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What have we learnt from the Alder Hey affair?

That monitoring physicians' performance is necessary to ensure good practice

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In 1999 it emerged that various whole organs, including hearts and brains, had been removed at necropsy from children at Alder Hey Hospital in Liverpool without the knowledge and consent of parents. Parents buried their children without knowing that many had been "systematically stripped of their organs."[1] As parents and physicians we join in the general condemnation of this activity. The important question, however, is what remedies are necessary to ensure that these events—or others that show a similar disrespect for patients' feelings and wishes—do not occur again.

The report of the Royal Liverpool Children's inquiry, published at the end of January,[1] identifies malpractice by one particular pathologist, who removed thousands of organs without consent and stored them unexamined and uncared for. But it also highlights confusion about the coroner's role, management failings in the hospital and university, and, perhaps most pervasive of all, evasive and paternalistic attitudes towards bereaved parents—both during the tenure of the particular pathologist and after the retention of organs came to light.[2]

Among the report's major conclusions are that there were flagrant violations of the Human Tissue Act 1961 relating to organ or tissue removal, retention, and disposal and that Alder Hey and the University of Liverpool, which manages the hospital's Institute of Child Health, failed to provide adequate oversight of staff and to respond to numerous complaints and audits. The report makes many recommendations, both about the legal provisions and the behaviour of clinicians and hospitals towards bereaved parents and relatives. It recommends that the Human Tissue Act should be amended to eliminate any confusion between "lack of objection" and "informed consent"; that the Department of Health and Royal College of Pathologists should instruct pathologists that written consent is necessary to retain samples and organs beyond those necessary to establish the cause of death; and that consent must include the identity of each organ to be retained. A bereavement advisor should be available to help obtain consent in every hospital. If a coroner orders a post mortem then he or she should also ensure that the next of kin know the reason for and nature of the examination and of the need for samples and possible retention of organs.

Anticipating the inquiry and its findings the Royal College of Pathologists released new guidelines last year governing post mortem examinations.[3] These too emphasise the need for pathologists to obtain written agreement to retain whole organs and recommend that hospitals should provide relatives with an information leaflet explaining the purpose of post mortem examinations, the medical benefits of tissue and organ retention, and their rights to grant or withhold consent. The guidelines also state that if the primary purpose of retention of tissue or organs is for research then a research ethics committee must also give its approval. Moreover, unless agreement has been obtained for long term retention for teaching or research, hospitals must give relatives the chance to dispose of retained tissue.

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Why are such guidelines necessary? Why were children's organs removed and saved without the knowledge of their parents? We suggest a number of reasons. Firstly, discussions with parents about necropsies and the retaining of organs for teaching or research at the time of bereavement are complex, time consuming, emotionally difficult, and poorly taught in medical training. Secondly, doctors' decision making has largely been paternalistic. Only in the past few years has shared decision making been recognised as more effective, relevant, and appropriate than the traditional physician-directed model.[4 5] The guidelines from the Royal College of Pathologists[3] and the college's pamphlet on *Examination of the Body After Death: Information about Post-mortem Examination for Relatives*,[6] now reflect this concept of patient-physician communication. But the inquiry suggests that it was not only in Alder Hey that clinicians often assumed a "lack of objection" rather than testing it with uncomfortable information. Thus it is not clear how many of roughly 54 000 organs retained in English hospitals (and identified by the chief medical officer's census[7]) had explicit consent for their retention. There are always physicians who believe that they are above institutional norms and regulations, and the language of the Human Tissue Act—in particular, the phrase "has no objections"—clearly was not always construed to imply the need for informed consent.[7] Finally, and most importantly, without continuing monitoring of physician performance it is always impossible to know whether practice is consistent with standards.

Will the inquiry and guidelines prevent the future occurrence of similar abuses? Unfortunately, we know that passive distribution of educational materials rarely changes how doctors practise medicine. Although these documents, and, more powerfully, public outrage, are likely to influence doctors' behaviour in the immediate future, the NHS and the royal colleges will have to adopt well known and effective measures, such as educational outreach, reminders, and multifaceted interventions,[8–11] to ensure long lasting adherence to the many recommendations. Obtaining truly informed consent from relatives at the time of death will be difficult. We applaud the inquiry's lengthy discussion of, and recommendations on, what constitutes truly informed consent and the royal college's call for more education of clinicians in how to request and obtain agreement for necropsy.

Both the inquiry and royal college guidelines distinguish between organs and tissues retained for educational purposes and those kept for research, and require ethics committee approval if specimens are to be used for research. Distinguishing research from education is important, as most ethics committees have imposed less rigorous standards for education with respect to informed consent and families might feel differently about participating in education and research. We applaud this distinction, but often activities that are initially considered educational become research, so close monitoring of consent for organ and tissue retention will be necessary.

What have we learnt from the Alder Hey affair? First and foremost, unethical and unconscionable practices occurred. Healthcare systems around the world should learn from this and review their practices in obtaining consent at the time of necropsy. Secondly, medicine should never rely on old standards or laws to guide practice. They must be updated regularly, reflecting changes in contemporary medicine. Thirdly, doctors must understand that many patients want to relate to healthcare providers in a different way—they want to be partners in the decision making process. Fourthly, all doctors need to be educated about how to obtain appropriate consent, because it is not usually pathologists who are responsible for obtaining consent. Finally, it is critically important that behaviours that are deemed important in doctors—in this case obtaining written informed consent for organ and tissue removal and retention at the time of necropsy—need to be continuously monitored to ensure adherence with standards.

It may never be possible to remedy the pain and suffering of the families at Alder Hey; their legacy, however, must be that activities like those at Alder Hey never occur again.

Howard Bauchner *professor of paediatrics and public health and scholar, Agency for Healthcare Quality and Research*

(hbauchne@ahrq.gov)

Robert Vinci *associate professor of paediatrics*

Boston University School of Medicine-Boston Medical Center, 91 East Concord St, Boston, MA 02118-2393, USA

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Failure to refer for testing for cystic fibrosis

Doctors must ensure that those with a family history are advised appropriately

The genetics of cystic fibrosis are well understood. It is an autosomal recessive disorder, and relatives of a person with cystic fibrosis have a greatly increased chance of being carriers (two of three healthy siblings of an affected person will be carriers as will one in two aunts or uncles). People without a family history of the disease have a 1 in 25 chance of being carriers. Thus, a couple in which one member carries the disease and one has no family history is 12 to 16 times more likely to have an affected child (that is, in 1 in 150 to 1 in 200 births the child will be affected) than a couple in which neither partner carries the gene (in which 1 in 2500 newborns will be affected). Accurate, quality controlled tests for the common cystic fibrosis mutations have been available through regional genetics services in the United Kingdom for a decade. Yet the number of instances in which a general practitioner has not referred a concerned patient or has behaved in a dismissive manner when informed by a patient of a family history of cystic fibrosis is still too great.

For example, we know of two cases in which children with cystic fibrosis were born to parents who had a family history of the disease; the parents would have opted for testing and prenatal diagnosis had they been offered. Both couples have said that they would have terminated the pregnancy. In one case the parents were told that there were no tests for the disease and in the other that it was too late for testing because the woman was already pregnant. The obstetrics departments involved compounded the problem by not arranging counselling or tests, even though the histories were highlighted in the patients' notes. In one case, the hospital trust settled out of court for £330 000 ($462 000), the other settled for £230 000.

The penalty for failing to look things up or ask for advice is not just litigation: patients or families are damaged for life. Yet in the United Kingdom the Cystic Fibrosis Trust, which maintains close contact with families, frequently hears similar stories. Recent comments made by general practitioners to the

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