

## The Alder Hey affair: implications for pathology practice

In recent years, the general public's confidence in the medical profession has been damaged by several serious incidents and the media fuelled storms that have followed. Notable among these are the murders committed by the general practitioner Harold Shipman, the inquiry into cervical screening at Kent and Canterbury, the activities of the gynaecologist Rodney Ledward, the Bristol Heart inquiry, and the inquiry into the retention of paediatric organs at the Royal Liverpool Children's Hospital NHS Trust (the "Alder Hey inquiry"). Of these, the Alder Hey inquiry is notable in that it will continue to have serious ramifications for the practice of morbid anatomy and surgical pathology.

The Royal Liverpool Children's inquiry was announced in December 1999 to investigate the removal, retention, and disposal of human organs and tissues following postmortem examinations at the Royal Liverpool Children's Hospital NHS Trust. Published in January 2001, the report highlights a catalogue of failures within the NHS Trust, the University of Liverpool, and the Liverpool Coroner's Office, which allowed the systematic removal of organs between 1988 and 1995. In many cases, these organs were removed without informed consent, were not subsequently subjected to histological examination or used for educational or research purposes, and preliminary postmortem reports were left unfinished.<sup>1</sup>

In this article, it is not our intention to comment on the activities of Professor van Velzen, which have rightly shocked both the public and the profession. Equally, we would not wish, in any way, to belittle or add to the distress caused to the families involved in the Alder Hey inquiry. Rather, some months after its publication and, when to a large extent, the media *furor* has subsided, we reflect on the wider implications of the Alder Hey report for diagnostic histopathology.

Despite the best efforts of the senior officers of the Royal College of Pathologists (RCPATH) to explain aspects of historical acceptable practice (RCPATH press releases, 27 September 2000 and 30 January 2001) and update guidelines for the retention of tissues and organs at postmortem examination,<sup>2</sup> the profession has been demonised in the minds of Alder Hey parents and the general public. This has not been helped by some immoderate comments made by the Secretary of State for Health Alan Milburn, although he has acknowledged the "enormous willingness on the professions' part to adapt to the new environment in which we all find ourselves".<sup>3</sup> Histopathologists the length and breadth of the UK have been left bewildered and drained, feeling that there has been a capitulation of professional representation in the face of hostile parents and a tabloid press baying for blood. The recently established Retained Organs Commission has the task of ensuring that all hospitals and universities catalogue their tissue archives and, for a limited time, respond to queries from the general public in a "constructive, honest, and helpful manner".<sup>4</sup> This has placed almost intolerable strains on some senior pathologists, wrestling with the complexities of archival postmortem material in their own institutions and, in good faith, struggling to provide accurate information. It has been immensely time consuming and, in some cities, has generated further hostile media interest.

### Removal of tissues and organs at necropsy

As recognised in the Alder Hey report<sup>1</sup> and the chief medical officer's census,<sup>5</sup> the removal and retention of

tissues and organs following postmortem examination has been widespread in hospitals around the country and is of long standing. Indeed, for many years histopathologists, particularly in teaching hospitals, have taken small samples of tissue at necropsy for histological examination to determine or confirm and refine the cause of death. In many cases, whole organs have been retained for further examination and for educational purposes. In retaining this material, pathologists have acted in good faith and in accordance with contemporary statements of best practice and appropriate consent, albeit with a broad interpretation of the word "tissue". Guidelines for the necropsy and audit,<sup>6</sup> published in 1991 by the joint working party of the Royal College of Pathologists, the Royal College of Physicians of London, and the Royal College of Surgeons of England, recommend that: "histological examination of paraffin sections should be performed in every case". Furthermore, the 1993 guidelines for postmortem reports<sup>7</sup> recommended that in the case of necropsies performed to investigate postneonatal death, histology be performed on at least one block each of epiglottis and larynx, trachea and thyroid; four lobes of lung, heart, thymus, duodenum, head of pancreas, ileum, liver, spleen, mesenteric lymph node, adrenal gland, kidney, costochondral junction of right sixth rib, and muscle; and four to six blocks of the cerebral hemispheres, brain stem, cerebellum, and meninges. Both the Alder Hey report<sup>1</sup> and the chief medical officer's census<sup>3</sup> recognise that the Human Tissue Act 1961<sup>8</sup> was generally adhered to in the way in which necropsies were performed and tissues retained, but this act required only a lack of objection to retention, not consent. Such a concept is now regarded to be overly paternalistic.<sup>3</sup>

Because babies and infants are so small and because of the need to look for congenital abnormalities, it has been common practice to remove most, if not all, of their organs for subsequent examination. Furthermore, although the interests of research in necropsy material have been exaggerated, the outstanding exceptions are in neuropathology and in the investigation of the sudden infant death syndrome. This is reflected in the fact that out of approximately 54 300 organs, body parts, stillbirths, or fetuses identified as being held by pathology services in England at the end of 1999 and retained from necropsies between 1970 and 1999, almost 50% were brains.<sup>3</sup> Although it cannot be denied that other examples exist, on the whole there has been comparatively little important original research that has accrued from the retention of tissues or organs from the adult necropsy.

The value of material retained from necropsies for the education and training of undergraduate medical and dental students and the training of junior pathologists, however, is a different matter. It is no coincidence that the chief medical officer's census<sup>3</sup> showed that most retained organs reside in teaching hospital departments. Has this occurred because the pathologists who work in such departments are perverted and maliciously wish to distress the relatives of the deceased? Of course not. Regular post-mortem meetings and the substantial collections of organs and tissues held within pathology museums around the country (most of which were assembled before 1970 and are regarded as a historical resource of medical and scientific importance<sup>3,9</sup>) have provided an invaluable educational resource which, one hopes, has enhanced medicine in general.

### Implications for the future of histopathology

It is likely that the Alder Hey inquiry will only serve to exacerbate the downward spiral of loss of confidence in the medical profession, which in part is the result of the series of other highly publicised incidents alluded to above. Several years of careful prospective data collection are needed before the full extent to which the Alder Hey inquiry will affect medical practice is known. At present, one can only speculate on the impact that the Alder Hey report will have on the future of pathology in the UK (and around the world). However, it is likely that the report's effects will be wide ranging and impinge on manpower, postmortem practice, surgical pathology practice, and histopathological/molecular research undertaken on human tissues.

### Manpower

Histopathology, and academic histopathology in particular,<sup>10</sup> already faces a manpower crisis, with a pronounced shortage of senior staff across the UK and a predicted 400 vacant posts by 2004.<sup>11</sup> The publication of the Alder Hey report is likely to exacerbate this problem in both the short and long term. In the short term, several pathologists (and in particular, paediatric pathologists<sup>12 13</sup>) have left or are leaving the profession, unwilling to work in such a hostile media climate. In the longer term, the current shortage of academics available to train medical students, coupled with a declining number of school leavers applying to read medicine, as a result of a combination of factors, including rising tuition fees and continued negative publicity that the profession faces,<sup>14</sup> makes it likely that there will be an increased number of unfilled vacancies in histopathology in the future.

### Implications for postmortem practice

The necropsy rate has been in gradual decline for many years.<sup>3 15-17</sup> As yet, there is only anecdotal evidence to suggest that the Alder Hey inquiry has exacerbated this,<sup>15</sup> and it will be some time before the full impact on the necropsy rate is known (JL Burton, JCE Underwood, 2001, unpublished data). The negative publicity attached to necropsies may serve to further this decline by reducing the willingness of clinicians to seek consent, and the general public to grant consent, for hospital necropsies not requested by the coroner. This would have a considerable negative impact on the following: (1) attempts to gain accurate statistics regarding causes of death; (2) the audit of medical care; (3) research where death is an endpoint; (4) the postgraduate training of pathologists and other specialties; and (5) undergraduate medical education. At the present rate of decline, clinical necropsies and the pathologists sufficiently trained to perform them face extinction.<sup>18</sup> Reluctance to grant permission for the retention of tissue, and increased unwillingness to retain small amounts of tissue for histological examination, are likely to result in suboptimal necropsies, whether or not they are performed for the coroner.<sup>9</sup> Given the already low necropsy rate, a further decline would be disastrous and would have implications for the future care of patients in the UK. A reduction in the retention of brains at necropsy would be detrimental to future advances in neuropathology.<sup>18</sup>

The role of the necropsy in research lies principally in determining the cause of death in patients enrolled in clinical trials.<sup>15</sup> In such cases, death may be the result of the intervention under investigation, the disease for which the intervention is being administered, or an unrelated cause. Given that the process of death certification is known to be

flawed, with an error rate approaching 30%,<sup>19 20</sup> it is worrying that so few studies that cite death as an endpoint confirm the cause of death by necropsy,<sup>21</sup> and the possibility that this situation may worsen is alarming. We are now faced with the paradoxical situation of the need for a greater number of and more thorough necropsies for the public good, in the light of the Shipman case, in a climate of increasing public distaste of the procedure and their inexorable decline.

Despite the media furore generated by the Alder Hey report, some comfort can be drawn from the fact that many of the parents involved in the inquiry stated that their objection was not to the autopsy per se, but rather to the undertaking of such examinations without informed consent.<sup>1</sup> The Human Tissue Act 1961<sup>8</sup> states that:

"1-(2) Without prejudice to the foregoing subsection, the person lawfully in possession of the body of the deceased person may authorise the removal of any part from the body for the use of said purposes if, having made such reasonable enquiry as may be practicable, he has no reason to believe—

(a) that the deceased had expressed an objection to his body being dealt with after his death, and had not withdrawn it;

or

(b) that the surviving spouse or any surviving relative of the deceased objects to the body being so dealt with."

Thus, in law, informed consent is not required, one must merely establish a "lack of objection". The Alder Hey inquiry has shown this to be overly paternalistic. In anticipation of the inquiry, the Royal College of Pathologists produced guidelines in 2000 for the manner in which informed consent is obtained. This document includes a sample consent form that specifically seeks to establish not only a lack of objection to the necropsy, but also to the retention, disposal, and use for medical research or teaching of material removed at necropsy.<sup>2</sup> Recently published guidelines on consent and the law in England<sup>22</sup> (available online at [www.doh.gov.uk/consent](http://www.doh.gov.uk/consent)) further emphasise that consent should be informed, that relatives must receive as much information as they reasonably need to make a decision in a form that they can understand, and consent obtained must be voluntary.

It becomes apparent that the solution to this problem lies not in abandoning the necropsy but in ensuring that informed consent is obtained. The Alder Hey report<sup>1</sup> suggests that relatives should be informed of the nature of the examination and given the options to: consent or object to the retention of organs, tissues, and fluids for diagnosis, teaching, and research; to limit the period for which the material is retained; and to state how the material is to be disposed of. The Royal College of Pathologists anticipated this in guidelines for the structure of consent forms published in 2000.<sup>2</sup> These have been widely adopted.

### Implications for surgical pathology practice

In the months following the publication of the Alder Hey report, there has been increasing concern at the knock on effects for surgical pathology practice as pathologists and patients turn their attention to the material generated by routine surgical practice that is stored as part of the patient's medical record in pathology archives. It is not always easy for the lay person to appreciate the distinction between the various types of "retained tissues" and it is, perhaps, not widely appreciated that surgical specimens are retained in the form of tissue blocks for long periods. A tsunami of requests for the return of such material has not yet occurred; were it to do so it would probably paralyse the

service, with the efforts of staff diverted away from current specimens to retrieving those from the archives.

Materials retained from surgical specimens in the form of slides and paraffin wax blocks form a valuable part of the patient's medical record, which allows future reassessment of the diagnosis, clinical audit, the application of new diagnostic techniques as they become available, and research (under the guidance of the appropriate local ethics committee).

How then should pathologists respond to requests for the return of such material? The debate as to who (if anyone) owns surgically removed tissue is complex and beyond the scope of this article. However, traditionally, pathologists have adopted the paternalistic attitude that they have a claim to the material once tissue crosses the threshold of the department. The Alder Hey report and the subsequent public reaction highlight that this is no longer acceptable.

We have seen that it is possible to alter the practice of obtaining consent to render practice more transparent and allow a relative to choose the fate of tissue retained at necropsy. With liaison between clinicians and pathologists it would surely be possible, in the future, to achieve the same for surgical specimens. Although this will require a major change in attitude, it could prevent the need for the implementation of immensely time consuming measures in histopathology laboratories that are already understaffed.

At present, many pathologists, hardened by their years of medical training, would regard requests received from parents for the return of products of conception as an absurd over reaction, given that such material most often is composed of decidua, chorionic villi, and blood clot, but does not include the fetus. Pathologists must come to realise that the discipline serves the public, not vice versa, and, like its ward based counterparts, shares in the duty of care to the patients' psychological well being. It is not our role to impose moral judgements upon parents requesting the return of such material. To the parents the presence or absence of the fetus in the specimen, and its size, may be immaterial. What is mere blood clot and decidua to the pathologist may have been a much loved and wanted pregnancy to the parents.

### Implications for research

Material retained in paraffin wax blocks from surgical specimens once the diagnostic process has been completed provides an invaluable resource for future research on human tissues, particularly with the increasing application of molecular pathology. If this research is to continue, a programme of continuing education of the public is needed. We must emphasise the immense value of the research undertaken on such tissues, but the Alder Hey inquiry has raised the public's awareness of consent issues and, by the same token, we have to earn our rights to custodianship of the surgical pathology archive.

The recently published guidelines from the General Medical Council are primarily concerned with the use of tissue in the context of Medical Research Council funded research projects.<sup>23</sup> The guidelines acknowledge that it is not practicable to seek retrospective consent from individuals for the use of archival tissue for an ethically legitimate purpose and indeed this is not necessary where it is used in an anonymous and unlinked manner. Nevertheless, ethics committee approval must be obtained "for all research projects using samples of human material". However, this still creates problems for histopathologists who carry out "microresearch" on small numbers of cases often accrued from numerous different

centres. Then, there is the use of archival tissue for other purposes such as slide seminars, external quality assurance schemes, and publications. Worryingly, as we write, there are anecdotal reports of certain hospital trusts in the UK having put a blanket embargo on the use of archival tissue.

The highly constructive deliberations of a working party chaired by Peter Furness have recently been published and provide, at last, a pragmatic approach to the way forward and, as such, a lifeline to many histopathologists, who are feeling that key aspects of their professional activity are under threat.<sup>24</sup> These guidelines state the following: "Most research projects will need individual review by a research ethics committee, but this would be unnecessarily bureaucratic for some other uses of human tissue, such as medical audit, routine laboratory quality control, and most teaching applications. Here it will be necessary to approve general procedures. A project would then require specific review only if variation from the agreed general procedure is envisaged.

To avoid curiosity driven microresearch, it may be possible to use approval of a standard procedure for some types of very simple research. An example might be where a pathologist merely wishes to review systemically a group of previously reported histological sections, and no new processing of tissue is involved." These are sensible and welcome suggestions and we hope that common sense will prevail. Meanwhile, pathologists have an uphill struggle to inform the public that we are not merely "doctors of the dead"<sup>25</sup> but are passionately concerned for the well being of the living.

J L BURTON  
M WELLS

*Academic Unit of Pathology, Division of Genomic Medicine,  
University of Sheffield Medical School,  
Beech Hill Road, Sheffield S10 2RX, UK  
m.wells@shef.ac.uk*

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H HOLZEL

P VAN DIEST



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