**Maternal Medicine CSG Meeting Notes**

**Thursday 27th September 2012, RCOG, Wyeth Pavilion**

1. Present: Prof Lucilla Poston, Dr Lucy Chappell, Dr Jenny Myers, Prof Catherine Nelson-Piercy, Prof Shakila Thangaratinam, Dr David Williams

On the phone: Prof Fionnuala McCauliffe, Dr Shireen Meher, Dr Fiona Denison

Apologies: Dr Ian Crocker, Prof Marian Knight, Prof David McCance, Dr Dharmintra Pasupathy, Prof Steve Robson; Prof Jim Thornton, Prof Cath Williamson; Dr Jason Waugh

1. Ongoing/planned studies update
2. EMPIRE trial. Women with epilepsy; management trial, (Shakila Thangaratinam, QMUL).

NIHR funded trial in women with epilepsy on AEDs randomised to revealed therapeutic monitoring vs. concealed (managed on clinical grounds only). 50 patients recruited since Nov 2011 (projected 240 in this time period) over 25 centres. Aiming to go into Scotland with assistance of Prof Jane Norman and potentially Ireland. LOOKING FOR NEW CENTRES. PLEASE CONTACT SHAKILA

1. IMPROVED; 1st trimester study EU. (Louise Kenny, Cork) EU FP7 funding given for 1st trimester prediction of pre-eclampsia study to include biomarkers. Recruitment across Europe.
2. STRIDER; Sildenafil for IUGR (Louise Kenny, Cork). Outcome of WellBeing Application? Submitted to HTA? LK to update.
3. PROPS (RCT antibiotics and glucose intolerance in pregnancy (Fionnuala McCauliffe, Dublin). RCT of probiotics in 150 obese pregnant women and 150 gestational diabetic women to see if they reduce fasting glucose. Ongoing single centre- Dublin.
4. TEST– first trimester screening for pre-eclampsia and fetal growth restriction, a RCT pilot. (Fionnuala McCauliffe, Dublin). Being undertaken by Perinatal Ireland network in collaboration with Prof Zarko Alfirevic with pilot of 1000 nulliparous women in preparation for possible large study of 25000 to 30000 women. Three armed approach with 75mg aspirin as intervention, following Prof Nicolaides’ algorithm for first trimester screening. At protocol development stage.Suggestions welcomed! Ps contact Fionnuala.
5. PITCH – follow on trial. (Cath Williamson, Lucy Chappell, Jim Thornton). RCT of UDCA vs. placebo to be submitted for NIHR EME commissioned call in Women’s Health.
6. PARROT; RCT of revealed vs. concealed PlGF for pre-eclampsia diagnosis (following PELICAN observational study). HTA submission planned January 2013. (Andy Shennan, Lucy Chappell)
7. La Vida; RCT of 2000iu (50micrograms) vitamin D to reduce risk of pre-eclampsia and improve outcome in women at increased risk (judged as requiring aspirin) being prepared for NIHR EME commissioned call. Vitamin D measurements would be concealed, but women could continue to receive recommended supplement eg 400iu. Forthcoming RCOG SAC statement recommending 800-1000iu dose for certain groups of pregnant women may influence supplemental level given to all women (David Williams UCL and Elina Hypponen)
8. FACT; folate for pre-eclampsia prevention RCT from Canada (Steve Robson). 750 women (as part of larger international trial) in RCT of 5mg folic acid in women at increased risk of pre-eclampsia with aim of prevention. Anticipated start date April 2013. Opportunity for additional sample to be taken at first trimester for prediction studies discussed. Will commence in 2 CLRN networks (Newcastle, South London).
9. HTA applications for HTA call for planned delivery of pre-eclampsia 34-37 weeks’. (Lucy Chappell/ Andrew Shennan and Shakila Thangaratinam/ Khalid Khan). Two applications were submitted despite work by Chair (LP) to encourage single collaborative application only.

*Action: All study PIs to submit MM CSG proforma to Lucilla Poston*

1. CoLaboratory; GATES funded pre-eclampsia group. LP reported that an international group existed to enable collaboration between different databases and biobanks related to pregnancy using the LINK registry. <http://www.linkregistry.org/search.aspx>. This is a very useful resource and beginning to be widely used by the Obstetrics community, RISK has already led to several new collaborative studies. LP recommended that those with relevant databases/biobanks and willing to collaborate should enter the modest fields required on the database. Shakila Thangaratinam offered to contribute PREP database. If any senior academic would like to join the CoLab group please contact LP.
2. **Brain storming session to set priorities for maternal medicine trials/observational studies – to report to RCOG Academic Committee- and thence to HTA**.

LP tabled list of NICE research recommendations from relevant guidelines, which were discussed as basis for development of recommendations for HTA calls in Maternal Medicine.

The following suggestions were put forward following discussion

1. **Development of outcomes in obstetrics**: i) core outcome set; ii) development of composite maternal and perinatal outcomes for major diseases (diabetes and pre-eclampsia/ hypertension in pregnancy) potentially stratified by term and preterm birth iii) identification of component outcomes for use in prospective meta-analyses iv) use of biomarkers as alternative surrogate markers for certain disease states. *Action: Shireen Meher (Liverpool) to develop HTA vignette for this topic*
2. **Diabetes in pregnancy**: The NICE research recommendations were reviewed.

* Submission has been made by Diabetes CSG for evidence synthesis to assess screening criteria for GDM from UK HAPO centres, to include cost-effectiveness;
* The diabetes CSG had also addressed the NICE recommendation for further assessment of intensive vs. less intensive surveillance for women positive on screening;
* It was noted that a submission fro the Diabetes CSG for RCT of use of insulin pump (a NICE recommendation) had not been not funded
* The group agreed that there a need to undertake an RCT to compare outcome of GDM diagnosed by fasting glucose as recommended by IADPSG (HAPO based) against conventional criteria*. Action: Jenny Myers(Manchester) to develop an HTA vignette.*

1. **Hypertension in pregnancy**: The NICE research recommendations from the 2010 hypertension guidelines were reviewed

* RCT of calcium in pregnancy (previously rejected by HTA).
* Choice of antihypertensive drug for i) chronic hypertension ii) gestational hypertension iii) post-partum hypertension – consider undertaking in stages with evidence synthesis, feasibility, main RCT

Action: *Shireen Meher to develop HTA vignette for RCT of calcium; Lucy Chappell, Cathy Nelson-Piercy, Jenny Myers, David Williams to collaborate on HTA vignette for antihypertensive drugs in pregnancy and post-partum.*

1. **Obstetric cholestasis**: PITCH team (Cath Williamson, Jim Thornton, LucyChappell) may develop a vignette depending on outcome of outline EME call.
2. **Obesity in pregnancy**: The NICE research recommendations for weight management in pregnancy were reviewed including the need for intervention studies in obese pregnancies. In view of current HELP (Cardiff ) and UPBEAT studies (KCL) it was agreed there was no need for a new call).
3. **Mental health in pregnancy**: The research recommendation for assessing the effect of an intervention for depression in pregnancy has been addressed by recent commissioned calls.

Note webaddress for HTA vignette: <http://www.hta.ac.uk/suggest/index.shtml>

Vignette writers are asked to submit to Lucilla Poston. Any MM CSG members not able to attend meeting can suggest additional topics for development.

1. Dates of next meeting: to be confirmed

At Annual Academic Meeting RCOG. December 6th  before Meeting Dinner

Provisional: Friday 26th April (lunchtime) at BMFMS, Dublin.