

COSTIL Study: core outcomes in stillbirth trials

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Rationale

- Large variation in how and which outcomes are reported
- Core outcome sets help consistent reporting across studies and systematic reviews
- This makes research (and practice) more useful
- Parents need to be involved in deciding which outcomes are 'core'

**How can we do this for stillbirth?
*specifically for interventions to
prevent stillbirth***

Stages

**Review of reviews;
Which outcomes are most important for parents?**



Agreeing which outcomes to collect



Finalising a core outcome set related to stillbirth prevention

Background

Preventing stillbirth - high research priority for parents

Many stillbirths are preventable

Potentially modifiable factors: e.g. maternal obesity, smoking, diabetes, hypertension

In four of every 10 Cochrane reviews of interventions where stillbirth was judged to be a relevant outcome, this outcome was not reported at all (Middleton 2015)

Need to avoid 'research waste'

e.g. inability to combine data from different studies

Parents need to have a voice here

Review of reviews;

Which outcomes are most important for parents? (1)

Originally intended comprehensive 'traditional' searches, but...

- Very few intervention studies specifically address stillbirth prevention
- ...so would need to cast the net wide (e.g. to large numbers of observational studies)
- Now restricting to systematic reviews
- May need a conceptual 'causes/risks' framework

Review of reviews;

Which outcomes are most important for parents? (2)

Collecting outcomes - cascade (till saturation):

- Cochrane overview of antenatal interventions to prevent stillbirth (35 CSRs)?
- Other intervention SRs
- Observational SRs of risk factors (e.g. Flenady et al Lancet 2011)

- Any other similar core outcome sets/projects [COMET bereavement care, DFM]

- How much 'noise' in the outcomes??

Midwife-led CSR outcomes (in overview)

Primary outcomes

Birth and immediate postpartum

Regional analgesia (epidural/spinal)
Induction of labour
Caesarean birth
Instrumental vaginal birth (forceps/vacuum)
Spontaneous vaginal birth (as defined by trial authors)
Intact perineum

Neonatal

Preterm birth (less than 37 weeks)
All fetal loss before and after 24 weeks plus neonatal death

Secondary outcomes

Antenatal hospitalisation
Antepartum haemorrhage
Amniotomy
Augmentation/artificial oxytocin during labour
No intrapartum analgesia/anaesthesia
Opiate analgesia
Attendance at birth by known midwife
Episiotomy
Perineal laceration requiring suturing
Mean labour length (hours)

Postpartum haemorrhage

Breastfeeding initiation

Duration of postnatal hospital stay (days)

Low birthweight (less than 2500 g)

Five-minute Apgar score

Neonatal convulsions

Admission to special care nursery/NICU

Mean length of neonatal hospital stay (days)

Fetal loss less than 24 weeks & neonatal death

Fetal loss equal to/after 24 weeks & neonatal death

Perceptions of control during labour and childbirth

Mean number of antenatal visits

Maternal death

Cord blood acidosis

Postpartum depression

Any breastfeeding at three months

Prolonged perineal pain

Pain during sexual intercourse

Urinary incontinence

Faecal incontinence

Prolonged backache

Breastfeeding on hospital discharge (not pre-specified)

Maternal satisfaction (not pre-specified)

Cost (not pre-specified)

Review of reviews; Which outcomes are most important for parents? (3)

Interviews with parents of a stillborn baby (15-30 couples)

To discuss “what you knew about stillbirth before your loss, what you wish you knew and what you think are gaps in knowledge about identifying your risk of, or preventing, stillbirth”

For COS component, researchers will extract outcomes mentioned in transcripts

Review of reviews; Which outcomes are most important for parents? (4)

- What outcomes will parents be interested in?
- Will they be interested in neonatal outcomes?
- Likely to add outcomes not yet reported (as in preterm COS development – van't Hooft et al O&G 2016)

Agreeing which outcomes to collect (1)

Combined list of outcomes from parents and from systematic reviews

Restrict systematic review outcomes to 'plausible' ones?

30 more couples/families

50 health professionals/researchers

3 Delphi rounds

Agreeing which outcomes to collect (2)

3 Delphi rounds

- 1) Score list of outcomes 1-9 and add any missing outcomes
- 2) Rescore – drop outcomes scored as ‘unimportant’ by >70% or critical by <15%
- 3) Rescore and classify – consensus in; consensus out; no consensus

Finalising a core outcome set related to stillbirth prevention

- Determine how to define and measure the core outcomes
- Write up as a COS and send document out for consultation
- Wide dissemination, translation and implementation

Significance

- embedding COS in future clinical trials, systematic reviews, and clinical practice guidelines useful to inform clinical practice, enhance care, and improve outcomes.
- help with selecting research priorities and developing guidelines

