

Date and Time: 22nd and 23rd May 2013 10:00 – 16:00

Minutes: Confirmed

Guideline Development Group Meeting Preterm labour and birth

Place: Royal College of Obstetricians and Gynaecologists
London

Present:	Jane Norman (JN) (Chair) Judi Barratt (JB) Paul Eunson (PE) Jane Hawdon (JH) Philip Owen (PO) Farrah Pradhan (FP) Marianne Rountree (MR) Meekai To (MT) Jane Plumb (JP) Martin Ward-Platt (MWP) Louise Weaver-Lowe (LW-L)	(Present for notes 1 – 23) (Present for notes 1 – 13) (Present for notes 1 – 23) (Present for notes 1 – 23)
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In attendance:

NCC-WCH staff: Zosia Beckles (ZB) Liz Bickerdike (LB) (day 1 only) Maryam Gholitabar (MG) David James (DJ) Juliet Kenny (JK) Paul Jacklin (PJ) David James (DJ) Roz Ullman (RU)		(Present for notes 1 – 23) (Present for notes 1 – 13) (Present for notes 1 – 23) (Present for notes 1 – 23)
NICE attendees: Sarah Dunsdon (SD) Emma Chambers (EC)		(Present for notes 1 – 19) (Present for notes 1 – 7)

Observers:

None		
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Notes

Day 1

1. JN welcomed the group to the meeting and introduced herself. The group introduced themselves to each other. PO gave apologies in advance for the second day of the meeting. JN gave a presentation about the ground rules for GDG meetings and roles of responsibilities of the group members.
2. JK explained the importance of declarations of interest (DOI) and clarified the terms used in the National Institute for Health and Clinical Excellence (NICE) DOI form. All the GDG members and other attendees were asked to summarise their interests for the group.

JN

Personal pecuniary:

Receives funding to cover expenses from British Maternal and Fetal Medicine Society, Society of Gynaecological Investigation (USA) and Global Alliance to Prevent Prematurity and Stillbirth (USA) to attend executive committee meetings. Received funding to cover

expenses from March of Dimes (a not-for-profit organisation in USA whose aim is to improve the health of babies by preventing birth defects, premature birth, and infant mortality) to attend meeting in December 2012 on preterm birth. Received funding to cover expenses from Royal College of Obstetrics and Gynaecology and the Obstetrical and Gynaecological Society of Malaysia for lectures given in Malaysia on preterm birth in 2013. Received hospitality from Besins Healthcare while attending Advisory Board meeting in 2013 on Cervical Incompetence and Preterm Birth but declined honorarium and additional hospitality that was offered after the meeting.

Non-personal pecuniary:

University of Edinburgh receives funding from UK government agencies in payment for reports produced by JN on maternal deaths (less than £5000 received since 2010), from Preglem (a small drug company with an interest in obstetric and gynaecological drugs) for consultancy work undertaken by JN (less than £5,000 received between 2010-12) and from charities and other non-commercial organisations for research undertaken by JN on various aspects of pregnancy problems. Centres recruiting to OPPTIMUM (a clinical trial led by JN) receive fibronectin 'kits' manufactured by Hologic at a reduced price. OPPTIMUM and EMPOWaR (clinical trials led by JN) receive free investigational medicinal products and placebos from Besins Healthcare and Merck.

Personal non-pecuniary

Undertook unpaid consultancy work for Hologic (manufacturer of products relating to preterm labour and birth).

JB

Personal non-pecuniary

Chair of local guidelines group which recently updated preterm birth guidelines which included recommendations on diagnosis of preterm pre-labour rupture of membranes.

JH

Personal pecuniary

Receives payment for occasional medico-legal work (cases undertaken have involved representing both claimants and defendants) in which JH has provided evidenced-based feedback on the outcomes of preterm labour and birth. Honoraria and funding to cover expenses received from Cheisi to speak at and chair meetings. Honoraria for invited published articles and book chapters on neonatal care of preterm babies. Payment from BBC for work as medical advisor to 'Holby City' regarding aspects of neonatal care of premature babies. Funding for expenses and hospitality received from sponsors with no known interest in the products covered in the scope of this guideline to speak at a conference in Athens.

Personal non-pecuniary

Member of the board of trustees and media panel of BLISS (charity promoting care and support for preterm babies). Member of the Independent Reconfiguration Panel (an organization that provides advice to the Secretary of State for Health on contested proposals for health service change in England). As clinical lead for North Central London Perinatal Network, oversaw development of network guidelines on topics specific to the scope of this guideline (fibronectin testing and magnesium sulphate for neuroprotection). Reviewer of research applications and journal submissions relating to neonatal care of preterm babies. Spoken and published papers and articles on neonatal care of preterm babies. Member of the Royal College of Paediatrics and Child Health media panel.

PO

Personal pecuniary

Receives payment for medico-legal work (cases undertaken have involved representing both claimants and defendants) in which PO provides expert opinion in court on obstetric and intrapartum care including the outcomes of preterm labour and birth. Receives small honoraria from European Journal of Obstetrics & Gynecology and Reproductive Biology for work as editor. Received funding to cover expenses, hospitality and products for use in clinical research from manufacturers with an interest in preterm labour and birth (historical interest only – none received in last 12 months).

Personal non-pecuniary

Chair of RCOG guidelines committee and edits guidelines on topics specific to the scope of this guideline including cervical cerclage, tocolysis and maternal corticosteroids.

MT**Personal non-pecuniary**

Author of several publications on value of cervical length as screening test for preterm birth and the use of cervical cerclage. Co-author of RCOG Greentop guideline on cervical cerclage.

JP**Personal non-pecuniary:**

Made public statements on behalf of Group B Strep Support (charity providing information and support to the public and health care professionals on Group B Streptococcus) on topics not specific to the scope of this guideline.

MW-P**Personal pecuniary:**

Receives payment for occasional medico-legal work (cases undertaken have involved representing both claimants and defendants and working with coroners and family courts) in which MW-P has provided expert feedback on aspects of perinatal care including the management of preterm birth from a paediatric perspective. Received payment for consultancy work from Mothercare Plc on aspects of care not specific to the scope of this guideline. Receives payment from Archives of Disease and Childhood for work as deputy editor. Receives payment from Tees Child Death Overview Panel for work as Independent Chair.

Personal non-pecuniary:

Reviewer for the Health Technology Assessment stream of the National Institute for Health Research. Reviews obstetric and perinatal research papers for a variety of journals. Clinical Director of the Regional Maternity Survey Office (part of Public Health England). Audit lead for the Northern Neonatal Network. Member of the Northern Maternity Strategic Network. Member of HTA funded study BRACELET (Bereavement in the context of randomised controlled trials) steering group. Chair of the Ethics Advisory Board for Tinn2 study of azithromycin for preterm babies. Member of the Royal College of Paediatrics and Child Health media panel. Chair of the Tiny Lives Trust (charity supporting neonatal care in Newcastle).

LW-L**Personal non-pecuniary**

Participated in the development of local maternity and neonatal guidelines. Proofread preterm birth booklet published by Tommy's (charity that funds research into stillbirth, premature birth and miscarriage and provides information to parents).

No other declarations of interest were received from the GDG members or the other attendees. It was agreed that no interests declared at the meeting or previously warranted exclusion of any GDG members from discussions of evidence or formulation of recommendations at the meeting.

Declarations are kept on record at the NCC-WCH and will be published in the full guideline.

3. SD presented an overview of the work of NICE, and the role of clinical guidelines. After the presentation, the group had an opportunity to ask questions.
4. EC gave a presentation on the NICE Public Involvement Programme (PIP). After the presentation, the group had an opportunity to ask questions.
EC is going on maternity leave. PIP (probably via the tech team) will keep the group informed about who will replace her.
5. JN presented the topics that would be covered in the guideline scope. After the

presentation, the group had an opportunity to ask questions.

6. RU explained the purpose of topic groups in the guideline development process and invited members to sign up to the groups they were interested in at the breaks.
7. PJ gave a presentation on the role of health economics in guideline development. After the presentation, the group had an opportunity to ask questions.
8. JN presented a clinical overview of magnesium sulphate for neuroprotection in preparation for the GDG's discussion of the evidence review documents for this topic. After the presentation, the group had an opportunity to ask questions.
9. RU gave a presentation about finalising review questions, planning systematic reviews and drafting protocols using the draft magnesium sulphate for neuroprotection protocol as an example. After the presentation, the group had an opportunity to ask questions.
10. MG presented an overview of study designs and their relevance to review questions. After the presentation, the group had an opportunity to ask questions.
11. The GDG broke into small groups to discuss draft protocols for the questions on prophylactic cerclage for women at risk of preterm labour and birth, non-prophylactic 'rescue' cerclage for women in suspected preterm labour, repeat courses maternal corticosteroids for fetal lung maturation, maternal corticosteroids for fetal lung maturation given at different gestational ages, diagnosis of preterm pre-labour rupture of membranes (P-PROM), routine temperature monitoring for women with suspected or diagnosed P-PROM, routine cardiotocography for women with suspected or diagnosed P-PROM and timing of cord clamping.
12. The group reconvened and feedback was received from the first small group on the draft protocols for prophylactic cerclage for women at risk of preterm labour and birth, non-prophylactic 'rescue' cerclage for women in suspected preterm labour, repeat courses maternal corticosteroids for fetal lung maturation, maternal corticosteroids for fetal lung maturation given at different gestational ages. The GDG discussed the draft protocols in light of this feedback and chose their seven key outcomes. Notes were made live on screen.
13. JN closed the meeting due to time constraints noting that the following day's agenda would be adjusted to allow time for the rest of the protocols to be discussed and finalised by the full group.

Notes

Day 2

14. JN opened the meeting and outlined the tasks for the day. Apologies were received from PO and LB.
15. ZB gave a presentation on identifying the evidence using the draft magnesium sulphate for neuroprotection search strategy as an example. After the presentation, the group had an opportunity to ask questions.
16. MG gave a presentation on reviewing evidence and explained the GRADE approach to quality appraisal. After the presentation, the group had an opportunity to ask questions.
17. RU gave a presentation on linking the evidence to recommendations. After the presentation, the group had an opportunity to ask questions.
18. RU presented the draft review for the question on magnesium sulphate for neuroprotection (the protocol, the list of excluded studies, the evidence tables, the evidence profiles and the evidence summary). The group had an opportunity to discuss the results and ask questions.
19. JN led the group through the process of interpreting the evidence and drafting recommendations. Notes were made live on screen.
20. RU explained the need to select a priori a threshold for a clinically important change (known as a minimally important difference (MID)) when using continuous outcomes with reference to some of the continuous outcomes that had been prioritised during the previous day's discussion of the draft protocols. The group had an opportunity to discuss and select MIDs for continuous outcomes of interest.
21. Feedback was received from the second and third small groups on the draft protocols for diagnosis of preterm pre-labour rupture of membranes (P-PROM), routine temperature monitoring for women with suspected or diagnosed P-PROM, routine cardiotocography monitoring for women with suspected or diagnosed P-PROM and timing of cord clamping. The GDG discussed the draft protocols in light of this feedback and chose their seven key

- outcomes. Notes were made live on screen.
- 22. JK reminded the group of the date for the next GDG and checked that everyone had noted the dates for the remaining GDGs.
 - 23. There was no other business. JN thanked the participants for attending and closed the meeting.

Date, time and venue of the next meeting

Tuesday 25th June 2013, 10:00 – 16:00 at the Royal College of Obstetricians and Gynaecologists, London