Return to an Address of the Honourable the House of Commons
dated 30 January 2001 for

The Royal Liverpool Children's Inquiry

Summary & Recommendations

ordered by The House of Commons *to be printed 30 January 2001*

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This is a short summary of key findings and the main recommendations contained in The Royal Liverpool Children's Inquiry Report.
It is intended for reference purposes only.

Summary

Introduction

1. We set out to enquire into the removal, retention and disposal of human tissue and organs following Coroners' and hospital post mortem examinations and the extent to which the Human Tissue Act 1961 (HTA) had been complied with. This involved examination of professional practice and management action and systems including what information, if any, was given to parents of deceased children relating to organ or tissue removal, retention and disposal.

The Human Tissue Act 1961

2. The clinician's obligation under Section 1 (2) of the HTA is to ascertain if, having made such reasonable enquiry as may be practicable, he has no reason to believe that any surviving relatives of a deceased child object to the body being used for therapeutic purposes, medical education or research. The starting point must be that the clinicians do have reason to believe that parents might object. The scope of the inquiry must be such that at the end of it the clinician can truly say he has no reason to believe that there might be objection.

3. There is abundant evidence of failure on the part of clinicians to make the requisite enquiries of parents to see if they objected. There is no evidence that the medical profession ever attempted to construe the HTA. Even now, we are told that these matters are not dealt with at any stage in the process of medical education and training. However, clinicians did acknowledge in evidence the difficulties in reconciling their 'paternalistic attitude' to the wording of the HTA. They conceded that parents should have been asked, for instance, about retention of hearts. Consequently, the paternalistic attitude cannot be sustained as an explanation for what has occurred. The bald fact is that on the evidence the medical profession did not properly consider the HTA in the first place.

4. The failure to comply with the HTA and the enormity of what happened in the eyes of parents in the van Velzen years can be summed up in the following question:

> 'Would any parent not have objected if told that every organ of their child would be taken and in most cases left untouched for years without even an attempt at clinical histological examination'

The Coroner

5. Organs and tissue were removed and retained at post mortem examination. The provisions of Section 1 (2) and 1 (3) of the HTA apply to retention following hospital post mortem examination. The Coroner has no power to authorise retention of organs for the purposes of medical education and research upon conclusion of a Coroner's post mortem.

6. A clouded view of what the Coroner's jurisdiction requires of clinicians has emerged generally in the course of our Inquiry. There was a lack of precision in the minds of clinicians as to when a death is strictly reportable to the Coroner. Failure to carry out a Coroner's post mortem examination (CPM) in cases where such examination should be performed results in a lack of proper scrutiny of medical practice and the benefits of openness and transparency are lost.

7. The difficulties were compounded in Liverpool because HM Coroner, Mr Roy Barter, considered the decision whether to carry out a CPM as a simple administrative decision which he wrongly delegated to the Coroner's Officer. The decision is one to be taken personally by the Coroner. If there is an intention to retain organs for medical education and research upon conclusion of the Coroner's jurisdiction, the clinician should obtain consent from the Coroner and the parents at the outset, otherwise retention following completion of a Coroner's post mortem examination is illegal.

8. Mr Barter had no proper system for specifying the cases in which histology was required or identifying the organs or tissue to be preserved for histological examination by the pathologists. On several occasions, Sudden Infant Death Syndrome (SIDS) was accepted by him as the proper cause of death without histological examination being carried out, when he knew or should have known that SIDS was a diagnosis of exclusion. In failing to insist upon histology, he must have recorded an inaccurate cause of death in a number of cases.

9. He should have known that the reports he received from Professor van Velzen were preliminary reports without histology, particularly in SIDS cases. His systems were inadequate and there was no system for chasing up histology or final reports.

10. Clinicians were uncertain as to which deaths should be reported to the Coroner. Some clinicians applied the threat of a Coroner's post mortem examination to obtain consent to a hospital post mortem examination. The Liverpool Coroner's Officer in determining whether there should be a Coroner's post mortem examination was satisfied as to the cause of death identified by the clinician in circumstances where the Coroner might well not have been satisfied.

11. Slackness in Mr Barter's procedures undoubtedly contributed to the delay in identifying Professor van Velzen's abuse of post mortem procedures.

Organ Retention 1948–1988

12. The heart collection started in 1948. The period in question can be conveniently referred to as the 'pre van Velzen era'. Throughout this period, hearts were collected usually without parental knowledge or lack of objection having been established. The evidence indicates that it was normal practice to remove organs at post mortem examination and take samples for microscopic examination, thereby enabling the organ to be returned to the body for the funeral. However, any organs such as the heart or brain which had to be fixed before they could be examined, necessarily meant that not only were they usually retained without consent, but they could not have been returned to the body because they would take between six and eight weeks to fix.

13. The practice we have described seems to have been of general application. The medical justification is a manifestation of the paternalistic approach, namely the policy of restricting the freedom and responsibility of parents in their supposed best interests. In mitigation, it is stated that the heart collection has served to reduce the mortality rate following cardiac surgery for some serious conditions and malformations from 33% to 3%. This benefit cannot be ignored, but it is no justification for ignoring the parents' rights.

The Collections

The Heart Collection

14. The heart collection was started in 1948 by Dr John Hay, subsequently Professor of Child Health, and became clearly established in the period 1948–1954 and since then has continued to grow. It resides at the Institute of Child Health (ICH) at Alder Hey. In October 1999 the heart record books released to the Inquiry referred to 2,128 hearts. It is regarded as one of the leading two collections in the country and one of the most extensive in the world. It has been used by many specialists, both national and international. In 1978 it attracted funding from the National Heart Research Fund and subsequently the Greenwood Trust, the British Heart Foundation and the Endowment Fund of the Royal Liverpool Children's Hospital. The University of Liverpool is responsible for management of the ICH. The premises are actually at the Alder Hey site where clinicians have direct access for education, research and surgical purposes. Overall, on all the evidence, we concluded that the ultimate responsibility for the collection was joint, between the University and Alder Hey.

The Fetal collection

15. The fetal collection at the ICH was recorded in February 2000 as containing 1,564 stillbirths or pre-viable fetus including 52 late premature or term fetus, although none since 1973. The store of primarily intact fetal tissue started in 1955 with identification details from 1975 and ceased in 1992. The collection was again started by Dr Hay. In 1986 the new ICH building was opened and included a room specifically designed for the fetal store. At one stage the collection contained a total of 3,575 fetus but in the three years before transferring to the new ICH building, a substantial number were incinerated. In replying to the Chief Medical Officer's census in February 2000, the University accepted that it bore responsibility for the fetal collection in the ICH.

The Fetal Collection at Myrtle Street

16. Following Professor van Velzen's arrival in 1988, fetus began to be referred to his Unit of Fetal and Infant Pathology by the Unit 3 management group including Mill Road Hospital, which closed in 1992, Liverpool Maternity Hospital, which closed in 1995, and the Women's Hospital in Catherine Street, which closed in 1995. The three hospitals were subsequently incorporated into the Liverpool Women's Hospital NHS Trust which was established in 1992. This was essentially a diagnostic regional service for fetal abnormalities and approximately 100 fetus per year were received. The service did not exist prior to Professor van Velzen's appointment. Due to Professor van Velzen's failure to attend to the fetal pathology service, a backlog built up and was never resolved. In December 1999, 445 fetus were retained at Myrtle Street dating back to 1989–1991. Of the 445 fetus, 198 were intact. In February 2000, a further 30 fetus were identified. There seems little doubt that the majority of fetus at Myrtle Street came through the NHS diagnostic route and the remainder were transferred by the ICH. Limited research has been carried out upon this fetal collection. Alder Hey must accept broad responsibility for the Myrtle Street fetal collection. However, its uses included research activity by the University, who must accept some responsibility for its existence.

The Collection of Children's Body Parts at the Institute of Child Health

17. The store contains a number of children's heads and intact bodies dating back to dental cleft palate research in the 1960s. Some material was disposed of by proper funeral arrangements and much was disposed of at the time of the move from the Dental Hospital. The material transferred to the ICH did form the basis for research until 1973/74. A number of hospitals supplied bodies, once consent had been provided, for research purposes. The store now consists of 22 body parts from 15 children. There are 13 post natal heads/parts of heads from children from a few days old to 11 years of age dating back to the 1960s and 22 heads from late premature/term fetus. There are two containers with a whole body of a child in one and the separated head in the other. Perhaps the most disturbing specimen is that of the head of a boy aged 11 years. The most recent specimen was obtained in 1973. There was extensive publication in

relation to the work undertaken in respect of cleft palate malformation. There is no doubt that responsibility for this collection lies with the University, given the nature and purposes of the collection.

The Eye Tissue Collection at the Royal Liverpool University Hospital

18. The University notified the Inquiry of the fetal eye collection on 24 March 2000. It took some time for us to obtain facilities to view the collection. We established that the store contains 188 eyes and 2 optic nerves from 109 specimens. The majority consists of both left and right eyes but there are some specimens where only one eye is present. A number of the eyes were removed from children at post mortem examination at Alder Hey. The majority were obtained from fetus but we highlighted 12 cases where eyes had been taken from identified neonates and children. The youngest child had lived for only an hour, the oldest for 21 months. The specimens were taken from fetus as long ago as 1988. A total of 79 of the 109 specimens had been used in research. The other specimens in the collection remain intact, stored in fixative. There are 100 analysed eyes and 88 unanalysed eyes. All the eyes have been retained and are stored in a double locked room in the Royal Liverpool University Hospital. The eye collection is clearly a store for which the University has ultimate overall responsibility.

Animal Material at the ICH/Myrtle Street

19. Within the heart collection but separate from it are a small number of animal hearts retained essentially for comparative work. There are a small number of hearts from pigs, lambs, rats and chicks. There are some hearts from very rare species of animals including a red kangaroo, a gibbon and a giant tortoise, given to the ICH for comparative studies. These hearts are kept on a completely separate shelf from human hearts and are clearly identified. There is no suggestion that the animal hearts have been stored in the same containers as human hearts. Some animal material was also stored at Myrtle Street in the basement. In particular, there was research on lamb and piglet hearts in relation to cot death. This material was stored separate from human material and there is no question of animal material having been held in the same container as human tissue or organs.

Cerebellum Collection

20. In August 2000 we discovered the existence of a cerebellum collection. The cerebella had been taken from brains already held at Myrtle Street, where they had accumulated during the van Velzen years. Alder Hey revealed that 147 families were affected and in particular, 58 sets of parents who had already had second funerals were told that there were cerebella yet to be buried. The University held back the existence of the collection in late 1999, probably in order to complete research. It retained the collection despite public knowledge of return of organs for second funerals and the inevitability of third funerals.

1988 to 1995 – The van Velzen Years

21. On 20 March 1987 the Foundation for Sudden Infant Death (FSID) made an offer of £250,000 over a five-year period to fund a new Chair in Fetal and Infant Pathology in the Department of Pathology. The sum was to provide salaries for two clinical lecturers, a research technician and a secretary. Support from FSID was on the understanding that a substantial part of the research effort would be devoted to the problem of cot death. The offer was accepted.

22. Professor Wigglesworth, one of the external assessors, did not believe that the planned resources were sufficient to underpin the successful provision of a clinical service and felt that the Chair would fail on that ground.

23. There was a feeling within the selection committee that Dr van Velzen was to be appointed despite the fact that he had only published about 27 papers, 20 of which were in Dutch although English is the language of choice in international publications. Even his supporters identified him as a risky appointment. He was 38 years old. He told the interview committee that he had been to see Miss Malone, the Unit General Manager of Alder Hey, to discuss the clinical service. This was a lie.

24. The appointment was against a background of almost unanimous concern for the resources available. The premises and equipment were inadequate. The clinical resource amounted to 1–1½ days per week. The University authorities ignored all convincing advice and informed warnings.

25. The post of Senior Lecturer was not filled apart from Dr Chan at lecturer level between late 1989 and early 1991 and a locum, Professor Ronald Kaschula, throughout 1994. The two clinical lecturers' positions were only filled with one clinical lecturer, Dr Khine, and only after 14 October 1991.

26. Within a week of taking up the Chair in 1988, Professor van Velzen issued an instruction in the Unit of Fetal and Infant Pathology that there was to be no disposal of human material. The store of material began to grow and due to his practice and need for samples, this meant whole organs. The decision not to dispose of any material was taken before any backlog developed and indicates that lack of resource was not the overriding motive for retention of organs.

27. Shortly afterwards, Professor van Velzen stopped histological analysis of organs as part of his routine clinical analysis. Instead, he prepared lengthy and apparently detailed reports based upon naked eye findings at the time of evisceration.

28. In 1989 a computer system was installed at Myrtle Street and Professor van Velzen started using a template for post mortem reporting which he amended himself in each case.

29. Professor van Velzen submitted preliminary reports without histological analysis. A backlog of preliminary post mortem reports built up, as well as a backlog of post mortem histology and final reports.

30. Professor van Velzen made no secret of the fact that he was no longer providing post mortem histology which had been provided by his predecessors.

31. Research became the main activity of Professor van Velzen, particularly into SIDS with the main research being into the consequences of intra-uterine growth retardation. He used the research tool of stereology which required whole organs.

32. By the spring of 1991 at the latest, the Executive Board at Alder Hey knew that post mortem histology was not being carried out.

33. By the autumn of 1992 at the latest, the University knew that Professor van Velzen was not fulfilling his contract for clinical sessions.

34. A joint NHS and University audit in 1992/3 was ineffectual.

35. A joint NHS and University review in June 1993 failed to identify and act upon the shortcomings of the Department as a unit when it was known to both parties that post mortem histology was still not carried out.

36. The management vacuum at the University caused by the retirement of Professor Heath as Head of the Department of Pathology was not effectively filled until 1994 upon the arrival of Professor Christopher Foster.

37. Professor Foster was the first person to provide proper supervision, appraisal and a job plan for Professor van Velzen in early 1995, which should have been the result of the joint University and Alder Hey review in 1993.

38. During the course of his period in Liverpool, Professor van Velzen was guilty of the following activities:

- immediately upon his arrival, Professor van Velzen ordered the unethical and illegal retention of every organ in every case for the overriding purpose of research;
- falsifying records, statistics and work output;
- falsifying research applications;
- falsifying post mortem reports;
- falsely representing that SIDS diagnoses were supported by histological examination and presenting peer reviewed papers on the basis that the subject-matter was based upon authenticated SIDS cases when no histology had been carried out;
- ignoring written consents to limited post mortem examination;

- lying to parents about his post mortem methods and findings;
- misleading the Chief Executive at Alder Hey, Miss Hilary Rowland, about his clinical practice at post mortem examination;
- failing to respond to the exhortations of clinicians and management for the timely provision of post mortem reports and histology;
- delaying reporting on post mortem examination and histology to such an extent that in at least one case a second child was born with the same genetic condition as an earlier child of the family;
- failing to provide a fetal pathology service in the early years and later an effective service;
- causing an unnecessary excessive, illegal and unethical build up of organs following post mortem examination, ostensibly for research but with no likelihood that the bulk of the organs stored in containers would ever be used for research;
- failing to keep a proper catalogue or record of the stored organs;
- failing to keep a proper record of access to the stored organs for research purposes;
- encouraging staff to falsify records and statistics;
- failing to maintain proper accounting procedures in his Department;
- absenting himself from clinical practice without any or proper cause;
- practising deceit upon the Foundation for Sudden Infant Death, the University and Alder Hey;
- denying clinicians the opportunity of providing proper clinical advice to their patients and the opportunity to consider referrals for genetic counselling; and
- taking with him complete medical records from Alder Hey when he left and leaving the Department with a budgetary deficit of more than £70,000.

39. Professor van Velzen must never be allowed to practise again. We will report his conduct to the General Medical Council and the Director of Public Prosecutions.

Management Failings

40. Alder Hey and the University failed properly to resource the Chair of Fetal and Infant Pathology from the outset.

41. Alder Hey and the University ignored warnings from independent assessors about the essential requirements of the post not being available.

42. Alder Hey and the University, knowing of the risks inherent in the appointment of Professor van Velzen to the Chair of Fetal and Infant Pathology, failed to supervise and performance manage the new unit.

43. Alder Hey and the University failed in conjunction with the Mersey Regional Health Authority to provide resources for the perinatal pathology service in response to Professor van Velzen's cries for help in 1988 and 1990.

44. The University failed at any stage to recognise their responsibility to resource the Chair of Fetal and Infant Pathology.

45. Alder Hey and the University failed to implement the job plan and additional supervision laid down by their Joint Review in 1993.

46. The Chief MLSOs were complicit in Professor van Velzen's falsifications and the Service Manager at Alder Hey allowed himself to be sidelined.

47. Alder Hey and the University failed to ensure that histology was reinstated when they became aware that Professor van Velzen had abandoned the service from spring 1991 in the case of Alder Hey and June1993 in the case of the University.

48. Alder Hey and the University failed to monitor and follow up complaints about delay in providing post mortem and histology reports.

49. Alder Hey and the University permitted Professor van Velzen to abdicate his clinical duties and responsibilities.

50. Alder Hey and the University missed numerous opportunities to discipline Professor van Velzen for justifiable reasons from 1989 onwards.

51. Alder Hey and the University failed to investigate Professor van Velzen's post mortem practice in the period 1988 to 1995 which would have revealed the retention of every organ in every case.

52. Alder Hey and the University failed to apply or follow up proper audit procedures and management systems to Professor van Velzen's Unit of Fetal and Infant Pathology throughout his tenure when there was reason for continuing audit.

53. Alder Hey failed to institute proper cataloguing of organs and left them to the University without establishing a proper audit trail in the event of future inquiry.

54. The University failed to institute a proper system for cataloguing organs.

55. The University consistently ignored its conflict of interest with Alder Hey and FSID.

56. Alder Hey and the University failed to prevent Professor van Velzen's excesses, thereby imperilling patient care.

Handling the News of Organ Retention from September 1999

57. Alder Hey and the University should have retained a paediatric pathologist to head a team to catalogue the retained organs and fragments in September 1999. This exercise would have revealed the impossibility of accounting accurately for all the organs retained because of poor record keeping and unrecorded research access to the organs. Neither Alder Hey nor the University will ever be able accurately to tell parents what happened to every organ of every child who died between 1988 and 1995. The University has never accepted its responsibility in the matter and has left Alder Hey to make a sequence of mistakes. These include four or five attempts to provide parents with accurate information relating to organ retention, not learning from and compounding mistakes made in each previous attempt. The cerebellum collection and the eye collection should have been identified and revealed earlier by both Alder Hey and the University.

58. Alder Hey failed to make sufficient provision for face to face communication of the news of organ retention to parents. They failed to provide suitable advice, counselling and support necessary to affected families. Even though Alder Hey were faced with a unique situation in terms of the amount and condition of organs at Myrtle Street, there was a lack of proper management which resulted in the dripfeeding of information to parents and the provision of information which was frequently inaccurate. No proper attempt at cataloguing was carried out until June 2000. The result was that each piece of news given to parents had the cumulative effect of exacerbating their reaction. From the outset they should have retained a Consultant Psychologist to assist in devising the best method for approaching parents affected.

The Parents

59. Throughout this Inquiry, the parents' interests have remained paramount. Only by analysing their evidence is it possible to appreciate the impact of these events upon them. The essence of their complaint is that they were deliberately misled into thinking that they were burying their deceased children intact, when in fact each child had been systematically stripped of his or her organs, a large majority of which remained stored and unused from 1988 to 1999. The inadequate handling strategy adopted by Alder Hey merely served to aggravate the situation to the extent that some families have faced numerous funerals as a result of organs being returned to them on a piecemeal basis over the past 14 months. There are still organs awaiting repatriation.

Recommendations

Chapter 3. Handling of the organ retention issue September 1999 to date

Recommendations

To prevent mishandling of this kind in the future we make the following recommendations:

- Serious Incident Procedures should be developed and put in place.
- In the event of a serious incident the Chief Executive and Trust Board shall devise a suitable Serious Incident Procedure similar to those already in place for major disasters and review it from time to time making any necessary alterations.
- When the procedure has been devised and prior to implementation the NHS Executive Regional Office shall assess its suitability and thereafter manage its performance, devising and instigating any necessary alterations from time to time.
- In devising a Serious Incident Procedure the Chief Executive and Trust Board shall consider the need for a serious incident team independent of the hospital.
- In devising a Serious Incident Procedure the Chief Executive and Trust Board shall consider the need for urgent professional counselling:
  - A proportion of individuals within any group is always likely to require psychological support in the aftermath of disaster.
  - An individual within the serious incident team shall be nominated to take responsibility for the arrangements and the identification of all those in need.
  - Suitably trained practitioners shall provide the counselling.
- In devising a Serious Incident Procedure the Chief Executive and Trust Board shall take advice from and where necessary include within the serious incident team appropriate experts in bereavement, pathological reactions to bereavement and therapy.

- The Chief Executive and Trust Board shall make available suitably trained staff for implementing the Serious Incident Procedure.
- The Chief Executive and Trust Board shall inform all staff when a Serious Incident Procedure is in force.
- The Chief Executive and Trust Board shall ensure the proper debriefing and support of all staff associated with a serious incident.
- Universities and other public bodies shall adopt compatible procedures when acting in conjunction with an NHS serious incident.

Records should be reviewed and updated and an audit trail should be developed and put in place.

- The Chief Executive and the Trust Board shall review and update medical and pathology records to include, preferably on computer and cross-referenced, the following information:
  - name, medical record reference number and date of birth;
  - date, place of death and death certificate;
  - name and address of next of kin;
  - whether Coroner's or hospital post mortem examination;
  - date of consent for hospital post mortem examination;
  - names of pathologist and those in attendance;
  - post mortem examination reference number;
  - date of examination;
  - date of preliminary/final post mortem reports;
  - date histology completed;
  - record of specific instructions from the Coroner or clinicians;
  - record of retained organs, samples, wax blocks, slides, photographs, X-rays, date and method of dispersal or disposal;
  - case notes;
  - signed consent form;
  - copy of any other relevant correspondence or notes;
  - name and address of general practitioner;

- date post mortem report sent to general practitioner;
- record of communication of findings to the next of kin.

- University records shall provide a confidential audit trail back to the clinical record.
- University records shall identify receipt, use, dispersal and ultimate disposal of any organ or sample.

Chapter 8. The van Velzen Years

Recommendations

The following recommendations arise out of the mistakes in the 'van Velzen Years' and are essential to avoid their repetition in the event of the coming of another Professor van Velzen. The recommendations are evidence-based in the sense that they are straightforward safeguards based on our analysis of the actual mistakes made by both Alder Hey and the University. Many of the mistakes are of a type that must be frequent but do not in the usual course of events lead to disaster. They are nevertheless better avoided.

Our recommendations are also evidence-based in a different sense. The themes in the recommendations formed the basis of the actual questioning during the course of the Inquiry. They have been tested not just by us in our deliberations but also gauged against the reaction of witnesses to the potential criticisms raised. Very few witnesses had any difficulty in seeing the force of the points and most were comfortable to concede what should have been the tests governing the behaviour of them and others involved. The difficulty came not in terms of the concept but when people found on reflection that they had not lived up to the sentiments expressed. Mutual trust between universities and hospitals could have avoided the worst excesses of Professor van Velzen. All witnesses agreed that such trust is essential for the future.

Relationship Between Universities and Trusts

Whatever the underlying contractual position, the relationship between Universities and Trusts, in respect of individuals and departments with dual clinical and academic functions, shall be one of the utmost good faith in both directions.

The duty of utmost good faith shall require either party to disclose to the other any substantial matter relating to the performance of the individual or department, whether clinical or academic.

Where there is any doubt as to whether a matter is of a substantial nature, if it relates to patient care the doubt shall always be resolved in favour of disclosure.

The appointment of clinical academics shall be approached with fair representation on each side reflecting the proposed split between clinical and academic sessions.

The appointment of external advisors shall be approached on the basis that they are truly external, if not strictly independent in a legal sense. There is no point having external advisers as 'window dressing' for a fixed internal view. Where they or representatives of the Royal Colleges give advice, proper weight shall be given to that advice. In giving advice, external advisers shall bear in mind the paramount requirement of patient care where there is a conflict of interest.

A single job description for clinical academics shall be drawn up jointly to represent a fair and realistic expectation of the work envisaged by both parties.

There shall be a joint procedure for disciplinary action against an individual perceived to be failing. It shall contain provision for immediate suspension from patient care as a minimum, irrespective of academic requirements and positions.

There shall be formal annual appraisal of an individual by both parties. They shall share their information in line with the duty of utmost good faith in order to draw up a joint statement of aims in the following 12 months against which the next appraisal is to be judged.

Where there is disagreement each party shall reconsider bearing in mind that patient care is of paramount importance. In the event of continued disagreement an arbitrator may be appointed, but in any case the Trust shall take immediate steps to secure proper patient care.

The relationship between Universities and funding bodies shall be of the utmost good faith and similar considerations shall apply.

New Ventures

Where a new venture, such as the establishment of a Chair or department, is contemplated, both parties where appropriate shall consider in detail the aims and resources available and draw up a realistic business plan before any final commitment is made. As in all these matters, if patient care is to be included in the venture, patient care shall be paramount in its consideration.

There shall be close performance management of any new venture in its early stages and appropriate steps taken to modify the business plan as required.

Any substantial alteration in an existing venture shall be treated as if a new venture.

Audit

Where there is good reason to believe that an individual or department may be failing and affecting patient care, it shall be the duty of the Trust with the co-operation of the university, and if appropriate on a joint basis, to investigate. Investigation shall continue until the problems are identified or it is found that in reality no problem exists. Where appropriate, independent outside assistance shall be obtained.

Where problems are identified a plan, jointly where necessary, shall be drawn up to resolve them as soon as possible.

If no solution is found after all diligent attempts, the parties should keep records of their attempts and the reasons why they have failed, such records to be lodged by way of report to the relevant NHS Executive Regional Office.

Management Standards

No clinician shall be appointed to a position of managerial authority in a hospital without having relevant clinical experience for the position.

No clinician should take effective control of a management position until trained in all necessary management techniques and in any relevant legal requirements.

No clinician shall be asked to take on responsibilities that impair the ability to carry out patient care to the appropriate standard.

Hospital managers shall be of a suitable background and calibre for the role expected of them, provided with all necessary training (including continued education) and themselves regularly appraised for the quality of their performance.

Hospital managers without medical qualification shall seek medical advice on matters requiring it. If there is doubt as to the need for advice on any matter relating to patient care, the doubt shall be resolved by seeking advice.

While hospital managers will usually seek medical advice from the medical director or clinical directors in the first instance, if any substantial doubt remains they shall seek advice from independent specialist medical advisers or the Royal Colleges, whether directly or through their regional advisers.

Chapter 9. The Coroner

Recommendations for Clinicians

- The Department of Health, the Royal Colleges and medical schools shall instruct members of the medical profession in the precise terms and provisions of the Coroner's Act 1988 and in particular the circumstances in which it is obligatory to report cases to the Coroner.
- Clinicians shall give the following basic information to the next of kin when a Coroner's post mortem examination is to be performed.
  - The nature of the examination, including the need to open the body and to remove and weigh organs.
  - The need for samples and possible retention of organs.
- Clinicians wishing to retain organs or samples after the end of the Coroner's process for the purposes currently allowed under the Human Tissue Act 1961 shall follow the Recommendations in Chapter 10.
- Clinicians shall not mention to the next of kin the possibility of an examination under the Coroner's jurisdiction unless the death is reportable to the Coroner.
- Clinicians requesting a hospital post mortem examination after the Coroner has declined to authorise an examination shall make it clear to the next of kin that there is no compulsion remaining for such an examination.
- Clinicians shall explain the contents and implications of a Coroner's post mortem report to the next of kin as if the examination had been carried out as a hospital post mortem examination on their own recommendation.

Recommendations for Coroners

- The Coroners' Society shall instruct Coroners that:
  - in the proper exercise of their judicial discretion, the decision to order a post mortem examination is not to be delegated to Coroner's Officers and Deputy Coroners must be available at all times;
  - organs are not to be retained unless relevant to establishing the cause of death and only when specified by the pathologist in writing.
- The Home Office and the Coroners' Society shall ensure all necessary medical education for Coroners.
- The Home Office and the Coroners' Society shall ensure all necessary training of Coroner's Officers and ancillary staff.
- Coroners shall be introduced, their function and procedures explained and the next of kin invited to express any specific concerns and requests.
- If a decision is made to authorise a post mortem examination Coroners shall ensure that the next of kin are advised of:
  - the reasons for authorising the post mortem examination;
  - their right to ask the Coroner that the examination be carried out by a pathologist independent of the hospital in which the deceased died;
  - the place and time of the examination and the identity of the pathologist;
  - the nature of the examination, including the need to open the body and to remove and weigh organs;
  - the need for samples and possible retention of organ;
  - their option to delay the funeral, while the pathologist fixes and examines any organs, to enable the return of the organs to the body for burial or cremation;
  - their option for a funeral without the return of the organs, in which case they shall be invited to consent to respectful disposal by the Coroner;
  - their option to make their own arrangements for respectful disposal of the organs.
- If a decision is made not to authorise a post mortem examination, Coroners shall notify the next of kin of that decision and give sufficient reasons for the decision.
- Coroners shall ensure the expeditious examination and recording of samples and organs.

- Coroners shall establish efficient systems for securing final post mortem reports following histological examination.
- Coroners shall ensure that all existing retained organs, tissue, blocks, slides, photographs and X-rays are specified within any preliminary and final post mortem reports.

Recommendations for Pathologists

- The Royal College of Pathologists shall instruct all practising histopathologists that they shall not retain samples and organs beyond those reasonably incidental to establishing the cause of death unless there is also written consent properly obtained under the Human Tissue Act 1961.

Chapter 10. Human Tissue Act

Recommendations

We respectfully recommend that:

- The Department of Health, the Royal Colleges and medical schools shall instruct members of the medical profession in the precise terms and provisions of the Human Tissue Act 1961, on the basis of our analysis, and the need for strict compliance.
- The Human Tissue Act 1961 shall be amended to provide a test of fully informed consent for the lawful post mortem examination and retention of parts of the bodies of deceased persons. While we have concluded that there has been little difference between 'lack of objection' and 'informed consent' in practical terms for the next of kin, it is important that the law and future practice are brought into line and updated.
- The class of persons relevant to the obtaining of fully informed consent shall be defined as the 'next of kin'.
- The class of 'any surviving relative' shall no longer be relevant to post mortem examination.
- There shall be a programme of health education for the public relevant to the medical need for continued post mortem examination and access to organs and samples for therapeutic, educational and research purposes.

- The Department of Health, the Royal Colleges and medical schools shall provide training for all those involved in obtaining fully informed consent.
- The Human Tissue Act 1961 shall be amended to impose a criminal penalty by way of fine for breach of its provisions in order to encourage future compliance.
- Guidelines relating to the requirements of the Human Tissue Act 1961 and the obtaining of fully informed consent shall be drawn up and provision made for breach to result in disciplinary proceedings which could lead to suspension, dismissal or financial penalty.
- The Human Rights Act 1998 makes provision for an effective remedy other than in criminal proceedings. If breaches of the Human Tissue Act 1961 amount to breaches of the Human Rights Act 1998 consideration shall be given to incorporating a financial remedy with the Human Tissue Act 1961 itself. If necessary, reference should be made to the Law Commission.

Chapter 11. Consent

The whole of Chapter 11 is included. It sets out a way forward for fully informed consent and makes recommendations for a new NHS post mortem consent form for children.

Contents

1. Consent to Post Mortem Examination of Children

1.1 In the preceding Chapter we concluded that fully informed consent is required and nothing less. Fully informed consent must be freely given without imposition of pressure. It is the application of basic principles of respect for the person, their welfare and wishes.

1.2 Comprehensive information is required to obtain a valid consent. Parents must be informed of the identity of each organ to be retained and the purpose for which it is to be used. Dr Peart, a Consultant Paediatric Cardiologist at Alder Hey, accepts that consent forms must be specific about every organ to be retained. Blanket consent is inadequate for organs but is worthy of further consideration with regard to the retention of small tissue samples for diagnostic purposes, medical education and research.

1.3 Fully informed consent means that a person must have all the information required to form a final decision. It is not enough for clinicians to tell the next of kin that they would like to examine the body after death and this might involve taking some tissue. The next of kin need to understand what is involved in a post mortem examination, including a description of whole body systems, removal of the brain and the steps necessary to remove various organs, no matter how distasteful the giving of this information might be to the clinician concerned.

1.4 Paternalism is defined in the *Concise Oxford Dictionary* as follows:

> 'the policy of restricting the freedom and responsibilities of ones dependents in their supposed best interest'.

1.5 We accept that for some clinicians it might be unpleasant to provide the detailed information necessary to obtain consent. However, their responsibility cannot be avoided. A practical test for the clinician in considering whether he has given full information is to question whether any significant detail not mentioned could have led to a different decision by the next of kin. If so, then the test for fully informed consent will not been met.

1.6 The issue of consent arises at a time of extreme grief. Nevertheless, a post mortem examination should be completed as soon as possible to obtain the best clinical results. It is not possible to allow sufficient time to assuage grief. Therefore, consent must be discussed with sensitivity, openness and the necessary detail to enable clinicians to discharge their duty.

1.7 Clinicians agree that they are best placed to obtain fully informed consent. With proper training, they should be able to communicate effectively and sympathetically with the necessary medical knowledge to inform the next of kin. They must understand the value and process of post mortem examination in the clinical setting and also what it means for relatives. We regard it as best clinical practice for clinicians to work closely with pathologists who can assist in determining which organs should be retained for the relevant purposes. They can also assist parents in providing detail relating to the cause of death.

1.8 The general public should be educated to understand how human tissue is stored and archived as an ongoing resource for the general benefit of society. For example, the general population benefits from a better understanding of disease and more effective

treatment becomes available. The annual influenza epidemic is better managed now than ever before. Researchers are able to access archives to study a previous particular strain of influenza virus and can therefore improve preventative treatment when that strain reappears in any particular year.

1.9 If the Liverpool experience represents general practice there must be substantial archives of human material at various locations around the country, most of which have been obtained unlawfully. We cannot undo the wrongs perpetrated in obtaining that material, but can now consider what should happen in the future. In relation to retained organs or tissue it is the right of surviving relatives to request respectful disposal, and they must be given that opportunity. If relatives do not demand respectful disposal now this material may be of great value to society, if it is used for research and education in the future.

2. Consent Forms in the Future

2.1 We have considered a number of consent forms for hospital post mortem examination. Until recently all Alder Hey consent forms referred solely to 'tissue' and not 'organs'. The parents are keen to use the terms which are defined by the *Concise Oxford Dictionary* as follows:

'Tissue': A collection of cells specialised to perform a particular function.

'Organ': A part of the body composed of more than one tissue that forms a structural unit responsible for a particular function.

2.2 We have also considered a model consent form contained in the publication by The Royal College of Pathologists in March 2000 entitled 'Guidelines for the Retention of Tissues and Organs at Post Mortem Examination'. The model is formal and complex.

2.3 None of the forms we have seen provide the basis for clinicians to obtain fully informed consent and properly to set out and record the decision. Clear, informal language is essential. It appears to us that the more official the form, the less efficient it is in practice. Understanding, particularly in grief, is vital. We suggest a new approach.

3. New Approach to Consent

3.1 A more flexible yet formal document is required, setting out all the options clearly. It should be used nationally. The document should be in a question and answer format capable of covering the needs of any individual case. It should be completed jointly by the clinician, a bereavement adviser and the next of kin. We have heard evidence

that the specialist cardiac liaison nurses at Alder Hey have successfully taken up a role supporting parents and clinicians in the obtaining of consent. It works well and clinicians, as much as the parents, value the support that this system provides. This role should be performed in a wider context by bereavement advisers and we recommend that it is adopted nationally.

3.2 The form will be longer than the existing form. This will allow the questions to be drawn up more sensitively and to cover all areas necessary for fully informed consent. It should include any instruction from the next of kin for final disposal of organs or tissue. The next of kin should be provided with a copy of the document which should be signed by the clinician, bereavement adviser and next of kin. Later sections of the same form could deal with other matters related to the death, with which the bereavement adviser can assist. This written record will ensure that clinicians discharge their responsibility to provide all necessary information to the next of kin. The next of kin can then discharge the responsibility placed upon them by the Human Tissue Act 1961 to make an informed decision.

3.3 Once the consent form is signed we favour the next of kin relinquishing further control. This relinquishment is to be subject to the next of kin having the right to specify how, following completion of the purpose for which it was retained, the material should be disposed of respectfully. This is to include their specified religious requirements. We have already stated that the intended use of any organ to be retained must be explained fully to the next of kin. A more liberal attitude should be considered with regard to the retention and use of tissue, particularly in the form of wax blocks and slides. These are of invaluable benefit for research and teaching. They may also be an important resource for families who may seek access to archived material for the benefit of their family and future generations.

3.4 Retained tissue is an invaluable asset for diagnostic as well as research purposes. Once fully informed consent has been obtained for its retention and use, the hospital's undertaking to use it and dispose of the remainder respectfully should be enough. Were it otherwise we would have a situation where clinicians/researchers/teachers would have a difficult obstacle course to negotiate. This could involve repeated requests to parents for additional consent as the original research developed and diversified or as new interests arose. The consent to retain tissue should be general, to permit use within ethically approved research projects so long as it is treated respectfully throughout, including its ultimate disposal.

3.5 We set out below an illustration of the content of the consent form we envisage. The list is for discussion purposes and is not prescriptive.

4. National Health Service Hospital Post Mortem Consent Form for Children

4.1 **Section 1**

Patient Details:

- Name of hospital
- Name of child
- Address
- Date of birth
- Date of death
- Place of death
- Next of kin
- Relationship to child
- Address
- Hospital consultant
- Contact number
- Hospital reference number
- Telephone/fax numbers
- General practitioner
- Address
- Telephone/fax numbers
- Allocated bereavement adviser
- Date of appointment
- Telephone/fax numbers

4.2 **Section 2**

Purpose of hospital post mortem examination to establish:

- Cause of death
- Effects of surgery
- Effects of treatment
- Accuracy of diagnosis

4.3 **Section 3**

Post mortem examination may extend to:

- The whole body
- The chest and abdomen
- Access restricted to a surgical incision
- Small samples from specified organs

4.4 **Section 4**

Consent:

- Consent to full post mortem examination
- Consent can be refused
- Consent can be limited to specified organs

4.5 **Section 5**

Purposes for retaining organs:

- Diagnostic
- Therapeutic
- Medical education
- Research

4.6 **Section 6**

Purposes for retaining tissue:

- Diagnostic
- Therapeutic
- Medical education
- Research
- To enable organs to remain in the body
- To enable organs to be returned to the body for the funeral

4.7 **Section 7**

A request for consent to retention of organs or tissue *following completion* of the Coroner's process should be made *before* the Coroner's post mortem examination is carried out. There should be no distinction in the consent process between organ retention following completion of the Coronial process and a hospital post mortem examination

4.8 **Section 8**

Retention – individual attitudes to the body following death must be identified, acknowledged and respected

Identify, explain and discuss with next of kin:

- Each organ to be retained
- Purpose of retention
- Confirmation that retained organ(s) will only be used for purpose consented to by next of kin

- Whether organs to be examined will be returned to body prior to funeral – if not:
  - How long the funeral would have to be postponed to complete examination before organs can be returned to body
  - Whether next of kin wish to postpone the funeral or not
  - Certificate to confirm organs returned to body prior to funeral to be issued to next of kin
  - Organs retained beyond funeral will be identified and accompanied by signed consent form throughout use for relevant purpose
  - Tissue samples and purpose for retention
  - Whether tissue may be used for therapeutic, medical education or research purposes following diagnostic use
  - Whether next of kin consent to retention of organ or tissue:
    - In a collection
    - In an archive
    - As microscopic samples
    - Date when, place where and by whom ethical approval granted if purpose of retention for research
    - Whether organ or tissue can be retained without limit of time for medical education and research so long as it is handled respectfully
    - Next of kin have right to give instruction for respectful disposal following completion of purpose for which organ or tissue retained

4.9 **Section 9**

Signatures:

- Next of kin for post mortem examination
- Countersignature of clinician, bereavement adviser or other witness as appropriate
- Date, time and place of signing of consent

We have tried to set out the matters that the clinician must consider in order to obtain fully informed consent from the next kin. The standard is high but achievable given openness, frankness and honesty between clinician and next of kin. We feel that this process can be assisted by the availability of a bereavement adviser, particularly as the next of kin is likely to be suffering a grief reaction. The function of the bereavement adviser is considered in the next chapter.

5. Recommendations

5.1 We respectfully recommend that:

- Following examination of the retained organs or tissue, there should be a meeting between the clinician and parents and referral for genetic counselling or other specialist advice if appropriate.
- Once fully informed consent is obtained for research purposes, the researchers are entitled to remain in possession of the material retained while research continues. We recommend this extends to accessing archives and DNA analysis. All research remains subject to ethics committee approval.
- Local ethics committees be given a supervisory role to police approved research.

Chapter 12. Bereavement Adviser

The whole of Chapter 12 is included. It looks at the role of the bereavement adviser and includes recommendations.

Contents

1. Background

1.1 In the late 1980s and early 1990s cardiac social workers provided a 24-hour on call service in the Alder Hey Cardiac Department and would sit with bereaved parents and talk to them. Clinicians would often take their lead from the cardiac social workers in terms of when the parents were able to cope with being given the necessary information following their child's death. The system worked very well, and in the mid 1990s the cardiac social workers were replaced by cardiac liaison nurses. The service now is equally as good as the system it replaced.

1.2 There is always a cardiac liaison nurse available for consultation at Alder Hey. There is also a community-based cardiac liaison nurse supported by the British Heart Foundation who is available to speak to parents at any time.

1.3 In their evidence the parents identified the need for this type of service. It should not be restricted to the cardiac department, but should be generally available. In his Interim Guidance on Post Mortem Examination issued on 1 March 2000, the Chief Medical Officer indicated that all NHS Hospital Trusts should designate a named individual in a Trust who will be available to provide support and information to families of the deceased where post mortem examination may be required, whether this is requested by a hospital doctor or the Coroner. This person should be trained in the management of bereavement. We feel that a bereavement adviser would be the person to discharge this role.

1.4 Parents must be involved in decision making as well as in requesting and accepting support. The aim is to assist them in the difficult period following death. Their individual feelings and needs must be identified and respected. Their paramount need is for accurate, consistent, co-ordinated information. Choices available to parents should be fully explained, with all the necessary information provided. They must be given time together and time with their child. Time must also be available to make practical arrangements. They must be treated with respect and dignity at all times.

1.5 The bereavement adviser should not be judgmental in dealing with parents. Parents must be supplied with clear, factual, unbiased information. Confusion must be avoided. Parents may need help with thinking what they want to ask and even asking their clinician questions. No subject should be avoided and they must be treated with honesty even if the truth is painful. Their confidentiality must be respected at all times. The bereavement adviser should try and ensure that parents are dealt with on equal terms by the clinician and other professionals and time must be made available to meet the parents' needs.

1.6 It should be understood that grief can be expressed differently in different cultures. The nature of grief is personal and private. In a hospital, which often appears impersonal and public, there should be a private place where the bereavement adviser and parents can meet and have time together or alone. Parents must have time, space and support to relive, think and talk about what has happened to them.

1.7 The training of a bereavement adviser should include the appropriate use of language, the need to provide individual attention and to anticipate the requirements of bereaved relatives.

1.8 They must have a full understanding of post mortem procedures and the issue of consent. This will include identifying and distinguishing between a Coroner's and hospital post mortem examinations. They should be able to obtain information from clinicians and pathologists about the identification of organs to be retained and whether or not they will be retained beyond the funeral. Training must include why certain organs have to be 'fixed' before examination and the length of time necessary to 'fix' and examine a particular organ.

1.9 The bereavement adviser must be able to advise on all aspects of the funeral including return of organs to the body following post mortem examination, or identification of organs, tissue, blocks, slides, X-rays and photographs retained beyond the funeral. An awareness of all funeral procedures, religious requirements and the purpose of memorial services is necessary.

1.10 There will be a psychological component in bereavement advisers' training, relating to sensitive and respectful communication as well as gentle treatment of stressful topics such as consent to post mortem procedure. They will require liaison skills in order to discuss matters with clinicians, Coroners and other professionals.

1.11 The bereavement adviser should try to involve the pathologist more openly with clinicians and parents. The pathologist will be of particular assistance with regard to explaining why organs are retained and what purposes, including therapeutic, medical education and research, are served by retention of organs or tissue.

1.12 Parents should be given every opportunity to express their wishes about the eventual disposal of organs. A bereavement adviser can facilitate this. Parents' wishes must be respected. The need for respect cannot be overstated.

1.13 Every hospital should have a bereavement adviser. A dedicated office should be provided and include a private sitting area for parents or surviving relatives.

2. Recommendations

2.1 We have considered the evidence and recommend that the functions of a bereavement adviser include:

- Explaining the circumstances of death, identifying when, where and who was present.
- Arranging and attending a meeting for relatives with anyone who was present at the death if requested.
- Encouraging a meeting between relatives and the treating clinician to explain the clinical circumstances of death and, if requested, arranging and attending the meeting.
- Ensuring that relatives have a full explanation of the reasons for post mortem examination including therapeutic, medical education and research.
- Explaining the need for consent to carry out a hospital post mortem examination (HPM) and the retention of organs.

- Explaining that consent is necessary for the retention of organs following a Coroner's post mortem examination (CPM) and that the consent must be obtained before the CPM is undertaken.
- Ensuring relatives have sufficient time, privacy and support to reflect upon the request for consent to an HPM or the retention of organs following a CPM or an HPM.
- Ascertaining whether a clinician will attend the post mortem examination.
- Facilitating meetings between parents, clinician and pathologist as appropriate.
- Noting discussions between relatives, clinicians and pathologists and providing a copy to each party involved.
- Developing and using information packs for relatives on all aspects of death in hospital.
- Assisting relatives in the following practical matters:
  - collecting the deceased's personal belongings and arranging return to relatives;
  - ensuring provision of certificate of death and the formal notice;
  - explaining the procedure to register the death;
  - providing support in attending the registry office if requested;
  - arranging contact with funeral director;
  - arranging contact with hospital chaplain and/or local priest as required;
  - contacting the Coroner's office as appropriate;
  - offering to attend if contact with police necessary;
  - ensuring that the General Practitioner is informed;
  - ensuring that schools are informed as appropriate (including the schools of siblings);
  - assisting the relatives in informing other persons including other relatives, friends and employers, of the death and its consequences;
  - assisting the relatives in dealing with the Benefits Agency, insurance company and housing matters;
  - assisting the relatives to place announcements in newspapers if wished.

- Discussing counselling or long-term support needs with relatives, including the needs of wider family members and making contact with appropriate counselling/support agencies if requested.
- Ensuring that relatives are aware of the full range of counselling/support resources available, including those external to the hospital and bringing these matters to the attention of the relatives.
- Accessing translation/interpreting services including services for people with hearing or visual impairment and providing appropriate written/taped information.
- Assisting with any other individual problem presented by relatives in consequence of death.
- Undertaking general liaison duties.

2.2 We intend this list to be illustrative rather than prescriptive. There must be recognised training courses for bereavement advisers. Qualification should be certificated, perhaps at a National Vocational Qualification level. Annual assessment and appraisal should be routine and the role should be performance managed. Continuing education and training is essential. The bereavement adviser should work closely with the hospital management, clinicians, the Coroner and the full range of non-medical services including counsellors and other non-medical professionals. There will of course be relatives who do not wish to avail themselves of the services of a bereavement adviser. Nevertheless the service should be offered to everyone, as should the facility to return to the bereavement adviser in the event of their services having been declined in the first instance.

2.3 The distinction between a cardiac liaison nurse and the bereavement adviser is that the nurse has the advantage of contact with the parents in the period prior to death. We suggest that some aspect of the bereavement adviser's multi-factorial function will bring them into contact with the parents before the death of their child.

2.4 We have been heartened at the support for the concept of bereavement adviser from parents and clinicians. We commend the concept for development and implementation.

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