Consent for Post Mortem Examination in Royal Hospitals during 2000

Following the publication of the Kennedy (Bristol) and Redfern (Alderhey) Inquiry Reports the issue of consent for post mortem examination and retention and further use of human tissue was of significant public concern. From January 2001 within Northern Ireland there was intense scrutiny of pathology practices in relation to consent, retention, storage, disposal and archiving of human tissue, primarily from post mortems but also from surgical biopsies. This culminated in a review by the Chief Medical Officer in January 2001 of the archive of organs retained by hospitals across the region. Later in 2001 the Human Organs Inquiry, chaired by John O'Hara QC commenced a rigorous review of past and current practices, which published its report and recommendation in June 2002 (summarised in Appendix 1).

The Human Tissue Act 1962

At that time approximately 9% of the 15,000 annual deaths in Northern Ireland resulted in a post mortem examination. For sudden or unexplained deaths this was carried out under the authority of HM Coroner, where relatives' consent was not required. Until 2005 when the new Human Tissue Act 2004 was implemented hospital (consented) post mortem examinations were conducted under the terms and conditions of the Human Tissue Act 1962, where the purposes were identified as:

> "establishing or confirming the cause of death or of investigating the existence or nature of abnormal conditions" and further that
>
> any part may be removed from the body "for therapeutic purposes or for medical education or research".

The issue of relatives' consent under the 1962 Act was more equivocal and in 2000 was not well understood by the service, as identified in the O'Hara Report. The main difficulty arose from Appendix 9 of the Act which allowed hospitals to undertake a post mortem examination "having made such reasonable enquiry as may be practical" that there was no reason to believe that the deceased had expressed an objection to his body being so dealt with after death and not withdrawn that objection or "the surviving spouse or any surviving relative of the deceased objects to the body so being so dealt with".

The Act did not contain any criminal sanction for breach of its provisions.

The Royal Hospitals and the Human Tissue Act 1962

At the Inquiry into Human Tissue (O'Hara 2002) it was accepted by the Royal Hospitals that breaches of the 1962 Act occurred in some cases in respect of insufficient enquiry into likely objections of relatives to the removal, retention or disposal of organs and tissue from post mortem examinations. The 1962 Act was not phrased in terms of "consent" but in terms of "no reason to believe" that there was an objection. It was however the view of the Inquiry that there was no real distinction between these two concepts.

The crux of the difficulty appeared to have been that unlike almost every other instance of consent to examination or treatment in clinical practice at that time, those taking consent (medical ward based clinicians) were not those either undertaking or capable of undertaking the procedure for which they were acquiring consent (or in this case, not objecting to a procedure). All post mortem examinations were conducted by pathologists based within the Belfast Link Laboratories with limited regular contact between clinicians and pathologists.

It was standard practice until 2001 when it became a matter of public concern, as elsewhere in the UK, to outline in general terms what was involved in a post mortem. There was variation in practice between individual clinicians in what information was given to families about post mortem procedures and the Trust in response to the O'Hara Inquiry 2002 accepted that the information provided up to that time was in general inadequate. Information booklets were available from 1993 and refined at different stages from that point onwards. Unfortunately, however, the use of the booklets was variable with no record kept of when such information was provided.

New consent forms were introduced in 2005, revised in 2012 under the requirements of the Human Tissue Authority.

The Human Tissue Bill 2004

The highly criticised 1962 Act was replaced in 2004 with the Human Tissue Act and the creation of the Human Tissue Authority (HTA) in 2005 as the competent authority. The HTA set out a higher standard for informed consent, place stringent controls on the removal, storage and use of tissue with criminal sanctions for breaches of the Act. Standards will be regulated through the Human Tissue Inspection Authority with establishments requiring to be licensed to undertake activities under the Schedules of the Act. Northern Ireland is enjoined with the English legislation.

The Royal Hospitals obtained an HTA Licence for the storage and retention of human tissue and for undertaking post mortem examinations in 2005 and has subsequently been

inspected by the HTA, meeting all requirements under the schedules for: consent; governance; facilities, premises and equipment; and disposal.

Northern Ireland

In Northern Ireland, the Department of Health Social Services and Public Safety (DHSSPS) undertook an extensive consultation on standards for post mortem examinations "Good Practice in Consent and the Care of the Bereaved" with the development of new consent forms, advice to relatives, standards for bereavement care and the holding of human tissue archives, which were implemented in 2005. These were revised in 2012 and issued to the service by the DHSSPS for implementation by 1 November 2012. All consent processes meet the standards under the HTA requirements for scheduled purposes.

APPENDIX 1

Summary of recommendations from Human Organs Inquiry 2002 Impacting on the Royal Hospitals

3. Guidelines should be issued by the Department and adopted by each Trust defining the circumstances in which any person can have legitimate access to or make use of these blocks and slides. This can be done in conjunction with Research Ethics Committees. The Department itself should also be required to report annually and publicly on the way in which its guidelines have been observed by each hospital which has a bank of blocks and slides. If the guidelines are not being followed no use of any blocks or slides should be permitted by the doctors or Trust involved until all deficiencies are corrected (see paragraph 6.12.)

4. No research should be permitted using human materials removed at post mortems in the future unless the consent of the next of kin has been explicitly obtained (see paragraph 9.10).

7. Every hospital Trust should have a statutory duty to report annually to the Department whether post mortem practice in that Trust was in accordance with the principles outlined in this Report and the new legislation recommended in Chapter 4 (see paragraph 10.3).

8. The Department should keep under active review whether external audit of human material retained by Trusts is necessary in the interests of rebuilding public confidence (see paragraph 10.3).

11. Where first trimester pregnancies result in identifiable fetal remains, these should be disposed of with respect in line with current practice at the Royal, not disposed of as surgical biopsy material (see paragraph 10.5).

15. We accept the importance of the existing archive of blocks and slides both for immediate families and the public at large. We recommend that these archive collections are maintained unless the individual families concerned specifically request their return (see paragraph 10.8).

16. The Department should engage in a two-year multimedia publicity campaign informing relatives that they may reclaim blocks and slides (see paragraph 10.8).

17. In respect or organs which have been retained without consent under the Human Tissue Act and not under the provision of the Anatomy Act 1832 or the Anatomy (NI) Order 1992, we recommend a two-year publicity campaign inviting reclamation via a Departmental enquiry line (see paragraph 10.8).