

A core outcome set for stillbirth care: an international consensus study

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INTRODUCTION

Stillbirth has profound psychological, emotional, and social consequences for families. Despite its impact, evidence-based guidelines for bereavement care are lacking, and research often fails to report outcomes consistently. Bereaved parents and professionals have identified improving stillbirth care as a top research priority.

A systematic review revealed significant variation in outcome reporting and omission of key outcomes such as grief, isolation, and experiences in subsequent pregnancies. To address these gaps, the iCHOOSE Study aimed to develop a **core outcome set (COS)**—a minimum set of outcomes to be reported in all stillbirth care studies. This will enhance comparability, ensure that outcomes important to stakeholders are consistently measured and reduce outcome reporting bias.

OBJECTIVE

To develop an internationally agreed core outcome set (COS) for stillbirth care research using robust consensus methods with input from parents, professionals, and researchers.

METHODS

Study Design: Modified Delphi survey and Nominal Group Technique

Registration: COMET (ID: 77514)

Participants: 542 stakeholders (381 parents/family members; 192 professionals; 29 countries). 95.6% of parents and 86.5% of professional stakeholders were from in high-income countries.

Outcome Identification:

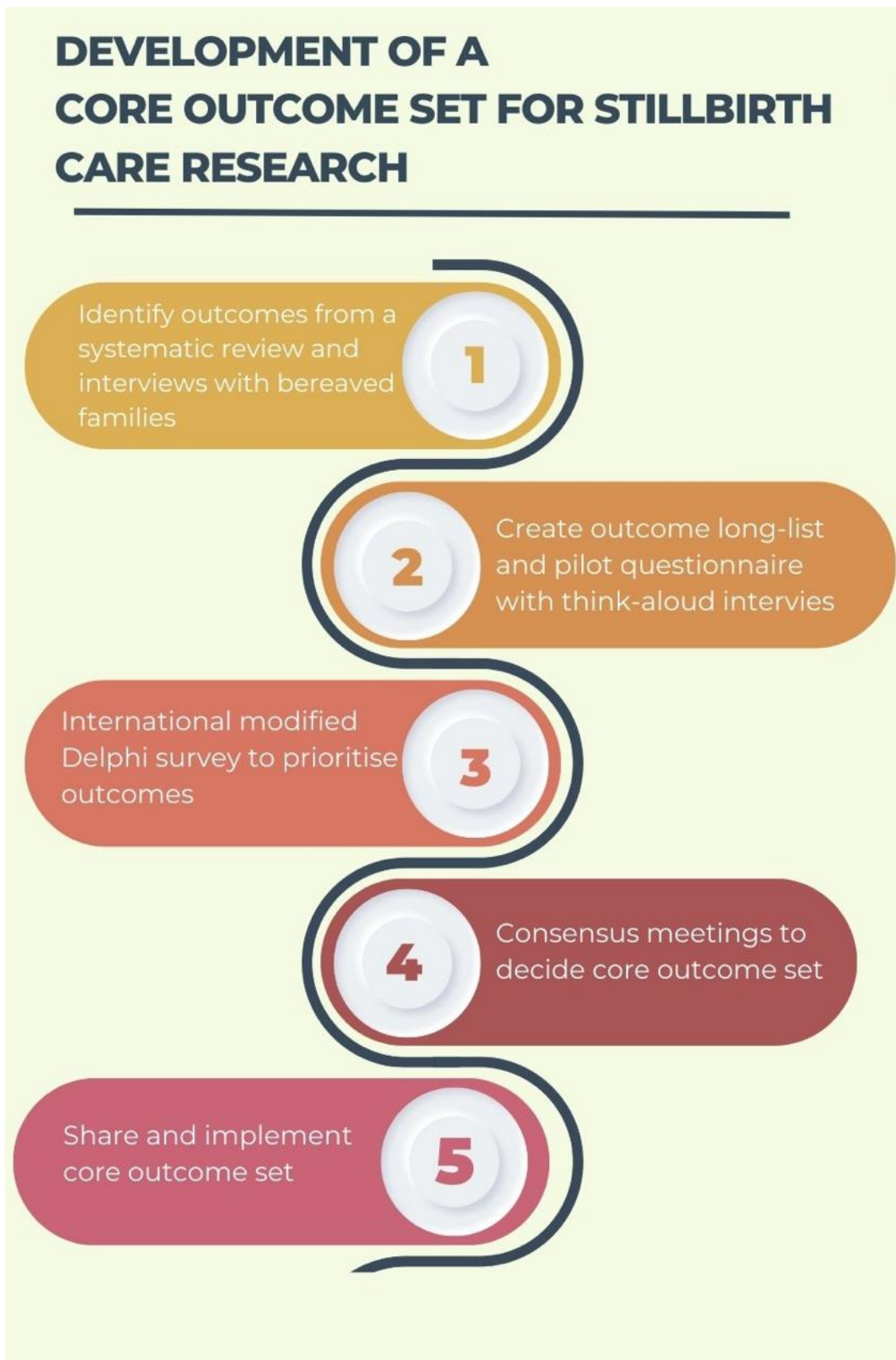
- A systematic review identifying 240 studies + 40 parent interviews
- Think aloud interviews to pilot survey
- 108 outcomes included in Delphi survey

Delphi Process:

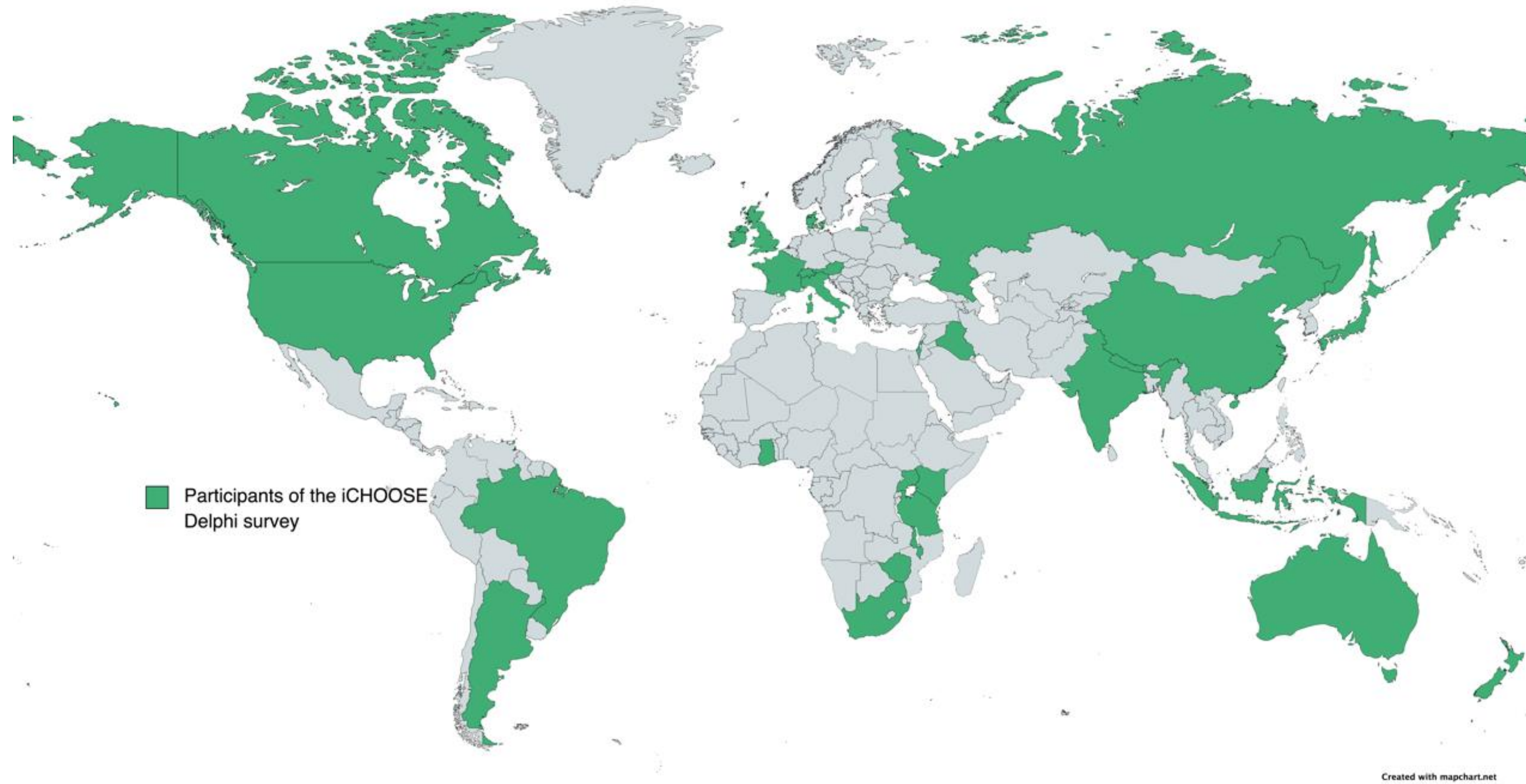
- 2 round international Delphi survey using a 9-point GRADE scale
- Stakeholders re-scored based on group feedback
- Consensus criteria: ≥75% of at least one stakeholder group rated outcome as “critical” (score 7–9)

Consensus Meetings:

- 4 meetings via Zoom
- Stakeholders discussed and voted on outcomes



Outcome	Plain language definition
A. Core outcomes for stillbirth care research	
Life-threatening complications and death	Life-threatening complications in parents, for example, organ failure, excessive blood loss requiring transfusion, shock, blood clots or a severe infection (sepsis), retained placenta, near-misses for mortality and morbidity, complications that may require surgery or hospital readmission. The death of a parent while pregnant, during or following birth, including suicide.
Parents’ experience of respectful and supportive care	Parent’s experience of care, before, during and after birth including experience of support, communication, perceived recognition of parenthood, and shared decision making.
Grief	Grief including overwhelming or complicated grief, coping and living with grief, feelings of self-blame, guilt or failure, acknowledgement of grief.
Mental health and emotional wellbeing	Mental health and wellbeing including depression, anxiety, PTSD, other mental health difficulties, mental functioning, mental health treatment, suicidal thoughts and emotional wellbeing.
Isolation	Social isolation, for example, feeling alone or abandoned, loneliness, isolation and avoidance.
Stigma	Stigma, for example, perceived shame, discrimination and opportunities to talk about stillbirth and baby.
Impact on work	Impact on occupation (paid or unpaid work), for example, impact on job, being able to do job, unemployment, change of career, parental leave, support for return to work.
Impact on relationship with immediate family	Impact on relationship with immediate family, such as partner, family and children, for example, positive or negative relationship consequences and perceived support.
A. Core outcomes for studies of specific interventions or care	
B1. Investigation of stillbirth outcomes	
Cause of death identified	Cause(s) of death from the medical investigations to understand why a stillbirth happened.
Parents’ understanding of the cause of death	Measurement of whether parents understand the cause(s) of death or that no cause of death was found, including understanding risk of recurrence and management in subsequent pregnancy.
B2. Subsequent pregnancy outcomes	
Antenatal complications for mother	Antenatal complications for mother, for example, bleeding, obstetric cholestasis, low lying placenta, premature rupture of membranes, gestational diabetes, pre-eclampsia.
Antenatal complications for baby	Antenatal complications for baby, for example, growth restriction, genetic or congenital anomaly.
Survival of baby	Baby survival outcomes, for example, live birth, miscarriage, stillbirth, termination of pregnancy, neonatal death of baby in a subsequent pregnancy.
Neonatal outcomes	Newborn outcomes, for example, Apgar score, birth weight of baby, admission to neonatal intensive care unit, gestational age, resuscitation of baby.
Attachment to baby	Attachment to baby during subsequent pregnancy after stillbirth, for example, perceived connection or bonding with new baby and acceptance of pregnancy.
B3. Outcomes for when a stillbirth occurs in multiple pregnancy	
Survival of baby/ies	Baby survival outcomes, for example, live birth, miscarriage, stillbirth, termination of pregnancy, neonatal death of surviving baby/ies.
Preterm birth	Number of surviving baby(ies) born before 37 weeks, 34 and 28 weeks
Pregnancy complications for baby	Complications that risk the life of the surviving baby(ies). For example, growth restriction, fetal anaemia, requiring intrauterine transfusion, premature labour
Neonatal outcomes	Newborn outcomes. For example, admission to neonatal intensive care unit, Apgar score, birth weight.



DISCUSSION

- This study developed a core outcome set for stillbirth care through a robust, international consensus process.
- A major strength was the high level of parent involvement: 70% of participants had lived experience of stillbirth.
- *Isolation and stigma*, which emerged from qualitative interviews, were including in the core outcome set and demonstrates the value of patient and public involvement in research.
- An outcome framework was proposed—ensuring core outcomes are relevant across different types of stillbirth care studies (e.g., investigations, subsequent pregnancies, multiple pregnancies).
- Despite broad international participation, 90% of respondents were from high-income countries, and only English-speaking participants were included—highlighting a limitation in global generalisability. A core outcome set for low- middle in come countries has since been developed.

RECOMMENDATION

Researchers are encouraged to use this COS in all future studies on stillbirth care. It is aligned with COMET and SPIRIT guidelines and supported by funders and journal editors. Additional outcomes may be reported as appropriate, but these core outcomes should be reported as a **minimum**.

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