

**MCRN/BAPN Paediatric Nephrology CSG Meeting; Monday 6<sup>th</sup> December 2010 (09:00 – 12:00), MRC Head Office, London.**

**Attendees:** Moin Saleem (MS), William Van't Hoff (WvH), Caroline Jones (CJ), Manish Sinha (MaS), Simon Waller (SW), Kjell Tullus (KT) Larissa Kerecuk (LK), Mine Orlu Gul (MOG), Leah Krischock (LAK) and Andy Lunn (AL)

**Via teleconference:** Wendy Cook (WC), Sally Feather (SF), Sally Johnson (SJ), Laura Pilkington (LP)

**Apologies;** Mark Woodward (MW), Rodney Gilbert (RG), Nick Webb (NW)

**Additional attendees:** Ania Koziell (AK).

AGENDA ITEM	SUB-TOPIC	KEY DISCUSSION POINTS	ACTION POINT(S)
<b>1. Welcome and apologies</b>	N/A	The chair opened the meeting and welcomed everyone in attendance. Apologies were noted, as above.	None.
<b>2. Introduction of new members</b>		Andrew Lunn was introduced to the Group. Andrew has taken over from Alan Watson who has recently retired. He will represent the paediatric nephrology units in Nottingham on the Group.  Larissa Kerecuk informed the Group that she has moved to Birmingham. She will officially represent this region on the CSG and Sally Johnson will represent Newcastle.	None.
<b>3. Review of minutes from previous meeting and matters arising</b>	<b>[Paper 1]</b>	The minutes from the last meeting held on 6/07/2010 were reviewed by the group and were accepted as an accurate record of the discussions that took place. The following matters arising were discussed:  Jenny Newman (JN) (MCRN Consumer Liaison Officer) is coordinating consumer activities centrally. JN wants a formal process for widening consumer representation and her plan for all CSGs is to involve a number of lay Members. The CSG is still waiting for JN's reply regarding the appointment of additional Consumers to assist Wendy.	MS: To speak to JN again.
<b>4. Update from the MCRN CC</b>	<b>[Paper 2/3]</b> Supporting	MS presented paper 3 which provided an overview of the meeting held on 24 September to develop links between the MCRN CSGs, AMRC Member Charities, NIHR research funders and	LP: To disseminate both reports as and when they have been

	<p>development and delivery of the very best paediatric research across the UK</p>	<p>major funding councils. LP reported that the meeting had exceeded expectations and advised that Simon Denegri / Michael Beresford are drafting a more formal report which will be disseminated to all those who attended the meeting and to AMRC Member charities in due course. LP also reported that a guide is being prepared between the MCRN and AMRC Member Charities about the points to consider when assessing the feasibility of research involving children.</p> <p>MS mentioned that a deputy should be designated to attend CSG related meetings on his behalf when he could not attend. It was noted that next CSG Chairs Forum will take place on 10th March 2011 and that a deputy might be required to represent the CSG.</p> <p>MOG brought up the idea of engaging with main kidney charities at an early stage and the possibility of inviting the selected charity members to a CSG meeting.</p>	<p>finalised.</p> <p>MS: To invite Kidney Research UK and Kids Kidney Research representatives to a future CSG meeting.</p>
	<p><b>[Paper 4]</b> CSG annual report</p>	<p>MS has produced and submitted a report on the progress, activities and achievements of the CSG to the MCRN. LP thanked MS for putting this together. Feedback on the key findings from all of the reports will be presented at the next CSG Chairs' Forum and subsequently shared with CSG Members.</p>	<p>None.</p>
	<p><b>[Paper 5]</b> CSG objectives</p>	<p>Members reviewed the 18 objectives that have been developed by the MCRN CC and discussed how they might be achieved. It was agreed that this should be a rolling agenda item at each meeting.</p> <p>SJ mentioned the lack of trainee representatives on the CSG. LP informed Members that Ann Byrne (AB) has taken over the appointment process of new Members to CSGs. LP will ask AB to liaise with MS re an advert for a trainee representative.</p> <p>AL suggested developing a list of ongoing multicentre studies recruiting patients for wide distribution to the research community.</p> <p>MS mentioned that he gave a presentation about research and the Nephrology CSG at the BAPN winter meeting.</p> <p>LP suggested that Nick Webb could contribute to the objective re CSG impact on studies by</p>	<p>CSG Chair / Members: To review the objectives in a timely manner and keep up to date records of activity.</p> <p>Ann Bryne: To put an advert together and circulate to the appropriate Groups.</p> <p>CSG Chair / Members: To create a quick list of studies which have an approval for recruiting at their centre.</p> <p>CSG Chair / Members: To keep a record of their activity re CSG promotion e.g. presentations at</p>

		<p>providing information (? In case study style) on the PREDNOS study.</p> <p>MS recommended sending the CSG meeting minutes formally to non-medicines or publishing the minutes on the updated MCRN website.</p>	<p>key events.</p> <p>MS: To contact Nick Webb.</p> <p>LP: To share minutes from CSG meetings with non-medicines group / see if they can be included on the new MCRN website.</p>
	<p><b>[Paper6]</b> MCRN Key stakeholder meeting</p>	<p>This meeting will take place on Thursday 3<sup>rd</sup> March 2010 at the Manchester Conference Centre and will focus on sharing best practice on widening participation in children's research. LP encouraged CSG Members to attend. Registration is free and will be available from the MCRN website in due course.</p>	<p>LP: To notify CSG Members when registration is available.</p>
<p><b>5. Update on consumer activities</b></p>	<p>N/A</p>	<p>WC attended the 'Open Day' on September 17<sup>th</sup> to celebrate the 5th anniversary of 'Nephrotic Syndrome Trust' (Nest) and the opening of new research laboratories at Southmead Hospital, Bristol. Parents attended with their children together with medical staff and the Deputy Lord Mayor. MS and colleagues gave a seminar on the latest developments of NS research and afterwards parents had the opportunity to ask questions. A buffet lunch was provided and craft activities were laid on for the children. It was noted that the tour of the new laboratory was a great success as was the opportunity of parents being able to speak in person to researchers and to others coping with the same kidney condition. The 'Open Day' received very good feedback from parents.</p> <p>WC informed Members that the Nest Website <a href="http://www.nstrust.co.uk">www.nstrust.co.uk</a> is currently being rebuilt on a bigger &amp; better server. This will create more space to offer more information. The NEST newsletter is hopefully going to be produced over the next few weeks for families. WC encouraged Members to let her know if they have got any news or links that they would like to be added either to the website or newsletter, which would benefit parents and their children. WC is also in the process of getting the NEST leaflets reprinted. WC asked for any changes to be sent to MS.</p> <p>WC has also agreed to be a consumer representative for the PREDNOS study and</p>	<p>CSG Members: To send any links / news that they would like to be included in the NEST newsletter or website to WC.</p> <p>WS: To keep the group up to date with consumer related activities / news.</p>

		<p>weather/train permitting; she is planning on attending the joint AMRC &amp; RDUK Rare Disease Workshop on Thursday 9<sup>th</sup> December.</p> <p>WC informed Members that some of her international colleagues (e.g. Elena Levtchenko and Johan) would very like to do a joint science activity together with UK doctors and at least 1 representative from each NS patient Organization in Brussels, in May/June next year. However it was noted that this will depend on funding. WC agreed to keep the group up to date with details.</p> <p>WC submitted the following additional points after the meeting:</p> <p>“Parents still requesting advice on toxicity of drugs etc.. Could perhaps do a doctors list of meds with possible side effects etc... Still would like some help doing a most frequently asked question &amp; answer page for families???”</p> <p>“Perhaps we should advertise link to RaDaR on website for families?”</p>	
<b>6. KKR / CSG funding update</b>	N/A	MS informed Members that the projects that were prioritised at the last CSG meeting have been submitted to KKR. A panel has been convened to review the applications. This panel includes: Neil Turner, Mary McGraw and Dick Trompeter and will meet shortly.	MS: To keep the group up to date with the outcomes following the review panel meeting.
<b>7. Update on studies in development</b>	<b>[Paper 7]</b> ACHIEVE (RS)	Dr Rukshana Shroff submitted an update on progress in advance of the meeting. This read as follows: “We have 47 children randomised and with a follow-up time of 6 - 22 months. An interim analysis shows that ergo supplementation delays the onset of secondary hyperparathyroidism. More data will follow at the next CSG meeting. No adverse events”	RS: To submit an update on progress in advance of the next CSG meeting. LP to remind RS.
	APPROVE (JD)	The study team are still thinking about the next steps (? developing a study looking at infants with antenatal hydronephrosis) and are planning to meet in Liverpool over the next couple of weeks to discuss things in more detail.	JD: To submit an update on progress in advance of the next CSG meeting.

ARB Study (KT)	KT presented an update to the Group. KT mentioned that now they have a CTU which will redo the power calculations. After some discussion, It was agreed that KT should convene a working group in order to move things forward with the protocol. It was decided that this Group should include: KT, LK, NW, WVH and Joanna Clothier from Birmingham Children's Hospital. Manish Sinha will also be part of the working group due to the overlaps in topic area / study design with the study that he is developing looking at blood pressure and target organ damage in children with CKD.	KT: To convene a meeting of the working group and submit an update on progress in advance of the next CSG meeting.
C1q Antibody (SJ)	80+ samples were collected across three centres (Birmingham, GOSH and Liverpool), all of which have now been analysed. A teleconference will take place later this week to go through the results.	SJ: To submit an update on progress in advance of the next CSG meeting.
Taurolock (CJ)	CJ gave an update to the Group. She mentioned that the feasibility study is going on and she is working with Helen Hickey (MCRN CTU Senior Trials Manager). CJ explained that MCRN CTU will send a report to the researching unit/nurse to complete a log each month. However, she shared her concern on the lack of a working group and lack of information on patient view. She mentioned the need for feedback by LRN nurses. With regards to this, WVH recommended that CJ should contact dialysis nurses and LK offered to email the contact details of Birmingham research nurses. The CSG Group is still keen to support this study.	CJ: To contact with dialysis nurses.
Rituximab (AK)	AK presented an update to the Group. 300k funding was approved by Guy's and St Thomas's Hospital NHS Foundation Trust (GSTT) which covers one Band 7 research nurse. However, the study is not eligible for adoption by NIHR due to the DoH ruling on the approved funders which excludes some charities, like GSTT. AK indicated that Andrew Rose is look into this issue. AK mentioned that there is no final protocol available yet due to the need for evaluation by a clinical trial statistician. AK is waiting to meet with Colin Baigent, (Clinical Trials Lead in Renal Association, Clinical Trial Service Unit and Epidemiological Studies Unit, Oxford University). Following the feedback from Colin Baigent, AK's plan is to ask nephrotic leads more about the study to refine the protocol.	AK: To organise a working group meeting.
Adherence (VS)	MS informed the group that the study development is led by Veronica Swallow (Senior Lecturer in Children's Nursing, University of Manchester).	MS: To provide feedback on progress of the study development at the next meeting.

	CKD (MaS) [Papers circulated electronically on 01/12/2010]	MaS gave a presentation and the Group gave their feedback. The discussions highlighted that the protocol required more detail and that MaS / KT should work together as much as possible given the overlaps in topic area / study design (see ARB notes above).	MaS: To update the protocol based on the comments made by CSG Members and send to the CSG for further review.  CSG Members: To review the protocol and make further comments.
<b>8. Update on funded/portfolio studies</b>	Funded studies	MPGN - SJ presented an update to the Group. The study is on hold due to R&D problems. Birmingham Children`s Hospital has not signed off this study and the plan is to transfer to Newcastle R&D. MS gave a message that MPGN patients should be recruited to RADAR.	SJ: To keep the group up to date.
	MCRN portfolio adopted publicly funded studies	<p>RaDaR - MS presented an update to the Group. Recruiting is continuing. 92 patients have been recruited in total so far (61 in SRNS, 21 in MPGN, 10 unclassified). The funders (BKPA/KRUK) jointly agreed to support the infrastructure with £500k over 3 years. MS mentioned that the website is working better and a page will be designed for each specific disease group. One CSG member referred to the adults group`s interest to involve in RADAR.</p> <p>RaDaR (The SRNS Study) – All UK centres can recruit patients for clinical data collection to MPGN and SRNS. For SRNS sample collection, 11 of 13 centres now approved by local R+D and recruiting patients.</p> <p>A Rare Disease Committee has been formed by the Renal Association, with Mark Taylor as the Chair. This committee will shortly call for new Disease Working Groups to form and apply for funding, available from the BKPA/KRUK donation mentioned above. This is a unique opportunity to utilise the RADAR infrastructure to study and manage renal diseases.</p>	
	MCRN portfolio adopted commercially funded studies	MS explained that in the case of a local approach by industry, it should be sent to the CSG Chair who will then flag this to the MCRN Industry Team. Following this, each local centre will then be contacted re their interest.	None.

	Paediatric (Non-Medicines) Nephrology studies	It was mentioned that the CSG has very few non-med studies on the paediatrics (non-medicines) specialty group portfolio. The strategic priority should be to have more non-med studies in the future.	
<b>9. EBV Vaccine</b>	N/A	It was mentioned that Jane Tizard has received expressions of interest directly, following a request via CSG members.	None.
<b>10. EMA Concept paper</b>	Clinical investigation of medicinal products to slow progression of renal insufficiency	The document is available for consultation. The EMA deadline for comments is 1 <sup>st</sup> Jan 2011. KT sent his comments to MS and was thanked for this. CSG members mentioned that input from Renal Associations (ESPN, BKPN, BRS, Nurses group etc.) would be valuable.	MS: To send a reply to the EMA on behalf of the Group.
<b>11. Any other business</b>	N/A	PREDNOS study: An update and newsletter regarding PREDNOS was submitted by Nick Webb for CSG Members` information. The funding has been all agreed. The Trial team have been appointed and are in post in Birmingham Clinical Trials Unit. The website has gone live. The full protocol has been agreed. MHRA approval granted. MCRN approval granted. Being heard at REC 13 12 2010. The drug is currently being manufactured. The Trial Steering Committee and Data Safety Monitoring Committees have been appointed and meetings scheduled. They are hoping to recruit first patient early in 2011. Over 80 centres signed up and named on the first REC submission. Other centres (which expressed an interest) will be included by a REC amendment submission. WVH highlighted the importance of HTA funded studies and drew attention to the fact that PREDNOS can be a headline study if delivered successfully.	None.
<b>12. Date, time and location of next meeting</b>	N/A	Three face-to-face meeting dates will be confirmed in due course.	Ann Byrne to arrange three face to face meetings for the CSG in 2011.