Screening for Down, Edwards & Patau syndromes

Classification:	Guideline
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Guideline to be followed by (target staff): Midwives, Sonographers, Obstetric doctors and the Laboratory staff

To be read in conjunction with the following documents:

- Public Health England (PHE) (2017) Screening Tests for You and Your Baby' leaflet. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/800673/Screening_tests_for_you_and_your_baby.pdf
- Milton Keynes University Hospital, *Screening in Pregnancy Guideline,* MIDW/GL/145, 2018, version 6
- Milton Keynes University Hospital, Down's *Syndrome - Management of suspected or confirmed Down's Syndrome on Postnatal Ward/ Neonatal Unit Guideline,* PAED/GL/97,2017, version 2

CQC Fundamental standards:

Regulation 9 – person centred care
Regulation 10 – dignity and respect
Regulation 11 – Need for consent
Regulation 12 – Safe care and treatment
Regulation 13 – Safeguarding service users from abuse and improper treatment
Regulation 16 – Receiving and acting on complaints
Regulation 17 – Good governance
Regulation 19 – Fit and proper

Disclaimer –

Since every patient's history is different, and even the most exhaustive sources of information cannot cover every possible eventuality, you should be aware that all information is provided in this document on the basis that the healthcare professionals responsible for patient care will retain full and sole responsibility for decisions relating to patient care; the document is intended to

supplement, not substitute for, the expertise and judgment of physicians, pharmacists or other healthcare professionals and should not be taken as an indication of suitability of a particular treatment for a particular individual.

The ultimate responsibility for the use of the guideline, dosage of drugs and correct following of instructions as well as the interpretation of the published material **lies solely with you** as the medical practitioner.

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Guideline Statement

To enable staff to provide a comprehensive antenatal and newborn screening service

Executive Summary

Screening is a process of identifying apparently healthy people who may be at an increased risk of a disease or condition. They can then be offered information, further tests, and appropriate treatment to reduce their risk and/or any complications arising from the disease or condition. [2]

The UK National Screening Committee (UK NSC) has responsibility for setting screening policy. It recommends that all eligible pregnant women in England are offered screening to assess the risk of the baby being born with Down's (Trisomy 21/T21), Edwards' (Trisomy 18/T18) and Patau's (Trisomy 13/T13) syndromes or a number of fetal anomalies (structural abnormalities of the developing fetus). [1.]

Fetal Anomaly Screening Programme (FASP) aims to ensure that there is equal access to uniform and quality assured screening across England and that women are provided with high quality information so they can make an informed choice about their screening options and pregnancy choices. Some women may choose not to be screened at all or accept screening for some conditions and it is important that this choice is respected. The screening policy is to offer screening to assess the risk of the baby being born with Down's, Edwards'/Patau's syndromes. [1, 2]

The test of choice for both singleton and twin pregnancies is first trimester combined screening.

Women can choose:

- not to have screening
- to have screening for T21 and T18 / T13
- to have screening for T21 only
- to have screening for T18 / T13 only [1,2]

The first scan usually takes place between 10 to 14 weeks and includes a blood sample taken to test for Down's, Edwards'/Patau's syndromes, with a second scan for fetal anomalies between 18+0 to 20+6 weeks. The timing of the scans allows for further diagnostic tests if required and ensures women have time to consider decisions about continuing their pregnancy. [1, 2]

The National Standards are[1] - thresholds for performance:

Detection rate (DR): the proportion of affected individuals with a positive screening result.
Screen positive rate (SPR)

Screening strategy	Thresholds	
	Acceptable	Achievable
T21	Standardised DR 85%	
	Standardised SPR 1.8-2.5%	Standardised SPR 1.9-2.4%
T18/T13	Standardised DR 80%	
	Standardised SPR 0.1-0.2%	Standardised SPR 0.13-0.17%
T21/T18/T13	Standardised SPR 1.8-2.5%	Standardised SPR 1.9-2.4%
Quadruple (T21)	Standardised DR 80%	
	Standardised SPR 2.5-3.5%	Standardised SPR 2.7-3.3%

*The DR and SPR for the quadruple test relate to singleton pregnancies only

The following guideline document relates to the screening programme currently offered in Milton Keynes University Hospital NHS Foundation Trust and is benchmarked to the national standards set out in April 2018. It is therefore an evolving document that will need revisiting and revising to encompass any future developments and recommendations from national bodies.

The aims of this screening programme are:

- To offer screening and diagnosis to all 'eligible' women booked before 20 weeks of pregnancy and attending for antenatal care within the area covered by the Milton Keynes University Hospital NHS Foundation Trust.
- To provide adequate high-quality information on the screening process to support each woman to make an informed decision on whether to accept or decline the offer of screening.
- Provision of adequate information and support to enable the woman and her partner to make an informed decision on the outcome of the pregnancy
- For women with a confirmed diagnosis as the result of screening, who choose to continue the pregnancy, provide optimal management of the pregnancy, birth, and newborn period
- For women with a confirmed diagnosis as the result of screening who opt for termination of pregnancy to provide the optimal care and support including bereavement counselling

Objectives

- To process and report on screening tests in a timely manner as detailed in the United Kingdom (UK) National Screening Committee (NSC) working standards and programme specific standards.
- To offer appropriate tests and methods of screening that meet national standards. To offer appropriate diagnostic tests to all women with screen positive results within programme specific recommended timescales.
- To promote an appropriate level of knowledge for all health professionals involved in the screening programme as recommended by the UKNSC.
- To minimise the adverse effects of screening: anxiety, misunderstanding, inaccurate information, unnecessary investigation and follow-up, and inappropriate disclosure of patient specific information.

- To have in place systems for risk assessment and management of adverse incidents occurring during the screening process.

1.0 Roles and Responsibilities

There are many healthcare professionals involved in the screening for Down's, Edwards' & Patau's syndromes including Community Midwives, Midwives, Sonographers, Sonographer Assistants, MK Pathology department, Screening laboratory at Oxford, Antenatal & Newborn Screening Team and Obstetricians. Please see the main body of the document for the outline of the roles and responsibilities. Other healthcare professionals should be aware of this document.

2.0 Implementation and dissemination of document

This guideline will be available on the Trust intranet.

Dissemination will be through community midwife team meetings, obstetric ultrasound department meetings and included in 'Risky bits and bobs'.

3.0 Processes and procedures

3.1 1st Trimester Screening for Down's, Edwards' & Patau's syndromes

The combined test uses maternal age, the nuchal translucency measurement (NT) and two biochemical tests, free beta human chorionic gonadotrophin (hCG) and PAPP-A, together with the gestational age calculated from the crown rump length (CRL) measurement, to calculate the risk of the pregnancy being affected by T21 or T18/T13. The optimal time to perform the combined test is between 11 weeks 2 days to 14 weeks 1 day of gestation, which corresponds to a CRL of 45.0 mm to 84.0 mm.

In cases where screening is accepted but it is not possible to obtain the NT measurement at the first appointment, at least one other attempt should be offered on the same day. If it is not possible to obtain an accurate NT measurement despite 'twice on the couch' then further attempts do not have to be offered and the woman should be referred in to the second trimester screening pathway. If the ultrasound measurement shows that the CRL is less than 45.0 mm, the woman should be recalled for a further scan to measure the NT. If the CRL is greater than 84.0 mm, the second trimester quadruple test should be offered. The first trimester combined test allows earlier decision making for parents.

3.2 2nd Trimester Screening for Down's syndrome

The quadruple test uses maternal age and four biochemical markers measured from 14 weeks 2 days until 20 weeks 0 days – alpha fetal protein (AFP), hCG (total, intact or free beta subunit), uE3 and Inhibin-A. Although this combination of markers has a lower detection and standardised screen positive rate than the combined test, it is the nationally recommended screening strategy in the second trimester. The optimum time for testing in the second trimester is around 16 week's gestational age. There will always be a need for a screening test in the second trimester for those women who book too late for first trimester testing or when an NT measurement cannot be obtained (despite 'twice on the couch') in the first trimester. An ultrasound scan will be required to date the

pregnancy and a fetal head circumference is the recommended measurement used for women presenting in the second trimester.

3.3 Vanishing twins

The sonographer should contact the ANSC or deputy to re-counsel the woman in relation to 1st and 2nd trimester screening, when:

- Ultrasound shows there is an empty second pregnancy sac, the biochemical markers appear no different to those in a singleton pregnancy and the combined test of NT, PAPP-A and free beta HCG can be used to calculate the risk.

- Ultrasound shows that there is a second sac containing a non-viable fetus (sometimes called 'vanished' twin), it is possible there could be a contribution to the maternal biochemical markers for many weeks. It is recommended that in this event services undertake the risk calculation based on the maternal age and nuchal translucency only (i.e. without biochemistry).

3.4 Screening in twin pregnancies

Women with a twin pregnancy are eligible for combined screening or quadruple screening dependent on gestational age.

When a twin pregnancy is confirmed at the dating scan, the sonographer should contact the ANSC or deputy to re-counsel the woman in relation to 1st and 2nd trimester screening. Choice and decision making in twin pregnancies is more complicated than in a singleton pregnancy and women need to understand the full screening pathway. The following should be discussed:

Limitations of the screening test and the possible outcomes
Implications of being given a higher chance result, including possible options for diagnostic testing
Risks of diagnostic testing for the pregnancy and each twin
Dilemmas they may have to address if diagnostic testing confirms one or both babies are affected

3.5 Screening in Milton Keynes University Hospital NHS Foundation Trust

In Milton Keynes University Hospital NHS Foundation Trust screening is primarily offered in the first trimester using the Combined Test. For women who miss the first trimester screening window or in whom it has not been possible to obtain an adequate nuchal translucency measurement, second trimester screening by Quadruple Test will be offered.

3.6 Roles and responsibilities

3.6.1 Community midwives

- To discuss screening with women and their families at the booking appointment and ensure clients have a copy of *"Screening tests for you and your baby"* leaflet. This is also available online in several languages.

- Document on maternal electronic records (e-Care) that screening has been discussed and if a client has either declined or accepted for both T21 and T13/T18.
- Refer **all** women for a dating scan to be performed when the woman is 12/40 gestation from LMP: request on e-care

3.6.2 Sonographers

- Ensure the woman has made an informed decision and it is documented by the community midwife that screening has been discussed and accepted.
- If from dating scan, the CRL is greater than 84mm then the Sonographer Assistant will perform the quadruple test if the patient consented to combined screening.
- When an antenatal woman attends for her dating/nuchal ultrasound scan and 1st trimester screening is not able to be completed; >14+1 and </=20+0 weeks gestation or the NT is unable to be examined, they are referred onto the 2nd trimester screening pathway. For women who are too early for 2nd trimester screening to be completed on the day of their ultrasound scan; less than 14+2 weeks gestation, they are booked into the designated once a week 'quad clinic' at the optimal gestation of 15 to 16 weeks

- The sonographer to document on the ultrasound report:

- *'Consented for 1st trimester screening, NT not examined, therefore, referred onto 2nd trimester screening pathway; designated Quadruple clinic appointment to be arranged by ANNB between 15- and 16-weeks' gestation.'*

- The sonographer will explain to the woman, she will be contacted by the ANNB screening team, and an appointment will be arranged and sent for her to attend, the first available designated 'quad clinic', between 15 and 16 week's gestation.

- Sonographer to ensure a copy of the dating ultrasound report is sent ***each day*** to Antenatal & Newborn (ANNB) screening team informing them of all women referred onto the 2nd trimester screening pathway.

3.6.3 Sonographer Assistant

- Obtain an accurate weight from the client on the day of the scan/blood sample.
- Ensure the rest of the request form is fully completed, including the sonographer who performed the NT, with a copy of the scan report stapled to the request form.
- With consent take a 3.5ml sample in a gold top tube; ensure the tube is labelled clearly with name (first name and surname), date of birth, hospital number, date sample taken and sign.
- The request form for Combined Screening is scanned onto the CRIS system along with the consent form with weight and height on.

The rest of the roles and responsibilities apply to both 1st and 2nd Trimester screening

3.6.4 Pathology (MK)

- To spin samples prior to transporting to Oxford
- Safely package samples to prevent damage to tube during transit

- Send daily list of samples sent to Oxford to ANSC
- Any rejected samples will be notified to the ANSC, who will arrange for a repeat sample to be completed

3.6.5 Screening Laboratory

- To inform ANSC of any incorrect or missing details via Lifecycle link and/or secure nhs.net account (mkg-tr.mkscreeningmidwives@nhs.net)
- To inform ANSC of a higher chance result via nhs.net account
- For lower chance results – to send letter to client informing them of their result
- Send a "midwife" result letter to ANSC for all lower chance results. The failsafe officer updates the antenatal screening spreadsheet with the results. Any missing results are reported to the ANSC and/or deputy screening midwife, who will then follow-up to ensure if a woman has accepted screening, she has completed the pathway.

3.6.6 Antenatal & Newborn Screening Department

- To obtain a list from MK laboratory of samples sent to the screening laboratory each day
- Check daily for missing information and complete as appropriate with correct information
- The ANSC and deputy will observe Lifecycle daily for higher chance results. The Oxford laboratory will notify the ANSC or deputy via generic nhs.net email to inform them of a higher chance result. This will then be available to view on Lifecycle in the co-ordinator report section.
- The ANSC, deputy screening midwife and failsafe officer will monitor the generic nhs.net email and Lifecycle FASP IT data center frequently throughout each working day. This is to ensure all higher chance results are acted upon.
    - The failsafe and tracking process for the FASP IT system is shown in Appendix 3.
- If a higher chance result, arrange an appointment within 3 working days for counselling with one of the ANSC team. Send letter to community Midwives office to be hand delivered to the woman if ANSC or deputy unable to contact the woman directly.

3.6.7 Midwives

- It is the responsibility of all midwives, irrespective of maternity setting to ensure they complete up-to-date training in antenatal and newborn screening. When providing care for any woman who attends any of the clinical areas, midwives should ensure they follow local guidelines and processes.

See flow chart in Appendix 1 for further information.

4.0 Statement of evidence/references

References:

[1] NHS Screening Programmes (2018) NHS Fetal Anomaly Screening Programme Standards valid for data collected from 1 April 2018

Available at: https://www.gov.uk/goernment/publications/fetal-anomaly-screening-programme-standards/standards-valid -from-1-april-2019

[2] NHS Screening Programmes (2018) Fetal Anomaly Screening Programme. Programme Handbook, Valid from September 2018, Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/749742/NHS_fetal_anomaly_screening_programme_handbook_FINAL1.2_18.10.18.pdf

External weblinks: Please note that although Milton Keynes University Hospital NHS Foundation Trust may include links to external websites, the Trust is not responsible for the accuracy or content therein.

5.0 Governance

5.1 Record of changes to document

Version number: 5		**Date:** 05/2020		
Section Number	**Amendment**	**Deletion**	**Addition**	**Reason**
Executive Summary			Detection rate (DR): the proportion of affected individuals with a positive screening result. Screen positive rate (SPR)	Updated
3.6.1	Document in the notes in the appropriate section that screening has been discussed and if a client has either declined or accepted for both T21 and T13/T18. Changed to: Document on maternal elelctronic records (e-Care) that screening has			Updated: electronic maternity records implemented.

	been discussed and if a client has either declined or accepted for both T21 and T13/T18.			
3.6.1		If the woman has booked late and is over 14+1/40 gestation to offer 2nd Trimester screening as stated above. If accepts 2nd Trimester screening: Obtain an accurate weight from the client on the day of the scan/blood sample. With consent take a 3.5ml sample in a gold top tube; ensure the tube and request form is labelled clearly with name (first name and surname), date of birth, hospital number, date sample taken and sign. The AntenatalFailsafe Officer will notify individual community midwives, by completing a request for antenatal visit sheet, informing them when a Quadruple Test is		Updated: This is no longer completed by community midwives.

		required following the woman's attendance at her dating scan.		
3.6.2		If from the dating scan, the CRL is 45mm to 84mm and have been unable to obtain a NT measurement despite 2 attempts, the woman is referred to the community midwife when they are between 14+2 weeks and 20+0 weeks gestation. This is documented on the woman's individual ultrasound report at the dating scan.	When an antenatal woman attends for her dating/nuchal ultrasound scan and 1st trimester screening is not able to be completed; >14+1 and </=20+0 weeks gestation or the NT is unable to be examined, they are referred onto the 2nd trimester screening pathway. For women who are too early for 2nd trimester screening to be completed on the day of their ultrasound scan; less than 14+2 weeks gestation, they are booked into the designated once a week 'quad clinic' at the optimal gestation of 15 and 16 weeks The sonographer to document on the ultrasound report: *'Consented for 1st trimester screening, NT not examined, therefore, referred onto 2nd trimester screening pathway; desiignated Quadruple clinic appointment to be arranged by ANNB between 15- and 16-weeks' gestation.'* The sonographer will explain to the woman, she will be contacted by the ANNB screening team, and an appointment will be arranged and sent for her to attend, the first available designated 'quad clinic', between 15 and 16 week's gestation. Sonographer to ensure a copy of the dating ultrasound report is sent ***each day*** to Antenatal & Newborn (ANNB) screening team informing them of all women referred onto the 2nd trimester	

			screening pathway.	
3.6.5	Send a "midwife" result letter to ANSC for all lower chance results. The failsafe officer updates the antenatal screening spreadsheet with the results. Changed to: Send a "midwife" result letter to ANSC for all lower chance results. The failsafe officer updates the antenatal screening spreadsheet with the results. Any missing results are reported to the ANSC and/or deputy screening midwife, who will then follow-up to ensure if a woman has accepted screening, she has completed the pathway.			
3.6.6	The ANSC and deputy will observe Lifecycle daily for higher chance results. The Oxford laboratory will notify the ANSC or deputy via	Telephone	Changed to: generic nhs.net email	Updated: Failsafe and tracking process implemented, with flow chart explaining the process

	telephone generic nhs.net email to inform them of a higher chance result. This will then be available to view on Lifecycle in the co-ordinator report section.		Added: in the co-ordinator report section	added as Appendix 3
3.6.6			The ANSC, deputy screening midwife and failsafe officer will monitor the generic nhs.net email and Lifecycle FASP IT data center frequently throughout each working day. This is to ensure all higher chance results are acted upon. The failsafe and tracking process for the FASP IT system is shown in Appendix 3.	
Appendix 3			Appendix 3: Failsafe and Tracking Flow Chart for Higher Chance FASP results	

5.2 Consultation History

Stakeholders Name/Board	Area of Expertise	Date Sent	Date Received	Comments	Endorsed Yes/No
Julie Cooper	Head of Midwifery		26.05.2020	Received	
Miss M Fynes	Locum Consultant Obstetrician		26.05.2020	No comments	Yes

5.3 Audit and monitoring

This Guideline outlines the process for document development will be monitored on an ongoing basis. The centralisation of the process for development of documents will enable the Trust to audit more effectively. The centralisation in recording documents onto a Quality Management database will ensure the process is robust.

Audit/Monitoring Criteria	Tool	Audit Lead	Frequency of Audit	Responsible Committee/Board
• The uptake of screening • Screen positive rates (SPR) • Detection rate (DR) • False positive rate (FPR) • No of babies born and found to have Down' s syndrome	Oxford Screening Laboratory provides a quarterly report specifically for Milton Keynes, together with an SHA report to compare.	Screening Laboratory Manager	Quarterly	ANSSG committee, PCT, SHA
Identify the eligible population: have systems in place to: • Record all pregnant women booking for antenatal care • Collect and submit data for FASP coverage Key Performance Indicators (KPIs)	KPI FA3	Antenatal & Newborn Screening Co-ordinator (ANSC)	Quarterly	Milton Keynes ANNB Screening Programme Management Board
Number of women with higher chance results offered an appointment within 3 working days	NHS Fetal Anomaly Screening Annual Data Return	Antenatal & Newborn Screening Co-ordinator (ANSC)	Annually	Milton Keynes ANNB Screening Programme Management Board

5.4 Equality Impact Assessment

As part of its development, this Guideline and its impact on equality has been reviewed. The purpose of the assessment is to minimise and if possible remove any disproportionate impact on the grounds of race, gender, disability, age, sexual orientation, religion or belief, pregnancy and maternity, gender reassignment or marriage and civil partnership. No detriment was identified. Equality Impact assessments will show any future actions required to overcome any identified barriers or discriminatory practice.

Equality Impact Assessment			
Division	Women and Children's Health	Department	Maternity
Person completing the EqIA	Anita Males	Contact No.	85236
Others involved:		Date of assessment:	14/05/2020
Existing policy/service	Yes	New policy/service	No

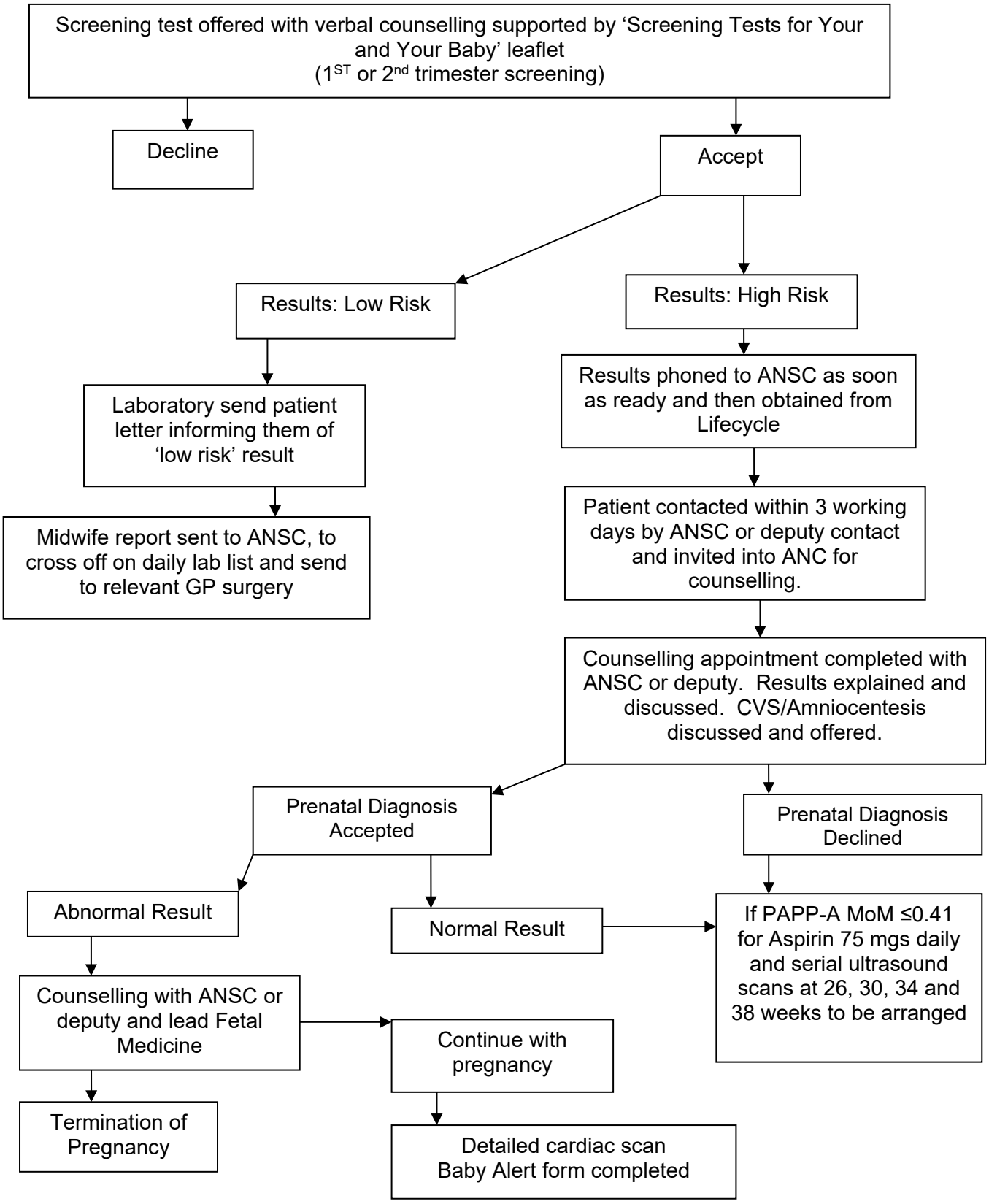
Will patients, carers, the public or staff be affected by the policy/service?	Yes
If staff, how many/which groups will be affected?	Community midwives, sonographers, sonography assistants, antenatal and newborn screening midwives

Protected characteristic	Any impact?	Comments
Age	NO	Positive impact as the policy aims to recognise diversity, promote inclusion and fair treatment for patients and staff
Disability	NO	
Gender reassignment	NO	
Marriage and civil partnership	NO	
Pregnancy and maternity	NO	
Race	NO	
Religion or belief	NO	
Sex	NO	
Sexual orientation	NO	

What consultation method(s) have you carried out?
Email, Guideline review group meeting
How are the changes/amendments to the policies/services communicated?
intranet
What future actions need to be taken to overcome any barriers or discrimination?

What?	Who will lead this?	Date of completion	Resources needed
Review date of EqIA			

Appendix 1: Flow chart for maternal screening for Down's syndrome, Edward's & Patau's syndromes



Appendix 2: Aetiology of Down's, Edwards' & Patau's

Down's syndrome:

People with Down's syndrome (T21) have extra chromosome 21 in the cells of their body. A baby born with T21 will have a learning disability. They may have communication problems and difficulty managing some everyday tasks. It is impossible to know what level of learning disability a baby with T21 will have. It can vary from mild to severe. Some health problems are more common in people with T21, for example, heart conditions, and problems with the digestive system, hearing and vision. Some problems can be serious, but many can be treated. With good healthcare, someone with Down's syndrome is expected to live to around 60 years. People with Down's syndrome have distinctive facial features including almond shaped eyes. Like all children, they also inherit features from their parents. T21 affects 1 in every 1000 births.

- Most cases arise when the chromosomes donated by the mother or father have failed to divide correctly. This type is called Standard or Regular Trisomy 21 and accounts for 95% of people with this condition. Regular Trisomy 21 is not hereditary, but it is known from statistical analysis that if a woman has a child with this type of condition then the risk will be higher of it occurring in the next pregnancy.
- Other types of Down's syndrome occur due to translocation of genetic material between chromosome 21 and another chromosome (e.g. Chromosomes 14 and 21 known as Robertsonian translocation). This type occurs in 4% of cases.
- The remaining 1% occurs when there is mosaicism – where normal and Trisomy 21 cells are found within the individual.

Edwards' and Patau's syndromes:

Sadly, most babies with T18 or T13 will die before they are born, be stillborn or die shortly after birth. Some babies may survive to adulthood, but this is rare. The correct terminology to use when discussing this with parents is 'life limiting condition.' In Edwards' syndrome (T18) there is an extra copy of chromosome 18 in each cell. All babies born with T18 will have a wide range of problems, which are usually extremely serious - these may include major brain abnormalities. Babies affected by T18 can have heart problems, unusual head and facial features, growth problems and be unable to stand or walk. T18 affects about 3 of every 10,000 births. In Patau's syndrome (T13) there is an extra copy of chromosome 13 in each cell. All babies born with T13 will have a wide range of problems, which are usually extremely serious - these may include major brain abnormalities. Babies affected by T13 can have heart problems, a cleft lip and palate, growth problems, poorly formed eyes and ears, problems with their kidneys and are unable to stand or walk. T13 affects about 2 of every 10,000 births.

Appendix 3: Failsafe and Tracking Flowchart for Higher Chance FASP results

Antenatal & Newborn Screening Co-ordinator (ANSC) and/or deputy screening midwife will monitor daily the Dell Wyse vWorkspace/Lifecycle Data Centre each working day for any higher chance FASP results that require action as per Fetal Anomaly Screening Programme (FASP) Standard 7: Time to intervention (T21, T18, T13 screening).

The process is as follows via MKUH computer desktop access:

1. Log into Dell Wyse vWorkspace
2. Log into LifeCycle 4.0
3. Click on Data Centre
4. Go to Milton Keynes
5. Click on Co-ordinator Report
    a. Run
6. Open case
    a. Print report

To move case out of co-ordinator report:

7. Go to set reported
    a. Set case status reported
    b. Run