Interim Clinical Commissioning Urgent Policy Statement:

Perinatal post-mortem investigation of fetal and neonatal deaths (England, Scotland and Wales)

Summary

This interim policy statement sets out the criteria for perinatal post-mortem investigation of fetal and neonatal deaths in England, Scotland and Wales.

The new interim access policy and the histopathological examination of placenta guidance aim to support greater standardisation in access to perinatal post-mortem investigations and placental examinations, and the prioritisation of available perinatal pathology capacity.

Links and updates to other policies and documents

This policy relates to the following guidance, practices and specification:

- Royal College of Pathologists:
  - G160: Guidelines on autopsy practice: Third trimester antepartum and intrapartum stillbirth
  - G161: Guidelines on autopsy practice: Fetal autopsy (2nd trimester fetal loss and termination of pregnancy for congenital anomaly)
  - G108: Tissue Pathway for histopathological examination of the placenta
  - G143: Guidelines on staffing and workload for paediatric and perinatal pathology departments
- National Institute for Health and Care Research (NIHR):
  - Minimally invasive autopsy for fetus' and children based on a combination of post-mortem MRI and endoscopic examination: a feasibility study
- Human Tissue Authority (HTA):
  - Code A: Guiding principles and the fundamental principle of consent
  - Code B: Post-mortem examination
- (England only) NHS England Commissioning Service Specification: Perinatal Pathology

Plain language summary

About perinatal autopsy services

Perinatal post-mortem examination (also called an autopsy) refers to a specialist medical examination undertaken following the death of a fetus or baby. Post-mortem examination traditionally refers to a collection of investigations including: external examination, examination of all of the internal organs (usually via two or more incisions), examining small samples of tissue under a microscope, and a range of imaging techniques as appropriate, medical photographs and other tests such as genetic investigations. Tests may also be done for infection and other possible teratogens, causes of death or complications. The placenta where relevant will also be examined.

Post-mortem examination can be carried out from 12 to 40 weeks gestation and after. For the purposes of this interim policy, this period is referred to as the perinatal period and relates to post-mortem examinations performed up to the first 28 days of life.

The role of the autopsy is twofold; firstly, the pathologist reviews the clinical and post-mortem examination findings to suggest a mode and (where possible) a cause of fetal or neonatal death. Perinatal autopsy is also used to identify diseases that may have implications for future pregnancies (including genetic diseases) and therefore plays a valuable role in aiding parents to understand the cause of fetal death, access appropriate support and counselling services and make decisions about future pregnancies.

The purpose of this policy statement is to outline the interim criteria such that access to perinatal post-mortem services results in optimisation of resources to maximise yield and benefit. Liaison between the parents, referring clinician, consultant perinatal pathologist and wider clinical team will help to determine the most appropriate investigation(s).

Perinatal post-mortem examination (outside of HM Coronial system) can only be performed if informed consent has been given, typically by the mother or birthing person. This represents the ceiling of consent of further investigations after death. Fetal tissue is considered in law to be the tissue of the mother or birthing person, and therefore tissue from the living. In cases where the fetus has survived outside of the womb, consent can be obtained from either the mother, birthing person or the maternal partner if they are married, in a civil partnership or with declared parental responsibility.

In the United Kingdom existing perinatal pathology protocols are published by the Royal College of Pathologists (RCPath) and their implementation overseen by the United Kingdom Accreditation Service (UKAS) as per ISO standard 15189. In England, Northern Ireland and Wales, autopsy facilities and procedures must be covered by appropriate licencing issued in line with the Human Tissue Act (HTA) 2004, and consent procedures must be compliant with the relevant HTA Code of Practice. In Scotland, autopsy facilities and procedures are covered by the Human Tissue (Scotland) Act 2006. The Human Tissue Regulations 2007 cover England, Northern Ireland, Wales and Scotland. It is expected that this urgent policy accepted as interim good clinical practice in line with HTA and put forth for adoption by the Royal College of Pathologists.

Epidemiology and needs assessment

Extended perinatal mortality in the UK has reduced by 20% over seven years, from 6.04 per 1,000 total births in 2013 to 4.85 per 1,000 total births in 2020, equivalent to approximately 820 fewer deaths in 2020 (MBRRACE-UK, 2022). Stillbirth rates in the UK have reduced by 21%, from 4.20 per 1,000 total births in 2013 to 3.33 per 1,000 total births in 2020, representing approximately 605 fewer stillbirths in 2020 (MBRRACE-UK, 2022).

Across the four UK nations the lowest stillbirth rate is 2020 was in England (3.29 per 1,000 total births) whilst the lowest rate of neonatal mortality was in Scotland (1.47 per 1,000 lives births) (MBRACCE-UK, 2022). Neonatal mortality in the UK has reduced by 17% from 1.84 per 1,000 live births in 2013 to 1.53 deaths per 1,000 live births in 2020, representing approximately 215 fewer neonatal deaths in 2020 and an increased rate of reduction. (MBRRACE-UK, 2022).

Parents were offered a post-mortem for 98% of stillborn babies but only 86% of neonatal deaths in 2020 (MBRACCE-UK 2022). Where a post-mortem examination was offered, consent was given for half of stillbirths (53%) and one-third of neonatal deaths (34%) (MBRACCE-UK, 2022).

Policy Criteria

Perinatal pathological examination will be commissioned in England, Scotland and Wales in line with the following criteria:

Inclusion Criteria

- Fetus is of 12-23 completed weeks gestation (See workflow guidance Appendix 1 for approach to macerated vs. unmacerated); OR
- Stillbirth from any cause > 24 weeks gestation; OR
- Fetal anomaly without a unifying diagnosis (including suspected skeletal dysplasia); OR
- Referral from specialist fetal medicine team; OR
- Intra partum death (if not referred to His Majesty's (HM) Coroner); OR
- Neonatal death (if not referred to HM Coroner)

Exclusion Criteria

- Fetal gestation < 12 weeks
- Clinically documented abruption at delivery (send placenta as per RCPath G108 guidelines)
- All antenatally diagnosed aneuploidy (e.g., Known T13/18/21 monosomy X/22q deletion)
- Uncomplicated anomaly where the unifying clinical and/or genetic diagnosis has been definitively determined (e.g., uncomplicated neural tube defect) and post-mortem examination is unlikely to yield any further useful information
- Cases where the only clinical question is determination of sex
- Cases which require cytogenetic sampling only

The need for a perinatal pathological examination in exceptional scenarios can be considered by the responsible pathologist as per the inclusion criteria. The extent of the examination should be determined by the ceiling of consent provided by the parents and the clinical judgement of the responsible pathologist, guided by the ultimate goal of the likelihood of identification of significant findings. See workflow guidance Appendix 1.

Audit requirements

Laboratory and mortuary services are accredited by UKAS under ISO18159. Policy audit forms an important part of the clinical governance of mortuary services and should be covered as part of accreditation at local trust / health board level.

Policy review date

This document will be reviewed when there are significant changes in clinical evidence and/or change in perinatal pathology capacity which indicate that the policy requires revision. If a review is needed due to a new evidence base then a new Preliminary Policy Proposal needs to be submitted by contacting england.CET@nhs.net.

Equality statement

Promoting equality and addressing health inequalities are at the heart of the three nation's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Definitions

Gestational age	The term used to describe the age of the pregnancy. It is measured in weeks, from the first day of the woman's last menstrual cycle to the current date. A normal pregnancy can range from 37-42 weeks.
Intrapartum	Occurring during labour or delivery.
Intrauterine growth restriction (IUGR)	When a baby in the womb does not grow as expected and is not as big as would be expected for the stage of the mother's pregnancy.
Maceration	Describes the softening effect of soaking on tissues and is applied to the degenerative changes that occur in the fetus when retained in utero after death.
Neonatal	Relating to the newborn infant in the first 28 days (4 weeks) following birth.
Perinatal	Defined here as pregnancy to a corrected age of 40 weeks gestation and up to and including 28 days following birth.
Placental abruption	Occurs when the placenta separates from the wall of the uterus prior to the birth of the baby.

Post-mortem	A specialist medical examination undertaken following death. This is also referred to as an autopsy.
Stillbirth	When a baby is born dead after 24 completed weeks of pregnancy

References

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Appendix 1

Evidence to support the value of specific post-mortem investigations is limited [1]. In this table, references to support variations from the current RCPath guidelines are given where available. This represents minimum standards recommended by the clinical members of the Policy Working Group.

	Macerated fetus 12-23 completed weeks gestation	Non macerated fetus 12-23 completed weeks gestation	STB >24 weeks	Fetal anomaly (unknown cause)[2]	Skeletal dysplasia	Intrapartum death	Neonatal death
Fetal weight	✓	✓	✓	✓	✓	✓	✓
Fetal foot length	✓	✓	✓	✓	✓	✗	✗
Other fetal morphometry	✗	✗	✗	✗	✗	✗	✗
Radiology [3]	✗	✗	✗	✓	✓	✗	✗
External examination	✓	✓	✓	✓	✓	✓	✓
Internal examination	If dysmorphic	If dysmorphic	✓	✓	✗	✓	✓
Fetal organ weights [4]	✗	✗	Brain:liver ratio and lung:body weight ratio recommended [5]	✓	✗	✓	✓
Fetal histology[6]	✗	✗	Determined at post-mortem; not if organs normally formed	Targeted e.g., renal anomaly = kidney + liver	Targeted bone histology only	✓	✓
Neuropathology[7]	✗	✗	Weight only[5]	Determined at post-mortem	Determined at post-mortem	✓	✓
Virology	Determined at post-mortem e.g., suspected parvovirus	✗	Determined at post-mortem e.g., suspected parvovirus	Determined at post-mortem e.g., suspected CMV with brain abnormality	✗	Determined at post-mortem	Determined at post-mortem
Bacteriology	✗	✓ (if available)	Determined at post-mortem	✗	✗	Determined at post-mortem	Determined at post-mortem
Cytogenetics	✓	✓	✓	✓ (N if already tested)	✓	Determined at post-mortem	Determined at post-mortem
Archive genetics samples [8]	✗ if non dysmorphic	✗ if non dysmorphic	✗ if non dysmorphic	✓ (frozen liver +/- frozen placenta)	✓ (frozen liver or lung +/- frozen placenta +/-	Determined at post-mortem	Determined at post-mortem

	Macerated fetus 12-23 completed weeks gestation	Non macerated fetus 12-23 completed weeks gestation	STB >24 weeks	Fetal anomaly (unknown cause)[2]	Skeletal dysplasia	Intrapartum death	Neonatal death
					cultured fibroblasts)		
Placental weight [9]	✓	✓	✓	✓	✓	✓	✓
Placental macroscopic appearances including cord*	✓	✓	✓	✓	✓	✓	✓
Placental histology [10,11]	✓	✓	✓	Determined at post-mortem	Determined at post-mortem	✓	✓

*if clear cord accident, give as cause of death and proceed to external examination only

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