influences	2.36
Beliefs about consequences	2.10
Motivation, goals and priorities	1.98
Action planning	1.93
Memory, attention, and decision processes	1.87
Knowledge	1.60
Professional role and identity	1.44
Emotion	1.28
Skills	1.06
Beliefs about capabilities	1.04
Environmental contexts and resources	0.88

Analysis of the findings and interventions

- The process is complex with many individuals adding information to the request card at different times and locations.
- No one takes ownership of the request card leading to the assumption that someone previously has asked the question eg smoking in pregnancy
- Lack of knowledge of the process and consequences of not completing the request card correctly.

The process needs change and a small scale pilot was carried out in a health board in Wales where a small number of health professionals were tasked with undergoing all quadruple screening tests in the health board and completed the pathway from beginning to end.

- Using this model, it was found that tasking a small number of health professionals to complete the pathway for request card and sample taking the error rate decreased to approximately 8% within a few months of the intervention. Although this rate exceeded ASW expected rates of request card error (<2%), the improvement was one of celebration and to continue on the downward trajectory of errors.
- Adopted behaviour change initiatives within the health board on request card errors:
- Team leaders will be provided with further instruction and support on delivering the request card errors to their Teams via a dashboard
- Individual feedback will be changed to Team feedback (remove blame culture)
- Encouragement to complete e learning package that focuses on correct completion of the request card. Increase uptake of health board mandatory training
- Change terminology from request card errors to mother and baby safety initiatives
- Use Antenatal Screening Coordinators as expert clinicians to remove the blame culture from the hierarchy of Team Leader providing (+/-) feedback to individuals
- Liaise with Quality Improvement Lead to support-map the process (on site) to identify any issues. Compare this with Biochemistry mapping exercise.
- Follow up on the effects of the pilot in 3 months-if this demonstrates an improvement in practice-to increase across the health board
- Follow up on use of the dashboard as a tool for improvement
- Present findings Health Board Quality Improvement Meeting/ASW Screening Coordinators and MAC Governance Leads meetings

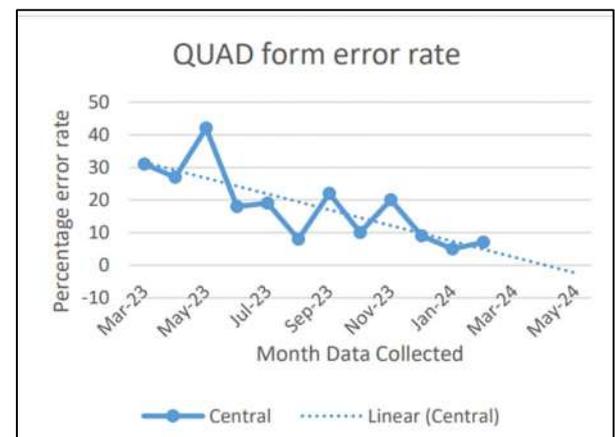


Figure 25 : graph demonstrating the decrease in request card errors

Request card Intervention Tool

As a recommendation of the behaviour course and pilot findings, ASW has produced and published a short video intervention tool on request card completion with information on what are the consequences for each incorrect data entry. This is also available as a hard copy template.

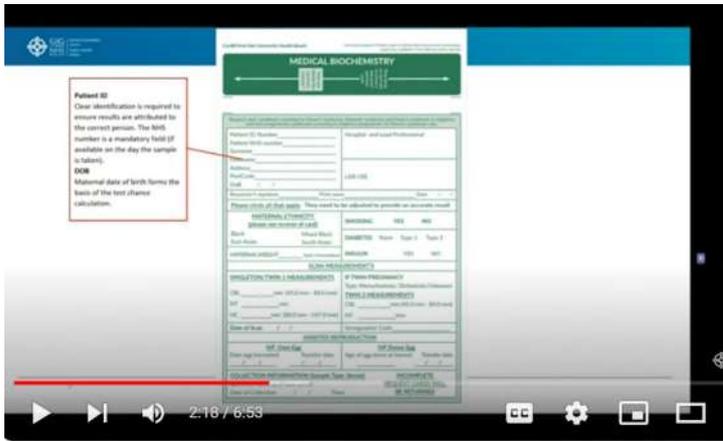


Figure 26: Screenshot from video intervention tool

Changes to the combined and quad request card

ASW has worked with All Wales Biochemistry Laboratory to update the combined and quadruple request card to include data for more improved analysis of the results.

Additions and amendments are:

- assisted reproductive information 'age of egg donor at harvest' and 'transfer date'
- mandatory inclusion of NHS numbers (if available on the day the sample is taken)
- more improved criteria for maternal ethnicities

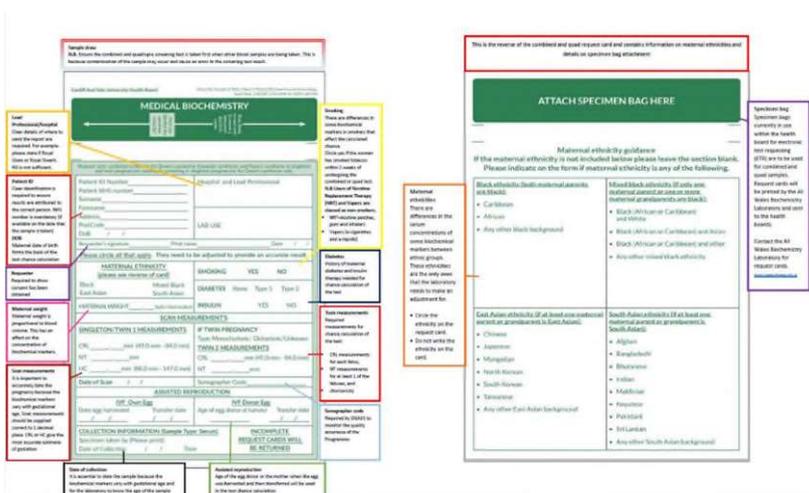


Figure 27 : Updated request card showing importance of completing each section

Re-Audit for the reasons women undergo quadruple screening

Since the implementation of the combined test (11⁺²-14⁺¹) to the antenatal screening pathway for the offer of T13, T18 and T21, the number of quadruple screening tests for T21 only (15⁺⁰-18⁺⁰) expectedly decreased. It was noted on Performance Indicator reporting that there was a variation in ratio of combined to quad screening noted within the health boards and within individual sites within the health boards. The variation also changed within each health board on a monthly basis. An all Wales snapshot audit was performed in 2019 to explore the reasons why women undergo quadruple screening. A re-audit in 2023 found similar themes to that of the 2019 audit.

Findings on why women underwent a quadruple test:

- Around 60% of women who undergo quadruple screening is because the nuchal translucency (NT) measurement on the back of the fetal neck is unobtainable. The nuchal translucency is unobtainable due to numerous factors e.g. fetal lie, large maternal body mass index (BMI).
- There are a cohort of women who are either unsure of their LMP, or assume their gestation, only to find on their ultrasound dating scan that they are at a more advanced gestation than they thought. This was 64% actual in comparison to 90% presumed on 2023 audit.
- Some women cancel their appointment for combined screening, or do not attend, and then on rescheduling the screening test, are outside of the parameters to offer combined screening.

Recommendations from the re-audit

Table 4 : Recommendations from the hepatitis B audit

Recommendations from the audit	
Maternal and Child Governance Leads to review where	receipt of the ultrasound card and timeliness of arranging the ultrasound scan
	completion of the ultrasound request card by the midwife and to return cards where there is no LMP or history pertaining to gestation arranging the ultrasound scan for 12 weeks gestation by LMP (if the woman presents for care before 12 weeks gestation)
	women being counselled on the difference between the combined test and the quadruple screening test that they will now undergo
NT Leads to review where:	the NT was unachievable (NTNOTS) per health board and per individual sonographer

	continue to offer quadruple screening test in the second trimester and monitor any local trends
ASW	To re-audit whether recommendations have had impact.

Vanished/vanishing twin update

ASW has previously produced guidance for the offer of screening for T13, T18 and T21 where there was initially a twin pregnancy where one of the twins has demised (vanishing/vanished twin). This was updated in 2023 to include guidance on the rarer scenarios where there would be a multiple pregnancy of three or more fetuses and one or more with a fetal demise found at the time of the early pregnancy dating scan.

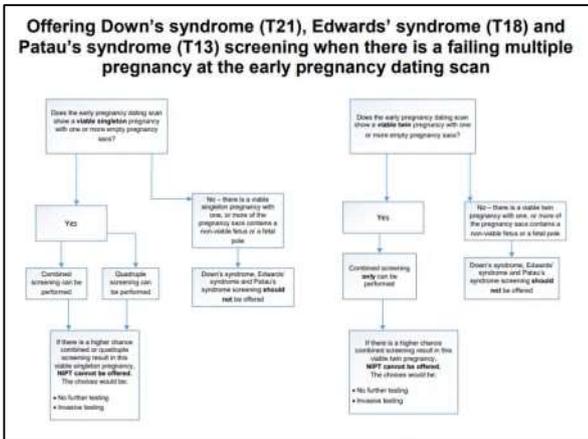
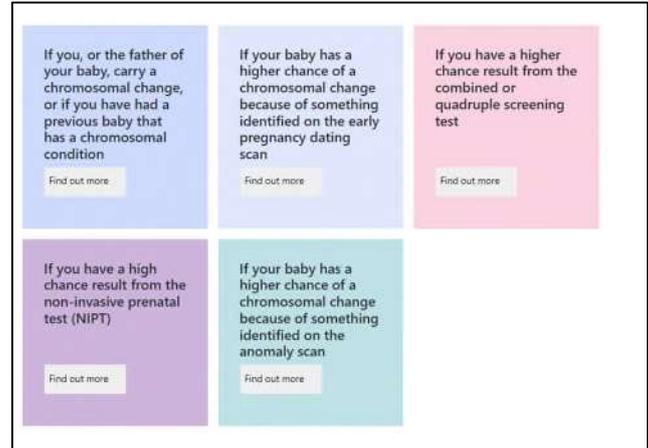


Figure 28 : Pathway for vanishing/vanished twin

Resource when there has been the offer of further tests for suspected chromosomal conditions

ASW publishes and prints "This information is for you if you have been offered further tests for suspected chromosomal conditions" which is a resource for women who have been informed that



the baby may have a higher chance of having a chromosomal condition. Not all of the sections in the booklet will be relevant to each woman or family offered the information and the health professional will discuss the sections that are relevant to read. The publication is also available on the ASW website and has now been split into the reasons that the women would be offered the information. This is to enable easier navigation of the information for users. ASW plan to work with service users for their feedback on the change in format.

Figure 29 : Screenshot from ASW website showing how the information has been reformatted

Communicable Diseases

Infections and Rashes in pregnancy

Infections and Rashes in Pregnancy: A Guide for Health Professionals

This document was reviewed by experts in Wales and published in May 2023. Its aim is to provide guidance to health professionals on the management of rashes in pregnancy and when serological tests should and should not be offered and which tests may be relevant following specific ultrasound findings. This version includes amendments on

- Immunisations recommended in pregnancy
- Virology updates for some conditions
- Updating fetal medicine referral with ultrasound findings

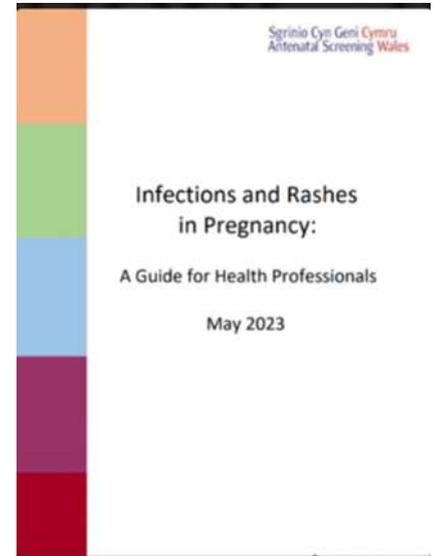


Figure 30 : Front cover of the Infections and Rashes in Pregnancy guide

Syphilis and HIV data surveillance

Previously, data for HIV in pregnancy in the UK was reported to the National Study of HIV in Pregnancy and Childhood (NSHPC), which was subsequently commissioned by Public Health England (PHE) and became the Integrated Screening Outcome Surveillance Service (ISOSS) in 2018 to continue the surveillance of HIV, syphilis and hepatitis B in pregnancy. However, due to data sharing barriers for the devolved nations, this National study only covers England for these conditions.

In Wales, the surveillance of hepatitis B in pregnancy and neonatal vaccination is undertaken by CDSC (Communicable Diseases Surveillance Centre, Public Health Wales). ASW, in partnership with Congenital Anomaly Register and Information Service (CARIS) and Health Protection PHW, have established a data surveillance system for HIV and syphilis in pregnancy in Wales collecting data retrospectively from positive screening results from 1 Jan 2023.

Information for Professionals

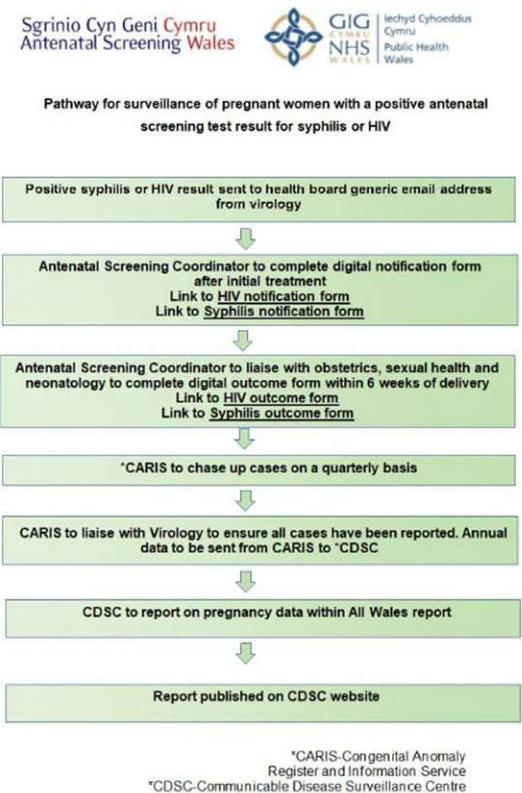


Figure 31: Pathway for management of surveillance for syphilis and HIV data in pregnancy in Wales

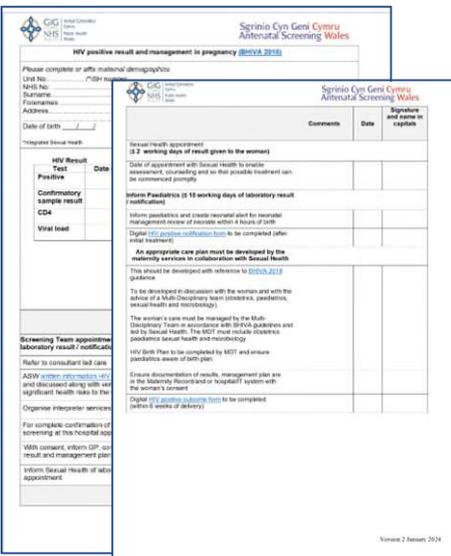
Health boards will complete an all Wales notification form and outcome form for all pregnant women that test positive for syphilis or HIV in pregnancy.

This person identifiable information (PII) will be forwarded to the Congenital Anomaly Registration & Information Service (CARIS) team who will collate and include in the official statistics annually updated data tables. The CARIS team will share the data with the Communicable Disease Surveillance Centre (CDSC) team on an annual basis for analyses, and reporting with context in their established Communicable Diseases Surveillance Centre PHW (CDSC) All Wales Annual Report.

This information is currently not captured in Wales and, therefore, surveillance of both conditions does not occur in Wales. Collecting and reporting on screening outcome data for the infectious diseases in pregnancy screening (IDPS) programme will support ASW and CDSC to assess the impact of the conditions in Wales. This leads to recommendations being made locally and nationally, strengthening policy and practice, and improving care for mothers and their children within Wales. By collecting data on a national level within Wales, CDSC can contribute to other national and international public health surveillance services to add to wider global intelligence on infectious diseases.

Aide memoires for the Management of HIV, syphilis and hepatitis B in pregnancy

ASW has produced and published aide memoires for clinicians leading on the the management of HIV, hepatitis B and syphilis in pregnancy. Their purpose is that all recommended areas of management are located in one easily assessable document. A link to the CARIS data surveillance forms was added following the implementation of data surveillance for HIV and syphilis in pregnancy in December 2023.



HIV positive result and management in pregnancy (SHTA 2023)

Please complete or refer maternal/obstetrician

LHM No. (PII required)
 NHS No.
 Surname
 Forename
 Address
 Date of birth / /

*Interpret Sexual Health
 HIV Result
 Test Date
 Positive
 Confirmatory sample result
 CCA
 Viral load

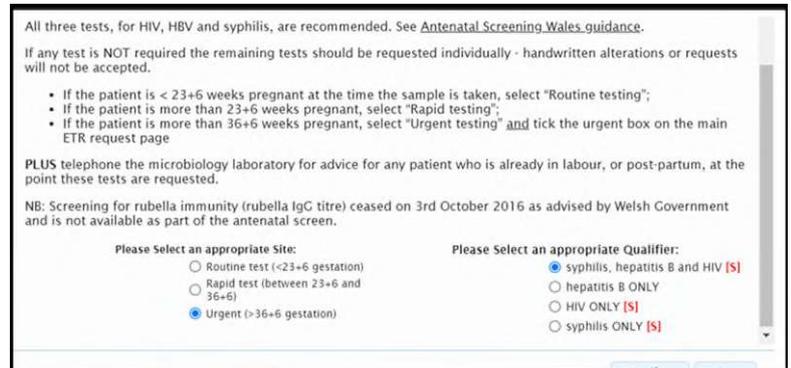
Comments	Date	Signature and name in capital
Sexual health appointment 12-13 working days of result given to the woman		
Date of appointment with Sexual Health to review assessment, counselling and so that possible treatment can be commenced promptly		
Inform Paediatrics (15 working days of laboratory result notification)		
Inform paediatrics and create neonatal and foetal management review of neonate within 4 hours of birth		
Digitally sign maternal outcome form to be completed (after initial treatment)		
An appropriate care plan must be developed by the maternity services in collaboration with Sexual Health		
This should be developed with reference to SHTA 2023 guidance		
To be developed in discussion with the woman and with the advice of a Multi-Disciplinary team (obstetrician, paediatrician, sexual health and microbiology)		
The woman's care must be managed by the Multi-Disciplinary Team in accordance with SHTA guidance and led by Sexual Health. The MDT must resolve issues to coordinate sexual health and microbiology		
HIV Data Plan to be completed by MDT and ensure paediatrician aware of Data plan		
Ensure documentation of results, management plan are in the Maternity Record and/or hospital system with the woman's consent		
Digitally sign maternal outcome form to be completed (within 8 weeks of delivery)		

Version 2 January 2024

Figure 32 : Screenshot of aide memoire

Electronic test requesting (ETR)-addition of clinical information

The Team has been working with colleagues in Virology and Welsh Laboratory Information System implementation group to add gestational age at the time of the test to electronic test requesting. This added information will enable the laboratories to assess the urgency of analysis of the test ie routine, rapid, or urgent as indicated in the screenshot. Urgent and rapid testing should be analysed and reported upon within 1 working day of the sample arriving at the laboratory.



All three tests, for HIV, HBV and syphilis, are recommended. See [Antenatal Screening Wales guidance](#).

If any test is NOT required the remaining tests should be requested individually - handwritten alterations or requests will not be accepted.

- If the patient is < 23+6 weeks pregnant at the time the sample is taken, select "Routine testing";
- If the patient is more than 23+6 weeks pregnant, select "Rapid testing";
- If the patient is more than 36+6 weeks pregnant, select "Urgent testing" **and** tick the urgent box on the main ETR request page

PLUS telephone the microbiology laboratory for advice for any patient who is already in labour, or post-partum, at the point these tests are requested.

NB: Screening for rubella immunity (rubella IgG titre) ceased on 3rd October 2016 as advised by Welsh Government and is not available as part of the antenatal screen.

Please Select an appropriate Site:

- Routine test (<23+6 gestation)
- Rapid test (between 23+6 and 36+6)
- Urgent (>36+6 gestation)

Please Select an appropriate Qualifier:

- syphilis, hepatitis B and HIV [S]
- hepatitis B ONLY
- HIV ONLY [S]
- syphilis ONLY [S]

Figure 33: Updated electronic test page

Communicable Diseases E learning

ASW has produced and published an e learning package for all health professionals involved in the offer and subsequent management of screening for HIV, syphilis and hepatitis B in pregnancy. The package consists of 4 modules:

- HIV
- Syphilis
- Hepatitis B
- Screening and management of the conditions in pregnancy

With permissions from NHS England, ASW has edited the package where there are differences in pathway in Wales. The ASW communicable diseases screening in pregnancy e-learning module for midwives and obstetricians is a training resource to support health professionals in the delivery of HIV, hepatitis B and syphilis screening programme in the NHS in Wales. The recommendation is that it is completed every two years.

Laboratory re-audit of results for the management of chronic hepatitis B in pregnancy

A previous audit in 2019 was carried out to review the protocols for hepatitis B screening in pregnancy. This audit was timely, as an additional protocol to recommend hepatitis B DNA (viral load) testing at the time of the confirmatory sample had been offered to all pregnant women who were diagnosed with hepatitis B. This was so that treatment could be offered to a mother with a high viral load in the third trimester, thus reducing the risk of vertical transmission and to identify the at-risk babies and to further decrease vertical transmission.

A re-audit in 2023 was undertaken in conjunction with Virology, ASW, PHW Specialist Registrar and Health Protections to retrospective audit compliance with ASW standards and protocols. Additionally on this audit, the babies of the mothers were followed up for the first 13 months of life to monitor whether they received their neonatal vaccinations as recommended. At 13 months of age a serum test should be taken from the baby to confirm that vertical transmission has not occurred.

Similar themes emerged as with the audit findings of 2019. The compliance to the ASW standards for confirmatory serology samples and HBV DNA viral-load testing following a reactive or positive HBsAg result respectively was high. However, for women known to have hepatitis B at the time of having their consented screening bloods taken, 6% of eligible women underwent timely testing of DNA viral-load, showing poor compliance to this protocol. As previous audit indicated, barriers to following the appropriate clinical pathway included non-attendance of the woman, late booking of the pregnancy, and women moving outside of the Health Board and “lost to follow-up”.

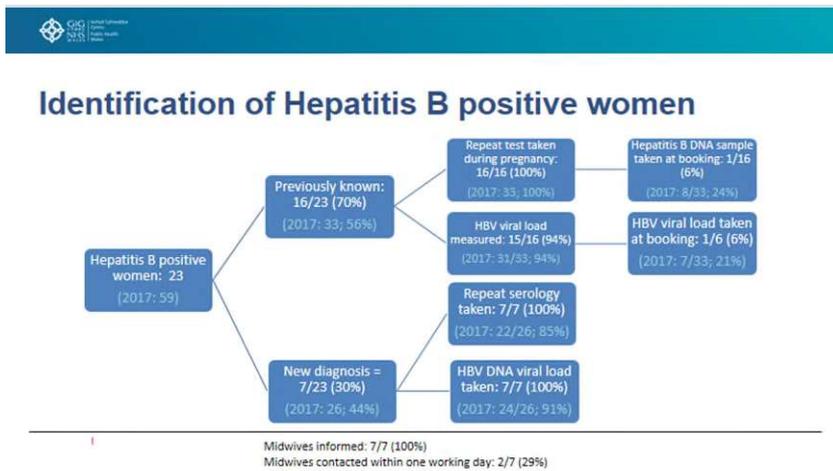


Figure 34 : Diagram demonstrating numbers of diagnosed hepatitis B in pregnancy and follow up testing

A high percentage of patients had a review with Gastroenterology/ Hepatology, although a sub-optimal proportion of these reviews were within 6 weeks of a positive antenatal screening result.

Following this audit, ASW will amend the protocol for turnaround times for assessment by Gastroenterology/ Hepatology within 6 weeks for women with:

- a confirmed hepatitis B screen positive result for the first time in this pregnancy
- a result with higher infectivity markers for a woman known to be living with hepatitis B

All other women should be assessed by Gastroenterology/Hepatology within 18 weeks from positive result.

Compliance to the ASW standards for reactive hepatitis B results was high. All samples that had a reactive result during the audit period were confirmed as negative when the samples were repeated, thus providing continuous reassurance of the ASW protocol for management of reactive results in pregnancy.

Neonatal and infant vaccination

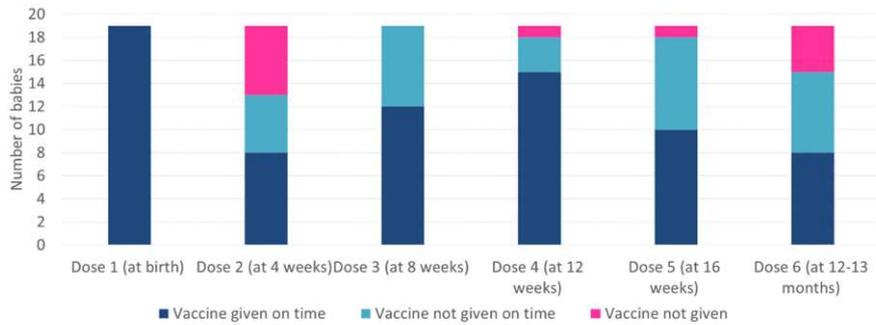


Figure 35 : Graph demonstrating neonatal and infant vaccination

All babies that were identified as high risk of vertical transmission received timely HBIG hepatitis B immunoglobulin at the correct time during the early neonatal period. A high proportion of the babies received all recommended vaccinations on time whilst a smaller number received the vaccinations but not on time. Some babies did not attend for their vaccinations and documentation demonstrated that some babies were not in the country when their vaccinations were due.

Most babies received a serological test after their vaccination regime and all the tested babies were identified as hepatitis B negative.

The audit results were shared with:

- Health Board Heads of Midwifery
- Antenatal Screening Coordinators
- MAC Governance Leads
- Virology/microbiology laboratories in Wales
- All-Wales Health Board Gastroenterology Leads.

Audit results were presented and discussed at the joint screening coordinator and governance leads meeting in October 2019. A poster presentation of the audit was accepted for inclusion at the Public Health Wales Research and Evaluation Conference. ASW, in conjunction with screening coordinators and MAC Governance Leads, have decided to develop a template/checklist for Hepatitis B positive women for use by health boards.

Information for women who have a positive result for HIV, hepatitis B or syphilis in pregnancy

The ASW suite of on-line information for women who are diagnosed with HIV, syphilis and hepatitis B in pregnancy and where there is a “reactive result” for one of the conditions has been reviewed and updated. The leaflets have been précised without removing content and are published on ASW internet site in HTML for ease of access on mobile devices.

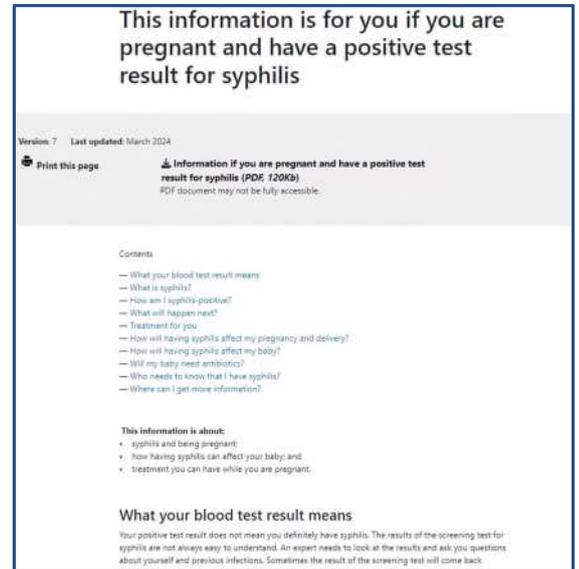


Figure 36 : Screenshot from ASW website showing information in pregnancy where there has been a positive test result for syphilis

Looking forward to the next screening year

ASW looks to 2024/25 to continue to work in partnership with health boards and support organisations to continue to ensure the successful delivery of the antenatal screening programmes

Key developments will include-

- Evaluation of cffDNA in clinical practice. There will be an evaluation of the project which will commence in July 2024 and form a one year evaluation which aims to monitor the pathway and the performance of the screening test.
- Ongoing support of the MAC Governance Lead role. The findings from the interviews will be explored by the Heads of Programme to understand workload, effectiveness of the role and if any barriers impeding the strategic governance role. Recommendations will be fed back to the Health Boards.
- ASW will continue to increase accessibility for service users and health professionals within the online documents. Reformatting of the Policy, Standards and Protocols will take place before the next formal review which will commence in 2026
- Adaptation of student midwife training package for year 1 and year 2 students.
- Analysis of service user and health professional surveys. Understanding why women accept or decline screening for Down's syndrome, Edwards' syndrome and Patau's syndrome. To provide assurance to the Programme that women make their decisions based on personal informed choice.
- Service User feedback on the post test information re-format *"This information is for you if you have been offered further tests for suspected chromosomal conditions"*
- Implementation of the addition of measuring the abdominal circumference on the anomaly scan. The implementation is scheduled for October 2024 for all Health Boards in Wales and ASW will provide ongoing evaluation of the pathway.
- Re-audit within the Programme-
 - Sickle cell and thalassaemia request card completion. Accuracy of the result and timely turnaround times of the sample is dependent on correct information documented on the request card.
 - Imaging guidance on the ultrasound finding of echogenic was revised in 2022-23 with input from obstetric ultrasound Leads around Wales. The aim of the revision was to improve diagnostic confidence of the unexpected finding. ASW plan to re-audit in 2024/2025 to gauge whether there has been improvement in diagnostic accuracy.



Summary

This two-year annual report has been a busy period for Antenatal Screening Wales. The Team has worked hard to ensure that the screening programmes are delivered and managed in a coordinated way within the health boards. The project to develop and implement the new cell free fetal DNA (cffDNA) test to the Blood Group and Antibodies screening pathway has taken up a large proportion of time for some of the Team. ASW has continued to work in partnership with colleagues throughout Wales to improve the screening pathways, provide informative material for women and their families and educational material for health professionals to ensure women who choose to have antenatal screening have made a personal informed choice.

The regular work of ASW has continued including monitoring of screening, supporting health board antenatal screening coordinators, MAC governance leads and lead sonographers.

Production team

The production team for this report are all employed within Public Health Wales and are listed below:

Sarah Fox	Head of Programme Antenatal Screening Wales
Kindry Williams	Programme Coordinator Antenatal Screening Wales
Laura Macdermott	Programme Coordinator Antenatal Screening Wales
Natasha Thomas	Programme Coordinator Antenatal Screening Wales
Ann-marie Donaghy	Programme Support Manager for Maternal and Child Screening
Elisabeth Radford	Administrative Support, Antenatal Screening Wales



GIG
CYMRU
NHS
WALES

Iechyd Cyhoeddus
Cymru
Public Health
Wales

Gweithio gyda'n gilydd
i greu Cymru iachach

Working together
for a healthier Wales