

Ethics and the laboratory professional: Pragmatic observations in the post-Madden era

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Ethical and Legislative Guidance

- Widely available
 - Medical Council
 - Royal College Pathologists
 - Defence Unions
 - ISO 15189 Appendix
 - Human Tissue Act 2004 (UK)
 - Data Protection Act

Presumptions (1)

- Post mortems are an essential part of a “healthy” health service
 - Epidemiology
 - Education of staff
 - Research and development
 - Audit

“ Autopsy establishes truth, detects change, provides data, instructs learners and promotes justice”

Hill and Anderson 1988

Presumptions (2)

- Pathologists don't like doing post mortems

Conclusions

- Hospitals with the highest autopsy rates would receive the gratitude of the public, respect of the media and the unqualified support of the DOHC

Organ scandal leads to autopsy backlash

THE controversy over the removal of organs at Our Lady's Hospital in Crumlin has led to a backlash by parents.



CRUMLIN: Row

The number of autopsies being carried out on children has plummeted because parents are refusing consent.

However a doctor warns they're denying themselves information about why their children died that could be comforting.

And Dr Michael McDermott, a consultant histopathologist at the hospital, said that providing full information to parents about

what happens during a post mortem is "brutal".

In a letter to the Department of Health, he said that in effect the only autopsies being carried out at the moment are those ordered by a Coroner.

These are carried out with the knowledge of parents but not necessarily with their permission.

"The media have portrayed the former situation of organ retention in the absence of informed discussion as evil and unconscionable.

"Our own practical experi-

ence of this matter is that the new system of fully informed consent has its own inadequacies.

"It ultimately fails to deliver information to families about the death of their child, which may be of great value and comfort to them because they refuse permission for an autopsy.

"Furthermore it is unnecessarily brutal to families faced with a Coroner's post mortem who are not in a position to refuse either the post mortem or the retention of organs," he said.

HOSPITAL 'STOLE' SOUL OF OUR BABY

Cot death child's brain was thrown away

BY RACHEL ELLIS

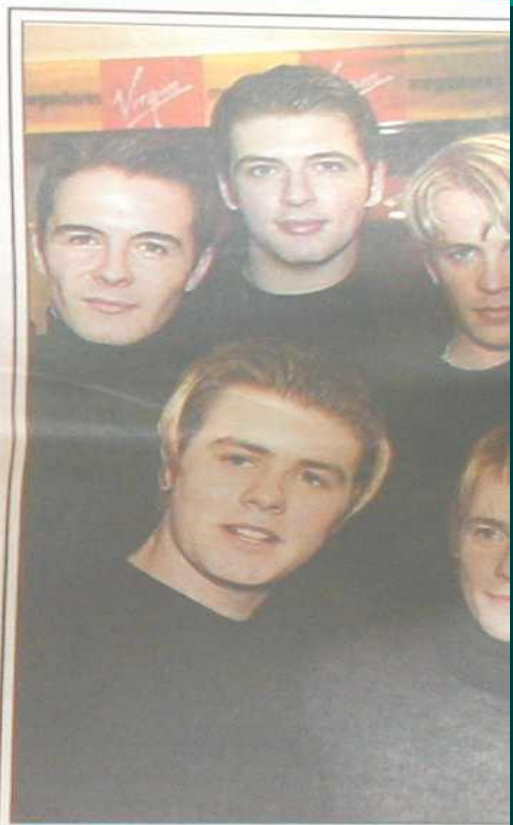
HEALTH CORRESPONDENT

A HOSPITAL removed a dead baby's brain without his parents' consent and then threw it away as "medical waste", it emerged.

son Marc intact after he was a cot death victim when he was three weeks old. Yesterday the couple spoke of their horror after discovering that doctors had not only taken their baby's brain without telling them but

bury it with him. They have mutilated a baby far beyond the needs of a post mortem examination. The hospital has abused its position and our trust and faith in them.

Barbie, 33, added: "We are



**WHY WESTLIFE ARE
NOBODY'S FOOLS**

Consent and Information: The Past

- Coroner
 - No *consent* necessary
 - No contact made by coroner
- House cases
 - Consent is necessary
 - Informed or genuine or neither?

Limitations

- Knowledge of clinician
- Knowledge of the next-of-kin
- Distress at time of death
- Paternalism/Arrogance?
 - Avoid further distress relatives
 - Focus on issues of perceived importance

“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. The incompleteness cannot be remedied by the devising of more elaborate consent forms and procedures. Fully informed consent is therefore an unattainable ideal”

“The ethically significant requirement is not that consent be complete, but that it be genuine. If reasonable care is exercised, adequate and genuine consent may be established, although it will necessarily fall short of fully informed consent.”

Nuffield Council on Bioethics 1995

Genuine consent?

- Nature and purpose of a post mortem examination should be explained to relatives in both coroner and non-coroner post mortems
- Opportunity to impose limitations provided

Madden Report

- Completely accepted both the scientific merit underlying and the motives behind the actions of pathologists

Perceptions/Perspectives

- Doctors and families viewed organs and tissues from very different perspectives leading to very different perceptions of organ retention
- Emotional and spiritual vs detached and professional

Allegations include...

- “Don’t care about children...only cared about organs”.
- Disrespectful to organs.
- Disrespectful to children-limited autopsy

Consent and Information: The Present

- Discussion with bereavement officers prior to procedure
- Provision of information
- Facilitate choice of individual families
- Substantial bureaucracy required to administer it

Present

- Shortage of autopsies
 - Physician
 - Next-of-kin
 - Coroner
- Shortage of people to do them
 - Threat to pathology services
 - Spill-over into surgical pathology tissues and other areas of laboratory practice

Wider implications?

- Surprise at response to routine practice
- Other areas of routine medical practice offer similar potential for misunderstanding

- teaching, conferences, data collection and reporting, audit, quality control, medical record based research.

...between a rock and a hard place?

- Continue practice with new consent procedures
- Abandon procedures
- Choice between continuing or abandoning past practice should not be made in haste or in fear

Consent required?

- Do we need specific consent for these routine procedures?
- Controversial and counterintuitive

■ Problems abound

- Time consuming
- Tick-box nightmare
- Logistics of acquiring and then policing the consent offered
- Diminished quality of epidemiological info

Quality of Consent: MDU

- Bolam: Reasonable medical practitioner, supported by relevant professional opinion
- Sidaway: “if there is significant risk which would affect the judgement of a reasonable patient, the doctor needs to inform, irrespective of medical opinion”

MDU

- Experienced doctor, preferably the one doing the procedure
- Appropriate time
- Separate anaesthetic discussion
- Serious harm defence-does not include become upset or refuse treatment

Quality of Consent: Medical Council

- Implied consent recognised
- Verbal or written encouraged
- IC required for teaching images
- IWC for research

Quality of Consent: CCHC

- Parents empowered
- Parents wishes respected regarding level of information
- Verbal, written or implied
- Sufficiently experienced HCP
- Written consent guidelines widely available

Quality of Consent: External Review Suggestions

- Principal performer should take consent
- Document the individual risks that have been explained

Quality of Consent: HTA

- Consent hierarchy
- Info to be given
- Who should ask
- No consent required for QA/Audit/education on residual live samples
- Form does not prove validity-only evidence of consent
- Retrospective amnesty

HTA-PM Procedures

- Consent required for blocks and slides and audit/education, establishing cause of death, even in coroner cases
- Scottish Proposals differ

Irish Council Bioethics

- Fragmented consent form with multiple options
- No amnesty for archival material for research
- Anonymous vs anonymised?
- Audit requires information and not consent but opt-out clause encouraged

Information overload

- Counterproductive-Oncology experience
- Freedom of Information Act

- Explicit consent for surg path analysis?
- Explicit consent for genetic analysis?
- Explicit consent for HIV analysis?
- Explicit consent for residual tissue research?
- Explicit consent for residual samples for QA?

Dangerous future

- Protocols designed by hospital solicitor
- Human tissue Act 2004 -Human Tissue Authority.
- Irish Council for Bioethics
- Irish Legislation to flow from Dunne/Madden?
- Enterprise Liability

Lessons learned

- Cannot count on
 - The public to support you just because your practices are in line with standard care
 - Your colleagues to support you if it means exposing themselves to similar allegations
 - Your hospital or the DOHC to support you if they are faced with a choice between you and the public

Lessons learned

- Cannot count on
 - The public, your colleagues, your hospital or the DOHC to support you if your practices are not in line with standard care

Science and Perception

- Scientific and quality arguments appropriate for one forum
- Public forum very different with public perception based at least partly on an emotional level and people increasingly suspicious of medical professionals in general

Pragmatic Guidance

- Is the procedure necessary for safe care and good laboratory practice?
- Is the procedure an intrinsic or implied part of the diagnostic procedure?
 - If not, it is potentially open to misinterpretation.

Patient consent needed

- Consent needed for
 - patient intervention
 - research where not anonymised, even if residual sample
 - banking
 - ?others

Definition of Informed Consent

- Take in information
- Understand and remember it
- Make a decision
- Communicate decision
- Lab professionals reliant on others to obtain valid consent

Facilitating IC

- Time
- Empathy
- Repetition
- Simplicity
- Pictorial

Laboratory responsibility

- Can't abandon a professional obligation
- Can't allow it to be dependent on the explicit agreement of public
- Can't afford to leave your actions open to criticism

Consent or information?

- Consent to “treatment”
- Information about the procedures necessary to support that treatment
- No opt-out available from above

Keeping out of trouble

- Be logical
- Be consistent
- Have paperwork

Paperwork

- Consent forms
- Information Leaflets/Posters
 - Samples *will* be examined, stored, disposed of, utilised in QA, shared with other labs etc
 - Data *will* be stored, processed, audited, shared etc



Giving Your Consent

“For the purpose of this leaflet, we use the word procedure to include investigation, treatment or operation”.

It is the policy of this hospital to empower parents and children to make informed decisions regarding their child's treatment. This decision is based on suf-

ficient information being provided in a way that is easily understood so that you can give consent when it is required.

When your child is going to have a procedure we will ask you to give your permission before it is done. To help you understand your treatment you will be given information about your child's, or your care and any procedures that your child or you undergo. The doctor will have explained the procedure to you during your hospital visit but you may have some questions that need answering before you give your final decision.

We have designed this leaflet to help and guide you in your discussion before you give your permission for a procedure. Below are some helpful questions to guide you.

- What is wrong with my child, what tests will my child need and what does it mean for the future?
- What does the treatment involve?
- How will this help my child?
- What happens during the procedure?
- What will happen if my child does not have this procedure?
- Are there any other options for my child?
- What are the benefits?
- What can go wrong?
- Will my child need an anaesthetic? If so, will it be a local or general anaesthetic?



Changes to PM consent and information

- Results in a clarity and lack of ambiguity for both parents and pathologist that is beneficial to both

(British Medical Journal 2003; 327:804-806)

(Archives Disease in Childhood, 2004; 89:F198-9)

Pre-autopsy “Next of Kin Clinics”

Is consent the most appropriate word to describe the interaction?

Consent and Information: The Future?

- Family may *request* that a pathologist undertake a post mortem
- Pathologist may *consent* to perform the procedure for the family

Request Forms

- All future medical investigations and treatments regarded as services proposed by HCP and *requested* by patients/families
- Legal consequences....?