





## HSE National Clinical Guidelines for Post Mortem Examination Services (2023)

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# **HSE National Clinical Guidelines for Post Mortem Examination Services**



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Is this document a: Guideline ✓

Clinical guidelines (or "clinical practice guidelines") are "statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options". They have the potential to reduce unwarranted practice variation, enhance translation of research into practice, and improve healthcare quality and safety, if developed and implemented according to international standards.

https://www.ncbi.nlm.nih.gov/books/NBK549283/ Panteli (2019)

"Evidence-based clinical guidelines are recommendations to assist practitioners and patients to make decisions about appropriate healthcare for specific clinical circumstances. Guidelines should integrate best research evidence in conjunction with clinical expertise, patient values and cost (Sackett et al., 2000)." HSE. HSE National Framework for developing Policies, Procedures, Protocols and Guidelines (PPPGs). (2016)

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## **Abbreviations**

APT Anatomical pathology technician

CCO Chief Clinical Officer

CJD Creutzfeldt-Jakob disease (prion disease)

CT Computed tomography

DOH Department of Health

EHCR Electronic health care record

HIQA Health Information and Quality Authority

HPSC Health Protection Surveillance Centre

HSE Health Service Executive

ISO International Organization for Standardization

IT Information technology

MRI Magnetic resonance imaging

NQPSD National Quality and Patient Safety Directorate

OSP Office of the State Pathologist

PALS Patient Advocacy and Liaison Service

PPPG Policies, procedures, protocols and guidelines

PME Post mortem examination

QPS Quality and patient safety

RCPath Royal College of Pathologists United Kingdom

RCPI Royal College of Physicians Ireland

REC Research Ethics Committee

SOP Standard operating procedure

## **Glossary of terms**

#### **Adult**

A person over the age of 18 years.

## Age of majority

The age at which a person normally becomes an adult in law.

#### Anonymised data

Personal data that has been amended in such a way that no individuals can be identified from the data, having regard to all methods reasonably likely to be used by the data controller or any other person to identify the data subject, directly or indirectly. (HSE National Policy for Consent in Health and Social Care Research (2022))

#### **Antepartum**

Before labour or childbirth.

### Anatomical pathology technician

Anatomical pathology technician (APTs) carry out a range of tasks related to many different aspects of mortuary work. Two of their main tasks are to assist and support pathologists during post mortem examinations and to perform reconstruction of the deceased afterwards. (https://www.aaptuk.org/)

#### **Blocks and slides**

Paraffin wax blocks and microscopic glass slides are tools which enable the histological examination of tissue samples and organs. Identifiable by laboratory numbers linked to the deceased's medical record, they are retained as part of the laboratory record and kept as part of and for the lifetime of the healthcare record. (Please see Appendix nine for a photograph of a block and slide).

#### Clinician

For the purposes of these clinical guidelines, a clinician is understood to be a registered medical practitioner having direct contact with and responsibility for treating service users, rather than one involved with theoretical or laboratory studies.

#### Child

In these guidelines we use the terms 'child' when referring to someone up to the age of 18.

## Coercion / duress

Forcing a person to behave in a particular way by use of threats or intimidation or some other form of pressure or force to consent or refuse treatment.

#### Consent

Consent is the giving of permission or agreement for a treatment, investigation, receipt or use of a service or participation in research or teaching (intervention). Consent involves a process of communication about the proposed intervention in which the person has received sufficient information to enable them to understand the nature, potential risks and benefits of the proposed intervention.

## Consent for research

The term 'consent' in the context of research refers to the informed and explicit agreement of a prospective research participant to take part in a research study and, when relevant, to the use of their personal data for such research. The agreement for both must be ethically obtained, recorded, and retained; the proposed consent protocol must be approved by an appropriate Research Ethics Committee (REC) and, when applicable, comply with Irish data protection legislation. (HSE National Policy for Consent in Health and Social Care Research (2022))

#### Consultant

A consultant is a registered medical practitioner who, by reason of their training, skill and experience in a designated specialty, is consulted by other registered medical practitioners and undertakes full clinical responsibility for service users in their care, or that aspect of care on which they have been consulted,

without supervision in professional matters by any other person. A consultant in a particular speciality is usually registered on the Specialist Division of the Register of Medical Practitioners maintained by the Medical Council of Ireland. (Services should contact the Human Resources Department for further information as required.)

#### Coroner

An independent office holder charged with the legal responsibility (Coroners Acts 1962, Coroners (Amendment) Acts 2005 and 2019, Coroners (Amendment) Act 2019 (Commencement) Order 2020) for the investigation of sudden, unexplained, violent and unnatural deaths in their district. They must be either a medical practitioner or a lawyer of at least five years experience.

#### Coroner's district

The coroner's district refers to the geographical area covered by a coroner. Please see <a href="www.coroners.ie">www.coroners.ie</a> for further information.

#### **Deceased person**

Where a deceased person is referred to in this document, this includes all ages from a fetus to an adult. Services may use different terms to refer to the deceased person depending on what is appropriate or in accordance with the wishes of the family, for example fetus or baby may be used in the perinatal setting.

#### **Decision-making capacity**

Decision-making capacity is the person's ability to understand, at the time that a decision is to be made, the nature and consequences of the decision to be made by the person in the context of the available choices at that time.

## **Designated person**

In these clinical guidelines, the person giving consent is referred to as the 'designated person'. Throughout the document they may also be referred to as family for ease of reference.

## Designated healthcare professional

In these clinical guidelines, the person taking consent is referred to as the 'designated healthcare professional'. This is usually a consultant or registrar; however, this role may be delegated to another trained healthcare professional.

## **Designated family liaison**

In these clinical guidelines, the identified person / role(s) responsible for liaising with the family in hospital and / or community deaths is referred to as the 'designated family liaison'. This person may work in different fields, for example the multi-disciplinary team, bereavement support, medical social worker. This title may also refer to a position. In state cases, the family liaison will usually be a member of An Garda Síochána.

#### **Designated PME liaison**

In these clinical guidelines, the identified person / role(s) responsible for tracking, overseeing and monitoring of organs in all PMEs in each mortuary is referred to as the 'designated PME liaison'. This title may also refer to a position. This person may also be referred to as the 'nominated person'.

## Family

May include immediate biological family and / or other relatives, spouses, partners (including civil, same sex and de facto partners).

Coroners (Amendment) Act 2019, definition of family member, in relation to a deceased person, means:

- (a) a parent, grandparent, child, brother, sister, nephew, niece, uncle or aunt, whether of the whole blood, of the half blood or by affinity, of the person,
- (b) a spouse, a civil partner within the meaning of the Civil Partnership and Certain Rights and Obligations of Cohabitants Act 2010 or a cohabiting partner of the person,
- (c) any other person who is ordinarily a member of the person's household, or any child who has been placed in foster care with the person or any person referred to in paragraphs (a) to (c), and includes a reference to any such member of the person's family who is adopted.

#### **Fetus**

An offspring of a human in the stages of prenatal development that follow the embryo stage (taken as beginning eight weeks after conception).

#### **Fixation**

A method of chemically preserving tissue samples for diagnostic evaluation.

#### Forensic pathologist (State pathologist in Ireland)

A forensic pathologist is a medical doctor who specialises in anatomical pathology, histopathology and the interpretation of injuries at post mortem examination.

## **General practitioner (GP)**

A doctor based in the community who provides initial, on-going and continuous personal medical care, with responsibility for integrating care, treating people with acute, minor or chronic illnesses, and referring those with serious conditions to a hospital when specialist treatment is likely to be necessary, and of benefit.

## Gynaecology

The study of the functions and diseases of the female reproductive system.

#### Healthcare record

The healthcare record refers to all information collected, processed and held in both manual and electronic formats pertaining to the service user and service user care. It includes demographics, clinical data, images, unique identification, investigation, samples, correspondences and communications relating to the service user and their care.

#### **Healthcare workers**

Healthcare workers refers to the various health and social care staff who support people while they are receiving healthcare treatment, investigation, using a health or social care service or taking part in research or teaching. These include but are not limited to doctors, dentists, psychologists, nurses, midwives, paramedics, social workers and social care staff. The term also covers all health and social care professions whether or not the profession is a designated profession within the meaning of Section 3 of the Health and Social Care Professionals Act 2005.

## Histology

The study of the structure of tissues by means of special staining techniques combined with light and electron microscopy.

## Histopathology

The branch of medicine concerned with the changes in tissues caused by disease. It involves the microscopic examination of human tissue for the diagnosis of disease (histology).

## Histopathologist

A qualified pathologist who has training and experience in the performance of microscopic examination of biological samples and post mortem examinations, and who is a Registered Medical Specialist on the Register of Medical Specialists (Division of Histopathology) of the Medical Council of Ireland.

#### Incident

An event or circumstance which could have, or did lead to unintended and/or unnecessary harm. Incidents include adverse events which result in harm; near misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention; and staff or service user complaints which are associated with harm. Incidents can be clinical or non-clinical and include incidents associated with harm to:

- patients, service users, staff and visitors
- the attainment of HSE objectives
- ICT systems
- data security e.g. data protection breaches
- the environment. (HSE Incident Management Framework (2020))

#### Infant death

Infant death means the death of a live born child occurring immediately after birth or within 365 days of birth. (Coroners (Amendment) Act 2019)

#### Inquest

An inquest is a public inquiry held by a coroner, in some cases with a jury, into the circumstances of unnatural, unexplained or violent death. The coroner or jury makes findings on the identity of the deceased person, how, when and where the death occurred and records a verdict. Issues of criminal or civil liability are not considered at an inquest. (Definition via Dublin District Coroner.)

#### Intrapartum

During labour and delivery or childbirth.

## Legal guardian

A person who is entitled to exercise rights and who has duties in respect of someone under the age of 18 years. (HSE National Consent Policy (2022))

#### Live born baby

A live born baby is defined as any baby born with evidence of life such as breathing movements, presence of a heartbeat, pulsation of the cord or definite movement of voluntary muscles.

(<a href="https://www.ucc.ie/en/media/research/nationalperinatalepidemiologycentre/PerinatalMortalityForm20">https://www.ucc.ie/en/media/research/nationalperinatalepidemiologycentre/PerinatalMortalityForm20</a> <a href="https://www.ucc.ie/en/media/research/nationalperinatalepidemiologycentre/PerinatalMortalityForm20">https://www.ucc.ie/en/media/research/nationalperinatalepidemiologycentre/PerinatalMortalityForm20</a> <a href="https://www.ucc.ie/en/media/research/nationalperinatalepidemiologycentre/PerinatalMortalityForm20">https://www.ucc.ie/en/media/research/nationalperinatalepidemiologycentre/PerinatalMortalityForm20</a> <a href="https://www.ucc.ie/en/media/research/nationalperinatalepidemiologycentre/PerinatalMortalityForm20">https://www.ucc.ie/en/media/research/nationalperinatalepidemiologycentre/PerinatalMortalityForm20</a> <a href="https://www.ucc.ie/en/media/research/nationalperinatalepidemiologycentre/PerinatalMortalityForm20">https://www.ucc.ie/en/media/research/nationalperinatalepidemiologycentre/PerinatalMortalityForm20</a> <a href="https://www.ucc.ie/en/media/research/nationalperinatalepidemiologycentre/PerinatalMortalityForm20">https://www.ucc.ie/en/media/research/nationalperinatalepidemiologycentre/PerinatalMortalityForm20</a> <a href="https://www.ucc.ie/en/media/research/nationalperinatalepidemiologycentre/Per

#### Maternal death

A maternal death means the death of a woman while pregnant, or within 42 days of the end of pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes and, without prejudice to the generality of the foregoing, includes a direct maternal death or an indirect maternal death occurring during that period. (Coroners (Amendment) Act 2019)

## **Direct obstetric deaths**

Direct obstetric deaths are those resulting from obstetric complications of the pregnancy state (pregnancy, labour and the puerperium), from interventions, omissions, incorrect treatment, or from a chain of events resulting from any of the above.

(https://www.ucc.ie/en/mde/definitionandclassificationofmaternaldeath/)

## Indirect obstetric deaths

Indirect obstetric deaths are those resulting from previous existing disease or disease that developed during pregnancy and which was not due to direct obstetric causes, but which was aggravated by physiologic effects of pregnancy.

(https://www.ucc.ie/en/mde/definitionandclassificationofmaternaldeath/)

## **Coincidental maternal deaths**

Deaths from unrelated causes which happen to occur in pregnancy or the puerperium. (https://www.ucc.ie/en/mde/definitionandclassificationofmaternaldeath/)

#### Indirect maternal death

An indirect maternal death means the death of a woman resulting from a pre-existing disease, or a disease that developed during pregnancy, and which was not the result of direct obstetric causes, but which was aggravated by the physiological effects of pregnancy. (Coroners (Amendment) Act 2019)

## Late maternal death

The death of a woman from direct or indirect obstetric causes, more than 42 days, but less than 1 year after termination of pregnancy.

(https://www.ucc.ie/en/mde/definitionandclassificationofmaternaldeath/)

A late maternal death means the death of a woman occurring more than 42 days and less than 365 days after the end of pregnancy from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes and, without prejudice to the

generality of the foregoing, includes a direct maternal death or an indirect maternal death occurring during that period. (Coroners (Amendment) Act 2019)

## Microbiology

Microbiology is the examination of specimens for the isolation and identification of micro-organisms.

#### Microscopy

The use of a microscope to greatly magnify an image of an organ, tissue, etc., which may be so small as to be invisible to the naked eye.

#### Minor

Formal legal description of someone under the age of majority, which in Ireland is 18 years. (HSE National Consent Policy (2022))

#### Miscarriage

A miscarriage is the loss of pregnancy before 24 weeks gestation. (HSE)

#### Neonatal

Relating to the first 28 days of an infant's life.

#### Early neonatal death

Death of a live born baby occurring before seven completed days after birth. (<a href="https://www.ucc.ie/en/media/research/nationalperinatalepidemiologycentre/PerinatalMortalityForm2022.pdf">https://www.ucc.ie/en/media/research/nationalperinatalepidemiologycentre/PerinatalMortalityForm2022.pdf</a>)

## Late neonatal death

Death of a live born baby occurring from the seventh day and before 28 completed days after birth.

(https://www.ucc.ie/en/media/research/nationalperinatalepidemiologycentre/PerinatalMortalityForm2022.pdf)

## Neuropathologist

A pathologist who specialises in diseases of the nervous system.

#### Organ

A part of the body, composed of more than one tissue that forms a structural unit responsible for a particular function (or functions). Examples are the heart, lungs and liver. (Oxford Concise Medical Dictionary as used in Report of Dr. Deirdre Madden on Post Mortem Practice and Procedures.)

## **Paediatric**

Refers to infants, children and adolescents from birth up to the age of 16.

## **Pathology**

Pathology is the study of disease. It is the bridge between science and medicine. It underpins every aspect of patient care, from diagnostic testing and treatment advice to using cutting-edge genetic technologies and preventing disease. (https://www.rcpath.org/discover-pathology/what-is-pathology.html)

## **Pathologist**

A doctor qualified in the study of pathology. For the purposes of this document 'pathologist' should be interpreted as histopathologist unless otherwise specified.

#### **Perinatal**

The perinatal period is that which occurs in, is concerned with, or is in the period around the time of birth. It generally refers to the period from 24 weeks gestation up to seven days after birth. The way the term is used varies widely for example, perinatal pathology tends to refer to all foetal and placental pathology irrespective of gestational age (adapted from the Merriam-Webster dictionary). The first seven days after birth is also known as the early neonatal period.

## Post mortem examination

## Coroner's post mortem examination

A detailed examination of a body after death, ordered by a coroner in order to determine the cause of death and any contributing factors. It involves:

- the noting and description of marks or injuries on the body.
- the dissection of organs from the head, chest and abdomen.
- ancillary investigations where appropriate to include toxicology, histopathology, microbiology and any other investigations that may be required.

This is a compulsory post mortem examination required by law and consent from the deceased's family is not required.

## Hospital post mortem examination (also known as consented or non-coroner PME)

A detailed examination of a body after death requiring the consent of the family. It is carried out at the request of the family or of the clinician in order to provide further information about an illness / condition / disease process or to investigate the effect and efficacy of treatment. A full hospital post mortem examination involves the dissection of the organs of the head, chest and abdomen and ancillary investigations as appropriate (for example histopathology, microbiology).

For the purposes of this document, hospital PME refers to consented or non-coronial PMEs.

#### **Full PME**

A full PME involves a detailed external examination as well as an examination of all the internal organs, from the head, chest and abdomen. This includes a detailed examination of all the internal organs, including the brain, heart, lungs, liver, kidneys, intestines, blood vessels and small glands.

#### **Limited PME**

A limited PME is usually confined to an examination of those organs most likely to have been directly related to the cause of death. This means that only certain parts of the body are examined.

## Minimally invasive post mortem examination

Includes those in which needle biopsies through the skin are taken to sample internal organs and tissues, and examinations that use an endoscope or laparoscope to provide internal access to the gastrointestinal tract and the abdominal cavity. Needle autopsies are undertaken for only the most limited of examinations, for example when the body poses a high risk of serious infection, or when there are neither the time nor conditions for a complete post mortem examination. Endoscopic post mortem examinations require specialist equipment and expertise. They have been used in cases in which consent for a more complete post mortem examination has not been obtained. (Human Tissue Authority, United Kingdom)

## Virtual post mortem examination

The use of imaging (radiological imaging such as CT or MRI) for PME instead of invasive procedures.

## Post mortem report

The report compiled from information obtained as a result of post mortem examination. A post mortem report includes:

- a. Basic demographic details.
- b. A brief clinical summary.
- c. Description of external and internal examinations.
- d. A report of histology and other investigations, where appropriate.
- e. A summary of findings.
- f. A concluding commentary.
- g. A 'cause of death' in the standard international form for the 'medical certificate of the cause of death'.

#### Post mortem radiology

Any imaging carried out on the deceased's remains following death, for example, x-rays, CT scan, and MRI.

#### **Postpartum**

After delivery or after childbirth.

## **Pregnancy**

Pregnancy is the time in which a fetus develops inside a woman's womb. The Coroners (Amendment) Act 2019 states that 'pregnancy' includes an ectopic pregnancy.

#### Pseudonymous data

Personal data that can no longer be attributed to a specific data subject without the use of additional information (i.e. a key / code). Such additional information must be kept separate and technical and organisational measures for the protection of the data should be in place. (HSE National Policy for Consent in Health and Social Care Research (2022))

#### Registered medical practitioner

A person who holds a basic medical qualification, and who is registered under Section 46, 47, 48, 49 or 50 of the Medical Practitioners Act 2007.

## **Retained organ**

An organ that is removed from the body at post mortem examination and temporarily retained for further specialist examination after the body is reconstructed.

#### Sensitive management of a temporarily retained organ(s)

The burial or cremation of an organ retained for a limited (not permanent) time which shows consideration for and is respectful of the human origin of the organ.

## State forensic case

Colloquial term used to describe deaths referred to the Office of the State Pathologist for formal forensic post mortem examination. These include suspicious, criminal and unusual deaths.

#### Stillbirth

A baby delivered without signs of life from 24 weeks' gestation and/or with a birth weight of ≥ 500 grams. \*If the birth occurred unattended and there was no lung aeration seen at Post Mortem Examination (PME) and no other circumstantial evidence of life at birth, it should be assumed that the baby was stillborn. (https://www.ucc.ie/en/media/research/nationalperinatalepidemiologycentre/PerinatalMortalityForm20 22.pdf)

#### Stillborn child

Stillborn child means a child of not less than 24 weeks' gestation, or of birth weight of not less than 500 grams, who is delivered without signs of life. (Coroners (Amendment) Act 2019)

## Sudden infant death syndrome

Sudden unexpected death of an infant less than 1 year of age, with the onset of the fatal episode apparently occurring during sleep, that remains unexplained after a thorough investigation, including performance of a complete autopsy and review of the scene and circumstances of death and the clinical history. (Krous et al, 2004)

## **Temporary**

Limited (not permanent).

#### Tissue

A collection of cells specialised to perform a particular function.

## **Toxicology**

Toxicology is the examination of biological specimens for the detection and quantification of alcohol, drugs and poisons.

## Ultimate disposal

Relating to the final arrangements for tissues retained at post mortem examination.

## Valid

Valid is the state of being officially legally binding or acceptable.

## Witness

A witness is a person who has observed an event taking place.

For additional definitions in relation to the antenatal or perinatal period please see the National Perinatal Epidemiology Centre website <a href="https://www.ucc.ie/en/npec/">https://www.ucc.ie/en/npec/</a>.

## **Preface**



These guidelines are ultimately for the people using the Post Mortem Examination Services (PME) in the HSE and HSE funded facilities. A significant amount of learning has emerged in recent years through audits, investigations and through the recent COVID-19 pandemic. Bereaved families are more aware of how the PME process can serve to answer questions they may have around the death of a person, especially where there are pathological conditions that may have implications for other family members. There has also been key learning about what needs to happen to ensure that the post mortem examination service is

compassionate and centred on the needs of families and individuals using the service while also being reflective of international recommended practice.

Of greatest importance is the role that healthcare professionals have in the empathetic and effective establishment of recommended practices and guidelines. How we communicate, the information we share and our engagement with families has a significant impact, not only at the time of the PME but with a lasting effect on each person and family's experience of loss and bereavement.

In developing the HSE National Clinical Guidelines for Post Mortem Examination Services (2023) we were extremely fortunate to have strong foundations on which to build it: The HSE Standards and Recommended Practices for Post Mortem Examination Services 2012. A review group consisting of 26 individuals, including patient representatives, coroners and healthcare professionals from diverse backgrounds and specialties, undertook to update and add to the 2012 standards. Over six months, with both targeted and wider consultations incorporating health care, cultural and religious groups, patient partners and organisations involved in various healthcare programmes, an updated set of national clinical guidelines evolved.

New developments and updated information incorporated in the revised guidelines include:

- a greater focus on coronial PMEs as they make up over 95% of all PMEs performed in Ireland.
- outlining the different requirements of coronial and hospital (non-coronial) PMEs.
- a consideration of new technologies, such as post mortem radiology (where available), to assist with or provide limited options in both hospital (consented) and coronial PMEs.
- the consent process for PME and for clinical research, which should be supplemented by the HSE National Consent Policy (2022) and the HSE National Policy for Consent in Health and Social Care Research (2022).
- a new toolkit of template forms and patient information booklets to assist healthcare
  professionals in establishing and / or improving a standardised, high quality and sensitive
  service for bereaved families in HSE and HSE funded facilities throughout the country.

These guidelines are comprehensive, with an easy to follow table of contents. We hope they will provide a framework to assist healthcare staff as they provide support and guidance to families during a PME. It is our aim that these guidelines will inform a clear, open and comprehensive communication and consent process that is considerate of the emotional impact on bereaved families.

As a forensic and histopathologist who has contributed to the provision of both the coronial and consented/hospital post mortem examination services since 2005, I was honoured to be nominated by the RCPI at the invitation of the HSE, to chair the Review Group tasked with updating the HSE Standards and Recommended Practices for Post Mortem Examination Services 2012.

I would like to express sincere thanks to all of the Review Group members who gave their time and expertise to formulating this document. A particular thanks to our patient partners and patient representatives, who ensured a sensitive and empathetic approach to our clinical guidelines, with a focus on families and their needs. A big thanks to Therese Yore, Patient Liaison Officer (CNM2) with the Emergency Department, James Connolly Memorial Hospital who developed the guidance for healthcare professionals providing information on state forensic cases. I would like to thank all those who provided input and expertise throughout the process.

Thanks to Mr. Gethin White, Dr. Triona McNicholas, Dr. Yvonne McCartney and Dr. Shane Eakins for their invaluable work on the literature review which informed the guidelines. Thanks also to the Faculty of Pathology, Royal College of Physicians Ireland, for their endorsement of the literature review.

I especially want to acknowledge the vital contribution of those involved in formulating the HSE National Consent Policy (2022) and the HSE National Policy for Consent in Health and Social Care Research (2022) - I have learned so much from them and was privileged to be part of the extensive and constructive conversations about consent that informed this document.

I would also like to thank our two external experts Dr. Margaret Bolster, Assistant State Pathologist and Professor Mike Osborn, President of the Royal College of Pathologists, UK who gave of their time and expertise so willingly.

Last, but not least, I would like to express my deep gratitude to the National Quality and Patient Safety Directorate Project Team (Juanita Guidera, Dr. Maureen Flynn, Dr Mary Browne, and Killian Aughey-Evans) without whose advice, support, diligence and dedication, this document would not be here.

**Professor Linda Mulligan** 

Chief State Pathologist

Clinical Professor UCD School of Medicine

Chair of the HSE National Clinical Guidelines for Post Mortem Examination Services: Review Group

## **Foreword**

We would like to express our thanks to the Faculty of Pathology, Royal College of Physicians of Ireland, for nominating Prof. Linda Mulligan as chair of this group and for her leadership of the group throughout the process. Prof. Mulligan and all members of the group have gone above and beyond what was required of them from the initial terms of reference. Through the engagement of members, the output has not only been the update of the original 2012 standards to an all-encompassing main document, but also the development of a toolkit of templates and five information booklets to assist mortuaries and staff and to help bereaved relatives and families.

Thanks to each member of the group for their willingness to work within a concentrated period to produce such important work. This unique group of 26 members included four patient partners, and every member brought essential insight to the deliberations over the six months.

A sincere thank you to the National Consent Team and the HSE National Policy for Consent in Health and Social Care Research Group who have been essential to producing this document. Their time and input was invaluable and helped to minimise duplication creating complimentary documents for the HSE.

Thanks also to the Childrens Health Ireland and Cork University Hospital teams for sharing their draft information booklets, which formed the foundations of the paediatric and perinatal sample booklets.

The new Human Tissue Bill which was published in December 2022 will potentially change the landscape of post mortem examination services again; however, in the interim, it has been helpful to collaborate with the Department Of Health in relation to the Bill to inform the development of the document where possible.

External contributors were comprehensively involved with both targeted, open and individual consultation sessions. In particular the engagement of the End of Life Co-ordinators, the Quality and Patient Safety Leads and the Anatomical Pathology Technicians has been fundamental to creating a robust guideline.

Thanks to the Faculty of Pathology, RCPI also for their endorsement of the rapid literature review that was carried out to inform these clinical guidelines.

Finally, we would like to extend a very sincere thanks to our international external experts Professor Mike Osborn, President of the Royal College of Pathologists UK and Dr. Margot Bolster, Assistant State Pathologist, for their crucial contribution to the final document.

Dr. Orla Healy

**QPSD Clinical Director** 

National Quality and Patient Safety Directorate

Dr. Colm Henry / Chief Clinical Officer

# **Part one: Introduction**



## 1. Part one: Introduction

## 1.1. Who is the target audience for these clinical guidelines?

This document is a Health Service Executive (HSE) national evidence-based clinical guideline for staff in the health service and HSE funded services who are involved in any stage of the provision of post mortem examination (PME) services.

## 1.2. What is the objective of these clinical guidelines?

The objective of these clinical guidelines is to support the consistent delivery of person centred effective PME Services throughout the Heath Service Executive (HSE) and HSE funded services. These clinical guidelines include all steps of the process from the time of the person's death to the issuing of the death certificate. They also detail the steps staff can take to support high quality communication, consent, record management (including authorisation from the coroner) and the management of tissue samples, biological fluids and temporarily retained organs following a PME.

## 1.3. What is the scope of these clinical guidelines?

## 1.3.1. What is in the scope of these clinical guidelines?

There are documented policies, procedures, protocols and guidelines (PPPGs) governing all elements of service provision relating to all coroners' and hospital PMEs. These clinical guidelines form part of this structure and outline the HSE's recommended practices for PME services, based on current legal requirements, professional standards, clinical expertise and international best practice. Please see Appendix one for information on the development of the HSE National Clinical Guidelines on Post Mortem Examination Services (2023).

## 1.3.2. What is outside the scope of these clinical guidelines?

The scope of these guidelines does not cover the mortuary facilities, equipment or staffing resources to support the PME process. It also does not cover the implementation of the guidelines (including governance structures and budgetary considerations), the communication plan and provision for training and education of healthcare staff. The governance of and consent process for organ donation for transplantation is outside the scope of the PME Process and should be managed accordingly.

At the time of revising these guidelines, the Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Bill 2022 (Bill 121 of 2022) (referred to as the Human Tissue Bill 2022 throughout this document) is under consideration. Following the enactment of this legislation, this document may need to be updated to take consideration of the relevant policy direction.

A number of other PPPGs and programmes of work address elements of PME service provision outside the scope of these guidelines. These include but are not limited to:

PME PPPGs and programmes of work with additional / separate governance arrangements			
A coroner's PME	A hospital PME		
Notification of a reportable death to the coroner (Coroners Act 1962 - 2020)	The process of seeking consent (Guidelines for Post Mortem Consent and Retention of Samples, RCPI (2000) and HSE National Consent Policy (2022)).		
Documentation of the decision taken by the coroner's office (Certificate under section 41, Civil Registration Act 2004 to be sent to the Registrar, Births, Deaths and Marriages and inquest outcome).	The respectful handling, transportation and storage of deceased persons, tissue samples and organs (HSE Guidelines for the Preparation for Transport of Patient Specimens and other Biological Materials (2019) and European legislation).		
Communication of information to families regarding the coroner's PME (Care for the Deceased Guidance and locally available information)	The ultimate disposal of retained tissue samples and the management of organs HSE Guidelines for the Preparation for Transport of Patient Specimens and other Biological Materials (2019) and European legislation).		
Direct communication between the coroner's office and family / designated person (regional coronial practice)	Communication of information to families regarding the hospital PME (Care for the Deceased Guidance and locally available information).		

Table 1: PME PPPGs and programmes of work with additional / separate governance arrangements

The following resources may also be helpful to address items out of scope.

Guidance on:	Resource
Guidanie Gin	113334132
Care	
Supporting care of the deceased	HSE Guidance for Care of the Deceased Person [In development]
Supporting the needs of diverse religious communities and cultures at the time of death	Health Services Intercultural Guide (2009)
The care parents and families can expect to receive following a pregnancy loss or perinatal death	National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death (2022).  National Clinical Practice Guideline: Stillbirth: Prevention,
Consent	Investigation, Management and Care [In development]
Consent, capacity and assisted decision making	<u>HSE National Consent Policy (2022)</u> and <u>RCPI Guidelines for Post</u> <u>Mortem Consent and Retention of Samples (2000)</u> .
Consent in research	HSE National Policy for Consent in Health and Social Care Research (2022).
Technical performance, quality and a	audit
Technical performance of the autopsy	Royal College of Pathologists Guidelines (UK). <u>www.rcpath.org</u> .
Quality assurance and audit on the PME process	National Quality Assurance and Improvement Programme, Faculty of Pathology, Royal College of Pathology Ireland (RCPI). <a href="www.rcpi.ie">www.rcpi.ie</a> .
Covid-19	
PME in Covid-19	RCPI Faculty of Pathology, <u>Recommendations relating to PME</u> <u>Practice during the Covid-19 Pandemic (2021)</u>
Coronial PMEs in Covid-19	Guidance in relation to the Coroners Service and Deaths due to Covid-19 infection.

Table 2: Guidance on items outside of scope

## 1.4. Rationale for these guidelines

Healthcare facilities operated or funded by the Health Service Executive (HSE) provide many of the core support services required for both coroners' and hospital post mortem examinations. These include mortuary and post mortem facilities, pathology, histology, general laboratory services such as microbiology / biochemistry, post mortem radiology, hospital administration services and the provision of bereavement support to families.

Formal documented control of the services required for PME is necessary to monitor each aspect of service provision. This will support services to demonstrate compliance with relevant Irish legislation, HSE guidance and current professional standards and international best practice.

## 1.5. How do these clinical guidelines work?

These guidelines reflect the values and priorities of the HSE and will be used to:

- define the correct management of PME services,
- direct and support PME services in healthcare facilities, and
- serve as the basis for policy and procedure development in PME services in the HSE.

Each part of these guidelines has an introduction, which explains the objective of the section and information on how it can be achieved. Two different colours have been used to help readers differentiate between guidance specific to the **coroner's PME (purple text / shading)** and **hospital PME (blue text / shading)**. Where content is **relevant to both processes**, it is in black text.



Throughout these guidelines, where a deceased person is referred to, this includes all ages from a fetus to an adult. While we recognise that these guidelines have a broad reach, in paediatric and perinatal settings different language may be used in communication with families. It is important to take cues from parents about their preferred language when discussing their baby or child.

While certain parts of these guidelines are underpinned by legislation, which must be adhered to, a significant part of their implementation is dependent on communication processes and pathways with professionals, services and families. It is acknowledged, that it is not possible to account for every scenario within this document, and in this regard, it will be necessary for each professional using these guidelines to use their professional judgement, codes of professional practice, regulatory body codes of practice and other clinical guidelines while taking the circumstances of each individual case into consideration.

In **Part two: The post mortem examination**, you will find information on the two main processes; a coroner directed PME and a hospital PME.

In Part three: Consent and the post mortem examination, you will find information on consent. The Guidelines for Post Mortem Consent and Retention of Samples, RCPI (2000), the HSE National Consent Policy (2022) and the HSE National Policy for Consent in Health and Social Care Research (2022) provide additional information on consent, capacity and assisted decision making.

In Part four: Communication and the post mortem examination, you will find key information on communicating with families before, during and after the PME process. The HSE Guidance for Care of the Deceased Person [In development] and the <a href="National Standards">National Standards</a> for Bereavement Care Following Pregnancy Loss and Perinatal Death (2022) provides additional information on communication.

In Part five: Records management following coroner and hospital post mortem examination, you will find information on records management. This information may need to be adapted depending on the type of PME service provided (perinatal, paediatric or adult) within each local area. The Health Service Executive Standards and Recommended Practices for Healthcare Records Management (2011) and the HSE, Record Retention Periods Health Service Policy (2013) provide additional information on records management.

In Part six: Storage, transportation and ultimate disposal of tissue samples and management of retained organs following post mortem examination you will find recommended practices on these topics in accordance with existing European legislation. This information will be further informed by the Human Tissue Bill when enacted.

In Part seven: Training, you will find guidance on helpful training supports.

In **Part eight: Appendices** you will find additional resources and information on the development of this guidance and information on the background of PME services.

# Part two: The post mortem examination



## 2. Part two: The post mortem examination

The objective of this section is to set out key information about what a PME is and the process flow.

## 2.1. An introduction to the post mortem examination process flow

## 2.1.1. What is a post mortem examination?

Post mortem is a Latin phrase which means 'after death'. A post mortem examination is a medical examination carried out on the body of the person after they have died. It is also called an autopsy (which means 'to see for oneself'). It is carried out by an appropriately qualified registered medical practitioner or by an appropriately trained and experienced healthcare professional under their direction. For the purposes of this document and in practice, this registered medical practitioner is known as a pathologist.

Samples of organs, tissues and / or other body fluids may be sent for detailed laboratory examination and diagnosis. Small pieces of tissue from relevant organs are examined under the microscope. This process is called histology.

The definition of the PME under the Coroners Act 1962 is as follows:

'post-mortem examination' includes an examination of marks or injuries on a body, a full three cavity examination, and any ancillary examination by way of analysis, test or otherwise of the body or of material (whether of tissue, organs, biological fluids or other parts or contents of the body or of any other substance or thing relevant to such examination) carried out by an appropriately qualified registered medical practitioner or under his or her direction;

Extract from Coroners Act, 1962 Revised

## 2.1.2. What is the difference between a full and limited post mortem examination?

In the case of a hospital PME (but not a coroner's PME), families must give consent for either a full or limited hospital PME.

## What is a full examination?

A full PME involves a detailed external examination and examination of the head, chest and abdomen. This includes a detailed examination of all the internal organs, including the brain, heart, lungs, liver, kidneys, intestines, blood vessels and small glands.

## What is a limited examination?

A limited PME is usually confined to an examination of those organs most likely to have been directly related to the cause of death. This means that only certain parts of the body are examined. For example:

- The PME may be limited to one or more body areas, for example to a body cavity such as the chest and / or abdomen.
- Particular organs or tissues for biopsy might be specified by the family, for example in a death resulting from congenital heart disease, examination could be limited to the heart and lungs.
- In certain circumstances a minimally invasive or virtual (imaging based) PME may be possible, and should be explained to the family. The use of a virtual PME is limited

- in Ireland and is always subject to local practice and resource availability. Further information on a minimally invasive and virtual PME can be found in the glossary.
- In the perinatal setting, while all of these options are possible (subject to availability), in some circumstance, a limited examination may only consist of an external examination. This is particularly relevant where parents do not want a full or targeted PME.

## 2.1.3. Understanding the post mortem examination process

The following table (Table 3: Post mortem examination services in Ireland) includes information about the type of PME available in Ireland including a coroner's PME (required by law) and a hospital PME (which requires consent).

Post mortem examination services in Ireland			
Question	A Coroner's PME	A Hospital PME	
When is a PME carried out?	A Coroner's PME is obliged by law (Coroners Acts 1962 - 2020).	A hospital PME (which requires consent) is carried out at the request of the family <sup>1</sup> or deceased's representative, or at the request of the deceased's treating clinician. <sup>2</sup>	
What is the purpose of the PME?	To inquire into and investigate certain deaths as set out by the Coroners' Acts:  a. To establish or clarify the cause of death.  b. To identify conditions that may have contributed to the cause of death.  c. To identify unnatural causes of death.	To gain a fuller understanding of the deceased's illness or condition, the possible effects of treatment provided to the deceased prior to death, possible implications for family members, and to enhance the provision of medical care for future service users.  Perinatal PMEs may provide information on potential recurrence risks in future pregnancies and may provide information that would allow a plan of care in a future pregnancy.	
What happens during the PME?	Removal and examination of organs, tissues and / or other body fluids for detailed laboratory examination and diagnosis. Following the PME all organs are returned to the body, unless there is an indication for organs to be temporarily retained for specialist examination. See section 4.3.21 - 4.3.24 for further information on the burial or cremation of temporarily retained organs.		
Are organs retained in every PME?	No. Organs may only be retained in line with relevant Irish legislation, HSE and RCPI guidance and current professional standards and international best practice.  Reasons why organs may be retained include the following:  a) In order to determine a cause of or contributory factor to death (in a coroner's PME), or  b) When consent given for examination (in a hospital PME)  c) When consent has been given by the family for donation of organs for clinical teaching, medical education and / or research purposes (all PMEs).		

Table 3: Post mortem examination services in Ireland

<sup>&</sup>lt;sup>1</sup> For information on the family, please see Section 3.3 Who may give valid consent?

<sup>&</sup>lt;sup>2</sup> See glossary.

## 2.1.4. Why is a post mortem necessary?

Post mortem examination can provide objective information on the cause of death, which may be of value to the family of the deceased, healthcare professionals and other interested parties. It is an important part of high quality clinical care. It is one of the most informative investigations in medicine.

From the perspective of the bereaved families, a PME can provide information about the risk of inherited diseases. This may be of benefit to family members seeking necessary care and treatment.

In perinatal deaths, information from a PME may identify why the baby's death occurred. Even if it does not identify a particular cause, it can provide information on what did not cause it or that the baby was normally developed. The PME can thus provide information on potential recurrence risks and help develop a plan of care for any potential future pregnancy.

- Perinatal pathology involves the study of disorders of the placenta, problems
  affecting unborn babies' development, and causes of miscarriage, stillbirth and
  neonatal death. The objective of perinatal pathology PMEs is to establish the
  specific cause of the death or the complication, and risk of recurrence in
  subsequent pregnancies. Perinatal Pathology PME services works closely and
  collaboratively with obstetric and maternity teams to provide where possible
  answers in terms of pregnancy loss, miscarriage and / or neonatal death.
- PMEs can provide important information for families in cases of stillbirths, fatal
  foetal anomalies, intra-uterine death, late miscarriages, recurrent miscarriage,
  early neonatal death and indeed products of conception prior to 12 weeks. The
  provision of these services is underpinned by the HSE's National Standards for
  Bereavement Care following Pregnancy Loss & Perinatal Death (2022), and
  relevant clinical guidelines are in place or being developed in the area of
  maternity care in Ireland.

Family members may also be comforted by the knowledge that information gained at PME can improve understanding of how disease is caused. This may advance medical knowledge and help others by contributing to the fight against disease and how it can best be treated.

In Ireland, there is legislation (the Coroners Acts 1962 - 2020) which directs that a PME must be carried out in certain types of deaths. This is a legal requirement and does not require consent from the family / designated person. See Figure 2: What type of deaths do coroners' review? (Second Schedule, Coroners (Amendment) Act 2019).

## 2.1.5. The post mortem examination process flow

Figure 1 includes a process flow, which sets out the key steps of the process for PME.

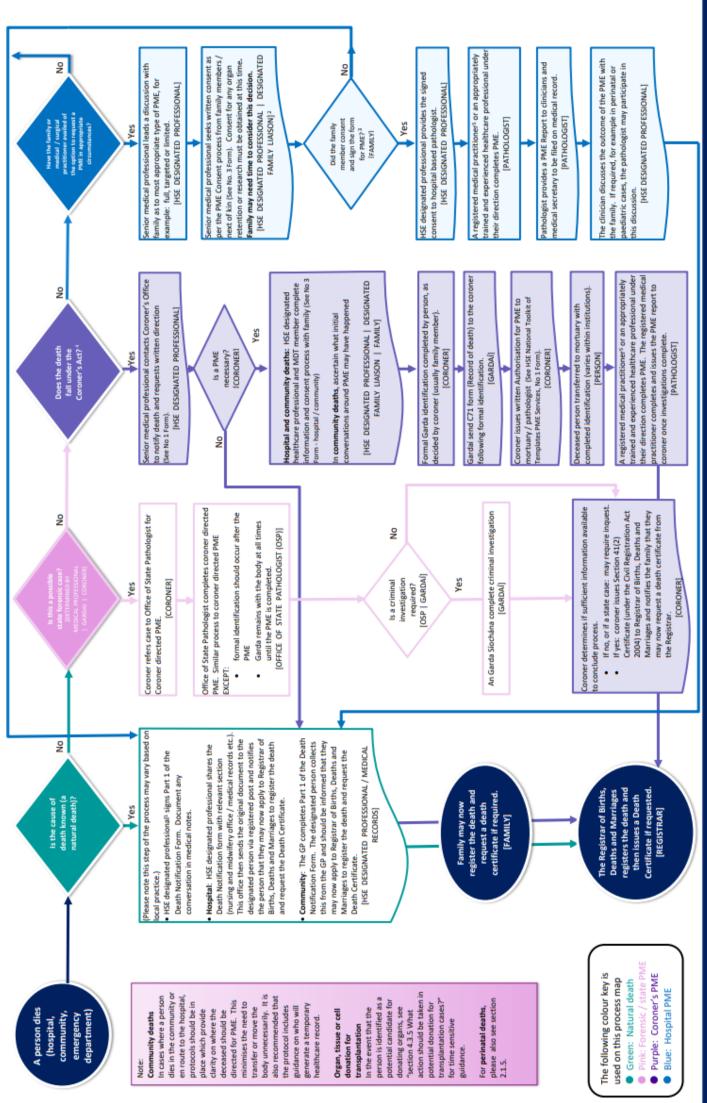
In perinatal cases where the baby dies after a short period of life, then their death must be registered in the normal way that is, a Death Notification Form should be completed and the process for hospital and community deaths should be followed as detailed in Figure 1: Post mortem examination process flow.

In cases where a baby is stillborn, (with a weight of not less than 500 grams or has a gestational age of not less than 24 weeks and shows no sign of life), a Medical Certificate / Hospital Post Mortem Certificate or Coroners Stillbirth Certificate is required to register the event. For additional information, please see <a href="https://www2.hse.ie/services/births-deaths-and-marriages/order/stillbirth-certificate/">https://www2.hse.ie/services/births-deaths-and-marriages/order/stillbirth-certificate/</a>

The HSE Civil Registration Service registers all deaths Ireland, for additional information, please see: <a href="https://www2.hse.ie/services/births-deaths-and-marriages/find-a-civil-registration-service/">https://www2.hse.ie/services/births-deaths-and-marriages/find-a-civil-registration-service/</a>

Please note that the following process flow is available as a standalone document, which can be printed on A3 paper.

Figure 1: Post mortem examination process flow



nsible person includes the medical professional should also include a member of the multidisciplinary team. Designated healthcare professional This is usually a consultant or registrar; however, this role may be delegated to another trained healthca Designated family liaison includes a member of the multi-disciplinany team for example bereavement support, medical social worker senior

For the purposes of this document and in practice, the registered medical practitioner is known as a pathologist.
See HSE National Toolikit of Templates Post Mortem Examination Services for copies of templates to support the process. For information on the registration of deaths, see https://www2.hze.ie/services/births-deaths-and-marriages/register/death/ \* Please note that this sequence may change depending on local practice.

<sup>\*</sup> Designated family laison includes a member of the multi-disciplinary team for example becavement support, medical social worker senior nurse or a designated becavement officer.
\* For information on: Consent set ESE National Consent Post Mortem Consent and Retention of Samples, RCP (2000) and the HSE National Consent for Research in Health and Social Care Policy (2022) [In development], Communication and Cultural considerations see Care of the Deceased Guidance (2022) FENDING.

## 2.2. Deaths reportable to the coroner

The **objective** of this section is to provide guidelines to relevant staff regarding the reporting to the coroner of all sudden, unexplained, violent deaths and any death due directly or indirectly to any unnatural cause.

## 2.2.1. What does the coroner do?

A coroner in Ireland is an independent office holder charged with the legal responsibility for the investigation of sudden, unexplained, violent and unnatural deaths in their district.<sup>3</sup> A death of this nature may require a coroner's PME, sometimes followed by an inquest. See Figure 2: What type of deaths do coroners' review? (Second Schedule, Coroners (Amendment) Act 2019).

An inquest is a public hearing into the circumstances of death and will be held on a case by case basis at the discretion of the coroner. More information regarding inquests can be found at <a href="https://www.coroners.ie">www.coroners.ie</a> or the Dublin Coroners' website <a href="https://www.dublincoronerscourt.ie">www.dublincoronerscourt.ie</a>, which also has useful general information.

## 2.2.2. Who should report a death to the coroner?

In the case of such deaths (see section 2.2), there is a legal responsibility on one of the following individuals / parties to report the death to the coroner:

- the registered medical practitioner,
- registrar of deaths,
- funeral director / undertaker,
- householder,
- an Garda Síochána, and
- any person in charge of any institution or premises in which the deceased person was residing or working at the time of their death.

Deaths are reportable to the coroner under the Coroners Act 1962 - 2020 (rules of law) and under rules of good practice as determined by the coroner for the district in which the hospital or institution is located.<sup>4</sup>

The fact that a death is reported to the coroner does not mean that a PME will always be directed.

## 2.2.3. General guidance

A registered medical practitioner may not certify any death(s) due directly or indirectly to any unnatural cause (Coroners Acts 1962 - 2020). If a registered medical practitioner has any doubt about whether or not a death is reportable to the coroner, they should contact the coroner for the district for advice on the matter. There should be documentation of all deaths reported to the coroner as outlined in Part five: Records management following coroner and hospital post mortem examination.

<sup>&</sup>lt;sup>3</sup> Coroners Act 1962 - 2020.

<sup>&</sup>lt;sup>4</sup> Rules of good practice have evolved in certain coroners' jurisdictions in Ireland to supplement the rules of law and to ensure compliance with the legislation. (Farrell 2000).

## 2.2.4. Deaths reportable to the coroner under the rules of law

See Figure 2: What type of deaths do coroners review? (Second Schedule, Coroners (Amendment) Act 2019) on the next page.

## 2.2.5. Examples of deaths reportable to the coroner in line with good practice

This list is not exhaustive. Additional local requirements should be ascertained by contacting the coroner for the district in which the hospital or institution is located.

- a. Death occurring suddenly in a hospital department (including Outpatient Department, Physiotherapy, Radiology, etc.).
- b. Chronic end stage alcohol related disease (e.g. cirrhosis of the liver).

## 2.2.6. Deaths reportable in the case of maternal death, stillbirth or infant death

Schedule 2, Coroners (Amendment) Act 2019 includes that the following deaths are reportable to the coroner:

- Any death of a stillborn child, intrapartum or infant death.
- Any maternal death or late maternal death.

## 2.2.7. Deaths occurring before arrival at the hospital / mortuary

In cases where a person dies in the community or en route to the hospital, protocols should be in place to provide clarity on where the deceased should be directed for PME. This minimises the need to transfer or move the body unnecessarily. It is also recommended that the protocols include guidance on who will generate a temporary healthcare record within the hospital / mortuary.

## Second Schedule, Coroners (Amendment) Act 2019

- (a) Any death that may be murder, manslaughter or infanticide.
- (b) Any death that appears to be connected with a crime or suspected crime.
- (c) Any death, whether or not accidental, caused wholly or partly by stabbing, drowning, poisoning, hanging, electrocution, asphyxia or a gunshot wound.
- (d) Any death where the deceased person is dead on arrival at a hospital.
- (e) Any death which may be by suicide.
- (f) Any death where the body of the deceased person is unidentified.
- (g) Any death where no family member of the deceased person can be traced within a reasonable time of the death.
- (h) Any death where the body of the deceased person is found or recovered in circumstances that indicate that the death may have occurred a considerable period of time previously.
- (i) Any death (other than in circumstances to which paragraph 8 applies) in respect of which the date of death may not be ascertainable.
- (j) Any death caused wholly or partly by any of the following:
  - an incident, whether or not accidental, resulting in any physical injury, including a cut, fracture or contusion;
  - (b) a fall;
  - (c) self-neglect;
  - (d) an eating disorder;
  - (e) exposure or hypothermia;
  - (f) burns.
- (k) Any death which may be by assisted suicide.
- (I) Any death caused wholly or partly by any of the following:
  - (a) an accident arising out of the use of a vehicle in a public place;
  - (b) an incident occurring on a railway;
  - (c) an incident arising on a train, aircraft, ship or other vessel.
- (m) Any death caused wholly or partly by any of the following:
  - (a) a notifiable disease or condition that is, under provisions in that behalf in any other enactment, required to be notified to a Minister of the Government, a Department of State or a statutory body or to an inspector or other officer of a Minister of the Government, a Department of State or a statutory body;
  - (b) an adverse reaction to any drug;
  - (c) a drugs overdose or the presence of toxic substances;
  - (d) in the case of an infant death, maternal drug addiction;
  - (e) an infection contracted as a result of previously contaminated blood product administration;
  - (f) a lack of care or neglect;
  - (g) starvation or malnutrition.
- (n) Any death which may be due to a prion disease.
- (o) Any death caused wholly or partly by an accident at work or due to industrial or occupational injury or disease.
- (p) Any death occurring in a hospital or other health institution—
  - (a) that is unexpected,
  - (b) within 24 hours of presentation or admission, whichever is the later, or
  - (c) of a person transferred from a nursing home.
- (q) Any maternal death or late maternal death.
- (r) Any death of a stillborn child, death intrapartum or infant death.
- (s) Any death occurring in a hospital or other health institution that is directly or indirectly related to a surgical operation or anaesthesia (including recovery from the effects of anaesthesia) or to any other medical, surgical or dental procedure, regardless of the length of time between the procedure and death.
- (t) Any death which may be due to any healthcare acquired infection.
- (u) Any death where an allegation is made or a concern has been expressed regarding the medical treatment provided to the deceased person or the management of his or her healthcare.
- (v) Any death which may be as a result of an unconventional medical procedure or treatment.
- (w) Any death occurring in—
  - an institution for the care and treatment of persons with a physical or mental disability, or
  - any public or private institution for the care of elderly or infirm persons, including a nursing home.
- (x) Any death where the deceased person was at the time of his or her death, or immediately before his or her death, in State custody or detention.
- (v) Any death of a child in care.

Figure 2: What type of deaths do coroners review? (Second Schedule, Coroners (Amendment) Act 2019)

## 2.2.8. Guidelines for state forensic PMEs (suspicious or unusual deaths)

When a sudden, unexplained, suspicious or criminal death occurs, the coroner will direct a state forensic PME under section 33 (2) Coroners Act 1962. In these cases, certain procedures need to be followed. This will aid any garda investigation and allow for the chain of evidence to be kept intact.

## Immediately after death

- Once death is pronounced, the deceased, all tissues from the deceased and all the property on the deceased come under the jurisdiction of the coroner.
- All lines, chest drains, medical airway tubes, bandages and electrodes need to be left in place.
- The deceased should not be cleaned or washed before the PME.
- The deceased should be placed into a body bag. If there is a concern about contamination from bodily fluids, it may be beneficial to use a second bag.

#### Access to the deceased

- It is recommended that nobody outside of the investigation or the team completing the PME will be allowed access to the deceased until after the PME.
- In order to preserve forensic evidence a member of An Garda Síochána will secure (stay with) the deceased until after the PME. In rare circumstances, a family may view the deceased under Garda supervision but will not be allowed to touch the deceased until after the PME.
- No mementos, handprints or memory making should occur until after the PME.
- The garda will keep a record of anyone who is near or around the deceased.

## **Property**

- Property left on the deceased should not be removed or disturbed by staff, as this will be done as part of the PME.
- Any items that were removed during medical intervention prior to death must be
  placed into an official forensic evidence bag and should be detailed on an itemised
  list.
  - The list must be documented in the presence of both a healthcare professional and a member of An Garda Síochána.
  - o Both the healthcare professional and garda then co-sign the property list.
  - The original list should be kept with the patient's notes and a copy given to An Garda Síochána.

## Identification

- On receipt of the deceased into the mortuary, an identification tag should only be placed on the outside of the body bag in order to preserve forensic evidence.
- In a State forensic case, it is recommended that family identification is carried out after the PME. After formal identification, identification tags should be applied to the ankle and wrist.
- A Garda Liaison will be assigned to the family to share information about these procedures with them.

## **Investigations**

- Any blood samples taken immediately on admission and prior to any transfusions or any medications come under the jurisdiction of the coroner and the samples must be handed over to An Garda Síochána at the coroner's request.
- Radiology, for example a CT scan or x-rays, may be required in certain cases prior to the PME at the request of the pathologist and / or coroner. At all times during these

investigations, the deceased should be accompanied by a member of An Garda Síochána.

## **Documentation**

The following documentation should be sent to the pathologist with the deceased:

- a copy of their Emergency Department notes,
- the ambulance record sheet,
- any healthcare professional records / notes including printouts of relevant electronic healthcare record notes, and
- the results of any investigations performed.

Please note that the above records should all be filed in the healthcare record.

A Notification of Death form should be completed and forwarded to the Hospital Mortuary (as applicable to local service).

The patient's chart may be formally requested by the Coroner's office.

#### **Transport**

- Any transport of the deceased in state forensic cases should be arranged by the coroner and An Garda Síochána.
- In cases where the deceased needs to be transferred to another facility, to prevent contamination the remains should not be transferred to the local hospital mortuary but go directly to that facility.

If the hospital has any queries in state forensic cases, the on call forensic pathologist should be contacted. Their contact details can be obtained from the investigating Gardaí or the coroner. The contact details for the Office of the State Pathologist may also be found on the website: <a href="https://www.justice.ie/en/JELR/Pages/office">https://www.justice.ie/en/JELR/Pages/office</a> of the state pathologist.

## Part three: Consent and the post mortem examination



## 3. Part three: Consent and the post mortem examination

Consent for PMEs should be discussed with sensitivity, and openness and with the necessary detail to enable families to make relevant decisions at what may be a difficult time for them.

The **objective** of this section, is to provide clarity on the consent process and to support the designated healthcare professional to seek consent as required.

The process of seeking consent should be further informed by HSE National Consent Policy (2022), the Guidelines for Post Mortem Consent and Retention of Samples, RCPI (2000) and the HSE National Policy for Consent in Health and Social Care Research (2022).

In perinatal settings, it may also be helpful to refer to the <u>National Standards for</u> <u>Bereavement Care Following Pregnancy Loss and Perinatal Death (2022)</u> and any other relevant clinical / professional guidelines.

It is acknowledged that the HSE National Consent Policy (2022) was written for living people consenting to decisions about their treatment and care. However, the principles of the policy are also applicable after death in relation to decisions by the family of the deceased about PMEs. In this regard, these clinical guidelines are written in accordance with the ethos of the HSE National Consent Policy (2022). Extracts from and references to the HSE National Consent Policy (2022) have been included where they inform healthcare staff to support and facilitate conversations and decisions about informed consent.

All healthcare workers are responsible for ensuring that they adhere to consent processes in the HSE National Consent Policy (2022) and the HSE National Policy for Consent in Health and Social Care Research (2022). All healthcare workers must be aware of and understand their responsibilities in terms of the consent process to ensure they gain valid consent for interventions and / or research.

## 3.1. An introduction to consent

In all PMEs, the examination procedure is technically the same. However, the conversation around consent is different for coroner directed PMEs and hospital PMEs according to legal requirements and best practice.

To begin a conversation about consent, it is essential to understand the PME process (see Part 2: The post mortem examination). It may also be helpful for the designated healthcare professional seeking informed consent to have witnessed a PME and to have knowledge of the types of PME available at their facility.

Each service should have a formal system with trained staff in place to provide relevant information to the family of the deceased regarding the PME process.<sup>5</sup> The giving of this information should be documented in the healthcare record.

<sup>&</sup>lt;sup>5</sup> See Section 3.4 Who is responsible for sharing information about the PME and seeking and obtaining consent?

## 3.2. When is consent required?

## 3.2.1. Consent and the coroner's post mortem examination

Consent is not required for a coroner's PME, which is a mandatory process under Irish law.

Consent is not required for the temporary retention of organs to establish the cause of death in a coroner's PME.

Consent is required for the retention of organs for any reason's PME and any other legal functions are complete.

## 3.2.2. Consent and the hospital post mortem examination

Consent is required for all hospital PMEs.

Consent is required for the retention of organs for any reason when warranted.

Table 4: 'When is consent needed from the deceased's family?' sets out a quick reference for consent in the coroner's and hospital PME. Please note that while consent may not be necessary for all items on this list, each item should be discussed with the family for their information.

Is consent needed from the deceased's family for the following?	A Coroner's PME	A Hospital PME
Post mortem examination	No	Yes
Temporary retention of organs to determine cause of death	No	Yes
Retention of organs, tissues and/or other body fluids for clinical teaching, medical education and / or research purposes	Yes	Yes
Burial or cremation of organs	Yes	Yes
Disposal of tissue samples	No	No
Disposal of sampled body fluids	No	No
PME photography	No	Yes
PME radiology	No	Yes

Table 4: When is consent needed from the deceased's family?

## 3.2.3. Why is consent not required for the disposal of tissue samples / body fluids?

As part of a PME, small samples of tissues and / or body fluids are taken as part of the medical investigation. Given the small size of these samples, consent is not required for their collection or disposal as it is considered part of the normal PME process. These samples are usually kept on file as a medical record in the form of histological blocks and slides. A histological sample is chemically treated tissue preserved in paraffin block (histological block) and a small sample on a glass slide.

## 3.3. Who may give valid consent?

## 3.3.1. Who may give valid consent when the deceased is an adult?

## Pre mortem consent

In a healthcare setting, consent is usually sought from the person the decision relates to. In life, a person may give or decline consent for a PME to be completed on themselves after they die. This may include any part of the PME process as outlined in Table 4. The deceased person's decision must be respected, unless their death falls under the remit of the coroner's jurisdiction (Coroners Acts 1962 - 2020) or their family objects (in accordance with the Anatomy Act 1832<sup>6</sup>).

In the case of an objection from the family, the designated healthcare professional may meet with them to share the wishes of the deceased; however, if the family continue to object, the PME should not happen.

## Post mortem consent

In most instances, the deceased person will not have given consent in advance so any required decisions are made by people who had a close, ongoing personal relationship with the person, such as family or friends, or by anybody chosen by the person in advance. The knowledge that these people may have of the deceased, will be helpful in eliciting the person's values, beliefs and goals in life. This approach is in keeping with the principles of the HSE National Consent Policy (2022).

For the purposes of this document, we refer to the person who gives consent as the 'designated person'. Throughout the document, they may also be referred to as family for ease of reference. The 'designated person' must be 18 years of age or more, immediately before the deceased person's death. The list<sup>7</sup> below includes, in order of priority, persons who may be contacted during the consent process who are, or at the time of the deceased person's death, were:

- (a) a spouse or civil partner of the relevant person,
- (b) a cohabitant of the relevant person,
- (c) a child of the relevant person,
- (d) a parent of the relevant person or a person who was a guardian of the relevant person before that relevant person attained 18 years,
- (e) a brother or sister (whether of the whole or half-blood) of the relevant person,
- (f) a grandparent of the relevant person,
- (g) a grandchild of the relevant person,
- (h) an uncle or aunt (whether or the whole or half-blood) of the relevant person,
- (i) a niece or nephew of the relevant person, or
- (j) a close friend of the relevant person who can demonstrate to the satisfaction of the person seeking consent or confirmation, as the case may be, that he or she can determine and accurately convey the wishes of the relevant person concerned.

<sup>&</sup>lt;sup>6</sup> Anatomy Act 1832 "VIII. And be it enacted, That if any Person, either in Writing at any Time during his Life, or verbally in the Presence of Two or more Witnesses during the Illness whereof he died, shall direct that his Body after Death he examined anatomically, or shall nominate any Party by this Act authorized to examine Bodies anatomically to make such Examination, and if, before the Burial of the Body of such Person, such Direction or Nomination shall be made known to the Party having lawful Possession of the dead Body, then such last-mentioned Party shall direct such Examination to be made, and, in case of any such Nomination as aforesaid, shall request and permit any Party so authorized and nominated as aforesaid to make such Examination, unless the deceased Person's surviving Husband or Wife, or nearest known Relative, or any One or more of such Person's nearest known Relatives, being of Kin in the same Degree, shall require the Body to be interred without such Examination."

<sup>&</sup>lt;sup>7</sup> Please note this list may be updated once the Human Tissue Bill 2022 is enacted.

Although this represents the order in which people should usually be contacted to provide consent, a number of exceptions may arise, for example

- a. The person at the highest level on the list does not wish to make a decision on the issue of consent.
- b. It is not reasonably practicable to communicate with the person at the highest level on the list in the time available.
- c. The designated healthcare professional has reason to believe that the person at the highest level of the list may be unable to make a decision or participate in the decision making process regarding a PME because, for example, of cognitive or communication problems OR cases of great emotional distress for that person, which may hinder informed decision making.

In the context of obtaining consent for PME, assessing capacity may not be a reasonable approach. The current or prior views of this person, if ascertainable - for example, by another family member – remain important and should generally be complied with. In these circumstances, the healthcare professional should engage with and seek informed consent from a person (s) at the next level on the list above.

If there is more than one possible 'designated person' at a given level of priority, it is reasonable for the healthcare professional to consult initially with someone of that level who had been the family contact or key person prior to the deceased person's death. The key person should be asked to consult other family members and /or people close to the person. Those to be consulted with will depend on the individual circumstances.

If the person consulted reports agreement among the family that a PME should proceed and consents to the PME, it is reasonable for the healthcare professional to accept that consent and proceed in good faith with the PME.

If the designated healthcare professional is aware of a disagreement amongst the family, it may be helpful to facilitate a discussion between the people or groups involved. If there is continued disagreement, especially between family members of the same decision-making priority, a hospital PME should generally not be carried out.

At any time, it is open to the people involved to contact the coroner's office in relation to queries or concerns they may have about whether or not their relative's death falls under the Coroners Acts (1962 - 2020).

Below, is the definition of family in the Coroners Acts (1962 - 2020) which is provided for information purposes and may also be helpful where the relationship in question is not covered by the definition above.

Coroners (Amendment) Act 2019, Definition of family member, in relation to a deceased person, means:

- a. a parent, grandparent, child, brother, sister, nephew, niece, uncle or aunt, whether of the whole blood, of the half blood or by affinity, of the person,
- b. a spouse, a civil partner within the meaning of the Civil Partnership and Certain Rights and Obligations of Cohabitants Act 2010 or a cohabiting partner of the person, any other person who is ordinarily a member of the person's household,
- c. or any child who has been placed in foster care with the person or any person referred to in paragraphs (a) to (c), and includes a reference to any such member of the person's family who is adopted.

## 3.3.1.1. In what circumstances may a person be outside of the decision making process?

In some instances, there may be a time when for the purpose of consent, the designated healthcare professional may acknowledge a person as outside of the decision-making process, for example:

- a. the person is less than 18 years of age immediately before the adult's death.
- b. the person does not wish to or is unable to make a decision on the issue of consent.
- c. it is not reasonably practicable to communicate with the person in the time available.
- d. to whom a deed of separation or a decree of judicial separation is granted in relation to the relevant person.
- e. who has entered into a written agreement to separate with the relevant person.
- f. who has separated and ceased to cohabit with the relevant person for a continuous period of at least 12 months.

## 3.3.2. Who may give consent in the case of children (including babies who died before or during birth or deceased infants and children)?

The designated healthcare professional should review the HSE National Consent Policy (2022) for information on consent as it pertains to children and in particular, reference Appendix Five of the HSE National Consent Policy (2022) for further information on who a child's legal guardians are.

Consent should be sought from a parent or legal guardian of the baby, infant or child. Please note:

- a. only parent(s) who are legal guardians can give consent on behalf of their children. An unmarried father is not automatically a legal guardian.<sup>8</sup>
- b. not all parents have parental responsibility for their children.
- c. where only one parent is the legal guardian, the organisation is legally entitled to proceed with the consent of that parent.
- d. where both parents are legal guardians, either parent is legally entitled to give consent.
- e. where the parents of the baby/infant/child disagree as to whether or not to give consent, the organisation is legally entitled to proceed with the consent of one parent. However, irrespective of the marital or living arrangements of the parents, best practice is not to proceed in the face of objection from either parent, where both parents are legal guardians.

## 3.3.3. Who may give consent in the case of children in care, or where a care order is in place?

The death of a child in care or cases where a care order is in place should be reported to the coroner. In relation to decisions about the management of any retained organs in a coroner's case or alternatively, where the coroner decides not to direct a coroner's PME following the death of a child in care or subject to a care order, the medical practitioners and or the family request a PME, consent should be sought from:

- a. Legal guardian.
- b. Parent(s) or legal guardian(s) are generally considered best placed to safeguard the interests of their deceased child even in circumstances where a care order was in

<sup>&</sup>lt;sup>8</sup> See Appendix five in the HSE National Consent Policy (2022).

place at the time of the child's death. In complex situations, case conferences (special meetings to discuss a person's care) involving TUSLA<sup>9</sup>, the parent(s) and / or legal guardian(s) and all relevant healthcare workers are often a useful way of ensuring that parent(s) or legal guardian(s) and healthcare workers work in partnership in decision-making for the deceased child. If it is not possible to gain consensus between the parents and / or legal guardians, the parties may wish to seek legal advice.

Please refer to section 4.3.20 - 4.3.21 for the sensitive management of temporarily retained organs in both hospital and coroner's PMEs. In the case that the family cannot be contacted, after frequent and documented attempts to make contact, direction in relation to the sensitive management of temporarily retained organs and the burial or cremation of the deceased child or infant should be provided for in accordance with the local hospital procedures as appropriate. See also section 4.3.25 'What to do if the family do not specify their wishes?'.

All reasonable efforts should be made to recognise and respect the views of parent(s) or legal guardian(s) as regards to what is in the best interests of the child, including when these views differ from those of the service provider.

## 3.3.4. Who may give consent in the case of a parent aged under 18 years?

Where a hospital PME is proposed on a deceased child, stillborn infant or miscarried pregnancy, consent should be sought from a parent or legal guardian; however when the parent(s) / legal guardian is less than 18 years of age, a complicated situation arises. This situation is not specifically addressed by Irish legislation or case law and is legally complex. Please see section six of the HSE National Consent Policy (2022) (extract below) for guidance on this matter.

## Extract from section 6 "The parent aged under 18 years"

Parents or legal guardians are presumed to be the best decision-makers for their child and to act in their child's best interests. This presumption holds even if the parent is a child or young person under 18 years. All of the requirements in respect of parents identified in the previous sections apply where the parent is under 18 years.

Healthcare workers should support parent(s) aged under 18 years in making decisions in the best interest of their child. As with any decision made by parent(s) or legal guardian(s), if a healthcare worker is concerned that a decision made by a parent aged under 18 years is not in the best interests of the child, they should engage in dialogue with the parent(s) about the decision and take the steps outlined above to try to reach a consensus on the decision to be made. Ultimately, if a consensus cannot be reached, the healthcare worker should seek legal advice.

In some circumstances and depending on the nature of the relationship, it may be appropriate to involve other people, for example the child's grandparent(s) in the discussion of best interests. This should only be done with the consent of the parent(s) or legal guardians who are under 18 years.

Extract: HSE. HSE National Consent Policy (2022) p. 57

<sup>&</sup>lt;sup>9</sup> When a care order under Section 18, Child Care Act (known as Full Care Order) is in place, Tusla is in loco parentis for the child. However, on the death of a child in care, the care order ceases.

## 3.3.5. Who may give consent in the case of a ward of court?

When a ward of court dies, the role of the 'committee' (the person appointed to act on their behalf) ends. In these cases, it would fall to a designated person to request or consent to a PME. See section 3.3 for further details on seeking consent.

## 3.4. Who is responsible for sharing information about the PME and seeking and obtaining consent?

The organisation should have documented procedures in place that clearly set out the roles and responsibilities of all those involved in the process of seeking valid consent for all aspects of the hospital PME and for the management of organs in all PMEs. This process includes sharing information about the PME process.

In these clinical guidelines, the person taking consent is referred to as the designated healthcare professional.

## Deaths occurring in a hospital setting:

Primary responsibility for seeking and obtaining consent should rest with the registered medical practitioner / consultant who is responsible for care of the deceased prior to their death and with whom the family have a pre-existing relationship (where possible). This practice may vary locally and depending on the type of PME required, for example, paediatric or perinatal pathologists may be involved in the consent process in some instances.

If this task is delegated, the responsible consultant or hospital manager should ensure that the designated healthcare professional to whom they have delegated responsibility, has the appropriate training and understanding to undertake this function. Interns should not undertake this responsibility. This is in accordance with the Irish Medical Council guidelines.<sup>11</sup>

## Deaths occurring in a community setting:

Primary responsibility for seeking and obtaining consent should rest with a designated healthcare professional. It should be noted that in community deaths, the initial conversations around PME with the family may have occurred prior to arrival at the hospital / facility (this may be through the ambulance service, An Garda Síochána, the GP or the coroner's office). It is important for the designated healthcare professional to ascertain if this conversation has happened and if the individual understands the PME process prior to the conversation about management of organs.

Section 2.1 of the HSE National Consent Policy (2022) sets out "Who should seek consent from a person?" which should be followed in all relevant sections of the PME process as set out in Table 4.

If the consent is being sought by a designated healthcare professional who does not have a pre-existing relationship with the family, this individual should introduce themselves by name, position and department prior to commencing the consent process with the family.

<sup>&</sup>lt;sup>10</sup> See Section 3.4 Who is responsible sharing information about the PME and seeking and obtaining consent?

<sup>&</sup>lt;sup>11</sup> See The Guide to Professional Conduct and Ethics for Registered Medical Practitioners 7th Edition 2009, Section 38.2.

## Extract from section "2.1 Who should seek consent from a person?"

"The healthcare worker who is providing a particular health and social care intervention is responsible for ensuring the person has given consent for what is to be done.

The treating healthcare worker should usually give information and seek the person's consent. The task of providing information and seeking consent may in some circumstances be undertaken by another healthcare worker, as long as that healthcare worker:

- Is suitably trained and qualified;
- Has sufficient knowledge of the proposed intervention and of the benefits and risks;
- Is able to provide the information the person requires.

However, the healthcare worker who actually provides the particular intervention remains responsible for ensuring that the person has given a valid informed consent<sup>2</sup>.

Delegating the seeking of consent to a healthcare worker with inadequate knowledge of an intervention could mean that informed consent is not obtained.

If different aspects of the intervention are to be provided by different healthcare workers, each should obtain consent for their particular aspect of care."

Extract: HSE. HSE National Consent Policy (2022) p. 15

In this instance, the suitably qualified and trained individual is as outlined on the previous page.

In addition to following this guidance, the designated healthcare professional who seeks consent should:

- a. have a good understanding of the issues relating to PME, organ retention and their burial or cremation,
- b. be responsible for ensuring that the person giving consent has sufficient information to enable them to provide valid consent. The person seeking consent may provide this information or they may be supported in the communication of the relevant information by a member of the multidisciplinary team (see section 3.5 Involving the multidisciplinary team in seeking and obtaining consent).

## 3.5. Involving the multidisciplinary team in seeking and obtaining consent

A multidisciplinary team should be available and be drawn on as required to support the family in the process of seeking consent. Where possible a member of the multidisciplinary team should also participate in the consent process with the registered medical practitioner or designated healthcare professional. This individual may provide additional bereavement support, may be familiar with the family or may be a witness to remote / verbal consent.

While the second person may wish to make a note in the healthcare record of their role in the process, they are not required to sign the consent form unless they are acting as a witness to verbal consent. Examples of where verbal consent may be taken include where a person is unable to sign due to a physical disability, literacy or in cases with the individual is completing the process by phone or online.



Figure 3: Involvement of the multidisciplinary team in the consent process

## 3.6. What are the requirements for valid consent?

In this instance, we understand valid consent to be consent sought from the 'family', unless the deceased has made a decision about PME before they died.

Please see the HSE National Policy on Consent (2022) for information on the requirements for valid consent and in particular Part One, Section Four. The following guidance on valid consent is particularly relevant in PME services.

## Extract from section "3. Defining valid consent"

For consent to be valid, the person must:

- Have received sufficient information in a comprehensible manner about the nature, potential risks and benefits of the proposed intervention, of any alternative intervention and of not receiving the intervention;
- Not be acting under duress; and
- Have the decision-making capacity to make the decision (even if requiring support to do so).

The information to be provided for a valid consent and how it should be provided are discussed in Part One, Section Four.

Extract: HSE. HSE National Consent Policy (2022) p. 19

## 3.6.1. Decision making under duress

Please see section 3.1 of the HSE National Consent Policy (2022) for further information on decision making in cases of duress. This is where an individual may be subject to pressure from third parties to accept or reject a particular approach. A third party may include family, friends or healthcare workers.

## 3.6.2. Decision making capacity of the person making the decision

The designated healthcare professional seeking informed consent should work on the basis that the family member has capacity. The assumption of a person's capacity to make informed choices is made in good faith. Every effort should be made to support the family member during the consent process to make the decision.

However, occasionally there may be concerns about a person's capacity to give valid consent. When this happens, it may be helpful to consult with the family and those with a close relationship with the deceased as part of the consent process. Where there is a disagreement amongst family members, the guidance is not to proceed with a PME. In the

case of consent relating to children see section 3.3.2 'Who may give consent in the case of children (including babies who died before or during birth or deceased infants and children)?'.

In some cases, if a PME is not completed, important information may not be identified and this may result in an adverse outcome for other members of the family (for example, the potential to identify an inherited or genetic medical condition). If there is a question of capacity with one of the key decision makers in this instance (for example, a spouse/ child), the designated healthcare professional should consult section 3.2 and Part One, Sections 4 and 5 of the HSE National Consent Policy (2022). These set out the principles of determining a person's capacity to provide consent.

If the person is subsequently found to have the decision-making capacity necessary to provide or decline consent, their decision must be respected.

## 3.7. What is the process of seeking consent?

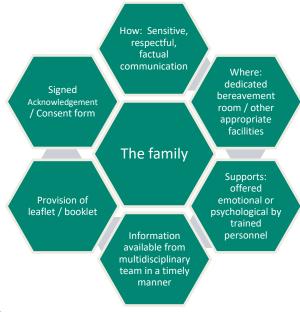


Figure 4: The process of seeking consent

Families should be at the centre of decision-making and control in respect of any decisions they need to make before or after the PME. See Part 3 of this document "Communication and the post mortem examination" for more detailed information on communication.

## 3.8. How should consent be documented?

As a PME may be considered an invasive and complex procedure and is part of the clinical care of the deceased person, signed consent is required from the designated person for the management of organs in coroner's PME and for the whole procedure in a hospital PME (see Table 4: When is consent needed from the deceased's family?).

The following section includes text from the HSE National Consent Policy (2022).

## 3.8.1. How should verbal consent be recorded?

Consent should be given in writing; however, in exceptional cases verbal consent may be allowed. If the person gives a verbal consent, but is unable to sign the consent form, the HSE designated professional should have another member of the multidisciplinary team witness the consent. At the time consent is given, the HSE designated professional and the witness should record the consent in the healthcare record, on the consent form and provide a copy to the person who gave the verbal consent for their records.

The giving of verbal consent in person or over the telephone must be witnessed by two members of the multidisciplinary team (the HSE designated professional obtaining consent and one other). Where the giving of verbal consent over the telephone is proposed, great care should be taken to confirm the identity of the person giving consent. A copy of the witnessed consent form must be placed in the healthcare record and provided to the family as soon as possible.

## 3.8.2. How should consent be recorded if a person cannot write?

If the person is unable to write, a mark on the form to indicate consent is sufficient, if that is possible. It is recommended practice for the mark to be witnessed by another member of the multidisciplinary team other than the HSE designated professional seeking consent. The fact that the person has chosen to make their mark in this way should be recorded in the healthcare record and on the consent form and witnessed.

## 3.8.3. What information should consent forms include?

The consent form should include:

- a. The name, date of birth, and deceased person's healthcare record number and name of primary consultant. A hospital addressograph label should be used if available.
- b. Date of death and if it is known the time of death.
- c. The printed name, signature and contact number of the person giving consent and their relationship to the deceased.
- d. The printed name, signature, medical council number, job title and contact/ bleep number of the registered medical practitioner obtaining the consent (where relevant).
- e. All signatures should be dated and timed (including any witnesses).

Consent forms should clearly show all the various options available to the family, including:

- a. Options with regard to any PME limitations required by the family.
- b. Options with regard to their wishes / further communication in relation to the burial or cremation of temporarily retained organs.
- c. A section on the use of any retained tissue and / or organs for clinical teaching, medical education and / or research purposes.
- d. Options in relation to communication of the hospital PME results.

Consent forms should provide for the documentation of verbal consent including such consent given over the phone and the subsequent receipt of written confirmation of consent where applicable (exceptional circumstances).

Consent forms documenting verbal consent should include the printed name, signature, job title and contact number (bleep/telephone) of the HSE designated professional taking

consent and the member of the multidisciplinary team who witnesses the giving of verbal consent.

The HSE National Toolkit of Templates for Post Mortem Examination Services includes templates that services may adapt for:

- Template Form 3: Acknowledgement of information received and consent form for the management of any organs temporarily retained in a coroner's post mortem examination.
- Template Form 4: Consent form for hospital post mortem examination (also known as a consented or non-coronial PME).

## 3.8.4. Where should the consent form be filed?

kept in the healthcare sent to the mortuary The consent form record of the department where sent to the pathologist offered to the family must be filed as deceased person / the PME is to be [COPY]. [COPY]. follows: relevant maternal file carried out [COPY] [ORIGINAL].

Figure 5: Where should the consent form be filed?

If local practice dictates that the pathologist has access to and uses the healthcare record, a separate copy may not be required by the pathology department.

In community deaths, the practice may vary from hospital to hospital and a local SOP should be in place to capture the recommended local practice.

In perinatal PME, the healthcare record of the baby may be kept with the maternal records, in other scenarios it may be kept separately as a standalone medical file.

The pathologist should ensure that consent has been obtained prior to proceeding with the hospital PME and for the management of organs in the coroner's PME. This should be documented appropriately as per the local standard operating procedures.

Where consent is not given for a hospital PME following discussion with the family, this discussion, the decision reached and any subsequent action (for example the family wish to discuss with the coroner) should be documented in the healthcare record of the deceased person.

A copy of the consent form must be offered to the family.

## 3.9. Consent for organ and tissue retention for clinical teaching, medical education and / or research

Organs and tissue samples may be a valuable resource for clinical teaching, medical education and / or research and may advance medical knowledge and benefit society. However, retention will not take place without the consent of the family.

Consideration should always be given to the timing of the consent process for these activities and it is generally not appropriate to engage a family with detailed discussions about consent immediately after a death when decisions about a PME also need to be made.

Consent for the continued retention of organ(s) for use in clinical teaching, medical education and / or research purposes following the coroner's / hospital PME should be documented on an appropriate consent form. The original consent form should be stored in the patient's healthcare record. A copy of this consent form should be offered to the family and a copy should be provided to the coroner and pathologist.

In order that services might seek to ensure informed consent is obtained for tissues or organs to be retained for clinical teaching, medical education and / or research purposes, it is recommended that services adopt a two-phase process.

Please see the HSE National Toolkit of Templates for Post Mortem Examination Services Template Form 3 and 4. The family may give consent in the following ways:

## Option 1

Using option one, the designated person will give / decline consent using a twophase process.

**Preliminary consent:** In the first phase (preliminary consent), the designated person gives consent to be contacted in approximately 12 weeks to discuss the possibilities for clinical teaching, medical education and /or research and in doing so to ensure that they fully understand what they are consenting to. As the consent for research and other purposes is discussed at a later date, the designated person is also consenting to the retention of tissue and / or organs during the preliminary consent period pending the outcome of the discussion in the second phase.

**Final consent:** The second phase (final consent) is completed approximately 12 weeks after the post mortem examination. At that time the designated person's wishes in relation to clinical teaching, medical education and / or research should be documented on a consent form.

All consent forms used by local services should be developed in accordance with HSE National Policy for Consent in Health and Social Care Research (2022).

## Option 2

**Broad consent:** This option can be used when the designated person is not interested in being contacted at a later stage and where the facility / hospital can share sufficient information about the potential use of the tissue or organ as part of the facility / hospitals research programmes. This is to enable the designated person to make an informed decision.

In the case of clinical teaching, medical education and /or research, please see the HSE National Policy for Consent in Health and Social Care Research (2022) for guidance on the essential information to be included during a broad consent process. When this option is used, the section of the form used to seek broad consent for research should be approved by a HSE research ethics committee.

## Who is responsible for taking consent in these cases?

Table 5 sets out when and by whom consent should be taken in cases of clinical teaching, medical education and / or research.

Consent for clinical teaching, medical education and / or research			
	When	By whom	
Option 1: Preliminary and Final consent	Two phase process at the time of PME and approximately 12 weeks later	Preliminary consent This will be the responsibility of the medical professional (usually the consultant or registrar).	
		Final consent This will be the responsibility of the hospital pathologist. In cases where a research purpose has been identified, it may be completed by the researcher.	
Option 2: Broad Consent	At the time of the PME	This will be the responsibility of the medical professional (usually the consultant or registrar). In cases where the facility has established research options, the researcher may be involved in this process.	

Table 5: Consent for clinical teaching, medical education and / or research

The consent process for clinical teaching and medical education is separate from the consent process for research purposes. Please see below additional considerations for both.

## General information on research

Consent for research should be completed in accordance with the HSE National Policy for Consent in Health and Social Care Research (2022). Both approval by an appropriate REC and / or consent are required for the use of biological material for research purposes following the death of the individual.

In cases where the specific research purpose is not available at the time of seeking consent, (whether this is at the time of the PME or later), the requirements specified in the HSE National Policy for Consent in Health and Social Care Research (2022) related to "Consent for storage, maintenance, and secondary research use of identifiable personal data or identifiable biological material", should be followed. In all cases, a research ethics committee should approve the information provided for seeking broad consent.

## General information on clinical teaching / medical education

If it is proposed to use tissues or organs for clinical teaching or medical education purposes, in addition to the information outlined above, and in the absence of alternative arrangements, explain to the family that:

a. Tissues / organs that are used for clinical teaching or medical education should be appropriately prepared and anonymised or pseudonymised so that the identity of the deceased person will not be disclosed. In some instances, the family will indicate that they would prefer that tissues / organs were not anonymised and /or in cases of rare disease, it may not be possible to fully anonymise tissues / organs.

- b. In the event of a family providing consent for organ retention for clinical teaching or medical education it is not the practice to return the temporarily retained organ to them at a later date. This is because these organs are:
  - usually anonymised so identification would be difficult, and
  - often used over an extended period of time and so a considerable amount of time may pass prior to completion of their use in this context.
- c. The organ(s) will be buried or cremated in a respectful and dignified manner, in line with these guidelines, on completion of any educational use. The facility involved in the burial or cremation of the organ(s) should maintain a full record of the process.
- d. In a very small number of cases, organs may be used as medical museum specimens for teaching purposes.

## 3.10. What happens if consent is declined or withdrawn?

The following section applies to the consent given regarding the:

- A Coroner's PME: retention of organs, tissues and / or other body fluids for clinical teaching, medication education and / or research and the burial / cremation of retained organs
- A Hospital PME: all stages

Where consent is withdrawn or declined, it should be documented on the consent form. The following extracts from the HSE National Consent Policy (2022) set out what happens if consent is withdrawn or declined.

It should be noted that in some instances the withdrawal of consent may be time sensitive.

## Extract from section "2.6 What happens if consent is refused?"

If an adult with decision-making capacity to make an informed decision makes a voluntary and informed decision to refuse an intervention, the healthcare worker must respect this decision.

...it is particularly important to accurately document the discussions with the person in their healthcare record including:

- a. The intervention that has been offered;
- b. Whether an alternative intervention is acceptable to the person;
- c. The person's decision to refuse the intervention offered;
- d. Details of the full implications of the decision to refuse an intervention.

Extract: HSE. HSE National Consent Policy (2022) p. 18

## Extract from section "2.7 What happens if consent is withdrawn?"

A person with decision-making capacity is entitled to withdraw their consent at any time, including during the performance of an intervention. The person may show that they want the intervention to stop either verbally or non-verbally. Where a person signals that they want to withdraw their consent during the intervention, the healthcare worker must:

- a. Stop the intervention;
- b. Establish the person's concerns;
- c. Explain the consequences of not completing the intervention, and
- d. Respect the withdrawal of consent if the person retains decision-making capacity.

If the person withdraws their consent during an intervention, the healthcare worker should document this in the person's healthcare record.

Extract: HSE. HSE National Consent Policy (2022) p. 18

## Part four: Communication and the post mortem examination



## 4. Part four: Communication and the post mortem examination

## 4.1. An introduction to communication and the post mortem examination

Effective communication in all aspects of care following death is of paramount importance to bereaved families. It is particularly important when a PME is proposed. Families may be unfamiliar with what a PME entails or in the case of a coroner's directed PME, may not understand why the PME is required or the role of the coroner. A PME should be discussed with sensitivity, openness and with the necessary detail to help families to make decisions and support them.

Death and bereavement affect individuals in different ways. Responses are influenced by beliefs, culture, religion, values, life-style and social diversity. Those with responsibility for communicating with the family should be alert to their individual needs, and where possible be flexible in attempting to meet them.

## It is recommended that each hospital identifies:

- a designated PME liaison / position for tracking, overseeing and monitoring of organs in all PMEs in each mortuary, and,
- a designated family liaison / position (in hospital and / or community deaths, for example from the multi-disciplinary team, bereavement support, medical social worker).

At minimum, a Standard Operating Procedure should also be in place to ensure these roles are covered in the event of the absence or unavailability of a designated staff member for any reason.

The **objective** of this section is to provide practical guidelines for all those directly involved in communicating with families about PMEs and the consent process.

Where there is cross over between a coroner directed PME and a hospital based PME the information is presented together. Information specific to each type of PME is included as individual points using different coloured font / shading.

- Communication specific to a coroner's PME (in purple text / shading)
- Communication specific to a hospital PME (in blue text / shading)
- Communication regarding both the coroner's and hospital PME (in black text)

To support the reader, we have included key information on communication and consent together. However, the following additional resources may also be helpful.

Additional resources on communication and consent for PMEs		
Communication	HSE Guidance for Care of the Deceased Person [In development]  National Standards for Bereavement Care following Pregnancy Loss and  Perinatal Death	
Intercultural needs at the time of death	Health Services Intercultural Guide (2009).	
Consent, capacity and assisted decision making.	Part 3: Consent and the Post Mortem Examination.  HSE National Consent Policy (2022)  RCPI Guidelines for Post Mortem Consent and Retention of Samples (2000)  HSE National Policy for Consent in Health and Social Care Research (2022)	

Table 6: Additional resources on communication and consent for PMEs

## 4.2. Section one: General guidance for communication with the family of the deceased

All communication should be delivered with sensitivity and keeping in mind some simple principles.

## Simple principles of communication with the family of the deceased

## Where should the conversation about PME take place?

- Communication should happen in a confidential context, in an appropriate environment while respecting the dignity and privacy of the family as much as possible.
- Ideally, the conversation should take place in a dedicated bereavement room / other appropriate space. It may arise that family members are abroad or unable to travel and in this instance, this may require a remote communication process (telephone or preferably a secure video link).

## May the family have an advocate present?

- Yes. It may be helpful to invite the person to have an advocate / support person with them for the communication and consent process.
- Where resources are available, for example the Patient Advocacy and Liaison Service (PALS) or bereavement support may also assist.

## What style of communication should be used?

- Communication with the family about the PME process should be sensitive, honest and respectful to the needs of the family and to the dignity of the deceased person.
- Use plain language, explain appropriate terminology and use non-technical terms.
- "Words matter. It is important to take cues from parents regarding preferred language when discussing their infant." See <u>Determination of signs of life for births before 23+0 weeks (hse.ie)</u>

## What information should be shared with the family?

- During the process of seeking consent, a HSE designated professional accompanied by a member of the multidisciplinary team should explain what is involved in clear language and in a form and manner to help the family understand what is involved.
- Encourage and allow adequate time for the family member(s) to ask any question(s) they wish and to discuss any decisions with other family members, if appropriate.
- A booklet with detailed information in relation to the PME should be provided to the family. This should be written in appropriate and accessible language.
- Share factual information, for example booklets that the family may take away (if they wish).
- Refer the family to any relevant online resources for example, the coroners' dedicated website via <a href="https://www.coroners.ie">www.coroners.ie</a>. In perinatal cases, <a href="https://www.pregnancyandinfantloss.ie">www.pregnancyandinfantloss.ie</a> may be a useful resource.

## How much information does a family need about PME to support informed consent?

• Families may seek very little or very detailed explanations of what a PME involves and information should be tailored to their needs but be sufficient for informed consent.

## Simple principles of communication with the family of the deceased

- The family should have the option to decline detailed as opposed to general information if satisfied that they have enough information to make a decision. The provision of general information is essential to ensure that informed consent may be given. The sections below are divided into general and detailed information where appropriate to support the consent process.
- It is important to be aware of the individual needs of the family, as people may have different capacities for understanding information in the context of the emotional distress they may also be experiencing.

## Who may be able to assist the family?

- Share information on support services that may be available to them and how these services may be accessed (including independent support services).
- Offer emotional or psychological support by appropriately trained professionals.
- Offer any additional supports that may be required; for example, contacts for the hospital chaplain, Patient Advocacy and Liaison Service (PALS), access to interpreters (including sign language interpreters).

## **Timing**

- Apart from situations where an individual wishes to give consent while alive (pre mortem), for their body / tissues or organs to be donated for clinical teaching, medical education and /or research, conversations regarding the need to perform a PME should not take place until after the person is deceased (unless this is initiated by the family) and then at an appropriate time and in an appropriate location, for example a bereavement room. It may be necessary to begin the conversation sooner if organ donation is being considered.
- Allow the family reasonable time to receive information and where applicable, make decisions.
- It may not be appropriate to give all of the information at the same time; therefore, each family should have an identified hospital contact person with relevant contact details who can provide information and support throughout the process.

## Do I need to document the discussion?

Yes. The discussion on seeking consent and the decision made by the family should be documented in the healthcare record of the deceased and on the relevant Acknowledgement / Consent form (see the HSE National Toolkit of Templates for Post Mortem Examination Services, Template Form 3 or 4). A copy of the acknowledgement / consent form must be offered to the family.

Table 7: Simple principles of communication with the family of the deceased

## 4.3. Section two: Communication and consent regarding the post mortem examination

The following section outlines the process of communication and consent regarding the PME. This section is designed to support the designated healthcare professional <sup>12</sup> (preferably a consultant or registrar) to engage with the family or deceased's representative to establish valid consent. <sup>13</sup> This section should be read in conjunction with Part 3: Consent and the post mortem examination of this document.

## 4.3.1. What information should be included in the discussion?

The family should be informed that this conversation is to help share information about the PME process and options they have in relation to:

- the performance of a hospital PME
- the retention of organs (for diagnosis and / or for clinical teaching, medical education or research purposes)
- the ultimate return or sensitive management of temporarily retained organs and timescales involved
- the communication of PME examination results.

Regardless of the perceived benefits of a PME or the healthcare professional's personal views, during the communication and consent process, it is important to share information in an objective manner. This is to create an opportunity for the family to make an informed decision, which does not seek to influence them in any way.

It is important to assure the family that while time sensitive, decisions do not need to be made immediately and that they may ask questions and / or discuss the options with their family.

It is also important to assure the family that the PME will be carried out according to professional standards and international best practice guidelines, with great care and respect to protect the **dignity of the deceased**.<sup>14</sup>

## 4.3.2. Key contact / designated family liaison

Each family should have an identified key contact person who is responsible for follow-up contact with the family during and following completion of the PME. The following table sets out where the key contact will be based.

Key contact / designated family liaison				
Type of PME	Coroner's	State Case	Hospital	
Key contact person(s) from	Hospital Coroner's office	Garda Liaison Officer	Hospital	

Table 8: Where are key contacts based?

It is recommended that at the time of the consenting process, the family contact specifies how they wish to be contacted.

 $<sup>^{12}</sup>$  See section 3.4 Who is responsible for sharing information about the PME and seeking and obtaining consent?

 $<sup>^{\</sup>rm 13}$  For information on the family, please see Section 3.3  $\,$  Who may give valid consent?

<sup>&</sup>lt;sup>14</sup> See 'Appendix three: References' for information on professional standards and international best practice guidelines.

The family member should also be advised that it is vital for them to update their identified key contact person if their details change. This is to ensure that their wishes may be followed and that they may be updated as needed throughout the process. This should be documented in the healthcare record.

## 4.3.3. Reasons for undertaking a PME

## A coroner's PME

Coroners are obliged by law to inquire into and investigate certain deaths to determine the cause of death. 15

A coroner's PME is carried out at the direction of the coroner:

- a. To establish or clarify the cause of death.
- b. To identify conditions that may have contributed to the cause of death.
- c. To identify unnatural causes of death.

When a coroner's PME is legally required, the reasons should be clearly and sensitively explained to the family.

## A hospital PME

A hospital PME may be requested:

- To provide further information about an illness or condition, at the time of death. (If the cause of death is not known, then a coroner's PME is required.)
- b. To investigate the effect and efficacy of a medical or surgical intervention provided to the deceased prior to death.
- To obtain information that may directly affect the health of current or future family members.
- d. To enhance understanding of the disease or condition from which the deceased died in order to provide improved medical care to future service users with similar conditions.
- e. To provide information on potential recurrence risks in future pregnancies and to provide information that would allow a plan of care in a future pregnancy.

If a hospital PME is proposed, the reason(s) should be clearly and sensitively explained to the family.

## 4.3.4. What options do the family have?

## A coroner's PME

## What options do the family have?

Inform the family that they have the option:

- to discuss the death with the coroner,
- to receive clear, comprehensive and accurate information about the coronial process including the coroner's PME entails,<sup>16</sup>
- to discuss any queries they may have,
- to give direction as to their wishes for how temporarily retained organs will be managed on completion of the coroner's PMF

## A hospital PME

## What options do the family have?

Inform the family that they have the option:

- to ask for a hospital PME (including limited options),
- to receive clear, comprehensive and accurate information about the hospital PME, to help them to make informed decisions,<sup>17</sup>
- to discuss any queries they may have,
- to give or to decline consent for a hospital PME. It will not take place without their consent.

<sup>&</sup>lt;sup>15</sup> Coroners Acts 1962 - 2020.

<sup>&</sup>lt;sup>16</sup> See Part two: The post mortem examination.

<sup>&</sup>lt;sup>17</sup> See Part two: The post mortem examination.

## 4.3.5. What action should be taken in potential donation for transplantation cases?

### A coroner's PME

## What action should be taken in potential donation for transplantation in coronial PME cases?

In a person is identified as a potential candidate for donation for transplantation, and the family do not object to this, the HSE designated professional should liaise with the coroner's officer to seek authorisation for the removal of any organs, tissues or cells for the purpose of transplantation activities before any action is taken.

This authorisation should take into consideration whether or not the examination of the body is required to enable the coroner to perform their function.

While verbal confirmation may be given by the coroner initially, written confirmation including details of the date and time of the provision of the authorisation should be provided as soon as practicable.

The governance of and consent process for the donation for transplantation is outside the scope of the PME Process and should be managed accordingly.

## A hospital PME

## What action should be taken in potential donation for transplantation in hospital PME cases?

In a person is identified as a potential candidate for donation for transplantation, and the family do not object to this, the HSE designated professional should liaise with the family to explain what if any impact the removal of organs, tissues or cells may have on the PME process.

The governance of and consent process for the donation for transplantation is outside the scope of the PME Process and should be managed accordingly.

## 4.3.6. Who can report a death to the coroner or request a hospital PME?

## A coroner's PME

## Who can report a death to the coroner?

- the deceased's clinician,
- An Garda Síochána,
- Any person identified in the Coroners Act 1962 - 2020.

## A hospital PME

## Who can request a hospital PME?

- the family, <sup>18</sup>
- the deceased's clinician with valid consent of the family.

In cases where a family seeks a PME but the clinicians deem there is no medical reason for same, consideration should be given to the wishes of the family. A PME should only be refused in exceptional circumstances.

If following careful consideration, the clinicians decide not to proceed with a PME, in this instance, the family should be informed that it is open to them to contact the coroner for their opinion on the matter.

<sup>&</sup>lt;sup>18</sup> See section 3.3 Who may give valid consent?

## 4.3.7. What does a PME entail?

### A coroner's PME

The coroner's PME includes the removal and examination of organs, which are subsequently returned to the body. It also involves a sampling of tissues and/or other body fluids for detailed laboratory examination and diagnostic purposes in the context of establishing the cause of death.

In some instances it is necessary to temporarily retain organs for specialist examination when they directly relate to the cause of death (consent from the family is not required). Following the investigation process, in accordance with the wishes of the family, the temporarily retained organs are returned to the family or the hospital for burial or cremation unless arrangements are in place for clinical teaching, medical education or training.

### A hospital PME

The hospital PME may include the removal and examination of organs, which are subsequently returned to the body. It also involves the sampling of tissues and/or other body fluids for detailed laboratory examination and diagnostic purposes.

In some instances, it is necessary to temporarily retain organs for specialist examination, and this will only be done with the consent of the family. Following the PME process, in accordance with the wishes of the family the temporarily retained organs are returned to the family or the hospital for burial or cremation unless arrangements are in place for clinical teaching, medical education or training.

## 4.3.8. Communication specific to the PME

## A coroner's PME

## Communication specific to the coroner's PME

Inform the family of the deceased when a death is reportable to the coroner. However, reporting the death to the coroner should not be delayed in order to allow notification of the family.<sup>19</sup>

### A hospital PME

Communication specific to the hospital PME Inform the family of the deceased that they have an option to:

- a. request a full PME,<sup>20</sup> or
- b. request a limited PME,<sup>21</sup> or
- c. decline the hospital PME.

In many cases, a limited PME may provide important diagnostic information. In these cases, discussions should involve the pathologist who will perform the PME. However, the family should be informed that a limited hospital PME may:

- a. lead to an incomplete or partial assessment,
- not provide either the family or the pathologist with sufficient information to establish / clarify a definite diagnosis.

Any limitations required by the family should be conveyed to the pathologist through documentation on the consent form for the hospital PME. A pathologist may decline to conduct a limited PME where they believe that it is unlikely to provide a diagnosis or the answer to the question being asked.

<sup>&</sup>lt;sup>19</sup> See section 2.2 Deaths reportable to the coroner.

<sup>&</sup>lt;sup>20</sup> See section 2.1.2 What is the difference between a full and limited post mortem examination?

<sup>&</sup>lt;sup>21</sup> See section 2.1.2 What is the difference between a full and limited post mortem examination?

## A coroner's PME A hospital PME The family should also be informed that even a full hospital PME may not answer all questions in relation to the death. Minimally invasive PMEs require specialist equipment and expertise and may not always be available or suitable. Give the family: Give the family: a. information about the office and role of a. an information booklet setting out the PME the coroner. process. b. an information booklet setting out the powers and functions of the coroner and the procedural aspects of coronial jurisdiction, including death certification and the PME process.

## 4.3.9. Who will perform the PME?

## A coroner's PME

### The coroner's PME:

- a. will be performed by a pathologist who acts as the coroner's agent for this purpose or by an appropriately trained and experienced healthcare professional under their direction,<sup>22</sup>
- b. in some cases the PME may not be undertaken in the hospital, or by a hospital pathologist, as these matters are entirely at the coroner's discretion.

The coroner may direct that the coroner's PME be carried out at another hospital or at a municipal mortuary in cases where there is a perceived conflict of interest, in cases where there is no available pathologist or there are suspicious circumstances pertaining to the death.

If the coroner's PME is undertaken by a hospital pathologist, in these circumstances the pathologist is directed by the coroner and is acting independently of the hospital on the coroner's behalf.

## A hospital PME

The hospital PME will be performed by a hospital based pathologist or by an appropriately trained and experienced healthcare professional under their direction.

## 4.3.10. When and where will the PME happen?

Explain where and when the PME will take place and if the body of the deceased needs to be transferred to another hospital/location for the PME to be conducted.

<sup>&</sup>lt;sup>22</sup> A person acting on behalf of the coroner.

## 4.3.11. Information on the timing of when the PME is completed

### A coroner's PME

In general, a PME should be carried out as soon as possible after death to get as much information as possible.

In **suspicious deaths** a coroner's PME may be time sensitive.

In **perinatal / paediatric** PMEs, it can be helpful to complete metabolic and genetic sampling as soon as possible. Radiology is usually performed prior to the PME.

In perinatal / paediatric PMEs, the family may request to spend time with the baby or child immediately after their death including holding the baby or child. Where possible the healthcare professionals should try to facilitate requests of this nature; however, it is important to establish a balance between the requirements of the coronial investigation and the needs of the family, with precedence given to the coroner's requirements. Any decisions of this nature should be made by the coroner's office.<sup>23</sup>

In **perinatal / paediatric PMEs**, in cases where the mother is an inpatient at the time of the PME, it is recommended that the baby should be returned to the mother as soon as possible after the PME (if there are no medical contraindications). This allows the service to recognise the importance of time spent by the parents with their baby.<sup>24</sup>

Share an estimation of how long the PME will take.

The family should be given an indication as to when to they may expect results from the coroner's PME. However, they should also be made aware that this is not a definitive timeline. An update may be required as part of the progress report if necessary.

Some laboratory tests can take time to complete and an inquest may be required, therefore final conclusions and a death certificate may not be available for a significant period of time. It is very important that the family are made aware of these facts and for this reason it is not possible to give a definitive timeline as to when they may expect to receive results from the coroner's PME.

### A hospital PME

In general, a PME should be carried out as soon as possible after death to get as much information as possible.

In **perinatal / paediatric PMEs**, it can be helpful to complete metabolic and genetic sampling as soon as possible. Staff should be aware that this shorter timeframe poses particular challenges in relation to the provision of information to families and the seeking of consent.

In perinatal / paediatric PMEs, the family may request to spend time with the baby or child immediately after their death including holding the baby or child. It is important to establish a balance between the clinical need and the needs of the family. Where possible clinicians should facilitate requests of this nature. In some instance, it may be helpful to share with the family any implications in terms of the quality of the PME if it is delayed.

In **perinatal / paediatric PMEs**, in cases where the mother is an inpatient at the time of the PME, it is recommended that the baby should be returned to the mother as soon as possible after the PME (if there are no medical contraindications). This allows the service to recognise the importance of time spent by the parents with their baby.<sup>25</sup>

Share an estimation of how long the PME will take. It is reasonable to expect that the investigations associated with:

- A standard PME, where no toxicology is required, would be completed within two months.
- A more complex PME, where toxicology or other specialised tests or expert opinion are required would be completed within four months.

The family should be informed that it is not possible to give a definitive timeline as to when the post mortem report will be completed as timeframes vary depending on circumstances such as what laboratory tests or expert opinion may be required. An update may be required as part of the progress report if necessary.

The family should be informed that, at their request, the report of the hospital PME will be made available to them when completed.

<sup>&</sup>lt;sup>23</sup> See also section 2.2.8 Guidelines for state forensic PMEs (suspicious or unusual deaths) where relevant.

<sup>&</sup>lt;sup>24</sup> See the National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death (2022).

<sup>&</sup>lt;sup>25</sup> See the National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death (2022).

## 4.3.12. Formal identification of the body

If the Coroner directs a PME formal identification of the body is required:<sup>26</sup>

- In State forensic cases, any formal identification will usually occur following the PME, in order to preserve any evidence that may be relevant to the criminal or coronial investigation.<sup>27</sup>
- In cases where there are no suspicious or unusual circumstances, then a family member will be asked to formally identify the body prior to the PME.

## Who identifies the body?

The identification is normally made by an adult member of the family of the deceased in accordance with section 27, Coroners Act 1962 as amended by the Coroners (Amendment) Act 2019<sup>28</sup>, to a member of An Garda Síochána acting on behalf of the coroner or an appropriate person. The Coroner's Society of Ireland have provided additional information on this process, which can be found in the <u>Guidance in relation to the Coroners Service and Deaths due to Covid-19 infection</u>.

In certain circumstances such as perinatal or paediatric deaths (which are not suspicious), the coroner may accommodate an alternative process for identification. Any deviation from the standard identification process should be agreed with the local coroner, must still satisfy the legal requirements and must be documented in the healthcare record.

## Is a family member compelled to view the body for the purposes of identification?

No. Family members should not be compelled to view the deceased's body against their wishes. In circumstances where family members are not available or are otherwise unable or too distressed to carry out the identification, it may be appropriate with the coroner's permission, for a friend, long-term acquaintance or a member of the clinical team to carry out such identification.

## Where does the formal identification take place?

Formal identification may entail attendance at the hospital mortuary to identify the body to the Garda who in turn will identify the body to the pathologist or technician. (Sometimes identification takes place in locations other than the mortuary such as in the Emergency Department or on a hospital ward or other care setting).

## 4.3.13. Information on the appearance of the deceased before the family view the body

Share information on the appearance of the deceased before and after the PME including:

a. Normal changes occur after death even if there is no PME. The cause of death may also impact on the post mortem appearance of the body.

<sup>&</sup>lt;sup>26</sup> Please see Appendix five: Principles of care during the identification of the deceased person.

<sup>&</sup>lt;sup>27</sup> For additional information on state forensic cases, please see section 2.2.8 Guidelines for State Forensic PMEs (suspicious or unusual deaths).

<sup>&</sup>lt;sup>28</sup> Extract from the Coroners (Amendment) Act 2019. Section 27 (1) For the purpose of establishing the identity of a deceased person, a coroner may request a member of the Garda Síochána, a designated officer of the Ombudsman Commission where there is a relevant Ombudsman Commission investigation concerning the death of that person, a family member of the deceased person or, if the circumstances of the death so require, a suitably qualified person who has expertise regarding the identification of human remains—
(a) to view the body of the deceased person, or

<sup>(</sup>b) if such a viewing would not assist with the identification of the deceased person or in circumstances to which section 22 or 23 relates, to examine and consider other evidence of identity of the deceased person, and the person so requested shall give evidence of identity of the deceased person to the coroner.

- b. Great care is taken with the external appearance of the deceased. The PME will be carried out in a sensitive way so that most of the incisions will be hidden by clothes or hair.
- c. In paediatric and perinatal cases, the family may wish to see their baby/child's body and hold and dress them again. This should be facilitated where possible.
- d. In cases of traumatic injury or other significant changes to the appearance of the deceased, the family will be advised to link with the funeral director / undertaker / embalming services. Embalming is not part of the PME process in the healthcare facility.
- e. Take any cultural requirements into consideration where possible. See the Health Services Intercultural Guide (2009).

## 4.3.14. Clinical audio or visual media

### A coroner's PME

Inform the family that visual media (for example photographic, radiological images) may be taken to assist with the coroner's investigation. This should be clearly outlined in the pathologist's PME report to the coroner<sup>29</sup>.

## A hospital PME

Inform the family that visual media (for example photographic, radiological images) may be used as part of the hospital PME process and become part of the PME record. Media in which:

- the deceased is identifiable will only be undertaken with documented consent.
- the deceased's identity is anonymised for clinical teaching, medical education and / or research purposes and does not require documented consent.

It is standard practice for most pathologists to use audio recording (dictation) during the completion of a PME.

Audio or visual media form part of the healthcare record and should be stored and managed confidentially in accordance with the Health Service Executive Standards and Recommended Practices for Healthcare Records Management (2011) and the HSE, Record Retention Periods Health Service Policy (2013).

## 4.3.15. Information about the PME process

Share with the family that they can determine the level of information they wish to receive and information will be provided on an individualised basis.

Emphasise to the family that the PME will be carried out with great care and respect for the body of the deceased according to professional standards and international best practice.

Share a basic explanation of what happens in a PME.<sup>30</sup> The following general information should be communicated unless the family has indicated that they do not wish to receive any information.

<sup>&</sup>lt;sup>29</sup> Please see 'Appendix three: References' for information on professional standards and international best practice guidelines.

<sup>&</sup>lt;sup>30</sup> See Part two: The post mortem examination.

## 4.3.16. Information on the taking of tissue and blood samples

## General information on tissue samples and body fluids

## Why are tissue samples and body fluids taken during the PME?

Small samples of tissue and blood may be taken during the PME for the purposes of diagnosis.

## What happens to samples of tissue during the PME?31

Where necessary, samples of tissue are sent for detailed laboratory examination and diagnosis.

These samples are examined under the microscope. This process is called histology. The samples are retained as histological blocks and slides. These blocks and slides are kept as part of the PME record and are therefore available for subsequent review if required.

## Is consent needed for the storage of and / or sensitive management of tissue samples / body fluids?

No. The preparation of tissue blocks and slides for histological sampling and the taking of body fluids/tissues for additional laboratory testing (for example, biochemical analysis) is included in the consent given for hospital PMEs. This includes their storage and / or disposal at a future date.<sup>32</sup>

Consent is not necessary in this instance because, as part of a PME, small samples of tissues and / or body fluids are taken as part of the medical investigation. Given the small size of these samples, consent is not required for their collection or disposal as it is considered part of the normal PME process. These samples are kept on file as a medical record in the form of histological blocks and slides. A histological sample is chemically treated tissue preserved in a paraffin block (histological block) and a small sample on a glass slide.

## Detailed information on tissue samples and body fluids

The family should be given the option to discuss the taking of tissue samples at PME in greater detail, with the provision of the following more detailed information as required:

- a. The **retention of tissue samples** is an integral part of high quality PMEs; the relevance and completeness of the examination would be substantially compromised if the retention of such samples were precluded.
- Tissue samples are chemically treated in order to create blocks and slides for viewing under a microscope to facilitate initial diagnosis and to allow preservation of the tissue samples.
- c. The preservation of blocks and slides for the purpose of audit, clinical governance and quality assurance is a requirement of many of the professional bodies that regulate pathology practice.

<sup>&</sup>lt;sup>31</sup> See section 4.3.16 Information on the taking of tissue and blood samples.

<sup>&</sup>lt;sup>32</sup> Specific guidance on consent is given in Part 3: Consent and the post mortem examination.

- d. In addition to forming part of the PME record, these blocks and slides are also available for **further study where specific approval has been granted by a Research Ethics Committee (REC) and/or valid consent has been given.**<sup>33</sup> This may be of potential benefit to the family in the future as it may allow the objective evaluation and re-evaluation of disease processes in an individual should any new knowledge or medical insights arise years after the death of the individual.
- e. The **storage and management of these blocks and slides** follow the same laboratory procedures that are in place for dealing with samples from surgical procedures. These are in line with best practice international standards in relation to the following:<sup>34</sup>
  - i. Identification and indexing.
  - ii. Security.
  - iii. Storage, archive and retrieval.

## 4.3.17. Communication regarding the removal and temporary retention of organs

## General information on the removal and temporary retention of organs

When discussing the PME, communicate general information regarding the removal of organs:

- a. **Internal organs** are removed from the body during the standard PME so that they may be fully examined to identify any abnormality.<sup>35</sup> The organs are then returned to the body prior to the burial.
- b. In certain circumstances, it may be necessary to temporarily retain organ(s) for further diagnostic purposes in order to complete the examination. Retained organs are not usually returned to the body prior to burial / cremation. The family participate in the consent process to decide what happens in the event that the organs have not been returned to the body prior to burial / cremation.<sup>36</sup>
- c. Some families choose to allow organs to be retained for use in clinical teaching, medical education and / or research purposes but this will not occur without consent from the family.<sup>37</sup>
- d. Explain that organs or tissues must not be removed from the body of a deceased person during or after a PME, for supply by hospitals to any pharmaceutical company or other third party<sup>38</sup>, without the knowledge and / or consent of the family.<sup>39</sup>

<sup>33</sup> See the HSE National Consent for Research in Health and Social Care Policy (2022) for further guidance on this matter.

<sup>&</sup>lt;sup>34</sup> Requirements for laboratory procedures for the control of clinical material (including blocks and slides) are specified in ISO 15189:2012 Medical laboratories - Particular requirements for quality and competence.

 $<sup>^{\</sup>rm 35}$  See section 6.1  $\,$  Storage and management of tissue samples and retained organs.

 $<sup>^{\</sup>rm 36}$  See section 6.1  $\,$  Storage and management of tissue samples and retained organs.

<sup>&</sup>lt;sup>37</sup> See section 6.1 Storage and management of tissue samples and retained organs.

<sup>&</sup>lt;sup>38</sup> In this context, third party does not include situations where organs and tissues are referred for specialist examination and/or second opinion.

<sup>&</sup>lt;sup>39</sup> If the family give consent for supply of organs or tissues to a third party, all arrangements should be clearly approved and documented by hospital management.

## Detailed information on the removal and temporary retention of organs

Give the family the option to discuss the removal of organs at PME. Share the following more detailed information as required:

- a. The internal examination consists of examining all body cavities (head, chest and abdomen) and inspecting the internal organs of the body.
- b. In order to fully examine the organs, it is necessary to remove them from the body for weighing, measuring and dissection.
- c. Dissection involves making incisions to facilitate detailed examination of the organ.
- d. Small tissue samples are taken in the form of slices or biopsy samples that can be easily viewed under a microscope.
- e. At the end of the removal and dissection, the organs are returned to the body unless there is a need to temporarily retain one or more for diagnostic purposes.

Prior to seeking consent for the temporary retention of organs or in the provision of information about the coroner's PME, the following should be communicated to the family:

- a. the possible reasons for the retention of organs (see section 4.3.18),
- b. how retained organs will be stored (see section 4.3.20),
- c. how temporarily retained organs will be returned and / or buried or cremated if organised by the hospital (see section 4.3.21 and 4.3.22).

This should be included in the discussion unless the family decline detailed (as opposed to general) information. The following more detailed information may be helpful to some families.

## 4.3.18. Possible reasons for the retention of organs

## A coroner's PME

Communicate to the family that:

- Organs may only be temporarily retained as part of this process for as long as is necessary to establish or clarify the cause of death and to identify factors that may have contributed to death.
- Retention for any other purpose such as clinical teaching, medical education and / or research purposes is outside of the remit of the coroner and familial consent is required.

## A hospital PME

As the need for retention of organs may only become apparent during the hospital PME itself, this should be discussed in advance with the family.

The family should be clearly informed that:

- They have the right to give or decline consent for the retention of organs for any reason including:
  - Diagnostic purposes (detailed laboratory examination for investigative purposes) as part of the hospital PME.
  - Clinical teaching, medical education and / or research purposes.
- That organs will not be retained for any reason without their knowledge and consent.

Possible reasons for the retention of organs:

- Referral to a specialist pathologist may be necessary so that the best possible information is obtained. For example, in circumstances of neurological disease, it may be necessary to retain the brain for examination by a pathologist specialising in brain diseases (a neuropathologist). Similarly, genetic cardiac conditions may require referral to a specialist cardiac pathologist and/ or a geneticist.
- The temporary retention of organs allows for specialist examination to obtain comprehensive information from the PME. This may require an organ to be placed in a fixative prior to examination. Where fixation is required, it is important to note that:
  - i. The timeframe required for this to take place, does not usually allow return of the organ to the body prior to its release for burial.
  - ii. In some cases, it may be possible to carry out rapid fixation which facilitates examination and diagnostic evaluation. This may facilitate return of the organ to the body before release of the body for burial.
  - iii. The practice of rapid fixation is limited as it is not suitable in many situations.

If possible, information regarding the timeframe for such retention should be given to the family.

## 4.3.19. What happens in the exceptional case where it is necessary to examine an organ which is too small to be sampled or temporarily retained?

In cases where a PME is required (coroner's PME) / proposed (hospital PME), it should be explained to the family that in rare circumstances:

- a. Certain organs from very small babies may be too small to enable them to be examined without retaining the whole organ. In such circumstances, it may be necessary to place the whole organ on a histological block or slide for diagnostic purposes.
- b. Any such blocks or slides are kept as part of the PME record.

See section 4.3.16: Information on the taking of tissue and blood samples for more detailed information on the preservation of blocks or slides.

## 4.3.20. Communication regarding the storage and sensitive management of retained organs

Assure the family that:

- a. The storage of retained organs complies with relevant Irish legislation and current standards of best practice.<sup>40</sup>
- b. All retained organs will be treated in a respectful manner. Retained entire organs will be kept in appropriate individual containers that are clearly identified, traceable and stored in a designated secure area.

Where there is more than one retained organ from the deceased following a PME, the hospital will ensure that these are stored together as far as is practicable.

<sup>&</sup>lt;sup>40</sup> Requirements for laboratory procedures for the control of clinical material (including blocks and slides) are specified in ISO 15189:2012 Medical laboratories - Particular requirements for quality and competence.

### A coroner's PME

Organs temporarily retained for the purpose of completing the coroner's PME, will be released in accordance with the family's wishes, following completion of the investigative process, as soon as appropriate authorisation is received from the coroner or their agent, who in this instance will normally be the pathologist / HSE designated PME Liaison.

## A hospital PME

Organs temporarily retained for the purpose of completing the PME process, will be released in accordance with the family's wishes following completion of the investigative process and the PME Process.

## 4.3.21. Communication regarding the burial or cremation of temporarily retained organs

As part of the PME consent process, inform the family that they can decide what happens the organs (return and / or burial or cremation) once the coroner or pathologist acting on the coroner's behalf authorises their release. The following issues should be discussed with the family:

- 1. Options for burial or cremation of temporarily retained organs (see section 4.3.22).
- 2. Consent for the continued retention of organs for use in clinical teaching or medical education, and / or research purposes in line with the HSE National Policy for Consent in Health and Social Care Research (2022) (see section 3.9 and section 4.3.26.)

## 4.3.22. Options for the burial or cremation of temporarily retained organs

The following guidance does not apply to organs retained prior to their implementation. In this instance, organs should be managed in accordance with local standard operating procedures.

In cases where the family have not indicated that they wish to donate the organs for clinical teaching, medical education and / or research, the healthcare professional (person completing the consent form with the family) should inform them of their options in relation to the burial or cremation of temporarily retained organs. While the giving of such information at this point in time may be difficult for the family, it is crucial that the family understand that temporarily retained organs may not be available for return to the body in time for the funeral.

It should be communicated to the family that an immediate decision in relation to the burial or cremation of temporarily retained organs is not necessary. However, this varies based on local practice. It is possible for the designated healthcare professional (key contact) to contact the family once the examination of the organs is complete to determine their wishes.

The family should also be made aware that in cases where a decision has not been made, and it is not possible to contact them following repeated efforts to do so, the hospital will arrange for the burial or cremation of the temporarily retained organs one year after completion of the post mortem examination report (please see section 4.3.25 What to do if the family do not specify their wishes).

Burial or cremation may differ as per local arrangements; however, please see section 6.3 for further information.

Families should be given the following options for sensitive management of temporarily retained organs.

# Option 1: The temporarily retained organs may be returned to the family so that they may arrange for the burial or cremation.

- •When a family wish to make their own burial or cremation arrangements, the hospital should ensure that the family receives the organs of the deceased in a dignified manner and setting [for example, in an individual casket appropriately sealed and labelled with the name of the person and in a suitable location such as a hospital oratory or family room].
- •The hospital should strongly encourage families to use the services of a funeral director for this process, so as to ensure that the organ(s) will be buried or cremated in a suitable place/manner.

# Option 2: The temporarily retained organs will be either buried or cremated. This is arranged by the hospital in line with the family's preferences.

- •In this instance the hospital will arrange for the burial or cremation based on the wishes outlined by the family in the relevant forms (1. preference for burial, 2. preference cremation or 3. no preference (burial or cremation will be managed in line with the hospital policy)).
- •The cremation / burial process may require a signature from the family to proceed in some crematoriums / cemeteries. Where the family have disengaged from the process, please refer to the HSE Toolkit of Templates for Post Mortem Services, Template Form 6 'Request from pathologist to crematorium for cremation of organs in the absence of ongoing family contact'.

Option 3: The family member does not wish to make a decision about the burial or cremation at this time and wishes to be contacted to discuss this at a later stage.

Option 4: The family member wishes for the retained organs to be used for clinical teaching, medical education and / or research.

Figure 6: Options for the sensitive management of temporarily retained organs

It should be noted that there may be either a religious or cultural preference for either burial or cremation. In cases where the family have not indicated a preference, it may be helpful to contact a representative from the relevant faith or cultural group (where known). "When discussing post mortem examinations cultural stereotyping and cultural based assumptions should be avoided as diversity exists in all cultural groups"<sup>41</sup>. Further information on cultural beliefs and contact details can be found in the Health Services Intercultural Guide (2009).

The staff member may be asked about the costs of funeral services. In this instance, they may wish to refer families to the local funeral director / undertaker.

In the event that there is no designated person available, the service should contact the local authority (in all cases) and coroner (in coroner's cases) in relation to burial / cremation arrangements.

<sup>41</sup> Extract from National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death. Version 2.0. Dublin: HSE.

## 4.3.23. Hospital arranged burial

Arrangements in individual hospitals will vary depending on local practices. When the hospital undertakes the responsibility for burial of the organ(s), give the family the following information:

- a. Organ(s) will be appropriately sealed, clearly identified and buried in a hospital plot at a named cemetery. Where possible this should be done in accordance with the cultural and / or religious beliefs of the deceased, for example the family may request a non-denominational plot.
- b. If the hospital buries temporarily retained organs communally (that is, the organ(s) from a number of deceased individuals are buried together in a single casket), it should be explained to the family that:
  - Organs from each deceased individual are kept together and prior to burial the organ(s) will be appropriately sealed, clearly identified and placed in a communal casket.
  - ii. Burial will take place when there are a sufficient number of organs for burial, or at the latest within a year of completion of the PME report.
- c. A register of hospital arranged burials will be maintained by the hospital. Relevant information from this register will be made available to the family of the deceased on request.

## 4.3.24. Hospital arranged cremation

When the hospital undertakes the responsibility for cremation of the deceased's organs, the family should be made aware of the following details:

- a. Organ(s) will be appropriately sealed, identified and transported to a named crematorium.
- b. Cremating any part of the body in the absence of bone does not usually result in ashes. Therefore the family should be informed that it is unlikely that there will be any ashes remaining after the cremation of the organ(s) and that most crematoria do not return ashes following such a cremation.
- c. Before cremation, there are certain forms, which need to be completed to ensure that crematorium requirements are met. This includes an application for cremation, which is normally completed by the family. If the hospital arranges cremation, details of what paperwork is required for the cremation of temporarily retained organs should be obtained from the crematorium and it should be ensured that the appropriate form(s) are completed prior to transport to the crematorium.
- d. If the hospital cremates temporarily retained organs communally (i.e. the organ(s) from a number of deceased individuals are cremated together in a single casket), it should be explained to the family that:
  - Organs from each deceased individual are kept together and prior to cremation separate documentation is completed for each set of organs. The organ(s) will then be appropriately sealed, clearly identified and placed in a communal casket.
  - ii. Cremation will take place when there are a sufficient number of organs for cremation, or at the latest within a year of completion of the purposes of the coroner's PME / hospital PME.
- e. A register of hospital arranged cremations will be maintained by the hospital. Relevant information from this register will be made available to the family of the deceased on request.
- f. Where individual ashes are available, the designated person will be contacted to identify if the family would like them returned to them via their nominated funeral director / undertaker or alternatively for the hospital to manage same.

## 4.3.25. What to do if the family do not specify their wishes

The timely and respectful burial or cremation of organs, which were temporarily retained for specialist examination is an important component of the PME process which recognises and acknowledges the continuing dignity of the deceased person or child. Every effort should be made to ascertain the wishes of families in this regard. However, decisions about the burial or cremation of organs may be difficult for family members, especially in the immediate aftermath of a person's death. While every effort should be made to facilitate the family to make a decision, this may not always prove possible.

In such cases, it is recommended that each hospital should have a documented local procedure in place. This should ensure the timely, respectful and sensitive management of organs where following repeated efforts to contact the family:

- a family has not made a decision or
- it is not possible to carry out the initial instructions of the family to return the organs to them for burial or cremation.

This should be documented in the healthcare record and action taken as outlined below.

In cases where there is contact with the family; however, they wish to delay decision making on the management of organs, the service should continue to engage with them.

## When should a final decision be made in the absence of contact from the family?

In order to ensure the timely and respectful burial or cremation of organs temporarily retained for specialist examination, the hospital should arrange for the burial or cremation of the temporarily retained organs as follows:

Circumstances	Timeframes
Where a decision has not been made by the family	One year after completion of the post mortem report
Where the family have given an instruction; however, it is not possible to contact them at the end of the process to give effect to original instruction	Three years after completion of the post mortem report

Table 9: Timeframes for decision making in the absence of family contact

This guidance should only be enacted, in the absence of final instructions from the family, following frequent, repeated and clearly documented contact via multiple methods in accordance with the local hospital procedures. Please see additional information to be taken into consideration during this process in the next section.

Information on local arrangements for burial or cremation of organs should be included in the local booklet and consent forms as required.

## How frequently should we contact the family if their wishes are not known?

Contact should be frequent (suggested twelve week intervals), regular and well documented as the designated healthcare professional seeks to establish the family's wishes (the responsible role should be identified within the local procedure). The designated healthcare professional should be mindful of when contact happens for example, the deceased's anniversary.

In state cases, the contact with the family should happen via the Garda Liaison Officer.

#### What communication methods should be used?

In the event of no contact from the family, attempts should be made to contact them using an alternative method of communication (phone, letter, email etc.) in case their contact details have changed.

#### How should the decision be documented?

The decision including attempts to contact the family should be documented in the healthcare record and in the PME and organ registers as required.

#### Who is responsible for that decision?

Each service should have a local policy in place that sets out a formalised way of making a transparent decision under local governance arrangements. In the event of a:

- Coroner directed PME, the coroner formally transfers the responsibility for the management of organs to the hospital once their investigation is complete. The final direction should only be given on receipt of this notice.
- Hospital PME, final direction should be given by the pathologist in accordance with the hospital policy.

What happens when a decision has been made for the return of the organs but this cannot be facilitated due to family circumstances (such as delays with payment to funeral director / undertaker by the family)?

In this instance, the service should continue to actively engage with the family on a regular basis and provide all reasonable support to encourage a resolution.

## 4.3.26. Organ and tissue retention for clinical teaching, medical education and / or research

Organs and tissue samples may be a valuable resource for clinical teaching, medical education and / or research and may advance medical knowledge and benefit society. However, retention of organs for these purposes will not take place without the consent of the family and consent should always be obtained in a sensitive and appropriately timed manner. Please see section 3.9 for guidance on the consent process required.

#### 4.3.27. Documenting acknowledgment of information / consent

Following communication of information and discussion with the family, the wishes of the family and their informed consent should be noted. Once the family has reviewed and completed the form, the family should sign the form (where possible) and be given a copy to take away with them.<sup>42</sup> See the HSE National Toolkit of Templates for Post Mortem Examination Services templates, which provide a suggested format which may be adapted as needed:

- Form 3: Acknowledgement of information received and consent form for the management of any organs temporarily retained in a coroner's post mortem examination.
- Form 4: Consent form for hospital post mortem examination (also known as a consented or non-coronial PME).

The family should be informed if there has/has not been temporary retention of organs. Ask how they wish to be contacted about this information.

<sup>&</sup>lt;sup>42</sup> See Part 3 Consent and the post mortem examination.

#### Seek consent as required on the following items:

#### A coroner's PME

#### Consent

Consent is not required for a coroner's PME, which is a mandatory process under Irish law.

During the information sharing process for the coroner's PME, <sup>43</sup> seek specific consent for action on the completion of the coroner's PME and any other legal functions:

- a. Retention of organs, tissues and/or other body fluids for research / medical education / training purposes
- b. Process for the sensitive management of organs (burial or cremation)

Consent is not required for the temporary retention of organs for diagnostic / investigative purposes to establish the cause of death and complete the coroner's PME.

#### Documenting acknowledgement and consent form

On completion of the consent process, ask the family to sign the Template Form 3, which documents:

- the receipt of information regarding the coroner's PME and other legal functions,
- their understanding and preliminary consent as appropriate for the continued retention of organ(s) for use in clinical teaching, medical education and / or research following the coroner's PME
- their wishes for the burial or cremation of temporarily retained organ(s).

The family may interpret this as a consent form for PME despite being told that consent is not required for PME; therefore, this form needs to be very clearly explained.

A copy of the consent form must be:

- filed in the healthcare record of the deceased,
- · sent to the coroner, and
- offered to the family.

#### A hospital PME

#### Consent

Consent is required for all hospital PMEs. During the process of seeking consent for the hospital PME,<sup>44</sup> seek specific consent for:

- a. The PME
- b. Temporary retention of organs to determine cause of death
- Retention of organs, tissues and/or other body fluids for research / medical education / training purposes
- d. Process for the sensitive management of organs (burial or cremation)

#### **Documenting consent**

On completion of the consent process, ask the family to sign the Template Form 4, which documents their understanding and consent.

If consent was obtained for a hospital PME, a copy of the consent form must be:

- filed in the healthcare record of the deceased, and
- offered to the family.

<sup>&</sup>lt;sup>43</sup> See Part 2 The post mortem examination and section 3.2.2 Consent and the hospital post mortem examination, Table 4.

<sup>&</sup>lt;sup>44</sup> See Part 2 The post mortem examination and section 3.2.2 Consent and the hospital post mortem examination, Table 4.

#### 4.3.28. What happens where consent is not given?

**In a coroner's PME,** where consent is not given for the retention of organs for research or training purposes, the family should not be pressurised into changing their minds.

**In a hospital PME,** where consent is not given, the PME is not carried out and the family should not be pressurised into changing their minds.

#### 4.3.29. Sharing a progress report

There should be follow up support offered to the family and a progress report (see sample content below) in a format agreed with the coroner/family, should also be arranged.

Procedures should be developed between each hospital and the office of the coroner for the district in which the hospital is located to ensure that there is no gap in the provision of information to the family of the deceased person. There should be clear delineation of responsibility in this regard.

#### What information should be included in the progress report?

Unless the family have expressed their wish for no information regarding the temporary retention of organs, this notification (progress report) should also include the following as appropriate:

- a. **No organs have been retained.** However, tissue samples for blocks and slides and blood samples were retained as part of standard practice for laboratory examination.
- b. **Organ(s) have been retained**. The organ(s) should be identified and the purpose and expected duration of retention explained. Individual circumstances should determine if it is appropriate at this stage to:
  - discuss with the family the burial or cremation of the organ(s), or
  - inform the family that they will be sent a letter detailing their options with regard to sensitive management (burial or cremation) of the organs(s), or
  - inform the family that the hospital will arrange burial/cremation in line with the previously recorded instructions given by the family.

Where written correspondence is being used in relation to sensitive matters, verbal contact (for example, by phone, secure video link) should happen in advance to notify the individual of pending correspondence. An exception is in circumstances where written communication has been identified as the preferred method of contact by the individual.

The notification should be recorded in the healthcare record of the deceased and supported by communication in writing to the family in accordance with their wishes. A contact number should be provided to allow for further information and discussion as required.

The designated staff member should share the progress report with available information.

In the case of a coroner's PME, the coroner should be appraised of the progress report. The coroner's office may also have their own process for the provision of information / updates to the family.

## 4.3.30. Contact with the family following completion of the PME - communication of the PME results

#### A coroner's PME

At the end of the communication process about the coroner's PME, the family should be provided with the following information as appropriate:

- a. The report from a coroner's PME can only be released on foot of approval of the coroner.
- b. A meeting can be arranged with hospital staff to discuss the findings of the PME once the family have been provided with the report.
  - As some laboratory tests can take time to complete and an inquest may be required, final conclusions and a death certificate may not be available for a significant period of time.
- c. If the family do not wish to attend a meeting but would still like specific information about the PME, share with them that:
  - They can request a copy of the post mortem report from the coroner.
  - ii. This may take some time while laboratory tests are being completed.
- d. As post mortem reports contain a lot of specialist clinical/medical terminology, it might be more helpful to have the report released to an appropriate person who can help to interpret the findings - for example the deceased's general practitioner or in perinatal deaths an obstetrician or neonatologist, as appropriate. This facility should be offered to families.
- e. It should be clearly communicated to the family that the coroner may decide that an inquest is also necessary following the PME.

Communication of this information and relevant discussions should be documented in the healthcare record of the deceased.

#### A hospital PME

If consent has been given, the family should also be given the following options in relation to communication of the hospital PME results:

- a. No communication this applies where the family indicates that they do not want to be given details of the results. A record of the hospital PME findings will be maintained, if the family wish to request this information at a future date.
- b. A meeting with hospital staff offer the family a meeting with hospital personnel as appropriate, when the report is available. In this context, the hospital consultant / registrar requesting the hospital PME, should be involved in communicating the results to the family.
- c. A referral to general practitioner (GP) or other healthcare professional as appropriate- the results of the PME can be sent to the deceased's treating clinician, so that they can discuss the findings with the family at their request.
- d. A copy of the hospital PME report will be made available to the family at their request. However, it is highly advisable that this is done with appropriate clinical and bereavement support.

#### 4.3.31. Documentation of communication

Accurate records of all discussions held between the family and any member of the multidisciplinary team should be recorded in the healthcare record of the deceased or in perinatal deaths - the mother's healthcare record, in line with HSE Standards and Recommended Practices for Healthcare Records Management. This file should also hold a detailed record of all communication, including verbal, with family regarding the temporary retention of organs and their burial or cremation, outlining dates and times where applicable. The names of staff member(s) and family members spoken to should be recorded.

A record of the hospital PME findings will be maintained in the patient record or uploaded onto the EHCR as appropriate.

If a copy of the coroner's PME findings are required, it must be requested from the coroner as release of the coroner's report is at their discretion. The coroner's post mortem report should not form part of the main healthcare record (unless consent is obtained from the coroner). Please note this practice is in accordance with the Health Service Executive Standards and Recommended Practices for Healthcare Records Management 2011 (p157).

Any difficulties communicating with the family (e.g. language, literacy, hearing difficulty) and an explanation of how these were overcome (e.g. through an independent interpreter), should be documented.

Any difficulties contacting the family and an explanation of the decisions made should be documented.

Information given to the family in the form of booklets/leaflets should also be documented.

Please see HSE National Toolkit of Templates for Post Mortem Examination Services, Template Form 9: Template checklist, which may assist designated healthcare professionals communicating with the designated person / family about post mortem examinations, for a sample checklist.

#### 4.4. Section three: General guidance for communication with the coroner

The coroner's PME is an independent process underpinned by legislation and as such it is essential that healthcare professionals involved take the necessary actions to ensure the integrity of the process and in particular:

- maintain confidentiality throughout the process, and
- avoid any actions that may result in bias or perceived bias during or after the coroner's investigation into the death.

However, there may be occasions where due to the nature of the case (for example medical need such as future pregnancy planning, patient safety incident, risk management, complaint etc.), it may be necessary for the healthcare professional to take action on information, which is identified as time sensitive and may have an immediate impact on service provision or the healthcare needs of the family, prior to the conclusion of the coroner's investigation.

In this instance, the healthcare professional should notify the coroner of the requirement to share this information. This:

- Respects the role of the coroner.
- Ensures that in the case of sharing learning as part of the mortality and morbidity meetings, there is no critical reason why the information should not be released prior to the conclusion of the coroner's investigation. The coroner should make all reasonable efforts to accommodate this as soon as possible.
- Maintains the integrity of internal complaint and / or incident management framework, which are independent of the coroner's investigation. An incident is an adverse outcome identified and reviewed through the Incident Management Framework. The review is undertaken for the purpose of learning and not apportioning blame.

The complaints officer may provide a copy of their completed report where this is formally requested by the coroner. A complaints officer's report is not stored on the healthcare record.

# Part five: Records management following coroner and hospital post mortem examination



## 5. Part five: Records management following coroner and hospital post mortem examination

The **objective** of this section is to provide guidelines to ensure that every PME is fully documented, and the content and management of the healthcare record of deceased persons following PME, and all necessary registers are retained and maintained in accordance with best practice.

This section should be read in conjunction with the relevant HSE policies and procedures for records management including:

- Health Service Executive Standards and Recommended Practices for Healthcare Records Management (2011).
- Record Retention Periods Health Service Policy (2013).

#### 5.1. Why is records management important?

Effective records management is of vital importance in ensuring an acceptable outcome to all aspects of the PME process, from ensuring that the right body is examined and any test results (for example toxicology) are correctly assigned, through to ensuring that returned or buried / cremated organs are correctly identified and associated with the appropriate deceased person.

When record management is effective, it provides the organisation and families with transparency and assurance that the PME service is adhering to local and national policies and procedures.

#### 5.2. What is good records management in PME services?

The content of each healthcare record following PME complies with legislation, HSE guidance and current professional standards and international best practice.

Each service should ensure that they make provision for:

- a. Formal register(s) (preferably electronic) to record all relevant data relating to bodies or retained organs, thereby facilitating traceability following PME.<sup>45</sup>
- b. Effective monitoring mechanisms to ensure that accurate records and associated traceability registers are maintained and retained following PMEs.

<sup>&</sup>lt;sup>45</sup> Please see the Coroners' Rules definition of a body in Ireland: "The complete body of a dead human being, the body of a fetus or of a stillborn child, old human remains, a partially destroyed body or an essential part or parts of a body, calcined remains or ashes." <a href="https://www.justice.ie/en/JELR/coronersfulljob.pdf/Files/coronersfulljob.pdf">https://www.justice.ie/en/JELR/coronersfulljob.pdf</a>/Files/coronersfulljob.pdf

#### 5.2.1. Record management following coroner and hospital post mortem examination

- Record keeping should start on admission to hospital or, where death has occurred prior
  to admission, with the receipt of the deceased's body or tissue into the healthcare
  organisation. The organisation should ensure that there are electronic systems in place
  to maintain proper records and documentation for all bodies or retained organs or
  tissues in its care.
- 2. Systems should be in place to ensure that relevant data is recorded in a well-structured manner and in sufficient detail to facilitate ease of tracking through the system and to provide a complete and comprehensive audit trail.
- 3. Manually based systems should only be used for small units with a very low through-put or for back-up in the event of IT failure. Where there is an electronic record, any hardcopies of relevant documents should be scanned and stored on the electronic file or managed in accordance with the local policies and procedures.
- 4. If a paper based system is employed, all materials used should be durable, easily maintained and suitable for long-term use and retention, for example, a permanently bound hard back book system consisting of paper that meets quality standards for long term use (archival quality paper) completed using permanent high quality ink.
- 5. Registers recording details of the following should be maintained:
  - a. All bodies transferred into and out of hospital mortuary facilities.
  - b. All PMEs (coroner's and hospital) carried out at the facility.
  - c. The progress of all organs removed from the body at PME with tracking through all examination processes until return to the body, the family or burial or cremation by the hospital.

Irrespective of where the histology is processed, records should be maintained on site to provide a complete audit trail of:

- · organs removed and retained, and
- tissue samples referred to another centre as part of the PME.

If following PME, tissue and / or organs are referred to another hospital/site, the referring and receiving hospital / site will ensure that they have appropriate systems in place to maintain proper records and documentation for all tissue and/or organs they receive or pass on to others. See Template Form 7: Post mortem examination or specialist examination transfer and receiving form.

- 6. There should be effective monitoring mechanisms in place to ensure that:
  - a. Accurate records are kept in relation to all PME services.
  - b. All related registers are properly maintained and retained.

- 7. The following documents must be kept in Mortuary / Pathology Record:
  - a. Template Form 1: Reporting a death to the coroner and record of coroner's directions (hospital based deaths) / Template Form 2: Request for coroner's direction (community based deaths) (best practice record keeping).
  - b. Any acknowledgment by the coroner of information received.
  - c. Template Form 3: Acknowledgement of information received and consent form for the management of any organs retained in a coroner's post mortem examination (a copy where applicable).
  - d. Template Form 4: Consent form for hospital post mortem examination (also known as a consented or non-coronial PME) (a copy where applicable).
  - e. Template Form 7: Post mortem examination or specialist examination transfer and receiving form.
  - f. Any record around the sensitive management of tissues or organs including their burial or cremation where applicable.
- 8. There should be a clear line of overall responsibility for ensuring that registers and documentation are accurate and kept up to date. This should be determined by local line management within the healthcare facility.

#### 5.2.2. Content of the healthcare record following post mortem examination

Content of the healthcare record following post mortem examination		ollowing post mortem examination
A coroner's PME		A hospital PME

The healthcare record of every deceased person who undergoes a PME should contain the following information:

- a. Name, healthcare record number and date of birth. (In some perinatal cases, the baby's records may be held on maternity file or in a separate file related to the fetus / baby)
- b. Date, time and place of death, miscarriage or stillbirth (as relevant).
- c. Name, address and contact number of designated family member.
- d. Record of communication with family.
- e. Record of family choices in relation to:
  - i. Retention of organs for education and research purposes (if applicable).
  - ii. Options for burial or cremation of retained organs (if applicable).
- f. Record of date and method of sensitive management (burial or cremation if applicable).
- g. Documentation of notification of death to the coroner noting:
  - Circumstances of death that warranted notifying the coroner
  - ii. Name of the person who made the decision to notify the coroner.
  - iii. Date and time of notification.

- g. Name and address of general practitioner.
- h. Dated and signed consent form.
- i. Record of specific request and instruction(s) from clinicians.
- j. The post mortem report in which the following should be documented:
  - i. Reference number for PME
  - ii. Date of PME

coroner's PN	IE .	A hospi	tal PME	
iv.	Name of the coroner, Garda <sup>46</sup> or coroner's staff notified.		iii.	Name of pathologist and others in attendance.
v. vi.	Decision taken by the coroner.  Record of specific request and instruction(s) from the coroner.	Record of specific request and	iv.	Details of retained organs, relevantissue samples, photographs and x rays.
vii. viii. ix.	Coroner's Authorisation Form (best practice record keeping) <sup>47</sup> .  Confirmation that the PME was carried out and that it was ordered by the coroner.  Date final PME report sent to coroner. The report resulting from a coroner's PME is the property of the coroner and therefore is not filed as part of the healthcare record of the deceased unless permission of the coroner is received.	k. I. m. n. o.	and resstored mortual Laborate System should Date of Any oth Date fir Date Pl (if applied the MD)	nal report sent to other members of T (only where appropriate).

Table 10: Content of the healthcare record following post mortem examination

#### 5.2.3. Minimum information to be included in registers and electronically

It is essential that records are kept of all bodies transferred into and out of hospital mortuary facilities. Registers should contain the following data:

Minimum information to be included in registers and electronically		
Mortuary registers should contain the following data:	a.	Demographic details as applicable including name, address, date of birth, healthcare record number, occupation and details in relation to the death including the time and date of death, place and brief circumstances of death.
	b.	Name, address and contact details of designated family member.
	C.	Record of completion of death notification form and if a hospital or coroner's PME is to take place (PME number if applicable). Note: The death notification form is not completed when a coroner's PME is required.
	d.	Name of funeral director / undertaker.
	e.	The date and time when the deceased is transferred into and out of the mortuary and the names and signatures of the persons accepting, releasing and collecting the body.
	f.	List of property / valuables.

<sup>&</sup>lt;sup>46</sup> See section 18 (5) Coroners Act 1962.

<sup>&</sup>lt;sup>47</sup> Template Form 1: Reporting a death to the coroner and record of coroner's directions (hospital based deaths) / Template Form 2: Request for coroner's direction (community based deaths).

#### Minimum information to be included in registers and electronically

#### **PME** register

The PME register should contain the following information:

- a. Demographic details as applicable including name, address, date of birth and healthcare record number.
- b. Date, time and location of pronouncement of death, miscarriage or stillbirth.
- c. Date and time of arrival in mortuary.
- d. List of property/valuables.
- e. PME number.
- f. Type of PME (i.e. coroner or hospital).
- g. For a hospital PME, confirmation that there is a copy of the consent, including notation of any limitations or special considerations.
- h. For a coroner's PME, confirmation that coroner's authorisation has been received (email/letter) to include date and time of receipt.
- i. Name of pathologist/name of technician.
- j. Date and time PME commenced.
- k. If any organs are removed and retained, confirmation that these have been logged in retained organ register.
- I. Date and time of release, name of funeral director / undertaker and name of releasing staff member.
- m. List of property collected in the mortuary facility and by whom (record if property returned to family, especially jewellery).
- n. Date of preliminary report (if applicable).
- o. Date of final PME report.

### Organ retention register

In addition to section a, b, e, h of the PME Register, the organ retention register should contain the following information:

- a. Date of PME and removal of organ(s).
- b. Details of any organ(s) removed and retained at PME.
- c. Confirmation that there is consent for examination/temporary retention in the case of a hospital PME.
- d. Retention period of organ(s).
- e. Referral to other site (when, where and to whom transferred).
- f. Organs released and date(s) of release.
- g. Details relating to the sensitive management of organs for example:
  - Details of burial or cremation method, arranged by whom and date of same.
  - Retained for education or research purposes with appropriate consent.

Where a single register has the facility to record all the information listed in PME and Organ retention registers, it should not be necessary to maintain two distinct registers.

In rare cases, some information may not be available, for example, demographic details and details relating to the family of the deceased in the case of an unidentified deceased person (this data may become available at a later date through liaison with the office of the coroner). However, all other information regarding the PME should be recorded in accordance with this recommended practice.

Table 11: Minimum information to be included in registers and electronically

Part six: Storage, transportation and ultimate disposal of tissue samples and management of retained organs following post mortem examination



## 6. Part six: Storage, transportation and ultimate disposal of tissue samples and management of retained organs following post mortem examination

The storage, transportation and ultimate disposal of all tissue samples and management of retained organs following PME should be carried out with respect for the deceased, sensitivity for the family of the deceased, and should adhere to all relevant Irish legislation, regulation and best practice international standards.

Local arrangements that clearly delineate a named individual / position responsible for each step in the process should be documented. This will vary from hospital to hospital dependent on local line management structures. It is beneficial to have a Standard Operating Procedure in place in the event of changes in staff

#### It is recommended that each hospital identifies:

- a designated PME liaison / position for tracking, overseeing and monitoring of retained organs in all PMEs in each mortuary
- a designated family liaison (example MDT member, medical social worker, bereavement support etc.)

The **objective** of this section is to provide guidelines in relation to the storage, management, transportation and ultimate disposal of tissue samples and retained organs following PME.

#### 6.1. Storage and management of tissue samples and retained organs

The storage and management of tissue samples prepared as blocks and slides and of retained organs following PME should comply with requirements for laboratory procedures for the control of clinical material as specified in <a href="ISO 15189:2012">ISO 15189:2012</a> (third revised technical edition) including:

Key areas for ISO compliance - storage and management of tissue samples prepared as blocks and slides following PME	Key areas for ISO compliance - storage and management of retained organs following PME	
<ul><li>a. identification and indexing</li><li>b. security</li><li>c. storage, archive and retrieval</li></ul>	<ul> <li>a. identification and indexing</li> <li>b. security</li> <li>c. retention</li> <li>d. storage and retrieval</li> <li>e. sensitive management (burial or cremation)</li> </ul>	

Table 12: Key areas for ISO compliance - storage and management of tissue samples and retained organs

There should be procedures in place for the management of data and information relating to all tissue samples and retained organs following PME as outlined in Part five: Records management following coroner and hospital PME.

Retained organs should be kept in appropriate containers that are clearly identified, traceable and stored in a designated secure area. Once they are fixed in formalin, they may be stored at room temperature.

Retained organs for ongoing specialist examination as part of the PME and retained organs for research purposes should be stored separately.

Where more than one organ is retained from a single individual following a PME, the organs from that individual should be stored together as far as is practicable. In some instances, diagnostics may happen in different institutions.

Organs temporarily retained for the purpose of completing the hospital PME process should be released as soon as possible following completion of the diagnostic / investigative process. Management of the organs should be in accordance with the wishes of the family and the family may need to be contacted again at this time.

A system must be in place to ensure that there is documented **periodic review / audit** of all retained organ stores to ensure compliance with the HSE National Clinical Guidelines for Post Mortem Examination Services (2023). This also includes determining whether or not the service is compliant with the wishes of the family as determined in the consent forms.

When organs are retained for **medical education / research purposes**, the following should also apply:

- a. There is documented consent from the family of the deceased for such use.
- b. The organ(s) are appropriately prepared and anonymised.
- c. The organ(s) should be sensitively disposed of in compliance with the wishes of the family in a respectful manner on completion of any educational purpose or research use (this may exclude cases where the organs have been anonymised).

#### 6.2. Transport

There should be documented policies and procedures, cognisant of relevant Irish legislation and guidelines, <sup>48</sup> governing all elements of the handling or transportation within the organisation or between sites of deceased persons, tissue samples and / or organs retained following PME. Documented standard operating procedures should be in place and include:

- a. Procedures for safe handling and transport. This includes the use of funeral directors, undertakers and /or specialised courier services where appropriate and reference to relevant infection control procedures.
- b. Details of required packing, labelling and documentation.

These should be drafted taking into consideration any policies, procedures, protocols or guidance from the HSE and in particular the HSE Guidelines for the Preparation for Transport of Patient Specimens and other Biological Materials (2019) and the Guidelines for the Management of Deceased Individuals Harbouring Infectious Disease (2013).

The family and (if required) the coroner and funeral directors / undertakers should be informed if there is a need to move the deceased to another hospital / site for PME, for example specialised cases: Creutzfeldt-Jakob disease (CJD) / prion disease cases, COVID-19.

Knowledge of transport arrangements may reduce distress and anxiety on the part of the family and facilitate funeral arrangements.

<sup>48</sup> Please see 'Appendix three: References' for information on professional standards and international best practice guidelines.

When a deceased person is transferred to another hospital for a PME, referring and receiving hospitals should have procedures in place to ensure that there is appropriate contact and interaction with the family whether they accompany the remains or not.

#### Referring hospitals should:

- Ensure that there are suitable recording and tracking systems in place underpinned by appropriate policies, procedures, protocols and guidelines (PPPGs) with regard to all referrals / transfers to other sites or organisations.
- Maintain full records and an audit trail of any referrals / transfers.
- Ensure that there are effective monitoring mechanisms in place to track all referrals / transfers and their return to the hospital.
- Ensure that all necessary documentation including information regarding plans for the burial, cremation or donation following completion of the PME is sent with all referrals / transfers. Please see Figure 7: Documentation required by referring and receiving hospitals.
- Ensure that a bereavement support plan is in place for the family, if the deceased is being transferred to another hospital mortuary for PME. The bereavement team in referring hospital may choose to care for the family if they have already established a relationship with them (for example, if caring for a long time for a dying patient). If both sites have bereavement teams available, the family preferences should be considered.

Where transfer of an organ to another site / organisation occurs, the wishes of the family for the burial, cremation or donation of the organ should be adhered to in deciding whether the organ is to be returned to the referring hospital.

#### Receiving hospitals should:

- Have mechanisms in place to ensure that all specimens they receive are accompanied by the necessary information and documentation.
- Ensure that all referring organisations are aware of their responsibility to meet these requirements and that referrals are not accepted unless these processes are adhered to.
- Have appropriate systems in place to maintain full records and documentation for all referrals they receive. Please see Figure 7: Documentation required by referring and receiving hospitals.
- Must ensure that a bereavement support plan is in place for family of deceased from the referring hospital.

#### Documentation required by referring hospital

- details of what is being referred, who is making the referral, name of transferring hospital and to whom the referral is being made.
- PME number (if applicable).
- •reason for referral/transfer.
- •any relevant medical notes.
- •confirmation to receiving hospital that there is appropriate valid consent or coroners authorisation.
- coroner's district (where relevant)
- •information relating to the wishes of the family regarding burial or cremation/use for other purposes (where applicable).

#### Documentation required by receiving hospital

- •details of what was received and the name of the referring centre.
- •date and time of receipt.
- PME number.
- •any relevant medical notes.
- •name of pathologist to whom specimen was sent/technician who received specimen.
- •examination to be performed whilst in the establishment's care.
- •date of transfer elsewhere/return to referring centre and to whom.
- •date, time, place, mode of and reason for burial or cremation if applicable.
- •who arranged and completed disposal.
- •if released: what organs were released and date of release.
- •name and contact details of medical team caring for deceased prior to death (where appropriate) and bereavement support person in transferring hospital.

Figure 7: Documentation required by referring and receiving hospitals

## 6.3. Ultimate disposal of tissue samples and sensitive management of organs

#### 6.3.1. What happens to blocks and slides from tissue samples?

Blocks and slides prepared from tissue samples taken at PME (coroner and hospital) should be preserved and kept as part of the PME record in line with best practice standards.<sup>49</sup>

#### 6.3.2. Guidelines on the sensitive management of organs (burial, cremation or donation)

Families should be given information to help them make an informed choice about sensitive management of retained organs. See:

- Section 4.3.21 Communication regarding the burial or cremation of temporarily retained organs
- Section 4.3.22 Options for the burial or cremation of temporarily retained organs
- Section 4.3.26 Organ and tissue retention for clinical teaching, medical education and / or research.

<sup>&</sup>lt;sup>49</sup> See <u>ISO 15189:2012</u> (third revised technical edition).

#### 6.3.2.1. Supporting the family to make their own arrangements

When the family wish to make their own burial or cremation arrangements the hospital should recommend that organs are not released directly to family members and should be handled by funeral directors, undertakers or qualified transport personnel. The hospital should:

- Ensure that the family receives the organs of the deceased in a dignified manner and setting, for example in an individual casket appropriately sealed and in a suitable location such as a hospital oratory or family room.
- Actively encourage families to use the services of a funeral director / undertaker for this process to ensure that the organs will be buried or cremated in a suitable place / manner.

#### 6.3.2.2. Hospital arranged burial or cremation of retained organs

See section 4.3.23 and 4.3.24 for detailed information on hospital arranged burial or cremation of temporarily retained organs. A record of hospital arranged burials and cremations should be maintained in the organ retention register and relevant information from this register should be made available to the family of the deceased on request.

#### 6.3.2.3. What to do if the family do not specify their wishes

For information on what to do if the family do not specify their wishes, please see section 4.3.25.

#### 6.3.3. What to do in the rare event that a temporarily retained organ cannot be located?

The upmost care should be taken with retained organs. If in the rare instance an organ cannot be located, the incident needs to be reported onto the National Incident Management System and managed in line with the appropriate guidance in the <a href="HSE Incident Management Framework">HSE Incident Management Framework (2020)</a>. The incident should be immediately communicated to the family in accordance with the <a href="HSE Open Disclosure Policy">HSE Open Disclosure Policy (2019)</a>.

In cases where the family have expressed that they do not wish for further contact, the matter should still be managed in accordance with the <a href="HSE Incident Management Framework">HSE Incident Management Framework (2020)</a>.

## 6.4. Release of body / retained organs to funeral directors / undertakers following post mortem examination

On completion of the PME, where the body and / or organs are being released to the funeral director / undertaker for burial or cremation, each service should have a release form in place. See Template Form 10: Confidential: Release certificate to funeral director following a post mortem examination.

This form should indicate if the body or organs are being released and include detail in relation to organs being returned. It should also indicate any potential infection risk for the funeral directors / undertakers. A copy of this form should be stored on the mortuary records and the relevant registers should be updated.

## Part seven: Training



#### 7. Part seven: Training

#### 7.1. Introduction to training

The HSE should make training available for all relevant staff in effective communication and interpersonal skills to enable them to communicate clearly and confidently with bereaved families about PME and related practices.

Specific training should be made available to all relevant staff in order that appropriate members of the multidisciplinary team are enabled to:

- Sensitively deliver accurate and adequate information to bereaved families in relation to the temporary retention of organs.
- Understand and adapt the toolkit of forms available to support the stages of the PME process.
- Be alert to the needs of families from different ethnic, cultural and religious communities/backgrounds.
- Understand the consent process including procedures for seeking consent for PME.
- Understand how to access available occupational health supports for themselves as and if required.

The organisation must maintain training records to demonstrate the content, frequency of and attendance at training sessions and refresher sessions.

It is helpful for those managing the consent process to also complete the:

- HSELand elearning programme on the HSE National Consent Policy (2022), and
- the National Healthcare Communications Programme https://www.hse.ie/eng/about/our-health-service/healthcare-communication/.

It may be helpful for those involved in the PME Process for paediatric or perinatal deaths to receive focused or specialised training in this area. In particular:

- TEARDROP a perinatal bereavement care training programme for healthcare professionals.
- Training in the National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death (July 2022).

Please contact your line manager to find out about relevant training.

## **Part eight: Appendices**



#### 8. Part eight: Appendices

#### 8.1. Appendix one: Part B - Development Cycle

#### 8.1.1. Initiation

#### Background on PME reports, audit and planned legislation.

Post mortem examination practices in Ireland came under public scrutiny in late 1999 and 2000 following inquiries held in England, which highlighted concerns about PME practices there. Between 2006 and 2009, three reports were issued that related to post mortem practices in Ireland:

- The Report of Dr. Deirdre Madden on Post Mortem Practice and Procedure (2006)
- Report of the Working Group on Post Mortem Practice (2006)
- The Willis Report (2009).

The HSE established a National Advisory Group to review previous guidance in light of the recommendations made in these reports and to oversee the development of standards and recommended practices for PME. This led to the publication of the "Health Service Executive Standards and Recommended Practices for Post Mortem Examination Services" (2012).

In 2021, the HSE Internal Audit Division completed an audit of PME services to determine the assurance level that could be given that the requirements of the "Health Service Executive Standards and Recommended Practices for Post Mortem Examination Services" were being complied with. The Audit report had a number of findings and recommendations such as the need to update the 2012 Standards. As a result, the Chief Clinical Officer (CCO) requested the National Clinical Director, Quality and Patient Safety to review and update the existing HSE Standards and Recommended Practices guidance. The National Clinical Director established a Review Group led by Professor Linda Mulligan to oversee the review of these guidelines.

The Human Tissue Bill 2022 is a priority for the Department of Health. Consideration is being given to licensing of PME services in the Human Tissue Bill 2022 and giving regulatory responsibility to HIQA. It is anticipated that the work of the Review Group will be complete prior to the enactment of pertinent new legalisation and will help inform its development. However, the legislative process is not within the Review Group's remit and therefore the focus of this group was the provision of 'HSE National Clinical Guidelines for Post Mortem Examination Services (2023)'.

#### 8.1.2. Purpose

The purpose of this document is to build on the previous standards from 2012 and outline recommended practices required in PME Services, based on current legal requirements, professional standards and international best practice.

#### 8.1.3. Scope

#### What is in the scope of these clinical guidelines?

There are documented policies, procedures, protocols and guidelines (PPPGs) governing all elements of service provision relating to all coroners' and hospital PMEs. These guidelines form part of this structure and outline the HSE's recommended practices for PME services, based on current legal requirements, professional standards, clinical expertise and international best practice.

#### What is outside the scope of these clinical guidelines?

The scope of these guidelines does not cover the mortuary facilities, equipment or staffing resources to support the PME process. It also does not cover the implementation of the guidelines (including governance structures and budgetary considerations), the communication plan and provision for training and education of healthcare staff.

At the time of revising these guidelines, the Human Tissue Bill 2022 is under consideration. Following the enactment of this legislation, this document may need to be updated to take consideration of the relevant policy direction.

A number of other PPPGs and programmes of work address elements of PME service provision outside the scope of these guidelines. See Table 1 and Table 2.

#### 8.1.4. Objectives

The objective of these clinical guidelines is to support the consistent delivery of person centred effective PME Services throughout the Heath Service Executive (HSE) and HSE funded services. These clinical guidelines include all steps of the process from the time of the person's death to the issuing of the death certificate. They also detail the steps staff can take to support high quality communication, consent, record management (including authorisation from the coroner) and the management of tissue samples, biological fluids and temporarily retained organs following a PME. (Section 1.2)

The objectives of the review group were to:

- Minimise the potential for ambiguity in interpretation of the guidelines (previously standards and recommended practices) by providing clarity and specificity of language.
- Revised guidelines pertain to both coroners' and hospital PMEs.
- Commission a rapid literature review, performed by Dr. Triona McNicholas, Dr. Yvonne McCartney, Dr. Shane Eakins and Professor Linda Mulligan with assistance from Mr. Gethin White and the HSE Library team and endorsed by the Faculty of Pathology, RCPI. This covered national and international best practice for PME services to inform review.
- Complete the review and submit the revised document to the HSE Chief Clinical Officer for authorisation and publication.

#### 8.1.5. Outcomes

Healthcare facilities operated or funded by the Health Service Executive (HSE) provide many of the core support services required for both coroner's and hospital post mortem examinations. These include mortuary and post mortem facilities, pathology, histology, general laboratory services such as microbiology / biochemistry, post mortem radiology, hospital administration services and the provision of support to families.

Formal documented control of the services required for PME is necessary to monitor each aspect of service provision. This will support services to demonstrate compliance with relevant Irish legislation, HSE guidance and current professional standards and international best practice.

The overall aim of the guidelines for PME is to drive high quality PME services through the:

- reflection of learning from key reports on post mortem practice and procedures,
- defining and supporting the embedding of good practice in key areas relevant to PMEs (coroner and hospital), and
- supporting an effective interface between the Health Service Executive and the Coronial System in relation to coroner's PMEs.

## 8.1.6. PPPG Development Group - Membership of the HSE Guidelines for Post Mortem Examination Services: Review Group

- 1. Professor Linda Mulligan, Chief State Pathologist and Clinical Professor UCD School of Medicine (Chair of the Review Group)
- 2. Dr. Maureen Flynn, Director of Nursing (NQPSD Lead)
- 3. Juanita Guidera, Quality Improvement Facilitator (NQPSD Review Lead)
- 4. Dr. Mary Browne, Specialist in Public Health, QPS Education Lead
- 5. Dr. Myra Cullinane, Dublin Coroner, Coroner's Society of Ireland
- 6. Dr. Michael McDermott, Paediatric Pathologist, Consultant Histopathologist, Children's Health Ireland at Crumlin
- 7. Dr. Brendan Fitzgerald, Perinatal Pathologist, Consultant Histopathologist, Cork University Hospital
- 8. Sabrina Mullahy, Anatomical Pathology Technician / Mortuary Manager, Senior Pathology Technician, University Hospital Limerick
- Mohammad Radiom, Mortuary Manager Anatomical Post Mortem Technologist, Children's Health Ireland at Temple Street
- 10. Professor Peter Gillen, Associate Professor of Surgery, Royal College of Surgeons in Ireland, HSE National Healthcare Communication Programme
- 11. Winifred Ryan, HSE National HR, Leadership, Learning and Talent Management, National Healthcare Communication Programme
- 12. Mairead Twohig, HSE National Acute Operations, Quality and Patient Safety
- 13. Dr. Ciaran Browne, HSE National Acute Operations, Mortuary Improvement Programme
- 14. Margaret McKiernan, Director of Nursing, Mercy University Hospital, Chair of the Deceased Person Guidance Development Group
- 15. Paula Cussen Murphy, Director of Quality and Patient Safety, UL Hospitals Group
- 16. Caoimhe Gleeson, General Manager Human Rights and Equality Policy, HSE National Strategy and Research
- 17. Professor Mary Donnelly, Director of Law School, University College Cork, Co-lead HSE National Consent Policy Group
- 18. Professor Shaun O'Keeffe, Consultant Geriatrician, Merlin Park Galway, Co-lead HSE National Consent Policy Group
- 19. Dr. Francesca Brett, Consultant Neuropathologist, Beaumont Hospital, Dublin
- 20. Sharon Slattery, Director of Nursing, St. James's Hospital, Dublin
- 21. Bernadette Campion, Voices4Care (Patient representative nominated via All Ireland Hospice and Palliative Care Institute)
- 22. Fiona Somers, Voices4Care (Patient representative nominated via All Ireland Hospice and Palliative Care Institute)
- 23. Mary Vasseghi, Patients for Patients Safety Ireland (Patient representative)
- 24. Marie Cregan, Patients for Patients Safety Ireland (Patient representative)
- 25. Alice Anderson, Programme Manager for the Hospice Friendly Hospitals Programme
- 26. Andrea McGrail, Director of Midwifery, Mayo University Hospital

Killian Aughey-Evans, NQPSD Educate (note taker)

#### Observers

John Tuffy, Head of Programme, Healthcare, Health Information and Quality Authority attending meetings of the Review Group in an observatory capacity.

Dr. Triona McNicholas, Specialist Registrar in Public Health Medicine in an observatory capacity.

#### 8.1.7. PPPG Governance Group

In response to several recent reports and audits, the Chief Clinical Officer (CCO) requested the National Clinical Director, QPSD to review and update the existing HSE Standards and Recommended Practice for Post Mortem Examination Services 2012. The National Clinical Director, QPSD established a review group to oversee the review of these guidelines.

The Review Group is operationally accountable to the National Clinical Director Quality and Patient Safety. The Review Group chair provides feedback and updates to the National Clinical Director QPS and the HSE Chief Clinical Officer on behalf of the Review Group.

The HSE National Clinical Guidelines for Post Mortem Examination Services (2023) were also reviewed by two independent, external experts Professor Mike Osborn, President of the Royal College of Pathologists, UK and Dr. Margaret Bolster, Assistant State Pathologist.

#### 8.1.8. List of consultees

- A Little Lifetime Foundation
- African Community, Emmanuel Njume Sone
- An Garda Síochána
- Anatomical Pathology Technicians of Ireland
- Cairde
- Clinical Directors
- Community Healthcare Organisations
- Coroners Operations Service
- Coroners Society of Ireland
- Department of Health
- Department of Justice, Equality and Law Reform
- Directors of Midwifery Forum
- Emergency Medicine Programme
- Emergency Nursing Interest Group
- End of Life Co-ordinators
- Faculty of Pathology, Royal College of Physicians of Ireland
- Feilican (Marie Creegan)
- First Light
- End of Life Co-ordinators
- Health Information and Quality Authority
- Health Service Executive National Patient and Service Users Forum - Ashling O'Leary
- Healthcare Audit
- Hospice Friendly Hospitals
- Hospital Group Chief Directors of Nursing and
   Tusla Midwifery

- Hospitals Acute Operations
- Irish Association of Directors of Nursing and Midwifery (IADNAM)
- Irish Association of Funeral Directors
- Irish Association of Social Workers
- Islamic Cultural Centre of Ireland
- Lead National Consultant Hospital Doctor
- Miscarriage Association
- National Ambulance Service
- National Association of Healthcare Chaplains **ACPE**
- National Womens' and Infants Programme
- Office of the Nursing and Midwifery Services Director (ONMSD)
- Office of the State Pathologist
- Paediatrics Networks Group
- Patients for Patients Safety Ireland
- **Private Hospitals Association**
- Professional Embalmers Association Of Ireland
- PSPA Ireland, Caroline Dooley Martyn
- **Quality and Patient Safety Leads**
- Quality, Safety & Service Improvement Leads
- Roma Community Marianna Prontera (Cairde - Roma Project); Danut Nae (Cairde - Roma Project), Mirela Tanase (Cairde - Roma Project)
- State Claims Agency

#### 8.1.9. Supporting Evidence

The HSE National Clinical Guidelines for Post Mortem Examination Services (2023) are derived from recommended practice identified through a literature review and experts in the field, the experience of patient partners and learning from recent reports, audits and investigations. See Appendix three: References and Appendix four: Relevant Irish legislation for further information.

## 8.2. Appendix two: Development of the HSE National Clinical Guidelines for Post Mortem Examination Services (2023)

#### 8.2.1. Questions (clinical / non-clinical)

The HSE National Clinical Guidelines for Post Mortem Examination Services (2023) supersedes and replaces the HSE National Standards and Recommended Practice for Post Mortem Examination Services (2012).

Where possible, the guidelines reflect proposed upcoming changes to legislation including the Human Tissue Bill and amendments to the Coroners Acts. However, it is anticipated that further amendments to this guideline will be required after their enactment.

The revised guidelines also reflect the introduction of the HSE National Consent Policy (2022), the HSE Guidance for Care of the Deceased Person [In development], the HSE National Policy for Consent in Health and Social Care Research (2022) and the introduction of HIQA and TUSLA. The section on Wards of court has been updated in accordance with guidance from the Office of the Ward of Court.

#### 8.2.2. Literature search strategy

The aims of this literature review were to:

- summarise international standards and best practice relating to PME, and to outline new PME options and alternatives in our culturally diverse society,
- review best practice guidelines regarding communication and consent in the PME setting,
- look at quality assurance recommendations around PME, and
- capture any learning points from the recent COVID-19 pandemic.

The primary databases searched were Medline, Embase, Web of Science, Proquest Health Premium, Cochrane, Scopus and Cinahl. Other secondary sources used included: Core (Grey Literature), Base (Grey Literature), Global Health, Taylor & Francis (Journal Collection), Science Direct, Sage health Collection, Up To Date, BMJ Best Practice, Google Scholar, Websites: National Association of Medical Examiners (Name), College of American Pathologists (USA), Royal College of Pathologists (UK), and the Victorian Institute of Forensic Medicine (Aus).

Multiple searches were conducted using the following terms: autopsy, post mortem, virtual autopsy, non-invasive autopsy, targeted autopsy, guidelines/practice guidelines, policy/procedure/standard of care, standards or PPPG, quality assurance, health care, quality improvement, consent forms, informed consent, presumed consent, parental consent, communication, forms, records and various combinations of same.

The search ran from 2012 - 2022 (present), to cover the period from the publication of the previous document, the HSE Standards and Recommended Practices for Post Mortem Examination Services. It was left quite broad, as there were a relatively small number of relevant references located via the search terms.

The authors of this literature review provided some core documents from some of the named institutions (e.g. Royal College of Pathologists, UK) which were added to the search result. The websites of these institutions were also double-checked in case more recent versions of the documents provided have now been published.

The terminology contained in the search strategy provides examples of some of the terms used by indexers of those databases for example, PubMed utilizes mesh headings (mh). Also examples of proximity operators such as n2 (which means two words have to appear within two words of each other to be retrieved), therefore effectively meaning it is searched as a phrase. The syntax will vary from database to database but the basic combination of free text and indexed headings based around the search terms outlined above were employed.

In completing the review, in addition to an extensive literature review, the review group also considered the findings and recommendations from:

- HSE Internal Audit report, "Review of the Operation of HSE Standards and Recommended Practices for Post Mortem Examination Services", REF: MT001ASOP0222, February 2022.
- "Review of Mortuary Services in University Hospital Waterford: Report", September 2021
- RCPI, Faculty of Pathology "Review of the Provision of Coronial Autopsy Service -Histopathology Standing Committee", January 2022.
- RCPI, Faculty of Pathology, "Guidelines for Post-Mortem Consent and Retention of Samples", February 2000.
- Experiences and learning from the provision of post-mortem examination services during the COVID-19 pandemic.
- HSE Guidance for Care of the Deceased Person [In development].
- National and international best practice.

#### 8.2.3. Method of appraising evidence

A critical appraisal and analysis of the recommended practice was completed by the authors of the review based on their expertise and validity of the sources using the inclusion and exclusion criteria set out below.

Consideration was also given the cultural context within Ireland which influences PME practice and which may vary from other jurisdictions.

The Prisma chart (figure 8) details the searches carried out. The authors conducted the final part of the graph "records assessed for eligibility".

#### **Inclusion criteria**

Sources were included as references if they:

- were in English,
- directly related to adult, paediatric and perinatal PME practice in an Irish context,
- covered consent and communication around PME,
- addressed quality assurance specific to PME practice,
- included discussion around the applicability of newer methods of PME including post mortem radiology,
- showed new developments in PME practice since 2012, and
- covered any legislation and guideline documents for PME standards.

#### **Exclusion criteria**

Sources were not included if they referred to public health and epidemiology or were not applicable to the Irish healthcare or death investigation systems. A large amount of sources retrieved mentioned PME or autopsy, but covered topics not relevant to this literature review.

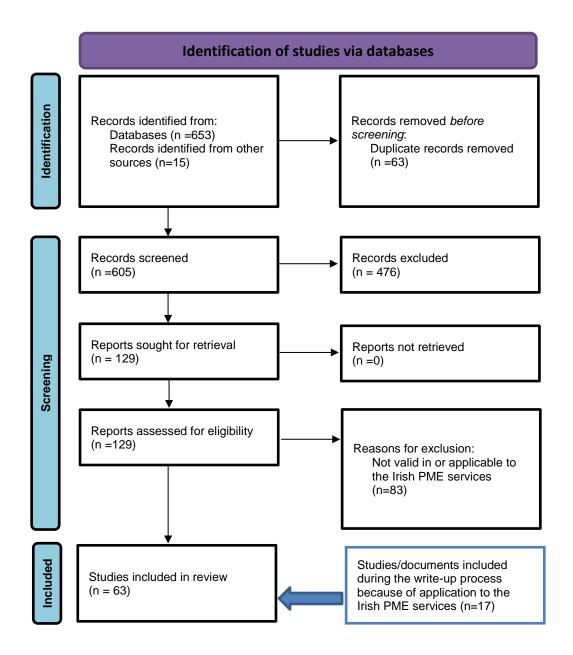


Figure 8: PRISMA flow diagram, including searches of databases

#### 8.2.4. Process the PPPG Development Group used to formulate recommendations

The revised guidelines were developed following:

#### **Expert knowledge of review group members**

- Feedback received from Review Group members and recommended practice informed the development of the initial draft guidelines for consultation
- Review group analysis of key feedback and the formulations of key recommendations from the consultation process, informed the final submission of the HSE National Clinical Guidelines for Post Mortem Examination Services (2023) for external review and submission to the Chief Operating Officer via Dr. Orla Healy.

#### This process included:

#### International evidence and recommended practice

- A rapid literature search.
- Consideration of the opinion of experts knowledgeable in the subject, including healthcare professionals working in this area.
- Consideration of the available recommended practice, both in Ireland and internationally, that may impact on PME services.

#### Internal and external consultation

- Focused consultation sessions with patient partners, representative groups and staff with special interest in this area to ensure their significant experience and expertise informed the draft guidelines. Consultation sessions were open and included PME practice, consent, the management of organs including clinical teaching, medical education and / or research benefited with key stakeholders
- Targeted consultation with direct feedback or feedback by survey.
  - The review group developed a short online clip sharing the purpose of the consultation. This was circulated with the draft guidelines for consultation.
  - Feedback was incorporated where appropriate (in scope and in accordance with current recommended practice), into the final version of the guidelines.

#### **External review**

 Professor Mike Osborne, President of the Royal College of Pathologists, UK and Dr. Margot Bolster, Assistant State Pathologist, Ireland. These identified experts undertook an external review of the draft prior to finalisation of the guidelines.

#### With special thanks to:

The review group is grateful to all parties who participated in consultation to support development of these guidelines, particularly Voices4Care, the Irish Hospice Foundation and Patients for Patients Safety Ireland, the HSE National Consent Policy Group, HSE National Policy for Consent in Health and Social Care Research (2022), HIQA and the Department of Health.

#### 8.2.5. Summary of the evidence from the literature

The recent SARS-CoV-2 (COVID-19) pandemic brought the importance of PME in medical practice in order to determine the natural course of a disease that was new and unknown. In order to obtain the most comprehensive information, it is vital that any PME is performed to a high standard and the literature review has highlighted both of these points: that PME needs to be quality assured but is also an important tool in quality assurance of medical and surgical practice.

The usefulness of PME in this setting does not take away from its invasive nature and prior to the pandemic, autopsy rates around the world had declined. However, new developments and the use of post mortem imaging such as Computed Tomography (CT) scans have proved extremely useful in determining cause of death both on their own and as an adjunct to limited or full PME. The option of non-invasive techniques may improve uptake for consented PMEs, particularly in the perinatal setting. In our multicultural Irish society, it is also important to be able to provide answers to bereaved families while considering their particular beliefs or cultural needs.

Through all of this, and something that underpins all of the sources included in the review, is the concept of robust and comprehensive communication to families, both in hospital (consented) and in legally required PMEs. It is imperative that families are communicated with at every step of the process. Empowering families ensures informed consent and that their needs and the needs of the law are met during every step of the PME process.

#### 8.2.6. Resources necessary to implement the PPPG recommendations

The implementation of the guidelines will be addressed by the Chief Operating Officer.

#### 8.2.7. Outline of PPPG steps / recommendations

See guideline document.

#### 8.2.8. Governance and approval

#### 8.2.8.1. Formal governance arrangements

- The National Quality and Patient Safety Directorate (QPSD) will lead and support the review processes. The NQPSD team are responsible for managing and co-ordinating the review processes, meeting set up, and document management.
- Dr. Orla Healy, National CD for QPS is the review sponsor reporting to Dr. Colm Henry, Chief Clinical Officer.
- Professor Linda Mulligan, Chief State Pathologist and Clinical Professor UCD School of Medicine is nominated to clinically lead and chair the Review Group by the RCPI Faculty of Pathology.
- The Review Group will support the Chair of the Group in reviewing and developing guidelines within the agreed timeframe.
- The Review Group will take account of all relevant documentation and consult with key informants as required to inform the update of the document.
- The HSE Chief Clinical Officer will provide the revised HSE National Clinical Guidelines for Post Mortem Examination Services (2023) to the HSE Chief Operations Officer for implementation.
- The revised Guidelines will inform the Acute Operations Mortuary Improvement Programme.

## 8.2.8.2. Method for assessing the PPPG in meeting the standards outlined in the HSE National Framework for developing PPPGs

The HSE National Framework for developing PPPGs was reviewed prior to commencing the review and key areas of attention were identified and addressed during the review of the HSE National Clinical Guidelines for Post Mortem Examination Services (2023).

#### 8.2.8.3. Copyright / permission sought

Consent for photo use sought and filed in NQPSD.

#### 8.2.8.4. Approved PPPG Checklist

#### HSE National Clinical Guidelines for Post Mortem Examination Services (2023)

Standards for developing Clinical PPPG	Checklist
Stage 1 Initiation	
The decision making approach relating to the type of PPPG guidance required (policy, procedure, protocol, guideline), coverage of the PPPG (national, regional, local) and applicable settings are described.	<b>I</b>
Synergies/co-operations are maximised across departments/organisations (Hospitals/Hospital Groups/Community Healthcare Organisations (CHO)/National Ambulance Service (NAS)), to avoid duplication and to optimise value for money and use of staff time and expertise.	V

	Checklist
The scope of the PPPG is clearly described, specifying what is included and what lies outside the scope of the PPPG.	Ø
The target users and the population/patient group to whom the PPPG is meant to apply are specifically described.	Ø
The views and preferences of the target population have been sought and taken into consideration (as required).	
The overall objective(s) of the PPPGs are specifically described.	<b>√</b>
The potential for improved health is described (e.g. clinical effectiveness, patient safety, quality improvement, health outcomes, quality of life, quality of care).	Ø
Stakeholder identification and involvement: The PPPG Development Group includes individuals from all relevant stakeholders, staff and professional groups.	<b>I</b>
Conflict of interest statements from all members of the PPPG Development Group are documented, with a description of mitigating actions if relevant.	In progress
The PPPG is informed by the identified needs and priorities of service users and stakeholders.	$\square$
There is service user/lay representation on PPPG Development Group (as required).	
Information and support is available for staff on the development of evidence-based clinical practice guidance.	<b>I</b>
Stage 2 Development	Checklist
The clinical question(s) covered by the PPPG are specifically described.	$\square$
Systematic methods used to search for evidence are documented (for PPPGs which are adapted/adopted from international guidance, their methodology is appraised and documented).	<b>V</b>
· · · · · · · · · · · · · · · · ·	
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).	<u> </u>
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations	
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).  The health benefits, side effects and risks have been considered and documented in formulating the	
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).  The health benefits, side effects and risks have been considered and documented in formulating the PPPG.	<b></b>
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).  The health benefits, side effects and risks have been considered and documented in formulating the PPPG.  There is an explicit link between the PPPG and the supporting evidence.	
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).  The health benefits, side effects and risks have been considered and documented in formulating the PPPG.  There is an explicit link between the PPPG and the supporting evidence.  PPPG guidance/recommendations are specific and unambiguous.  The potential resource implications of developing and implementing the PPPG are identified e.g.	
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).  The health benefits, side effects and risks have been considered and documented in formulating the PPPG.  There is an explicit link between the PPPG and the supporting evidence.  PPPG guidance/recommendations are specific and unambiguous.  The potential resource implications of developing and implementing the PPPG are identified e.g. equipment, education/training, staff time and research.  There is collaboration across all stakeholders in the planning and implementation phases to optimise	☑ ☑ ☑ Out of scope

Standards for developing Clinical PPPG	Checklist
Three additional standards are applicable for a small number of more complex PPPGs:  • Cost effectiveness analysis is documented.	Out of scope
A systematic literature review has been undertaken.	
Health Technology Assessment (HTA) has been undertaken.	
Stage 3 Governance and Approval	Checklist
Formal governance arrangements for PPPGs at local, regional and national level are established and documented.	Out of scope
The PPPG has been reviewed by independent experts prior to publication (as required).	$\square$
Copyright and permissions are sought and documented.	<b>V</b>
Stage 4 Communication and Dissemination	Checklist
A communication plan is developed to ensure effective communication and collaboration with all stakeholders throughout all stages.	Out of scope
Plan and procedure for dissemination of the PPPG is described.	Out of scope
The PPPG is easily accessible by all users e.g. PPPG repository.	Out of scope
Stage 5 Implementation	Checklist
Written implementation plan is provided with timelines, identification of responsible persons/units and integration into service planning process.	Out of scope
Barriers and facilitators for implementation are identified, and aligned with implementation levers.	Out of scope
Education and training is provided for staff on the development and implementation of evidence-based PPPG (as required).	Out of scope
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	Out of scope
Stage 6 Monitoring, Audit, Evaluation	Checklist
Process for monitoring and continuous improvement is documented.	Out of scope
Audit criteria and audit process/plan are specified.	Out of scope
Process for evaluation of implementation and (clinical) effectiveness is specified.	Out of scope
Stage 7 Revision/Update	Checklist
Documented process for revisions/updating and review, including timeframe is provided.	Out of scope
Documented process for version control is provided.	Out of scope

I confirm that the above Standards have been met in developing the: HSE National Clinical Guidelines for Post Mortem Examination Services (2023)

Name of person signing off on the PPPG Checklist:	
Name:	Signature: Date:

This signed PPPG Checklist must accompany the final PPPG document in order for the PPPG to be approved.

#### 8.2.9. Communication and dissemination

The implementation of the guidelines will be addressed by the Chief Operating Officer. This will include:

• A communication and dissemination plan

#### 8.2.10. Implementation

The implementation of the guidelines will be addressed by the Chief Operating Officer. This will include:

- An implementation plan listing barriers and / or facilitators
- Any education / training required to implement the PPPG
- Lead person(s) responsible for the Implementation of the PPPG
- Outline of specific roles and responsibilities.

#### 8.2.11. Monitoring, audit and evaluation

The implementation of the guidelines will be addressed by the Chief Operating Officer. This will include a plan and identification of lead person(s) responsible for the following processes:

- Monitoring
- Audit
- Evaluation.

#### 8.2.12. Revision / update

The revision / update of the guidelines will be addressed by the Chief Operating Officer as part of the implementation. It will include:

- The procedure for the update of the PPPG
- The method for amending the PPPG if new evidence emerges
- Version control update on the PPPG template cover sheet

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#### 8.4. Appendix four: Relevant Irish legislation

- Age of Majority Act, 1985
- Anatomy Act, 1832
- Child Care Act, 1991 and related regulations
- Children Act, 1997
- Children Act, 2001
- Child Care (amendment) Act, 2007
- Civil Law (miscellaneous provisions) Act, 2011
- Civil Partnership and Certain Rights and Obligations of Cohabitants Act, 2010
- Civil Registration Act, 2004
- Copyright and Related Rights Act, 2000
- Coroners (Amendment) Act 2019 (Commencement) Order 2020
- Coroners and Coroners (Amendment) Acts 1962 2020
- Data Protection Acts, 1988 and 2003 and related regulations
- European Communities (Carriage of Dangerous Goods by Road and use of Transportable Pressure Equipment) Regulations, 2011
- Freedom of Information Acts, 1997 and 2003 and related regulations
- Health Acts, 1947, 1953, 1970 and related regulations
- Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Bill 2022 (Bill 121 of 2022)
- Guardianship of Children (Statutory Declarations) Regulations, 1998
- Guardianship of Infants Act, 1964 as amended by the Status of Children Act 1987 and the Children Act, 1997
- Mental Health Acts, 1945 to 2001
- Non-fatal Offences Against the Person Act, 1997
- Safety, Health and Welfare at Work Act, 2005 and related regulations
- Succession Act, 1965

## 8.5. Appendix five: Principles of care during the identification of the deceased person

#### **Care during identification process**

This can be an extremely stressful, worrying and difficult time for family members. The person requesting the identification - Garda / representative - has a key role in adopting a supportive sensitive approach. It is imperative that they have training in advance and support from the mortuary and or hospital / care setting team.

#### Training needs around the identification process

Members of An Garda Síochána are welcome to contact the local hospital end of life care coordinator to discuss and identify training needs around the identification process.

#### **Specific considerations:**

- Preparation: if possible be familiar with the mortuary or ward setting in advance so that
  you know the environment, where you will be meeting the family member, who will be
  supporting them, where the identification will take place and what facilities are
  available.
- **Timing:** where the identification is to take place in a mortuary or hospital or care setting, contact the mortuary / hospital ward / nursing administration or site management, before arrival, to agree the most appropriate time. This allows the health care team / mortuary technician time to prepare the family and explain their role in the identification of the deceased person and what will happen.
- **Appearance:** give consideration to your professional appearance, avoid wearing high visibility jackets as part of your uniform as this may be frightening for the family.
- **Arrival:** use discretion on arrival to the place of care to avoid undue attention to the presence of a member of An Garda Síochána.
- Privacy: seek to meet in a private space to talk to the family before identification takes
  place. Some mortuaries, due to space availability, will limit the number of attendees but
  should always be mindful of the needs of the family.
- **Communication:** adopt a personal approach in communications, introduce yourself, address the person by name, explain your role, take time to answer questions and provide reassurance to the family on any concerns they may have arising from the involvement of the Gardaí during the identification process.

At all times acknowledge the potentially traumatic nature of this interaction for family members. In perinatal coronial cases, Garda identification of the baby's remains may be required but this should be organised and managed sensitively to acknowledge potential parental distress.

It may also be helpful to understand in advance if there are communication / language barriers (an interpreter may need be arranged) and cultural considerations.

Where possible, members of staff should be accompanied on their first identification process by a more experienced staff member. The Garda name, contact details and badge number should be documented in the healthcare record by the staff member accompanying them during the identification process.

#### 8.6. Appendix six: Local standard operating procedure - summary list

Please see the list below which details a summary of the standard operating procedures (SOP) which each service should have in place. Please note this is not an exhaustive list and services may need to put other SOPS in place as appropriate.

Area	Standard Operating Procedures List
Designated roles	<ul> <li>Each hospital should identify:         <ul> <li>a designated PME liaison / position for tracking, overseeing and monitoring of organs in all PMEs in each mortuary and,</li> <li>a designated family liaison / position (in hospital and / or community deaths, for example from the multi-disciplinary team, bereavement support, medical social worker).</li> </ul> </li> <li>Provisions should be in place to ensure these roles are covered in the event of the absence or unavailability of a designated staff member for any reason.</li> </ul>
Consent	SOP should be in place for ensuring the pathologist has confirmed and documented that the relevant consent has been received prior to commencing PME in both hospital and coroners' cases where relevant.
Transport	<ul> <li>SOP should be in place as follows:</li> <li>procedures for safe handling and transport (including the use of funeral directors, undertakers and / or specialised courier services where appropriate and reference to relevant infection control procedures).</li> <li>details of required packing, labelling and documentation.</li> </ul>
Deaths occurring before arrival at the healthcare facility	SOP to provide clarity on where the deceased should be directed for PME following a death in the community or en route to the hospital. This minimises the need to transfer or move the body unnecessarily.  It is also recommended that the protocol includes guidance on who will generate a temporary healthcare record.
Research for consent	SOP including forms where relevant which are informed by local practice and available information and the relevant guidance on broad consent in the HSE National Policy for Consent in Health and Social Care Research (2022). SOP should include in particular the topic of broad consent and the two phase process.
Records management	<ul> <li>SOP on record management including:         <ul> <li>maintaining registers and documentation.</li> <li>management of hardcopy data where there is an electronic record.</li> <li>management of healthcare records in hospital and community deaths.</li> </ul> </li> </ul>
Storage management, transportation and ultimate disposal of tissue samples and retained organs following post mortem examination	SOP on the local practice regarding the sensitive management of temporarily retained organs including but not limited to information on:  SOP in the event for contacting families in relation to the management of organs and timeframes for decision making  SOP on the access to healthcare records by the mortuary staff / pathologist etc.  SOP regarding the return of the organs to the family or the burial or cremation of organs by the hospital.  SOP including a named individual / position responsible for each step in the process.
Care during identification process	SOP on training needs around the identification process.

#### 8.7. Appendix seven: Signature Sheet

Sample signature sheet - HSE National Clinical Guidelines for Post Mortem Examination Services (2023)

I have read, understood and agree to adhere to HSE National Clinical Guidelines for Post Mortem Examination Services (2023).

Name (Block capitals)	Signature	Job title	Date

Sample signature sheet - HSE National Clinical Guidelines for Post Mortem Examination Services (2023)

I have attended training relevant to my role on the HSE National Clinical Guidelines for Post Mortem Examination Services (2023).

Name (Block capitals)	Signature	Job title	Date

#### 8.8. Appendix eight: Conflict of Interest Declaration Form



#### **CONFLICT OF INTEREST DECLARATION**

This must be completed by each member of the PPPG Development Group as applicable

Title of PPPG being considered:	
HSE National Clinical Guidelines for Post	: Mortem Examination Services (2023)
Please circle the statement that relates	to you
1. I declare that <u>I DO NOT</u> have any con	iflicts of interest.
2. I declare that <u>I DO</u> have a conflict of	interest.
Details of conflict (Please refer to speci	fic PPPG)
(Append additional pages to this stater	nent if required)
Signature	
Printed name	<del></del>
Registration number (if applicable)	
Date	
	coordance with data protection principles as set out in the Data Protection ommittee members act in the best interests of the committee. The her purpose.
A person who is covered by this PPPG is required	to furnish a statement, in writing, of:
(i) The interests of the person, and	
	knowledge, of his or her spouse or civil partner or a child of the person or
of his of her spouse which could materially influe	ence the person in, or in relation to, the performance of the person's

from, the person, or the spouse or civil partner or child, a substantial benefit.

official functions by reason of the fact that such performance could so affect those interests as to confer on, or withhold

#### 8.9. Appendix nine: A photo of a block and slide



A photo of a block with paraffin wax attached (on the left) and a glass slide with routine histological staining (H&E) of a small piece of lung tissue on it (on the right).

The measurement scale is in centimetres.

For queries, please contact:

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acutehospitals@hse.ie