**Maternal Medicine CSG Meeting Notes**

**Thursday 27th June 2013, RCOG**

* 1. Present: Prof Lucilla Poston, Dr Lucy Chappell, Dr Fiona Denison, Prof Fionnuala McAuliffe, Dr Kate Harding, Dr Tommy Mousa, Prof Catherine Nelson-Piercy, Dr Dharmintra Pasupathy, Dr Shakila Thangaratinam;
  2. On arrival from US at 1pm: Prof Louise Kenny, Dr Jenny Myers
  3. On telephone: Ms Jane Brewin, Dr Ian Crocker, Dr Fiona Denison, Dr Kate Harding, Professor Louise Howard
  4. Dr Cath Taylor and Prof Debra Bick (for presentation of proposal); Jim Thornton (for presentation of PICO)
  5. Apologies: Dr David Williams, Dr. Helen Spiby, Dr Joanna Girling, Professor Andrew Shennan, Professor Steve Robson, Professor Peter Brocklehurst, Dr Shiao Chan, Professor Marian Knight.

1. Review of previous meeting notes – no comments
2. Feedback from Research Committee – closer relationships with funders now – (NIHR, Wellcome Trust etc) so need to provide formal proformas for priorities for funding and intended projects. Proposals will then be discussed by CSG executives and scoring provided with the intention of providing support (not formal peer review). Formal letter of approval for funder will be generated by the Chair if approved. Remit: multi-centre studies involving human participants (basic science studies will be encouraged where there are human participants or clear clinical translation). A minimum of two weeks is needed for approval but, preferably, the suggestions for projects should be submitted at the earliest possible stage to enable full discussion and development of an optimal funding application. The project proposal proformas will be available on the RCOG MM CSG website. There will be an additional password-protected section of RCOG website where the collated national research recommendations will be available.
3. CSG proformas: reviewed; new logos had been added to reflect the sponsors.
4. New Chair: A re-advertisement for Chair of MM CSG would shortly be available on the RCOG website with a closing date of Mon 15th July. This follows LP’s appointment as Chair of the RCOG Research Committee. The Research Committee has recommended that a secretary be formally appointed to each CSG to take minutes and extract studies for database. For the MM CSG LP proposed Lucy Chappell (who had been undertaking this role informally for the past few years); LC agreed.
5. Proposals previously attached (email of 19th June 2013)
6. FD presented the new proposal for MAMAS trial – glibenclamide and metformin vs. standard care in GDM; primary outcome: proportion of women in each group who needed insulin treatment OR post-prandial glucose levels. The proposal was presented as a pilot trial with glycaemic control as a primary outcome. The CSG recommended that the study would be better submitted for funding as a feasibility study and that the primary outcome be recruitment rate/ proportion per site per month, with a wide range of secondary clinical outcomes. The group suggested that it would be important to gain information on willingness of women, obstetricians and diabetologists to take part. It was also suggested that the application include assessment of costs. It is intended that the proposal is submitted to the CSO in August. The group recommended that a health economist be appointed to the CSG.

*(Note – action: LP to invite health economist onto MM CSG, provide feedback and supporting letter)*

1. Dr Cath Taylor (senior lecturer in health services research) and Prof Debra Bick (Professor of evidence-based midwifery practice) presented their team’s proposal for MDT working in high-risk pregnancies (DM and cardiac disease) submitted as outline proposal to NIHR HSDR stream. This proposal had previously been submitted to the CSG in outline form and feedback had been provided, but the group had not had any detailed discussion previously. Systematic review had been undertaken as part of the outline proposal and had identified minimal evidence. A mapping survey across UK undertaken by the study team had shown large variation in models (constituent clinicians, timing of referral, means of communication) for these two diseases. A mixed methods study in 12 centres had been proposed as an observational study with the aim of making recommendations and/ or an RCT. Rationale for choice of DM and cardiac disease were discussed (impact on maternal morbidity/ mortality; maturity of development of MDTs). CNP supported the study in her role on specialist commissioning for maternal medicine and knowing the lack of evidence on this topic; it was agreed that there is a need to ensure that there is full understanding of what an MDT constitutes. FM pointed out that need to identify who is ultimately responsible for a pregnant woman when an MDT is in place. LP suggested consideration of long term follow-up for these women. There was unanimous support from MM CSG and LP suggested that a teleconference should be convened if the project were shortlisted for full application.
2. Prioritisation of HTA PICO proposals (attached) – notes reflect discussions in morning when first presented and in afternoon when presented again with JGT and JM present
   1. LCC presented proposal relating to RCT of PlGF as diagnostic test in women with suspected pre-eclampsia. A related proposal submitted to HTA as a responsive bid had been rejected. There was discussion over the change in physician behaviour needed and requirement for clear guidance on management algorithm if normal/ low/ very low PlGF detected. It was also possible to consider two trials: a) revealed vs. concealed and b) management strategies (e.g. guided management algorithm vs. clinician discretion) but the group expressed concern over harm if management was left to the clinician’s discretion, as a low PlGF result may be inappropriately used to decide delivery. There was general concern that there is only likely to be a small window of opportunity before this test is adopted into clinical practice. It was recommendewd that the PICO should include call for exploration of possible management strategies. It was noted that there was strong support for this trial from clinicians at ISSHP and internationally. The majority of CSG members participating (with one exception; JGT) supported this proposal.
   2. JGT presented proposal for timing of delivery for severe pre-eclampsia 28+0 to 33+6. Two old and small trials (Odendaal and Sibai); TOTEM (similar trial under consideration in Netherlands) not likely to go ahead. ACOG diagnostic criteria for severe pre-eclampsia were discussed. There was concern about feasibility over recruitment and that concerns about neonatal harm from iatrogenic preterm delivery particularly as maternal condition may stabilise. There was also uncertainty over which women with severe pre-eclampsia would be eligible for the trial – i.e. when would clinicians truly be in equipoise? Majority of CSG members participating had concerns over equipoise and feasibility.
   3. JM presented proposal relating to RCT of treatment of mild gestational diabetes (fasting hyperglycaemia) related to threshold for abnormal fasting glucose on screening criteria. Incremental benefit not clear therefore important to decide prospectively what benefit would be clinically important. Discussed that no RCT evidence that use of new criteria vs. existing criteria improves outcomes. Potentially 3-5% of women may be eligible for this study. It was agreed that the choice of entry criterion (fasting glucose of 5.1 to 5.4 and/ or 5.4 to 6.0) and primary outcome important were critical (LGA, neonatal outcome). It was considered whether it would be possible to stratify by fasting glucose and include mandatory OGTT in all centres (to ensure that overt GDM not missed). There was some discussion over the intervention and consideration that if NICE changed screening criteria then the trial might become difficult to undertake. Possible sample size: 1600 (but depends on basis of power calculation i.e. non-inferiority). JM will confirm rate of LGA at different levels of fasting glucose and undertake a survey of which RQ/ threshold is most important. Majority of CSG members participating supported the need for a RQ in this area with potential for precise details (e.g. thresholds for fasting glucose) to be finalised.

*Action: LP to send round voting form for these three PICOs to executive for decision.*

1. Update on planned studies
   1. WISP trial (iodine supplementation in pregnancy): not funded
   2. PHOENIX (timing of delivery in 34-37/ 40 pre-eclampsia): KCL group (Shennan/ Chappell) likely to be funded
   3. PARROT (PlGF in suspected pre-eclampsia): not funded
   4. UPBEAT (obesity in pregnancy): 1048 recruited and on target for finishing Feb 2014. Follow-up funding secured (EU); further funding for biomarkers awaited (MRC – July 2013); assessment of children’s cardiovascular function awaited (BHF – Sep 2013)
   5. FACT (folate supplementation in pregnancy): Prof Robson has reported to LP that despite considerable difficulties in arranging for drugs/ placebos, the trial will go ahead.
   6. EMPIRE (management of women with epilepsy in pregnancy): slow recruitment still an issue – trial noted to be labour-intensive. 180 recruited; 1000 total needed, with one year left to go.
   7. IMPROVED (prospective observational cohort study of screening tests for pre-eclampsia): funded by EU and due to start late 2013.
   8. STRIDER (sildenafil for FGR): awaiting final financial issues to be sorted then funding will be agreed by NIHR
   9. PROPS (RCT probiotics in a) obese women and b) GDM with outcome – fasting blood glucose)
   10. TEST (3-arm RCT first trimester trial: aspirin/ 1st trimester screen +/- aspirin/ control) – feasibility study funded by Perinatal Ireland. Note EU study by Nicolaides.
   11. PITCH 2 (RCT of UDCA vs placebo): through to final round of NIHR EME call with decision July 2013
   12. StAmP (statins in early onset pre-eclampsia) – awaiting decision on extension
2. Thanks give to Lucilla Poston for her work as chair of MM CSG.
3. Date of next meeting: Thurs/ Friday in early November tbc by Doodle Action LP’s PA