Clinical Practice Guideline for Care Around Stillbirth and Neonatal Death

Version 3.0, March 2018

Endorsed by

Produced by:

This clinical guideline was produced by the Perinatal Society of Australia and New Zealand(PSANZ) Care around the time of stillbirth and neonatal death guidelines group, under the auspices of the Stillbirth and Neonatal Death Alliance (SANDA) of PSANZ and in partnership with the Centre of Research Excellence in Stillbirth. Support for guideline development was received from PSANZ

Endorsed by:

The clinical guideline has been endorsed by: Australian College of Midwives (ACM); Australian and New Zealand Neonatal Network Stillbirth Foundation Australia; South Australian Maternal and Perinatal Mortality Committee; Tasmanian Council of Obstetric and Paediatric Mortality and Morbidity; Women's Healthcare Australasia

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Disclaimer:

The main objective of the guideline is to assist clinicians in the investigation and audit of perinatal deaths, including communication with the parents, to enable a systematic approach to perinatal mortality audit in Australia and New Zealand. The overall aim is to reduce the risk of perinatal death and provide appropriate assistance to parents.

The guideline is not intended to be prescriptive, but is designed to provide reliable, up-to-date information enabling integration of best evidence, clinicians' judgement and individual choice in arriving at decisions about care. Clinical practice guidelines may be considered as generally recommended practice. Inevitably, given the nature and sensitivity of the subject and the lack of high quality studies, some contentious issues remain. The Working Party welcomes comments which will assist with further refinement of the Guideline in the future. Comments should be sent to Vicki Flenady, Email: stillbirthcre@mater.uq.edu.au with 'Clinical Practice Guideline for Care Around Stillbirth and Neonatal Death' in the subject line.

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SECTION 1
OVERVIEW AND SUMMARY OF RECOMMENDATIONS

1.1 Introduction

The loss of a child who is either stillborn or dies in the neonatal period has enormous psychosocial impact on parents and their care providers[1], and wide-ranging economic impact on health systems and society at large[2]. The care that parents receive is critically important to how they cope with this tragedy [2]. However, care often does not meet parent's needs.

Stillbirths make up the majority of perinatal deaths where efforts to improve the quality of data on causes and contributing factors is critically important. Many stillbirths are not appropriately investigated or classified in terms of their cause, with around 50% at term classified as "unexplained"[3]. The lack of a diagnosis adds to parents' distress, as they struggle to understand "what went wrong" and "will it happen again" in a subsequent pregnancy. In 20-30% of stillbirths, deficiencies in the quality of care are implicated. National perinatal mortality audit programs can help to reduce these deaths[4,5].

This update of the guideline has been undertaken through a partnership between PSANZ and the NHMRC Stillbirth Centre of Research Excellence in Stillbirth.

For further assistance and clarification in this section of the PSANZ Clinical Practice Guideline for Care Around Stillbirth and Neonatal Death, see *Appendices A – Y*.

1.2 Objective of the guideline

The overarching objective of the PSANZ Clinical Practice Guideline for Care Around Stillbirth and Neonatal Death is to ensure best practice across Australia and New Zealand (ANZ) around the time of a perinatal death to improve maternity and newborn care for bereaved parents and families and to improve the quality of data on causes of stillbirth and neonatal deaths through appropriate investigation, audit and classification.

With effective implementation of this guideline the anticipated benefits are:

- Effective monitoring to reducing perinatal deaths;
- Increased understanding of causes to further reduce perinatal deaths; and
- Better care and outcomes in future pregnancies.
- Improved psychosocial outcome for parents and families;

1.3 Intended audience

The intended audience for the guideline is clinicians providing maternity and newborn care in hospitals in Australia and New Zealand.

1.4 Structure of the guidelines

This first section contains an overview of the guideline including a summary of key recommendations. The guideline is presented in 7 Sections as follows:

Section 1 - Overview and summary of recommendations;

Section 2 - Institutional perinatal mortality audit;

Section 3 - Psychological and social aspects of perinatal bereavement;

Section 4 - Perinatal autopsy examination;

Section 5 - Investigations for stillbirth;

Section 6 - Investigation of neonatal deaths; and

Section 7 - Perinatal mortality classifications.

Resources are provided to assist clinicians in implementation of the recommendations and to enhance the quality of information available for audit and research activities. To ensure the guideline remains relevant and useful, review, and revision as required, is planned as a minimum every two years. To ensure the most up-to-date version of the guideline is easily accessible, the guideline will not be produced as a bound document but rather each section will be made available in a downloadable format from the Stillbirth CRE (https://www.stillbirthcre.org.au/) and PSANZ website: https://psanz.com.au/

1.5 Definitions of stillbirth and neonatal death

Differences in definitions and reporting processes across regions within ANZ make comparisons of perinatal mortality rates difficult, and it is hoped that these differences will be addressed by the various reporting agencies.

In Australia, according to the Australian Institute of Health and Welfare (AIHW)[6], perinatal deaths consist of stillbirths (the death of an unborn baby at 20 or more completed weeks gestation or at least 400 grams birthweight) and neonatal deaths (the death of a live born baby within 28 days of birth). However regional differences exist.

In New Zealand, perinatal death consists of fetal death (the death of a fetus of from 20 weeks gestation or weighing at least 400 grams if gestation is unknown[7]) and early neonatal death (the death of a liveborn baby that occurs before the 7th day of life[5]). Perinatal related mortality is fetal and neonatal deaths (up to 28 days) at 20 weeks or beyond, or weighing at least 400g if gestation is unknown. Fetal death includes stillbirth and termination of pregnancy[8].

Please refer to *Appendix T – Australian and New Zealand definitions of perinatal mortality* for a summary of definitions across the jurisdictions.

1.6 Rates and causes of stillbirth and neonatal death

Australia and New Zealand have one of the lowest perinatal mortality rates in the world, however areas for further improvement are clear; notably the slow progress in reducing the rates of stillbirth - similar to many high income countries[9]. Stillbirths make up the majority of perinatal deaths and have been identified as an unaddressed global public health problem[10,11]. In Australia and New Zealand, one in 165 women who reach 20 weeks gestation will have a stillbirth and for many, the loss occurs unexpectedly towards the end of pregnancy and a cause in never identified[5,12-14].

At the time of updating these guidelines, the most recent national data available in Australia was for the year 2014[6] where there were 312,548 births, and 2986 perinatal deaths giving a perinatal mortality rate (PMR) of 9.6 per 1000 births including 2200 stillbirths (7.0 per 1000 births) and 786 neonatal deaths (2.5 per 1000 livebirths). The first comprehensive report on stillbirths was in Australia was in 2014[15] and for perinatal deaths was released in 2016 covering the period 1993–2012[16].

In New Zealand in 2014, there were 58,647 births and 656 perinatal deaths, giving a PMR of 11.2 per 1000 (8.1 and 3.1/1000 for fetal and neonatal death rates respectively)[5].

For Indigenous and other disadvantaged women in both settings (similar to other high income settings), the risk of perinatal death is around double[5,6,9,17].

Using the PSANZ classification system the leading causes of stillbirth are congenital anomaly and spontaneous preterm. However in approximately 20-30% of stillbirths, a cause is never identified. Similarly, for neonatal mortality, the main cause of death using the PSANZ PDC is congenital anomaly and spontaneous preterm[16].

Contributing factors relating to care (also called sub-optimal, avoidable or suspected preventable factors) have been reported in approximately 30-50% of perinatal deaths[5,18-20]. Recent reports have reinforced that prevention is possible and that there is clear potential to reduce these deaths through improved quality of care driven by high quality perinatal mortality audit (e.g. the Bacchus Marsh enquiry into cases of substandard care in Victoria, the perinatal mortality report from Western Australia[21], and the confidential enquiries from the UK[22] and NZ[8]).

1.7 Changes in this update

In this update, revisions have been made to all sections apart from Section 3 Psychological and social aspects of perinatal bereavement (previously updated in 2014, Version 3.0), which will be completed by December 2017. The changes are listed within each of the sections.

1.8 Summary of key recommendations

Section 2: Hospital Perinatal Mortality Audit

Section 2 Recommendations

1	All hospitals where births occur should implement a formal process for perinatal mortality audit of all perinatal deaths occurring in that hospitals. The process should be overseen by an interdisciplinary Perinatal Mortality Steering Committee.
2	Staff should be provided with appropriate training on best practice around the time of a perinatal death through the IMPROVE Program and access to support.
3	The review of perinatal deaths should occur as soon as possible after the death aiming to have results in time for the initial follow-up visit with parents. It may be necessary to re-review the death if test results are delayed.
4	A comprehensive clinical summary, including a detailed interview with the mother as soon as possible after the death, should be completed for every perinatal death to facilitate institutional audit using the recommended paper-based form or on-line tool (APMAT) which, following the completion of the audit, should be provided to the jurisdictional perinatal mortality council or respective body. Clinicians should ensure clear and accurately documentation in the medical record at the time of the event to facilitate this process.
5	The perinatal mortality audit meetings should have an experienced chairperson capable of ensuring a no-blame environment within an appropriate legal framework.

6	As part of the audit meeting, the PSANZ Classification system should be used to assign the cause of death and associated conditions for every perinatal death
7	As part of the audit meeting, the presence of contributing factors relating to care should be assessed and documented for every perinatal death using the format recommended in this guideline.
8	Recommendations emanating from the audit process should be carefully developed and accompanied by an implementation plan which should be completed within a nominated time frame e.g. following the PDSA and SMART cycles.
9	Initiate discussions with parents as soon as possible after the perinatal death, using an open disclosure framework
10	Senior clinicians should schedule follow-up meetings with the parents following perinatal death when relevant tests and reviews are complete, involving other specialists and additional investigations if indicated.
11	Senior clinicians should notify the General Practitioner and other relevant care providers of the death as soon as possible and a comprehensive clinical summary sent to them promptly after the audit meeting.
12	The Consultant responsible for care should complete or supervise completion of the Medical Certificate of Perinatal Death. The death certificate should be revised as required based on the outcome of the perinatal mortality audit meeting.
13	To ensure consistency and comparability in perinatal death data across ANZ, the definitions recommended in this guideline are used including presenting data with and without the inclusion of perinatal deaths resulting from termination of pregnancy.

Section 3: Psychological and social aspects of perinatal bereavement

Section 3 Recommendations

Section 3 recommendations as per the Perinatal Society of Australia and New Zealand Clinical Practice Guideline for Perinatal Mortality; Third Edition, Version 3, 2014

1 ***Respect:***

- For baby: deceased baby to be treated with same respect as live baby.
- For parents: parents need to feel supported and in control; death validated.
- Cultural/religious practices: different approaches to death and rituals respected.

2 ***Provision of information***

- Timing of information: allow plenty of time to discuss issues at most appropriate time.
- Delivery of information: clear, honest and sensitive. Repeat important information. Ensure both parents are present Mode of information: fact sheet/written information given for frequent reference Withdrawal of support: parents given prognostic information to reach decision.
- Terminology: parent friendly language. Do not use terms such as fetus Post-mortem examination: verbal and written information given. Allow time for discussion.

3 ***Birth options***

- Timing: ascertain appropriate time to discuss birth options following determination of a fetal death in utero or abnormalities.
- Mode of delivery: benefits of birthing options given.

4 ***Time***

- Parents are given time to make decisions.
- Inform parents of how much time can be spent with baby.

5 ***Hospital stay***

- Environment: parents are given the option of a private room in surgical, maternity or gynaecological ward.
- Universal symbol placed outside room to alert all staff of death.

6 ***Creating memories***

- Spending time with baby: no hurry to leave baby or hospital. Option to take baby home**.**
- Parenting baby: inform parents that they can hold, undress, bath baby.
- Mementos: helpful for long-term grief outcome.
- Baptism/blessing: inform parents that this can be arranged through the hospital.

Special circumstances

- Multiple Pregnancies: special care is required in the circumstance where some infants in a multiple pregnancy survive.
- Maternal illness: consideration given regarding access to baby/memory creation. Previous perinatal/child death: consider impact of previous death/s on emotional response to and coping with current death.

Aftercare

- Maternal changes: advise on milk production and methods to manage supply.
- Support services for parents and children: written information given regarding available support services for parents and children.
- Grief: inform parents of expectations of grief journey
- Follow up/Appropriate referral: expectations for 6 week check up – other babies present.

Autopsy

- Parents given choice of funeral director
- No urgency to organise funeral
- Continued access to baby if desired

Health care professionals

- Education: specific training in support skills given to relevant staff.
- Access to support: debriefing/support services available to staff working with perinatal death.

Section 4: Perinatal Postmortem Examination

Section 4 Recommendations

1	Clinicians should discuss the value of an autopsy with parents in all cases of perinatal death and offer them the option of the procedure.
2	To increase the rates of perinatal autopsy: • Clinicians should collaborate with pathologists and parent based organisations to raise public awareness of the value of perinatal autopsy and to advocate for high standards in perinatal autopsy at local and government level. • Clinical leaders should promote formal and informal educational opportunities for clinicians on: post-mortem examination procedures; the potential benefits of an autopsy; compassionate counselling and obtaining parental consent; and address specific local barriers to the conduct of perinatal autopsy. All clinicians providing maternity and newborn care should attend the IMproving Perinatal Mortality Review and Outcomes Via Education (IMPROVE) Workshops educational program (https://sanda.psanz.com.au/improve/).
3	Seek advice from the coroner or an experienced coronial officer if any doubt exists as to whether a death should be referred to the coroner.
4	Clinicians need to be aware of costs associated with transferring an infant from non-metropolitan areas to tertiary centres for autopsies within their region and inform parents of any personal cost implications relevant to their decision-making.
5	The Guidelines on Autopsy Practice produced by the Royal College of Pathologists[23] should be used for guidance on minimum standards until guidelines for Australia and New Zealand are developed.
6	Specific protocols developed for post-mortem examination in the event of Sudden Unexpected Death in Infancy and death with suspected genetic metabolic disorders should be followed.
7	A perinatal/paediatric pathologist should perform or supervise all perinatal post-mortems. Clinicians should request autopsies from the service providing the highest quality.
8	Transport to a centre with appropriate expertise should be arranged to ensure that all perinatal post-mortem examinations are of sufficient quality. Transport should be arranged with a registered undertaker.
9	A comprehensive maternal history should accompany the baby for a post-mortem examination including: • Clinical/obstetric history including relevant previous obstetric history • Copies of all ultrasound reports • Copy of the death certificate if available • Copy of amniocentesis report if available.

10 Guidelines for post-mortem reports produced by the Royal College of Pathologists[24] should be used as a guide for reporting of perinatal post-mortem examinations.

11 Ideally, a preliminary post-mortem report should be forwarded to the referring clinician within three working days of the post-mortem. The final report should be forwarded to the referring clinician ideally within eight weeks of the autopsy.

12 The post-mortem report should be made available to the parents at a time when the primary care clinician is present to discuss the findings.

13 A Plain Language Report (PLR) should be available to parents on request.

14 A request for the General Practitioner (GP) to receive a copy of the report (including the PLR, if available) should be explicit on the request form, as they are the main care provider on discharge.

15 Where possible, a senior clinician who has established a rapport and understanding with the parents should discuss the value of an autopsy and offer the option of the procedure. Such clinicians should have high level communication skills and knowledge of all post-mortem examinations, and preferably witnessed several perinatal autopsies.

16 Any clinician approaching parents for autopsy consent should discuss:

- Options for full, Less invasive autopsies (LIA), minimally invasive autopsies (MIA), Non-invasive autopsies (NIA) or stepwise post-mortem examinations
- Issues related to retained tissues, organs and DNA for genetic and other tests
- The value of autopsy
- Possibility that cause of death may not be determined
- Possibility that some potential causes of death could be excluded
- Information gained may not directly benefit the family but may benefit others
- Possible implications for future pregnancies
- The care and respect that will be given to the baby

17 Discussion with parents should be supplemented by written information explaining autopsies to help in their decision on autopsy for their baby.

18 When consent is obtained for specific organ/s to be retained for further examination, parents should be offered the option of either delaying the funeral until the organs can be returned to the body or specifying their preferred method of organ disposal.

19 Consent for the autopsy which clearly outlines the extent of the investigation should be recorded on an approved consent form, relevant to the jurisdiction.

20 Where possible the pathologist should be available to discuss the autopsy with the parents before and/or after the procedure and, where feasible, the requesting clinician should attend the autopsy and provide the parents with a preliminary report immediately after the examination.

21	Placentas should be sent for examination by the perinatal/paediatric pathologist regardless of whether consent for an autopsy has been gained following stillbirths, neonatal deaths in the delivery room or birth of high risk infants.
22	Consent should be sought from parents for less invasive testing if permission for an autopsy is not obtained, including: external examinations by skilled clinician; an MRI scan; babygram; ultrasound scan; post-mortem needle biopsy; laparoscopic autopsy and small incision access.
23	When an MRI scan is undertaken it should be undertaken as soon as possible after a stillbirth.

Section 5: Investigations for Stillbirth

Section 5 Recommendations

1 A non-selective approach according to the recommended core investigations should be adopted for all stillbirths (unless the cause of death has been unequivocally determined antenatally). These investigations are:

- Comprehensive maternal (medical, social, family) and pregnancy history
- Kleihauer-Betke test/Flow cytometry for fetal to maternal haemorrhage
- External examination of the baby performed by the attending clinician
- Clinical photographs of the baby
- Autopsy
- Detailed macroscopic examination of the placenta and cord
- Placental histopathology
- Cytogenetics (Chromosomal microarray (CMA) or karyotype if CMA is not available).

2 Further sequential and/or selective investigations should be undertaken according to the particular clinical scenario based on a comprehensive history, and information gained from core investigations.

3 An external examination of the baby should be performed at birth by the attending clinician using the recommended checklist *(Please refer to Appendix D – Clinical examination of baby checklist)* and clearly documented in the medical record. Where the family has consented to autopsy, all information gained from the initial external examination (along with comprehensive maternal (medical, social, family) and pregnancy history) should be forwarded to the pathology service to guide this procedure.

4 Following a stillbirth, the placenta, membranes and cord should be kept refrigerated and, where feasible, sent fresh and unfixed for macroscopic and histological examination by a perinatal pathologist. The pathology service should be informed if the parents have requested return of the placenta following examination.

5 Clinicians should discuss the value of a full autopsy with parents in all cases of perinatal death where the cause of death is not already known. If the parents decline a full autopsy, a limited/partial autopsy should be offered.

Section 6: Investigations of Neonatal Death

Section 6 Recommendations

1	Obstetric and neonatal care teams should collaborate closely to ensure that all relevant maternal (pregnancy and birth) and neonatal factors are considered in the investigation of the neonate. Comprehensive maternal medical, social and antenatal history including results of all investigations documented in the medical record by obstetric staff. A comprehensive neonatal history including death scene analysis is always required.
2	A detailed external examination of the baby must be performed by a perinatal pathologist, neonatologist or paediatrician where possible. *(Please see Appendix D – Clinical examination of baby checklist).*
3	Accurate anthropometric parameters of birth weight, length and head circumference plotted on appropriate gender specific birth growth charts.
4	A newborn screening blood sample should be taken for all neonatal deaths.
5	Clinicians should discuss the value of an autopsy with parents in all cases of a neonatal death and offer the option of the procedure. *(Please see Section 4; Perinatal postmortem examination).*
6	Following consent from the parents, clinical photographs should be taken for later review, particularly in the circumstance of birth in non-tertiary hospital settings. These photos are additional to the bereavement photographs, and should be clearly labelled and filed in the medical record (not given to the parents) and be available for members of expert PNM committee to view The use of digital imaging for this purpose is optimal, however issues regarding storage and patient confidentiality mustbe considered.
7	For neonates at high risk of death at the time of birth, or in birth suite, targeted investigations based on the presenting scenario should be undertaken. • Detailed external examination of the baby by a neonatologist or paediatrician (where possible) with clear documentation of findings in the medical record • Where possible, cord blood gas analysis that includes both arterial and venous samples • Newborn screening blood sample • Detailed macroscopic examination of the placenta and cord with findings documented in the medical record by obstetric staff • Histopathological examination of fresh and unfixed placenta, cord and membranes. • Autopsy.
8	Clinicians should initiate investigations specific to the circumstances of the birth (*see Section 6.7 for targeted investigations*).

9 Clinicians should investigate possible thrombophilic disorders in mothers with preeclampsia or with a personal/family history of thrombosis, or following the birth of an infant with severe growth restriction.

10 Selective screening in addition to placental examination for thrombophilic disorders should be undertaken following the birth of high risk neonate or a neonatal death:

- Anticardiolipin, lupus anticoagulant, anti-B2 glycoprotein-1 antibodies
- Microarray/karyotype
- Autopsy

11 Investigation for maternal diabetes, if not previously undertaken, should include:

- Maternal HbA_{1c} level (as soon as possible after delivery); and
- If the HbA_{1c} level is raised, a fasting blood glucose should be undertaken and, if abnormal, a glucose tolerance test performed 6-8 weeks postnatally.

12 Other causes of macrosomia, such as Beckwith Wiedemann syndrome, should be investigated if there is no maternal or paternal diabetic history.

13 In the case of a suspected genetic metabolic disorder, Clinicians should discuss individual cases with their State Laboratory to identify the optimum tests to request and consult a clinical metabolic specialist if more expert guidance required.

14 All tissue samples should be stored and transported to a Specialist Metabolic Laboratory for investigation.

15 When a lethal genetic metabolic disorder is suspected prior to birth, clinicians should:

- Seek consent from the parents for a metabolic autopsy
- Consult a metabolic physician or a histopathologist before collecting the following samples:
  - Blood sample (0.8ml) in lithium heparin tube (refrigerate)
  - Urine sample (5-10ml)
  - Knee cartilage and/or skin biopsy (3 x 2 mm punch biopsies) (sent to cytogenetics with request for fibroblast culture and store)
- Liver and muscle biopsies (for electron microscopy, histopathology and enzymology).

16 Investigation of any sudden unexpected neonatal death should include:

- Coroner notification
- Thorough maternal and infant medical histories
- Full autopsy examination by a forensic pathologist skilled in perinatal autopsy or a forensic pathologist in conjunction with a perinatal pathologist
- Investigation of the various scenes where incidents leading to the death might have occurred including the infants sleeping environment.

17 Investigations for genetic metabolic disorders should be undertaken for all sudden unexpected neonatal deaths.

Section 7: Perinatal Mortality Classification

Section 7 Recommendations

1	All stillbirths and neonatal deaths should be classified according to the PSANZ SB&ND classification system to identify a single underlying cause of death for both stillbirths and neonatal deaths.
2	Following classification of a single underlying cause, up to two associated factors which contributed to the death (i.e. not considered as the underlying cause) should be classified using the PSANZ SB&ND associated conditions list.
3	The classification of stillbirths and neonatal deaths should be based on the best available information from a comprehensive history and appropriate investigation (as recommended in Sections 4 and 5 of this guideline) and should form part of a formal institutional clinical audit process as outlined in Section 2 of this guideline.
4	The classification should be included in the routine perinatal data collections across jurisdictions for every perinatal death to enable comprehensive reporting regionally and nationally including disaggregation and identification of timing of the death (i.e. antepartum, intrapartum, early and late neonatal deaths).
5	Following application of the PSANZ SB&ND system, mapping to ICD-PM categories should be undertaken to enable high quality global reporting.

1.9 References

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1.10 Appendices

Appendix A – Stillbirth investigations algorithm

Appendix B – Estimation of severity of feto-maternal haemorrhage

Appendix C – Placental examination; Accoucheur flow chart

Appendix D – Clinical examination of baby checklist

Appendix E – Australian perinatal mortality audit tool

Appendix F – New Zealand rapid reporting form for a perinatal death - baby

Appendix G – New Zealand Rapid reporting form for a perinatal death - mother

Appendix H – Instructions on taking clinical photographs

Appendix I – Autopsy clinical summary form

Appendix J – Perinatal mortality classifications: Quick reference sheet

Appendix K – WHO mortality audit meeting code of practice declaration

Appendix L – Birthweight percentiles

Appendix M – Infant autopsy consent brochure

Appendix N – Information for health professionals seeking consent

Appendix O– RCPath Guidelines for Autopsy Investigation of Fetal and Perinatal Death

Appendix P – Placental histopathology reporting form

Appendix Q – Suspected genetic metabolic disorders

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Appendix T – Australian and New Zealand definitions of perinatal mortality

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Appendix W – Methods

Appendix X – Glossary of terms and abbreviations

Appendix Y – Contact details and regional coordinators 2018