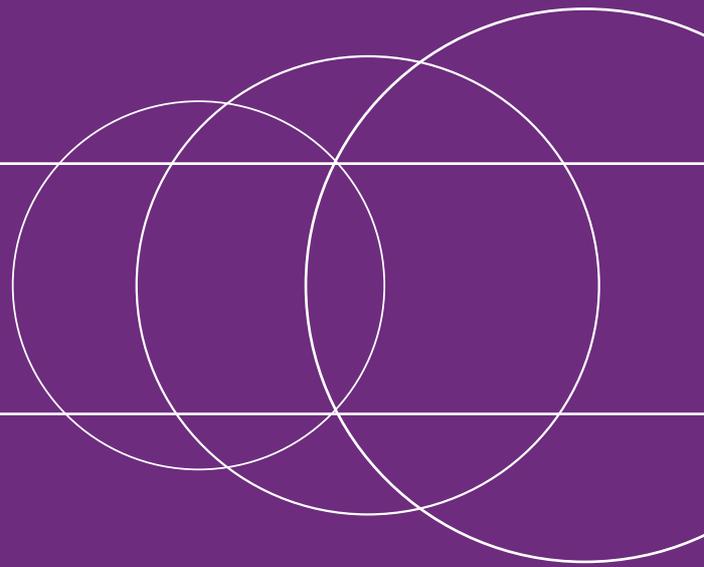


PERFORMANCE AUDIT

Organ retention
validation review



MARCH 2002

PREPARED BY AUDIT SCOTLAND

Organ retention validation review

A report to the Scottish Parliament by the Auditor General for Scotland

Auditor General for Scotland

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Audit Scotland

Audit Scotland is a statutory body set up in April 2000 under the Public Finance and Accountability (Scotland) Act 2000. It provides services to the Accounts Commission and the Auditor General for Scotland. Together they ensure that the Scottish Executive and public sector bodies in Scotland are held to account for the proper, efficient and effective use of public funds.

Acknowledgments

Rhona Jack, Sara Twaddle, Dot Anderson and Steve Engleman undertook the study, under the direction of Barbara Hurst, Director of Performance Audit. Audit Scotland is grateful to the staff in the trusts for their time and the information provided. Audit Scotland also gratefully acknowledges the input of representatives from Public Health Medicine during the visits.

Background

Post-mortem examinations are undertaken for diagnosis in order to identify the cause of death and any contributing factors. Organs may be retained after post-mortem for further diagnostic investigations, or for a longer period for teaching, clinical audit or research.

Post-mortems are either undertaken on behalf of a procurator fiscal or at the request of a hospital clinician or general practitioner. Different rules about granting permission apply to these situations:

- consent of relatives is not required for procurator fiscal post-mortems or for the removal and retention of an organ to further the procurator fiscal's inquiry
- consent of relatives is required for a hospital post-mortem and for subsequent organ retention.

In the past consent for the retention of organs was viewed as implicit in the granting of permission for post-mortem examination by relatives of the deceased. The potential for distress caused by this practice was largely unrecognised until recently.

In the light of the Alder Hey enquiry in England, the Minister for Health and Community Care announced in September 2000 the formation of an Independent Review Group to review post-mortem practice in Scotland. Professor Sheila McLean chaired this group and the final report was published for consultation during November 2001.

As part of the work of the Review Group on the Retention of Organs at Post-Mortem, trusts in Scotland were asked to provide information about the number of organs retained at post-mortem. These were published in the first report of the group during January 2001¹. In response to a request from the Minister during 2001, Audit Scotland was instructed by the Auditor General for Scotland to undertake an exercise to validate the information provided by the trusts. In addition, Audit Scotland was asked to:

- examine reasons for retention
- provide a breakdown of hospital and procurator fiscal post-mortems
- review the systems to record all materials held (including tissue blocks and slides)
- discuss findings with the Review Group and parents' support groups to give them an opportunity to comment on the shortcomings of existing systems and the way forward.

¹ Report of the Independent Review Group on the Retention of Organs at Post-Mortem, January 2001.

This report summarises Audit Scotland's findings from the validation exercise and the systems review undertaken during the period November 2001 to January 2002. At the same time as Audit Scotland was undertaking this review we understand that Scottish Executive Health Department has been addressing some of the issues in this report.

Aim

The Audit Scotland review aimed to establish:

- the number of organs retained after post-mortem in trusts in Scotland
- the robustness of hospital information systems, to ensure that a relative making an enquiry is provided with comprehensive and accurate information about any organs and tissues retained at post-mortem.

Approach

The review was carried out in all trusts in Scotland which provide a pathology service (Appendix 1).

Audit Scotland obtained information to place the workload associated with post-mortems in the context of total pathology workload and tested the systems in place to ensure that relatives' enquiries could be dealt with efficiently and effectively. These tests involved physically tracking from:

- retained organs to records and any other associated tissue held
- post-mortem records to retained organs, blocks and slides.

The review process is described in detail in Appendix 2.

In addition, Audit Scotland surveyed trust chief executives and medical directors on a range of issues surrounding organ retention, recognising that there is a wider impact on the trust than the implications for pathology staff. This survey asked trusts to rate the relative importance of a number of key issues and to identify actions being taken to address them.

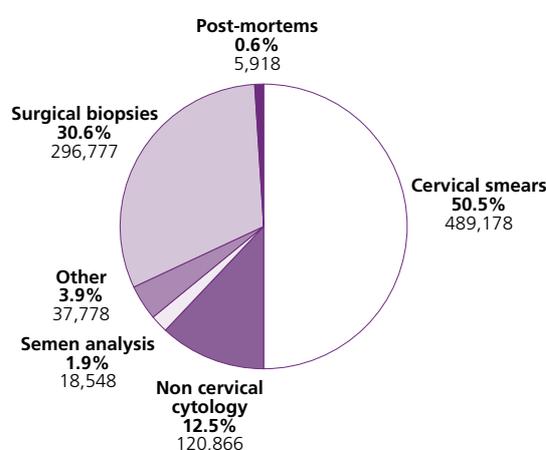
Findings

All fourteen trusts in Scotland which provide pathology services were visited during the period November 2001 to January 2002. NHS Borders, NHS Orkney, NHS Shetland and NHS Western Isles were not visited because there are no locally provided pathology services; post-mortems are carried out by staff from other areas. In all but one health board area (NHS Argyll & Clyde) consultants in public health medicine were involved in the process. Where trusts have more than one pathology laboratory, visits were made to each.

Pathology workload

All trusts provide a wide range of histopathology² and cytopathology³ services, although in some individual laboratories gynaecological cytology is no longer provided. Some trusts (South Glasgow, Lothian and Grampian) also provide specialist services to a number of health board areas. Post-mortems make up a small part of the workload in most laboratories (Exhibit 1).

Exhibit 1: Total pathology workload 2000



Procurator fiscal work

Eleven of the 14 trusts visited undertake post-mortems on behalf of procurators fiscal. In some cases, University Departments of Forensic Medicine are physically located within trust premises, although this does not necessarily mean that the services are integrated.

Trends in post-mortems

It proved difficult for many trusts to provide analyses of post-mortems by age group and by type (hospital and procurator fiscal) over the full period 1948-2000 because this required them to refer to manual systems. In most cases computerised laboratory systems have made this process much simpler,

² Histopathology is the science concerned with the study of microscopic changes in diseased tissues.

³ Cytopathology is the study of disease in cells.

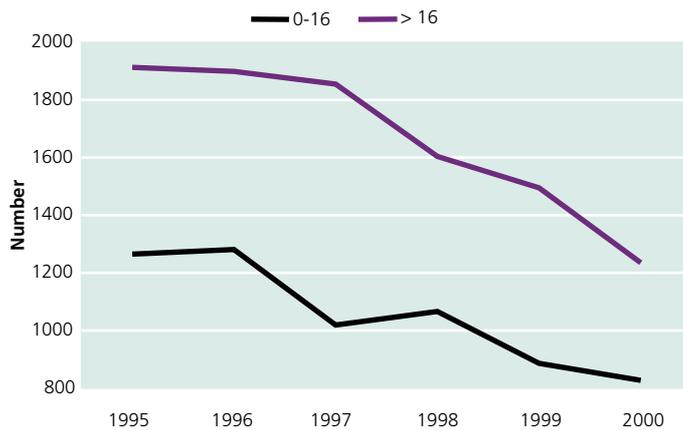
but have only been put in place in the last ten years. Where procurator fiscal post-mortems were performed in NHS settings, these have been included; many are undertaken in non-NHS settings, and these are not included.

There has been a significant reduction in the number of hospital post-mortems undertaken in the period 1980 to 2000 (Exhibit 2). Around 2,200 are now conducted annually compared with more than 6,600 in 1980. This trend is consistent in both adults and children over the past six years (Exhibit 3). For trusts undertaking post-mortems on behalf of procurators fiscal, there has been little change in the number of fiscal post-mortems, but a significant reduction in hospital post-mortems (Exhibit 4).

Exhibit 2: Trends in hospital post-mortems 1980 - 2000⁴



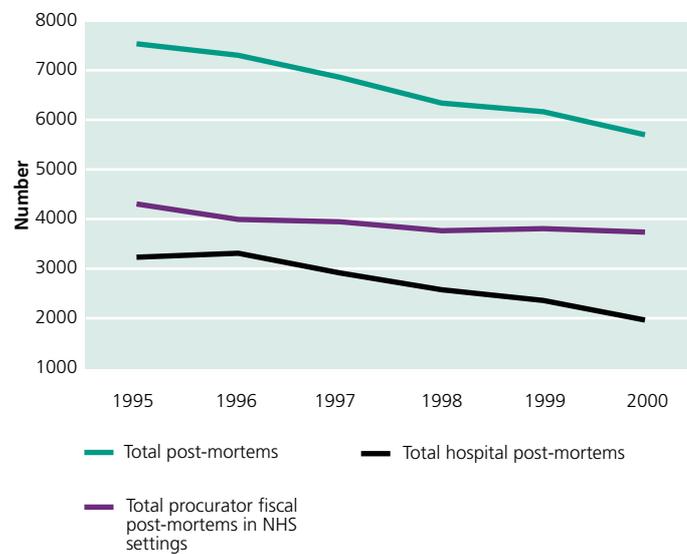
Exhibit 3: Trends in hospital post-mortems by age group 1995 - 2000⁵



⁴ Excludes Fife Acute Hospitals Trust, who did not provide information prior to 1993, and Lanarkshire Acute Hospitals Trust who provided only full information from 1990.

⁵ Excludes North Glasgow University Hospital NHS Trust, Lanarkshire Acute Hospitals Trust and West Lothian Healthcare Trust who did not provide an age breakdown.

Exhibit 4: Trends in hospital and procurator fiscal post-mortems 1995 - 2000⁶



Storage of retained organs, tissue blocks and slides

All trusts have taken steps to ensure that any retained organs are kept in designated areas only.

Seven trusts have formal links with university departments and staff have honorary university appointments. Audit Scotland included all organs held in university departments regardless of whether they were in the formal possession of the university or the trust.

In all NHS laboratories, tissue blocks and slides are stored indefinitely, except Dumfries and Galloway Royal Infirmary where slides are retained for ten years. Several laboratories raised concerns about the physical storage of tissue blocks and slides and await national guidance on this issue. The Clinical Standards Board for Scotland will publish standards relating to this issue.

Systems for identification of organs, tissue blocks and slides

The information systems available to trusts to identify retained organs, tissue blocks and slides vary widely across Scotland. The systems range from largely manual systems to integrated IT systems; some trusts use a mix of both manual and electronic systems. All the trusts demonstrated rigorous systems for identifying retained organs, tissue blocks and slides. In every situation the review teams' tests showed that even archived information can be obtained without significant difficulty.

⁶ Excludes trusts that do not undertake post-mortems on behalf of procurators fiscal (Grampian University Hospitals NHS Trust, Tayside University Hospitals Trust, West Lothian Healthcare Trust).

Dealing with enquiries from relatives

In accordance with a recommendation of the Review Group on the Retention of Organs at Post-Mortem⁷, all trusts have nominated a named point of contact to manage all enquiries. All trusts now have rigorous systems for dealing with relatives' enquiries.

In Scotland, more than 2,000 enquires have been made since the Alder Hey investigation. In cases where a large number of enquiries have been made, this has placed significant pressure on departments and on the staff involved. For a small number of these enquiries trusts had difficulty in responding timeously particularly in cases where enquiries related to deaths up to 40 years ago. Factors such as hospital closures and trust reconfigurations limited the ability of trusts to respond. Trusts expressed regret about the small number of mistakes made in the past, where wrong information had been passed to relatives, leading to distressing and sometimes acrimonious situations. All trusts were now able to demonstrate systems to prevent this situation in the future.

Transfer of organs between centres

For some specialist diagnostic procedures, such as neuropathology, organs may be transferred to another centre. Trusts reported that this had been problematic in the past, where the assumption was made that the receiving trust would be responsible for respectfully destroying the organs when diagnosis was complete. Where this assumption was incorrect, this had led to relatives being given wrong information about the current location of organs. Audit Scotland investigated this aspect in some detail and found that rigorous procedures are now in place, with receiving departments requesting written instructions for disposal from the referring trusts. In some cases the referring trusts have requested that all organs be returned for local disposal.

Retained organs

The Review Group on the Retention of Organs at Post-Mortem requested information on the numbers of retained organs in each trust. However, this request was not specific enough to ensure that all trusts reported numbers on the same basis. Audit Scotland found that trusts had interpreted the request differently, in particular with respect to museum collections, and how certain organs should be counted. Audit Scotland's review ensured that trusts included all retained organs and counted them on a consistent basis, as shown in Exhibit 5.

At the time of Audit Scotland's review and excluding the 237 cases currently undergoing diagnosis, there are a total of 10,625 organs retained in Scottish trusts. Of these, 1,651 organs were taken for diagnosis which has been completed, but are being held pending further instructions on disposal. The vast majority of the remaining organs (8,974) are from archive and museum collections.

The inclusion of museum and archive collections in all trusts accounts for most of the difference between the current numbers of retained organs and those declared to the Review Group on the Retention of Organs at Post-Mortem. In addition, the time period since these figures were originally provided allowed some trusts to undertake a more accurate count, allowing non post-mortem specimens to be excluded. Audit Scotland also included organs retained in the CJD Unit in Edinburgh, which was not included in the original declaration.

⁷ Report of the independent Review Group on the Retention of Organs at Post-Mortem, January 2001.

Of the 12 trusts holding organs as part of archive or museum collections, only five hold organs for research purposes. The majority of these collections are held for teaching purposes, including some specimens of diseases which are now unknown, medico-legal reasons, or clinical audit.

Trusts have spent considerable effort and resources to ensure that they have now identified all retained organs. Audit Scotland was able to provide each trust with a positive report.

Exhibit 5: Reconciliation of current holdings with numbers submitted to Review Group on Retention of Organs at Post-Mortem

The inclusion of museum and archive collections in all trusts accounts for most of the difference between the current numbers of retained organs and those declared to the Review Group.

| Trust | Organ Retention Review Group declaration | Current holding | | |
|------------------------------|--|--------------------|---------------------------|-------------------|
| | | Archive/museum | Transitional ⁹ | Current diagnosis |
| Argyll & Clyde | 75 | 75 | 0 | 0 |
| Ayrshire & Arran | 30 | 2 | 28 | 0 |
| Dumfries & Galloway | 7 | 7 | 0 | 1 |
| Fife | 0 | 0 | 0 | 0 |
| Forth Valley | 4 | 4 | 0 | 0 |
| Grampian | 154 | 576 | 335 | 32 |
| North Glasgow | 4453 ¹⁰ | 4175 | 0 | 45 |
| South Glasgow | 174 | 160 | 1 | 0 |
| South Glasgow Neuropathology | 1479 | 482 | 590 | 29 |
| Yorkhill | 432 | 540 | 405 | 0 |
| Highland | 1 | 22 | 0 | 6 |
| Lanarkshire | 19 | 28 | 0 | 5 |
| Lothian | 558 | 2071 ¹² | 195 | 104 |
| CJD Unit | 0 | 478 | 97 | 4 |
| West Lothian | 0 | 0 | 0 | 3 |
| Tayside | 500 | 354 | 0 | 8 |
| TOTAL | 7886 | 8974 | 1651 | 237 |

⁸ Documentation of reasons for disposal should be available at each laboratory.

⁹ These organs were retained for diagnosis, which is now complete, but which are being held pending the Review Group's code of practice.

¹⁰ Declared separately as 2527, plus 1926 museum.

¹¹ In addition, 820 forensic organs were declared.

¹² In addition, 207 forensic archival organs were declared.

¹³ Only 127 of these are Scottish cases.

| Total held | Reason for difference ^a |
|--------------------|---|
| 75 | <ul style="list-style-type: none"> No difference. |
| 30 | <ul style="list-style-type: none"> Original declaration was individuals, not organs. Deletion of misclassified organs. Sensitive disposal of organs. Additional organs identified. Transfer to Neuropathology Department, Southern General Hospital. |
| 8 | <ul style="list-style-type: none"> New case undergoing diagnosis. |
| 0 | <ul style="list-style-type: none"> No difference. |
| 4 | <ul style="list-style-type: none"> No difference. |
| 943 | <ul style="list-style-type: none"> Addition of museum specimens. New cases undergoing diagnosis. Cases in transitional period. Inclusion of brains held on behalf of Highland omitted from the original declaration. |
| 4220 ¹¹ | <ul style="list-style-type: none"> More accurate count. Inclusion of additional museum specimens. Deletion of some bone specimens. New cases undergoing diagnosis. |
| 161 | <ul style="list-style-type: none"> Deletion of non post-mortem specimens. Additions from other areas of trust. Sensitive disposal of organs. |
| 1101 | <ul style="list-style-type: none"> More accurate count. Transfer out to Yorkhill, Crosshouse and Forensic Medicine. Returns to relatives. |
| 945 | <ul style="list-style-type: none"> Addition of museum specimens. 405 brains returned from Neuropathology. Returns to relatives. |
| 28 | <ul style="list-style-type: none"> Addition of museum specimens. New cases undergoing diagnosis. Sensitive disposal of organs. |
| 33 | <ul style="list-style-type: none"> Original return was individuals not organs. Sensitive disposal of organs. Additional organ found when a hospital closed. |
| 2370 | <ul style="list-style-type: none"> Inclusion of medical school museum. New cases undergoing diagnosis. Deletion of cases not originating from post-mortems. Organs returned to relatives. Sensitive disposal of organs. |
| 579 ¹³ | <ul style="list-style-type: none"> Not included in original declaration. |
| 3 | <ul style="list-style-type: none"> New cases undergoing diagnosis. |
| 362 | <ul style="list-style-type: none"> Deletion of cases not originating from post-mortem. Addition of museum specimens. Transfer in of cases from primary care trust. New cases undergoing diagnosis. |
| 10862 | |

Related issues

During the course of Audit Scotland's visits a number of additional issues were identified.

Sensitive disposal and cremation

The lack of formal guidance on the sensitive disposal of organs is a significant issue for laboratories. Once investigations are completed and relatives have given permission for disposal, it is normal practice for organs to be disposed of as clinical waste, albeit with special procedures. Many pathologists felt that this does not constitute 'sensitive' disposal. This method of disposal results partially from the reluctance of crematoria to undertake cremation of body parts following prior cremation of the body.

Audit Scotland recommends that the Health Department should work with crematoria to ensure that sensitive disposal of organs can be achieved uniformly across Scotland.

Associated with this is the issue of disposal of foetuses. Many pathologists felt that there is a need for effective and accessible documentation of foetuses and their disposal, in light of the large number of enquiries from women who had suffered miscarriage or stillbirth. The forthcoming Clinical Standards Board standards on post-mortem and organ retention will address this issue.

Procurator fiscal practice variation

Laboratories undertaking post-mortems on behalf of procurators fiscal were concerned about the lack of formal guidance from the Crown Office to procurators fiscal. In addition, other issues raised included the significantly different approaches to communicating with families, and the requirement for organ retention for diagnosis. The need for absolute clarity about the role of fiscal post-mortems, the circumstances under which post-mortems should be undertaken, and the responsibility for speaking to the families of the deceased was stressed to the review teams.

Audit Scotland recommends that the Health Department and the Crown Office should work together to address these issues surrounding post-mortems undertaken on behalf of procurators fiscal.

Transfer between trusts

This has been a significant issue for several trusts in the past and the assumption that responsibility has passed from one trust to another has led to situations where bereaved relatives were given incorrect information. Although local solutions are now in place, formal guidance covering the responsibility of the referring and recipient trusts is required.

Audit Scotland recommends that the Health Department issue instructions about the relative responsibility of trusts when organs are transferred.

Reduction in number of post-mortems

Exhibits 2, 3 and 4 show the significant reduction in hospital post-mortems which has occurred over recent years. Several pathologists raised concerns about this because they believe it will lead to less definitive diagnoses and potentially a deskilling effect that, in turn, may have an effect on the future development of clinical care. This highlights the need for good information to be available, and for staff to be willing to approach relatives to ask for consent for hospital post-mortems.

Storage

Many pathologists reported that the transitional period has given rise to problems relating to the storage of organs. At present the majority of laboratories hold post-mortem reports, tissue blocks and slides in perpetuity, but storage of these is starting to be a problem in several laboratories. In some laboratories storage areas pose a health and safety risk to technical staff retrieving material. The Clinical Standards Board standards on post-mortem and organ retention will cover this issue.

Museums

The majority of additional organs identified by Audit Scotland's review are those held in museums and archival collections, largely for teaching purposes. Many of these are specimens which have been kept for thirty years or more, with no identifying information, and which are now starting to deteriorate. Many pathologists stressed the value of these collections, which include examples of diseases which are now rare or unknown. Consideration should be given to how they can be maintained for future use.

Audit Scotland recommend that the Health Department, trusts and universities should considers the future role of museum collections and their long-term maintenance.

Conclusion

All trusts have now put in place rigorous systems for identifying retained organs, reports, associated tissue blocks and slides. Trusts were very open in informing the review teams about mistakes made in the past. Audit Scotland is confident that enquiries can now be dealt with effectively to avoid additional distress to the relatives.

The numbers of retained organs identified in Scotland has increased as a result of significant work on behalf of many trusts to count and classify organs retained, and to identify organs which were not previously included for a variety of reasons. Audit Scotland is confident that the organs now included in Exhibit 5 represent the true picture of retained organs in NHS Scotland in the period November 2001 to January 2002.

Appendix 1: Trusts visited

Argyll & Clyde Acute Hospitals Trust
Ayrshire & Arran Acute Hospitals Trust
Dumfries & Galloway Acute Hospitals Trust
Fife Acute Hospitals Trust
Forth Valley Acute Hospitals Trust
North Glasgow University Hospitals NHS Trust
South Glasgow University Hospitals NHS Trust
Grampian University Hospitals NHS Trust
Highland Acute Hospitals Trust
Lanarkshire Acute Hospitals Trust
Lothian University Hospitals Trust
West Lothian Healthcare Trust
Tayside University Hospitals Trust
Yorkhill NHS Trust

Appendix 2: Review process

A letter to all trust chief executives confirmed the relevant trusts. Audit Scotland asked these trusts to nominate a consultant pathologist and a public health specialist contact.

In advance of visits by the Audit Scotland review team, Audit Scotland provided trusts with documentation setting out the information required (Exhibit 6). The review teams asked trusts to declare all retained organs in the three categories to establish a validated baseline.

Exhibit 6: Information requested

- A comprehensive account of all organs retained at post-mortem, categorised as:
 - archives/museums
 - transitional, ie, taken for diagnosis which has been completed but being held pending further instruction about how to deal with them
 - current ie, still undergoing diagnosis.
- Documentation about key information systems used to record post-mortem related data.
- Contextual information.
- Systems in place to deal with relatives' enquiries.

An Audit Scotland review team visited each pathology department. On completion of the review, Audit Scotland's analysis was discussed with the pathologist and the public health consultant to confirm the factual accuracy.

The review process carried out in each trust is shown in Exhibit 7.

Exhibit 7: Review process

Discussion of background information, covering:

- the scope of the pathology service provided
- the number of sites involved
- storage areas within the sites
- university links
- links with the procurator(s) fiscal
- links with other centres and the tracking of organs sent on for further analysis
- the system for handling enquiries about retained organs
- the number of enquiries received and whether any problems had been encountered.

Visits to mortuaries, museums and stores to view the conditions under which organs and tissue blocks and slides are kept.

Tests of systems to track from retained organs to records and other associated tissue held.

This tested the documentation of retained organs and how this linked to other laboratory information. The review team randomly selected cases from the retained organs store and asked to see all associated post-mortem records, tissue blocks and slides. Where it was not possible to identify these, trusts were asked to show the team's documented reasons why they could not do so.

Tests of systems to track from post-mortem records to retained organs, blocks and slides.

This tested the systems for identifying information about a person when a relative makes a request. The review team randomly selected post-mortem numbers from a number of years and asked to see post-mortem reports, retained organs, tissue blocks and slides for that case. Where it was not possible to identify these, trusts were asked to show the team's documented reasons why they could not do so.



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