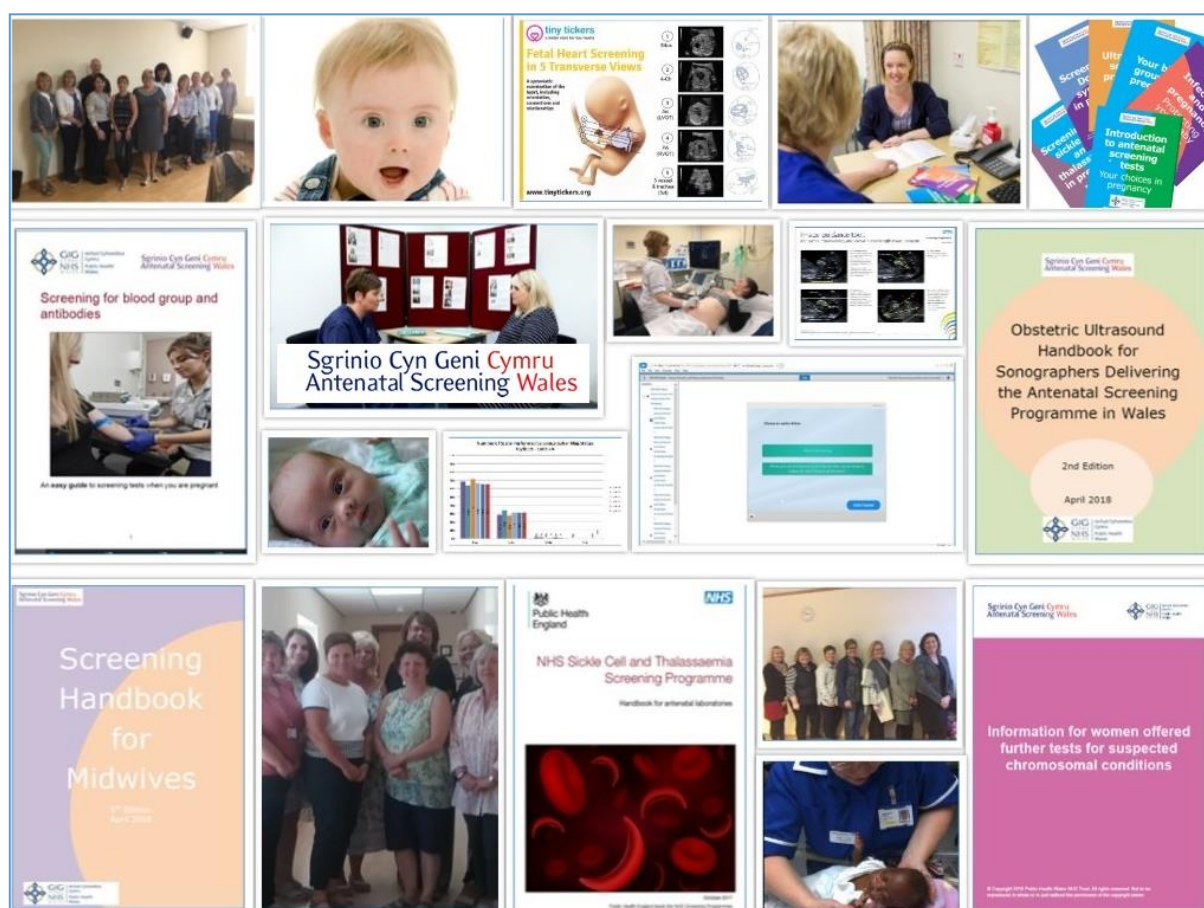




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Public Health
Wales

Antenatal Screening Wales Annual Report 2017-2018



Sgrinio Cyn Geni Cymru
Antenatal Screening Wales

About us

Public Health Wales exists to protect and improve health and wellbeing and reduce health inequalities for people in Wales.

We are part of the NHS and report to the Minister for Health and Social Services in the Welsh Government.

Our vision is for a healthier, happier and fairer Wales. We work locally, nationally and, with partners, across communities in the following areas:

Health protection – providing information and advice and taking action to protect people from communicable disease and environmental hazards

Primary, community and integrated care – strengthening its public health impact through policy, commissioning, planning and service delivery

Microbiology – providing a network of microbiology services which support the diagnosis and management of infectious diseases

Safeguarding - providing expertise and strategic advice to help safeguard children and vulnerable adults

Screening – providing screening programmes which assist the early detection, prevention and treatment of disease

Health intelligence – providing public health data analysis, evidence finding and knowledge management

NHS quality improvement and patient safety – providing the NHS with information, advice and support to improve patient outcomes

Policy, research and international development – influencing policy, supporting research and contributing to international health development

Health improvement – working across agencies and providing population services to improve health and reduce health inequalities

Further information

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Twitter: @PublicHealthW
Facebook: www.facebook.com/PublicHealthWales

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Executive Summary

The following report outlines the work undertaken by Antenatal Screening Wales (ASW) from 1 April 2017 to 31 March 2018. This summary report highlights the achievements of the team working closely with colleagues across Wales, and illustrates the wide variety of work carried out for the eight antenatal screening programmes.

Performance management

ASW continues to work in partnership with a wide group of stakeholders throughout Wales and the UK to monitor the standards and protocols for antenatal screening. Monitoring of standards occur via performance indicator reporting bi-annually or via regular audit process. Results from these processes are fed back to the Health Boards and action plans devised where performance is not reaching the standard. ASW meet with key health professionals at each of the Health Boards to discuss the performance indicator report. Development and on-going training of specific roles to manage the programmes within the Health Board are supported by ASW. A review of written information for women is undertaken on an annual basis and where evidence has changed, amendments are made. In 2018, easy read information for women for all eight antenatal screening programmes was finalised and published. Policy, Standards and Protocols for Down's syndrome, Edwards' syndrome and Patau's syndrome was produced in light of the implementation of the new antenatal screening tests.

Programme specific

Sickle cell and thalassaemia

A snapshot audit to monitor completeness of request cards was carried out within the Health Board laboratories during March 2017. ASW will produce a teaching aid for Antenatal Screening Coordinators that will enable them to feed back to health professionals the importance of correct request card completion. NHS Sickle cell and thalassaemia Screening Programme has updated the laboratory handbook. A review of the handbook, led by ASW, has resulted in changes to guidance within the laboratories in Wales. An information leaflet for fathers invited for a screening test has been published on the website.

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

In August 2017, Welsh Government (WG) recommended, in line with UK National Screening recommendations, the introduction of non-invasive prenatal testing (NIPT) within the antenatal screening programme in Wales. WG asked ASW to lead on the Health Board implementation of a new screening pathway for Down's syndrome, Edwards' syndrome and Patau's syndrome in singleton and twin pregnancies in Wales with the offer of NIPT as a contingency test for higher chance singleton pregnancies. This policy change affected maternity, ultrasound, biochemistry, genetic and transport services throughout Wales. The new screening pathway was implemented eight months later, on 30 April with an ongoing three year evaluation of the Programme. Wales is the first UK country to implement the UK NSC recommendations. This has included attending meetings around Wales and being actively involved in the implementation in each Health Board, writing and filming a film clip for women, producing an e-learning package and being involved in organising the education for implementation and updating all of the written information and guidance for these screening tests. The information is to ensure women are able to make a personal informed choice and are supported in their decision.

Ultrasound

Biannual monitoring of the ultrasound measurements needed for each Down's syndrome, Edwards' syndrome and Patau's syndrome screening test via the Down's Syndrome Quality Assurance Support Service (DQASS) is analysed and reported back to the individual sonographers via ASW. The programme continues to work alongside NHS Wales Informatics Service (NWIS) to produce the Radiology Information System (RadIS) which is a reporting module for scans to ensure that reporting is consistent throughout Wales thus allowing ease of data collection and analysis for audit purposes. A review of the guidelines for the specific observations of uncertain significance led to new pathways to be developed alongside information for women leaflets being produced.

Conclusion

Much of the work of the Antenatal Screening Wales team in the last year has focused on the implementation of screening for Down's syndrome, Edwards' syndrome and Patau's syndrome to include twin pregnancies and the offer of

NIPT to pregnant women with a higher chance screening result who have taken up the offer to have screening.

A set of new pathways and information leaflets for the standardisation of screening for ultrasound observations has also been developed and implemented.

The regular work of ASW has also continued including monitoring of screening, supporting Health Board Antenatal Screening Coordinators, MAC Governance Leads and Lead Sonographers. Regular audits, production and roll out of education materials and some hands on ultrasound training has also taken place.

1. Introduction

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

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

to detect defined serious conditions present in either the mother or baby that are likely to have an adverse effect on the health of either, and for which an effective intervention is available and warranted. For some conditions, preventive treatment is available during the antenatal period or after delivery to improve the baby's health. For others, the condition can be identified during the antenatal period but no preventive treatment is available. With high quality counselling women can make an informed choice about whether they wish to continue the pregnancy. Appropriate support, in line with the woman's choice, can be arranged.

ASW has delivered the all-Wales Managed Clinical Network for antenatal screening since 2003. ASW was asked by Welsh Government to establish policies, standards and a performance management framework for antenatal screening delivered by maternity services in Wales. ASW is part of Public Health Wales, Screening Division, who have extensive expertise in the management and provision of population based screening programmes. ASW has sat within Maternal and Child Screening (MAC) since 2014 (see appendix 1, p31). The Quality and Clinical Governance Group and the programme specific sub groups provide governance for the work. ASW does not provide, or directly manage, any antenatal screening services.



2. The team

In 2017-2018, the all-Wales team consisted of:

- ☐ Head of Programme (1.0 wte) for the 3 MAC programmes
- ☐ 3 Regional Coordinators - 2 midwives (1.8wte),
1 Ultrasound Obstetric Lead/Regional Coordinator (0.8 wte)
- ☐ Programme Support Manager (1.0 wte) for the 3 MAC programmes
- ☐ Administrative Support (2.0wte) for ASW and NBSW (Newborn Bloodspot Screening Wales)

The Head of Programme (HoP) manages Antenatal Screening Wales (ASW), Newborn Bloodspot Wales (NBSW) and Newborn Hearing Screening Wales (NBHSW) to deliver a safe and equitable programme. The HoP is responsible for meeting the standards agreed by the programmes and to deliver on the operational plan agreed by the programmes.

The Regional Coordinators lead on the implementation of Antenatal Screening Wales policies, standards, protocols and performance management framework within a defined region. They manage and coordinate delegated activities and lead all Wales projects on existing or proposed antenatal screening programmes in Wales. They professionally guide the Antenatal Screening Coordinators, Maternal and Child (MAC) Governance Leads, the Superintendent Sonographers, Nuchal Translucency (NT) Leads and Fetal Cardiac Leads to deliver and implement the all Wales antenatal screening programme in Health Boards within the regions.

The MAC Programme Support Manager works with the HoP to provide operational management support to MAC to ensure that the portfolio of tasks/projects is planned, managed and delivered effectively. They assist in managing the budgets, analysing the financial data and identifying areas for potential efficiency gains and cost saving. They monitor the programme performance against the ASW performance indicators.

The Administrative Support provides all areas of secretarial, administration and organisational support to the MAC Regional Coordinators and the MAC programmes. They support the delivery of training and education materials and sessions across Wales and assist in coordinating the production and distribution of public information. They update and populate databases to provide data for reports for Health Boards. These posts have a very positive impact on administrative support for the programme and within the team.

3. Operational plan

The team worked to an operational plan within 2017-2018 that covered the following areas:

- Audit of:
 - Sickle cell and thalassaemia request card completion
 - Down's syndrome, Edwards' syndrome and Patau's syndrome request card completion
 - Specific measurements and views on the anomaly scan
 - Service user experience
- Changes to the Down's syndrome screening programme and pathway
- Development of:
 - Easy read leaflet for blood group and antibody screening
 - The MAC Governance Lead role
 - The Cardiac Leads role
 - Pathways and information leaflets for ultrasound observations of uncertain significance
- Performance management:
 - Biannual performance indicators report
 - Image review
 - Quality assurance for sonographers
 - Ongoing support for sonographers
- Review of:
 - Pre and post test information for women leaflets
 - RadIS (Radiology Reporting Information System) as per business case (2010)
 - Antenatal Screening Wales base menu for anomaly scan reporting
- Working with stakeholders

4. What the team has accomplished

4.1 Cross-programme work

4.1.1 Working with stakeholders

Head of Midwifery Advisory Group (HOMAG)

The Head of Programme and ASW Regional Coordinators attended the Head of Midwifery Advisory Group (HOMAG) meetings and provide a summary paper to inform on work streams and provide discussions on ASW and Health Boards inter-partner working. A representative from HOMAG is also a member of the ASW sub groups.

Laboratories

Within the timeframe of April 2017 - March 2018 ASW liaised closely with the laboratories below and engaged in work specifically related to the programme:

- Haemoglobinopathy laboratories
- Down's Syndrome Screening Laboratory and DQASS (Down's Syndrome Quality Assurance Support Service)
- Virology/microbiology laboratories
- All Wales Medical Genetics
- Welsh Blood Service

UK national screening programmes

ASW Regional Coordinators attend Public Health England meetings of:

- Infectious Diseases in Pregnancy Screening Programme (IDPS)
- Sickle Cell and Thalassaemia Screening Programme
- Fetal Anomaly Screening Programme (FASP) Advisory Group
- FASP Laboratory and Ultrasound Subgroup
- FASP Non Invasive Prenatal Testing (NIPT) Project Board
- FASP NIPT Patient Information and Education Subgroup
- FASP NIPT Data Group

HOMed and universities

ASW has provided training on the antenatal screening programmes to student midwives in the four Welsh Universities since 2016. Maternal and Child Screening and Head of Midwifery educationalist group (HOMed) wanted to ensure that education for student midwives was offered in a consistent manner

and for all three MAC programmes. An update from ASW, NBSW, NBHSW and Cervical Screening Wales provide a screening day, separated into 2 half days, on the screening programmes and hot topics.

Feedback from the sessions included:

- ✓ Clinical scenarios were helpful. Enjoyed learning about Down's syndrome screening
- ✓ A great refresher for the second year and more information going forward
- ✓ Gave lots of tips for delivering this info to the women
- ✓ Possibly some group interactions/tasks needed rather than a PowerPoint

In 2018, students will be invited to view ASW e-learning package on Down's syndrome, Edwards' syndrome and Patau's syndrome prior to attending a face-to-face presentation to enable the time to be more interactive between students and presenter. This allows more focus and discussion on communication and informed consent issues.

Development of the Maternal and Child (MAC) Governance Leads role

The Health Boards in Wales have an identified named Governance Lead for Maternal and Child Screening who manages the strategic governance roles for these programmes. MAC funds this role for one day per week for each of the Governance Leads within the Health Boards. The Governance Leads meet quarterly with ASW to feedback on Health Board issues and provide support to each other within this role.



ASW provides an education element to enable development of the role. In 2017, two of the Governance Leads were seconded to ASW for 2 weeks each. This provided the opportunity to work within Public Health Wales on an area of work that would be role specific. The pieces of work commenced by the MAC Governance Leads were:

- Writing a Powerpoint presentation highlighting changes on the ASW website to be used in mandatory training for health professionals in the Health Boards
- Reviewing and updating Information for Women leaflets in preparation for the implementation of the changes to the Down's syndrome, Edwards' syndrome and Patau's syndrome screening programme.

A third Governance Lead has secured a secondment with MAC in the autumn of 2018.

Working in partnership with health boards



Ultrasound Obstetric Leads and NT Leads



Antenatal Screening Coordinators

ASW meet regularly, and work closely with Health Board Antenatal Screening Coordinators, Ultrasound Obstetric Leads, Ultrasound 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 programmes in Wales. This would include advising on the service implications of

- development of the antenatal screening programme
- development of policy, standards and protocols
- review and development of information for women
- development of performance management indicators, evaluation tools and audit protocols in conjunction with the Maternal & Child Governance Lead
- performance management and audit reports
- educational activities and education resources for health professionals

- performance management and high level programme risk issues, in conjunction with the Maternal & Child Governance Lead
- programme evaluation reports

Radiology Service Managers

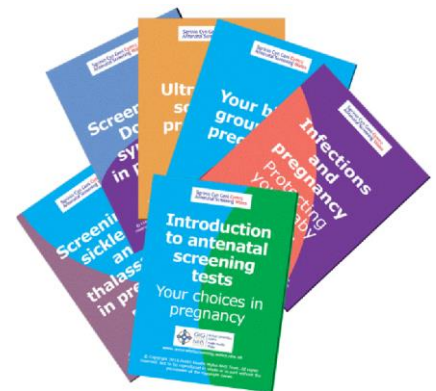
ASW are working with Health Board Radiology Service Managers (RSM) on quality issues pertinent to antenatal screening ultrasound issues. These include exploration of data retrieval in a more robust and streamline manner and liaising directly with ultrasound obstetric leads where there are issues with the all Wales sonographer performance monitored via DQASS.

4.1.2 Engaging with the public and professionals

Pre test information for women leaflets

An annual review of literature for women was undertaken. Amendments were considered where current guidance had changed. ASW worked with stakeholders to ensure that leaflets were amended in line with up to date research and evidence. The

'Introduction to antenatal screening tests', 'Screening for Down's syndrome in pregnancy' and 'Ultrasound Scans in Pregnancy' information for women leaflets have been reproduced to include information on screening for Edwards' syndrome and Patau's syndrome and the inclusion of the offer of NIPT as a contingency test which were implemented within Wales on 30 April 2018.



Development of easy read information

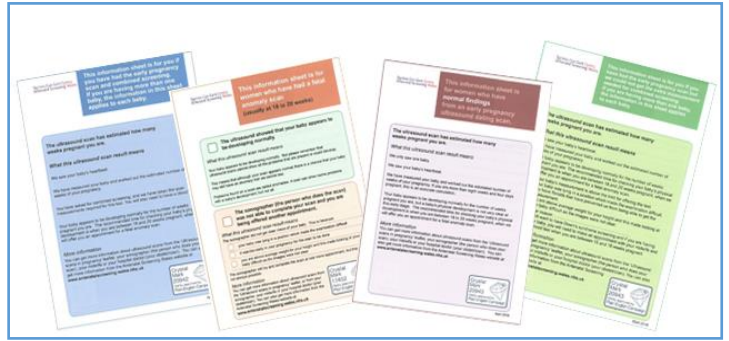


There was a need for easy read literature to be available for women accessing the antenatal screening programmes. ASW worked closely with the screening engagement team and focus groups to produce an easy read leaflet for blood group and antibody screening in pregnancy.

The publication of this leaflet in 2017 completes the suite of easy read leaflets on antenatal screening that ASW published in 2016. These are available on both the ASW and Screening for Life websites.

Post test information for women Ultrasound Pads

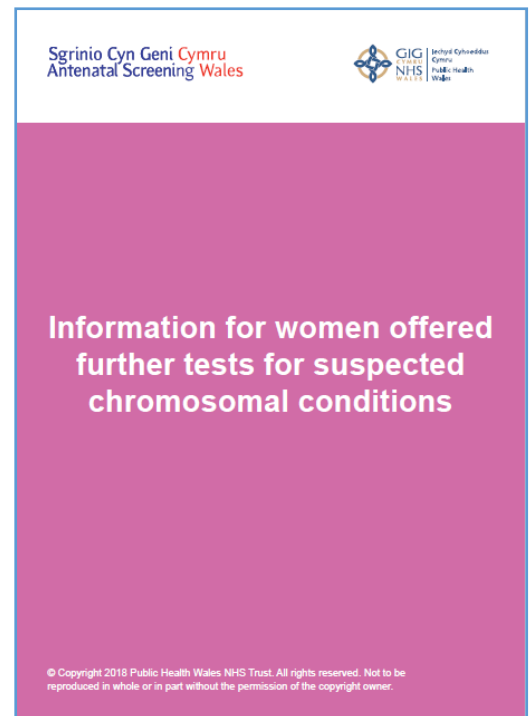
ASW updated their post early pregnancy dating scan information sheets to include information on screening for Down's syndrome, Edwards' syndrome and Patau's



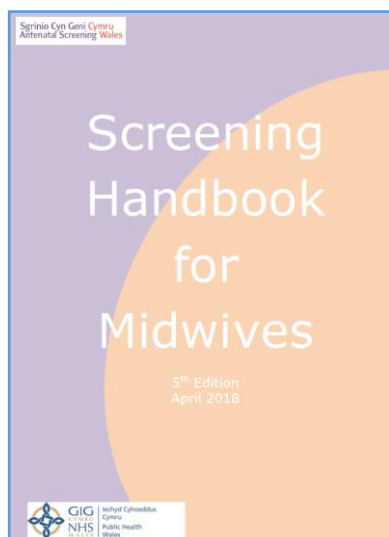
syndrome in a singleton and twin pregnancy. These leaflets are provided to women by the sonographer at the time of the scan as some women had previously fed back that they did not have enough information at the time that the scan was performed.

Information for women offered further tests for suspected chromosomal conditions

Due to the policy change to the offer for screening for Down's syndrome, Edwards' syndrome and Patau's syndrome this year, ASW took the opportunity to review the current leaflets for higher chance results and diagnostic tests and instead produced a booklet capturing all this information in one place. A comprehensive evaluation of the booklet, as part of the evaluation of the NIPT contingency test implementation project for Down's syndrome, Edwards' syndrome and Patau's syndrome, is currently underway. This will offer feedback from women who have been provided with the leaflet as part of their information giving, as well as feedback from voluntary agencies and health professionals who have used the booklet.



Review of midwives screening handbook



ASW had published a screening handbook for midwives since 2005. The handbook provides information for midwives on current epidemiology and All Wales pathways on the antenatal screening programmes.

During 2018, both the Down's syndrome screening and ultrasound screening section of the handbook were further updated in line with the policy change for Down's syndrome, Edwards' syndrome and Patau's syndrome screening implemented in Wales.

Service user experience

A biannual survey, performed for two weeks both in March and September, captures feedback from women who attend for their baby's newborn hearing screening. The MAC questionnaire seeks feedback on the core questions. The results are analysed by ASW and the information fed back to the programmes and the Health Boards.

An example of Health Board feedback is:

..... "Prompt, efficient service but above all very friendly. I felt very comfortable and informed by staff."

We found, We did



Service Users suggested some changes to be made to some aspects of the Antenatal Screening Programmes.

The changes were made and published on the ASW website.

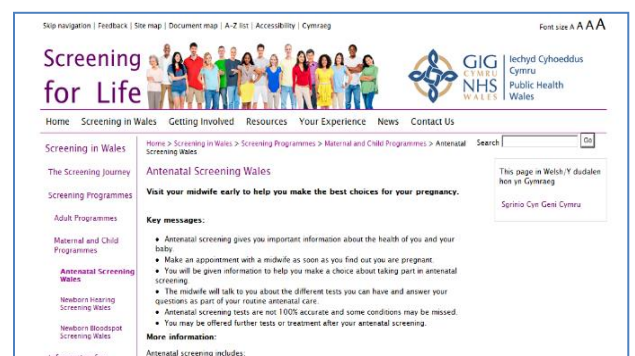
Ensuring websites are current ASW website review

The ASW professional and public sections of the website have been redesigned to enable easier user navigation. A survey asking for feedback from service users on some new information for women has been included on the website.



Screening For Life Website review

The screening for Life website was updated to include the information for Down's syndrome, Edwards' syndrome and Patau's syndrome screening. Information for rubella susceptibility screening was removed as the programme ceased in October 2016 with the last cohort of women delivering their babies in May 2017.



NHS Direct Wales website review

ASW contacted NHS Direct Wales to suggest some changes to the antenatal screening information that was published on their website. ASW worked with NHS Direct to ensure that the information of the website reflected the antenatal screening programmes in Wales.

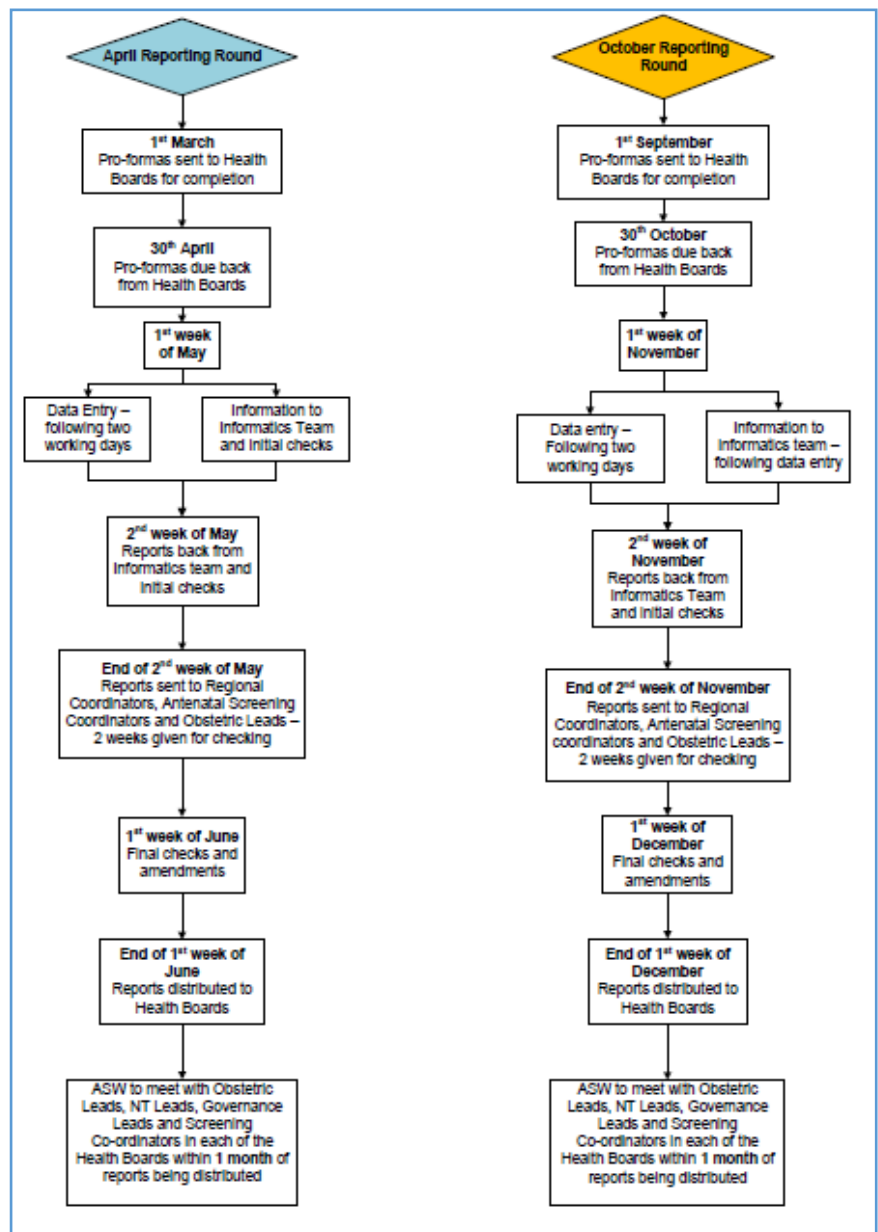


4.1.3 Performance management and governance within the Health Boards

ASW monitor the performance of specific standards and feedback this performance to the Health Boards. Health Board leads for the specific specialties are responsible for action plans where performance is below standard to improve the standards in their Health Board. ASW meet regularly with the Health Board Antenatal Screening Co-ordinators, MAC Governance Leads, and Ultrasound Obstetric Leads to discuss performance and provide support.

Biannual performance indicators report

Unlike the other population-based screening programmes in Wales, antenatal screening is not funded, or directly managed, by Public Health Wales but is delivered by and funded within Health Boards. ASW works collaboratively with multiple stakeholders who have responsibility for the quality of antenatal screening provision in Wales. Performance indicators are reported from the Health Boards to ASW every 6 months, in April and October. They monitor Health Board performance against ASW standards. During 2017, there were some changes to the way data was captured and results were reported.



Data capture is now electronic and reports contain four reporting rounds of data. ASW have been working collaboratively with Health Boards to ensure that denominator data provided is as robust as possible and this work is ongoing. The results reporting are suitable for performance monitoring within the Health Boards to identify areas of concern but the data is supplied by the Health Boards and cannot be verified by PHW. Performance indicators are reported to the Health Boards Director of Public Health, Head of Midwifery, MAC Governance Leads, Antenatal Screening Coordinators and Ultrasound Obstetric Leads for escalation within their Health Boards. ASW Regional Coordinators meet biannually with the lead professionals within each Health Board to discuss the performance indicator report and provide support in relation to the performance indicator report.

Audit of Down's syndrome, Edwards' syndrome and Patau's syndrome request cards

The All Wales Down's syndrome laboratory has a robust system for managing request card errors back to

the Health Board in a timely manner. This is to ensure that accurate reporting is

achieved. ASW report back to the Health Boards every

month with the Health Board error rate along with the

anticipated All Wales standard for errors. The Health Board

MAC Governance Lead and

Antenatal Screening Coordinators are then able to monitor errors and action education up-dates to individual health professionals who have multiple errors.

Demographics deleted for confidentiality

SCAN MEASUREMENTS	
SINGLETON / TWIN 1 MEASUREMENTS CRL <u>10.1</u> mm (45.0mm - 84.0mm) NT <u>1.6</u> mm HC <u> </u> mm (58.0mm - 147.0mm)	
IF TWIN PREGNANCY Type: Monochorionic/Dichorionic/Unknown TWIN 2 MEASUREMENTS CRL <u> </u> mm (45.0mm - 84.0mm) NT <u> </u> mm Sonographer Code <u> </u>	
DATE OF SCAN <u>18.9.18</u> MATERNAL WEIGHT <u>156.5</u> Kg (to 1 decimal place) Please circle any of the following that apply as they will need to be adjusted to provide an accurate result	
SMOKING YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	DIABETES None <input type="checkbox"/> Type 1 <input type="checkbox"/> Type 2 <input type="checkbox"/> INSULIN YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>
MATERNAL ORIGIN - Maternal Parents or Grandparents Black <input type="checkbox"/> East Asian <input type="checkbox"/> Indian <input type="checkbox"/> Pakistani <input type="checkbox"/> Bangladeshi <input type="checkbox"/>	
ASSISTED REPRODUCTION IVF Own Egg <input type="checkbox"/> IVF Donor Egg <input type="checkbox"/> Date egg harvested <u> </u> Age of egg donor at harvest <u> </u> Transfer date <u> </u> Transfer date <u> </u>	
COLLECTION INFORMATION (Sample Type: Serum) Specimen taken by <u> </u> Date of Collection: <u>18.9.18</u> Time: <u>PM</u>	

No information on maternal smoking

No information on maternal diabetes

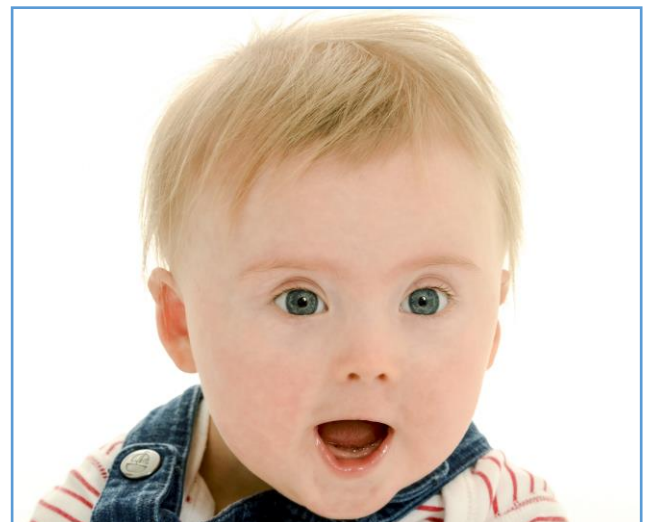
4.2 Programme specific

4.2.1 Implementation of Down's syndrome, Edwards' syndrome and Patau's syndrome screening

Within the timeframe of June 2017 to

March 2018, the project:

- scoped the issues to inform the Wales Screening Committee
- developed and recommended a proforma for use in Health Board implementation meetings to ensure all changes required were implemented
- wrote an e learning education package for health professionals
- produced a film clip for women to inform on the new screening pathway
<https://vimeo.com/259001620>
- produced a booklet for women who are at higher chance of having a baby with a chromosomal abnormality
- updated ASW Policy, Standards and Protocols



- produced and published bulletins on the project timeline
- updated information for women leaflets and information for women after an early pregnancy dating scan
- produced a twin information sheet for health professionals discussing screening for Down's syndrome, Edwards' syndrome and Patau's syndrome in a twin pregnancy
- worked with the All Wales Down's Syndrome Screening Laboratory and All Wales Medical Genetic Laboratory to produce new request cards, transportation links and Standard Operating Procedures for the tests
- updated websites and publications in collaboration with other organisations - Antenatal Screening Wales website, NHS Direct website and, Bump, baby and Beyond publication
- commenced a 3 year evaluation for the project as requested by the United Kingdom National Screening Committee (UKNSC).



Scoping issues to inform Wales Screening Committee

At the Wales Screening Committee in June 2017, the UKNSC recommendations were discussed and considered and recommendations that:

- Screening for Down's syndrome, Edward's syndrome and Patau's syndrome should be introduced in Wales for singleton and twin pregnancies using the combined test.
- Screening for Down's syndrome should not be introduced in Wales for twin pregnancies using the quadruple test.
- Non-invasive prenatal testing (NIPT) to be offered to women with a singleton pregnancy as a contingency test to those women who received a higher chance result from the combined or quadruple test.

Down's syndrome, Edwards' syndrome and Patau's syndrome Health Board implementation team meetings

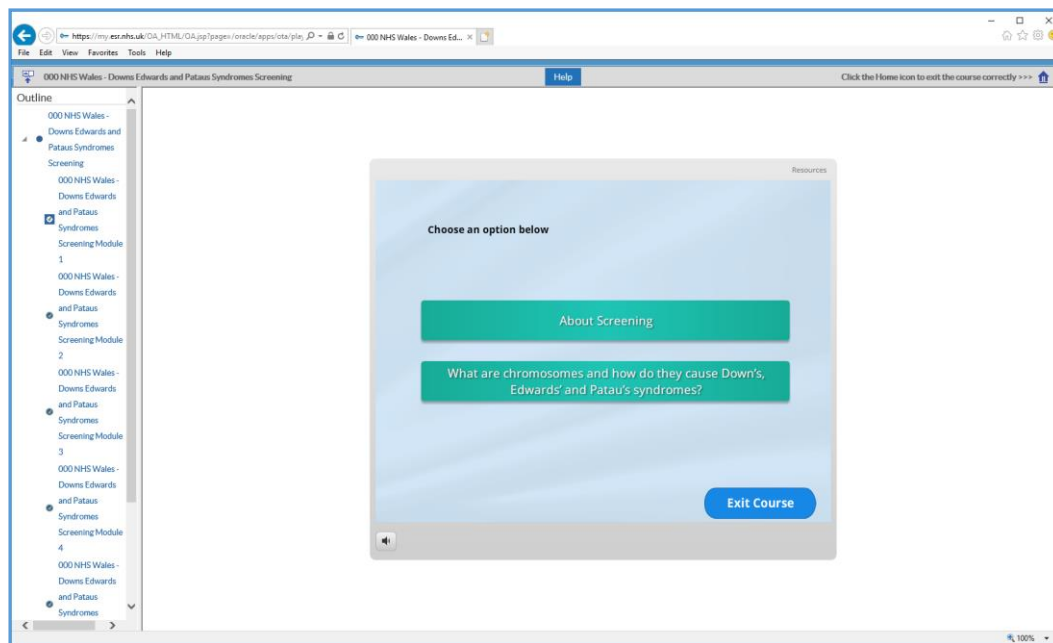
Each Health Board established a team to plan the implementation of the policy for combined screening for Down's syndrome, Edwards' syndrome and Patau's syndrome, in singleton and twin pregnancies and the offer of either NIPT or

invasive procedures for women with singleton pregnancies who had received a higher chance screening result. The Project Manager for ASW or her deputy attended each of the implementation team meetings, and post implementation team meetings to update on the progress of the project, provide support to implementation within the Health Boards and to feedback to the All Wales Project Board.

Education Strategy

Key to implementing the new Down's syndrome, Edwards' syndrome and Patau's syndrome screening programme, was ensuring that all health professionals had a good knowledge of the conditions and of the changes to the screening programme. With that in mind, ASW planned an education strategy to cover all aspects of the programme change.

E learning



There was an identifiable need to produce an education resource for all health professionals involved in screening for Down's syndrome, Edwards' syndrome and Patau's syndrome. ASW produced an e learning resource, which was published to ESR, and learning@Wales in January 2018. It was recommended that all health professionals who provide information to pregnant women on antenatal screening would complete and pass the e learning package by the end of March 2018, as at this time they would be offering the women the tests in readiness for implementation from 30 April. Health professionals are key to ensuring women have information on which to make personal informed choice on whether they want to take up the offer of screening.

Face to Face Training

A face to face training resource was co-produced by Public Health England, Antenatal Results and Choices (ARC), Down's Syndrome Association (DSA) and Support Organisation for Trisomy 13/18 (S0FT UK). ASW hosted a study day in January 2018 for Antenatal Screening Coordinators and MAC Governance Leads within Wales who would then cascade the training within their Health Boards for designated staff members. The training focused on informed choice and communication skills needed to provide the information to women to enable them to make a personal informed choice.

Film Clip

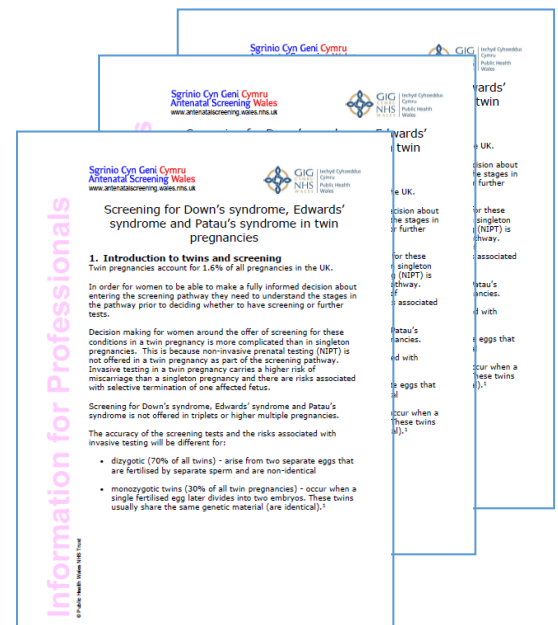


A film clip was produced by ASW to give women more information for Down's syndrome, Edwards' syndrome and Patau's syndrome screening and as an aid in their decision making on whether to have the screening

test or not. ASW worked in partnership with focus groups to develop this film clip which is hosted on the ASW website and is signposted in the pretest written information. Health professionals are asked to inform women about the film clip at their first contact with the woman and she should be asked to watch the film before her booking appointment. An English and Welsh version of the film clip was produced. This film clip will be evaluated.

Twin information sheet

An information sheet discussing the complex issues of offering screening for Down's syndrome, Edwards' syndrome and Patau's syndrome in a twin pregnancy was produced by ASW for designated health professionals within the Health Boards. This was produced to ensure that health professionals would be able to provide up to date and consistent information for women with a twin pregnancy to enable them to make informed choice.



Antenatal Screening Wales Policy Standards and Protocols

A review and partial revision was made to ASW Policy, Standards and Protocols in line with the implementation of Down's syndrome, Edwards' syndrome and Patau's syndrome screening in Wales. A full revision of the ASW Policy, Standards and Protocols is to be carried out during Autumn-Winter 2018.

Collaboration with laboratories to join up implementation

ASW worked closely with the All Wales Medical Genetic Laboratory, All Wales Down's Syndrome Screening Laboratory and Health Board Implementation Teams to produce and agree Standard Operating Procedures. This included ensuring that there were robust transportation systems in place for the samples to be taken to the laboratories. New request cards were produced for Down's syndrome, Edwards' syndrome and Patau's syndrome screening and NIPT. Health Boards were provided with a teaching aid for the correct completion of the Down's syndrome, Edwards' syndrome and Patau's syndrome screening card which would be available within the Health Board antenatal clinics. The need for a robust results handling process was discussed and each Health Board set up a secure email address to allow receipt and results management on a daily basis.

Cardiff and Vale University Health Board University Hospital of Wales, Dept of Medical Biochemistry and Metabolism, Health Box, Cardiff, CF14 4XN Tel: 0300 123 2123

MEDICAL BIOCHEMISTRY

Request card for combined screening for Down's, Edwards' and Patau's syndromes in pregnancy and NIPT. Requested by specialist, screening is required to complete the Down's syndrome only.

Requester: Hospital and Lead Professional

Lead Professional/Hospital: Clear details of where to send the report are required. Please state if Royal Glam or Royal Gwent. ID is not sufficient.

Requester: Required to show patient consent obtained for Down's, Edwards' Patau's screening

SONOGRAPHER CODE: Required by DOHS

Maternal weight: Maternal weight is proportional to blood volume. This has an effect on the concentration of biochemical markers. An accurate weight measurement (to the nearest kilogram) is needed to adjust for this.

Diabetes: There are differences in serum concentrations of some biochemical markers in smokers which affect the calculated risk. It is important to inform the laboratory so that an adjustment to the risk calculation can be made.

Assisted reproduction: The age of the egg donor or the mother when the egg was harvested will be used in the Down's, Edwards' Patau's risk calculation.

Countries of origin: East Asian - China, Hong Kong, Japan, Macau, Mongolia, North Korea, South Korea, Taiwan. Black - Black African or of Black African origin.

Callout boxes:

- Patient ID:** Clear identification of the patient is required to ensure results are attributed to the correct individual.
- DOB:** Medical date of birth forms the basis of the Down's, Edwards' Patau's risk calculation.
- Scan measurements:** It is important to accurately date the pregnancy because the biochemical markers vary with gestational age. Scan measurements should be supplied correct to 1 decimal place. A CRL or HC is required for the quadruple screening test. (A NT measurement is not required).
- Smoking:** There are differences in serum concentrations of some biochemical markers in smokers which affect the calculated risk. It is important to inform the laboratory so that an adjustment to the risk calculation can be made.
- Ethnic Origin:** There are slight differences in the serum concentrations of some biochemical markers between ethnic groups. Where there is a known effect this will be taken into account in the Down's, Edwards' Patau's ethnic calculation. The ethnic origins listed on the form are the ones that the laboratory needs to make a small adjustment for (see adjacent list).

Evaluation of the NIPT project

The UKNSC recommended screening using the NIPT test as an evaluative roll out. The questions the UKNSC asked were:

- What choices do women make in relation to the offer of NIPT in the pathway?
- How does NIPT perform in the laboratory for Edwards' syndrome and Patau's syndrome? and
- What is the failure rate of NIPT testing in the laboratory?

The project board has recommended the data that needs to be collected from the laboratories and other parts of the service to answer these questions but also felt that as the implementation in Wales was more than just NIPT other evaluation questions needed to be asked. These are:

- Did the uptake of screening increase after 30 April 2018?
- What percentage of women with twins choose to have screening? How many had only one measurement?

- What are the sample delivery and laboratory turnaround times?
- What is the true positive and true negative rate of NIPT?
- Evaluation of the film clip and post test information for women booklet.

The project board has now become an evaluation board and there will be a six monthly report of the data to this board. The board are committed to ensuring up to date and balanced information is available to women and will review information.

4.2.2 Sickle cell and thalassaemia

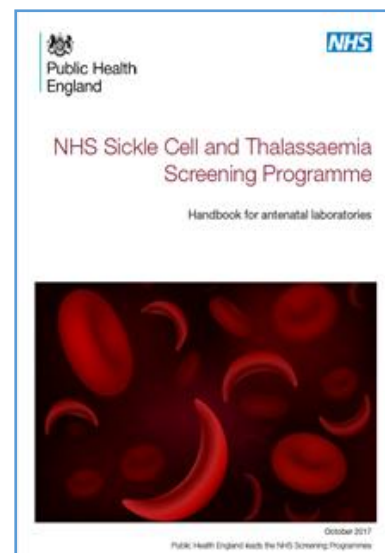
Audit of antenatal sickle cell and thalassaemia request card

Having identified a trend in errors being made in antenatal screening

Sickle cell and thalassaemia request card, ASW now carry out an annual audit on request card completion. A snapshot audit was carried out within the Health Board laboratories during March 2017 and information was analysed by ASW for 1240 sickle cell and thalassaemia antenatal screening request cards. A teaching aid will be produced for Antenatal Screening Coordinators for use within the Health Board and will enable them easily to feed back to health professionals the importance of correct request card completion.

Review of PHE Laboratory Handbook and implications for Laboratories in Wales

The PHE laboratory handbook for haemoglobinopathy screening was updated in September 2017. ASW reviewed the new guidance and agreed with laboratory staff and medical genetics amendments pertinent to haemoglobinopathy laboratories in Wales.



Review of antenatal and neonatal pathway for babies identified as at risk for haemoglobinopathies

ASW has been working in partnership with the Health Boards Antenatal Screening Co-ordinators, All Wales Medical Genetics and the Neonatal Network to produce an All Wales pathway to identify, refer and test babies identified as being at risk of a serious haemoglobinopathy.




Information Leaflet for Fathers

Antenatal Screening Coordinators suggested that it would be beneficial to provide fathers with written information when they are offered screening for sickle cell and thalassaemia.

PHE had published a leaflet for fathers and so, with permission, ASW was able to use the leaflet and amend for use within Wales.

Sgrinio Cyn Geni Cymru
Antenatal Screening Wales

 Iechyd Cyhoeddus
Cymru
Public Health
Wales

Information for fathers invited for a screening test for sickle cell disease and thalassaemia major

Who is this leaflet for?
This leaflet is for fathers invited to have a screening test for haemoglobin disorders such as sickle cell disease and thalassaemia major.

The test gives information which may be important for the health of your unborn baby and any future children. We explain the test, why we offer it, what it might show and the choices you can make.

If you want the test, it is important to have it as soon as possible – the earlier in your partner's pregnancy the better. Please make your appointment as soon as you can or, if you have already been offered one, confirm you will attend.

Why have I been invited for a test?
Test results for the mother of your baby show she carries a gene for an unusual type of haemoglobin. Haemoglobin is the substance in the blood that carries oxygen and iron around our bodies. We now need to know if you also carry a gene for an unusual type of haemoglobin.

For every pregnancy we need to test both parents to see if there is any risk for your baby.

If both parents are carriers of a gene for unusual haemoglobin, there is a 1 in 4 (25%) chance that your baby could inherit a haemoglobin disorder such as sickle cell disease or thalassaemia major. These are serious life-long health conditions.

What does the test involve?
It is a simple blood test which takes a few minutes. You should get your result within 3 to 5 days.


4.2.3 Ultrasound

Vanished twin literature review and recommendations

This guidance was updated in 2018 to reflect the changes to the Down's syndrome screening programme.

The guidance now includes information on screening for Edwards' syndrome and Patau's syndrome and screening for the three conditions in a twin pregnancy.

Sgrinio Cyn Geni Cymru
Antenatal Screening Wales
<http://www.antenatalscreening.wales.nhs.uk>

 Iechyd Cyhoeddus
Cymru
Public Health
Wales

Information for Professionals

Offering Down's syndrome, Edwards' syndrome and Patau's syndrome screening when there is a failing twin pregnancy at the dating scan

Where the ultrasound dating scan shows that there is an empty second pregnancy sac, Down's syndrome, Edwards' syndrome and Patau's syndrome screening can be offered. The Combined screening test can be offered between 11 weeks and 2 days and 14 weeks and 1 day of pregnancy and the quadruple test between 15 weeks and 3 days and 18 weeks and 0 days of pregnancy.

Non-invasive prenatal testing (NIPT) cannot be offered in this instance for higher chance results and the woman can only be offered an invasive test.

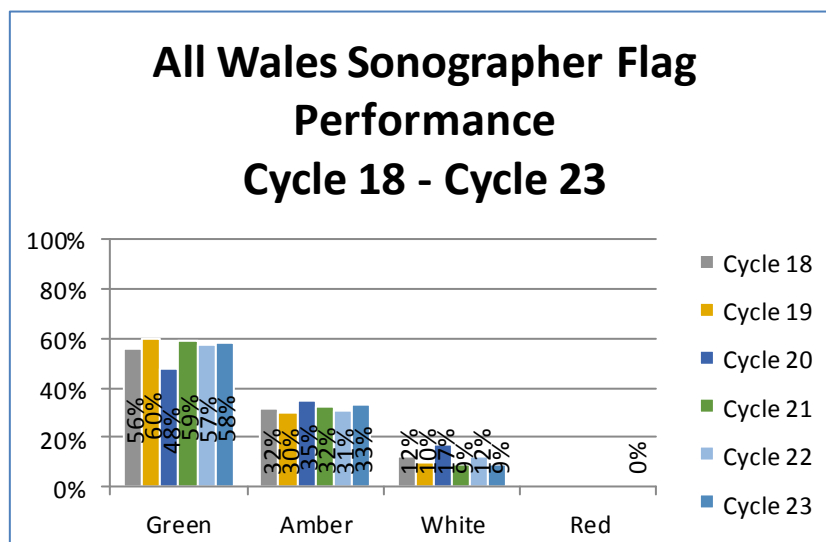
Where the ultrasound dating scan shows that there is a second pregnancy sac containing a non-viable fetus or a fetal pole, Down's syndrome, Edwards' syndrome and Patau's syndrome screening should not be offered (ASW 2016). Women should not be offered a further scan for the purposes of Down's syndrome, Edwards' syndrome and Patau's syndrome screening, this is because there could be a contribution to the maternal biochemical markers for many weeks (FASP 2010, Huang 2015) and therefore the screening result would not be accurate.

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Biannual DQASS report

Every CRL (crown rump measurement) and NT (nuchal translucency) that is obtained by a sonographer is documented on the Down's syndrome, Edwards' syndrome and Patau's syndrome screening request card. Each sonographer has a unique identification code which is submitted along with the

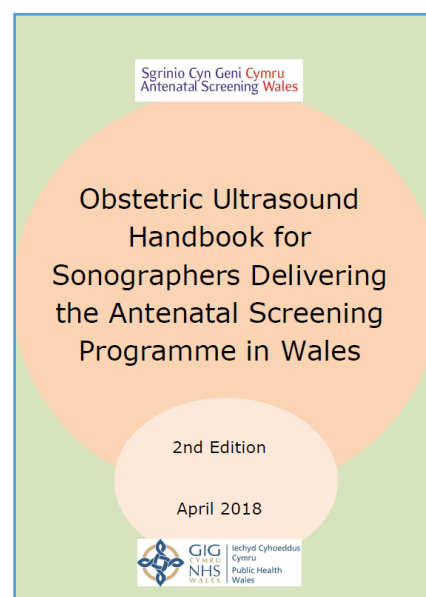
measurements on the same form. The All Wales Down's Screening Laboratory sends all their data including the sonographer codes to DQASS every 6 months. DQASS produce a plot for each individual sonographer from this information. Cycle 22 and 23 of this DQASS report were reported to the Health Boards in 2017-2018. A continual improvement is being demonstrated in the quality of the scans. This will reflect a higher detection rate and lower screen positive rate for the programme. Sonographers undertaking the screen in Wales clearly show their work is high quality.



Review of ultrasound handbook

This is an easy reference guide for sonographers delivering the antenatal screening programme in Wales and was amended in 2018 in line with the implementation of Down's syndrome, Edwards' syndrome and Patau's syndrome screening.

In the review of this publication, ASW has consulted with sonographers (including lead sonographers), Antenatal Screening Coordinators, Governance Leads and relevant stakeholders in All Wales meetings.



Ongoing training and audit of cardiac leads role

In 2016 a need was identified for each Health Board to have an Ultrasound Cardiac Lead for to monitor and audit the cardiac views of the anomaly scan. ASW support this role. These lead professionals continue to have clinical hands-on training from Fetal Cardiology Consultants in Wales. Inappropriate referrals to fetal cardiology for irregular fetal heartbeat has decreased during 2017-2018.

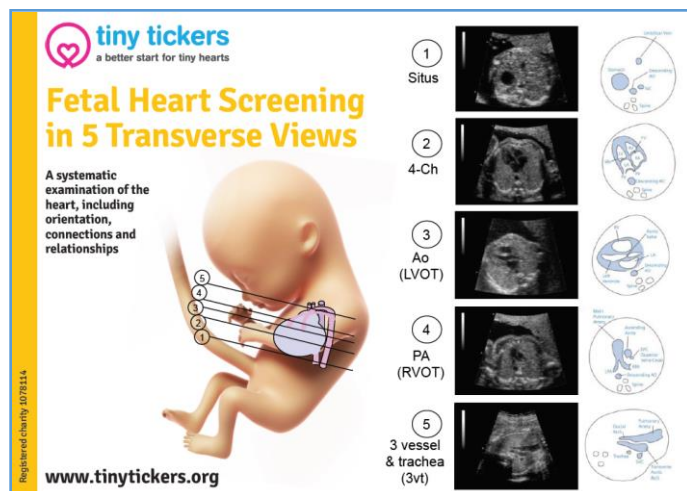
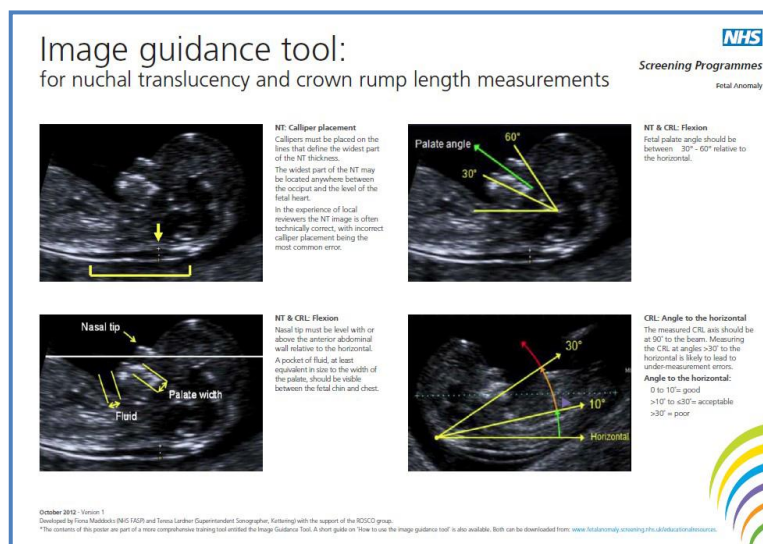


Image review in line with DQASS report

An ultrasound image review is carried out on a biannual basis. The ASW Ultrasound Coordinator reviews and assesses three paired images of crown rump length (CRL) and nuchal translucency (NT) for each of the Health Boards NT lead sonographers. In turn, the NT lead, on receipt of the biannual DQASS report, will assess the individual sonographer's plot and review it with the sonographer making comparisons with the previous cycle. The review follows strict criterion which assess the quality of the scans being performed for the screening programme.



RadIS reporting module

The RadIS obstetric reporting module is an electronic information system for radiological data reporting which is used for two obstetric ultrasound screening tests: the early pregnancy dating scan and the fetal anomaly scan. ASW

Sac?	<input type="radio"/> Yes <input type="radio"/> No	Amnioncity	<input type="text"/>	Chorioncity	<input type="text"/>
Fetus?	<input type="radio"/> Yes <input type="radio"/> No	Report to CARIS?	<input type="radio"/> Yes <input type="radio"/> No		
Heart pulsation?	<input type="radio"/> Yes <input type="radio"/> No				
Measurements					
Robinson and Fleming Data 2008 and Altman and Chitty 1997 updated					
CRL	<input type="text"/> mm	Head circumference	<input type="text"/> mm	Nuchal translucency	<input type="text"/> mm
BPD	<input type="text"/> mm	Femur length	<input type="text"/> mm	Down's syndrome screening requested	<input type="radio"/> Yes <input type="radio"/> No
Gestational age	<input type="text"/> weeks <input type="text"/> days	EDD	<input type="text"/> DD/MM/YYYY		
Free text box					

work with NHS Wales Informatics Service (NWIS) to continuously develop the reporting module to ensure that there is consistency in reporting throughout Wales and ease of data collection and analysis for audit purposes. A newer version of RadIS is currently being rolled-out throughout Wales. ASW are supporting the roll-out and ensuring that the sonographers are using the CARIS reporting tool within the screen which enables ultrasound anomalies detected on the dating scan and anomaly scan to be directly sent to CARIS for early and more accurate reporting.

Audit of sonographers

A baseline audit of head circumference (HC), Femur length (FL) and transverse section of the abdomen at the level of the kidneys on the anomaly scan was undertaken in Wales in 2018. Every sonographer participating in undertaking anomaly scans was asked to participate in this audit. The images were assessed by the Ultrasound Obstetric Lead on each site



against the proforma provided by ASW and the results were returned to ASW.

The ASW Obstetric Ultrasound Coordinator assessed the Ultrasound Obstetric Leads using the same criteria. A recommendation from the audit was that every sonographer undertaking anomaly scans in Wales should participate in regular audits of these measurements and views. Health Board Ultrasound Obstetric Leads would action the results of their own audit and ASW will provide an All Wales report.

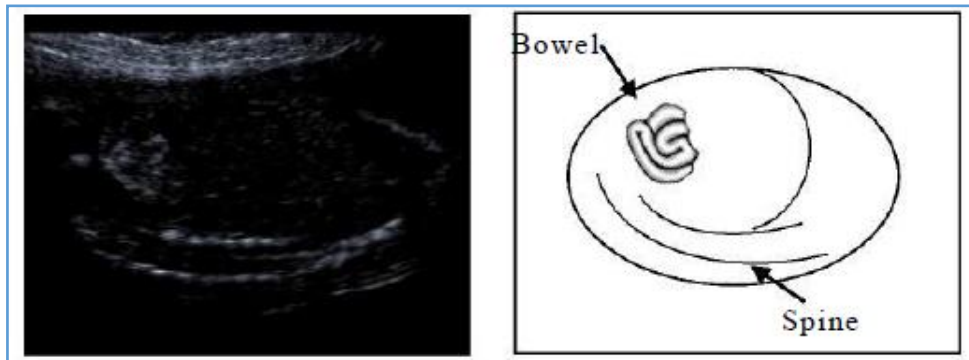
Review of the guidelines for ultrasound observations of uncertain significance

Following consultation, all Wales pathways were developed for the reporting of ultrasound observations. Review of the data, from the Welsh Study of Mother's and Babies follow-up study and CARIS, identified best practice for relevant ultrasound observations. Information for women leaflets, pathways and audit protocols have been produced for use within the Health Boards. Implementation of the new pathways will commence on 1 August 2018.

ASW will audit images from all cases of echogenic bowel recorded for a 12-month period from the date of implementation of the pathways. This will be to

quality assure the accuracy of the echogenic bowel image that is identified on the anomaly scan.

Example of echogenic bowel



Example of incorrect image



The gain is too high in this image and needs to be reduced to show echogenic bowel.

5. Conclusion

This period of time has been very busy with ASW focussed on the implementation of screening for Down's syndrome, Edwards' syndrome and Patau's syndrome to include twin pregnancies and the offer of NIPT as a contingency test to women identified as higher chance who have taken up the offer of screening.

A set of new pathways and information leaflets for the standardisation of screening for ultrasound observations has also been developed and will be launched on 1 August 2018.

The regular work of ASW has also continued including monitoring of screening, supporting Health Board Antenatal Screening Coordinators, MAC Governance Leads and Lead Sonographers. Regular audits, production and roll out of education materials and some hands on ultrasound training has also taken place.

Appendix 1

Organisational Structure 2017-2018 ASW within Maternal and Child Screening (MAC)

