Stillbirth Priority Setting Partnership

PROTOCOL

The purpose of this protocol is to set out the aims, objectives and commitments of the Stillbirth Priority Setting Partnership (PSP) and the basic roles and responsibilities of the partners therein.

Steering group

The stillbirth PSP will be administered and coordinated by Dr Alexander Heazell, Maternal and Fetal Health Research Centre, University of Manchester.

Other steering group members responsible for the management of the Stillbirth PSP include:

Parent representative/s:
- Sands - Stillbirth and Neonatal Death Charity
  - Charlotte Bevan
- National Maternity Support Forum
  - Andrew Canter
- Tommy’s the baby charity
  - Jane Brewin
- Holly Martin Stillbirth Research Fund
  - Isobel Martin

Clinical representative/s:
- British Maternal-Fetal Medicine Society
  - Dr Melissa Whitworth
- Royal College of Midwives
  - Gail Johnson
- Department of Health
  - Dr Catherine Calderwood
- British Paediatric and Perinatal Pathologists’ Association
  - Dr Flora Jessop

The Partnership and the priority setting process will be supported and guided by:
- The James Lind Alliance (JLA)
  - Leanne Metcalf

The Steering group includes representation of parent groups and clinicians with expertise from obstetrics, midwifery and pathology (the three most relevant clinical disciplines).

The Steering group have agreed the resources, including time and expertise that they will be able to contribute to each stage of the process, as documented in their Terms of Reference.
Background to the stillbirth PSP

The JLA is a project which is overseen by the National Institute for Health Research (NIHR) Evaluation, Trials and Studies Coordinating Centre (NETSCC). Its aim is to provide an infrastructure and process to help patients and clinicians work together to agree which are the most important treatment uncertainties affecting their particular interest, in order to influence the prioritisation of future research in that area. The JLA defines an uncertainty as a “known unknown” – in this case relating to the effects of treatment.

The Stillbirth PSP was originally explored as part of a programme of work investigating whether increased awareness and better management of reduced fetal movements was able to reduce stillbirth. A preliminary meeting was held in Manchester in December 2012 when a PSP for reduced fetal movements was proposed. Following discussion with members of this group, stakeholders, the stillbirth clinical studies group of the Royal College of Obstetricians and Gynaecologists and NETSCC it was decided to broaden the scope of the PSP to late stillbirth. The readiness questionnaire was submitted to NETSCC in April 2013 and the PSP topic was accepted subject to funding in Summer 2013. Funding was confirmed in Autumn 2013, enabling the core group to meet in November 2013.

Aims and objectives of the stillbirth PSP

The aim of the stillbirth PSP is to identify the unanswered questions about stillbirth from parent and clinical perspectives and then prioritise those that parents and clinicians agree are the most important.

The objectives of the stillbirth PSP are to:

- work with parents and clinicians to identify uncertainties about stillbirth
- to agree by consensus a prioritised list of those uncertainties, for research
- to publicise the results of the PSP and process
- to take the results to research commissioning bodies to be considered for funding

Partners

Organisations and individuals will be invited to take part in the PSP, which represent the following groups:

- people who have experienced stillbirth, directly or indirectly
- medical doctors, midwives, nurses and professionals allied to medicine with clinical experience of stillbirth

All identifiable organisations which can reach and advocate for these groups will be invited to become involved in the PSP. The JLA will take responsibility for ensuring the various stakeholder groups are able to contribute equally to the process.

Organisations wishing to participate in the PSP will be asked to affiliate to the JLA in order to demonstrate their commitment to the aims and values of the JLA. Details on the affiliation procedure can be found at www.lindalliance.org.

Exclusion criteria

Some organisations may be judged by the JLA or the steering group to have conflicts of interest. These may be perceived to adversely affect those organisations’ views, causing unacceptable bias. As this is likely to affect the ultimate findings of the PSP, those organisations will not be invited to participate. It is possible, however, that interested parties may participate in a purely observational capacity when the Steering Group considers it may be helpful.

METHODS
This section describes a schedule of proposed stages through which the PSP aims to fulfil its objectives. The process is iterative and dependent on the active participation and contribution of different groups. The methods adopted in any stage will be agreed through consultation between the partners, guided by the PSP’s aims and objectives. More details and examples can be found at www.JLAguidebook.org.

1. Identification and invitation of potential partners
Potential partner organisations will be identified through a process of peer knowledge and consultation, through the Steering Group members’ networks and through the JLA’s existing register of affiliates. Potential partners will be contacted and informed of the establishment and aims of the stillbirth PSP and invited to become involved. The Steering Group will draft the invitation, and agreement will be reached as to the best organisation/individual to distribute the invitations, depending on the partner in question. Given the connections of steering group members, the nature of the stillbirth field, and the initial interest demonstrated from a range of partners wanting to become involved, it has been decided that a large-scale stakeholder meeting to raise awareness of the PSP is not necessary. Presentations will instead be made at smaller gatherings of relevant partners and the steering group will use their knowledge of their contacts to decide the best mechanism of approach. A stillbirth PSP website will also be set up by the Steering Group, with input from the JLA, to achieve the following key objectives:

- to welcome and introduce potential members of the stillbirth PSP
- to present the proposed plan for the PSP
- to provide a mechanism to initiate discussion, answer questions and address concerns
- to identify those potential partner organisations which will commit to the PSP and identify individuals who will be those organisations’ representatives and the PSP’s principal contacts
- to establish principles upon which an open, inclusive and transparent mechanism can be based for contributing to, reporting and recording the work and progress of the PSP.

2. Identifying treatment uncertainties
Each partner will identify a method for soliciting from its’ members questions and uncertainties of practical clinical importance relating to stillbirth. A period of c.6 weeks will be given to complete this exercise.

The methods will be designed according to the nature and membership of each organisation, but must be as transparent, inclusive and representative as practicable. Methods may include membership meetings, email consultation, postal or web-based questionnaires, internet message boards and focus group work.

Existing sources of information about treatment uncertainties for parents and clinicians will be searched. These can include question-answering services for parents and carers and for clinicians; research recommendations in systematic reviews and clinical guidelines; protocols for systematic reviews being prepared and registers of ongoing research.

The starting point for identifying sources of uncertainties and research recommendations is NHS Evidence: www.evidence.nhs.uk.

3. Refining questions and uncertainties
The consultation process will produce “raw” unanswered questions about stillbirth. These raw questions will be assembled and categorised and refined by nominated steering group representatives (TBC) into “collated indicative questions” which are clear, addressable by research and understandable to all. Similar or duplicate questions will be combined where appropriate.

The existing literature will be researched by nominated steering group members (TBC) to see to what extent these refined questions have, or have not, been answered by previous research.
Sometimes, uncertainties are expressed that can in fact be resolved with reference to existing research evidence – i.e. they are "unrecognised knowns" and not uncertainties. If a question about treatment effects can be answered with existing information but this is not known, it suggests that information is not being communicated effectively to those who need it. Accordingly, the JLA recommends strongly that PSPs keep a record of these 'answerable questions' and deal with them separately from the 'true uncertainties' considered during the research priority setting process.

Uncertainties which are not adequately addressed by previous research will be collated and prepared for entry into a stillbirth section within the UK Database of Uncertainties about the Effects of Treatments (UK DUETS - www.library.nhs.uk/duets) by nominated steering group members (TBC). This will ensure that the uncertainties have been actually checked to be uncertainties. This is the responsibility of the Steering Group, which will need to have agreed personnel and resources to carry this accountability. The data should be entered into UK DUETs on completion of the priority setting exercise, in order to ensure any updates or changes to the data have been incorporated beforehand.

4. Prioritisation – interim and final stages
The aim of the final stage of the priority setting process is to prioritise through consensus the identified uncertainties relating to stillbirth. This will be carried out by members of the steering group and the wider partnership that represents parents and clinicians.

The interim stage, to proceed from a long list of uncertainties to a shorter list (e.g. up to 20), will be carried out remotely using a survey.

The final stage, to reach 10 prioritised uncertainties, will be conducted in a face-to-face meeting, using group discussions and plenary sessions. The JLA will facilitate this process and ensure transparency, accountability and fairness. Participants will be expected to declare their interests in advance of this meeting.

Findings and research
It is anticipated that the findings of the stillbirth PSP will be reported to funding and research agenda setting organisations such as the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), which includes the Healthcare Technology Assessment (HTA) Programme, and the Medical Research Council (MRC), as well as the major research funding charities. Steering group members, with input from partners where appropriate, will work to develop the prioritised uncertainties into research questions, and to work to establish the research needs of those unanswered questions to use when approaching potential funders, or when allocating funding for research themselves, if applicable.

Publicity
As well as alerting funders, partners and steering group members are encouraged to publish the findings of the stillbirth PSP using both internal and external communication mechanisms. The JLA may also capture and publicise the results, through descriptive reports of the process itself. This exercise will be distinct from the production of an academic paper, which the partners are also encouraged to do. However, production of an academic paper should not take precedence over publicising of the final results.

Signed by the Steering Group
The undersigned agree to follow the stillbirth Priority Setting Protocol.

- Dr Alexander Heazell, Maternal and Fetal Health Research Centre, University of Manchester
- Leanne Metcalf, James Lind Alliance
- Charlotte Bevan, Stillbirth and Neonatal Death Society
- Andrew Canter, National Maternity Support Forum
• Jane Brewin, Tommy’s the baby charity
• Isobel Martin, Holly Martin Stillbirth Research Fund -
• Dr Melissa Whitworth, British Maternal-Fetal Medicine Society
• Gail Johnson, Royal College of Midwives
• Dr Catherine Calderwood, Department of Health
• Dr Flora Jessop, British Paediatric and Perinatal Pathologists’ Association

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