The Shrewsbury and Telford Hospital NHS Trust

Standard Operating Procedure (SOP)

SOP Title	**Maternity Ultrasound Department Management of Screen Positive Results from Combined and Quadruple Screening tests.**		
SOP Number	038		
Care Group	Women and Children's		
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Approved by	Maternity USS Department, Maternity Governance		
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Document Control

Version	Date	Author	Status	Comments
1-1.4	23/9/16-19.4.19	Alison Readman	NEW	Version table amalgamated see version 1.4 for full history
2.0	23/10/2019	Alison Readman	Full review	Full version review and update to terminology and timing of Referral to Fetal Medicine
2.1	2nd December 2020	Jacqui Bolton	Revision	Revision to process for Low PAPPA results aspirin and USS management
2.2	19th October 2021	Alison Readman	Revision	minor amendment to comply with current practice
2.3	20th January 2023	Alison Readman	Revision	minor amendments reflecting current changes in practice
2.4	11th May 2023		Update	Appendix 1 – Auditable Standards added
2.5	July 2023	Louise Weaver		Audit & Monitoring paragraph update to reflect new process.
3	February 2024	Alison Reaman	Full review	Full review.
3.1	19th July 2024	Alison Readman	Update	

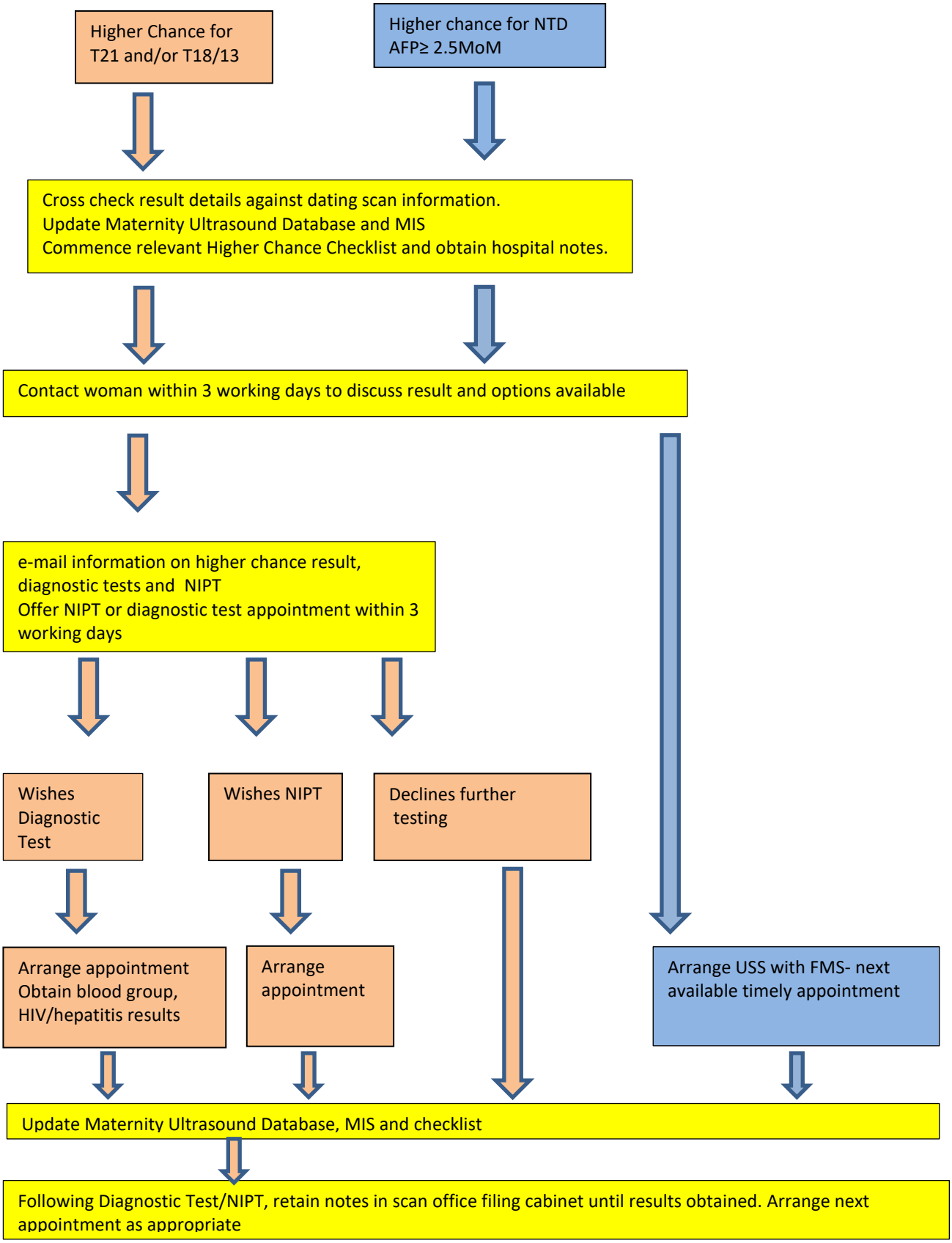
SOP Objectives	▪ To identify screen positive/increased chance results from combined or quadruple screening tests. ▪ To provide information on the inclusion and exclusion criteria of screen positive results. ▪ To provide information on the Maternity Ultrasound Department referral pathway for screen positive/increased chance results from combined or quadruple screening tests. ▪ To facilitate referral to Fetal Medicine Consultant. ▪ To facilitate the development and communication of an antenatal management plan for the woman receiving an increased chance result from a combined or quadruple screening test.
Scope	▪ Results from combined and quadruple antenatal screening tests performed between 11+2 - 20+0 weeks (CRL 45mm- HC 172mm) gestation. ▪ Care following diagnosis of a chromosomal or structural anomaly is not within the scope of this document. ▪ To be read in conjunction with the relevant maternity antenatal screening guideline and maternity ultrasound department guidelines. ▪ Where the NT measurement is 3.5mm or greater, the relevant pathway documented in the 'Dating Scan/Nuchal Translucency Measurement' Guideline is to be followed.
Audit/Monitoring	Compliance with this guideline / SOP will be audited as part of the Shrewsbury and Telford Hospital NHS Trust's five-year rolling programme of NICE and local guideline audits, unless circumstances require an earlier or more frequent audit. The audit will be carried out against the auditable standards and the results of the audit will be reported and acted on in accordance with the Trust Clinical Audit Policy (CG25).
	In this SOP we use the terms 'woman' or 'mother' throughout. These should be taken to include people who do not identify as women but are pregnant or have given birth.

Number	Brief	Responsibility
1	**Identification of Screen Positive Result** **Inclusion criteria** ▪ Increased chance result for Down's syndrome (T21) >1:150, from combined or quadruple test, highest chance reported as ≥1:2 . ▪ Increased chance result for Edward's (T18)/Patau's (T13) syndromes >1:150, from combined test, highest chance reported as ≥1:2. ▪ Increased chance result for Neural Tube Defect (NTD) -AFP ≥2.5 MoM from quadruple test. ▪ PAPP-A 0.415 MoM or less, from combined screening test. **Exclusion criteria** ▪ Lower chance results from combined or quadruple screening tests	Clinical Chemistry, BWH
2	**Results Reporting Process** ▪ **Screen positive/Increased chance results for T21, T18/T13 and NTD**, from combined or quadruple tests, will be reported daily (weekdays) to the Maternity Ultrasound Department by secure nhs.net email directly from the Clinical Chemistry laboratory at Birmingham Women's Hospital (BWH). ▪ **Low PAPP-A results** will be emailed to the Antenatal Screening Team refer to SOP Low PAPP-A results for management. ▪ The Maternity Ultrasound Department (sath.matyusscreening@nhs.net) email is checked daily by a midwife sonographer working at PRH to retrieve results.	Clinical Chemistry, BWH Biochemistry SaTH Midwife Sonographer
3	**Receiving and Confirming Screen Positive/Increased Chance Results** ▪ The midwife sonographer will print a copy of the increased chance result, and cross check the test details on the report with another midwife sonographer (ultrasound date and measurements, blood sample date, maternal D.O.B, ethnicity, weight and smoking status at test). ▪ The midwife sonographer will send an email confirming result received to clinical chemistry, BWH (for reports from BWH).	Midwife Sonographer
4	**Documentation of Increased Chance Results** ▪ The midwife sonographer will add the increased chance result details to the relevant Maternity ultrasound database (High Chance Down's Screen database for T21, Edward's/Patau's Risk Database for T18/T13 chances, Serum Anomaly database for increased NTD chance). ▪ The midwife sonographer will update the Maternity Information System (MIS) with the results (Scan result to Badgernotes (BN) and update Fetal Medicine Plan on BN) ▪ The midwife sonographer will commence the relevant increased chance checklist(Appendix. ▪ Patient loose sheets/checklists to be retained in the maternity ultrasound office until the episode has been concluded. Completed checklist scanned to BN.	Midwife Sonographer
5	**Informing the Woman of an Increased Chance Screening Result** ▪ The midwife sonographer will check availability of appropriate FMS ultrasound appointments and will contact the local FMS if no suitable planned appointments available.	Midwife Sonographer

	▪ The midwife sonographer will try to contact the woman by telephone within 3 working days of the result being received and will discuss the increased chance result and referral options with her. To aid understanding, the chance result will be discussed as a number and a percentage (eg. 1 in 5 chance or 20% chance). ▪ The woman will have had the 'Screening tests for you and your baby(STFYAYB)' information document discussed at the antenatal booking and at the dating scan and informed that the STFYAYB Information document on badgernotes, can be given in certain other languages). Further information document ' Down's syndrome, Edward's syndrome and Patau's syndrome: options after higher chance result' will be emailed to the woman or given as a printed copy at a face-to-face appointment ▪ If the woman wishes face to face consultation, this will be arranged. If unable to achieve contact by telephone, the Community Midwife will be asked to visit the woman. ▪ An interpreter will be arranged if required, as per Interpreter SOP. ▪ **For increased chance for T21 or T18/T13**. The options of no further testing, Non-Invasive Prenatal Tests (NIPT) or diagnostic testing (CVS or amniocentesis as appropriate, dependent on gestation), with associated miscarriage risks), will be discussed. ▪ An appointment for NIPT will be offered within 3 working days ▪ An appointment for a diagnostic test (if preferred option) will be offered within 3 working days local referral, within 5 working days for Tertiary Centre referral., ▪ If no local FMS appointment available within 3 working days, nearest available timely appointment will be offered following discussion with FMS. ▪ When no local FMS available, referral will be made following the pathway outlined in the SaTH 'Referral for Fetal medicine Services SOP', via secure NHS email to the relevant Fetal Medicine unit using the appropriate referral form and attaching a copy of the scan report, booking blood reports including antenatal serology and blood group. Information on diagnostic tests and NIPT will be emailed to the woman if possible. ▪ In twin pregnancy with higher chance result for one or both twins, where diagnostic testing is requested following discussion re diagnostic testing risks and follow up choices, referral is made to Tertiary centre as per national guidelines (RCOG, FASP, NICE). The woman will be offered an appointment with local FMS for discussion/assessment. ▪ Where a vanished twin/second empty sac has been identified at, or prior to the screening test, the woman will be made aware that NIPT cannot be offered; diagnostic testing can be offered. ▪ The woman will be advised that a diagnostic test will report for T21, T18 and T13, irrespective of which trisomy chances were requested for screening. ▪ **For Increased NTD chance**, anatomy scan with FMS will be discussed. Nearest available timely appointment will be offered following discussion with FMS.	Midwife Sonographer

6	**Follow Up Care** ▪ The woman will be given time to consider the information given and her options. ▪ Follow up telephone call for further discussion will be offered. ▪ FMS appointment will be arranged as appropriate. If the FMS appointment is at the tertiary centre (FMU BWH)or other unit, the woman will be informed that they will contact her directly with an appointment. ▪ For women with increased chance for T21or T18/T13 not associated with increased NT measurement, who decline further testing, routine mid pregnancy scan appointment will be with a midwife sonographer and pregnancy care will continue as planned pathway. (Fetal Medicine Scan referral will have been arranged where increased NT measurement was identified). ▪ For women with increased chance for T21 and/or T18/T13 who opt for NIPT, appointment will be arranged as soon as possible, within 3 working days. ▪ NIPT will be performed once exclusions checked. NIPT request form will be scanned to BN and Fetal medicine Plan and clinical narrative updated on BN. ▪ For women accepting an appointment for possible diagnostic testing, details of blood group, Rhesus factor and HIV/Hepatitis status will be obtained. The appointment will be arranged within 3 working days, local referral, or 5 working days, Tertiary center referral. ▪ The midwife sonographer will record details of discussions and appointments arranged on the MIS and update the Fetal medicine Plan as appropriate. ▪ The midwife sonographer will update the maternity ultrasound high chance database and complete the appropriate high chance checklist.	Midwife Sonographer Midwife Sonographer
7	**Aneuploidy result from diagnostic test (local FMS) or high chance result from NIPT**. ▪ The midwife sonographer will telephone the woman to discuss the result. ▪ An urgent appointment will be made with the FMS to discuss the result and options/ choices. ▪ Plan of care for the pregnancy will be made with the FMS at this appointment, and appropriate referrals/further appointments made. ▪ The midwife sonographer will record details of discussions and appointments arranged on the MIS, scan result to Badgernotes, update Fetal Medicine Plan on BN and update the maternity ultrasound database.	Midwife Sonographer
8	**Normal result from Diagnostic test or lower chance result from NIPT** ▪ The midwife sonographer will telephone the woman to discuss the result and will check that routine mid pregnancy scan appointment is arranged. ▪ The midwife sonographer will email a copy of the normal result from diagnostic test/ lower chance result from NIPT to the woman. The midwife sonographer will record details of discussions and appointments arranged on the MIS, scan result to Badgernotes, update Fetal Medicine Plan on BN and update the maternity ultrasound database.	Midwife Sonographer

Flowchart for Higher Chance Screening Results



Appendix 1- Auditable Standards

Management of Screen Positive Results from Combined and Quadruple Screening tests

1.0 Identification of Screen Positive Result

1.1 Criteria

- Increased chance result for Down's syndrome (T21) ≥1:2-1:150, from combined or quadruple test.
- Increased chance result for Edward's (T18)/Patau's (T13) syndromes ≥1:2- 1:150, from combined test.
- Increased chance result for Neural Tube Defect (NTD) -AFP ≥2.5 MoM from quadruple test.
- PAPP-A 0.415 MoM or less, from combined screening test.

2.0 Documentation of Increased Chance Results

- The midwife sonographer will add the increased chance result details to the relevant Maternity ultrasound database (High Chance Down's Screen database for T21, Edward's/Patau's Risk Database for T18/T13 chances, Serum Anomaly database for increased NTD chance and low PAPP-A results).
- The midwife sonographer will update the Maternity Information System (MIS) with the results (Scan result to Badgernotes (BN) and update Fetal Medicine Plan on BN)
- The midwife sonographer will commence the relevant increased chance checklist .

3.0 Informing the Woman of an Increased Chance Screening Result

- The midwife sonographer will try to contact the woman by telephone within 3 working days of the result being received, and will discuss the increased chance result and referral options with her.
- If the woman wishes face to face consultation, this will be arranged
- If unable to achieve contact by telephone, the Community Midwife will be asked to visit the woman.
- An interpreter will be arranged if required
- For increased chance for T21 or T18/T13. The options of no further testing, Non-Invasive Prenatal Tests (NIPT) or diagnostic testing (CVS or amniocentesis as appropriate, dependent on gestation), with associated miscarriage risks), will be discussed
- An appointment for NIPT will be offered within 3 working days
- An appointment for a diagnostic test (if preferred option) will be offered within 3 working days (local referral, or 5 working days Tertiary centre referral) ; if not possible, nearest available timely appointment will be offered following discussion with FMS
- When no local FMS available, referral will be made following the pathway outlined in the SaTH 'Referral for Fetal medicine Services SOP' via secure NHS email to the relevant Fetal Medicine Unit using the appropriate referral form and attaching a copy of the scan report,

booking blood reports including antenatal serology and blood group Information on diagnostic tests.

- In twin pregnancy with higher chance result for one or both twins, where diagnostic testing is requested following discussion re diagnostic testing risks and follow up choices, referral is made to Tertiary centre as per national guidelines. Offered appointment with local FMS for discussion/assessment
- T21 Where a vanished twin/second empty sac has been identified at or prior to the screening test, the woman will be made aware that NIPT cannot be offered, diagnostic testing can be offered.

- The woman will be advised that a diagnostic test will report for T21, T18 and T13, irrespective of which trisomy chances were requested for screening.

- For Increased NTD chance, anomaly scan with FMS will be discussed. Nearest available timely appointment will be offered following discussion with FMS.

4.0 Follow Up Care

- Follow up telephone call for further discussion will be offered.
- FMS appointment will be arranged as appropriate. If the FMS appointment is at the tertiary centre (FMU BWH) or other Fetal Medicine Unit, the woman will be informed that they will contact her directly with an appointment
- For women with increased chance for T21or T18/T13 not associated with increased NT measurement who decline further testing, routine mid pregnancy scan appointment will be with a midwife sonographer and pregnancy care will continue as planned pathway
- For women with increased chance for T21or T18/T13 who opt for NIPT, appointment will be arranged as soon as possible, within 3 working days
- For women accepting an appointment for possible diagnostic testing, details of blood group, Rhesus factor and HIV/Hepatitis status will be obtained.
    - The appointment will be arranged within 3 working days, local referral, or 5 working days, Tertiary centre referral.
- The midwife sonographer will record details of discussions and appointments arranged on the MIS.
- The midwife sonographer will update the maternity ultrasound high chance database and complete the appropriate high chance checklist.

5.0 Aneuploidy result from diagnostic test or high chance result from NIPT

- The midwife sonographer will telephone the woman to discuss the result.
- An urgent appointment will be made with the FMS to discuss the result and options/ choices.
- Plan of care for the pregnancy will be made with the FMS at this appointment, and appropriate referrals/further appointments made.
- The midwife sonographer will record details of discussions and appointments arranged on the MIS, scan result to Badgernotes, update Fetal Medicine Plan on BN and update the maternity ultrasound database.

6.0 Normal result from Diagnostic test or lower chance result from NIPT

- The midwife sonographer will telephone the woman to discuss the result and will check that routine mid pregnancy scan appointment is arranged.
- The midwife sonographer will email a copy of the normal result from diagnostic test/ lower chance result from NIPT to the woman.

Appendix 1

DOWN'S HIGH CHANCE RESULTS CHECK LIST

PATIENT I.D

	DATE/TIME/INITIALS
FORM CHECKED BY 2 MIDWIFE SONOGRAPHERS	
CHECK PAPP-A – IF 0.415 OR BELOW HIGHLIGHT ON REPORT	
CHECK MOM'S / COMMENTS ON REPORT.HIGHLIGHT ANY DEVIATIONS.	
PRINT COPY OF SCAN REPORT, PHOTOCOPY IF POWYS.	
CHECK PREVIOUS SCAN REPORT TO CONFIRM WHETHER OTHER SACS HAVE BEEN IDENTIFIED (Empty, YS and or CRL) - if so patient not eligible for NIPT.	
HAS PATIENT BEEN BOOKED?	
EDD & GESTATION	
PRINT PATIENT LABELS	
NOTES REQUESTED	
COMPLETE DATABASE	
PATIENT TEL No & EMAIL ADDRESS	
PATIENT INFORMED	
CONTACT No'S GIVEN.	
FOLLOW-UP PHONE CALL REQUESTED? WHEN?	
NIPT, CVS, AMNIO, INFO EMAILED/DISCUSSED	
ACCEPT NIPT /AMNIO/CVS? Appointment / Date/ Time /Place	
DECLINE TEST? Ensure notes sent to secretaries for decline letter to be sent.	
IF POWYS PATIENT, CMW contacted to inform them of Downs chance	
BLOOD GROUP /HIV STATUS printed	
BADGERNET UPDATED	

Upload High Chance Report onto BN	

Appendix 2

T13 & T18 HIGH CHANCE RESULTS CHECK LIST

PATIENT I.D

	DATE/TIME/INITIALS
FORM DETAILS CHECKED BY 2 MIDWIFE SONOGRAPHERS	
CHECK PAPP-A – IF 0.4 OR BELOW HIGHLIGHT ON REPORT	
CHECK ALL MOM'S / COMMENTS ON REPORT. HIGHLIGHT ANY DEVIATIONS.	
PRINT COPY OF SCAN REPORT, PHOTOCOPY IF POWYS	
CHECK PREVIOUS SCAN REPORT TO CONFIRM WHETHER ANY OTHER SACS HAVE BEEN IDENTIFIED (Empty, YS and or CRL) - if so patient not eligible for NIPT.	
HAS PATIENT BEEN BOOKED?	
EDD	
PRINT PATIENT LABELS	
COMPLETE MATERNITY DATABASE	
PATIENT TEL No & EMAIL ADDRESS	
PATIENT INFORMED	
CONTACT No'S GIVEN.	
FOLLOW-UP PHONE CALL REQUESTED? WHEN?	
NIPT, CVS, AMNIO, INFO EMAILED/DISCUSSED	
ACCEPT NIPT / /CVS/ Amnio? Appointment / Date / Time /Place	
DECLINE TEST- Update Badgernotes	
BLOOD GROUP / HIV STATUS printed	
BADGERNOTES UPDATED	

Appendix 3

HIGH AFP RESULTS CHECK LIST

PATIENT I.D

	DATE/TIME/INITIALS
FORM DETAILS CHECKED BY 2 MIDWIFE SONOGRAPHERS	
CHECK ALL MOM'S / COMMENTS ON REPORT. HIGHLIGHT ANY DEVIATIONS FORM NORMAL.	
PRINT COPY OF SCAN REPORT, PHOTOCOPY IF POWYS	
HAS PATIENT BEEN BOOKED?	
NOTES REQUESTED	
COMPLETE SERUM ANOMALY DATABASE	
PATIENT TEL No & EMAIL ADDRESS	
PATIENT INFORMED	
CONTACT No'S GIVEN.	
FOLLOW-UP PHONE CALL REQUESTED? WHEN?	
FMS APPOINTMENT DISCUSSED	
ACCEPT FMS SCAN APPOINTMENT APPT DATE/TIME/PLACE	
DECLINE FMS SCAN? Ensure notes sent to secretaries for decline letter to be sent.	
IF POWYS PATIENT, CMW CONTACTED TO INFORM THEM OF INCREASED AFP	
EDD	
MEDWAY UPDATED	