

MCRN/BAPN Paediatric Nephrology CSG Meeting; Tuesday 6th July 2010

Attendees: Moin Saleem (MS), William Van't Hoff (WvH), Wendy Cook (WC), Patrick McKiernan (PMc), Caroline Jones, Manish Sinha (MS), Leah Krischock (LK), Simon Waller (SW), Mark Taylor (MT), Mark Woodward (MW), Laura Pilkington (LP), Rodney Gilbert (RG); Sally Johnson (SJ).

Apologies: Kjell Tullus (KT); Nicholas Webb (NB); Alan Watson (AW); Sally Feather (SF); Larissa Kerecuk (LK); Mine Orlu Gul (MOG); Jan Dudley (JD).

Additional attendees: Meeta Mallik (MK) – representing Alan Watson; Ania Koziell (AK).

AGENDA ITEM	SUB-TOPIC	KEY DISCUSSION POINTS	ACTION POINT(S)	INITIAL(S)
1. Welcome, introductions and apologies	N/A	The chair opened the meeting and welcomed everyone in attendance. Apologies were noted, as above. Mark Woodward, a Paediatric Urologist, has joined the CSG - this was Mark's first meeting. It was noted that Alan Watson is retiring – an advert for his replacement will need to go out following the meeting with a view to attracting someone from Nottingham.	Find a replacement for AW by advertising through the usual MCRN communication routes.	LP
2. Review of minutes from previous meeting and matters arising	N/A	The minutes from the last meeting on 15/03/10 were reviewed by the group and were accepted as an accurate record of the discussions that took place.	No action required.	LP
3. Update on Cysteamine	N/A	An email from MOG was tabled for information. MOG will update the Group as and when more progress has been made.	Keep CSG up to date with any new developments.	MOG
4. Update on consumer activities	N/A	Since the last meeting, WC has delivered the opening address at the International Podocyte Congress and has consulted with a number of parents reading their views about the idea of setting up parent support groups at each local renal unit. MS commended WC's work through these activities. It was noted that parents would very much welcome the notion of parent support groups as many parents (including WC) currently feel isolated. WC informed the CSG that parents definitely want to know more information and would be willing to provide a parent perspective on studies. It was suggested by a Member of the CSG that a database containing the details of 'interested parents' would be a useful resource for the CSG to have access	Work closely with JN (MCRN Consumer Liaison Officer) to develop a Nephrology parent contact database. Seek JN's advice regarding advertising for more consumer CSG representatives [LP has	MS/WC MS/WC

		to. It was agreed that WC/MS should work closely with Jenny Newman (JN) (MCRN Consumer Liaison Officer) to take this forward. In addition it was decided that WC/MS should ask JN to recruit additional consumer representatives on to the CSG and see if some of the leaflets that JN has produced about consumer involvement could be circulated to each Nephrology Centre – this could be coordinated through the Nephrology CSG Members.	informed JN of this. JN will contact MS/WC shortly] See if some of the leaflets that JN has produced about consumer involvement could be circulated to each Nephrology Centre.	MS/WC – distribution facilitated by CSG Members
5. MCRN CSGs and Paediatric (Non-Medicines) Specialty Group	N/A	The process of appointing a Paediatric (Non-Medicines) Specialty Group representative (in an <i>ex-officio capacity</i>) to each CSG is underway. Applications for the Paediatric (Non-Medicines) Specialty Group representative for each CSG are being collated and will be considered by the Chair of the Paediatric (Non-Medicines) Specialty Group, Chair of the relevant CSG, Chair of the MCRN CSG Chair’s Forum and an MCRN Executive representative. This position will ensure full integration and detailed, bi-directional communication of Non-Medicines-related research activity with the activity of the CSG. A single representative, mapped to each CSG, will avoid imbalance within each CSG of Specialty Group representatives and avoid imbalance of Specialty Group representation across CSGs (dependent on relevant sub-specialty expertise within Specialty Group leads). Specialty Group leads were selected / appointed to represent the entire spectrum of Paediatric (Non-Medicines) disciplines within their CLRN, and not specifically their own sub-specialty; their principle role therefore as Paediatric (Non-Medicines) Specialty Group lead is to nurture a comprehensive portfolio of studies within their area, and not their own specific specialty; at the same time their specific specialty expertise is recognised in the advisory roles they provide to the local CLRN and Specialty Group itself; for those nominated, this will also include representation on the CSGs.	Keep the CSG up to date with integration of Specialty Group Members across CSGs.	LP
6. MCRN CSG Chairs’ forum	Opening meeting with AMRC Charities, Major funding Councils and NIHR Research Funders	The Forum is hosting, in collaboration with the Paediatric (Non-Medicines) Specialty Group (one of the CLRN Specialty Groups) and Simon Denegri, CEO of AMRC, an important meeting on the 24th September in London (venue to be confirmed) with AMRC Member Charities, Major Funding Councils and NIHR Research Funders. The main aim of the day will be to present the integrated role the CSGs have within the MCRN, in close collaboration with the Paediatric (Non-Medicine) Specialty Group, in supporting the development and delivery of the very best paediatric research across the UK. In this way it is hoped to encourage funders to support applications integrated into this process. The other aim of the day will be to provide a forum for	Feedback at the next CSG meeting.	MS/WvH/LP

		dialogue with AMRC Member Charities, Major Funding Councils as well as NIHR Research Funders to discuss a shared approach to these challenges. Representatives from several renal charities (suggested by MS) have been invited.		
7. Update on studies in development	ACHIEVE	No updates have been received since the last meeting.	Ask Rukshana Shroff for an update.	LP
	APPROVE	The study team are still thinking about the next steps but remain keen to develop a study looking at infants with antenatal hydronephrosis.	Contact JD for an update.	LP
	ARB Study	KJ is in the process of trying to convene a study group to take the study forward in light of the comments received from the HTA and CSG. He aims to have the group up and running by Autumn.	Contact KJ for an update.	LP
	C1q Antibody	80+ samples have been collated across 3 centres. These have been sent to Cardiff for analysis. SJ hopes to be able to report the results shortly.	SJ to share the results of the study with the CSG as and when they become available.	LP
	Taurolock	CJ gave an overview of progress made since the last meeting. After discussion, it was agreed that the following actions would be taken: 1) CJ will ask for expressions of interest again 2) CJ will convene a study group 3) CJ will speak to Ruth Gilbert (CI of the CATCH study) 4) CJ to aim for a September application.	Carry out the action points to the left.	CJ
	Rituximab	AK gave an overview of progress made since the last meeting. After discussion, it was agreed that the following action points would be taken: 1) AK/MS to convene a meeting of the study group as soon as possible to address the issues raised by the CSG (e.g. focussing on the steroid resistant arm; removing unlicensed medicines) 2) AK to submit a revised version of the protocol to the CSG (via MS/LP) in good time before the next meeting (date to be confirmed) 3) AK to consider seeking additional funds from an automatically eligible funder in order to get her study adopted on to the NIHR MCRN portfolio 4) CSG Members to count up how many clinicians prescribe Rituximab and consider how Rituximab and Prednisolone will work	Carry out the action points to the left.	AK/CSG Members

		together.		
8. Update on funded/portfolio studies	Nephrotic Syndrome (PREDNOS STUDY)	Contracts for this study have now been finalised with the HTA. The study has been allocated funding of £845,000. The final touches are being added to the study protocol. Ethical Committee application, CTA certificate application and MCRN adoption application = the next stages. As part of the Ethical Committee application, a comprehensive list of participating centres along with local principal investigators needs to be included. It is important to be as inclusive as possible in the initial submission, as the later addition of sites and PIs necessitate a substantial amendment to the application. It was agreed that BAPN centre leads would identify sites within their region that are willing to participate and forward this information to NW. It is hoped that the first centres will be up and running by the beginning of October. The CSG can really help to deliver the study on target and within budget.	Email list of sites. Identify sites within their region that are willing to participate and forward this information to NW.	NW CSG Members
	RADAR (publically funded)	MS gave an update. The steroid resistant arm has been completed, across all sites. The MPGN arm is slightly behind but there were no concerns regarding this. The website is up and running and is working well. Disease Specific Working Groups are in the process of being set up. The term 'Disease-Specific' might have to be changed for governance reasons. The Vasculitis Group has been formed (+ funds from KKR). The Ciliopathy and JDM Groups are in the pipeline. Need to think about concrete steps towards sustainable funding. Further grant funding needs to go in, in 12 months time.	SJ to summarise issues/problems	
	Kids Kidney Research; qualitative study (VS)	Recruitment due to start. No further details were discussed.		
9. Industry Matters	Portfolio Studies	The following commercial study updates were reported: In setup: MCRN047 (20050256) - Amgen - Darbepoetin alfa/Anaemia CKD Receiving/Not Receiving Dialysis (SD109) *LRNs: WM (BCH), L&SE (ECH) *CLRN: West Yorkshire (1)	Notify AR if aware of any industry studies that should be adopted. MS write to all applicants; invite top three to submit a full application and feedback	CSG Members

		<p>*Start of recruitment target: 09-11/2010 (first subject 02/2011) *End of recruitment: 11/2012 *Targets: 9 for UK? (3 per site?) *Concerns over protocol led to GOSH and NT&W site to drop out, Newcastle concerns</p> <p>Open: MCRN026 (0954_337-01) Merck/Parexel – losartan/hypertension *LRNs: GMLC (RMCH), L&SE (GOSH) *CLRNs: HIOW (1) *Start of recruitment: 17/07/2009 *End of recruitment: 31/01/2011 *Targets: GMLC = 2-3 (3), L&SE = 2-3 (1), HIOW=2-3 (0)</p> <p>MCRN063 (TAK-491_109) – Takeda/ICON – TAK-491/hypertension PK (SD075) *LRNs: GMLC (RMCH), L&SE (GOSH), T (QMC), SW (BRCH) *Start of recruitment: 16/03/2010 *End of recruitment: 01/03/2012 *Targets: GMLC (RMCH) = 3 (1), L&SE (GOSH) = 3 (0), T (QMC) = 3 (0), SW (BRCH) = 3 (0) *Recruitment of Cohorts 1 and 2 is planned to end on 8 November 2010 *Planned start for Cohort 3 is 20 December 2010 *First global patient</p> <p>Closed MCRN003 (MK0954-326) - MSD – Cozaar/Proteinuria *>100% recruitment, n=9, t=8 (2 MCRN sites) *Follow-up ends: 31/10/2011 *Positive outcomes and very low rate of adverse effects, changes to SmPC *3 year extension phase will potentially ascertain whether ARBs are superior to ACEIs in preventing decline in renal function. http://cjasn.asnjournals.org/cgi/content/abstract/CJN.06620909v1</p> <p>MCRN040 (C08-002B) – Alexion - Eculizumab/PT-resistant aHUS (SD063) MCRN041 (C08-003B) – Alexion - Eculizumab/PT-sensitive aHUS (SD089)</p>	<p>the CSG's comments to all.</p>	
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	<p>*0% recruitment for both, but target 0-1 for both as very rare, so not necessarily expecting to recruit (not included in metrics above)</p> <p>*2 adolescent and 2 adult studies, all related</p> <p>*4 subjects recruited in UK to 2 adult studies (target = 5-8; 80%)</p> <p>*40 subjects recruited globally to all 4 studies including 9 adolescents when UK sites closed</p> <p>*Target for all 4 studies = 45 (15 for resistant/30 for sensitive protocols)</p> <p>Pre-adoption – have been to SAC discussions on-going</p> <p>SD276 (M10-149) - Abbott - Paricalcitol Capsules/Chronic Kidney Disease (Zemplar study)</p> <p>*LRNs: - RMCH, GOSH, ECH, BCH, Southampton</p> <p>SD273 (20090005) – Amgen - CKD/Mimpara/Cinacalcet PK/PD</p> <p>*LRNs: GMLC+</p> <p>Pre-adoption – at present not clear which sites/LRNs will be involved</p> <p>SD298 – Amgen Cinacalcet - Hyperparathyroidism in Hemodialysis</p> <p>SD277 (FER-CKD-251) - AMAG Pharmaceuticals/Kendle – ferumoxytol/Iron Deficiency Anaemia/dialysis-dependent CKD</p> <p>SD278 (FER-CKD-252) - AMAG Pharmaceuticals/Kendle – ferumoxytol/Iron Deficiency Anaemia/nondialysis-dependent CKD</p> <p>SD279 (FER-CKD-253) - AMAG Pharmaceuticals/Kendle – ferumoxytol/Iron Deficiency Anaemia/CKD (extension)</p> <p>SD280 (FER-CKD-254???) - AMAG Pharmaceuticals/Kendle – ferumoxytol/Iron Deficiency Anaemia</p> <p>Other issues:</p> <p>There are a lot of commercial studies coming in at different levels. It was note that this process needs to be streamlined. Members were advised to notify Andrew Rose when they are aware of any industry studies coming up. He will then send the protocol to the Chair, who will then decide from amongst the group who is the most appropriate to undertake a review.</p>		
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10. KKR/CSG Funding

The CSG reviewed several studies that had been submitted in response to the KKR funding call. These studies were prioritised by the group using the following process.

1. For each application MS will nominate a 'designated member' (DM) from among the CSG members
2. At the meeting, DMs will briefly present the application, and each will be discussed in turn
3. All members will be asked to rate all the applications, on a scale 1-5
4. A provisional prioritisation list will be made on the day, based on the discussion and funding available
5. Those at the top of the list (i.e. top three/fundable studies) will be asked to submit a full application, for external peer review
6. Peer review will be conducted via KRUK mechanisms, and consideration for eligibility for additional KRUK funding will come at this stage
7. A final funding decision will be made based on the prioritisation and peer reviews.

Comments and ranking - The highlighted studies = those studies that will be asked to suit a full application for external peer review.

Name	Title of study	Comments	Average score	Ranking
Hugh McCarthy	Development and Maintenance of the National Renal Rare Disease Registry	Important topic; study proposal nearly there.	3.8	1
Karl McKeever	Surveillance of stage 5 chronic kidney disease (CKD) in early infancy in the United Kingdom	Important topic; creatine of 120 at 4 weeks = too soon; creatine of 120 at 6 months = more reasonable; ? most	2.59	5

			appropriate use of funding.				
		Larissa Kerecuk	National study of paediatric cystic kidney diseases ciliopathies	Good topic; well structured proposal; there are possibly cheaper ways of doing the study; ? similar study already running in GOSH.	3.05	4	
		Rukshana Shroff	The effects of Hemodiafiltration, quotidian hemoialysis (QHD) and conventional hemodialysis (HD) on cardiovascular risk markers and growth in children	Clear project with hypothesis, protocol and justified costs; Comes from internationally established team with broad regional representation; topic is very important; like to see health economic and quality of life metrics; 6 months is possibly too short - significant risk of not finding a difference.	3.71	2	
		Kjell Tullus	Cardiovascular morbidity in	Important topic; study design	2.44	6	

			children and young people with systemic lupus erythematosus	needs more thought; should be in radar; could be more focussed – cross sectional analysis of patients compared to controls leading to a larger prospective study linked with adult units.				
		Carol Inward	Quality of life, socioeconomic and medical outcomes of young adults who develop established renal failure in childhood	Important topic; links in nicely with work that the BAPN are doing already; might be better run by a psychologist than a doctor.	3.19	3		
11. Any other business		There was no any other business reported.					No action required.	N/A
12. Date, time and location of next meeting	N/A	Meeting dates for 2011 will be circulated in due course.					Confirm 2011 dates/venue with CSG Members.	LP