

THE NATIONAL CODE OF ETHICAL AUTOPSY PRACTICE



The Australian Health Ministers' Advisory Council

SUBCOMMITTEE ON AUTOPSY PRACTICE

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ACRONYMS

AHA	Australian Healthcare Association
AHEC	Australian Health Ethics Committee (principle committee of the NHMRC)
AHMAC	Australian Health Ministers' Advisory Council
AHMC	Australian Health Ministers' Conference
HREC	Human Research Ethics Committee
NATA	National Association of Testing Authorities
NHMRC	National Health and Medical Research Council
NPAAC	National Pathology Accreditation Advisory Council
RACGP	Royal Australian College of General Practitioners
RCPA	Royal College of Pathologists of Australasia

GLOSSARY OF TERMS

Autopsy	sometimes called a “post-mortem”. A detailed physical examination of a person’s body after death.
Coroner	A magistrate (who is a lawyer). When a death is reported, it is the Coroner’s responsibility to find out the deceased person’s identity, the cause of their death, how they died and the particulars necessary to register the death.
Coronial Autopsy	When a death is reported to the Coroner an autopsy may be necessary. There are differences in reportable deaths in different states, but they may include: <ul style="list-style-type: none">• the person died without known cause• the person died from an accident or injury• the person died during or as a result of an anaesthetic• the person was ‘held in care’ immediately before they died• a doctor has been unable to sign a death certificate giving the cause of death, or• the identity of the person is unknown.
Designated Officer	A medical practitioner appointed to be a person, who authorises autopsies for a specific hospital.
Non-coronial Autopsy	An autopsy performed where the agreement of relatives of the deceased person is necessary / sought.
Organ / Organs	A visibly recognisable functional unit of the body (eg liver, heart, brain), whole or substantial parts of such a unit or other body parts. - also includes whole or substantial parts of fetuses regardless of gestation period.
Organ / Tissue Retention	Sometimes it is necessary for selected tissues or organs to be retained for microscopic or extended studies or tests.
Partial / Limited Autopsy	An autopsy that involves the examination of only specified organs or tissues of the body.

PREFACE

On 1 August 2001 Australian Health Ministers directed the Australian Health Ministers' Advisory Council (AHMAC) to establish a subcommittee to continue the work recently completed by the Australian Health Ethics Committee (AHEC) on organs retained at autopsy.

TERMS OF REFERENCE

The terms of reference of the subcommittee were set out in the decisions of the Australian Health Ministers' Conference held on 1 August 2001:

- to consider the policy and ethical aspects of autopsy practice across Australia and information, reviews and policies already developed nationally and internationally in order to develop:
 1. nationally agreed guidelines for an autopsy request and authority form that addresses the community's concerns and expectations;
 2. a set of principles and a national code of practice for autopsy procedures with such a code to include informed consent; and
 3. agreed procedures for the handling and disposal of tissue and organs after the autopsy are completed.

The subcommittee's focus was to develop principles and guidelines, not a national model authority form. It was recognised that the form is secondary to the interview and the agreement to autopsy.

SCOPE

The scope of the deliberations included:

- the level of information about what happens at autopsy
- seeking informed agreement to non-coronial autopsy and recording of the interview in the records
- the conduct of autopsies
- autopsies performed as a result of requests regardless of place, including private hospitals, country hospitals and deaths outside of hospitals
- autopsies performed as a result of requests regardless of age, including paediatric cases, perinatal deaths, stillbirths and foetuses
- non-coronial and coronial autopsies, acknowledging the added constraints on coronial autopsies
- retention of organs and tissues following autopsy; disposal of organs, tissues and specimens; involvement of the family in decisions relating to such retention or disposal
- tissue donation and genetic testing
- museum specimens, teaching and research using tissues and organs from autopsies.

Consideration was given to the treatment of surgical specimens to the extent that issues are common to autopsy practice.

REVIEW OF EXISTING INFORMATION

The subcommittee gathered information from a number of sources including:

- legislation - related to use of tissues, consent, coroners, death, medical practice
- guidelines and policies from several states and territories
- autopsy request and agreement forms, especially those recently developed
- information and brochures provided to families and to requesting doctors
- reviews conducted in Australia and internationally
- current debates reflected in reports, the media, forums and on websites

There have been several reviews and inquiries conducted in Australia in the past 12 months including:

- the AHEC Review
- the NSW Walker Inquiry
- the SA Selway Inquiry
- the WA Review

Reports have largely confirmed that practice in Australia over many years has been consistent with legislation and in the great majority of cases not unlawful. However, staying within the law is not enough - practice needs to reflect what the community regards as acceptable in the environment in which autopsies are now performed.

Legislation at state and territory level will need to be reviewed once the Code is approved to ensure consistency with the Code. Any amendments required to local legislation are not likely to be major and would serve to convey publicly a shift in climate and encourage the culture change that is required.

The RCPA is currently reviewing its position statement on autopsy practice. These discussions will inform the implementation of the Code.

SUBCOMMITTEE MEMBERSHIP

The subcommittee had representation providing expertise from:

- professional groups - RACGP, AHA, RCPA and NPAAC
- community views - chaplains, GPs, counsellors, consumer representative
- ethicist - AHEC
- government policy - Commonwealth, Victoria and South Australia

Jim Davidson, Executive Director of Policy, Planning and Corporate in the South Australian Department of Human Services chaired the Subcommittee.

Organisation	Member	Role of organisation
AHA	Mark Cormack	Australian Healthcare Association National Director Membership includes CEOs of public and private hospitals
NHMR /AHEC	Dr Christopher Cordner Member of AHEC	National Health and Medical Research Council regulates human research. Australian Health Ethics Committee is a subcommittee of NHMRC and writes ethical policy in the medical research environment
AHAWC	Phoebe McFarlin Hospital Chaplain, RAH	Australian Health and Welfare Chaplains Assoc Inc. Support for patients and families in hospital, various religions Hospital Chaplain, RAH
RCPA	Prof David Davies President <i>Prof Davies is a histopathologist, which is the discipline of pathology that performs autopsies</i>	Royal College of Pathologists, Australasia Represents pathologists.
NPAAC	Dr Keith Shilkin Member	National Pathology Accreditation Advisory Committee sets standards for pathology

RACGP	Dr David Thompson Representative	Royal Australian College of General Practitioners represents GPs. Dr Thompson represents the country GPs on the College Council Rural Faculty although he is based in Adelaide
ACSQHC	Ms Maxine Drake Consumer Representative	Australian Council for Safety and Quality in Health Care Advises the Commonwealth government on safety and quality issues and has consumer representation
Counsellor	Michelle Daly Senior Counsellor Qld Health Scientific Services	Member of national counselling groups
Victoria	Dr Graham Tallis Manager, Communicable Diseases Section Disease Control & Research Branch Department of Human Services	Victorian government - health policy
C'wealth	Jonathan Benyei (until Jan 2002) A/Assistant Secretary Peter DeGraaff (from Feb 2002) Assistant Secretary, Blood and Organ Donation Taskforce,	Commonwealth government - health policy
SA Chair	Jim Davidson Executive Director, Strategic Planning and Policy, Department of Human Services	South Australian government - health policy

CONSULTATION

The subcommittee membership provided representation from consumers, counsellors and general practitioners in addition to ethical, policy and professional advice.

The terms of reference included addressing the community's concerns and expectations. The lack of qualitative and quantitative information about family and community concerns was recognised. Community consultation matters but in this case even more so, because lack of community consultation and involvement is a root cause of the concerns raised. We needed to know community views about autopsies generally and about the proposed inclusions in the form in particular in order to ensure the subcommittee had addressed the community's concerns and expectations.

Various mechanisms for gathering views were considered including:

- consulting representative bodies and community organisations to determine broader community views and expectations including those of ethnic groups, different religions and Aboriginal people
- forming focus groups of people not involved in organisations
- members liaising within their own constituencies.

The community consultation plan included:

- targeting consultations
- establishing focus groups
- gathering reports from community hotlines
- ensuring that views from Aboriginal and ethnic communities were included.

Other bodies have relevant contributions to make and it was important that they were heard. Professional groups were consulted through members' networks and were offered an opportunity to comment on the draft report. Other groups were also contacted.

Consultations were conducted in November and December and the report was reviewed in the light of feedback . The final report has been prepared for Health Ministers.

THE CODE

The Code will be a public document and will inform families and the community. Advice for informing and involving families has been developed.

The Code is accompanied by guidelines for developing:

- autopsy request forms completed by requesting doctors
- autopsy authority forms completed by families
- information for families
- information for medical officers that request autopsies.

The term consent is not used as legislation differs across jurisdictions as to whether a family member can consent to a procedure that occurs after death.

THE CODE OF ETHICAL AUTOPSY PRACTICE

The conduct of autopsies has recently become an issue of community concern. The medical community and the health system acknowledge this understandable concern. There is no doubt that families should be consulted and be able to be involved in making decisions about what happens to the body of their deceased relative when an autopsy is performed.

In particular it should be clear that a non-coronial autopsy can only be carried out with the permission of the next-of-kin. It has become clear that in agreeing to a hospital autopsy, or being informed about a coronial autopsy, many families have not been aware that the procedure may involve organs being removed from the body and never returned to it. This discovery has caused pain and anger in a significant number of these families.

It is now recognised that, as with other areas of medicine, autopsy practice must be based on honest and open communication between health professionals and those they deal with. Autopsy practice, both in the coronial and in the non-coronial setting, has already begun to reflect this recognition.

The benefits of autopsy are many. These benefits include providing valuable information to individual families, improving the quality and standard of medical care for all, and contributing to the continuing education of medical personnel and to the administration of justice.

These benefits must be sought only through autopsy practice that, as well as being honest and open, manifests respect at all times for the deceased and their families.

PRINCIPLES

The following principles describe what underpins the Code and what governs future directions for both coronial and non-coronial autopsies, acknowledging that coronial autopsies require the authorisation of the coroner rather than the family.

- It should be clear that a non-coronial autopsy can only be carried out with the permission of the next-of-kin.
- Respect must be shown towards the deceased and their families at all times.
- Full, open and attentive communication is fundamental to effectively involving families.
- Processes must be transparent and accountable and able to be assessed and reported.
- The public benefit of autopsies needs to be recognised.

In addition, autopsy practice must be governed by the following principles:

- The family must be consulted and given the opportunity to be involved to whatever extent they wish to be.
- The wishes of the deceased and the family in regard to the autopsy examination should be accommodated as far as possible
- Information must be provided in a timely, understandable and sensitive fashion and answers to questions must be open and honest.
- Only appropriately trained persons should provide information to families.
- Family members must be consulted and their agreement obtained about organ retention and disposal, (in person wherever possible) unless they have made it clear they do not want to be consulted.
- Appropriate bereavement support should be provided to families in acknowledgement of their loss.
- An appropriately qualified and authorised person should take responsibility for the performance of each and every autopsy.
- There must be a clear delineation between the uses to which retained tissues/organs can be put such as diagnosis, research or education.
- All research using organs or tissues derived from autopsies must have the approval of a properly constituted ethics committee.
- The guidelines that accompany the Code outline the information that should routinely be offered to families. They should form the basis of all request and authority forms for non-coronial autopsies and information brochures provided to families and requesting doctors.

ENSURING COMPLIANCE WITH THE CODE

A number of compliance mechanisms for the Code were considered, including legislation and harmonisation, accreditation, licensing, self-regulation and establishing a national advisory body.

The subcommittee believes that:

- a code or charter is appropriate in the area of autopsy practice.
- accreditation and associated compliance constraints are the most effective means of governance of best practice.
- given the existing structures used to maintain compliance in this area additional penalties or sanctions are not required.
- accreditation applies to all hospitals where autopsies are performed. Accreditation programs governing mortuary and laboratory practice require adherence to NPAAC and NATA / RCPA, standards and failure to comply results in loss of accreditation
- existing accreditation mechanisms should be enhanced to include further standards for autopsy practice and for communicating with families about autopsies. NPAAC is currently developing such standards for hospital and laboratory mortuary practice.
- all research connected with autopsies should be overseen by Human Research Ethics Committees.
- legislation at state and territory level will need to be reviewed once the Code is approved to ensure consistency with the Code.

Discussion with families about autopsies may occur in many environments other than major public hospitals, ranging from country hospitals to GP surgeries. In all situations there must be uniform compliance with these principles. An education program with clear guidelines is essential to achieve this.

Current state based health complaints mechanisms must provide sufficient cover. Analysis of complaints received will provide information about compliance in areas not covered by accreditation systems.

BEST PRACTICE GUIDELINES FOR INFORMING AND INVOLVING FAMILIES

Coronial and non-coronial autopsies should be conducted in a manner consistent with the Code.

It is important to acknowledge that in coronial autopsies the agreement of the family is not required, but wherever possible the Coroner should give regard to the family's wishes.

Traditionally professionals have sought to protect families from information that they may find distressing. However, experience has shown that timely information provided in a sensitive manner can empower families and is far less distressing than later disclosure.

Bereaved families have the right to clear, factual and sensitive communication from a skilled professional. Institutions have a responsibility to ensure that in each case there is a specifically trained staff member whose role is to engage with the bereaved family and provide clear, factual information in a sensitive manner following the death of a patient.

The approach to the family regarding autopsy is most appropriately made by the senior clinician treating the patient. This is not a duty to be delegated to a junior medical officer or untrained interviewing officer. Requesting an autopsy and discussing organ retention and use and other sensitive information should be conducted face to face wherever possible. Whilst an approach by telephone may be allowable and in some cases unavoidable, it is not ideal.

The appropriately trained person whose priority is the needs of the bereaved family should support the clinician in this role. The capabilities of such persons in providing assistance to the bereaved family should include:

- an understanding of the dynamics of the grief process
- counselling and communication skills to convey information at a pace and using language the family are able to understand,
- the capacity to recognise the needs of families where English is not the first language (including Aboriginal families), and the potential for diminishing fluency and comprehension or reversion to original language

- communication and advocacy skills to ensure the wishes of the family are conveyed and respected
- a good understanding of the difference between hospital autopsies and coronial autopsies and the legal and ethical issues related to agreement
- a good understanding of the autopsy process including the need for tissue/organ retention and options available for future use, release or disposal
- knowledge of all aspects of funeral arrangements.

Institutions involved with the bereaved family must recognise and provide for the following needs:

- a quiet, private area to undertake these discussions
- time to assimilate the impact of the death before being approached to discuss autopsy. Whilst it is acknowledged in certain situations the treating clinician may have had extensive discussions about the prognosis of the patient and the benefit of autopsy may have already been raised with the family, in most situations it is inappropriate to raise the issue until the family has had time to take in the death of the patient.
- information about events leading to the death, treatment attempts etc before feeling ready to discuss other issues
- support to facilitate their “goodbye” to their relative
- any special religious or cultural rituals which must be acknowledged and met where possible
- clear honest information
- Specifically families must be clearly informed of their rights:
 - to refuse the performance of a hospital autopsy or object to the performance of a coronial autopsy (subject to local legislation)
 - in hospital autopsies, to limit the extent of the examination and retention of tissue and organs, understanding that such limitations may compromise the information obtained from the autopsy
 - in regard to disposal options for retained tissues and organs
 - to be advised about uses other than diagnosis to which retained tissues/organs can be put
- access to interpreters and appropriate health workers where necessary
- information and assistance to make funeral arrangements
- assessment and referral for ongoing counselling if required.
- provision of autopsy results in an understandable form. They may prefer to meet with the clinical team who cared for their relative or with their own GP. In some situations discussion with the pathologist may be appropriate.

GUIDELINES FOR AUTOPSY REQUEST AND AUTHORITY FORMS (NON-CORONIAL)

REQUEST BY PRACTITIONER

The form should include:

1. name of medical practitioner requesting autopsy
2. name of deceased
3. the family member consulted, by whom and their relationship to the deceased
4. clinical report and reason for seeking autopsy
5. information on hazards presented to mortuary staff - infectious, radioactive etc
6. mode of request - in writing, in person or by telephone

Every reasonable effort must be made to contact the next of kin, recognising different kinship arrangements in some cultures (e.g. Aboriginal).

The role of the Designated Officer is to check and sign that the documentation reflects compliance with relevant legislation and the Code. Other roles may be applied by local legislation.

EXPLANATION OF AUTOPSY AND AGREEMENT BY FAMILY

The form should be simple and refer to comprehensive guidelines, and include a statement that the guidelines have been read and understood, with a copy provided to the family. The form should also include:

1. the name of the key person who discussed the issues with the family
2. the name of the person seeking the family's authorisation
3. that there was adequate explanation of the reason for and process of autopsy
4. options for both broad and conditional agreement
5. whether the deceased had previously agreed or objected to autopsy
6. whether any other next of kin had previously objected to autopsy
7. options for full or limited autopsy, specifying limitations
8. options for retention of organs, specifying limitations
9. agreement that specimens will be retained - the need for indefinite retention of blocks and slides must be explained to the family
10. whether retained organs or tissues can be used for education

11. whether retained organs or tissues can be used for approved research consistent with the national NHMRC National Statement on ethical conduct in research involving humans
12. options for disposal of retained organs including return to body, later return to funeral director nominated by the family or respectful disposal by the hospital
13. the date and time of planned funeral arrangements
14. name of doctor(s) to whom the report should be provided.

To an extent, consistent with meeting the requirements of the coroner, these features should be included in coronial autopsy authorisation forms.

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4. Both a general and specific agreement should be offered. Families should be offered the option to agree to an autopsy without specifying conditions, but also to agree individually to research, teaching, transplantation and return of organs. It is recognised that while many families want to be very informed and be provided with an opportunity to determine what organs are retained, what they can be used for and how they will be disposed of, not all families are comfortable considering these aspects.
 7. A partial autopsy may be more useful than no autopsy, but has the potential to be misleading. 10. and 11. must be offered separately.
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GUIDELINES FOR WRITTEN MATERIAL PROVIDED TO FAMILIES

Families should be provided with a copy of the authority form that they have completed. Explanatory information should be available to give to the family to supplement the discussions. Such explanatory brochures/booklets should include an explanation of the autopsy including what retention of tissues and organs means. It may be necessary to include a glossary to explain samples, tissues, organs and other terms. Jurisdictions are encouraged to provide this information in relevant local languages.

Information about non-coronial autopsies should include the choices about:

- the extent of the autopsy
- retention of organs
- the limitations on the information available if they choose to limit the autopsy
- their right to choose whether retained samples can be used for other purposes such as research, education and quality control
- who the report is provided to
- disposal of retained samples, e.g. return to the body before release, subsequent release to funeral director or respectful disposal by the institution.

Information about coronial autopsies should include:

- what deaths are reported to the Coroner, so they understand why this particular death is being reported
- what a coronial autopsy involves, including the need to retain samples, options for disposal and other uses to which tissues and organs may be put
- what rights the family have in that jurisdiction to object to the performance of the autopsy, to limit the extent of the autopsy or to appeal any decisions by the Coroner
- what rights the family have to be informed of retention of organs and disposal arrangements for these
- sources of assistance and further information.

Families affected by either coronial or non-coronial autopsies may also benefit from information about:

- obtaining the death certificate
- procedures for reporting complaints and concerns
- sources of further assistance including interpreters and counselling.

GUIDELINES FOR INFORMATION AND BROCHURES PREPARED FOR MEDICAL OFFICERS ORDERING AUTOPSIES

Information and brochures prepared for medical officers requesting autopsies should reflect these guidelines and the Code, with additional advice on how to approach families; how to explain what an autopsy is, why it is needed and what might be learnt from it; what makes a coronial autopsy different; the importance of counselling; what might be retained and what returned and why there may be delays; and what options there might be to contribute to research or teaching.

The death of a patient can be a difficult time for both the professional involved and the family. To obtain agreement to an autopsy is a delicate and challenging task. Experience has shown that a sensitively handled, well-informed discussion need not be distressing. Ideally, seeking agreement for an autopsy should be handled by a senior clinician.

There is some variation among clinicians in their experience in discussing death and autopsies with families. This information is therefore provided to enable them consistently to be able to sensitively and appropriately guide families through the processes involved, gain their involvement, ensure their rights are upheld and to provide support as necessary.

Requesting an autopsy

- Determine whether a coronial or non-coronial autopsy is necessary
- Have the necessary facts and forms
- Find out when the autopsy is scheduled
- Identify the family member who is the 'next of kin'

How to approach the family

- Be sensitive to the family's needs
- Give them time to come to terms with the death of their relative before you approach them regarding autopsy
- Make sure they have the details of what happened leading up to the death eg treatments, complications

How to ensure families' rights are met

- Provide written and verbal information, thereby involving them in the process. Include information about
 - the autopsy process
 - their rights at this time
 - the results of the autopsy
 - counselling and ongoing supports that are available
 - funerals

How to explain what an autopsy involves

- Use plain simple language to explain the procedure
- Be sensitive to their difficulties at this time
- Be prepared to repeat information as families may not take it all in at this time

Why an autopsy is needed and what might be learnt from it

- In what circumstances autopsies are necessary
- Why with this particular death an autopsy may be essential or helpful

What else must be covered in talking to the family

- When the body will be available for the funeral
- Where the autopsy will take place
- Who will be involved,
- Who the family can talk to if they have questions
- Whether the family have specific cultural or spiritual rituals or needs that they wish to be observed
- Whether they want counselling, other bereavement support or help with the funeral

The Importance of Counselling

- This is a very emotional time for families; they may require and appreciate the involvement of somebody with the experience, skills and knowledge to help them through the process
- Families may need support, guidance or advocacy to understand and cope with the information that they are expected to handle at this time
- Include discussion of genetic information and its implications where relevant

If this is a coronial autopsy, what is different for the families?

- Ensure that whilst they can express their wishes and objections, families understand the reasons why this particular death requires an autopsy
- Explain the family's rights in these circumstances
- Ensure that the final decision rests with the coroner.

Retaining, releasing and disposing of organs and tissues

- Families need to know why some organs or tissues may need to be kept for more in depth examination, or that testing may involve a longer wait for results
- Explain the options available to families in relation to limitation, release or disposal of organs

Why there may be delays

- The examination and testing necessary in completing an autopsy will take time
- A test may need repeating or another sample may be necessary

Options for contributing to teaching, research and furthering knowledge about disease, genetics etc

- If families agree to retention of organs or tissues, explain their options
- Explain the benefits and implications of each option

Providing the report

- Clarify who receives the report and how it will be explained to them
- Seek a plain language version of report from the pathologist if the family requests a copy

GUIDELINES FOR HANDLING AND DISPOSING OF ORGANS AND BODY PARTS

The handling and disposal of tissues and organs that had been retained in the past was dealt with retrospectively by AHEC in their recent report. It is timely to recommend protocols for the management of future practice.

Organs and body parts

- a visibly recognisable structural unit of the body (eg brain, heart, liver) or substantial parts of such an organ, or other large parts of the body such as limbs
- also includes whole or substantial parts of fetuses regardless of gestational age
- these are normally returned to the body following sampling.

Specimens, blocks and slides

- small samples required for testing by microscopic examination
- these are retained by the laboratory.

Options for disposal of retained organs should include return to body, later return to family via the funeral director or respectful disposal by the hospital. Sometimes it may be necessary for the purposes of autopsy that a whole brain or other organ be retained for further examination. With the permission of the family, these can be disposed of respectfully by the hospital after completion of testing, so as not to delay the funeral. Recognising that some organs have particular significance to families according to their culture, special arrangement should be offered if requested for disposal of heart, brain or other nominated organs.

Organs from autopsies are different from surgical specimens and their disposal needs to be respectful and reverential whether used only for diagnostic tests or for education or research. For this reason:

- organs from autopsies should be kept separate from routine surgical specimens and should not be disposed of through ordinary hospital waste processes
- organs disposed of by the hospital should not be incinerated as surgical waste; rather they should be cremated via a funeral director.
- ethics committees approving research involving use of retained tissue must be provided with details of its eventual disposal and this should conform with the requirements stipulated by the family on the form.
- use of organs for research should be the subject of a separate and specific consent. The approach to the family to seek this consent should be through a counsellor wherever possible