

E12/S/b

**2013/14 NHS STANDARD CONTRACT
FOR PERINATAL PATHOLOGY**

PARTICULARS, SCHEDULE 2 – THE SERVICES, A – SERVICE SPECIFICATION

Service Specification No.	E12/S/b
Service	Perinatal Pathology
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

All parents should have the option to know why their baby died. High quality perinatal pathology services are essential to ensure bereaved parents have informed choice. Across the spectrum of fetal, perinatal and perinatal related losses, high quality post mortems can provide additional important information or change the ascribed cause of death in 22-76% of cases. The information has important and often long- lasting personal implications, not least in planning and managing future pregnancies.

The UK perinatal mortality rate is 7.4 per 1,000 deliveries (Office of National Statistics (ONS) 2010). This includes stillbirths and deaths during the first week of life and amounts to a total 5,350 deaths per year. Stillbirth rates have remained static over the last 10 years. There are a few deaths occurring later in the first year where the death is caused by conditions that are either congenital (present at birth) or have arisen in the perinatal period.

There is a continuum of causes between early stillborn perinatal deaths and earlier spontaneous fetal losses which merit investigation. Autopsy is also particularly important to inform counselling where there has been a termination for fetal abnormality. Specialist examination of the placenta can be done where post mortem consent is withheld, where it may contribute significantly to an understanding of the cause of death (especially in stillbirth).

Evidence Base

Perinatal pathology is delivered as a subspecialist histopathology service, within the context of a diagnostic histopathology laboratory and autopsy unit. A working party of the Royal College of Pathologists (RCPATH) and the Royal College of Obstetricians and Gynaecologists (RCOG) published in 2001 recommended that:

- The organisation of specialised perinatal pathology services should be reviewed and improved. This will require new service specifications, manpower planning, resource allocation and changes to the training of perinatal pathologists.
- That regional specialised commissioning groups make perinatal pathology a priority to ensure that adequately funded, auditable and accountable services are in place.

Relevant published national guidance includes:

- *A regional audit of perinatal and infant autopsies in Northern Ireland.* C.M. Thornton, M.D.O'Hara. British Journal of Obstetrics and Gynaecology 1998; 105:18-23
- *Improving the quality of perinatal and infant necropsy examinations: a follow up study.* GM Vujanic, PH Cartlidge and JH Stewart. Journal of Clinical Pathology 1998; 51; 850-853.
- *How important is placental examination in cases of perinatal deaths?* Tellefsen C, Vogt C. Paediatric and Developmental Pathology 2010. Aug 18th. Epubl.
- *Autopsy after termination of pregnancy for fetal anomaly: retrospective cohort study.* Boyd PA, Tondi F, Hicks NR, Chamberlain PF. BMJ 2004; 328: 137.
- *Royal College of Obstetricians and Gynaecologists and Royal College of Pathologists, Fetal and Perinatal Pathology Report of a Joint Working Party,* London 2001

2. Scope

2.1 Aims and objectives of service

Aim:

The aim of the service is to provide family centred specialist care and to ensure equitable access to high quality, expert specialist perinatal pathology services for families in England; "Parents' needs include impartial, accessible and objective information delivered by empathic and sensitive caregivers, so that they can make choices consistent with their values." (Heazell et al, 2012)

Objectives:

To provide a timely service with provision of high quality post mortem or placental pathology reports, incorporating:

- Histological,

- Immunohistochemical,
- Ultra-structural and
- Diagnostic information from other investigations where appropriate
- (e.g. Microbiology, biochemistry, metabolic and genetic test results)
- To facilitate succession planning in this small sub-specialty
- To provide improved opportunities for teaching, research and development

2.2 Service description/care pathway

Service Description

This specification covers specialised perinatal post mortem services and histopathological examination of placentas.

Placental Examination

Histological examination of placentas is an important aspect of perinatal pathology services and makes a significant contribution to understanding the cause of death, especially in stillbirth. Thus, the **only** placentae that should be referred for specialist examination on a **regional** basis are those placentae associated with **fetal death**.

Any others could be referred but on a case-by-case and are not commissioned by NHS England.

Perinatal Post Mortem Examination

The following perinatal deaths are investigated and analysed by the service:

- Miscarriages from 12 up to 23 completed weeks of gestation
- Terminations of pregnancy for fetal abnormality
- Stillbirths: Intrauterine deaths of 24 completed weeks gestation or above
- Neonatal and late neonatal deaths: infant deaths up to 28 days of age dying usually from a range of complications arising out of prematurity; ante- or intrapartum hypoxia or trauma; or congenital malformation.
- Infant deaths: 28 days to 1 year commonly from late complications of conditions arising in the antepartum, intrapartum or neonatal period including congenital malformation. Rarely deaths will be due to conditions acquired outside of the neonatal period.

[NB: most deaths after the late neonatal period are accidental or unexpected and subject to investigation by the coroner, so are outside the remit of this description]

Paediatric histopathological examination of organ and tissue samples will continue to take place in most hospitals in England providing tertiary children's services and are **not** included within this specification.

Staffing

The core service requirements of the commissioned service(s) are to have an appropriately qualified team of consultant perinatal pathologists led by a consultant perinatal pathologist. The Royal College of Pathologists recommends that pathologists should undertake a minimum of 50 post mortems per year and that perinatal pathology departments should have a minimum of 2/3 whole time equivalent (WTE) perinatal pathologists.

Facilities

- A dedicated mortuary or dedicated section of a larger mortuary
- A ultra-low temperature freezer for storage of samples
- Access to appropriate radiology services for all cases
- Access to photography for all cases
- Access to clinical genetics and/or a clinical genetics database

Standards

Establish a common process within each referring hospital for obtaining informed consent for post mortem examination from parents. Service providers should use the Human Tissue Authority (HTA) approved form developed in collaboration with SANDS (a UK charity offering support following the death of a baby during pregnancy or after birth), which allows for some amendments to meet local needs and circumstances. Where this is not used, it should be adopted as the standard against which other forms are assessed.

Establish a common protocol for referral to the commissioned service by referring hospitals.

Undertake high quality post-mortem examinations which satisfy the minimum requirements listed in Appendix A

Offer limited post mortem examinations (in circumstances where parents decline a full post mortem). There are few circumstances in which a full post mortem should not be offered, but examples include known non-mosaic trisomies and third-trimester specimens after first-trimester multifetal pregnancy reduction.

Hold regular multidisciplinary meetings with fetal medicine specialists, obstetricians, neonatologists, clinical geneticists and other clinicians as required to determine the cause(s) of death, agree advice to be given to parents about future pregnancies and review where practice can be improved. This should occur locally but may only occur at regional hospitals if possible.

Participate in an active perinatal pathology research and teaching programme.

Establish peer review arrangements with other tertiary Perinatal pathology services

Participate in relevant national audit and quality assurance schemes such as the

External Quality Assurance (EQA) audit scheme run by the British and Irish Paediatric Pathology Association (BRIPPA).

Establish a complaints procedure with the referring hospitals to examine any concerns regarding timeliness of post mortem examinations, adequacy of reporting and communication.

Quality and Audit Standards

Perinatal pathology providers will work with NHS England establish and agree service standards as a measure of performance to include:

- Participation in continuous professional development and member of EQA and Certificate of Completion of Training (CCT).
- Identification of Commissioning for Quality and Innovation (CQUIN) proposals that may be included within contracts e.g. reporting times: participation in appropriate EQA.
- All post-mortem reports must meet the minimum standards recommended by the RCPATH & RCOG report on Fetal and Perinatal Pathology, June 2001.
- Single activity database –quarterly and annual reporting.
- Annual hub questionnaire.
- Standardisation of documentation e.g. post mortem request, consent form.
- 60% of final reports for routine post mortem examination will be issued to referrers within 42 days of examination and 90% should be issued within 56 days. This will exclude those cases in which there may be a specialist referral opinion required (e.g. neuropathology) or very complex metabolic or genetic testing required

Referral Pathway

Referral will be made by appropriate personnel, in each of the referring hospitals in line with a common protocol developed between referring hospitals and the designated perinatal post- mortem service.

Referral criteria, sources and routes

- Internally: from the hospital in which the perinatal pathology department is located
- Referrals from other hospitals with no perinatal pathology service
- Second opinion referrals from other hospitals which have a perinatal pathology service

Referrals are made by way of transport, usually by undertakers, of fetuses and babies to the provider base hospital for post mortem examination which may involve submitting tissue or fluids for ancillary testing in other departments such as genetics.

Other material is received in the form of blocks and/or slides and this is submitted for expert histological opinion. Criteria for referral should be agreed between the

designated service provider and all the referring hospitals, but cases benefitting from examination by a pathologist include:

- Terminations of pregnancy for fetal abnormality
- Deaths following amniocentesis or chorionic villus sampling
- Deaths following other intrauterine interventions
- Hydrops fetalis
- Suspected intrauterine infection
- Deaths of twins/higher order multiples
- Unexplained fetal growth retardation
- Unexplained fetal losses (from 12 weeks) including ante and intrapartum stillbirths
- All malformed fetuses and babies
- Deaths after neonatal intensive care
- Unexplained neonatal deaths (technically these should be referred to the coroner if death certificate cannot be signed)
- Post – neonatal deaths, up to 1 year of age
- Threatened litigation

Consent

In the case of coroner post-mortems consent from the parents is unnecessary, but parents should be fully informed about what is to happen to their child and why this is important.

For hospital post mortems it will be the responsibility of the local clinicians to ensure that informed consent for post-mortem is obtained from parents complying with national guidelines and in agreement with the perinatal pathologists at the designated service who may be required to support training.

The designated perinatal post-mortem service provider will need to ensure that appropriate mechanisms are in place to ensure that post-mortem examinations do not proceed without appropriate consent being obtained. The timescales for obtaining consent for post mortem is to be identified nationally. Service providers should use the HTA-approved form developed in collaboration with SANDS (which allows for some amendments to meet local needs and circumstances). Where this is not used, it should be adopted as the standard against which other forms are assessed.

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/modelconsentforms/thesandspostmortemconsentpackage.cfm>

Where consent is not provided for a full post mortem examination by the family, diagnostic and prognostic information can often still be obtained by limited post mortem or examination of the placenta alone.

Where the local clinicians taking consent have any uncertainty about the nature of the post mortem procedure, whether full or limited, the post mortem consent should be discussed with the Perinatal Pathologist. Staff taking consent must have received appropriate training which can include attending a post mortem examination. Perinatal pathologists should be involved in the training of consent

takers.

Transport

Transport must be organised between the referring / receiving providers to ensure a timely, efficient and safe transportation between the referring hospitals and the designated perinatal post-mortem service provider(s).

Post Mortem

All perinatal post mortem examinations will be carried out to a protocol that satisfies the requirements of national guidance and accepted good practice and has been agreed with commissioners.

Minimum standards for post mortem examination after fetal and perinatal death were published by the Royal College of Pathologist and the Royal College of Paediatrics and Child Health in 2001 and these must be complied with as a minimum.

Relevant published national guidance as outlined in:

Section 1.1 National / local context and evidence base

Section 3.1 Applicable national standards and Retention of organs/tissue samples

Post mortem examinations may take up to 5 – 7 working days to complete when the brain needs to be fixed for proper examination. Examinations should be completed within 3 days after receipt of the body if no special examination is required. Consent takers should be aware of these timescales so that parents can be informed

Where necessary, for instance when there is a religious requirement to hold a funeral, a post mortem examination should be completed within 24 – 48 working hours. Urgent post mortem examinations should be discussed with the pathologist by the consent taker.

Reporting

All post-mortem reports are expected to conform to, and include, details as described in the Royal College of Pathologists “Guidelines on Autopsy Practice” (2002).

60% of final reports for routine post mortem examination will be issued to referrers within 42 days of examination and 90% should be issued within 56 days. This will exclude those cases in which there may be a specialist referral opinion required (e.g. neuropathology) or very complex metabolic or genetic testing required

In these complex cases, an interim report summarising all available information

and indicating the outstanding information will be issued within 56 days.

Retention of organs/tissue samples

All tissue and organ sampling, use and subsequent retention, disposal, or return should be in accordance with consent and compliant with the Human Tissues Act and the Human Tissues Authority. Relevant published national guidance:

- The Human Tissue Act 2004 (covers England, Wales and Northern Ireland)
- Human Tissue Authority (HTA) Codes of Practice 2009:

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm>

Risk Management

Services delivered by the perinatal pathology service providers must be of a nature and quality to meet the standards, specification and Agreement for the service. It is the Trust's responsibility to notify the commissioner on an exceptional basis should there be any breaches of the standards. Where there are breaches any consequences will be deemed as being the Trust's responsibility.

2.3 Population covered

The service outlined in this specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England (as defined in *Who pays?, Establishing the responsible commissioner and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges*).

* Note: for the purposes of commissioning health services, this **excludes** patients who, whilst resident in England, are registered with a GP practice in Wales, but **includes** patients resident in Wales who are registered with a GP Practice in England.

2.4 Any acceptance and exclusion criteria

Perinatal pathologists commonly provide an autopsy service to H.M Coroner to assist in the investigation of unexpected or unexplained deaths, especially of infants in the community and deaths of infants or children in hospital that are either unexplained or in which the quality of medical management requires investigation.

However, this important component of work is funded by the coroner and will not be part of the NHS commissioned perinatal pathology service.

2.5 Interdependencies with other services

Whole System Relationships

All networks have a clinical governance framework in place. This framework enables the network to monitor the quality of care provided to clinicians and families, enable continuous service improvement, encourage clinical excellence and innovation and ensure clear accountability whilst maintaining high levels of safety.

Audit and clinical governance

NHS England commissioners and the provider will conduct a formal Joint Service Review at each centre at least annually and would expect to meet with the national clinical teams annually.

Minimum standards for post-mortem and post-mortem reports as agreed by the Royal College of Obstetricians and Gynaecologists and the Royal College of Pathologists in June 2001.

The designated provider should attend mortality meetings in local and referring hospitals if requested to promote good clinical care. Attendance at referring hospitals may, currently, be an aspiration but a target if local demand exists and resource permits.

Clinical meetings with fetal medicine specialists, obstetricians, neonatologists clinical geneticists and, where appropriate, other relevant professional groups should occur locally and where possible in referring hospital if resource exists

Interdependencies

Perinatal Pathology is recognised as a subspecialty of Histopathology by the Royal College of Pathologists. There are close dependencies with obstetric, fetal and maternal medicine, paediatric and medical genetic services.

3. Applicable Service Standards

3.1 Applicable national standards e.g. NICE, Royal College

Relevant published national guidance includes:-

- Royal College of Pathologists, Guidelines for Post Mortem Reports, London, 2000
- Royal College of Pathologists, Guidelines on Autopsy Practice, London, 2002
- Royal College of Obstetricians and Gynecologists and Royal College of Pathologists, Fetal and Perinatal Pathology Report of a Joint Working Party, London 2001
- Royal College of Obstetricians and Gynecologists, Late Intrauterine Fetal Death and Stillbirth (Green Top 55), London 2010
- Royal College of Pathologists and The Royal College of Paediatrics and Child

Health, Sudden Unexpected Death in Infancy: a multiagency protocol for care and investigation, London, 2004

- Royal College of Pathologists, Code of Practice for Histopathologists and Histopathology Services, London, 2005
- Department of Health, Families and Post Mortems: A code of practice, 2003
- Department of Health, Care and Respect in Death: good practice guidance for NHS mortuary staff
- Carter Review of Pathology Services. 2008
- Pathology Programme Update 2009. DOH 2010

3.2 Applicable local standards

See Appendix A & B

The service will be compliant with the standards agreed by the centres (Appendices A&B).

The nationally designated providers of the Perinatal Pathology service are required to demonstrate continual improvement in service delivery. This process will be informed by clinical and service audit, patient and public engagement and awareness of national and international clinical and policy developments that could inform service development. Where appropriate the nationally designated providers will work together to develop shared protocols and guidelines.

The services will agree service development improvement plans with NHS Specialised Services commissioners and demonstrate progress at Joint Service Review meetings

4. Key Service Outcomes

The service will be compliant with the standards agreed by the centres (Appendices A&B).

The nationally designated providers of the Perinatal Pathology service are required to demonstrate continual improvement in service delivery. This process will be informed by clinical and service audit, patient and public engagement and awareness of national and international clinical and policy developments that could inform service development. Where appropriate the nationally designated providers will work together to develop shared protocols and guidelines.

The services will agree service development improvement plans with NHS Specialised Services commissioners and demonstrate progress at joint service review meetings

Appendix A: Minimum standards for Post Mortem Examination after fetal and perinatal death. This should take into consideration the relevant parental consent.

External Examination

- Bodyweight (to nearest gram if less than 5kg)
- Head circumference
- Crown – heel and crown – rump lengths
- Foot length
- Apparent gestation
- Maceration (if baby born dead)
- Dysmorphic features/congenital malformations and deformities
- Other abnormalities (oedema, abnormal pallor, meconium staining)

Internal Examination

- Comment on cranial, thoracic and abdominal cavities
- Systematic description of major organs and tissues
- Weights of all major organs on digital balance
- Comment on skeleton
- Measurement of abdominal and thoracic fat thickness

Placenta

- Size
- Trimmed weight
- Umbilical cord length
- Membranes (complete, incomplete, abnormalities)
- Fetal, maternal and cut surfaces

Histology

- At least one block of all major thoracic and abdominal organs (right and left lungs, liver, kidney, thymus, adrenals and pancreas)
- Costochondral junction (over 24 weeks gestation)
- Adequate sample of brain (varies with case; minimum of one block from hind brain and one block from cerebral hemispheres)
- Adequate sample of placenta (cord, membranes, focal lesions, grossly normal parenchyma to include amnion and decidua)

Special procedures and investigations

- X-ray mandatory for suspected skeletal dysplasia and multiple malformations without ante mortem diagnostics
- Photography mandatory for dysmorphic fetuses and babies without ante mortem diagnosis; advised for other gross abnormalities
- Bacteriology (blood/spleen/lung/cerebrospinal fluid), if clinically indicated
- Virology, if clinically indicated

- Karyotype, if clinically indicated
- Storage of fibroblasts/frozen tissue/DNA, if clinically indicated
- Biochemistry, if clinically indicated
- Haematology, if clinically indicated

Appendix B: Service standards

Expertise

- The perinatal pathologist will be on the General Medical Council Specialist Register and have as a minimum, Fellowship Examination of the Royal College of Pathologists (FRCPath) in Paediatric and Perinatal pathology or equivalent; or FRCPath (General Histopathology, Neuropathology or Forensic Pathology) or equivalent and at least two year's specialist experience in perinatal pathology.
- In order to maintain expertise each perinatal pathologist should perform a minimum of 50 post-mortems per year.
- Each pathologist will participate in a continuous professional development scheme (e.g. the RCPATH continuous professional development scheme).
- Each pathologist will participate in the accredited Perinatal EQA scheme run by British and Irish Paediatric Pathology Association.
- Each service should participate in multidisciplinary team meetings in particular Perinatal Mortality and Dysmorphology Meetings. These will occur primarily in the hospital in which the Service is based but, where staffing levels allow, there should be an aspiration to be involved with multidisciplinary teams in referring hospitals

Turnaround

Prior to a post-mortem being performed parents must be given appropriate information about the post mortem examination. This should include information about its purpose, possible outcomes and when necessary, that the fetus or baby will be transferred to another hospital. Parents should always be told, before that, even after they have signed the consent form, they can change their minds about anything they have agreed to. It is rare for parents to complete the post mortem form themselves and they should not be expected to. Generally the person taking consent should complete the main body of the form as instructed by the parents and the parents then sign it.

Parents should have time to decide if they wish to have a post-mortem. They should have a minimum of 12 hours – the HTA recommends 24 hours – between giving consent and the start of the post mortem examination (HTA Code 3, 2009: 97). However, if parents want an urgent post mortem, they need to be told that there may not be time for them to change their minds.

The written consent together with the appropriate post mortem request forms and/or copies of the relevant clinical notes must be received by the pathologist prior to the post- mortem examination. The parents should receive a copy of the post mortem consent form together with a leaflet written in lay terms and including information

about the post- mortem examination and what is involved.

Facilities

Each centre will have the following facilities

- A dedicated paediatric mortuary or mortuary area with appropriate equipment including but not limited to: digital imaging facilities; dissecting microscope or appropriate magnifying lens; facility for whole body x-rays such as faxitron or equivalent.
- Access to laboratory with tissue block processing facilities, including frozen sections.
- Immunohistochemistry.
- Access to appropriate molecular pathology and cytogenetic laboratory services.
- Access to electron microscopy.
- Access to other relevant laboratory services including microbiology and virology; clinical chemistry and metabolic investigative service;
- Access to Clinical Genetics service.
- Each centre will have formal arrangements for contingencies and cross-cover with the other centres

Staffing

- Minimum of two perinatal pathologists (who may not be whole time) with sufficient programmed activity sessions (PAs) to cross cover and undertake projected workload based on RCPATH workload guidance.
- Appropriate Biomedical Scientist Support.
- Appropriate level of Mortuary support, preferably with specialist knowledge in perinatal autopsy and appropriate skills in reconstruction.
- Appropriate secretarial and clerical support (approx. 0.5 whole time equivalent per consultant).

Accreditation

Every laboratory should have technical EQA and Clinical Pathology Accreditation (CPA) accreditation; the service should be Human Tissue Authority (HTA) compliant.