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Management of Preterm Labour Guideline

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Guidelines Definition
Clinical guidelines are systemically developed statements that assist clinicians and patients in making decisions about appropriate treatments for specific conditions.

They allow deviation from a prescribed pathway according to the individual circumstances and where reasons can be clearly demonstrated and documented.

Minor Amendments
If a minor change is required to the document, which does not require a full review please identify the change below and update the version number.

Type of change	Why change made	Page number	Date of change	Version 1 to 1.1	Name of responsible person

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1. Introduction

These guidelines have been developed for Cwm Taf Morgannwg University Health Board, incorporating previous guidance from Cwm Taf University Health Board and Abertawe Bro Morgannwg University Health Board. These guidelines replace any previous health board versions.

Preterm labour is defined as onset of established labour between **24^{+0} and 36^{+6}** weeks of pregnancy inclusive. Diagnosis is made by the onset of regular uterine contractions leading to progressive cervical effacement and dilation.

Preterm labour complicates around 10% of all pregnancies. The majority of preterm births do so after spontaneous onset of preterm labour, however some women give birth preterm electively when this is thought to be in fetal or maternal interest. Preterm birth is the single biggest cause of neonatal mortality and morbidity in the UK. The risk of neonatal mortality increases as gestational age at birth decreases. Babies who survive preterm birth have increased rates of disability. The major long-term consequence of prematurity is neurodevelopmental disability.

Prevention of preterm birth is not always indicated and in most cases labour between 34 and 37 weeks will be allowed to continue.

This guideline covers recommendations on:

- prophylactic vaginal progesterone and prophylactic cervical cerclage
- magnesium sulphate ($MgSO_4$) for neuroprotection
- intrapartum antibiotics
- diagnosing preterm labour
- tocolysis
- maternal corticosteroids

- fetal monitoring
- mode of birth and clamping the cord

Preterm prelabour rupture of membranes (PPROM) is covered in a separate guideline.

2. Information and support

Provide the woman and her family with oral and written information on the care she will be offered. This information should include risks for the baby (long and short term morbidity and as well as mortality). The neonatal team should be closely involved in care planning and, where possible, the parents should be given opportunity to visit the neonatal unit as well as a consultation with a neonatal doctor.

3. Vaginal progesterone and cervical cerclage

Discuss both options and offer a choice of *prophylactic* vaginal progesterone (Cyclogest® pessary 400mg daily, unlicensed) or *prophylactic* cervical cerclage to women who have both:

- a history of spontaneous preterm birth up to 34^{+0} weeks of pregnancy or mid-trimester loss from 16^{+0} weeks onwards **and,**

- results from a transvaginal ultrasound scan carried out between 16^{+0} and 24^{+0} weeks that show a cervical length of 25 mm or less.

Prophylactic vaginal progesterone can be considered for women who have either:

- a history of spontaneous preterm birth up to 34^{+0} weeks or mid-trimester loss from 16^{+0} weeks onwards **or,**

- results from a transvaginal ultrasound scan carried out between 16^{+0} and 24^{+0} weeks that show a cervical length of 25 mm or less.

Treatment with vaginal progesterone should start between 16^{+0} and 24^{+0} weeks and continue until at least 34 weeks.

Prophylactic cervical cerclage can be considered for women when results of a transvaginal ultrasound scan carried out between 16^{+0} and 24^{+0} weeks show a cervical length of 25 mm or less, and who have had either:

- preterm prelabour rupture of membranes (PPROM) in a previous pregnancy **or**
- a history of cervical trauma (e.g. LLETZ or cone biopsy)

Rescue cervical cerclage

Rescue cervical cerclage should *not* be offered to women with:

- signs of infection **or**
- active vaginal bleeding **or**
- uterine contractions **or**
- ruptured membranes.

A rescue cervical cerclage can be considered for women between 16^{+0} and 27^{+6} weeks of pregnancy with a dilated cervix and exposed, unruptured fetal membranes.

The gestational age and the extent of cervical dilation should be taken into account and discussed with a consultant obstetrician.

The risks of the procedure as well as the aim to delay birth to increase the likelihood of the baby surviving and to reduce the risk of serious neonatal morbidity should be discussed with the woman (and her family).

4. Diagnosis of preterm labour (with intact membranes)

When preterm labour is suspected information for the woman should include:

- the clinical assessment and diagnostic tests that will be offered;
- how the clinical assessment and diagnostic tests are carried out;
- the benefits, risks and possible consequences of the clinical assessment and diagnostic tests, including the consequences of false positive and false negative test results taking into account gestational age.

Clinical assessment of women reporting symptoms of preterm labour should include:

- clinical history taking
- observations including maternal blood pressure, pulse, temperature and respiratory rate.
- urinalysis
- fetal auscultation and cardiotocogram (CTG) depending on gestation
- obstetric abdominal palpation including assessment of uterine activity
- a speculum examination (only using water as lubricant)

If the clinical assessment suggests that the woman is in suspected preterm labour and she is between **24^{+0} and 33^{+6}** weeks pregnant perform fetal fibronectin testing as a diagnostic test to determine likelihood of birth within 48 hours.

If the neonatal unit operates a 36 week model fetal fibronectin testing could be considered between **34^{+0} and 35^{+6}** weeks gestation.
A senior obstetrician should be informed of a positive diagnosis.

5. Fetal Fibronectin Testing

Fetal Fibronectin (fFN) is a simple and quick bed-side test that can be used to aid diagnosis, with high sensitivity. A negative test can be safely relied upon to rule out preterm labour and therefore reduce unnecessary intervention and hospital admissions.

Fetal fibronectin is a fibronectin protein produced by fetal cells. It is found at the interface of the chorion and the decidua (between the fetal sac and the uterine lining). Fetal fibronectin "leaks" into the vagina if a preterm delivery is likely to occur and can be measured in a screening test.

A fFN test result **<200 ng/mL** gives clinicians confidence that preterm labour is not imminent, as less than 1% of women with this result will deliver within 7 days and 8% of women will deliver within 14 days.

Please complete the fFN test proforma found in Appendix 1.

<u>Indications for fFN testing</u>

If the clinical assessment suggests that the woman is in suspected preterm labour and she is between **24^{+0} and 33^{+6}** weeks pregnant.
Consider fFN testing between **34^{+0} and 35^{+6}** weeks gestation if the neonatal unit operates a 36 week model.

<u>Contraindications for fFN testing</u>

fFN testing should not be used in any of the following occasions:

- Ruptured membranes
- Cervical dilation of 3cms or more
- Cervical cerclage in situ
- Placenta praevia

In the event of:

- moderate or gross vaginal bleeding **or**
- sexual intercourse within 24 hours

fFN can still be performed. However, only a result of <10 ng/mL can be interpreted as a valid negative result. If the result is ≥10ng/mL clinical judgement is advised.

Method for carrying out Fetal Fibronectin

The swab or specimen should not be contaminated with lubricants, soaps, disinfectants or creams and therefore it is recommended to collect the specimen prior to digital vaginal examination, collection of culture specimens or transvaginal scanning.

1. Perform speculum examination (using only water as a lubricant) and rotate swab across posterior fornix for 10 seconds to allow for absorption of secretions.
2. Thoroughly mix swab in liquid extraction buffer provided for 10 seconds.
3. Squeeze swab against inside of tube.
4. If not testing immediately, snap the swab shaft and replace cap onto test tube until it clicks. This sample is valid for testing for up to 8 hours at room temperature.
5. When testing, remove swab and discard and place tube into stand.
6. At PeriLynx analyser – select test patient on main menu, scan user ID (barcode) and press next.
7. Enter rapid fFN Cassette lot number and press next.
8. Enter patient ID and press next.
9. Insert the rapid fFN cassette and prepare pipette with 200µl (0.2ml) from the patient sample collected in the buffer solution and press next.
10. Pipette 200µl (0.2ml) from the sample collected in the buffer solution into the well of the rapid fFN cassette and press Start Test.
11. When testing is complete, the system will display and print the result.

12. Result will be given in ng/mL and should be interpreted and managed according to the table below taking clinical judgement into consideration:

fFn value ng/mL	% who will give birth within 7 days	% who will give birth within 14 days	% who will give birth before 34 weeks	Suggested management *Clinical judgement should always be taken into consideration.*
<10	1	<2	1.5	Consider alternative diagnoses. Discharge with routine midwife follow-up.
10-49	0	<2	8.2	
50-199	0	<8	11.5	Consider admission. Consider corticosteroids. Tocolysis not recommended.
200-499	14	29	33	Admit. Administer corticosteroids. Inform neonatal unit. Tocolysis. MgSO4 if in labour and <30/40. Antibiotics if in labour.
≥500	38	46	75	

6. Tocolysis

Tocolysis is to be considered when the risk of preterm delivery outweighs that of continuing the pregnancy. Tocolysis is only indicated if there is a need to give corticosteroids. It is reasonable not to use tocolytic drugs as there is no clear evidence that they improve outcome. However, tocolytics should be considered if the few days gained would be put to good use: completing a course or corticosteroids or completing an in-utero transfer.

Take the following factors into account when making a decision about whether to start tocolysis:

- whether the woman is in suspected or diagnosed preterm labour

- other clinical features (for example, bleeding or infection) that may suggest that stopping labour is contraindicated
- gestational age at presentation
- likely benefit of maternal corticosteroids
- availability of neonatal care (need for transfer to another unit)
- the preference of the woman.

Indication

Consider tocolysis for women between **24^{+0} and 25^{+6}** weeks of pregnancy who have intact membranes and are in suspected preterm labour (fFN ≥200 ng/mL or clinical judgement).

Offer tocolysis to women between **26^{+0} and 33^{+6}** weeks of pregnancy who have intact membranes and are in suspected or diagnosed preterm labour (fFN ≥200 ng/mL or clinical judgement).

Absolute contraindications

Maternal: cardiac shock, aortic stenosis, severe pre-eclampsia
Fetal: severe IUGR, fetal compromise
Obstetric: intra-uterine infection, abruption

Relative contraindications

Maternal: cardiac failure, diabetes mellitus, abnormal liver function, previous hypotensive reaction
Obstetric: ruptured membranes, cervical dilatation >4cm

Choice of drug

When tocolysis is indicated **nifedipine** is the drug of choice (calcium channel blocker, unlicensed for this indication). If nifedipine is contraindicated an oxytocin-reception antagonist (**atosiban**) should be offered.

Betamimetics (ritodrine) should not be used for tocolysis.

Nifedipine regime

- Loading: 10 mg orally followed by a further 10mg every 20 minutes for a maximum of 4 doses or until the contractions stop (if sooner).
- Maintenance: Then 4 hours after the first administration give 20 mg modified release orally 8 hourly for a maximum of 48 hours.
- Discontinue: 48 hours after commencement of regime OR if significant maternal hypotensive reaction occurs causing severe maternal symptoms, adverse CTG changes or meconium stained liquor.
- Side effects: transient hypotension, flushing, palpitations, headache.

Atosiban regime (second line)

- Bolus: 6.75mg intravenously over 1 minute (using 6.75mg/0.9ml solution for injection vial)
- Prepare maintenance infusion: remove 10mL from 100mL sodium chloride 0.9% bag and replace with two 5mL vials of atosiban 37.5mg/5ml concentrate for solution for infusion (total 75mg) to make up 100mL infusion solution.
- Maintenance: intravenous infusion of 18mg/hour (24mL/hour) for 3 hours followed by 6mg/hour (8mL/hour) for a maximum of 45 hours.
- Replacement infusion bags should be prepared as required and be used within 24 hours of preparation.
- Duration of treatment should not exceed 48 hours and the total dose given during the course should not exceed 330mg atosiban.

In certain cases, where there are contraindications to nifedipine and atosiban, **indometacin** (NSAID) can be used, but only in the second trimester as there is a risk of premature closure of the ductus arteriosus

in the third trimester. This is an unlicensed indication and must be a consultant decision.

Indometacin regime (consultant decision, second trimester only)

- 100mg suppository PR to be repeated 12-24 hours later.

7. Maternal Corticosteroids

For women between **23^{+0} and 23^{+6}** weeks of pregnancy who are in suspected or established preterm labour, are having a planned preterm birth or have PPROM *discuss* with the woman and her family the use of maternal corticosteroids in the context of her individual circumstances.

Offer maternal corticosteroids to women between **24^{+0} and 33^{+6}** weeks of pregnancy who are in suspected, diagnosed or established preterm labour, are having a planned preterm birth or have PPROM.

Consider maternal corticosteroids for women between **34^{+0} and 35^{+6}** weeks of pregnancy who are in suspected, diagnosed or established preterm labour, are having a planned preterm birth or have PPROM.

When offering or considering maternal corticosteroids, discuss with the woman and her family:

- how corticosteroids may help
- the potential risks associated with them.

Do not routinely offer repeat courses of maternal corticosteroids, but take into account the interval since the end of the last course, the gestational age and the likelihood of birth within 48 hours (fFN result).

For guidance on the use of corticosteroids in women with diabetes, see the diabetes in pregnancy guideline.

Corticosteroid regime

- Betamethasone 12mg intramuscular, 2 administrations 24 hours apart.

8. Magnesium sulphate for neuroprotection

For women between **23^{+0} and 23^{+6}** weeks of pregnancy who are in established preterm labour or having a planned preterm birth within 24 hours, *discuss* with the woman and her family the use of intravenous magnesium sulphate for neuroprotection of the baby, in the context of her individual circumstances.

Offer intravenous magnesium sulphate for neuroprotection of the baby to women between **24^{+0} and 29^{+6}** weeks of pregnancy in the following circumstances and *consider* this for women between **30^{+0} and 33^{+6}** weeks of pregnancy who are:

- in established preterm labour **or**
- having a planned preterm birth within 24 hours.

When delivery needs to be expedited for maternal or fetal wellbeing reasons then delivery should not be delayed solely for magnesium sulphate administration.

Magnesium sulphate infusions should not be used during antenatal in-utero transfer.

If the infusion is solely given for neuroprotection of the fetus the infusion should be discontinued at birth.

Magnesium sulphate regime (unlicensed)

- Bolus: 4g intravenous bolus over 15 minutes. Ideally given 4 hours prior to delivery.
- Maintenance: intravenous infusion of 1g per hour until the birth or for 24 hours (whichever is sooner).

For women on magnesium sulphate, monitor for clinical signs of magnesium toxicity at least every 4 hours by recording pulse, blood pressure, respiratory rate and deep tendon reflexes.

If a woman has or develops oliguria or other signs of renal failure monitor more frequently for magnesium toxicity and think about reducing the dose of magnesium sulphate.

Antidote

- Calcium gluconate 1g intravenously (10ml of 10% calcium gluconate in 50ml NaCl 0.9%) given over 10 minutes.

9. In-utero transfer

Women presenting in suspected or established labour between **24^{+0} and 31^{+6}** weeks gestation or a multiple pregnancy of **less than 34^{+0}** weeks should be cared for in a hospital where level 3 Neonatal Intensive Care is available.

This assessment should be based on the safety of mother and baby requiring possible transfer. Tocolysis can be considered during the transfer, however delivery during transfer needs to be avoided. Therefore a careful assessment of the stage and progress of labour will have to be made before the transfer.

The neonatal unit needs to be informed of an admission with suspected or established preterm labour and discussion between the neonatologist

and obstetrician should take place whether in-utero transfer is required and appropriate.

An All Wales in-utero transfer form (see Appendix 2) should be completed and the transfer should be agreed by neonatal, obstetric and midwifery team of the receiving unit.

10. Intrapartum antibiotics

The risk of early onset Group B Streptococcal (GBS) disease in infants delivered prematurely is estimated to be 2.3 per 1000. The risk of GBS infection is higher with preterm delivery and the mortality rate from infection is increased (20-30% vs 2-3% at term).

Offer intrapartum antibiotics to women in confirmed preterm labour, with or without intact membranes.

Intrapartum antibiotics for the prevention of GBS are not recommended for women having a planned preterm caesarean section with intact membranes.

If the woman decides to take intrapartum antibiotic prophylaxis, give the first dose as soon as possible and continue prophylaxis until the birth of the baby.

<u>Choice of antibiotic</u>

Benzylpenicillin sodium (first line)

- Bolus: 3g intravenous as soon as possible after the onset of labour.
- Maintenance: 1.8g intravenous every 4 hours until delivery.

Penicillin allergy

The antibiotic chosen will depend on the confidence of the diagnosis of penicillin allergy and the severity of penicillin allergy.

If the history suggests that the reaction described is *not* likely to be allergic in nature (e.g. vomiting only) then penicillin should be given.

If the history suggests an **allergy** to beta-lactams, but one that is **not severe** (i.e. no anaphylaxis, angioedema, respiratory distress or urticaria), then a cephalosporin can be administered intravenously: *cefuroxime 1.5g loading dose followed by 750 mg every 8 hours until delivery.*

If the **allergy** to beta-lactams is **severe** then intravenous *vancomycin 1g every 12 hours* is recommended until delivery.

Pre-dose vancomycin levels are only required if the patient is to receive more than 4 doses. Contact the Pharmacy Department for advice if necessary.

Clindamycin can no longer be recommended as the current resistance rate in the UK is 16%.

11. Fetal monitoring

Discuss with women in suspected, diagnosed or established preterm labour (and their family):

- the purpose of fetal monitoring and what it involves.
- the clinical decisions it informs at different gestational ages.
- if appropriate, the option not to monitor the fetal heart rate (for example, at the threshold of viability).

Involve a senior obstetrician in discussions about whether and how to monitor the fetal heart rate for women who are between **23^{+0} and 25^{+6}** weeks pregnant.

Explain the different fetal monitoring options to the woman and her family, being aware that:

- there is limited evidence about the usefulness of specific features to suggest hypoxia or acidosis in preterm babies
- the available evidence is broadly consistent with that for babies born at term
- a normal cardiotocography trace is reassuring and indicates that the baby is coping well with labour, but an abnormal trace does not necessarily indicate that fetal hypoxia or acidosis is present.

Explain to the woman and her family that there is an absence of evidence that using cardiotocography improves the outcomes of preterm labour for the woman or the baby compared with intermittent auscultation.

Offer women in established preterm labour but with no other risk factors a choice of fetal heart rate monitoring using either:

- cardiotocography using external ultrasound **or**
- intermittent auscultation.

<u>Fetal Scalp Electrode</u>

Do *not* use a fetal scalp electrode (FSE) for fetal heart rate monitoring if the woman is **less than 34^{+0}** weeks pregnant unless all of the following apply:

- it is not possible to monitor the fetal heart rate using either external cardiotocography or intermittent auscultation
- it has been discussed with a senior obstetrician
- the benefits are likely to outweigh the potential risks
- the alternatives (immediate birth, intermittent ultrasound and no monitoring) have been discussed with the woman and are unacceptable to her.

Discuss with the woman and her family the possible use of a FSE between **34^{+0} and 36^{+6}** weeks of pregnancy if it is not possible to monitor the fetal heart rate using either external cardiotocography or intermittent auscultation.

Fetal Blood Sampling

Do *not* carry out fetal blood sampling (FBS) if the woman is **less than 34^{+0}** weeks pregnant.

Discuss with the woman the possible use of FBS between **34^{+0} and 36^{+6}** weeks of pregnancy if the benefits are likely to outweigh the potential risks.

When offering FBS, discuss this with the woman including the risks of FBS and advise her that if a blood sample cannot be obtained a caesarean section is likely.

12. Mode of birth

Discuss the general benefits and risks of caesarean section and vaginal birth with women in suspected, diagnosed or established preterm labour (and their family).

Explain to women in suspected, diagnosed or established preterm labour about the benefits and risks of caesarean section that are specific to gestational age. In particular, highlight the difficulties associated with performing a caesarean section for a preterm birth, especially the increased likelihood of a vertical uterine incision and the implications of this for future pregnancies.

Explain to women in suspected, diagnosed or established preterm labour that there are no known benefits or harms for the baby from caesarean section, but the evidence is very limited.

Consider caesarean section for women presenting in suspected, diagnosed or established preterm labour between 26^{+0} and 36^{+6} weeks of pregnancy with breech presentation.

13. Timing of cord clamping for preterm babies (born vaginally or by caesarean section)

If a preterm baby needs to be moved away from the mother for resuscitation, or there is significant maternal bleeding:

- consider milking the cord **and**
- clamp the cord as soon as possible.

Wait at least 30 seconds, but no longer than 3 minutes, before clamping the cord of preterm babies if the mother and baby are stable.
Position the baby at or below the level of the placenta before clamping the cord.

14. Auditable standards

- Percentage of women presenting in suspected preterm labour that had a fetal fibronectin test performed before 34 weeks gestation.
- Percentage of women presenting in suspected preterm labour that had a positive fetal fibronectin test (fFN >199).
- Percentage of women presenting in suspected preterm labour that had a fetal fibronectin test result between 50-199.
- Percentage of women presenting in suspected preterm labour that had a positive fetal fibronectin test (fFN >199) and delivered within 2 weeks.

- Percentage of women with a positive fetal fibronectin test (fFN >199) before 34 weeks gestation that were offered steroids (100%) and received steroids (100%).
- Percentage of women with a positive fetal fibronectin test (fFN >199) before 30 weeks gestation that were offered magnesium sulphate ($MgSO_4$) (100%) and received $MgSO_4$ prior to delivery (100%).
- Percentage of women in confirmed preterm labour that were offered intrapartum antibiotics (100%) and received these (100%).

15. References

1. NICE Guideline 25: Preterm Labour and Birth, Updated August 2019.
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3. Swansea Bay UHB Guideline: Management of Pre-Term Labour, November 2018.
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Appendix 1 Fetal Fibronectin (fFN) Test Proforma

Fetal Fibronectin (fFN) Test Proforma

Addressograph

Date:

Test requested by:

Designation:

If previously performed, date of last test: ……/……/……

Only perform fFN test if **all** of the following criteria are met:

Criteria	**Please tick if met**
24+0 – 33+6 gestation	
Intact membranes	
Cervix ≤ 3cm dilated	
Fetal well-being established	
>14 days since last fFN test	
Absence of placenta praevia	
Absence of cervical cerclage	

Moderate or gross vaginal bleeding		If result ≥10ng/mL clinical judgement advised. If result <10 ng/mL interpret as negative.
Sexual intercourse within 24 hours		

Test result sticker

Test performed by:

Designation:

Sign:

Date:

Time:

Management plan	**Please tick**
Discharged and routine follow-up	
Steroids given (Specify)?	
Admitted for observation	
Tocolysis given (Specify)?	
Magnesium sulphate given	
In-utero transfer	

Appendix 2

ALL WALES IN-UTERO TRANSFER COMMUNICATION FORM

ADDRESSOGRAPH

S I T U A T I O N	**MATERNAL DETAILS**	**FETAL DETAILS**
	Gravida …….. Para …… **SROM** Y/N Date …….. Time…….. **Blood Group** …… Rh …… Antibodies …….. **Medication** …… **Comments** ……	**EDD** …….. **Gestation** …… **Multiple Pregnancy** Y/N No. of fetuses ……
B A C K G R O U N D	**Previous pre-term birth:** Y/N Details …… **Obstetric History** …… …… **Medical history** …… …… **Has Mother?** • Received health care treatments (inc IVF), in other countries outside Wales during last year? Y/N • If yes, details of treatment……..…..……Country……..…… • Had any infections/positive screening results during pregnancy Y/N • If Yes, please specify……	**Anomalies** Y/N Details …… …….. **Safeguarding issues** Y/N Details …… …….. ……..
A S S E S S M E N T	**Pre-Term Labour Test:** Pos/Neg fetal fibronectin/Actim Partus **Vaginal Examination:** Date…..Time…….Findings…… …… **Is Mother?** • Currently infected or colonised with organism/virus that is multi-resistant or could cause harm to baby? Y/N/Unknown • If yes, Sensitivities of organism…… • Currently on any antimicrobial treatment? Y/N • If yes, please specify…… **HVS:** Y/N Dates/s …… Sensitivities of isolates…… **Outstanding Microbiology Results?** Y/N Please specify ……	**Fetal Compromise?** Y/N Comments…… …… **Maternal Steroids?** Y/N Date…… Gest…… **USS** Date…… AC…… HC…… FL…… AFI…… Doppler…… EFW…… Comments……

R E C O M M E N D A T I O N	**TRANSFER FROM:**	**TRANSFER TO:**
	Consultant Obstetrician	Consultant Obstetrician
	SPR:	DUTY SPR informed ❑ LW Coordinator informed ❑ Neonatal Unit informed ❑ ***NB: All must be informed prior to transfer***
	Named midwife for transfer:	
	Person completing form: **NAME:** **DESIGNATION:** **SIGNATURE:**	