

The Rotunda Hospital Look Back Exercise

relating to:

- **Post Mortem Practice**
- **Organ Retention**

Look Back Exercise – The Rotunda Hospital

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I would like to acknowledge the very evident willingness of all staff to participate in the Review Exercise.

I would also like to acknowledge and thank the (previous) Master Dr. Michael Geary, who generally ensured documentation requests, access to facilities and necessary staff interviews were provided and arranged in a timely manner.

Ian Carter
Chairman of Review Group

EXECUTIVE SUMMARY

1. Introduction

This is an Executive Summary of the Findings and Recommendations of the Review Group tasked in May 2008 to consider and examine Organ Retention, Post Mortem Management / Practices and associated Control provision with the Rotunda Hospital.

1.1 Context

In December 2007, as part of the National Independent Audit of Retained Organs, Willis M attended the Rotunda Hospital. Initial findings identified 5 areas of concern:

- substantial retention of organs
- the retention of unblocked organs for long periods – potentially unknown to families
- undertaking superficial examinations including including skin swabs, Xrays and photographs on a mandatory basis
- absence of a single comprehensive and accurate data base in relation to organ retention, disposal, reburial, thereby not facilitating validation, either internally or for the purposes of the national audit
- incomplete post mortem reports

1.2 Terms of Reference

Having regard to the issues raised by Willis as part of the National Independent Audit of Retained Organs, the Terms of Reference addressed the following:

- policy and practices in relation to seeking consent from families in relation to non coroner (hospital) post mortems since 2000. In this context, it will be necessary to assess the scope of consent and individual consultant's compliance with the consent process.
- policy and practice in relation to the retention, storage, management and disposal of all organs and tissues associated with hospital and coroner post mortems since 2000
- A review of written and verbal communication processes with families in relation to coroner and non coroner post mortems. In this context, it will be necessary to review the hospital's information leaflets on post mortem and organ retention practice
- A review of policy and practice in relation to the documenting of organs retained, disposed and returned to families
- A review of practice in relation to clinical examination of remains brought to the mortuary.

1.3 Review Group Membership

- Ian Carter, CEO, St. James's Hospital **Chairman of Review Group**
- Carol Hickey, Quality Manager, St. James's Hospital
- Michael Green, Emeritus Professor of Forensic Pathology, University of Sheffield

1.4 Review Structure and Methodology

1.4.1 Work Objectives

- Identify all organs retained and rationale for retention
- Review and consider post mortem practices for period 2000-2007
- Review and consider consent policy / practice / management for period 2000-2007
- Review control provision in relation to post mortem practice and process
- Identify key findings in relation to post mortem practice / consent application / organ retention and associated control provisions
- Identify key recommendations in relation to post mortem practice / consent application / organ retention and associated control provision

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1.4.1.1 Organs retained

Organs retained were examined by the Consultant Pathologist from the Review Group, identifying and recording organs / part organs / tissue retained

1.4.1.2 Records

Whilst summary data sheets identifying organ retention and rationale were supplied by the hospital, given previous (apparent) problems with accuracy and completeness, the Review Team predominantly focused on individual records held by the hospital.

1.4.2 Post Mortems

- in total the records pertaining to 933 post mortems were considered

1.4.3 Superficial Examinations

- in total the records pertaining to 748 superficial examinations were considered.

1.4.4 Consent Practice / Management

- in addition to examination of consent policies (2000-2007), the Review Group also interviewed members of the interdisciplinary team to ascertain actual application of policy.

1.4.5 Control Provision

- the Review Group confirmed related control provision in terms of governance, executive accountability / structure and audit through the provision of documentation by the hospital and further interviews with hospital staff.

1.4.6 Immediate Requirement for Organ Release

- on commencement of the Review, the Hospital identified 24 cases of organ retention, where families were apparently anxious to secure organ release / reburial and requested that the Review Group provide immediate advice. Examination of these cases, identified in fact only 1 instance where families were waiting for organ release. This inaccuracy was further evidence of previously stated inaccuracy and general incompleteness of inventory records held by the hospital

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2. Key Findings of Review

Key Findings of the Review Group in relation to:

- organ retention
- post mortem practice / management
- consent policy, practice, management
- control provision

2.1 Organ retention

In total there are 460 autopsies where organs have been retained: [at time of Review Exercise]

- **59% (n=271) relating to period 1983 - 1999**
 - 15% (n=41) retained for purposes of Research + Education period 1983 - 1999
 - 85% (n=230) retained temporarily by Hospital period 1983 - 1999
 - It should be noted
 - applicable consent policy identified by Hospital for this period [**3.1.1 Main Report**] secured consent for autopsy only and not organ retention for research and education purposes
 - therefore there are 271 cases of organ retention with no consent for retention
 - there are 230 cases of organ retention where this temporary retention is for periods > 8 years, this practice is contrary to described practice by hospital
 - it is likely that families are unaware that these organs have been retained
- **41% (n=189) relating to period 2000 - 2007**
 - 21% (n=40) retained for purposes of Research + Education (98% Consultant A)
 - 62% (n=118) retained temporarily by Hospital
 - 16% (n=31) retained temporarily by Hospital awaiting family confirmation as to disposal
 - It should be noted:
 - 2000 January – April 2000 consent secured agreement to autopsy only – 24 instances where organs retained
 - 92 instances where organs retained temporarily (not awaiting parent confirmation as to disposal / reburial) > 1 year (not compliant with consent policy [**3.3.1 Main Report**])
 - it is likely that families are unaware that these organs have been retained.

The Hospital has also identified 7 cases in which families have formally identified concerns / dissatisfaction in relation to post mortem practice:

- post mortem not completed 13 months after delivery
- post mortem report issued very late
- organs not available for release 2 years after delivery – as a result of blocking having not been undertaken
- temporary organ retention for 2 years

Of the autopsies where organs have been temporarily retained

1991 – 1999

- 56% (n=123) post mortems undertaken by Consultant A
- 35% (n=84) post mortems undertaken by Consultant B
- 9% (n=21) post mortems undertaken by Consultant (Other)
 - in 2 additional instances no documentation supplied to Review team

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2000 – 2007

- 89% (n=133) post mortems undertaken by Consultant A
- 8% (n=12) post mortems undertaken by Consultant B
- 3% (n=4) post mortems undertaken by Consultant (Other)

2.1.1. Temporary Retention – Volume of Organs Retained

- **post mortems which resulted in temporary (not consented) organ retention**
(period 2000-2007)
 - Consultant A – 89% (n=133) – total post mortems undertaken – 429 – 31% resulted in organ retention
 - Consultant B – 8% (n=12) – total post mortems undertaken – 223 – 5% resulted in organ retention
- **Volume of Organs retained (period 2000 – 2007)**
 - Consultant A – average number of organs retained 21
 - Consultant B – average number of organs retained 2
 - The Review Group would suggest that contemporary practice now tries to ensure a limited number of tiny cassette size blocks being retained, with sampled organs generally being returned to the body within 3-7 days, rarely retaining anything for long periods – obviously with the exception of the brain (and then for periods < 4 weeks)

2.1.2 Key causal factors identified by Hospital for organ retention volume / retention time period – particularly those ‘temporarily’ retained./ delays in post mortem report production

The Hospital has identified significant organ retention volume / prolonged retention time has arisen from 4 causal factors

- **significant delay in block / slide preparation (necessary) before organ disposal**
This is attributed to:
 - reduced Consultant provision – relating to post mortem practice
 - during 2000 Consultant B spent significant time assisting Temple Street Children’s Hospital in connection with organ retention enquiries and had to reduce input to Rotunda Hospital and again in 2003
 - subsequently deployed locum input had limited input to post mortem practice as a result of inexperience / at times full locum provision was not securable – post (3) not filled until 2008
 - during 2004 – centenary year for the foundation of the laboratory, a meeting was arranged with international speakers by Consultant A – considerable time was spent in organising this event
 - preparation for CPA accreditation in March 2007

It should be noted that internal bereavement records confirm multiple instances in each year (period 2001 – 2007 where organ disposal has been delayed as a result of “awaiting blocking of tissue”

- the Review Group would suggest that this practice of significant organ / unblocked tissue retention, rather than contemporary practice [4.1.1 Main Report] would itself have been a significant contributory factor in relation to delays experienced
- **increased general pathology workload**
 - the hospital has demonstrated an overall work load increase from 2000 onwards, particularly across the disciplines of Cytology, Histology and autopsy. It is noted 2000 / 2007 post mortems have increased by 34%

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- **post mortem report completion**
 - in terms of report completion [4.2.5 Main Report] delays were arising as a result of insufficient secretarial staff support
- **policy change**
 - In 2000 (then) Master confirmed that there should be no further disposal of organs / tissue until Dunne Enquiry had been completed – documentation to support this policy change was not supplied to the Review Group
 - It should be noted that bereavement files do identify in 2000 **only** delays being attributed to *'awaiting outcome of enquiry'*

2.1.3 Comparison of Organ Retention post 2000– with other Irish Maternity Hospitals undertaking autopsy

National Audit¹ identifies for designated hospitals the cases of organ retention – post 2000 (excluding adult cases)

- | | |
|-------------------------|--|
| Hospital A: | - 43 cases of retention <ul style="list-style-type: none">- of which 40 identifiable pre viable foetus- of which none retained for Research and Education |
| Hospital B: | - 70 cases of retention <ul style="list-style-type: none">- 5 cases of retention for Research and Education |
| Rotunda Hospital | - 189 cases of retention <ul style="list-style-type: none">- 40 cases of retention for Research and Education |

The Review Group note that whilst it is appropriate practice to ensure sampling of organs⁵, it would not be excepted practice to retain organs for such protracted periods of time.

Excepting delivery value variance between hospitals, the Review Group would suggest that the Rotunda Hospital does have practice variance with other Irish maternity units, both in terms of overall organ retention and as well retention of organs for Education and Research purposes

Overall the Review Group would suggest this significant delay in blocking tissue is unacceptable and has inappropriately resulted in:

- [non consented] organ retention for periods > 1 year in 92 cases
- significant delays for families wanting to secure reburial

2.2 Post mortem practice / management 2000 - 2007– Key Findings

2.2.1 Post Mortems undertaken

In total 667 post mortems were undertaken during this period

- 87% Hospital
- 7% Coronary
- 6% Other Hospital
 - demonstrating hospital's role as a tertiary service provider in relation to histopathology

Consultant A – **429** post mortems undertaken

Consultant B – **223** post mortems undertaken

Consultant C (Other) – **15** post mortems undertaken

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2.2.2 Superficial examinations

In total 748 were undertaken during this period [4.3 Main Report]

2.2.3 Record Availability

- Post Mortem File - 100% available
- Bereavement File - 98% available
- Patient File (Maternity) - 97% available
- Consent for autopsy record - 97% available
- Post Mortem Report - 100% available
- Retention Record - 83% available
- excluding 2000 – retention record introduced in 2001

The Review Group would note appropriate performance (in relation to record availability) is demonstrated with the exception of Consent Record and Retention Record

2.2.4 Non Compliance with consent obtained

5 causal types identified

- Retrospective Consent to autopsy securement apparent – **10 cases**
- Organs (temporarily retained) noncompliant with policy of disposal within 1 year – **92 cases**
- Limitations identified by parents / Organs retained – parents did not consent to retention – requirements identified by parents not adhered to – **8 cases**
- Failure to obtain Consent – **1 case**
- Missing Consent Record – **18 cases**

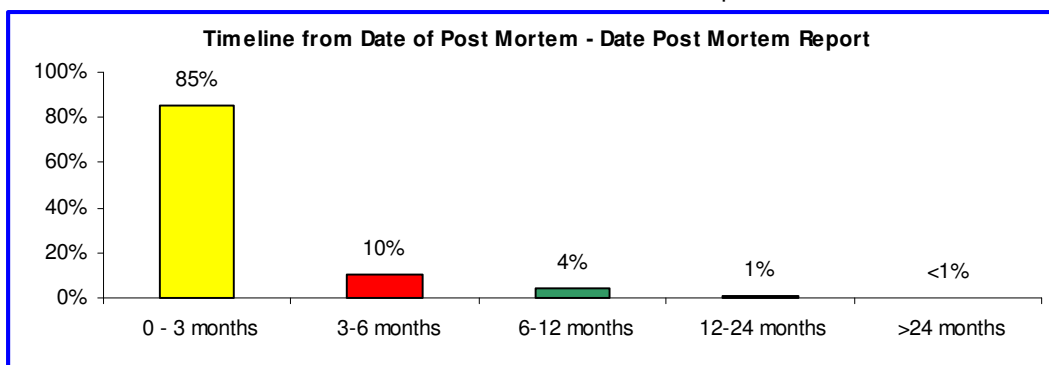
In total 129 cases of organ retention have been identified as non compliant

As previously stated, there are also a total of 295 cases pre April 2000 where no consent to organ retention has been secured [3.3.5 Main Report]

Therefore total 424 cases of non compliance with consent obtained have been identified.

2.2.5 Post Mortem Report

Timeline from Date of Post Mortem → Date of Post Mortem Report



- 71% of reports are dated (n=472) by the Pathologist
- 29% of reports are undated (n=195) by the Pathologist
- of the 71% of reports which are dated (n=472):
- 85% are dated 0-3 months of the Post Mortem
- 10% are dated 3-6 months of the Post Mortem
- 4% are dated 6-12 months of the Post Mortem
- 1% are dated 12-24 months of the Post Mortem

EXECUTIVE SUMMARY

2.2.6 Target set for report availability ERHA (national) guidelines 6 weeks

Rotunda Hospital performance:

Consultant A – 12% compliant with 6 week target

Consultant B – 41% compliant with 6 week target

- denotes first section of post mortem report availability

The Review Group would suggest that this is unacceptable performance

The Review Group note that delays in post mortem report completion have been identified as arising from

- delay in block / slide preparation [4.1 Main Report]
- insufficient secretarial support [4.1.2 Main Report]
- case complexity

The Review Group would suggest practice of significant organ / unblocked tissue retention, rather than excepted contemporary practice [4.1.1 Main Report] would itself have been a significant and potentially unnecessary contributory factor in relation to delays experienced

2.2.7 Examination of Report content

Full Post mortem report

- 234 are incomplete / not validated by Consultant Pathologist – representing 35% of full post mortem reports

Superficial Examination report

- 35 are incomplete / not validated by Consultant Pathologist – representing 5% of superficial examination reports
- 32 instances the superficial report was not available for review

Consultant A has identified that as a result of parents requesting copies of post mortem report, a practice change was introduced (1995) whereby

- only the diagnostic part of the report – identifying all critical findings would be released to the designated clinical team
- the second half of the report which identifies a description of external / internal examination / organ appearance would be retained in the laboratory and not released
- a note is placed at the end section of the report being released, stating that second half of report could be accessed on request – but would require a pathologist for interpretation

Consultant A has also explained that in 2000 a requirement for full report disclosure was identified by the Master. The Review Group note that this requirement has not been actioned by Consultant A. [4.2.2 Main Report]

The Review Group would also note that 'Frequently Asked Questions about the Autopsy' identifies that autopsy report is written using medical terminology – requiring (usually) a doctor directly involved in the care of the mother to explain it. It is not explained to the parent that unless specifically requested, they will not receive full post mortem report [3.3 Main Report]

The Review Group would also note that the majority of post mortem reports identified as incomplete / not validated - relate only to the contents of the second half of the report only.

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2.2.8 Retention sheet Record

The Review Group have identified that Retention Record was not available for 17% of all autopsies undertaken 2001-2007 and 38 instances where retrospective organ inventories had been compiled by Consultant A.

With regard to failure to complete inventory record at time of autopsy Consultant A has explained:

- inventory record introduced by Consultant A in response to Hospital solicitors requiring a mechanism to effect documenting of organ retention at autopsy – necessary to enable / satisfy parental enquiries. This was then adapted as an inventory record to be used prospectively.
- non completion of this record arose because of work ‘back log’ – which is felt to have commenced in 2000
- this specific record was not the sole source on which an organ inventory could be established, other sources being:
 - tissue blocking ‘out form’
 - histology record
 - histology slides
 - gross description in post mortem report
 - Post Mortem photography

The Hospital have explained:

- following the audit in December 2007 and the concerns raised with the Management Executive Team, the Master agreed to free up Consultant Pathologist A from clinical commitments to address the issue of unblocked tissues and incomplete retention sheets. This work would be validated subsequently by an independent pathologist. The information used to complete the retention sheets was taken from the post mortem reports and no reference was made to examination blocks or any other material available. In effect, Consultant A was freed up from all clinical work to address issues which had arisen from the national audit. This agreement was communicated to the Network Manager at the time. Subsequently, concerns were raised with the Management Executive by the independent auditors and the work was ceased with immediate effect.

The Review Group would note:

- in many instances there has been a significant delay in blocking / slide production
 - thereby negating certain records as being able to provide an organ inventory Record
- many of the post mortem reports (second half) are incomplete / not validated by Consultant – thereby not necessarily the most reliable record
- it is unclear why some of the inventory records have been completed retrospectively – not necessarily as a result of purely work pressure – as non completion not evidenced in 2003, 2004, 2007 and as well:
 - in 31 instances inventory record was completed after organs had already been returned for reburial
 - in 2 instances no organs were retained
 - the review Group also observed 2 instances where a retrospective record inventory has been completed by Consultant A in relation to autopsies undertaken by Consultant B

Consultant A has identified that retrospective completion of record was undertaken at the request of Hospital Management.

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2.3 Consent policy, practice, management – Key Findings

- consent policy [for period undated] in terms of issue, application, review and ownership is undated / unspecified
- pre April 2000 no evident mechanism for securing consent for organ retention
 - post April 2000 evident mechanism for securing consent for organ retention
- temporary retention for periods of up to one year in policy is excessive and inappropriate. **[3.2.1.3 Main Report]** also multiple instances where the hospital is not even in compliance with this limited standard
 - Current contemporary practices³ recommend the avoidance of unnecessary prolonged periods of temporary organ retention through:
 - utilisation of MRI or percutaneous needle biopsy alternatives
 - prompt preparation of blocks / slides
 - prompt completion of full post mortem report - target 6 weeks
- consent policy, when considering the need for temporary organ retention is generally non specific – tissue – with the exception of support document which does identify specific requirements relating to the brain and that temporary retention may also apply to other organs such as the heart and lung
- policy does not require consent for slide / block [permanent] retention – rather there is instead a requirement for the parent to understand necessity for this requirement – in terms of being part of the baby's medical record
 - it should be noted that exemplar sites⁷ now seek consent for the retention of blocks and slides
- the taking of photographs is not explicit for period pre 2000 – November 2005 and then is identified as a requirement for the purposes of maintaining a medical record. As previously identified guidelines² have identified constraints on the taking of photographic images **[3.3 Main Report]**
 - it should be noted that exemplar sites⁷ now seek consent for the retention of images
- policy states that full post mortem report will usually be available within six to eight weeks
 - **[3.2.10 Main Report]** multiple instances where the hospital is not compliant with this standard
- it remains questionable practice to require parents to formally record that they do not consent to the undertaking of a post mortem – the rationale stated by the hospital is so that parents are clear that not undertaking an autopsy may significantly limit the establishment of cause of death.
 - should be noted that exemplar sites⁷ do not seek to secure this agreement
- overall in relation to overall obtainment of consent in relation to post mortem practices, it should be noted that exemplar sites⁷ now seek separate consent for:
 - post mortem examination
 - retention of blood / fluids
 - retention of slides and blocks
 - retention of images
 - retention of material for genetic investigations
 - retention of organs
- parents were not routinely supplied with a copy of consent record
 - it should be noted that exemplar sites⁷ do provide a copy to parents

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2.3.1 Consent 2007

- whilst not within terms of reference for review, the Review Group did consider provided Consent Policy / Record – introduced in 2007 and noted:
 - policy still requires parent to understand (rather than consent to):
 - retention of tissue for microscopic examination
 - retention of organs and tissues for detailed examination
- policy identifies “tissue / samples” retention rather than “organ” retention for Research and Education purposes - this does not necessarily enable ‘informed’ consent
- policy requires parent to identify and record they do not want an autopsy undertaken, but (at the same time) consent to a superficial examination – this is inappropriate:
 - parents should not have to record they do not agree to an autopsy
 - in identifying non agreement to autopsy – this should not place parents (having) to consent to a superficial examination
 - policy requires hospital staff member responsible for obtaining consent to identify ‘that consent to autopsy has been given freely on an informed basis’ – this is a judgement for the parent and not the hospital

The Review Group would also note that (appropriately) this policy identifies:

- copy of consent record is supplied to parent
- (temporary) organ retention is identified to parent

2.4 Key Findings – Control Provision

This section of the Review identifies key findings in relation to Control provision and application

2.4.1 Organisational Structure – Corporate / Executive

- necessary accountability structure is less than optimally defined in terms of oversight
- in terms of corporate / executive accountability, no one individual appears holds ownership for totality of autopsy process in terms of performance
- the Risk Management Function did not appear engaged in the identified instances of complaint relating to consent practice or the management, retention and subsequent disposal of organs.

2.4.2 Orientation / Functionality of Post Mortem Group

This Group was initially established to manage concerns / information requirements of parents [3.1.1 Main Report], it has evolved to include:

- development of consent policies and procedures
- responses to problems identified by committee members
- general oversight of autopsy process

The Review Group would suggest that the Group’s performance from an oversight function perspective has been less than optimal, specifically:

- problems arising / complaints appear to have been treated on a case by case basis, rather than a necessary system ‘diagnosis and treatment’ approach
- inappropriate formality of communication [3.4.3 Main Report]
- identifying (as late as 2007) the requirement to establish a process or system to deal with delays [3.4.3 Main Report]
- the problem of ‘awaiting blocking’ is consistent across years 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007

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- the absence of robust performance measurement
- the absence of audit structure and process
- policy implementation **[4.1.2 Main Report]** **[4.2.5 Main Report]**
 - policy to retain organs not identified to Review Group in written format **[4.1.2 Main Report]**
 - policy of full post mortem availability not implement **[4.2.5. Main Report]**
- policies not version controlled **[3.3.1 Main Report]**
- no complete organ inventory system / data base **[2.6 Main Report]**
- very limited examination of post mortem practice (as opposed to process) – particularly evident consultant variation

The Review Group would suggest that certain responsibility for these shortcomings also lie with two other specific groupings:

Hospital Management Team **(3.4.1)**

Laboratory Management Committee **(3.4.2)**

The Review Group would further emphasise:

Performance Measurement

The Hospital does not have necessary set of performance measurements across all areas of work process – rather an overly simplistic focus on a case by case basis - of availability on post mortem report after six weeks

Inventory Records

The absence of a robust inventory management data base further limits the Hospital's ability to audit performance and have necessary oversight and understanding **[2.6 Main Report]** in relation organ retention and subsequent disposal

Audit

In the absence of performance related information, there is not surprisingly no appropriately vigorous and systematic audit provisions

Medical Manpower

Whilst recognising the limited availability of appropriately 'experienced' consultant medical staff in this field. The Review Group would suggest Hospital's effort / actions to secure (i) permanent post holder (ii) interim locum provision was less than optimal **[4.1.2 Main Report]**

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3. Key Recommendations

Recommendations relating to organ retention, consent, governance / control and autopsy practice. In total, the Review Group have made 31 recommendations

3.1 Organ Retained by the Rotunda Hospital pre April 2000 – for which parents did not consent to retention

Recommendation 1

The Review Group would suggest that parents have a right and need to know that organs have been retained without their consent and recommend that parents should be informed by the Hospital **[3.3 Main Report]** – this should include consideration of autopsy cases identified as non compliant with consent obtained **[4.2.4 Main Report]**

- the process by which parents are informed, requires careful consideration, as this information after such an elapse of time may well be extremely distressing **[3.3.5 Main Report]**

Recommendation 2

The Review Group recommend that parents should be given a choice of disposal **[3.3.5 Main Report]**

Recommendation 3

Should it not be possible to contact the families, the Review Group recommend that the hospital dispose of these organs within a three month period – obviously maintaining a record of organs retained and then subsequently disposed. The method and place of disposal must be clearly stated.

3.2 Organs retained by the Rotunda Hospital (post April 2000) for parents who were informed that the hospital would dispose of organs within one year **[3.3.1 Main Report]**

Recommendation 4

The Review Group would suggest that parents have a right and need to know that the Hospital has retained organs and recommend that parents should be informed by the Hospital – this should include consideration of autopsy cases identified as non compliant with consent obtained **[4.2.4 Main Report]**

- the process by which parents should be informed, requires careful consideration, as this information after such a elapse of time may well be extremely distressing

Recommendation 5

The Review Group recommend that parents should be given a choice of disposal

Recommendation 6

Should it not be possible to contact the families, the Review Group recommend that the hospital dispose of these organs within a three month period – obviously maintaining a record of organs retained and then subsequently disposed. The method and place of disposal must be clearly stated.

3.3 Consent Practice, Policy and Application

Recommendation 7

The Review Group would recommend adoption of exemplar site consent policy / practices¹, specifically informed separate consent for:

- post mortem examination
- retention of blood and other body fluids
- retention of slides and blocks
- retention of images
- retention of material for genetic investigations
- retention of organs

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Recommendation 8

[Within a wider context] the Review Group recommend the HSE consider the development of a country wide consent policy in relation to autopsy, thereby achieving standardisation of practice nationally

Recommendation 9

The Review Group recommend that parents should not have to formally record they do not consent to the undertaking of an autopsy

Recommendation 10

The Review Group recommend that parents are given a full copy of consent record

Recommendation 11

The Review Group recommend the continuation of information packages – ‘FAQ’ – and suggests the Hospital may wish to secure views of parents as to content

Recommendation 12

The Review Group would recommend that the parents (and general practitioner or referring consultant) receive a full copy of the post mortem report automatically – unless they specify a different requirement [3.3.6 Main Report]

Recommendation 13

There must be **no** instances of a Hospital autopsy being undertaken or subsequent organ retention without appropriate advance consent formally and correctly recorded

3.4 Control

The Review Group would identify the following recommendations in relation to governance / control and executive responsibility

Recommendation 14

Post Mortem Group hold responsibility for oversight of overall autopsy process, practice and corrective actions where performance targets are not being achieved. Significant non compliance instances should be considered routinely by the Risk Management Function

Recommendation 14.1

The Hospital may wish to consider ‘parent’ representation on this grouping.

Recommendation 15

Reporting on performance should be through the Master to the Board on a periodic and exceptional basis

Recommendation 16

Diagnostic Services Consultant / Director of Pathology hold executive responsibility for overall autopsy process and adherence to practice policy

Recommendation 17

Individual consultants must adhere to both process and practice policy

Recommendation 17.1

Other Laboratory staff must also adhere to both process and practice policy

Recommendation 18

The establishment of clear written standard operating procedures for all stages of the autopsy work process – all version controlled – particular focus to be given time limits for specific work processes – thereby ensuring consistent practice and more effective co-ordination / communication between Bereavement Sister and Clinicians

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Recommendation 19

The development and ongoing maintenance of an organ inventory record (recognising generally it will not be policy or practice to keep organs for long periods unless consented to by parents and then generally only in the form of blocks and slides.

Recommendation 20

The establishment of performance measurement across all areas of the autopsy work process

Recommendation 21

The establishment of a robust audit (control) function including the production of a composite report enabling actual performance .v. target performance to be ascertained by Oversight Group - this should include external and external examination of performance

Recommendation 22

The Hospital should consider alternatives to previously described recruitment practices and locum deployment

3.5 Autopsy Practice

Recommendation 23

No autopsy to commence until written consent or coronial authorisation has been received by the prosecutor.

Recommendation 24

The date and time of receipt to be recorded **[3.2.9.5.6 Main Report]**

Recommendation 25

Written notes to be made during or immediately after each autopsy (not just contemporaneous dictation). **[4.2.6 Main Report]**
These notes to be retained as part of the patient's medical record.

Recommendation 26

The record of organs / tissues blocked / retained to be signed by the pathologist and countersigned by the assisting APT immediately upon completion of the gross examination

Recommendation 27

A "Cassette only" policy for the principal organs should be routine practice

In the case of tiny organs, e.g. testis, ovary, pituitary gland, organ of Zuckerkandl, the Group understands that selective tissue blocking is not possible, and that the entire organ needs to be retained. This fact should be recorded on the blocking sheet.

In those cases where immediate blocking out is impossible e.g. in autolysed still births, or where detailed dissection of a heart anomaly is needed, rapid fixation (48-72 hours max) should be undertaken, so that the tissue(s) can be returned to the body before release for disposal.

The Review Group recognise that the brain and spinal cord present special difficulties and that detailed examination of the unfixed material is usually impossible.
There is present no general agreement on the best method of rapid fixation of these organs, and practice varies widely through the United Kingdom and Ireland.

Recommendation 28

The Review Group would recommend that a national code of best practice be agreed, drawn up and implemented – this would require HSE engagement.

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Recommendation 29

The Review Group would emphasise that it should not be necessary to retain the brain for more than 4 weeks.

Recommendation 30

The Review Group suggest it might be helpful if the Anatomical pathology technician(s) involved in the service be offered refresher training in an established centre of excellence (e.g. The Royal Liverpool Children's Hospital) to reinforce current day techniques and practice.

Recommendation 31

Records in relation autopsy

All records must be completed in a timely manner and signed by the designated consultant

**Ian Carter
Chairman
Review Group**

1 Introduction

This Report is the Findings and Recommendations of the Review Group tasked in May 2008 to consider and examine organ retention, post mortem management / practise and associated control provision within the Rotunda Hospital

The Report is divided into 5 main sections:

- Section One - Terms of Reference**
 - Context within which the Review has been undertaken
 - Review Group Membership

- Section Two - Review Methodology and Structure**

- Section Three - Review**
 - Organ retention
 - Review of Post Mortem Practice / Management (2000 – 2007)
 - Review of Consent Policy, Practice and Management (2000 – 2007)
 - Review of Control provisions 2000 - 2007

- Section Four - Key Findings of Review**
 - Organ Retention
 - Post Mortem Practice / Management
 - Consent Policy, Practice and Management
 - Control Provisions

- Section Five - Key Recommendations arising from Review**
 - Organ Retention
 - Post Mortem Practice / Management
 - Consent Policy, Practice and Management
 - Control provision

1.1 Terms of Reference for Look Back Exercise in the Rotunda Hospital relating to Post Mortem Practice and Organ Retention

Having regard to the issues raised by M. Willis and N. Harmey as part of the National Independent Audit of Retained Organs¹, it is proposed that the terms of reference for the Look Back would address the following

- 1 The policy and practices in relation to seeking consent from families in relation to non coroner (hospital) post mortems since 2000. In this context, it will be necessary to assess the scope of consent and individual consultant's compliance with the consent process
- 2 The policy and practice in relation to the retention, storage, management and disposal of all organs and tissues associated with hospital and coroner post mortems since 2000
- 3 A review of written and verbal communication processes with families in relation to coroner and non coroner post mortems. In this context, it will be necessary to review the hospital's information leaflets on post mortem and organ retention practice
- 4 A review of policy and practice in relation to the documenting of organs retained, disposed and returned to families
- 5 A review of practice in relation to clinical examination of remains brought to the mortuary

¹: Retained Organs Review (Draft) Willis M. (2007)

1.2 Context within which the Review has been undertaken

In December 2007, as part of the Independent Audit of Retained Organs¹, M. Willis and N. Harmeay attended the Rotunda Hospital.

Initial findings from this visit and subsequent other attendances identified 5 areas of concern:

- a substantial retention of organs
- the retention of unblocked organs for long periods – potentially unknown to families
- undertaking of superficial examinations including skin swabs, x-rays and photographs on a mandatory basis
- the absence of a single comprehensive and accurate data base in relation to organ retention and organ disposal / reburial / return to families, thereby not facilitating necessary validation, either internally, or for the purposes of the national audit exercise
- incomplete post mortem reports

The Review Group were also informed by the Master and the HSE Network Manager

- North Dublin, that as a result of these preliminary findings, the hospital was to:
 - introduce a new consent form and supporting documentation with immediate effect
 - effect a centralised database to record all information pertaining to retained organs including full details of organs and tissues disposed or / returned to families
 - provide necessary training for relevant staff

¹: Retained Organs Review (Draft) Willis M. (2007)

1.3 Review Group Membership

The following individuals were requested by the Health Service Executive to form the Review Group with previously identified terms of reference (1.1)

- **Ms Carol Hickey**
Quality Manager
St. James's Hospital
- **Professor Michael Green**
Emeritus Professor of Forensic Pathology
University of Sheffield
- **Mr Ian Carter (Chairman)**
Chief Executive Officer
St. James's Hospital

2 Review Structure and Methodology

This Section of the Report identifies Structure and Methodology

Work Objectives

The Review Group identified 6 work outcomes:

- **Identify organs retained and rational for retention**
 - this to include consideration of data base being developed at the time of this review
- **review and consider post mortem practice for period 2000-2007** particularly in relation to
 - compliance with consent obtained
 - organ retention
 - post mortem report content and production
- **review and consider consent policy / practice / management** applied during the period 2000-2007
 - comparison with accepted best practice / existing (Irish/UK) guidelines / recommendations in relation to
 - consent to post mortem examination
 - consent to organ retention
- **review control provision in relation to post mortem practice and process**
- **Identify key findings in relation to post mortem practice / consent application / organ retention and associated control provision**
- **Identify key recommendations in relation to post mortem practice, consent application / organ retention and association control provisions**

2.1 Organs retained

The Hospital identified that all organs were held in a single storage area. It should be noted that the Review Group did not seek to further validate this statement.

In each instance, on a case by case basis, retained organs / part organs / tissue were examined by the Consultant Pathologist from the Review Group, identifying and recording (where possible reconciling with hospital inventory records) organs / part organs / tissue retained.

In certain instances given size and condition of tissue arising from prolonged fixation in formalin, it was not always possible to identify organ / part organ retained.

2.2 Records

Whilst a summary data sheet identifying (then) organ retention and associated rational for organ retention was provided by the hospital and has been considered in this Review (**Section Three**). Given previous (apparent) problems with accuracy and general completeness of inventory records¹, the Review Group have predominantly focused on individual records held by the hospital.

¹: Retained Organs Review (Draft) Willis M. (2007)

Look Back Exercise – The Rotunda Hospital

Accordingly the following records (where available) were requested by the Review Group and particularly examined on an individual basis:

- Post Mortem file
- Post Mortem Report
- Bereavement file
- Patient File (maternity)

- Consent record
- Inventory Records
 - retained organ register
 - returned organ / tissue register
 - retention sheet record

[Where record was not provided by the Hospital, the Review Group have identified– record not available].

Post Mortem

In total the records pertaining to 933 post mortems were considered by the Review Group (excluding unidentified cases (n=3), 1993 cases (n=2) – no documentation supplied)

Superficial Examination

In total 748 records pertaining to superficial examination were considered by the Review Group

2.3 Consent Practice / Management

In addition to the examination of consent policies for the period 2000 – 2007, the Review Group interviewed necessary members of the interdisciplinary team to ascertain actual application of policy.

2.4 Control Provision

In addition to the examination of individual records, the examination of consent policy and actual application, the Review Group requested confirmation of related control provisions – in terms of governance, executive accountability / structure and audit. This information was secured through both the provision of further documentation by the hospital and interview with designated hospital staff.

2.5 Immediate Requirement for Organ release to families

Within the framework of this Exercise, the Rotunda identified that there were 24 cases of organ retention, where families were anxious to secure organ release / reburial and requested that the Review Group provide immediate advice as to proceeding.

On examination of these 24 cases, it was found in fact there was only 1 case where the family were waiting for organ release. Accordingly given the need to respect parents wishes, the full availability of necessary control documentation including inventory record, the Review Group recommended organs be released to the concerned family. This inaccuracy was further evidence of previously stated inaccuracies' and general incompleteness of inventory records / data base held by hospital (**Section 2**)

3 Organ Retention and Related Post Mortem Practises / Management

This Section of the Report considers and identifies:

- organ retention and rational
- post mortem practises / management
 - pre 2000
 - 2000 - 2007

Appropriately, whilst this Report considers all hospital organ retention, necessary focus in relation to post mortem practice has been given to the period 2000 – 2007. This focus recognises that although there was no national policy on post mortem practice until 2003, complaints from bereaved parents had arisen in 1999 in both England and Ireland (Late Late Show December 1999) and there were significant advance Irish / UK Health System responses to the concerns raised by parents particularly:

- Department of Health and Children identify to all Health Boards / Voluntary Hospitals undertaking post mortems, a requirement to ensure a policy of informed consent by next of kin in relation to post mortem and any organ retention
- Faculty of Pathology recommend that specific consent be obtained for the retention of tissue for all post mortem examinations²
- Faculty of Pathology post mortem practice / organ retention guidelines developed³
- Eastern Regional Health Authority produce guidelines relating to post mortem practice⁴
- Post Mortem Examinations – Good Practice in Consent and the Care of the Bereaved – A Consultation Document developed⁵.

Subsequently the Report of Dr Madden - Post Mortem Practice and Procedures was published in 2005⁶ and Ministerial Working Group identifying recommendations on policy and legislative modifications in relation to post mortem on babies⁷ was published in 2006

There is a general acceptance that all these reports should have shaped and informed internal hospital post mortem / organ retention practice. Accordingly actual practice within the Rotunda Hospital has been considered on an annual basis for the period 2000 – 2007. Thereby enabling specific post mortem and organ retention practice change / development to be considered over this period.

This review also incorporates examinations of specific concerns raised by the preliminary findings by Willis¹ in 2007 including:

- significant number of cases where organs were retained for long periods [and] had not been blocked
- an absence of a robust data base in relation to organ retention / held inventory
 - confirmation to Willis that superficial examinations including skin swabs, x-rays and photography were mandatory

¹: Retained Organs Review (Draft) Willis M. (2007)

²: Guidelines for Post Mortem Consent and Retention of Samples. Faculty of Pathology of the Royal College of Physicians of Ireland (2000)

³: Guidelines on Autopsy Practice: Report of a Working Group of The Royal College of Pathologists. The Royal College of Pathologists (UK) (2002)

⁴: Protocol / Guideline for Hospitals and other relevant Agencies in providing a Quality Response to Families in Relation to Non Coroners Post Mortem Practises. Eastern Regional Health Authority (2002)

⁵: Post Mortem Examinations – Good Practice in Consent and the Care of the Bereaved – A Consultation Document. Health, Social Services and Public Safety (2003)

⁶: Report of Dr Deirdre Madden on Post Mortem Practice and Procedures. Madden. D (2005)

⁷: Report on the Working Group on Post Mortem Practice (2006)

Look Back Exercise – The Rotunda Hospital

3.1 Organ Retention

TABLE 3.1 Period	Organs ¹ retained ² and rational					Total cases where organs are retained	% of Post Mortems for which organs have been retained ⁸
	Unknown ³	Research + Education ⁴	Identified by Hospital / Records as Awaiting parental confirmation as to disposal ⁵	Identified by Hospital as Held Temporarily awaiting hospital disposal			
				Retained ⁶	Retained ⁷		
Unknown	3	3				6	
1983		1				1	1%
1984		0				0	
1985		0				0	
1986		0				0	
1987		1				1	1%
1988		0				0	
1989		0				0	
1990		0				0	
1991				1		1	1%
1992		1		8		9	8%
1993		3		14	[1]	17	20%
1994		2		19		21	18%
1995		1		31	[1]	32	36%
1996		5		28	[4]	33	32%
1997		9		27	[6]	36	40%
1998		10		39	[10]	49	49%
1999		5		63	[5]	68	66%
2000		16	1	25		42	55%
2001		9	2	8		19	28%
2002		8	3	11		22	34%
2003		3	1	8		12	15%
2004		0	3	9		12	14%
2005		1	3	13		17	19%
2006		3	6	18	[1]	27	26%
2007			12	26		38	37%
Overall Total	[3]	81	31	348	[28]	460	25%

Note¹ denotes organ / part organ / tissue

Note² Hospital identified organs retained within the hospital

Note³ includes 3 foetus / organs retained for which the Hospital was unable to provide identification records rational for retention

Note⁴ denotes organs identified as being retained for Research and Education purposes

Note⁵ denotes organs retained awaiting parental confirmation as to disposal

Note⁶ identified by hospital as held temporarily awaiting hospital disposal

Note⁷ identified by hospital as held temporarily awaiting hospital disposal from a post mortem case for which organs have also been retained for Research & Education purposes (stored separately)

Note⁸ identified for comparator purposes

In total there are 460 autopsy cases where organs have been retained.

3.1.1 Specific Actions in relation to Organ Retention Pre 2000

In then considering this overall organ retention practice, the Review Group have noted in relation to pre 2000 (3) the specific actions the Rotunda Hospital have identified as undertaking in response to concerns raised by parents

In 2000 [then] Master issued a statement setting out:

- post mortem practices
- an invitation for parents to contact the hospital
- an apology for any hurt caused

Look Back Exercise – The Rotunda Hospital

The Hospital effected the establishment of an interdisciplinary committee to coordinate responses to parents contacting the hospital

In total 240 calls were received by the hospital

- arrangements were then made so that parents (who had contacted the hospital) could meet with hospital staff

The Review Group also note that in 2001, the hospital established a Bereavement Support Service **(3.2) (3.3.2)**

It is important to note and explain the contextual practice environment in which organs were retained pre 2000 – in the absence of national guidelines / recommendations particularly relating to consent / organ retention **(3.3.5)**

3.1.2 Period 1983 – 1999 – Organ Retention

- total of 1142 post mortems recorded as being undertaken for period, of which;
 - 23% resulted in organ retention (n=268)
 - 14% resulted in organ retention for purposes for Research and Education (n=38) as identified by the Hospital
 - 86% resulted in temporary organ retention by the hospital (n=230)
 - years not considered due to no (current) retention: 1984 / 1985 / 1986 / 1988 / 1989 / 1990
 - unidentified cases / fetuses not considered by Review Group

3.1.3 Period 2000 – 2007 – Organ Retention

- total of 667 post mortems recorded as being undertaken for period of which:
 - 28% resulted in organ retention (n=189)
 - 21% resulted in organ retention for purposes of Research and Education (n=40)
 - 79% resulted in temporary organ retention to date by the hospital (n=149)

Full organ / tissue inventory detail is not identified in this report, but is recorded in a supplementary report and current hospital organ inventory record data base.

3.2 Post Mortem Practice / Management

This Section of the Report identifies and considers:

- pre 2000
- 2000 – 2007
 - number of post mortem examinations
 - post mortem
 - Superficial examination

- review of related / relevant documentation 2000 - 2007 (particularly):
 - post mortem file
 - post mortem report

 - bereavement file

 - patient file (maternity)

 - consent practice evident

 - death → post mortem time period
 - post mortem → post mortem report production

 - organ inventory
 - returned tissue / organ register

 - retention records

 - overall management of post mortem cases

Look Back Exercise – The Rotunda Hospital

3.2.1 Post Mortem Practice / Management (Pre 2000)

3.2.1.1 Number of post mortems recorded

- 1,142 of which:
 - 1126 were Hospital post mortems
 - and
 - 16 were Coroner Post Mortems

3.2.1.2 Post Mortem numbers recorded per year

Table 3.2.1.1 Post Mortem Numbers recorded

Year	Full Post Mortem	Coroner Post Mortem	Total
1983	99		99
1987	120	2	122
1991	120	2	122
1992	108		108
1993	83	3	86
1994	120		120
1995	87	1	88
1996	102	2	104
1997	91		91
1998	98	1	99
1999	98	5	103
Total	1126	16	1142

- years not considered due to no current retention 1984 / 1985 / 1986 / 1988 / 1989 / 1990

3.2.1.3 Inventory of Organs / Part Organs currently stored at the Rotunda Hospital

- **Non Research / Education cases**
 - 230 instances where part organs / tissues are retained / stored at the Rotunda Hospital. It is noted these are not retained for the purposes of medical education / research
 - 217 Rotunda Hospital cases
 - 10 Coroner Cases (including 1 Adult Post Mortem)
 - of these 10 cases there is a documented copy of the report of the Pathologist sent to the Coroner in 1 instance.
 - 3 Externally referred cases
 - of these 3 cases there is a documented copy of the report of the Pathologist sent to the referring hospital in 2 instances
- **Research / Education cases**
 - 11 instances where part organs are retained specifically for the purpose of Medical Education / Research identified by the Rotunda Hospital.
- **Part Non Research (Stored) / Part retained for Research / Education cases**
 - 27 instances where part organs / tissues are retained / stored in the Mortuary and also part organs / tissues retained for medical education / research purposes.
 - in all cases (non research / research cases) retention is separate.
- **Unidentifiable Cases**
 - 3 instances where specimens for the purposes of medical education / research are retained with no supporting documentation to ascertain identification
 - 1 Polycystic Kidney
 - 1 Kidney / Bladder
 - 1 Liver

Look Back Exercise – The Rotunda Hospital

In total there are 271 cases where organs have been retained at the Rotunda Hospital for the period 1983 – 1999 (including unidentified cases)

- representing 24% of post mortems undertaken – of these only 14% of cases relate to retention for research & education purposes as identified by the hospital.

In all cases an independent Consultant Pathologist, as part of this review, has examined all retained material.

3.2.1.4 Unidentified Foetuses

- 3 instances
 - there is no documentation supporting identification in all cases
 - **Foetus A**
 - foetus and placenta of 18-20 week gestation.
 - **Foetus B**
 - a uterus, laid open to show a foetus of 30-32 week gestation with a low lying placenta. The specimen has been laid out as on museum display.
 - **Foetus C**
 - Full term foetus mounted in a museum display cabinet

3.2.1.5 Consent Practice / Policy

- Autopsy Permission Form in use for period pre 2000, listed for the purposes of this report as Consent form **A**

3.2.1.5.1 Consent Documentation Review

- **1983**
 - 1 case
 - No consent form on file
 - Case stored as Medical Education / Research based
- **1987**
 - 1 case
 - Consent for post mortem to be undertaken available
 - Case stored as Medical Education / Research based
- **1991**
 - 1 case
 - Consent for post mortem to be undertaken available
 - Case stored as non Medical Education / Research based
- **1992**
 - 9 cases
 - 8 cases stored as non Medical Education / Research based
 - 7 consent for post mortem to be undertaken unavailable
 - 1 case stored as Medication Education / Research based
 - No consent form in this instance available
- **1993**
 - 17 cases
 - 14 stored as non Medical Education / Research based
 - 7 consent forms not available
 - no documentation supplied in 2 instances
 - 2 Coroner Cases
 - 5 consent forms available for post mortem to be undertaken
 - 1 case part stored in Mortuary / Part retained for Medical Education / Research
 - No consent form available in this instance
 - 2 cases specifically stored for Medical Education / Research purposes
 - Consent form available for post mortem to be undertaken in both instances

Look Back Exercise – The Rotunda Hospital

- **1994**
 - 21 cases
 - 19 stored as non Medical Education / Research based
 - 13 consent forms available for post mortem to be undertaken
 - 6 consent forms unavailable
 - 2 cases stored as Medical Education / Research based
 - 1 consent form available for post mortem to be undertaken
- **1995**
 - 32 cases
 - 31 stored as Non Medical Education / Research based
 - 17 consent forms available for post mortem to be undertaken
 - 14 consent forms unavailable
 - 1 case part stored in Mortuary / Part retained for Medical Education / Research
 - consent form in this instance available for post mortem to be undertaken
- **1996**
 - 33 cases
 - 28 cases stored as Non Medical Education / Research based
 - 21 consent forms available for post mortem to be undertaken
 - 7 consent forms unavailable
 - 4 cases part stored in the Mortuary / Part retained for Medical Education / Research
 - 4 consent forms available for post mortem to be undertaken
 - 1 case specifically retained for Medical Education / Research purposes
 - Consent form unavailable in this instance
- **1997**
 - 36 cases
 - 27 cases stored as Non Medical Education / Research based
 - 19 consent forms available for post mortem to be undertaken
 - 6 consent forms unavailable
 - 2 Coroner Cases
 - 3 cases specifically retained for the purposes of Medical / Research
 - In all 3 instances there is a consent form available for post mortem
 - 6 cases part stored in the Mortuary / Part retained for Medical Education / Research
 - 5 consent forms available for post mortem to be undertaken
 - 1 instance Coroner Case
- **1998**
 - 49 cases
 - 39 cases stored as Non Medical Education / Research based
 - 21 consent forms available for post mortem to be undertaken
 - 14 consent forms unavailable
 - 2 Coroner cases
 - 2 referred cases – no consent form available in both instances
 - 10 cases part stored in the Mortuary / Part retained for Medical Education / Research
 - 7 consent forms available for post mortem to be undertaken
 - 3 consent forms unavailable
 - 1 instance external referral from Portlaoise

Look Back Exercise – The Rotunda Hospital

- **1999**
 - 68 cases
 - 63 cases stored as Non Medical Education / Research based
 - 30 consent forms available for post mortem to be undertaken
 - 30 consent forms unavailable
 - 3 Coroner cases
 - 5 cases part stored in the Mortuary / Part retained for Medical Education / Research
 - 3 consent forms available for post mortem to be undertaken
 - 2 consent forms unavailable

In all cases an independent Consultant Pathologist, as part of this review has examined all retained material.

3.2.1.5.2 Non Compliance with consent given

The following is a breakdown of non compliancy with consent process

- **Retrospective Consent secured** (apparent)
 - There is 1 case where consent form had been signed by parents after the date of autopsy stated in the PM report:
 - PM 1: Date of PM 12.12.97 → consent granted on 13.12.97

It should be noted however all cases Pre 2000 (n=271) are deemed non compliant, as where consent was granted, it was for the post mortem to be undertaken, not for the retention of organs. **(3.3.5)**

3.2.1.6 Prosector

- Consultant Pathologist A undertook 157 of post mortems for this period (58% of total post mortems)
- Consultant Pathologist B undertook 84 of post mortems for this period (31% of total post mortems)
- Consultant Pathologist C undertook 1 of post mortems for this period (<1% of total post mortems)
- Consultant Pathologist D undertook 4 of post mortems for this period (1% of total post mortems)
- Consultant Pathologist E undertook 1 of post mortems for this period (<1% of total post mortems)
- Consultant Pathologist F undertook 1 of post mortems for this period (<1% of total post mortems)
- Consultant Pathologist G undertook 6 of post mortems for this period (2% of total post mortems)
- Consultant Pathologist H undertook 2 of post mortems for this period (1% of total post mortems)
- Consultant Pathologist I undertook 1 of post mortems for this period (<1% of total post mortems)
- Consultant Pathologist J undertook 2 of post mortems for this period (1% of total post mortems)
- Consultant Pathologist K undertook 4 of post mortems for this period (1% of total post mortems)
- Consultant Pathologist L undertook 3 of post mortems for this period (1% of total post mortems)
- in addition
 - 3 instances unidentifiable cases (1% of total)
 - 2 instances no documentation supplied to ascertain Prosector (1% of total)

3.2.2 Post Mortem Practice / Management (2000)

3.2.2.1 Number of post mortems recorded

- 155 of which:
 - 77 were post mortems (50% of total)
 - 76 were superficial examinations (49% of total)
- and
- 2 where a post mortem reference number was assigned, but no post mortem subsequently recorded as being undertaken (1% of total)

3.2.2.2 Post mortems

There were 77 full post mortems undertaken at the Rotunda Hospital during 2000 of which:

- 34 related to miscarriage / still births < 500gm
- 26 related to still births
- 17 related to live births
 - 77 Full post mortems (50% of total)
 - Prosector
 - Consultant Pathologist A undertook 62 post mortems for this year (81% of total post mortems)
 - Consultant Pathologist B undertook 14 post mortems for this year (18% of total post mortems)
 - Consultant Pathologist M undertook 1 post mortem for this year (1% of total post mortems)

3.2.2.2.1 Post mortems (Rotunda Hospital)

74 post mortems – accounting for 96% of post mortems undertaken in 2000.

3.2.2.2.2 Post mortems (Coroner)

2 post mortems – accounting for 3% of post mortems undertaken in 2000

- PM 2 was referred from National Maternity Hospital, Holles Street for Coroner PM
- PM 3 was a Rotunda Hospital Coroner PM
 - There is documented evidence in both cases that the Post Mortem report was sent to the Coroner by the Pathologist.

3.2.2.2.3 Post mortems (Other Hospital)

1 post mortems – accounting for 1% of post mortems undertaken in 2000

- PM 4 referred from Limerick
 - there is no documented evidence the report was sent to referring hospital by the Pathologist.

3.2.2.2.4 Post Mortem – slide examination

None identified

3.2.2.2.5 Post Mortem – referral of wet tissue

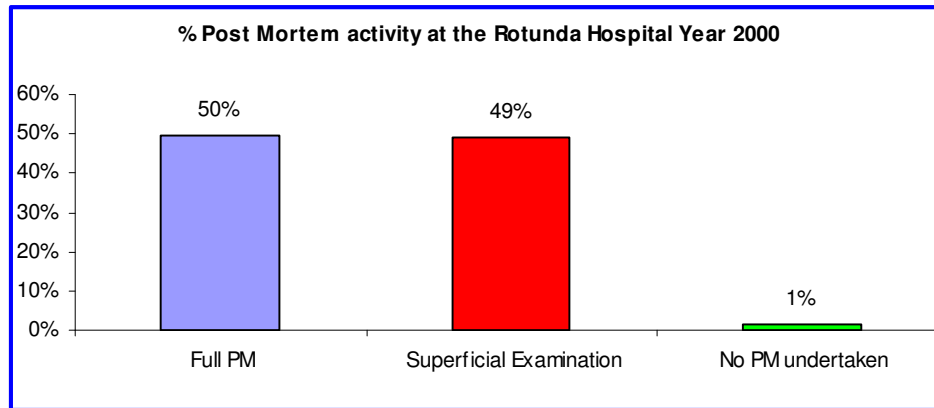
None identified

3.2.2.2.6 Post mortem reference number assigned, but no post mortem subsequently recorded as being undertaken

2 cases where a post mortem reference number was assigned, but no post mortem subsequently recorded as being undertaken

Look Back Exercise – The Rotunda Hospital

Graph 3.2.2.1 % Post Mortem activity at the Rotunda Hospital Year 2000



3.2.2.3 Superficial examinations

There were 76 superficial examinations undertaken at the Rotunda during 2000 of which:

- 40 related to miscarriage / still birth
- 15 related to still births > 500gm
- 21 related to live births
 - 76 Superficial examinations (49% of total)
 - Prosecutor
 - Consultant Pathologist A undertook 53 superficial examinations for this year (70% of total post mortems)
 - Consultant Pathologist B undertook 23 superficial examinations for this year (30% of total post mortems)

3.2.2.4 Review of related / relevant documentation (macro)

- post mortem file – 100% availability
 - post mortem Report – complete – 69%
 - post mortem Report – partial – 31% **(3.2.2.8)**
- superficial file – 100% availability
 - superficial examination report – complete 93%
 - superficial examination report – partial 7% **(3.2.2.8)**
- bereavement File – 99% availability
- patient File (Maternal) – 87% availability

3.2.2.5 Consent

3.2.2.5.1 Consent practice / policy

There were two consent forms in use in this year.

- **Autopsy Permission Form**
 - in use from January to April 2000 which was used to obtain consent for Full Post Mortems - listed for the purposes of this report as Consent form **A**
- **Perinatal Autopsy Permission Form**
 - in use from April 2000 to December 2000 to obtain consent – listed for the purposes of this report as Consent form **B**

3.2.2.5.2 Consent record availability

Table 3.2.2.2 Consent record availability full post mortems

Consent Record availability / Full Post Mortems	
Consent Record available – Rotunda Cases	72
Consent Record not available – Rotunda Cases	2
Consent record available – Referral Case	1
Coroner Cases	2
Total	77

- Of the total post mortems requiring consent 97% consent records available (n=73) (exclusion of 2 coroner cases)

Table 3.2.2.3 Consent record availability superficial post mortems

Consent Record availability / Superficial Exam	
Consent Record available	0
Consent Record not available	76
Total	76

- It should be noted no specific consent for superficial examination was in place for the year 2000.
In 6 instances where consent was not granted for a full post mortem, this form was filed in the superficial file - in each instance a superficial examination was undertaken.

Consent Documentation Review (Full Post Mortem)

Table 3.2.2.4 Consent documentation review

Consent Review	Number of cases
Granted for Post Mortem	70
Consent forms not available	2
Coroner Cases	2
Referral Hospital / Full Granted for Post Mortem	1
Limited Consent	2
Total	77

The following is breakdown of consent forms for 2000 post mortems:

- 91% consent forms authorising hospital to undertake a PM
- 3% consent forms not on file
- 3% Coroner Cases (parental consent is not required)
- <1% externally referred cases / consent granted for Post Mortem
- 3% Limited / restricted Post Mortem consent granted.

3.2.2.5.3 Limited / Restricted Post Mortem

PM 5

Perinatal Autopsy Permission Form states that parents agree that samples may be taken from organs for microscopic slide purposes only. Date of consent 23.06.00. Parents do not agree to the retention of any organs. Retention of tissues only for Education / Research granted. There is an undated note in the bereavement file stating no tissue was left after post mortem completed.

PM 6

There are two consent forms completed for this PM – first stating no organs to be removed / second form signed granting full consent. There is an undated note in the bereavement file stating no tissue was left after post mortem.

3.2.2.5.4 Non Research / Education Cases

- Of the 26 cases, which are stored in the mortuary (not retained for research / education purpose),
 - 24 instances there is a note in the bereavement file – ‘*awaiting outcome of enquiry*’. These notes are undated.
 - it should be noted that for Post Mortem 01-00 → 50-00, Consent form A was utilised which did not give consent to organ retention.
 - in 1 instance records indicate parents being in contact with hospital re: reburial – this has not been effected to date
 - 1 instance is a Rotunda Coroner Case / baby was interred privately - no documentation or letters on file in relation to reburial.
 - 1 instance it is noted that hospital to arrange reburial or organs / tissues / baby interred privately - in this case there is documentation from hospital contacting family.

3.2.2.5.5 Consent Medical Education / Perinatal Death

- Of the 16 cases, which are retained for research / education purpose),
 - 14 instances consent granted for retention medical Education / Perinatal Death
 - 1 instance consent granted for ‘samples may be taken from organs for microscopic slide purposes only / retention of tissues only granted for Education / Research’
 - 1 instance the consent form is not available

3.2.2.5.6 Non Compliance with Consent given

The following is a breakdown of non compliancy with consent process

- **Retrospective Consent secured** (apparent)

There are 2 cases where consent form had been signed by parents after the date of autopsy listed in the PM report:

 - PM 7 : Date of PM 10.01.00 → Consent granted 11.01.00
 - PM 8: Date of PM13.01.00 → Consent granted 14.01.00
- **Consent / Retention**

There is 1 case (also listed under **3.2.2.5.3 / PM 5**) where consent states that samples may be taken from organs for microscopic slide purposes only. Parents did not agree to the retention of any organs. Consent form has been ticked for tissues only for Education / Research purposes. There are 7 part organs / tissues retained for the purposes of Medical Education / Research as identified by the Rotunda Hospital.
- **Consent / Reburial**
 - of the 26 cases, which are stored in the mortuary (not retained for research / education purpose),
 - 24 instances there is a note in the bereavement file – ‘*awaiting outcome of enquiry*’. These notes are undated.
 - it should be noted that for Post Mortems 01-00 → 50-00 Consent form A was utilised which did not give consent to organ retention. (n=24)
 - in 1 instance records indicate for parents to contact the hospital – no record that this has occurred

Look Back Exercise – The Rotunda Hospital

- 1 instance is a Rotunda Coroner Case (note in bereavement file ‘? Pathology’) / no documentation or letters on file in relation to reburial.

In total 28 cases are deemed non compliant – representing 36% of post mortems

3.2.2.6 Date of delivery / death → date of post mortem

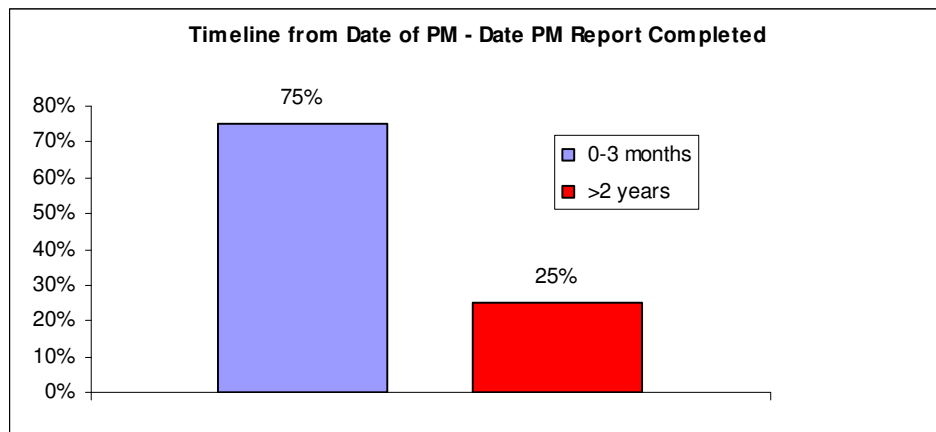
Table 3.2.2.5 summarises length of time from date of delivery/ death → date of post mortem

Timeline	Same day as Date of Death	1-2 days	> 2 < 7 days	≥7 days	Date of Death not listed	Date of PM Not Recorded	Total
Number	9	27	26	3	3	9	77
%	12%	35%	34%	4%	4%	12%	

3.2.2.7 Date of post mortem → date of post mortem report

- 95% of reports are undated (n=73) of the 5% reports which are dated
 - 75% are dated 0-3 months post post mortem
 - 25% are dated > 2 years after post mortem

Graph 3.2.2.6 Timeline from Date of Post Mortem – Date Post Mortem Completed



- As the majority of reports were undated, a sample of 18 cases pertaining to 2000 was reviewed in order to ascertain date of PM completion. No record of received dates (when blocks were received in Histology) was recorded, however a manual record showed in all 18 cases, slides made from blocks were released to the Pathologist in 2000, indicating blocking was undertaken in the year 2000.

3.2.2.8 Post Mortem Report

Full Post mortem report

- 24 are incomplete / apparently not validated by Consultant Pathologist – representing 31% of full post mortem reports

Superficial Examination report

- 5 are incomplete / apparently not validated by Consultant Pathologist – representing 7% of superficial examination reports

Look Back Exercise – The Rotunda Hospital

3.2.2.9 Inventory of Organs / Part Organs currently stored at the Rotunda Hospital

Table 3.2.2.7 Inventory of Organs

Origin of Cases	Cases
Rotunda Hospital cases	24
Coroner Case – not research based	1
Referral Hospital – not research based	1
Total Non research based	26 (62%)
Medical Research / Education	16
Total Medical Research based	16 (38%)
Total	42

There are 42 cases for 2000 where part organs / tissues are currently stored in the Mortuary.

- This figure represents 55% of full post mortems.
 - 26 cases were identified by the Rotunda hospital at start of review
 - 16 cases were identified by the Rotunda Hospital as Medical / Education specimens at review end.
 - In all of the above 42 cases an Independent Consultant Pathologist as part of this review has examined all material.
- of the 26 cases identified as stored / retained not for the purposes of Medical / Education
 - 21 instances Pathologist A undertook the post mortem
 - 5 instances Pathologist B undertook the post mortem

3.2.2.10 Returned Tissue / Organ Register

Table 3.2.2.8 Return Tissue / Organ Register

Returned Tissue Register	
Fully returned for burial	23
Part return for burial	15
Total	38

- 38 instances where the Return Tissue Register has logged a full / partial reburial of Tissue / Organs. Of these cases where the Post Mortem was undertaken in 2000:
 - 2 cases returned in 2000
 - 7 cases returned in 2001
 - 21 cases returned in 2002
 - 3 cases returned in 2003
 - 5 cases returned in 2004

3.2.2.11 Retention Sheet Record

No detailed retention sheets available in this year – Therefore the Review team were unable to compare numbers of organs retained by medical staff

Retrospective data entries

There are no cases where data has been entered retrospectively for the year 2000.

Look Back Exercise – The Rotunda Hospital

3.2.2.12 Overall Management of Cases

Table 3.2.2.9 Overall Management of Cases

Cases	No.
Returned Tissue Register	
- 38 cases	
- of these, 15 cases were part returned / part retained	23
Cases where part organ / tissues are stored in Mortuary	42
No Reburial details evident on documentation review	2
Documented evidence indicates organs were sampled at the time of Post Mortem and returned to body for reburial	1
Cases where documented evidence indicates there was no tissue left after Post Mortem Examination	9
Total	77

- in total there are 38 cases listed in the return tissue book as returned for reburial
 - of these 38 cases:
 - in 15 instances part were sent for reburial / part were retained for research.
 - 23 instances where all organs were sent for reburial.
 - 42 cases are currently stored in the Mortuary (26 cases non Research / 16 cases Medical Education / Research identified by the Rotunda Hospital)
 - 2 instances there are no reburial details documented on file
 - 1 instance the organs were sampled at the time of the post mortem and returned to the body
 - 9 instances there was no tissue left after the post mortem was completed.

3.2.2.13 Supplementary Report in relation to Organ Retention Status 21.12.07 / 20.02.08

A supplementary report was provided to the review team identifying for 2000

- Status 21.12.07
 - of the 26 cases of organ retention 26 were complete awaiting reburial
 - delay identified in 24 cases *'prior to change in consent form'*
 - delay identified in 1 case as *'difficulty contacting parents* (Coroner Case) – no supporting documentation on file
 - delay identified in 1 case as *'difficulty contacting parents* – documentation of phone calls / letters on file
- Status 20.02.08
 - of the 26 cases of organ retention 26 were complete awaiting reburial
 - key arrangement notes identify
 - 2 instances private grave - permission required.
 - 24 instances key arrangement sections blank

This report was designed to assist this Review in understanding actions undertaken by hospital following National Audit visitation December 2007 (2.5)

3.2.3 Post Mortem Practice / Management (2001)

3.2.3.1 Number of post mortems recorded

- 166 of which:
 - 67 were post mortems (40% of total)
 - 90 were superficial examinations (54% of total)
- and
- 1 slide(s) examination referred by external hospital (1% of total)
- and
- 8 where a post mortem reference number was assigned, but no post mortem subsequently recorded as being undertaken (5% of total)
 - this was further validated by the Report 'Details of Autopsies' provided by the hospital

3.2.3.2 Post mortems

There were 67 post mortems undertaken at the Rotunda Hospital during 2001 of which:

- 27 related to miscarriage / still births
- 21 related to still births > 500gm
- 19 related to live births
 - 67 Full post mortems (40% of total)
 - Prosector
 - Consultant Pathologist A undertook 44 post mortems for this year (66% of total post mortems)
 - Consultant Pathologist B undertook 23 post mortems for this year (34% of total post mortems)

3.2.3.2.1 Post mortems (Rotunda Hospital)

60 post mortems – accounting for 90% of post mortems undertaken in 2001.

3.2.3.2.2 Post mortems (Coroner)

5 post mortems – accounting for 7% of post mortems undertaken in 2001

- PM 9 referred from National Maternity Hospital, Holles Street
- PM 10 Rotunda Hospital Coroner PM
- PM 11 referred from Coombe Hospital for Coroner PM
- PM 12 Rotunda Hospital Coroner PM
- PM 13 domiciliary delivery, infant died at home - Coroner PM
 - of these 5 cases, there is a documented copy of report sent to Coroner in 3 instances by the Pathologist.

3.2.3.2.3 Post mortems (Other Hospitals)

2 post mortems – accounting for 3% of post mortems undertaken in 2001

PM 14 referral from Coombe Hospital

PM 15 referral from Coombe Hospital

- of these 2 cases – there is no copy of report sent to referring hospital in both instances by the Pathologist.

3.2.3.2.4 Post Mortem – slide examination

1 case which consisted of slides (from external hospital) examination only

3.2.3.2.5 Post Mortem – referral of wet tissue

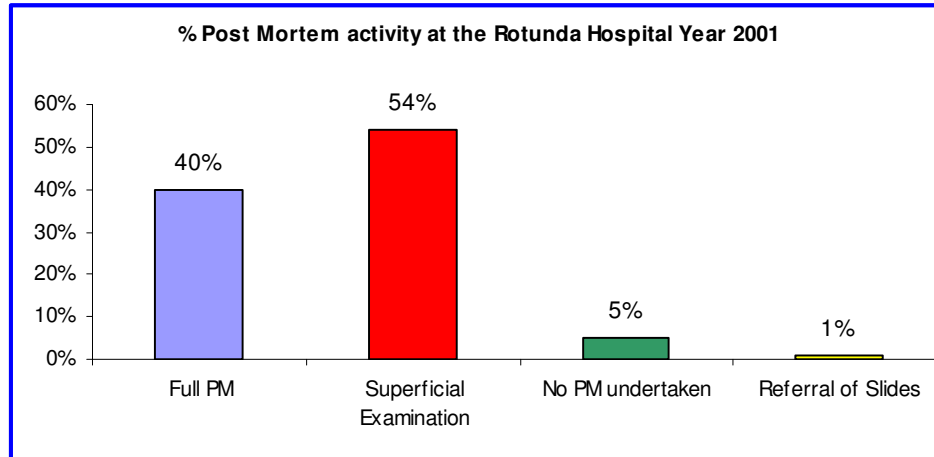
None identified

3.2.3.2.6 Post mortem reference number assigned, but no post mortem subsequently recorded as being undertaken

8 cases where a post mortem reference number was assigned, but no post mortem subsequently recorded as being undertaken

Look Back Exercise – The Rotunda Hospital

Graph 3.2.3.1 % Post Mortem activity at the Rotunda Hospital Year 2001



3.2.3.3 Superficial examinations

There were 90 superficial examinations undertaken at the Rotunda during 2001 of which:

- 59 related to miscarriage / still birth
- 13 related to still births > 500gm
- 18 related to live births
- 90 Superficial examinations (54% of total)
 - Prosector
 - Consultant Pathologist A undertook 57 superficial examinations for this year (63% of total post mortems)
 - Consultant Pathologist B undertook 31 superficial examinations for this year (34% of total post mortems)
 - Consultant Pathologist N undertook 1 superficial examination for this year (1% of total post mortems)
 - in one case the superficial report was not available (1% of total post mortems)

3.2.3.4 Review of related / relevant documentation (macro)

- post mortem file – 100% availability
 - post mortem Report – complete – 77% availability
 - post mortem Report– partial – 33% availability (**see 3.2.3.8**)
- superficial file – 100% availability
 - superficial examination report – 99% availability
 - superficial examination report – partial 11% (**see 3.2.3.8**)
- bereavement File – 98% availability
- patient File (Maternal) – 91% availability

3.2.3.5 Consent

3.2.3.5.1 Consent practice / policy

Rotunda Hospital Perinatal Autopsy Permission Form was in use for all 2001

- listed for the purposes of this report as Consent Form **B**.

3.2.3.5.2 Consent record availability

3.2.3.2 consent record available full post mortems

Consent Record availability / Full Post Mortems	
Consent Record available - Rotunda Cases	59
Consent Record not available – Rotunda Cases	1
Consent record available – Referral Cases	2
Coroner Cases	5
Total	67

- Of the total post mortems requiring consent 98% consent records available (n=61) / (exclusion of 5 coroner cases)

Table 3.2.3.3 Consent record availability Superficial Examinations

Consent Record availability / Superficial Examinations	
Consent Record available	0
Consent Record not available	90
Total	90

- It should be noted no specific consent form for superficial examination was in place for the year 2001. In 23 instances where consent was not granted for a full post mortem, this form was filed in the superficial file / in each instance a superficial examination was undertaken.

Consent Documentation Review

Table 3.2.3.4 Consent Documentation Review

Consent Review	Number of cases
Full Granted for Post Mortem	55
Consent forms not available	1
Coroner Cases	5
Referred Hospital / Full Granted for Post Mortem	1
Limited Consent (including 1 Referred case)	5
Total	67

The following is breakdown of consent for 2001 post mortems

- 82% consent forms authorising hospital to undertake a post mortem
- 1% consent forms not on file
- 7% Coroner Cases (parental consent is not required)
- 1% externally referred cases / Full consent granted for Post Mortem
- 7% Limited / restricted Post Mortem consent granted.

3.2.3.5.3 Limited / Restricted Post Mortem

- **PM 16** Parental Autopsy Permission Form states parents do not want whole organs to be retained. Pathologist B makes reference to all organs being returned to the body and no tissue left after post mortem was completed.
- **PM 17** Parental Autopsy Permission Form states the facial features were to be preserved.
- **PM 18** Parental Autopsy Permission Form states that parents do not wish organ retention, they requested that the organs be interred with baby on 24.05.01. There is no available retention sheet in this case to indicate what retention occurred. A reburial, as documented in the return tissue book occurred significantly later on - 26.09.02 denoting tissue / organs had been retained.
- **PM 19** Parental Autopsy Permission Form states no organs were to be retained. The retention sheet in this case has been compiled in retrospect by Pathologist A on 14.01.08, listing the Pituitary gland / Thyroid gland / Parathyroid gland as retained complete. A reburial

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as documented in the return tissue book occurred significantly later on - 20.08.05.

- **PM 20** Parental Autopsy permission Form states no entire organs were to be removed. There is no available retention sheet in this case to indicate what retention occurred. A reburial, as documented in the return tissue book occurred significantly later on - 20.08.05.

3.2.3.5.4 Non Research / Education Cases

- of the 10 cases, which are stored in the mortuary (not retained for research / education purpose),
 - 2 instances baby interred privately – hospital to arrange reburial of organ / tissue - there is no evidence of contact with the family by the Rotunda in both instances
 - 2 instances baby interred in Holy Angels – hospital to arrange reburial of organ / tissue – undated note in bereavement file in both instances *'awaiting blocking of tissue'*
 - 1 instance baby interred privately – hospital to arrange reburial of organ / tissue – there is evidence of 3 letters from the Rotunda Hospital to the family
 - 1 instance baby interred privately – family wish to make a personal arrangement for reburial of organ / tissue – family to contact hospital
 - 1 instance baby interred privately – no consent form on file to indicate reburial wishes.
 - 3 instances (Triplet case) babies interred privately – hospital to arrange reburial of organ / tissue – undated note in all bereavement files *'awaiting blocking of tissue'*

3.2.3.5.5 Consent Medical Education / Perinatal Death

- of the 9 cases, which are retained for Medical Education / Research purposes,
 - 6 instances consent granted for retention for Medical Education / Perinatal death
 - 1 instance consent granted for retention for Perinatal Death not Medical Education
 - 2 instances were referred hospital cases (Coombe consent form)
 - 1 instance consent granted for education of doctors and students / medical research
 - 1 instance consent granted for education of doctors and students / medical research – face to be preserved

3.2.3.5.6 Non Compliance with Consent given

The following is a breakdown of non compliancy with consent process

- **Retrospective Consent secured** (apparent)
There is 1 case where the consent form had been signed by parents after the date of autopsy listed in the PM report
 - PM 21: Date of PM 27.01.01 → Consent granted on 29.01.01
- **Consent / Retention**
 - PM 18 Parental Autopsy Permission Form states that parents do not wish organ retention, they requested that the organs be interred with baby on 24.05.01. There is no available retention sheet in this case to indicate what was retained. The parents stated on the consent form that the tissue was to be reburied at Holy Angels Glasnevin. A reburial is documented in the return tissue book occurred later on 26.09.02.

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- PM 19: Consent granted for Post Mortem but not retention of any organs. Therefore, the parents did not list / tick a reburial option for private / hospital arrangement. It is noted in the return tissue book that a reburial occurred on 2.08.05 to Holy Angels Glasnevin. The retention sheet in this case is compiled in retrospect by Pathologist A on 14.01.08. The three organs retained, in full, in this case were the Pituitary Gland / Thyroid Gland / Parathyroid Gland.
- PM 20: Consent granted for Post Mortem but not entire / complete organs to be removed. Therefore, the parents did not list / tick a reburial option for private / hospital arrangement. It is noted in the return tissue book that a reburial occurred on 20.08.05 at Holy Angels Glasnevin. There is no available retention sheet in this case available to indicate what was retained.
- **Consent / Reburial**
 - of the 10 cases, which are stored in the mortuary (not retained for research / education purpose)
 - 2 instances baby interred privately – hospital to arrange reburial of organ / tissue - there is no evidence of contact with the family by the Rotunda in both instances
 - 2 instances baby interred in Holy Angels – hospital to arrange reburial of organ / tissue – undated note in bereavement file in both instances *'awaiting blocking of tissue'*
 - 3 instances (Triplet case) babies interred privately – hospital to arrange reburial of organ / tissue – undated note in all bereavement files *'awaiting blocking of tissue'*
 - 1 instance baby interred privately – no consent form on file to indicate reburial wishes.

In total 12 cases are deemed non compliant – representing 18% of post mortems

3.2.3.6 Date of delivery / death → date of post mortem

Table 3.2.3.5 length of time from date of delivery/ death → date of post mortem

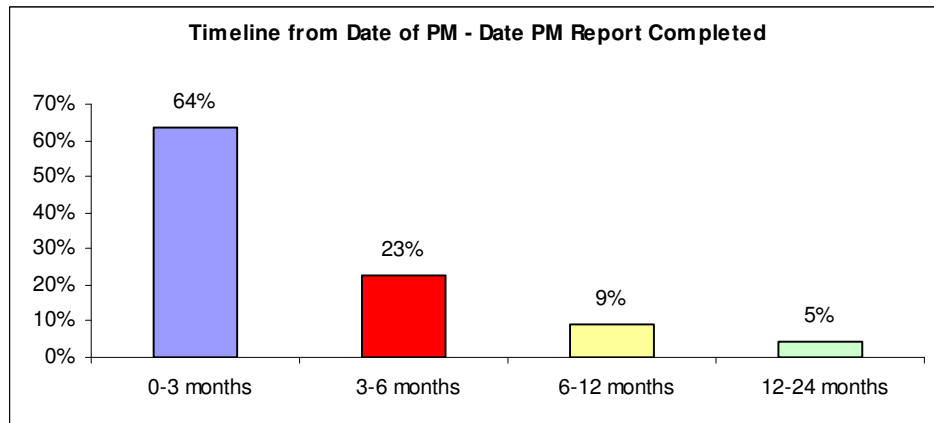
Timeline	Same day as Date of Death	1-2 days	> 2 < 7 days	≥7 days	Date of Death not listed	Date of PM Not Recorded	Total
Number	11	26	17	0	0	13	67
%	16%	39%	25%	0%	0%	19%	

3.2.3.7 Date of post mortem → date of post mortem report

- 67% of reports are undated
- of the 33% reports which are dated
 - 64% are dated 0-3 months post post mortem
 - 23% are dated 3-6 months post post mortem
 - 9% are dated 6-12 months post post mortem
 - 4% are dated 1 year - < 2 year post post mortem
 - in 13 instance where the Date of Post Mortem was not recorded, the Date of Death was used for the above comparator.

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Graph 3.2.3.6 Timeline from Date of PM – Date PM Report Completed



As some of reports were undated a sample of 19 cases were reviewed in order to ascertain Date of PM completion. Manual records provided from the hospital showed the dates on which slides made from blocks were released to the pathologist. Of these:

- 11 cases were released solely in 2001
- 2 cases were released in 2001 and another release date in 2002
- 1 case was released in 2001 and another release date in 2003
- 1 case was released solely in 2002
- 1 case was released in 2002 and another release date in 2008
- 1 case was released in 2002 with other release dates in 2003 and 2008
- 2 cases were released in 2003 and another release date in 2008

For cases that were dealt with after September 2003, the dates given are those on which blocks from which staining had not previously been requested are logged on the computer for staining

3.2.3.8 Post Mortem Report – examination

Full Post mortem report

- 22 are incomplete / apparently not validated by Consultant Pathologist – representing 33% of post mortem reports

Superficial Examination report

- 10 are incomplete / apparently not validated by Consultant Pathologist – representing 11% of superficial examination reports
 - in 1 instance the superficial examination report was not available

3.2.3.9 Inventory of cases currently stored at the Rotunda Hospital

Table 3.2.2.7 Inventory of Organs

Origin of Cases	Number of cases	
Rotunda Hospital cases	10	(53%)
Coroner Case – not research based	0	(0%)
Referral Hospital – not research based	0	(0%)
Total Non research based	10	
Medical Research / Education (inc. 2 referrals - of which 1 is referred Coroner Case)	9	(47%)
Total Medical Research based	9	
Total	19	

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There are 19 cases for 2001 where part organs / tissues are currently stored in the Mortuary.

- This figure represents 28% of full post mortems.
 - 10 cases were identified by the hospital at start of review
 - 9 cases were identified by the Rotunda Hospital as Medical / Education specimens at review end
 - In all of the above 19 cases an Independent Consultant Pathologist as part of this review has examined all material.
- of the 10 cases identified as stored / retained not for the purposes of Medical / Education
 - 9 instances Pathologist A undertook the post mortem
 - 1 instances Pathologist B undertook the post mortem

3.2.3.10 Returned Tissue / Organ Register

Table 3.2.2.8 Return Tissue / Organ Register

Returned Tissue Register	
Fully returned for burial	36
Part return for burial	9
Total	45

- 45 instances where the Return Tissue Register has logged a full / partial reburial of Tissue / Organs. Of these cases where the Post Mortem was undertaken in 2001:
 - 3 cases returned in 2001
 - 18 cases returned in 2002
 - 4 cases returned in 2003
 - 0 cases returned in 2004
 - 18 cases returned in 2005
 - 1 case returned in 2006
 - 1 case returned in 2007

3.2.3.11 Retention Sheet Record

51 retention sheets available - representing 76% of full post mortems undertaken
→ 24% unavailable

Average number of organs retained

- Consultant Pathologist A – 20
- Consultant Pathologist B – 2

Retrospective data entries

There are 6 cases where the retention sheet record has been completed retrospectively (RS)

- 5 cases relate to post mortems undertaken by Consultant Pathologist A
- 1 case relates to a post mortem undertaken by Consultant Pathologist B
 - **RS 1** retention sheet compiled in retrospect by Pathologist A on 11.01.08 → Organs / tissues returned for reburial on 20.08.05
 - **RS 2** retention sheet compiled in retrospect by Pathologist A on 11.01.08 → Organs / tissues returned for reburial on 26.09.02
 - **RS 3** retention sheet compiled in retrospect by Pathologist A on 14.01.08 → Organs / tissues returned for reburial on 19.11.05
 - **RS 4** retention sheet compiled in retrospect by Pathologist A on 14.01.08 → Organs / tissues returned for reburial on 31.05.06
 - **RS 5 / PM 19** retention sheet compiled in retrospect by Pathologist A on 14.01.08 → Organs / tissues returned for reburial on 20.08.05
 - **RS 6** retention sheet compiled in retrospect by Pathologist A on 14.01.08 → Organs / tissues returned for reburial on 26.09.02

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3.2.3.12 Overall Management of Cases

Table 3.2.2.9 Overall Management of Cases

Cases	Numbers
Returned Tissue Book - 45 cases - of these, there are 9 instances / cases where part organs / tissues are retained for Medical Research / Education.	36
Cases where part organ / tissues stored in Mortuary	19
No Reburial details evident in files	0
Cases where documented evidence indicates there was no tissue left after Post Mortem Examination	11
Documented evidence whereby organs were sampled at time of PM and returned to body for burial	1
Total	67

- in total there are 45 cases listed in the return tissue book as returned for reburial
 - of these 45 cases
 - in 9 instances part were sent for reburial / part were retained for research
 - in 36 instances the cases were completely sent for reburial
 - 19 cases are currently stored in the Mortuary (10 non research / 9 cases Medical Education / Research identified by the Rotunda Hospital)
 - No instances where reburial details were not evident
 - 11 instances there was no tissue left after the post mortem was completed
 - 1 instance the organs were sampled at the time of the post mortem and returned to the body

3.2.3.13 Supplementary Report in relation to Organ Retention Status 21.12.07 / 20.02.08

A supplementary report was provided to the review team identifying for 2001

- Status 21.12.07
 - of the 10 cases of organ retention 5 were complete awaiting reburial
 - delay identified in 2 cases '*private grave no reason in database*'
 - delay identified in 1 case '*had not been marked as complete*'
 - delay identified in 1 case '*?private grave – have not contacted*'
 - delay identified in 1 case '*private grave – 3 letters sent*'
 - of the 5 cases identified as incomplete on 21.12.07
 - delay identified in 4 cases as '*incomplete*'
 - delay identified in 1 case as '*unblocked*'
- Status 20.02.08
 - of the 10 cases of organ retention 10 were complete awaiting reburial
 - key arrangements note identified
 - 2 instances '*Private Grave*' – *Permission required*
 - 2 instances '*Holy Angels Plot – Hospital to arrange*'
 - 1 instance '*Private Grave – no consent form in Autopsy suite*'
 - 4 instances '*check bereavement file*'
 - 1 instance '*3 letters sent*'
- A subsequent report from the Rotunda Hospital indicated in 1 instance where status on 21.12.07 was identified '*unblocked*' → blocks had in fact been previously processed

This report was designed to assist this Review in understanding actions undertaken by hospital following National Audit visitation December 2007 (2.5)

3.2.4 Post Mortem Practice / Management (2002)

3.2.4.1 Number of post mortems recorded

- 159 of which:
 - 65 were post mortems (41% of total)
 - 83 were superficial examinations (52% of total)
- and
- 4 were slide examinations referred by external hospitals (3% of total)
- 2 were examination of wet tissue (1% of total)
- and
- 5 where a post mortem reference number was assigned, but no post mortem subsequently recorded as being undertaken (3% of total)

3.2.4.2 Post mortems

There were 65 post mortems undertaken at the Rotunda Hospital during 2002 of which:

- 26 related to miscarriage / still births
- 25 related to still births > 500gm
- 14 related to live births
 - 65 Full post mortems (41% of total)
 - Prosector
 - Consultant Pathologist A undertook 47 post mortems for this year (72% of total post mortems)
 - Consultant Pathologist B undertook 18 post mortems for this year (28% of total post mortems)

3.2.4.2.1 Post mortems (Rotunda Hospital)

59 post mortems – accounting for 91% of post mortems undertaken in 2002.

3.2.4.2.2 Post mortems (Coroner)

4 post mortems – accounting for 6% of post mortems undertaken in 2002

- PM 22 Rotunda Hospital Coroner Post Mortem
- PM 23 Rotunda Hospital Coroner Post Mortem
- PM 24 Rotunda Hospital Coroner Post Mortem
- PM 25 Referred case from Louth for Coroner Post Mortem
 - of these 4 cases, there is a documented copy of report sent to Coroner in 3 instances by the Pathologist

3.2.4.2.3 Post mortems (Other Hospitals)

2 post mortems – accounting for 3% of post mortems undertaken in 2002

- PM 26 referred from Temple Street Hospital
- PM 27 referred from Portlaoise Hospital
 - of these 2 cases, there is a documented copy of report sent to hospital in only 1 instance by the Pathologist

3.2.4.2.4 Post Mortem – slide examination

4 cases which consisted of slide (from external hospital) examination only

- PM 28 referral of slides from Cavan General Hospital
- PM 29 referral of slides from Cork University Hospital
- PM 30 referral of slides from University College Cork
- PM 31 referral of slides from Crumlin Hospital

3.2.4.2.5 Post Mortem – referral of wet tissue

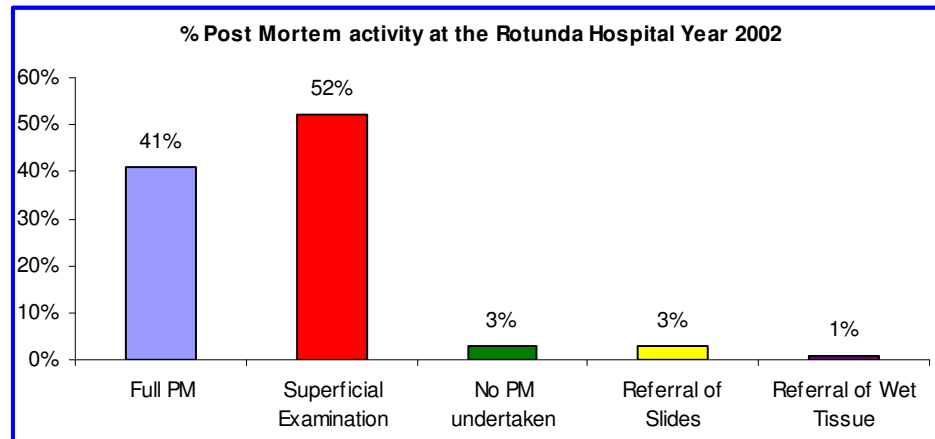
2 cases which consisted of wet tissue for examination only

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3.2.4.2.6 Post mortem reference number assigned, but no post mortem subsequently recorded as being undertaken

5 cases where a post mortem reference number was assigned, but no post mortem subsequently recorded as being undertaken

Graph 3.2.4.1 % Post Mortem activity at the Rotunda Hospital Year 2002



3.2.4.3 Superficial examinations

There were 83 superficial examinations undertaken at the Rotunda during 2002 of which:

- 61 related to miscarriage / < 500gm / did not live
- 13 related to still births > 500gm
- 9 related to live births
- 83 Superficial examinations (52% of total)
 - Prosector
 - Consultant Pathologist A undertook 50 superficial examinations for this year (60% of total post mortems)
 - Consultant Pathologist B undertook 32 superficial examinations for this year (39% of total post mortems)
 - Consultant Pathologist O undertook 1 superficial examination for this year (1% of total post mortems)

3.2.4.4 Review of related / relevant documentation (macro)

- post mortem file – 100% availability
- post mortem Report – complete – 69% availability
- post mortem Report – partial – 31% availability

- superficial file – 100% availability
- superficial examination report – 100% availability
- superficial examination report – partial 1% / 99% complete

- bereavement File – 99% availability

- patient File (Maternal) – 94% availability

3.2.4.5 Consent

3.2.4.5.1 Consent practice / policy

Consent Form **B** (reference) identified by Rotunda Hospital as being in use during 2002 (January - March)

Consent Form **C** (reference) identified by Rotunda Hospital as being in use during 2002 (March – December)

3.2.4.5.2 Consent record availability

Table 3.2.4.2 Consent record availability full post mortems

Consent Record availability / Full Post Mortems	
Consent Record available – Rotunda Cases	59
Consent Record not available – Rotunda Cases	0
Consent record available – Referral Cases	2
Coroner Cases	4
Total	65

- of the total post mortems requiring consent 100% consent records available (n=61) - (exclusion of 4 coroner cases)

Table 3.2.4.3 Consent record availability Superficial Examinations

Consent Record availability / Superficial Examinations	
Consent Record available	0
Consent Record not available	83
Total	83

- It should be noted no specific consent form for superficial examination was in place for the year 2002. 20 instances where consent was not granted for a full post mortem, this form was filed in the superficial file - in each instance a superficial examination was undertaken.
 - 1 instance documented evidence in the medical social work file that the mother granted full post mortem to be undertaken - this was subsequently retracted <15 minutes later. It is noted that mortuary staff were telephoned, the post mortem had not commenced and a superficial examination was subsequently undertaken.

Consent Documentation Review Full

Table 3.2.4.4 Consent Documentation Review Full

Consent Review	Number of cases
Granted for Post Mortem	57
Consent form not in file	0
Coroner Cases	4
Referred Hospital Cases / Full Granted for Post Mortem	2
Limited Consent	2
Total	65

The following is breakdown of consent forms for 2002 post mortems:

- 88% consent forms authorising hospital to undertake a post mortem
- 6% Coroner Cases (parental consent is not required)
- 3% Externally referred cases / Full consent granted for Post Mortem
- 3% Limited / restricted Post Mortem consent granted.

3.2.4.5.3 Limited / Restricted Post Mortem

- **PM 32** consent states agreement for all organs to be returned to the body, therefore the parents did not sign for reburial options Hospital or Personal arrangement. The consent form is witnessed by Consultant Pathologist A.
 - Retention of tissues and organs retained at autopsy may be made available Medical Education / Perinatal death.
- A memorandum as part of the Post Mortem report by Pathologist A states the parents were visited in order to obtain consent / explain the purpose of the autopsy.

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The memorandum is undated. No documented evidence of correction to the consent form post the Pathologists visit to the parents is noted.

- Three organs are listed on the retention sheet, Pituitary / Thyroid / Mesenteric, with a note stating tissues too small to be otherwise examined.
- Two months later the Royal Victoria Eye and Ear received blocks and slides titled 'Two halves of an eye' for microscopic examination. Tissue of the left eye is listed as retained on the retention sheet.
- There are 41 tissues in total listed as retained in this case.
- A reburial of organ is not listed in the return tissue book.
- A further 6 part organs / tissues have been retained for the purpose of medical education.
- **PM 33** states heart organ to remain with body – tissue of heart retained listed on retention sheet in accordance with consent form.

3.2.4.5.4 Non Research / Education Cases

- of the 14 cases, which are stored in the Mortuary (not retained for research / education purposes)
 - 6 instances baby was interred in Holy Angels Glasnevin – hospital to arrange reburial of organs / tissues – undated note in bereavement file *'awaiting blocking of tissue'*
 - 2 instances baby interred privately – hospital to arrange reburial of organs / tissues – documented letters from Rotunda to Family
 - 2 instances baby interred privately – hospital to arrange reburial of organs / tissues, note in bereavement file *'tissue only blocked 11.10.07 awaiting reburial'* / there is no evidence of correspondence to the families by the Rotunda Hospital
 - 1 Coroner Case, it is noted 'Rotunda had no involvement with the family – baby returned to Gardai 17.08.02 (Date of PM 16.08.02)
 - 1 instance baby interred in Holy Angels Glasnevin, hospital to arrange reburial of organs / tissues – undated note in the bereavement file *'awaiting reburial as blocking not completed by Pathology'*
 - 1 instance baby interred Holy Angels Glasnevin, personal arrangement for the reburial of organs / tissues – undated note in the bereavement file *'awaiting blocking of tissue'*
 - 1 instance baby interred privately - hospital to arrange reburial of organs / tissues – undated note in the bereavement file *'awaiting blocking of tissue'* / no evidence of letters sent to family by the hospital.

3.2.4.5.5 Consent Medical Education / Perinatal Death

- of the 8 cases, which are retained for Medical Education / Research purposes,
 - 7 instances consent granted for Medical Education / Perinatal Death
 - 1 instance consent granted for tissues only to be retained for Medical Education / Perinatal Death

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3.2.4.5.6 Non Compliance with Consent given

The following is a breakdown of non compliance with consent process

- **Retrospective Consent secured** (apparent)
There is 1 case where consent form had been signed by parents after the date of autopsy listed in the PM report:
 - PM 34 : Date of PM 27.09.02 → Consent granted 28.09.02
- **Limited consent / retention**
PM 32 reference **3.2.4.5.4** – consent record is contradictory in that family have stated all organs to be returned to the body and as well recorded agreement to tissue / organ retention for Medical Education / Perinatal death research.
- **Consent / Reburial**
 - of the 14 cases, which are stored in the Mortuary (not retained for research / education purposes)
 - 6 instances baby was interred in Holy Angels Glasnevin – hospital to arrange reburial of organs / tissues – undated note in bereavement file '*awaiting blocking of tissue*'
 - including PM 34 (apparent retrospective consent secured - for the purposes of non compliance it is listed once)
 - 2 instances baby interred privately – hospital to arrange reburial of organs / tissues, note in bereavement file '*tissue only blocked 11.10.07 awaiting reburial*' / there is no evidence of correspondence to the families by the Rotunda Hospital
 - 1 Coroner Case, it is noted 'Rotunda had no involvement with the family – baby returned to Gardai 17.08.02 (Date of PM 16.08.02)
 - 1 instance baby interred in Holy Angels Glasnevin, hospital to arrange reburial of organs / tissues – undated note in the bereavement file '*awaiting reburial as blocking not completed by Pathology*'
 - 1 instance baby interred Holy Angels Glasnevin, personal arrangement for the reburial of organs / tissues – undated note in the bereavement file '*awaiting blocking of tissue*' – no evidence of letters sent to family by the hospital
 - 1 instance baby interred privately - hospital to arrange reburial of organs / tissues – undated note in the bereavement file '*awaiting blocking of tissue*' / no evidence of letters sent to family by the hospital.

In total 13 cases are deemed non compliant – representing 20% of full post mortems

- **Consent Medical Education / Perinatal Death**
 - in 1 instance, parents deferred funeral arrangements until completion of post mortem. Organs were sampled at the time of the post mortem and returned to the body. Consent for retention of tissues only was granted for medical education / perinatal death. In this instance 7 part organs / tissues have been retained for the education / perinatal death.

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3.2.4.6 Date of delivery / death → date of post mortem

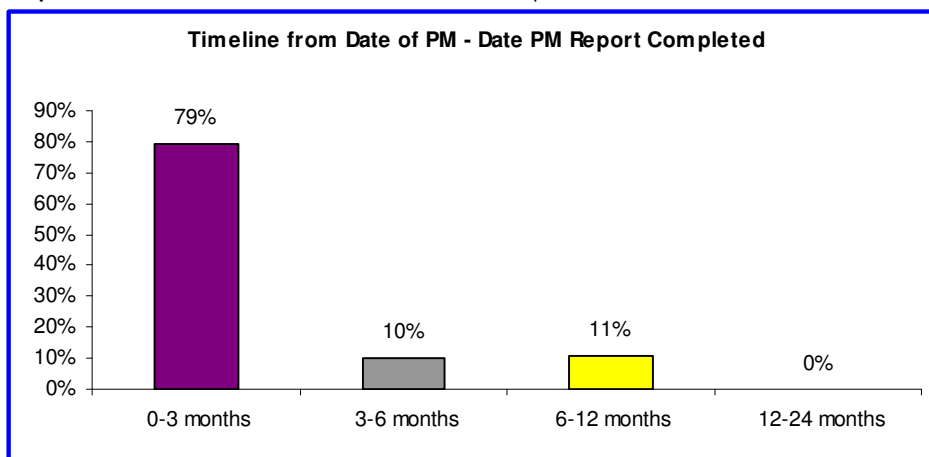
Table 3.2.4.5 summarises length of time date of delivery/ death → date of post mortem

Timeline	Same day as Date of Death	1-2 days	> 2 < 7 days	≥7 days	Date of Death not listed	Date of PM Not Recorded	Total
Number	6	33	24	0	1	1	65
%	9%	51%	37%	0%	2%	2%	

3.2.4.7 Date of post mortem → date of post mortem report

- 20% of reports are undated of the 80% reports which are dated
 - 79% are dated 0-3 months after post mortem
 - 10% are dated 3-6 months after post mortem
 - 11% are dated 6-12 months after post mortem
- in one instance where the Date of Post Mortem was not recorded, the Date of Death was used for the above comparator

Graph 3.2.4.6 Timeline from Date of PM – Date PM Completed



A sample of 19 cases were reviewed in order to ascertain Date of PM completion. Manual records provided from the hospital showed the dates on which slides made from blocks were released to the pathologist. Of these:

- 10 cases were released solely in 2002
- 1 case was released in 2002 and another release date in 2003
- 5 case was released solely in 2002 and another release date in 2008
- 1 case was released in 2002 with other release dates in 2003 and 2008
- 1 case was released in 2003 and another release date in 2008
- 1 case was released in 2005 and another release date in 2008

For cases that were dealt with after September 2003, the dates given are those on which blocks from which staining had not previously been requested are logged on the computer for staining

3.2.4.8 Post Mortem Report – examination

Post mortem report

- 20 are incomplete / not validated by Consultant Pathologist – representing 31% of full post mortem reports

Superficial Examination report

- 1 is incomplete / not validated by Consultant Pathologist – representing 1% of superficial examination reports

3.2.4.9 Inventory of cases currently stored at the Rotunda Hospital

Table 3.2.4.7 Inventory of Cases currently stored at the Rotunda Hospital

Origin of Cases	Number of cases
Rotunda Hospital cases	13
Coroner Case – not research based	1
Referral Hospital - not research based	0
Total Non research based	14
Medical Research / Education	8
Total Medical Research based	8
Total	22

There are 22 cases for 2002 where part organs / tissues are currently stored in the Mortuary.

This figure represents 34% of full post mortems.

- 14 cases were identified by the hospital at start of review
- 8 cases were identified as Medical / Education specimens at review end
 - In all of the above 22 cases an Independent Consultant Pathologist as part of this review has examined all material.
- of the 14 cases identified as stored / retained not for the purposes of Medical / Education
 - 14 instances Pathologist A undertook post mortem

3.2.4.10 Returned Tissue / Organ Register

Table 3.2.4.8 Returned Tissue / Organ Register

Returned Tissue Register	
Fully returned for burial	33
Part return for burial	6
Total	39

- 39 instances where the Return Tissue Register has logged a full / partial reburial of Tissue / Organs. Of these cases where the Post Mortem was undertaken in 2002:
 - 9 instances a return in 2002
 - 11 instances a return in 2003
 - 17 instances a return in 2005
 - 1 instance a return in 2006
 - 1 instance a return in 2007

3.2.4.11 Retention Sheet Record

64 retention sheets available - representing 98% of full post mortems undertaken
 → 2% unavailable

Average number of organs retained

- Consultant Pathologist A – 19
- Consultant Pathologist B – 2

Retrospective data entries

There are 3 cases where the retention sheet record has been completed retrospectively on 10.01.08. (RS)

- 1 case relate to post mortems undertaken by Consultant Pathologist A
- 2 cases relate to post mortems undertaken by Consultant Pathologist B
 - these retrospective entries were made by Consultant Pathologist A
 - **RS 7** compiled in retrospect by Consultant Pathologist A on 10.01.08 / Organs / Tissues returned for burial on 16.05.03
 - **RS 8** compiled in retrospect by Consultant Pathologist A on 10.01.08 / organs / tissues returned for burial on 02.02.07
 - **RS 9** compiled in retrospect by Consultant Pathologist A on 10.01.08 / no tissue left after post mortem completed on 08.11.02
 - it should be noted on compiling the retention sheet, Consultant Pathologist A listed one organ retained - confirmation

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subsequently by Consultant Pathologist B that infact no organs were retained in this case.

3.2.4.12 Overall Management of Cases

Table 3.2.4.9 Overall Management of Cases

Cases	Numbers
Returned Tissue Book	
- 39 cases	
- of these, there are 6 instances / cases where part organs / tissues are retained for Medical Research / Education.	33
Cases where part organ / tissues stored in Mortuary	22
Cases where documented evidence indicates there was no tissue left after Post Mortem Examination	7
No reburial details evident in files	0
Documented evidence whereby organs were sampled at time of PM and returned to body for burial	3
Total	65

- in total there are 39 cases listed in the return tissue book as returned for reburial
 - of these 39 cases
 - in 6 instances part were sent for reburial / part were retained for research
 - in 33 instances the case was completely sent for reburial
 - 22 cases are currently stored in the Mortuary (14 non research / 8 cases Medical Education / Research identified by the Rotunda Hospital)
 - 7 instances there was no tissue left after the post mortem was completed
 - No instances where no reburial details were evident in files
 - 3 instances the organs were sampled at the time of the post mortem and returned to the body

3.2.4.13 Supplementary Report in relation to Organ Retention Status 21.12.07 / 20.02.08

A supplementary report was provided to the review team identifying for 2002

- Status 21.12.07
 - of the 14 cases of organ retention 5 were complete awaiting reburial
 - delay identified in 2 cases 'private grave no reason in database'
 - delay identified in 1 case 'had *not been marked as complete*'
 - delay identified in 2 case 'private grave – 3 letters sent'
 - of the 9 cases identified as incomplete on 21.12.07
 - delay identified in 8 cases as '*incomplete*'
 - delay identified in 1 case as '*unblocked*'
- Status 20.02.08
 - of the 14 cases of organ retention 14 were complete awaiting reburial
 - key arrangements note identified
 - 7 instances 'Holy Angels Plot, Glasnevin – Hospital to arrange'
 - 3 instances 'Private Grave – permission required'
 - 2 instances '3 letters sent'
 - 1 instance 'personal arrangement – to be contacted'
 - 1 instance coroner case – '*no directions in autopsy suite – to be contacted*'
- A subsequent report from the Rotunda Hospital indicated in 1 instance where status on 21.12.07 was identified 'unblocked' → blocks had in fact been previously processed

This report was designed to assist this Review in understanding actions undertaken by hospital following National Audit visitation December 2007 (2.5)

3.2.5 Post Mortem Practice / Management (2003)

3.2.5.1 Number of post mortems recorded

- 193 of which:
 - 79 were post mortems (41% of total)
 - 109 were superficial examinations (56% of total)
- and
- 1 was examination of wet tissue (1% of total)
- and
- 4 where post mortem reference number assigned, but no post mortem subsequently recorded as being undertaken (2% of total)

3.2.5.2 Post mortems

There were 79 post mortems undertaken at the Rotunda Hospital during 2003 of which:

- 30 related to miscarriage / still births
- 29 related to still births > 500gm
- 19 related to live births
- 1 Adult case
 - 79 Full post mortems (41% of total)
 - Prosecutor
 - Consultant Pathologist A undertook 43 of post mortems for this year (54% of total post mortems)
 - Consultant Pathologist B undertook 33 of post mortems for this year (42% of total post mortems)
 - Consultant Pathologist P undertook 3 of post mortems for this year (4% of total post mortems)

3.2.5.2.1 Post mortems (Rotunda Hospital)

67 post mortems – accounting for 85% of post mortems undertaken in 2003.

3.2.5.2.2 Post mortems (Coroner)

7 post mortems – accounting for 9% of post mortems undertaken in 2003

- PM 35 Coroner case / infant transferred from Tralee subsequently died at Rotunda
 - whilst it is noted this case was not directed / initiated by the Coroner, the report was subsequently sent to the Coroner office. For the purpose of this report it is listed as a Coroner Case.
- PM 36 Rotunda Hospital Coroner Post Mortem
- PM 37 Adult Rotunda Hospital Coroner Post Mortem / elective caesarean performed and infant delivered at rotunda / mother died next morning
- PM 38 Referred Coroner Case from Our Lady of Lourdes Hospital, Drogheda for Post Mortem
- PM 39 Coroner case / infant delivered at home subsequently died at Rotunda
- PM 40 Rotunda Hospital Coroner Post Mortem
- PM 41 Rotunda Hospital Coroner Post Mortem
 - of these 7 cases, there is a documented copy of report sent to Coroner in 4 instances

Look Back Exercise – The Rotunda Hospital

3.2.5.2.3 Post mortems (Other Hospital)

5 post mortems – accounting for 6% of post mortems undertaken in 2003

- PM 42 referred from Limerick
- PM 43 referred from Portlaoise
- PM 44 referred from Portlaoise
- PM 45 referred from Beaumont
- PM 46 referred from Kilkenny
 - of these 5 cases – there is a copy of report sent to hospital in 3 instances

3.2.5.2.4 Post Mortem – slide examination

None identified

3.2.5.2.5 Post Mortem – referral of wet tissue

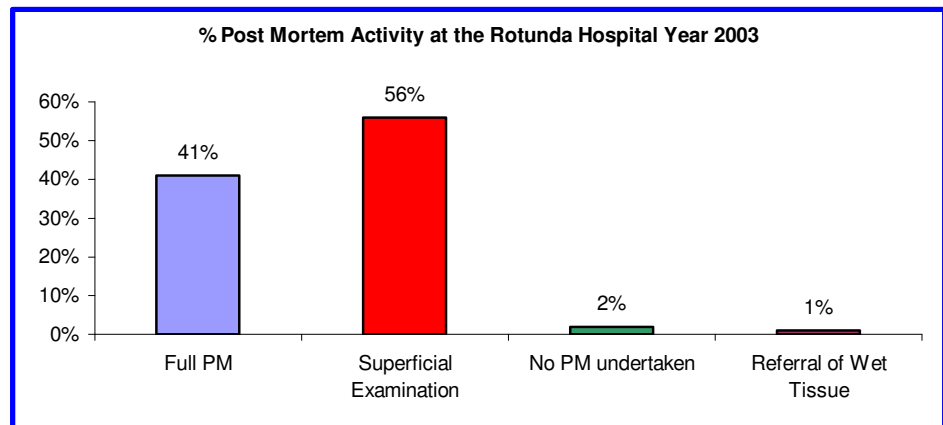
1 cases which consisted of wet tissue for examination only

3.2.5.2.6 Post mortem reference number assigned, but no post mortem subsequently recorded as being undertaken

4 cases where a post mortem reference number was assigned, but no post mortem subsequently recorded as being undertaken

In 1 instance the body was removed from NICU by the parents and was not taken to the mortuary. A report, generated by the pediatrician involved in the baby's care was typed by laboratory staff and signed by Pathologist B. No measurements / photographs / X-rays exist in this case.

Graph 3.2.5.1 % Post Mortem activity at the Rotunda Hospital Year 2003



3.2.5.3 Superficial examinations

There were 109 superficial examinations undertaken at the Rotunda during 2003 of which:

- 72 related to miscarriage / still births
- 18 related to still births > 500gm
- 19 related to live births
 - 109 Superficial examinations (56% of total)
 - Prosector
 - Consultant Pathologist A undertook 40 superficial examinations for this year (37% of total post mortems)
 - Consultant Pathologist B undertook 46 superficial examinations for this year (42% of total post mortems)
 - in 23 cases the superficial report was not available for review (21% of total)

Look Back Exercise – The Rotunda Hospital

3.2.5.4 Review of related / relevant documentation (macro)

- post mortem file – 100% availability
- post mortem Report – complete – 62% availability
- post mortem Report – partial – 38%

- post mortem (superficial) file – 100% availability
- superficial examination report – 79% availability
- superficial examination report – partial 3% / complete 97%

- bereavement File – 100% availability

- patient File (Maternal) – 93% availability

3.2.5.5 Consent

3.2.5.5.1 Consent practice / policy

Consent Form **C** (reference) identified by Rotunda Hospital as being in use during 2003 (Jan – December)

3.2.5.5.2 Consent record availability

3.2.5.2 Consent record availability Full Post Mortems

Consent Record availability / Full Post Mortems	
Consent Record available – Rotunda cases	63
Consent Record not available – Rotunda cases	4
Consent Record available – referred cases	5
Coroner Cases	7
Total	79

- of the total post mortems requiring consent 94% consent records available (n=68) / (exclusion of 7 coroner cases – although PM 35 is listed a Non Coroner directed PM full consent for PM was granted)

3.2.5.3 Consent record availability Superficial Examinations

Consent Record availability / Superficial Examinations	
Consent Record available	0
Consent Record not available	109
Total	109

- It should be noted no specific consent form for superficial examination was in place for the year 2003.
26 instances where consent was not granted for a full post mortem, this form was filed in the superficial file / in each instance a superficial examination was undertaken.

Look Back Exercise – The Rotunda Hospital

Consent Documentation Review Full

3.2.5.4 Consent Documentation Review Full

Consent Review	Number of cases
Granted for Post Mortem	63
Consent forms not in files	4
Coroner Cases (inc. PM01-03)	7
Referred Hospital Cases / Full Granted for Post Mortem	5
Limited Consent	0
Total	79

The following is breakdown of consent forms for 2003 post mortems:

- 80% consent forms authorising hospital to undertake a post mortem
- 5% consent forms not on file
- 9% Coroner Cases (parental consent is not required)
- 6% Referred cases / Full consent granted for Post Mortem

3.2.5.5.3 Limited / Restricted Post Mortem

None identified

3.2.5.5.4 Non Research / Education Cases

- of the 9 cases, which are stored in the Mortuary (not retained for research / education purposes)
 - 2 instances baby interred privately, hospital to arrange reburial of organ / tissues – undated note in bereavement file '*awaiting blocking of tissue*' no evidence of contact by Rotunda to families
 - 4 instances baby was interred in Holy Angels Glasnevin – hospital to arrange reburial of organs / tissues – undated note in bereavement file '*awaiting blocking of tissue*'
 - 1 coroner case, baby interred Holy Angels Glasnevin – note in bereavement file '*tissue only blocked 11.10.07* / report sent to Coroner 13.12.07
 - 1 instance baby interred privately, personal arrangement to be made, undated note in bereavement file '*? Pathology*'
 - 1 instance referred case, no bereavement file exists, however consent states hospital to arrange, there is no evidence of contact by Rotunda to the family

3.2.5.5.5 Consent Medical Education / Perinatal Death

- of the 3 cases, which are retained for Medical Education / Research purposes,
 - 3 instances consent granted for Medical Education / Perinatal Death

3.2.5.5.6 Non Compliance with Consent given

The following is a breakdown of non compliancy with consent process

- **Retrospective Consent secured**

There are 3 cases where consent form had been signed by parents after the date of autopsy listed in the PM report:

 - PM 47 : Date of PM 17.02.03 → Consent granted 18.02.03
 - PM 48 : Date of PM 14.04.03 → Consent granted 15.04.03
 - PM 49 : Date of PM 12.10.03 → Consent granted 13.10.03
 - it should be noted the hospital have subsequently identified that in 2 instances the signed pathology report identifying date of autopsy is inaccurate

Look Back Exercise – The Rotunda Hospital

- **Limited consent**
None identified

- **Consent / Reburial**
 - 2 instances baby interred privately, hospital to arrange reburial of organ / tissues – undated note in bereavement file ‘*awaiting blocking of tissue*’ no evidence of contact by Rotunda to families
 - *including PM47 (apparent retrospective consent secured - for the purposes of non compliance it is listed once)*
 - 4 instances baby was interred in Holy Angels Glasnevin – hospital to arrange reburial of organs / tissues – undated note in bereavement file ‘*awaiting blocking of tissue*’
 - 1 coroner case, baby interred Holy Angels Glasnevin – note in bereavement file ‘*tissue only blocked 11.10.07 / report sent to Coroner 13.12.07*’
 - 1 instance baby interred privately, personal arrangement to be made, undated note in bereavement file ‘*? Pathology*’
 - 1 instance referred case, no bereavement file exists, however consent states hospital to arrange, there is no evidence of contact by Rotunda to the family

In total 11 cases are deemed non compliant – representing 14% of full post mortems

3.2.5.6 Date of delivery / death → date of post mortem

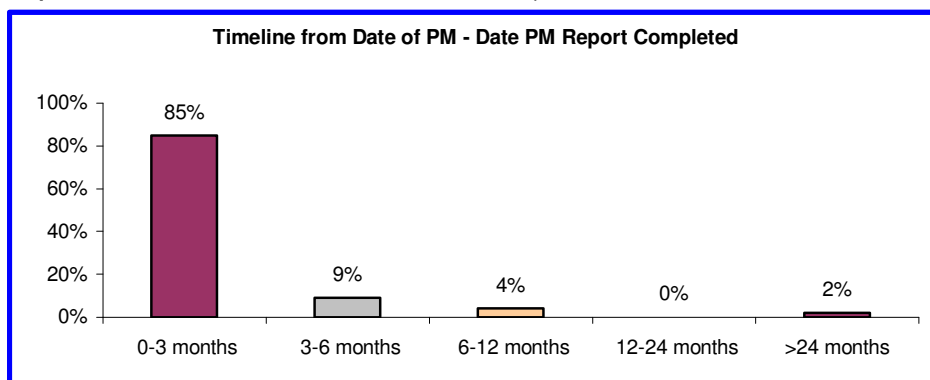
Table 3.2.5.5 summarises length of time from date of delivery/ death → date of post mortem

Timeline	Same day as Date of Death	1-2 days	> 2 < 7 days	≥7 days	Date of Death not listed	Date of PM Not Recorded	Total
Number	11	38	20	2	1	7	79
%	14%	48%	25%	3%	1%	9%	

3.2.5.7 Date of post mortem → date of post mortem report

- 30% of reports are undated
- of the 70% reports which are dated
 - 85% are dated 0-3 months after post mortem
 - 9% are dated 3-6 months after post mortem
 - 4% are dated 6-12 months after post mortem
 - 2% are dated > 2 years after post mortem

Graph 3.2.5.6 Timeline from Date of PM – Date PM Completed



Look Back Exercise – The Rotunda Hospital

A sample of 18 cases was reviewed in order to ascertain Date of PM completion. Manual records provided from the hospital showed the dates on which slides made from blocks were released to the pathologist.

For cases that were dealt with after September 2003, the dates given are those on which blocks from which staining had not previously been requested are logged on the computer for staining

- **for the period Jan – August 2003**
 - 8 cases where slides made from blocks were released to the Pathologist in 2003.
 - 2 cases were released in 2003 / other release date in 2008
 - 1 case released in 2003 / other release dates in 2005 and 2008
- **from September 2003:**
 - there is a computer record of the dates that staining was requested on blocks, and the dates on which the slides were released. The listed dates given to the audit team are the dates that stains were first requested on particular blocks. (circa PM39 onwards)
 - 2 cases were requested in 2003
 - 1 case was requested in 2003 / another request date in 2004
 - 1 case requested in 2003 / other request dates in 2003 and 2006
 - 1 case requested in 2003 / other request date in 2005
 - 2 cases requested in 2008 only

3.2.5.8 Post Mortem Report – examination

Full Post mortem report

- 30 are incomplete / not validated by Consultant Pathologist – representing 38% of full post mortem reports

Superficial Examination report

- 5 are incomplete / not validated by Consultant Pathologist – representing 6% of available superficial examination reports
 - in 23 cases the superficial report was not available (21% of total)

3.2.5.9 Inventory of cases currently stored at the Rotunda Hospital

Table 3.2.5.7 Inventory of cases currently stored at the Rotunda Hospital

Origin of Cases	Number of cases
Rotunda Hospital Cases	7
Referral Hospital – not research based	1
Coroner Case – not research based	1
Total Non research based	9
Medical Research / Education	2
Coroner Case – not coroner directed / research / education consent granted	1
Total Medical Research Based	3
Total	12

There are 12 cases for 2003 where part organs / tissues are currently stored in the Mortuary.

This figure represents 15% of full post mortems.

- 9 cases were identified by the hospital at start of review
- 3 cases were identified as Medical / Education specimens at review end of these:
- In all of the above 12 cases an Independent Consultant Pathologist as part of this review has examined all material.

Look Back Exercise – The Rotunda Hospital

- of the 9 cases identified as stored / retained not for the purposes of Medical / Education
 - 8 instances Pathologist A undertook the post mortem
 - 1 instances Pathologist B undertook the post mortem

3.2.5.10 Returned Tissue / Organ Register

Table 3.2.5.8 Returned Tissue / Organ Register

Returned Tissue Register	
Fully returned for burial	52
Part return for burial	3
Total	55

- 55 instances where the Return Tissue Register has logged a full / partial reburial of Tissue / Organs. Of these cases where the Post Mortem was undertaken in 2003:
 - 15 instances a return in 2003
 - 7 instances a return in 2004
 - 28 instances a return in 2005
 - 5 instances a return in 2006

3.2.5.11 Retention Sheet Record

53 retention sheets available - representing 67% of full post mortems undertaken

→ 33% unavailable

Average number of organs retained

- Consultant Pathologist A – 21
- Consultant Pathologist B – 3

Retrospective data entries

None identified.

3.2.5.12 Overall Management of Cases

Table 3.2.5.9 Overall Management of Cases

Cases	Numbers
Returned Tissue Book <ul style="list-style-type: none"> - 55 cases <ul style="list-style-type: none"> - of these, there are 3 instances / cases where part organs / tissues are retained for Medical Research / Education. 	52
Cases where part organ / tissues stored in Mortuary	12
No Reburial details evident in files	0
Cases where documented evidence indicates there was no tissue left after Post Mortem Examination	14
Documented evidence whereby organs were sampled at time of PM and returned to body for burial	1
Total	79

- in total there are 55 cases listed in the return tissue book as returned for reburial
 - of these 55 cases
 - in 3 instances part were sent for reburial / part were retained for research
 - in 52 instances the case was completely sent for reburial
 - 12 cases are currently stored in the Mortuary (9 non research / 3 cases Medical Education / Research identified by the Rotunda Hospital)
 - 14 instances there was no tissue left after the post mortem was completed
 - 1 instances the organs were sampled at the time of the post mortem and returned to the body

3.2.5.13 Supplementary Report in relation to Organ Retention Status 21.12.07 / 20.02.08

A supplementary report was provided to the review team identifying for 2003

- Status 21.12.07
 - of the 9 cases of organ retention 3 were complete awaiting reburial
 - 1 case of organ retention is listed as 'fragments only'
 - delay identified in 1 case 'not *not been marked as complete*'
 - delay identified in 1 case (Coroner) '? Letter sent'
 - delay identified in 1 case 'wish to make own arrangements ? letter sent
 - of the 6 cases identified as incomplete on 21.12.07
 - delay identified in 4 cases as '*incomplete*'
 - delay identified in 1 case as '*unblocked*'
- Status 20.02.08
 - of the 9 cases of organ retention 9 were complete awaiting reburial
 - key arrangements note identified
 - 4 instances 'Holy Angels Plot, Glasnevin – Hospital to arrange'
 - 3 instances 'Private Grave – permission required
 - 1 instance 'Holy Angels' '?letter required'
 - 1 instance 'desiccated fragments only – difficulty contacting undertakers'
- A subsequent report from the Rotunda Hospital confirmed in 1 instance where status on 21.12.07 was identified 'had not been marked as complete' / additional blocking had in fact taken place in 2008

This report also confirms in 1 case status on 21.12.07 as '*unblocked*' – no record of previous blocking exists

This report also confirms in 1 case status on 21.12.07 'not complete' / no record of blocks before 2008 and therefore should be included as 'unblocked'.

This report was designed to assist this Review in understanding actions undertaken by hospital following National Audit visitation December 2007 **(2.5)**

3.2.6 Post Mortem Practice / Management (2004)

3.2.6.1 Number of post mortems recorded

- 177 of which:
 - 83 were post mortems (47% of total)
 - 89 were superficial examinations (50% of total)
- and
- 1 were slide examinations referred by external hospitals (<1% of total)
- 1 were specimen for electron microscopy only (< 1% of total)
- and
- 3 where post mortem reference number was assigned, but no post mortem subsequently recorded as being undertaken (2% of total)

3.2.6.2 Post mortems

There were 83 post mortems undertaken at the Rotunda Hospital during 2004 of which:

- 33 related to miscarriage / still births
- 35 related to still births > 500gm
- 14 related to live births
- 1 adult case
 - 83 Full post mortems (47% of total)
 - Prosector
 - Consultant Pathologist A undertook 48 post mortems for this year (58% of total post mortems)
 - Consultant Pathologist B undertook 34 post mortems for this year (41% of total post mortems)
 - Consultant Pathologist P undertook 1 post mortem for this year (1% of total post mortems)

3.2.6.2.1 Post mortems (Rotunda Hospital)

74 post mortems – representing 89% of post mortems undertaken in 2004.

3.2.6.2.2 Post mortems (Coroner)

- 3 post mortems – accounting for 4% of post mortems undertaken in 2004
 - PM 50 Adult Post Mortem referred from the Mater Hospital
 - PM 51 Referred Coroner case from OLOL Hospital, Drogheda
 - PM 52 Rotunda Hospital Coroner Post Mortem
 - of these 3 cases, there is a documented copy of report sent to Coroner in all 3 instances.

3.2.6.2.3 Post mortems (Other Hospital)

6 post mortems – accounting for 7% of post mortems undertaken in 2004

- PM 53 referral from Portlaoise Hospital
- PM 54 referral from Coombe Hospital
- PM 55 referral from Coombe Hospital
- PM 56 referral from Portlaoise Hospital
- PM 57 referral from Cavan Hospital
- PM 58 referral from Portlaoise Hospital
 - of these 6 cases – there is a copy of report sent to hospital in only 3 instances

3.2.6.2.4 Post Mortem – slide examination / electron microscopy

1 cases which consisted of slide (from external hospital) examination only
1 case which consisted of specimen for electron microscopy only

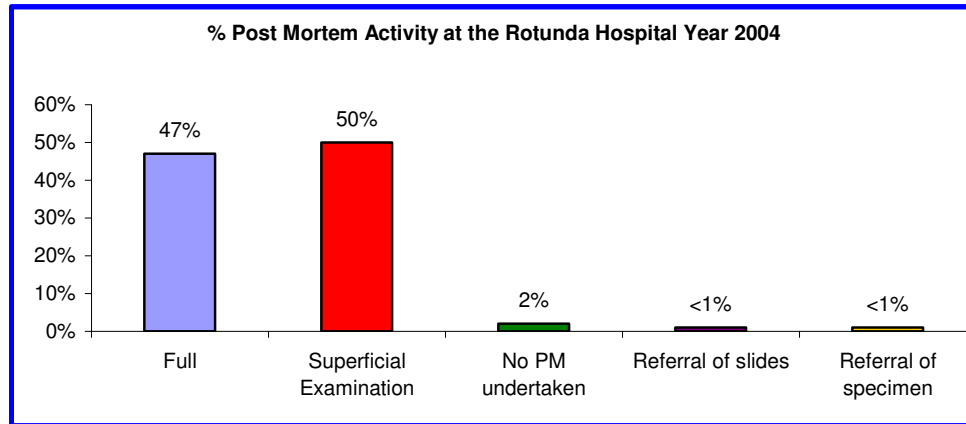
3.2.6.2.5 Post Mortem – referral of wet tissue

None identified

3.2.6.2.6 Post mortem reference number assigned, but no post mortem subsequently recorded as being undertaken

3 cases where a post mortem reference number was assigned, but no post mortem subsequently recorded as being undertaken

Graph 3.2.6.1 % Post Mortem activity at the Rotunda Hospital Year 2004



3.2.6.3 Superficial examination

There were 89 superficial examinations undertaken at the Rotunda during 2004 of which:

- 47 related to miscarriage / still birth
- 24 related to still births > 500gm
- 18 related to live births
- 89 Superficial examinations (50% of total)
 - Prosector
 - Consultant Pathologist A undertook 46 superficial examinations for this year (52% of total post mortems) – including referred superficial examinations.
 - Consultant Pathologist B undertook 33 superficial examinations for this year (37% of total post mortems)
 - Consultant Pathologist Q undertook 1 superficial examination for this year (1% of total post mortems)
 - in 1 instance both Pathologist A and B are listed for undertaking the superficial examination (1% of total post mortems)
 - in 8 instances the superficial report was not available for review (9% of total post mortems)

3.2.6.4 Review of related / relevant documentation (macro)

- post mortem file – 100% availability
 - post mortem Report – complete – 63% availability
 - post mortem Report – partial – 37% availability
- superficial file – 100% availability
 - superficial examination report – 91% availability
 - superficial examination report – partial 12% / 88% complete
- bereavement File – 99% availability
- patient File (Maternal) – 92% availability

3.2.6.5 Consent

3.2.6.5.1 Consent practice / policy

Rotunda Hospital Perinatal Autopsy Permission Form was in use for the full year 2004 - listed for the purposes of this report as Consent form C.

3.2.6.5.2 Consent record availability

Table 3.2.6.2 Consent record availability full post mortems

Consent Record availability / Full Post Mortems	
Consent Record available - Rotunda cases	68
Consent Record not available – Rotunda cases	6
Consent Record available – referred cases	6
Coroner Cases	3
Total	83

- of the total post mortems requiring consent 93% consent records available (n=74) / (exclusion of 3 coroner cases)

Table 3.2.6.3 Consent record availability superficial examinations

Consent Record availability / Superficial Examinations	
Consent Record available	0
Consent Record not available	89
Total	89

- It should be noted no specific consent form for superficial examination was in place for the year 2004. There are 14 instances where consent was not granted for a full post mortem, this was filed in the superficial file / in each instance a superficial examination was undertaken.

Consent Documentation Review Full

Table 3.2.6.4 Consent Documentation Review Full

Consent Review	Number of cases
Full Granted for Post Mortem	67
Consent forms not in files	6
Coroner Cases	3
Referred Hospital Cases / Full Granted for Post Mortem	6
Limited Consent	1
Total	83

The following is breakdown of consent forms for 2004 post mortems:

- 81% consent forms authorising hospital to undertake a post mortem
- 7% consent forms not on file
- 4% Coroner Cases (parental consent is not required)
- 7% Referred cases / Full consent granted for Post Mortem
- 1% Limited / restricted Post Mortem consent granted.

3.2.6.5.3 Limited / Restricted Post Mortem

PM 59 – limited consent granted which stipulated skull and no parts of CNS were to be examined. There is no retention sheet available in this case – however it is documented the post mortem was undertaken in compliance with parental consent / no tissue left after PM completed.

3.2.6.5.4 Non Research / Education Cases

- of the 12 cases, which are stored in the Mortuary (not retained for research / education purposes)
 - 3 instances baby interred in Holy Angels Glasnevin, hospital to arrange reburial of organ / tissues – undated note in bereavement file '*awaiting blocking of tissue*'
 - 2 instances baby interred privately, hospital to arrange reburial of organ / tissues, letters on file from Rotunda to families
 - 1 instance baby interred privately, there is no consent form on file (*see misplaced consent form (PM63)*)
 - 1 instance baby interred in Holy Angels Glasnevin, no consent form on file – undated note in bereavement file '*awaiting details from Pathology database*'
 - 1 instance baby interred privately – hospital to arrange cremation of organs / tissues – undated note in bereavement file '*awaiting blocking of tissue*'
 - 2 instances baby interred privately, personal arrangement for reburial of organs / tissues – undated note in bereavement file '*awaiting blocking of tissue*'
(1 case also retrospective consent secured apparent PM60)
 - 1 instance baby interred privately, hospital to arrange reburial of organs / tissues. No documented notes evident in this case / no evidence of contact from the Rotunda Hospital to the family.
 - 1 instance baby interred privately, private arrangement for reburial of organs / tissues – note in bereavement file '*tissue only blocked 12.10.07.*'

3.2.6.5.5 Consent Medical Education / Perinatal Death

None identified

3.2.6.5.6 Non Compliance with Consent given

The following is a breakdown of non compliancy with consent process

- **Retrospective Consent secured** (apparent)
There are 2 cases where consent form had been signed by parents after the date of autopsy listed in the PM report:
 - PM 60 : Date of PM 03.02.04 → consent granted on 04.02.04
 - PM 61 : Date of PM 03.05.04 → consent granted on 04.05.04
- **Apparent failure to obtain consent (PM62)**
 - Documented evidence on review of this case showed:
 - Date of Autopsy not listed
 - Witness to consent form not listed
 - Consent form not in file
 - Paediatric chart not available for review
 - Retention sheet is not in file
 - A memorandum on Page 13 of the Post Mortem Report exists titled 'Failure to obtain autopsy consent in infant (child's name)'
 - This memorandum states the autopsy permission being sought was in the interest of the parents rather than in the interest of the hospital's (Department of Paediatrics). The registrar was sent to the mother to discuss the possibility of recurrence – '*this however was of no avail*'. This memorandum suggests that a full post mortem was undertaken without parental consent, stating 'it is noteworthy

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where a consultant feels an autopsy is required it is likely the consultant will actually make the request’.

The memorandum states ‘the autopsy could have revealed something of the cause for respiratory insufficiency occurring at 5 hours’

- on review of Histopathology records the following dates where stains were first requested on particular blocks are as follows:
 - 17.06.04 - 74 blocks
 - 02.07.04 - 10 blocks
 - 04.01.05 - 7 blocks (Total 91 blocks)
- documented evidence states a reburial of part organ/tissue was undertaken on 12.04.05 to Holy Angels, same location where the baby was interred one year earlier on 22.04.04
- The report is signed by Pathologist A on 25.08.06

Consultant A has explained:

- memorandum written before consent was subsequently obtained
- based on clinical history / superficial examination undertaken, requirements to undertake autopsy to establish cause of death
- consent subsequently obtained from mother
- autopsy undertaken

However the Review Team would emphasis consent record not made available by Hospital.

- **Misplaced consent form (PM63) – also listed under Non Research / Education Cases**
 - documented evidence on review of this case showed no consent form on file. A memorandum dated Sunday 7.11.04 exists as part of the PM report titled ‘Missing Autopsy Consent Form, PM63’.
 - The memorandum, by Pathologist A states that the consent form was not in the maternity file on review.
 - Subsequently the pathologist contacted the consultant by telephone who confirmed permission had been granted / said consultant had witnessed consent form.
 - The Pathologist undertook the Post Mortem on the conclusion that the form had been misplaced.
 - There is no evidence that the consultant / pathologist contacted the parents to seek new written consent / clarify full permission for autopsy granted.
 - 17 part organs / tissues pertaining to this case are currently stored in the Mortuary.
- **Consent / Reburial**
 - of the 12 cases, which are stored in the Mortuary (not retained for research / education purposes)
 - 3 instances baby interred in Holy Angels Glasnevin, hospital to arrange reburial of organ / tissues – undated note in bereavement file ‘awaiting blocking of tissue’
 - 1 instance baby interred privately, there is no consent form on file
(see misplaced consent form (PM63 - for the purposes of non compliance it is listed once)

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- 1 instance baby interred in Holy Angels Glasnevin, no consent form on file – undated note in bereavement file *'awaiting details from Pathology database'*
- 1 instance baby interred privately – hospital to arrange cremation of organs / tissues – undated note in bereavement file *'awaiting blocking of tissue'*
- 2 instances baby interred privately, personal arrangement for reburial of organs / tissues – undated note in bereavement file *'awaiting blocking of tissue'*
(1 case also retrospective consent secured apparent PM60-for the purposes of non compliance it is listed once)
- 1 instance baby interred privately, hospital to arrange reburial of organs / tissues. No documented notes evident in this case / no evidence of contact from the Rotunda Hospital to the family.
- 1 instance baby interred privately, private arrangement for reburial of organs / tissues – note in bereavement file *'tissue only blocked 12.10.07.'*

In total 12 cases are deemed non compliant – representing 14% of full post mortems

3.2.6.6 Date of deliver / death → date of post mortem

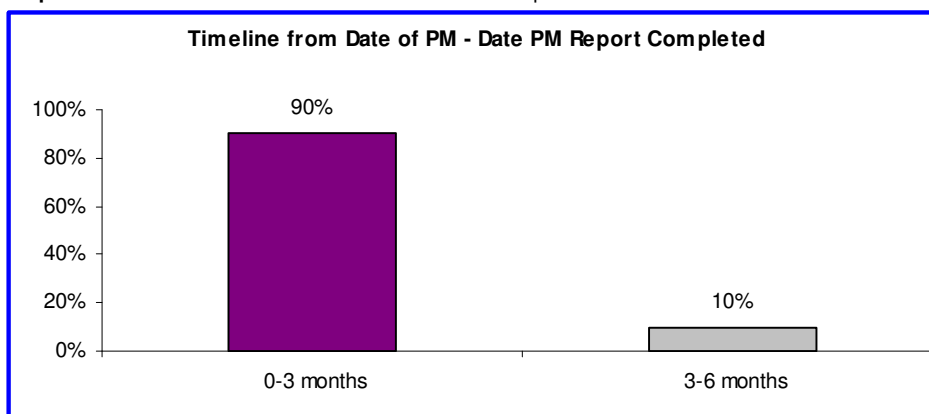
Table 3.2.6.5 summarises length of time from date of delivery/ death → date of post mortem

Timeline	Same day as Date of Death	1-2 days	> 2 < 7 days	≥7 days	Date of Death not listed	Date of PM Not Recorded	Total
Number	5	50	16	0	1	11	83
%	6%	60%	19%	0%	1%	13%	

3.2.6.7 Date of post mortem → date of post mortem report

- 13% of reports are undated
- of the 87% reports which are dated
 - 90% are dated 0-3 months after post mortem
 - 10% are dated 3-6 months after post mortem
- in 11 instances where the Date of Post Mortem was not recorded, the Date of Death was used for the above comparator

Graph 3.2.6.6 Timeline from Date of PM – Date PM Completed



A sample of 18 cases was reviewed in order to ascertain Date of PM completion. Computerised records showed the dates that the stains were first requested on blocks by the Pathologist.

Look Back Exercise – The Rotunda Hospital

Of these:

- 9 cases were request solely in 2004
- 2 cases was request in 2004 and another request date in 2008
- 2 cases were requested in 2004 and another request date in 2005
- 1 case was requested in 2004 and other request dates in 2006 and 2008
- 1 case was requested solely in 2005
- 2 cases was request in 2006 and another request date in 2008
- 1 case was request solely in 2008

3.2.6.8 Post Mortem Report – examination

Full Post mortem report

- 31 are incomplete / not validated by Consultant Pathologist – representing 37% of full post mortem reports

Superficial Examination report

- 10 are incomplete / not validated by Consultant Pathologist – representing 12% of available superficial examination reports
 - In 8 instances the superficial examination report was not available

3.2.6.9 Inventory of cases currently stored at the Rotunda Hospital

Table 3.2.6.7 Inventory of cases currently stored at the Rotunda Hospital

Origin of Cases	Number of cases
Rotunda Hospital Cases	12
Referral Hospital –not research based	0
Coroner Case – not research based	0
Total Non Research Based	12
Medical Research / Education	0
Total	12

There are 12 cases for 2004 where part organs / tissues are currently stored in the Mortuary.

This figure represents 14% of full post mortems.

- all 12 cases were identified by the hospital at start of review
 - In all of the above 12 cases an Independent Consultant Pathologist as part of this review has examined all material.
- of the 12 cases identified as stored / retained not for the purposes of Medical / Education
 - 11 instances Pathologist A undertook the post mortem
 - 1 instances Pathologist B undertook the post mortem

3.2.6.10 Returned Tissue / Organ Register

Table 3.2.6.8 Returned Tissue / Organ Register

Returned Tissue Register	
Fully returned for burial	47
Part return for burial	0
Total	47

- 47 instances where the Return Tissue Register has logged a full reburial of Tissue / Organs. Of these cases where the Post Mortem was undertaken in 2004:
 - 3 cases returned in 2004
 - 35 cases returned in 2005
 - 4 cases returned in 2006
 - 5 cases returned in 2007

3.2.6.11 Retention Sheet Record

59 retention sheets available - representing 71% of full post mortems undertaken
 → 29% unavailable

Average number of organs retained

- Consultant Pathologist A – 22
- Consultant Pathologist B – 2
- **PM 64**
 - 2 retention sheets on this case in the PM file. The first retention sheet lists 24 complete organs / 15 tissues. The second retention sheet lists 21 complete organs / 16 tissues retained. For the purposes of the above comparator this case was excluded.

Retrospective data entries

None identified

3.2.6.12 Overall Management of Cases

Table 3.2.6.9 Overall Management of Cases

Cases	Numbers
Returned Tissue Book	47
Cases where part organ / tissues stored in Mortuary	12
No Reburial details evident in files	1
Cases where documented evidence indicates there was no tissue left after Post Mortem Examination	21
Documented evidence whereby organs were sampled at time of PM and returned to body for burial	2
Total	83

- in total there are 47 cases listed in the return tissue book as returned for reburial
 - 12 cases are currently stored in the Mortuary (12 non research)
 - 21 instances there was no tissue left after the post mortem was completed
 - 2 instances the organs were sampled at the time of the post mortem and returned to the body
 - 1 instance no reburial details evident in file

3.2.6.13 Supplementary Report in relation to Organ Retention Status 21.12.07 / 20.02.08

A supplementary report was provided to the review team identifying for 2004

- Status 21.12.07
 - of the 12 cases of organ retention 5 were complete awaiting reburial
 - delay identified in 1 case 'letter written 17.11.07'
 - delay identified in 1 case 'private grave – to contact'
 - delay identified in 1 case 'hospital to bury or cremate; where? to Contact'
 - delay identified in 1 case '1st and 2nd registered letters of 16.08.07 and 07.11.07 returned'
 - delay identified in 1 case 'private grave; no consent form in pm file'
 - of the 7 cases identified as incomplete on 21.12.07
 - delay identified in 4 cases as '*unblocked*'
 - delay identified in 3 case as '*not complete*'
- Status 20.02.08
 - of the 12 cases of organ retention 11 were complete awaiting reburial
 - key arrangements note identified

Look Back Exercise – The Rotunda Hospital

- 1 instance unblocked status on 20.02.08 *'not complete'*
 - 1 instance cremation form needs to be completed
 - 2 instances *'private grave – permission required'*
 - 2 instances *'Private Grave – personal arrangements – to be contacted'*
 - 3 instances hospital to arrange reburial of organ / tissues at Holy Angels Glasnevin
 - 1 instance *'check bereavement file'*
 - 1 instance *'3rd registered letter required'*
 - 1 instance *'? Consent form for instructions'*
- A subsequent report from the Rotunda Hospital confirmed in 3 instances where status on 21.12.07 was identified 'unblocked' / blocks were previously processed in these cases.

This report also confirms in 1 case status on 21.12.07 as 'unblocked' – no record of previous blocking exists

This report was designed to assist this Review in understanding actions undertaken by hospital following National Audit visitation December 2007(2.5)

3.2.7 Post Mortem Practice / Management (2005)

3.2.7.1 Number of post mortems recorded

- 197 of which:
 - 89 were post mortems (45% of total)
 - 97 were superficial examinations (49% of total)
- and
- 3 were slide examinations referred by external hospitals (2% of total)
- and
- 8 where post mortem reference number assigned, but no post mortem subsequently recorded as being undertaken (4% of total)

3.2.7.2 Post mortems

There were 89 full post mortems undertaken at the Rotunda Hospital during 2005 of which:

- 41 related to miscarriage / still births
- 36 related to still births > 500gm
- 12 related to live births
 - 89 Full post mortems (45% of total)
 - Prosecutor
 - Consultant Pathologist A undertook 57 post mortems for this year (64% of total post mortems)
 - Consultant Pathologist B undertook 31 post mortems for this year (35% of total post mortems)
 - Consultant Pathologist P undertook 1 post mortems for this year (1% of total post mortems)

3.2.7.2.1 Post mortems (Rotunda Hospital)

78 post mortems – accounting for 88% of post mortems undertaken in 2005

3.2.7.2.2 Post mortems (Coroner)

5 post mortems – accounting for 6% of post mortems undertaken in 2005

- PM 65 Coroner case referred from Mt. Carmel
- PM 66 Rotunda Hospital Coroner Post Mortem
- PM 67 Rotunda Hospital Coroner Post Mortem
- PM 68 Rotunda Hospital Coroner Post Mortem
- PM 69 Rotunda Hospital Coroner Post Mortem
 - of these 5 cases, there is a documented copy of report sent to Coroner in 2 instances.

3.2.7.2.3 Post mortems (Other Hospital)

6 post mortems – accounting for 6% of post mortems undertaken in 2005

- PM 70 referred from Portlaoise Hospital for full post mortem
- PM 71 referred from Portlaoise Hospital for full post mortem
- PM 72 referred from Portlaoise Hospital for full post mortem
- PM 73 referred from Mullingar Hospital for full post mortem
- PM 74 referred from Portlaoise Hospital for full post mortem
- PM 75 referred from Portlaoise Hospital for full post mortem
 - of these 6 cases – there is a copy of report sent to hospital in only 1 instance

3.2.7.2.4 Post Mortem – slide examination

3 cases which consisted of slide (from external hospital) examination only

3.2.7.2.5 Post Mortem – referral of wet tissue

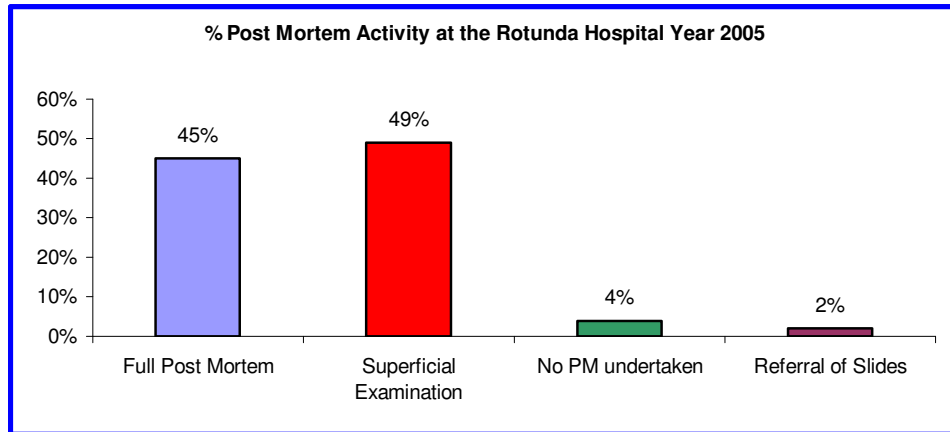
None identified

Look Back Exercise – The Rotunda Hospital

3.2.7.2.6 Post mortem reference number assigned, but no post mortem subsequently recorded as being undertaken

8 cases where a post mortem reference number was assigned, but no post mortem subsequently recorded as being undertaken

Graph 3.2.7.1 % Post Mortem activity at the Rotunda Hospital Year 2005



3.2.7.3 Superficial examinations

There were 97 superficial examinations undertaken at the Rotunda during 2005 of which:

- 70 related to miscarriage / < 500gm / did not live
- 15 related to still births > 500gm
- 12 related to live births
- 97 Superficial examinations (49% of total)
 - Prosector
 - Consultant Pathologist A undertook 52 superficial examinations for this year (54% of total post mortems)
 - Consultant Pathologist B undertook 31 superficial examinations for this year (32% of total post mortems)
 - Consultant Pathologist R undertook 7 superficial examinations for this year (7% of total post mortems)
 - in 7 instances there was no superficial examination report available for review (7% of total post mortems)

3.2.7.4 Review of related / relevant documentation (macro)

- post mortem file – 100% availability
- post mortem Report – complete – 64% availability
- post mortem Report – partial – 36% availability

- superficial examination report – 93% availability
- superficial examination report – partial 1% / complete 99%

- bereavement File – 100% availability
- patient file (Maternal) – 94% availability

3.2.7.5 Consent

3.2.7.5.1 Consent practice / policy

Rotunda Hospital Perinatal Autopsy Permission Form was in use from January – November 2005 / listed for the purposes of this report as Consent form **C**.

Rotunda Hospital Perinatal Autopsy Permission Form was introduced in November 2005, listed for the purposes of this report as Consent Form **D**.

Look Back Exercise – The Rotunda Hospital

3.2.7.5.2 Consent record availability

Table 3.2.7.2 Consent Record Availability Full Post Mortems

Consent Record availability / Full Post Mortems	
Consent Record available - Rotunda cases	75
Consent Record not available – Rotunda cases	3
Consent Record available – referred cases	6
Coroner Cases	5
Total	89

- of the total post mortems requiring consent 96% consent records available (n=81) / (exclusion of 5 coroner cases)

Table 3.2.7.3 Consent Record Availability Superficial Examinations

Consent Record availability / Superficial Examinations	
Consent Record available	3
Consent Record not available	94
Total	97

- consent record available
 - 1 instance stating – consent for blood (skin genetics only)
 - 1 instance stating – consent for skin biopsy only
 - 1 instance stating – consent for skin biopsy and superficial examination
 - 3% consent records available (n=3).
 - It should be noted no specific consent form for superficial examination was in place for the year 2005, however the consent form **D** was introduced in November 2005 incorporated the following:
 ‘N.B. I understand that all babies removed to the mortuary that are not having an autopsy performed, undergo a brief external examination which includes photographs, an x-ray and body measurements for the purposes of maintaining a medical record for the baby’
 - There are 14 instances where consent was not granted for a full post mortem, this was filed in the superficial file / in each instance a superficial examination was undertaken.

Consent Documentation Review Full

Table 3.2.7.4 Consent Documentation Review Full

Consent Review	Number of cases
Full Granted for Post Mortem	74
Consent forms not in files	3
Coroner Cases	5
Referred Hospital Cases / Full Granted for Post Mortem	5
Limited Consent (1 referral / 1 rotunda case)	2
Total	89

The following is breakdown of consent forms for 2005 post mortems

- 83% consent forms authorising hospital to undertake a post mortem
- 3% consent forms not on file
- 6% Coroner Cases (parental consent is not required)
- 6% externally referred cases / Full consent granted for Post Mortem
- 2% Limited / restricted Post Mortem consent granted.

3.2.7.5.3 Limited / Restricted Post Mortem

- **PM 71** Referred Post Mortem from Portlaoise
 - In this instance consent states that all organs to be returned to the body prior to burial
 - the bereavement file in this case does not exist as it was an external referral from Portlaoise

Look Back Exercise – The Rotunda Hospital

- The parents have ticked 'no' to receiving a copy of the 'frequently asked questions booklet'.
- The retention sheet has 23 complete organs listed as retained - 11 samples / tissues retained.
- It is noted in the return tissue book that on 10.06.05 a return was made to Portlaoise.
- There is no evidence that the report of Pathologist A was sent to Portlaoise.

- Consultant A has identified meeting with the parents to advise consent inadequate, subsequent agreement to securing organ retention. It should be noted no revised consent evident.

- **PM 76**
 - Parents have stated on consent form that baby's heart be returned to body prior to burial.
 - The retention sheet has sample of heart ticked as retained conforming with the consent given and brain removed for examination.
 - There is no documented evidence by Pathologist A to indicate the heart was fast fixed and returned to the body.
 - A reburial of organ retained is noted in the return tissue book on 19.05.06 to Holy Angels Glasnevin.

3.2.7.5.4 Non Research / Education Cases

- of the 16 cases, which are stored in the Mortuary (not retained for research / education purposes)
 - 9 instances baby interred at Holy Angels Glasnevin, hospital to arrange reburial of organ / tissue – undated note in bereavement file '*awaiting blocking of tissue*'
 - 3 instances baby interred privately, hospital to arrange reburial of organ / tissue – note in bereavement file '*tissue only blocked 11.10.07*'
 - 2 instances baby interred privately, personal arrangement for reburial of organ / tissue – note in bereavement file '*tissue only blocked 11.10.07*'
 - 1 instance baby interred at Holy Angels Glasnevin, hospital to arrange cremation of organ / tissue, undated note in bereavement file – '*awaiting blocking of tissue*'
 - 1 instance baby interred at Holy Angels Glasnevin, personal arrangement for reburial of organ / tissue, undated note in bereavement file '*awaiting blocking of tissue*'

3.2.7.5.5 Consent Medical Education / Perinatal Death

- of the 1 case which is retained for Medical Education / Research purposes
 - consent is granted for Perinatal Death Research – also specific consent for retention of heart (hyponastic left heart with attached lungs)

3.2.7.5.6 Non Compliance with Consent given

The following is a breakdown of non compliancy with consent process

- **Retrospective Consent secured** (apparent)
None identified
- **Limited consent**
PM 71 (**reference 3.2.7.5.3**)

Look Back Exercise – The Rotunda Hospital

Consent / Reburial

- of the 16 cases, which are stored in the Mortuary (not retained for research / education purposes)
 - 9 instances baby interred at Holy Angels Glasnevin, hospital to arrange reburial of organ / tissue – undated note in bereavement file *'awaiting blocking of tissue'*
 - 3 instances baby interred privately, hospital to arrange reburial of organ / tissue – note in bereavement file *'tissue only blocked 11.10.07'*
 - 2 instances baby interred privately, personal arrangement for reburial of organ / tissue – note in bereavement file *'tissue only blocked 11.10.07'*
 - 1 instance baby interred at Holy Angels Glasnevin, hospital to arrange cremation of organ / tissue, undated note in bereavement file – *'awaiting blocking of tissue'*
 - 1 instance baby interred at Holy Angels Glasnevin, personal arrangement for reburial of organ / tissue, undated note in bereavement file *'awaiting blocking of tissue'*

The Review Group would highlight minutes of Post Mortem Committee recording in relation to reburial of tissue *"no major problem for previous six months"*

In total 17 cases are deemed non compliant – representing 19% of full post mortems.

3.2.7.6 Date of delivery / death → date of post mortem

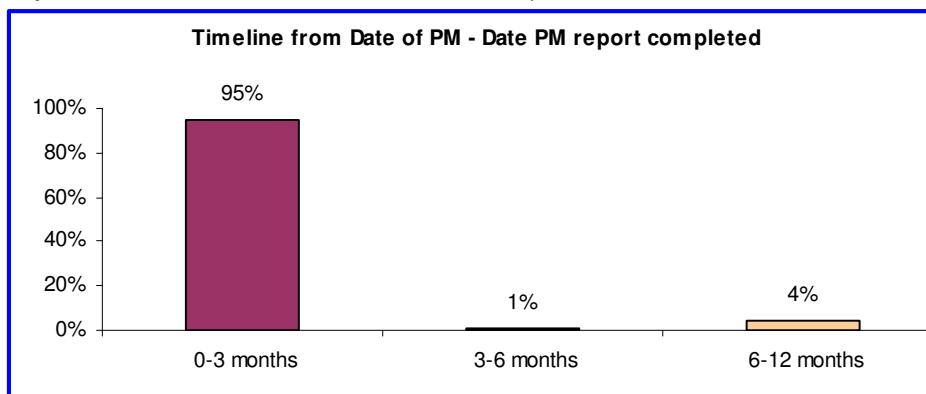
Table 3.2.7.5 summarises length of time from date of delivery/ death → date of post mortem

Timeline	Same day as Date of Death	1-2 days	> 2 < 7 days	≥7 days	Date of Death not listed	Date of PM Not Recorded	Total
Number	4	41	20	1	0	23	89
%	4%	46%	22%	1%	0%	26%	

3.2.7.7 Date of post mortem → date of post mortem report

- 7% of reports are undated
- of the 93% reports which are dated
 - 95% are dated 0-3 months after post mortem
 - 1% are dated 3-6 months after post mortem
 - 4% are dated 6-12 months after post mortem
- in 23 instance where the Date of Post Mortem was not documented, the Date of Death was used for the above comparator

Graph 3.2.7.6 Timeline from Date of PM – Date PM Completed



Look Back Exercise – The Rotunda Hospital

A sample of 19 cases was reviewed in order to ascertain Date of PM completion. Computerised records showed the dates that the stains were first requested on blocks by the Pathologist. Of these:

- 9 cases were requested solely in 2005
- 3 cases was requested in 2005 and another request date in 2006
- 2 cases were requested in 2005 and another request date in 2008
- 2 cases was requested in 2005 and other request dates in 2006 and 2008
- 2 cases was requested solely in 2006
- 1 case was requested in 2006 and another request date in 2008

3.2.7.8 Post Mortem Report – examination

Full Post mortem report

- 32 are incomplete / not validated by Consultant Pathologist – representing 36% of full post mortem reports

Superficial Examination report

- 1 are incomplete / not validated by Consultant Pathologist – representing 1% of available superficial examination reports

3.2.7.9 Inventory of cases currently stored at the Rotunda Hospital

Table 3.2.7.7 Inventory of cases currently stored at the Rotunda Hospital

Origin of Cases	Number of cases
Rotunda Hospital cases	16
Referred Hospital – not research based	0
Coroner Cases – not research based	0
Total Non Research based	16
Medical Research / Education (referral case Mullingar)	1
Total	17

There are 17 cases for 2005 where part organs / tissues are currently stored in the Mortuary.

This figure represents 19% of full post mortems.

- 16 cases were identified by the hospital at start of review
- 1 case identified as Medical / Education specimen at review end
 - In all of the above 17 cases an Independent Consultant Pathologist as part of this review has examined all material.
- of the 16 cases identified as stored / retained not for the purposes of Medical / Education
 - 15 instances Pathologist A undertook the post mortem
 - 1 instance Pathologist B undertook the post mortem

3.2.7.10 Returned Tissue / Organ Register

Table 3.2.7.8 Return Tissue / Organ Register

Returned Tissue Register	
Fully returned for burial	51
Part return for burial	1
Total	52

- 52 instances where the Return Tissue Register has logged a full / partial reburial of Tissue / Organs. Of these cases where the Post Mortem was undertaken in 2005:
 - 24 cases returned in 2005
 - 27 cases returned in 2006
 - 1 case returned in 2007

3.2.7.11 Retention Sheet Record

84 retention sheets available - representing 94% of full post mortems undertaken

→ 6% unavailable

Average number of organs retained

- Consultant Pathologist A – 21

- Consultant Pathologist B – 2

- **PM 77**

- There are 2 retention sheets on this case in the Post Mortem file – 1 of which is listed under Retrospective data entries below. For the purpose of the above comparator this case was excluded.

Retrospective data entries

There are 16 cases where the retention sheet record has been completed retrospectively (RS)

- all cases relate to post mortems undertaken by Consultant Pathologist A
 - **RS 10** compiled in retrospect by Consultant Pathologist A on 15.01.08 → Organs / tissues returned for reburial on 28.08.05
 - **RS 11** compiled in retrospect by Consultant Pathologist A on 15.01.08 → Organs / tissues returned for reburial on 29.07.05
 - **RS 12** compiled in retrospect by Consultant Pathologist A on 15.01.08 → Organs / tissues returned for reburial on 20.08.05
 - **RS 13** compiled in retrospect by Consultant Pathologist A on 15.01.08 → Organs / tissues returned for reburial on 20.08.05
 - **RS 14** compiled in retrospect by Consultant Pathologist A on 15.01.08 → Organs / tissues returned for reburial on 20.08.05
 - **RS 15** compiled in retrospect by Consultant Pathologist A on 15.01.08 → Organs / tissues returned for reburial on 17.06.05
 - **RS 16 / PM 70** compiled in retrospect by Consultant Pathologist A on 15.01.08 → Organs / tissues returned for reburial on 21.06.05 / Portlaoise case (reference 3.2.7.2.3)
 - **RS 17** compiled in retrospect by Consultant Pathologist A on 15.01.08 → Organs / tissues returned for reburial on 20.08.05
 - **RS 18** compiled in retrospect by Consultant Pathologist A on 15.01.08 → Organs / tissues returned for reburial on 12.08.05
 - **RS 19** compiled in retrospect by Consultant Pathologist A on 15.01.08 → documented evidence - no tissue left after PM completed
 - **RS 20** compiled in retrospect by Consultant Pathologist A on 15.01.08 → Organs / tissues returned for reburial on 19.05.06
 - **RS 21 / PM 73** compiled in retrospect by Consultant Pathologist A on 14.01.08 → Organs / tissues returned for reburial on 10.09.06 / Mullingar case (reference 3.2.7.2.3)
 - **RS 22** compiled in retrospect by Consultant Pathologist A on 14.01.08 → Organs / tissues returned for reburial on 02.06.06
 - **RS 23 / PM 74** compiled in retrospect by Consultant Pathologist A on 15.01.08 → Organs / tissues returned for reburial on 01.09.06
 - **RS 24 / PM 77** compiled in retrospect by Consultant Pathologist A on 14.01.08 → Organs / tissues returned for reburial on 10.09.06 (there are 2 retention sheets listed in this case) / Coroner case (reference 3.2.7.2.2)
 - **RS 25** compiled in retrospect by Consultant Pathologist A on 14.01.08 / Organs / tissues returned for reburial on 10.10.06

Look Back Exercise – The Rotunda Hospital

There are 7 cases where the superficial examination report has been compiled / signed in retrospect (RS)

- all cases relate to superficial examinations undertaken by Consultant Pathologist A
 - **RS 26** compiled / signed in retrospect by Consultant Pathologist A on 31.01.08
 - **RS 27** compiled / signed in retrospect by Consultant Pathologist A on 31.01.08
 - **RS 28** compiled / signed in retrospect by Consultant Pathologist A on 31.01.08
 - **RS 29** compiled / signed in retrospect by Consultant Pathologist A on 31.01.08
 - **RS 30** compiled / signed in retrospect by Consultant Pathologist A on 31.01.08
 - **RS 31** compiled / signed in retrospect by Consultant Pathologist A on 01.02.08
 - **RS 32** compiled / signed in retrospect by Consultant Pathologist A on 01.02.08

3.2.7.12 Overall Management of Cases

Table 3.2.7.9 Overall Management of Cases

Cases	Numbers
Returned Tissue Book <ul style="list-style-type: none"> - 52 cases <ul style="list-style-type: none"> - Of these, there is 1 instance / case where part organs / tissues are retained for Medical Research / Education 	51
Cases where part organ / tissues stored in Mortuary	17
No Reburial details evident in files	1
Cases where documented evidence indicates there was no tissue left after Post Mortem Examination	20
Documented evidence whereby organs were sampled at time of PM and returned to body for burial	0
Total	89

- in total there are 52 cases listed in the return tissue book as returned for reburial
 - of these 52 cases
 - in 1 instances part were sent for reburial / part were retained for research
 - in 51 instances the case was completely sent for reburial
 - 17 cases are currently stored in the Mortuary (16 non research / 1 cases Medical Education / Research identified by the Rotunda Hospital)
 - 20 instances there was no tissue left after the post mortem was completed
 - 1 instance no reburial details were evident

3.2.7.13 Supplementary Report in relation to Organ Retention Status 21.12.07 / 20.02.08

A supplementary report was provided to the review team identifying for 2005

- Status 21.12.07
 - of the 16 cases of organ retention 8 were complete awaiting reburial
 - delay identified in 3 cases *'had not been marked as complete'*
 - delay identified in 3 cases *'private grave – no reason in database'*
 - delay identified in 1 case *'private grave – family wish to make personal arrangement'*
 - delay identified in 1 case *'burial or cremation ? contacted'*
 - of the 8 cases identified as incomplete on 21.12.07
 - delay identified in 2 cases as *'unblocked'*
 - delay identified in 6 case as *'not complete'*
- Status 20.02.08
 - of the 16 cases of organ retention 16 were complete awaiting reburial
 - key arrangements note identified
 - 9 instances hospital to arrange reburial of organs / tissues in Holy Angels Glasnevin
 - 4 instances *'private grave'*
 - 1 instance *'personal arrangement – to be contacted'*
 - 1 instance *'Holy Angels – personal arrangement – to be contacted'*

Look Back Exercise – The Rotunda Hospital

- 1 instance cremation form needs to be completed
- A subsequent report from the Rotunda Hospital confirmed in 2 instances where status on 21.12.07 was identified 'unblocked' / blocks were previously processed in these cases.

This report was designed to assist this Review in understanding actions undertaken by hospital following National Audit visitation December 2007. **(2.5)**

3.2.8 Post Mortem Practice / Management (2006)

3.2.8.1 Number of post mortems recorded

- 197 of which:
 - 104 were full post mortems (53% of total)
 - 89 were superficial examinations (44% of total)
- and
- 3 were slide examinations referred by external hospitals (2% of total)
- and
- 1 where post mortem reference number was assigned, but no post mortem subsequently recorded as being undertaken (1% of total)

3.2.8.2 Post mortems

There were 104 full post mortems undertaken at the Rotunda Hospital during 2006 of which:

- 40 related to miscarriage / still births
- 46 related to still births > 500gm
- 18 related to live births
 - 104 Full post mortems (53% of total)
 - Prosecutor
 - Consultant Pathologist A undertook 70 post mortems for this year (67% of total post mortems)
 - Consultant Pathologist B undertook 34 post mortems for this year (33% of total post mortems)

3.2.8.2.1 Post mortems (Rotunda Hospital)

85 post mortems – accounting for 82% of post mortems undertaken in 2006.

3.2.8.2.2 Post mortems (Coroner)

11 post mortems – accounting for 10% of post mortems undertaken in 2006

- PM 78 Coroner case referred from Portlaoise
- PM 79 Rotunda Hospital Coroner Post Mortem
- PM 80 Coroner case referred from National Maternity Hospital
- PM 81 Rotunda Hospital Coroner Post Mortem
- PM 82 Rotunda Hospital Coroner Post Mortem
- PM 83 Rotunda Hospital Coroner Post Mortem
- PM 84 Coroner case referred from Coombe Hospital
- PM 85 Coroner case referred from Portlaoise
- PM 86 Rotunda Hospital Coroner Post Mortem
- PM 87 Coroner case referred from Portlaoise
- PM 88 Rotunda Hospital Coroner Post Mortem
 - of these 11 cases, there is a documented copy of report sent to Coroner in 9 instances by the Pathologist
 - 2 post mortem reports had not been completed by Pathologist A at the time of review.

3.2.8.2.3 Post mortems (Other Hospital)

8 post mortems – accounting for 8% of post mortems undertaken in 2006

- PM 89 referred from Portlaoise Hospital for post mortem
- PM 90 referred from Portlaoise Hospital for post mortem
- PM 91 referred from Clonmel Hospital for post mortem
- PM 92 referred from Portlaoise Hospital for post mortem
- PM 93 referred from Portlaoise Hospital for post mortem
- PM 94 referred from Portlaoise Hospital for post mortem
- PM 95 referred from Mullingar Hospital for post mortem
- PM 96 referred from Portlaoise Hospital for post mortem
 - of these 8 cases – there is a copy of report sent to referring hospital in only 3 instances by the Pathologist

Look Back Exercise – The Rotunda Hospital

3.2.8.2.4 Post Mortem – slide examination

3 cases which consisted of slide (from external hospital) examination only

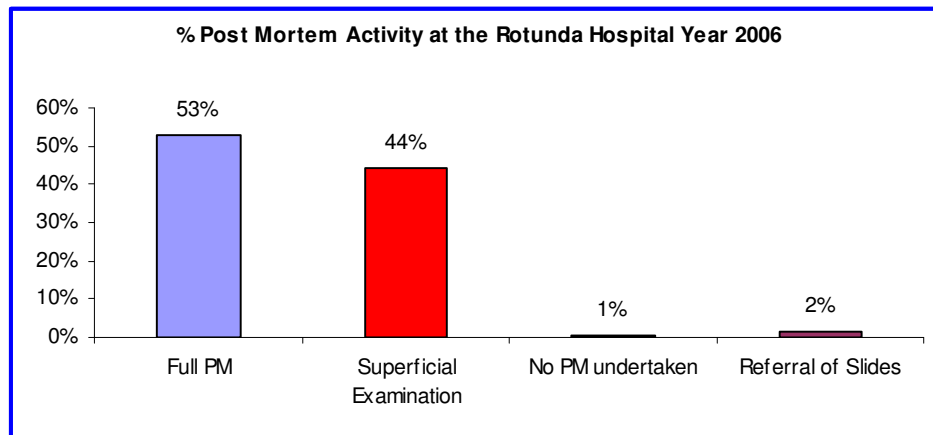
3.2.8.2.5 Post Mortem – referral of wet tissue

None identified

3.2.8.2.6 Post mortem reference number assigned, but no post mortem subsequently recorded as being undertaken

1 cases where a post mortem reference number was assigned, but no post mortem subsequently recorded as being undertaken

Graph 3.2.8.1 % Post Mortem activity at the Rotunda Hospital Year 2006



3.2.8.3 Superficial examinations

There were 89 superficial examinations undertaken at the Rotunda during 2006 of which:

- 62 related to miscarriage / < 500gm / did not live
- 11 related to still births > 500gm
- 16 related to live births
- 89 Superficial examinations (44% of total)
 - Prosecutor
 - Consultant Pathologist A undertook 46 superficial examinations for this year (52% of total post mortems)
 - Consultant Pathologist B undertook 31 superficial examinations for this year (35% of total post mortems)
 - 2 cases the Prosecutor name is not documented (2%)
 - in 10 cases the superficial examination report was not available for review (11% of total)

3.2.8.4 Review of related / relevant documentation (macro)

- post mortem (Full) file – 100% availability
- post mortem Report (Full) – complete – 62% availability
- post mortem Report (Full) – partial – 38% availability

- post mortem (superficial) file – 100% availability
- superficial examination report – 89% availability
- superficial examination report – complete 97% / partial 3%

- bereavement File – 100% availability

- patient File (Maternal) – 99% availability

3.2.8.5 Consent

3.2.8.5.1 Consent practice / policy

- Rotunda Hospital Perinatal Autopsy Permission Form, listed for the purposes of this report as consent form **D** was in use from January to May 2006.
- Consent form **E** came was introduced by the Rotunda Hospital, in use from May – December 2006.

3.2.8.5.2 Consent record availability

3.2.8.2 Consent record availability Full Post Mortems

Consent Record availability / Full Post Mortems	
Consent Record available - Rotunda cases	83
Consent Record not available – Rotunda cases	2
Consent Record available – referred cases	6
Consent Record not available – referred cases	2
Total	93

- Of the total post mortems requiring consent 96% consent records available (n=93) / (exclusion of 11 coroner cases)

3.2.8.3 Consent record availability Superficial Examinations

Consent Record availability / Superficial Examinations	
Consent Record available	17
Consent Record not available	72
Total	89

- consent record available
 - 1 instance stating – consent for blood (skin genetics only)
 - 14 instances where parents have signed ‘N.B. I understand that all babies removed to the mortuary that are not having an autopsy performed, undergo a brief external examination which includes photographs, an x-ray and body measurements for the purposes of maintaining a medical record for the baby’
 - 2 instances due to maceration – full post mortems could not be undertaken
 - There are 13 instances where the parent(s) did not consent to full post mortem, were found in the superficial file.
- **Superficial PM 97**
 - A memorandum exists in this case unsigned / undated by Pathologist A with reference to a conversation between Registrar in Obs / Gynae Registrar and Pathologist. It is stated the mother did not wish to know about the embryo found in material, however the specimen was received in formalin (sent for genetics). On contacting the Obstetrician, the pathologist states ‘felt the mother would probably want to know about the embryo, for this reason it was sent to the Mortuary for formal interment procedure.’ ‘In light of the latter communication, the fetus is being returned to the Laboratory and will be embedded in the Paraffin block’.
 - No consent form, in this case, was available for review.

Consent Documentation Review Full

Table 3.2.8.4 Consent Documentation Review Full

Consent Review	Number of cases
Full Granted for Autopsy	80
Consent forms not in files (2 Rotunda / 2 Referred)	4
Coroner Cases	11
Referred Hospital Cases / Full Granted for Autopsy	6
Limited Consent (3 Rotunda cases)	3
Total	104

The following is breakdown of consent forms for 2006 post mortems:

- 77% consent forms authorising hospital to undertake a post mortem
- 4% consent forms not on file
- 11% Coroner Cases (parental consent is not required)
- 6% Referred cases / Full consent granted for Post Mortem
- 2% Limited / restricted Post Mortem consent granted.

**3.2.8.5.3 Limited / Restricted Post Mortem
PM 98**

- documented evidence on review of this case showed:
 - consent granted for limited post mortem / clearly stipulated on the consent form 'Parents do not wish hospital to retain any organs' and further in the comments box 'Parents want the hospital to retain only the tissues (small pieces for microscopy investigation – Not Organs'.
 - although consent form **D** was in use during this period – consent form **C** (introduced in March 2002) was used to obtain consent in this case
 - The retention sheet was compiled in retrospect by Pathologist A on 14.01.08 listing 18 complete organs retained including the brain and spinal cord / 15 samples or tissues.
 - There is no documented evidence in the Post Mortem report that a rapid fixation process occurred / organs returned to the body at the time of the autopsy.
 - A total of 80 blocks were taken in this case and all stains were requested on these blocks in February 2006 (02.02.06 / 03.02.06 / 06.02.06)
 - The body was removed for cremation on 10.02.06.
 - Parents listed for hospital to arrange reburial of tissues only however there was no tissue left on completion of the autopsy.
 - The Post Mortem report has not been signed / dated by the Pathologist.

PM 99

- documented evidence on review of this case showed:
 - consent granted for limited post mortem where parents have stipulated on the consent form 'facial features to be preserved'
 - The retention sheet lists the Right and Left Eye as retained in complete form for diagnostic reasons. The orbits, eyelids were completely restored after the autopsy.
 - Consent form states consent for research / medical education not granted
 - The body was interred privately in Co. Laois on 25.03.06 / private arrangement for the reburial of organs / tissues was also undertaken privately on 16.09.06.

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- The Post Mortem report was signed by Pathologist A on 11.07.06.
- Consultant A has identified that the orbits, eyelids were completely restored after the autopsy.

PM 100

- documented evidence on review of this case showed:
 - two consent forms exists in file
 - First Consent Form: consent granted for limited post mortem / clearly stipulated on the consent form 'Parents are happy for organs to be biopsied but wish for rest of organs to be buried – do not agree to whole organs being held'. This consent form is dated 20.07.06
 - Second Consent Form: consent granted for 'only the brain being kept for full investigation (retained)'. This consent form is dated 21.07.06.
 - The baby died on 20.07.06 and the Post Mortem was undertaken on 20.07.06
 - There are 22 complete organs listed as retained on the retention sheet / 14 samples / tissues retained.
 - The body was interred privately in Co. Dublin on 22.07.06
 - The section of both consent forms has not been filled indicating whether the hospital / family to make arrangements for reburial of tissues
 - The section where consent for retention for medical research is blank on consent form dated 20.07.06 and ticked yes for research on consent form dated 21.07.06.
 - Part organs currently stored in the Mortuary include the Brain and Spinal Cord.
 - This case is not listed for retention for medical research by the Rotunda Hospital.
 - The Post Mortem report was signed by Pathologist A on 29.09.06

3.2.8.5.4 Non Research / Education Cases

- of the 24 cases, which are stored in the Mortuary (not retained for research / education purposes)
 - 12 instances baby interred at Holy Angels Glasnevin, hospital to arrange reburial of organs / tissues – undated notes in bereavement files '*awaiting blocking of tissues*'
 - 1 instance baby interred at Holy Angels – Personal arrangement for reburial of organ / tissues – no documented evidence of letters on file
 - 1 instance baby interred privately – personal arrangement for reburial of organ / tissue – undated note in bereavement file '*awaiting blocking of tissue*'
 - 1 Coroner NMH Case – no bereavement file exists
 - 1 instance baby interred privately – deferred decision by family – letter sent 22.11.07
 - 1 instance baby interred privately – consent form for reburial is 'blank'
- PM 100 (3.2.8.5.3)
 - 1 instance baby interred privately – personal arrangement- undated note in bereavement file '*awaiting blocking of tissue*'
 - 1 instance Portlaoise Case – family require reburial at Holy Angels Portlaoise in due course

Look Back Exercise – The Rotunda Hospital

- 1 Coroner Case Coombe Hospital – bereavement file in this instance does not exist
- 1 instance baby interred privately, private arrangement for reburial of organs / tissues. Letter sent from Rotunda Hospital 22.11.07
- 1 instance baby interred privately, personal arrangement for reburial of organs / tissues – undated note in bereavement file ‘*awaiting Pathology details*’
- 1 Coroner Portlaoise Case – bereavement file does not exist
- 1 Portlaoise case – Bereavement file does not exist

3.2.8.5.5 Consent Medical Education / Perinatal Death

- of the 3 cases which are retained for Medical Education / Research purposes
 - 1 instance specific consent has been signed for retention of brain tissue (also part retained temporarily by hospital)
 - 2 instances specific consent signed for retention of heart and lungs

3.2.8.5.6 Non Compliance with Consent given

The following is a breakdown of non compliancy with consent process

Retrospective Consent secured (apparent)

None identified

Limited consent (detailed above)

PM 98 (reference 3.2.8.5.3)

PM 100 (reference 3.2.8.5.3)

- Consent / Reburial

- of the cases, which are stored in the Mortuary (not retained for research / education purposes)
 - 12 instances baby interred at Holy Angels Glasnevin, hospital to arrange reburial of organs / tissues – undated notes in bereavement files ‘*awaiting blocking of tissues*’
 - 1 instance baby interred at Holy Angels – Personal arrangement for reburial of organ / tissues – no documented evidence of letters on file
 - 1 instance baby interred privately – personal arrangement for reburial of organ / tissue – undated note in bereavement file ‘*awaiting blocking of tissue*’
 - 1 Coroner NMH Case – no bereavement file exists
 - 1 instance baby interred privately – consent form for reburial is ‘blank’ PM 100 (reference Limited Consent - for the purposes of non compliance it is listed once)
 - 1 instance baby interred privately – personal arrangement-undated note in bereavement file ‘*awaiting blocking of tissue*’
 - 1 instance Portlaoise Case – family require reburial at Holy Angels Portlaoise in due course
 - 1 Coroner Case Coombe Hospital – bereavement file in this instance does not exist
 - 1 instance baby interred privately, personal arrangement for reburial of organs / tissues – undated note in bereavement file ‘*awaiting Pathology details*’
 - 1 Coroner Portlaoise Case – bereavement file does not exist
 - 1 Portlaoise case – Bereavement file does not exist

Look Back Exercise – The Rotunda Hospital

In total 23 cases are deemed non compliant – representing 22% of post mortems.

3.2.8.6 Date of delivery / death → date of post mortem

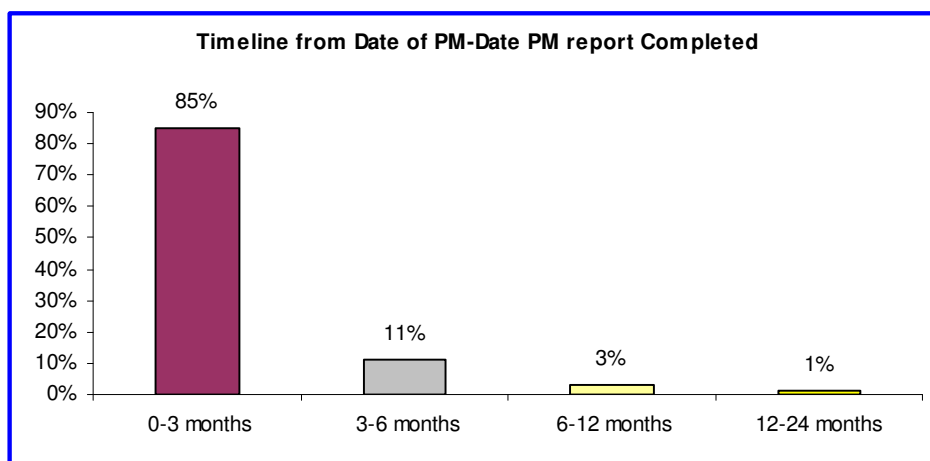
Table 3.2.8.5 summarises length of time from date of delivery/ death → date of post mortem

Timeline	Same day as Date of Death	1-2 days	> 2 < 7 days	≥7 days	Date of Death not listed	Date of PM Not recorded	Total
Number	6	46	14	2	1	35	104
%	6%	44%	13%	2%	1%	34%	

3.2.8.7 Date of post mortem → date of post mortem report

- 13% of reports are undated of the 87% reports which are dated
 - 85% are dated 0-3 months post post mortem
 - 11% are dated 3-6 months post post mortem
 - 3% are dated 6-12 months post post mortem
 - 1% are dated 1 year - < 2 year post post mortem
 - in 35 instance where the Date of Post Mortem was not recorded, the Date of Death was used for the above comparator

Graph 3.2.8.6 Timeline from Date of PM – Date PM report Completed



A sample of 20 cases was reviewed in order to ascertain Date of PM completion. Computerised records showed the dates that the stains were first requested on blocks by the Pathologist. Of these:

- 10 cases were requested solely in 2006
- 9 cases were requested in 2006 and another request date in 2008
- 1 case was requested in 2007 and another request date in 2008

3.2.8.8 Post Mortem Report – examination

Full Post mortem report

- 40 are incomplete / not validated by Consultant Pathologist – representing 38% of full post mortem reports

Superficial Examination report

- 2 are incomplete / not validated by Consultant Pathologist – representing 2% of superficial examination reports

Look Back Exercise – The Rotunda Hospital

3.2.8.9 Inventory of cases currently stored at the Rotunda Hospital

Table 3.2.8.7 Inventory of cases currently stored at the Rotunda Hospital

Origin of Cases	Number of cases
Rotunda Hospital Cases	20
Referred Hospital Cases – not research based	2
Coroner Cases – not research based (both referred)	2
Total non research based	24
Medical Research / Education	3
Total	27

¹ case identified by hospital as held temporarily awaiting hospital disposal from a post mortem case for which organs had also been retained for Research & Education purposes (Separately)

There are 27 cases for 2006 where part organs / tissues are currently stored in the Mortuary.

This figure represents 26% of full post mortems.

- 24 cases were identified by the hospital at start of review
- 3 cases were identified as Medical / Education specimens at review end
 - In all of the above 27 cases an Independent Consultant Pathologist as part of this review has examined all material.
- of the 24 cases identified as stored / retained not for the purposes of Medical / Education
 - 24 instances Pathologist A undertook the post mortem

3.2.8.10 Returned Tissue / Organ Register

3.2.8.8 Returned Tissue / Organ Register

Returned Tissue Register	
Fully returned for burial	52
Part return for burial	2
Total	54

- 54 instances where the Return Tissue Register has logged a full / partial reburial of Tissue / Organs. Of these cases where the Post Mortem was undertaken in 2006:
 - 23 cases returned in 2006
 - 28 cases returned in 2007
 - 3 cases returned in 2008

3.2.8.11 Retention Sheet Record

98 retention sheets available - representing 94% of full post mortems undertaken

→ 6% unavailable

Average number of organs retained

- Consultant Pathologist A – 21
- Consultant Pathologist B – 2
- **PM 80**

There are two retention sheets on this case in the Post Mortem file. For the purposes of this comparator, case was excluded.

Retrospective data entries

There are 13 cases where the retention sheet record has been completed retrospectively (RS)

- **RS 33** compiled in retrospect by Consultant Pathologist A on 14.01.08 → Organs / tissues returned for reburial on 10.10.06
- **RS 34 / PM 98** compiled in retrospect by Consultant Pathologist A on 14.01.08 → no tissue left after PM completed
- **RS 35** compiled in retrospect by Consultant Pathologist A on 14.01.08 → no tissue left after PM completed

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- **RS 36** compiled in retrospect by Consultant Pathologist A on 14.01.08 → Organs / tissues returned for reburial on 01.12.06
- **RS 37** compiled in retrospect by Consultant Pathologist A on 14.01.08 → Organs / tissues returned for reburial on 16.09.06
- **RS 38** compiled in retrospect by Consultant Pathologist A on 14.01.08 → Organs / tissues returned for reburial on 02.02.07
- **RS 39** compiled in retrospect by Consultant Pathologist A on 14.01.08 → Organs / tissues returned for reburial on 02.02.07
- **RS 40** compiled in retrospect by Consultant Pathologist A on 14.01.08 → Portlaoise Case
- **RS 41 / PM 87** compiled in retrospect by Consultant Pathologist A on 14.01.08 → wet tissue currently retained in Mortuary
- **RS 42** compiled in retrospect by Consultant Pathologist A on 15.02.08 → no tissue left after PM completed
- **RS 43** compiled in retrospect by Consultant Pathologist A on 14.01.08 → no tissue left after PM completed
- **RS 44** compiled in retrospect by Consultant Pathologist A on 14.01.08 → Organs / tissues returned for reburial on 18.08.07
- **RS 45** compiled in retrospect by Consultant Pathologist A on 14.01.08 → Organs / tissues returned for reburial on 18.08.07

There are 9 cases where the superficial examination report has been compiled / signed in retrospect (RS)

- **RS 46** compiled / signed in retrospect by Consultant Pathologist A on 06.02.08 / baby interred privately on 14.07.06
- **RS 47** compiled / signed in retrospect by Consultant Pathologist A on 11.02.08 / baby interred privately on 19.07.06
- **RS 48** compiled / signed in retrospect by Consultant Pathologist A on 11.02.08 / baby interred privately on 19.07.06
- **RS 49** compiled / signed in retrospect by Consultant Pathologist A on 11.02.08 / baby interred at Holy Angels Glasnevin on 24.07.06
- **RS 50** compiled / signed in retrospect by Consultant Pathologist A on 12.02.08 / baby interred at Holy Angels Glasnevin on 25.07.06
- **RS 51** compiled / signed in retrospect by Consultant Pathologist A on 12.02.08 / baby interred privately on 11.08.06
- **RS 52** compiled / signed in retrospect by Consultant Pathologist A on 06.02.08 / baby interred privately on 27.09.06
- **RS 53** compiled / signed in retrospect by Consultant Pathologist A on 11.02.08 / baby interred privately on 20.11.06
- **RS 54** compiled / signed in retrospect by Consultant Pathologist A on 11.02.08 / baby interred at Holy Angels Glasnevin on 29.11.06

3.2.8.12 Overall Management of Cases

Table 3.2.8.9 Overall Management of Cases

Cases	Numbers
Returned Tissue Book	
- 54 cases	
- Of these, there is 2 instance / case where part organs / tissues are retained for Medical Research / Education	52
Cases where part organ / tissues stored in Mortuary	27
No Reburial details evident in files	3
Cases where documented evidence indicates there was no tissue left after Post Mortem Examination	22
Documented evidence whereby organs were sampled at time of PM and returned to body for burial	0
Total	104

- in total there are 54 cases listed in the return tissue book as returned for reburial

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- of these 54 cases
 - in 2 instances part were sent for reburial / part were retained for research
- in 52 instances the case was completely sent for reburial
- 27 cases are currently stored in the Mortuary (24 non research / 3 cases Medical Education / Research identified by the Rotunda Hospital)
 - 28 cases identified at review start however 1 case was returned for reburial during audit on 04.04.08.
- 22 instances there was no tissue left after the post mortem was completed
- in 3 instances there are no reburial details evident in files

3.2.8.13 Related observations from National Audit Organ Retention¹

As part of the national exercise the review team audited 100 post mortem files – period Jan – June 2006. Audit undertaken 06.12.07 – 07.12.07.

In 11 instances retained organs were found to be unblocked

Specific Post Mortems being:

- PM 101
- PM 102
- PM 103
- PM 104
- PM 105
- PM 106
- PM 107
- PM 108
- PM 109
- PM 110
- PM 111

During this Review, in all instances these organs were found to have been subsequently blocked

3.2.8.14 Supplementary Report in relation to Organ Retention Status 21.12.07 / 20.02.08

A supplementary report was provided to the review team identifying for 2006

- Status 21.12.07
 - of the 26 cases of organ retention 8 were complete awaiting reburial
 - delay identified in 1 instance – seeking permission to retain organs'
 - delay identified in 2 instances as '?'
 - delay identified in 2 instances as 'private grave – letters on file from Rotunda hospital to families
 - 1 coroner case – documented evidence of contact between Rotunda Hospital and NMH (Medical Social Work)
 - Delay identified in 1 instance as '*MSW dealing with this case*'
 - Delay identified in 1 instance as '*registered letter 15.08.07 not collected, mother is pregnant again, do not contact at this time*' / this case has been reburied 04.04.08
 - of the 18 cases identified as incomplete on 21.12.07
 - delay identified in 4 cases as '*unblocked*'
 - delay identified in 13 case as '*not complete*'
 - delay identified in 1 instance as '*for additional renal tract sampling*'

It should be noted of 26 cases are listed above

Of these:

- 1 instance a reburial of organs / tissues occurred on 04.04.08 – for the purposes of the audit team look back 2006 exercise, this case was listed in the return tissue book – no part organs / tissues are stored in this instance at this time.

Look Back Exercise – The Rotunda Hospital

- 1 instance PM 112 listed as '1 case' above – has part organs / tissues retained in the mortuary (no reburial) also part organs / tissues retained for the purposes of Medical Education / Research.

- Status 20.02.08
 - of the 26 cases of organ retention 25 were complete awaiting reburial
 - key arrangements note identified
 - 1 instance 'not complete' note – *'for additional renal tract sampling'*
 - 1 instance *'Holy Angels Glasnevin, personal arrangement'*
 - 3 instances *'to be returned to Portlaoise'*
 - 6 instances *'private arrangement / private grave – permission required'*
 - in 1 instance it is noted *'permission letter received'*
 - 2 instance *'MSW dealing with this'*
 - 11 instances *'Holy Angels Plot; hospital to arrange'*
 - 1 instance reburial listed on 04.04.08 / there are no part organs / tissues retained

- A subsequent report from the Rotunda Hospital confirmed in 4 instances where status on 21.12.07 was identified 'unblocked' / blocks were previously processed in these cases.

This report also confirms in 1 case status on 21.12.07 as 'unblocked' – no record of previous blocking exists

This report was designed to assist this Review in understanding actions undertaken by hospital following National Audit visitation December 2007 **(2.5)**

3.2.9 Post Mortem Practice / Management (2007)

3.2.9.1 Number of post mortems recorded

- 227 of which:
 - 103 were post mortems (45% of total)
 - 115 were superficial examinations (51% of total)
- and
- 4 were slide examinations referred by external hospitals (2% of total)
- 1 were examination of wet tissue (0% of total)
- and
- 4 where post mortem reference number was assigned, but no post mortem subsequently recorded as being undertaken (2% of total)
 - this was further validated by the report 'Details of Autopsies' provided by the hospital

3.2.9.2 Post mortems

There were 103 post mortems undertaken at the Rotunda Hospital during 2007 of which:

- 42 related to miscarriage / still births
- 44 related to still births > 500gm
- 17 related to live births
 - 103 Full post mortems (45% of total)
 - Prosecutor
 - Consultant Pathologist A undertook 58 of post mortems for this year (56% of total post mortems)
 - Consultant Pathologist B undertook 36 of post mortems for this year (35% of total post mortems)
 - Consultant Pathologist S undertook 9 of post mortems for this year (9% of total post mortems)

3.2.9.2.1 Post mortems (Rotunda Hospital)

83 post mortems – accounting for 81% of post mortems undertaken in 2007.

3.2.9.2.2 Post mortems (Coroner)

13 post mortems – accounting for 13% of post mortems undertaken in 2007

- PM 113 Coroner case referred from Portlaoise
 - whilst it is noted this case was not directed / initiated by the Coroner, the report was subsequently sent to the Coroner office. For the purpose of this report it is listed as a Coroner Case.
- PM 114 Rotunda Hospital Coroner Post Mortem
- PM 115 Coroner case referred from Portlaoise
- PM 116 Rotunda Hospital Coroner Post Mortem
- PM 117 Rotunda Hospital Coroner Post Mortem
- PM 118 Rotunda Hospital Coroner Post Mortem
- PM 119 Rotunda Hospital Coroner Post Mortem
- PM 120 Coroner case referred from Portlaoise
- PM 121 Rotunda Hospital Coroner Post Mortem
- PM 122 Rotunda Hospital Coroner Post Mortem
- PM 123 Coroner case referred from Mt. Carmel
- PM 124 Rotunda Hospital Coroner Post Mortem
- PM 125 Rotunda Hospital Coroner Post Mortem
 - of these 13 cases, there is a documented copy of report sent to Coroner in 7 instances.

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3.2.9.2.3 Post mortems (Other Hospital)

7 post mortems – accounting for 6% of post mortems undertaken in 2007

- PM 126 referred from Portlaoise Hospital for post mortem
- PM 127 referred from Portlaoise Hospital for post mortem
- PM 128 referred from Mullingar Hospital for post mortem
- PM 129 referred from Portlaoise Hospital for post mortem
- PM 130 referred from Portlaoise Hospital for post mortem
- PM 131 referred from Portlaoise Hospital for post mortem
- PM 132 referred from Portlaoise Hospital for post mortem
- of these 7 cases – there is a copy of report sent to hospital in only 4 instances

3.2.9.2.4 Post mortem – slide examination

4 cases which consisted of slide (from external hospital) examination only

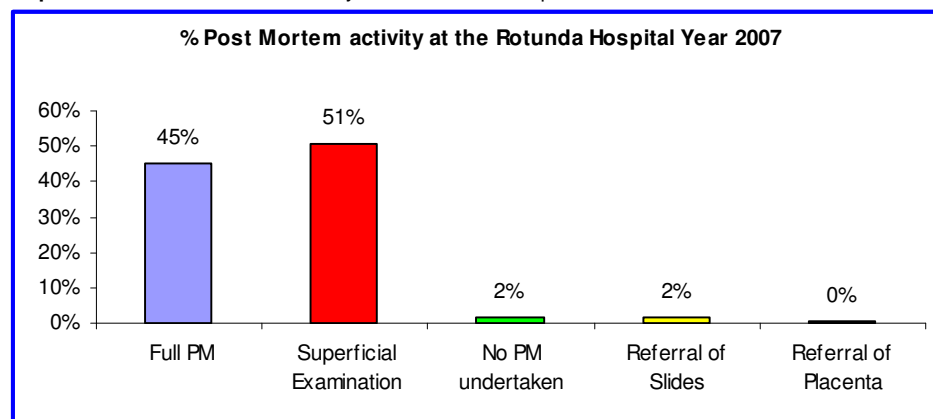
3.2.9.2.5 Post Mortem – referral of wet tissue (Placenta)

1 cases which consisted of wet tissue for examination only

3.2.9.2.6 Post mortem reference number assigned, but no post mortem subsequently recorded as being undertaken

4 cases where a post mortem reference number was assigned, but no post mortem subsequently recorded as being undertaken

Graph 3.2.9.1 % Post Mortem activity at the Rotunda Hospital Year 2007



3.2.9.3 Superficial examinations

There were 115 superficial examinations undertaken at the Rotunda during 2007 of which:

- 73 related to miscarriage / still births
- 22 related to still births > 500gm
- 20 related to live births
- 115 Superficial examinations (51% of total)
- Prosector
 - Consultant Pathologist A undertook 65 superficial examinations for this year (56% of total)
 - Consultant Pathologist B undertook 42 superficial examinations for this year (37% of total)
 - Consultant Pathologist T undertook 2 superficial examinations for this year (2% of total)
 - Consultant Pathologist S undertook 6 superficial examinations for this year (5% of total)

Look Back Exercise – The Rotunda Hospital

3.2.9.4 Review of related / relevant documentation (macro)

- post mortem file – 100% availability
- post mortem Report – complete – 66% availability
- post mortem Report – partial – 34% availability

- post mortem (superficial) file – 100% availability
- superficial examination report – 100% availability
- superficial examination report – complete 99% / partial 1%

- bereavement File – 94% availability

- patient File (Maternal) – 98% availability

3.2.9.5 Consent

3.2.9.5.1 Consent practice / policy

Rotunda Hospital Perinatal Autopsy Permission Form, listed for the purposes of this report as consent form **E** - in use for the full year 2007

3.2.9.5.2 Consent record availability

3.2.9.2 Consent record availability Post Mortems

Consent Record availability / Full Post Mortems	
Consent Record available - Rotunda cases	83
Consent Record not available – Rotunda cases	0
Consent Record available – referred cases	7
Consent Record not available – referred cases	0
Total	90

- Of the total post mortems requiring consent, 100% of consent records available (n=90) / (exclusion of 13 coroner cases)

3.2.9.3 Consent record availability Superficial Examinations

Consent Record availability / Superficial Examinations	
Consent Record available	32
Consent Record not available	83
Total	115

- 28% consent records not available (n=83).
 - There is 1 instance where the parent(s) did not consent to post mortem, consent form filed in the superficial folder.
 - With the introduction of consent form E in May 2006, in 32 cases parents have ticked Yes / Signing stating they understand that 'all babies removed to the mortuary that are not having an autopsy performed, undergo a brief external examination which includes photographs, an x-ray and body measurements for the purposes of maintaining a medical record for the baby

Look Back Exercise – The Rotunda Hospital

Consent Documentation Review Full

Table 3.2.9.4 Consent Documentation Review Full

Consent Review	Number of cases
Full Granted for Autopsy	82
Consent forms not in files	0
Coroner Cases	13
Referred Hospital Cases / Full Granted for Autopsy	7
Limited Consent (Rotunda case)	1
Total	103

The following is breakdown of consent forms for 2007 post mortems:

- 80% consent forms authorising hospital to undertake an autopsy
- 13% Coroner Cases (parental consent is not required)
- 7% Referred cases / Full consent granted for Post Mortem
- 1% Limited / restricted Post Mortem consent granted.

3.2.9.5.3 Limited / Restricted Post Mortem

PM 133 parents requested for no whole organs to be retained, retention only of tissue samples. The retention sheet in this case was not available for review - there is no documented reburial noted in the return tissue book - documented evidence states that no tissue was left after completion of the post mortem.

3.2.9.5.4 Non Medical Education / Research cases

- of the 38 cases, which are stored in the Mortuary (not retained for research / education purposes)
 - 8 instances baby interred at Holy Angels Glasnevin, hospital to arrange reburial of organ / tissue – there is an undated note in the bereavement file '*awaiting blocking of tissue*'
 - 6 instances baby interred at Holy Angels Glasnevin, hospital to arrange reburial of organs / tissues
 - 1 instance baby interred at Holy Angels, hospital to arrange reburial of organ / tissue – there is an undated note in the bereavement file '*? Pathology*'
 - 1 instance baby interred privately – hospital to cremate the organs / tissues – cremation forms signed
 - 1 Coroner case, baby interred at Holy Angels, hospital to arrange reburial of organ / tissues at Holy Angels
 - 3 instances baby interred privately – personal arrangement to be made for reburial of organ / tissue and will contact the hospital <3 months
 - 2 of these instances are Coroner Cases
 - 1 instance baby interred privately – hospital to arrange reburial of organ / tissue, letter on file from parents 24.05.07 authorising reburial at Mt. Venus Cemetery
 - 1 instance baby interred privately – undated note in the bereavement file 'awaiting return of form given to parents 07.11.07 for cremation / mother is this instance was pregnant again
 - 1 Coroner Case – no consent form on file
 - 1 instance baby interred privately – hospital to arrange reburial at family grave, hospital awaiting grave details
 - 1 instance baby interred privately, hospital to arrange reburial at family grave, plot / section number given
 - 1 instance baby interred privately, hospital to arrange at family grave and wish to be informed of the date

Look Back Exercise – The Rotunda Hospital

- 2 instances baby interred privately, hospital to arrange reburial of organ / tissue at private grave – undated note in the bereavement file '*awaiting blocking of tissue*'
- 1 instance baby interred privately, note in bereavement file 26.04.07 parents undecided – forms given to parents / awaiting decision
- 1 instance baby interred at Holy Angels Glasnevin, reburial section of consent is blank – undated note in bereavement file '*awaiting blocking of tissue*'
- 1 Portlaoise Case, bereavement file does not exist, personal arrangement to be made for the reburial of organ / tissue.
- 1 instance baby interred privately, reburial section of consent is blank. Note in bereavement file '*family remain undecided* (Oct 07)
- 1 Mullingar Case – bereavement file in this instance does not exist, personal arrangement for reburial of organ / tissue and will contact the hospital
- 1 instance baby interred privately – reburial section is blank and noted in the bereavement file '*parents will make a decision when they see the doctor*'
- 1 Portlaoise case – bereavement file in this instance does not exist, it is noted mother wishes for hospital to arrange reburial
- 1 instance baby interred privately, personal arrangement for reburial of organ / tissues, undated note in bereavement file '*? Pathology*'
- 1 instance no bereavement file was supplied, consent states personal arrangement to be made for reburial of organ / tissues.
- 1 instance no bereavement file was supplied, hospital to arrange reburial at Holy Angels Glasnevin.

3.2.9.5.5 Consent Medical Education / Perinatal Death

None identified

3.2.9.5.6 Non Compliance with Consent given

Retrospective Consent secured (apparent)

There is 1 case where consent form had been signed by parents after the date of autopsy listed in the PM report:

PM 134: Date of PM 27.02.07 → Consent granted on 28.02.07

Consent / Reburial

- of the 38 cases, which are stored in the Mortuary (not retained for research / education purposes)
 - 8 instances baby interred at Holy Angels Glasnevin, hospital to arrange reburial of organ / tissue – there is an undated note in the bereavement file '*awaiting blocking of tissue*'
 - including PM 134 (apparent retrospective consent secured - for the purposes of non compliance it is listed once)
 - 6 instances baby interred at Holy Angels Glasnevin, hospital to arrange reburial of organs / tissues
 - 1 instance baby interred at Holy Angels, hospital to arrange reburial of organ / tissue – there is an undated note in the bereavement file '*? Pathology*'
 - 1 instance baby interred privately – hospital to cremate the organs / tissues – cremation forms signed
 - 1 Coroner case, baby interred at Holy Angels, hospital to arrange reburial of organ / tissues at Holy Angels

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- 1 instance baby interred privately – hospital to arrange reburial of organ / tissue, letter on file from parents 24.05.07 authorising reburial at Mt. Venue Cemetery
- 1 Coroner Case – no consent form on file
- 1 instance baby interred privately, hospital to arrange reburial at family grave, plot / section number given
- 1 instance baby interred privately, hospital to arrange at family grave and wish to be informed of the date
- 2 instances baby interred privately, hospital to arrange reburial of organ / tissue at private grave – undated note in the bereavement file '*awaiting blocking of tissue*'
- 1 instance baby interred at Holy Angels Glasnevin, reburial section of consent is blank – undated note in bereavement file '*awaiting blocking of tissue*'
- 1 Portlaoise case – bereavement file in this instance does not exist, it is noted mother wishes for hospital to arrange reburial
- 1 instance baby interred privately, personal arrangement for reburial of organ / tissues, undated note in bereavement file '*? Pathology*'
- 1 instance no bereavement file was supplied, consent states personal arrangement to be made for reburial of organ / tissues.
- 1 instance no bereavement file was supplied, hospital to arrange reburial at Holy Angels Glasnevin.

In total 28 cases are deemed non compliant – representing 27% of full post mortems

3.2.9.6 Date of delivery / death → date of post mortem

Table 3.2.9.5 summarises length of time from date of delivery/ death → date of post mortem

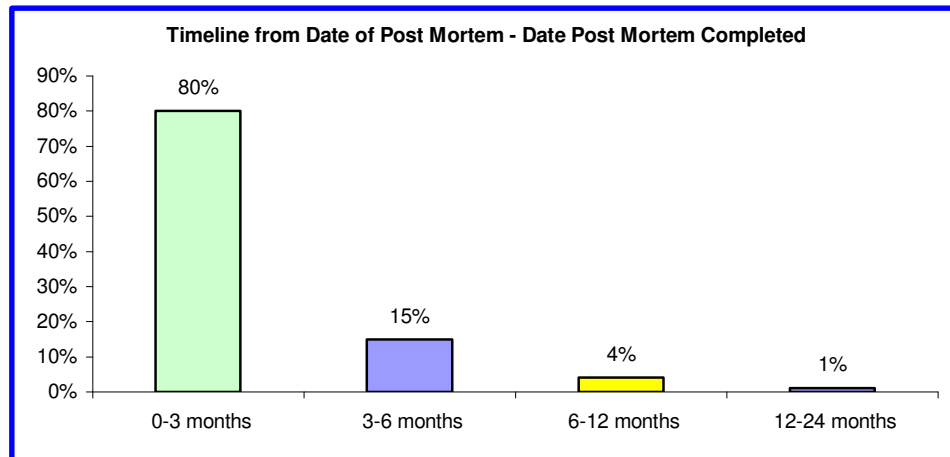
Timeline	Same day as Date of Death	1-2 days	> 2 < 7 days	≥7 days	Date of Death not listed	Date of PM Not Recorded	Total
Number	10	52	17	0	2	22	103
%	10%	50%	17%	0%	2%	21%	

3.2.9.7 Date of post mortem → date of post mortem report

- 9% of reports are undated of the 91% reports which are dated
 - 80% are dated 0-3 months post post mortem
 - 15% are dated 3-6 months post post mortem
 - 4% are dated 6-12 months post post mortem
 - 1% are dated 1 year - < 2 year post post mortem
 - in 22 instance where the Date of Post Mortem was not recorded, the Date of Death was used for the above comparator

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Graph 3.2.9.6 Timeline from Date of PM – Date PM Report Completed



A sample of 21 cases was reviewed in order to ascertain Date of PM completion. Computerised records showed the dates that the stains were first requested on blocks by the Pathologist. Of these:

- 11 cases were requested solely in 2007
- 9 cases were requested in 2007 and other request dates in 2008
- 1 case was solely requested in 2008

3.2.9.8 Post Mortem Report – examination

Full Post mortem report

- 35 are incomplete / not validated by Consultant Pathologist – representing 34% of full post mortem reports

Superficial Examination report

- 1 is incomplete / not validated by Consultant Pathologist – representing <1% of superficial examination reports

3.2.9.9 Inventory of cases currently stored at the Rotunda Hospital

Table 3.2.9.7 Inventory of cases currently stored at the Rotunda Hospital

Origin of Cases	Number of cases
Rotunda Hospital	31
Medical Research / Education	0
Coroner Case – not research based	4
Referral Hospital	3
Total	38

There are 38 cases for 2007 where part organs / tissues are currently stored in the Mortuary.

This figure represents 37% of full post mortems.

- In all of the above 38 cases an Independent Consultant Pathologist as part of this review has examined all material.
- of the 38 cases identified as stored / retained not for the purposes of Medical / Education
 - 31 instances Pathologist A undertook the post mortem
 - 3 instances Pathologist B undertook the post mortem
 - 4 instances Pathologist SM undertook the post mortem

3.2.9.10 Returned Tissue / Organ Register

3.2.9.8 Returned Tissue / Organ Register

Returned Tissue Register	
Fully returned for burial	42
Part return for burial	0
Total	42

- 42 instances where the Return Tissue Register has logged a full reburial of Tissue / Organs. Of these cases where the Post Mortem was undertaken in 2007:
 - 35 cases returned in 2007
 - 7 cases returned in 2008

3.2.9.11 Retention Sheet Record

84 retention sheets available - representing 82% of full post mortems undertaken

➔ 18% unavailable

Average number of organs retained

- Consultant Pathologist A – 20
- Consultant Pathologist B – 2
- **PM 123**
 - There are two retention sheets on this case in the Post Mortem file. For the purposes of the above comparator this case was excluded.

Retrospective data entries

None identified

3.2.9.12 Overall Management of Cases

Table 3.2.9.9 Overall Management of Cases

Cases	Numbers
Returned Tissue Book	42
- Cases	
Cases where part organ / tissues stored in Mortuary	38
No Reburial details evident in files	6
Cases where documented evidence indicates there was no tissue left after Post Mortem Examination	16
Documented evidence whereby organs were sampled at time of PM and returned to body for burial	1
Total	103

- 42 cases listed in the return tissue book as returned for reburial
- 38 cases are currently stored in the Mortuary (all non research cases)
- 16 instances there was no tissue left after the post mortem was completed
- 6 instances there are no reburial details evident in files

3.2.9.13 Supplementary Report in relation to Organ Retention Status 21.12.07 / 20.02.08

A supplementary report was provided to the review team identifying for 2007

- Status 21.12.07
 - of the 42 cases of organ retention 4 had since been sent for reburial

Of the 38 cases that remain:

- 14 were complete awaiting reburial
 - delay identified in 5 instances 'had not been marked as complete'
 - delay identified in 1 instance 'for renal tract sampling'
 - delay identified in 1 instance mother pregnant again – hospital not to contact
 - delay identified in 2 instances family undecided
 - delay identified in 1 instance 'personal arrangement – to be contacted'
 - delay identified in 1 instance 'family to be contacted'
 - delay identified in 1 instance 'reference number of grave to be sent to hospital by family'
 - in 2 instances the delay identified section of supplementary report is blank.

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Of the 24 cases identified as incomplete on 21.12.07

- delay identified in 18 cases as 'not complete'
- delay identified in 3 cases as 'unblocked'
- in 3 instances the delay identified section of supplementary report is blank.

- Status 20.02.08

- of the 38 cases of organ retention 32 were complete awaiting reburial
- key arrangement note identified
 - 11 instances Holy Angels Glasnevin, hospital to arrange'
 - 2 instances 'personal arrangement – to be contacted'
 - 3 instances private grave permission letter received
 - 2 instances permission required
 - 1 instance cremation form needs to be completed – mum pregnant again
 - 1 instance consent form not signed – to be contacted
 - 3 instances private grave – permission required
 - 1 instance cremation form needs to be completed
 - 1 instance parents undecided – to be contacted
 - 1 instance 'to be returned to Mullingar'
 - 1 instance parents will make a decision when they see the doctor
 - 1 instance to be returned to Portlaoise
 - 1 instance cremation form signed – hospital to arrange
 - 1 instance private grave – permission required / family wish to be informed
 - 2 instances 'arrangements to be made section' is blank.

This report was designed to assist this Review in understanding actions undertaken by hospital following National Audit visitation December 2007 **(2.5)**

3.3 Review of Consent Policy, Practice and Management

The practice of post mortem examination, the adequacy of parental consent obtained in the case of Hospital post mortems and the subsequent retention or disposal of organs / tissue has since 1999 been the subject of significant public and professional debate

Madden⁶ centres parental concerns on one key causal theme, this being that parents routinely experienced a general lack of information from the concerned hospital / clinician in relation to what a post mortem entailed, what information they did receive was often given at an inappropriate time or setting and accordingly parents were not able to make an informed decision when consenting to a post mortem examination

Within this paradigm, it is not surprising the anger and hurt that ensued⁸, when parents became aware that without their knowledge (following a post mortem being undertaken):

- organs had been removed and not returned when their child was buried
- organs / tissue had been retained – whole organ / part organ / block / slide – sometimes for long periods of time
- organs had been subsequently disposed – often long after the actual post mortem had been undertaken

As a result contemporary (Irish / UK) best practice now recommend that consent policy, practise and management must recognise and incorporate certain key issues

3.3.1 General Principles relating to post mortem process and required consent

- post mortem results have the potential to be important for parents in terms of recovering from the loss of a child⁵
- the post mortem examination is a process – with the actual autopsy being the first stage and further examination of organs / tissue generally likely^{3,5}
- with regard to Coroner's post mortem, whilst these examinations do not require consent of the next of kin, there remains
 - the duty to inform relatives about purpose and nature of this type of examination²
 - the requirement to still secure consent from the next of kin for any subsequent retention of organs / tissue for research / education purposes²
- the obtainment of parental consent for post mortem examination must secure a difficult balance between ensuring sufficient information provision to the parent to enable 'informed' consent and the need for sensitivity and empathy at a time of great distress⁴

3.3.2 Consent Obtainment - specifics

- parents must not only receive sufficient information in relation to post mortem practices, but as well their right in related decision making – if possible this information should be given to both parents – reasonable time must also be given to enable the parents to reach a decision – where possible professional advice / support e.g. bereavement counselling should be easily available for the parents^{2,3,4,5}
- (then) ERHA guidelines⁴ identify that in the case of a non coroner post mortem, relatives should understand clinical photographs / x-rays may be taken, used and become part of the post mortem record and that body fluids / tissues are (sometimes) taken for analysis and genetic testing
- (then) UK guidelines in relation to photography in general have identified³:
 - recordings for which permission is not required
 - images taken from pathology slides
 - images of internal organsbut recommended informing the next of kin
 - recordings for which permission is required
 - any recording from which the deceased is identifiable

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- recordings for use in publically accessible media – whether or not pathologist considers the patient to be identifiable
- UK (exemplar sites) consent practices⁸ (now) include consent requirement for:
 - post mortem examination
 - retention of blocks and slides
 - retention of images
 - retention of material for Genetic investigations
 - retention of organs

3.3.3 Consent Record

- a signed record of consent should be made and stored with the relevant patient record and a copy as well supplied to the parent– this should also indicate any specific or special requirements indicated by the parents – these must be respected by the hospital^{3, 4, 5}

3.3.4 Organ Retention

- in certain circumstances (Hospital post mortem) it may be necessary to temporarily retain organs for further diagnostic purposes – this requires prior knowledge by the parent, particularly as this may affect funeral arrangements – temporary storage must be for a minimal (necessary) time period only^{2, 4}
 - within UK, specific ‘time’ performance metrics have been identified⁵ thereby setting out time framework for which temporarily retained organs can be released
 - preliminary report sent to requesting clinician within 2 working days of the post mortem examination, and final report in routine cases to referring clinician within six weeks (90% compliance)– thereby enabling prompt organ disposal
 - where a pathologist considers to retain organs for education and/or research purposes separate consent is required and must be recorded²
 - with regard to the retention of slides and blocks:
 - (then) Irish Pathology guidelines² identified that preservation of microscopic slides and blocks is ‘*demande*d’ by professional pathology practice regulators for the following reasons:
 - forming part of the medical record
 - material is available for further (future) study – of potential benefit for the family
 - enables an objective evaluation / revaluation of disease process in an individual should new knowledge present²
 - (then) ERHA guidelines identify requirement that parents understand that tissue samples are taken and retained as blocks and slides – which form part of the hospital’s post mortem record and therefore are available for subsequent review if required – storage management following procedures as those in place for dealing with samples from surgical procedures⁴
 - College of Pathology (UK) view that return of slides and blocks to parents is not supported – because it prevents re-evaluation / re-examination and audit³
 - provided a valid authorisation is given, slides and blocks may be retained and subsequently used⁷
 - more recent (exemplar site) guidelines⁸ in relation to consent and retention identifies:
 - purpose of slides and blocks
 - practice is to retain small samples indefinitely (kept for at least ten years) but do seek to secure specific consent for this practice – identifying potential shortcomings should this consent not be obtained
 - organs / part organs following post mortem examination are not retained without consent or other lawful authorisation, such as the Coroner^{2, 3, 4, 5, 6}

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- disposal of organs / tissue should comply (where possible) with the pre expressed (and recorded) wishes of the parent²

3.3.5 Communication of the results of the post mortem examination

- communication of post mortem results – families should be given a clear choice ranging from no communication → full disclosure including a copy of post mortem report – choice requirement should be recorded in writing⁷

3.3.6 Review of specific consent policies – Rotunda Hospital

In the context of then reviewing Consent policy, practice and management within the Rotunda Hospital for the period 2000 – 2007, whilst the performance yardstick used by the Review Group is current contemporary best practice, it must be recognised:

- pre 1999 / 2000, it is generally recognised that hospitals did not fully inform parents as to what a post mortem entailed or equally important what happened afterwards⁵
- necessary responses from Irish Health System – in terms of guidelines / recommendations in relation to the undertaking of post mortem examination and subsequent organ / tissue retention or disposal only really commenced in 2000

Therefore as previously stated (**Section 3**) it would be expected when considering pre 2000 practice, the obtainment of *'informed'* consent was significantly limited – with a more paternalistic approach being instead very much evident and consent to autopsy being viewed by hospitals in many instances as to include agreement to subsequent organ retention. There is though the expectation with the development and promulgation of guidelines / recommendations in relation to consent that individual Hospital practice changed / evolved to ensure parents were able to make informed decisions and that the hospitals respected and complied with these wishes

Accordingly, this section of the Review considers consent practice within the Rotunda from two perspectives, firstly contemporary best practice and secondly, in terms of compliance with guidelines / recommendations as they were developed within Ireland and the United Kingdom over the period 2000 - 2007

- ²: Guidelines for Post Mortem Consent and Retention of Samples. Faculty of Pathology of the Royal College of Physicians of Ireland (2000)
- ³: Guidelines on Autopsy Practice: Report of a Working Group of The Royal College of Pathologists. The Royal College of Pathologists (UK) (2002)
- ⁴: Protocol / Guideline for Hospitals and other relevant Agencies in providing a Quality Response to Families in Relation to Non Coroners Post Mortem Practices. Eastern Regional Health Authority (2002)
- ⁵: Post Mortem Examinations – Good Practice in Consent and the Care of the Bereaved – A Consultation Document. Health, Social Services and Public Safety (2003)
- ⁶: Report of Dr Deirdre Madden on Post Mortem Practice and Procedures. Madden. D (2005)
- ⁷: Report of the Working Group on Post Mortem Practice (2006)
- ⁸: Consent to a Hospital Post Mortem examination on a baby or child Version 5 Royal Liverpool Children's NHS Trust – Alder Hey (2007) – hospital examined in 2001 'Royal Liverpool Children's Inquiry'

3.3.7 Consent Policy

During the period 2000 – 2007 (January) the Rotunda had a total of 5 consent policies evident

Autopsy Permission Form	Consent A
- application period pre 2000 – April 2000	
Rotunda Hospital – Perinatal Autopsy Permission Form	Consent B
- application April 2000 – March 2002	
Rotunda Hospital – Perinatal Autopsy Permission Form	Consent C
- application March 2002 - November 2005	
Rotunda Hospital – Perinatal Autopsy Permission Form	Consent D
- application November 2005 – May 2006	
Rotunda Hospital – Perinatal Autopsy Permission Form	Consent E
- application May 2006 – January 2008	

3.3.7.1 Consent Policy A – application pre 2000 – April 2000

Policy Record is undated in terms of issue, time application and review

Records consent for an examination (autopsy) after death

- single (parent guardian) consent (signature) requirement – record requires identification of relationship
- date of consent obtainment recorded

Key Observations

- Policy is undated in terms of issue, time application and review
- Documentation does not readily facilitate any special requirements / wishes that the parent may have identified with regard to autopsy / organ retention / organ reburial
- Copy of consent record not routinely supplied to parent
- Policy does not record / identify any consent for organ retention (**see Section 3.2.1**)
- Policy does not identify the need / likelihood of temporary organ retention
- Policy documentation does not identify that slides / blocks will be retained (**see Section 3.2**)
- Policy makes no reference to superficial examination undertaken in all instances including photography – regardless of whether consent for autopsy was secured / or autopsy was undertaken

3.3.7.2 Consent Policy B – application April 2000 – March 2002

Policy Record is undated in terms of issue, time application and review

Records consent for an post mortem examination

- parent (guardian) consent (signature) and witness (signature) requirement – record requires identification of relationship

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Record requires parent to confirm their understanding that tissue may be retained from the autopsy and for parent to identify in that event whether:

- they want the hospital to dispose through either burial or cremation facilities
- make personal arrangements for disposal of tissues
- for this requirement parent is to contact the hospital within six months after the autopsy

Record also requires parent to confirm their understanding that organs removed during autopsy may be of value in medical education and research and

- confirm agreement to tissue retained at autopsy to be made available for medical education
- confirm agreement to tissue retained at autopsy to be made available for research into the causes of perinatal death conducted by the hospital

Record also requires parent to confirm that they have either been given or had read to them 'Frequently Asked Questions about Autopsy.

The Rotunda Hospital have confirmed that there are two versions and as well a document titled Bereavement Information for Parents - the second versions were in final print format in March 2003 and would have been in circulation soon after – 'one week or so' (no date specified)

Record also identifies a requirement for the parent to record not consenting to an autopsy being undertaken – rather inappropriately it is next to the statement "I understand that the autopsy may provide important information about the cause of death

There is also a comment section box – enabling in free text for the parent to identify any special requirements they may have in relation to autopsy, organ retention or disposal

Document: Frequently Asked Questions about the Autopsy (Post Mortem) (undated)

Provided as a written support guide, this document provides in succinct terms **Definitions**

- a definition of a Hospital Autopsy – identifying that it can not be undertaken without parent consent, Coronary Autopsy – identifying it can be undertaken without consent
- rational for autopsy – identification of cause of death and in relation to future pregnancies and what it will involve and who will undertake autopsy

Funeral Arrangements

Document specifies that every effort is made to ensure that the autopsy does not interfere with funeral arrangements

Organ Retention rational

In relation to organ retention document identifies

- brain will be retained in preserving fluid – necessary to enable more detailed examination which cannot be performed immediately after removal
- retention may also apply to other organs such as the heart and lungs
- retention format
- organ and tissue samples
- whole organs or small tissue samples preserved in a preserving solution

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- tissue blocks (potentially including whole small organs and Glass slides)
- a description of each is provided

Research

In relation to Research document identifies rationale and importance

Report Availability

Document identifies initial findings (report) will be available within 2 days” and final report generally within “6 – 8 weeks”

Organ Disposal

Document identifies

- the hospital will arrange for burial / cremation in a dedicated facility – approximately one year after autopsy
- or
- that the parent can specify a requirement that they wish to make private funeral arrangements

Document: Bereavement Information for Parents (undated)

This sets out

Introduction

- sets out information for a parent when a baby dies before or soon after birth

Post Mortem Examination

- states requirement for parents to consent to the undertaking of a post mortem examination and rationale and identifies that baby will be released for reburial after autopsy has been completed

Burial Arrangements

- identifies one of the staff from Bereavement Support will meet with the parent and discuss burial options and as well answer any questions the parent may have
- identifies two options
 - Private arrangements
 - whereby existing family plot or new plot can be used – Funeral Undertaker to assist in arrangements and provide costing
 - Holy Angels Plot (Glaasnevin Cemetery)
 - where parent decides they do not wish to have a private reburial, the hospital will assist in having the baby buried in one of the graves in the Holy Angels Plot

Document also offers the option of cremation – this to be undertaken with the assistance of the Funeral Undertaker – requiring a specific consent form

Spiritual Care

- identifies opportunity for parent to avail of services from parent’s priest / spiritual leader or those of hospital chaplain including a designated prayer service prior to burial

Information on Registration

- provides information in relation to the obtainment of birth / death / still birth certificate and contact details for Birth Registration staff

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Support

- identifies social work support and opportunity to avail of bereavement counselling.
- identifies that where possible a photograph (for the parent) will be taken
- in the instance of the baby having an abnormality – document also identifies that contact details of related support groups can be supplied

Follow Up Care

- identifies (if discharged home before baby's burial) contact person to liaise with in relation to seeing baby / confirm funeral arrangements
- post natal check up six – eight weeks after discharge
- for parents with history of recurrent miscarriages – referral to Pregnancy Loss Clinic
- if an autopsy has been undertaken – confirmation that an appointment will be arranged once results are available (no time period specified)

Key Observations

- Policy is undated in terms of issue, time application and review
- Hospital have identified temporary retention (without consent) for periods of up to one year (for hospital disposal process) and by inference six months (for private disposal) (**see section 3.1**)
- Consent to organ retention is non specific – tissue and does not readily enable the family to record any limitation or know exactly what organs have been retained
- statement in relation that every effort is made to ensure that the autopsy does not interfere with funeral arrangements does not recognise that significant organ retention may have in many instances a potential negative impact on funeral ceremony in the eyes of the parents - retrospectively
- cremation option not available
- copy of consent record not routinely supplied to parent
- Policy does not easily identify that slides will be retained regardless of whether consent to organ retention has been secured (**see Section 3.2.2**) – ***'form part of (the) baby's medical record'***
- policy states that tissue samples may be sent to external laboratories – these samples are not returned
- no specific reference to the potential undertaking of photographs of the baby
- It is unclear as to why parents have to identify that they do not want an autopsy performed
- it is inappropriate that section for parent recording they do not want an autopsy performed on their baby immediately supersedes the statement "I understand that the autopsy performed may provide important information about the cause of death.
- policy states that final post mortem report is usually ready within 6 – 8 weeks (**see Section 3.2**)

3.3.7.3 Consent C – application March 2002 – November 2005

Policy Record is undated in terms of issue, time application and review requirement

Record enables the recording of parental consent for the undertaking of an autopsy

- parent (guardian) consent (signature) and witness (signature) requirement – record requires identification of relationship

Policy document requires parent to record / confirm their understanding of

- an autopsy
- that the information secured will be discussed with parents and medical staff
- that in accordance with best practice, it will be necessary to temporarily retain tissues and some organs

and

- in that event, the parent is required to record
 - wish for the hospital to arrange burial / cremation
 - wish for personal arrangements for the burial / cremation of (temporarily retained) organs
 - to effect this arrangement policy requires the requirement to contact the hospital within 1 year of the autopsy (if parent does not contact policy states that the hospital will contact the parent)

Policy requires the parent to identify their agreement that tissues / organs retained at autopsy be made available for research into the causes of perinatal death.

Policy document also states that this research will be subject to the approval of the Research and Ethics Committee

Policy requires the parent to confirm that they have received 'Frequently Asked Questions about the Autopsy' (or had the booklet read to me) and have had the opportunity to ask questions in relation to the autopsy

The Policy document also requires parents that do not want an autopsy undertaken to record this requirement – again this is inappropriately written next to the statement 'I understand that the autopsy may provide information about the case of death'

There is also a section marked comments – with no instructions as to purpose

Key Observations

- Policy is undated in terms of issue, time application and review
- Hospital have identified temporary retention (without consent) for periods up to one year (for hospital process) and also one year for private burial (**see section 3.1**)
- consent to organ retention is non specific- tissue / organs and does not readily enable the family to place limitations on retention or know exactly what has been retained
- copy of consent record not routinely supplied to parent

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- Policy does not easily identify that slides will be retained regardless of whether consent to organ retention has been secured (**see Section 3.2**)
– ***‘form part of (the) baby’s medical record***
- policy states that tissue samples may be sent to external laboratories – these samples are not returned
- no specific reference to the potential undertaking of photographs of the baby
- It is unclear as to why parents have to identify that they do not want an autopsy performed
- it is inappropriate that section for parent recording they do not want an autopsy performed on their baby immediately supersedes the statement “I understand that the autopsy performed may provide important information about the cause of death”.

3.3.7.4 Consent D – application November 2005 – May 2006

Policy Record is undated in terms of issue, time application and review requirement

Record enables the recording of parental consent for the undertaking of an autopsy

- parent (guardian) consent (signature) and witness (signature) requirement – record requires identification of relationship

Policy requires parent to record that that they have received ‘Frequently Asked Questions about the Autopsy’ (or had the booklet read to me) and have had the opportunity to ask questions in relation to the autopsy

Policy requires parent to confirm that they understand :

- autopsy involves the examination of the body, its organs to establish cause of death / possible risk to future pregnancies and that the information derived from the autopsy will be discussed with parent and medical staff
- that tissues and organs that are removed during the autopsy may be of value to research

Policy requires parent to confirm agreement

- that tissues / organs retained at autopsy may be made available for research into the causes of perinatal death. Policy document also states that this research will be subject to the approval of the Research and Ethics Committee

There is also a section marked comments – with no instructions as to purpose

The Policy then identifies to the parent

- if their baby is buried in The Holy Angels Plot in Glasnevin, then if they wish, any remaining post mortem tissue can be reburied by the hospital in the same grave as the baby (cross referenced with option a)

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- if the parent wishes to make personal arrangements for reburial, then this is discussed at the post mortem follow up appointment and 'the necessary discussion entailed for this'
- if their baby is buried in a private grave, the hospital requires written permission to rebury organs.
 - should the parent not wish to return to the hospital, then this can be effected through the undertaker previously used for the initial burial of the baby (and that he will contact the hospital with your permission) (cross referenced with option b)
- should the parent decide to make personal arrangements for reburial of organs and then later change that decision where you do not wish to be involved the parent must contact the hospital in writing giving the hospital permission to carry out reburial of tissue – giving details of grave name, number and cemetery
- should the parent wish that any remaining post mortem tissue be cremated then the necessary cremation forms must be completed by the parent.
 - The Policy also makes the observation that the only ashes remaining after cremation of post mortem tissue are those of the casket, which are not normally returned to the parents unless specifically requested (cross referenced with options d and e)

The policy also states that in accordance with best practice, it will be necessary temporarily retain tissues and some organs in the autopsy and in this event

The parent is required to give consent:

- (a) for the hospital to rebury any remaining tissue / organs in the baby's grave in the Holy Angels Glasnevin Cemetery
- (b) for the hospital to rebury any remaining tissue / organs in the private/ family grave
- (d) for the hospital to cremate any tissues / organs in the appropriate manner and confirm they do not wish the casket ashes be returned
- (e) for the hospital to cremate any tissues / organs in the appropriate manner and confirm they do wish the casket ashes be returned
- (c) option enables the parent to confirm to make personal arrangements for burial of any remaining tissues/ organs and that they will contact the hospital within three months

The last section of the Policy document is titled 'Perinatal Autopsy Non Permission Form'

This firstly identifies that all babies removed to the mortuary that are not having an autopsy performed undergo a brief examination which includes photographs, an x-ray and body measurements for the purposes of maintaining a medical record for the baby and for the parents to record their understanding of these actions – Yes / No

The Policy document also requires parents that do not want an autopsy undertaken to record this requirement – again this is inappropriately written next to the statement 'I understand that the autopsy may provide information about the case of death

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There is also a section marked comments – with no instructions as to purpose

Key Observations

- Policy is undated in terms of issue, time application and review
- Hospital have identified temporary retention (without consent) for periods up to one year (for hospital process) and no time period for private burial – beyond confirming this will be discussed at the post mortem follow-up appointment
- consent to organ retention is non specific- tissue / organs and does not readily enable the family to place limitations on retention or know exactly what has been retained
- copy of consent record not routinely supplied to parent
- Policy does not easily identify that slides will be retained regardless of whether consent to organ retention has been secured (**see Section 3.2**) – ***‘form part of (the) baby’s medical record***
- policy states that tissue samples may be sent to external laboratories – these samples are not returned
- It is unclear as to why parents have to identify that they do not want an autopsy performed (Perinatal Autopsy Non-Permission Form)
- it is inappropriate that section for parent recording they do not want an autopsy performed on their baby immediately supersedes the statement “I understand that the autopsy performed may provide important information about the cause of death.
- This section also requires the parents to confirm their understanding that all babies removed to the mortuary that are not having an autopsy performed, undergo a brief examination which includes photographs (unspecified), an x-ray and body measurements – this structuring is inappropriate

3.3.7.4 Consent E – application May 2006 – January 2008

With exception of some very minor grammatical changes, this policy document is identical to **Policy D**

Key Observations – remain as with **Consent D**

- Policy is undated in terms of issue, time application and review
- Hospital have identified temporary retention (without consent) for periods up to one year (for hospital process) and no time period for private burial – beyond confirming this will be discussed at the post mortem follow-up appointment
- consent to organ retention is non specific- tissue / organs and does not readily enable the family to place limitations on retention or know exactly what has been retained
- copy of consent record not routinely supplied to parent

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- Policy does not easily identify that slides will be retained regardless of whether consent to organ retention has been secured (**see Section 3.2**) – ***‘form part of (the) baby’s medical record***
- policy states that tissue samples may be sent to external laboratories – these samples are not returned
- It is unclear as to why parents have to identify that they do not want an autopsy performed (Perinatal Autopsy Non-Permission Form)
- it is inappropriate that section for parent recording they do not want an autopsy performed on their baby immediately supersedes the statement “I understand that the autopsy performed may provide important information about the cause of death”.
- This section also requires the parents to confirm their understanding that all babies removed to the mortuary that are not having an autopsy performed, undergo a brief examination which includes photographs (unspecified), an x-ray and body measurements – this structuring is inappropriate

3.4 Review of Control Provision

This section of the Review identifies and considers related control provisions in summary format

Figure 3.4.1 identifies Organisational Structure: Rotunda Hospital

Figure 3.4.2 identifies Organisational Structure: Department of Pathology

Figure 3.4.3 identifies Current (2007) Work Process Flow Chart – as identified by Hospital in relation to autopsy

3.4.1 Organisational Structure – Rotunda Hospital (Figure 3.4.1)

The Hospital have identified that designated Directors met with the Master every two months to consider hospital business / direction – also attending this meeting – Hospital Secretary Manager and Director of Midwifery

- related responsibilities for all clinical midwifery / nursing staff and Clinical Risk Manager held by the Director of Midwifery
- related (corporate) responsibility for Quality (and marketing) identified as being held by the Hospital Secretary Manager

The Hospital have also identified the Post Mortem Grouping – attending Master (Chair), and including Consultant Obstetrician, Bereavement Sister, Director of Midwifery and Director of Pathology (**3.1.1**)

From staff interview and supplied documentation, this group's function has included (in the review period being considered) the following responsibilities:

- dealing with responses to parents in terms of:
 - reburial
 - contacting parents
 - Meeting with parents
- Post mortem report availability and action requirements to secure associated performance targets / remedial action where necessary

and

- reviewing consent policy and agreeing necessary change (**3.3.1**)

3.4.2 Organisational Structure Department of Pathology (Figure 3.4.2)

The Hospital have identified that the Diagnostic Services Consultant / Director of Pathology reports to the Master

- this post carries responsibility in 2 areas:
 - strategic service development
 - oversight of day to day laboratory management

The Hospital have also identified the role Head of Histopathology / Cytopathology

- this post carries responsibility in 4 areas:
 - strategic development of both laboratories
 - administrative day to day management
 - clinical meetings / conferences
 - diagnostic work – surgical pathology, cytology and perinatal autopsy

Consultant A has also identified there were also related responsibilities with regard to undergraduate / post graduate education and research in perinatal medicine

Consultant A confirmed to the Review Group, as holding both these posts during 2000 – 2006

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Within the Pathology Department, Consultant A has also identified the existence of a Laboratory Management Committee – operational responsibility for day to day service delivery – comprising Director, all Consultants and Chief Technologist

Relevant Consultant Staffing – commitment to Rotunda Hospital

Consultant post (1) 8 sessions Rotunda : 3 sessions St. James's
Consultant post (2) 5 sessions Rotunda : 6 sessions Temple Street
Consultant post (3) 8 sessions Rotunda : 3 Mater – not filled on a permanent basis until October 2008

- total commitment pre 2008
 - Royal Liverpool Children's Trust 2.7 wte Consultant provision dealing with 278 post mortems annually (2006) .v. 197 post mortems Rounda Hospital (2006) 1.2 wte
 - The Review Group were informed that post (3) approved by ERHA in 2004
 - advertised March 2005 - no interview
 - advertised November 2006 - no interview
 - advertised 2007 - interviews January 2008
 - post filled October 2008
 - the Review Group would suggest that this is an excessively long period to secure a permanent post holder

Locum deployment

- (1) August 2003 - July 2005
- (2) January 2007 – February 2007
- (3) June 2007 – August 2007
- (4) April 2008 - June 2008

It should be noted that no further consultant requirements have been identified by the hospital

3.4.3 Current Work Process / Flow Map – Post Mortem (Figure 3.4.3)

Work process identified in **Figure 3.4.3**

The Review Group noted that in terms of accountability for totality of work process

- performance was considered / overviewed by Post Mortem Grouping
- no one individual was accountable for totality of work process

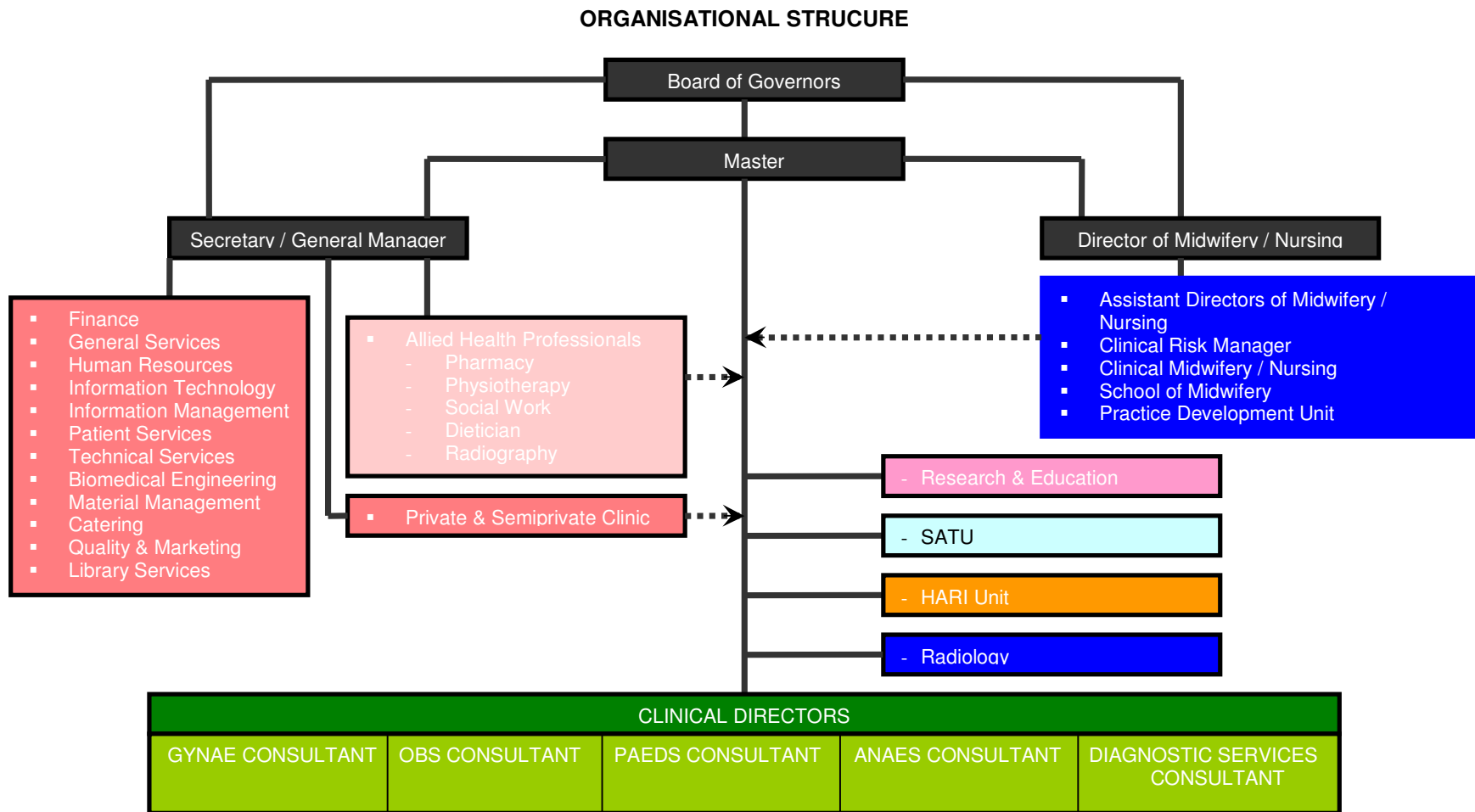
The Review Group also noted that whilst there were periodic reports identifying work load in terms of autopsy volumes / type, there was no singular composite report available considering actual performance against target performance for all associated work process deliverables including consent and status of organ inventory

These two issues the Review Group would suggest, account for:

- yielding less than accurate information from one work process perspective **(3.2.7.5.6)**
- insufficient oversight knowledge by Post Mortem Committee in relation unblocked organs for long periods **(3.4.1)**

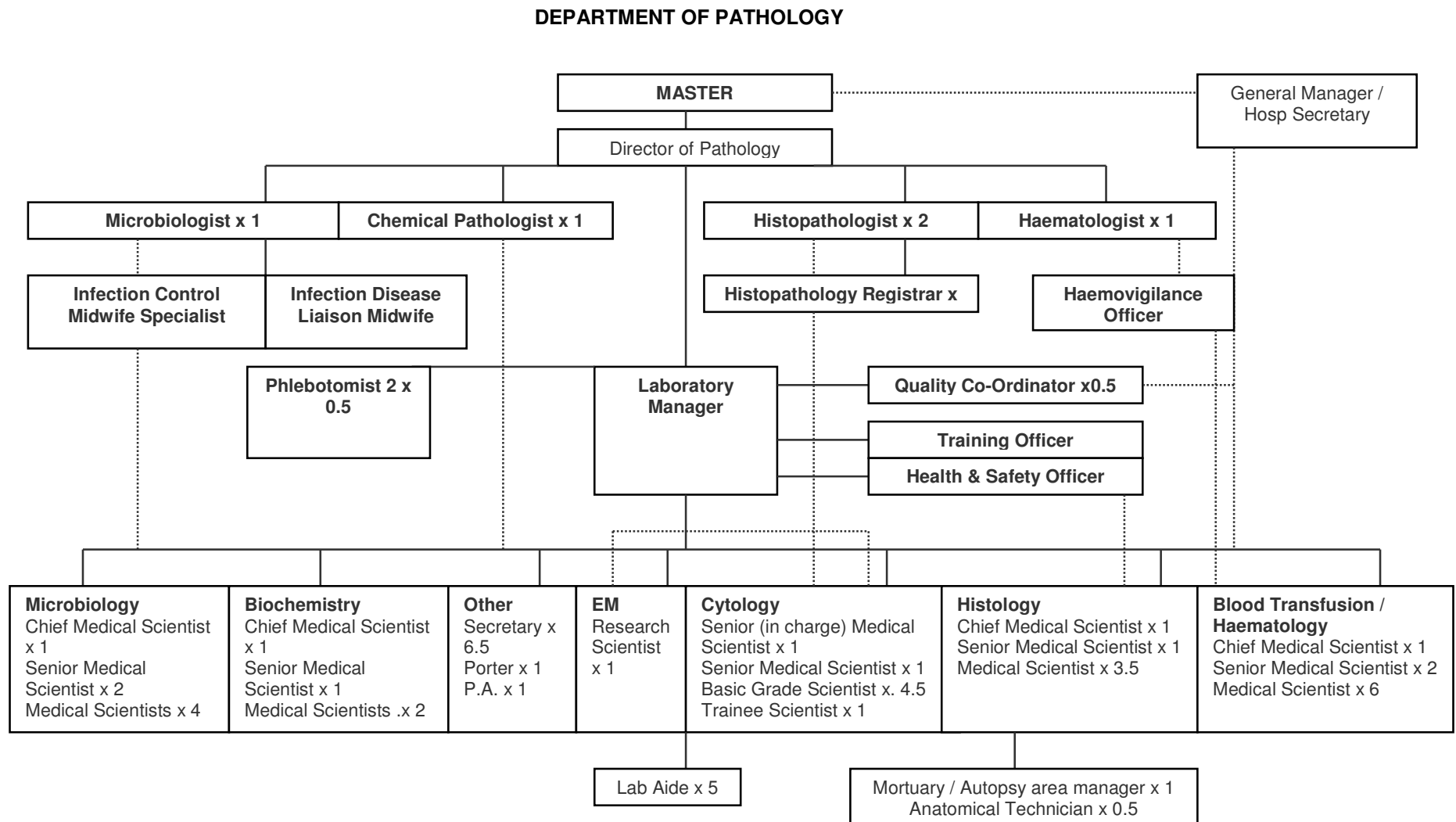
In terms of specific control application relating to post mortem process, the Hospital also identified to the Review Group that in October 2007, the Director of Midwifery had written to Consultant A, identifying a requirement for a system to be put in place to deal with enquiries from parents where pathology work had not been completed. The Hospital have also confirmed that no formal response has been received in relation to this matter

Figure 3.4.1 Structure Rotunda Hospital – as identified by Hospital



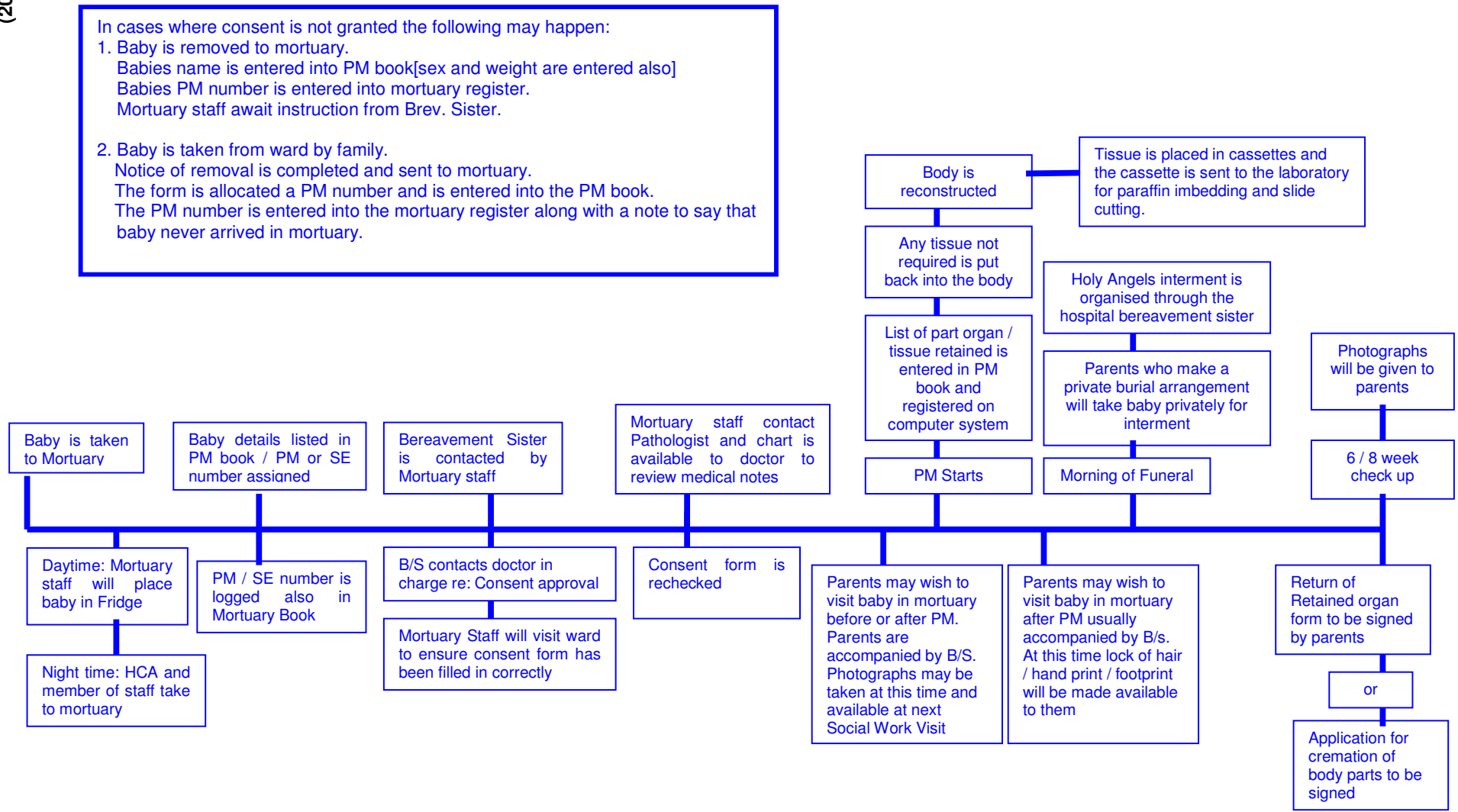
Look Back Exercise – The Rotunda Hospital

Figure 3.4.2 Department of Pathology Organisational Structure – as identified by Hospital



Look Back Exercise – The Rotunda Hospital

Figure 3.4.3 Current Work Process Flow Chart – as identified by the Hospital in relation to autopsy (2007)



4 Key Findings of Review

This section of the Review identifies Key Findings of the Review Group in relation to:

- organ retention
- post mortem practice / management
- consent policy, practice, management
- control provision

Where discernable, apparent causal factors in relationship to performance / compliance with set standards, obtained through record review, and or staff interview have been considered, and identified

4.1 Organ retention

In total there are 460 autopsies where organs have been retained:

- **59% (n=271) relating to period 1983 - 1999**
 - 15% (n=41) retained for purposes of Research + Education period 1983 - 1999
 - 85% (n=230) retained temporarily by Hospital period 1983 - 1999

Pathologist A has explained that prior to 2000, tissue samples and organs retained at the time of autopsy were held in storage for approximately 5 years. This was to enable same tissues to be used for research purposes into causes of death in-utero and during the neonatal period.

Pathologist A also identified that occasionally cases – ‘uncertain cause of death’ (pre 1995) had also been retained with the agreement of the Master

- It should be noted though
 - applicable consent policy identified by Hospital for this period (**3.1.1**) secured consent for autopsy only and not organ retention for research and education purposes
 - therefore there are 271 cases of organ retention with no consent for retention
 - there are 230 cases of organ retention where this temporary retention is for periods > 8 years, this practice is contrary to described practice by hospital
 - it is likely that families are unaware that these organs have been retained
- **41% (n=189) relating to period 2000 - 2007**
 - 21% (n=40) retained for purposes of Research + Education (98% Consultant A)
 - 62% (n=118) retained temporarily by Hospital
 - 16% (n=31) retained temporarily by Hospital awaiting family confirmation as to disposal

It should be noted:

- 2000 January – April 2000 consent secured agreement to autopsy only – 24 instances where organs retained
- 92 instances where organs retained temporarily (not awaiting parent confirmation as to disposal / reburial) > 1 year (not compliant with consent policy (see section **3.3.1**)
 - it is likely that families are unaware that these organs have been retained.

The Hospital has also identified 7 cases in which families have formally identified concerns / dissatisfaction in relation to post mortem practice

- post mortem not completed 13 months after delivery
- post mortem report issued very late
- organs not available for release 2 years after delivery – as a result of blocking having not been undertaken
- temporary organ retention for 2 years

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Of the autopsies where organs have been temporarily retained

1991 – 1999

- 56% (n=123) post mortems undertaken by Consultant A
- 35% (n=84) post mortems undertaken by Consultant B
- 9% (n=21) post mortems undertaken by Consultant (Other)
 - in 2 additional instances no documentation supplied to review team

2000 – 2007

- 89% (n=133) post mortems undertaken by Consultant A
- 8% (n=12) post mortems undertaken by Consultant B
- 3% (n=4) post mortems undertaken by Consultant (Other)

4.1.1 Temporary Retention / Volume of Organs Retained

- **post mortems which resulted in temporary (not consented) organ retention** (period 2000-2007) [denotes organs retained at the time of this review]
 - Consultant A – 89% (n=133) – total post mortems undertaken – 429 – 31% resulted in organ retention
 - Consultant B – 8% (n=12) – total post mortems undertaken – 223 – 5% resulted in organ retention
 - it should be noted in terms of practice variance that majority of temporary organ retention pertains to Consultant A
- **Volume of Organs retained (period 2000 – 2007)**
 - Consultant A – average number of organs retained 21
 - Consultant B – average number of organs retained 2
 - Consultant A has explained that conventional standard of perinatal autopsy has in general provided a poor level yield and instead Consultant A has adopted a “very searching approach” to the use of both light and electron microscopy – practice requirement resulting in an increase in the number of specimens samples and the use of special staining techniques. Consultant A identifies that this practice has secured a specific diagnosis in over 90% of cases
 - The Review Group would suggest that contemporary practice now tries to ensure a limited number of tiny cassette size blocks being retained, with sampled organs generally being returned to the body within 3-7 days, rarely retaining anything for long periods - obviously with the exception of the brain (and then for periods < 4 weeks)

4.1.2 Key causal factors identified by Hospital for organ retention volume / retention time period - particularly those ‘temporarily’ retained./ delays in post mortem report production

The Hospital has identified significant organ retention volume / prolonged retention time has arisen from four causal factors

- **significant delay in block / slide preparation (necessary) before organ disposal**

As evidenced by:

 - national audit¹ identified that organs pertaining to death arising in 2006 had not been blocked at time of preliminary review (December 2007)

Look Back Exercise – The Rotunda Hospital

These are attributed by Consultant A as a result of:

- reduced Consultant provision – relating to post mortem practice
 - during 2000 Consultant B spent significant time assisting Temple Street Children’s Hospital in connection with organ retention enquiries and had to reduce input to Rotunda Hospital and again in 2003
 - subsequently deployed locum input had limited input to post mortem practice as a result of inexperience / at times full locum provision was not securable – post (3) not filled until 2008
 - during 2004 – centenary year for the foundation of the laboratory, a meeting was arranged with international speakers by Consultant A – considerable time was spent in organising this event
 - preparation for CPA accreditation in March 2007

It should be noted that internal bereavement records confirm multiple instances in each year (period 2001 – 2007 where organ disposal has been delayed as a result of “awaiting blocking of tissue”

2001 (3.2.3.5.6)

2002 (3.2.4.5.6)

2003 (3.2.5.5.6)

2004 (3.2.6.5.4)

2005 (3.2.7.5.6)

2006 (3.2.8.5.4)

2007 (3.2.9.5.4)

- the Review Group would suggest that this practice of significant organ / unblocked tissue retention, rather than contemporary practice (4.1.1) would itself have been a significant contributory factor in relation to delays experienced
- **increased general pathology workload**
 - the hospital has demonstrated an overall work load increase from 2000 onwards, particularly across the disciplines of Cytology, Histology and autopsy. It is noted 2000 / 2007 post mortems have increased by 34%
- **post mortem report completion**
 - in terms of report completion (4.2.5) Consultant B has identified in 2000 delays were arising as a result of insufficient secretarial staff support
- **policy change**
 - Pathologist A has explained in 2000 (then) Master confirmed that there should be no further disposal of organs / tissue until Dunne Enquiry had been completed – documentation to support this policy change was not supplied to the Review Group
 - It should be noted that bereavement files do identify in 2000 only delays being attributed to ‘awaiting outcome of enquiry’

4.1.3 Comparison of Organ Retention post 2000– with other Irish Maternity Hospitals undertaking autopsy

National Audit¹ identifies for designated hospitals the cases of organ retention – post 2000 (excluding adult cases)

- Hospital A:**
- 43 cases of retention
 - of which 40 identifiable pre viable foetus
 - of which none retained for Research and Education

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- Hospital B:**
- 70 cases of retention
 - 5 cases of retention for Research and Education
- Rotunda Hospital**
- 189 cases of retention
 - 40 cases of retention for Research and Education

The Review Group note that whilst it is appropriate practice to ensure sampling of organs⁵, it would not be excepted practice to retain organs for protracted periods of time.

Excepting delivery value variance between hospitals, the Review Group would suggest that the Rotunda Hospital does have practice variance with other maternity units, both in terms of overall organ retention and as well retention of organs for Education and Research purposes

Overall the Review Group would suggest this significant delay in blocking tissue is unacceptable and has inappropriate resulted in:

- non consented organ retention for periods > 1 year in 92 cases
- significant delays for families wanting to secure reburial

4.2 Post mortem practice / management 2000 - 2007– Key Findings

4.2.1 Post Mortems undertaken

In total 667 post mortems were undertaken during this period

- 87% Hospital
 - 7% Coronary
 - 6% Other Hospital
 - demonstrating hospital's role as a tertiary service provider in relation to histopathology
- Consultant A – **429** post mortems undertaken
Consultant B – **223** post mortems undertaken
Consultant C (Other) – **15** post mortems undertaken

It should be noted

- Consultant Pathologist A has identified a variance in autopsies undertaken by individual consultants based on own [self] records held
 - Review Group have examined this record in comparison with document review and have noted in relation to this supplied report (pertaining to years 2000, 2001, 2002, 2003, 2007)
 - 7 instances where Prosector not identified
 - 2 instances where Consultant A identified as Prosector / review of individual post mortem report / documentation identifying Consultant B / Other as Prosector.

The Review Group would again emphasise this highlights the concerns identified by Willis (1.2) in relation to a singular comprehensive database.

Superficial examinations

In total 748 were undertaken during this period (4.3)

4.2.2 Record Availability

- | | |
|--|------------------|
| Post Mortem File | - 100% available |
| Bereavement File | - 98% available |
| Patient File (Maternity) | - 97% available |
| Consent for autopsy record | - 97% available |
| Post Mortem Report | - 100% available |
| Retention Record | - 83% available |
| - excluding 2000 – retention record introduced in 2001 | |

The Review Group would note appropriate performance (in relation to document availability) is demonstrated with the exception of Consent Record and Retention Record

4.2.3 Organ Retention Rational (identified in Section 4.1)

4.2.4 Non Compliance with consent obtained

Section 3.2 identifies 5 causal types

- Retrospective Consent to autopsy securement apparent – **10 cases**
- Organs (temporarily retained) noncompliant with policy of disposal within 1 year – **92 cases**
- Limitations identified by parents / Organs retained – parents did not consent to retention – requirements identified by parents not adhered to – **8 cases**

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- Failure to obtain Consent – **1 case**
- Missing Consent Record – **18 cases**

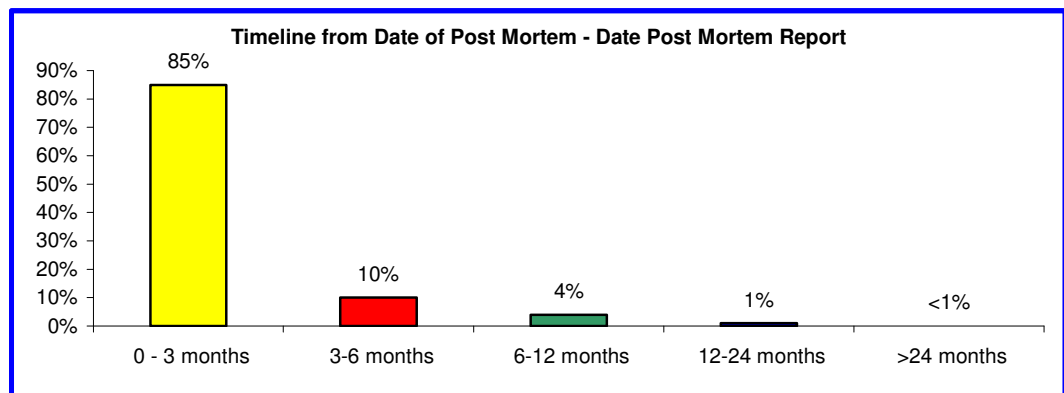
In total 129 cases of organ retention have been identified as non compliant

As previously stated, there are also a total of 295 cases pre April 2000 where no consent to organ retention has been secured **(3.3.5)**

In total 424 cases of non compliance with consent obtained have been identified.

4.2.5 Post Mortem Report

Timeline from Date of Post Mortem → Date of Post Mortem Report



- 71% of reports are dated (n=472) by the Pathologist
- 29% of reports are undated (n=195) by the Pathologist

of the 71% of reports which are dated (n=472):

- 85% are dated 0-3 months of the Post Mortem
- 10% are dated 3-6 months of the Post Mortem
- 4% are dated 6-12 months of the Post Mortem
- 1% are dated 12-24 months of the Post Mortem
- it should be noted in cases where the date of Post Mortem was not listed, the Date of Death was used for this comparator.

Target set for report availability ERHA (national) guidelines 6 weeks

Rotunda Hospital performance:

Consultant A – 12% compliant with 6 week target

Consultant B – 41% compliant with 6 week target

- denotes first section of post mortem report availability

The Review Group would suggest that this is unacceptable performance

The Review Group note that delays in post mortem report completion has been identified as arising from

- delay in block / slide preparation **(4.1)**
- insufficient secretarial support **(4.1.2)**
- case complexity

As previously identified the Review Group would suggest that this practice of significant organ / unblocked tissue retention, rather than excepted contemporary

practice (4.1.1) would itself have been a significant and potentially unnecessary contributory factor in relation to delays experienced

Examination of Report content

Full Post mortem report

- 234 are incomplete / not validated by Consultant Pathologist – representing 35% of full post mortem reports

Superficial Examination report

- 35 are incomplete / not validated by Consultant Pathologist – representing 5% of superficial examination reports
 - 32 instances the superficial report was not available for review

Consultant A has identified that as a result of parents requesting copies of post mortem report, a practice change was introduced (1995) whereby

- only the diagnostic part of the report – identifying all critical findings would be released to the designated clinical team
- the second half of the report which identifies a description of external / internal examination / organ appearance would be retained in the laboratory and not released
- a note is placed at the end section of the report being released, stating that second half of report could be accessed on request – but would require a pathologist for interpretation

Consultant A has also explained that in 2000 a requirement for full report disclosure was identified by the Master. The Review Group note that this requirement has not been actioned by Consultant A. (4.2.2)

The Review Group would also note that ‘Frequently Asked Questions about the Autopsy’ identifies that autopsy report is written using medical terminology – requiring (usually) a doctor directly involved in the care of the mother to explain it. It is not explained to the parent that unless specifically requested, they will not receive full post mortem report (3.3)

The Review Group would also note that the majority of post mortem reports identified as incomplete / not validated - relate only to the contents of the second half of the report only.

4.2.6 Retention sheet Record

The Review Group have identified that Retention Record was not available for 17% of all autopsies undertaken 2001-2007 and 38 instances where retrospective organ inventories had been compiled by Consultant A.

With regard to failure to complete inventory record at time of autopsy Consultant A has explained:

- inventory record introduced by Consultant A in response to Hospital solicitors requiring a mechanism to effect documenting of organ retention at autopsy – necessary to enable / satisfy parental enquiries. This was then adapted as an inventory record to be used prospectively.
- non completion of this record arose because of work ‘back log’ – which is felt to have commenced in 2000
- this specific record was not the sole source on which an organ inventory could be established, other sources being:
 - tissue blocking ‘out form’
 - histology record
 - histology slides
 - gross description in post mortem report

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- Post Mortem photography

The Hospital have explained:

- following the audit in December 2007 and the concerns raised with the Management Executive Team, the Master agreed to free up Consultant Pathologist A from clinical commitments to address the issue of unblocked tissues and incomplete retention sheets. This work would be validated subsequently by an independent pathologist. The information used to complete the retention sheets was taken from the post mortem reports and no reference was made to examination blocks or any other material available. In effect, Consultant A was freed up from all clinical work to address issues which had arisen from the national audit. This agreement was communicated to the Network Manager at the time. A letter from the Master to the Network Manager dated 8th February 2008 confirms this and is available for review. Subsequently, concerns were raised with the Management Executive by the independent auditors and the work was ceased with immediate effect.

The Review Group would note:

- in many instances there has been a significant delay in blocking / slide production
 - thereby negating certain records as being able to provide an organ inventory record
- many of the post mortem reports (second half) are incomplete / not validated by Consultant – thereby not necessarily the most reliable record
- it is unclear why some of the inventory records have been completed retrospectively – not necessarily as a result of purely work pressure – as non completion not evidenced in 2003, 2004, 2007 and as well:
 - in 31 instances inventory record was completed after organs had already been returned for reburial
 - in 2 instances no organs were retained
 - the review Group also observed 2 instances where a retrospective record inventory has been completed by Consultant A in relation to autopsies undertaken by Consultant B

Consultant A has identified that retrospective completion of record was undertaken at the request of Hospital Management.

4.2.7 Release of Slides

A sample of cases were reviewed from each year (2000 – 2007) in order to ascertain timelines for the creation of blocks and slides from organs retained. This exercise demonstrates a small but consistent pattern, whereby sets of slides (being made from retained blocks) are released to the Consultant and then further (new) sets of slides are prepared and released several years after initial autopsy. – 2000, 2001 – predominantly relating to autopsies undertaken by Consultant A

4.3 Consent policy, practice, management – Key Findings

- consent policy [for period undated] in terms of issue, application, review and ownership is undated / unspecified

- pre April 2000 no evident mechanism for securing consent for organ retention
 - post April 2000 evident mechanism for securing consent for organ retention

- temporary retention for periods of up to one year in policy is excessive and inappropriate. **Section 3.2.1.3** also identifies multiple instances where the hospital is not even in compliance with this limited standard
 - Current contemporary practices³ recommend the avoidance of unnecessary prolonged periods of temporary organ retention through:
 - utilisation of MRI or percutaneous needle biopsy alternatives
 - prompt preparation of blocks / slides
 - prompt completion of full post mortem report - target 6 weeks

- consent policy, when considering the need for temporary organ retention is generally non specific – tissue – with the exception of support document which does identify specific requirements relating to the brain and that temporary retention may also apply to other organs such as the heart and lung

- policy does not require consent for slide / block [permanent] retention – rather there is instead a requirement for the parent to understand necessity for this requirement – in terms of being part of the baby’s medical record
 - it should be noted that exemplar sites⁷ now seek consent for the retention of blocks and slides

- the taking of photographs is not explicit for period pre 2000 – November 2005 and then is identified as a requirement for the purposes of maintaining a medical record. As previously identified guidelines² have identified constraints on the taking of photographic images (**see section 3.3**)
 - it should be noted that exemplar sites⁷ now seek consent for the retention of images

- policy states that full post mortem report will usually be available within six to eight weeks
 - **Section 3.2.10** demonstrates multiple instances where the hospital is not compliant with this standard

- it remains questionable practice to require parents to formally record that they do not consent to the undertaking of a post mortem – the rationale stated by the hospital is so that parents are clear that not undertaking an autopsy may significantly limit the establishment of cause of death.
 - should be noted that exemplar sites⁷ do not seek to secure this agreement

- overall in relation to overall obtainment of consent in relation to post mortem practices, it should be noted that exemplar sites⁷ now seek separate consent for:
 - post mortem examination
 - retention of blood / fluids
 - retention of slides and blocks
 - retention of images
 - retention of material for genetic investigations
 - retention of organs

- parents were not routinely supplied with a copy of consent record
 - it should be noted that exemplar sites⁷ do provide a copy to parents

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Consent 2007

- whilst not within terms of reference for review, the Review Group did consider provided Consent Policy / Record – introduced in 2007 and noted:
 - policy still requires parent to understand (rather than consent to):
 - retention of tissue for microscopic examination
 - retention of organs and tissues for detailed examination
 - policy identifies “tissue / samples” retention rather than “organ” retention for Research and Education purposes - this does not necessarily enable ‘informed’ consent
 - policy requires parent to identify they do not want an autopsy undertaken, but (at the same time) consent to a superficial examination – this is inappropriate:
 - parents should not have to record they do not agree to an autopsy
 - in identifying non agreement to autopsy – this should not place parents (having) to consent to a superficial examination
 - policy requires hospital staff member responsible for obtaining consent to identify ‘that consent to autopsy has been given freely on an informed basis’ – this is a judgement for the parent and not the hospital

The Review Group would also note that (appropriately) this policy identifies:

- copy of consent record is supplied to parent
- (temporary) organ retention is identified to parent

²: Guidelines for Post Mortem Consent and Retention of Samples. Faculty of Pathology of the Royal College of Physicians of Ireland (2000)

³: Guidelines on Autopsy Practice: Report of a Working Group of The Royal College of Pathologists. The Royal College of Pathologists (UK) (2002)

⁵: Post Mortem Examinations – Good Practice in Consent and the Care of the Bereaved – A Consultation Document. Health, Social Services and Public Safety (2003)

⁷: Consent to a Hospital Post Mortem examination on a baby or child Version 5 Royal Liverpool Children’s NHS Trust – Alder Hey (2007) – hospital examined in 2001 ‘Royal Liverpool Children’s Inquiry’

4.4 Key Findings – Control Provision

This section of the Review identifies key findings in relation to Control provision and application

4.4.1 Organisational Structure – Corporate / Executive

- necessary accountability structure is less than optimally defined in terms of oversight
- in terms of corporate or executive accountability, no one individual appears holds ownership for totality of autopsy process in terms of performance
- the Risk Management Function did not appear engaged in the identified instances of complaint relating to consent practice or the management, retention and subsequent disposal of organs.

4.4.2 Orientation / Functionality of Post Mortem Group

This Group was initially established to manage concerns / information requirements of parents (3.1.1), it has evolved to include:

- development of consent policies and procedures
- responses to problems identified by committee members
- general oversight of autopsy process

The Review Group would suggest that the Group's performance from an oversight function perspective has been less than optimal, specifically:

- problems arising / complaints appear to have been treated on a case by case basis, rather than a necessary system 'diagnosis and treatment' approach
- inappropriate formality of communication (3.4.3)
- identifying (as late as 2007) the requirement to establish a process or system to deal with delays (3.4.3)
- the problem of 'awaiting blocking' is consistent across years 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007
- the absence of robust performance measurement
- the absence of audit structure and process
- policy implementation (4.1.2) (4.2.5)
 - policy to retain organs not identified to Review Group in written format (4.1.2)
 - policy of full post mortem availability not implemented (4.2.5)
- policies not version controlled (3.3.1)
- no complete organ inventory system / data base (2.6)
- very limited examination of post mortem practice (as opposed to process) – particularly evident consultant variation
 - (4.1.1) - temporary organ retention
 - (4.1.3) - organ retention variance with other maternity hospitals
 - (4.2.5) - organ retention with other maternity hospitals

The Review Group would suggest that certain responsibility for these shortcomings also lie with two other specific groupings:

Hospital Management Team (3.4.1)

Laboratory Management Committee (3.4.2)

The Review Group would further emphasise:

Performance Measurement

The Group do not have necessary set of performance measurements across all areas of work process – rather an overly simplistic focus on a case by case basis - of availability on post mortem report after six weeks

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Inventory Records

The absence of a robust inventory management data base further limits the Hospital's ability to audit performance and have necessary oversight and understanding (2.6) in relation organ retention and subsequent disposal

Audit

In the absence of performance related information, there is not surprisingly no appropriately vigorous and systematic audit provisions

Medical Manpower

Whilst recognising the limited availability of appropriately 'experienced' consultant medical staff in this field. The Review Group would suggest Hospital's effort / actions to secure (i) permanent post holder (ii) interim locum provision was less than optimal (4.1.2)

5 Key Recommendations

This Section of the Review identifies Key Recommendations relating to organ retention, consent, governance / control and autopsy practice. In total, the Review Group have made 31 recommendations

5.1 Organ Retention for which there is no parent consent (3.1)

5.1.1 Organ Retained by the Rotunda Hospital pre April 2000 – for which parents did not consent to retention

Recommendation 1

The Review Group would suggest that parents have a right and need to know that organs have been retained without their consent and recommend that parents should be informed by the Hospital (3.3) – this should include consideration of autopsy cases identified as non compliant with consent obtained (4.2.4)

- the process by which parents are informed, requires careful consideration, as this information after such a elapse of time may well be extremely distressing (3.3.5)

Recommendation 2

The Review Group recommend that parents should be given a choice of disposal (3.3.5)

Recommendation 3

Should it not be possible to contact the families, the Review Group recommend that the hospital dispose of these organs within a three month period – obviously maintaining a record of organs retained and then subsequently disposed. The method and place of disposal must be clearly stated.

5.1.2 Organs retained by the Rotunda Hospital (post April 2000) for parents who were informed that the hospital would dispose of organs within one year (3.3.1)

Recommendation 4

The Review Group would suggest that parents have a right and need to know that the Hospital has retained organs and recommend that parents should be informed by the Hospital – this should include consideration of autopsy cases identified as non compliant with consent obtained (4.2.4)

- the process by which parents should be informed, requires careful consideration, as this information after such a elapse of time may well be extremely distressing

Recommendation 5

The Review Group recommend that parents should be given a choice of disposal

Recommendation 6

Should it not be possible to contact the families, the Review Group recommend that the hospital dispose of these organs within a three month period – obviously maintaining a record of organs retained and then subsequently disposed. The method and place of disposal must be clearly stated.

5.2 Consent Practice, Policy and Application

Recommendation 7

The Review Group would recommend adoption of exemplar site consent policy / practices¹, specifically informed separate consent for:

- post mortem examination
- retention of blood and other body fluids
- retention of slides and blocks
- retention of images
- retention of material for genetic investigations
- retention of organs

Recommendation 8

Within a wider context, the Review Group recommend the HSE consider the development of a country wide consent policy in relation to autopsy, thereby achieving standardisation of practice nationally

Recommendation 9

The Review Group recommend that parents should not have to formally record they do not consent to the undertaking of an autopsy

Recommendation 10

The Review Group recommend that parents are given a full copy of consent record

Recommendation 11

The Review Group recommend the continuation of information packages – ‘FAQ’ – and suggests the Hospital may wish to secure views of parents as to content

Recommendation 12

The Review Group would recommend that the parents (and general practitioner or referring consultant) receive a full copy of the post mortem report automatically – unless they specify a different requirement (**3.3.6**)

Recommendation 13

There must be **no** instances of a Hospital autopsy being undertaken or subsequent organ retention without appropriate consent formally and correctly recorded

See also recommendations in relation to Process, Practice, Performance Measurement and Audit

5.3 Control

The Review Group would identify the following recommendations in relation to governance/control and executive responsibility

Recommendation 14

Post Mortem Group hold responsibility for oversight of overall autopsy process, practice and corrective actions where performance targets are not being achieved. Significant non compliance instances should be considered routinely by the Risk Management Function

Recommendation 14.1

The Hospital may wish to consider ‘parent’ representation on this grouping.

Recommendation 15

Reporting on performance should be through the Master to the Board on a periodic and exceptional basis

Recommendation 16

Diagnostic Services Consultant / Director of Pathology hold executive responsibility for overall autopsy process and adherence to practice policy

Recommendation 17

Individual consultants must adhere to both process and practice policy

Recommendation 17.1

Other Laboratory staff must also adhere to both process and practice policy

Recommendation 18

The establishment of clear written standard operating procedures for all stages of the autopsy work process – all version controlled – particular focus to be given time limits for specific work processes – thereby ensuring consistent practice and more effective coordination / communication between Bereavement Sister and Clinicians

Recommendation 19

The development and ongoing maintenance of an organ inventory record (recognising generally it will not be policy or practice to keep organs for long periods unless consented to by parents and then generally only in the form of blocks and slides.

Recommendation 20

The establishment of performance measurement across all areas of the autopsy work process

Recommendation 21

The establishment of a robust audit (control) Function including the production of a composite report enabling actual performance .v. target performance to be ascertained by oversight group (**Recommendation 14**) - this should include external and external examination of performance

Recommendation 22

The Hospital should consider alternatives to previously described recruitment practices and locum deployment

5.4 Autopsy Practice

The Review Group would make the following recommendations:

Recommendation 23

No autopsy to commence until written consent or coronial authorisation has been received by the prosecutor.

Recommendation 24

The date and time of receipt to be recorded (**example 3.2.9.5.6**)

Recommendation 25

Written notes to be made during or immediately after each autopsy (not just contemporaneous dictation). (**4.2.6**)

These notes to be retained as part of the patient's medical record.

Recommendation 26

The record of organs / tissues blocked / retained to be signed by the pathologist and countersigned by the assisting APT immediately upon completion of the gross examination

Recommendation 27

A “Cassette only”¹ policy for the principal organs should be routine practice

In the case of tiny organs, e.g. testis, ovary, pituitary gland, organ of Zuckerkandl, the Group understands that selective tissue blocking is not possible, and that the entire organ needs to be retained. This fact should be recorded on the blocking sheet.

In those cases where immediate blocking out is impossible e.g. in autolysed still births, or where detailed dissection of a heart anomaly is needed, rapid fixation (48-72 hours max) should be undertaken, so that the tissue(s) can be returned to the body before its release for disposal.

The Review Group recognise that the brain and spinal cord present special difficulties and that detailed examination of the unfixed material is usually impossible.

There is present no general agreement on the best method of rapid fixation of these organs, and practice varies widely through the United Kingdom and Ireland.

Recommendation 28

The Review Group would recommend that a national code of best practice be agreed, drawn up and implemented – this would require HSE engagement.

Recommendation 29

The Review Group would emphasise that it should not be necessary to retain the brain for more than 4 weeks.

Recommendation 30

The Review Group suggest it might be helpful if the Anatomical pathology technician(s) involved in the service be offered refresher training in an established centre of excellence (e.g. The Royal Liverpool Children’s Hospital) to reinforce current day techniques and practice.

Recommendation 31

Records in relation autopsy

All records must be completed in a timely manner and signed by the designated consultant

¹ Cassette – a small perforated container, the size of which varies between 5 cent piece and postage stamp, in which a tissue sample is placed for fixation and wax embedding prior to sectioning for microscopical examination.)