

Report of
Dr. Deirdre Madden
on
Post Mortem Practice and
Procedures

Presented to Mary Harney T.D., Tánaiste
and Minister for Health and Children on 21st December 2005

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ón
OIFIG DHÍOLTA FOILSEACHÁN RIALTAIS,
TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,
nó tríd an bpost ó
FOILSEACHÁIN RIALTAIS, AN RANNÓG POST-TRÁCHTA,
51 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2,
(Teil: 01 - 6476834/35/36/37; Fax: 01 - 6476843)
nó trí aon díoltóir leabhar.

DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased directly from the
GOVERNMENT PUBLICATIONS SALE OFFICE,
SUN ALLIANCE HOUSE, MOLESWORTH STREET, DUBLIN 2,
or by mail order from
GOVERNMENT PUBLICATIONS, POSTAL TRADE SECTION,
51 ST. STEPHEN'S GREEN, DUBLIN 2,
(Tel: 01 - 6476834/35/36/37; Fax: 01 - 6476843)
or through any bookseller.

© Copyright Government of Ireland, 2006.

Acknowledgements

I would like to express my gratitude to the parents who made submissions to the Inquiry and for whom the telling of their stories was painful and distressing. Their participation was fundamental to my understanding of the practices of the past and the need for legislative change for the future. I am also very grateful for the co-operation I received from organisations involved in supporting bereaved families as their expertise and experience in this regard was essential to my recommendations.

I would also like to thank most sincerely the clinicians, pathologists, medical social workers and hospital managers who assisted the work of the Inquiry in any way. Their professionalism and acceptance of the need for change was of great benefit in writing this Report.

I would like to record my appreciation to colleagues in Northern Ireland, England and Scotland whose experience of dealing with similar Inquiries was of immense interest and value to me.

A handwritten signature in black ink that reads "Deirdre Madden". The signature is written in a cursive style and is underlined.

Dr. Deirdre Madden
Chairperson

20th December 2005

Acknowledgements	iii
Index	v
Executive Summary	1
Recommendations	9
Chapter One: Background to the Inquiry and Terms of Reference	19
1. Introduction	
2. Terms of Reference	
3. Approach to the Report	
4. Conclusion	
Chapter Two: What Happens at a Post-Mortem Examination?	25
1. Introduction	
2. Paediatric Post-Mortem Examinations	
3. Distinctions between Adult and Paediatric Pathology	
4. Removal and Retention of Organs	
5. Storage of Organs	
6. Disposal of Organs	
7. Conclusion	
8. Recommendations	
Chapter Three: Conduct of Post Mortems in Ireland	37
1. Coroner Post Mortems	
2. Current Arrangements	
3. Duties of the Coroner	
4. Powers of the Coroner	
5. Objectives of Coroner Post-Mortem Examination	
6. Conduct of a Coroner's Post Mortem	
7. Hospital Post Mortems	
8. Benefits of Hospital Post Mortems	
9. Role of Clinicians in Relation to Post Mortems	
10. Public Attitudes to Post Mortems	
11. Role of Department of Health and Children	
12. Conclusion	

Chapter Four: Submissions from Parents

53

1. Introduction
2. When was the Post Mortem Discussed with Parents?
3. Where were They Told?
4. Who told Them?
5. What was Their State of Mind at This Time?
6. How Much Time were They Given to Consider the Request?
7. Location of Post Mortem
8. Reasons for Post Mortem
9. What were They Told?
10. What was Their Understanding of a Post Mortem?
11. Objection to Post Mortem
12. Limited Post Mortem
13. Form of Consent Given
14. Organ Removal
15. Length of Time for Examination of Organs
16. Retention and Disposal of Organs
17. Returning the Child for Burial
18. Coroner Post Mortems
19. Communication of Post Mortem Results
20. Pituitary Glands
21. Trauma of Controversy
22. Attribution of Blame and Loss of Trust in Medical Professionals
23. Parents' Views on Retention of Organs
24. Conclusion
25. Recommendations

Chapter Five: Submissions from Hospitals

69

1. Introduction
2. Post Mortems on Children Between 1970 and 2000
3. Policies Regarding Post Mortems
4. Policies Regarding Consent
5. Hospital Practices for Obtaining Consent to a Post Mortem
6. Information Provided to Parents
7. Hospitals Perceptions about the Expectations/Knowledge of Parents
8. Was Consent Requested for Organ Retention?
9. Did Hospitals Retain Organs for a Period after Post Mortems?
10. Why were Organs Retained by Hospitals?
11. Storage of Retained Organs
12. Return of Organs
13. Disposal of Organs
14. Maintenance of Records

15. What Information was given to Parents following Post Mortem?
16. Coroner Post Mortems
17. Conclusion
18. Recommendations

Chapter Six: Pituitary Glands

87

1. Introduction
2. What is the Pituitary Gland?
3. Retention of the Pituitary Gland
4. The Pharmaceutical Companies
5. Distribution of the Human Growth Hormone
6. Exclusion of Certain Pituitary Glands
7. Withdrawal of Human Growth Hormone
8. Payment for Glands
9. Collections
10. Supply Chain of Human Growth Hormone Medication
11. Collection Period of Pituitary Glands in Ireland
12. Irish hospitals involved in Supply of Pituitary Glands
13. Was Consent Obtained?
14. Knowledge by the Department of Health and Children
15. Conclusion
16. Recommendations

Chapter Seven: Disclosures in 1999/2000 and Hospitals Responses

97

1. Introduction
2. Awareness of Organ Retention Issue and Contact with the Hospital
3. Delay in Receiving Information
4. How was the Information Conveyed?
5. Inaccurate Information
6. Explanation of Organ Retention Practices
7. Support offered to Parents by Hospitals
8. Changes in Policy regarding Post Mortems and Consent
9. Conclusion
10. Recommendations

Chapter Eight: Legal and Ethical Issues relating to Post Mortems and Organ Retention

107

1. Introduction
2. Consent
3. Respect for Autonomy
4. Changing Culture of Consent
5. Modern Legal Foundation for Consent Requirement

6. Legal Doctrine of Informed Consent
7. Is Informed Consent Achievable?
8. Disclosure of Information
9. Application to Post Mortems
10. Parental Authority
11. Authorisation
12. Property in the Human Body
13. Right to Possession of the Body
14. Conclusion
15. Recommendations

Chapter Nine: The Use of Autopsy Material in Medical Education and Research

123

1. Introduction
2. Uses of Autopsy Material
3. Medical Education and Training
4. Audit and Quality Assurance
5. Research
6. Consent for Research
7. Retention of Organs for Research
8. Conclusion
9. Recommendations

Chapter Ten: The Way Forward

133

1. Introduction
2. Existing Legislative Provisions in Ireland
3. Professional Guidelines
4. European Tissue and Cells Directive 2004
5. Human Tissue Legislation (UK)
6. Human Tissue (Scotland) Bill 2005
7. The Way Forward for Ireland
8. Recommendations

Executive Summary

1 General Overview

1.1 This Report aims to set out the general facts in relation to paediatric post-mortem practice in Ireland from 1970 to 2000, the way in which information was communicated to parents of deceased children in relation to post-mortem examinations, and how these practices might be improved upon for the future. It is written in the knowledge that many of the practices related here are historical, and that professional guidelines and hospital policies have changed significantly since 2000. It is acknowledged that some of the recommendations made herein may already have been implemented in many hospitals. However, despite the changes that have been made, it is important for bereaved families and the general public to be made aware of the practices of the past in order that the recommendations for legislative change made in this Report can be understood in context.

1.2 The death of a loved one is probably the most difficult event any of us will experience in our lifetime. When the death is that of a child, the trauma and grief is immeasurably increased, whether or not death was expected. The death of a child is inherently against the natural order of life where the oldest die first, and it can cause lifelong heartbreak for parents, siblings, grandparents and extended families. Parents instinctively seek to protect their child's body from any further perceived invasion and simply want to bury him/her with as much love and dignity as possible.

1.3 In some circumstances a coroner may order a post-mortem examination to be carried out to ascertain the cause of the child's death. This is done in order to comply with the legal requirements of the justice system. It is a compulsory post mortem and the consent of the child's parents is not required or sought. Compulsion is always difficult, and having choices taken from them often angers parents. However, despite their grief and anger, many parents want to know as much as possible about the process of the coroner's post-mortem examination. Although they are not in control of the legal process, they want to be informed as to what the process entails, and as to what choices they have following the conclusion of the post mortem.

1.4 In other cases that do not involve the coroner, hospital clinicians may seek to have a post mortem carried out on a child who has died in the hospital. This is to ensure that all appropriate clinical procedures were carried out to the child's best possible advantage, and that as much information as possible may be given to the family as to why the child died.

1.5 Removal of organs during a post mortem is a necessary element of the examination. Standard practice in this respect remains the same today as it was in 1970. Organs are removed, weighed, examined and sampled in an effort to establish in detail the cause of the patient's death. In the past, organs were retained for further examination and sometimes subsequently used for educational and research purposes. Retention is particularly required for examination of the brain as it is an extremely soft tissue which requires fixation for a period of time prior to examination. In the case of other organs such as the heart, retention facilitates more detailed and specialist

examination, often in consultation with surgeons and other clinicians involved in the patient's treatment. This is done in order to provide a more accurate and detailed diagnosis of the cause of death and is not confined to paediatric post mortems.

1.6 Although this Report frequently refers to 'clinicians' or 'medical professionals' or 'doctors', other healthcare professionals were, and are, also very much involved in caring for bereaved families. These expressions are intended to encompass all those involved in the team caring for the child and its parents. 'Autopsy' and 'post mortem' are used interchangeably throughout the Report. 'Parent(s)' is intended to include the child's legal guardian(s).

2 Communication

2.1 It is important to stress at the outset the distinction between coroner and hospital post mortems in relation to the communication and consent process. In a coroner's case, a hospital pathologist acting on behalf of the coroner will usually carry out the post-mortem examination. It has not always been explained to parents that the pathologist in such cases is not entitled to discuss the post mortem with the family, as this is a matter for the coroner. Communication in such cases has usually been very limited and this has often caused distress and anxiety to families. Information has not always been disclosed to families in relation to the legal process undertaken by the coroner and any rights the parents may have on conclusion of the investigation by the coroner. Consent is neither required nor sought from parents in such cases.

2.2 In hospital post mortems, the evidence submitted to the Inquiry shows that in the past the policy in all hospitals was to seek a form of consent from parents for the examination. However, it was not hospital or professional policy to inform parents that in the course of a post mortem to be carried out on their child, organs may be retained, stored, and subsequently disposed of. The shock, anger and betrayal felt by families at the revelation of these long-standing practices highlight the existence of a significant communication gap between the medical establishment and the general public that has been at the root of this controversy.

2.3 In the past, communication regarding post-mortem practice was not always what it should have been when judged by today's standards. The standards of disclosure of information and the legal norms upon which those standards were based would undoubtedly be judged inadequate today. The discomfort that may have accompanied discussions around the issue of hospital post mortems in the past may sometimes have been interpreted as clinical arrogance or insensitivity, but there is no evidence to suggest that it was malevolent or ill-intentioned. It may well be described as professional paternalism, typified by the attitude that 'doctor knows best'.

2.4 In the context of disclosure of information to patients relating to retention and ultimate disposal of organs, doctors argue that their reluctance to inform families of the details surrounding the post-mortem examination and retention of organs was to protect rather than insult, that they had a different professional perspective of the body, that the information was likely to cause more grief and pain than it alleviated, and that therefore they were behaving ethically. This argument has a clear and

reasonable humanitarian appeal but rests on a paternalistic basis that patients, parents, and the general public now interpret as unnecessarily secretive and disrespectful. Medical paternalism is unacceptable by modern standards whereby doctor and patient now stand in a different relationship to each other, one that is based on mutual trust and shared understanding.

2.5 For the future, communication and authorisation are vital and must be enshrined in legislation. Language, timing, and venue are all-important aspects of this process. It is not intended to prescribe how the information is imparted to parents, as each family will react differently to the situation. Disclosure of information should evolve in a discussion between clinician and family, assisted by the expertise of a pathologist if required by the family, and/or an information booklet that the parents can read, have explained to them if necessary, and take home with them if they so wish. Given the importance of commencing an autopsy within a certain time after death, it may not always be possible for parents to have as much time as they would like to reflect on the choice they are presented with. However, this does not detract from the obligation to impart as much information as necessary in the circumstances and to answer any questions the family may have regarding the process.

3 Consent

3.1 Although pathologists have been denounced for the practices of the past, they generally had no involvement in obtaining consent for hospital post-mortem examinations. This was seen as the responsibility of the clinical team looking after the patient and the pathologist rarely had any direct contact with the child's parents. The treating clinician was deemed best placed to discuss the child's death and post mortem with the family as he/she already had a relationship with them in many cases. Also it was not deemed appropriate or desirable that the parents should meet the pathologist who would perform this procedure on their child, as such an encounter might be too distressing for parents. This situation remains unchanged, though pathologists now receive a copy of the consent form signed by parents prior to performance of the post-mortem examination. Exceptionally, in one hospital the pathologist routinely meets the parents prior to the post-mortem examination and explains the performance of the examination to them. Some pathologists in other hospitals also facilitate such meetings on request.

3.2 Although it was and is hospital policy to obtain consent from parents for a hospital post-mortem examination to be carried out on their child, up to 1999 this was generally not informed by an explanation of what the examination entailed or the possibility of organ retention. In the context of post-mortem examinations, consent was and is not required or sought to an autopsy ordered by a coroner in the exercise of his/her legal functions on behalf of the State.

3.3 A balance must be struck between ensuring that the appropriate amount of information is given which facilitates a genuine choice, and causing further distress and anguish to grieving parents. This is a balance that may only be struck on an individualised basis as people differ widely in their informational needs and

comprehension levels. The clinician who is engaged in discussion with the parents must take on the responsibility of ensuring that parents are given the information they require to put themselves in the position whereby they are equipped to ask pertinent questions and to make a genuine decision. Details as to what the autopsy involves must always be offered but should not be forced on unwilling and grieving parents against their will. To do so would be a denial of choice and respect for their autonomy, as well as being harsh and cruel.

4 Why were Parents not Told about Organ Retention?

4.1 This Report concludes that, up to 1999, parents were generally not told that organs might be retained at a post-mortem examination carried out on their child. There are differing perspectives on the reasons why parents were not told of organ-retention practices. This Report cannot reconcile these views in individual cases.

4.2 Doctors argue that they did not tell parents about organ retention for the parents' own good; parents were upset enough already and did not need the information. The giving of such disturbing and distasteful details to distressed and vulnerable parents could be a complex, lengthy and upsetting process, not easily or speedily undertaken. It was thought to be unnecessarily cruel to discuss incisions and organ retention with newly bereaved parents. This approach contrasts sharply with the views of some parents that, for them, the worst had already happened – the death of their child – and that further information could not have added to their upset. Parents are angry and distressed that this practice took place without their knowledge, that their child's organs were retained for various periods of time, and then disposed of in a manner and place unknown to them.

4.3 Another reason given for the non-disclosure is that doctors had a different perspective in relation to organs and did not equate organs with the body as a whole. Doctors generally did not see the organs as having any emotional significance once the child was dead – ensuring that the body be released for burial within the timeframe sought by the family was more significant, in their view, than all the organs being replaced in the body for burial. Doctors were trained to pay less attention to the emotional and symbolic aspects of organs, and to concentrate on the functional or medical aspects. Doctors looked at organs to determine how well they were working or whether a particular intervention had been successful. They generally did not consider that relatives might have looked at organs in a different way. Pathologists also held this functional view of organs. They felt that organs, though clearly deserving of respect, could be considered separately from the body and were not essential for the purposes of viewing and burying the body. Clearly, many parents did not and do not share this view, and regard the heart or brain as symbolic of their child's spirit and personality. For these parents, the burial of the body without the organs is an affront to their grief and the child's dignity.

4.4. Some parents perceive that doctors did not tell them because the doctors believed that parents would not consent if they were told the truth of what was involved in the post mortem, or that parents would not understand, or that doctors did not have the inclination to spend the necessary time explaining the process to the parents. Some

parents are of the view that the actions of pathologists in performing a post mortem and retaining organs showed disrespect for the child's body.

5 Medical Culture

5.1 The truth as to why parents were not told about organ retention is probably a mixture of the motivations outlined above, depending on the individual clinician and the time and culture when the child died. There is no doubt that in recent years paternalism has dissipated to a large degree in Irish medical practice, with greater recognition of the autonomy of the patient and the therapeutic alliance formed by trust and communication between doctor and patient. However, during the earlier years which are the subject of this Report, paternalism was very much part of the culture and ethos of the profession, with the result that many clinicians who may be the subject of complaint by parents in their submissions to the Inquiry may have been behaving no differently from their peers in other branches of medicine. Their attitude was not one of disrespect, but rather a pragmatism borne from medical education and training. This is not to seek to justify the practices of the past, but rather to put them in the context of the time.

5.2 Although the stories recounted by the parents are traumatic and shocking by today's standards, fairness demands that the conduct of doctors be judged by the standards of the time, not by the ethical principles that are now expected as standard practice. However, as the culture of the medical relationship changed over the years, particularly since the early 1990s, anyone in the medical profession who reflected on the practice of retaining organs without consent should have recognised that it was contrary to changing expectations of openness and transparency. That this reflection, and corresponding change in practice, did not take place within the medical profession sooner than it did, must be recognised as a serious weakness in the system.

5.3 Every profession must review its practices on a regular basis to ensure that the highest standards are being maintained and that practices comply with changing societal and ethical expectations. Although the technical performance of post mortems in Ireland was in keeping with best international practices, this does not entirely excuse the profession of its responsibilities. Medical education and training in the 1990s began to emphasise the importance of keeping patients informed and obtaining consent in relation to surgical and other medical treatment. Although there was a general policy to obtain consent to hospital post-mortem examinations, this did not commonly include disclosure of the details of the examination and the possibility of organ retention. The need to apply the same standards of disclosure to post-mortem practice does not appear to have been considered by the profession.

5.4 Hospital management also have a role to play here. Although it is not their role to interfere in clinical autonomy and decision-making in the treatment of individual cases, they nevertheless owe a duty to patients and next-of-kin to ensure that all treatments and services provided by the hospital are of the highest clinical and ethical standard. Hospital managers were unaware of pathology practices and post-mortem retention of organs, in the same way as they would have been unaware of the details of clinical procedures or pharmacological treatments. Their remit was confined to resource and budgetary issues, quality control management, and other administrative

matters. This position would have been common to all hospitals through the 1970s and 1980s. In the 1990s more emphasis began to be placed on medico-legal considerations as litigation became more commonplace in the healthcare sector. Consent forms began to be more carefully drafted, protocols became more tightly controlled and so-called 'defensive' practices began to creep in. However, none of this appears to have impacted upon hospital post mortems, save that written consent forms became more common in hospitals and, in some cases, more detailed. Consideration does not appear to have been given to the disclosure of organ retention as part of that process, or whether in the absence of such disclosure consent could be 'informed'.

6 Post-1999

6.1 When organ retention practices became public knowledge in late 1999 parents were confused, distressed, hurt and angry. They felt betrayed by the hospitals and doctors who had cared for their children in life, and were distrustful of the information they now received about the care of their children after death. For the parents, the whole controversy shows a failure to empathise with those who have faced the devastation of losing a child, and the failure to recognise the parent's need to protect the child after death. The fact that for many parents the essence of the child is contained in organs such as the heart or the brain engendered feelings that the child had been violated, and that the parent had not been able to protect him/her. The way in which some elements of the media highlighted this sensitive and emotive area did not help to ease the renewed grief of these parents.

6.2 The function and responsibility of hospital managers became crucial when revelations about organ retention began to be published in 1999. At that point, their role was to set clear protocols for the accurate dissemination of information to parents. In some cases managers and boards quickly realised the scale of the controversy and set about putting in place structures to ensure that information was disseminated as accurately and quickly as possible in the circumstances. In other cases, the reaction of management was not as well coordinated as it should have been. Inaccurate information, delays, and insensitivity exacerbated the grief and anger of the parents in many cases. Though the hospitals defend their responses on the basis that they were unprepared, that the controversy was unprecedented, that information was not readily available, and that records were sometimes poorly maintained, the effect on the parents was an additional trauma that perhaps could have been avoided or minimised by a more centralised leadership from the health boards and the Department of Health and Children. As occurred in other countries, a moratorium could have been imposed on the dissemination of information until audits had been carried out and accurate and complete details collated. Though this would inevitably have led to a further delay for the parents, it may have proved to be a better option.

6.3 The Department of Health and Children did not see itself as having any role or function in relation to the regulation of post-mortem practices until this controversy arose in 1999. There appears to have been no discussion at policy level, and no issues were raised or questions asked by officials within the Department regarding hospital post mortems, other than in relation to the safe and hygienic disposal of clinical waste in accordance with European Directives. Until the issue of organ retention arose in the

course of the Bristol Inquiry in England, no one in the Department appears to have considered the issue, or the likely effect of the subsequent revelations on bereaved parents and families. When the controversy became public in late 1999, the Department should have made more strenuous efforts to reassure the public that although there were issues to be addressed regarding consent and communication, the practice of organ retention was a standard and necessary part of post-mortem examinations, and that post mortems were carried out in Ireland to the highest international standards. This might have allayed some of the fears and concerns of parents at that time.

6.4 It is clear from evidence submitted to the Inquiry that significant changes have been made in recent years in hospital policies, though the changes are not necessarily consistent across all hospitals. Since 2000 the Faculty of Pathology and the National Working Group on Organ Retention have issued guidelines in relation to post-mortem practices. Both sets of guidelines stress the importance of communication and consent. Guidance is also given on the storage of organs, choices to be given to families regarding the disposal of organs and record keeping. It was not the function of this Inquiry to carry out an audit of conformity by the hospitals with the national guidelines.

7 Conclusion

7.1 On the evidence submitted to the Inquiry, this Report concludes that post-mortem examinations were carried out in Ireland according to best professional and international standards and that no intentional disrespect was shown to the child's body. The root causes of this controversy have been a lack of communication with parents as to why organs were retained, the difference in perspective as to their symbolic significance, and the legislative vacuum on the role of consent in post-mortem practice.

7.2 There are lessons to be learned from this controversy. There has been a breakdown in communication, and consequently in trust and confidence, between parents and medical professionals. This will not be resolved by blame. The practices of the past were not due to personal or individual misconduct, but rather to a system and culture that failed to take into account the views and feelings of parents. It may be some explanation for organ-retention practices to say that there was no legislation governing post mortems in Ireland, and that, in the legal vacuum that existed, doctors followed the custom and practice of their profession. The practice of retaining organs without the knowledge and authorisation of parents, which would now be unacceptable, was the product of the paternalistic culture of the time and a lack of consideration of the rights and interests of parents. That was how things were, not only in Ireland but also in other countries.

7.3 This Report concludes that the best resolution of this issue for bereaved parents is to enact clear and unambiguous legislation to ensure that such practices cannot happen again in the future without their knowledge and authorisation.

Recommendations

The terms of reference of this Report deal with paediatric post mortems and the recommendations are based on findings made in that regard. However, the principles that underpin these recommendations, in particular, respect for the dignity of the deceased, and the importance of communication and authorisation are equally applicable to all post mortems.

Consideration should be given to the implementation of the recommendations made in this Report to other post mortems, namely those carried out on babies who have died before or during birth, minors and adults. Although this Report does not specifically address post mortems in those groups, many of the recommendations may apply generically to all post-mortem practice. However, it should be acknowledged that these post mortems also raise distinct legal and ethical issues that were not within the Terms of Reference of this Report. If the recommendations in this Report are adopted, a Working Group should be established to ensure that appropriate adaptation in relation to those issues takes place. It must include membership from relevant stakeholders and family representative organisations.

It is acknowledged that some of the recommendations made in this Report have already been implemented at a policy level in many hospitals since 1999/2000, and particularly since national protocols were adopted in 2002. However, to ensure clarity and consistency across all hospitals, these recommendations must form the basis of new legislation, which would serve to restore public trust and confidence in post-mortem practice in Ireland.

1 Need for legislation

1.1 Legislation must be introduced as a matter of urgency to ensure that no post-mortem examination will be carried out on the body of a deceased child and no organ will be retained from a post-mortem examination for any purpose whatsoever without the authorisation of the child's parent/guardian, or the authorisation of the coroner in an appropriate case.

1.2 The removal of organs from the body of a deceased child at post mortem is carried out as a necessary part of the examination of the body and diagnosis of the cause of death. It must be made clear in legislation that a post-mortem examination includes the necessary removal of organs for this purpose. Subject to recommendation 2.3, parents must be clearly informed of this prior to their authorisation of the hospital post-mortem examination.

1.3 The retention of organs at post mortem may be necessary in certain circumstances in order to make an accurate diagnosis of the detailed cause of death. Subject to recommendation 2.3, parents should be clearly informed of this prior to their authorisation of the hospital post-mortem examination. As part of this process parents must be informed as to the reasons for retention, the likely retention period, and must be offered such further information as they require.

- 1.4 Subject to recommendation 2.3, parents must be informed of the benefit of retained organs for audit, education and research, and given the option to authorise retention for such purposes. Parents must also be given choices in relation to subsequent return, burial or cremation of the organs.
- 1.5 It is recommended that legislation should provide that where both parents are legal guardians of a deceased child either parent should be able to give authorisation for a hospital post-mortem examination, though ideally both should participate in the decision. Situations may exceptionally arise in which the parents of the child disagree as to whether or not to authorise a hospital post mortem on their child. In such situations or where only one parent is the legal guardian, the hospital would be legally entitled to proceed with the post mortem on the authorisation of one parent. However, best practice should ordinarily be not to proceed with a hospital post mortem in the face of objection from either parent irrespective of their marital or living arrangements.
- 1.6 The health and safety aspects of the storage, use and disposal of human organs derived from post-mortem examinations must be regulated by legislation.
- 1.7 Legislation must prohibit the removal of human organs from a deceased child at post mortem examination for supply by hospitals to any pharmaceutical company or other third party without the knowledge and authorisation of the parents. Where such organs are supplied, such arrangements must be clearly approved by hospital management and documented, and all information supplied to the parents on request.
- 1.8 An appropriate legislative framework must be put in place to govern hospital post mortems. A regulatory model that facilitates guidelines to be updated when necessary to keep pace with medical and scientific developments is recommended. Legislation must clearly set out the purposes for which a post-mortem examination may be performed. In order to restore and maintain public confidence in the system, the legislation must set out clear safeguards for patients and their families, and encourage medical education and research. Penalties must be imposed for non-compliance with these safeguards.
- 1.9 Although not specifically addressed within the terms of reference of this Report, it is clear that human tissue legislation is urgently required to deal with issues relating to removal, storage and uses of human biological material from the living and the deceased. Provision should be made in such legislation to facilitate and encourage medical education and training, and approved medical research, while maintaining the principle of respect for the donor, the deceased person and the bereaved.

2 Information for parents and the authorisation process

- 2.1 The grief and anguish suffered by parents who discovered that their children's organs had been retained and in some cases later disposed of by hospitals, was caused by a failure by medical professionals to communicate openly and honestly with parents at the time of death. The main aim of this Report is to place parents/guardians at the centre of decision-making and control in respect of hospital post-mortem examinations to be carried out on their children. However, the doctrine and language of informed consent is considered to be inappropriate in this context and is not recommended.
- 2.2 It is recommended that the alternative concept of authorisation be adopted. This is a stronger and more powerful recognition of the active role and choice of parents in decision-making in relation to post mortems. It is recommended that systems and policies be put in place to ensure that all parents are offered such information as they require to make the decision as to whether or not to authorise a post mortem examination to be performed on their child. This must be viewed as a process and not a once-off event.
- 2.3 Parents must be given the option of authorising a post-mortem examination to be carried out on their child on the understanding that this is being performed to provide further information as to the cause of death and the possible effects of treatment. Some parents may wish to authorise a post mortem without wanting to receive any further information or consultation. Their right not to receive this information must be respected. It must be made clear to them that they can come back with a future request for more information at any time. For those parents who choose this option, it must be stated on the authorisation forms that this includes authorisation of all actions necessary as part of that examination. The accompanying information booklet to be given to parents to read if they so choose must explain that this will include removal and sampling of organs, and may include retention of organs for diagnostic purposes. It must be made clear that organs retained at post-mortem examinations will not be used for any purpose other than diagnosis without the authorisation of the parents/guardian.
- 2.4 If they require further information prior to authorisation, parents must be told that the performance of a post-mortem examination involves the examination of the body of the deceased child. It includes the dissection of the body and the removal of organs, tissue samples and blood/bodily fluids. It is carried out to provide information about or confirm the cause of death, to investigate the effect and efficacy of a medical or surgical intervention, to obtain information regarding the health of another person/future person, and for audit, education, training or research purposes. Parents must be made aware that in certain circumstances it may be necessary to retain organs in order to complete the examination.
- 2.5 Parents should also be informed of the potential benefits of retention in terms of education, training and research. If the retention period is short, they must be made aware that it may be possible to delay the funeral in order that the organs may be reunited with the body. In other cases, they must be made aware of their options in relation to disposal of the organs at a later date.

- 2.6 Parents must be given the option to authorise a limited post mortem. They may choose to limit the examination to particular organs but, in making that choice, must be informed that this will mean that samples will be taken from the organs being examined, and that information will not be available on other organs which may have contributed to the child's death.
- 2.7 It is recommended that the means by which and the place in which parents are informed about the post mortem process be as sensitive and respectful as possible in the circumstances. If possible, a dedicated bereavement room should be available and adequate time should be given to parents to consider the issue. Information must be offered to parents/guardians and an open dialogue entered into prior to the authorisation of the hospital post mortem. The information must be presented in a clear and comprehensible but sensitive manner. A bereavement liaison officer should assist the parents in getting the information they need prior to their decision.
- 2.8 It is not intended to make specific recommendations as to the most appropriate person to discuss post mortems with the family, as this is deemed unnecessarily prescriptive. It will usually be a senior clinician who has a relationship with the parents, though a team approach may be preferable in some cases, involving nursing and midwifery staff in particular. Where possible, consultation with the hospital pathologist should take place prior to discussion with the parents so as to concentrate that discussion on issues of most relevance to the particular child. If the parents so request it, a pathologist must be available to answer specific queries or explain the post mortem in more detail.
- 2.9 The confidentiality of the post mortem report raises issues regarding its disclosure to other persons. Hospital post-mortem reports must be made available to the consultant clinician who treated the child, if there was one, and the child's general practitioner. It is recommended that the post-mortem report must also be offered to parents of deceased children with advice to seek any necessary explanations from their general practitioners, consultants or the relevant pathologists. Where possible, a follow-up meeting between parents and clinicians must be arranged to discuss the post-mortem findings in as much detail as the parents require. If necessary or desirable in the circumstances, the pathologist may also be requested to attend such meetings. This facility must be made known to parents at the time of authorisation of the hospital post-mortem examination. Protocols must be put in place to provide a structure whereby parents receive a timely and appropriate response to their request for information.
- 2.10 Standardised authorisation forms and clearly written information booklets must be drafted and used on a national basis to ensure consistency and transparency.

3 Coroners Post Mortems

- 3.1 The recommendations of the Report of the Working Group on the Coroners Service must be implemented without further delay. A new Coroners Act must be enacted to clarify the legal duties and rights of coroners, and the procedures to be followed from the reporting of a death through to the holding of inquests. Clear structures must be established to deal with information to be provided to families, the appointment of a coroner's officer to liaise with parents following a post mortem, and the provision of support to families through the inquest process.
- 3.2 The role and responsibility of the coroner's office in relation to communicating with families must be clearly outlined in coroner's rules. Although it is common for the coroner's post mortem to take place within a hospital, hospital staff are obliged not to discuss the post mortem with the family as this is a matter for the Coroner. This can create difficulty and tension between the hospital and the family and must be avoided by clear mechanisms being put in place to inform families of the process and their rights. Disclosure arrangements with relatives must be reviewed so as to ensure that relatives are kept informed as far as possible, subject to the proviso that there may be circumstances in which the coroner cannot provide full information because of the nature of his inquiry and any accompanying criminal investigation. Coroners post mortem reports must state when organs have been retained and the reasons for retention.
- 3.3 Where a coroner's post mortem is required, parents must be so informed clearly and without delay. They must be told that their consent is not required. An information booklet setting out the powers and functions of the coroner, and the procedural aspects of the coronial jurisdiction, must be made available to the family. They must also be told that organs may only be retained as part of this process for as long as is necessary to establish the cause of death and other relevant matters relating to the child's death. Parents must be told that they have the opportunity to decide on disposal of the organs once the coroner's purposes have been satisfied. Good effective communication in all aspects of this discussion is of paramount importance.
- 3.4 Coroners are entitled and obliged at law to direct retention of organs to assist in the investigation of the cause of death. Retention for any other purpose such as teaching or research is outside of the remit of the coroner and, if it is to take place, must be clearly authorised by the child's parent/guardian.
- 3.5 The legal position pertaining to the status of organs lawfully retained as part of a coroners post-mortem examination must be clarified by legislation. Pathologists performing post-mortem examinations at the request of a coroner must have clear protocols agreed with the coroner for the retention of organs.
- 3.6 In some cases there may be cultural or religious objections by the family of the deceased to the holding of a post mortem examination and/or the retention of organs. Insofar as it is possible to do so, these objections should be respected. However, such objections cannot interfere with the lawful exercise of the coroners' jurisdiction and obligation to investigate the cause of death.

- 3.7 All instructions from the coroner to the pathologist must be documented in writing. The responsibilities and rights of pathologists carrying out coroner post mortems must be clearly established by legislation.
- 3.8 It is recommended that the new Coroners Act provide for options to be made available to families of deceased persons in relation to disposition of the organs when the death investigation has concluded. These options would include return of the organs to the family for burial, donation of the organs to an appropriate hospital for teaching or research, burial in a hospital plot, or cremation. The cost implications of these options should also be dealt with by the legislation.
- 3.9 In the case of a coroner's post-mortem, parents must be given the post mortem report on request, though the timing of its release may depend on whether or not an inquest is required in the circumstances. This must be made clear to parents in information provided to them from the outset of the process.

4 Hospital post-mortem policy

- 4.1 All post mortem examinations must be carried out by a qualified pathologist in accordance with the professional guidelines of relevant training bodies. This does not necessarily mean that a specialist paediatric pathologist will perform all paediatric post mortems as this may be impossible from a resource and personnel perspective.
- 4.2 Standardised authorisation forms must be drafted in consultation with interested parties, and used in all hospitals in conjunction with standard information booklets. A copy of the authorisation form must be kept on the patient's medical record as well as sent to the pathology department where the post mortem is carried out. The pathologist must ensure that authorisation has been given prior to proceeding with the examination. Parents must also be given a copy of the authorisation form.
- 4.3 Measures must be adopted by all health service providers to ensure that all patient care staff receive mandatory training in responding to grief and bereavement.
- 4.4 Each hospital must have a bereavement liaison officer available to offer practical help and support to bereaved families and staff caring for those families. This officer must liaise with the relevant pathology department and should have a good understanding of pathology practices so as to provide assistance to the family if required. Although it is the clinician's responsibility to discuss the post mortem with the parents, this may be done as part of a team approach with the bereavement liaison officer, who may provide appropriate follow-up support.
- 4.5 Post mortems must be viewed as a continuation of patient care and therefore part of clinical governance within the hospital. Although professional autonomy dictates the technical detail of the performance of the post mortem, responsibility for the administrative aspects of the process rests with hospital management who

must make certain that protocols are in place to ensure all legal requirements as to authorisation and record keeping are satisfactorily complied with. This also requires that an effective audit of post mortem practice be regularly undertaken to reassure the public that past practices cannot recur and that the hospital's policies and practices conform to current legal requirements.

- 4.6 Healthcare providers must ensure that health service employees are instructed in post-mortem policy and relevant procedures for giving information to parents. This must be included as part of the induction process for new entrants to the healthcare service.
- 4.7 An independent audit must be carried out of currently retained organs in all hospitals in the State. The Department of Health and Children and the Health Service Executive should engage in a public information campaign informing relatives that they may reclaim any currently retained organs within a 12-month period from the date of this Report. This should be organised and managed via a central enquiry line rather than by individual hospitals. Families who do not contact hospitals in this regard should not be approached with this information. Their right not to know must be respected, provided reasonable efforts have been made to disseminate information publicly.
- 4.8 If, after this 12-month period, organs remain unclaimed, they must be disposed of respectfully by the hospital in line with written policies. This must be done in accordance with health and safety regulations and will entail either burial in an approved hospital plot, or cremation. Conformity with national policies and regulations must be demonstrated in accurate record keeping and monitored by periodic audit.
- 4.9 Accurate and detailed record keeping of retention and disposal of organs at post mortem must be maintained in all pathology departments in accordance with best practice guidelines. Physical disposal or return of organs to families must be carried out by technical services staff or the bereavement liaison officer respectively, in accordance with hospital policy and the wishes of the parent/guardian.
- 4.10 It is recommended that guidance be given by the hospital to families regarding burial or cremation of the organs and that they be advised to use an undertaker for this process. An information sheet setting out the necessary information must be given to families to whom organs are being returned.
- 4.11 Where organs are to be disposed of by the hospital in accordance with the wishes of the family, this must be done in accordance with health and safety guidelines established by the Department of Health and Children. These guidelines must ensure that the organs are treated with dignity and respect insofar as this can be facilitated by the safe and hygienic disposal method chosen.
- 4.12 Clear national protocols must be put in place by the Department of Health and Children and Health Services Executive to deal with queries from families in respect of post mortem practices as well as the provision of standardised forms to be used on a national basis. The language to be used in such forms must be clear

and comprehensible, and must avoid medical or legal terminology as much as possible. Existing guidelines produced by the National Working Group on Organ Retention in 2002, and adopted by National Chief Officers in 2003 may be used as the basis on which to make any adaptations recommended in this Report. This should be done in consultation with relevant stakeholders.

5 Public awareness

- 5.1 Measures should be taken to inform the public that post mortem examinations are carried out to safeguard and promote health and well being. The welfare and best interests of the families of the deceased, as well as that of society in general, requires steps to be taken to promote the importance of the autopsy in our health care system.
- 5.2 The public should be made aware of the process of a post mortem examination, the fact that organs are removed for examination and small specimens kept as part of their medical records for further tests, in their interests. They should also be made aware that, in certain circumstances, it may be necessary to retain whole organs for examination and that the body may not always be returned intact for burial.
- 5.3 The Department of Health and Children should engage in a public education and information programme to ensure that members of the public are informed as much as possible as to the post-mortem procedure, the value of retention of organs and tissue, the importance of pathology practices in our healthcare system, the value of post mortems in the education of medical professionals and in the carrying out of significant research, and the rights of families in this regard. Restoration of public confidence in medical practice, and specifically pathology practices, is vitally important to encourage a higher rate of post mortems in our hospitals.

6 Medical education and training

- 6.1 It is recommended that medical and nursing students be permitted and encouraged to attend post-mortem examinations. Legislation should provide for authorisation for such educational viewing to be sought from the parent/guardian of the deceased child or the coroner as appropriate. Guidelines should be drawn up to ensure that such attendance will be carried out in a controlled and respectful manner.
- 6.2 As part of the education and training of medical professionals, increased attention must be paid to communication skills and the legal and ethical issues involved in the removal and use of human organs and tissue. All relevant hospital staff must be trained in relation to the authorisation process.

6.3 It is recommended that anonymised organs currently retained in pathology museums for teaching purposes should be maintained as a valuable educational resource. Any proposed inclusion of an organ in such a museum in the future must be specifically authorised and documented.

7 Medical Research

7.1 In any discussion about organ retention, parents must be given information about potential uses and benefits of retention for purposes of education and research, unless they indicate that they do not wish to receive such information. Sometimes comfort may be afforded to parents who feel that something positive may come from their child's death. It is recommended that organs may be removed and retained from the body of a deceased child at a hospital post mortem for purposes of education and research, only where the removal and retention for such purpose has been authorised by the child's parent/guardian.

7.2 It is recommended that authorisation of retention for research purposes may be general or specific. Choice must be given to parents as to what form of authorisation they wish to give. A general authorisation will facilitate the use of the retained organs for research purposes that are not presently foreseeable. A specific authorisation may limit the research use of the organs by prohibiting certain types of research being carried out with the organs. The authorisation form must enable full account to be taken of parents' views in this regard.

7.3 Where the purpose of the organ retention following a post-mortem examination is research, it is recommended that in addition to the requirement that the retention be authorised, the research must be also subject to ethical review by an approved Research Ethics Committee.

7.4 Parents may not wish to be told the details of a post-mortem examination and may nonetheless choose to authorise such examination to take place. In these circumstances, authorisation of organ removal and retention for any purpose other than diagnosis of the cause of death cannot be presumed and must therefore be specifically obtained for education, training and research.

Chapter One

Background to the Inquiry and Terms of Reference

1 Introduction

1.1 The background to the establishment of the Post Mortem Inquiry in Ireland is inextricably linked to events that took place in the United Kingdom in June 1998 when the Secretary of State for Health established a Public Inquiry. The terms of reference of that Inquiry, known as the *Bristol Inquiry*,¹ were to inquire into the management of the care of children receiving complex cardiac surgical services at the Bristol Royal Infirmary and relevant related issues. It was conducted between October 1998 and July 2001. The Inquiry heard evidence in relation to the treatment of the child's body after death and the information given to the child's parents in that regard. There was an outcry that, without the parents' knowledge or consent, hearts had been systematically taken from the bodies of children undergoing post-mortem examinations at Bristol and used for a variety of purposes such as audit, medical education or research, or had simply been stored. The *Alder Hey Inquiry*² confirmed that these practices were not confined to the Bristol Royal Infirmary but were in fact common practice in other hospitals also.

1.2 As a consequence of the media and public attention focused on this issue in the United Kingdom, questions began to be asked in Ireland as to whether similar practices could have taken place in Irish hospitals. A parent of a child who had died at Our Lady's Hospital for Sick Children at Crumlin in Dublin (Crumlin Hospital) telephoned the hospital on 12 February 1999 to ascertain whether her child's organs had been retained. This was not, in fact, the first such enquiry to the hospital relating to organ retention as the hospital had dealt with one other such enquiry prior to this time.

1.3 On 12 September 1999 a national Sunday newspaper, *Ireland on Sunday*, published an article about the retention of children's organs at Crumlin Hospital. It was followed on 7 December 1999 by a detailing of the issue on the main RTE news bulletin and was raised in Dáil Éireann on 9 December. On that date the Minister of State for Health informed the Dáil that Crumlin Hospital had retained the organs of 98 children on whom post-mortem examinations had been carried out. On 10 December there was a detailed discussion on the television programme *The Late Late Show* about the retention of children's organs and a number of parents recounted their own personal stories on that programme. As a consequence there was further publicity in the media about the issue and hospitals quickly began to receive telephone calls from worried and distressed parents anxious to discover whether organs from their deceased children and relatives had been retained.

¹ *Learning from Bristol: the Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995*, CMND 5207

² *The Report of the Royal Liverpool Children's Inquiry*, 2001

1.4 On 19 December 1999 a group of over 200 parents met to formally establish the Parents for Justice group in order to establish the facts about what happened to the organs of their deceased children. The group advocated strongly for an Inquiry to be established in order to ascertain the facts in relation to organ retention at post-mortem examinations.

1.5 On 9 February 2000 the Minister for Health, Mr Micheál Martin, announced that he was to establish an Inquiry relating to all post-mortem examinations, organ removal, retention and disposal at Crumlin Hospital and that it might also be extended to other hospitals.

1.6 The Post Mortem Inquiry was established by decision of the Government on 4 April 2000. Ms Anne Dunne SC was appointed Chairman of the Inquiry on 6 April 2000. This Inquiry ceased to exist on 31 March 2005 following a Government decision to that effect. On that date Ms Dunne delivered to the Tánaiste and Minister for Health, Ms Mary Harney, a report dealing with the three Dublin paediatric hospitals. This report comprised 3,500 pages and was accompanied by 51 boxes of appendices in the form of submissions from parents/next-of-kin, hospitals, health boards and professional bodies. On the advice of the Attorney General it was decided not to publish this report. On 3 May 2005 the Government appointed Dr Deirdre Madden to complete a final report on post-mortem practice and organ retention by 21 December 2005.

2 Terms of Reference

Terms of reference for Dr Madden's work were published on 14 July 2005 as follows:

- 1 To inquire into policies and practices relating to the removal, retention and disposal of organs from children who have undergone post-mortem examination in the State since 1970
- 2 To inquire into allegations that pituitary glands were removed from children undergoing post-mortem examination for sale to pharmaceutical companies within and outside the State
- 3 To examine professional practice in relation to the information given to children's parents in respect of the removal, retention and disposal of tissue and organs and the appropriateness of practices of obtaining consent
- 4 To review the manner in which hospitals responded to concerns raised by bereaved families relating to post-mortem practices carried out on children
- 5 To make recommendations for any legislative and/or policy change as deemed appropriate.

Note: Organs removed with consent for transplantation purposes are excluded from the inquiry.

For the purposes of this report:

‘Organ’ is to be interpreted as a part of the body composed of more than one tissue that forms a structural unit responsible for a particular function(s), for example, the brain, heart, lungs and liver.

‘Post mortem’ refers to any post-mortem examination of a body after death, including those directed by the coroner.

‘Child’ or ‘children’ refers to those born alive and less than twelve years of age at the date of death.

3 Approach to the Report

3.1 The time frame for this Inquiry was from 3 May to 21 December 2005. During that period it was necessary to read as much relevant information as possible within a reasonably short period of time before commencing the drafting of this Report. The volume of documentation collated by the Dunne Inquiry over the period of its existence was considerable, including many thousands of documents, files, reports, research papers, transcripts and statements.

3.2 All submissions from parents of children within the terms of reference were read carefully and analysed to ascertain the principal concerns and grievances of parents. All relevant transcripts of evidence given to the Dunne Inquiry were also taken into account in this regard. Individual cases have not been selected or identified in this Report so as to protect the privacy of the families who made submissions. Their experiences are set out, using their own words, in Chapter Four.

3.3 All submissions from hospitals and health boards (as they then were) within the terms of reference were read carefully and analysed to ascertain the principal facts of post-mortem practice in Irish hospitals since 1970. The length and complexity of the submissions varied between hospitals, with some producing vast amounts of documents, minutes of meetings, clinical audit reports, and other correspondence over the time period covered by the Inquiry. Other hospitals produced little documentary evidence and relied on detailed answers to a set of scheduled questions put to each hospital at an early stage of the Dunne Inquiry. Some hospitals were hampered by lack of post-mortem reports or log books, and in some cases relied on the memory of personnel working at the hospital over the relevant period. In the absence of an independent audit of the pathology department of each individual hospital, the absolute accuracy of the details of post mortems carried out and organs retained, as submitted by the hospitals, cannot be objectively verified.

3.4 In the course of her work Dr Madden read the report prepared by Ms Dunne, together with the appendices submitted with the report. She met with Parents for Justice, the Infant Stillbirth and Neonatal Death Society (ISANDS), Heart Children Ireland, the Faculty of Pathology, perinatal and paediatric pathologists, and professors of pathology from the medical schools of Irish Universities. She visited the Pathology Departments of Crumlin Hospital and St James’s Hospital. Dr Madden travelled to Manchester, Belfast, Edinburgh and Glasgow to meet with members of inquiry teams

in the UK, Northern Ireland and Scotland who had carried out similar work in those jurisdictions. She also attended two conferences at the Royal College of Pathology in London in relation to the implementation of the UK Human Tissue Act, 2004.

3.5 It had originally been envisaged that some aspects of Dr. Madden's work might be carried out in public and initial attempts were made to organise a public meeting during July. However, having discussed the possibility of a public meeting with the various interested parties, Dr Madden concluded that such a meeting would not be productive at the present time.

3.6 Following publication of the Terms of Reference on 14 July, Parents for Justice called on their members to boycott the work of the Inquiry. Following this decision, no further meetings took place between Dr Madden and Parents for Justice.

4 Conclusion

4.1 The purpose of this Inquiry is to be a fact-finding exercise, not a method of apportioning guilt or blame for what happened in the past. It does not address disputes or conflicts arising in individual cases.

4.2 Parents and families are entitled to have the facts of this controversy set out publicly and acknowledged. They are equally entitled to have their pain, distress and anger recognised and addressed. Parents are justifiably anxious to ensure that the practices of the past never happen again and that the system within which such practices existed changes for the better. These issues were the driving force behind the establishment of the Inquiry. The facts of organ-retention practices must be established so that we can begin to move ahead with recommendations for the future. Public confidence has been damaged by the controversy that led to this Inquiry and must be re-established so that the public can be assured that deceased patients and their families are treated with the utmost sensitivity and respect, and that the importance of medical education and legitimate research is not foregone.

4.3 This Inquiry has examined both coroner and hospital post mortems. It is clear from the submissions of parents that their fundamental concerns relate to the issue of consent to hospital post-mortem examinations, the lack of information given in relation to coroner post mortems, and concerns relating to the storage, use and disposal of retained organs.

4.4 While the terms of reference of this Report focus on the retention of organs from children, the recommendations contained herein may be broadly applied to post-mortem practice in all age groups. Consideration should be given to the application of these recommendations, with adaptations where necessary and appropriate, to post mortems carried out on miscarried fetuses, stillbirths, minors and adults.

4.5 In conclusion, this Report aims:

- To summarise past and current practice in relation to the retention of organs from children
- To set out the main issues and concerns that have arisen from these practices
- To recommend changes to these practices, at both a hospital policy and legislative level, which will ensure:
 - respect for the deceased child and its parents
 - compassionate treatment of bereaved families
 - provision of clear information and explanations by clinicians on the purposes of organ removal and retention
 - effective participation by families in taking key decisions
 - that, with the support of the public, the benefits of greater understanding of disease through research, audit and teaching, using retained organs after death, will help future generations of patients.

Chapter Two

What Happens at a Post-Mortem Examination?

1 Introduction

1.1 There are two categories of post-mortem examination: the coroner's post mortem (also called medico-legal or forensic post mortem) and the hospital post mortem (also called clinical, diagnostic or 'house' post mortem). The post-mortem examination is sometimes referred to as an autopsy (or necropsy). This is argued to be a more accurate description of the examination as including an internal examination of the body. 'Post mortem' and 'autopsy' are used interchangeably in this Report. There is no difference in the technical performance of the different types of post-mortem examination, though the hospital case may be directed to particular problems. The coroner's case is perhaps more extensive in some circumstances, particularly in suspicious deaths, and will include a full external examination, likely time of death, nature of any injuries, toxicological analysis, as well as the usual histology and other investigations carried out in any post-mortem examination.

1.2 Post-mortem examinations are unfamiliar to most people outside of the medical profession. On the rare occasions when those without medical training or education reflect upon such procedures, the details are likely to be inherently unpleasant. One of the reasons why controversy arose in relation to post-mortem practices in this country was the lack of information given to parents or next-of-kin of the deceased person. The public did not and probably still do not have any deep understanding of what a post-mortem examination entails and why it may be necessary or advisable in particular circumstances. This chapter attempts to de-mystify the post-mortem examination and place it in the context of medical practice in general. Emphasis is placed here on paediatric post-mortem examinations, as this is in keeping with the Terms of Reference under which this Report has been written.

1.3 Some readers may find the detailed description of post-mortem examinations in this chapter distressing.

2 Paediatric Post-Mortem Examinations³

2.1 This is a short description of the paediatric post-mortem examination. Although the post-mortem examination is often regarded as that part of the examination taking place in the post-mortem room, it should be emphasised that the process begins with an assessment of the clinical history of the deceased and continues until the history and pathology observations have been integrated.

In principle, the technical aspects of paediatric autopsies are no different to adult autopsies, although there are certain points that tend to be more critical. Further, not all examinations are exactly the same, as the procedure will vary depending on the

³ This description was provided by Dr Steve Gould, Consultant Paediatric Pathologist at the Department of Paediatric Pathology, John Radcliffe Hospital, Oxford.

underlying problem and, of course, the conditions of consent. Despite the events of recent years, the examination itself has not changed.

This description will focus on the internal examination, describing it in sufficient detail to ensure an overall understanding of the examination, but not covering every technical detail. Major technical variation will be covered and important ancillary investigations will be included, as the results of many of these studies may influence the conclusions. This does not describe the additional detailed dissection procedures required in forensic paediatric autopsies where suspicion of non-accidental injury is overt.

2.2 History

The examination starts with the pathologist having a full clinical history of the deceased. An incomplete history may lead to an inappropriate lack of focus in some areas of the examination. More importantly, the conclusions drawn are likely to be inaccurate. Pathology diagnoses do not exist in a vacuum.

2.3 External Examination

The body is examined with the same sort of care that any physician or surgeon would make of a living baby or child. This will include a description of structural abnormalities, features of dysmorphism (facial characteristics that make the baby or child look abnormal), the presence or otherwise of jaundice, rashes or other features of disease. In cases of sudden unexpected death, a record of any bruise or sign of trauma will need to be made.

In all cases, a series of measurements will be recorded including bodyweight, height, head circumference and, usually in small babies, foot length and sitting height. Sometimes the abdominal circumference will be recorded. This can be used to assess whether the baby or child has been well nourished and has been growing normally.

2.4 Photography

No amount of description can replace a photograph, so this is routine in many situations. Photographs form part of the medical record and, for instance, may:

- in dysmorphism allow referral to a clinical geneticist for specialist opinion
- provide a record of any pathological feature
- record evidence of trauma for use in medico-legal proceedings
- be used as a teaching aid.

2.5 Radiology

This is a routine requirement in some types of baby or childhood death. In particular:

- in the context of structural or congenital abnormality, radiology may identify bony abnormality not apparent by external examination. This may affect diagnosis which in turn will influence genetic counselling
- in some hospital deaths, radiology will help to demonstrate the position of cannulas and other tubes to ensure inappropriate placement has not contributed to death

- X-rays can help to show calcium deposits which may occur in different pathological conditions
- all unexpected death (cot death) will require complete skeletal examination to demonstrate or exclude old or recent traumatic injury.

2.6 Internal Examination

(a) Incisions

There are a number of initial incisions which may be used, and their use will depend partly on the personal preference of the pathologist but also on the nature of the case. All will include a long incision from the top of the sternum (breastbone), down the midline to pubis. If possible, the incision will be made along previous surgical incisions.

Many pathologists prefer to make a further shallow U-shaped incision at the top, roughly between the shoulders. This has advantages in that these incisions allow access to neck structures, but are kept low so that afterwards these incisions can be easily hidden by the appropriate clothes.

(b) Organ Removal

The next step involves reflecting back the skin to expose the ribcage and the abdominal contents. An anterior, shield-shaped section of the ribcage is then removed to expose the thoracic content. At this stage, most organs can be inspected to identify any major pathology and assess whether any variation in approach to the next stage is required.

There are two major variations in the following step of the examination. Perhaps the more common involves completely eviscerating the body, removing all organs in continuity, from the top of the neck to the lower abdomen including the bladder. The alternative is to remove the organs in particular 'blocks' in sequence. Depending on circumstance, both have advantages. The latter approach will be described.

(c) Thorax

Immediately below the thoracic shield lying in front of the heart is the thymus. This is removed before the major dissection of the chest takes place. The first major block to be removed includes the heart and lungs, together with the neck structures which will include the oesophagus and tongue.

(d) Cardiovascular System

After removal, because numerous vessels connect the heart and lungs, they are dissected in continuity to demonstrate normal or abnormal communication. The heart itself is then examined and this includes opening the chambers to assess their normality or otherwise, the four main sets of valves, the blood supply to the heart itself (i.e. the coronary arteries) and the heart muscle, this latter process requiring section of the myocardium (heart muscle).

Such an approach may be inadequate when the heart shows a major complex structural abnormality. In this circumstance, it may be preferable to keep the heart and lungs (or at least part of each lung) and fix in formalin solution. The heart then

becomes more rigid and can be examined, usually within 24–48 hours, often with clinical colleagues, and a fuller appreciation of the abnormality acquired.

After the heart has been examined, the other major arterial branches are explored and this will include the aorta and the main arterial branches to the neck.

(e) Respiratory System

The larynx and trachea is part of the thoracic block and, after inspection, it is opened along its length. The examination of the lung connections with the heart have been described above. The lungs are then removed from the ‘block’ and examined separately.

The arterial supply and the main bronchi within the lung itself are opened along their length. The lung tissue is then sliced to look for other focal lesions or processes such as infection.

(f) Abdomen

The small and large bowel are inspected and then removed in entirety. The next organ block removed includes the liver, stomach, pancreas and spleen.

(g) Gastro-Intestinal System

The oesophagus is opened along its length as part of the thoracic block. The stomach is opened and the content and lining inspected. The small and large bowel, having been removed, as described above, may be opened depending on the background of the case. The connection between the liver and first part of the small bowel, the bile duct, is checked. The liver is inspected and then sliced.

(h) Genito-Urinary System

The kidneys are removed and examined in continuity with the ureters and bladder. After slicing the kidney, the ureters and bladder are opened.

Male genitalia are examined by pulling the testes back into the abdomen and inspecting and slicing. The female genitalia are examined in the same block of tissues as the urinary bladder and require opening.

(i) Endocrines

The endocrine organs, although usually described together, are examined individually as part of their respective organ block with which they are removed. The pituitary, which sits in the base of the skull, is examined after the brain has been removed (see below), and may require the small plate of bone lying just to the back of it to be removed first.

The thyroid is examined as part of the thoracic and neck organ block. It can be dissected away from the front of the trachea and inspected. The pancreas is inspected and sliced as part of the liver and stomach block (see above). The adrenals, sitting just above the kidney, may be removed and inspected separately.

(j) Reticulo-Endothelial System

The thymus gland which lies at the front of the chest, as described above, has already been examined. The spleen is removed from near the tail of the pancreas, inspected

and sliced. Lymph nodes, distributed around the body, are examined and a general note of the lymph node size is recorded, to ascertain whether or not they are increased in size.

(k) Central Nervous System

Although described last, the brain is often the first organ examined.

The incision in the head is made behind one ear and this passes upward over the crown of the head to the rear of the other ear. An attempt is made to make this incision as far back as possible and thus make it invisible when a small cap or bonnet is used later to cover the incision.

The scalp anterior to the incisions is reflected forward, and the scalp posterior to the incision is reflected backward to expose the skull. The skull may be opened in one of two ways, depending on the age of the baby or child. In the older age group the top part of the skull is removed by a largely horizontal cut through the skull, normally by use of a mechanical saw.

In young babies, sometimes the skull can be opened by incising along the yet unfused or loosely fused suture lines; scissors are commonly adequate for this procedure. The resulting incisions allow the individual bones of the skull to be opened outward in a 'butterfly' fashion to expose the brain.

When the brain has been removed, if there is any question of pathology, it needs to be fixed in formalin. In recent years by using a variety of techniques and stronger formalin, the period felt necessary to fix, or preserve, the brain has reduced considerably. This period may be anything between 3–4 days up to about 7–10 days. There will still be some circumstances when even longer fixation is to be preferred. Fixation makes the brain more firm and allows accurate inspection of the fixed slices and of sampling (see below).

After fixation, examination of the brain involves external inspection and then slicing into 0.5–1 cm slices. Where there is likely to be complex structural abnormality or an underlying neurological condition, it is far preferable for the brain to be examined by a specialist neuropathologist, if possible.

The spinal cord is not examined as a routine. Usually the spinal cord is removed only in the presence of a suspected significant neuromuscular disease or perhaps suspected trauma (e.g. shaken baby syndrome). The usual route by which the spinal cord is approached is from the front, after all the other organs have been removed. The bony vertebral column that sits in front of the cord is removed, allowing access to the cord. This approach means no further incisions other than those described above need to be made.

The eyes are usually examined only in the context of possible shaken baby syndrome.

(l) Musculo-Skeletal System

As indicated above, the initial part of the examination of the skeletal system is an X-ray. Often, little more is needed as direct examination of a bone may reveal relatively little additional information. A sample growing point between the cartilage and bone

in the rib may be removed. Histologically, it may show abnormal growth when the baby or child has been ill in previous weeks.

Specific muscle examination is not routine. However, in the presence of a suspected neuromuscular disorder a small biopsy may be removed from exposed muscle such as that on the front of the chest. Occasionally, a biopsy from the muscle on the front of the thigh is preferred.

2.7 Organ Weighing and Tissue Sampling

As part of the examination of every organ, it is separated and weighed. A small sample is then taken for histology. Organ weights are a critical measurement and, in each case, the organ weight is compared to normal charts so that any variation from the expected weight may be determined. Significant variation from normal may provide objective evidence of a disease process. In some situations, it is the ratio between various organ weights that is as critical as the absolute values.

All organs need sampling for histological examination.⁴ Especially in paediatric autopsy, abnormality may be hidden to the naked eye; normality also needs to be confirmed if present. Further, tissue sampling after processing to paraffin wax block allows the block to be stored and for there to be a permanent record of the pathology. This can be revisited at any time in the future and diagnoses reconsidered.

2.8 Microbiological and Other Sampling

Sampling of tissues for bacteriological and/or virological study is a part of most paediatric autopsies. The most common samples taken during the course of the procedure include: blood, cerebro-spinal fluid, samples of lung, spleen and any other potentially infected organ.

Some samples may be valuable for metabolic or genetic studies and should be taken depending on the case history. This may include: skin and spleen samples for genetic or DNA studies; bile or urine for metabolic studies; vitreous humour for biochemical studies.

2.9 Reconstruction

At the end of the autopsy the body should be reconstructed carefully. Organs that are replaced in the body are not returned to the site from which they were removed but are placed in the abdomen. In some hospitals in the United Kingdom the brain is returned to the cranium, but this is not usual practice in Ireland.

While the major lines of incision cannot be completely hidden, they should be sufficiently discreet that with appropriate clothing it is possible for viewing to occur after the autopsy.

2.10 Conclusion

The autopsy may be considered finished when the post-mortem findings, the histology and the results of all the various ancillary investigation are collated and interpreted in the light of the history.

⁴ Histology is concerned with the study of the structure, composition and function of tissues.

3 Distinctions between Adult and Paediatric Pathology⁵

3.1 Paediatric pathologists confine their work to the foetus, infant and child. The scope of their work is defined by the age of the patient rather than the disease or organ affected. This speciality involves clinical services including surgical and post-mortem pathology, teaching, research, and audit. Although this Report concentrates on paediatric post-mortem examinations, the principles of post-mortem practice outlined here are generally applicable to all post mortems irrespective of age. However, there are a number of distinctions between paediatric and adult pathology:

- The spectrum of disease in the child is different from that in adults, particularly in relation to inherited and congenital disorders, and malignant tumours.
- Understanding abnormalities in children requires a detailed knowledge of normal developmental changes and processes.
- Preparation of samples from a child requires a more labour-intensive and individualised approach.
- Access to a dedicated paediatric pathologist is regarded as essential in a paediatric hospital to which children with complex or serious disorders are referred.
- There are distinct dedicated textbooks, journals, and international meetings covering paediatric pathology.
- Neonatologists treat and care for small, immature and often sick infants, some of whom do not survive. A post mortem carried out on a newborn baby will usually examine both the infant and placenta. It will provide feedback to the bereaved parents, with information that may be important in understanding why their baby died and for making future plans. It may help the neonatologist in auditing the effectiveness and appropriateness of treatment. It may also be beneficial to obstetricians in providing information about infant and placenta, which will be useful in managing future pregnancies.
- An Inquiry in the UK into stillbirths and deaths in infancy concluded that there was an association between unsatisfactory post-mortem reports and examinations carried out by non-specialist pathologists. ‘This supports the strong argument for all perinatal autopsies to be performed by specialist perinatal pathologists.’ (2003 Confidential Enquiry into Stillbirths and Deaths in Infancy, Project 27/28, www.cemach.org.uk).
- Deaths following paediatric surgery require specialist investigation in order to enable the bereaved families and the clinicians to understand why the surgery went wrong, and whether there were previously undiagnosed anomalies.
- In the treatment of paediatric cancer, accuracy of diagnosis and disease classification is essential, as survival depends on targeting treatment to the

⁵ Royal College of Paediatrics and Child Health: *The Future of Paediatric Pathology Services* (March 2002)

specific type, grade and stage of tumour. Many tumours are unique to children; specialist knowledge and experience are required to interpret samples sent for testing.

4 Removal and Retention of Organs

4.1 It has always been common practice in pathology to remove and retain specimens derived from post-mortem examination for a period of time, primarily in order to be able to answer further questions in relation to the post-mortem report or diagnosis. This is common to all post-mortem examinations, irrespective of the age of the deceased person. Organ retention may also be necessary for the following reasons:

- Retention facilitates further examination if necessary, in the light of the development of a possibly related condition by a family member.
- In circumstances where the post-mortem examination is incomplete at the time at which the funeral has been arranged, pathologists retain organs for later examination rather than delay the funeral.
- In some circumstances the organ removed at post mortem cannot readily be examined or dissected while fresh and it is necessary to fix it for a period of time in order to enable examination to be made at a later date.
- Retention of organs for teaching in medical schools has long been advocated as the best means of instruction of medical students. The organs are stored in transparent containers and coded so as to preserve anonymity.
- Organs may also be retained for research purposes so as to enable review and comparison between healthy and diseased organs in order to investigate the cause of death. This is illustrated in the case of research carried out into the causes of Sudden Infant Death Syndrome (SIDS) in which organs from children diagnosed as having died from this syndrome would be compared with organs of children who had died from other causes in order to try to discover what organs were affected by SIDS and why this might have occurred.
- For safety reasons, in cases of known or suspected infectious disease where the health of the pathologist or post-mortem technician is at risk, organs may be retained and fixed for later examination. This applies, for example, in the cases of Hepatitis B, HIV, Tuberculosis and variant CJD.
- In cases where death may have been caused by disease of the central nervous system, examination of the brain and/or spinal cord is necessary. Although it is possible in some cases to examine the fresh brain, this examination is not possible in infants or young children where dissection is prevented by the fluidity or soft structure of the brain. Fixation is necessary in order to enable the pathologist to carry out a thorough examination of the brain and is recommended as best practice

- by guidelines from professional organisations. In some cases the brain may be sent for specialist neuropathological examination to Cork University Hospital, Beaumont Hospital or St James's Hospital. The Department of Health and Children has established guidelines for the referral of brains from patients with suspected CJD to Beaumont for examination.⁶
- In examination of the lung, inflation by infusion of formalin into the air spaces facilitates thorough histological examination. Sometimes the pathologist will examine one lung at the time of post mortem and retain the other for inflation-perfusion. This is particularly relevant in paediatric post mortems where assessment of pulmonary maturity is greatly aided by this procedure.
- The heart is usually examined fresh at the time of autopsy. However, previous cardiac surgery or congenital heart disease may make this impossible. In these cases the quality of the dissection is improved by fixation and sometimes perfusion of the heart. Children's hearts may be referred to Our Lady's Hospital for Sick Children in Crumlin for examination by paediatric pathologists there. The examination will be carried out in consultation with paediatric cardiologists and cardio-thoracic surgeons in the hospital who have special expertise in this area.
- Sometimes it is necessary to retain other organs for detailed examination, for example retention of the eye in cases of suspected non-accidental injury in children such as shaken baby syndrome. In such cases the globe of the eye is removed and fixed for examination.
- In the case of foetal or perinatal death, the clinician may seek specialised examination by paediatric or perinatal pathologists. This may involve referral of the whole body or of certain organs to another hospital for examination.

5 Storage of Organs

5.1 In the past, organs retained for the reasons set out above were usually stored on shelves in or beside the autopsy room and, if not retained for teaching purposes, later disposed of. Records of retention were rarely maintained other than perhaps in the case of brains kept for examination by a neuropathologist. Organs were usually disposed of within months, but in some cases the disposal was delayed by the necessity of having to carry out a further review or examination for a specific diagnostic purpose, or for teaching/research. In some cases organs were not disposed of due to human error in filing or dating the organs incorrectly, or due to difficulties in arranging for disposal facilities to be made available. In some cases organs were retained for longer than five years and became dried out or desiccated.

5.2 Policies and practices of hospitals in relation to storage, record keeping and disposal of organs have changed significantly in recent years. This is elaborated further in later chapters of this Report.

⁶ *Creutzfeldt-Jakob Disease Surveillance Associated Costs of Transportation for Post Mortems.* Department of Health and Children Memorandum. Staunton N., Secondary Care Division

6 Disposal of Organs

6.1 Best pathology practice advocates the retention of tissue, and in some cases whole organs, for further investigation and histological examination. Having derived the necessary information from the tissue, and created wax blocks and slides for permanent storage as part of the medical record of the deceased, the surplus material is then commonly disposed of. In some cases where storage capacity is problematic, blocks and slides have also had to be destroyed.

6.2 Until recent years hospitals did not commonly differentiate between tissue removed at post mortem and that removed during surgical intervention on a live patient. All surplus tissue, including organs, was destroyed according to hospital policy and guidelines issued by the Department of Health and Children.⁷ Safety in handling and disposal of clinical waste was the primary consideration rather than the need for respectful disposal or consultation with next-of-kin. European Directives also cover safe disposal of human organs and tissues as waste but are silent about the wishes and intentions of relatives of the deceased person.

6.3 Many hospitals had an incinerator to which this material was sent for disposal. In the late 1990s waste material was exported abroad for appropriate disposal in keeping with environmental protection standards and protection from hazardous risk.⁸ According to a circular from the Department of Health and Children in 1999, to which all hospital laboratories had to subscribe, identifiable anatomical waste was to be placed in a rigid box with a black lid for export. In the case of large amputations, disposal was to be carried out in accordance with the patient's wishes, but no mention was made of consultation with the patient or next-of-kin in relation to disposal of organs or other waste.

6.4 Disposal of retained organs is now carried out in consultation with the family of the deceased. Families are given the option of having organs returned to them for burial or disposed of by the hospital. This is discussed later in the Report.

7 Conclusion

7.1 It is not the function of this Report to second-guess the expertise of pathologists whose training and experience determine the technical performance of the post-mortem examination. It is presumed that a qualified pathologist carries out post-mortem examinations to the highest professional standards and subject to any limitations imposed by request of the family. Anything less than that would clearly be unacceptable.

⁷ *Civil Service Laboratories Advisory Committee Guidelines for the Disposal of Laboratory Waste 1993*. Circular BMC.PH10.TB. Circulated to all laboratories operating under the remit of the Department of Health and Children. 'In general, samples of materials such as bodily fluids, tissues, organs and faeces etc. should be destroyed by incineration.'

⁸ Department of Health and Children Circular, 'Segregation, packaging and storage guidelines for healthcare risk waste' 29/10/99 (as amended).

8 Recommendations

- 1 The public should be made aware of the process of a post-mortem examination, the fact that organs are removed for examination and small specimens kept as part of their medical records for further tests, in their interests. They should also be made aware that, in certain circumstances, it may be necessary to retain whole organs for examination and that the body may not always be returned intact for burial.
- 2 All post-mortem examinations must be carried out by a qualified pathologist in accordance with professional guidelines of the relevant training bodies. This does not necessarily mean that all paediatric post mortems will be carried out by a paediatric pathologist as this may be impossible from a resource and personnel perspective.

Chapter Three

Conduct of Post Mortems in Ireland

1 Coroner Post Mortems

1.1 The history of the coroner in Ireland probably begins sometime in the late twelfth or early thirteenth centuries, though the exact date is impossible to ascertain with certainty.⁹ The office of coroner was exercised by city sheriffs until 1617 when a court of the King's Bench decided that the office should be exercised by two elected aldermen with terms of office ranging between one and three years. The coroner swore to perform the duties of the office in the interests of the Crown. Violent deaths would often bring revenue to the Crown and, thus, the coroner had a duty to inquire into unnatural or suspicious deaths. The identity of the deceased was always a fundamental priority and the coroner usually viewed the body at the place of death if possible. Inquests were held with juries in the presence of the body. The coroner's inquest had an important role in criminal investigation and law enforcement at this time and although there were no specific legislative enactments dealing with the office of coroner, provisions relating to coroners sometimes came within enactments dealing with the administration of justice.

As the financial connotations of sudden death gradually relaxed, or were diverted to other offices, the position of coroner declined until it was revived in the middle ages. At that time the coroner's attention was specifically directed to the establishment or exclusion of criminality, a principle that persisted until the nineteenth century. Gradually, with changing conditions, the importance of the coroner's fiscal duties declined and the holding of inquests on unnatural deaths became for all practical purposes his only function.¹⁰

1.2 Between 1829 and 1908 there were nine acts specifically dealing with the office of coroner, and sections on coroners were also contained in other pieces of legislation. The modern office of coroner was established by the Coroners (Ireland) Act, 1846 which provided for the division of each county into districts, the election and appointment of coroners, and their remuneration. The Coroners Act, 1881 had required a coroner to be qualified as a medical practitioner, a barrister or a solicitor. The executive functions of the coroner and his duties to safeguard the financial interests of the Crown changed over time with increased importance being placed instead on investigation of the cause of death and judicial functions. In the newly independent Ireland, Coroners Acts were introduced in the 1920s, based in large part on similar provisions in England at that time. However, the principal legislation dealing with coroners in Ireland is the Coroners Act, 1962, which remains the primary Act at the present day.

⁹ Farrell B., *Coroners: Practice and Procedure* (2000), Ch. 1

¹⁰ *Review of the Coroner Service*, Report of the Working Group, p.24

1.3 A Working Group was established in 1998 to examine the role of the coronial service and how it might be developed. This Group reported in 2000 with over 100 recommendations, including the necessity for a new Coroners Act.¹¹ It also recommended that the concept of regulation-based Coroners Rules should be an essential element of a new legislative environment for the new Coroner Service. These rules ‘should be established by statutory regulation and be capable of being amended. They should cover the various options and procedures available to coroners throughout the cycle of their functions from death reporting right through to the carrying out of formal inquests.’ The report recommended the establishment of a Rules Committee to devise these rules. A Rules Committee was subsequently established, and Coroners Rules published in 2003 following discussion between appointed experts and consultation with interested parties and the public. It is anticipated that a new Coroners Bill is to be published shortly.

2 Current Arrangements

2.1 Responsibility for the coroner service lies across a number of government departments at the present time. The Department of Justice, Equality and Law Reform deals with legislation and policy relating to the office of coroner. The Department of the Environment, Heritage and Local Government has responsibility, through the local authorities, for the appointment and remuneration of coroners and in some areas the maintenance of mortuary facilities. The Department of Health and Children has responsibility to fund pathology services and post-mortem facilities used by coroners.

2.2 There are 48 coronial districts in the State with a coroner and deputy coroner in each district. Approximately half of the coroners currently in office are doctors, and the remainder are solicitors or barristers. They are paid a basic set fee depending on the size of the district and additional fees for various duties they perform. There are approximately 32,000 deaths annually in Ireland of which approximately 7,250 are reported to coroners.¹² Coroners do not generally have dedicated office premises or staff and tend to work out of their own professional offices, though this is not the case in Dublin or Cork City.

2.3 The Coroner is indemnified by the State in respect of an award of damages made against him, and/or costs, in relation to performance of his duties. He is traditionally given immunity and absolute privilege in the same way as a judge, while performing the duties of the office. The High Court is empowered to judicially review the acts of coroners.

3 Duties of the Coroner

3.1 A coroner is an independent office holder with legal responsibility for the investigation of sudden, unexplained, violent and unnatural deaths within his district. This may require a post-mortem examination followed by an inquest if the death was

¹¹ *Review of the Coroner Service*, Report of the Working Group (2000)

¹² *Review of Coroner Service*, p. 25

due to unnatural causes. The inquest is inquisitorial by nature, as opposed to adversarial. The focus is on a finding of fact, not on apportionment of blame.

3.2 The principal relevant duties of the coroner include the following:¹³

- **To be available at all times to receive notification of deaths, to make preliminary inquiries, and to direct post-mortem examinations to be undertaken.** Under the 1962 Act, section 18 (5), particular persons are obliged to notify the coroner of a death. This duty is discharged if notification is made to a member of the Garda Síochána, not below the rank of sergeant. A medical practitioner in the hospital or place where the body is located pronounces death before the body is removed to the mortuary. The Garda notifies the coroner under s.18(3), usually by telephone or fax to the coroner's office or home. This is recorded on a telephone report form. A C.71 form is sent to the coroner with demographic information, a description of the circumstances of the death, confirmation of the identity of the deceased, and the identity of the doctor who pronounced the death.
- **To direct the performance of a post-mortem examination.** Where a coroner is informed that a body is lying within his district and that the circumstances of death require investigation, he must make a preliminary inquiry as to whether the death had occurred with no apparent unnatural cause and whether a medical practitioner is in a position to sign a medical certificate as to the cause of death. This may be the deceased's general practitioner or a hospital doctor. A doctor signing the medical certificate of the cause of death must have seen and treated the patient within one calendar month before death. The doctor must know the cause of death, and death must be due to natural causes. If this is not the case, he must report the death to the coroner who will arrange for a post-mortem examination to be carried out on the body. If, having discussed the circumstances of the death with the doctor, the coroner is satisfied that despite not having seen the deceased for more than one month prior to death, the cause of death is clear, he may direct the doctor to certify the death (known as the Pink Form). This may occur, for example, where a person has been chronically ill for some time and was expected to die. Where a person is dead on arrival at hospital or dies shortly after admission (usually within 24 hours), the hospital doctor will not usually be in a position to give a medical certificate as to cause of death and will notify the coroner.
- **To inform certain persons.** The coroner or his officer (usually a member of the Garda Síochána) will inform family or next-of-kin of the deceased of the time and place of the post-mortem examination. A family member will usually be asked to formally identify the deceased to the Garda, who in turn will identify the body to the pathologist prior to commencing the post-mortem examination.
- **To release the body.** The coroner will authorise the release of the body following the post-mortem examination. In cases of suspicious deaths, this will be done in consultation with the state pathologist who will usually have performed the

¹³ Farrell, Ch. 2

autopsy and may take a number of days. The body is released to the family for burial only after the coroner is satisfied that no further examination is necessary.

- **To hold an inquest.** Section 17 of the 1962 Act provides: ‘Subject to the provisions of this Act, where a coroner is informed that the body of a deceased person is lying within his district, it shall be the duty of the coroner to hold an inquest in relation to the death of that person if he is of opinion that the death may have occurred in a violent or unnatural manner, or suddenly and from unknown causes or in a place or in circumstances which, under provisions in that behalf contained in any other enactment, require that an inquest should be held.’ This means that if the coroner has reasonable cause to believe that death occurred within the criteria set out in the Act, he must hold an inquest.
- **To send a certificate to the Registrar of Births and Deaths.** When the coroner has completed his inquiry or inquest he must furnish a certificate as to the cause of death to the Registrar, to enable the death to be registered.

Certain deaths must be reported to the coroner, either under legal rules or rules of practice that have evolved in the coronial system.¹⁴ These include the following:

- Sudden, unexpected or unexplained deaths
- Where a medical certificate as to cause of death cannot be obtained because the deceased had not seen a doctor within the previous month
- Where the deceased’s doctor is not satisfied as to the cause of death even where the deceased was treated within one month prior to death
- Sudden infant death syndrome (SIDS), also known as cot death
- Where a death was directly or indirectly due to unnatural causes such as a road traffic accident or any other accident, any physical injury, drug abuse, burns, starvation, neglect, exposure, poisoning, drowning, hanging, firearms
- Where the death resulted from an industrial disease or accident
- Where the death may be attributable to any surgical or medical procedure regardless of the lapse of time between the procedure and death
- Where there is any allegation of medical negligence or misconduct
- Septicaemia which may be caused by an injury
- Death occurring during a surgical procedure or anaesthesia
- Abortions and certain stillbirths
- Acute alcoholism/alcohol poisoning
- Deaths connected with suspected criminal activity
- Where death may be due to homicide or suspicious circumstances
- Death of a person in custody
- Death of a person connected with a pensionable disability
- Death of a patient in a mental hospital
- Death of a child in care
- Where a person is found dead
- Where the cause of death is unknown
- Where the body is to be removed outside of Ireland

Deaths reportable under rules of practice include the following:

¹⁴ Farrell , Ch 7

- Where a person is brought in dead to hospital
- Where a person dies in casualty department of hospital
- Where death occurs within 24 hours of admission to hospital
- Where death occurs after the administration of an anaesthetic, surgical or other procedure
- Certain deaths which occur in a hospital department such as radiology, or out-patients
- Where a person dies in hospital having recently been transferred from a nursing home or other residential institution including a prison
- Where there is any doubt as to the cause of death.

4 Powers of the Coroner

4.1 A coroner has legal possession of the body of the deceased from the moment his jurisdiction arises. This occurs on notification that the body of a deceased person lies within his district. The coroner then commences his inquiry into the cause of death. The right of the coroner to possession of the body pending investigation of the cause of death means that no other person has prior rights in respect of the body. This may be difficult for family members or next-of-kin to understand at the time of bereavement, particularly if they are unhappy at the concept of a post-mortem examination being carried out. However, the coroner is obliged by law to investigate the cause of death and to do so must have prior rights in relation to possession of the body for examination.

4.2 Subject to the coroner's powers in relation to possession of the body in order to carry out his functions under the Act, the personal representatives of the deceased (as opposed to family members) have the right to possession of the body, once the coroner has released it for burial purposes. The personal representatives of the deceased are either the executor of the deceased's estate, as identified in the deceased's will, or the administrator of the estate in cases where the deceased dies intestate or without having made a will. The personal representatives are entitled to act in relation to the affairs of the deceased from the moment of death.

5 Objectives of Coroner Post-Mortem Examinations

5.1 The objectives of a post-mortem examination differ as between a coroner's case and a hospital case. Some may not apply at all in the context of the death of an infant or child but are stated here for the sake of completeness. In a coroner's case the general objectives may be stated as follows:

- To positively identify the deceased. The spouse, next-of-kin or friend of the deceased identifies the deceased to a member of the Garda Síochána acting as coroner's officer. The Garda will in turn identify the deceased to the pathologist carrying out the examination
- To ascertain the time of death. This information is of particular relevance in criminal cases but may also be sought by relatives of the deceased. It is not always

possible to pinpoint the time of death with strict accuracy but an external examination of the body together with evidence of witnesses may be of some assistance

- To determine the cause of death.
- To determine and describe all external and internal abnormalities, diseases and other findings. The latter may be of relevance to relatives, medical practitioners, and others
- To retain appropriate samples for toxicological analysis, histology, microbiology, virology and serology as appropriate
- To retain any specimens found on the deceased which may provide evidence in a criminal investigation
- To provide a full written report of the findings, with photographs or drawings
- To take account of the implications of toxicological reports
- To give an account of the cause of death and any contributing diseases
- To describe the cause of death from the anatomical findings.

6 Conduct of a Coroner's Post Mortem

6.1 If a coroner reasonably believes that it is necessary to conduct an investigation into a death, he requests a histopathologist to carry out a post-mortem examination. The pathologist is given access to the clinical history and circumstances surrounding the death so as to enable special focus to be given to particular areas during the autopsy if appropriate.

6.2 Though the examination will usually take place in hospital premises, when performing a coroner's post mortem, the pathologist is acting independently of the hospital as an officer of the coroner. The pathologist should therefore not discuss the findings of the autopsy with any person other than the coroner, unless authorised to do so. On completion of the examination the post-mortem report will be sent to the coroner. Though the post mortem may have been carried out at a hospital facility, the family should be made aware that the hospital is not at liberty to make any post-mortem findings known to them as this is a matter for the coroner's office.

6.3 If the death is due to natural causes the Coroner's Certificate will be issued to the Registrar of Births and Deaths who will proceed to register the death. The Registrar will then issue the Death Certificate. If the death is due to unnatural causes an inquest must be held. The death will be registered when the inquest is concluded.

6.4 Where an inquest is not required by the coroner, the post-mortem report is generally made available to families, often through their general practitioners, on

request to the coroner's office. Where an inquest is required, the report is not available until after the legal process has ended and the verdict recorded.

6.5 Consent from the family or next-of-kin of the deceased for a coroner's autopsy is not required by law, and is therefore not sought by the coroner. Authorisation of retention of tissue samples for further investigation as to the cause of death is encompassed in the authorisation to perform the autopsy. However, this does not include authorisation to retain organs or tissue for any other purposes such as teaching or research as this is outside the remit of the coroner. The Working Group on the Review of the Coroner Service stated that the coroner has the right, through the pathologist who acts as his/her agent, in performing the post mortem, to authorise the removal and retention of organs, body parts and ante-mortem samples. 'This right applies solely in the context of establishing the cause of death.' This was subsequently reiterated in paragraph 3.4 of the Coroners Rules.

6.6 Once the investigation is complete, the status of the organs or tissue retained as part of the investigation into the cause of death is unclear. On the one hand it might be argued that once the coroner's function has ended, the tissue is regarded as the property of the pathologist who has worked on it, on the basis of the exception to the 'no property in the human body' rule.¹⁵ Based on this argument, the pathologist could legitimately use the tissue for research or teaching purposes without seeking consent from relatives.

6.7 On the other hand, it could be counter-argued that since the coroner's jurisdiction displaces the right of next-of-kin to possession of the body for burial, once the coroner's function ends, the right to possession reverts to the next-of-kin for burial purposes. If the next-of-kin choose not to exercise this right, the pathologist may dispose of the material. The *Bristol Report* accepted the latter view as the more accurate representation of the law in the UK at that time. The legal position in Ireland is unclear.

6.8 The Coroners Rules state that the bereaved family has the right to make a choice in relation to the context and timing of information about organs and body parts. This should be discussed with a designated bereavement liaison officer. The Rules Committee recommends that there should be legislation enshrining these rights for the bereaved families and a corresponding duty on coroners. However, it also recognises the impracticability of imposing a personal duty on coroners to ensure that the rights of the bereaved have been respected in each case, and states that coroners should be able to ensure that appropriate arrangements are in place. It also recommends the provision of an information leaflet for relatives, setting out the relevant information and the choices they have the right to make.

6.9 The Review of the Coroner Service recognised that 'one of the weaknesses in the existing service lies in the lack of administrative support required to deliver optimal services to relatives.' The Review acknowledged the critical importance of continuing support of, and provision of information to, relatives during the coroner's investigation, but pointed out that the lack of administrative support often puts impossible strain on the coroner's resources in this regard. It recommended that a new

¹⁵ Discussed further at Ch. 8, para.12.3

post of coroner's officer should be introduced at a regional level to support the services provided by the coroner.¹⁶ The duties of this officer would include, insofar as is relevant to this Report, liaison with pathology services and families, ensuring that families are kept as informed as possible about the current progress of the investigation and ensuring that appropriate support is provided for relatives through voluntary and statutory agencies. This Report strongly endorses that recommendation.

7 Hospital Post Mortems

7.1 The purpose of the hospital post mortem, or 'house case' as it is sometimes called, is to confirm or clarify the nature and extent of disease, the patient's response to treatment, and the detailed cause of death. Hospital autopsies are currently carried out at the request of a clinician with the consent of the next-of-kin of the deceased. In many hospital autopsies the principal cause of death is already known, the identity of the deceased is clear, and the time of death is also certain.

7.2 Whereas the coroner's post mortem falls within the legal jurisdiction bestowed by the Coroners Act, 1962, the hospital post mortem does not have a statutory framework within which to operate.

8 Benefits of Hospital Post Mortems

8.1 In relation to hospital post mortems, some of the foregoing objectives also apply. However, there are also other benefits of post mortems that may be seen as particular to this category.

- In up to approximately 20 per cent of cases, post-mortem examinations yield new information about the deceased's condition which doctors did not know when treating the patient. The rate is higher in perinatal post-mortem examinations as the infant may not have been treated for a lengthy period of time prior to death and very little may have been known about his/her condition. This enables doctors to discover more information that might be of benefit to future patients with the same condition. Such has been the case, for example, in relation to congenital heart disease in children. Examination of paediatric hearts has enabled significant advances to be made in the diagnosis and treatment of such abnormalities.
- In relation to post mortems carried out on babies or young children, the information obtained from the examination may be of assistance in advising the child's parents in regard to existing siblings or any future pregnancies.
- Material and information obtained at post mortems provide an invaluable and essential source of education and training to medical students. Pathology and anatomy form an essential part of the education of future doctors and enable them to understand how disease changes organs and tissue. Training in diagnosis and treatment pathways cannot be accomplished to the high standards expected by society without access to such material. It also helps to inform attitudes to death

¹⁶ *Review of the Coroner Service*, Report of the Working Group (2000) para. 3.4.2

amongst future practitioners and helps to instil in them respect for the dignity of the human body after death.

- Post mortems provide a means of auditing the performance of the medical teams and the hospital by establishing the cause of death. It can help to clarify whether the patient's diagnosis was accurate and whether treatment was administered appropriately. Given continued discrepancies between perceived clinical diagnoses and post-mortem results, quality assurance demands that treatment outcomes be benchmarked to ensure the highest possible standards of care. The general level of medical care within an institution such as a general hospital is lowered in the absence of routine autopsy work.
- Post mortems help doctors to identify and understand new diseases or variants of existing conditions previously unknown, for example AIDS and variant CJD, by the maintenance of archived tissue.
- The information derived from the post mortem may provide assistance to the family in their bereavement by answering questions relating to the death. This may help alleviate any guilt they might feel as to whether their intervention or actions might have contributed to the death. It may be of comfort to them to know that no action on their part could have prevented the death.
- Provision of accurate information relating to the cause of death is important for the compilation of national mortality statistics and the identification of health hazards. Although some statistical data can be gleaned from medical certificates of death, these are not necessarily reliable sources of information as to the exact cause of death. Studies have shown a large disparity between causes of death when an autopsy has or has not been carried out. In the absence of autopsies, the precision of the death certificate may be inadequate, which in turn is damaging for the development of surgery and for hospital practice in general. Accurate data are necessary in the development of national healthcare policy and in decisions as to the allocation of healthcare resources. The importance of accurate data can also be seen in relation to epidemiological studies such as in the monitoring of infectious diseases.
- Post mortems help in the validation of the effectiveness of new therapies or surgical techniques. Although new imaging techniques have been introduced in the past two decades to the benefit of patients, autopsies may disclose findings missed or misinterpreted by these techniques. The correlation between images in life such as CAT scanning, or MRI, and the post mortem have been of immense value in learning about these new techniques.
- Benefits to the community may be seen in relation to changes in the labelling and packaging of medicinal products following information derived from post-mortem examinations. For example, Reye's Syndrome was discovered by a paediatric pathologist who compared tissue from children who had died unexpectedly after a febrile illness. The syndrome was later linked to use of aspirin in children following chicken pox, influenza and viral fevers. As a result of the identification of this link, aspirin packaging carries a warning against use for children with these

conditions. Consequently, the incidence of this syndrome dropped dramatically from 555 deaths in the US in 1980, to 7 cases annually in the late 1990s.

- Post mortems contribute to advancement of medical research. Some of the research using organs and tissue obtained post mortem are of major significance for the health of people in this country and elsewhere. These benefits include, for example:
 - the analysis of organs following death to understand better the long-term effects of drug therapy, both to develop improved treatments and identify side-effects that might have gone unrecognised in life
 - the study of cells taken from organs after death to explore the way in which cancers progress or might be stopped from developing
 - the examination of tissue from people with Parkinson’s disease to understand the cause of this disease and potential cures, treatment and prevention
 - the study and monitoring of the levels of chemicals and radioactive elements absorbed from the environment.

8.2 There are also many examples where researchers have been able to go back to tissue collected many years previously and held in archives, to establish important links in the causation of disease. For example, the study of brains of people who have died from dementia can be to investigate whether they had Alzheimer’s disease or whether they were undiagnosed cases of variant Creutzfeldt-Jakob disease (vCJD).

8.3 Large-scale storage of human biological materials occurs in other countries. The 1999 report of the National Bioethics Advisory Commission (NBAC) in the USA estimates that over 282 million specimens had been stored and were accumulating at around 20 million specimens per year. This comprised all types of human biological material including blood, tissue samples taken during diagnosis or treatment as well as material taken after death. Individual collections of human biological materials ranged from fewer than 200 to more than 92 million individual quantities of material. They ranged from large tissue banks, repositories and organ banks to unique tissue collections covering specialist areas. The NBAC report does not identify the size of pathology holdings of organs or tissue specifically gathered after post-mortem examination but these are likely to be very substantial. The National Disease Research Institute provides 140 different types of human tissues obtained from post-mortem examination and delivers them to researchers across the US for research into over 100 different types of disease. Other repositories in the US loan pathological material for patient treatment or research, whilst banks of organs, for example brain banks, are also seen as a valuable resource for biomedical research or educational purposes.

8.4 Despite these benefits, the use of tissue and organs after death other than for transplantation has become a source of serious public concern. It is noteworthy that the taking and use of tissue during life has not raised the same level of controversy.

9 Role of Clinicians in Relation to Post Mortems

9.1 In Ireland there is no statutory obligation to obtain consent prior to the carrying out of a hospital post-mortem examination. However, it is clear from the evidence

submitted to the Inquiry that since 1970 it has been general hospital policy to have consent obtained for a hospital post-mortem examination.

9.2 The role of the clinician in relation to a post-mortem examination insofar as the family is concerned is primarily to discuss a hospital post mortem with the relatives of the deceased and provide follow-up information when the post-mortem report has been completed. It has been the tradition and culture in Irish hospitals, as elsewhere, that the clinician who treated the deceased in life is the most appropriate person to broach the subject of a post-mortem examination with the deceased's family, though in some cases families have been approached by nurses, midwives or other hospital personnel. The subject matter is a difficult and emotional one and sometimes clinicians do not feel it appropriate in particular circumstances to raise the issue. This is particularly the case since the controversy surrounding organ retention began, as some clinicians have expressed the view that they are now even more uncomfortable than in the past in bringing up the subject with the bereaved family.

9.3 In treating patients in hospital, a close relationship often develops between clinicians and nurses and the patient's family. Ideally, information is mutually exchanged and the clinical team is usually trusted and appreciated for its hard work and dedication in caring for the patient. In those circumstances the clinician knows best the family member who may be able to take in the important information regarding a post-mortem examination, and is able to gauge the timing of that conversation.

9.4 In some cases, however, perhaps where no pre-existing relationship exists between the clinical team and the next-of-kin, or where the deceased has died suddenly, this element of trust may be absent. Sometimes the bereaved family are in deep shock and may not be in a position to engage in a conversation regarding post-mortem examination at all. In these cases it is very difficult for a treating clinician to approach a family to discuss an autopsy, and very difficult for a family to cope with the necessary information about a post-mortem examination.

9.5 In the past, clinicians approached families for verbal consent and recorded this on the patient's medical chart or asked families to sign a basic consent form to indicate permission for a post mortem. They were motivated by conflicting aims, to impart relevant information to families by which they might be able to make a decision in relation to a post-mortem examination (which the clinician felt to be in their best interests), and to protect them from further grief (which the clinician also felt to be in their best interests). Sometimes in these conversations clinicians undoubtedly struck the wrong balance and underestimated the family's wish and need for information, and their right to the appropriate information on which to base their decision. This is discussed further later in the Report.

10 Public Attitudes to Post Mortems

10.1 In a recent study commissioned by the Department of Health and Children¹⁷ and conducted by a team of researchers based at the Royal College of Surgeons in Ireland

¹⁷ *Public Perceptions of Biomedical Research*, a survey of the general population in Ireland, June 2005

(RCSI), of those involved in the decision to allow a hospital post mortem, 64 per cent considered that the explanation given to them about what a post mortem involves was good or very good. Satisfaction with the explanation given in relation to a coroner's post mortem was lower at 44 per cent. Similar ratings (60 per cent and 46 per cent respectively) were found in relation to satisfaction with how post-mortem findings are reported. The authors suggest that the lack of engagement with the coroner's post-mortem process, the lack of contact with a hospital bereavement co-ordinator, and the higher level of uncertainty where a coroner's post-mortem examination is ordered within a short time of a sudden death, may account for the differences in the rates of satisfaction between the two.

10.2 Another relevant finding in this study points to the difference in satisfaction levels amongst those on whose relatives post mortems had been carried out in recent years. Seventy-five per cent of those who reported on a post mortem carried out in the last 5 years considered the explanation they received to be good or very good, as opposed to 63 per cent in the last 6-10 years, and 62 per cent in the last 10-25 years. This indicates that satisfaction with the information given to relatives prior to consenting to a post-mortem examination has changed over time or that, at least, contact with a bereavement co-ordinator has yielded higher levels of satisfaction with the process.

10.3 The authors conclude that: 'these findings suggest that satisfaction with post-mortems have not been significantly negatively influenced by the recent organ retention controversy in the last five years. Furthermore, the majority of participants (68 per cent) who reported that a post mortem had never been conducted on a deceased family member, indicated that they would consent to a hospital request to conduct a post mortem on a family member. Nine per cent indicated that they would not agree and 23 per cent were unsure. This indicates a relatively high level of public support for post mortems. However, willingness to allow the use of organs or tissue of a deceased family member for medical research was lower than consent to conduct a post mortem, with just over half (51 per cent) supporting the use of such tissue. Twenty-two per cent stated that they would not agree and a further 27 per cent were unsure what they would do if asked.'¹⁸

10.4 In relation to the reasons why relatives were not told about organ retention, 24 per cent believed it was because doctors did not want to cause further upset to the family. Fifty-one per cent believed it was because doctors did not want the added trouble of having to ask the family. Twenty-five per cent were unsure. Eighty-one per cent identified the lack of hospital policies as a major problem and 78 per cent felt that the way in which the hospitals dealt with the families concerned was unsatisfactory. Eighty-three per cent considered it a major problem that organs were disposed of without asking the family's wishes, and the same number considered it a major problem that most cases involved young children and babies. Seventy per cent considered the response of the Department of Health and Children to be unsatisfactory.

¹⁸ para. 3.4

11 Role of Department of Health and Children

11.1 There was no official national policy on post mortems in Ireland from 1970 to 2002. No guidance was issued by the Department of Health and Children relating to the benefits of post mortems, the information to be provided to relatives, the distinction to be drawn between coroner and hospital post mortems, the retention of organs, the dissemination of post-mortem results to families, or the need to respect the wishes of bereaved parents in this regard.

11.2 The only area in which the Department seems to have taken a role in this context is in relation to the disposal of healthcare risk waste. As a result of the closing down of some hospital incinerators by 1993, the Department prepared a Health Services Waste Policy in 1994. The purpose of this policy was to minimise the impact of waste on the environment and to ensure the safety of those handling waste. A strategy was developed for the shredding and decontamination of healthcare risk waste on three sites within the country. Incineration was not favoured due to high costs and technical difficulties, as well as localised public opposition to incineration facilities. By 1995 all hospital incinerators had been forced by the Environmental Protection Agency to close, and risk waste was exported to England for incineration. This was subsequently discontinued by a prohibition in the UK on importation of waste for incineration, and was replaced by export to Belgium and Holland.

11.3 The Department of Health and Children does not seem to have been aware of the issues surrounding organ retention until 1999 when the first complaint was made by a bereaved parent against Crumlin Hospital. There does not appear to have been any discussion at a policy level within the Department before that time relating to pathology practice. In late 1999 the Chief Medical Officer wrote to the Chief Executives of all the voluntary hospitals and health boards asking them to ensure that a policy of informed consent by next-of-kin to the carrying out of post mortems and organ retention was operational in their agency. This letter instructed them to put mechanisms in place to dispose sensitively of any remaining organs retained by the hospitals, and to deal sympathetically with families.

11.4 In relation to the extraction of pituitary glands at post mortems, the National Drugs Advisory Board at the Department of Health and Children was aware of the distribution of growth hormone to Irish patients since the license for the product was issued in 1976. No concern appears to have been raised by the Department regarding the issue of consent for the extraction and supply of the pituitary glands used in the manufacture of this product until 2000. The supply of pituitary glands by Irish hospitals is dealt with further in Chapter Six.

11.5 The Faculty of Pathology of the Royal College of Physicians of Ireland raised concerns with the Department in August 1999 regarding the retention of tissue for diagnoses, training and research. It recommended that specific consent be obtained for retention of tissue for all post-mortem examinations and informed the Department that export of tissue for incineration was unacceptable in the view of the Faculty. It forwarded to the Department a consultation document emanating from the Royal

College of Pathologists in England which had been drafted following the Bristol Inquiry. The issue was raised in Dáil Éireann on 30 September 1999 when the then Minister for Health and Children, Mr Brian Cowen, referred to the review of consent arrangements undertaken by the Faculty.

11.6 Guidelines published by the Faculty of Pathology in 2000 were circulated by the Department to all hospitals where post mortems were undertaken. The Eastern Regional Health Authority also produced guidelines for hospitals in responding to families in relation to post-mortem practices.¹⁹ Following the establishment of a National Working Group in 2000 and consultation with relevant stakeholders, these guidelines/protocols were adopted by the National Chief Officers in March 2003 as the national protocols in relation to post-mortem practice and responding to families' requests for information. An implementation plan was subsequently endorsed in January 2004.

12 Conclusion

12.1 Post-mortem examinations take place in Ireland either under the legal direction of the coroner, or by consent of the family of the deceased. The jurisdiction of the coroner is crucially important to our justice system and must be maintained and protected. The Coroners Act 1962 must be updated as a matter of urgency. In order for the coronial system to continue to develop in tandem with modern advances in medicine and corresponding changes in legal principles, a regulation-based system of rules would best accommodate the necessity for amendment.

12.2 Hospital post-mortem examinations are carried out to confirm or clarify the patient's response to treatment and the detailed cause of death. They are carried out at the request of a clinician with the consent of the next-of-kin of the deceased. The hospital post mortem does not take place under any legislative framework at the present time. This is clearly highly unsatisfactory as it places families, clinicians, pathologists and hospitals in an ambiguous position regarding their rights and duties in relation to the post-mortem procedure.

12.3 The lack of a national policy on post-mortem practice until 2002 is not unique to Ireland. However, when the organ retention controversy arose, more could have been done by the Department of Health and Children to reassure the public that although families were rightly concerned about the lack of consent for retention, the practices themselves were in line with best international standards.

¹⁹ Eastern Regional Health Authority, *Protocol/Guideline for Hospitals and other relevant agencies in providing a quality response to families in relation to queries from past post mortem practices* (2001); *Protocol/Guideline for Hospitals and other relevant agencies in providing a quality response to families in relation to Coroners post mortem practices* (2002); *Protocol/Guideline for Hospitals and other relevant agencies in providing a quality response to families in relation to non coroners post mortem practices* (2002)

13 Recommendations

13.1 The recommendations of the Report of the Working Group on the Coroners Service must be implemented without further delay. A new Coroners Act must be enacted to clarify the legal duties and rights of coroners, and the procedures to be followed from the reporting of a death through to the holding of inquests. Clear structures must be established to deal with information to be provided to families, the appointment of a coroner's officer to liaise with parents following a post mortem, and the provision of support to families through the inquest process.

13.2 The role and responsibility of the coroner's office in relation to communicating with families must be clearly outlined in coroner's rules. Although it is common for the coroner's post mortem to take place within a hospital, hospital staff are obliged not to discuss the post mortem with the family as this is a matter for the Coroner. This can create difficulty and tension between the hospital and the family and must be avoided by clear mechanisms being put in place to inform families of the process and their rights. Disclosure arrangements with relatives must be reviewed so as to ensure that relatives are kept informed as far as possible, subject to the proviso that there may be circumstances in which the coroner cannot provide full information because of the nature of his inquiry and any accompanying criminal investigation. Coroners post mortem reports must state when organs have been retained and the reasons for retention.

13.3 Where a coroner's post mortem is required, parents must be so informed clearly and without delay. They must be told that their consent is not required. An information booklet setting out the powers and functions of the coroner, and the procedural aspects of the coronial jurisdiction, must be made available to the family. They must also be told that organs may only be retained as part of this process for as long as is necessary to establish the cause of death and other relevant matters relating to the child's death. Parents must be told that they have the opportunity to decide on disposal of the organs once the coroner's purposes have been satisfied. Good effective communication in all aspects of this discussion is of paramount importance.

13.4 Coroners are entitled and obliged by law to direct retention of organs in order to assist in the investigation of the cause of death. Retention for any other purpose such as teaching or research is outside of the remit of the coroner and, if it is to take place, must be clearly authorised by the child's parent/guardian.

13.5 The legal position pertaining to the status of organs lawfully retained as part of a coroner's post-mortem examination must be clarified by legislation. Pathologists performing post-mortem examinations at the request of a coroner must have clear protocols agreed with the coroner for the retention of organs.

13.6 In some cases there may be cultural or religious objections by the family of the deceased to the holding of a post mortem examination and/or the retention of organs. Insofar as it is possible to do so, these objections should be respected. However, such objections cannot interfere with the lawful exercise of the coroners' jurisdiction and obligation to investigate the cause of death.

13.7 All instructions from the coroner to the pathologist must be documented in writing. The responsibilities and rights of pathologists carrying out coroner post mortems must be clearly established by legislation.

13.8 It is recommended that the new Coroners Act provide for options to be made available to families of deceased persons in relation to disposition of the organs when the death investigation has concluded. These options would include return of the organs to the family for burial, donation of the organs to an appropriate hospital for teaching or research, burial in a hospital plot, or cremation. The cost implications of these options should also be dealt with by the legislation.

13.9 In the case of a coroner's post-mortem, parents must be given the post mortem report on request, though the timing of its release may depend on whether or not an inquest is required in the circumstances. This must be made clear to parents in information provided to them from the outset of the process.

13.10 Hospital post-mortem reports must be made available to the consultant clinician who treated the child, if there was one, and the child's general practitioner. It is recommended that the post-mortem report must also be offered to parents of deceased children with advice to seek any necessary explanations from their general practitioners, consultants or the relevant pathologists. Where possible, a follow-up meeting between parents and clinicians must be arranged to discuss the post-mortem findings in as much detail as the parents require. If necessary or desirable in the circumstances, the pathologist may also be requested to attend such meetings. This facility must be made known to parents at the time of authorisation of the hospital post-mortem examination. Protocols must be put in place to provide a structure whereby parents receive a timely and appropriate response to their request for information.

13.11 An appropriate legislative framework must be put in place to govern hospital post mortems. A regulatory model that facilitates guidelines that can be updated when necessary in order to keep pace with medical and scientific developments best achieves this. Further legislative recommendations are provided through other chapters in this Report.

13.12 Measures should be devised to inform the public through appropriate means of the benefits of hospital post-mortem examinations.

13.13 The Department of Health and Children and the Health Service Executive should ensure that a national policy and appropriate protocols in relation to post-mortem practice are adopted and implemented in all Irish hospitals as a matter of urgency. The existing policy presented by the National Working Group on Organ Retention in 2002, and adopted by National Chief Officers in 2003, provides a useful template and could be adapted where necessary to take into account the recommendations in this Report.

Chapter Four

Submissions from Parents

1 Introduction

1.1 This chapter concentrates on accounts submitted to the Inquiry by parents of deceased children as to their experiences of post-mortem practices and how the organ-retention controversy has affected them. It was not taken as the function of this Inquiry to investigate individual cases in order to ascertain the precise facts of each case. Instead an overall picture of post-mortem practice from the parents' perspective has been presented. While names of parents and children are not used, in order to protect their privacy, parts of their stories are used along with quotations from their submissions/transcripts of evidence. Direct quotations are italicised. The parents can recount their experiences and perceptions much better than anyone else could ever hope to do.

1.2 It is clear from reading the stories of parents who have been affected by the organ-retention controversy that the grief and heartbreak of losing a child is not temporary or transient; it is a lifelong bereavement process that is replete with emotion, distress, anger, guilt and loneliness. Irrespective of the age of the child or whether the death was anticipated, the natural order of life is disrupted and may never be righted in the minds of the parents. Over time, parents may come to some level of acceptance of their child's death, though the evidence submitted to the Inquiry demonstrates that parents whose children died twenty or thirty years ago often still feel the grief and distress of bereavement as keenly as if the death was much more recent.

1.3 Added to the pain of the child's death has been the discovery that during a post-mortem examination carried out on their child, organs were retained without their knowledge. This has caused anger and renewed hurt for many parents who perceive their child's body to have been '*desecrated*' or '*mutilated*'. One parent said, '*I was devastated to think that they'd do that without even telling one of us ... And for them to go and cut her right down, it was just devastating.*' Parents see themselves as protectors of their children, even after death, and sometimes feel that they have let their child down by not preventing this invasion of the child's body. When they learned that not only were organs removed from their children, but also retained and sometimes disposed of in a manner and time unknown to them, many parents were plunged back into grief and a cycle of serial loss: loss of the child, loss of their belief in the wholeness of their child's body, loss of any emotional stability they had achieved since the death, and loss of trust in the medical profession and hospital where their child had been treated.

1.4 As demonstrated by their submissions to the Inquiry, the main grievance that parents have is in relation to the lack of information and participation in decision-making given to them by doctors about what a post mortem involves and what happens to parts of the body that have been removed and retained. As is the case in other jurisdictions that have had similar controversies, there is no real factual dispute on this issue. Hospitals and clinicians accept that until relatively recently, they generally did not tell parents what happened at a post mortem or subsequent to it.

1.5 Parents therefore did not know that their child's brain could be removed and fixed for a period of time prior to examination or that other organs, principally hearts and lungs, were commonly removed and retained for examination. They did not know that blocks of tissue were inevitably retained on a permanent basis as part of the medical record, nor did they know that after examination the organs would be incinerated with other hospital waste. They did not know any of these things because they were not told, and did not know to ask.²⁰

1.6 The parents' submissions have been analysed according to a set of themes or questions designed to elucidate the main facts around post-mortem and organ-retention practices. In many submissions the parents did not clarify whether the post mortem was a coroner's case or a hospital case and it has been necessary, where possible, to draw conclusions from surrounding circumstances evidenced in their communication to the Inquiry. In relation to some of the issues and concerns discussed below, the distinction between coroner and hospital post mortems is not relevant. Where parents raise the issue of consent, this refers to hospital post mortems only, as consent is not necessary in a coroner's case. The communication of information relating to the post-mortem examination was undoubtedly shaped by whether or not the post mortem was a coroner's case, as hospital staff are constrained in the information they provide in such cases, though the experiences related by parents indicate that they were not always aware of the relevance of the distinction.

2 When was the Post Mortem Discussed with Parents?

2.1 The timing of the approach to parents about the post-mortem process varied, with most parents being approached in the hours after the death of the child or, if the child died during the night, the following morning. Some parents recall discussions taking place 10–15 minutes after the death, and some recall the request for consent being made during the same telephone call in which they were informed of their child's death. Discussion about hospital post mortems also took place in a small number of cases before the child died, where death was anticipated and it might be necessary to perform the post mortem within a short period following the death.

3 Where were They Told?

3.1 Most commonly the discussion about a post-mortem examination took place in a hospital corridor close to the unit or ward where the child had been cared for. In particular instances, parents recalled being brought to a room adjacent to the ward or theatre where the child had died, or the discussion may have taken place in the ward where the mother may have been treated. One set of parents recall the discussion taking place in a room full of relatives, a priest and a Garda.

²⁰ *Human Organs Inquiry Report*, Northern Ireland, June 2002, para.4.3

4 Who told Them?

4.1 There is no consistency in the cases submitted to the Inquiry on this point. Different personnel mentioned include senior consultants, junior doctors, nurses, nuns, social workers, Gardaí, and a hospital chaplain. Some parents remember the individual by name, whereas others had never met the person before, despite the child having been in hospital for a period of time prior to death. Some parents did not know to which hospital department the individual was attached.

4.2 In some instances, parents were asked by more than one person to consent. In cases where they were unwilling to consent, parents recall the extent to which different people spoke to them about the post mortem. One mother remembers two different nurses asking her for consent and, having refused, a doctor then spoke to her and again tried to obtain consent.

5 What was Their State of Mind at This Time?

5.1 At the time when the issue of a post-mortem examination was raised with the parents, they were in a state of shock and grief. All parents who made submissions to the Inquiry related the fact that the discussion took place in circumstances of extreme stress. One parent recalls that she was *'too shocked with grief to do anything else but say yes'* to the request to give her consent. Some parents recall how they found it difficult to comprehend what was being asked of them during the discussions, with one parent saying that she felt she *'could have signed anything'*.

5.2 In some instances parents recall the discussion taking place while they were holding their deceased child in their arms. Some mentioned that they themselves were ill at the time of the request, or on medication, or were hospitalised. One mother said she was *'in an awful state'* because she was on painkillers and other medication in the hospital.

6 How Much Time were They Given to Consider the Request?

6.1 The decision about a post mortem was made during the discussion. In most cases parents say they were not given an opportunity to discuss the matter alone between themselves, though some did report having been given some time to think about it. None reported having been given time to get advice on the matter.

7 Location of Post Mortem

7.1 The location for the post mortem was assumed by parents rather than explained by the person seeking consent. A few parents were taken by surprise when they later discovered that the post mortem had occurred in a different hospital. They had not been so informed at the time.

8 Reasons for Post Mortem

8.1 Generally speaking, consent for a hospital post mortem was sought in three sets of circumstances as outlined to the parents. Firstly, to establish the cause of death. Sometimes this was linked to the need to establish if a genetic or other disorder was involved that might affect present or future siblings of the child. Secondly, to help the doctors understand the disease the child suffered from, or the medication/treatment the child had been given. Thirdly, to help others.

8.2 Parents recall the discussion being very brief, though this was not always due to a lack of explanation by the clinicians. In many cases the parents themselves wanted a post mortem to take place because they wanted to know the exact cause of death or because they were worried about having further children with the same condition. Some parents were also highly altruistic, with one parent saying that although a post mortem '*horrified*' her, she thought it was important because it could help in the treatment of others.

8.3 In cases where parents were reluctant to consent to a post mortem, this was often because they were already aware of the child's illness and did not see the need for a post mortem. A number of parents said they did not want a post mortem because their child had already been '*through enough*'. One set of parents referred to their religious beliefs as the reason for their refusal. Most parents were prepared to consent when it was explained to them that it might help other children with similar conditions.

9 What were They Told?

9.1 Parents say they were generally informed of the possibility or necessity of a post mortem occurring, although the word 'post mortem' or 'autopsy' was not always used. In a small number of cases submitted to the Inquiry, parents assert that they never knew that a post mortem had been carried out on their child, or had refused consent for a post mortem, and only discovered that one had been performed from subsequent enquiries made by them. The period of time during which parents remained unaware varied from seven months to 26 years. In the latter case the parents reported that the only information they received was that '*we were told our daughter was dead. Told to go home and come back with the christening robe as they were going to put it on her in the coffin.*' Another set of parents said they were told that a '*blood test*' would be performed and were asked to return to the hospital later. It transpired that a post mortem had been carried out.

9.2 None of the parents recall being given written information about the post-mortem process. Discussions tended to be brief and lacked in-depth detail. The majority of parents submitted that they were provided with little or no information about the process when consent was requested.

9.3 The parents did not generally seek details from the clinicians. Parents explain this by reference to the level of trust they had in the personnel involved. One parent recalls that they trusted the hospital and '*would have done anything they suggested*'. Many were therefore content to agree to what the doctors asked of them because they trusted them with their child. One parent stated that the parents had given permission '*in good*

faith that the post mortem would be carried out with the greatest of respect shown' to the child's body.

9.4 Where parents did ask questions or seek further information, explanations were generally given to allay fears of reluctant parents. One set of parents was told that the doctors would *'re-open the incisions and look at the heart, that would be all'*. Another was told that the doctors intended to *'have a look at the baby's head'*. Parents were also given assurances that the child would be treated as if he/she was *'having an operation ... he will be treated with the same respect.'* One parent asked if it was like a biopsy and was assured that it was, while another was told it was like an exam.

9.5 Where parents had worries about the incisions that would be made, they recall being told that they were just going to take a *'tissue sample'*, or that cuts would be made to *'just take swabs and little tissue samples'*, and that *'little incisions'* would be made. In one case the parent recalls being informed that any organs removed would be *'all put back in place'*. Where parents sought assurances that only existing incisions would be re-opened, they were assured that this was the case. Parents accepted the assurances given to them.

10 What was Their Understanding of a Post Mortem?

10.1 There was wide variation in what parents understood was entailed in a post-mortem examination. Some said that they did not know what was involved, though the majority understood it to be an examination to establish the cause of death. Opinions varied as to what parents thought happened at a post mortem. One described it as follows: *'I literally thought they were going to be looking at her heart because the child died of a heart complaint. There was no way I thought when I got her back she was going to be opened everywhere.'*

10.2 Some parents understood that tissue samples would be taken during a post mortem, though they differed on what a tissue sample might be. Some thought that *'microscopic parts'* would be taken, while others envisaged that it entailed the taking of a sample from an organ. Some parents knew that organs would be removed but thought that they would be replaced in the body before it was released for burial. One said they believed that *'they would remove her main organs, examine them in microscopic detail and somehow replace them ... I never for a second thought that we buried our baby without them.'*

10.3 Irrespective of what they understood about the procedure itself, one parent summed up the generally expressed expectations of parents by saying that he thought there *'would not be any desecration of the body'*.

11 Objection to Post Mortem

11.1 Parents were generally not told that they could object to a hospital post mortem. Many recounted that they thought the post mortem was a *'formality'* and that they were informed out of courtesy. On the other hand, some parents stated that they knew they could object to a post mortem from discussions they had about it.

11.2 Where parents did object, they report that staff tried to persuade them to change their minds, with some parents reporting that staff were insistent about it. Numerous attempts to obtain consent were sometimes made by different personnel. In a small number of cases where one parent refused consent, an approach was subsequently made to the other parent. Some parents felt pressurised, with one parent feeling that the doctor was aggressive in his approach. One parent reports that the doctor said he *'would not take no for an answer'*, and another recalls being told that, having refused consent twice to two different nurses, *'it will have to be done anyway'*. Some parents gave permission because they felt it would otherwise be done without their permission, and they received assurances about the procedure to persuade them to consent.

12 Limited Post Mortem

12.1 Parents recall that they were not advised about the possibility of consenting to a limited post mortem. In particular cases parents requested that the post mortem should take place on specified organs only. This request does not always appear to have been observed. In one case the medical records showed that a limited post mortem was carried out on a child, though the parents do not recall limiting their consent in this way.

13 Form of Consent Given

13.1 The predominant mode of consent to a hospital post mortem was verbal, though there are instances where parents recall giving written consent in 1980. The form of consent depended on the hospital and personnel involved. No definitive practice existed across the hospitals.

13.2 In some cases parents are adamant that no consent was given for a post mortem even though one was performed on their child. In some cases where the parents do not recall giving consent, a written record of consent is in existence.

14 Organ Removal

14.1 No information about the removal of organs from the body was provided to parents in the cases submitted to the Inquiry. Most parents did not understand that this would occur during the post-mortem examination. One parent whose child died in 1999 was told that the post mortem was akin to a liver biopsy. She recalls that *'no one told me that organs would be removed from the body. I didn't think anything would happen (sic) to the organs as I never thought that they would be touched.'*

14.2 However, a small number of parents stated that they were aware through their own knowledge and understanding that organs would be removed during autopsy. For example, one set of parents acknowledged that they knew a post-mortem examination would involve *'the removal and examination of organs'*. In addition, some parents

submitted that they would have expected that organs would be removed during the post-mortem examination and *'replaced in the body for burial'*.

15 Length of Time for Examination of Organs

15.1 Information was not generally provided to parents about the length of time required to carry out the necessary tests to establish the cause of death. Parents submit that they were not told that some tests could not be done between the time of death and the funeral or at the time of the post mortem itself. One parent explains, *'Nobody told me that samples would be taken for the purpose of a detailed examination under a microscope and I didn't understand what happened during the course of a post-mortem examination.'*

15.2 Some parents say that they were told about the results of the hospital post mortem a few days after the death. But a few parents did realise that samples would be taken for detailed examination under a microscope. In those cases, parents were not given such information and relied on their own understanding that samples would be taken for more detailed examination.

16 Retention and Disposal of Organs

16.1 The singular observation by parents about the retention and disposal of organs was that they were unaware that it would occur during a post mortem. One parent said, *'it never crossed our minds that any organ would be retained for any reason.'* They were not provided with any information nor were they asked for consent to retention. They assumed that they were burying the entire body of their deceased child. *'At no stage did I think that organs would be taken without my consent.'*

16.2 A small number of parents thought that any organs removed during post mortem would be replaced in the body before the child was returned to them for burial. Parents who thought that organs were removed and replaced were resolute in stating that they did not foresee any possibility of organs being retained by the hospital. Where parents were given a post-mortem report they did not realise that the report might have indicated that organs were retained for some time for tests. Parents describe the report as full of medical terminology and *'gobbledeygook'*. In one case where a post-mortem report stated that the brain would be fixed the parent said, *'if we saw that the brain will be fixed, we would have assumed that it would have been removed from the body and had been replaced.'*

16.3 On the other hand, one parent whose child died in 1996 related her attempts to query, in a meeting with a hospital representative, the contents of the post-mortem report where it stated, 'brain retained, photographs taken'. At the meeting she was informed that *'issues'* would have been taken for examination and the references in the report were explained in that way. The parent was only informed about organ retention in the aftermath of the controversy.

16.4 Some parents offered their child's organs for donation to others, but in several cases the organs were unsuitable for transplantation. Parents were aggrieved that,

having made this suggestion, the organs were retained by the hospital for other purposes. One parent said that she thought organ donation was the only circumstance in which organs were retained. Another said, *'we had already ... offered to sign anything for the use of her organs. Now, if we had been informed at that stage that they were going to retain her brain for research, we would gladly have done so.'*

17 Returning the Child for Burial

17.1 Some parents related their anxiety in relation to the delay in carrying out a post mortem. Observations by parents in relation to the appearance of their child after the post mortem varied. In most cases the parents did not examine the child for any signs of surgical procedures. Some did not see their child again once the child was taken from them after death. Many parents were very distressed when hospital staff refused to let them dress their child after the post mortem.

17.2 Where parents recalled the appearance of their child after post mortem, they remembered different things. In a few instances, parents noticed marks on the head and/or stitching on the body when they received the child back from the hospital. One set of parents recalled holding the child and questioning how light the body was. When this was queried with the staff, the parent was told she was mistaken and that *'babies lose fluid'*. Another parent recalled that her child *'just wasn't the baby that I held the week before'* and said that she *'knew something had happened'*.

17.3 Another source of distress and anger is the mode that parents took when leaving the hospital with their child. Parents recall receiving the casket after the post mortem and being asked to leave the hospital by a side door. Others recall prayer services at the hospital before they left.

18 Coroner Post Mortems

18.1 Where coroner post mortems were involved, many parents were informed that a *'post mortem had to be carried out'*. Hospital staff generally imparted the information about a post mortem, with two instances encountered where parents recalled that a Garda provided information. The discussion took place close to the time of death and/or when the baby arrived at the hospital. Where children died from sudden infant death syndrome, parents were informed about a post mortem either upon removal from the family home or upon arrival at the hospital concerned.

18.2 No rationale was provided to most parents to explain the requirement for a coroner's post mortem, nor could they recall any discussion explaining the circumstances leading to a coroner's post mortem and the rules applying to it. In the majority of submissions relating to coroner post mortems, parents said they received no information about a coroner's post mortem and/or that they were not informed that there was a distinction between a hospital post mortem and a coroner's post mortem. Indeed, the term *'coroner's post mortem'* was not something parents recollected being informed of. The distinction between hospital post mortems and coroner post mortems was not mentioned in conversations with hospital staff on the matter.

18.3 In one case, however, the parents submitted that they were informed that a post mortem was required by law and that the coroner would direct that a post mortem be carried out. The parents recalled that they were informed that ‘*blood and tissue samples*’ would be taken during it. Some parents recalled that they knew at the time that a post mortem was obligatory, but they remembered being unable to say why they knew so. In one case confusion was engendered in a parent’s mind when she was presented with a form to sign but was told that she could not object in any case to the post mortem.

18.4 Parents recalled that there were no arrangements made for obtaining the post-mortem results. One set of parents received them through their general practitioner after the disclosures in 1999. Some parents discovered that a coroner’s post mortem took place when they sought the post-mortem records from the hospital. Few mentioned any interaction with the coroner’s office, save where they had investigated organ retention after the media disclosures about the issue.

19 Communication of Post-Mortem Results

19.1 Results of post mortems were communicated to parents in a variety of ways, both formal and informal. A large number of parents were never provided with a copy of the post-mortem report. Some parents recalled being told in the day(s) after the death in hospital corridors of the cause of death. In other cases, parents received information through their own general practitioner or through a phone call to the hospital involved. Parents criticised the informality with which results were communicated to them in a number of instances. In some cases parents may have already known the cause of the illness from which their child died and, therefore, were not disturbed when they did not receive any formal post-mortem report. In other cases, parents were dissatisfied that they had received no post-mortem report about their child’s death until the organ retention controversy arose.

19.2 Where parents had requested post-mortem reports at the time of the death itself, some found difficulty in receiving the written report. In one case, a parent received a report from the hospital by contacting a clinician working in another hospital to get it for her. Some parents received such post-mortem reports upon making enquiries about organ retention in the last few years. In many cases, a meeting occurred between the treating clinician and the parents a few weeks after the death. Parents were told the cause of death. Some praised the staff for explaining everything in detail so that they could understand the circumstances of their child’s death. In contrast, others found that the information was conveyed in technical language that they did not understand. The failure to explain to parents at such meetings that organs were retained for further examination or tests caused them anger and resentment when the controversy arose in 1999–2000.

19.3 In a few instances, parents were not informed of the full post-mortem results in subsequent communications with the hospital. One parent who queried the references to ‘retention’ in an autopsy report was informed at a meeting that ‘*tissues*’ had been retained for examination.

20 Pituitary Glands

20.1 In a few cases parents were informed that pituitary glands were removed. However, most parents who made submissions to the Inquiry did not address the issue. This is dealt with separately in Chapter Six.

21 Trauma of Controversy

21.1 The overriding emotion of many parents was that their assumption that they had buried their child with all of their organs intact was now incorrect. One set of parents described how they felt cheated that their child had been violated once he died. Others described difficulties in coping with the matter because they felt that *'something was missing'* and that they *'did not bury our child the way God gave it to us'*. One parent commented that *'no family should have to bury [their child] twice.'* Another stated: *'Every time I now go to the grave I don't feel that I have the same kind of sense of contact or belonging.'*

21.2 Parents expressed their anger that their child's body had been treated like a *'piece of meat'* or a *'piece of rubbish and unwanted flesh'*, while another parent described the practices uncovered as *'an immoral, degrading mutilation'* of the body. All parents were upset and hurt by the entire matter. One parent stated: *'These were not just body parts and tissues, these were the physical parts of our dearly loved children.'* Others felt guilty for not *'protecting'* their children, with one submitting that, *'I feel I let her down when she most needed me.'*

21.3 Parents relived the trauma of the death itself and described the emotional difficulties involved in having a second burial in some cases. One parent described her feelings as follows: *'I was depressed and felt all the feelings when she died all over again.'* Parents recounted that they had nightmares after receiving the information about retention. One parent stated that she had suffered a nervous breakdown, while another said that she suffered panic attacks and depression in the aftermath of the revelations to her. One parent recorded her feelings as follows: *'... I feel very angry and at the same time powerless. I did not know what was being done to my baby boy and I could not protect him.'*

21.4 In one instance, the parents decided to have the burial of returned organs after Christmas so as not to upset the child's grandparents because they would visit the grave at Christmas. In other cases, parents expressed their anxiety at being unable to bury the organs because they had now been incinerated or otherwise disposed of. One parent stated that she felt *'hard done by'* because organs had not been returned to her but had been returned to other families that she knew. Parents were upset by the news that organs had been disposed of. One parent expressed it in the following terms: *'I thought entire organs to be incinerated in that fashion ... was very insensitive and I was very hurt over that. I would have liked if they had the [organ] and if they wanted to incinerate it and they looked for my permission to incinerate it.'*

22 Attribution of Blame and Loss of Trust in Medical Professionals

22.1 The medical professionals were criticised by most parents for the practices operated by them. Some parents cited the arrogance of doctors as a cause of the controversy, with parents describing the attitude of doctors as one where they could do as they liked. One parent described his perception of the medical professionals' attitude: *'I found that the general attitude and demeanour of the medical profession in general ... was condescending, bordering on arrogance and that "We know best and you don't have to know anything about this".'*

22.2 Some parents expressed their shock and amazement that there were no written procedures for organ retention and disposal, and highlighted this in criticising the medical professionals. A significant factor in the responses of parents was the loss of trust engendered by the disclosures about post-mortem practices. As recounted above, many parents had placed enormous trust in the medical personnel involved in caring for their child. Parents stated that their trust in medical professionals was now damaged. As one parent remarked: *'The deception is what gets to me. It's not being told exactly what is going to be done before it's done, and then not being told for 18 years afterwards that it was done.'*

22.3 Another stated: *'One feels that the medical profession have failed our innocent children.'* In this regard, parents who recalled their misgivings about having a post mortem and/or their questions about the procedure were critical that the responses they received to assure them about it turned out to be inaccurate and misleading. This level of mistrust also extends to the information now furnished by the hospitals. Some parents expressed doubts about whether all of their child's organs were returned and/or whether they had received comprehensive information from the hospitals about the practices employed in them.

23 Parents' Views on Retention of Organs

23.1 Differing views on whether parents would consent to retention of organs were articulated. Parents do not understand why retention was necessary in many cases. This is exacerbated in those cases where the cause of death was known at or close to the time of death itself. Some parents were adamant that they would never have consented to the post mortem, given the details of the procedure which they now know. Parents with this viewpoint wanted to bury their child intact. One parent submitted: *'If it was explained to me what they were going to do I would have told them "No. He is to be left alone".'*

23.2 Other parents focused more on the fact that they were not given an opportunity to consider the matter at the time. One parent stated they would have wished that at the time of death doctors would *'let us make a decision whether we want to do something with her brain or whether we want to bury the brain with her'*.

23.3 Some parents stated that they might have been prepared to consent to organ retention if it would assist research into illnesses or if told that the organs were needed for further examinations. One parent remarked that he *'would donate the organs for*

research', another parent stated that he would consent on the basis that *'if I thought that something good was going to come out of it ... I would have done that'*, while another remarked that had he been asked to consent to retention for research purposes he *'would have readily agreed to that'*. One parent gave the retained organs back for research purposes when informed that they had been retained without her consent.

23.4 In their submissions, all parents were agreed that the issue should not be allowed to recur, with one stating that *'this cannot ever happen to anyone again'*. Parents wanted the truth of the practices employed to be uncovered. Some parents wanted an apology from the hospitals, whereas others felt that any apologies would be worthless.

24 Conclusion

24.1 This chapter has relayed the accounts given by parents of the circumstances in which a post mortem was carried out on their child, and how the retention of organs has affected them. As stated in the introduction to the chapter, parents' stories are presented as their own recollections and opinions about what happened to their family. It was not taken as the function of this Inquiry to investigate individual cases in order to ascertain the precise facts of each case. Instead an overall picture of post-mortem practice from the parents' perspective has been presented. Much of their accounts are uncontroverted by the hospitals' submissions.

24.2 Parents were generally not told about the retention of their child's organs. If a consent form for post mortem was signed at all, there was little or no information on the removal or retention of organs. Where the word 'tissue' was used on such forms, it was not defined, and was not understood by parents as possibly including whole organs. They commonly understood it to mean small amounts of tissue for microscopic examination.

24.3 Families were not always given time to deal with their grief. They were not always provided with support and clear, unbiased information. They feel that they were not always treated with dignity and respect.

24.4 Parents were sometimes given inaccurate information about what was and was not being retained, and some initial information proved misleading. When organs were returned, this was sometimes done in an inconsistent or insensitive manner. Some parents had to endure multiple funerals as organs were returned on separate occasions.

24.5 No choices were given on methods of disposal of retained tissue or organs. It was taken for granted that human tissue, removed at post-mortem and no longer required, would be disposed of as clinical waste. This came as a huge shock to parents, some of whom feel revulsion at the categorisation of parts of their children as 'clinical waste', and strongly object to the idea of incineration as opposed to burial or cremation.

24.6 In coroner post mortems, little information was given to families on the procedures to be followed. Families were not always given feedback on the results of the post mortem.

24.7 The submissions from the parents outlined in this chapter clearly articulate the anger and grief they sustained as a result of the lack of communication about post-mortem practices and organ retention. Their stories recount distress, guilt and disbelief that this happened to their child. Many now distrust the medical profession and healthcare system and feel let down by their experiences in dealing with hospital authorities.

25 Recommendations

It is acknowledged that some of the following recommendations have already been implemented in a number of hospitals, but for consistency the recommendations are stated here without reference to the practice in individual hospitals.

- 1 Legislation must be introduced as a matter of urgency to ensure that no post-mortem examination will be carried out on the body of a deceased child and no organ will be retained from a post-mortem examination for any purpose whatsoever without the authorisation of the child's parent/guardian, or the authorisation of the coroner in an appropriate case.
- 2 The grief and anguish suffered by parents who discovered that their children's organs had been retained and in some cases later disposed of by hospitals, was caused by a failure by medical professionals to communicate openly and honestly with parents at the time of death. The main aim of this Report is to place parents/guardians at the centre of decision-making and control in respect of hospital post-mortem examinations to be carried out on their children. However, the doctrine and language of informed consent is considered to be inappropriate in this context and is not recommended.
- 3 It is recommended that the alternative concept of authorisation be adopted. This is a stronger and more powerful recognition of the active role and choice of parents in decision-making in relation to post mortems. It is recommended that systems and policies be put in place to ensure that all parents are offered such information as they require to make the decision as to whether or not to authorise a post mortem examination to be performed on their child. This must be viewed as a process and not a once-off event.
- 4 Parents must be given the option of authorising a post-mortem examination to be carried out on their child on the understanding that this is being performed to provide further information as to the cause of death and the possible effects of treatment. Some parents may wish to authorise a post mortem without wanting to receive any further information or consultation. Their right not to receive this information must be respected. It must be made clear to them that they can come back with a future request for more information at any time. For those parents who choose this option, it must be stated on the authorisation forms that this includes authorisation of all actions necessary as part of that examination. The accompanying information booklet to be given to parents to read if they so choose must explain that this will include removal and sampling of organs, and may include retention of organs for diagnostic purposes. It must be made clear that

organs retained at post-mortem examinations will not be used for any purpose other than diagnosis without the authorisation of the parents/guardian.

- 5 If they require further information prior to authorisation, parents must be told that the performance of a post-mortem examination involves the examination of the body of the deceased child. It includes the dissection of the body and the removal of organs, tissue samples and blood/bodily fluids. It is carried out to provide information about or confirm the cause of death, to investigate the effect and efficacy of a medical or surgical intervention, to obtain information regarding the health of another person/future person, and for audit, education, training or research purposes. Parents must be made aware that in certain circumstances it may be necessary to retain organs in order to complete the examination.
- 6 Parents should also be informed of the potential benefits of retention in terms of education, training and research. If the retention period is short, they should be made aware that it may be possible to delay the funeral in order that the organs may be reunited with the body. In other cases, they should be made aware of their options in relation to disposal of the organs at a later date.
- 7 Parents must be given the option to authorise a limited post mortem. They may choose to limit the examination to particular organs but, in making that choice, must be informed that this will mean that samples will be taken from the organs being examined, and that information will not be available on other organs which may have contributed to the child's death.
- 8 It is recommended that the means by which and the place in which parents are informed about the post mortem process be as sensitive and respectful as possible in the circumstances. If possible, a dedicated bereavement room should be available and adequate time should be given to parents to consider the issue. Information must be offered to parents/guardians and an open dialogue entered into prior to the authorisation of the hospital post mortem. The information must be presented in a clear and comprehensible but sensitive manner. A bereavement liaison officer should assist the parents in getting the information they need prior to their decision.
- 9 It is not intended to make specific recommendations as to the most appropriate person to discuss post mortems with the family, as this is deemed unnecessarily prescriptive. It will usually be a senior clinician who has a relationship with the parents, though a team approach may be preferable in some cases, involving nursing and midwifery staff in particular. Where possible, consultation with the hospital pathologist should take place prior to discussion with the parents so as to concentrate that discussion on issues of most relevance to the particular child. If the parents so request it, a pathologist must be available to answer specific queries or explain the post mortem in more detail.
- 10 The confidentiality of the post mortem report raises issues regarding its disclosure to other persons. Hospital post-mortem reports must be made available to the consultant clinician who treated the child, if there was one, and the child's general practitioner. It is recommended that the post-mortem report must also be offered to parents of deceased children with advice to seek any necessary

explanations from their general practitioners, consultants or the relevant pathologists. Where possible, a follow-up meeting between parents and clinicians must be arranged to discuss the post-mortem findings in as much detail as the parents require. If necessary or desirable in the circumstances, the pathologist may also be requested to attend such meetings. This facility must be made known to parents at the time of authorisation of the hospital post-mortem examination. Protocols must be put in place to provide a structure whereby parents receive a timely and appropriate response to their request for information.

- 11 It is recommended that parents be told in clear language when a coroner's post mortem is necessary and that, consequently, their consent is not required. They must also be told that organs may only be retained as part of this process for as long as is necessary to establish the cause of death and other relevant matters relating to the child's death. Parents must be given information and options in relation to disposal of the organs. Good, effective communication in all aspects of this discussion is of paramount importance.
- 12 In the case of a coroner's post-mortem, parents must be given the post mortem report on request, though the timing of its release may depend on whether or not an inquest is required in the circumstances. This should be made clear to parents in information provided to them from the outset of the process.
- 13 Where both parents are legal guardians of the child, it is recommended that either parent should be able to give authorisation for a hospital post-mortem examination. In the situation where only one parent is the legal guardian, the hospital would be legally entitled to proceed with the post mortem on the authorisation of that parent. Situations may exceptionally arise in which the parents of the child disagree as to whether or not to authorise a hospital post mortem on their child. Although the hospital would be entitled to proceed with a post mortem on the authorisation of one parent, irrespective of the marital or living arrangements of the child's parents, best practice should be not to proceed with a hospital post mortem in the face of objection from either parent.
- 14 It is recommended that the Department of Health and Children develop a public education and information programme about post mortems so that the public will have a better understanding of what is involved. This will serve to restore and improve public confidence in pathology and, it is hoped, improve post-mortem rates in Irish hospitals.
- 15 As part of the education and training of medical professionals, increased attention must be paid to communication skills and the legal and ethical issues involved in the removal and use of human organs and tissue. All relevant hospital staff must be trained in relation to the authorisation process.
- 16 Standardised authorisation forms must be drafted in consultation with interested parties, and used in all hospitals in conjunction with standard information booklets. A copy of the authorisation form must be kept on the patient's medical record as well as sent to the pathology department where the post mortem is carried out. The pathologist must ensure that authorisation has been given prior to

proceeding with the examination. Parents must also be given a copy of the authorisation form.

- 17 Measures must be adopted by all hospitals to ensure that all patient care staff receive mandatory training in responding to grief and bereavement.
- 18 Each hospital must have a bereavement liaison officer available to offer practical help and support to bereaved families and staff caring for those families. This officer must liaise with the relevant pathology department and must have a good understanding of pathology practices so as to provide assistance to the family if required. Although it is the clinician's responsibility to discuss the post mortem with the parents, this may be done as part of a team approach with the bereavement liaison officer, who may provide appropriate follow-up support.
- 19 Post mortems should be viewed as a continuation of patient care and therefore part of clinical governance within the hospital. Although professional autonomy dictates the technical detail of the performance of the post mortem, responsibility for the administrative aspects of the process rests with hospital management who must make certain that protocols are in place to ensure that all legal requirements as to authorisation and record keeping are satisfactorily complied with. This also requires that an effective audit of post-mortem practice be regularly undertaken to reassure the public that past practices cannot recur and that the hospital's policies and practices conform to current legal requirements.

Chapter Five

Submissions from Hospitals

1 Introduction

1.1 This chapter analyses the practices that existed in Irish hospitals from 1970 to 2000 in relation to post mortems and organ retention, and the policies, if any, that existed in relation to the obtaining of consent. It also reflects changes in policies and practices that have taken place since 2000. As part of the Dunne Inquiry process, hospitals were invited to answer a set of detailed questions in order to elicit the relevant information on these issues. The information submitted by the hospitals varied enormously in length and complexity, with some hospitals additionally submitting clinical reports, minutes of meetings, any relevant correspondence, consent forms used since 1970, research publications and so on.

1.2 Rather than analyse each hospital in turn, the terms of reference for this report support an examination of general post-mortem practice across the various hospitals surveyed. The evidence presented to the Inquiry demonstrates a high level of consistency between the hospitals in relation to post-mortem practices. For that reason it would be unnecessarily repetitive to detail each hospital in turn. Therefore, an overview of post-mortem practice is presented here rather than an investigation of each individual hospital.

1.3 As in other countries, it has not been usual practice in Irish hospitals to provide information about organ retention to relatives of a deceased person. For many years consent was obtained, either verbally or on a very basic written form, following disclosure of minimal information. Parents of deceased children were usually not told about the incisions that would be made as part of the post-mortem process, or the extent and nature of the procedure, or how the body would be reconstructed following the examination. It was generally felt that disclosure of such disturbing details would be cruel in the circumstances. Retention of organs was felt to be one of the details that the family did not need to know.

1.4 Consent to post mortem was widely acknowledged as a necessary pre-requisite to performance of the procedure in hospital cases. This is clearly evident from documents dating back to the 1970s. However, the validity of such consent and the form in which it was obtained was very much a sign of the times, and has changed significantly over the period considered by this Inquiry. Some hospitals took the view that verbal consent was sufficient, which was then recorded on the patient's medical chart. Others produced a very simple consent form for relatives to sign, indicating their permission for the procedure to take place. By their own admission, clinicians commonly did not disclose details of the post-mortem procedure prior to asking relatives to sign these consent forms. As times changed over the 30-year time span covered by this Report, the concept of informed consent became more widely accepted in medical decision-making and consent forms became more informative. However, retention of organs was not explicitly stated on the consent forms in the description of the post-mortem process up to 1999.

1.5 The retention of *tissue* for diagnosis, education and research was included in the forms used by some hospitals, particularly in later years, but the word ‘tissue’ was not explained or described either on the form itself or verbally by the clinician. It may have been understood by the medical professionals to include organs, but those to whom the form was presented for signature did not share this understanding.

1.6 Tissue blocks and slides are an important part of the patient record and can provide important information for future reproductive and healthcare decisions. However, as this Report deals only with the retention of whole organs, the status of blocks and slides are not considered herein.

2 Post Mortems on Children Between 1970 and 2000

2.1 The statistics on post mortems provided by hospitals varied. Some hospitals gave a breakdown of figures for coroner and hospital post mortems. However, most hospitals or health boards did not generally provide individual statistics for post mortems performed on children, as this information had not been requested of them in the original set of scheduled questions put to the hospitals by the Dunne Inquiry. It was therefore assumed for the purposes of this Report that hospitals performing a large number of post mortems and/or those with large catchment areas performed post mortems on children at some point during the 30-year time period. In addition, the presence or otherwise of a maternity unit, paediatric unit, gynaecological service or obstetrics service was used in deciding whether to assess a hospital’s statement as being within the remit of this Report. It is accepted that this assumption may be mistaken because there is no guarantee that hospitals carrying out large numbers of post mortems necessarily performed examinations on children. However, it was decided that in cases where the issue was unclear, inclusion rather than exclusion was the better approach.

2.2 Submissions were received from some health boards, as they then were, on behalf of hospitals in their area. Following the re-organisation of the health service administration, these health boards have been reconfigured and the hospitals are now under the responsibility of network managers within the National Hospitals Office of the Health Service Executive. Therefore, the following list, though accurate at the time of submission, may not be strictly accurate now. The following acute and private hospitals were included in this part of the survey for the reasons outlined in the preceding paragraph:

- Tralee General Hospital
- Our Lady’s Hospital, Drogheda
- Portiuncula Hospital
- Cavan General Hospital
- Monaghan Hospital
- Roscommon County Hospital
- Bantry Hospital
- St James’s Hospital, Dublin
- St Vincent’s University Hospital, Dublin
- Beaumont, including St Laurence’s Hospital and Jervis Street Hospital, Dublin

- Mallow General Hospital
- Mater Private Hospital, Dublin
- St Finbarr's Hospital, Cork
- St Columcille's Hospital, Loughlinstown
- Blackrock Clinic, Dublin
- National Rehabilitation Hospital, Dublin
- St Luke's Hospital, Rathgar, Dublin
- Our Lady's Hospital, Navan
- Letterkenny Hospital
- St Mary's Orthopaedic Hospital, Cork
- Erinville Hospital, Cork
- Our Lady's Hospital for Sick Children, Crumlin, Dublin
- Children's University Hospital, Temple Street, Dublin
- AMNCH (Adelaide and Meath Hospital incorporating the National Children's Hospital), Dublin
- The Coombe Women's Hospital, Dublin
- National Maternity Hospital, Holles Street, Dublin
- Rotunda Hospital, Dublin
- Cork University Hospital
- St Michael's Hospital Dún Laoghaire
- Naas General Hospital
- Mount Carmel Hospital, Dublin
- Mayo General Hospital
- Galway Regional Hospital
- Mercy Hospital, Cork
- South Infirmary/Victoria Hospital, Cork
- Sligo General Hospital
- St John's Hospital, Limerick
- Barrington's Hospital, Limerick (closed 31 March 1988)
- South Eastern Health Board, encompassing Waterford Regional; St Luke's Hospital, Kilkenny, St Josephs Hospital, Clonmel; and Wexford General Hospital
- Mid-Western Health Board encompassing Mid-Western Regional Hospital, Limerick; Ennis General Hospital; and the Hospital of the Assumption, Thurles
- Midland Health Board including Midland Regional Hospital at Portlaoise; Midland Regional Hospital at Tullamore; Midland Regional Hospital at Mullingar; and St Joseph's Hospital, Longford.

3 Policies Regarding Post Mortems

3.1 The majority of hospitals reported that they had not developed any written policies on post mortems during the period under investigation. The lack of a post-mortem policy was explained by stating that 'professional judgement' was used and that 'standard custom and practice applies'. The lack of discussion of post-mortem policy, practice and procedure by medical committees or boards was widespread. Most hospitals stated that they had no record of the matter being discussed until the organ retention controversy broke in 1999–2000.

3.2 Most hospitals have now drafted post-mortem policies in line with Faculty of Pathology Guidelines, Coroner and Non-Coroner Protocols and Procedure documents, and the Quality Response to Families drafted by the National Liaison Group on Organ Retention. An implementation plan for these protocols was agreed by the National Chief Officers in 2003.

4 Policies Regarding Consent

4.1 References to consent in this section, and in other sections of this chapter, necessarily refer to hospital post mortems and not coroner cases as consent was not, and is not, required for the latter.

4.2 Most hospitals had no *written* policy regarding consent, though they informed the Inquiry that they had a policy of obtaining consent for a hospital post mortem or stated that the clinician was charged with obtaining consent.

4.3 For the majority of hospitals, there appears to have been no policy pertaining to methods used or the information provided in requesting consent. Neither did they disclose any evidence that protocols existed for the amount of information to be provided to the next-of-kin when seeking consent. Medical professionals followed the custom and practice of those around them in the hospitals.

4.4 Some hospitals testified to using written consent forms during the relevant period. Most of these forms can be categorised as basic, meaning that they recorded consent to an examination, but this could not be described as informed consent. They do not refer to consent to the retention of organs and/or tissue, nor do they refer to the issue of a limited post mortem.

4.5 In general, most hospitals and health boards first grappled with the issue of informed consent to post mortem and organ retention in a concentrated manner when the controversy broke in 1999–2000, though some had introduced more detailed forms before that date, dealing with retention of ‘tissue’.

5 Hospital Practices for Obtaining Consent to a Post Mortem

5.1 It is difficult to establish any patterns in the practice of the hospitals regarding the obtaining of consent. Hospitals within the same geographical area diverged on the methods used, while some acknowledged that the ways in which consent was requested varied from case to case.

5.2 Generally, the clinician who cared for the deceased person was the person responsible for obtaining consent. The individual who spoke to parents varied, however, with hospitals submitting that a range of personnel, including consultants, junior doctors or senior nurses would request consent. No predominant pattern emerges about the identity of the person who spoke to families about the matter.

5.3 Likewise, there is no predominant pattern showing that verbal consent or written consent to a post mortem was the norm across the hospitals surveyed. Indeed, some

hospitals or groups stated that they had introduced written forms but admitted that verbal consent would, nevertheless, have been used in some cases. This practice was discouraged but accepted in a few exceptional cases subject to a policy of a written note being entered on the hospital chart and a signed form being sent in the post by the relatives.

5.4 Written consent forms were introduced in a majority of the hospitals surveyed at some point in the period under review, with more details given on the form in recent years. The consent form used by most hospitals up to recent years was basic and simply stated that the signatory gave permission for a post-mortem examination on his/her child. Such forms did not seek consent for organ retention. Neither did they usually mention the possibility of consenting to a limited post mortem, though this was expressly raised as a possibility in at least one hospital from 1997.

5.5 A written form of consent was introduced at Cork University Hospital (then Cork Regional Hospital) in 1979. This was based on a form of consent used in the United Kingdom under the Human Tissue Act, 1961. It specifically provided for the retention of tissue for laboratory study and for the treatment of other patients, and for medical education and research. On the evidence produced to the Inquiry, this represents the earliest introduction of a written consent form which informed the person that 'tissue' might be retained in the course of the post mortem. 'Tissue' was not defined on the form. A number of other hospitals also submitted that they addressed consent to retention of 'tissues' in the written consent forms used. Some hospitals explain that if the reference to retention of tissues was deleted on the form, organs were not retained for these purposes. This may be a suggestion that consent to organ retention was sought, though it appears that the meaning of 'tissues' was not explained to parents.

5.6 Although some hospitals used a written consent form, it was acknowledged that locum pathologists may have accepted verbal consent during the period under investigation. Consent was also obtained by telephone in some cases where the patient's family was not present in the hospital at the relevant time. Where verbal consent was sought, some hospitals acknowledge that it was not always recorded on the patient's chart.

6 Information Provided to Parents

6.1 The general practice was for the consultant with responsibility for the patient to obtain consent from the family. If the consultant were not available, the next most senior clinical person would do so. The person seeking consent made a subjective determination on how much information to provide to the family. Up to 1999 it was not the practice of clinicians at most hospitals to obtain consent to organ retention.

6.2 The pathologist would proceed with the post mortem on the basis of a request form from the clinician. This usually did not make any reference to whether or not consent from the parents had been obtained.

6.3 In relation to the information usually given to parents during the consent process, it was rarely reported prior to 2000 that information was sought by parents as to the technical nature of the post mortem. It became common practice by the late 1980s to

specifically state that the body would be opened up, similar to having an operation, that there would be an incision, that the internal organs would be examined, and that there would be a cranial incision and examination. There might be specific reference to the heart, kidneys or whatever organ was the primary cause of concern, being examined. Although these discussions were not recorded, some hospitals noted that the nature and extent of the discussions changed over the years, becoming lengthier over time.

6.4 A number of submissions addressed the issue of the training of personnel for the task of requesting consent. Most staff gained experience from witnessing their peers obtain consent and thus developed expertise in clinical practice. As such, this appears to suggest that on-the-job training was the order of the day in requesting consent, and established habits were followed.

6.5 It is difficult to categorise the practices used by the hospitals. Some required only verbal consent until the late 1990s. Others had introduced written forms but did not refer to the retention of organs on those forms. There were inconsistencies in the practices adopted within health board areas and within hospitals themselves. No standardised approach is apparent. Moreover, few hospitals addressed the issue of what information was afforded to parents/next-of-kin when clinicians or other personnel made the request.

6.6 Hospitals have changed their policies and practices on the matter since 1999–2000. In most hospitals the clinician must now ensure that the family understands the reasons for the post mortem and an information leaflet is usually provided. This is recorded further in other sections.

7 Hospitals' Perceptions about the Expectations/Knowledge of Parents regarding the Post Mortem Process

7.1 There was a perception amongst the hospitals that families had little understanding of the post-mortem process. According to some hospitals, the next-of-kin would expect to be informed of the purpose and scope of the autopsy and the difference between a diagnostic and coroner's autopsy. But they acknowledged that there would generally not have been a great awareness of the issues pertaining to post-mortem practice and procedure until recent years.

7.2 A contrasting view is given by other hospitals, which state that they assumed that the next-of-kin understood that part of the post mortem involved the sampling of tissues and, on occasion, the removal of organs for microscopic examination.

7.3 Hospitals generally accept that information was not provided to families about the details of the procedure. The underlying reason advanced for this appears to have been a desire not to upset them with the details of the procedure. Requesting consent to post mortem is very difficult at a time of trauma for parents and next-of-kin. Prior to the controversy that arose in 1999–2000, hospitals state that pathologists were not aware that next-of-kin had particular expectations in relation to the removal, retention, storage or disposal of organs. Pathologists were aware, however, that families

expected post mortems to be conducted quickly so as not to delay the funeral and they would also expect the body to be returned in a good condition.

7.4 Some hospitals stated that it was difficult to generalise about the expectations of parents, because some parents wanted minimal information, whereas others wanted more information. Hospitals state that senior clinicians could assess the expectations of families on a case-by-case basis.

7.5 A number of hospitals referred to the issue of trust as a factor that impacted on the expectations of families. Hospitals comment that relatives expected that their loved one was treated with respect and dignity at all times, and that a post mortem would be performed in accordance with 'good clinical practice'. Other hospitals also spoke of the expectation of parents that the post mortem would be conducted with dignity, sensitivity and respect.

7.6 Apart from that it was noted that where there was a possibility of hereditary transmission involved or where family members were at risk of developing a similar disorder, they would expect to receive genetic counselling and advice from an expert.

7.7 It is acknowledged in the submissions received from hospitals that the expectations of parents have changed over the time period covered by this report. From 1970-1980 parents may have expected to be informed of some of the procedures involved in a post mortem. Given the culture at the time they probably did not generally expect bereavement support or a discussion about the information obtained at post mortem, though this did happen on occasion. From 1980-1990 bereavement and terminal care support were sometimes provided for families as a response to new thinking in the area of bereavement. From 1990-2000 parents expected to receive information regarding the post mortem and some hospitals undertook to meet bereaved families to explain the cause of death and the post mortem to them, though this support was not always well-coordinated within the various departments of the hospitals.

7.8 It is difficult to avoid viewing times past without the application and benefit of hindsight. Moreover, it is difficult to apply the proper wider context of the particular time, given the cultural, technological, economic and other advances that have taken place since 1970. However, in general, hospitals acknowledge that the expectations of parents may have included the following:

- that a post-mortem examination would not be carried out unless they gave their consent
- that, if consent was given for a post-mortem examination, a post-mortem examination would be carried out
- that any post-mortem examination would be carried out by a suitably qualified person in an appropriate setting
- that the funeral of their deceased infant/next-of-kin would not be unduly delayed, or indeed, delayed at all
- that the body would be able to be viewed in the usual way, that is, any incisions made would not extend down onto the face or be apparent when the body was dressed

- that the parent/next-of-kin might wish to touch or hold their deceased infant following completion of the autopsy
- that their deceased infant would be treated with care and respect at all times whilst in the care of the hospital within the context of the post-mortem examination
- that the results of the post-mortem examination would be made available to them and discussed with them by an appropriate medical professional
- that the results of the post-mortem examination would have been accompanied by appropriate follow-up and referral, for example, to genetic counselling services
- that, for those parents who considered the issue, the body of their child would be returned to them complete with its organs.

7.9 Since 2000, parents may also have additional expectations to be provided with sufficient information to enable them to make an informed decision regarding the post mortem, retention of tissues, and disposal. Parents also reasonably expect to be given an opportunity to ask questions, to limit the post-mortem examination, to receive communication regarding the post-mortem results, and to have their wishes respected.

8 Was Consent Requested for Organ Retention?

8.1 The definition of ‘human tissue’ adopted by the Dunne Inquiry as ‘human material’ appears to have impacted on some hospital submissions, because all pathologists considered that taking tissue samples is an integral part of any post mortem, and some therefore believed that the consent given for post mortem necessarily included consent for the taking of tissue samples and organs if necessary. Consent forms used by some hospitals specifically referred to seeking consent for retention of ‘tissues’. Some hospitals contend that seeking consent for retention of tissues equated to seeking consent for organ retention.

8.2 According to the submissions surveyed, express consent for organ retention was not specifically sought by hospitals. Until 2000, it was generally not the practice of hospitals to inform parents or next-of-kin of the full details of organ removal, retention, storage or disposal. Most hospitals considered that the consent to conduct a post mortem implied consent to retain an organ, and this was the prevailing standard practice of hospitals for the period from 1970 to 2000.

8.3 There was a general feeling on the part of medical staff that to give such detail in the absence of any evidence to suggest that it was required, or was necessary, or was common practice, would be considered cruel and insensitive to parents and next-of-kin. Most hospitals accept that parents would be unlikely to be aware of organ retention, and that even where there were follow-up consultations in relation to post-mortem results or subsequent pregnancies, these meetings did not prompt queries relating to retention of tissue or organs.

8.4 As regards coroner post mortems, hospitals submitted that consent for organ retention did not arise in such circumstances, so that it was not deemed necessary to seek consent. Hospitals viewed the retention of organs as a matter for the coroner to determine in such cases. In some hospitals pathologists occasionally retained organs at a coroner’s post mortem for teaching purposes. Consent to this retention was not obtained.

8.5 All of the hospitals referred to the change in practice brought about by the controversy. In all hospitals, the matter is now addressed in a specific way with families by the provision of information and discussion with staff. Consent is sought for organ retention and the family make a decision on organ disposal prior to the commencement of the post mortem. This decision is implemented when the examination of the organs is completed.

9 Did Hospitals Retain Organs for a Period after Post Mortems?

9.1 Some submissions disagreed with the definition of ‘organ’ given by the Dunne Inquiry and stated that their retention practices were related to ‘tissue’ rather than ‘organs’. For example, one hospital states that in 21 per cent of cases the brain was retained, and in 1 per cent of cases the spinal cord was retained. Other whole organs were retained in less than 1 per cent of cases. Tissue samples were retained in 89 per cent of cases in accordance with best practice guidelines.

9.2 Most hospitals stated that organ retention was confined to a small number of cases though the estimation of numbers or percentages is usually vague due to the absence of records of retention. There is also an apparent divergence in the approach of some practitioners evident from the submissions, both in their understanding of the necessity of organ retention and its frequency in practice. Some submissions take the view that where pathologists were not retaining organs or tissues they were not doing their job to the best of their ability.

9.3 All internal organs would commonly be removed during the post-mortem process and organs would be retained at the pathologist’s discretion. Organs were retained for diagnostic purposes or for teaching if there was a complex defect or unusual lesions detected at autopsy. The most common organ retained was the brain.

10 Why were Organs Retained by Hospitals?

10.1 Diagnostic purposes was the primary reason advanced for organ retention by most hospitals. The organ may be retained to obtain a second opinion by a more specialised pathologist and/or for further extended examination where the cause of death was unclear or in doubt. In a paediatric situation it was easier and more practical to keep the entire lung for examination because it was so small to begin with. Some hospitals noted it was difficult to examine the brain in its ‘fresh’ state, so it would have to be retained for a period of time.

10.2 Although most hospitals submitted that organ retention was common practice, particularly in paediatric pathology, a small number of pathologists expressed the view that retention was unnecessary in most cases. In the hospitals at which these pathologists worked, the rate of organ retention was therefore relatively low. According to this minority view, although the organs, particularly the brain, would always be removed for examination, once tissue sampling of the organ was carried out the organ could be replaced in the body. This view is not reflected in professional guidelines and other statements of international best practice.

10.3 It was also acknowledged in some submissions that hospitals with national specialities would have retained a greater proportion of organs in those specialities than other hospitals. For example, hearts would be more frequently retained in a hospital that specialises in congenital heart disease.

10.4 A few hospitals stated that organs were retained for teaching and research, as two additional purposes of the practice of pathology. It has been stated that doctors may be educated as a result of autopsy findings and therefore it is not possible fully to separate diagnosis and education, although the primary purpose of the autopsy is neither education nor research. Others emphasise that the diagnostic efficacy of post mortems has hinged directly on contemporary and past research, and that it should be regarded as an ongoing process. In a minority of hospitals, organs were retained from post mortems for research both in Ireland and the United Kingdom. Consent was sometimes obtained for retention of 'tissue' for these purposes but organs were not referred to. In a small number of teaching hospitals organs were retained in pathology museums on an anonymous basis.

10.5 The necessity for organ retention has generally been considered best determined by the appropriate consultant pathologist according to the needs of each particular case, taking into account international practice at the relevant time. However, the absence of national guidelines in relation to the retention of organs contributed to a perception of inconsistency across pathologists and hospitals.

11 Storage of Retained Organs

11.1 Organs were fixed in formalin and stored in plastic containers. Containers were labelled and numbered so that they could be identified. Organs were generally stored in the pathology laboratories/departments, mortuary rooms or histopathology storerooms. During the retention period the pathologist and/or scientific staff in the pathology department would manage them and the clinicians had no role in this regard. According to most hospitals, organ storage was in accordance with health and safety regulations.

11.2 Organs were stored for the period required for examinations to take place. Thereafter, the organs would be disposed of as clinical waste. Estimates for the periods of organ retention varied between 2 and 3 months, while some hospitals stated that the retention period was determined by the pathologist's examination. They go on to state that the pathologist may retain organs for a longer period in some cases and it appears that, in some hospitals, organs were stored for a number of years rather than months. These instances would usually involve medico-legal, forensic or occupational health issues. Some hospitals provided no estimates of the amount of time organs were retained. In some hospitals the retained organs were not catalogued and became desiccated over time. A routine review of stored organs was not common practice.

11.3 In maternity hospitals more emphasis is placed on the fact that a woman's normal reproductive life spans 25 years or more. In the early 1980s, in keeping with advances in perinatal medicine and ultrasound diagnosis, some of the maternity

hospitals began to retain organs for longer periods to try to elucidate causes for unexplained stillbirths.

11.4 In some cases organs have been sent to other institutions for further specialist examination and analysis. In other cases, the post mortem itself occurred at the other hospital. Hospitals now have a practice of retaining organs until families have expressed their wishes as to their disposal.

12 Return of Organs

12.1 Few hospitals addressed this issue. The prevalence of organ disposal via incineration at some time after the examination by the pathologists may explain this. A small number of hospitals have returned organs for burial since 2000 at the request of the families. Details are given of the arrangements made in this regard to comply with the family's wishes, with hospitals generally providing financial and bereavement support for the burial where required by the family.

13 Disposal of Organs by Hospitals

13.1 The hospitals' submissions recorded that the prevailing length for retention was until such time as the examinations by the pathologist were carried out. Thereafter, it appears that most hospitals disposed of the organs, though some were retained for lengthier periods. Disposal appears to have been within the control of the pathology department of the hospitals, with little or no medical or management oversight. There was generally no record kept of organ disposal and in some cases organs were stored for a number of years instead of being disposed of, probably due to administrative oversight. Methods of disposal used were burial and incineration, with incineration being the more prevalent form of disposal. Some hospitals had their own incineration facilities for some of the period under investigation and some hospitals used private companies or other hospitals to dispose of organs.

13.2 Following Department of the Environment regulations in 1989 and the establishment of the Environmental Protection Agency in the early 1990s some hospitals were forced to close their incinerators and had to make alternative arrangements. A number of hospitals contracted with a private company for disposal, and that company exported clinical waste to other countries such as the United Kingdom and Holland. A number of hospitals subsequently purchased burial plots in cemeteries to deal with situations in which the families chose not to make their own arrangements for burial of the organs. Cremation of individual organs was also facilitated in recent years where this was specifically requested.

13.3 Most hospitals submitted that disposal was carried out in accordance with applicable clinical waste procedures and Department of Health and Children guidelines. There were no specific guidelines from the Department of Health and Children in relation to the disposal of organs following post-mortem examination at any time since 1970. Guidelines have emanated from the Department in relation to the disposal of clinical healthcare waste generally, which encompasses organs. In 1994 the Department issued a policy document dealing with the Air Pollution Act, 1987

and EC Directive 91/689. In April 1996 draft specifications were sent to hospitals for dealing with the treatment or disposal of clinical healthcare waste, and in June and October 1996 the Department issued further communication relating to management plans for exports and imports of waste. A circular was also issued by the Department advising hospitals not to enter into contractual arrangements for the disposal of healthcare waste without prior consultation with the Department, and informing hospitals that the Department had entered into an agreement with a private company for the disposal of clinical waste. Further communication was issued in 1997 relating to contractual arrangements for collection and disposal of waste. A more detailed document called *Segregation and Storage Guidelines of Health Care Risk Waste* was issued in 1999.

13.4 Hospitals have responded to the controversy by providing families with pre-examination options for disposal of organs after the post mortem has been concluded. Where families want organs returned to them this is organised by the relevant hospital.

14 Maintenance of Records for Organ Retention

14.1 Formal recording of organs retained by hospitals was not commonplace amongst those surveyed. Generally the only formal records relating to the issue would have been within the post-mortem examination report itself. However, while the report usually states whether the brain was retained, it rarely records if an organ was retained for education purposes.

14.2 Few hospitals kept a register of retained organs. Furthermore, no standard practice for recording retention on post-mortem reports appears to have been operating because hospitals recorded organ retention to varying degrees in reports. Once again, hospitals have accounted for the change in practices and the implementation of national protocols since the controversy broke in 1999–2000.

15 What Information was Given to Parents following the Post Mortem?

15.1 Methods of providing information to parents after the post mortem varied. The hospitals addressed the issue of how post mortem results were communicated. Little or no information was provided on any other issues. All hospitals noted that the requesting clinician was supplied with a copy of the post-mortem report in hospital post-mortem situations. The prevailing practice in most hospitals was that the notification of the family was the responsibility of the clinician in charge of the case.

15.2 How the results were communicated varied, however, and no predominant practice is apparent from the submissions surveyed. Some hospitals stated that the clinician or medical team informed the families. In contrast, sometimes the practice was that the results were sent to the family's general practitioner so that he/she could inform the family. In some hospitals families were offered the opportunity to return to the hospital some time after their bereavement so as to discuss their child's illness and death with medical staff. These meetings became accepted as standard practice,

although not all families took up the opportunity. When a post mortem had been carried out discussion about post-mortem findings usually took place at these meetings.

15.3 The 1990s saw significant changes in the level of information being provided to families after post-mortem examination. It became more common for consultants in some hospitals to provide parents/next-of-kin, at their request, with copies of the post-mortem report. As a result, some hospitals decided to alter the format of the post-mortem report so that the first section only was provided to parents, and not details of the anatomical dissection. This decision was taken on the basis that it was thought that giving parents the full report would be insensitive and would cause additional, unnecessary distress. A designated member of the midwifery or nursing staff also sometimes provided bereavement support services.

15.4 None of the submissions stated that the post-mortem report was given to families as of right. Submissions referred to a *request* for a copy of the report by families.

16 Coroner Post Mortems

16.1 Few hospitals addressed the practice and procedure of coroner post mortems in detail in their submissions for the relevant period. Some noted that the pathologist was independent of the hospital and was, therefore, acting as an agent of the coroner while performing the post-mortem examination. The general policy was for medical staff to contact the Garda Síochána, who then liaised with the coroner. In some cases the Garda contacted the pathologist.

16.2 Little information was provided about the discussions held with families regarding a coroner's post mortem. Instructions from a coroner to carry out a post mortem were invariably verbal (by telephone) and did not include an instruction in relation to organ retention.

16.3 Hospitals submitted that consent for organ retention was not sought in coroner post mortems because it did not arise or it was not deemed necessary to do so.

16.4 In relation to coroner post mortems, some hospitals noted that requests for the reports had to be made to the coroner's office. Information was given to families about results when the coroner's permission had been obtained to do so.

16.5 Some hospitals provided information about the practices now applicable to coroner post mortems. Several referred to the provision of information leaflets about the procedure, which began in 2000. Some ask families to sign a form indicating that they have been informed that a coroner's post mortem is taking place and that body parts may be retained. Hospitals require direct confirmation from the coroner of the direction to perform a post mortem before commencing the procedure, either by telephone call which is logged in the post-mortem diary, or by written direction.

16.6 Other hospitals make provision for the families to choose an option for organ disposal after the coroner's process is complete. Some provide for consultations with families in relation to organ disposal following post mortem.

17 Conclusion

17.1 As with Chapter Four, which deals with the accounts submitted by parents, this chapter sets out the hospitals' perspective on post mortems carried out during the period covered by the Inquiry. There was a large and unsurprising degree of consistency between the hospitals in relation to the technical performance of post mortems and the necessity for organ retention. Differences between the hospitals existed principally in relation to the form of consent used.

17.2 The practice in Irish hospitals since 1970 was, and is, to carry out post-mortem examinations either on the authorisation of the coroner or at the request of a clinician involved in the care of a patient during life. Hospital post mortems have been assumed to require the consent of the family of the deceased, though this is not set out in any legislative provision.

17.3 Post mortems are of benefit to the child's family in helping to complete the picture of why the child died, and may also be of value to future patients and medical professionals in increasing the level of knowledge relating to the condition from which the child died or the treatment the child received. As a necessary part of post-mortem examinations, pathologists use their professional expertise to determine whether or not to retain organs in order to assist in the diagnostic process. This is in keeping with best practice and international guidelines. However, revelations that organs were retained without the knowledge of the parents and families of the deceased child have caused immense distress and distrust amongst bereaved families. Although some parents understood what a post-mortem examination entailed and why it might have been recommended to them, the hospitals did not have a policy of informing parents of post-mortem practices or organ retention. This is not disputed by the hospitals.

17.4 It is clear from the evidence submitted to the Inquiry that organs were retained in some cases for longer periods than was necessary for diagnosis, and may have been used for education and training of medical professionals, or for research purposes in a small number of cases. Storage facilities were not always sufficient for maintenance of these organs and it appears that there was no effective protocol in most hospitals for disposing of organs no longer required for diagnosis. The common practice seems to have been to have 'clear-outs' of these storage facilities at regular or irregular periods, or at the discretion of the supervising pathologist. This is reflective of a professional pragmatism in relation to storage capacity, and a difference in perspective in relation to the symbolic significance of the organs.

17.5 A lack of care in the storage of these retained organs is apparent from the failure to maintain appropriate records of retention and disposal and may be explained by the different professional perspective pathologists had towards such organs. They did not appreciate the emotional attachment parents had to the child's organs. In many cases records are missing or incomplete and, even where post-mortem records are available, they commonly do not refer to organ retention or disposal. Educated guesses may be made as to retention based on the diagnosis entered on post-mortem records but this is clearly unsatisfactory.

17.6 Following the retention period, organs were commonly incinerated as healthcare waste either at the hospital itself, or transferred to other hospital sites, or in latter years transferred to private companies for disposal abroad. Though parents were outraged at the revelations of these practices and the categorisation of their children's organs as 'waste', the system of disposal employed by hospitals was not intentionally disrespectful to the children or their families. Hospitals were constrained by health and safety regulations in this regard and were obliged to consider organs as clinical waste.

17.7 Hospitals report changes in practice since this controversy arose in 1999. Hospitals, clinicians and pathologists are now aware of the importance attached by parents towards the organs of their deceased children and endeavour to ensure that parents are given all appropriate options in relation to the organs following the post mortem. Options available to families include, in some cases, postponement of the funeral until the organs can be reunited with the body; respectful disposal of the organs by the hospital at the family's request; return of the organs to the family at a later date for subsequent burial if they so wish.

17.8 It was the policy in all hospitals that consent should be obtained for diagnostic post-mortem examinations, though it is impossible to conclude whether or not this policy was always complied with, as records are no longer available in many cases. The means of obtaining consent varied between hospitals and over the years spanned by this report. Verbal consent may have been obtained and not recorded on the patient's chart, though some parents are clear in their recollection that their consent was not obtained at all. It was not the function of this Inquiry to investigate individual cases to attempt to resolve these factual disputes.

17.9 'Informed consent', as we know it today, was not obtained up to the 1990s or even later in some cases. This was due to many factors including the paternalistic culture of the time, and the context of grief in which the discussion about post mortem arose. In some hospitals verbal consent recorded on the patient's clinical notes was deemed adequate until the late 1990s, whereas in other hospitals a basic consent form was introduced in the 1970s. Detailed explanation of post-mortem procedures was not usually a feature of the consent process up to the 1980s and 1990s, with consent sometimes regarded as simply the formality of obtaining a signature. Where written forms were available, the language used was sometimes vague and misleading, particularly with references to 'tissue', which was not understood by parents to possibly mean whole organs.

17.10 Parents were not informed that it was common practice during post-mortem examinations to consider the necessity to retain organs for diagnostic, and sometimes other purposes such as teaching. The hospitals' view is that parents were not told or asked for consent to this practice because it was not in their best interests at the time of bereavement and it was also deemed implicit in the consent given to post-mortem examination that all necessary procedures would be carried out in order to reach a diagnosis, including retention of organs if appropriate. Parents were not told about the storage and subsequent disposal of organs for much the same reasons.

17.11 Whatever the justification advanced by the hospitals, the fact remains that parents were not informed or asked for their consent to retain organs from a post mortem carried out on their child. There is no real factual dispute on this issue. In the absence of legislative provisions to the contrary, clinicians either assumed that consent to post mortem included all that was necessarily involved in that examination, or took it upon themselves to give parents as much information as they thought the parents needed to know. The conclusion of this Report on the issue is that, though well motivated and within the accepted culture of the time, this does not provide sufficient justification for practices that were paternalistic and would now be unacceptable.

18 Recommendations

These recommendations are made in the knowledge that national protocols were drafted and adopted in 2003 following consultation with stakeholders. Some of these recommendations have therefore already been implemented in many Irish hospitals. However, in the interests of consistency and clarity across the hospital networks, it is deemed desirable to set out the recommendations here.

- 1 Clear national protocols must be put in place by the Department of Health and Children and Health Services Executive to deal with queries from families in respect of post mortem practices as well as the provision of standardised forms to be used on a national basis. The language to be used in such forms must be clear and comprehensible, and must avoid medical or legal jargon. Existing guidelines produced by the National Working Group on Organ Retention in 2002, and adopted by National Chief Officers in 2003 may be used as the basis on which to make any adaptations recommended in this Report. This must be done in consultation with relevant stakeholders.
- 2 Healthcare providers must ensure that health service employees are instructed in post-mortem policy and relevant procedures for giving information to parents. This must be included as part of the induction process for new entrants to the healthcare service.
- 3 Each hospital must have a bereavement liaison officer available to offer practical help and support to bereaved families and staff caring for those families. This officer must liaise with the relevant pathology department and should have a good understanding of pathology practices so as to provide assistance to the family if required. Although it is the clinician's responsibility to discuss the post mortem with the parents, this may be done as part of a team approach with the bereavement liaison officer, who may provide appropriate follow-up support.
- 4 Post mortems must be viewed as a continuation of patient care and therefore part of clinical governance within the hospital. Although professional autonomy dictates the technical detail of the performance of the post mortem, responsibility for the administrative aspects of the process rests with hospital management who must make certain that protocols are in place to ensure all legal requirements as to authorisation and record keeping are satisfactorily complied with. This also

requires that an effective audit of post mortem practice be regularly undertaken to reassure the public that past practices cannot recur and that the hospital's policies and practices conform to current legal requirements.

- 5 An independent audit must be carried out of currently retained organs in all hospitals in the State. The Department of Health and Children and the Health Service Executive should engage in a public information campaign informing relatives that they may reclaim any currently retained organs within a 12-month period from the date of this Report. This should be organised and managed via a central enquiry line rather than by individual hospitals. Families who do not contact hospitals in this regard should not be approached with this information. Their right not to know must be respected, provided reasonable efforts have been made to disseminate information publicly.
- 6 If, after this 12-month period, organs remain unclaimed, they must be disposed of respectfully by the hospital in line with written policies. This must be done in accordance with health and safety regulations and will entail either burial in an approved hospital plot, or cremation. Conformity with policies and regulations must be demonstrated in accurate record keeping and monitored by periodic audit.
- 7 Accurate and detailed record keeping of retention and disposal of organs at post mortem must be maintained in all pathology departments in accordance with best practice guidelines. Physical disposal or return of organs to families must be carried out by technical services staff or the bereavement liaison officer respectively, in accordance with hospital policy and the wishes of the parent/guardian.
- 8 It is recommended that guidance be given by the hospital to families regarding burial or cremation of the organs and that they be advised to use an undertaker for this process. An information sheet setting out the necessary information must be given to families to whom organs are being returned.
- 9 Where organs are to be disposed of by the hospital in accordance with the wishes of the family, this must be done in accordance with health and safety guidelines established by the Department of Health and Children. These guidelines must ensure that the organs are treated with dignity and respect insofar as this can be facilitated by the safe and hygienic disposal method chosen.
- 10 The Department of Health and Children must engage in a public education and information programme to ensure that members of the public are informed as much as possible as to the post-mortem procedure, the value of retention of organs and tissue, the importance of pathology practices in our healthcare system, the value of post mortems in the education of medical professionals and in the carrying out of significant research, and the rights of families in this regard. Restoration of public confidence in medical practice, and specifically pathology practices, is vitally important to encourage a higher rate of post mortems in our hospitals.

- 11 Parents must be offered information as soon as possible following the post-mortem examination. If they seek to receive a copy of the post-mortem report, this request must be facilitated and any necessary explanations of medical terms provided by the treating clinician or general practitioner. Where possible, a follow-up meeting between parents and clinicians must be arranged to discuss the post-mortem findings in as much detail as the parents require. If necessary or desirable in the circumstances, the pathologist may also be requested to attend such meetings. Protocols must be put in place to provide a structure whereby parents receive a timely and appropriate response to their request for information.
- 12 Where a coroner's post mortem is required, parents must be so informed clearly and without delay. An information booklet setting out the powers and functions of the coroner, and the procedural aspects of the coronial jurisdiction, should be made available to the family. The appointment of coroner's officers is strongly recommended as a necessary facet of the provision of information to families.

Chapter Six

Pituitary Glands

1 Introduction

1.1 In addition to the question of whether organs were retained from post mortems carried out on their deceased children, in 2000 parents also became aware that pituitary glands may have been removed from their children without their knowledge or consent and supplied to pharmaceutical companies for the manufacture of growth hormone.

1.2 This chapter sets out the facts relating to the removal of pituitary glands from children undergoing post-mortem examinations in Irish hospitals. Although this Report deals only with paediatric post mortems and therefore concentrates on pituitary glands supplied from post mortems carried out on children, it is important to note that the supply of pituitary glands was not confined to paediatric cases. It is estimated that 90 per cent of the pituitary glands supplied in this country were removed at post mortems performed on deceased adults. The supply of pituitary glands for the manufacture of growth hormone was also common practice in other jurisdictions at the same time that it was taking place in Ireland.

1.3 This chapter sets out the general practice in relation to the storage and subsequent use of those glands by two pharmaceutical companies, Kabi Vitrum and Nordisk Gentoft, for the manufacture of human growth hormone. It was not feasible during the course of this Inquiry to correlate hospital post-mortem record numbers with consignment numbers provided by the pharmaceutical companies involved in this arrangement. The companies do not have any means of identifying the deceased from whom the glands may have been removed. This chapter is therefore concerned only with the generality of the practice and cannot address whether glands were taken in individual cases.

2 What is the Pituitary Gland?

2.1 The pituitary gland is located in the skull at the base of the brain and is responsible for the production of different types of hormones, including growth hormones. It influences height and also has other benefits in relation to bone and muscle building. In the normal person the human growth hormone is produced naturally during the course of life. The content of growth hormone in the gland depends on the size of the gland and the amount of growth hormone-producing cells in the gland.

2.2 The use of the human growth hormone, made from the gland and injected into patients, stimulated growth in young children who were deficient in the natural production of the hormone. Until the introduction of a biosynthetic form of the hormone in the mid-1980s, the only source of the pituitary gland was from dead bodies.

3 Retention of the Pituitary Gland

3.1 Pituitary glands were retained by the pathology departments of many hospitals at the request of pharmaceutical companies and used for the purpose of the manufacture of human growth hormone on a commercial basis. It was used in the treatment of a condition affecting children and known as short stature or, more technically, 'dwarfism'. The collection of pituitary glands occurred worldwide.

3.2 Justification for the practice was provided by some hospitals who regarded it as a humanitarian act. The practice of supplying pituitary glands to the pharmaceutical company developed over a period of time in the belief that it was necessary in the best interest of society. This was at a time when pituitary glands were in very short supply due to the absence of a synthetically manufactured substitute.

3.3 Hospitals viewed the provision of pituitary glands as common practice at the time because it was the only way of collecting material for the manufacture of growth hormone. Some hospitals seeking growth hormone therapy at that time stated that they were obliged to contribute glands in exchange for the treatment. In the case of Kabi Vitrum, there was no known relationship between the number of vials available for distribution in Ireland and the number of pituitary glands supplied to the company.

3.4 The use of the pituitary glands in this way was at a time when consent to a hospital post-mortem examination was regarded by clinicians and pathologists as giving an implied authority to do all that was necessary at that examination.

4 The Pharmaceutical Companies

4.1 From the evidence presented to the Inquiry, two international pharmaceutical companies were involved in the collection of pituitary glands from hospital pathology departments in Ireland in the 1970s and 1980s. These were: Kabi Vitrum (later known as Pharmacia and Upjohn and now by the name Pharmacia Ireland Ltd) and Nordisk Gentoft (now Nova Nordisk A/S). Kabi Vitrum collected glands at various hospitals including Our Lady's Hospital for Sick Children, Crumlin and the Children's University Hospital, Temple Street.

4.2 In the mid 1960s Nordisk Gentoft (now Novo Nordisk A/S) started to produce pituitary human growth hormone. The hormone was produced from human pituitary glands collected at post-mortem examinations throughout Europe and elsewhere. Its collection of pituitary glands in Ireland occurred between 1976 and 1988. In 1973, the growth hormone was registered in Denmark under the name *Nanormon* and from around that time was made available to children in a number of countries including Ireland and throughout the world. Nordisk Gentoft maintained a supply principle related to the post-mortem collection of pituitary glands worldwide including Ireland. For every pituitary gland collected from a country, the company would sell to hospitals in that country one capped vial of *Nanormon*. This was because the product was in short supply due to the difficulty of obtaining raw material for the manufacture of the product. The hormone was licensed in Ireland up to 30 September 1986.

5 Distribution of the Human Growth Hormone

5.1 Kabi Vitrum sold human growth hormone in Ireland and elsewhere under the brand name Crescormon®. It was a licensed prescription medicine in Ireland and a product authorisation was granted by the Department of Health and Children on 26 November 1976 to Kabi's Irish agent. An amended product authorisation was issued on 25 July 1978. The product was ultimately withdrawn on 25 April 1985.

5.2 Nordisk Gentofte was facilitated by a local distributor in Ireland, Leo Laboratories Ltd, who up to the mid-1980s carried out the collection of pituitary glands from hospitals in Ireland on behalf of Nordisk Gentofte. After this time Nordisk Gentofte carried out the collection by its own representative office.

6 Exclusion of Certain Pituitary Glands

6.1 Detailed written instructions were given by Kabi Vitrum and Nordisk Gentofte concerning the glands to be included in the consignments. A deceased person was not eligible for the post-mortem extraction of the pituitary gland if:

- the cause of death was hepatitis, sepsis, meningitis, encephalitis or multiple sclerosis
- the deceased had had dialysis or a transplant
- the deceased had signs indicating an addiction to self-injected narcotics
- the deceased had a macroscopically changed pituitary gland
- the deceased had been embalmed
- the deceased was suspected of being at increased risk of transmitting viral infections.

In addition, the post-mortem examination had to have been performed within 72 hours of death.

6.2 Kabi Vitrum submitted to the Inquiry that in addition to the specific exclusions referred to above, it specified during meetings with chief hospital pathologists that pituitary glands were only to be extracted from deceased patients upon whom a post mortem had been directed, and that the post mortem had to involve the opening of the skull for reasons separate from and independent of the collection of the pituitary gland. No documentary evidence was available to the Inquiry to corroborate this submission by

Kabi Vitrum and therefore no finding is made in this regard.

7 Withdrawal of Human Growth Hormone

7.1 The use of the human growth hormone derived from pituitary glands came to an end in April 1985 for Kabi Vitrum, and in October 1988 for Novo Nordisk, following

concerns in the United States as to its safety and was replaced by a biosynthetic hormone, which had no connection with the human pituitary gland. The use of human pituitary glands has featured in the controversy over the development of Creutzfeldt-Jakobs disease and has been the subject of international investigation in that regard.

8 Payment for Glands

8.1 Kabi Vitrum paid a fixed nominal sum for the work involved in the extraction of each pituitary gland. These sums were intended to defray the cost of performing the additional work required during the post mortem to extract, remove and store the pituitary gland.

8.2 In 1978 the payment was IR£1.50 per pituitary gland collected. In about November 1981 the payment was increased to IR£2.50, and by 1985 the payment had risen to between IR£3.00 and IR£ 3.50 for each pituitary gland delivered.

8.3 The supply hospitals were often given equipment and tools necessary for the proper removal, treatment and storage of the glands. Where necessary a small, inexpensive deep freezer was supplied for the proper storage of pituitary glands until their collection. In addition, Kabi Vitrum also supplied items such as a histopathologist's lamp and textbooks.

8.4 Most hospitals had no documentation relating to the supply of pituitary glands or any payment that may have been received. Some stated they received textbooks or teaching slides. Another stated that payment was made to a research charity. In some hospitals a nominal handling fee was paid to the mortuary technician. The submissions suggest that monetary gain was not a factor in the supply of pituitary glands to the companies.

9 Collections

9.1 Periodic collections of pituitary glands were made by Kabi Vitrum every four to eight weeks at large centres and two to three times per annum at other smaller centres. Kabi Vitrum no longer possesses complete records of the number of pituitary glands collected at individual hospitals or the dates upon which they were collected. However, to the best of its ability in 2002, Pharmacia Ireland Ltd set out the total numbers of pituitary glands believed to have been dispatched for the production of Crescormon® from all hospitals from which Kabi Vitrum collected glands each year between 1977 and 25 April 1985. The figures show that over that eight-year period, a total of 6,418 pituitary glands was collected in the State by Kabi Vitrum.

9.2 According to its records, Nordisk Gentofte received its first pituitary glands from Ireland in May 1976. In the years 1976-1980, Nordisk Gentofte received less than 200 per year. From 1980 until 1988 Nordisk Gentofte received more than 500 glands per year. According to its records, the total number of human pituitary glands received from Ireland by Nordisk Gentofte at its production site in Copenhagen, Denmark, was 7,511. The amount of *Nanormon* supplied to Irish patients over that time period was

greater than the amount of human growth hormone that could be extracted from these glands. From 1982 to 1986, the total number of vials supplied to Ireland was 31,300.

9.3 Nordisk Gentofte continued with the collection of a back-up stock of pituitary glands after Kabi Vitrum had discontinued its collection of pituitary glands in mid-1985. In 1988, Nordisk Gentofte received approval for its biosynthetic growth hormone product, *Norditropin*, and the production of *Nanormon* was phased out; 388 pituitary glands collected in Ireland in 1988 were therefore never used for the production of *Nanormon*, and remained, according to good practice and procedures, in frozen storage as a back-up stock in the premises of Nordisk Gentofte in Denmark. The back-up stock was retained in case the new biosynthetic human growth hormone *Norditropin* failed, or in case there was a continued need for pituitary human growth hormone in excess of the production of *Nanormon* that was in stock at the time Nordisk Gentofte ceased its manufacture. Of these 388 glands, 8 have numbers that may be hospital post mortem numbers. However, the company does not have the means by which to identify the deceased persons from whom the glands were removed, and the relevant hospital from which it is believed these glands were supplied does not have any records relating to the supply of pituitaries.

10 Supply Chain of Human Growth Hormone Medication

10.1 Kabi Vitrum supplied Crescormon® to its primary distributor in Ireland, Cahill May Roberts, on a consignment basis and pharmacies distributed the product on foot of prescriptions written for patients by qualified medical practitioners. Some or all prescriptions for Crescormon® may have been channelled through the General Medical Services system, through which the medicine was supplied free of charge to patients. There does not appear to have been any relationship between the number of vials of the medication available in Ireland and the number of pituitary glands supplied to Kabi Vitrum from Ireland.

11 Collection Period of Pituitary Glands in Ireland

11.1 Pharmacia Ireland Ltd stated that Kabi Vitrum collected pituitary glands from Irish hospitals between a date unknown in 1977 until 25 April 1985. It had been thought previously that Kabi Vitrum started collecting pituitary glands in 1974. The 1974 date was the date used in Pharmacia Ireland Ltd's statement on the matter in February 2000.

11.2 Novo Nordisk state that Nordisk Gentofte were supplied with glands by Irish hospitals between 1976 and 1988.

12 Irish Hospitals Involved in the Supply of Pituitary Glands to Pharmaceutical Companies

12.1 The arrangements with Irish hospitals were not based on formal written agreements but were developed over the years through personal contact between representatives of the hospitals and representatives of the pharmaceutical companies. For this reason, data are sometimes incomplete as recounting of information is dependent on personal recollection or correspondence discovered during preparation of submissions to the Inquiry.

12.2 The hospitals that stated they had extracted pituitary glands and supplied them to pharmaceutical companies were generally unable to provide precise details about the practice, the numbers of glands involved or the dates on which they may have been supplied. In the case of some of the hospitals listed below, the pharmaceutical companies have provided some details in the absence of any confirmation from the hospitals concerned. This is not an exhaustive list of hospitals involved in the practice. The pharmaceutical companies also listed other hospitals not covered by the terms of reference of this Inquiry as having supplied pituitary glands to them.

12.3 From the evidence submitted to the Inquiry, it appears that approximately 90% of pituitary glands were supplied from post mortems performed on adults. However, the hospitals were not asked in their original submissions to the Dunne Inquiry to compile statistics on post mortems carried out on children and the pharmaceutical companies did not know the identity of the deceased persons from whom the glands were taken. Therefore some of the hospitals listed hereunder may not have supplied pituitary glands from post mortems performed on children.

Hospitals that supplied glands:

- Tralee General Hospital
- Our Lady's Hospital, Navan
- Our Lady's Hospital, Drogheda
- Waterford Regional Hospital
- St James's Hospital, Dublin
- Midland Regional Hospital at Mullingar
- Midland Regional Hospital at Tullamore
- Midland Regional Hospital at Portlaoise
- St Joseph's Hospital, Longford
- Mayo General Hospital
- Letterkenny Hospital
- Sligo General Hospital
- Portiuncula Hospital
- Beaumont Hospital, Dublin
- St Laurence's Hospital (services transferred to Beaumont 1987)
- Our Lady's Hospital for Sick Children, Crumlin, Dublin
- Children's University Hospital, Temple Street, Dublin
- National Maternity Hospital, Holles Street, Dublin
- The Coombe Women's Hospital, Dublin

- Cork University Hospital
- St Vincent's Hospital, Dublin
- Galway Regional Hospital
- Limerick Regional Hospital
- St John's Hospital, Limerick
- Barrington's Hospital, Limerick
- North Infirmary, Cork

For most hospitals, it appears that pituitary glands were supplied during the late 1970s to the mid-1980s, though very few hospitals can provide any documentation in this regard.

12.4 The hospitals listed hereunder state that they had no involvement with pharmaceutical companies. Some of the hospitals surveyed provided no response to the question and reliance was placed on documentation submitted by the pharmaceutical companies.

Hospitals that did not supply glands:

- Blackrock Clinic, Dublin
- Bantry General Hospital
- St Mary's Orthopaedic Hospital, Cork
- Mallow General Hospital
- Rotunda Hospital, Dublin
- Cavan General Hospital
- Monaghan General Hospital
- Erinville Hospital, Cork
- South Infirmary/Victoria Hospital, Cork
- Roscommon Hospital
- Mater Private Hospital, Dublin
- St Columcille's Hospital, Loughlinstown
- Adelaide and Meath Hospital incorporating the National Children's Hospital

13 Was Consent Obtained?

13.1 No consent was obtained for the extraction and supply of pituitary glands. Although motivated to meet the medical needs of children suffering from growth hormone deficiency, this practice was inappropriate without the knowledge and authorisation of the parents of the deceased children from whom the glands were removed. Many parents would undoubtedly have consented to the extraction and supply of the glands if asked. The supply of pituitary glands by hospitals was done at a time when verbal consent to post-mortem examination was often regarded as giving implied authority to do all that was necessary at that examination. However, this argument of implied authority does not apply to the removal of pituitary glands, which was not a necessary facet of the examination.

13.2 In the case of one hospital that has made submissions to the Inquiry, its Ethics Committee discussed the retention of pituitary glands in 1980. Minutes of two meetings in 1980 were supplied to the Inquiry at which it was agreed to introduce a 'special authorisation form' to be completed by relatives of the deceased person. This form was not provided to the Inquiry and therefore it is unclear whether or not it was part of the general Autopsy Consent Form also mentioned in the minutes of those meetings, or indeed whether a specific authorisation form for pituitary glands was devised. However, it demonstrates that the appropriateness of obtaining consent for the practice was at least considered at the time.

14 Knowledge by Department of Health and Children

14.1 The National Drugs Advisory Board and the Department of Health and Children were aware of the distribution of growth hormone to Irish patients since the license for the product was issued in 1976. No concern appears to have been raised by the Department regarding the issue of consent for the extraction and supply of the pituitary glands used in the manufacture of this product until 2000.

15 Conclusion

15.1 The two pharmaceutical companies involved in this country in the collection of pituitary glands went to very considerable efforts to furnish information and documentation to the Inquiry.

15.2 The total number of pituitary glands collected by Kabi Vitrum in Ireland (based on a 2002 calculation) is 6,418, which includes glands collected from adult and children's hospitals. The Novo Nordisk A/S (Nordisk Gentofte) figure for pituitary glands received from Ireland by the company at its production site in Denmark between May 1976 and October 1988 is calculated as 7,511. The combined total indicates that 13,929 pituitary glands were collected in Ireland between 1976 and 1988 by the two companies. A small percentage of these glands were collected from post mortems performed on children. It is estimated that approximately 90 per cent were collected from post mortems carried out on adults, though it is impossible to ascertain what exact percentage is accounted for by such post mortems. Figures from each hospital cannot be ascertained with certainty.

15.3 These glands were consistently taken at post-mortem examination without any specific consent of parents or next-of-kin and without any statutory regime in place for so doing.

15.4 Overall, there was a paucity of documentation about the matter, which indicates a degree of informality in the arrangements between the hospitals and the companies. The lack of records about the numbers of glands supplied also indicates that the issue was not dealt with in a formal manner by hospitals.

15.5 The retention could only have been made with the authority of the pathologist in charge of the relevant hospital department. However, those retaining the pituitary glands did not intend to cause harm or distress. Their motivation was for a positive

medical and public benefit, notwithstanding the lack of specific consent for retention and use of the glands.

15.6 The payment made was modest and was not a payment for the pituitary gland itself but for the additional work required in its recovery and storage, pending delivery to the pharmaceutical companies concerned. There was no known commercial motive on the part of any hospital or its staff in the supply of pituitary glands for the manufacture of human growth hormone. On the evidence to the Inquiry, pathologists did not profit personally in any manner from the supply of the pituitary glands to the pharmaceutical companies, given the sums of money involved and their application to educational or research purposes.

16 Recommendations

- 1 No human organs removed from a deceased child at post-mortem examination should be supplied by hospitals to any pharmaceutical company or other third party without the knowledge and authorisation of the parents.
- 2 Where such organs are supplied, arrangements should be clearly approved by hospital management and documented, and all information supplied to the parents on request.
- 3 The use of human organs derived from post-mortem examinations should be regulated by law. Use of organs for educational and research purposes is dealt with in Chapter Nine of the Report.

Chapter Seven

Disclosures in 1999–2000 and Hospitals' Responses

1 Introduction

1.1 In late 1999 the post-mortem practices in Our Lady's Hospital for Sick Children in Crumlin came under public scrutiny. Media revelations about the retention of organs at the hospital led to similar disclosures by other hospitals in 2000. The Department of Health and Children issued instructions to hospitals and health boards to provide for the needs of parents as speedily and sympathetically as possible, and to ensure that a policy of informed consent operated in all the relevant agencies. Counselling services were put in place and help lines established in order to respond to the concerns of parents and families. Where the families sought the return of retained organs, this was arranged by the relevant hospital.

1.2 Following the media revelations, parents contacted various institutions seeking information as to any post-mortem practices involving their deceased child. This chapter examines the issues arising from the parents' attempts to gather information as to the circumstances surrounding the post mortem of their child, and the ways in which the hospitals responded to those issues. Some of the information recounted in this chapter is taken directly from the submissions of parents as well as the hospitals' responses to the Inquiry.

2 Awareness of Organ Retention Issue and Contact with the Hospital

2.1 Parents became aware of the controversy through various electronic and print media. The various sources mentioned by parents in their submissions in this regard included *The Late Late Show* television programme in December 1999, news broadcasts on television and radio, newspaper reports and notices printed in the newspapers and magazines. In a few instances, parents were contacted directly by hospital staff about the matter.

2.2 The majority of parents contacted the hospital concerned in the days following the awareness that the issue may have affected them. Individual parents reported that it took them some time to summon up the courage to contact the hospital. Parents recalled that they worried about the effect on their families of receiving new information and they feared it would bring back the terrible grief they suffered at the death of their child. One parent expressed the fears she held about making enquiries because her husband had suffered a nervous breakdown previously.

2.3 Many hospitals recorded that they had set up help lines at some stage to answer queries by concerned families. Other hospitals appointed full-time liaison officers for a period to deal with queries or referred queries to a liaison officer working in another hospital. In a few instances, medical staff such as the director of nursing, a clinician or the pathologist dealt with queries. Some hospitals retained records of the responses to parents.

2.4 Examples of how some hospitals responded to the concerns raised by parents are given below. It is stressed that these are intended to be illustrative of the methods employed by hospitals generally.

2.5 Our Lady's Hospital for Sick Children, Crumlin

Subsequent to the media attention on the topic of organ retention on 6 December 1999, Crumlin Hospital bore the lion's share of enquiries at that time and in the following two years. It received a total of 706 enquiries, of which 559 had post mortems. Initially the consultant histopathologist at the hospital contacted each family within 24–48 hours and arranged to discuss each individual case with the family concerned, either by telephone where organ retention was not a feature of the case, or by meeting the family (usually within a week of their call) to explain the nature and purpose of a post mortem and the necessity for retention of tissue and organs in their specific case.

As a result of the volume of enquiries received by the hospital in the week of 6 December, Crumlin Hospital set up a Patient Support Unit to handle the enquiries it received from parents. The Unit was run by senior administrative staff and supported by a retired clinician, a clinical psychologist, the chaplaincy team and social workers. Other clinical consultants, members of the pathology department and medical records staff gave additional support. Two dedicated help lines were set up and a standard set of questions asked of each enquirer in order to establish the necessary facts. Due to the volume of enquiries, the consultant histopathologist could not meet each family individually and it was decided to refer the enquiries to the original consultant who had treated the child. This usually involved a meeting or telephone contact between the clinician and the family, followed up by written confirmation of the relevant information.

Crumlin Hospital states that its intention to provide a full response was hampered by the fact that the pathologist who had worked at the hospital for 28 years was deceased. There was a lack of documentary evidence of practices and procedures, the post-mortem reports rarely recorded the retention of organs unless the central nervous system had been referred to a neuropathologist for expert opinion, and there was also a significant time pressure imposed on staff to respond quickly to enquiries. Due to the lack of information recorded on the reports, the consultant histopathologist used his expertise and experience to interpret the reports to the best of his ability and to form an opinion as to whether or not organs had been retained. Information subsequently came to light in 2000 which caused him to reassess the usefulness of his interpretation of the post-mortem reports in circumstances where he did not have full information of the practices of his deceased predecessor. As a result he decided to discontinue the practice of providing an opinion as to whether or not organs had been retained. As a consequence of the difficulty in ascertaining the relevant information, sometimes information had to be relayed to families on a second occasion, and the hospital acknowledges that the families may have perceived this as a drip-feed of information.

Crumlin Hospital was perhaps unique in being the focus of attention for the media and the public in late 1999. Some families believed from inaccurate media reporting that

the organ retention was carried out only in Crumlin, that post mortems had been carried out without families' knowledge, and some believed that organs had been used for transplantation without their knowledge. In dealing with the enquiries that were made to the hospital, social workers, clinical nurse specialists, pathologists, medical and support staff had to correct these misapprehensions as well as deal with the distress, hurt and anger caused and support the families who were trying to cope with upsetting information.

2.6 The Rotunda

When the revelations regarding organ retention practices began to be highlighted by the media in late 1999, the Rotunda Hospital confirmed to the Department of Health and Children that it retained tissues from post mortems. In early 2000, the Master issued a statement setting out post-mortem practices and inviting parents to contact a help line. The hospital placed a notice in newspapers in March 2000 inviting contact with the help line and apologising for any hurt caused to families. Calls were directed to the head medical social worker and clinical risk manager. The matron and master's offices also received calls at this time. An *ad-hoc* multi-disciplinary committee was formed to co-ordinate the hospital's response. The hospital received 240 enquiries up to March 2000. Initial letters were sent to families who had contacted the hospital and arrangements made for them to attend meetings with hospital staff. In some cases families requested meetings with a pathologist and this was facilitated by the hospital. A full-time bereavement support service was provided from July/August 2001.

2.7 The Coombe

The Coombe issued a public statement in February and March 2000 stating that organ retention may be a necessary part of post-mortem examinations, and that subsequent to examination, organs were incinerated by the hospital. The hospital set up a help line in March 2000. It received 130 queries, not all of which are relevant to the terms of reference of this Inquiry. Each telephone call was logged and callers were asked to confirm their query in writing so as to protect confidentiality. Each query was acknowledged in writing and searches were made to identify relevant records. Parents were invited to attend a meeting with a clinician/pathologist.

2.8 National Maternity Hospital, Holles Street

In December 1999/January 2000 the hospital set up a team of 50 individuals to deal with enquiries. This group was drawn from senior staff members from midwifery, management, nursing staff, chaplaincy, and social workers. A clinical psychotherapist was engaged by the hospital to train hospital staff in dealing with the issues that might arise. From January 2000 to April 2002, the hospital dealt with 818 cases where organs had been retained. A full-time bereavement liaison officer was employed by the hospital in September 2001 and works in close contact with social workers and the hospital chaplain to ensure that all bereaved parents are dealt with sensitively. Counselling is provided by the bereavement counselling services at the hospital in conjunction with clinicians.

2.9 Children's University Hospital, Temple Street

Temple Street received 193 enquiries during 2000. Extra staff were employed in the Medical Social Work department to deal with these enquiries. The hospital appointed a medical social worker as post-mortem co-ordinator to co-ordinate the hospital's response to the enquiries. On receipt of an enquiry a social worker contacted a

consultant pathologist at the hospital to review the post-mortem report and clinical notes if available. From mid-2000, the practice was altered by facilitating a meeting between the post-mortem inquiry officer and the parents. In addition, the pathologist was available to meet the parents, if required. The hospital established an incident room and a freephone help line to deal with enquiries.

2.10 AMINCH

AMINCH state that they first received an enquiry in 1998 relating to post-mortem practices, and dealt with any queries on a case-by-case basis until 2000. Since that year a special projects office has been established to deal with queries and find out the relevant information for families who request it.

2.11 Overview of responses

Hospitals received varying types of queries, necessitating differing responses. Hospitals attempted to find relevant information for families. This was given to families in a variety of ways. Submissions from hospitals noted that information was provided through general practitioners or third parties where families so desired. Hospitals also communicated with parents themselves through phone calls, letters or meetings. In some instances, requests for information were passed on to the coroner or other hospitals. Counselling and bereavement counselling was offered and arranged for people who requested it.

Information and assistance was sought and provided about various matters, including registration of births and deaths, arrangement of baptismal certificates, whether consent was obtained for hospital post mortems, consent to coroner post mortems, whether organ retention had occurred and access to post-mortem results and reports. In some cases, information could not be accessed, such as instances where post-mortem reports could not be located.

3 Delay in Receiving Information

3.1 The swiftness of the responses to queries by concerned parents differed according to the hospital and the staff involved. Many parents found that they had to make repeated attempts to contact the relevant hospital before information was provided. Parents recalled making successive phone calls before receiving information. In some cases, hospital staff responded to queries by arranging a meeting with the relevant personnel to discuss the matter.

3.2 In a few cases, the time period between the initial contact and the receipt of information by parents stretched for months, with one family encountering a delay from May 2000 to February 2001 before having their queries answered, while another waited from February to July 2000 to receive answers. By contrast, some parents were provided with information within days. Any delays encountered in obtaining information increased the anguish for parents, with one set of parents complaining that the hospital concerned was not helpful in scheduling a meeting with the hospital representatives. Information provided was incomplete or misleading in some cases, thereby necessitating further contacts with the relevant hospital to secure more information.

3.3 As mentioned in Section 2 above, the complexity and breadth of some of the queries necessitated very detailed responses and follow-up contact. This may account for the delay encountered by families in some cases.

4 How was the Information Conveyed?

4.1 The information was conveyed by phone calls, letters and meetings. Families were generally given choices in relation to the method of communication. In some cases, families did not want telephone or written communication. Where telephone contact was acceptable to the parents, different hospital personnel made telephone calls at various times during the day. One parent recalled a telephone call at 8 pm from the hospital representative. Some telephone calls were made to parents at their places of work or while they were doing housework, with children in the vicinity. While some parents were content to receive the information as soon as possible, others viewed such communications as insensitive or '*a disgrace*', with one parent recounting that she fainted from shock after receiving the information via a phone call. Some parents recalled remarks made during such telephone calls as being hurtful and unhelpful and many felt that such information was not imparted sympathetically. One parent recalls being told that the parents had '*only buried tissue*'.

4.2 In other cases, an initial letter was sent to parents informing them of the general practice of the hospital and advising them that further information would be given to them. Some parents stated that they felt misled by such letters because they referred to '*tissue samples*', whereas parents were later informed that organs had been retained. Subsequent letters provided further information to parents about organ retention in their case. In some instances a list of organs was included with a letter about the topic, which was described as '*horrible, cold and unsympathetic*' by one set of parents.

4.3 In some cases, parents recalled that hospital staff were unwilling to convey the information on the phone. Instead the staff set up meetings about the issue with the parents. Parents had varying memories of meetings with hospital representatives. There was praise for the conduct of some meetings and parents were grateful to have somebody to discuss the matter with them. One parent recalled that she thought the hospital representative was forthcoming at the meeting. Other parents criticised the fact that they were asked to submit a list of questions to be answered at meetings, which caused parents to question whether the doctors were going to be '*open and honest*' about the matter. Another parent criticised the fact that four sets of parents attended a meeting with hospital representatives.

4.4 Some parents criticised the '*matter-of-fact*' manner in which the information was presented to them. Others submitted that staff were defensive in their dealings with them and felt that '*no straight answers*' were being provided to them. In those situations, parents reported that they had to ask a lot of questions to get the required answers, one parent said they had to '*drag answers*' from the doctor, and another parent related how they had to ask particular questions to get information. The parent recalled that: '*Now the atmosphere was if they were holding ... we were asking ... questions and they just didn't want to answer, you know. We just felt as if they were trying to hide something on us ... that they didn't want to tell us.*'

4.5 Parents left some meetings unhappy because of their perception that staff were not volunteering information and observed that hospital representatives at meetings read from reports but did not give them copies of the reports. Parents were shocked, stunned and upset by the revelations at the meetings. Some left the meetings in anger.

4.6 Several parents criticised the fact that the hospitals did not have records for the length of time that organs were retained, the date of disposal, who carried out the disposal, the location of the disposal and whether the organs had been incinerated or disposed of in some other manner. In one case the parents recalled that the pathologist in question had no records and no recollection of retention or disposal; they criticised his refusal to meet them. Another parent commented: *'One of the things I think about is the fact that nobody seems to know where [my son's] organs were incinerated. We were told it was not at the hospital, so where were they sent?'*

4.7 Others saw the lack of records as something that showed that the medical personnel thought they could *'take organs and do as they please'*.

5 Inaccurate Information

5.1 In some instances, hospitals had to communicate with the parents on a number of occasions because earlier communications had subsequently been proved inaccurate by further investigations. In those cases, parents reported that the distress caused by further information being communicated was heightened. Such information meant that the parents were trying to cope with revelations about organ retention when further information came to light, thus increasing their anxiety. It also eroded further any trust that the parents had in the hospital authorities to deal with the issues. One parent stated: *'I think that's what makes you think, well, maybe there's more coming because there's their lack of honesty.'*

5.2 In one such case, the parents held two meetings with hospital representatives. At an initial meeting, they were informed that *'slivers'* of tissue from organs may have been taken from deceased children but the hospital representatives denied that organs were taken. After subsequent media revelations about organ retention in that hospital, a second meeting was held where the hospital representatives informed the parents that their child's organs had, indeed, been retained. The parents felt that the hospital representatives *'gave us a raw deal'*. In another case, at one meeting parents were informed that the pituitary gland was taken. They recalled asking a lot of questions about organ retention during the meeting. Notwithstanding this, they were only informed about the retention of their child's heart at a later stage.

6 Explanation of Organ Retention Practices

6.1 No explanation was provided for the practices to many parents. Such explanations as were provided by hospital staff were brief, with hospital representatives stating that it was *'normal practice'* or *'standard practice'* or *'hospital policy'* to retain organs. Parents were dissatisfied with these explanations. Parents did not understand why retention occurred when they had known for a number of years the cause of death. This increased their anguish. One parent stated: *'I just cannot understand why they*

retained the organs ...They knew exactly what she had died from. If it had been the case that they could not identify what had gone wrong, that might be a different matter, but it is just not the case.'

7 Support Offered to Parents by Hospitals

7.1 Each hospital developed its own methods for offering support to parents. Some parents reported that they were offered counselling by the hospital. Others acknowledged that the hospitals had paid for the costs of the burial of the organs of their child. In other cases, the parents had no further contact with the hospital once they had received the information they sought and had received their child's organs where that applied. In some of these latter cases parents did not want more contact with the hospital, whereas for others it was a further source of annoyance that the hospitals did not attempt to provide some support for them during the stress caused by the disclosures. One parent recalled that she had to leave by the back door again when she collected her child's organs and also stated that a prayer service was held, despite her wishes that there would be no such service.

8 Changes in Policy Regarding Post Mortems and Consent

8.1 All of the hospitals reported changes in the practices and procedures employed since the controversy broke in 1999–2000. The controversy brought about a change in the consent forms used, and their introduction where only verbal consent had previously been required. In the case of some hospitals, changes in policy and practice had already begun to be implemented before the controversy arose in 1999. For example, consent forms and protocols changed in Crumlin Hospital in 1997 and on a number of subsequent occasions.

8.2 Another factor that has assisted the standardisation of procedures is that the locations of post-mortem examinations have been centralised in some health service areas.

8.3 The Eastern Regional Health Authority produced guidelines for providing a quality response to families in relation to queries from post-mortem practices. These guidelines were endorsed by the National Liaison Group on Organ Retention in 2001 and shaped the development of the National Protocols and Guidelines for Organ Retention and Post Mortem Practices, which were adopted at the end of 2003. An implementation plan was drawn up to include the appointment and training of bereavement officers, standardised consent forms, arrangements for disposal of organs, and requirements for management of records.

8.4 The issues of organ removal, retention, storage and disposal are now discussed with families. In addition, families make the decisions regarding retention and disposal. Information leaflets and booklets are provided to families to assist them in making their decision, so that they are now informed about the details of the post-mortem procedure when the request for a post mortem is made. Parents are informed if organs have had to be retained and will be asked to indicate their wishes as to the

disposal of the organs. The available options are generally a second burial, cremation, or disposal in a hospital plot. A service is sometimes performed at the hospital, attended by the social worker and chaplain if the parents so wish. When the post mortem report has been issued, a meeting is facilitated for parents with the clinicians and the pathologist at which the findings are discussed. Bereavement support is now commonly offered to families.

9 Conclusion

9.1 When parents became aware of the practice of organ retention in late 1999–2000, it became necessary for hospitals, some more than others, to respond quickly to enquiries in specific cases. Some hospitals received hundreds of enquiries from parents and other family members, while other hospitals received only a handful of calls. Although parents may perceive there to be inadequacies in the means by which their enquiries were dealt with by the hospitals, as a general rule hospital staff responded to the best of their ability at the time. This is in the context of some hospitals having difficulty locating documentary evidence relating to post mortems in particular cases, and the absence of a hospital protocol for dealing with situations of this nature. There is no doubt that in some cases mistakes were inadvertently made, inaccurate information unwittingly relayed, necessitating the subsequent correction of information in traumatic circumstances for the families. This undoubtedly caused a feeling of distrust and anger amongst affected families but may be at least partly explained by the hospital's wish to answer queries as quickly as possible so as to avoid further distress.

9.2 With the benefit of hindsight it may have been preferable for a moratorium to be imposed on the giving of information until all cases had been fully investigated internally and documented so as to ensure the accuracy of the information that was available. However, hospitals did not take this approach on the basis that delay could potentially cause further stress for the families. It was also the case that hospitals came under pressure to respond quickly from the Department of Health and Children, the media, and public representatives. The media environment at the time when this controversy arose was difficult for both hospitals and parents to cope with, given the sensitivity of the issues involved.

9.3 Irish hospitals did not anticipate the controversy that arose in late 1999. Although some hospitals had already begun a review of their procedures and had redrafted their consent forms before the controversy arose, most hospitals were nonetheless largely unprepared for the queries that came in late 1999–2000. In some cases contact was made by telephone call between the parents and the hospital. This was in response to the setting up of help lines to deal with queries. Parents were then usually given the option of response by telephone or post. If organs were still retained at the hospital, parents were offered a consultation with hospital staff. Due to the volume of cases to be dealt with, it was not possible for consultations to be offered to every person making an enquiry, as this would have seriously delayed the dissemination of information to the families.

9.4 Following the public reaction to the publication of organ retention practices, hospital managers introduced new policies and protocols dealing with consent for

hospital post-mortem examinations. As stated above, the Eastern Regional Health Authority produced guidelines for responding to families in relation to queries from post-mortem practices. These guidelines were endorsed by the National Liaison Group on Organ Retention in 2001 and shaped the development of the National Protocols and Guidelines for Organ Retention and Post Mortem Practices, which were adopted at the end of 2003. An implementation plan was drawn up to include the appointment and training of bereavement officers, standardised consent forms, arrangements for disposal of organs, and requirements for management of records.

10 Recommendations

- 1 Clear national protocols must be put in place by the Department of Health and Children and Health Services Executive to deal with queries from families in respect of post mortem practices as well as the provision of standardised forms to be used on a national basis. The language to be used in such forms must be clear and comprehensible, and must avoid medical or legal terminology as much as possible. Existing guidelines produced by the National Working Group on Organ Retention in 2002, and adopted by National Chief Officers in 2003 may be used as the basis on which to make any adaptations recommended in this Report. This should be done in consultation with relevant stakeholders.
- 2 An independent audit must be carried out of currently retained organs in all hospitals in the State. The Department of Health and Children and the Health Service Executive should engage in a public information campaign informing relatives that they may reclaim any currently retained organs within a 12-month period from the date of this Report. This should be organised and managed via a central enquiry line rather than by individual hospitals. Families who do not contact hospitals in this regard should not be approached with this information. Their right not to know must be respected, provided reasonable efforts have been made to disseminate information publicly.
- 3 Each hospital must have a bereavement liaison officer available to offer practical help and support to bereaved families and staff caring for those families. This officer must liaise with the relevant pathology department and should have a good understanding of pathology practices so as to provide assistance to the family if required. Although it is the clinician's responsibility to discuss the post mortem with the parents, this may be done as part of a team approach with the bereavement liaison officer, who may provide appropriate follow-up support.

Chapter Eight

Legal and Ethical Issues Relating to Post Mortems and Organ Retention

1 Introduction

1.1 This chapter considers legal and ethical issues raised by post-mortem practice and organ retention. It is important to stress that although comparisons are commonly made with the system in operation in the United Kingdom, the legal situation is markedly different there. Since 1961 a Human Tissue Act has been in existence in the United Kingdom, under which a post-mortem examination could legitimately take place as long as reasonable steps were taken to discover whether the relatives of the deceased raised any objection to such examination. Although this was not the same as ‘informed consent’, it was often interpreted in that way. The Bristol²¹ and Alder Hey²² Reports into organ retention must therefore be read in light of the existence of governing, though outdated, legislation. By contrast, Ireland has never had human tissue legislation and is governed, in the absence of such legislation, by common law principles.²³

1.2 Contemporary medical ethics is a discipline in which a range of philosophical theories intermingle, from deontology (which focuses on the rightness or wrongness of an act in itself) to utilitarianism (which classically views the morality of an action as dependent on the extent to which it maximises happiness and enhances autonomy). Autonomy is the most significant value that has been promoted by contemporary medical ethics, and has dominated medical ethics discourse since the 1960s. The acknowledgement of this concept has led to the discrediting of medical paternalism and to the promotion of the patient as a partner in his/her healthcare. This, in turn, has led to the evolution of the doctrine of consent over the past four decades, though in a different way to its legal development.

1.3 As clearly demonstrated in the submissions and evidence given by parents whose children were the subject of post-mortem examinations, the issues of consent and control are paramount in their minds. They relate their hurt and anger at not being informed as to what was to happen to their child’s organs, and at not having been given a choice as to the ultimate disposal of those organs. They also feel deceived by the manner in which information was finally given to them by the hospitals. This raises both legal and ethical issues relating to whether or not consent was necessary, and the extent to which information should have been provided to the parents. Consideration of these issues will demonstrate the different views of consent taken by lawyers and ethicists.

²¹ *Learning from Bristol: the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995* CMND 5207

²² *The Report of the Royal Liverpool Children’s Inquiry*, 2001

²³ Common law operates through a system of precedent whereby legal principles are passed down through decades, and sometimes centuries, of judicial decisions and are accepted by courts unless the facts of the present case are different, or unless legislation has intervened to deal with the issue in the meantime.

1.4 Another issue raised by the practice of organ retention is that of rights over the dead body. We may generally think of ourselves as the ‘owners’ of our bodies, but in strict legal terms, this may not be an accurate statement. Respect for autonomy and for the freedom to make choices in respect of our bodies does not necessarily imply that we have property rights in them. Nor does the fact of parental responsibility mean that parents have ownership over the body of their deceased child. This is considered further below.

2 Consent

2.1 Throughout this report and the controversy that led to the establishment of this Inquiry, much attention has been paid to the ethical and legal concept of consent. This section of the report summarises what is meant by ‘consent’ and in particular ‘informed consent’ in the context of medical practice. The development of the law in this regard has been dominated by cases in relation to disclosure to individuals prior to making decisions as to their own health care, and therefore may not be seen as having immediate relevance to the issue under consideration in this Report. However, if there is to be a requirement that a form of consent should be obtained from parents/legal guardians prior to hospital post-mortem examinations, it is important to be aware of the parameters of what consent means in the medical context.

3 Respect for Autonomy

3.1 The value of consent in medical law and medical ethics is paramount as it serves primarily to preserve the autonomy and dignity of the individual. The central idea of autonomy is that one’s actions and decisions are one’s own, to be exercised free from external influences. This does not mean that one cannot be receptive to the views of others, but that one does not accept them unquestioningly. In medical practice it is important to recognise that patients may or may not want to have the necessary information about their medical problem, and may or may not want to be the one to make the important decision about what treatment to take. While many people may feel and act as autonomous individuals, some people act quite differently; their desire for information is less pronounced, their personal beliefs are less developed, relevant or strong, and their desire for control is more ambivalent. Therefore any process of consent should recognise and reflect the complex range of human experience and respect the concept of welfare as well as autonomy.

4 Changing Culture of Consent

4.1 Medical practice has traditionally been influenced by a paternalism characterised by non-disclosure by the doctor, and deference by the patient. Paternalism may be defined as the policy of restricting the freedom and responsibilities of one’s dependants in their supposed best interest. The traditional Hippocratic Oath, sworn by generations of doctors, requires the doctor to ‘prescribe regimen for the good of my patients according to my ability and my judgement and never do harm to anyone.’

Neither the Hippocratic tradition nor any of the ancient or even early modern medical ethics literature discuss any obligations of disclosure on the doctor, although concern did exist about how to make disclosures to the patient without harming him/her. Benevolent deception was the main practice in the nineteenth century with the patient's right to be informed being overruled by the duty to benefit the patient in cases where the information may harm the patient.

4.2 Up to the 1950s permission for surgery was sought from patients in a fairly rudimentary way that absolved the doctor of responsibility in cases of malpractice. The concept of 'informed consent' emerged in the 1960s in the United States when medical ethicists began to emphasise the importance of patient autonomy and began to question the presumption that a doctor is in a better position to assess benefits for patients than the patients themselves. Medical ethics came to be seen as a conflict between the old Hippocratic paternalism and a principle of autonomy. Within a short time autonomy had won the battle, and informed consent became the central focus in relation to all medical interventions. It has since been incorporated into Irish and English jurisprudence, to the criticism of some commentators who see it as unfortunate and prone to mislead.

4.3 Thus, the culture by which informed consent became a necessary pre-requisite in medical treatment is a relatively recent phenomenon, as is the accompanying focus on providing information. The history of medicine and medical research is full of examples of interventions and procedures carried out without consent, where this was considered perfectly legitimate by society at that time. For example, in an Irish Supreme Court case in 1954, *Daniels v Heskin*,²⁴ the court considered whether a doctor should have informed a woman who was suffering from post-partum discomfort that a needle had accidentally been left in her body following stitching after childbirth. A majority of the court rejected the notion of a general duty to disclose information to patients. Justice Kingsmill Moore said it 'all depends on the circumstances – the character of the patient, her health, her social position, her intelligence...and innumerable other considerations.' The issue of the patient having the right to know this information was not even considered. The accepted wisdom at the time was that because doctors knew more about medical matters, they were in a better position than the patient to know what was in the patient's best interests. This meant that giving the patient the information necessary to make consent meaningful, or the information required to make a choice, was simply not an option.

4.4 In the middle of the twentieth century other societal changes began to impact upon the culture of consent. The Nuremberg Code (1947) and the Declaration of Helsinki (1964) prioritised voluntary consent as an absolute necessity. This was, and is, in keeping with growing respect for autonomy and self-determination, and also served to promote public confidence in medicine and research. Other developments included a growing concern for issues of equality and civil rights, consumerism and an increasingly technology-driven healthcare system. Knowledge became the fundamental constituent of self-determination. The law also began to become involved in the relationship between doctor and patient and, having traditionally deferred to the profession, now began to move the legal notion of consent to a more central role.

²⁴ *Daniels v Heskin* [1954] IR 73

4.5 The most widely cited decision in modern legal jurisprudence in relation to the requirement for informed consent is an American case called *Canterbury v Spence* (1972).²⁵ In this case the Court held:

True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. The average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision. From these almost axiomatic considerations springs the need, and in turn the requirement, for a reasonable divulgence by physician to patient to make such a decision possible.

5 Modern Legal Foundation for Consent Requirement

5.1 The basic legal principle described above has now been accepted in most jurisdictions worldwide, though it is not regarded as absolute. The doctor retains a 'therapeutic privilege' not to provide information to a patient if he/she believes that the disclosure of the information would result in a serious deterioration of the patient's condition, or would render the patient incapable of making a rational decision.

5.2 The right to autonomy is not explicitly referred to in the Irish Constitution or the European Convention on Human Rights (ECHR). However, the right has been judicially recognised as being encompassed in these instruments. The right to autonomy has been held to be one of the unenumerated personal rights of the citizen, protected by Article 40.3.1 of the Irish Constitution, though in the few judicial decisions in point, the right has been interpreted as a limited one. The ECHR has been incorporated into Irish law since 2003 though it is presumed to add little to existing constitutional protections in this regard. The Commission and Court have found that the right of autonomy comes within Article 8 of the ECHR, which provides protection of the right to respect for private and family life, though this protection is not absolute. It is possible that the lack of an effective sanction for wrongful removal of tissue might be considered incompatible with Article 8 but this would be contingent on proof of transgression of the law by failing to get consent from relatives, and acceptance by the court that removal and retention of tissue at post mortem constitutes lack of respect for private and family life. The courts have not yet considered this.

5.3 The Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo 1997) is designed to protect the dignity and integrity of human beings and to guarantee respect for their rights and freedoms with regard to the application of biology and medicine. Although Ireland has not yet signed the Convention, it is important to note that a number of Articles have possible relevance to the issue of organ retention.

²⁵ *Canterbury v Spence* 464 F 2d 772 (1972)

Article 2: ‘The interest and welfare of the human being shall prevail over the sole interest of society or science.’

Article 5: ‘An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.’

Article 22: ‘When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done with appropriate information and consent procedures.’

5.4 Although the Convention is concerned with the protection of living persons, the principles may also be relevant to the removal and retention of organs post mortem. An additional protocol to the Convention was published in 2002 concerning organ and tissue transplantation. Some of the relevant articles state as follows:

Article 17 – Consent and authorisation: Organs or tissues shall not be removed from the body of a deceased person unless consent or authorisation required by law has been obtained. The removal shall not be carried out if the deceased person had objected to it.

Article 18 – Respect for the human body: During removal the human body must be treated with respect and all reasonable measures shall be taken to restore the appearance of the corpse.

5.5 A further Protocol was published in January 2005 dealing with biomedical research. Its provisions are concerned with research on living persons and give details of the information to be provided to research participants, and the requirement for consent.

6 Legal Doctrine of Informed Consent

6.1 The term ‘informed consent’ is often used to describe the process whereby a healthcare professional discloses necessary information to a patient prior to obtaining the patient’s permission to go ahead with a procedure. Its purpose is to ensure that sufficient information has been provided to the patient to ensure that the patient is aware of the risks and benefits of the procedure, and its alternatives, before proceeding. In the context of consenting to one’s own medical treatment one can confidently presume that an act is an informed consent if a patient or subject agrees to an intervention on the basis of an understanding of relevant information, the consent is not controlled by influences that engineer the outcome, and the consent given was intended to be a consent, and therefore qualified as permission for an intervention.

7 Is Informed Consent Achievable?

7.1 One of the difficulties in the area of consent is that there is often a substantial difference between the appearance of consent and the reality. If a patient is simply asked to sign a consent form it loses all significance, as it becomes just a formality that must be complied with for legal purposes to protect the doctor and the hospital from being sued. If, on the other hand, consent becomes too demanding in terms of what is to be disclosed to and understood by the patient, then it will never be achievable.

7.2 Some doctors misinterpret the obligation to obtain consent as a simple requirement to disclose facts and get a signature, rather than a process of discussion of facts and acquiring permission. In many instances the most inexperienced doctor is sent to 'consent the patient' as part of a formulaic process done to avoid legal liability, rather than a process in which the patient actually participates or controls. The junior doctor may not be able to answer reasonable questions from the patient and may have difficulty in explaining an unfamiliar procedure to a patient, particularly where the doctor has not previously performed or participated in the procedure him/herself.

7.3 The fundamental characteristics of the ideal of informed consent are that patients substantially understand both the nature of the procedure they are permitting and the fact that they are permitting it, in other words that they have a choice in the matter. Many patients seem to feel that they are simply being informed as to what is about to happen to them and that their signature is an acknowledgement of their having been informed. Pressure or coercion is never compatible with informed consent.

7.4 Many clinicians and other commentators criticise the ideal of informed consent on the basis of its impossibility, or at least impracticability. They reasonably point to the strain on time and resources in modern hospital settings, the difficulties involved in explaining complicated medical facts, and the unpleasant and often distressing nature of the subject matter. However, the *Charter of Rights for Hospital Patients* agreed by Irish hospitals in 1992 tells patients that, generally, treatment should only be given to a patient with his/her informed consent and the consent form should clearly state the nature of the procedure to be undertaken. Patients also have a right to be informed as to the nature of the illness or condition in language they can understand.

7.5 The *Guide to Ethical Conduct and Behaviour* (sixth ed.) issued by the Irish Medical Council in 2004 provides for implied consent to certain procedures by virtue of the fact that the patient has presented for treatment. It also stipulates that informed consent can only be obtained by a doctor with sufficient training and experience to be able to explain the procedure to the patient. In obtaining consent, the doctor must satisfy him/herself that the patient understands what is involved by explaining it in appropriate terminology. Patients are to be encouraged to ask questions, which should always receive a positive response from the doctor, and a careful answer in non-technical terms.

7.6 It is important to point out that the ideal of informed consent is not necessarily that the patient has *full* understanding of the medical facts, but rather a *substantial* understanding. Complicated medical information that may be difficult to comprehend

may be explained in lay language, using common everyday analogies and explanations. Communication between doctor and patient should be regarded as a two-way process where the doctor listens to the patient in order to find out what information is relevant to his/her particular wishes and circumstances.

7.7 There is nothing about the consent process that requires written information to be given. In some medical procedures consent to minor procedures may be seen as implicit in consent given to a surgical or medical treatment. For example, when a patient is hospitalised for a surgical procedure, blood samples may be taken for analysis, medications may be given, and anaesthesia may be provided. In some cases written, or more commonly, verbal information will be given regarding these minor procedures, in others it will be assumed that the patient's consent to the surgery encompasses all that is necessary to facilitate that surgery and the patient's recovery.

8 Disclosure of Information

8.1 Given the limited human capacity to take in information, massive information overload is as likely to cause confusion and impair understanding as the provision of inadequate information. The ideal of informed consent does not require that all imaginable information be conveyed. Ethicists use a two-tiered standard to determine how much information should be given. Firstly, there are the 'core' disclosures. This is information that patients usually consider material in deciding whether to consent, and also the information that the doctor believes to be material about the proposed intervention. Unlike the legal position, the ethical focus is on what patients usually consider important, rather than whether or not they are reasonable in considering it to be important. These disclosures commonly relate to success rates, risks, side effects, alternatives, the doctor's experience of the procedure, and the costs involved.

8.2 The goal of achieving substantial understanding can only be realised on an individualised basis; simply because most people would understand something does not necessarily mean that a specific individual understands it. Therefore an additional second level of disclosure is required, that which asks what the specific individual considers relevant information. The only way for the doctor to discover what the individual patient considers relevant is by listening to the patient and participating in discussion rather than simply imparting information.

8.3 In relation to the legal test of what information must be disclosed to patients, there are traditionally two standards: the patient standard, and the professional standard. The former test would insist that the doctor reveal all relevant facts as to the proposed procedure; it is not for the doctor to determine what the patient should or should not hear. On this basis the patient should be as fully informed as possible so that he/she can make up her/his own mind in light of all the relevant circumstances. The quality of information supplied is to be judged from the perspective of the patient. Proponents of this test argue that it most fully satisfies the requirements of respect for autonomy, but even its advocates would usually accept that the doctor should be accorded a 'therapeutic privilege' to withhold information which would distress or confuse the patient.

8.4 On the other hand, the professional standard of disclosure takes the position that counselling and informing the patient are part of the clinical management of the patient. The extent and detail of the information supplied is a matter for decision by the doctor. The quality of the information supplied is viewed from the perspective of the doctor.

8.5 Irish law has traditionally taken the professional standard to be the appropriate one in deciding upon medical negligence actions. In the context of informed consent this means that if the doctor has followed the practice of his peers in deciding what information to disclose, he has complied with his obligation to his patient. However, if the actions of the doctor in giving information were inherently defective, the Irish courts might be prepared to judge that the doctor had not fulfilled his duty of disclosure prior to obtaining consent. It has also been decided that where the procedure is elective, in the sense that there is a choice to be made by the patient as to whether or not to proceed with the proposed treatment, a more stringent test of disclosure is required. Cases in recent years have moved towards a patient-centred test and have taken the view that where the patient has a choice to make as to whether to undergo a medical procedure, he/she has the right to make that choice with full knowledge of all material facts.²⁶

9 Application to Post-Mortem Examinations

9.1 There is an argument that the law relating to consent does not apply at all to post mortems as the legal doctrine was developed in relation to interactions between doctors and living patients in the context of a proposed medical treatment. In the circumstances under discussion here, the patient is no longer alive, no medical treatment is proposed, the benefit is not to the patient him/herself, risks are not expected, the time within which the decision must be made is limited, and those who must make the decision may be extremely distressed. On this analysis, the law relating to consent is not applicable at all.

9.2 However, as pointed out by the Bristol Report, discussion of a post mortem to be carried out on a deceased child is sufficiently closely related in time and context to the care of the child that it could be said that the law remains the same. It might also be said that the child's parents become the patients as they are cared for in their bereavement by the medical and nursing staff of the hospital, and perhaps the duty is owed to them rather than to the child. This is particularly the case where a child has died shortly after birth and the mother remains the patient of the obstetrician who has a duty to advise her in relation to future pregnancies. There is no clear legal answer to this issue.

9.3 Consent is not required to be given where a post-mortem examination is authorised by a coroner within the terms of his powers under the Coroners Act, 1962. This report does not recommend any change in the law relating to this aspect of the Coroners Act as it is seen to be necessary in the public interest that the coroner be so authorised.

²⁶ *Geoghegan v Harris* [2000] 3 IR 536

9.4 The issue of a post mortem arises at a time of extreme grief. Nevertheless, a post mortem has to be completed as soon as possible in order to get the best clinical results. It is not possible to allow sufficient time for the grief to abate. Therefore, it must be discussed with sensitivity and openness for the clinician to discharge his/her duty. With proper training, clinicians should be able to communicate effectively and sympathetically with the necessary medical knowledge to inform the child's parents. Clinicians must understand the value and process of post-mortem examination in the clinical setting and also what it means for relatives. It is 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 details relating to the cause of death.

9.5 Many, though not all, parents feel that they must be informed of the details of each organ to be retained and the purpose for which it will be used. It is not enough for clinicians to tell such parents that they would like to examine the body after death and that this might involve taking tissue. Some parents 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. Other parents prefer not to know the details of the procedure but are nonetheless satisfied to allow the examination to proceed. Both sets of parents must somehow be accommodated in whatever information process is adopted. This is discussed further below.

10 Parental Authority

10.1 Under the Irish Constitution, *Bunreacht na hÉireann* 1937, the position of the family is recognised as predominant in terms of its place in society. Article 41.1.1 provides that 'the State recognises the Family as the natural primary and fundamental unit group of Society, and as a moral institution possessing inalienable and imprescriptible rights, antecedent and superior to all positive law.' Article 41.1.2 provides that the State guarantees 'to protect the Family in its constitution and authority, as the necessary basis of social order'.

10.2 Parents/guardians make decisions for their children on a daily basis, ranging from the clothes they wear, the food they eat, and the schools they attend. In the medical context, they are generally given wide authority to make decisions on behalf of their children though, in exceptional cases, legal provisions may be invoked to deal with situations in which parents breach their duties towards their children. In law, parental decision-making is limited to decisions that are in the child's best interests. Parents cannot, for example, give consent to a procedure to be carried out on their child for the benefit of themselves or the child's sibling. However, at least in the Irish constitutional context, the circumstances in which the State might intervene to overrule the decision of a parent are quite limited following the decision of the Supreme Court in *North Western Health Board v HW and CW*.²⁷ In that case the Court held by majority decision that the State could only interfere where there were exceptional circumstances, such as where the child's life was in imminent danger.

²⁷ *North Western Health Board v HW and CW* [2001] IESC 90

10.3 Therefore, while the child is alive, doctors and nurses must be careful not to infringe the autonomy and privacy of the family, though at the same time acting as an advocate for the child's interests. Getting the balance right is not an easy task. The Bristol Report acknowledged that although children's needs are ordinarily expressed through their parents, their interests do not always coincide. While alive, children must be listened to, provided with information that they want in an appropriate way, and encouraged to participate in decisions.

10.4 Difficult situations can arise where the parents of a child disagree on decisions relating to the child's treatment or other important issues. Where both parents are legal guardians of the child and agreement cannot be reached between them, an application can be made to the court to make the decision in the best interests of the child. Where one parent is the legal guardian, treatment may proceed on the consent of that parent alone, though best practice would indicate that if the other parent were also involved in the care and custody of the child, he/she should be involved in the decision-making process. The application of these principles in the case of a deceased child is more difficult.

11 Authorisation

11.1 As stated above, it is generally accepted that parents/guardians have the authority to make treatment decisions on behalf of their children, though these decisions may be challenged in exceptional cases. In relation to hospital post-mortem examinations, there is neither legislative guidance nor legal precedent in Ireland that outline parental authority in this regard. Despite this, it is self-evident that parents have a unique and continuing role to play in decisions relating to their children after death. Respect for this role demands that their permission be obtained for a hospital post-mortem examination.

11.2 In relation to hospital post-mortem examinations, the Scottish Report on Organ Retention²⁸ (2001) took the view that the language of consent is inappropriate here, for two main reasons. Firstly, there may be families who are content to allow the retention of organs taken from their relatives but who do not want or feel able to participate in a process akin to giving a fully informed consent to medical treatment in life. Secondly, since parents can only consent to procedures that are in the best interests of their child, and since it could be said that deceased children have no interests in law, parents cannot be empowered to give consent to a post-mortem examination to be carried out on their child. As pointed out by the Chairperson of the Scottish Inquiry, Professor Sheila McLean,

The interests of others can clearly be enhanced by accurate diagnosis, sound medical research and the education and training of doctors, but there is no possibility of a benefit accruing to the specific child.

11.3 The Scottish Inquiry recommended that parents must have overriding authority in respect of post-mortem examinations to be carried out on their children. However, the means by which to recognise such authority is not through consent, but

²⁸ *Independent Review Group on Retention of Organs at Post-Mortem*, Final report, November 2001

authorisation. The Report takes the view that the use of the word ‘authorisation’ rather than ‘consent’ clarifies the scope of the decision-making powers of parents in these circumstances. It also meets the concerns of those parents who do not wish to receive information about post-mortem examination and/or organ retention, but who nonetheless do not object to these procedures being carried out. ‘Consent’ requires the provision and comprehension of information, whereas ‘authorisation’ does not impose this requirement. Parents may thus authorise procedures without having information forced upon them.

11.4 It is clear that parents are entitled, if they so wish, to receive information relating to the purpose of the post-mortem examination, the procedures to be carried out as part of that examination, and the retention of any organs or tissue pursuant to that examination. Their informational needs and decision-making authority must be prioritised and enshrined in legislation. The use of ‘authorisation’ as a means of empowering parents to maintain control of what happens to their child’s body confirms their unique bond with their child, and facilitates their active involvement in all decisions relating to post mortems. Whereas ‘consent’ may be seen as a passive acceptance of a proposal put to the parents by someone else, ‘authorisation’ is a more active participation – the parents can choose, with the benefit of as much information as they require, whether to give someone power to do something in relation to their child. Without the exercise of their authority, the hospital post mortem will not take place.

11.5 The forms recommended by the Scottish Report invite the parents to consider initially whether they wish to be given further information about the hospital post-mortem examination. If they decide that they do not wish to have further information they may nonetheless authorise the performance of the post mortem examination and any action the hospital considers appropriate following that examination. They may choose to be informed later of the findings of the examination, or to request further information in the future. The alternative for the parents is to receive information about the post mortem, including retention of organs and tissue, and the preparation of blocks and slides. They may also authorise retention for approved medical research and educational purposes. Choices are also made available regarding the disposal of retained organs.

12 Property in the Human Body

12.1 One of the options for the recognition of the authority of parents in relation to the bodies of their deceased children is the property model. This argument would follow the line of thought sometimes expressed by bereaved parents to the effect that their children’s bodies ‘belong’ to them, and that any removal or retention of organs was akin to ‘stealing’ what rightfully belongs to the parents. Other families find the language of ownership insensitive and abhorrent, as they prefer to identify with a sense of continuing parenthood, and see the child as a continuing member of the family.

12.2 The common law has rejected a property approach to the human body. Early cases seem to support the principle that there is no right of ownership in a corpse, though many commentators argue that the foundation of this principle rests on flimsy

evidence from misreported cases. In any event, the principle of ‘no property in the human body’ has long stood the test of time and, although English cases are not legally binding on an Irish court, the common law principle is likely to be accepted by the Irish courts. This was pointed out in *AB & Ors. v Leeds Teaching Hospital*²⁹ referring to the decision of *R v Kelly*³⁰ below,

However questionable the historical origins of the principle, it has now been common law for 150 years at least that neither a corpse nor parts of a corpse are in themselves and without more capable of being property protected by rights.

12.3 *R v Kelly* confirms an exception to this principle where work or skill has been applied to the corpse/body part such as to endow it with different attributes or commercial value. In such circumstances the application of skill would give a right of possession of the body to the person applying the skill. Applying this exception to pathology practice, there is a possibility that the law might take the view that, for example, the fixation of the brain gives that organ attributes or potential which are different to the unfixed brain. Therefore, the pathologist who applies his skill to this technique has a right of possession to the brain. However, in an earlier case in 1996, *Dobson v North Tyneside Health Authority and Newcastle Health Authority*,³¹ the court held that there was nothing to suggest that the fixing of a brain was on a par with stuffing or embalming a corpse or preserving an anatomical or pathological specimen for scientific collection.

12.4 In the more recent *AB* case the judge addressed this point as follows:

The principle that part of a body may acquire the character of property which can be the subject of rights of possession and ownership is now part of our law. In particular, in my opinion, Kelly's case establishes the exception to the rule that there is no property in a corpse where part of the body has been the subject of the application of skill such as dissection or preservation techniques. The evidence ... shows that to dissect and fix an organ from a child's body requires work and a great deal of skill, the more so in the case of a very small baby ... The subsequent production of blocks and slides is also a skilful operation requiring work and expertise of trained scientists.

12.5 The differing views expressed by the English courts on this point indicate the lack of clarity that exists in relation to whether or not the pathologist's act of fixing the organ transforms it into an item of property to which the next-of-kin might be entitled. It is similarly unclear whether or not the ‘work and skill’ exception would be applied in these circumstances in Irish courts but, as with the ‘no property’ rule itself, it is likely to be followed unless affected by legislative change. The interpretation of the rule in the context of pathology practice and organ retention remains undecided.

12.6 In any event, it is recommended that the language of ownership is not appropriate to the body of a deceased child. Whether or not one takes the view that the deceased person remains a ‘person’ in the eyes of the law, the use of concepts of property and ownership do not rest comfortably with notions of parenting and family.

²⁹ *AB & Ors. v Leeds Teaching Hospital* [2004] EWHC 644 (QB)

³⁰ *R v Kelly* [1999] QB 621

³¹ *Dobson v North Tyneside Health Authority and Newcastle Health Authority* [1996] 4 All ER 474

The care and protection of children enveloped in the parenting role, the prioritisation of the family under the Constitution, and the privacy of the family unit, strengthens the need to recognise the clear authority of parents in relation to their deceased children.

13 Right to Possession of the Body

13.1 Although there is no property or ownership in a dead body, the common law does recognise a possessory right – the right to take or keep possession of the body in certain circumstances and for certain purposes. If it is necessary for the coroner to take possession of the body for the purposes of his investigation into the cause of death, he has an absolute right in common law to possession of the body until the investigation is concluded. Subject to this, the personal representatives of the deceased have a right to possession of the body until it is disposed of. This is derived from their duty to dispose of it. In the case of a child, the duty falls on the parents/guardians and they therefore have a right to possession of the body for burial purposes.

13.2 Even where there is a right in the next-of-kin to call for possession of the body for burial purposes, whether or not this right extends to all parts of the body has not been decided at common law. As the Bristol Report concluded:

The common law is entirely unclear as to whether each and every part of a body which might be discovered, for example after an accident, or after burial of the rest of the body or every slide and tissue sample in a pathology examination, should be regarded as within the definition of ‘the body’, for the purposes of the duty to dispose. If the duty to bury does not extend this far, then it would follow that neither does the corresponding right to call for possession for the purposes of disposal. Thus, institutions in possession of archives or ‘banks’ of tissue, need not as a matter of law at least, give up that possession, even if the material has not ‘acquired different attributes’. This appears so, even if the initial separation of the body part from the rest of the body was itself unauthorised.

13.3 The Bristol Report also recognised the necessity of giving detailed and specific information to parents but acknowledged that this would be painful for some parents already reeling from the loss of their child, while other parents will find the information to be helpful. The Report concludes that it is not possible to ‘square this particular circle’ and that ‘there is a price to be paid for being informed’.

13.4 The suggestion of replacing the consent model with ‘authorisation’ as recommended by the Scottish Report appears to strike an appropriate balance between those who wish to exercise their right to know the relevant information, and those who wish to exercise an equal right not to know. This empowers parents whose child has died to make a choice as to how much information they wish to be given prior to making a decision in relation to a post-mortem examination. Given that much of the criticism of the procedures and practices of the past have been related to such choices not being given to parents, this may deal with some of those criticisms without forcing such information on those who would prefer not to hear it. Rather than have such a

decision being made by the clinician, as was the case in the past, parents themselves are given the choice as to how much they can deal with at this time.

14 Conclusion

14.1 Many benefits are obtained from post-mortem examinations, both for families and for future patients. For those benefits to be properly obtained it is vital that parents are not excluded from the process. The Post Mortem Inquiry was established as a result of the distress, grief and anger felt by families when they discovered that the organs of their children, and other relatives, had been retained and disposed of without knowledge or consent. The overriding recommendation of this Report is that legislation be enacted to ensure that this will not happen again.

14.2 In a general sense, authorisation is always preferable to conscription as it is in keeping with respect for family life, privacy, and the emotions of the bereaved. Parental permission for the examination and any retention of organs must be given freely. Insofar as they request it, their authorisation must be based on clear and comprehensible information provided in a sensitive and supportive way.

14.3 It is inherent in the circumstances surrounding the communication process in this context that time may be limited, and parents will undoubtedly be grieving and in shock. In that sense, the process is very far from ideal in terms of imparting information and ensuring as far as possible that it is understood. In the past, it has been clinicians who have taken it upon themselves to decide the level of information to be given to parents. This has not always proved to be sufficient and has resulted in anger, distrust and suspicion in many instances where parents felt they were not told the full truth. Although it is painful to be told, parents have the right to honesty.

14.4 Parents must be recognised as partners with medical professionals in the task of making decisions regarding their children. Yet the difficulties are enormous. The parents are under huge emotional stress, and are being asked to make an important decision that they will have to live with for the rest of their lives. It is futile to simply go through the motions of reciting details to grieving parents, and obtaining their signatures on forms. A great deal more effort at communication is required if authorisation of the procedure is to be meaningful.

14.5 *Authorisation*, as described in the Scottish Report on Organ Retention outlined above, is based on recognition of the intimate bond between parents and children, the constitutional privacy of the family unit, and the right to prevent interference with that unit. It recognises the role that parents must be given to make decisions in relation to how their children should be dealt with after death. *Authorisation* implies an active decision-making function by the parents/guardians who are in a recognised position of power, and is therefore in keeping with a modern interpretation of the relationship between patients/carers and doctors as a partnership or therapeutic alliance. *Authorisation* allows those who do not wish to be given details about organ removal to nonetheless make a valid decision. It therefore empowers parents to remain in control of the post-mortem process while at the same time respecting their right not to be told the distressing details of it. Information is not being withheld from them,

rather they are exercising their choice not to access such information and yet remain involved in the decision-making process.

15 Recommendations

1. The main aim of this Report is to place parents/guardians at the centre of decision-making and control in respect of hospital post-mortem examinations to be carried out on their children. However, for the reasons outlined, the doctrine and language of informed consent is inappropriate here and therefore is not recommended for use in such legislation. The alternative concept of *authorisation* is to be preferred. This is a stronger and more powerful recognition of the active role and choice of parents in decision-making in relation to post mortems.
2. Parents must be given the option of authorising a post-mortem examination to be carried out on their child on the understanding that this is being performed to provide further information as to the cause of death and the possible effects of treatment. Some parents may wish to authorise a post mortem without wanting to receive any further information or consultation. Their right not to receive this information must be respected. It must be made clear to them that they can come back with a future request for more information at any time. For those parents who choose this option, it must be stated on the authorisation forms that this includes authorisation of all actions necessary as part of that examination. The accompanying information booklet to be given to parents to read if they so choose must explain that this will include removal and sampling of organs, and may include retention of organs for diagnostic purposes. It must be made clear that organs retained at post-mortem examinations will not be used for any purpose other than diagnosis without the authorisation of the parents/guardian.
3. If they require further information prior to authorisation, parents must be told that the performance of a post-mortem examination involves the examination of the body of the deceased child. It includes the dissection of the body and the removal of organs, tissue samples and blood/bodily fluids. It is carried out to provide information about or confirm the cause of death, to investigate the effect and efficacy of a medical or surgical intervention, to obtain information regarding the health of another person/future person, and for audit, education, training or research purposes. Parents must be made aware that in certain circumstances it may be necessary to retain organs in order to complete the examination.
4. Parents must be given the option to authorise a limited post mortem. They may choose to limit the examination to particular organs but, in making that choice, must be informed that this will mean that samples will be taken from the organs being examined, and that information will not be available on other organs which may have contributed to the child's death.

5. Parents should also be informed of the potential benefits of retention in terms of education, training and research. If the retention period is short, they must be made aware that it may be possible to delay the funeral in order that the organs may be reunited with the body. In other cases, they must be made aware of their options in relation to disposal of the organs at a later date.

6. Legislation must be introduced as a matter of urgency to ensure that no post-mortem examination will be carried out on the body of a deceased child and no organ will be retained from a post-mortem examination for any purpose whatsoever without the authorisation of the child's parent/guardian, or the authorisation of the coroner in an appropriate case.

Chapter Nine

Use of Autopsy Material in Medical Education and Research

1 Introduction

1.1 This chapter examines the relevance of post-mortem practice to medical education and training, audit, and medical research. The benefits to patients that can follow from teaching and research on human tissue are undeniable. Many bereaved families affected by the organ-retention controversy are anxious to see the realisation of these benefits. However, the uses to which organs and pathology specimens have been put in the past have raised concerns with parents regarding the level of respect shown to their deceased children's organs, and the lack of information they were given about those uses.

1.2 There is significant concern amongst pathologists in relation to the use of surgically removed tissue and the extent to which archived blocks and slides of tissue retained as part of the patient's medical record may be utilised. However, the terms of reference of this Inquiry deal only with whole organs retained at post-mortem examinations, and therefore this Report does not address the use of surgical tissue from living donors. It is clear that this issue requires detailed and urgent consideration and legal clarification.

2 Uses of Autopsy Material

2.1 The taking of tissue from almost every organ of the body is an integral part of the post-mortem examination. The pathologist removes tissue in order to correctly identify and definitively confirm any abnormality suspected by naked eye examination. There may also be abnormalities not visible to the naked eye, which can only be detected by microscopic examination. Tissue sampling of organs is therefore a necessary part of the competent performance of a post mortem and essential to a thorough diagnosis. Most pathologists would regard a post-mortem examination carried out without such sampling as incomplete and unprofessional.

2.2 There may be circumstances in which the pathologist requires to retain a whole organ, commonly the brain or heart, for further detailed examination so as to ensure an accurate diagnosis. This may involve consultation with surgeons or other clinicians who treated the child, or it may necessitate referral to a specialist in another hospital.

2.3 Autopsy material may also be retained for purposes of audit, clinical governance and quality assurance. Audit is a necessary facet of hospital management as it serves to ensure the highest possible standards of patient care. The autopsy is the most effective way of scrutinising surgical and medical competencies in the hospital, and is in keeping with models of transparency and peer review of patient management. Case conferences are commonly held in many hospitals on a regular basis where diagnoses are reviewed with an interdisciplinary clinical team, including pathologists who may

present both images and whole organs so as to facilitate discussion of diagnoses and surgical techniques. Quality assurance in pathology laboratories is essential to ensure the highest standards of testing and accuracy in diagnosis.

2.4 It has already been noted in this Report that in the past, organs were retained from hospital post mortems carried out on children without the knowledge or consent of the child's parents. Although the primary use of these retained organs was for diagnostic purposes, other use was also sometimes made of the retained organs. Historically, organs were sometimes anonymously preserved in specimen jars in pathology museums for teaching purposes. Organs were also used in research projects carried out by, or in association with, some hospitals and medical schools in Irish universities. Consent was not obtained for retention for either purpose until recent years, though a small number of hospitals had consent forms that specifically referred to the retention of 'tissue' for medical education and research. As discussed in other sections of this Report, this was not generally understood by parents to refer to retention of whole organs. Since 2000, practices have changed and consent is now specifically sought for organ retention for education and research purposes.

3 Medical Education and Training

3.1 Pathologists are registered medical practitioners who have studied medicine for six years and spent a further year in intern hospital training. They then follow a training course for a further six to seven years studying histopathology (study of cells and tissues) and autopsy pathology under expert supervision in Ireland and abroad. The Faculty of Pathology and equivalent professional bodies in other countries such as the United Kingdom and United States set out training requirements to be fulfilled prior to acquisition of specialist qualification. Pathologists may specialise in microbiology, biochemistry, or haematology (blood diseases) as well as histopathology. The majority of the work done by hospital pathologists relates to living patients who are admitted for tests and surgical treatment. The hospital pathologists who carry out autopsies are histopathologists. There are currently 73 consultant histopathologists listed on the Specialist Register of the Irish Medical Council as resident in Ireland, and 39 specialist registrars in training. There are a further 18 in positions of senior house officer. Each major hospital has one or more histopathologist(s) on staff.

3.2 The importance and value of medical education and training cannot be underestimated. Discussion of the way in which education and training of undergraduate and postgraduate medical professionals is structured is clearly outside the remit of this Report. However, serious concerns have been expressed to the Inquiry in relation to the decline in the post-mortem rate in Irish hospitals, and the consequent detrimental effect on education and training of medical practitioners and pathologists.

3.3 It is vitally important that medical students are facilitated and encouraged to observe post mortems in order to fully appreciate the progression of disease and the complexity of the human body in both its normal and abnormal condition. The basics of anatomy can be taught on cadavers that have been donated to medical science. These donations demonstrate a huge commitment to scientific and medical endeavour,

and the generosity of such donors is gratefully acknowledged. The altruistic spirit of individuals and families who have provided this benefit to society should be recognised and applauded.

3.4 Pathology is an essential component of an undergraduate medical education and ideally requires students to observe autopsies and organs. However, due to the reduction in hospital post-mortem rates, many medical students and aspiring doctors do not see an autopsy in the course of their training. This may leave them uninformed and unprepared to explain post-mortem examinations if required to do so in the course of their career. Attendance at autopsies facilitates a better understanding of pathology and medicine by students, and also encourages respect for the dead.

3.5 Trainee pathologists require access to tissue and organs retained from autopsies and surgery in order to become sufficiently trained in diagnosing both common and rare conditions. Practical training in the complexities of dissection can only be realistically obtained through attendance and eventual participation in post-mortem examinations. Experience and discussion with treating clinicians form an important basis of competence in this speciality. Competent performance of an autopsy is a necessary and fundamental constituent of specialist qualification as a pathologist.

3.6 Organs retained over many years are sometimes preserved in pathology museums to allow visual inspection by medical students and are of huge value to teaching. Most medical schools at Irish universities maintain pathology museums. The size and content of these museums vary from college to college. Many of the specimens maintained at these museums are over fifty years old and none is identifiable. The museums are not open to the public. The collections are used to teach medical students and trainee surgeons in diagnostic and technical skills, and to ensure that they have reached appropriate levels of competency both prior to qualification and as part of continuing professional development during their careers.

3.7 The value of pathology museums for teaching purposes is incontrovertible. The specimens maintained at such museums play a major role in medical education and training of undergraduate and postgraduate doctors. However, consent to retention was not obtained from the families of the deceased for such use. No opportunity was thus given to them to donate these organs in the interests of medical science, as many would have wished. It is unclear from the documentation submitted to the Inquiry how many of the organs maintained in pathology museums are from post mortems performed on children.

4 Audit and Quality Assurance

4.1 Medical audit is a process of assessing the quality of health care. This may be done at an individual, local or national level but the objective remains the same. Audit is carried out to assess the structure, process and outcome in a healthcare setting and compare it with previously agreed standards or past results. It is an essential process in a healthcare system that prioritises quality and safety.

4.2 The relevance of post-mortem examinations to quality assurance and audit processes is abundantly clear. Despite advances in medical technology, in particular

diagnostic imaging, numerous studies demonstrate continued discrepancies between clinical diagnoses and autopsy findings. It is self-evident that in circumstances where error rates and unsuspected findings are high, there must be a system for reviewing patient care and management in order to ensure the best possible quality of care for patients. The autopsy performs a critical function in this regard as it is the best means by which errors might be detected and standards consequently improved. In this sense the autopsy rate might be said to be an indicator of the quality of a hospital.

4.3 Quality assurance may involve the review of patient records to analyse the outcome of surgical procedures, or the use of a blood sample to ensure that accuracy levels in testing are maintained. Consent is not generally sought from living patients for retention of tissue samples as part of their medical record as it is taken to be implicit in consent for treatment. Consideration of the legal issues involved in the retention of tissue blocks and slides is outside the scope of this Report, which is focused on retention of whole organs at post mortem.

5 Research

5.1 The advancement of medical science depends on research, which may be broadly defined as the process by which new facts are established. Medical research ranges from traditional laboratory studies, to assessment of patient outcomes, to a statistical analysis of populations. There is often a blurred line between medical audit and medical research, both of which can have significant impact on future practice. This Report does not intend to address this long-standing debate.

5.2 Autopsies on individual patients or groups of patients with similar conditions provide insights into disease and responses to treatment. Such autopsies are fundamentally important in leading to greater understanding and recognition of symptoms of disease processes. The collection and use of biological samples from surgery and autopsy for medical research is invaluable. Medical research cannot progress without the use of such samples which are therefore of huge scientific significance. Their value to society is immeasurable.

5.3 To be acceptable, medical research can only be carried out according to legal and ethical requirements, which are imposed to ensure protection of the interests of all participants and researchers. The increasing scrutiny of medical research and clinical trials over the period spanned by this Report demonstrates a growth in concern and respect for the welfare and rights of participants, and a recognition of the fundamental importance of voluntary informed consent. Principles of respect for self-determination and the dignity of the human body are universal principles that do not depend on national legislation or legal precedent, and are inherent in numerous international declarations and conventions, most importantly the Declaration of Helsinki.³²

5.4 In the European context, the most influential statements have been the European Convention on Human Rights, the Council of Europe Convention on Human Rights and Biomedicine (1997), and the additional protocols mentioned in Chapter Eight.

³² World Medical Association. *Declaration of Helsinki: Recommendations Guiding Physicians in Biomedical Research involving Subjects* (1964, 2000)

Ireland has not yet signed the Convention. There has been a determined drive to respect human rights in the context of medical treatment and clinical research across the European Union, with an extensive public policy debate taking place in many European countries in relation to informed consent and the nature and appropriateness of regulatory models of research ethics review.

5.5 Clinical research involving trials of medicinal products on human subjects is subject to regulation through the EU Clinical Trials Directive, as implemented. This imposes a structure on the approval process for medicinal products across the EU, requires ethics committee review of such trials, and establishes binding requirements of consent. Regulation of research is not uniformly welcomed – some researchers view such oversight as an impediment to valuable research. However, regulation can also be seen as a means by which individual rights and autonomy can be safeguarded by the anticipation of dilemmas and difficulties. Further development of these arguments is outside the scope of this Report.

5.6 Research activity is generally now subject to ethical review, though the extent and quality of such review has varied over the years covered by this Report. In Ireland, the role of ethical review of trials on medicinal products is given to Research Ethics Committees (RECs), whose role and function has become more formalised since the implementation of the Clinical Trials Directive. Even prior to the Clinical Trials Directive, approval by an REC was usually considered a necessary precondition for funding, insurance and publication of research findings. RECs generally review research protocols with the following principles in mind: informed consent, freedom to withdraw without adverse consequences, benefit to participants, privacy and data protection. Despite the increased formalisation and regulation of the ethical review process, concern nonetheless exists in relation to research that falls outside the scope of the Directive, as well as the membership of RECs and the level of inconsistency in decision-making at local level.

5.7 Research on human tissue, including organs, has contributed to improvements in disease diagnosis and treatment. Scientific and medical literature is replete with examples of how research using human material has contributed to understanding of the causes of disease, as well as the development of cures and treatments. For example, children's organs were sometimes used in research projects aimed at investigating the cause of death of children who died of Sudden Infant Death Syndrome (SIDS, or commonly called 'cot deaths'). The organs of children who died from other conditions were also used in these research projects for comparison purposes in order to ascertain which organs were affected by SIDS. It is vitally important that such research be allowed and encouraged to continue and grow, and that the scientific value of pathology archives be promoted. However, in light of past practices, this must be done in a way that restores and stimulates public confidence, and balances the rights and interests of individuals with the public interest in ethical research.

6 Consent for Research

6.1 As discussed at various points throughout this Report, consent is widely regarded as one of the fundamental principles of medical ethics. It is emphasised in numerous research ethics codes and regulatory processes. For example, Article 22 of the Declaration of Helsinki provides that:

In any research on human beings each subject must be adequately informed of the aims, methods, sources of funding, possible conflicts of interests, institutional affiliations of the researcher, the anticipated benefits and risks of the study and the discomfort that it might entail. The subject shall be informed of the right to abstain from participation in the study and to withdraw consent at any time without fear of reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely given consent preferably in writing. If consent cannot be obtained in writing the non-written consent must be formally documented and witnessed.

6.2 Despite the emphasis clearly placed on the importance of consent in the research process, there is an argument that in relation to the use of human material, the concept of consent might be curtailed by an appeal to the public interest in research. The broader issues in this debate focus on rights of ownership over excised tissue, distinctions between surgical waste and post-mortem tissue, self-determination and utilitarianism. Concerns are commonly expressed within the research community that the imposition of a rigid consent structure will inhibit research, and that due consideration should also be given to the benefit of research to humankind. Various recommendations have emanated from professional bodies and legislative processes in the United Kingdom and Scotland, some of which rely heavily on the notion of anonymity and regulation as a safeguard against any undue interference with individual rights.

6.3 The Irish Council for Bioethics has published recommendations dealing with the collection, use and storage of human biological material in research.³³ While much of this report and its recommendations relate to material taken from living donors, there is also, *inter alia*, discussion of the importance of informed consent, and the use of pathology archives in research.

6.4 The Steering Committee on Bioethics (CDBI) at the Council of Europe has published draft recommendations on research on human biological materials, which will be submitted to the Committee of Ministers of the Council in 2006. The recommendations provide in Article 10.2 that information and consent or authorisation to obtain human biological materials should be as specific as possible with regard to any foreseen research uses and the choices available in that respect. Article 12 states that biological material removed for purposes other than storage for research should not be made available for research activities without appropriate consent or authorisation, and whenever possible, information should be given and consent/authorisation requested before biological materials are removed. Article 13 provides that biological materials should not be removed from the body of a deceased

³³ *Human Biological Material: Recommendations for Collection, Use and Storage in Research 2005*. Irish Council for Bioethics

person for research activities without appropriate consent or authorisation, and should not be removed or supplied for research activities if the deceased person is known to have objected to it.

7 Retention of Organs for Research

7.1 In the past, organs retained at post mortems carried out on children were sometimes used for research purposes without the consent of the child's parents. Some post-mortem consent forms referred to retention of 'tissue' for such purposes but although the clinicians understood this to include organs, the child's parents generally did not. The reasons why parents were not given this information and choice are outlined in earlier chapters of the Report.

7.2 Following consultation with stakeholders in 2002 guidelines were drafted by the National Working Group on Organ Retention and adopted by the National Chief Officers in 2003. An audit of conformity with these guidelines across all hospitals was outside the scope of this Inquiry. The guidelines provide that in discussion of a hospital post mortem with relatives of the deceased, the relatives should be informed that the pathologist might consider retaining organs for education and/or research purposes. In these circumstances specific consent is required. Relatives should be informed about the storage, use and ultimate disposal of the organs and the anonymisation of all samples.

7.3 In keeping with recommendations dealing with organ retention generally, in order for research to be undertaken on organs retained from a deceased child at post mortem, authorisation must be given by the child's parent/guardian. This applies to all post mortems, including those authorised by the coroner. The coroner's functions cease to exist once the investigation into the cause of death is complete. Therefore, further retention for any other purpose can only be done with the authorisation of the child's parent/guardian.

7.4 The process by which authorisation is given is a continuous one, dependent on good communication, disclosure of relevant information if required, competence and voluntariness. These components have already been discussed in Chapter Eight of this Report and apply here in equal force.

7.5 However, there are some potential problems where parents/guardians are invited to authorise the use of retained organs for research purposes. In many cases the research that may be undertaken on the retained organs in the future is not yet contemplated and therefore cannot be disclosed to the parents. An issue arises as to whether specific consent is necessary or appropriate in these circumstances at all, given the impossibility of predicting the research that may be undertaken in the future.

7.6 The Nuffield Council on Bioethics said in this regard:

Expressions such as informed consent and fully informed consent are often used in medical ethics. They are somewhat misleading. Consent can be given to some course of action only as described in a specific way. Since the description can never be exhaustive, consent will always be to an action that is incompletely

described; moreover, the descriptions offered are often incompletely understood. This incompleteness cannot be remedied by the devising of more elaborate consent forms and procedures for patients, donors and relatives. Fully informed consent is therefore an unattainable ideal.

The ethically significant requirement is not that consent be complete but that it be genuine. Obtaining genuine consent requires medical practitioners to do their best to communicate accurately as much as patients, volunteers or relatives can understand about procedures and risks and to respect the limits of their understanding, and of their capacity to deal with difficult information. If all reasonable care is exercised, adequate and genuine consent may be established, although it will necessarily fall short of fully informed consent.³⁴

7.7 It may be that a general form of consent may suffice which is unspecified, or a 'blanket' consent to use the organs for a broad category of research without necessarily knowing the details of each project that may use the organs in the future. However, if the language of informed consent is used in this context, it may be argued that such broad consent is insufficient as it is given in the absence of full and complete disclosure of the uses to which the organs might be put.

7.8 Those who argue for specific consent take the view that each time research is proposed in relation to the organ, the donor (in this case the parents of the deceased child) should be contacted for consent. In this way their wishes are fully respected in making choices as to what forms of research are acceptable to them and what forms are not. However, it must be recognised that it is not always possible or practicable to return to parents to seek new consent on each occasion on which it is proposed to carry out research using the donated organ. It may be that authorisation at the time of post mortem, the use of the organs on an anonymous basis, and a requirement for oversight by a Research Ethics Committee, would suffice to allay any fears that parents may have in this regard.

7.9 This Report is concerned to ensure that parents are as informed as they wish to be in relation to the retention and potential use of their child's organs. In relation to retention for diagnosis or educational purposes, the information given to parents can be as specific as the parents themselves require. However, in relation to future possible research uses of the organs, there would appear to be no means by which the information to be made available to parents at the time of the post-mortem examination can be specific.

7.10 The authorisation model proposed in this Report enables parents to control the amount of information they wish to receive, as well as controlling what they wish to be done to or with their child's organs. In this way they may choose the broad option of facilitating research to be carried out using the organs, without necessarily receiving details of the specific research projects. Alternatively they may choose to authorise research on specific conditions only, such as the condition from which their child died. They may authorise research on the basis that they wish to be re-contacted on each occasion on which it is proposed to use the organs for a research project. By

³⁴ *Human Tissue: Ethical and Legal Issues*. Nuffield Council on Bioethics, London (1995) para.6.19–6.21

giving parents these options, their decision in relation to how much information they would like to have and their wishes in respect of their child's organs are respected.

8 Conclusion

8.1 It is paramount that the highest standards of medical education and training be promoted and maintained for the benefit of our healthcare system. On this issue there is consensus. Patients, bereaved families and medical professionals share this common interest. The interests of educators and researchers do not diminish the interests of patients and families. There must be recognition that it is a shared goal, one that those outside the medical profession are encouraged to understand and participate in.

8.2 A model of partnership has supplanted the traditional prevalence of a deferential ethos to the medical profession. This modern culture of rights leads to expectations of consultation and mutual respect. This should not be seen as threatening the ability and flexibility of clinicians and researchers to continue to do their work. The authorisation process should not be seen as a hurdle that makes education and research more difficult. Public confidence in medical education and research must be revitalised and strengthened by openness and transparency in the system. The experiences of the past should be used to encourage higher standards of inclusiveness and shared understanding.

8.3 The conclusions reached in this Chapter apply equally to hospital and coroner post mortems following the discharge of the latter's functions. The coroner has no function or power to authorise the retention of organs at post mortem other than to establish the cause of death. When such cause has been established to his satisfaction, with or without an inquest, the coroner no longer has any powers in relation to the retained organs.

8.4 The parents/guardians of the deceased child must be given the choice to authorise the use of their child's organs for education and research purposes, and have the right to receive information on those choices as they require. Their authorisation of medical education and research to be carried out with their child's organs may provide some positive comfort to the parents in their bereavement.

9 Recommendations

- 1 Legislation must be introduced as a matter of urgency to ensure that no post-mortem examination will be carried out on the body of a deceased child and no organ will be retained from a post-mortem examination for any purpose whatsoever without the authorisation of the child's parent/guardian, or the authorisation of the coroner in an appropriate case.
- 2 The removal of organs from the body of a deceased child at post mortem is carried out as a necessary part of the examination of the body and diagnosis of the cause of death. It must be made clear in legislation that a post-mortem

examination includes the necessary removal of organs for this purpose. The retention of organs at post mortem may be necessary in certain circumstances in order to make an accurate diagnosis of the detailed cause of death.

- 3 It is recommended that public awareness of post-mortem practices be improved, including the necessity for organ removal, weighing and sampling for further tests.
- 4 In a coroners post mortem, the coroner may only authorise the retention of organs for the purpose of establishing the cause of the child's death. Retention following a coroner's post mortem for any other purpose must be authorised by the child's parents.
- 5 In any discussion about organ retention, parents must be given information about potential uses and benefits of retention for purposes of audit, education and research, unless they indicate that they do not wish to receive such information. It is recommended that organs may be removed and retained from the body of a deceased child at a hospital post mortem for purposes of audit, education and research, only where removal and retention for such purpose has been authorised by the child's parent/guardian.
- 6 It is recommended that authorisation of retention for research purposes may be general or specific. Choice must be given to parents as to what form of authorisation they wish to give. A general authorisation will facilitate the use of the retained organs for research purposes that are not currently foreseeable. A specific authorisation may limit the research use of the organs by prohibiting certain types of research being carried out with the organs. The authorisation form must enable full account to be taken of parents' views in this regard.
- 7 Where the purpose of organ retention is research, it is recommended that in addition to the requirement that retention be authorised, the research must be subject to ethical review by an approved Research Ethics Committee.
- 8 It is recommended that anonymised organs currently retained in pathology museums for teaching purposes should be maintained as a valuable educational resource. Any proposed inclusion of an organ in such a museum in the future must be specifically authorised and documented.
- 9 It is recommended that medical and nursing students be permitted and encouraged to attend post-mortem examinations. Legislation should provide for authorisation for such educational viewing to be sought from the parent/guardian of the deceased child or the coroner as appropriate. Guidelines must be drawn up to ensure that such attendance will be carried out in a controlled and respectful manner.
- 10 Information relating to post-mortem examinations and organ retention must be made available to bereaved parents in a comprehensible and sympathetic way. A bereavement liaison officer should be involved in these discussions so as to enable families to access the relevant information, and to reassure them that their decisions will be respected.

Chapter Ten

The Way Forward

1 Introduction

1.1 This Report has discussed the accounts given by parents of deceased children as to their experience of post-mortem practices and organ retention in Ireland from 1970 up to the controversy that arose in 1999 when organ-retention practices were publicised by the media. It has also examined the technical and practical aspects of the performance of post-mortem examinations in Ireland, the accounts given by some Irish hospitals of the post mortem practice prevalent in their hospital during the period under review, and the changes that have been made since 2000. Throughout this Report the following key issues have been clear:

- In the past, there was sometimes inadequate recognition or acknowledgement of the feelings parents have on the recent loss of a child, and the extent to which they feel the need to protect the child even after death.
- The failure to inform parents that organs might be retained as part of the post mortem carried out on their child caused huge distress and anger.
- The lack of information and choice in coroner post mortems is very difficult for some parents to accept.
- The level of information given, the standard of communication and the skill in supporting bereaved parents was often poor.
- The legal vacuum in relation to hospital post mortems is unsatisfactory, as neither families nor doctors know the parameters within which hospital post mortems can take place within the law.

1.2 The communication deficit that existed in the past must be corrected so that families do not feel marginalised in the system and instead are considered to be equal partners in the decision-making process relating to their child. Though hospital practices and policies have addressed many of these issues over the last five years, legislation is recommended to standardise and copper-fasten these changes.

2 Existing Legislative Provisions in Ireland

2.1 There is a dearth of legal provisions dealing with post-mortem examinations in Ireland with only the Coroners Act 1962, the Anatomy Act 1832 and the Registration of Births and Deaths Acts 1863–1996 providing even limited assistance in this regard. This distinguishes the situation in Ireland from that in existence during the same

period of time covered by this Report in the United Kingdom where human tissue legislation has been in existence since 1961.

2.2 The Anatomy Act, 1832 provides a statutory framework for regulating schools of anatomy. At the time of its introduction, the legal supply of bodies was inadequate for the purposes of acquiring medical knowledge. This resulted in illegal trafficking of bodies. The Act provides for the granting of licenses to persons practising anatomy and for the appointment of Inspectors of places where such examinations are carried out. In relation to consent the Act provides that an executor, or other party having custody of the body, could permit an anatomical examination save in circumstances where the deceased, during his/her lifetime, had indicated that his/her body after death might not undergo such examination or where next-of-kin refused to consent to such examination. Even where a person during his/her lifetime had indicated that his/her body might undergo anatomical examination after death, this could not take place without the consent of next-of-kin.

2.3 The provisions of the Coroners Act, 1962 have already been detailed in Chapter Two. In addition to the summary of the Act set out there, it is noteworthy that the Act does not give specific statutory recognition to the role of State Pathologist. The function of state pathologist is covered by sections 33(2) and (3) of the Coroners Act, 1962. Insofar as relevant, Section 33(2) states as follows: ‘A coroner may request the Minister (for Justice) to arrange (a) a post-mortem examination by a person appointed by the Minister of the body of any person in relation to whose death the coroner is holding or proposing to hold an inquest ...’ Section 33 (3) states that ‘it shall be the duty of the coroner to exercise his powers of request to the Minister under subsection (2) in every case in which a member of the Garda Síochána not below the rank of inspector applies to him so to do and states his reasons for so applying.’ The Working Group on the Review of the Coroner Service recommended that coroners should be given the power to order a post mortem from the state pathologist on request from the Gardaí and without prior approval of the Minister, and that the rules and procedures governing these post mortems should be set out in Coroners Rules.³⁵ This Report concurs with that recommendation.

2.4 The first full-time state pathologist was appointed in 1974, with the post of deputy state pathologist established in 1997. The functions of the state pathologist include the following:

- Attendance at scenes of discovery of dead human bodies
- Removal of trace evidence from bodies for forensic examination
- Performance of external examination of bodies and autopsies
- Retention of samples, including organs, for further examination
- Production of reports for submission to the Director of Public Prosecutions and local coroners
- Attendance at criminal prosecutions to give evidence
- Attendance at coroner inquests
- Provision of instruction in forensic medicine
- Provision of advice on forensic pathology.

³⁵ *Review of the Coroner Service*, Report of the Working Group, para. 3.3.5

2.5 The Registration of Births and Deaths Acts 1863–1996 provide that all deaths occurring in Ireland should be registered, in the Registrar’s district in which it occurred, as soon as possible but no later than five days after the death, except where the death has been referred to the coroner. The 5-day period may be extended to 14 days if the Registrar is notified in writing of the death and supplied with a medical certificate of the cause of death. A registered medical practitioner who treated the deceased within 28 days before the death must sign the medical certificate. If a doctor did not see the deceased within 28 days, or if the person died as a result of an accident or in violent or mysterious circumstances, the death must be referred to the coroner, in which case the death will be registered on foot of a certificate issued by the coroner to the registrar.

2.6 Historically all information on the certificates, other than the name of the medical practitioner certifying the death, was recorded in the Register of Deaths. The certificates were then sent to the Central Statistics Office in order to compile statistics on causes of death. The certificates were subsequently forwarded to the General Register Office for storage, and later destroyed after a number of years. The General Register Office has medical certificates from 1989 to 1996 and the Central Statistics Office has certificates from 1997. Certificates from the year 1993 were badly damaged by floodwater in 1998 and had to be disposed of. All certificates are now electronically scanned and indexed.

3 Professional Guidelines

3.1 In 2000 the Faculty of Pathology of the Royal College of Physicians of Ireland issued guidelines to the profession in relation to post-mortem consent and retention of tissue. The guidelines state that consent for a hospital post-mortem examination should be requested by a senior clinician, nursing officer or bereavement officer. Consent for teaching or research should be specifically sought and an information leaflet should be available with details of autopsies, funeral arrangements, disposal of retained organs, and death certification. Pathologists should make themselves available to families who require further clarification on details of the post-mortem examination.

3.2 The retention of blood, organ and tissue samples is clearly and strongly endorsed by the Faculty of Pathology as ‘an integral part’ of the post-mortem examination. According to the guidelines, retention must remain at the discretion of the pathologist performing the examination. Detailed examination of retained samples may prevent their return to the body prior to its release for burial. The Faculty distinguishes this from the situation in England where funeral arrangements generally run over a longer period of time, thereby enabling return of the organs to the body after examination. Families who are prepared to delay the funeral to facilitate the return of retained organs should be accommodated. The wishes of the family in relation to disposal of the retained organs should be adhered to as far as possible. This applies equally to coroner post mortems when the investigation has been closed by conclusion of the

inquest, or death certification. The guidelines also include draft consent forms and information leaflets.

3.3 The Eastern Regional Health Authority produced guidelines for providing a quality response to families in relation to queries from post-mortem practices. These guidelines were endorsed by the National Liaison Group on Organ Retention in 2001 and shaped the development of the National Protocols and Guidelines for Organ Retention and Post Mortem Practices, which were adopted at the end of 2003. An implementation plan was drawn up to include the appointment and training of bereavement officers, standardised consent forms, arrangements for disposal of organs, and requirements for management of records.

4 European Tissue and Cells Directive 2004

4.1 The EU Tissues and Cells Directive 2004/23/EC was adopted by Council of Ministers on 2 March 2004. Member States are obliged to comply by 7 April 2006. The purpose of the Directive is to introduce high common safety and quality standards across the EU concerning the exchange of tissues and cells between States, and to secure protection for patients receiving tissue and cell treatments.

4.2 Basic requirements of the Directive include an inspection and licensing scheme, an adverse incident reporting scheme, and a documented quality assurance scheme. Tissue and cells used for industrially manufactured products and medical devices are covered by the Directive only as far as donation, procurement and testing are concerned. Other Directives cover other aspects. The Directive applies to tissues and cells including umbilical cord and bone-marrow cells, reproductive cells (sperm and eggs), foetal tissues, and stem cells (adult and embryonic). It excludes blood and blood products, human organs, and cells of animal origin. Autologous grafting, i.e. tissues removed and later transplanted to same patient, are not covered.

4.3 The Directive does not cover research using tissue and cells unless applied in clinical trials to the human body. It does not interfere with Member States' decisions as to use of stem cells, or to decisions as to meaning of 'person' or 'individual'. It states that the donation of cells from a living body must be preceded by a medical examination to ensure that the donor's health will not be affected. Donation from deceased persons must respect the dignity of the deceased, particularly by reconstruction of the body.

4.4 The Directive states that donation should be based on voluntariness, altruism, and anonymity. Donors must be given assurances regarding confidentiality of their donation and any related test results, and traceability of their donation. The Data Protection Directive 1995 applies to personal data processed in application of this directive.

4.5 The Directive provides that States must organise inspections and control measures to ensure that tissue establishments comply with the Directive. Personnel involved in tissue establishments must be appropriately qualified and provided with relevant training. Adequate tracing of tissue must be established through identification procedures, record maintenance, and appropriate labelling system. As a general rule,

the identity of recipients should not be disclosed to the donor and vice versa. However, member states may provide for the lifting of anonymity in exceptional cases such as in gamete donation.

5 Human Tissue Legislation (UK)

5.1 Reference has been made in this Report to the human tissue legislation in the United Kingdom. The Human Tissue Act, 1961 came into force on 27 September 1961 in that jurisdiction. The purpose of the Act was to provide for:

- the use of parts of bodies of deceased persons for therapeutic purposes and purposes of medical education and research
- the circumstances in which post-mortem examinations may be carried out
- the permission for the cremation of bodies removed for anatomical examination.

5.2 Section 1(2) of the Act provides that the person lawfully in possession of the body of a deceased person may authorise the removal of any part from the body for use for therapeutic purposes or for purposes of medical education or research if, having made such reasonable enquiry as may be practicable, he has no reason to believe that any surviving relative of the deceased objects to the body being so dealt with. Section 2 deals with a hospital post mortem where there is no intention to retain tissue for therapeutic purposes, medical education or research. In this situation the examination is for the purpose of establishing or confirming the causes of death, or of investigating the existence or nature of abnormal conditions. The Act does not contain any criminal sanction for breach of its provisions.

5.3 Organ Retention Inquiries

The main findings of the *Bristol*³⁶ and *Alder Hey*³⁷ *Inquiries* have already been mentioned earlier in this Report and deal with the fundamental importance of communication and consent in the area of post-mortem retention of organs. Another report called the *Isaacs Report*³⁸ was commissioned following the discovery by the family of the late Cyril Isaacs that his brain had been retained following post-mortem examination, and used for research purposes. This was done without the family's knowledge or consent. The Report showed that storage and use of organs and tissue without proper consent after people had died were commonplace. Though the Report deals with coroner post-mortem examinations and organ retention in the context of deceased adults, the latter of which is outside the remit of this Inquiry, it is nonetheless worth summarising the main conclusions and recommendations of this report:

- The public was unaware of what happened at a post mortem and of the possibility of organ retention.

³⁶ *The Bristol Royal Infirmary Inquiry Report* 2000

³⁷ *The Royal Liverpool Children's Inquiry Report* 2001 (the Alder Hey or Redfern Report)

³⁸ *Investigation into events that followed the death of Cyril Mark Isaacs*, HM Inspector of Anatomy 2003

- Those who knew about organ retention did not discuss it with relatives and did not consider this to be unethical.
- Despite the radical shift in demand for information, many people still do not wish to be told the details of post-mortem examinations. Their right ‘not to know’ should be respected.
- The fact that a post mortem has been carried out for the coroner does not mean that the relatives consent to carry out research can be assumed once the coroner’s need to retain organs has ended.
- The discovery that organs were retained without their knowledge has been the cause of great distress to some families. This has been exacerbated by uncertainty as to disposal of organs in cases where records have not been kept.
- The importance of research on retained organs cannot be underestimated and steps must be taken to encourage organ donation for research, but this must always be with the safeguard of informed consent by the relatives in every case.
- There is no system of quality assurance or audit of coroner post mortems, and there is confusion as to responsibilities.
- Though non-disclosure of organ retention may have been well intentioned, it is no longer acceptable or compatible with the culture of openness which must now prevail.
- It is essential that steps be taken to re-establish public confidence that research will only be undertaken with consent. Complete openness is required. Nevertheless, there will be some relatives who do not wish to be informed of the details. For those, unwelcome information must not be forced upon them.
- The recommendations contained in the Isaacs report are intended to introduce legal, administrative, ethical and other requirements designed to ensure that organs retained from coroner post mortems will not be retained for, or used in, teaching or research without the knowledge and consent of the relatives. It is also intended that the recommendations will help to restore public confidence in the post-mortem procedures and practices and thus enable organs to be used in beneficial research with full consent from relatives.

5.4 Human Tissue Act, 2004 (UK)

A new Human Tissue Act, which repeals the 1961 Act, will come into force in England, Wales and Northern Ireland in 2006. The Act has been lauded and criticised in equal measure in those jurisdictions. It aims to provide a framework for regulating the storage and use of human organs and tissue from the living, and the removal, storage and use of tissue and organs from the deceased, for specified health-related purposes and public display. The main features of the new legislation include the following:

- The Act makes consent the fundamental principle underpinning the lawful retention and use of body parts, organs and tissue. It does not cover *removal* of material from the living, which continues to be dealt with by the common law.
- It regulates removal, storage and use of human tissue, defined as material that has come from a human body and consists of, or includes, human cells.
- It lists the purposes for which consent is required – referred to as scheduled purposes. Consent required is called ‘appropriate consent’. Penalties are imposed as a deterrent to failing to obtain consent.
- It establishes a Human Tissue Authority to ensure compliance. The Authority will issue good practice guidelines in statutory codes of practice and will also licence and inspect post-mortem activities.

Under the Act consent is required for ‘Scheduled purposes’. These are as follows:

Part 1 – purposes generally requiring consent where the tissue is from the living/dead:

- 1 Anatomical examination. This requires witnessed consent in writing before death
- 2 Determining the cause of death, except where ordered by coroner
- 3 Establishing after a person’s death the efficacy of any drug or other treatment, i.e. a hospital post mortem
- 4 Obtaining medical information about a person that might be relevant to someone else, such as genetic information
- 5 Public display; requires witnessed consent in writing before death
- 6 Research in connection with disorders or the functioning of the body
- 7 Transplantation.

Part 2 – purposes requiring consent where the tissue is from deceased persons:

- 8 Clinical audit
- 9 Education or training relating to human health
- 10 Performance assessment
- 11 Public health monitoring
- 12 Quality assurance.

There is an exception to the requirement for consent, which makes it lawful to use for scheduled purposes without consent human tissue already held in storage for a scheduled purpose on April 2006. Storage and use of existing holdings will be subject to good practice guidelines to be issued by the Human Tissue Authority.

6 Human Tissue (Scotland) Bill 2005

6.1 At the date of writing, the Human Tissue (Scotland) Bill was progressing through the Scottish Parliament.³⁹ The Bill contains three main strands: transplantation, modernisation of the Anatomy Act, and hospital post mortems. It also deals with retention of material from post mortems carried out under the authorisation of the

³⁹ Human Tissue (Scotland) Bill (SP Bill 42) introduced in the Scottish Parliament on 3 June 2005

Procurator Fiscal, whose office is similar in some respects to that of the coroner in this jurisdiction. The Bill was introduced following the publication of the report of the Independent Review Group on Retention of Organs at Post Mortem in 2001.

6.2 The basic principles underpinning the Bill are the need to respect people's wishes regarding post-mortem examination and retention of organs, and to provide clarity about the roles and responsibilities of those involved in post-mortem practice. A post-mortem examination is defined in section 19 of the Bill as follows:

In this Act, 'post-mortem examination' means examination of the body of a deceased person involving its dissection and the removal of organs, tissue sample, blood (or any material derived from blood) or other body fluid which is carried out for any or all of the following purposes –

- (a) Providing information about or confirming the cause of death
- (b) Investigating the effect and efficacy of any medical or surgical intervention carried out on the person
- (c) Obtaining information which may be relevant to the health of any other person (including a future person)
- (d) Audit, education, training or research.

Save as discussed below, the provisions of the Bill in relation to post-mortem examinations do not apply to those carried out with the authorisation of the Procurator Fiscal.

6.3 The Scottish Review Group recommended the introduction of the concept of authorisation to replace that of consent to post-mortem examination.⁴⁰ The Bill accepts that recommendation by providing that the post-mortem examination and use of retained material must be authorised. Standardised authorisation forms and information leaflets are to be used across Scotland to ensure uniformity of approach in all hospitals.

6.4 The Report of the Review Group, and the Bill, draw a clear distinction between the retention of blocks and slides necessarily created at a post-mortem examination and which should be considered part of the deceased's medical record, and organs which should only be retained in exceptional circumstances and with specific authorisation. This distinction is based on the greater emotional significance generally attached to whole organs by families, as well as the potential clinical benefit to be obtained for the family from the retention of blocks and slides. In relation to samples retained following an examination authorised by the Procurator Fiscal, the Bill provides that they should become part of the medical record of the deceased and may be used for diagnostic and audit purposes without authorisation from relatives. Authorisation is however required for use of the samples for any other purpose.

6.5 Provision is made in the Bill for retention of tissue samples in existing holdings. If retained following post mortem authorised by the Procurator Fiscal before the coming into force of the Bill, the samples may be retained for education, training, and

⁴⁰ See Chapter 8, section 11 for further discussion of authorisation.

research purposes without further authorisation. For organs retained in similar circumstances, the Bill provides that they may be retained with appropriate authorisation, and the approval of a Research Ethics Committee if for a research purpose.

6.6 Penalties are imposed for non-compliance with the Bill. It will be an offence to perform a hospital post mortem or retain organs/tissue without authorisation or a reasonable belief that authorisation had been given.

7 The Way Forward for Ireland

7.1 This Report has presented the experiences of parents who have been affected by post-mortem practices and organ retention. Their grief and anger at the failure to inform them of the retention of their child's organs is palpable. Their shock and hurt at the way in which their child's organs were stored and disposed of was exacerbated by the difficulties many of them encountered in trying to establish whether and what organs had been retained and for how long. Many parents feel they have been let down by medical professionals, hospitals and the healthcare system in the lack of respect shown to them and their child.

7.2 Medical professionals have also been affected by this controversy. Many pathologists have been distressed at the way in which this issue has been portrayed, and some feel aggrieved that their adherence to the standards of their profession has led to criticism. Some clinicians have become reluctant to discuss post-mortem examinations with bereaved parents, leading to a serious decline in the hospital post-mortem rate.

7.3 Despite the problems of the past, parents and professionals should not be seen as taking opposing sides for the future. There is common ground on the need for legislative reform of both hospital and coroner post-mortem practice. There is consensus that respect for the wishes of the bereaved must be of paramount importance in this reform and that any legislation that may be introduced should be clear, consistent and transparent. The public must be encouraged to have confidence in the post-mortem system and must be satisfied that there are sufficient safeguards in the legislation to ensure respect for the wishes of bereaved parents. This will help to increase hospital post-mortem rates, which in turn will support medical education and research. As has been stressed throughout this Report, communication and authorisation are the key factors in the re-establishment of trust in the system.

7.4 Legislation dealing with hospital post mortems is required as a matter of urgency. The lack of clarity regarding the rights of parents/guardians of deceased children in this regard must be addressed in order to assure those affected by the organ-retention controversy and the general public, that communication, transparency and authorisation will be the hallmarks of the post-mortem system for the future.

7.5 There is inevitable overlap in this area between coroner post mortems and hospital post mortems. The clinical performance of the examination is largely the same. Some of the parents who made submissions to the Inquiry were distressed that their child had been the subject of a coroner's post mortem in which they had no control or no

choice. As discussed in Chapter Three of this Report, it is essential that the coroner's jurisdiction to authorise a post-mortem examination in appropriate circumstances should be continued. It is vital that the independence of the office of coroner to investigate the cause of death be clearly understood as part of the administration of justice. It is not recommended that the system of authorisation proposed for hospital post mortems in this Report be extended to coroner post mortems, as this would be in conflict with the exercise of the coroner's functions. However, clear communication with the parents of the deceased child is necessary to ensure that they are informed as to, firstly, the reasons for the post mortem and, secondly, their options in relation to use or disposal of any material that might be retained as part of that examination.

7.6 The Review of the Coroner Service recognised that 'one of the weaknesses in the existing service lies in the lack of administrative support required to deliver optimal services to relatives'. The Review acknowledged the critical importance of continuing support and provision of information to relatives during the coroner's investigation, but pointed out that the lack of administrative support often puts impossible strain on the coroner's resources in this regard. It recommended that a new post of coroner's officer should be introduced at a regional level to support the services provided by the coroner.⁴¹ The duties of this officer would include, insofar as relevant to this Report, liaison with pathology services and families, ensuring that families are kept as informed as possible about the current progress of the investigation and ensuring that appropriate support is provided for relatives through voluntary and statutory agencies. This Report strongly endorses this recommendation.

7.7 Once the functions of the coroner are complete and a cause of death certified, the coroner should notify the relevant pathologist that any further retention of organs from the post mortem are not authorised by the coroner. Arrangements should be put in place to ensure a clear line of communication between coroner and pathologist in this regard. Any further retention of the organs for clinical audit, education or research purposes must be authorised by the child's parents/guardians.

8 Recommendations

1. Consideration should be given to the implementation of the recommendations made in this Report to other post mortems, namely those carried out on babies who have died before or during birth, minors and adults. Although this Report does not specifically address post mortems in those groups, many of the recommendations may apply generically to all post-mortem practice. However, it should be acknowledged that these post mortems also raise distinct legal and ethical issues that were not within the Terms of Reference of this Report. If the recommendations in this Report are adopted, a Working Group should be established to ensure that appropriate adaptation in relation to those issues takes place. It must include membership from relevant stakeholders and family representative organisations.

⁴¹ *Review of the Coroner Service*, Report of the Working Group (2000) para. 3.4.2

2. Legislation must be introduced as a matter of urgency to ensure that no post-mortem examination will be carried out on the body of a deceased child and no organ will be retained from a post-mortem examination for any purpose whatsoever without the authorisation of the child's parent/guardian, or the authorisation of the coroner in an appropriate case.
3. An appropriate legislative framework must be put in place to govern hospital post mortems. A regulatory model that facilitates guidelines to be updated when necessary to keep pace with medical and scientific developments is recommended. Legislation must clearly set out the purposes for which a post-mortem examination may be performed. In order to restore and maintain public confidence in the system, the legislation must set out clear safeguards for patients and their families, and encourage medical education and research. Penalties must be imposed for non-compliance with these safeguards.
4. Although not specifically addressed within the terms of reference of this Report, it is clear that human tissue legislation is urgently required to deal with issues relating to removal, storage and uses of human biological material from the living and the deceased. Provision should be made in such legislation to facilitate and encourage medical education and training, and approved medical research, while maintaining the principle of respect for the donor, the deceased person and the bereaved.
5. The recommendations of the Report of the Working Group on the Coroners Service must be implemented without further delay. A new Coroners Act must be enacted to clarify the legal duties and rights of coroners, and the procedures to be followed from the reporting of a death through to the holding of inquests. Clear structures must be established to deal with information to be provided to families, the appointment of a coroner's officer to liaise with parents following a post mortem, and the provision of support to families through the inquest process.