Date and Time: Wednesday 17 and Thursday 18 October 2012

10:00 - 16:30

Minutes: Confirmed

Guideline Development Group Meeting Diabetes in pregnancy guideline update

Place: Royal College of Obstetricians and Gynaecologists

London

Present: Rudy Bilous (Chair) (RB)

Jacqueline Berry (JB) (Present for notes 1 – 17)
Anne Dornhorst (AD) (Present for notes 1 – 17)
Aderonke Kuti (AK) (Present for notes 1 – 17)
Michael Maresh (MM) (Present for notes 1 – 17)
Judy Shakespeare (JS) (Present for notes 1 – 17)

Stacia Smales Hill (SSH) (Present for notes 1 – 11 and 15 - 17)

Katharine Stanley (KS) (Present for notes 1 – 17) Diane Todd (DT) (Present for notes 1 – 17)

In attendance:

NCC-WCH staff: Zosia Beckles (ZB) Paul Jacklin (PJ) David James (DJ) Juliet Kenny (JK) Moira Mugglestone (MMu) Nitara Prasannan (NP) Shona Burman-Roy (SBR)	(Present for notes 1 – 17)
Cristina Visintin (CV) NICE attendees: Emma Chambers (EC) Sarah Dunsdon (SD)	(Present for notes 1 – 11) (Present for notes 1 – 8) (Present for notes 1 – 22)

Observers:

None		
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- 1. RB welcomed the group to the first meeting of this guideline development group (GDG) and introduced himself as the Chair. RB asked each GDG member to introduce themself. Apologies were received from Elizabeth Stenhouse.
- 2. RB gave a presentation on the roles and responsibilities of GDG members as part of the guideline development process. After the presentation, the group had an opportunity to ask questions.
- 3. JK explained the importance of declarations of interest (DOIs) 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.

RB

Personal pecuniary: speaker fees from Boehringer Ingelheim, Novo Nordisk and Roche

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diagnostics (no ongoing links with any of these companies in terms of topics covered by the guideline update); consultancy for Roche diagnostics and Roche Pharma (to advise on a peroxisome proliferator-activated receptor (PPAR) alpha and gamma agonists for type 2 diabetes and renal disease); meeting expenses from Animas (insulin pumps), Boehringer Ingelheim, Johnson and Johnson (insulin pumps); invited to act as Principal Investigator on a study of a new insulin pump being developed by Roche

Non-personal pecuniary: department receives funding from Diabetes UK; department participates in a clinical trial on diabetes and hypertension through the Comprehensive Clinical Research Network (CCRN)

Personal non-pecuniary: member of the Medicines and Healthcare products Regulatory Agency (MHRA) Cardiovascular, Diabetes, Renal, Respiratory and Allergy Expert Advisory Group (CDDRAEG) of the Commission on Human Medicines and the MHRA Insulin Use group; GDG member for the National Kidney Foundation guideline on chronic kidney disease and diabetic kidney disease; published research on diabetes and pregnancy based on the Northern Regional Diabetes Database of the Regional Maternity Survey Office (RMSO); member of data monitoring safety boards of the Adolescent type 1 Diabetes cardio-renal Intervention Trial (AdDIT) and the atrasentan trial (not related to diabetes in pregnancy)

JB

Personal non-pecuniary: member of the Royal College of Nursing; seconded to King's College London; speaker at a Diabetes UK meeting (sensor-augmented pump therapy in diabetes in pregnancy)

AD

Personal pecuniary: meeting expenses from Reata Pharmaceuticals (clinical trial of bardoxolone methyl; the meetings were also funded by Eli Lilly); seeking funding from Boehringer Ingelheim and Eli Lilly for a randomised controlled trial (RCT) of asymptomatic hypoglycaemia in people with type 2 diabetes and chronic kidney disease using glicazide (a sulfonylurea) and linagliptin (a dipeptidyl peptidase-4 (DPP4) inhibitor); honoraria for speaking about diabetic renal guidelines at North West Thames consultants and general practitioners (GPs) meetings funded by Boehringer Ingelheim and Eli Lilly; honorarium and expenses for speaking about diabetes in pregnancy at a diabetes symposium in Bristol funded by NovoNordisk

Personal family: husband is employed by Quintiles, which undertakes clinical trials for pharmaceutical companies (involves contact with scientific advisors at various companies)

Non-personal pecuniary: co-applicant for funding from the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme for research relating to hyperglycaemia in pregnancy

Personal non-pecuniary: board member of the NovoNordisk Foundation

MM

Personal pecuniary: speaker expenses from Diabetes UK

Non-personal pecuniary: department is funded by Diabetes UK to develop a test for fetal wellbeing in pregnancies complicated by type1 diabetes (the test will not available before 2014); department funded by Bridges for an RCT using a DVD for women with gestational diabetes; department funded by the National Institutes of Health (NIH), USA for a follow-up of women and children from the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study; co-applicant for funding from the NIHR HTA programme for research relating to hyperglycaemia in pregnancy

Personal non-pecuniary: spoke about non-applicability of the World Health Organization diagnostic criteria for gestational diabetes, advantages of centralisation of care for type 1 diabetes, individualisation of decision making for timing and mode of birth, and results of the HAPO study

KS

Personal pecuniary: honorarium and meeting expenses from Diabetes UK

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Non-personal pecuniary: department received a midwifery research grant from NovoNordisk

DT

Personal non-pecuniary: member of the Diabetes UK conference organising committee, the NHS Diabetes Pregnancy Audit Group and Diabetes in Pregnancy Network Steering Group

MMu

Non-personal pecuniary: co-applicant for funding from the NIHR HTA programme for research relating to hyperglycaemia in pregnancy

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.

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

- 4. 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.
- 5. EC gave a presentation on the Patient and Public Involvement Programme (PPIP) at NICE. After the presentation, the group had an opportunity to ask questions.
- 6. RB presented the topics that would be covered in the guideline scope, and outlined the draft review questions. After the presentation, the group had an opportunity to ask questions.
- 7. SBR gave a presentation on developing review questions. MMu then introduced the GDG to the draft review questions, after which the group discussed and finalised the review questions.
- 8. MMu presented an overview of study designs and their relevance to review questions. After the presentation, the group had an opportunity to ask questions.
- 9. RB introduced the topic of postnatal testing for type 2 diabetes, covering:
 - diagnostic accuracy associated with different tests
 - the ideal timing of testing.

After the presentation, the group had an opportunity to ask questions.

- 10. MMu presented draft review protocols for the review questions relating to postnatal care. The group then discussed and finalised the protocols.
- 11. SBR and DJ presented draft review protocols for the review questions relating to gestational diabetes (covering diagnostic criteria, screening in the first and second trimesters, and interventions for gestational diabetes). The group then discussed and finalised the diagnosis and screening protocols. Changes to the draft protocol for the interventions guestion were also agreed by the GDG.
- 12. ZB gave a presentation to explain the method for identifying evidence, including the process for developing a search strategy based on the protocol and the process for sorting the results identified from bibliographic databases. After the presentation, the group had an opportunity to ask questions.
- 13. NP presented the process for reviewing evidence and explained the GRADE approach to

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reviewing evidence. After the presentation, the group had an opportunity to ask questions.

- 14. PJ presented the concepts of health economics and how they are used in guideline development. After the presentation, the group had an opportunity to ask questions.
- 15. NP and MMu presented the draft reviews for the questions on postnatal testing (the list of excluded studies, the evidence tables, the evidence profiles and the summaries of the evidence for both questions). The group had an opportunity discuss the evidence presented and then agreed principles for completing both reviews.
- 16. JK gave a presentation to explain how to link evidence to recommendations. The group had an opportunity to discuss this and to ask questions.
- 17. There was no other business. RB thanked the participants for attending and closed the meeting.

Date, time and venue of the next meeting

Monday 10 December 2012, 10:00 – 16:30 at the Royal College of Obstetricians and Gynaecologists, London