Stillbirth Clinical Studies Group

**Meeting minutes
16 November 2018, 10:30-13:30**

**Attending:** Sarah Stock (SS), Gordon Smith (GS, by phone); Baskaran Thilaganathan (BT), Kate Walker (KW), Steve Charnock-Jones (SCJ), Jane Sandall (JaS), Julia Sanders (JuS), Dharmintra Pasupathy (DP; standing in for Hannah Knight), Janet Scott (JSc), Mehali Patel (MP)

**Apologies:** Alex Heazell (AH), Jim Thornton (JT), Peter Brocklehurst (PB), Alyson Hunter (AH), Dimitrios Siassakos (DS), Tracey Mills (TM), David Cromwell (DC)

1. Welcomed Mehali Patel, new Senior Research Officer with Sands, and Dr Kate Walker as permanent trainee member.
2. Minutes of the last meeting 25 April 2018, approved.

Actions arising:

* + 1. PICO on smoking. KW established research study on this topic already underway. Agreed not to proceed with PICO.
		2. Website up-dates. SS up-dated details on the RCOG website. Up-dated text/minutes provided to BMFMS site and awaiting posting. Agreed to post minutes on Sands website instead. Discussed options for wider dissemination to parent and research-peer audiences.
		ACTION: JSc/MP to work up dissemination plan for next meeting and post minutes on Sands site with links through.
		3. Membership: Perinatal Pathologist invited to join the group but not confirmed. Researcher from Eire has asked to join. There may be issues with non-UK membership.

ACTION: JSc/MP to check TOR and budget for travel and follow up Pathology vacancy

1. **Up-dates on on-going projects**
	1. HTA-funded evidence synthesis/health economic analysis of universal late pregnancy ultrasound (GS): Going well. Systematic review underway of US as diagnostic test in unselected, nulliparous, term pregnancies to predict stillbirth risk. Health economics analysis of three screening models underway. Due to complete mid-2019.
	2. Each Baby Counts and NMPA (DP): Both projects reported on 15 November.
	NMPA reporting timelines extending due to new NHSE/HQIP sign-off processes. Annual clinical report held up due to data delays.

EBC: latest progress report here: <https://www.rcog.org.uk/globalassets/documents/guidelines/research--audit/each-baby-counts/each-baby-counts-report-2018-11-12.pdf> . Improved quality of reporting and parent engagement noted but no change to 70% poor outcomes that might be avoided with different care. Discussed dearth of high quality clinical data linked to outcome.

* 1. PARENTS2 & iCHOOSE (DS): PARENTS2 final report and Policy Consensus published <http://www.bristol.ac.uk/media-library/sites/policybristol/PolicyBristol-report-oct18-engaging-parents-baby-loss.pdf> . iCHOOSE (NIHR-funded project to establish Core Outcome Set for research into care after stillbirth): at stage of co-design with parents. Co-produced recruitment video: <https://vimeo.com/292143259/f2edb109dd>. Interviews started.
	BJOG Stillbirth issue very successful - over 31,000 downloads.
	2. DESiGN (DP): Cluster RCT comparing GAP and GROW. Primary outcome US detection of SGA babies. Includes implementation stream (JaS leading) and economic analysis stream – both underway. All Trusts randomised and 5/7 gone live. Reporting late 2019.
	3. ARRIVE-UK (KW): ARRIVE–US <https://www.nejm.org/doi/full/10.1056/NEJMoa1800566> study found no increased risk in elective IoL in low risk nulliparous women at 39 weeks. Although SCSG had been supportive of proposals for ARRIVE-UK study (minutes April 2018) agreed not pursue. ARRIVE-US doesn’t suggest IoL reduces SB for low risk women, but confirms those women can safely choose IoL if they wish.
	4. CoOPT (SS): early stages, going well.
	5. DIPLOMATIC study (SS): submitted first report. Underway in Malawi/Zambia.
	6. IPD Meta-analysis of stillbirth – global network IPD (BT): Moderating inclusion criteria – completion by early 2019; research protocol in final draft. Data outputs from 2million pregnancies – now standardising datasets.

ACTION: JSc/MP/SS to devise a structured feedback form for studies by next meeting

1. **Completed projects**

AFFIRM (SS, AH): published in Lancet in September. [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)31543-5/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2818%2931543-5/fulltext) . Unclear outcomes have left questions about clinical care. RCOG GTG being up-dated. Scottish Govt advising RFM remains important and care should follow GTG as minimum. Sands advice to women remains to report concerns straight away. Awaiting international meta-analysis.

1. **RCOG Research Committee**

Feedback from HTA to RCOG very positive – highest submission of successful PICOs; SCSG contributed highest proportion of those. No recent submissions – members urged to consider new topics.

SS described recent changes in HTA structures. PICOs can go to other programs such as HDR. Target perinatal mental health/bereavement care too.

ACTION: SS to prepare summary funding options for clinical studies

1. **Funding calls**
2. HTA call: <https://www.nihr.ac.uk/funding-and-support/funding-opportunities/?&start=1&custom_in_Specialty=3939>
3. Sands research funding call 2018-19 (MP): Open. Deadline 3rd December 2018. <https://www.sands.org.uk/our-work/research/apply-research-funding-live-call> . Grants up to £40,000: includes pump-priming, seed awards, part-funding.

1. **PICOs**
Discussed possible PICO for intermittent auscultation. What is actually being done on labour wards as opposed to what’s in guidance? Agreed first step is to facilitate agreement on what good intermittent monitoring looks like, via round table discussion.

ACTION: JSc to investigate possible Sands support. SS/JaS/JuS to work up discussion day format/aims.

ACTION: ALL to submit new PICOs

1. **CSG membership**
2. New members – see item 2 above
3. Trainee observers – SS advertised on RCOG website but no response yet. Attending the CSG would count as part of RCOG Advanced Professional Model in Clinical Trials. Agreed to invite two observers per meeting.

ACTION: KW and JaS to advertise

ACTION: JSc/SS to develop pro forma for applicants with brief details and confidentiality agreement for interested trainees to complete and sign

ACTION: MP to ensure all CSG members have signed confidentiality agreements too

1. **AOB**

Discussion of Welsh Government maternity statistics bulletin – concerns about definition of ‘healthy birth’ as a performance indicator. Should be ‘uncomplicated’. Should CSG raise concerns?

ACTION: JuS to find out where definition came from. SS to recirculate for email input to discussion.

**Next meetings:**

**26th April 2019, 10:30-13:00, RCOG, London**

**14th November 2019, 10:30-13:00, RCOG London** NB this date is different from that agreed in the meeting due to availability of rooms