Screening in Pregnancy

Classification :	Guideline
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Authors Division:	Women & Children's
Departments/Group this Document applies to:	Maternity

Approval Group: Women's Guideline Review Group, Women's Health CIG	**Date of Approval:**	07/10/2020
	Last Review:	Sept 2020
	Review Date:	01/10/2023

Unique Identifier: MIDW/GL/145	**Status:** Approved	**Version No:** 7

Guideline to be followed by (target staff): This guideline applies to all healthcare professionals involved in antenatal and newborn screening; this includes midwives, sonographers, obstetric doctors, neonatologists and other medical specialties and the laboratory staff.

To be read in conjunction with the following documents:

- HIV Antenatal and Perinatal Management of Women Known to be HIV Positive and their Infants guideline
- Referral protocol for the management of women testing positive for syphilis in the antenatal setting
- Hepatitis B Guideline
- Sickle Cell and Thalassaemia guideline
- Down's, Edwards' and Patau's Screening guideline
- Fetal Anomalies guideline
- Training Needs Analysis guideline

Are there any eCARE implications? No

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 17 – Good governance

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:

Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or better informed decisions. National population screening programmes are implemented in the National Health Service (NHS) on the advice of the United Kingdom National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the four UK countries. The Screening Quality Assurance Service ensures programmes are safe and effective by checking that national standards are met. PHE leads the NHS Screening Programmes and hosts the UK NSC secretariat (PHE, 2017).

The UK National Screening Committee (UK NSC) has responsibility for setting screening policy.

Executive Summary:

The Antenatal and Newborn (ANNB) Screening Programme is overseen by Public Health England. Its aim is to ensure that all women and babies have access to high quality antenatal and newborn screening programmes. Milton Keynes University Hospital NHS Foundation Trust (MKUH) has adopted the national service specifications for antenatal and newborn screening.

NHS England retains overall responsibility for ANNB commissioning and leads on performance management, pathway co-ordination, incident management and the implementation of new standards. Key performance indicators (KPIs) are established for each programme and MKUH submits these on a quarterly basis.

There are six antenatal and newborn programmes:

- NHS Fetal Anomaly Screening Programme (FASP)
- NHS Infectious Diseases in Pregnancy Screening (IDPS) Programme
- NHS Sickle Cell and Thalassemia (SCT) Screening Programme
- NHS Newborn Blood Spot (NBS) Screening Programme
- NHS Newborn and Infant Physical Examination (NIPE) Programme
- NHS Newborn Hearing Screening Programme (NHSP)

Definitions:

NHS – National Health Service
UKNSC – United Kingdom (UK) National Screening Committee
PHE – Public Health England
MKUH – Milton Keynes University Hospital NHS Foundation Trust
SCT – Sickle Cell & Thalassaemia
PND – Prenatal Diagnosis
CVS – Chorionic Villus Sampling
IDPS – Infectitious Diseases in Pregnancy Screening
FASP – Fetal Anomaly Screening Programme
ANSC – Antentatal & Newborn Screening Programme
GP – General Practitioner
LMP – Last Menstrual Period
HIV – Human Immunodeficiency Virus
HBV – Hepatitis B
FBC – Full Blood Count

1.0 Roles and Responsibilities:

See 3.0 Processes and procedures

2.0 Implementation and dissemination of document

Electronic copies will be available on the intranet. Training and updates are provided by the Antenatal and Newborn Screening Co-ordinator (ANSC) as per Training Needs Analysis.

3.0 Processes and procedures

3.1 Booking

An online self-referral is available via MKUH website for all women who request to book for maternity care at MKUH. If the woman has no access to the electronic referral system, they can contact their GP to facilitate a paper referral to their named community midwife.

On receipt of the referral each woman receives a confirmation email with information about how they will be contacted by the community midwife to arrange the antenatal booking appointment. The email also provides a link to the 'Screening Tests for You and Your Baby' leaflet. This enables the woman to access antenatal and newborn screening information prior to the first antenatal appointment.

The named community midwife will then contact the woman to arrange an appropriate date and time to complete the booking; the gestation is calculated using LMP and any urgent bookings >9 weeks highlighted and prioritised to the first available booking clinic that week.

At the booking appointment, the woman is provided with both verbal and written information on antenatal and newborn screening tests that are offered and recommended. Opportunities are provided for discussion, to enable informed consent before proceeding with any screening tests.

The 'Screening Tests for You and Your Baby' leaflet is provided in the booking pack for all women. If the woman's first language is not English, the leaflet can be accessed in several languages and also as easy read versions online via: https://www.gov.uk/government/publications/screening-tests-for-you-and-your-baby-description-in-brief

If required an interpreter is requested, either face-to-face or via interpreter telephone.

Informed consent should be gained for all screening tests and it is the women's right to decline screening. If screening is declined then the community midwife must document in the woman's electronic maternity records, on the green antenatal booking assessment form and inform the ANSC and/or deputy screening midwife, who will make a formal re-offer to the woman by 20 weeks gestation.

ANNB screening team can be contacted via:

- generic email address: mkg-tr.mkscreeningmidwives@nhs.net
- or direct line telephone: 01908 995236
- or in person in ANNB screening office

If informed consent gained then the community midwife will take all routine booking bloods for; SCT, IDPS, Group and Screen and Full Blood Count.

Blood specimen bottles to use:

- Gold top for IDPS x1
- Purple top for FBC and SCT x1
- Pink top for Blood Group and Antibodies x1

Booking bloods should be requested electronically or if unavailable to use the paper antenatal booking bloods request form with attached family origin questionnaire (FOQ).

N.B. with SCT request, a Family Origin Questionnaire (FOQ) form **MUST** be completed and sent with the blood specimen and the gestation clearly documented on it (Standard 3).

When requesting screening bloods, any previous known status; known HIV, known Hepatitis B positive, previous syphilis infection or known SCT carrier, must be identified on the request form. Use danger of Infection Stickers where appropriate.

If the woman is a known screen positive for HIV, Hepatitis B or previous syphilis infection, the woman should be 'fast tracked' to the ANSC and/or deputy to expedite referral to the relevant clinicians/services.

If a woman identifies she is a carrier of a haemoglobin variant when asked at her booking appointment and the biological father is also present; discuss inheritance risk with parents and obtain consent to test the biological father. We are required to offer biological father SCT screening in each pregnancy.

- SCT screening (1x Purple EDTA blood bottle)
- Identify on the blood request order that this is a biological father test and include maternal MRN / NHS number

The community midwife should inform the ANSC and/or deputy screening midwife of any known carriers, and in particular, if both parents are carriers to 'fast track' the couple to discuss and offer prenatal diagnosis.

For all women who book late or transfer their care, all screening tests should be offered. However, the woman should be informed that some tests may not be available dependent on their current gestation.

Routine booking bloods are offered and recommended to all women who transfer their care from another NHS maternity provider to MKUH. If the woman declines, then the ANNB screening team will contact the previous NHS maternity provider for their screening results and ensure appropriate care is provided if required.

At the booking appointment the community midwife will discuss and offer a dating/nuchal ultrasound scan, as well as discussing and offering, the options for 1st and 2nd trimester screening. The routine fetal anomaly ultrasound scan will also be discussed and offered at this appointment.

The community midwife should clearly document in the woman's electronic maternity records the discussion, offer and whether consent has been obtained for each of the antenatal and newborn screening programmes.

Each antenatal appointment should be an occasion for the community midwife to review all screening blood results and review ultrasound appointments and reports.

3.2 Blood Group and Antibody screen:

Blood group and atypical antibody screening is performed routinely at booking and repeated at 28 weeks gestation and prior to the administration of Anti-D in Rh Negative women.

The exception to these would be patients who have a positive atypical antibody screen or have a previous history of atypical antibodies. The care pathway and frequency of repeat testing depends on the specificity of the antibody, paternal testing and the results of any maternal/fetal DNA testing if applicable.

The failsafe officer reviews all booking bloods and escalates to the ANNB screening midwives of any woman where atypical antibodies are detected to action accordingly.

Blood group and antibody screen sample bottles MUST have handwritten patient identifiable information on them. ICE labels will not be accepted.

3.3 Sickle Cell & Thalassaemia (SCT) Screening

See Haemoglobinopathy (Sickle Cell & Thalassaemia) (SCT) Screening in Pregnancy guideline.

Milton Keynes has been classified as a 'High Prevalence' trust therefore universal screening for SCT is offered routinely to all women at the antenatal booking appointment.

Timeliness of antenatal SCT screening (Standard 2):

- The proportion of pregnant women having antenatal SCT screening for whom a screening result is available ≤10 weeks + 0 days gestation.

- In order to, maximise the opportunity of informed choice for the woman and couple by identifying carrier and affected women ≤10 weeks + 0 days gestation.

Antenatal and newborn screening will be notified by MKUH laboratory of any carrier results within 3 working days of test (Standard 4).

- This is via generic email to mkg-tr.mkscreeningmidwives@nhs.net account with a read receipt.

On receipt of the woman's SCT carrier result or notification of a known carrier, the ANSC and/or deputy screening midwife will contact the woman directly via telephone to arrange an appointment to discuss the result of screening. If unable to contact the woman directly within three working days, an appointment letter is sent, and the community midwife asked to perform a wellbeing check (*see SOP: Antenatal Cohort Tracking and Failsafe Processes*).

PHE patient information leaflets are provided on the specific carrier status, along with the biological father screening leaflet. The appointment will provide the woman with information regarding the variant found and for biological father testing to be offered, in order to achieve the offer of PND by 12+0 weeks gestation (Standards 5a and 5b) and completion of PND by 12+6 weeks gestation (Standard 6). The results of PND will be notified to the woman/couple ≤ 5 working days of the test (Standard 7).

3.4 Infectious Diseases in Pregnancy Screening (IDPS)

Infectious Diseases in Pregnancy screening for HIV, Hepatitis B and Syphilis is routinely offered to all women booked for maternity care at MKUH. Women can accept or decline screening for one or all three infectious diseases. If the woman declines then the community midwife should inform the ANSC and/or deputy screening midwife either via:

- generic email: mkg-tr.mkscreeningmidwives@nhs.net
- or direct line telephone: 01908 995236
- or in person

It should be clearly documented on the woman's electronic maternity record and green antenatal booking risk assessment form.

The ANSC and/or deputy screening midwife will make a formal re-offer by 20 weeks.

IDPS screening should be offered and completed at any time during the pregnancy including if a woman presents in labour.

Any known HIV positive, known Hepatitis B positive or previous Syphillis infections should be 'fast tracked' to the ANNB screening midwives to ensure appropriate referrals are expedited.

MKUH laboratory inform the ANNB screening midwives of any screen positive results for HIV, Hepatitis B and Syphilis via the generic email (mkg-tr.mkscreeningmidwives@nhs.net) with a read receipt.

On receipt of a confirmed screen positive result the ANSC and/or deputy screening midwife will contact the woman directly via telephone and invite into ANC for a face-to-face counselling appointment to discuss the result. This appointment should be completed ≤ 10 days of receipt of the result.

If the ANNB screening midwives are unable to contact the woman via telephone, an appointment letter will be sent and the community midwife asked to complete a wellbeing check (*see SOP: Cohort Tracking and Failsafe Processes*).

All relevant referrals are then completed by the ANSC and/or deputy screening midwife and sent for further specialist management and plan of care.

Please see relevant guideline:

HIV – Antenatal and Perinatal Management of Women known to be HIV Positive and their Infants

Hepatitis B Screening of Pregnant Women and Immunisation of Babies at Risk

Referral Policy for the Management of Women Testing Positive for Syphilis in the Antenatal Setting

3.5 Fetal Anomaly Screening Programme (FASP):

Down's syndrome, Edward's and Patau Screening – 1st trimester (Combined) screening:

See Screening for Down's, Edwards' and Patau's Syndromes Guideline

At the antenatal booking appointment the community midwife will discuss the ultrasound scans offered during pregnancy as part of the FASP screening programme; dating/nuchal and fetal anomaly.

The 'Screening Tests for Your and Your Baby' leaflet is provided, which is also accessible online in several languages and as easy read options via: https://www.gov.uk/government/publications/screening-tests-for-you-and-your-baby-description-in-brief

The community midwife will request at the antenatal booking appointment via e-Care, a dating/nuchal ultrasound scan providing LMP and EDD. This will be booked by departmental obstetric ultrasound administrators at 12 weeks gestation and an appointment letter sent directly to the woman.

All women eligible for combined screening on the day they attend for their dating/nuchal ultrasound scan, who accept screening, have it completed on the same day following the scan.

For any eligible women whereby consent has not been obtained prior to attending for the dating/nuchal ultrasound scan, the sonographer will contact the ANNB screening midwives to attend and counsel the woman on both 1st and 2nd trimester screening; if accepted the nuchal ultrasound scan is completed and the sample obtained on the same day following the scan.

If the woman is outside the timeframe for 1st trimester screening, attends between 14+2 and 20+0 weeks gestation, 2nd trimester screening is offered and if accepted, completed on the same day following the scan.

If the sonographer is unable to measure the nuchal translucency (NT), therefore 1st trimester screening cannot be completed; the woman is referred onto the 2nd trimester screening pathway *(see SOP: Referral to Quad Clinic).*

For any women who DNA their dating/nuchal ultrasound scans, these are followed-up by the ANNB screening midwives and re-booked if required *(see SOP: Antenatal & Newborn Failsafe and Tracking Processes).*

Following completion of the dating/nuchal ultrasound scan, all eligible women are offered a routine fetal anomaly ultrasound scan; between 18+0 and 20+6 weeks gestation. If accepted this is booked the same day and they are provided with an appointment letter confirming the date and time of the next appointment.

Any women who decline or DNA the routine fetal anomaly ultrasound scan are followed-up by the ANNB screening midwives (see SOP: Antenatal & Newborn Failsafe and Tracking Processes). A 'baby alert' is completed for all women who do not have a completed fetal anomaly ultrasound scan and sent to the paediatric team via email to put a management plan into place for when the infant is born.

If a fetal anomaly is suspected and/or confirmed at the routine fetal anomaly ultrasound scan, the woman is referred to the ANNB screening midwives for counselling and offered referral for further review by a fetal medicine consultant (***see Fetal Anomalies guideline***).

1st and 2nd Trimester Screening Results:

FASP defines the national cut-off set at 1 in 150 at term for both first and second trimester screening tests. A woman with a result of 1 in 150 or greater (between 1 in 2 and 1 in 150), of having a pregnancy affected by T21, T18/T13 in the 1st trimester or T21 only in the 2nd trimester will be considered to be in the 'higher chance' group and offered an invasive diagnostic test.

Lower Chance: Women will be notified of a low chance result by letter, which will be sent from OUH screening laboratory within 10 working days of the reported result.

***Higher Chance*:** The OUH screening laboratory informs the ANNB screening team of any higher chance results via the generic email, as well as reporting them in the Co-ordinator Report section within Delwyse/vWorkSpace; within 3 working days of sample receipt (Standard 5). The ANSC and/or deputy screening midwife monitor the generic email: mkg-tr.mkscreeningmidwives@nhs.net and the Co-ordinator Report every working day and action. Women are contacted usually on the same day or within 3 working days of receipt of the higher chance result and offered a counselling appointment (Standard 7).

If the ANSC and/or deputy screening midwife is unable to contact the woman then failsafe processes are followed (*see SOP: Antenatal & Newborn Tracking and Failsafe Processes*).

If following counselling the woman chooses to have an invasive diagnostic test, either CVS or amniocentesis an appointment will be arranged with a fetal medicine consultant; either locally (MKUH) within 3 working days (Standard 8a), or at a tertiary unit (OUH), within 5 working days (Standard 8b).

PHE (2020) NHS Fetal Anomaly Screening Programme – Chorionic Villus sampling (CVS) and amniocentesis: information for parents leaflet is provided. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/899793/Fetal_anomaly_screening_CVS_and_amniocentesis_information_for_parents.pdf

Low PAPPA

If low PAPPA identified from combined screening results (0.41 or lower) ANNB screening to:

- Document result in the woman's electronic maternity records
- Inform community midwife to update in patient maternal records.
- Arrange consultant obstetrician appointment, which will action Saving Babies Lives Pathway.
- Send information letter to patient.
- Send request for prescription for aspirin to GP.
- Request departmental ultrasound scans for growth and dopplers

3.6 16 week antenatal appointment:

At the 16 week antenatal appointment the community midwife should ensure:

- All antenatal booking bloods accepted have been completed and a result available
- Any screen positive results have been actioned; appointments and referrals made
    - If unsure appointments and/or referrals have been completed, then contact the ANNB screening team via email, telephone, or in person
- The dating/nuchal ultrasound scan has been completed and if 1st/2nd trimester screening was accepted a result has been received
    - If no result received contact the ANNB screening team to follow-up
- The routine fetal anomaly ultrasound scan has been arranged.
    - If no appointment booked community midwife to request one via e-Care

3.7 Antenatal Screening Test results for women who have miscarried or termination of Pregnancy:

All women who miscarry or terminate their pregnancy after screening should receive their results and are followed up as required (*see SOP: Antenatal & Newborn Failsafe and Tracking Processes*).

3.8 Antenatal & Newborn Screening Governance:

All Antenatal & Newborn Screening data returns and reports, audits, SOPs/guidelines and screening incidents need to be reported and monitored through the relevant trust governance meetings/structure (***see Appendix 2 for the ANNB Governance Structure***).

Internal risk and governance arrangements are to ensure there are clear lines of accountability and pathways for escalation of risks/concerns and regular monitoring of the quality of ANNB screening programmes by trust governance.

4.0 Statement of evidence/references

References:

NHS Public Health Functions Agreement 2015 – 2016 available from:

Public Health England NHS Infectious Diseases in Pregnancy Screening Programme Standards 2016 – 2017 Available from:
https://www.gov.uk/topic/population-screening-programmes/infectious-diseases-in-pregnancy

NHS Sickle Cell and Thalassaemia Screening Standards April 2017 Available from:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/614950/Sickle_cell_and_thalassaemia_screening_standards.pdf
NHS Fetal Anomaly Screening Programme 2015 – 2016 Available from:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/421650/FASP_Standards_April_2015_final_2_.pdf

NICE 2008 (reviewed January 2017) Antenatal Care for uncomplicated pregnancies. Available from: https://www.nice.org.uk/guidance/cg62/resources/antenatal-care-for-uncomplicated-pregnancies-pdf-975564597445

External weblink references: 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 Document review history

Version number	Review date	Reviewed by	Changes made
6	July 2017	Women & Children's	Updated
7	August 2020	Antenatal & Newborn Screening Co-ordinator (ANSC)	Updated

5.2 Consultation History

Stakeholders Name/Board	Area of Expertise	Date Sent	Date Received	Comments	Endorsed Yes/No
Irene Miotto	Quality Assurance Adviser	Nov 2019	07.05.20	Comments acknowledged and included	
Anita Males	ANSC	07.05.20	20.08.20	Reviewed and updated	
Julie Cooper	Head of Midwifery	18.09.20			
Janice Styles	Matron for Communit y, ANC and ANNB Screenng	18.09.20			
Monica Wilson	Deputy Screening Midwife	18.09.20			

5.3 Audit and monitoring

Audit/Monitoring Criteria	Tool	Audit Lead	Frequency of Audit	Responsible Committee/Board
Audit of maternal records – antenatal and newborn	20 consecutive sets of maternity notes, paired with the respective newborn hospital notes 6 sets of paired screen positive result notes	ANSC	Annually	Women's Health CIG

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 & Children	Department	Maternity
Person completing the EqIA	Anita Males – ANSC	Contact No.	01908 995236
Others involved:		Date of assessment:	20.08.20
Existing policy/service		New policy/service	

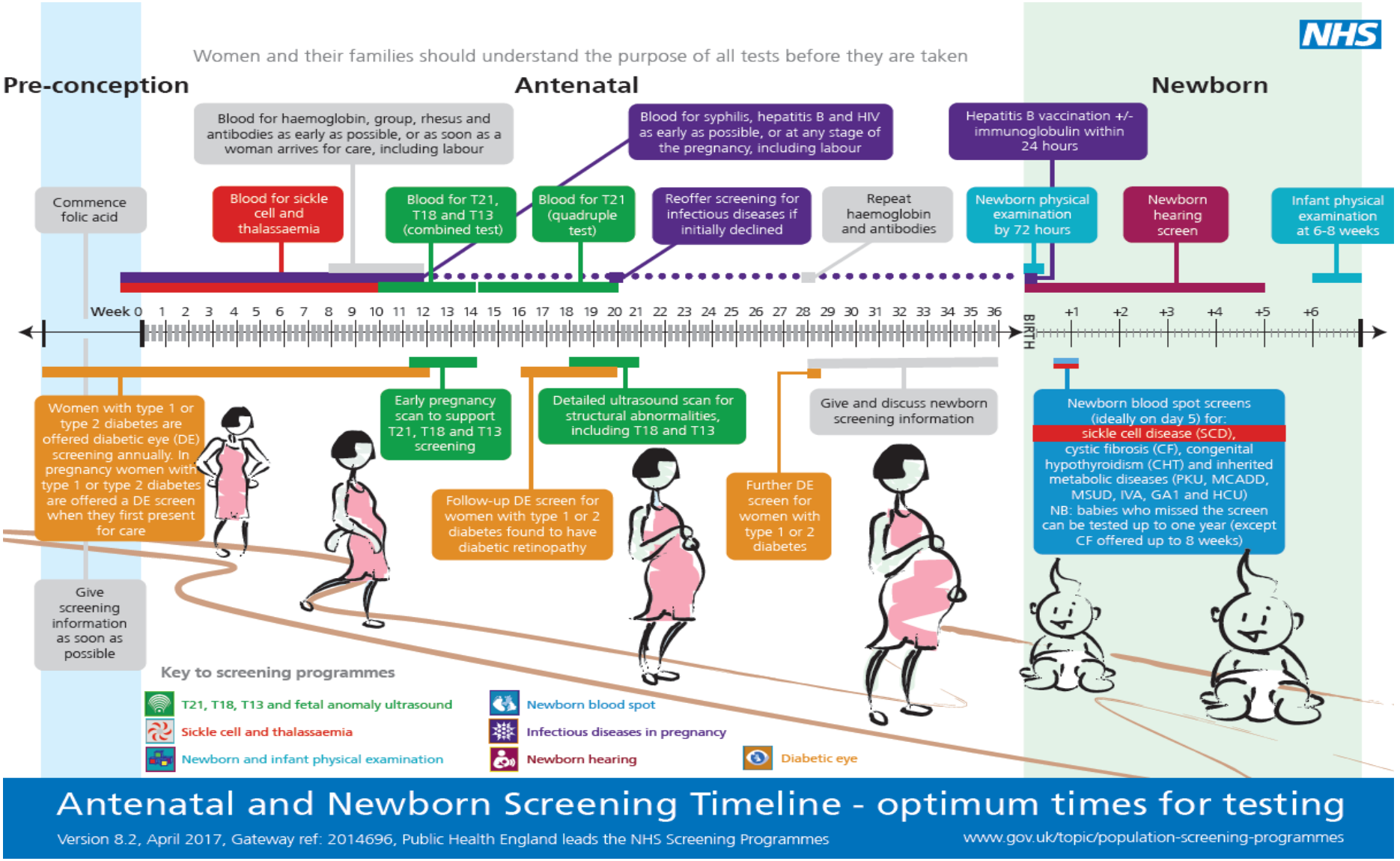
Will patients, carers, the public or staff be affected by the policy/service?	Yes
If staff, how many/which groups will be affected?	Community Midwifes, ANNB screening midwives, sonographers, obstetricians, labour ward and postnatal ward midwives

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, uploaded to Microsoft teams
How are the changes/amendments to the policies/services communicated?
email, team meetings, intranet post
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:



Appendix 2: Antenatal & Newborn Screening Governance