Consultative Council on Obstetric and Paediatric Mortality and Morbidity

Background paper for researchers

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Consultative Council on Obstetric and Paediatric Mortality and Morbidity

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1.1 Characteristics of the Council

The Consultative Council on Obstetric and Paediatric Mortality and Morbidity (the Council) was established in 1962 to improve outcomes relating to paediatric and maternal morbidity and mortality in Victoria.

The Council consists of twelve members appointed by the Minister and four subcommittees:

- Maternal Mortality Committee
- Stillbirth Committee
- Neonatal Mortality & Morbidity Committee
- Child & Adolescent Mortality & Morbidity Committee.

Members of the Council and its committees have widely diverse areas of expertise. The primary role of the Council is to review all maternal, perinatal and paediatric deaths in Victoria in order to consider clinical features of each case and to assess preventability.

Information provided to the Council is privileged by legislation, and (unless it is released by Council) is not accessible by any third party, including the Courts.

1.2 Legislated functions

In recent years the Victorian Government has conducted a number of legislative reviews which have impacted upon the monitoring and investigation of cases of paediatric and obstetric morbidity and mortality, including (but not limited to):

- The Health and Wellbeing Act 2008
- The Coroners Act 2008

As a result of legislative review, access to data for statistical and research purposes can now be granted to researchers in addition to medical professionals. However, the Council is restricted by Regulation 10 of the Public Health and Wellbeing Regulations 2009 and can not release information which identifies any patient, practitioner or institution, without the appropriate consents being obtained.

The legislated functions of the Council as outlined in the Public Health and Wellbeing Act (The Act) specifies that Council is to:

a) Conduct study, research and analysis into the incidence and causes in Victoria of maternal deaths, stillbirths and the deaths of children;

b) Conduct study, research and analysis into the incidence and causes of obstetric and paediatric morbidity;

c) Conduct a perinatal data collection unit for the purpose of -

i. collecting, studying, researching and interpreting information on and in relation to births in Victoria;

ii. identifying and monitoring trends in respect of perinatal health including birth defects and disabilities;
iii. providing information to the Secretary on the requirements for and the planning of neonatal care units;
iv. providing information for research into the epidemiology of perinatal health including birth defects and disabilities; and
v. establishing and maintaining a register of birth defects and disabilities.

d) Provide to health service providers -
   i. information on obstetrics and paediatrics; and
   ii. strategies to improve obstetric and paediatric care.

e) Consider, investigate and report on any other matters in respect of obstetric and paediatric mortality and morbidity referred to the Council by the Minister or the Secretary;

f) Liaise with any other Consultative Council (whether or not prescribed) on any matter relevant to the functions of the Council;

g) Publish an annual report on the research and activities of the Council;

h) Perform any other prescribed function; and

i) Collect information for the purpose of performing its functions as outlined in the Act.

1.3 Guiding principles for research

The Council aims to promote high quality research related to obstetric and paediatric mortality and morbidity which will benefit the communities we engage with and serve. Principles that underpin the conduct of such research align closely to the legislated functions of the Council and state that data collected on behalf the Council will be used to undertake:

a. research and study on the incidence and causes in Victoria of maternal deaths, stillbirths and the deaths of children;

b. research and study on the incidence and causes of obstetric and paediatric morbidity;

c. research on and in relation to births in Victoria;

d. research into the epidemiology of perinatal health including birth defects and disabilities; and

e. research on any other matters in respect of obstetric and paediatric mortality and morbidity referred to the Council by the Minister or the Secretary of the Victorian Department of Health.

f. In addition, the Council supports research which is strategic and targeted at priority areas for which evidence is needed.

The Council is required to publish an annual report incorporating research activities undertaken using the data collected by Council.
2. Accountability and Influence of Council

2.1 Mechanisms of accountability

The Council is supported by the Quality, Safety and Patient Experience branch which lies within the Department of Health’s Hospital and Health Service Performance Division. The Council is appointed by order of the Minister for Health to carry out the key functions specified in the Health and Wellbeing Act. As the advisory body to the Minister for Health on maternal, perinatal and paediatric deaths, the Council may interact with:

- the Minister for Health;
- the Department of Health, acting on behalf of the Minister; and
- a range of other stakeholders involved in the provision of services.

2.2 Mechanisms of influence

In order to achieve the goal of improving outcomes relating to paediatric and maternal morbidity and mortality in Victoria, the Council interacts with a range of other stakeholders, including (but not limited to):

- Australian Institute of Health & Welfare (National PDCU);
- Clinicians & Health Services;
- Department of Education and Early Childhood Development (DEECD);
- Maternity & Newborn Clinical Network;
- Maternity & Newborn Program;
- National Maternity Council (National Perinatal Reporting);
- Office of the State Coroner;
- Other National and State bodies;
- Professional Colleges, CRAFT Group Associations & Societies;
- Registry of Births, Deaths & Marriages (Department of Justice);
- Safety & Quality Program;
- Universities & Research Institutes;
- Victorian Child Death Review Committee;
- Victorian Consultative Council on Anaesthetic Morbidity and Mortality;
- Victorian Managed Insurance Authority; and
- Victorian Surgical Consultative Council.
3. Data Collection and Management

3.1 Purpose of data collection

The collections held by the Council, within the Clinical Councils Unit (CCU), are clinical data collections and include identified individual level data provided by hospitals and individual medical practitioners. Data are provided to the Council by all public and private hospitals (including private day procedure centres) as is required by the Public Health and Wellbeing Act 2008.

The purpose of these data collections is to conduct study and research into mortality and morbidity in selected populations, to support health service planning and develop government policy with the aim of preventing avoidable deaths and promoting healthy outcomes. The data collections also support Victoria’s reporting obligations under the National Health and Hospitals Agreement and the National Health Agreement.

3.2 Data management and maintenance

The Council maintains databases and collects data from Victoria on all:

- births;
- perinatal deaths (stillbirths and neonates) from 20 weeks gestation or 400 gm birth weight;
- birth defects;
- infant and child deaths up to, but not including the eighteenth birthday;
- and maternal deaths.

A health service provider who is requested by the Council to provide information on any of the above is authorised to do so under Section 39 (2) of the Public Health and Wellbeing Act. The Act places strict confidentiality provisions on the Council and the information it collects. This involves not publishing identifying information, and not releasing information to any other party except in the limited circumstances prescribed in the Act.

3.3 Data sources

**Births**

The Victorian Perinatal Data Collection (VPDC) was established as a population based surveillance system to collect and analyse information on and in relation to the health of mothers and babies. The data collected via a birth report contains information on obstetric conditions, procedures and outcomes, neonatal morbidity and birth defects relating to every birth in Victoria.

The majority of data items, of which there are over 100, comply with the National Perinatal Minimum Data Set and are sent to the National Perinatal Statistics Unit for the production of the annual report on Australia’s mothers and babies.

**Perinatal deaths**

The Council relies on the co-operation of obstetricians, neonatologists, paediatricians, midwives, general practitioners and medical records personnel to assist with gaining the maximum amount of relevant information on each case. The Perinatal Death Certificate and the Confidential Medical Report on Perinatal Death are completed for stillbirths and neonatal deaths.

**Infant, Child & Adolescent deaths**

These cases are notified to the Council via death certificates issued by the Registry of Births, Deaths and Marriages.

**Maternal deaths**

In the case of a maternal death, the Council is notified directly.

**Birth Defects**

The Victorian Birth Defects Register (VBDR) collects data on all birth defects for livebirths, stillbirths and terminations of pregnancy occurring since January 1 1982, irrespective of the age at diagnosis, up to 15 years of age. Data are obtained from multiple sources of which the primary sources are birth forms and hospitals.
4. Data release and research

4.1 Data release policy

The release of identifiable information to any persons not listed in Section 41 of the Act is only permissible for the purpose of research with the consent of the mother, the health service where the child was born and if possible the medical practitioner or midwife present at the birth. Non-identifiable information may be released by the Council under Section 10 (2) of the Public Health and Wellbeing Regulations 2009. The Council’s data release framework is outlined in Attachment 1.

4.2 Data requests for simple statistical use

Applications for the release of de-identified aggregate data can be submitted online to the Council via its web page, http://www.health.vic.gov.au/ccopmm/requestsdata.htm. Requests will then be referred on to the CCU for consideration.

Applications will be assessed against the mandatory criteria that the data requested is de-identified and statistical in nature, and that release of the data satisfies current operational and legal considerations, including the Health Privacy Principles (HPP’s) contained in the Health Records Act 2001, http://www.legislation.vic.gov.au/Domino/Web_Notes/LDMS/LTObject_Store/LTObjSt2.nsf/DDE300B846EE D9C7CA257616000A3571/590D6475502B6A5DCA25776100220E3A/$FILE/01-2a022.pdf. A public interest assessment will also be undertaken on a case by case basis to ensure consideration of all relevant circumstances.

Health services, after sending their information to the Council, can request access to their own information as the Victorian Perinatal Data Collection (constituted under the Council) recodes information submitted to the Council. This collection is considered more accurate than that held by health services and health services make requests to use it on this basis. Health services requisition of data is usually to review practices and improve quality; there is a significant public interest in making this information available to them.

4.3 Research requests and identifiable data

Requests for data for the purpose of undertaking research are to be submitted to the Council for consideration. The Council will consider the need for each data item requested.

4.3.1 Individual level data that is non-identifiable

Individual level data that is non-identifiable, that is, not capable of establishing the identity of any person in respect of whom information has been collected, will be made available if the proposed research aligns to the functions and work plan of the Council, satisfy’s a public interest test and accords with both the requirements of the Victorian Human Rights Charter and the Health Privacy Principles contained in the Health Records Act 2001.

4.3.2 Identifiable data

Identifiable information, including proposals to link data using identifying information, will only be released in accordance with section 10 (3) the Public Health and Wellbeing Regulations 2009, which provides for the release of identifying information to a researcher for the purpose of undertaking research, if:

(a) written permission has been given by the mother concerned; and

(b) if possible, written permission has been given by either the medical practitioner or midwife who attended the birth; and
(c) if the birth occurred in a hospital, written permission has been given by the proprietor of the hospital.

Where the above conditions cannot be met, a research proposal requesting identifiable information can only proceed if the Council elect to undertake the research themselves. In such circumstances, the proposed research must align to the functions and work plan of the Council, satisfy a public interest test and accord with both the requirements of the Victorian Human Rights Charter and the Health Privacy Principles contained in the Health Records Act 2001.

In circumstances where identifiable information is required to link perinatal data with information from other data sources; this can only be undertaken within the Department of Health through the Victorian Data Linkages Unit, or by staff in the CCU, depending on the size of the linkage project. These research proposals will be assessed on a case by case basis following submission of the research data request, and output files supplied to the researcher will not contain any identifiable or re-identifiable patient information. As with any other research data request to the Council the proposed research must align to the functions and work plan of the Council, satisfy a public interest test and accord with both the requirements of the Victorian Human Rights Charter and the Health Privacy Principles contained in the Health Records Act 2001.

4.4 Key priorities for research

The Council supports external research in accordance with its legislative requirements and research principles. Proactive strategies have been employed to foster research in a number of priority areas. For 2011 the Council has identified the following areas which will be given priority:

- Pregnancy associated with significant risk factors; especially obesity, diabetes, low socio-economic status, and indigenous status.
- Hospital systems management, including the acceptance, admissions and transfer, of complex obstetric and paediatric cases.
- Cultural and ethnic factors influencing perinatal and child deaths.
- Regional variants in obstetric and paediatric mortality and morbidity.
- Management of vaccine preventable disease.
- Management of decreased fetal movement at term.
- SIDS/SUDI.

These areas have been identified by the Council and its Sub-Committees and are indicative of the Council’s desire to further its focus on issues that may lead to improved clinical and population outcomes. However, this list is in no means exhaustive or binding.

Expressions of interest to undertake research, especially within the above areas, are encouraged by the Council.
Attachment 1

RESEARCH ONLINE REQUEST FORM

Requests for data for the purpose of research

Consultative Council on Obstetric and Paediatric Mortality and Morbidity (CCOPMM)
Victorian Perinatal Data Collection (VPDC)
Victorian Birth Defects Register (VBDR)

Request details (* Mandatory Fields)

1. Date of request*
   dd/mm/yyyy
2. Name of requesting person*
3. Organisation*
4. Position/Job title*
5. Contact phone number*
6. Address*
   Street
   Suburb/Town
   State
   Postcode
7. Email Address*
8. Are you employed by the Department of Health?*
   Yes  No
   If yes, which Division?*
9. Title of research project.

Any formal proposal involving extensive perinatal data provision must conform to the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research 2007. Before the project can begin, a properly constituted Human Research Ethics Committee (HREC) must have given approval.

10. Has approval been given by an Ethics Committee?*
    Yes  No

UPLOAD ethics submission and approval

11. If you answered no to question 10, please advise the current status of your ethics submission and the name of the proposed HREC.

12. What is the objective/aim of this research?

13. Outline the research methodology and inclusion criteria.

14. If you are using more than one data collection, do you have plans to link this data with CCOPMM data? Describe your proposed linkage methodology and indicate which other data collections will be used.
15. Data items requested. Please provide a rational for each item requested.*

16. Is identifying information required?*
   Yes  No

17. If you answered yes to the above question, specify why you require identifying information and consult Regulation 10 of the Public Health and Wellbeing Regulations 2009.

18. Why is the release of this data beneficial to the public? ie Public interest statement.

19. When do you propose to commence the research/require the data?

20. Advise how this data will be stored and used and how the research findings will be disclosed/disseminated?*

All papers/reports/publications using the requested data must be submitted to CCOPMM prior to publication, report or release and must carry the appropriate citation.

Commencement of your research request will not begin until your Ethics Submission, a completed ‘Declaration of Conflict of Interest Statement’ (\N060\GROUP\Q & S Branch\Clinical Councils\Data Management\Research Requests 2010-11\Templates\declaration_conflict_interestsV2.doc) and a Statement outlining compliance with the Human Rights Charter has been received by this Department. To access the Charter of Human Rights and Responsibilities Act 2006 please click on this link.
   (http://www.legislation.vic.gov.au/Domino/Web_Notes/LDMS/PubStatbook.nsf/f932b66241ecf1b7ca256e92000e23be/54D73763EF9DCA36CA2571B6002428B0/$FILE/06-043a.pdf)

UPLOAD Signed declaration of conflict of Interest form

UPLOAD a Statement outlining compliance with the Victorian Human Rights Charter

It is your duty to ensure that the data are used responsibly and respectfully, and that the privacy of individuals is safeguarded.

To accept these terms and conditions please tick this box, then hit the ‘Submit’ tab below.
DECLARATION OF INTERESTS (Including conflict of interest)

What is a conflict of interest, and how do I identify if I have a conflict of interest?

Everyone has interests that are personal to them or someone close to them. It is inevitable that sometimes these interests conflict your work decisions or actions. In particular it is important to appreciate that perceived conflicts of interest can be just as damaging as actual conflicts, and that the way in which perceived conflicts are managed should therefore be considered with equal care.

A conflict of interest can exist even if no ethical or improper act results from it. A conflict of interest will arise when a person has two duties which conflict. For example a personal relationship and a professional obligation, or dual professional roles that overlap. A common example is where an employee has a responsibility for managing or controlling financial matters and their sibling, wife or other family member submits a tender to supply products to the manager's employer. In research cases procurement of a population of participants is routinely done by persons not contributing to the research activities, and Data is collected and verified independently.

Declared Interests

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<td>Please provide details of any contract, agreement or understanding entered into by you or a family member, of which you are aware, that gives rise to an obligation or an expectation of reward, such as an agreement about future employment once the research project is completed. Only provide information which could reasonably raise an expectation of conflict of interest or a material interest with your research project.</td>
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<th>A2. Other interests:</th>
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<td>Please provide details of any other significant financial or other interest held or accruing to you or a member of your family, of which you are aware, which could reasonably raise an expectation of a conflict of interest or material interference with your application.</td>
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Examples of a substantial financial or other interest include:

- being a principal or key employee of a material professional adviser supplying services; and
- interests in contracts, trusts or other business arrangements not already covered.

The CCOPMM treats all personal information provided by an individual in support of an application in accordance with the Information Privacy Act 2000 (Vic) and the Public Records Act 1973 (Vic). The personal information you provide in this form is required for application processing and assessment purposes.

When you provide us with information about other individuals, we rely on you to make them aware that such information will or may be provided to us as part of the application process. If all or part of the requested information is not provided this failure may impact on your application.

I declare that to the best of my knowledge, the information I have provided in this declaration is true and correct. I undertake to advise the responsible CCOPMM through the Manager, Clinical Councils Unit in writing if a conflict or potential conflict arises in the future. If there is any change to the interests set out in this declaration I undertake to advise CCOPMM through the Manager, Clinical Councils Unit of any alterations or additions to my declaration as soon as practicable.
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<td>Title:</td>
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<td>Signature of Witness:</td>
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<td>Name (please print):</td>
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(Please type or write your answers in block capitals.)

I, (insert full name)  
am the lead researcher on the (insert project name)  
and consent to the Consultative Council on Obstetric and Paediatric Mortality and Morbidity (CCOPMM)  
collecting and using this information on a confidential basis as described in this form.