Bedfordshire Hospitals
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CLINICAL PROCEDURAL DOCUMENTS

Document Title:
Dealing with Pregnancy Tissue following Pregnancy Loss & Termination of Pregnancy less than 20 weeks gestation

This document is relevant for staff at: *(please indicate)*	**Luton Hospital site** X	**Bedford Hospital site**		**Both Hospital sites**
Document Type: *(please indicate)*	**Clinical Guideline** X	**Standard Operating Procedure**	**PGD**	**Integrated Care Pathway**

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Is this document new or revised / or has minor amendments?
Revised

Reason for minor amendments?
Due update and action following SI STEIS 2020/22176 and 2021/12979

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CG394L	3
Target Audience/Scope:	All clinicians in O&G, Ward 34 staff, A&E staff, Theatre staff, EPC staff, Delivery Suite staff

Associated Trust Documents:
CG265 Protocol for Non-surgical management of miscarriage
CG237 Diagnosis and management of ectopic pregnancy and pregnancy of unknown location
CG238 Early Pregnancy Clinic Protocol
CG349 Management of molar pregnancy
CG186 Dealing with Pregnancy Loss including medical termination of pregnancy

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DEALING WITH PREGNANCY TISSUE FOLLOWING PREGNANCY LOSS & TERMINATION OF PREGNANCY < 20 WEEKS GESTATION

Introduction:

This guideline has been developed in compliance with the recommendations of Human Tissue Authority regarding disposal of pregnancy remains from all miscarriages and terminations. Human Tissue Authority recommends that due to the sensitive nature of this tissue, the wishes of the woman and her understanding of the disposal options open to her are of paramount importance and should be respected and acted upon.

Purpose / Scope:

This guideline is applicable to all miscarriages / Termination of Pregnancy (TOP) below 20 weeks (up to 19+6 weeks), molar pregnancies and ectopic pregnancies.

Duties and Responsibilities:

All members of staff looking after women undergoing a pregnancy loss or termination, and members of staff dealing with disposal of the pregnancy remains have the responsibility of ensuring this guideline is adhered to and appropriate documentation and record keeping is maintained. Bereavement midwife will be overall responsible to ensure that the disposal procedures are carried out in line with the policy and regular review and audit of the service is conducted.

Definitions:

Pregnancy Remains: This term is used for products of conception from all pregnancy losses, for example as a result of ectopic pregnancy, miscarriage or early intrauterine fetal death; it also applies to terminations of pregnancy that have not exceeded the 24th week of pregnancy.

Diagnosis & Management:

For diagnosis and management of ectopic pregnancies, miscarriages and molar pregnancies, please refer to guidelines – CG265, CG237, CG238 and CG349.

All women with the diagnosis of a missed / incomplete miscarriage should be offered expectant management, medical management and surgical management. However, surgical management should not be routinely offered for miscarriages that are of gestation ≥13weeks by ultrasound scan. Women requiring admission will be looked after on ward 34 by the gynaecology team.

Investigations:

Histopathology:
For all miscarriages < 13 weeks, all pregnancy remains should be sent for histopathology to rule out molar pregnancy. For miscarriages ≥ 13 weeks gestation, the placenta should accompany the fetus, in a dry pot, to the mortuary with a histopathology form.
It is not necessary to obtain explicit consent for disposal of tissue from an early pregnancy loss where there is no clearly identifiable fetus, such tissue will be treated as part of the mother's medical record and disposed of by histopathology as per routine arrangements (see below 'options for disposal').
Women should be informed that this investigation does not determine the cause of miscarriage.

The mother should be asked to choose a method of disposal only when a fetus is clearly identified (either following a miscarriage or termination).

Pregnancy remains from Terminations of pregnancies do not need to be sent for histopathology routinely.

Post-mortem:
Post-mortem should not be routinely offered for a fetus below 20 weeks. However, for a fetus of ≥ 13 weeks the gynaecology registrar / Consultant should be consulted, as in selected cases, post-mortem may help management of future pregnancies and it should be discussed with the woman.

In the cases where the woman wants to have this investigation, a Post-mortem consent form, Post-mortem request form and Post-mortem checklist should be completed by a Consultant or registrar that has completed the post mortem consent training. A copy of the consent form should be given to the parent(s). The original copies should go to the mortuary with the fetus. Copies of all 3 documents should be filed in the notes.
An up to date version of these forms should be used which is available from delivery suite.

The placenta should also be sent to the mortuary in a dry pot. Both the fetus and placenta should be sent to the mortuary as soon as possible to prevent deterioration or stored in ward 34 fridge if there is any delay.

Cytogenetics:
In the case of a post mortem request or a third subsequent consecutive miscarriage, pregnancy remains / placental tissue should be sent for cytogenetics to Addenbrookes in a dry pot, labelled on the side with the mother's details. The post mortem request and consent forms incorporate the cytogenetic investigation. If cytogenetics is to be performed without post mortem then a separate cytogenetics request form should be completed. An up to date version of this form should be used which is available from delivery suite.

Any tissue to be sent for cytogenetics should be sent as soon as possible to pathology or refrigerated in Delivery Suite to prevent deterioration of the sample.

A referral to recurrent miscarriage clinic by the woman's GP should be made for a third subsequent miscarriage if not done already.

Maternal Investigations:

In second trimester pregnancy loss, depending upon the history and events leading onto the miscarriage, maternal investigations to check for infections, medical diseases etc. may be considered and should be carried out at the discretion of the gynaecology registrar / Consultant. (**Appendix 2**)

Options for Disposal:

For all pregnancy remains from miscarriages, TOPs and ectopic pregnancies, options of dignified disposal should be discussed with the woman.

Written information, in the form of "Arrangements for the sensitive handling of pregnancy remains" should be given to the woman at the time of decision of expectant / medical / surgical management of miscarriage, surgical management of ectopic pregnancy and in the TOP clinic.

A woman who miscarries at home can, if she wishes, choose to bring the pregnancy remains into the hospital for disposal.

The options form should not be discussed or completed until the POC have been passed and only then if there is a clearly identifiable fetus.

The following options are available for disposal of a fetus

- Sensitive Incineration
- Cremation – Communal / Individual*
- Burial – Communal / Individual*
- Women can choose to make their own arrangements (including taking the pregnancy remains home)

*The Hospital would not be able to offer individual cremation / burial for pregnancy remains at gestation < 13 weeks. If a family would like to have an individual funeral service for pregnancy remains below 13 weeks gestation, then they will be required to make their own arrangements. The hospital chaplain will be able to provide guidance and support to the family in making the private arrangements.

Parents may take the fetus / pregnancy remains home with them (see Appendix IV for documentation). If the fetus has already been transferred to the Mortuary, arrangements will be made for collection of the fetus by Ward 34 staff.

In the following situations, "*Routine disposal arrangements*" should be carried out:

- If a woman does not want to make a choice and permits the hospital to arrange a dignified disposal as per routine arrangements
- If the woman is undecided and does not inform the hospital about her decision within 6 weeks of the pregnancy loss or post-mortem result

- If the woman wants to make her own arrangements but does not collect the pregnancy remains from the hospital within 6 weeks of pregnancy loss or post-mortem result

Routine arrangements for disposal according to gestational age of pregnancy remains will be as follows:

- <13 weeks – sensitive incineration
- 13 to 19+6 weeks – communal cremation

The cremation will be conducted at the following place:

The Vale Cemetery and Crematorium
Butterfield Green
Hitchin Road
Luton LU2 8DD

Following a communal cremation, the ashes will be scattered in the garden of remembrance (the rose beds) in Vale Crematorium.
Following individual cremation, it may or may not be possible to retrieve any ashes to return to the parents. Parents can discuss individual requests with the Chaplain.

The pregnancy remains that have undergone histological examination will be treated as any other medical record / specimen and can be disposed of as any other pathology specimens and will not be cremated or buried. The pregnancy remains that have gone to another hospital for genetic testing will be returned to L&D and will be disposed of sensitively by the Mortuary.

The disposal contractors at the following incineration site will carry out the sensitive incineration:

Tradebe Healthcare Ltd
Redditch Clinical Waste Incinerator
Alexandra Hospital
Woodrow Drive
Redditch
Worcestershire, B98 7UB

Documentation:

It is the responsibility of the doctors and nurses, looking after the woman to ensure completion of documentation before the patient is discharged from the hospital.
In the case of a woman going home from A&E or another area, the gynaecology doctor seeing the patient should complete the documentation. The pregnancy remains should be sent directly to the mortuary or pathology, or out of hours to ward 34 to ensure appropriate storage and record keeping.

Forms to be completed for Pregnancy Remains <13 weeks gestation:
(**Appendix 1**)

1. Certificate of Non-viable fetus / pregnancy remains
2. Information Form
3. Options Form – if appropriate

Forms to be completed for Pregnancy Remains 13-19+6 week's gestation:
(**Appendix 1 and 2**)

1. Certificate of Non-viable fetus / pregnancy remains
2. Information Form
3. Options Form – if appropriate
4. Checklist for relevant investigations (to be filed in the notes)

3 copies of each document 1, 2 and 3 should be made and distributed as follows:

- Original should accompany the pregnancy remains.
- 1 copy should be filed in the notes,
- 1 copy should be sent to the chaplaincy team
- 1 copy should be sent to Ward 34 ward manager

1 additional copy of document 3 (options form) should be given to the parent(s).

Parents wishing to take their pregnancy remains home will be required to complete the *'form for parents who take their pregnancy loss remains/baby home'* (**Appendix 4**). This should be filed in the notes.
The original *'certificate of Non-viable fetus / pregnancy remains'* should be given to the parents.

Memorial Book:
The Chaplain's office maintains a memorial book into which the details of the pregnancy loss can be recorded.
Parents wishing to record their loss can complete the form which should be sent to the Chaplaincy team (**Appendix 3**)

Storage Arrangements:
All the pregnancy remains that require histopathological examination (e.g. all 1st trimester miscarriages, salpingectomy specimen after surgical management of ectopic pregnancy, suspected molar pregnancy etc.), should be sent to the pathology department with a histopathology request form and the documents listed above if there is an identifiable fetus.

All the pregnancy remains that are appropriate for sensitive incineration should be stored in Anatomical Bins with a Red Lid. These bins should be present in all the clinical areas that deal with pregnancy loss i.e. EPC, ward 34, maternity theatres, main theatres, A&E and delivery suite.

These bins should be labelled as “Respectful Incineration”. These will be collected by the incineration team and incinerated respectfully, separate from the rest of the hospital waste.

All the pregnancy remains that are supposed to have cremation / burial, awaiting collection by parents for own arrangements, awaiting decision by parents and to be sent for post-mortem should be sent to mortuary along with the documents as listed above, either in a dry pot (no formalin or sodium chloride) if less than 13 weeks, or wrapped and sent in a baby body bag if greater than 13 weeks (obtained from ward 34 or delivery suite) with the placenta in a dry pot (no formalin or sodium chloride), labelled on the side with the mother’s details. The fetus should have the mother’s wristband either around its abdomen or next to it within the wrapping. Two of the mother’s labels should also be on the outside of the wrapping to enable identification if a label becomes contaminated or detached.

Record keeping:

Details of pregnancy remains where there is a visible fetus should be entered onto sheets in the purple folder situated in A&E, ward 34 and EPC to enable full traceability of the pregnancy remains. These details will then be entered onto the excel sheet on the share drive.

The following people will be given access to the excel sheet, although the Bereavement midwife and her team will maintain the database:

- EPC nurses
- Band 7 midwives
- Bereavement Midwives / Nurses
- Ward 34 nurses
- Pathology department / Mortuary staff
- Chaplaincy department
- A&E nurses
- Maternity theatre staff
- Main theatre staff

The following information should be recorded in the excel sheet:

- Hospital number
- Date of pregnancy loss
- Place (EPC/ward 34/ delivery suite etc.)
- Gestation
- Option chosen by woman
- Post mortem – to be done or not
- Pregnancy Remains (PRs) sent to Incineration / pathology department / mortuary / ward
- Date PRs sent
- Review date if undecided (6 weeks from date of pregnancy loss or 6 weeks from PM result - if opted for post-mortem)

Audit / Monitoring Compliance:

Standard / Audit Criteria	Time Frame	Method	Reviewed and action plan development by	Action plans monitored by
Options discussed as per guidance for various gestations	6 monthly	Log of cases + review of case notes on EVOLVE	Bereavement Nurse / Midwife in women's and children's	Bereavement Nurse / Midwife in women's and children's
Appropriate documentation completed	6 monthly			

Standards / Key Performance Indicators:

Sensitive Tissue Disposal Group meetings chaired by policy holder.

Training:

For start of policy training to be provided in all areas of relevance and regular training for new recruits at induction.

References:

- NICE Guideline on ectopic pregnancy and Miscarriagehttps://www.nice.org.uk/guidance/CG154
- The Investigation and Treatment of Couples with Recurrent Miscarriage (RCOG Green-top Guideline no. 17) https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg17/
- Guidance on the Disposal of Pregnancy Remains following Pregnancy loss or Termination, by Human Tissue Authority, March 2015 https://www.hta.gov.uk/.../Guidanceonthedisposalofpregnancyremains.pdf
- 2013/14 NHS Standard Contract for Perinatal Pathology https://www.england.nhs.uk/wp-content/.../e12-perinatal-path.pdfCached

Acknowledgement

Miss Kapilmeet Kaur, Consultant Obstetrician and Gynaecologist, for her work in creating the original policy

APPENDICES

Appendix 1 – SEPARATE PRINT VERSION BELOW MAIN GUIDELINE

Appendix 2 – SEPARATE PRINT VERSION BELOW MAIN GUIDELINE

Appendix 3 – SEPARATE PRINT VERSION BELOW MAIN GUIDELINE

Appendix 4 – SEPARATE PRINT VERSION BELOW MAIN GUIDELINE

Appendix 5:

SIGNS OF LIFE

Live birth and Neonatal Death A baby born at any gestation that breathes or shows other signs of life after complete expulsion from its mother is born alive: if such a baby dies within the first 28 days of life it is termed a neonatal death.

Observing signs of life

Observe for visible persistent signs respectfully while holding baby. Use of a stethoscope is not necessary. Parents' observations of signs of life should be included in discussions if they wish to share them.

Live birth is determined by 1 or more persistent visible sign of life:
- Visible heartbeat
- Visible cord pulsation
- Breathing, crying or sustained gasps
- Definite movement of arms and legs

Fleeting reflex activity including transient gasps, brief visible pulsation of the chest wall or brief twitches or involuntary muscle movement observed only in the 1st minute after birth does not warrant classification as signs of life.

Following a live birth a doctor should be called to confirm and document live birth. This avoids potential distress when the doctor cannot complete a death certificate because they have not seen the baby alive. The birth and the death must both be registered.

POC (Products of conception) in the Emergency Department pathway (Less than 20 weeks only):