APPENDIX W
METHODS OF GUIDELINE DEVELOPMENT AND REVISION

The guideline has been developed by the Perinatal Society of Australia and New Zealand Perinatal Mortality (PSANZ-PMG)[1] The Centre for Clinical Studies (CCS) (now Mater Mothers' Research Centre - MMRC), Mater Health Services, Brisbane was originally commissioned by the PSANZ-PMG (through funding made available by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, SANDS Queensland and SIDS and Kids) to coordinate the development of the guidelines. The MMRC conducted the literature search and collated the review and assembled the draft guidelines in consultation with Working Party members. In the second revision (2008/2009), the PSANZ-PMG collaborated with Australia and New Zealand Stillbirth Alliance (ANZSA) with funds made available by PSANZ and ANZSA. In the third revision of the guideline in 2017, the PSANZ Stillbirth and Neonatal Death Alliance (previously PSANZ PMG) worked in partnership with NHMRC Centre of Research Excellence (previously ANZSA) following the methods of the original version of the guidelines. Literature searches were updated to Dec 2015.

Perinatal Mortality Guidelines Working Party

The Working Party was originally convened in March 2004 to:

- Produce a guideline on Perinatal Mortality Audit for use in Australia and New Zealand;
- Identify gaps in current information and data for the ongoing refinement and evaluation of the above guideline; and
- Collaborate with local and national bodies in the development, implementation and evaluation of the guideline including the impact on health outcomes

In fulfilling this task, the Working Party followed the procedures recommended in the NHMRC documents: Handbook series on preparing clinical practice guidelines, endorsed November 1999[2] and 2011[3] for subsequent updates This process included attention to the following steps:

- Define the scope of the guidelines in order to: ensure clinical relevance; identify further questions, target groups and relevant health outcomes to be addressed by the guidelines;
- Assess any existing guidelines;
- Undertake (or commission) a systematic review of the literature and evaluate the extent and strength of the scientific evidence relating to the effectiveness and appropriateness of the relevant interventions;
- Refine the evidence-based guidelines and other materials to explain guidelines to consumers and other defined target groups;
- Undertake wider consultation;
- Disseminate and implement guidelines; and
- Evaluate and maintain guidelines.

The Working Party was re-convened in February 2008 to review and update the guideline. A one-day meeting was held in Sydney to discuss the required changes on the basis of which amendments were made and finalised through email communication. Section 7 was finalised in April 2009.

Consultation process

For the first version of the guideline, two meetings were held in March 2004 at the PSANZ 8th Annual Congress, Sydney, Australia; one meeting involved the whole Working Party; the other, the perinatal pathologists. Subsequently, subgroups of the Working Party were set up for each of the major sections of the guideline based on the interests of the members. Consultation was undertaken with the subgroup members by email and telephone to produce a final draft for consultation.

Organisations included in the wider consultation up to and including the 2008/9 update were as follows:

ACMI	Australian College of Midwives Incorporated
ACNN	Australian College of Neonatal Nurses
HGSA	Human Genetics Society Australasia
PSANZ	Perinatal Society of Australia and New Zealand
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
SANDS (Qld)	Stillbirth and Neonatal Death Support Group (Qld)
SIDS & Kids	Sudden Infant Death & Stillbirth and Kids
ANZNN	Australian and New Zealand Neonatal Network
BBF	Bonnie Babes Foundation*
SBF	The Stillbirth Foundation Australia*

*second edition of the Guideline only.

Organisations included in the wider consultation for the 2017 update are as follows:

Australian College of Midwives

Australian College of Neonatal Nurses

Human Genetics Society Australasia

Perinatal Society of Australia and New Zealand

Royal Australian and New Zealand College of Obstetricians and Gynaecologists

Women's Healthcare Australasia

Stillbirth and Neonatal Death Support National

Red Nose

Australian and New Zealand Neonatal Network

The Stillbirth Foundation Australia

Still Aware

Bears of Hope

Queensland Maternal Perinatal Quality Council

Consultative Council on Obstetric and Paediatric Morbidity and Mortality, Victoria

Maternal and Perinatal Mortality Committee, South Australia

Council on Obstetric and Paediatric Mortality, Tasmania

Perinatal and Infant Mortality Committee of Western Australia

Perinatal Mortality and Morbidity Review Committee, New Zealand

Search strategy

A comprehensive search strategy was developed based on the initial discussions of the Working Party and those of the Working Party's subgroups. The search strategy included an electronic database search and guideline website search. In addition, the CCS and members of the Working Party searched previous reviews including cross references and contacted experts in the field for additional information.

The search strategy for the first edition included searches of the following electronic databases: The Cochrane Library (Issue 2, 2004); MEDLINE (1966-2004); and CINAHL (1982-2004). Generic terms were used throughout the guideline, with additional terms included in the section specific searches.

Generic search terms included: text terms; f?etal death, f?etal wastage, perinatal mortality, perinatal death, stillb*, neonatal mortality, neonatal death, NND and MeSH terms; fetal death and perinatal death.

The generic search terms were combined with section specific terms, including the following: review, audit, classification, investigat*, guideline, protocol, test*, explor* rural, non-metropolitan, outreach, isolat*, info*, brochure*, pamphlet*, parent*, mother*, father*, profession*, nurs*, midwi*, doctor*, p?ediatric*, neonatolog*, bereave*, grief, emotion*, care, psycho*, funeral, social*, suboptimal, substandard, standard*, inadequate, compliance, manage*, HBA1c, glucose tolerance test, GTT, Fasting blood glucose.

This search was updated and expanded in February 2008, searching the years 2004 to March 2008.

The following guideline web sites were searched in March 2008 for existing perinatal mortality audit guidelines.

Web site name/Organisation name	Web site address/URL
Alberta Medical Association, Canada	http://www.albertadoctors.org/home
American College of Obstetrics and Gynecology	http://www.acog.com/
Association of Women's Health, Obstetric and Neonatal Nurses	http://www.awhonn.org/awhonn
Australian Government, Department of Health & Ageing: Safety & Quality in Health Care	http://www.health.gov.au
Australian Government, National Health & Medical Research Council	http://www.nhmrc.gov.au
British Columbia Perinatal Care Program,, Canada	http://www.bcphp.ca/Perinatal%20Mortality%20Guidelines.htm
Canadian Paediatric Society	http://www.cps.ca/english/publications
Canadian Task Force On Preventive Health Care: Evidence-Based Clinical Prevention	http://www.ctfphc.org/
Confidential Enquiry into Maternal and Child Health (CEMACH)	http://www.cemach.org.uk/Publications.aspx
Department of Health, New South Wales	http://www.health.nsw.gov.au/

Department of Health, United Kingdom	http://www.dh.gov.uk/Home/fs/en
Department of Health, Western Australia	http://www.health.wa.gov.au/
Guideline Advisory Committee, Ontario, Canada	http://www.gacguidelines.ca/
HSTAT – Health Services/Technology Assessment Text	http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat
Human Tissue Authority, United Kingdom	http://www.hta.gov.uk/guidance/codes_of_practice.cfm
Institute of Clinical Systems Improvement	http://www.icsi.org/guidelines_and _more/
King Edward Memorial Hospital for Women, Subiaco, Western Australia	http://www.kemh.health.wa.gov.au/
National Guideline Clearinghouse	http://www.guideline.gov/
National Institute for Clinical Excellence, UK	http://www.nice.org.uk/
Neonatology on the Web	http://www.neonatology.org/
New Zealand Guidelines Group	http://www.nzgg.org.nz/index.cfm?screensize=1024&ScreenResSet=yes
Princess Margaret Hospital for Children, Subiaco, Western Australia	http://www.pmh.health.wa.gov.au/
Queensland Health, Australia	http://qheps.health.qld.gov.au/
Royal Children's Hospital, Melbourne, Australia	http://www.rch.org.au/clinicalguide/index.cfm?doc_id=5033
Royal College of Obstetricians and Gynaecologists, UK	http://www.rcog.org.uk/index.asp?PageID=8
Royal College of Pathologists	http://www.rcpath.org/
Royal Prince Alfred Hospital, Camperdown, New South Wales	http://www.cs.nsw.gov.au/rpa/
Scottish Intercollegiate Guidelines Network (SIGN)	http://www.sign.ac.uk/
Society of Obstetricians and Gynaecologists of Canada	http://www.sogc.org/index_e.asp
Three Centres Collaboration, Australia	http://www.3centres.com.au/
University of California and San Francisco, United States	http://medicine.ucsf.edu/resources/guidelines/
University of Manitoba, Canada	http://umanitoba.ca/

Wisconsin Stillbirth Service Program	http://www.wisc.edu/wissp/
Women's and Children's Hospital, Adelaide, Australia	http://www.wch.sa.gov.au/

The guideline web site search yielded the following 22 guidelines on aspects of perinatal mortality audit:

Association	Guideline
Alberta Medical Association	Alberta Medical Association. Investigation of Stillborn Protocol. In: Alberta Medical Association; 1998 (updated 2005). http://www.albertadoctors.org/bcm/ama/ama-website.nsf/AllDoc/FB1F65D913EDB64787256E2A005E700E?OpenDocument accessed 2008
British Columbia Reproductive Care Program	British Columbia Reproductive Care Program. Perinatal Mortality Guideline 1: The Perinatal Mortality Review Process. British Columbia; 1999. http://www.bcrcp.xplorex.com//sites/bcrcp/files/Guidelines/Pmg/MasterPM1ReviewProcessApril99.pdf accessed 2008
British Columbia Reproductive Care Program	British Columbia Reproductive Care Program. Perinatal Mortality Guideline 2: Hospital Perinatal Mortality Review Committee: Terms of Reference. British Columbia; 1999. http://www.bcrcp.xplorex.com//sites/bcrcp/files/Guidelines/Pmg/MasterPM2TORHospReviewCommApril99.pdf accessed 2008
British Columbia Reproductive Care Program	British Columbia Reproductive Care Program. Perinatal Mortality Guideline 3: Classification of Perinatal Deaths. British Columbia; 1999. http://www.bcrcp.xplorex.com//sites/bcrcp/files/Guidelines/Pmg/MasterPM3ClassifDeathsApril99.pdf accessed 2008
British Columbia Reproductive Care Program	British Columbia Reproductive Care Program. Perinatal Mortality Guideline 4: Clinical Examination of the Placenta. British Columbia; 1999. http://www.bcrcp.xplorex.com//sites/bcrcp/files/Guidelines/Pmg/MasterPM4ExamPlacentaApril99.pdf accessed 2008
British Columbia Reproductive Care Program	British Columbia Reproductive Care Program. Perinatal Mortality Guideline 5: Investigation and Assessment of Stillbirths. British Columbia; 1999. http://www.bcrcp.xplorex.com//sites/bcrcp/files/Guidelines/Pmg/MasterPM5InvestAssesStillbirthsMay2000.pdf accessed 2008
Canadian Paediatric Society	Canadian Paediatric Society Statement. Guidelines for health care professionals supporting families experiencing a perinatal loss. Paediatric Child Health 2001;6(7):469-477. (Re-affirmed May 2007) http://www.cps.ca/english/statements/FN/FN01-02.pdf accessed 2008
South Australian Department of Human Services	Department of Human Services South Australia. Maternal, Perinatal and Infant Mortality in South Australia 2006. Including South Australian Protocol for investigation of stillbirths. In: Department of Human Services, South Australia; 2007. http://www.dh.sa.gov.au/pehs/PDF-files/0712-mortality-report-2006.pdf accessed 2008
Royal Prince Alfred Hospital, Sydney, NSW	Department of Neonatal Medicine RPAH. Stillbirths. In: Central Sydney Area Health Service. http://www.cs.nsw.gov.au/rpa/neonatal/default.htm accessed 2008

Department of Health, UK	DH Clinical Ethics and Human Tissue Branch. Families and post mortems - A code of practice. Best Practice Guideline. London: Department of Health; 2003 April 2003. http://www.dh.gov.uk/assetRoot/04/05/43/12/04054312.pdf accessed 2008
Department of Health, UK	DH Clinical Ethics and Human Tissue Branch. A guide to the post mortem examination procedure involving a baby or child. In: Department of Health; 2003. http://www.dh.gov.uk/assetRoot/04/08/39/60/04083960.pdf accessed 2004
Queensland Department of Health	Queensland Maternal and Perinatal Quality Council. Maternal and Perinatal Mortality Audit: Guidelines for Maternity Hospitals. Queensland: Queensland Government, Queensland Health; 2003.
Royal Children's Hospital, Melbourne, VIC	Kane H, Wilkinson G. Reproductive Loss: Pre 20 Week / Stillbirth / neonatal death / infant death, Melbourne. Melbourne: Royal Children's Hospital, Melbourne; 2003 19/05/2003. Report No.: 9W-04-1-002. http://www.rch.org.au/intranet/policy/9W041002.htm accessed 2004 Not able to be accessed March 2008
Royal Children's Hospital, Melbourne, VIC	Kane H, Wilkinson G. Reproductive Loss: Stillbirth 20 weeks and over, Melbourne. Electronic. Melbourne: Royal Children's Hospital, Melbourne; 2003 17/05/2003. Report No.: 9W-04-2-038. http://www.rch.org.au/intranet/policy/9W042038.htm accessed 2004 Not able to be accessed March 2008
Western Australia Department of Health	McLaughlin V. Non-Coronial Post-Mortem Examinations: Code of Practice 2007, WA: Health Department, WA; 2007. http://www.health.wa.gov.au/postmortem/docs/Non-Coronial_Post-Mortem_Examinations_Code_of_Practice_2007.pdf accessed March 2008
New South Wales Department of Health	NSW Health Department. Stillbirth: Management and Investigation.. Electronic/circular. Sydney: NSW Health Department; 1997 27/10/1997. Report No.: 97/107. http://www.health.nsw.gov.au/policies/pd/2007/pdf/PD2007_025.pdf accessed March 2008
New South Wales Department of Health	NSW Health Department. Hospital Procedures for review and reporting of perinatal deaths. In; 2006. http://www.health.nsw.gov.au/policies/pd/2006/pdf/PD2006_006.pdf accessed March 2008
Royal College of Pathologists, UK	Royal College of Pathologists. Appendix 6: Guidelines for autopsy investigation of fetal and perinatal death. London: Royal College of Pathologists; 2002 Sept 2002. http://www.rcpath.org/resources/pdf/appendix_6.pdf accessed March 2008
Royal Children's Hospital, Melbourne, VIC	Ross J, Smith M, Dutton G. Reproductive Loss: Neonatal / Infant Death. Electronic. Melbourne: Royal Children's Hospital, Melbourne; 1999 18/11/99. Report No.: 9W-04-2-019. http://www.rch.org.au/intranet/policy/9W042019.htm accessed March 2008
King Edward Memorial Hospital, WA	Women's and Children's Health Services WA. Perinatal Death. In: King Edward Memorial Hospital; 2001. http://www.kemh.health.wa.gov.au/development/manuals/guidelines.htm accessed March 2008

Women's and Children's Hospital, Adelaide, SA	Women's and Children's Hospital Adelaide. Perinatal Protocols and Guidelines for Management; 1996. http://www.wch.sa.gov.au/services/az/divisions/wab/deliverysuite/ accessed 2004 Directed to South Australian Government. (below)
Government of South Australia. Department of Health.	South Australian Perinatal Practice Guidelines http://www.health.sa.gov.au/PPG/Default.aspx?tabid=113 accessed March 2008.

Levels of evidence

As defined by "A guide to the development, implementation and evaluation of clinical practice guidelines"[4], http://www.nhmrc.gov.au/publications/synopses/cp30syn.htm

Level I evidence obtained from a systematic review of all relevant randomised controlled trials.

Level II evidence obtained from at least one properly designed randomised controlled trial.

Level III-1 evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).

Level III-2 evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case control studies, or interrupted time series with a control group.

Level III-3 evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group.

Level IV evidence obtained from case series, either post-test or pre-test and post-test.

Although an attempt was initially made to apply the above quality ratings to the available literature, due to limited resources available for development of the guideline combined with the apparent paucity of high quality evidence, it was decided not to continue with this activity. Therefore, recommendations are based on consensus by the Working Party after review of the available information and levels of evidence are not referred to in the guideline.

2. Section notes

Section 2

In the development of this section an attempt was made to obtain all existing national and international guidelines and protocols on perinatal mortality review. The following guideline/policy statements were used as a basis for development of this guideline:

1. Queensland Maternal and Perinatal Quality Council. Maternal and Perinatal Mortality Audit: Guidelines for Maternity Hospitals. Queensland: Queensland Government, Queensland Health; 2003[5].

2. Centre for Epidemiology and Evidence. Deaths - Review and Reporting of Perinatal Deaths. North Sydney: Ministry of Health, NSW; 2011.

3. Perinatal Mortality Guidelines in British Columbia. Vital Statistics. In. Victoria, British Columbia; 1998[6].

Section 3

We would like to acknowledge those who have significantly contributed to the review and update of this section of the guidelines.

First edition: Kylie Lynch, Liz Davis, Sonia Herbert, Ros Richardson, Dell Horey, Vicki Flenady

Second edition: (minor review): Liz Davis, Ros Richardson and Vicki Flenady

Third edition: (major review): Trish Wilson, Belinda Jennings, Diana Bond, Paula Dillon, Fran Boyle

Section 4

This section was first developed by Adrian Charles, Susan Arbuckle, Diane Payton, Vicki Flenady, Jane Dahlstrom, Jane Zuccolo, Yee Khong and Nick Smith.

The main resource documents used in the development of this section were:

1. The Royal College of Pathologists of Australasia Autopsy Working Party. The decline of the hospital autopsy: a safety and quality issue for healthcare in Australia. Med J Aust 2004;180(6):281-5.

2. The Royal College of Pathologists of Australasia. Autopsies and the use of tissues removed from autopsies. In. Sydney: Royal College of Pathologists of Australasia; 2002.

3. The Royal College of Pathologists. Guidelines for Post Mortem Reports. London: The Royal College of Pathologists; 1993.

4. The Royal College of Pathologists. Guidelines on autopsy practice: Report of a working group of the Royal College of Pathologists. In. London: Royal College of Pathologists; 2002.

5. AHMAC Subcommittee on Autopsy Practice. The national code of ethical autopsy practice. Adelaide: SA Department of Human Services; 2002 5 April.

6. SIDS & Kids Australia. SIDS Focussing on Stillbirth: Investigation and Prevention of Stillbirth: Setting the Policy and Research Agenda: SIDS and Kids Australia; 2001 29/11/2001.

7. SIDS & Kids Australia. SIDS and Kids Focussing On Stillbirth: Report from the SOS Pathology Workshop. Sydney: SIDS & Kids Australia; 2002 22 Nov.

8. Royal College of Paediatrics and Child Health. The future of paediatric pathology services: fetal, perinatal and paediatric pathology; a critical future. Report of a working group to restore and develop specialist paediatric pathology: a critically important specialty, essential for the best quality care of children. London: Royal College of Paediatrics and Child Health; 2002 March.

Section 5

A subgroup of the Working Party (Glenn Gardener, Lesley McCowan, James King, Jane Zucculo, Katie Day (nee Waters), Gus Dekker, Hanna Reinebrant, Kimberly Abussi and Vicki Flenady) drew on existing national and international protocols for stillbirth investigation and the findings of a comprehensive literature search in the initial development of this section of the guideline.

The main initial resource documents used in the development of this section were:

1. Queensland Maternal and Perinatal Quality Council. Maternal and perinatal mortality audit: Guidelines for maternity hospitals. Queensland: Queensland Government, Queensland Health; 2003.

2. Department of Human Services South Australia. Maternal, Perinatal and Infant Mortality in South Australia 2002. Including South Australian Protocol for investigation of stillbirths. In: Department of Human Services, South Australia; 2002.

3. Wisconsin Stillbirth Service Program. Guide to etiologic evaluation of the stillborn infant: The WiSSP Protocol. In. Wisconsin: Wisconsin Stillbirth Service Program.

4. British Columbia Reproductive Care Program. Perinatal Mortality Guideline 5: Investigation and Assessment of Stillbirths. British Columbia; 1999.

5. The American College of Obstetricians and Gynecologists. Management of Stillbirth. In: ACOG Practice Bulletin: Clinical management for Obstetricians and Gynaecologists; 2009.

6. Alberta Perinatal Health Program. Stillborn Protocol: Investigation of Stillborn protocol. In Alberta Medical Association, Alberta; 1998.

7. Institute of Obstetricians and Gynaecologists, Royal College of Physicians of Ireland. Investigation and Management of Late Fetal Intrauterine Death and Stillbirth Clinical Practice Guideline; 2011

8. Iowa Department of Public Health. Fetal Death Evaluation Protocol. Iowa State Health; 2011

9. Royal College of Obstetricians and Gynaecologists. Late intrauterine Fetal Death and Stillbirth. In Greentop Guideline No. 55; 2010

10. Maternal Fetal Medicine Committee of Society of Obstetricians and Gynecologists of Canada. Stillbirth and Bereavement: Guidelines for investigation. In: SOGC Clinical Practice Guidelines; 2006

Section 6

A subgroup of the Guideline Working Party worked collaboratively in the development of this Section, the members were: Alison Kent, Lucy Cooke, David Tudehope, Ross Haslam, Jane Dahlstrom and Adrienne Gordon.

Section 7

A subgroup of the Guideline Working Party worked collaboratively in the development of this Section. We wish to acknowledge and Annabelle Chan and James King for their leadership in reaching consensus on the initial PDC system and Ross Haslam and Andy McPhee for development of the NDC. All revisions will be summarized in the Appendix of Section 7.

5. References

1. PSANZ PMN-SIG. Perinatal Society of Australia and New Zealand: Special Interest Group. Australia and New Zealand: PSANZ, 2004.
2. National Health and Medical Research Council. How to present the evidence for consumers: Preparation of consumer publications. Canberra: NHMRC, 1999.
3. National Health and Medical Research Council. 2011. Melbourne: National Health and Medical Research Council; Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines
4. National Health and Medical Research Council. A guide to the development, implementation and evaluation of clinical practice guidelines. Canberra: Commonwealth of Australia, 1998.
5. Queensland Maternal and Perinatal Quality Council. Maternal and perinatal mortality audit: Guidelines for maternity hospitals. Queensland: Queensland Government, Queensland Health, 2003.
6. British Columbia vital statistics agency. Vital Statistics. Victoria; 1998 http://www.vs.gov.bc.ca/.