Stillbirth
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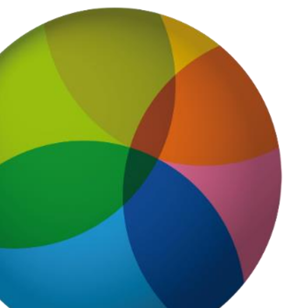
NHMRC Centre of Research Excellence in Stillbirth

Report on the 2015 Stillbirth CRE Priority Setting Exercise

Version 1



Publication details

Publication title: NHMRC Centre of Research Excellence in Stillbirth Report on the 2015 Stillbirth CRE Priority Setting Exercise

Published: January 2019

Publisher: NHMRC Centre of Research Excellence in Stillbirth

Suggested citation: Flenady V, Boyle FM, Schirmann A, Wojcieszek AM, Horey D, Ellwood D, on behalf of the priority setting working group. NHMRC Centre of Research Excellence in Stillbirth Report on the 2015 Stillbirth CRE Priority Setting Exercise. January 2019. Brisbane: NHMRC Centre of Research Excellence in Stillbirth.

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Background

Globally, over 3 million women each year have a stillborn baby; the majority preventable through known effective interventions. While the global burden of stillbirth lies predominantly in low- and middle-income countries, more than 2,000 stillbirths occur each year in Australia and New Zealand, reflecting stillbirth rates that are approximately 30% to 50% higher than the best performing country (Flenady et al., 2011; Flenady et al., 2016). In Australia, almost 3,000 families each year suffer this loss, and there has been no improvement in stillbirth rates for over 20 years. One in every 137 women who reach 20 weeks' gestation will have a stillborn child (Li, Zeki, Hilder, Sullivan, 2013). In Australia, while our research team has reported some recent improvements (Oliver et al., 2015), the stillbirth rate for Aboriginal and Torres Strait Islander women is almost double that of non-Indigenous women (Flenady et al., 2016; Ibiebele, Coory, Boyle, Humphrey, Vlack, Flenady, 2015). Stillbirth rates have shown little or no improvement, in contrast to neonatal death rates, which continue to decline. Globally, suboptimal data on causes and contributing factors and inadequate methods to detect women at increased risk are major obstacles to further reductions in stillbirth (Flenady et al., 2011; Flenady et al., 2016).

The 2011 and 2016 Lancet series on stillbirths brought attention to stillbirth, highlighting fatalism and stigma as major issues inhibiting action to reduce these deaths. In the lead up to the publication of the 2016 series (see https://www.thelancet.com/series/ending-preventable-stillbirths), the need to capitalise on progress and respond to the call-to-action in Australia was clear. As an already active collaboration of researchers, care providers, parents, stillbirth advocates and others, we initiated a priority setting exercise to accelerate progress on addressing stillbirth in the Australian context. The aim of this priority setting exercise was to establish of a set of agreed research priorities to guide a targeted and coordinated research agenda, which would also form the foundations of a bid for funding from the Australian National Health and Medical Research Council (NHMRC) to establish a Centre of Research Excellence in stillbirth (The Stillbirth CRE). In addition to establishing research priorities (unanswered questions that need to be addressed), we aimed to identify user-defined action priorities (implementable practices known to be beneficial). These action priorities served to highlight gaps in current practice and to identify effective strategies for the implementation of best practice, such as education, and changes to guidelines and policies.

In line with the NHMRC statement on consumer and community involvement in health and medical research (NHMRC, 2016), incorporating the views and gaining the endorsement of parents, care providers, and researchers in Australia was recognised as essential to ensuring a relevant and meaningful research program. Therefore, at the core of the priority setting methodology was the engagement of parents and other end-users of research and actions to address stillbirth.

The priority setting process

Establishment of the research and action priorities underpinning the Stillbirth CRE was achieved via two major consultation activities. First, data from large-scale surveys of parents and care providers, initiated as part of the 2016 Lancet series on Ending Preventable Stillbirths, were analysed to extract preliminary research questions. These research questions were then refined with the assistance of invited stakeholders through a one-day priority setting symposium. Detailed methods are described below.

The Lancet Ending Preventable Stillbirths Series surveys

Multi-language web-based surveys of parents, care providers, and general community members were administered as part of the 2016 Lancet series on Ending Preventable Stillbirths (see Flenady et al., 2016 for more information and methods). The surveys were broad in content, measuring knowledge of stillbirth risk factors and prevention strategies, experiences of antepartum and bereavement care, processes for the investigation of stillbirth, stillbirth auditing procedures, among other constructs. The surveys concluded with two open-ended questions addressing **Research Priorities** (e.g. *"What do you think we still need to know more about to help prevent stillbirth, and/or to help parents who have a stillborn baby?"*) and **Action Priorities** (e.g. *"What about the knowledge we already have? What do you think should happen now with what we already know to prevent stillbirth, improve management and improve bereavement and postnatal care?"*).[1] Participants could type as little or as much as they liked in response to these questions.

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[1] Survey items were worded slightly differently depending on the intended participant (i.e. parent, care provider, or community member).

The surveys yielded 6636 responses across 32 high-income countries (Flenady et al., 2016). For the current exercise, a subset of data from 497 parents and 638 care providers in Australia and New Zealand was analysed and major questions identified as described below.

Data Analyses

Synthesis of data obtained via the open-ended questions on research and action priorities was undertaken to determine answerable questions, aiming to identify the top 20 priorities (approximately 10 relating to research and 10 relating to action). Microsoft Excel was used to organise, code and collate the data. A coding frame was developed to categorise responses according to an agreed set of categories. These categories were based on an initial detailed reading of a subset of 200 responses, the 2011 Lancet stillbirth series, and expert opinion. Three overarching categories were established to capture the full set of responses: *Aftercare; Prevention;* and *Investigation.* Each of these headings was then subdivided into two further subcategory levels that contained more detailed coding categories based on analysis of the content of responses. For example: *Prevention -> Screening -> USS; Aftercare -> Best Practice -> Hospital*. Developing a coding frame to account for the responses contained in the dataset was necessarily an iterative process, with new codes added to the preliminary set of codes where needed, and the expanded set of codes discussed among members of the research team, agreed and applied. As coding was time-intensive due to both the volume of responses and the complexity and subjectivity of many responses, multiple coders representing multiple disciplines, both clinical and non-clinical, independently coded and then collectively reviewed subsets of the data to establish and maintain consistency and ensure rigour and validity.

Priority setting symposium

The priority setting symposium was held on Sunday 12th April 2015 in Brisbane, as a satellite meeting prior to the Royal College of Obstetricians & Gynaecologists World Congress. This one-day symposium, titled *'Reducing stillbirth and its aftermath in Australia and New Zealand; what needs to happen now?'* brought together a multidisciplinary group of individuals with an interest in stillbirth, including prevention, bereavement care, data quality improvement, raising public awareness, and more.

The symposium opened with a summary of priorities emerging from the Lancet survey data, presented Associate Professor Fran Boyle. The remainder of the symposium was structured

into three sections, corresponding roughly to the three overarching data categories. An introduction was presented for each section by an invited symposium facilitator with expertise in the given area, after which specific priorities were proposed and finessed as part of break-out groups. The symposium agenda and facilitators are presented in Appendices A and B, respectively.

Participants

Symposium participants were identified through the existing collaborative research networks of the research team and, in particular, the Perinatal Society of Australia and New Zealand Stillbirth and Neonatal Death Alliance (PSANZ-SANDA). Members of the PSANZ consumer advisory panel were also invited to participate, along with relevant consumer organisations such as Stillbirth and Newborn Death Support (Sands) and Red Nose (formerly SIDS and Kids). Organisations were contacted via their most senior gatekeeper (e.g., CEO) with details of the symposium and were asked to nominate an appropriate representative if they were not able to attend the symposium themselves. Specific representation from Indigenous groups was also sought through existing networks within The University of Queensland and The Institute for Urban Indigenous Health in Brisbane, as part of the Indigenous Reference Group for Stillbirth Prevention that had been established at Mater Research.

Selection of priorities

The research priority list presented to participants included 20 preliminary research priorities. Participants chose their top five research priorities, following discussion of each individual question as part of the large group. Each question was written down (with any resultant rewording from the discussion) and attached to butchers' paper placed on the wall. Each participant was given five coloured dots, which they placed beside their top five research priorities (see image).

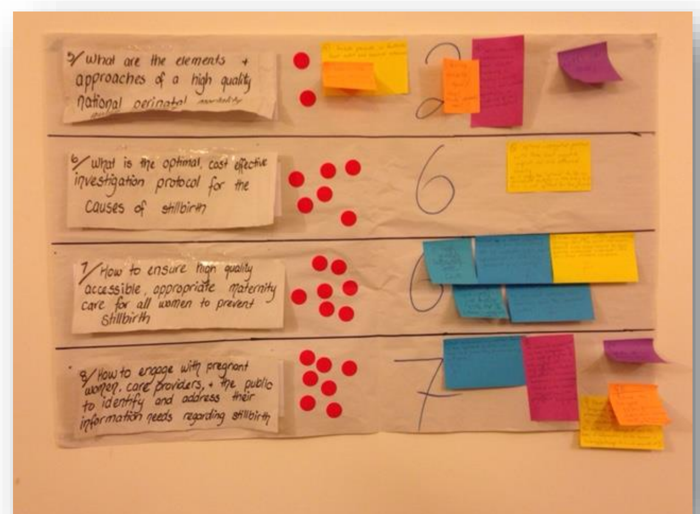

Image: Butchers' paper and coloured dots used for voting

Selected priorities

The research priority list was refined from 20 to 17 items. Original items, preliminary revised wording, arising comments, and number of votes attached to each of the 20 preliminary priorities are presented in Appendix C, alongside the extra research questions and cross-cutting issues that emerged.

The number of votes received for the given priorities ranged from 0 to 16. The highest-ranking priorities, which received 10 votes or more, centred on identifying optimal approaches to bereavement care and care in subsequent pregnancies; improving prediction of late-gestation stillbirth and appropriate timing of delivery; improving the detection of fetal growth restriction; identifying major modifiable stillbirth risk factors; and understanding pathways to unexplained and late-gestation stillbirth.

Wording of priorities was further refined by the study group following the symposium. The final list of 17 research priorities is presented below.

Care after stillbirth

1. What are the elements of optimal **care for parents and families following a stillbirth**?
2. What **education/training** is needed for clinicians – what are the gaps?
3. What are the **psychosocial effects** of stillbirth on parents and families?
4. How can we optimise parental and baby outcomes in **subsequent pregnancies** following stillbirth?

Investigation

5. What are the elements and approaches of a high-quality national **perinatal mortality audit program**?
6. What is the optimal, cost-effective **investigation protocol** for investigating the causes of stillbirth?

Prevention

7. How can we ensure **high-quality, accessible, appropriate maternity** care for all women to prevent stillbirth?

8. How can we engage with pregnant women, care providers, and the public to identify and address **information needs**?
9. What are the possible causal pathways of **unexplained and late pregnancy stillbirth**?
10. What are the underlying **root causes** of stillbirths that have known direct causes e.g., placenta abruption, pre-eclampsia?
11. Does increasing awareness and encouraging **maternal reporting of decreased fetal movement** reduce stillbirth?
12. What are the effective strategies to improve detection and management of **fetal growth restriction**, and can these reduce stillbirth?
13. What are the placental and cord pathologies that cause or contribute to stillbirth?
14. Can **screening in early pregnancy** accurately quantify and reduce the risk of stillbirth?
15. What are the major **modifiable risk factors** for stillbirth?
16. How can the **risk of stillbirth for obese women** be reduced?
17. For which women, and when, does **early planned birth** to prevent stillbirth versus expectant management have more benefit than harm?

Agreed next steps

Although some Indigenous representation had been successfully sought prior to the symposium, the need for wider consultation with Indigenous families and their care providers was acknowledged. It was agreed at the conclusion of the symposium that further engagement with these and other disadvantaged groups via a tailored consultation process should be carried out in the next round of priority-setting.

The Stillbirth CRE plans to lead this next round of priority setting during or before 2020 to renew priorities in alignment with the latest research and emerging areas of need, including prevention of stillbirth and culturally-appropriate care after stillbirth for Indigenous families.

Acknowledgements

We thank the following collaborators for attending the priority setting symposium:

- Frank Bloomfield: Professor of Neonatology and Consultant Neonatologist at the University of Auckland
- Stephanie Brown: Social Epidemiologist at Murdoch Children's Research Institute (expertise in social inequities in health including Indigenous health)
- Catherine Chamberlain: Evidence-based practice specialist at La Trobe University (expertise in program evaluation, public health equity, and Indigenous health)
- Kate Cowmeadow: State Manager of SANDS Queensland
- Melinda Cruz: CEO and Founder of Miracle Babies
- Heather D'Antoine: Division leader of Education and Capacity Building and associate director for Aboriginal Programs; Menzies School of Health Research
- Natasha Donnolley: Health Information Manager at the National Perinatal Epidemiology and Statistics Unit and PSANZ consumer advisory panel chair
- Christine East: Professor of Midwifery and Clinical Research at Monash University
- Adrienne Gordon: Neonatologist at the Royal Prince Alfred Hospital and NHMRC Early Career Fellow at the University of Sydney
- Jill Green: General Manager of Research, Advocacy and Change, Red Nose (formerly SIDS & Kids)
- Jan Hamill: Ethnographer at The University of Queensland (expertise in epigenetic and developmental influences of health especially for Indigenous families and children)
- Nicole Ireland: President of SANDS Queensland
- Kay Jones: Midwifery Lecturer at Griffith University
- Sue McDonald: Professor of Midwifery at La Trobe University and Mercy Health
- Lesley McCowan: Professor of Obstetrics and Gynaecology at the University of Auckland
- Kelly Merchant: Counsellor and Support Services Coordinator at Bears of Hope
- Philippa Middleton: Associate Professor, Perinatal Epidemiologist and Implementation Scientist, South Australian Health and Medical Research Institute (SAHMRI) and School of Medicine, The University of Adelaide
- Heidi and Ned Mules: Brisbane-based bereaved parents of baby Sophie (stillborn in 2011)

- Patricia Wilson: Bereavement Midwife at Mater Mothers' Hospital
- Anne Tremellen: Clinical Trials Manager, Mater Mothers' Hospital
- Sue Vlack: Public Health Physician and Health Services Researcher at The University of Queensland (clinical experience in Indigenous community Women's and Children's Health)
- Sue Walker: Professor of Obstetrics and Gynecology and Director of Perinatal Medicine at the Mercy Hospital for Women

Financial support

We thank Heidi and Ned Mules for their fundraising efforts, and the Perinatal Society of Australia and New Zealand (PSANZ) and Mater Research Institute for providing financial and in-kind support for this symposium.

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Appendix A. Priority setting symposium agenda

Stillbirth and Neonatal Death Alliance (SANDA) incorporating the
Australian and New Zealand Stillbirth Alliance Research Consortium

Stillbirth Priority Setting Symposium

Reducing stillbirth and its aftermath in Australia and New Zealand:
What needs to happen now?

10:30 am to 5:00pm, 12th April 2015

Venue: Diana Plaza, Woolloongabba, Brisbane

Time	Program	Speakers/facilitators
10:00-10:30	Coffee upon arrival	
10:30-10:45	Welcome	Jeremy Oats and Heidi Mules
10:45-10:55	Priorities: What parents and clinicians say	Fran Boyle
10:55-11:15	Section1: Prediction of women at risk - Intro	Euan Wallace
11:15-12:45	Section1: Identifying priorities	Break out groups with feedback
12:45-13:25	Section1: Priority finessing	All
13:25-14:10	Lunch	
14:10-14:30	Section 2: Data and clinical audit - Intro	Jeremy Oats & Vicki Flenady
14:30-14:50	Section 3: Bereavement care - Intro	Fran Boyle
14:50-16:10	Sections 2 & 3: Identifying priorities	Break out groups with feedback
16:10-16:30	Afternoon tea	
16:30-16:50	Bringing it together	Jeremy Oats & Vicki Flenady
16:50-17:00	Wrap up	Prof David Ellwood

Appendix B. Symposium facilitators

Vicki Flenady: Professor of Clinical Perinatal Epidemiology with expertise in stillbirth risk factors, audit and classification of perinatal deaths, and clinical trials and implementation. Symposium co-facilitator for Section 2: Data and clinical audit.

Fran Boyle: Associate Professor of Social Science with expertise qualitative research methods, perinatal bereavement, and the lived experiences of health and the health system. Symposium facilitator for Section 3: Bereavement care.

Euan Wallace: Professor of Obstetrics and Gynaecology at Monash University and Director of Obstetric Services at Monash Health with expertise in fetal growth restriction, preeclampsia, placental ageing, and cell therapies. Symposium facilitator for Section1: Prediction of women at risk.

Heidi Mules: Brisbane-based bereaved mother of baby daughter Sophie, stillborn in 2011. Actively engaged in stillbirth research and financial contributor to the current symposium through fundraising alongside husband Ned.

Jeremy Oats: Professor of Obstetrics and Gynaecology and consultant Obstetrician at the Royal Women's Hospital Melbourne with expertise in perinatal mortality audit and classification. Symposium co-facilitator for Section 2: Data and clinical audit.

David Ellwood: Professor of Obstetrics and Gynaecology at Griffith University School of Medicine and Director of Maternal Fetal Medicine at Gold Coast University Hospital.

Appendix C. Summary of major group priorities

Question Number	Question	Revised Wording	Comments	Votes
Care after stillbirth				
1	How to provide optimal psychosocial care for parents following a stillbirth?	What are the elements of optimal care for parents and families following a stillbirth?	• What's available versus what's needed. • How parents access/know about care? • Definition of 'optimal' needs to be clear to answer this. • Includes planning for next pregnancy. • Liked 'How to respond holistically…' (to encompass cultural & spiritual aspects, etc.). • Include preconception planning. • Cost-benefit not just cost (applies to preventing stillbirth).	12
2	How to provide education/training to clinicians caring for parents following a stillbirth?	What education/training is needed for clinicians – what are the gaps?	• Need to define what we mean by 'care' – is this specifically emotionally or does it also include medical care? Highly relevant when defining questions around training.	9
3	What are the psychosocial effects on parents and families of stillbirth?	**Wording from symposium** Understanding the positive and negative psychosocial impacts of stillbirth on parents and families? **Suggested change** Understanding the range of psychosocial impacts of stillbirth on parents and families?	• Q3 is a foundation for Q1 and Q2 a subsequent/ translational question following on from Q1. • Consider mediating factors to support resilience and healing. • What enables parents and families to be resilient after experiencing a stillbirth?	3

Question Number	Question	Revised Wording	Comments	Votes
4	What is best practice for women in a subsequent pregnancy after stillbirth?	How to optimise parental & baby outcomes in subsequent pregnancies following stillbirth?	• Addressing the range of needs of women. • Outcomes should include the psychological, physical experience, not just 'clinical' & statistical outcomes. • Best outcome will also be very dependent on what was the cause of the Stillbirth. • Is this a separate sub-question under Q1? • What care practices in a woman's pregnancy following a previous stillbirth lead to optimal outcomes for parents and their baby? • Lots of overlap in Questions 1-4.	12
Investigation				
5	How to implement a high quality national perinatal mortality audit program?	What are the elements & approaches of a high quality national perinatal mortality audit program?	• Who is the audit process for? Following Q1 cycle. • Include parents in feedback from audit and research outcomes. • This is the only question which comes close to focussing on equity & access to care for vulnerable populations, so wondering if this should be explicit. • Have lay representatives on regional/national perinatal mortality audit program. • Gaps in Information. • What is the optimal classification system for stillbirth. • What interventions work to close the audit loop.	2

Question Number	Question	Revised Wording	Comments	Votes
6	What is the optimal investigation protocol for the cause of stillbirth?	What is the optimal, cost effective investigation protocol for the causes of stillbirth?	• Optimal investigation protocol with the least negative impact on the affected family e.g. it may be "optimal" to do an immediate autopsy on the baby but this is not optimal for the parents.	6
Prevention				
7	How to ensure high quality accessible antenatal care for all women?	How to ensure high quality, accessible, appropriate maternity care for all women to prevent stillbirth?	• High quality, culturally safe care. • Including groups at high risk of stillbirth (obese, indigenous, etc.). • What is best practice regarding pre-conceptual care for women who have experienced a stillbirth in a previous pregnancy? • I am not sure of where this question is coming from with the point that even parents who have access to high quality accessible antenatal care still have stillborn children. • What is known about stillbirth and its prevention by pregnant women, their families & the general public.	6

Question Number	Question	Revised Wording	Comments	Votes
8	How to provide education to pregnant women, the public and care providers on stillbirth?	How to engage with pregnant women, care providers & the public to identify and address their information needs regarding stillbirth?	• What is known by women, families & the general public about having a healthy pregnancy outcome? • Like comments on empowerment issue with Indigenous women. A high perception of risk coupled with low 'self-efficacy' which is associated with avoidance behaviour and disengagement. There is a lot of work needed around how to promote/support 'self-efficacy'. • Need to separate educating pregnant women about stillbirth prevention and the possibility of stillbirth occurring. The later will always be possible, even if information on the former is lacking. • Need to break down into 3 areas; Clinicians; Parents, and Public. • Need to target primiparous women about 'bad' pregnancy outcomes. • How do you best provide education on stillbirth to pregnant women, the public & care providers.	7

Question Number	Question	Revised Wording	Comments	Votes
9	What are the causes of stillbirth?	What are the possible causal pathways of unexplained and late pregnancy stillbirth?	• Split question into 2 parts: 1. What are the causes of unexplained stillbirth? 2. What are the root causes of explained stillbirth? • "Unexpected" might be good to include in an overall note on stillbirth (as is done for SUDI & SIDS). For research question though, is it sufficient to imply that all stillbirths are unexpected? • What may be the causes of sudden, unexplained (currently) fetal demise in late pregnancy? • Unexpected? & Unexplained? • Agree with Jeremy's comment – many "explained" stillbirths are probably inaccurately categorised – need to understand causal pathways clearly for prevention – important for all public health, including DOHAD as stillbirths 'tip of iceberg'	16
10	What genetic factors contribute to stillbirth?	What are the causative pathways of stillbirth & how do genomic factors interact with these? **Alternative Q10** What are the underlying root causes of stillbirths that have known direct causes e.g., placenta abruption, pre-eclampsia?	• When we know what caused stillbirth but don't know why? • Confusing wording. First part of question is important; we are trying to understand the mechanism.	3

Question Number	Question	Revised Wording	Comments	Votes
11	What is the contribution of cord abnormalities to stillbirth and how to reduce stillbirth associated with cord problems?	**Removed**		
12	How to reduce the risk of stillbirth associated with diabetes?	What is best care for women with pre-existing diabetes to reduce stillbirth?	**Removed**	0
13	How to increase awareness and optimal maternal reporting of decreased fetal movements?	Does increasing awareness & encouraging maternal reporting of decreased fetal movement reduce stillbirth?	• How to address misinformation given to women about decreased fetal movements. • Can increased fetal movement monitoring & reporting reduce the occurrence of stillbirth? • What technology exists or is being developed to assist in monitoring & reporting? • Is there a process pregnant women can follow to collect useful data on their fetal movements?	7
14	How to improve detection and management of FGR antenatally?	What are the effective strategies to improve detection and management of fetal growth restriction, and can these reduce stillbirth?	• And what are the consequences of these strategies for neonatal morbidity and mortality.	10
15	What placental pathologies cause or contribute to stillbirth?	What are the placental and cord pathologies that cause or contribute to stillbirth?	• ? "pathologies" understood.	7

Question Number	Question	Revised Wording	Comments	Votes
16	Can a test in early pregnancy accurately predict the risk of stillbirth?	Can screening in early pregnancy accurately quantify and reduce the risk of stillbirth?	• What possible screening or testing can be done in the child bearing years that may reduce the known risks associated with stillbirth? • Might be better not to phrase as a yes/no question e.g., What screening can be done…?	2
17	What are the risks factors for stillbirth?	What are the major modifiable risk factors for stillbirth?	• The parents' ages are not modifiable for a given pregnancy but they still want to know if it is a risk. • Need to know all risks to then see if any can be modifiable at any point of pregnancy care. • Major risk factor? Wouldn't any risk factor that could lead to a stillbirth be important or a parent?	15
18	How to reduce the risk of stillbirth for obese women during pregnancy?	How can the risk of stillbirth for obese women be reduced?		5
19	In women at term when should elective induction of labour be performed to avoid stillbirth?	For which women, and when, does early planned birth to prevent stillbirth v's expectant management have more benefit than harm?	• Needs clarification for understanding. • Is there a framework for practitioners and parents to decide when, how, and if to induce or perform a caesarean.	16
20	What is the role of routine fetal USS in preventing stillbirth?	**Removed** (incorporated in 'What are the effective strategies to improve detection and management of fetal growth restriction, and can these reduce stillbirth?)		

Extra research questions

Preconception care and prevention of stillbirth

Preconception care to prevent stillbirth

Cross cutting issues

Issues that have been identified as affecting all or most questions in the above list

- Cost
- Communication
- Access
- Equity
- Evaluation & continuous improvement
- Translation/implementation
- *Aligned with the principles of National Maternity document
    - e.g. Woman centred care, care close to home, equity of access
- *Plan, Do, Study, Act. Cycles of any actions
- *(Study to) include the effectiveness and acceptability

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