



The Royal College of Pathologists
London

SERVICE SPECIFICATION FOR PAEDIATRIC
and
PERINATAL HISTOPATHOLOGY

Guidance for Purchasers

September 1995

Published by the Marks and Spencer Publications Unit of the
Royal College of Pathologists

Summary of Service Specification Criteria

- *The service should be led by a full-time consultant paediatric/perinatal pathologist with appropriate qualifications. 24 hour specialist cover should be available at all times.*
- *The laboratory should be accredited; at the present time CPA accreditation is the best guide.*
- *Staffing and facilities should be as recommended by the Royal College of Pathologists for specialist paediatric pathology laboratories.*
- *The laboratory should have an adequate workload to maintain expertise, eg 100 paediatric postmortems and/or 100 fetal examinations or 500-1000 paediatric biopsies for laboratories providing those services.*
- *Participation in continuing medical education, internal and external quality assurance schemes, medical and clinical audit, research and development, and national review panels.*
- *Performance audited and monitored through an annual report to purchasers.*

Introduction

What are Paediatric Pathology and Perinatal Pathology?

The rapid development of new clinical specialties has led to a need for equivalent specialised diagnostic services to support them. In the fields of obstetrics and paediatrics developments in antenatal diagnosis, neonatal intensive care, neonatal surgery, oncology, cardiac surgery, bone marrow transplantation, clinical genetics and other disciplines have resulted in the emergence of paediatric and perinatal histopathology as recognised specialties with their own techniques and body of knowledge.

- Perinatal pathology has come to mean the pathology of the embryo, fetus, newborn and infant.
- Paediatric pathology covers diseases of infants and older children.

These overlapping specialties are often provided by the same unit or individual depending on the conformation of the corresponding local clinical services. Much routine work is carried out by district general histopathologists. In many areas individual pathologists have developed a special interest most often in perinatal pathology, and provide a valuable service in non-specialised units. *This paper refers only to tertiary paediatric/perinatal histopathology services*, although even general departments should work to many of the standards set out here.

Why should purchasers make provision for specialised paediatric/perinatal pathology?

Perinatal pathology

Perinatal pathology is an almost exclusively autopsy based service. Access to expert postmortem examination of their child is seen by many as a parental right.

In contrast to conventional autopsy services which are retrospective, perinatal necropsies are prospective investigations seeking to provide clinical and genetic information essential for the management of future pregnancies. Thus, while adult postmortem rates continue to fall to less than 10% of all hospital deaths in many centres, the national perinatal necropsy rate is approximately 50% and reaches 90% in the best units reflecting the importance clinicians and parents place on this investigation. The Royal College of Obstetricians and Gynaecologists has recommended 75% as a minimum rate for accreditation purposes.

Effectiveness of Perinatal Pathology

Numerous published audits have confirmed the contribution of expert perinatal pathology to patient care¹. A recent study has demonstrated that the probability of perinatal postmortem examination providing clinically significant information is directly related to the quality of the examination as assessed by the detail of the report and the number of ancillary investigations undertaken, and that examination in a specialist centre is more likely to contribute useful information for clinical management and audit^{2a & 2b}.

Antenatal Diagnosis

Perinatal pathology is an important audit of expensive antenatal screening programmes. All fetuses aborted after an antenatal diagnosis of congenital abnormality should be examined by a perinatal pathologist not only to confirm the suspected abnormality, but also to provide additional information as a basis for the final diagnosis on which genetic advice is given. Studies have shown that the antenatal diagnosis is incorrect in 12%, and that additional information required for counselling is obtained in 30% of cases³.

Stillbirths

Expert examination of stillborn babies may not always give a clear cause of death, but usually gives useful information about the mode and time of death, growth and development and medical conditions in the mother that may have contributed to the baby's death. Careful examination even of babies that have been retained in the womb for several weeks after death occasionally shows malformations or other conditions explaining death and of great importance for future pregnancies.

Neonatal intensive care

Examination of babies that have died after a period of neonatal intensive care requires specialised knowledge of the clinical care of very small babies, and familiarity with neonatal autopsy techniques. Expert examination is an important audit of this expensive branch of paediatrics, and has contributed significantly to the development of neonatology by recognising complications of new therapies, monitoring infection and facilitating comparisons between individual units.

Obstetric litigation

A properly conducted postmortem examination is probably the best protection against misguided obstetric litigation. Expert examination of the placenta has assumed increasing importance in this regard. Findings in the placenta almost invariably support the clinical point of view and demonstrate that adverse pregnancy outcome was associated with factors independent of clinical care.

Cot death

The examination of infants who die unexpectedly in the community is under the direction of local Coroners. However, the support of skilled staff and proper facilities for these examinations should be a priority for purchasers as expert examination of cot deaths regularly reveals serious infectious diseases such as meningitis, rare genetic diseases, and occult child abuse which have important healthcare implications. The cost of some additional investigations in these cases should be met by Health Authorities (FDL(91)127)

The Clothier Report on the Allitt Inquiry recommended that the services of paediatric pathologists should be engaged for all examinations of children who die unexpectedly whether in hospital or in the community. Research into the sudden infant death syndrome based on expert postmortem examinations has resulted in a marked fall in the rate of cot deaths so that it is now possible for a regional department of paediatric/perinatal pathology to examine all such deaths that occur in its population.

Paediatric Pathology

Pathology services for older children are either provided by paediatric pathologists working in a children's hospital, or by one or more pathologists in a large University department who have developed a special interest corresponding to a regional tertiary clinical service, such as paediatric oncology sited in their hospital.

Paediatric pathology involves both surgical biopsies and postmortem examinations.

Paediatric biopsies

The interpretation of paediatric surgical biopsies involves the same principles as adult biopsies, although different ancillary techniques may be

necessary. Examples include the use of histochemistry for biopsies from children with suspected metabolic disorders, and the use of methods for acetylcholinesterase for the diagnosis of Hirschsprung's disease. The diagnosis of muscle and renal biopsies from children is often carried out by pathologists specialising in these organs who have knowledge of their diseases at all ages. The need for pathologists reporting renal biopsies to have special knowledge of diseases of the kidney in childhood has recently been stressed by the British Association for Paediatric Nephrology.

Paediatric tumours

Children's tumours are unique to this age group and present particular problems in diagnosis often requiring ancillary tests such as immunohistochemistry, electronmicroscopy, cytogenetics and molecular genetics as well as knowledge of current treatment protocols. Paediatric oncologists will generally only treat on the basis of a diagnosis confirmed by their own specialised pathologist who is part of their multidisciplinary team, and it is not infrequent that biopsies have to be repeated before treatment can be started because essential investigations were not carried out on the first biopsy taken at a district general hospital.

To minimise the chance of misdiagnosis, paediatric tumours should be examined by pathologists with special experience working in specialist centres who see a sufficient number of these tumours to appreciate the range of appearances they may present, are aware of current treatment protocols, contribute their cases to national review panels, have access to specialised investigative techniques, and take part in an appropriate audit/EQA scheme. The importance of this has been highlighted by recent widely publicised tragedies.

Postmortem examination

Autopsy of older children involves the same techniques as adult necropsy, although the diseases involved and their implications for family members may be different. Centres providing regional paediatric services should have provision for expert postmortem examination of children dying in their care. Recent studies have confirmed the value of postmortem examination in recognising diagnostic and surgical errors in regional paediatric cardiology⁴, and undiagnosed complications in paediatric oncology⁵. The report of the *National Confidential Enquiry into Perioperative Deaths* (1989) emphasised the role of postmortem examination in investigating these deaths in children.

Why are specialised departments of perinatal pathology necessary?

Perinatal pathology requires knowledge of obstetrics, paediatrics, genetics, syndromology and diseases of the newborn usually acquired during a period of prolonged training over and above that undertaken by general pathologists. Expertise in paediatric/perinatal pathology is sustained by regular contact with specialists in the corresponding clinical disciplines. An important feature of perinatal postmortems is the meticulous documentation of abnormality and normality by photography, radiology, cytogenetics and other laboratory tests, and discussion of findings with colleagues in clinical genetics, microbiology, clinical chemistry, paediatric haematology, and paediatric radiology. Interpretation requires access to specialist books, journals and computer databases. These resources are seldom available in district general hospitals.

For this reason, and to make best use of scarce resources perinatal necropsies are best carried out in a regional centre rather than by the specialist pathologist travelling to the hospital in which the baby died. In most instances the postmortem can be carried out within a few hours, and the baby returned to its hospital of origin. This is contrary to the established principle that hospital necropsies should be carried out locally to enable clinicians to attend the examination and contribute to the interpretation of findings. To compensate for this, regional departments must provide excellent communications, and paediatric/perinatal pathologists must be enabled to attend local mortality/audit meetings and take part in local postgraduate activities.

In an ideal world all perinatal postmortems would be carried out by someone with specialist knowledge. In practice the number of these examinations makes this unrealistic, and criteria for referral should be decided according to local needs by the clinicians and pathologists involved. Examples of cases benefiting from detailed examination include:

- All fetuses aborted following antenatal diagnosis of congenital abnormality
- Deaths following amniocentesis or chorionic villus sampling
- Deaths following other intrauterine interventions
- Hydrops fetalis
- Suspected intrauterine infection

- Deaths of twins
- Unexplained intrauterine growth retardation
- All malformed fetuses and babies
- Deaths after neonatal intensive care
- Unexplained neonatal deaths
- Threatened litigation

What are the resource implications?

A regional paediatric/perinatal department staffed by two pathologists with appropriate technical and secretarial support may be sufficient to meet the needs of a population of 3 million people depending on the local conformation of pathology and clinical services. Regions with a large children's hospital will need more. The cost per specimen may appear high because tertiary referral implies low specimen numbers of high complexity compared to non-specialised laboratories. Many of the functions of a regional paediatric/perinatal service are hard to cost or quantitate. Regional departments of paediatric and perinatal pathology have an essential role in raising, setting and maintaining standards throughout their regions, providing reliable mortality statistics and underpinning the national Confidential Enquiry into Stillbirths and Deaths in Infancy. They provide telephone advice to clinicians and pathologists in other hospitals. They are a source of expert opinions for health authorities in cases of obstetric litigation. They play an essential part in the training of obstetricians and paediatricians through postgraduate activities, and are a required part of the formal training of histopathologists. However, the overall cost of the service to any one purchaser is small, certainly minimal compared to the total cost of the corresponding clinical services, and probably one of the smallest contracts it negotiates.

All units providing maternity or paediatric care should have made provision for specialist paediatric pathology, and evidence of such provision should be a quality measure required by purchasers in contracts for these clinical services.

The repetitive use of small bill cross charging is organisationally demanding and expensive for small departments, and may inhibit tertiary referral for thorough investigation in some circumstances. The encouragement of block contracts or purchaser levies would avoid these problems.

Guidelines for the Service Specification

A model service specification should enable purchasers to recognise and contract for a quality service and specify the essential elements of such a service.

Many of the key elements of a tertiary paediatric pathology service are common to pathology services in general:

- Consultant led
- Accredited laboratory
- Appropriate facilities
- Adequate workload
- Appropriate performance
- Participation in EQA and CME
- Appropriate audit
- Research and development

Consultant led

The service should be headed by a full-time consultant paediatric/perinatal pathologist as set out in HSC(1S)16 and HN(90)18.

In the absence of a formal qualification this is defined by the consultant's contract, but purchasers should be aware that most recognised paediatric pathologists are members of the Paediatric Pathology Society and have completed or are attending the International Paediatric Pathology Association Advanced Course in Paediatric Histopathology. The Royal College of Pathologists now offers a specialist examination for trainees seeking membership.

Pathologists providing diagnoses of children's tumours should be members of the United Kingdom Children's Cancer Study Group so that they have access to current treatment protocols and their diagnoses are subject to external panel review.

It should become a requirement for paediatric pathologists to take part in Continuing Medical Education, and the Royal College of Pathologists has established a scheme from April 1995.

Although an ideal tertiary service should have two consultant paediatric pathologists, in practice some do not. In the latter case there should be a *formal arrangement with a neighbouring unit to ensure specialised cover at all times.*

Accredited Laboratory

All laboratories offering paediatric/perinatal pathology should be **accredited** as evidence that they provide a safe and high quality service. At the present time many paediatric pathology laboratories are sections of larger histopathology laboratories, and are not separately accredited by Clinical Pathology Accreditation (CPA). CPA has appointed inspectors for paediatric pathology laboratories, and the issue of separate accreditation should be kept under review.

Appropriate facilities

The Royal College of Pathologists has provided guidance on the staffing and facilities required for a paediatric pathology laboratory. Purchasers may contract separately for perinatal and paediatric surgical pathology. Key requirements are:

Perinatal pathology

- Availability of specialist consultant advice
- Adequate secretarial support and communications
- Dedicated mortuary or section of a larger mortuary
- Access to radiology for all cases
- Photography of all cases
- Access to cytogenetics
- Access to clinical genetics and/or a clinical genetics database
- Ultra-low temperature freezer for storage of samples including DNA
- Adequate viewing room or chapel
- Proper arrangements for disposal of fetuses
- Specialist textbooks and journals

Paediatric surgical pathology

- Availability of specialist consultant advice
- Dedicated laboratory or section of larger laboratory
- 24 hour facilities for frozen sections
- Histochemistry (Acetylcholinesterase for Hirschsprung's disease)
- Immunohistochemistry
- Electronmicroscopy
- Ultra-low temperature freezer for tumour samples
- Arrangements for tissue culture and cytogenetics of tumour samples
- Facilities as for equivalent adult tertiary services if undertaking renal, brain or muscle biopsies
- Specialist textbooks and journals
- Adequate storage and records system

Adequate workload

It is unlikely that a perinatal pathology department can maintain expertise if it undertakes less than *100 paediatric postmortems and/or 100 fetal examinations each year*. Similarly, a tertiary paediatric surgical pathology laboratory should receive at least 500-1000 patient requests each year including a sufficient number of referred cases or cases from regional or supraregional clinical specialties. In practice this probably means that this service will only be provided by Children's Hospital laboratories or sections of large University laboratories serving a large children's unit. *For paediatric oncology it is suggested that a minimum of 50 new malignancies per year is required to maintain expertise. For renal biopsies, 20-25 biopsies per year from children are a necessary minimum.*

Appropriate performance

Postmortems should be carried out according to the minimum guidelines provided by the Royal College of Pathologists and the National Advisory Body of the Confidential Enquiry into Stillbirths and Deaths in Infancy.

Postmortems may involve transport of fetuses and babies between hospitals. The provider must make *adequate arrangements for the proper receipt of bodies and their return if required.*

There should be written procedures for the handling of bodies and fetuses, including confirmation of postmortem consent and identification of referred cases.

Arrangements should be in place for the **proper disposal** of pre-viable fetuses according to Department of Health guidelines.

The service specification should stipulate participation in audit including that of **turn-around times**. Provisional postmortem reports should be completed within 2 working days, and final reports within 6 weeks. Surgical biopsy reporting times will vary widely with the complexity of the case, but a telephone call to the submitting pathologist or clinician within 2 working days of receipt and a written report within one week should be attainable for most samples not requiring complex electronmicroscopy, molecular or other non-routine techniques.

Performance should be monitored through an annual report to purchasers including workload and audit figures.

Participation in External Quality Assurance (EQA)/Audit

Evidence of participation in an appropriate nationally recognised **laboratory EQA** scheme should be required by purchasers. This is particularly important for laboratories providing immunohistochemistry for the diagnosis of children's tumours.

All departments should take part in medical and clinical audit, including the audit of other disciplines such as obstetrics, midwifery and antenatal diagnostic services.

Pathologists should take part in nationally recognised EQA/audit schemes such as that run by the British Paediatric Pathology Association. Pathologists providing diagnoses of children's tumours must submit slides for review by national panels such as those run by the United Kingdom Children's Cancer Study Group, and keep records of their own and the panel's diagnoses.

Research and Development

In common with most tertiary specialties, research and development is an essential element of the work of paediatric and perinatal pathology laboratories enabling them to provide an up to the minute diagnostic service and leadership to other pathology departments in their catchment areas.

Appendices

References

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- 2a. The value and quality of perinatal and infant postmortem examinations. Cartlidge PHT, Dawson AJ, Stewart JH, Vujanic GM. BMJ 1995;310:156-158
- 2b. Perinatal and infant postmortem examinations: how well are we doing? Vujanic GM, Cartlidge PHT, Stewart JH, Dawson AJ. J Clin Pathol 1995;48 (in press)
3. Correlation of antenatal ultrasonography and pathological examinations in 153 malformed fetuses. Weston MJ, Porter HJ, Andrews HS, Berry PJ. J Clin Ultrasound 1993;21:387-392
4. Postmortem audit in a paediatric cardiology unit. Russell GA, Berry PJ. J Clin Pathol 1989;42:912-918
5. Is postmortem examination useful in pediatric oncology? Koszyca B, Moore L, Toogood I, Byard RW. Pediatr Pathol 1993;13:709-716

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Relevant Reports

Report of the RCOG & RCPATH Working Party on Fetal and Perinatal Pathology (1988)

The Report of the National Confidential Enquiry into Perioperative Deaths 1989 (Surgical and Anaesthetic Treatment of Children)

Report of the Royal College of Pathologists Working Party on Fetal and Perinatal Pathology (1990)

Guidelines for Post Mortem Reports, Royal College of Pathologists (1993)

CESDI minimum guidelines for postmortems. Department of Health (1993)

Guidelines for professionals on miscarriage, stillbirth, and neonatal death. Stillbirth and Neonatal Death Society

EL(91)144 Sensitive disposal of the dead fetus and fetal tissue

HSG(91)19 Disposal of fetal tissue

The Allitt Inquiry. Independent inquiry relating to deaths and injuries on the children's ward at Grantham and Kesteven General Hospital during the period February to April 1991 (The Clothier Report). HMSO (1994)

The Provision of Services in the United Kingdom for Children and Adolescents with Renal Disease. Report of a working party of the British Association for Paediatric Nephrology. British Paediatric Association (1995)

Guidance for Purchasers of Pathology Services. Royal College of Pathologists (1995)

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Some relevant professional organisations

Specialist Advisory Committee on Pre/Perinatal/Paediatric Pathology, Royal College of Pathologists

British Paediatric Association (BPA)

British Paediatric Pathology Association (BRIPPA)

Paediatric Pathology Society (PPS)

International Pediatric Pathology Association (IPPA)

United Kingdom Children's Cancer Study Group (UKCCSG)

Clinical Pathology Accreditation (CPA)