2013/14

ANNUAL REPORT

NICRN

CLINICAL RESEARCH NETWORK

NICRN Co-ordinating Centre
Northern Ireland Clinical Research Network
2013/14

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Introduction

The Northern Ireland Clinical Research Network (NICRN) is a regional research platform, established in 2008 to support the contribution of the clinical research community in NI to the work of the UK Clinical Research Collaboration (UKCRC) and the associated Devolved Nations clinical research networks (CRN's). The NICRN is funded by the HSC Research & Development Division of the Public Health Agency and has a remit of supporting and facilitating clinical trials and other high quality clinical research projects.

Our aims are to

- Enhance the ability of patients and health care professionals to participate in and benefit from clinical research by providing full regional coverage when and where appropriate
- Enhance the quality of clinical research undertaken within HSC by providing a centrally managed approach
- Improve the speed of delivering research outcomes by ensuring continued monitoring of our portfolio in line with anticipated and informed targets
- Enhance the regional coordination of clinical research across Trusts and academic organisations through simple but effective communication pathways
- Improve local integration of clinical research within HSC structures and services by engaging across groups and with all relevant stakeholders

Our organisational structure is built around a hub and spoke design to facilitate connectivity, shortened communication pathways and quicker reaction time, which are strengths inherent to our regional scale. The network is operationally managed via a central coordinating centre hosted by Belfast Health & Social Care Trust (BHSCT). This places the co-ordination of the NICRN close to the majority of active researchers from Northern Irelands HSC trusts.

Reporting period

This document presents the activity and performance outputs from the NICRN disease specific interest groups for the period from 1st April 2013 to 31st March 2014 against their core performance targets.

Core performance targets

Each group is expected to achieve targets set in line with predicted activity, strategic direction, core staffing level and regional working. This is to ensure productive health and financial returns on core

funding in terms of numbers of patients and health care professionals engaged with via study screening and active accrual or participation, development of collaborative relationships locally across other research structures and with industry partners, Development of a high quality local portfolio and regional approach to conducting research. The table of group objectives can be reviewed in appendix 2

Network development over reporting period

Table 1 summarises some core data from the groups and compares this year's activity against the previous 2 years.

Interest group	Total active studies 13/14(12/13)(11/12)	No. Studies Adopted 13/14(12/13)(11/12)	Total Patients screened 13/14(12/13)(11/12)	Total Patients Accrued 13/14(12/13)(11/12)
Cardiovascular	**31** (17) (16)	**12** (4) (3)	**1641**(900) (2744)	**1116**(291)(541)
Children's	**16**(19) (22)	**5**(1)(7)	**1026**(462)(360)	**241**(162)(360)
Critical Care	**23**(10)(10)	**15**(4)(3)	**3707**(2797)(1816)	**623**(127)(479)
Dementia	**2**(1)(4)	**1**(1)(0)	**162**(102)(239)	**151**(97)(66)
Diabetes	**15**(10)(13)	**7**(6)(7)	**798**(462)(1458)	**415**(53)(406)
Primary Care	**15**(12)(11)	**6**(5)(7)	**6515**(2294)(2952)	**1344**(532)(1173)
Renal	**22**(15)(NA)	**8**(15)(NA)	**207**(231)(NA)	**82**(179)(NA)
Respiratory	**19**(15)(27)	**6**(4)(9)	**1370**(430)(1448)	**146**(206)(150)
Stroke	**9**(9)(8)	**3**(2)(0)	**2921**(5961)(4058)	**55**(106)(104)
Vision	**18**(19) 17	**4**(4) 8	**223**(223) 146*	**230**(151) 146
TOTAL	**170**(127) 128	**67**(46) 44	**18580**(13862) 15221	**4403**(1904) 3425

As can be seen from table 1-3 the general trend over 13/14 has been a significant increase in activity as compared to 12/13. All groups saw rises over most portfolio data elements, with the increase in activity across groups such as Cardiovascular, Children's, and Critical Care are worth highlighting. Over this reporting period the NICRN was undertaking 170 active studies, which equates to a 34% increase across groups over 12/13. Of these 67 were newly secured and adopted again an increase of some 43%. A total of 18580 screening actions had been performed ranging from simple data searches to full interactive screening with possible participants (a 34% increase) and of these 4403 participants were accrued by the staff across all interest groups. This equates to a massive 131% increase in accrual versus 12/13. Such an increase is indicative of changes in portfolio balance where more registry or observational studies have been adopted. Also it must be noted that this reflect changes from 12/13 where we observed a marked reduction I activity as compared to 11/12 reporting period.

In line with these increases across the board the number of commercial studies being undertaken rose by 12, although a 10 of these were in the highly successful cardiovascular group. Also the number of studies being run at more than 1 NI site increased from 43 in 12/13 to 70 in 13/14. This illustrates the collective approach and resultant benefit that networking brings to the delivery of R&D. In total the NICRN groups have shown an impressive and welcome increase in activity over this reporting period.

Table 2

Interest Group	No active studies 2012/13	Commercial		Randomised		Multi-Centred		Screened	Recruited
		No Studies	Proportion (%)	No Studies	Proportion (%)	No Studies	Proportion (%)		
Cardiovascular	17	6	35%	11	65%	5	29%	900	291
Childrens	19	2	11%	10	53%	6	32%	462	162
Critical Care	10	0	0%	6	60%	3	30%	2797	127
Dementia	1	0	0%	0	0%	0	0%	102	97
Diabetes	10	4	40%	4	40%	3	30%	462	53
Primary Care	12	2	17%	4	33%	9	75%	2294	532
Renal	15	9	60%	6	40%	7	47%	231	179
Respiratory Health	15	9	60%	9	60%	2	13%	430	206
Stroke	9	1	11%	7	78%	8	89%	5961	106
Vision	19	12	63%	11	58%	0	0%	223	151
Totals	**127**	**45**	**35%**	**68**	**54%**	**43**	**34%**	**13862**	**1904**

Table 3

Interest Group	No active studies 2013/14	Commercial		Randomised		Multi-Centred		Screened	Recruited
		No Studies	Proportion (%)	No Studies	Proportion (%)	No Studies	Proportion (%)		
Cardiovascular	31	16	52%	15	48%	8	26%	1641	1116
Childrens	16	1	6%	5	56%	8	50%	1026	241
Critical Care	23	1	4%	12	52%	11	48%	3707	623
Dementia	2	1	50%	1	50%	0	0%	162	151
Diabetes	15	4	27%	7	47%	8	53%	798	415
Primary Care	15	4	27%	8	53%	11	73%	6515	1344
Renal	22	8	36%	7	32%	11	50%	207	82
Respiratory Health	19	11	58%	11	58%	5	26%	1370	146
Stroke	9	1	11%	8	89%	8	89%	2921	55
Vision	18	10	56%	10	56%	0	0%	233	230
Totals	**170**	**57**	**34%**	**84**	**49%**	**70**	**41%**	**18580**	**4403**

Staffing compliment only rose by 2.5 WTE over the reporting period, so increases are more reflective of changes in portfolio balance than increased resource. The stability of the staffing record is also worth noting. Although there were some notable losses such as the loss of a CRN and principal investigator in the NHSCT for Cardiovascular, generally staffing was stable. This was in no small part down to the new staffing role within the co-coordinating centre and having a visible champion on site.

The most notable change was the activity of the staff management function under the direction of Mrs Sonia McKenna. Improved induction protocols, staff appraisal systems in line with each HSC Trust, managed training and education programmes, improved accountability pathways across sites were just some of the notable activities during the year. A key role was the staff manager's presence across all Trusts. This enabled better communication and provided a easy and efficient route for cascading and escalating information around the groups and network.

The role of the co-ordinating centre was also amended for efficiency. Previously under the flat management structure the coordinator role included, staff management, adoption and portfolio management. Although cost effective, this approach did not provide the depth of experience and more importantly focus to fulfil any of the functions adequately. To that end the functionality of the co-ordinating centre role was reviewed. The result was the need to focus on the key issues of efficiently adopting high quality studies, quality assurance based portfolio management processes and high quality staff management. With staff management already somewhat addressed the focus over the last quarters of 13/14 needed to be on the portfolio management system and ensuring it was fit for purpose locally and useable nationally. Our sister network, the NI Cancer Trails Network (NICTN) had already been using the EDGE portfolio management system under the direction of the national cancer research network and had been appraised as suitable. It is intended to implement the use of EDGE and roll out to all centres over the first half of 14/15. To ensure the system is developed, implemented a managed appropriately the necessary IT skill mix will need developed within the co-ordinating centre.

The network was established to support clinical trials and other high quality research projects. The portfolio for 13/14 was well balanced across most (90%) of active groups with at least 50% of portfolio studies being either Clinical Trials of Investigational Medicinal Products (CTIMPs) of other trials.

The success of the network is dependent on the delivery of the portfolio to target. The exact level of recruitment to target is presented within each interest group activity report however over the reporting period the overall recruitment to target for entire portfolio was around 74%.

Finance overview

The NICRN is financially supported by HSC R&D Division of the Public Health Agency. Along with the Coordinating Centre; HSC R&D funds a cadre of core staff, mainly nursing and AHPs, to allow each group's study delivery objectives to be achieved. They also support the clinical leads by funding protected time as programmed activities (PAs) to enable the development of their specific Interest Group activities.

Separately from the NICRN, HSC R&D also fund core staff in Trust R&D offices along with pharmacy and finance services across the 5 NI Trusts. This support enables the network to be embedded in a cohesive matrix of staff designed to facilitate study set up, approval and conduct throughout NI's HSC structures.

NICRN financial management is principally achieved through the Coordinating Centre. Planned budgets are agreed between the NICRN co-ordinating centre and HSC R&DD. These are set in line with national and regional priorities, group objectives and requirements. The core staff are employed by host organisations but funded via HSC R&DD, with the NICRN CC liaising between funder and Interest Group to justify annual expenditure for specific activities. The NICRN CC is also the

processing body for costs incurred by Interest Groups such as essential travel, training, education and ICT. As the Coordinating Centre is hosted by BHSCT, an overhead of 46% is placed on all staff salaries within the Coordinating Centre.

As hosting organisations incur costs associated with this function, an 8% fee on all staff salaries is made available to employing Trusts to offset any administrative and hosting costs. This is agreed and funded by HSC R&D as part of overall Trust involvement in hosting NICRN staff.

Over 13/14 the total costs for the network equated to spend of **£2,036,269**. The majority **£1,489,125**(73%) is on core CRN and AHP staff, whilst the co-ordinating centre accounted for **£311,517** (15%) of spend, including the staff , overhead at 46%, overall budget for travel and expenses, training and education and goods and services. The clinical lead 0.1 PA costs accounted for the remaining **£235,627** (12%).

In terms of local interactions the network staff engage daily with platforms such as the NICTN, NICRF, HSC Trust R&D governance offices, NI gateway and outside bodies such as Patient and Client council, Queens University and University of Ulster.

One key development has been the work across Trust R&D offices. This has initially been highlighted by the staff manager's position and regular presence within each Trust. This has enabled mutual appreciation for each other's roles and issues. Most areas of work are complimentary however there are areas around accountability of staff that are difficult for a regional unit working across 5 distinct legal entities. However through working together none of the issues which have materialised have not been insurmountable to date.

Section 3 Topic Specific Reports

Cardiovascular Interest Group


Co clinical leads Professor Donna Fitzsimons and Dr Patrick Donnelly

Introduction

NICRN-CV in year 2013-14 had a number of key objectives;

- Replenish study portfolio
- Increase commercial activity
- Support local investigators in project development and delivery

Consult with Principle Investigators and key stakeholders regarding a SWOT analysis of the Network and development of a 5 year strategy for regional CV research

This year has witnessed significant growth in the cardiovascular research portfolio, with the number of active studies and sites almost doubling to 31 and 40 respectively. In total 1641 NI citizens were screened for participation in CV research, with 1116 of these were recruited to network adopted clinical trials. This represents a 56% uplift in research activity from the previous year and means that over the last five years almost 10,000 people in Northern Ireland have been screened for participation in NICRN-CV research and almost 4,000 participated. This demonstrates that the Network is bringing the very latest international developments in cardiac treatment and care to within the reach of many more of our citizens.

The portfolio achieved an equipoise between commercial and non-commercial studies, with commercial research projects representing 52% of total network activity – this is significantly improved from 35% in the previous year. The adopted commercial studies aligned with local investigators expertise, but also importantly with the UK national cardiovascular research portfolio. The network PIs attracted both interventional and non-interventional Phase III high profile studies that would normally have been performed in mainland UK. The interventional projects included novel coronary artery stent and percutaneous balloon platforms. The non-interventional studies included genomics of cardiovascular disease, new molecular treatments for cholesterol and novel oral anticoagulants for the treatment of cardiovascular disease. The Network received very positive feedback from industry regarding the role of NI investigators within their trials and studies as a recent quote from Bayer confirms.

"We found working with the NICRN CVS Nurse Lisa Lusk excellent. The original site recruitment target for STREAM has far surpassed all expectations. Data quality has also been excellent. The STREAM Steering Committee comprising of Professors of Cardiovascular medicine and Interventional medicine along with Sponsor representative Linda Kelly Boehringer Ingelheim have highly praised Lisa Lusk NICRN CVS Nurse. Lisa has been instrumental in ensuring the smooth running of a complex CVS trial which has involved several levels of care (ambulance, emergency department, coronary care and cath lab). Lisa's work has been hugely valuable. Thank you so much Lisa for fantastic work!"

The non-commercial portfolio represents the best in knowledge development often pioneered by local research teams and included the NIH sponsored ISCHEMIA trial and a number of local research initiatives including POPs MI, NGAL, RADAR, and CAPP. The latter studies have been successful in achieving international peer reviewed presentations and publications and have promoted Northern Ireland as a centre for robust hypothesis synthesis, and research delivery. In fact each of these non-commercial studies have served as a platform for on-going collaborations with local industry, academia and healthcare trusts.

The CMG met in the Spring of 2014 to undertake an assessment of progress to date, using the format of Strengths, Weaknesses, Opportunities & Threats analysis. A number of core themes were discussed including need for greater time for PIs to devote to research and an ambition to increase cross-site activity, greater collaboration with sister networks such as stroke, primary care and diabetes, and better engagement with the public and charitable sectors. These will be developed into a Strategic Plan for the coming year at a workshop to be convened by the Clinical Leads.

Workforce

The cardiovascular group had a number of changes in staffing over the reporting period. In BHSCT an additional 1.0 WTE was awarded due to predicted uplift in activity at this site. Previous to this post the BHSCT was supported by covering a 1.0 WTE position as part of the existing BHSCT cardio research infrastructure and any accrual for adopted studies was reported as NICRN activity. This essentially amounted to NICRN paying for a clinical research nurse (CRN) service from the existing BHSCT cardio research team.

With the advent of the new post, it enabled the accountability of staff covered by core funding to be clearly responsible via NICRN structures and it is anticipated that this will make the management of studies more transparent. The NICRN dedicated post was filled on the 10th March and so any real benefit at this site will be expressed in 14/15 annual report.

In the NHSCT our CV group lost a long standing CRN to retirement. This retirement coincided with a down turn in activity at the NHSCT due to the site not being able to accommodate the research staff close to the clinical setting which made it so difficult for the local PI's that they decided the burden of conducting research was to great and so withdrew from research entirely. The network manager and clinical leads all met with the local PI and tried to provide solutions and workarounds, however this was unsatisfactory and so the site withdrew. To maintain the follow up activity, the NICRN coordinating centre arranged for the visits to be undertaken by other NICRN staff and we redirected a 0.2 WTE to do this until study close out which was anticipated in Dec 14.

The WHSCT also had staff changes due to a career break over first quarter of year. The staff member returned at start of July providing a 0.75 WTE over the year.

Another change occurred in the SEHSCT, where at end of second quarter, the group lost their 1.0 WTE to the commercial sector. However the post was filled within a month, on temporary basis, by our current SEHSCT cardio CRN and so this change had little impact on accrual.

Also during 13/14 the group and clinical leads were supported by securing a dedicated 1.0 WTE, band 4 administrator to work to the busy leads and organise any group meetings or events, however this post was vacant for a significant period of time and so the leads only had 0.6 WTE over reporting period in real terms. Full staff breakdown for the group is shown below.

BHSCT	2.0 WTE
NHSCT	0.2 WTE
SEHSCT	0.9 WTE
SHSCT	1.0 WTE
WHSCT	0.75 WTE
TOTAL	Band 6-4.85 WTE BAND 4-0.6 WTE

Education and Training

Staff were supported for a number of extra training events as highlighted in appendix 3, including workshops on clinical trials legislation, source data verification and monitoring, local presentation of the new NI research gateway, and Trust record management policies. The NICRN Coordinating centre also held 3 additional training events entitled "Recruitment and retention in clinical trials", "Informed consent training for adult and children" and "time management". These were presented by Professor Allan Gaw and were extremely well attended and received. In addition the group also supported attendance of staff at the Euro Heart Care conference in Glasgow in March 13.

Financial Statement

With its 2 clinical leads, 4.85 WTE band 6 CRNs and 0.8 WTE band 4 administrator the staff costs for running the group over 13/14 were £171,779 on staff and £23,729 on clinical lead PA's. The group has a large commercial portfolio and as such does generate a significant amount of potential income. Currently income management is the responsibility of the local Trust R&D governance teams and as such the NICRN coordinating centre staff cannot access or report on NICRN Interest group income.

Cardiovascular Activity Report

Table 4

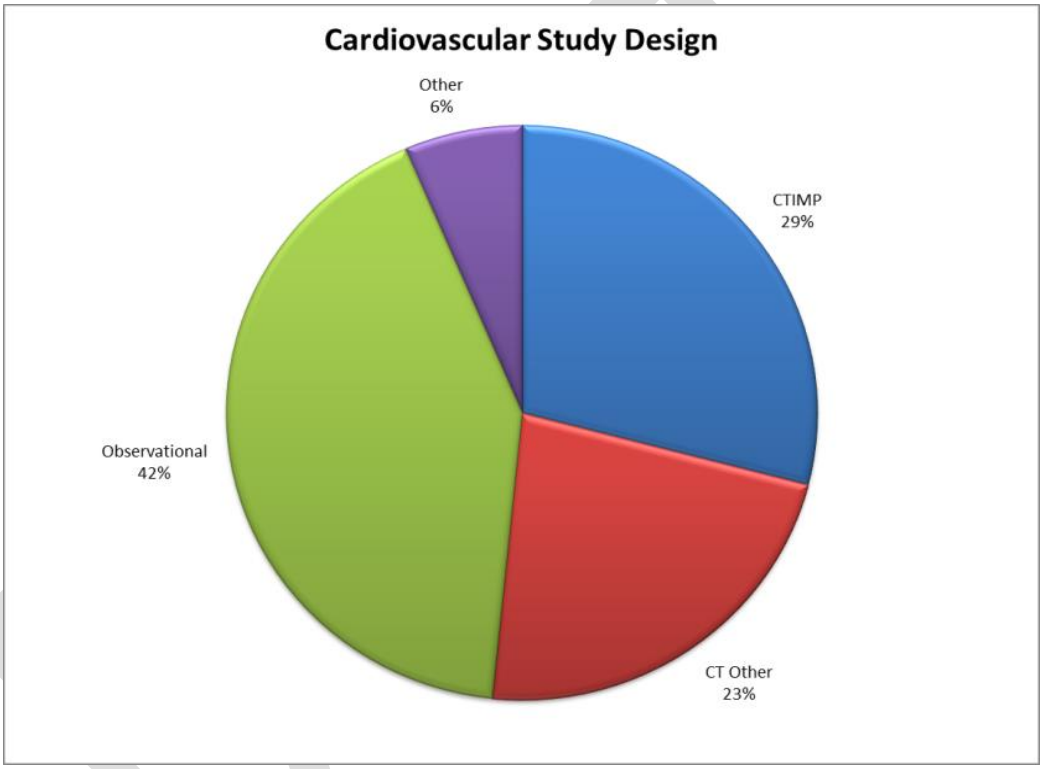
Study Name	Commercial	Randomised	Multi-Centre	Design	Phase	Adopted in 13/14	Accrual Status	Trust	NI / Site Accrual Target	Patients Screened (2013/14)	Patients Recruited (2013/14)	Total Screened to eof Mar 14	Total Recruited to eof Mar 14	Recruitment as % of Target
The AIMS Study	N	Y	N	CTIMP	III	N	In Setup	BHSCT	24	0	0	0	0	0%
Needs and QOL of HF Patients and Carers	N	N	Y	Observational	N/A	Y	Open	BHSCT	140	2	2	2	2	1%
							In Setup	SEHSCT	80	0	0	0	0	0%
COMPASS - RCT	Y	Y	Y	Other	N/A	Y	In Setup	SEHSCT	20	0	0	0	0	0%
							Open	WHSCT	30	3	3	3	3	10%
NOBLE Study	N	Y	Y	CTIMP	N/A	N	Open	SHSCT	60	16	14	55	53	88%
						N	Open	BHSCT	90	27	20	200	84	93%
ISCHEMIA	N	Y	Y	CT Other	N/A	N	Open	SEHSCT	10	23	4	23	4	40%
							Open	BHSCT	10	5	5	5	5	50%
Management of ICD's in Adv HF	N	N	N	Observational	N/A	N	Open	BHSCT	40	16	12	16	12	30%
EBC TWO	Y	Y	N	CT Other	N/A	Y	Open	BHSCT	10	6	6	11	11	110%
REDUCE	Y	Y	N	CT Other	N/A	Y	Open	BHSCT	20	6	6	6	6	30%
SAPIEN 3	Y	N	N	CT Other	N/A	N	Open	BHSCT	30	12	12	13	13	43%
GLOBAL	Y	N	N	CT Other	N/A	Y	Open	SEHSCT	100	72	70	72	70	70%
REMEDEE	N	N	N	Observational	N/A	Y	Open	SHSCT	100	128	128	128	128	128%
MILES-UK	Y	N	N	Observational	N/A	N	Open	SHSCT	30	31	31	31	31	103%
H-FABP Treadmill	N	N	N	Observational	N/A	N	Open	SHSCT	50	21	21	35	35	70%
FOURIER	Y	Y	N	CTIMP	III	Y	Open	SEHSCT	15	99	2	99	2	13%
LIVE:LIFE	Y	N	N	Observational	N/A	Y	Open	SEHSCT	10	14	2	14	2	20%
LEADERS FREE	Y	Y	Y	CT Other	N/A	Y	Open	SHSCT	30	35	35	35	35	117%
							Follow-up	BHSCT	30	14	11	14	11	37%
ODYSSEY - ALTERNATIVE	Y	Y	N	CTIMP	III	Y	Follow-up	WHSCT	4	300	2	300	2	50%
NGAL	N	N	N	Observational	N/A	N	Follow-up	SHSCT	250	45	45	307	307	123%
PEGASUS	Y	Y	N	CTIMP	III	N	Follow-up	NHSCT	15	0	0	234	11	73%
IMPROVE IT	Y	Y	Y	CTIMP	IV	N	Follow-up	NHSCT	62	0	0	449	15	24%
						N	Follow-up	BHSCT	62	0	0	140	1	2%
						N	Follow-up	WHSCT	62	0	0	852	2	3%
COMPASS - Registry	Y	N	Y	Other	N/A	Y	Follow-up	SEHSCT	200	201	201	201	201	101%
							Follow-up	WHSCT	200	200	200	200	200	100%
STREAM	Y	Y	N	CTIMP	IIIB	N	Closed	SEHSCT	15	0	0	138	18	120%
POP MI	N	N	Y	Observational	Pilot / Feasibility	N	Closed	SEHSCT	25	0	0	408	46	184%
						N	Closed	BHSCT	50	0	0	364	58	116%
BIOFLOW III	N	N	N	Observational	N/A	N	Closed	SHSCT	21	0	0	24	24	114%
CAPP	N	Y	N	CT Other	Pilot / Feasibility	N	Closed	SEHSCT	500	0	0	574	500	100%
Alecardio	Y	Y	N	CTIMP	III	N	Closed	WHSCT	5	80	0	1500	2	40%
RADAR ACS	N	N	N	Observational	N/A	N	Closed	SHSCT	650	0	0	2315	637	98%
RADAR PCI	N	N	N	Observational	N/A	N	Closed	SHSCT	275	275	275	275	275	100%
SOLID-TIMI 52	Y	Y	N	CTIMP	III	N	Closed	NHSCT	24	0	0	108	1	4%
FMI	N	N	N	Observational	N/A	Y	Closed	SEHSCT	10	8	7	8	7	70%
Diagnosis of PHT: Pilot study	N	N	N	Observational	Pilot / Feasibility	N	Closed	SEHSCT	20	2	2	22	21	105%
	52%	**48%**	**26%**			**39%**			**3379**	**1641**	**1116**	**9181**	**2835**	**65%**

The cardiovascular group had an extremely successful year in 13/14. Their total portfolio of active studies rose to 31 in 13/14 compared with 17 over same period last year. The total number of patients screened also rose from 900 in 12/13 to 1641 over 13/14 and the actual accrual figure rose from 291 over 12/13 to 1116 over 13/14. This significant increase is in part due to the increase in

registry type work which the group has strategically been targeting for future efficiency protocols in defining feasibility. Of the 40 studies in their portfolio, 12 (39%) were newly adopted in year fulfilling their annual objective of a 6 new studies. Of these new studies 9 (75%) were commercially sponsored, again fulfilling their annual objective of maintaining a minimum of 50% commercially funded.

One objective which the group has continued to find difficult to achieve is working across sites. The objective is set to develop a groups working practice across the region as a whole. In 12/13 the percentage of studies at 2 or more site was 29%; in 13/14 this was marginally less at 26%. This is indicative of local clinical/research interests, competencies and capabilities across sites. The group is committed to working to increase this level over coming years.

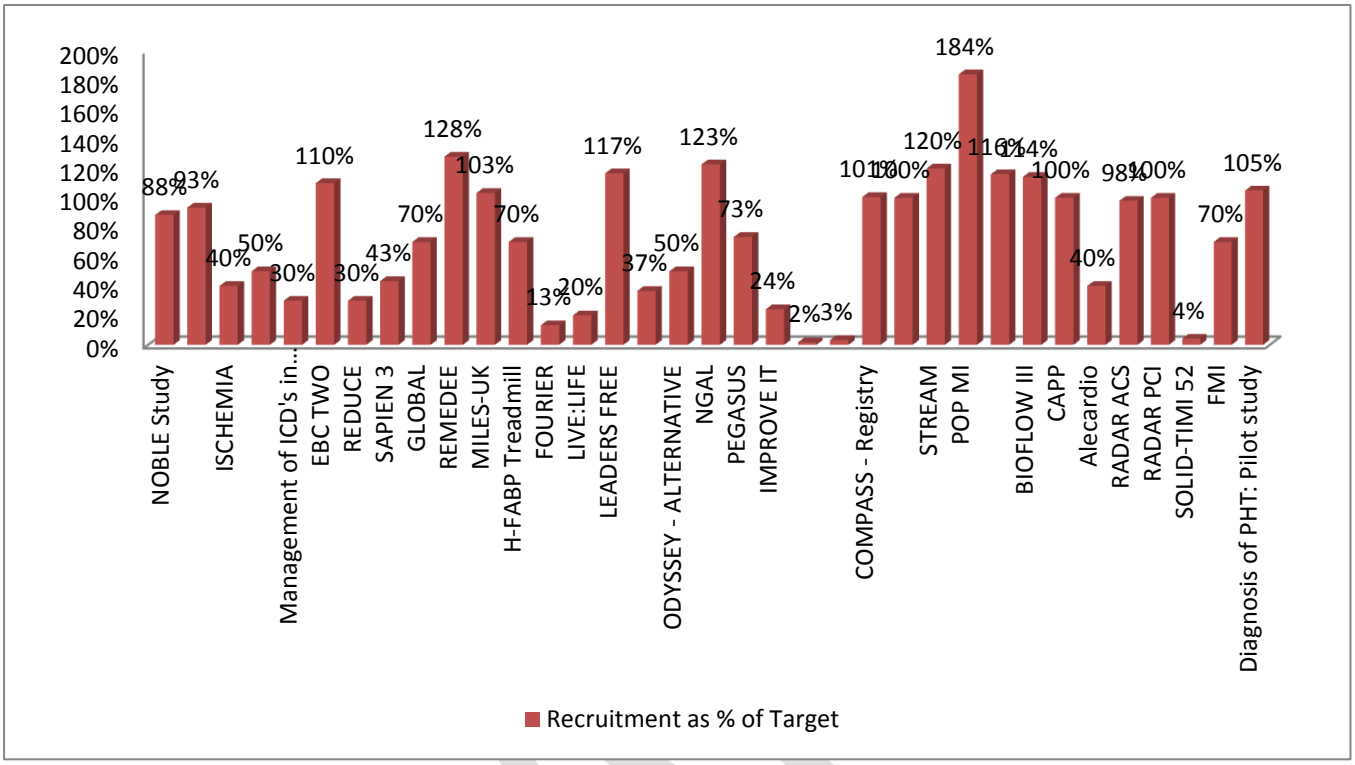
Figure 1



The percentage of randomised trials fell from a previous level of 65% of portfolio to 48% in 13/14. This is also indicative of the group's strategy to adopt more registry based studies to develop a better picture of the NI environment and hence to make study feasibility clearer and quicker. Of the clinical trial almost a third (29%) were Clinical Trials of Investigational Medicinal Products (CTIMP's) and a further 23% were non-CTIMP trials.

In terms of accrual to target the groups result over 13/14 was 65% of target. Obviously this includes the studies newly adopted and being set up. If however we look at cumulative target for entire CV portfolio then the group is currently achieving a highly respectable average of 83% accrual to target. An illustration of the portfolios accrual to target is shown if figure 2.

Figure 2



Childrens Interest Group

Clinical lead, Dr Michael Smith

Introduction

Children deserve the same high standards as adults in the assessment of the safety and effectiveness of the medicines that they use. Yet half of the medicines used for children are prescribed without license or off-label. The over-arching aim of the Children's group is to develop and deliver paediatric medicines research across the province in partnership with children and families. This is especially important given the relative paucity of paediatric research when compared to the adult sector. Having achieved success in

the first few years, we are committed to build on our accomplishment in the future. With the support of the Medicines for Children Research Network (MCRN) coordinating centre located in Liverpool, we are fortunate to receive regular supply of UK wide research projects. We also receive requests for research participation through direct personal contact with principal investigators. Unfortunately we are unable to adopt many studies in part because our research infrastructure funding per capita falls very much short of our colleagues in the other UK research systems.

Despite the current restraints, we have had considerable improvement in study adoptions over the previous year mostly in the neonatal area. There has been geographic spread with most of the trusts engaged in the delivery and follow-up of clinical research. Our research nursing team has developed into an effective team with excellent cross-trust working and communication which has proved to be crucial as research projects often continue across hospital boundaries.

The portfolio has a heavy reliance on neonatal studies and there is an increasing desire to increase the number of paediatric, child and adolescent research projects. Unfortunately, with the limited number of research nurses spread over the province, we have had to restrain our acceptance of new paediatric studies. Our staff problem has also been exacerbated by maternity and sick leave.

Portfolio

In terms of absolute numbers, there has been a significant increase in studies adopted over the previous year. The majority of studies are publicly funded which is a common feature of paediatric research given the limited financial benefit from children's medicines to pharmaceutical companies

Neonatal research

The preponderance of the portfolio is made up of neonatal studies which reflect the well-established expertise, enthusiasm and research culture in this specific clinical area. Previous research supported through the network has changed the delivery of care for babies with perinatal asphyxia, with cooling now well established as a proven treatment option (TOBY trial). Completion of the NIPPV trial showed no benefit of nasal ventilation over CPAP in terms of reducing chronic lung disease. Follow up of babies in the caffeine for apnoea of prematurity has shown that this beneficial perinatal treatment is not associated with longer term adverse effects up to the age of 5 years. Completion of the ADEPT trial showed that there was no increased risk of necrotising enterocolitis with early initiation of milk feeding compared with later feeding.

Recruitment and follow-up has been good in the Belfast, Southern and Northern Trusts but the major problem has been the on-going follow-up of research subjects in the South-eastern and Northern Trusts due to the lack of local research nurses and Trust processes. This has been resolved with discussion with the R+D teams at each trust and it is hoped that in future no patients will be lost to follow-up when transferred to their home hospital.

Paediatric research

Previous and current projects have covered a broad area including epilepsy (choice of anticonvulsants), food allergy and eczema (association of food allergy with severity of eczema), asthma (nebulised magnesium sulphate), renal studies (nephrotic syndrome treatment) and others. All of these studies will have an impact on the health of children by better and more effective use of

specific medications and improved understanding of prognosis. In addition, pharmacokinetic and pharmacogenetic studies have improved our understanding of therapeutics in epilepsy, critically ill children, asthma and rheumatic diseases.

Paediatric studies have made up a smaller proportion of the portfolio for a number of reasons. Firstly, there have been limited numbers of research nursing staff available (especially in the Belfast Trust) to support the investigators in the execution of the study. Secondly, the types of paediatric projects available are variable. Whether these projects are taken up in Northern Ireland at the Royal Belfast Hospital for Sick Children depends on the level of research capability and enthusiasm by the specific sub-specialty paediatrician. However, general paediatric projects are often adopted in the Trusts outside of Belfast as there is more often research nurse capacity and quicker R+D approval processes. Unfortunately, general paediatric research is much less available to our group as these projects are completed most efficiently in the larger regions in the UK. Despite these trends, the CMG has been encouraged by the emergence of enthusiastic clinician investigators in several subspecialty areas (respiratory, diabetes, renal) who are keen to get involved in new projects. Because of the staffing difficulties (especially in the Belfast Trust), a proposal has been submitted for a full time paediatric research nurse for the next five years.

Activity report

The children's group also showed a significant increase in activity over the 13/14 reporting period. Their total number of active studies increased from 19 in 12/13 to 29 active studies across 13/14. This represents an increase of 52% over same time last year. They met their objective of 3-6 new studies across the year by adopting 5 new studies, though none were commercially sponsored and therefore did not meet this objective. Their screening activity rose by 120% from 462 on 12/13 to 1026 in 13/14. Likewise their accrual rate rose from 162 in 12/13 to 241 in 13/14 an increase of almost 49%.

That being said the accrual to target over their entire portfolio only stands at 45% which will need addressing in terms of greater focus at adoption figure 3.

Workforce

The childrens group came under a great deal of pressure over 13/14 due in part to their success in securing studies in the BHSCT. This placed a burden on the existing 1.5 WTE and so a significant proportion of time was directed at solutions. Due to the loss of cardiovascular activity in the NHSCT, we tried to redirect CRN spend allocated to NHSCT to the BHSCT. This proved problematic as the site viewed this as a loss of income and associated impact. Following discussion with the associated leads, our director and funder we all agreed that this redirection of funds was a necessity and the only means of maintaining activity in the childrens group in BHSCT, resulting in an increase of 0.5 WTE. The SHSCT was also impacted by a period of long term (3 months) sick leave which placed considerable strain on remaining staff.

BHSCT	1.5 WTE
SHSCT	0.875 WTE
WHSCT	0.55 WTE

TOTAL Band 6 2.92 WTE

Financial Statement

The financial support for this group equated to a spend of £125,143 on staff and £25,464 on lead PA's. They did however have a commercial study on the portfolio and so this spend would be offset by some minimal income. As stated previously the recording of income is a research governance remit and at present the NICRN does not have sight of this data.

Education and Training

The staff availed of the additional training and education sessions provided under the NICRN as set out in appendix 3. Additional to this and their mandatory training, they were also supported in terms of leave and finance to attend Bayley III training, and a workshop entitled "Delivering Neonatal studies on the NIHR portfolio " The Bayley's training provides additional skills used across a number of studies and the NIHR workshop facilitated the awareness of common working patterns across national networks

Interaction with other Research Infrastructure

The clinical director is a member of the Medicines for Children Research Network and the UK Clinical Research Network devolved nations group. In both these organizations there is considerable enthusiasm to engage all areas of the UK in research endeavours and to overcome the barriers to more extensive participation. There is a continual pipeline for new research projects and the opportunity to express an interest in participation. Because of the small population size, Northern Ireland is not always as attractive a site when compared to the larger UK networks. Nevertheless, there are more studies available than we can take on. In addition, a number of our CMG members have contacts within the island of Ireland, Australia and Canada and as a result, have brought in international research projects. The clinical director is also a member of the Royal College of Paediatrics and Child Health Research strategy group which has as its mission to further develop relevant research throughout the UK.

Patient and Public Involvement

Locally, we have done very little in general to increase patient and family involvement in the promotion and development of research. However, our parent organization, MCRN has become a world leader in involving children and young people in the development of research projects. As a result, we indirectly benefit from this expertise when we accept UK studies which have gone through the extensive review by patients and families.

Childrens Activity Report

Table 5

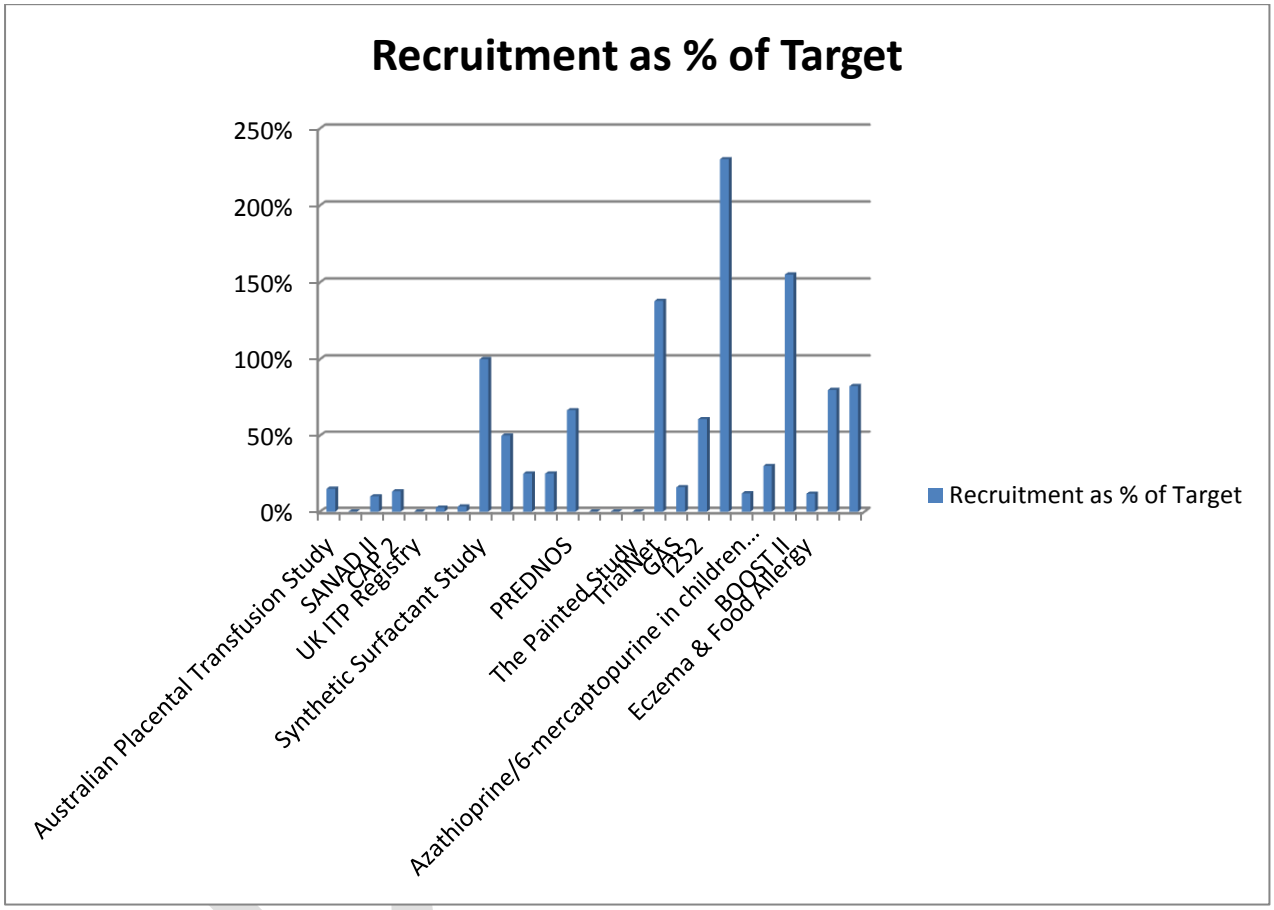
Study Name	Commercial	Randomised	Multi-Centre	Design	Phase	Adopted in 13/14	Accrual Status	Trust	NI / Site Accrual Target	Patients Screened (2013/14)	Patients Recruited (2013/14)	Total Screened to eof Mar 14	Total Recruited to eof Mar 14	Recruitment as % of Target
SIFT	N	Y	Y	CT Other	III	Y	In Setup	BHSCT	100	0	0	0	0	0%
							In Setup	SHSCT	50	0	0	0	0	0%
							In Setup	WHSCT		0	0	0	0	0%
PREDNOS 2	N	Y	N	CTIMP	III	Y	In Setup	BHSCT	10	0	0	0	0	0%
Australian Placental Transfusion Study	N	Y	Y	CT Other	N/A	N	Open	BHSCT	180	32	27	32	27	15%
							In Setup	SHSCT	15	0	0	0	0	0%
SANAD II	N	Y	N	CTIMP	IV	Y	Open	SHSCT	50	77	5	77	5	10%
CAP 2	N	N	N	Observational	N/A	N	Open	BHSCT	15	18	2	18	2	13%
UK ITP Registry	N	N	Y	Observational	N/A	Y	Open	BHSCT	0	0	0	0	0	0%
							Open	SHSCT	38	1	1	1	1	3%
							Open	WHSCT	30	1	1	1	1	3%
Synthetic Surfactant Study	Y	N	N	CTIMP	I/II	N	Open	BHSCT	8	11	6	30	8	100%
PlaNet-2 - Platelets for Neonatal Transfusion study 2	N	Y	Y	CT Other	N/A	N	Open	BHSCT	6	36	3	43	3	50%
							Open	SHSCT	4	4	1	4	1	25%
							Open	WHSCT	4	11	1	14	1	25%
PREDNOS	N	Y	Y	CTIMP	III	N	Open	BHSCT	3	3	2	3	2	67%
							Open	SHSCT	3	0	0	0	0	0%
							Open	WHSCT	3	1	0	1	0	0%
The Painted Study	N	N	N	Observational	N/A	Y	Suspended	SHSCT	0	0	0	0	0	0%
TrialNet	N	N	N	Observational	N/A	N	Open	BHSCT	900	152	152	1241	1241	138%
GAS	N	Y	N	CTIMP	IV	N	Follow-up	BHSCT	25	0	0	9	4	16%
I2S2	N	Y	Y	CTIMP	IV	N	Follow-up	BHSCT	120	0	0	73	73	61%
							Follow-up	WHSCT	10	19	10	54	23	230%
Azathioprine/6-mercaptopurine in children with IBD	N	N	Y	Observational	N/A	N	Follow-up	BHSCT	100	0	0	191	12	12%
							Follow-up	WHSCT	30	4	1	18	9	30%
BOOST II	N	Y	N	CTIMP	IV	N	Follow-up	BHSCT	20	0	0	39	31	155%
Eczema & Food Allergy	N	N	Y	Observational	N/A	N	Closed	BHSCT	85	600	8	704	10	12%
							Closed	NHSCT	5	39	4	39	4	80%
							Closed	SHSCT	40	17	17	34	33	83%
	6%	56%	50%			31%			1854	1026	241	2626	1491	45.08%
	1	5	8			5								

The childrens group also showed a significant increase in activity over the 13/14 reporting period. Their total number of active studies increased from 19 in 12/13 to 29 active studies across 13/14.

This represents an increase of 52% over same time last year. They met their objective of 3-6 new studies across the year by adopting 5 new studies, though none were commercially sponsored and therefore did not meet this objective. Their screening activity rose by 120% from 462 on 12/13 to 1026 in 13/14. Likewise their accrual rate rose from 162 n 12/13 to 241 in 13/14 an increase of almost 49%.

That being said the accrual to target over their entire portfolio only stands at 45% which will need addressing in terms of greater focus at adoption figure 3.

Figure 3



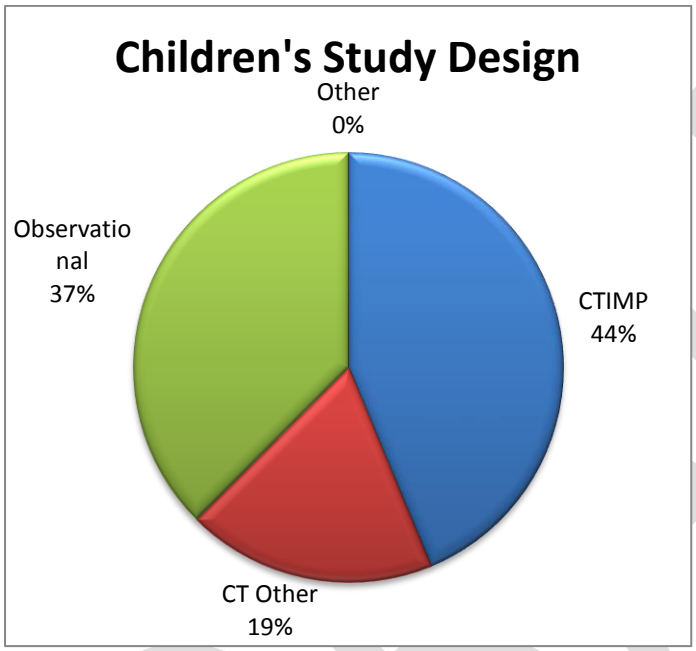
The portfolio is relatively well balanced in that almost 60% of portfolio is clinical trials (44% CTIMP's and 19% other clinical trials). Most of these being phase 2-3. With approximately a third being observational in nature figure 4.

One particular issue in childrens is the collection of follow up data across HSC Trusts. As the provision of health care is centralised to the Royal Jubilee Maternity hospital and the Royal Belfast Hospital for sick Children both located in the BHSCT. Many of these sick babies and children are initially seen at these units. Therefore governance approval is sought from BHSCT only, however due to bed demands etc. these participants are often moved by to district general hospitals for continuing care and this presents governance problems as these sites are often not opened as

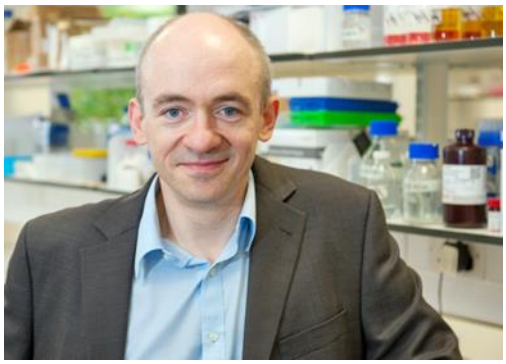
research site. This is an on-going issue which the lead intends to escalate to the regional Directors of R&D platform for discussion and hopefully a pragmatic approach to this.

Finally even with a reduced workforce the group still managed to operate regionally. The staff manager has worked with the Trust R&D managers to break down barriers to movement across NI sites and so we have created honorary contract in all 5 trust for each NICRN childrens nurse so if governance approval is in place then this does not hold up data collection.

Figure 4



Critical Care Interest Group



Clinical lead Professor Danny McAuley

Introduction

In keeping with the other groups, we aim to deliver high quality clinical research, with a focus on clinical trials. We have several additional key strategic aims within the group

1) Ensure equity of access for patients to clinical research across NI
2) Develop protocols which are led by local researchers which attract NIHR funding and are not only delivered in NI but are led from NI and delivered across the UK and Ireland
3) Help build research capacity in critical care in NI
4) Build collaborative links and establish a network which supports critical care research across the Island of Ireland

Portfolio

There are a number of key achievements, which are worth highlighting

1) Studies, where possible, are offered to all NI research sites which ensures equity of access for patients to research studies. This has been transformational in the amount of critical care clinical research undertaken in NI. Specific examples are the research activity which now exists in Antrim (one of the top recruiting sites in the NIHR EME funded LeoPARDS and HARP-2 studies), and Altnagelvin (recruitment to a large range of portfolio studies) where previously there was limited activity.
2) The value of the network in delivering struggling studies is fundamental. REVIVE was an investigator led phase 2 clinical trial investigating rehabilitation following critical illness which was struggling with recruitment but was prioritised by network and has now successfully reached it's recruitment target.
3) HARP-2, a multicentre study undertaken in 40 sites in the UK and Ireland, which was led from NI was completed and published in the NEJM and the support of the staff of the NICRN was acknowledged in the paper. Critical care network sites in NI recruited approximately 20% of the study population.
4) Sites in the network consistently recruit above average. For example the BHSCT was the 2nd highest recruiting site in ABLE (a study of old versus fresh blood) in the UK recruiting approximately 10% patients of the patients recruited in the UK.
5) Investigators in NI are either leading or are co-applicants on a large proportion of the national studies on the portfolio funded by the NIHR or TSB (eg HARP-2, sepsis diagnostic study, LeoPARDS, BREATHE, VAPRapid) and are continuing to lead applications to NIHR

studies eg (NIHR HTA commissioned call for venovenous extracorporeal carbon dioxide removal in adults with respiratory failure.)

Workforce

This group was only one of 2 which managed to secure additional core funding over the reporting period. This was increase by 0.5 WTE was due to the group's success in securing very high priority NIHR funded studies. Due to the local nature of the Department of Health investing in NIHR funding streams it was a strategic decision to ensure enough core staff were in place to deliver these and hence increase the potential to draw down more NIHR funding in the future. The group also secured a grant from the Technology Strategy Board's (TSB) Collaborative R&D Programme. This covered the additional cost of a 1.0 WTE band 6 CRN post.

BHSCT	2.5 WTE
	1.0 WTE (Band 4)
NHSCT	1.0WTE
SEHSCT	0.8 WTE
SHSCT	0.5 WTE
WHSCT	1.0 WTE
TOTAL	Band 6 5.8 WTE plus Band 4 1.0 WTE

Financial Statement

The success of the group and its increase in core funding resulted in an overall staff cost of £199,788 and clinical lead costs of £20,677 over this reporting period. This was minimally off set by the group having 1 commercial study on the portfolio.

Education and Training

As per all other groups, the critical care staff fully availed of the additional training provided by NICRN along with mandatory training in line with Trust policy. Additional to this a selection of staff were supported to attend and participate in 2 major conferences over this period. Full listing of all supported training and education is shown in appendix 3.

Interaction with other Research Infrastructure

McAuley is Director of the NI Clinical Trials Network and through this role encourages investigators developing proposals which are being developed for funding to utilise this infrastructure.

Specific examples of this related to critical care are the NIHR EME funded HARP-2 study and the TSB funded sepsis diagnostic study which are managed by the NI CTU

McAuley is a member of the Executive Committee of All-Ireland Hub for Trials Methodology Research and through this role ensures investigators developing proposals are aware of this infrastructure.

McAuley is acting Director of the NI CRF. While the majority of clinical trials in critical care are conducted while patients are in-patients, for those studies where the CRF would be required eg experimental medicine studies in healthy volunteers relevant to critical care eg ARENA, McAuley is able to advise on the process to access the CRF.

McAuley and McMullan are on the executive committee of the Translational Research Group for Critical Care. The funds which have been allocated by the Critical Care TRG have pump primed investigator led projects which have led to studies which have subsequently been adopted by the critical care network.

Patient and Public Involvement

This is critically important to our network. Although we do not have PPI representation on the CMG, the clinical trials which are supported by the network have active PPI involvement. For example in HARP-2, the PPI representative Mr Barry Williams sat on the Trial Steering Committee for the study. In addition McAuley presented at the R&D PPI forum in March 2014.

Other Initiatives

Capacity building

McAuley supported a successful NIHR clinician scientist award application for Dr Murali Shyamsundar. The multi-centre clinical trial associated with this award will be lead by Shyamsundar from NI and delivered through the critical care network in NI and UK.

The network has and continues to support HSC R&D funded PhD fellowships where the projects involved a clinical trial.

Infrastructure

McAuley was a co-applicant on a successful €2.3M application to the HRB to establish a Critical Care Clinical Trials Network in Ireland to improving outcomes after critical illness.

McAuley led a successful bid to the MRC with co-funding from the DHSSPSNI (total funding £2M) to establish a GMP cell therapy facility to support clinical trials for cell based therapies. This will facilitate a planned Wellcome Trust application to undertake a phase 1/2 clinical trial in ARDS which will be led from NI and delivered through the critical care network in NI and UK. This facility will also support cell therapy trials in other areas which are planned and are likely to be delivered by other topic groups in the NICRN.

Interaction with NIHR

Members of the NICRN actively engage with the NIHR HTA programme with a view to informing projects which are commissioned by the HTA. As a specific example members of the group were

involved in the commissioning process for the recent NIHR HTA commissioned call for venovenous extracorporeal carbon dioxide removal in adults with respiratory failure.

McAuley and McMullan sitting on HTA funding panels.Critical Care Activity Report

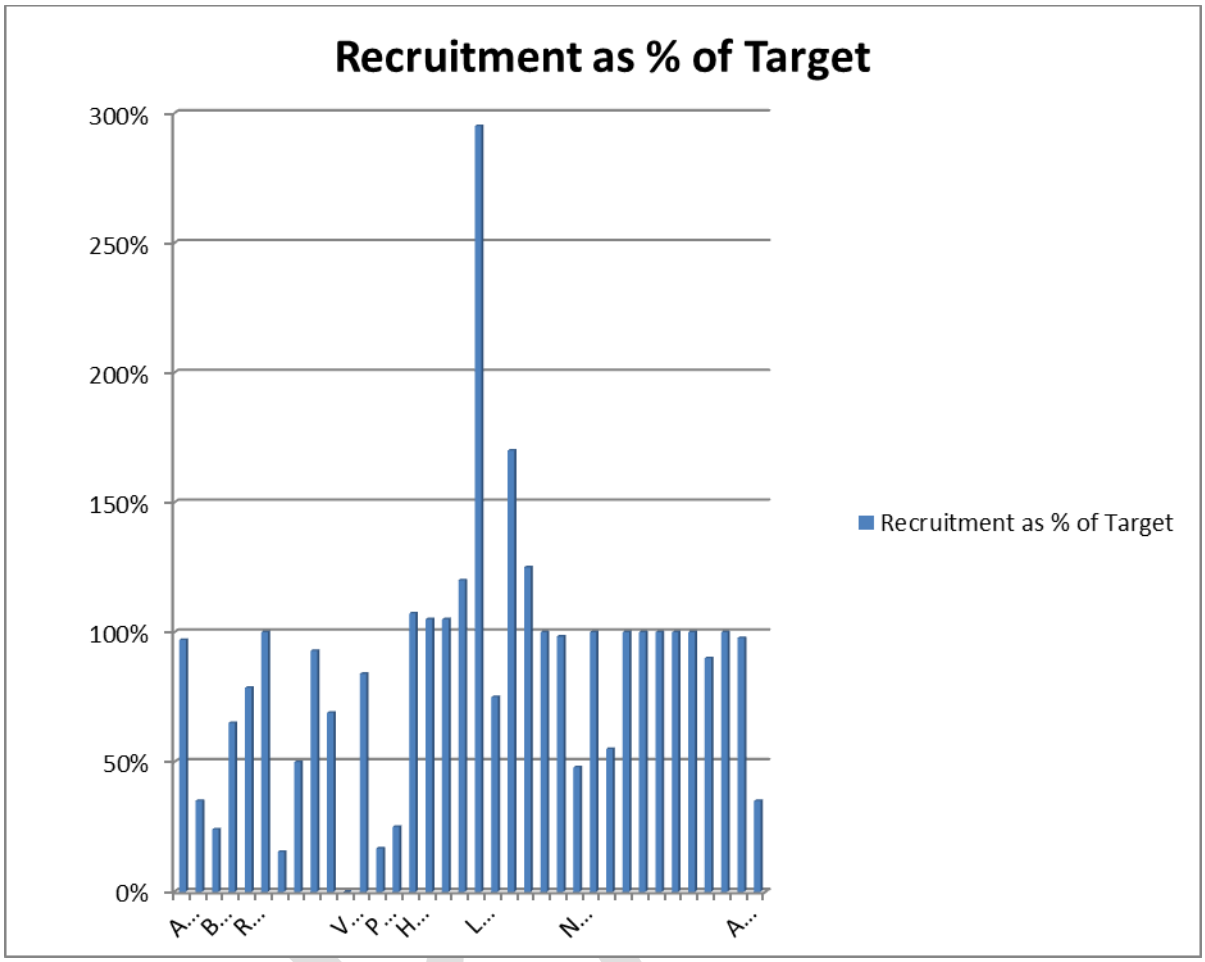
Outside of their objective to adopt a higher proportion of commercial studies, this group has had a very successful year too Table 6. Their overall active studies have increased from10 in 12/13 to 23 in 13/14, an increase of a massive 130%. Obviously this is a certain amount of roll over, however they also adopted 15 new studies during the reporting period, adding to the large body of work. This was balance by closing out 7 studies. Of these 7 all were quick turnaround studies adopted and completed in year.

Table 6

Study Name	Commercial	Randomised	Multi-Centre	Design	Phase	Adopted in 13/14	Accrual Status	Trust	NI / Site Accrual Target	Patients Screened (2013/14)	Patients Recruited (2013/14)	Total Screened to eof Mar 14	Total Recruited to eof Mar 14	Recruitment as % of Target
MANAGE Trial	N	Y	N	CTIMP	N/A	Y	In Setup	BHSCT	30	0	0	0	0	0%
NCEPOD - Sepsis Study	N	N	Y	Other	N/A	Y	In Setup	NHSCT	9	0	0	0	0	0%
							In Setup	SEHSCT	12	0	0	0	0	0%
RADAR ICU	N	N	Y	Observational	N/A	Y	In Setup	BHSCT	50	0	0	0	0	0%
							In Setup	NHSCT	50	0	0	0	0	0%
							In Setup	SEHSCT	50	0	0	0	0	0%
							In Setup	SHSCT	50	0	0	0	0	0%
							In Setup	WHSCT	50	0	0	0	0	0%
LeoPARDS	N	Y	Y	CTIMP	N/A	Y	In Setup	BHSCT	30	0	0	0	0	0%
							In Setup	NHSCT	20	0	0	0	0	0%
							In Setup	WHSCT	20	0	0	0	0	0%
ABLE-UK	N	Y	N	CTIMP	II	N	Open	BHSCT	34	935	16	952	33	97%
Eurotherm	N	Y	N	CTIMP	II	N	Open	BHSCT	20	17	0	80	7	35%
BREATHE	N	Y	N	CT Other	N/A	Y	Open	BHSCT	25	425	6	425	6	24%
Surgical Conditions Study	Y	Y	N	CTIMP	N/A	N	Open	BHSCT	20	13	13	13	13	65%
REVIVE	N	Y	Y	CT Other	II	N	Open	BHSCT	14	236	11	240	11	79%
							Open	NHSCT	13	73	6	151	13	100%
							Open	SEHSCT	13	92	2	92	2	15%
							Open	SHSCT	14	72	6	114	7	50%
							Open	WHSCT	14	98	4	192	13	93%
FREE	N	N	N	Observational	N/A	Y	Open	SEHSCT	300	388	207	388	207	69%
VAP-Rapid2	N	Y	N	CT Other	N/A	Y	Open	BHSCT	18	151	0	151	0	0%
End of Life	N	N	N	Observational	N/A	N	Follow-up	BHSCT	25	4	4	31	21	84%
POISE-2	N	Y	Y	CTIMP	II	N	Follow-up	NHSCT	24	14	1	118	4	17%
							Follow-up	WHSCT	24	49	2	205	6	25%
HARP2	N	Y	Y	CTIMP	II	N	Follow-up	BHSCT	55	120	17	404	59	107%
							Follow-up	NHSCT	20	115	11	199	21	105%
							Follow-up	SEHSCT	20	63	5	120	21	105%
							Follow-up	WHSCT	10	169	4	294	12	120%
LUNG-SAFE	N	N	Y	Observational	N/A	Y	Follow-up	BHSCT	20	120	17	404	59	295%
							Follow-up	NHSCT	20	25	15	25	15	75%
							Follow-up	SEHSCT	20	54	34	54	34	170%
							Follow-up	SHSCT	20	52	25	52	25	125%
							Follow-up	WHSCT	20	36	20	36	20	100%
KARE	N	Y	N	CTIMP	II	N	Follow-up	BHSCT	60	109	27	354	59	98%
NCEPOD - Adult Tracheostomy	N	N	N	Other	N/A	Y	Closed	SEHSCT	25	6	6	12	12	48%
FENICE Trial	N	N	Y	Observational	N/A	Y	Closed	BHSCT	20	20	20	20	20	100%
							Closed	SHSCT	20	11	11	11	11	55%
IC-GLOSSARI	N	N	Y	Other	N/A	Y	Closed	NHSCT	5	5	5	5	5	100%
							Closed	WHSCT	3	3	3	3	3	100%
GSK Zanamivir	N	N	Y	Observational	N/A	Y	Closed	NHSCT	7	7	7	7	7	100%
							Closed	WHSCT	2	2	2	2	2	100%
INS 2013	N	N	Y	Other	N/A	Y	Closed	NHSCT	20	59	20	59	20	100%
							Closed	SHSCT	20	18	18	18	18	90%
							Closed	WHSCT	20	73	20	73	20	100%
ARENA	N	Y	N	CTIMP	N/A	Y	Closed	BHSCT	45	59	44	59	44	98%
ETPOS	N	N	N	Other	N/A	Y	Closed	SHSCT	40	14	14	14	14	35%
	4%	52%	48%			65%			1050	3707	623	5377	844	86%
	1	12	11			15								

The group is well resources regionally and so their work across sites is very good with almost half of the portfolio operating at more than one clinical node or site. Their recruitment to target is very good also with an in-year figure of 86% recruitment to target figure 5.

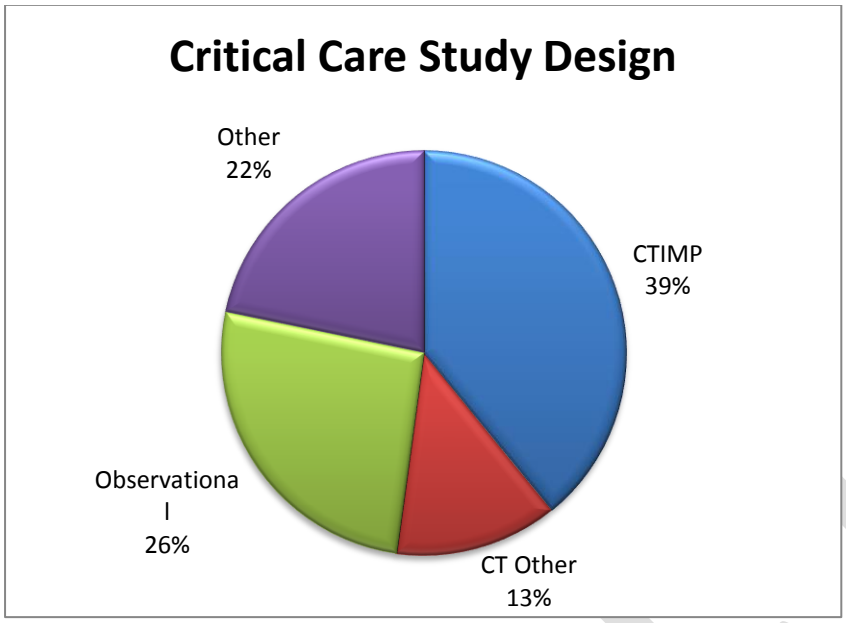
Figure 5



In terms of portfolio balance the group achieved a balance of just over 50% of studies being high quality clinical trials and 48% observational and other figure 6.

Focus for the group needs to be on fostering commercial engagement so that they can generate some income to offset expenditure. However this is very much dependant on the market. The lead is centrally placed in the UK network structures so can be made aware of any commercial studies pipeline at an early stage and their record to date on delivery is such that they should have a strong evidence base to draw prospective partners in with.

Figure 6



Dementia Interest Group


Co clinical leads Professor Peter Passmore and Dr Stephen Todd

Portfolio

The dementia interest group had two active studies in the portfolio: one commercial, multi-centre, randomised clinical trial of a novel investigational medicinal product was newly adopted in 2013/14 and one locally designed and led observational study was previously in the portfolio.

Recruitment to both studies was below target at 20 and 72% respectively, with a large number of screen failures in the RCT and a large target recruitment number in the observational study.

The dementia group maintains a database of interested potential participants and caregivers which is continually updated by referrals from clinicians throughout the province. RCTs in dementia are notoriously challenging studies to undertake with a usual requirement for at least 3 study personnel to conduct independent aspects of study visits. Our experienced NICRN nurses, with over 40 years combined in clinical trial research, are vital in the achieving the recruitment numbers for the studies adopted and crucial in training new raters, both within and without the network.

The dementia group, via the lead, have been approached with regard to a number of potential studies. These are often not feasible within the local governance and network infrastructure.

Workforce

Throughout the reporting period the dementia staff component remained stable at 2.0 WTE with little absenteeism.

Financial Statement

The group spend equated to a staff cost for the 2.0 band 6 WTE CRNs of £78,520 and clinical lead costs of £25,621

Education and Training

The staff attended all NICRN training and were essential in the induction of new staff into the regional NICOLA project. They provided cognisance testing training for all of the NICOLA team

Interaction with other Research Infrastructure

The dementia interest group had no interactions with local research infrastructure.

The group lead has regular contact with other national research leaders through the Dendron (England) and Scottish networks.

Patient and Public Involvement

Two caregivers for people with dementia sit on the group's clinical management group. One of these is an active member of Alzheimer's Society lay research panel and is a valued guide to the group in indicating the directions and priorities for research of people with dementia and their caregivers.

Dementia Activity report

The dementia group has had another successive difficult year. Only 1 study was adopted and 1 continuing. The workforce have done well to screen 162 possible participants and secure consent in 151 of these. Which is a rise in screening by almost 60% and a similar rise in accrual of 55%.

It should be noted that the relatively low accrual in the TauRX study is due to the test product having a number of odd and unusual side effects and so the study has been halted

Table 7

Study Name	Commercial	Randomised	Multi-Centre	Design	Phase	Adopted in 13/14	Accrual Status	Trust	NI / Site Accrual Target	Patients Screened (2013/14)	Patients Recruited (2013/14)	Total Screened to eof Mar 14	Total Recruited to eof Mar 14	Recruitment as % of Target
TauRx	Y	Y	N	CTIMP	III	Y	Follow-up	BHSCT	10	12	2	12	2	20%
Postoperative Delirium Study	N	N	N	Observa	n/a	N	Follow-up	BHSCT	350	150	149	254	251	72%
	50%	50%	0%			50%			**360**	**162**	**151**	**266**	**253**	**46%**
	1	1	0			1								

Diabetes Interest Group

Co clinical leads Professor Vivien Coates and Dr Hamish Courtney

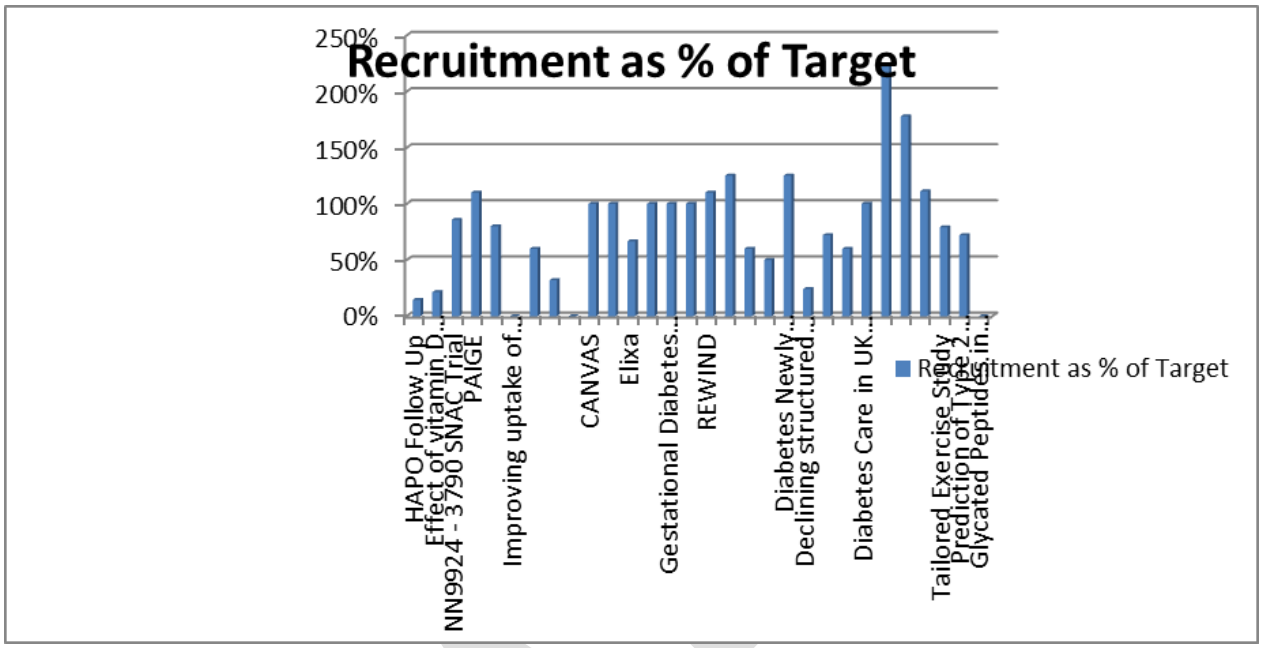
Introduction

The Diabetes Interest Group is co-led by Professor Vivien Coates and Dr Hamish Courtney, and currently has 4.0 WTE staff funded with 3.8 WTE in post. This is spread across 5 HSC trusts (1.3 WTE in BHSCT, 1.0 in WHSCT, 0.5 WTE in NHSCT, 0.5 WTE in SEHSCT and 0.5 WTE in SHSCT). These posts are all Band 6 Research Nurses.

In 2013/14, the group was involved in 15 studies of which 7 were newly adopted during the year. Of these 5 studies which are currently open and recruiting, 5 have completed recruitment and are in follow-up, 4 have closed and 1 is in set up.

Of those 9 studies which have completed their recruitment phases, 4 studies recruited over 100% of recruitment target (CANVAS 100%, Gestational diabetes DVD 100%, Newly diagnosed diabetes peptide study 125%, Care in UK Universities 153%), 4 further studies recruited over 70% of recruitment target (ELIXA 83%, REWIND 86%, Tailored exercise 79%, Shared family environment 72%) and only one study recruited to less than 70% of recruitment target (Declining structured education in type 1 diabetes 52%). (See Figure 7)

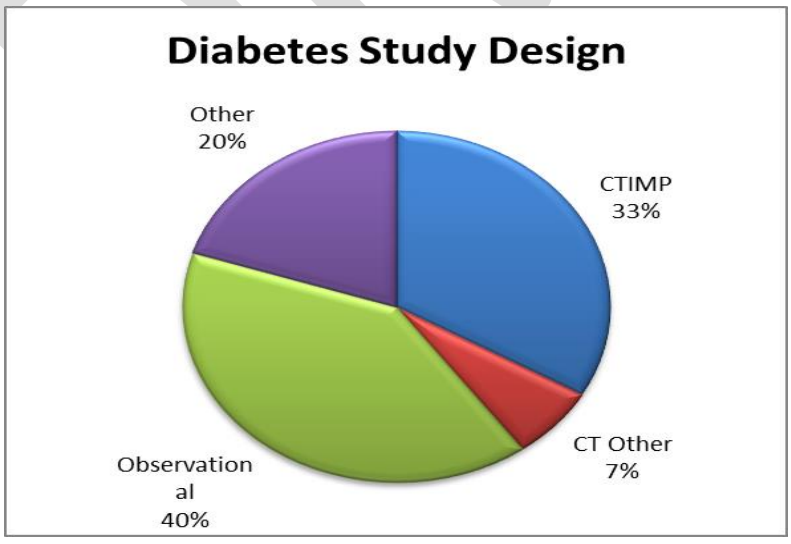
Figure 7



Of the 15 studies, 5 (33%) had commercial involvement and the remainder were funded through research councils, charities and R&D sources.

The design of the studies included six observational, five CTIMP, one CT other and the three remaining studies were of various other designs. (See figure 8)

Figure 8



Our objectives for the incoming year will be discussed at the next meeting of the Clinical Management Group scheduled for February 2014. These are likely to include further fostering of commercial partnerships. The group has already been successful in developing relationships with

several pharmaceutical companies such as Novo Nordisk. On-going negotiations are underway with Sanofi and Astra Zeneca to bring further studies to the group. Steps to enhance adoption of commercial studies include acquiring up to date data on regional diabetes incidence and prevalence and streamlining of research governance processes for multisite studies. A further objective would be the enhancement of multidisciplinary of the portfolio which will involve closer networking with university colleagues in both Ulster University and Queen's University. Partnership with the Primary Care Research Network was useful in recruitment in 2013/14 (SNAC Trial) and thus fostering of this relationship is likely to be of benefit to both groups in the future. Additionally the co-leads are collaborating with Professor Fidelma Dunne (National University of Galway) who has applied to the HRB for an all-Ireland clinical research network in diabetes.

Table 8

Study Name	Commercial	Randomised	Multi-Centre	Design	Phase	Adopted in 13/14	Accrual Status	Trust	NI Accrual Target	Patients Screened (2013/14)	Patients Recruited (2013/14)	Total Screened to eof Mar 14	Total Recruited to eof Mar 14	Recruitment as % of Target
HAPO Follow Up	N	N	N	Observational	Pilot / Feasibility	N	Open	BHSCT	800	218	116	218	116	15%
Effect of vitamin D supplementation on insulin resistance	N	Y	N	CTIMP	N/A	Y	Open	BHSCT	94	102	20	102	20	21%
NN9924 - 3790 SNAC Trial	Y	Y	N	CTIMP	II	Y	Open	SEHSCT	7	27	6	27	6	86%
PAIGE	N	Y	Y	CT Other	N/A	Y	Open	BHSCT	30	33	33	33	33	110%
							Open	SHSCT	20	26	16	26	16	80%
Improving uptake of structured diabetes education - T2DM	N	N	Y	Observational	N/A	Y	Open	BHSCT	35	0	0	0	0	0%
							Follow-up	NHSCT	25	15	15	15	15	60%
							Open	SEHSCT	25	15	8	15	8	32%
							Open	SHSCT	25	0	0	0	0	0%
CANVAS	Y	Y	Y	CTIMP	III	N	Follow-up	BHSCT	15	0	0	316	15	100%
							Follow-up	WHSCT	3	0	0	17	3	100%
Elixa	Y	Y	Y	CTIMP	III	N	Follow-up	WHSCT	3	15	0	104	2	67%
							Follow-up	NHSCT	3	15	2	77	3	100%
Gestational Diabetes DVD RCT	N	Y	Y	Other		Y	Follow-up	BHSCT	40	26	26	40	40	100%
							Follow-up	SEHSCT	40	40	40	40	40	100%
REWIND	Y	Y	Y	CTIMP	II	N	Follow-up	BHSCT	10	6	7	86	11	110%
							Follow-up	NHSCT	8	13	6	40	10	125%
							Follow-up	SEHSCT	10	12	2	37	6	60%
							Follow-up	WHSCT	4	12	0	17	2	50%
Diabetes Newly diagnosed Glycated Peptide Study	N	N	N	Observational	Pilot / Feasibility	N	Follow-up	WHSCT	12	0	0	46	15	125%
Declining structured diabetes education - T1DM	N	N	Y	Observational	N/A	Y	Closed	BHSCT	25	8	6	8	6	24%
							Closed	SEHSCT	25	24	18	24	18	72%
							Closed	SHSCT	25	26	15	26	15	60%
Diabetes Care in UK Universities	N	N	Y	Other	N/A	Y	Closed	BHSCT	9	9	9	9	9	100%
							Closed	NHSCT	9	20	20	20	20	222%
							Closed	SEHSCT	9	16	16	16	16	178%
							Closed	SHSCT	9	10	10	10	10	111%
Tailored Exercise Study	N	N	N	Other	N/A	N	Closed	NHSCT	24	40	19	40	19	79%
Prediction of Type 2 Diabetes: Shared Family Environment	N	N	N	Observational	II	N	Closed	WHSCT	25	70	5	137	18	72%
Glycated Peptides in Pre-Diabetes	N	N	N	Observational	Pilot / Feasibility	N	In Setup	WHSCT	50	0	0	0	0	0%
	27%	47%	53%			47%			**1419**	**798**	**415**	**1546**	**492**	**81%**
	4	7	8			7								

Mental Health Interest Group

Co clinical leads Professor Gerry Leavey and Dr Ciaran Mulholland

The mental health group was only going through its set up in 13/14 and therefore will not be presenting any data for this period. Some activity that did occur was the clinical leads liaising with the Scottish Mental Health Network leads and their colleagues across the North London Hub for Mental Health. Firstly to highlight the development of the NICRN mental Health group but also to garner support for study site selection and to review models of delivery. The out puts of these discussions will be implemented over 14/15.

Primary Care Interest Group

Co clinical leads Professor's Margaret Cupples and Carmel Hughes

Introduction

NICRN (Primary Care) continues to aim to support high quality clinical trials across all Health and Social Care Trusts in NI. We have developed productive working relationships with key individuals and groups to ensure that recruitment and retention of patients into trials are facilitated. A key aspect of our work is to support patients' involvement in research, and in planning and delivering trials, as well as in disseminating findings, so that research activity has real relevance and makes an impact on practice, improving the quality of care.

The clinical leadership is shared between Prof Margaret Cupples and Prof Carmel Hughes, each working one session per week. They work closely with the Primary Care Clinical Trials Practitioner, two clinical research nurses and a Clinical Management Group (CMG), comprising a range of individuals from different disciplines (general medical practice, nursing, pharmacy, physiotherapy, epidemiology, sociology, dentistry), different geographical areas across NI and different academic institutions (QUB and UU). The CMG's purpose is to advise regarding the adoption of studies into the group's portfolio and on its future direction; it meets three times per year and has facility for interim communications, to avoid undue delay in decisions. It has facilitated high quality research in primary care and allowed more patients the opportunity to participate in trials that are likely to lead to improved clinical care. The approach to adoption of studies aims to ensure that practitioners are well supported by the research nurses and that proper regulatory processes are in place.

The increasing devolvement of clinical care from hospital into the community has increased reliance on general practice's support in identifying and monitoring patients, both in relation to clinical care and research. Primary care has worked closely with other interest groups, specifically to date, with the respiratory, diabetes, cardiovascular and cancer groups.

Portfolio

The number of active studies has remained consistent in 2012/13 (n=12) and 2013/14 (n=15). In 2012/13, the majority of studies were observational in nature (58%), while in 2013/14, this decreased to 33%, with an increase in the number of CTIMP studies being adopted (17% 2012/13; 33% 2013/14). Due to the generalised nature of conditions managed in primary care, we have not specifically considered disease burden. However, as might be expected, there is a preponderance of studies which focus on long-term conditions. There has also been an increase in the number of commercial studies which have been adopted (n=2 in 2013/14 and 4 in 2013/14).

Our recruitment has been excellent, with the vast majority exceeding target numbers. The ICBP3 study which is now closed, achieved 60% of its target recruitment. This involved the distribution of questionnaires to GPs, and it has been noted across the literature that questionnaire response rates have been falling in similar studies. Therefore, 60% was considered a highly acceptable response rate and the study investigators were pleased with the findings. What should also be noted is the extent of screening which is required in order to identify potential participants for recruitment. For example, the REWIND study (see 2013/14) required screening of 2196 patients in order to recruit seven. A similar effort was required for SNAC and the Vitamin D studies.

We did not adopt 2 studies which applied to us for support, the primary reason being lack of feasibility in primary care.

Workforce

The workforce for the primary care group is based in the BHSCT, in Dunluce Health Centre, within the QUB Department of General Practice. This places their offices in close proximity to the clinical leads who are both from QUB. The staffing component is very stable at 1.0 WTE band 7 Clinical Trials Practitioner and 1.5 WTE band 6 CRNs. The staff have been highly productive in terms of high quality data collection and developing research in new sites and other disciplines within primary **care** including dentistry.
One point of note is that during the reporting period the quality of this group's work was recognised nationally when they were nominated for the UK General Practice Awards and were presented with Clinical Team of the Year Award at a ceremony in London **n** November 2013 and we are extremely proud to say that they were recipients of the Clinical team of the year award.

Very well deserved

Financial Statement

The primary care group cost £117,878 annually on staff costs and a further £23,009 on clinical lead PAs.

Education and Training

Outside of their mandatory training and the additional NICRN dedicated training events, appendix 3. The group did not attend any additional training over the reporting period

Interaction with other Research Infrastructure

Primary care has worked closely with other interest groups, specifically to date, with the respiratory, diabetes, cardiovascular and cancer groups. We have maintained communication with National Institute for Research (NIHR) Clinical Research Network (CRN) whilst they have undergone re-organisation and we look forward to linking with this group again as it evolves. We have also participated in a workshop, held at Stormont, to contribute to the development of the Health and Social Care R & D Strategy.

Patient and Public Involvement

To date, NICRN (Primary Care) has not recruited a PPI representative. This is primarily due to the diverse nature of primary care, and the difficulty in identifying who would represent primary care patients' interests. As mentioned above, our portfolio of studies encompasses a range of long-term conditions, and one patient with a particular condition may not be able to represent the interests of those with other conditions. However, we seek to ensure that the studies we support include active patient participation within their planning and management.

Other Initiatives

All Network staff have been actively engaged in supporting the Research Ready Accreditation Initiative, which has been pioneered by the Royal College of General Practitioners. This supports general practice in meeting the legal requirements of the UK for carrying out research. It is a self-assessment aligned with the UK's Research Governance Framework and has been developed in conjunction with the NIHR CRN. Network staff have been participating in the ongoing oversight of this process and in a number of work streams which are developing specific aspects of Research Ready notably:

- Redevelopment of the basic Research Ready Accreditation process and site
- Development of e-learning module
- Development of complex Research Ready (RR+) to support industry standard research

We have continued to organise the Northern Ireland Primary Care Research Forum, which is now badged as a NICRN event. This meeting is aimed at primary care health care professionals who are interested in research and increasingly acts as a showcase for our adopted studies. The last Forum held in October 2013, with Professor Frank Sullivan as our keynote speaker. It was attended by approximately 40 health and social care professionals and academics with interests in primary care research and from a range of locations across NI. Planning is underway for the next Forum event in 2015.

Professor Margaret Cupples spoke at the launch of the NICRN Mental Health Interest Group in February 2014, by invitation, to provide information about the range of research activities which we have undertaken and to share tips regarding successful recruitment and retention of participants in studies.

Primary Care Activity Report

For such a small unit the primary care group is one of the networks most successful in terms of recruitment to target. This is due in no small part to a robust focus on feasibility at the adoption stage, realistic target setting and by having a committed workforce who have developed excellent skill sets and knowledge of their particular environment and sites capabilities.

The portfolio increased overall by having 15 active studies over 13/14, an increase of 25% table 7. They adopted 6 new studies over the current year easily meeting their objective. Their screening figure do distort the picture slightly in that much of the screening activity in the primary care setting is data base focussed due to the necessity in primary care for robust data management and reporting. However even with that said the increase from 12/13 of 184% is still an very good achievement. Accrual to primary care studies increased by 152% over the same period in 12/13. However this needs tempered as a significant proportion was within a large observational study

Table 9

Study Name	Commercial	Randomised	Multi-Centre	Design	Phase	Adopted in 13/14	Accrual Status	Trust	NI / Site Accrual Target	Patients Screened (2013/14)	Patients Recruited (2013/14)	Total Screened to eof Mar 14	Total Recruited to eof Mar 14	Recruitment as % of Target
HEAT	N	Y	Y	CT other	IV	Y	In setup	NI	160	0	0	0	0	0%
POLYPHARMACY(P1)	N	N	Y	CT other	Pilot	Y	Open	NI	10	42	6	42	6	60%
Vitamin D Study	N	Y	N	CTIMP	N/A	Y	Open	NI	20	631	2	631	2	10%
PREFER in VTE REGISTRY	Y	Y	Y	CTIMP	N/A	Y	Open	NI	1	2	0	2	0	0%
GARFIELD	Y	N	Y	Observational	N/A	N	Open	NI	45	66	42	167	89	198%
MOSAICC	N	N	N	Observational	Pilot	N	Open	NI	50	308	26	308	26	52%
SNAC NN-9924-790	Y	Y	N	CTIMP	II	Y	Open	NI	2	1250	3	1250	3	150%
REWIND H9x-MC-GBDJ	Y	Y	Y	CTIMP	II/III	Y	Follow-up	NI	4	2196	7	2196	7	175%
Lung SEARCH	N	Y	Y	CT other	II/III	N	Follow-up	NI	100	n/a	0	166	106	106%
NIC PIP Dental study	N	Y	Y	CTIMP	IV	N	Follow-up	NI	1200	n/a	0	2488	1248	104%
Interval Dental Recalls Trial	N	Y	Y	CT Other	N/A	N	Follow-up	NI	156	457	156	457	156	100%
ICBP3	N	N	Y	Observational	N/A	N	Closed	NI	200	n/a	19	354	119	60%
Development of a Bronchiectasis-specific intervention focusing on adherence to treatment in bronchiectasis	N	N	Y	Other	II/III	N	Closed	NI	64	41	41	64	64	100%
Peer Support for Mediterranean Diet	N	N	N	Observational	N/A	N	Closed	NI	42	322	32	583	42	100%
Living with & beyond Prostate Cancer	N	N	Y	Observational	N/A	N	Closed	NI	630	1200	1010	1200	1010	160%
	27%	53%	73%			40%			**2684**	**6515**	**1344**	**9908**	**2878**	**107%**
	4	8	11			6								

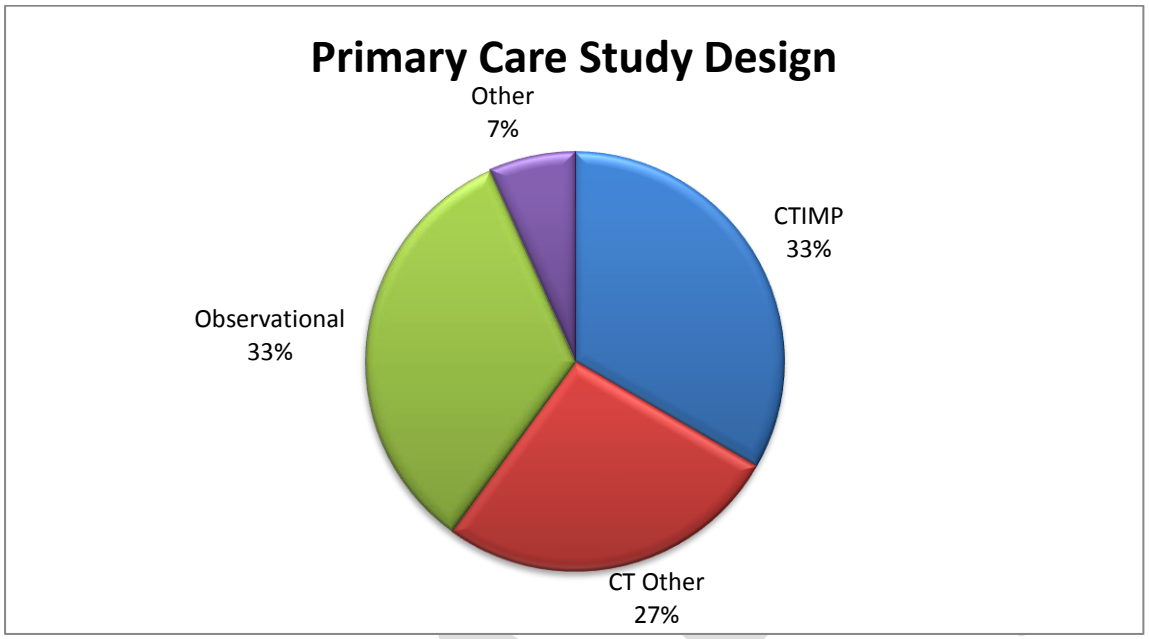
Of the 6 newly adopted studies, 3 were commercial and all were good quality Clinical trials in keeping with the networks remit and group objectives.

Their recruitment to target is exemplary (highest in NICRN) with a mean across the year of 107%, which again easily meets their annual objective Figure 9

Figure 9

In terms of portfolio balance they have a good equipoise between clinical trials and other more observational design studies. Over 13/14 clinical trials accounted for 60% of the portfolio with CTIMP (33%), other clinical trials (27%) and 40% being large observational studies to uplift study numbers figure 10.

Figure 10



Renal Interest Group

Co leads Professor Peter Maxwell and Dr Neal Morgan

Introduction

Now in its second year of operation the NICRN Renal portfolio has continued to expand and develop as evidenced by a 46% increase in total active studies. All NI HSC Trusts are involved in renal research. In 2012/13 there were 15 active studies (and 25 active sites), in 2013/14 there were 22 active studies (across 44 active sites) reflecting the excellent engagement from researchers across the network.

We have a broad research portfolio with a balance of commercial (36%) and non-commercial (64%) studies, the majority of which are on the UKCRN portfolio. The Renal network is proactive in seeking opportunities to engage with studies aligned to the needs of our renal population. The BHSCT site is maintaining a high profile in national and international studies and continues to be offered multiple opportunities to participate in academic and pharma-sponsored clinical research. The success of NICRN Renal in delivering high quality research data to network-adopted studies and the strong collaborative links we have established should encourage commercial partners to realise the benefits of investing across our active sites.

Recruitment to target of completed studies in 2013/2014 averaged 83% across both commercial and non-commercial studies. In the multiple sites recruiting to commercial studies recruitment was ≥100% in 75% of sites.

Internationally the UK Renal Registry (UKRR) is recognised as one of the few high quality clinical databases open to requests from researchers (www.renalreg.org). This comprehensive dataset is collected quarterly via an automatic download from renal unit databases with extensive reports published annually by the UKRR. The principal purpose of the UKRR is to act as a source of accurate clinical data for audit and benchmarking against quality care standards. This UK-wide comparative data is extensively employed in the commissioning of renal services. It also provides invaluable clinical epidemiological data for determining local disease incidence and prevalence which is essential in planning the strategic direction of our portfolio development.

Data held by the UKRR are a shared resource and are used to support research into kidney disease. A number of studies on the NICRN Renal portfolio (ATTOM, EQUAL and ALPHA studies) have considerable involvement from the UKRR registry.

All NI trusts are network linked by the eMED *Renal* clinical management software system which creates an integrated patient record capturing comprehensive clinical data on all patients with chronic kidney disease, acute kidney injury (AKI) and end stage renal disease (ESRD) - haemodialysis, peritoneal dialysis and kidney transplantation. The reporting capabilities of eMED *Renal* enable researchers to generate study specific reports to inform feasibility assessments on newly proposed studies. These scoping exercises are both accurate and invaluable in assessing our ability (as a network) to deliver our research objectives. With data from the UKRR we can characterise in great detail the disease burden of our local population and align our portfolio accordingly.

In a recent development, the UK Renal Data Collaboration (UKRDC) was formed in late 2012 aiming to further improve and standardise data communications between its member organisations, namely the UK Renal Registry UKRR, Renal Association, Scottish Renal Registry, Renal Patient View, UK Registry for Rare Kidney Diseases (RaDaR), British Association for Paediatric Nephrology, NHS Blood & Transplant, Northern Ireland Nephrology Forum and the Welsh Renal Clinical Network. Key benefits of this collaboration are the maintenance of a comprehensive data warehouse providing secure data for application to research and facilitating collaborative studies across UK sites.

The portfolio in 2013/14 has been largely committed to studies in haemodialysis, peritoneal dialysis and conservative management of ESRD. For instance, NI sites contributed to 20% of the total UK recruitment to the FEPOD (Frail Elderly Patients On Dialysis) study reflecting the appropriate prioritisation of adopted studies to the needs of our renal population.

We are cognisant of the need to develop further infrastructure and expertise to support studies in the fields of renal transplantation and haemodialysis vascular access. We have secured Research Ethics Committee approvals for long term NI research databases in three areas (kidney transplantation, chronic kidney disease and haemodialysis vascular access). Vascular access research is being developed in NI and in an academic collaboration with researchers at University Hospital Birmingham. Researchers are in the process of establishing research tissues banks to support clinical trials in renal transplantation and dialysis. A meeting for NICRN Renal supported staff and clinical investigators will be held to help plan the strategic direction over the next 2-5 years. The agenda will be agreed at the next CMG meeting this month (January 2015).

There are continued challenges negotiating (in a timely fashion) the various research ethics committee and Trust research governance requirements for research. We must continue to work with all colleagues to improve the efficiency of our interactions with Clinical Research Organisations and Principal Investigators (external to NI).

Workforce

The workforce has remained extremely stable across this group with no change over year. There has been little or no variance around absenteeism providing a stability and consistency to the group.

BHSCT	1.0 WTE

SEHSCT	0.5 WTE
SHSCT	0.6 WTE
WHSCT	0.5 WTE
TOTAL	Band 6 2.6 WTE

The network is co-led by Prof Peter Maxwell in the BHSCT and Dr Neal Morgan in the SHSCT. Strong regional engagement has been a feature of the Renal network with research leads and research nursing staff from each Trust attending our CMG meetings and proposing studies for adoption. A number of sites now have multiple PIs in named studies and an update on the work of our network is provided 6 monthly to the Northern Ireland Nephrology Forum (all NI renal consultants and trainees). Highlighting the depth of engagement across our specialty, of the 21 consultant nephrologists in post 43% are currently acting as local PIs/co-PIs for portfolio studies.

The NICRN Renal group has 3.1WTE funding for research nursing staff spread equably across the network - 0.5 WTE funding to NHSCT, SEHSCT and WHSCT, 0.6WTE funding to SHSCT and 1.0 WTE (2x 0.5WTE funded staff) to BHSCT. The SEHSCT has an additional 0.5WTE trust funded research nurse.

Local researchers have generated a number of studies suitable for our Renal research portfolio and we continue to see the development of locally initiated studies as a key priority for the network. We are striving to involve even more clinicians in networked studies and are looking to establish multidisciplinary sub-groups of interested staff to facilitate the development of grant applications in themed research areas deemed of strategic importance. The creation of NI Research Databases (for transplantation, chronic kidney disease and vascular access) will provide robust epidemiological frameworks for future studies. We plan to further expand existing research DNA repositories and explore development of tissue banks in the field of transplantation aligned to the direction of national clinical studies in these fields e.g. Renal Genomics interface with NHS England 100,000 Genomes Project. This research infrastructure helps us to engender collaborative research with UK partners with a view to generating highly competitive grant applications e.g. NIHR funding.

Financial Statement

The annual running cost for the renal group over 13/14 were £103,881 for staff and £25,889 on clinical leads. However with a higher proportion of commercial studies 8 (18%) this overall cost can potentially be offset by reinvestment and development.

The funding of research nursing staff in three sites across the region was initially dependent on commercial studies but this has now evolved to more secure posts enabled by Renal network funding. The stability of this funding stream will continue to provide a solid foundation for investigator-led studies as well as for projects with clinical relevance outside of commercial domains e.g. qualitative research on conservative and end-of-life care for ESRD as exemplified by the NIHR-funded PACKS study.

Funding has also been made available by the Western Trust, available on a competitive basis for locally designed studies. Likewise in the Southern Trust investigator designed studies are supported by competitive awards from R&D.

BHSCT costs are covered by commercial income from pharma-sponsored studies and it is generating a surplus on activity.

Education and Training

Staff did not request or need additional training over and above mandatory and NICRN dedicated training. So no additional cost or time required.

Networked nursing staff have greatly benefited from NICRN courses on Recruitment and Retention in Clinical Trials, Informed Consent Ethical, Legal and Practical Aspects and an Introduction to Clinical Research. South Eastern Trust research staff also attended a SQE Course Jan 2014.

Interaction with other Research Infrastructure

Dr Neal Morgan regularly attends the UKCRN Renal Disorders Specialty meeting and the renal clinical subgroups (CSG) meeting. Engagement with CSG leads in a variety of strategically relevant sub-specialty areas, namely AKI and ESRD has been of considerable benefit to the network. Dr Morgan is to present an overview of the NICRN Renal work to the UKCRN group at a forthcoming meeting, highlighting the achievements of network, looking to strengthen our established links and broaden the scope of our network's collaboration.

Prof Maxwell is now a member of the Renal Association (RA) Executive Committee which oversees national strategy for research supported by the RA.

The renal research activity in the Western Trust is based at the Clinical Translational Research and Innovation Centre (C-TRIC) campus, within the grounds of Altnagelvin Hospital.

Patient and Public Involvement

Northern Ireland Kidney Patients Association (charity for patients with end-stage renal disease supported by dialysis and transplantation) and Northern Ireland Kidney Research Fund (local charity supporting kidney research) have both been active in shaping the research agenda e.g. they have had direct input to the successful NIHR Fellowship award to Dr Helen Noble (QUB School of Nursing) for her PACKS study, influenced the design of the workshop and subsequent grant application to British Renal Society for the study of renal cachexia (Dr Joanne Reid QUB School of Nursing) and the study of non-melanoma skin cancer post kidney transplant (published Transplantation. 2014 Sep 27;98(6):646-52).

Colleagues in the Western Trust provided an overview of their research activity to the Altnagelvin Renal Patient Support Group and actively participated in International Clinical Trials day.

Dr Neal Morgan attended a one day meeting on Patient and Public Involvement in Research to better appreciate best practice in this area. As the network moves toward the development of larger

scale investigator led studies and competitive grant application the strength of our PPI (study design, patient engagement and feedback etc.) will be of paramount importance to success.

Other Initiatives

The network has adopted EDGE to manage the portfolio, all networked research nursing staff are fully trained on data entry and activity recording. This database provides comprehensive data capture and invaluable overviews of network performance, enabling timely intervention both to support studies in set-up and optimise recruitment to active studies where a need is identified.

The success of the network in delivering high quality research data and the collaborative links being established will hopefully encourage commercial partners to realise the benefits of investing across our networked sites. A recognised priority is the need to showcase the networks success, a key priority for discussion at our strategy meeting will be how best to optimise effective exposure for the network with key stakeholders (industry partners and PPI).

Renal Activity Report

This is the second year's activity for this group following their establishment in 12/13. Of the 15 studies adopted in 12/13 only one has closed over the reporting period. Leaving a total active portfolio, over this reporting period, of 22 studies. An additional 8 have been adopted over 13/14 which surpasses group objectives of 6 new studies table 10.

Table 10

Study Name	Commercial	Randomised	Multi-Centre	Design	Phase	Adopted in 13/14	Accrual Status	Trust	NI / Site Accrual Target	Patients Screened (2013/14)	Patients Recruited (2013/14)	Total Screened to eof Mar 14	Total Recruited to eof Mar 14	Recruitment as % of Target
EARNEST	N	N	N	Observational	n/a	Y	In Setup	BHSCT	16	0	0	0	0	0%
SONAR	Y	Y	N	CTIMP	III	Y	In Setup	BHSCT	10	0	0	0	0	0%
PIVOTAL	N	Y	N	CTIMP	IV	Y	In Setup	BHSCT	80	0	0	0	0	0%
ALPHA	N	N	Y	Observational	n/a	Y	In Setup	NHSCT	50	0	0	0	0	0%
							In Setup	SEHSCT	40	0	0	0	0	0%
							In Setup	SHSCT	50	0	0	0	0	0%
AKI Biomarkers	N	N	Y	Observational	n/a	Y	In Setup	BHSCT	10	0	0	0	0	0%
							Open	SHSCT	10	0	0	0	0	0%
PD-CRAFT	N	N	Y	Observational	n/a	Y	In Setup	NHSCT	10	0	0	0	0	0%
							Open	SHSCT	10	10	10	10	10	100%
							Open	WHSCT	10	12	0	12	0	0%
EQUAL	N	N	Y	Observational	n/a	Y	In Setup	BHSCT	10	0	0	0	0	0%
							In Setup	SEHSCT	10	0	0	0	0	0%
							Open	SHSCT	12	4	0	4	0	0%
							Open	WHSCT	10	13	0	13	0	0%
UK Calciphylaxis Study	N	N	N	Observational	n/a	N	Open	SEHSCT	2	0	0	1	1	50%
Bioimpedance Study	N	N	N	Other	n/a	N	Open	WHSCT	30	8	4	10	7	23%
Frail and Elderly Patient Outcomes on Dialysis (FEPOD): Part 1	N	N	Y	Observational	n/a	N	Open	BHSCT	10	6	2	6	2	20%
							Open	NHSCT	2	14	4	14	4	200%
							Open	SHSCT	4	5	12	14	12	300%
							Open	WHSCT	4	34	2	34	2	50%
Frail and Elderly Patient Outcomes on Dialysis (FEPOD): Part 2	N	N	Y	Observational	n/a	N	Open	BHSCT	10	3	3	3	3	30%
							Open	NHSCT	2	14	4	14	4	200%
							Open	SHSCT	12	6	12	16	12	100%
							Open	WHSCT	4	34	2	34	2	50%
Membranous Nephropathy Study	N	N	N	Observational	n/a	Y	Open	BHSCT	25	11	11	11	11	44%
The NEFIGAN Trial	Y	Y	Y	CTIMP	IIb	N	Open	BHSCT	5	17	0	17	0	0%
							Open	SEHSCT	3	2	2	2	2	67%
Mortality and CV Morbidity in CKD	Y	Y	Y	CTIMP	IV	N	Follow-up	SEHSCT	10	0	0	11	11	110%
							Follow-up	BHSCT	19	0	0	21	19	100%
TEMPO 4/4 (Otsuka 156-08-271)	Y	N	N	CTIMP	IIIb	N	Follow-up	BHSCT	2	0	0	2	2	100%
ATTOM	N	N	Y	Observational	n/a	N	Follow-up	BHSCT	110	0	0	90	90	82%
							Follow-up	NHSCT	30	0	0	22	22	73%
							Follow-up	SEHSCT	15	0	0	12	12	80%
							Follow-up	SHSCT	35	0	0	29	29	83%
							Follow-up	WHSCT	40	0	0	35	35	88%
Eculizumab in AMR in LD kidney transplant	Y	Y	N	CTIMP	II	N	Follow-up	BHSCT	3	4	1	6	3	100%
OVERTURE (Otsuka 156-10-291)	Y	N	N	Observational	n/a	N	Follow-up	BHSCT	10	0	0	9	2	20%
Prevalence and predictors of high grade ventricular arrhythmia	N	N	N	Observational	n/a	N	Follow-up	SHSCT	50	4	10	55	41	82%
CCX140-B in Diabetic Nephropathy	Y	Y	Y	CTIMP	II	N	Follow-up	SEHSCT	2	3	1	3	1	50%
							Follow-up	WHSCT	10	3	2	22	8	80%
ASTRAL	N	Y	Y	CTIMP	n/a	N	Follow-up	BHSCT	1	0	0	1	1	100%
							Follow-up	NHSCT	2	0	0	2	2	100%
STEERING	Y	N	N	Observational	n/a	N	Closed	WHSCT	10	0	0	8	8	80%
	36%	32%	50%			36%			800	207	82	543	358	67%
	8	7	11			8								

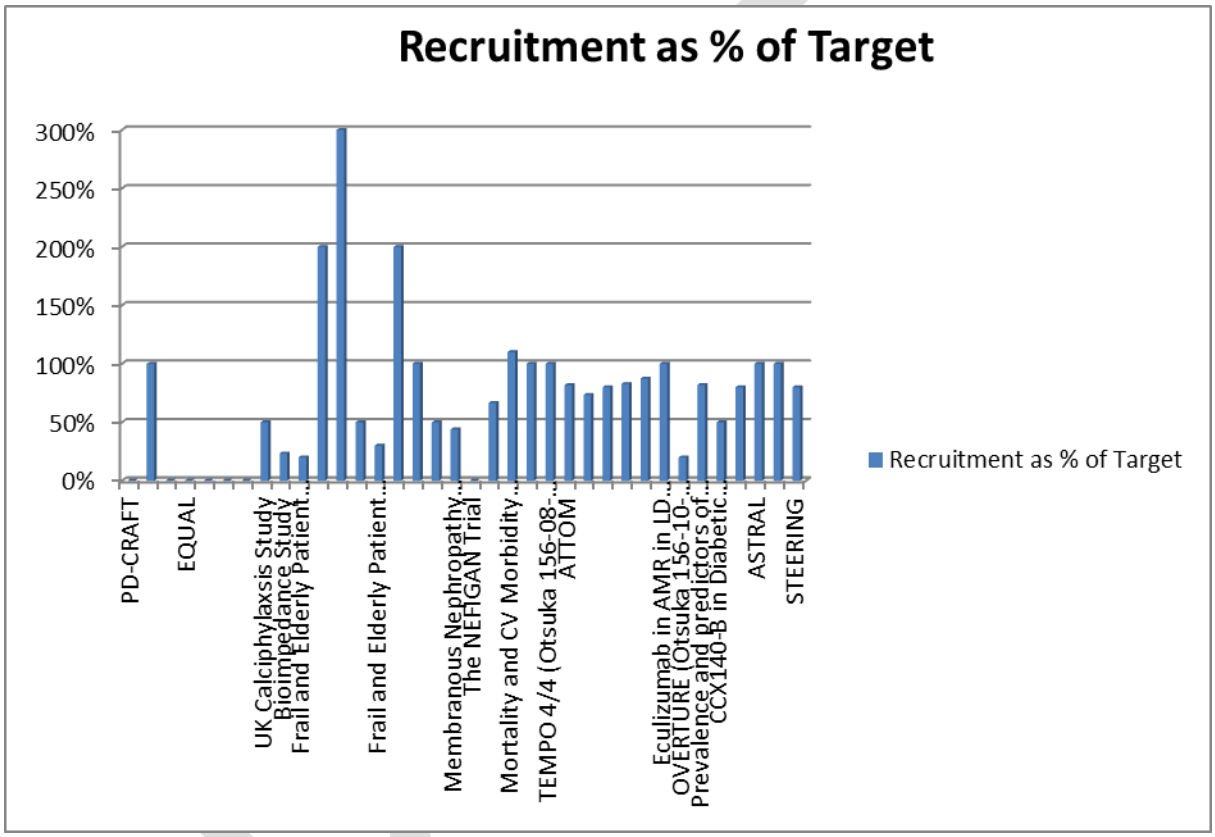
Their screening and accrual figures are marginally down on last year. Screening numbers are down by 24 overall and accrual is down by 97. As studies from 12/13 have moved from actively accruing to

follow up then we would expect to see such a reduction and the new studies in set up will start accruing over first quarter 14/15.

The group has met its target on regional working with 50% of overall portfolio occurring at more than one NI site. There was only 1 commercially sponsored study adopted in 13/14 as compared to 7 in 12/13.

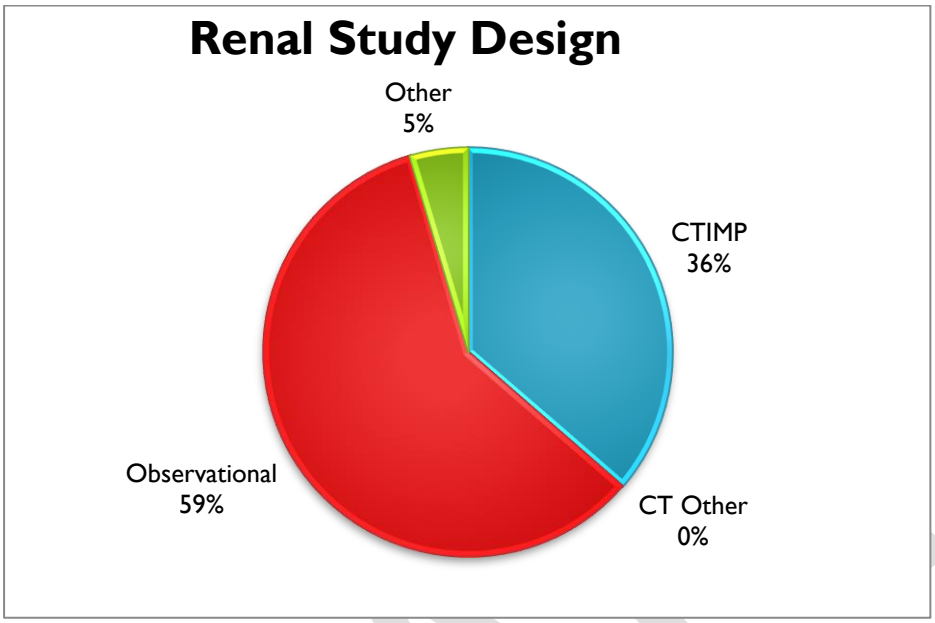
In terms of accrual to target, the group's portfolio figure stands at 67%, however this is due to the number of studies in set up and only open. When the figures is examined just for studies closed to recruitment then the mean accrual to target increases to a much healthier 83% figure 11.

Figure 11



In terms of the balance across the portfolio. It is somewhat weighted in favour of more observational studies rather than the preferred clinical trials. This is an area which may need some corrective action over 14/15 Figure 12.

Figure 12



Respiratory Health Interest Group

Respiratory Health co-leads; Professor Judy Bradley and Dr Lorcan McGarvey

Introduction

The Respiratory Health Group is a large and dynamic initiative within NICRN. Over the last five years this group has been proactive in income re-investment to support staff expansion which has been central to its rapid development since inception in 2008 and continued success through 2013/14. The group is Co-led by Professor Judy Bradley (Physiotherapy, BHSCT and Ulster) and Dr Lorcan McGarvey (BHSCT and QUB).

Portfolio

The Respiratory Health Interest Group has undertaken and successfully delivered on many Phase 2 proof of concept and phase III studies in carefully characterised patient cohorts in Severe Asthma, Cystic Fibrosis, Chronic cough, Bronchiectasis and COPD. Consistently high performance in delivering a broad portfolio of Industry and non-Industry sponsored studies with a strong emphasis on CTIMPs has been due to a number of key strengths:

Internationally recognised PIs

Well established, strong academic and industry collaborations

Participation in local, national and international Disease Networks

Workforce

There was some movement of staff during the 13/14 year which resulted in a reduction in staffing associated with post not being filled and staff being supported to proceed with secondments. This group like, Cardiovascular and vision has been approved a dedicated band 4 administrator. This post was filled in last quarter of 12/13 and the group have seen a great improvement in efficiency as much

of the administrative burden around study finance reconciliation has been taken up by this post, releasing CRN/AHP time. Staff expansion over time can be summarised as follows:

Core staff (2008) – 4 Trial Coordinators (2 nurses, 1 physiotherapist, 1 clinical physiologist)

Core staff (2014) - 3.5 nurses, 1 clinical physiotherapist, 2 physiotherapists, 1 administrator,

2 Physiotherapist and 1 nurse (1 year posts) funded from groups income.

Process to appoint the first Clinician to a Clinical Trial Fellowship is at an advanced stage

Respiratory Health is one of only two groups which currently employ AHPs within the workforce and as part of their induction they need additional training around venepuncture and the like to make them competent to deliver a wider range of research tasks appendix 3. This does require more focus by the NICRN staff manager but results in a very dynamic workforce

.BHSCT	4.75 WTE
	B4 1.0 WTE
WHSCT	0.5 WTE
TOTAL	Band 6 5.25 WTE plus Band 4 1.0 WTE

Financial Statement

Due to the higher staffing level the annual costs may be perceived as being high for the accrual rate. However it must be clearly stated that the intensity of the Respiratory health studies are such that participant visits can take several hours and so this group is more focussed on quality than quantity of participants. The annual costs for staffing equate to £221,918 with clinical lead costs of £21,093

Education and Training

As per appendix 3 and as stated above, this group utilises skilled AHPs to deliver study clinical endpoint trial measurements alongside their CRN colleagues. This obviously requires additional training which is reflected in their relatively heavy training schedule including, ECG, spirometry, cannulation, venepuncture. Together with coordinator colleagues with a nursing background they have undertaken training in more specialist respiratory based testing including inhalation cough challenge, ambulatory cough monitoring, lung clearance index measurements, sweat tests and nasal potential difference measurement.

Interaction with other Research Infrastructure

The respiratory group, through its proximity to the NI Clinical Research Facility and pressure on available clinical space on wards etc, has frequently used this infrastructural support unit in the delivery of its portfolio. To date they have collaborated in the successful delivery of 12 portfolio studies.

McGarvey represents the Respiratory Health Group on the UKCRN National Respiratory Health Specialty Group attending regular teleconferencing and face to face meetings through the year. He serves as Expert Reviewer for UKCRN Respiratory Portfolio studies.

McGarvey is the Academic Lead representing QUB on the NIHR Office for Clinical Research Infrastructure (NOCRI) Translational Research Partnership (TRP) for Inflammatory Respiratory Disease. The TRP was established to drive translational research and assist industry in early phase clinical trials and drug and device delivery.

The Respiratory Groups close links the with TRP supported laboratory facilities embedded in QUB has enhanced respiratory capability to undertake a range of Phase I and II studies requiring access to:

Induced sputum and Bronchoalveolar lavage; cell counts, bacterial culture, quantification, identification (PCR) and susceptibility testing

Analysis of single/multiplex assays for profiling biomarkers (cytokines) and cell signalling pathways

Flow cytometry - cell sorting, detection of extracellular and intracellular fluorescent markers, immunophenotyping, cell cycle analysis, cell proliferation & death, and intracellular cytokine detection

Immunocytochemistry; primary and cell line cultures

McGarvey was co-applicant on recent successful bid led by McAuley (Critical Care) for MRC with co-funding from the DHSSPSNI (total funding £2M) to establish a GMP cell therapy facility to support clinical trials for cell based therapies. In addition to the support of phase II cell therapy trials in ARDS and retinal diseases this facility will support any future cell therapy trials in other respiratory disease areas including COPD.

Other Initiatives

Respiratory Health Activity Report

The Respiratory Health Interest Group has been highly successful right from its creation and each year as continued to demonstrate a great ability to secure commercial partnerships. They have reinvested significant amounts of income into the development of their research potential and lead the way in NICRN in terms of collective leadership of PI's by the CMG.

Over period 2013/14 the group had 19 active studies running, which is an increase of 33% on the previous year. Of these 6 were newly adopted over reporting period, meeting their annual objective table 9.

Two notable changes were a significant increase in screening figure from 403 in 12/13 to 1370 in 13/14, an increase of 225%. And their working across sites, the group is naturally Belfast centric due to the regional centre being based in Belfast City Hospital site of BHSCT. However over 12/13 they deployed staff to the Western Health and Social Care Trust and Southern Health Trust. This has

enabled them to increase their multi centre studies to 28% of portfolio. This is great news for patients in the North West who can now access cutting edge therapies via research more easily.

Their accrual figures are marginally reduced as compared to 12/13. However in general the intensity of respiratory studies is extremely high and this slight reduction would be indicative of studies which are very resource heavy.

Their current portfolio had 11 (58%) of studies being commercial. Which gives the group great potential for expansion via reinvestment of capacity.

They also have a high accrual to target record with a mean in year accrual to target of 84% of targets met. Figure 13

The balance the Respiratory Group's portfolio is weighted in favour of clinical trials with approximately 70% of studies being CTIMP or CT other and only 26% being observational in nature.

2013/14 has seen a number of key achievements:

–

Phase II Severe asthma study – highest recruiter of 12 UK sites (Heaney)

Phase II Chronic cough study – 3rd highest of 13 UK sites (McGarvey)

Phase II COPD study – 2nd highest of 8 UK sites (McGarvey)

Key sites for two IMP (Ivacaftor and Mannitol which are now both licenced for treatment in CF. Ivacaftor is a CFTR potentiator drug that treats the underlying cause of CF in patients with specific mutations. Mannitol is mucolytic therapy which helps with airway clearance and therefore treats key symptoms of CF.

ECF CTN (Elborn/Bradley/Downey) upper quartile across the following performance measures
Total number recruited

Time from SIV to 1st patient

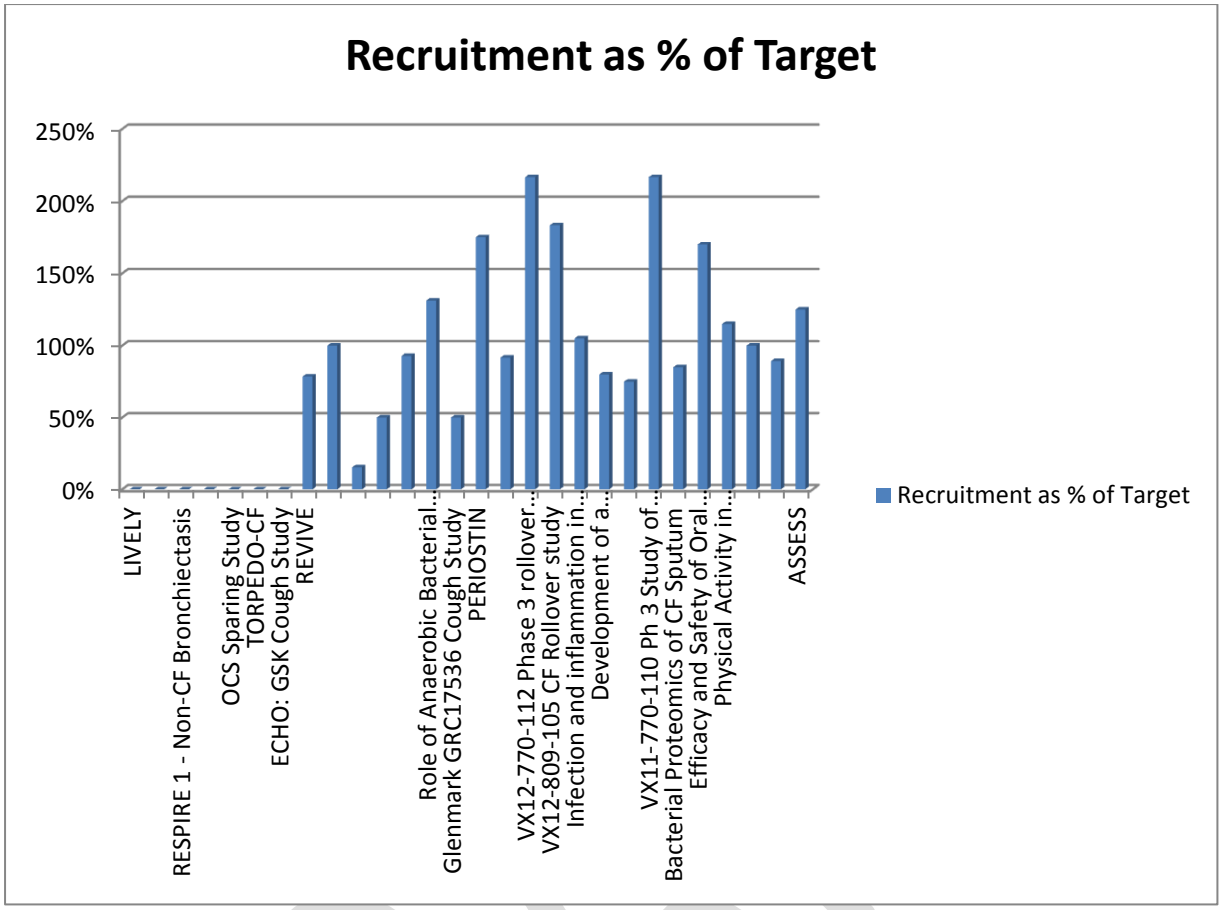
Overall site performance evaluation score

Applicants/Collaborators (Elborn/Bradley) on a MRC Partnership grant in a multicentre approach to Bronchiectasis and will contribute to the set up the UK national registry in bronchiectasis "BRONCH-UK" 2014-2017. Also within this grant lead site for a large trial exploring innovative outcome measures for bronchiectasis

Table 11

Study Name	Commercial	Randomised	Multi-Centre	Design	Phase	Adopted in 13/14	Accrual Status	Trust	NI Accrual Target	Patients Screened (2013/14)	Patients Recruited (2013/14)	Total Screened to eof Mar 14	Total Recruited to eof Mar 14	Recruitment as % of Target
LIVELY	N	Y	Y	CT Other	N/A	Y	Open	BHSCT	25	21	0	21	0	0%
							Open	WHSCT	25	34	0	34	0	0%
RESPIRE 1 - Non-CF Bronchiectasis	Y	Y	Y	CTIMP	III	N	Open	BHSCT	8	99	0	99	0	0%
							Open	WHSCT	5	72	0	72	0	0%
OCS Sparing Study	Y	Y	N	CTIMP	II	N	Open	BHSCT	17	3	0	3	0	0%
TORPEDO-CF	N	Y	N	CTIMP	III	N	Open	BHSCT	5	1	0	1	0	0%
ECHO: GSK Cough Study	Y	Y	N	CTIMP	II	Y	Open	BHSCT	10	15	0	15	0	0%
REVIVE	N	Y	Y	CT Other	II	N	Open	BHSCT	14	236	11	240	11	79%
							Open	NHSCT	13	73	6	151	13	100%
							Open	SEHSCT	13	92	2	92	2	15%
							Open	SHSCT	14	72	6	114	7	50%
							Open	WHSCT	14	98	4	192	13	93%
Role of Anaerobic Bacterial Infection in CF	N	N	N	Observational	N/A	N	Open	BHSCT	170	12	12	250	223	131%
Glenmark GRC17536 Cough Study	Y	Y	N	CTIMP	II	Y	Open	BHSCT	10	56	5	56	5	50%
PERIOSTIN	Y	N	N	CTIMP	II	Y	Follow-up	BHSCT	12	24	21	24	21	175%
VX12-809-103 Lumacaftor + Ivacaftor in CF TRAFFIC	Y	Y	N	CTIMP	III	Y	Follow-up	BHSCT	12	16	11	16	11	92%
VX12-770-112 Phase 3 rollover study of Ivacaftor in CF patients 6yrs	Y	N	N	CTIMP	III	N	Follow-up	BHSCT	6	13	13	13	13	217%
VX12-809-105 CF Rollover study	Y	N	N	CTIMP	III	Y	Follow-up	BHSCT	6	11	11	11	11	183%
Infection and inflammation in patients with COPD	N	Y	N	Observational	N/A	N	Follow-up	BHSCT	20	77	6	377	21	105%
Development of a Bronchiectasis-specific Intervention Focusing on adherence to Treatment in Bronchiectasis	N	N	Y	Other	N/A	N	Follow-up	BHSCT	10	0	0	13	8	80%
							Follow-up	WHSCT	20	0	0	15	15	75%
VX11-770-110 Ph 3 Study of Ivacaftor for CF R117HCFTR	Y	Y	N	CTIMP	II/III	N	Follow-up	BHSCT	6	0	0	48	13	217%
Bacterial Proteomics of CF Sputum	N	N	N	Observational	N/A	N	Follow-up	BHSCT	40	0	0	41	34	85%
Efficacy and Safety of Oral BC1036 in Management of Cough (HCR:	Y	Y	N	CTIMP	III	N	Closed	BHSCT	20	23	3	219	34	170%
Physical Activity in Bronchiectasis (PhAB)	N	N	Y	Observational	N/A	N	Closed	BHSCT	20	158	20	158	23	115%
							Closed	SHSCT	15	0	2	22	15	100%
							Closed	WHSCT	28	8	3	59	25	89%
ASSESS	Y	N	N	Observational	N/A	N	Closed	BHSCT	8	156	10	156	10	125%
	58%	58%	26%			32%			**566**	**1370**	**146**	**2512**	**528**	**84%**
	11	11	5			6								

Figure 13



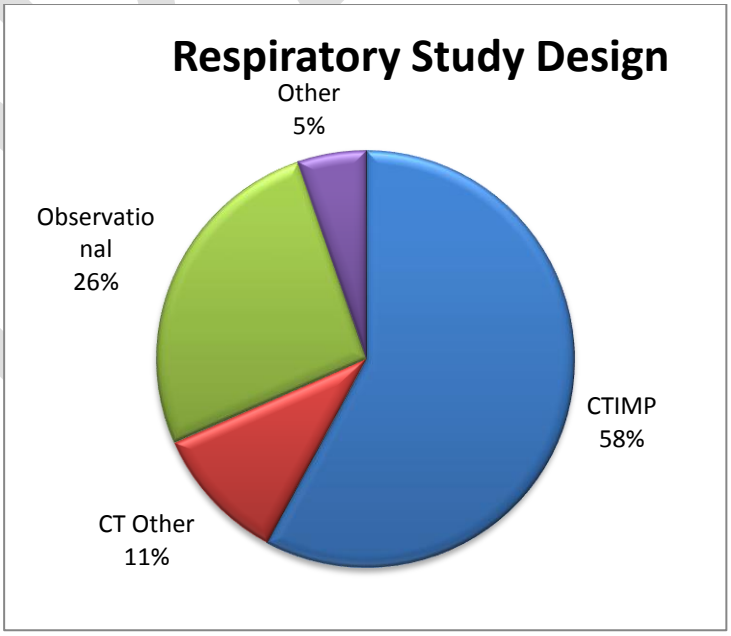


Figure 14

Stroke Interest Group

Co-clinical leads Dr Michael Power and Mrs Carolee McLaughlin

Introduction

NICRN Stroke was one of the first research networks to be established in Northern Ireland mainly because of the drive and enthusiasm of stroke practitioners in the province to cooperate and produce high quality research. From its inception the network has been collaborative involving NHS, academic, and voluntary sector staff. There has always been strong input from Allied Health Professionals who have made strong impacts as co-directors of the network. Stroke is a very challenging area to perform research particularly in the acute phase of the condition and this is reflected in very large number of patients screened when compared with the numbers of patients accrued to studies.

There have been challenges for the network during the year 13/14 not least because of significant service reorganisation in several Trusts relating to stroke services but also because of staffing changes and shortages.

The IRIS Study has been particularly successful in the South Eastern Trust where the Ulster Hospital was one of the top six UK sites for recruitment. IRIS (Insulin Resistance Intervention after Stroke) trial is funded by the US national institutes of health and has brought a £53,560 into the South Eastern Trust RND office. NICRN Stroke has recently adopted 'Big Cactus', an NIHRN funded study looking at new ways of managing dysphagia post stroke. NICRN Stroke's co-director Carolee McLaughlin has been closely involved in the NIHRN bid for funding for this trial which is due to open in Northern and Belfast trusts early in 2015.

Early in 2014 Randox Laboratories approached NICRN Stroke for help in developing a trial looking at bio markers for stroke which could be used in early identification of stroke and potentially be widely applicable. A protocol has been developed but is still being modified. We anticipate a final protocol mid-2015 with subsequent ethics approval and commencement of recruitment. A locally conceived study looking at the use of gaming for recovery of balance post stroke has been developed in the South Eastern Trust, and is now ready to commence recruitment. This is a pilot RCT but could be expanded depending on results.

The Belfast Trust has proposed the ESCAPE study for adoption during 2013/14. This study is an important study looking at the potential benefits of interventional treatment in the hyper acute phase of stroke. The Belfast Trust was one of the few chosen sites and the only European site to

participate in this trial.Recruitment to stroke studies is particularly challenging because of the complexity of acute stroke of patients but also the delays in accessing those patients in stroke units in the different Trusts. Recruitment would be enhanced substantially where all acute stroke patients admitted to a stroke unit as their ward of first admission. It is extremely challenging to recruit and randomise patients to trials outside of organised stroke services. One very big opportunity to enhance stroke research for the future is the development of the SSNAP web based audit tool for stroke based at the Royal College of Physicians in London. Lack of support in implementing this in Northern Ireland has hampered its development but if this can be overcome it could have very significant impact on stroke services and stroke research because of the quality of data that would be provided. One of the other significant barriers in Northern Ireland to high quality stroke research is the absence of an academic stroke department. Despite these barriers the performance of the stroke research network is creditable and will hopefully build on its successes in the next few years.

Portfolio and Recruitment

There are currently six studies in the portfolio with five more recently adopted. This includes pilot or CT's, large multi-centre studies, and worldwide registries. As mentioned we are also collaborating with Randox Laboratories to examine the feasibility of using bio markers for the very early diagnosis of a stroke. It is worth mentioning that the number of patients screened for studies in 13/14 was 2921 and the number actually recruited was 55. This reflects the very challenging environment in which to randomise stroke patients and also reflects the delays in stroke patients reaching organised stroke services where the stroke research nurses are based. One study on vascular dementia was not adapted because of the time commitments involved as indicated by the use of the intensity tool.

Workforce

The stroke group has an experienced staffing base deployed across all 5 NI HSC Trusts. This offers the group regional coverage. The group is core funded for 4.5 WTE positions. During the reporting period the BHSCT position was reduced to 0.25 due to maternity leave. This coincided with a radical restructuring of the stroke services across the 2 main BHSCT sites, with the new service being centralised to the Royal Victoria site. This obviously had a severe impact on the focus of research during this time

- BHSCT 0.25 WTE (Reduced from 1.0 over reporting period)
- NHSCT 1.0 WTE
- SEHSCT 1.0 WTE
- SHSCT 1.0 WTE
- WHSCT 0.5 WTE

Financial Statement

The stroke group costs amounted over the reporting period to £138,120 on staff costs and £17,624 for the clinical leads PAs. This has been offset somewhat by the commercial income derived from the IRIS study by £53,560 which came into the SEHSCT over this reporting period.

Education and Training

The stroke staff were provided with additional training as highlighted in appendix 3 in addition to the appropriate mandatory training as per their appraisal outputs.

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Collaboration with other Research Bodies

Over this reporting period with a downturn in activity, the group has not had the opportunity to engage with other research bodies either locally or nationally. The groups record for securing commercially sponsored research has not achieved the level anticipated over 12/13 and 13/14 with them again only being able to adopt 1 commercially sponsored studies in 2013/14. However over the last quarter of 13/14 the group has developed an exciting collaboration with a local commercial partner. This collaboration was initiated via the company with the NICRN Coordinating centre and has resulted in the group informing the collaboration from the very first design stages. This recognition by a highly successful local company, with a world leading brand, of the potential of local collaboration with the highly skilled and knowledgeable NICRN stroke work force is an exciting venture and it is hoped that this will form the focus of the groups partnering over the 14/15 period.

Patient and Public Involvement

The stroke group has always had an awareness and appreciation for their PPI responsibilities. This is in part due to the focus of a previous clinical lead, who drove the role of lay participation during their time in post. Therefore the group does have a PPI representative on their CMG group who is very active attendee and participates at each CMG.

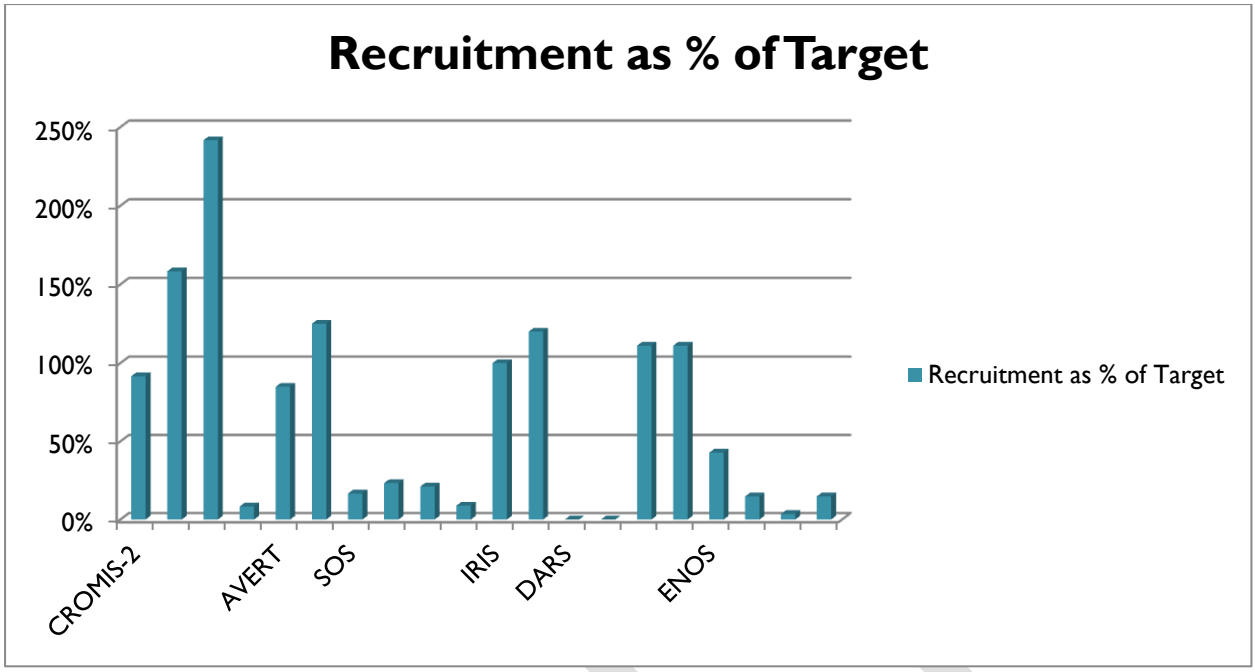
Stroke group Research Activity Report

The stroke group has shown a reduction in activity over 2013/14 as compared with 2012/13 period with a 50% reduction in screening and accrual. As shown in table 12, the group supported 9 studies in total over 2013/14 occurring at principally 4 of the NI trusts which is the same overall activity as 12/13. They only adopted 3 new studies over the period which is the lowest level of objective expected (3-6 new studies annually). However none of these were commercially sponsored and so don't meet their 30% objective for commercial activity. Out of the total portfolio of 9 studies 8 (89%) were randomised controlled trials and all were multi-centre in nature. This collective working practice meets the groups objective for the year of 50% of portfolio occurring at 2 or more clinical sites. They achieved a mean 68% accrual to target over the 6 actively recruiting studies during this period, which does meet the accrual to target objective of at least 50% figure 15. With a total number of screening events of 2921 versus 5961 in 12/13 and 55 accrued participants versus 106 for same period last year the reduction in activity is clear and in part due to the loss of the BHSCT activity.

Table 12

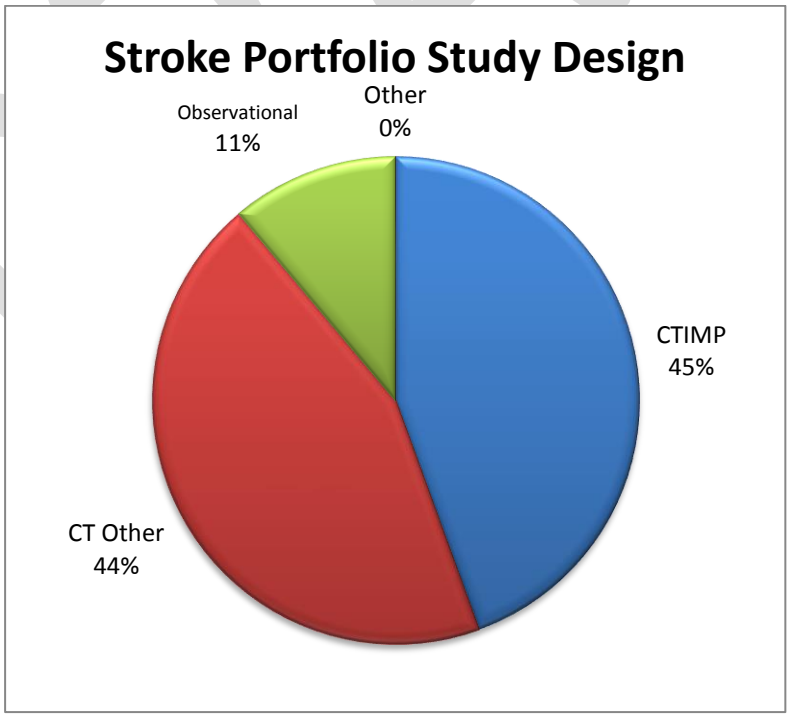
Study Name	Commercial	Randomised	Multi-Centre	Design	Phase	Adopted in 13/14	Accrual Status	Trust	NI / Site Accrual Target	Patients Screened (2013/14)	Patients Recruited (2013/14)	Total Screened to eof Mar 14	Total Recruited to eof Mar 14	Recruitment as % of Target
ESCAPE	N	Y	N	CT Other	III	Y	In Setup	BHSCT	25	0	0	0	0	0%
TARDIS	N	Y	Y	CT Other	III	Y	In Setup	NHSCT	36	0	0	0	0	0%
							In Setup	SEHSCT	36	0	0	0	0	0%
							In Setup	SHSCT	36	0	0	0	0	0%
							Open	WHSCT	36	11	0	0	0	0%
RESTART	N	Y	Y	CTIMP	N/A	Y	Open	SEHSCT	6	17	0	17	0	0%
							Open	SHSCT	14	2	0	2	0	0%
CROMIS-2	N	N	Y	Observational	N/A	N	Open	NHSCT	12	79	11	79	11	92%
							Open	SEHSCT	12	108	17	118	19	158%
							Open	SHSCT	12	186	8	330	29	242%
							Open	WHSCT	12	314	1	314	1	8%
AVERT	N	Y	Y	CT Other	III	N	Open	NHSCT	20	209	1	1129	17	85%
							Open	SEHSCT	20	366	1	1859	25	125%
SOS	N	Y	Y	CT Other	III	N	Follow-up	NHSCT	90	59	0	923	15	17%
							Follow-up	SEHSCT	90	78	1	1483	21	23%
							Follow-up	SHSCT	90	74	1	946	19	21%
							Follow-up	WHSCT	90	18	1	450	8	9%
IRIS	Y	Y	Y	CTIMP	II / III	N	Follow-up	NHSCT	5	0	0	194	5	100%
							Follow-up	SEHSCT	10	0	0	1433	12	120%
DARS	N	Y	Y	CTIMP	III	N	Closed	BHSCT	9	0	0	89	0	0%
							Follow-up	NHSCT	9	202	0	270	0	0%
							Follow-up	SEHSCT	9	195	8	254	10	111%
							Follow-up	SHSCT	9	257	5	485	10	111%
ENOS	N	Y	Y	CTIMP	II / III	N	Closed	NHSCT	28	277	0	1602	12	43%
							Closed	SEHSCT	27	292	0	700	4	15%
							Closed	SHSCT	28	177	0	1769	1	4%
							Closed	WHSCT	27	0	0	774	4	15%
	11%	**89%**	**89%**			**33%**			**798**	**2921**	**55**	**15220**	**223**	**56%**
	1	**8**	**8**			**3**								

Figure 15



In terms of composition of the portfolio, almost half 45% of studies were clinical trials of investigational Medicinal Products (CTIMP's) whilst another 44% of portfolio was made up of other clinical trials with only 11% being observational in nature figure 16.

Figure 16



Vision Interest Group

Dr Giuliana Silvestri , Clinical Lead

Introduction

This report will highlight the resources available to the Vision NICRN Group, the portfolio of diseases studied, the split between commercial versus non-commercial studies and the opportunities available through collaboration with other areas. A summary of strengths and challenges will be presented. Regarding the challenges a specific example of a study that posed particular problems for the group will be outlined. An overview will also be presented regarding the position of the group in terms of recruitment to target.

The NICRN Vision Group was established in 2008. The Clinical Lead position was shared equally by Dr G Silvestri & Professor A Jonathan Jackson until 2011 when Dr Silvestri assumed the role of sole Clinical Lead. The Core Staff has continued to evolve from the HPSS R&D core funded staff and has been expanded by use of monies from the Vision Research Capacity Fund. The staff includes:

2 Band 6 Nurses (full time):HPSS R&D Funded

1 Band 7 Imaging Technician (full time): HPSS R&D Funded

2nd Imaging Technician: Funded through Vision Capacity Fund

1 WTE optometrist (2-3 individuals) HPSS R&D Funded

Band 4 Administrator (1.0 WTE) HPSS R&D Funded

Staff

Both Imaging Technicians have global accredited with the following Reading Centres: Wisconsin; Cleveland; London, DARC; Digital OCT Reading Centre

All optometric staff are accredited for visual function testing with many of the major sites. This allows staring up of studies without training delay.

Facilities

NICRN Vision benefits from fully functional Clinical Research Suite at RVH, Ophthalmology Department BHSCT which facilitates easy communication with Ophthalmology NHS Staff and also benefits patient recruitment. The Vision Research Suite is fully equipped with the following:

- eCRF facilities
- Vision testing lanes
- Refraction/multiple accreditations
- Imaging facilities
- Colour fundus photography
- FFA
- Heidelberg Spectralis OCT
- MAIA/Visual field assessment
- Corneal endothelial cell count facilities

The group also has the opportunity to use the Clinical Research Facility for non-interventional studies.

Principal Investigators

The nature of the studies recruited to the portfolio is naturally related to the specialist interests of the PIs. As the first PIs had specialist interests in medical diseases of the retina and visual disability (Usha Chakravarthy, Giuliana Silvestri, Jonathan Jackson) most of the studies in the past 5 years have been on diseases of the retina such as age-related macular degeneration, diabetic retinopathy, uveitis/inflammatory diseases and low vision. More recently the number of PIs has expanded to include Dr Heping Xu, Dr Michael Williams, Miss Tanya Moutray, Professor Noemi Lois, Professor Augusto Azura-Blanco. With this the range of diseases under study has expanded to include retinal vascular occlusive diseases, diabetic maculopathy and glaucoma.

Collaboration with other Networks

Our group has been involved in supporting portfolio studies within the Cancer Network. A number of these studies require ophthalmic examination and imaging for safety monitoring. These studies could not proceed without the collaboration of the Vision Network. We have also engaged with the other local infrastructural support units in terms of the NI Clinical Trials Unit and the Clinical Research Facility.

NICRN Vision Portfolio Metrics

Since 2008, the Vision Network has provided support for 32 studies in total. Of these 20 are closed; 9 are open;2 are in follow-up and ?? are in in set-up

The ratio of commercial to non-commercial is 50:50 in closed/open phase. In terms of meeting recruitment targets our achievements are as follows:

Closed studies: 97% recruitment (12%-129%)

Open studies: 79% recruitment (88 – 143%).

Commercial Companies include:

Alcon Laboratories

Allergan

Bayer Healthcare

Bayer Schering

F. Hoffmann-La Roche Ltd

NeoVista Inc

Novartis

Oraya Therapeutics

Pfizer

Quark Pharmaceuticals Inc

Santen Inc

TRB Chemedica International

Strengths of the Vision Network Group

One of the best assets/strengths of the Vision Network Group is the core of experienced and dedicated staff who provide knowledge, skills in ophthalmic testing, imaging and nursing. In addition our staff have developed skills in assessing the needs of a new protocol, attributing time required and also in using the Intensity Costing Template. The addition of administrative staff will greatly increase the time available for clinical staff to spend on appropriate activities.

In addition we have the added strength of Professor Usha Chakravarthy being the ***Clinical Lead for UKCRN Ophthalmology Specialty Group,*** which affords increased visibility to the NICRN Vision group and gives better opportunity for studies to come to Northern Ireland. The group also enjoys excellent relationship with the Clinical Ophthalmology Department in the BHSCT which houses all Ophthalmic sub-specialities and with Pharmacy at BHSCT.

Opportunities for Collaboration with other Centres

In addition to the above the NICRN Vision Network has the opportunity for close collaboration with the Centre for Experimental Medicine (CEM) and with the Central Angiographic Reading Facility at QUB. CEM has a very active basic science research profile, which is becoming more translational. The Ophthalmology Programme within (CEM) is a leading UK group for basic and clinical research in retinal diseases. Multidisciplinary in nature and includes basic cell and molecular biology, pathophysiology of disease, genetic analysis, protein chemistry, retinal imaging, patient-based phenotyping/genotyping and co-ordination of multi-national clinical trials. The ophthalmology group was the focus for a £4.8 million Wellcome Trust Infrastructure grant £32 million award from UK-RPIF to create a Centre of Experimental Medicine (CEM). This new Centre has, at its core, three themes consisting of ophthalmology, diabetes and genomics research. This facility is where basic research will connect to clinical care and will open in January 2015. The Centre includes 4 Clinical Academics: 4 NIHR grant applications in currently in progress. A number of requests for investigator-led non-commercial proposals have come forward from CEM.

Challenges

In common with other Networks we have faced challenges in the areas of Trust Processes however these are improving steadily. The addition of new disease areas in our portfolio has been very welcome but has brought additional challenges as training for new techniques were required. Due to increasing demand and with the possibility of 4 NIHR studies pending we have rationalised our workforce and have appointed additional administrative staff from, the Research Capacity Budget. We have also requested additional funding (year start April 2015) through the HPSS R&D for a band 3 technician, which would free up nursing and optometric staff.

A further challenge is to try to become less Belfast-centric. We have tried to encourage participation from the only other large Ophthalmic Unit in the Western Trust but progress has been difficult. The Vision Network Group has shown willingness by offering staff on a sessional basis but realistically Ophthalmology is very equipment dependent which poses some practical issues. The CMG membership does include representation from the Western Trust and the University of Ulster. As specialist ophthalmic services for many sub specialities are sited in Belfast our studies do attract patients from the whole of Northern Ireland.

In order to improve recruitment the group has developed a *"Study Flyer"* which details the essential information for each study. These are displayed in Clinical Rooms and sent by email to all Ophthalmic Staff periodically. (Figure1)

Particular challenges

Recruitment targets have been improving steadily however the group has learnt some lessons from earlier studies. Some investigator-led studies performed particularly badly (12% recruitment) and some commercial studies were adopted too late in the process. We are now mindful to assess potential more stringently.

One study that posed particular difficulties for the group was the **Temporal Artery Biopsy vs ULtrasound in Diagnosis of Giant Cell Arteritis (GCA) (TABUL).** The aim of the study was to evaluate the diagnostic accuracy (sensitivity and specificity) of ultrasound as an alternative to temporal artery biopsy for the diagnosis of GCA in patients referred for biopsy with suspected GCA. The study also sought to evaluate the cost-effectiveness (incremental cost per QALY) of ultrasound instead of biopsy in the diagnosis of GCA. The study was very interesting and has the potential to result in very tangible benefits for patients and the NHS. The study also provided the opportunity to interface directly with Rheumatology. What our group failed to appreciate was that the technique of high-resolution ultrasound scanning of the temporal artery was extremely specialised and completely out of the remit and skill of the Vision team. This resulted in significant delays and recruitment fell short of target (60% recruitment by close of study).

In summary the NICRN Vision Network is a vibrant, active and dedicated group with excellent recruitment targets. The group has interfaced with a number of other specialities and groups and continues to grow. The staff complement has been expanded using the Research Capacity Fund to help meet the increasing and projected need for 2015.

Financial Statement

The group costs are £187,192 on staffing annually and £24,967 on lead costs. Again this group has access to a large pipeline of commercial activity and as such these costs could be off set against income.

Education and Training

The staff attended all provided training, mandatory and over 13/14 the optometrists were supported over a number of other additional training programmes as agreed with clinical leads appendix 3

Vision Research Activity Report

The vision group had a relatively static year compared to 12/13 with total active studies being 18 in 13/14 compared with 19 in 12/13. They adopted only 4 new studies during 13/14 which is the same

as 12/13 but significantly down from 11/12. Also the percentage of commercial studies stayed approximately the same 56% commercial in 13/14 and 58% in 12/13 table 13 .

As the group is purely Belfast centric there is not going to be any cross site working in NI.

Recruitment to target is still excellent at 85% of targets met table 13 and figure 18. Again if we correct for those studies closed to recruitment this group achieve an excellent 96% accrual to target.

The portfolio is well balance across clinical trials (55%) and observational/other (45%) studies.

Table 13

Study Name	Commercial	Randomised	Multi-Centre	Design	Phase	Adopted in 13/14	Accrual Status	Trust	NI / Site Accrual Target	Patients Screened (2013/14)	Patients Recruited (2013/14)	Total Screened to eof Mar 14	Total Recruited to eof Mar 14	Recruitment as % of Target
LEAD Study	N	Y	N	CT Other	N/A	Y	In Setup	BHSCT	20	0	0	0	0	0%
LiGHT	N	Y	N	CT Other	N/A	N	Open	BHSCT	40	10	10	10	10	25%
LUMINOUS	Y	N	N	Observational	IV	Y	Open	BHSCT	40	23	23	23	23	58%
QUB RUTH HOGG	Y	N	N	Observational	N/A	N	Open	BHSCT	40	0	0	17	7	18%
TABUL	N	Y	N	Observational	N/A	N	Follow-up	BHSCT	10	6	6	6	6	60%
CRYSTAL	Y	Y	N	CTIMP	III	N	Follow-up	BHSCT	5	0	0	5	3	60%
BRIGHTER	Y	Y	N	CTIMP	III	N	Follow-up	BHSCT	7	3	6	15	10	143%
Candidate Genes for AMD in NI (GDBA Study)	N	N	N	Observational	N/A	N	Follow-up	BHSCT	300	3	3	373	334	111%
AMD Immune Study	N	N	N	Other	N/A	N	Follow-up	BHSCT	350	0	0	200	167	48%
OCTAVE	Y	Y	N	CTIMP	III	Y	Follow-up	BHSCT	4	9	5	9	5	125%
SAKURA	Y	Y	N	CTIMP	III	N	Follow-up	BHSCT	3	1	0	3	2	67%
INTREPID	Y	Y	N	CTIMP	III	N	Follow-up	BHSCT	7	0	0	7	7	100%
MATISSE	Y	Y	N	CTIMP	I/II	N	Closed	BHSCT	6	0	0	21	4	67%
AURA	Y	N	N	Observational	N/A	N	Closed	BHSCT	40	0	0	157	44	110%
IVAN	N	Y	N	CT Other	III	N	Closed	WHSCT	40	0	0	106	43	108%
RELIGHT	Y	N	N	CT Other	IIIB	N	Closed	BHSCT	7	0	0	9	9	129%
AMD phenotype study	N	N	N	Observational	N/A	N	Closed	BHSCT	20	24	23	24	23	115%
ECHOES	N	N	N	Observational	N/A	Y	Closed	BHSCT	150	154	154	154	154	103%
	56%	56%	0%			22%			**1089**	**233**	**230**	**1139**	**851**	**85%**
	10	10	0			4								

Figure 18

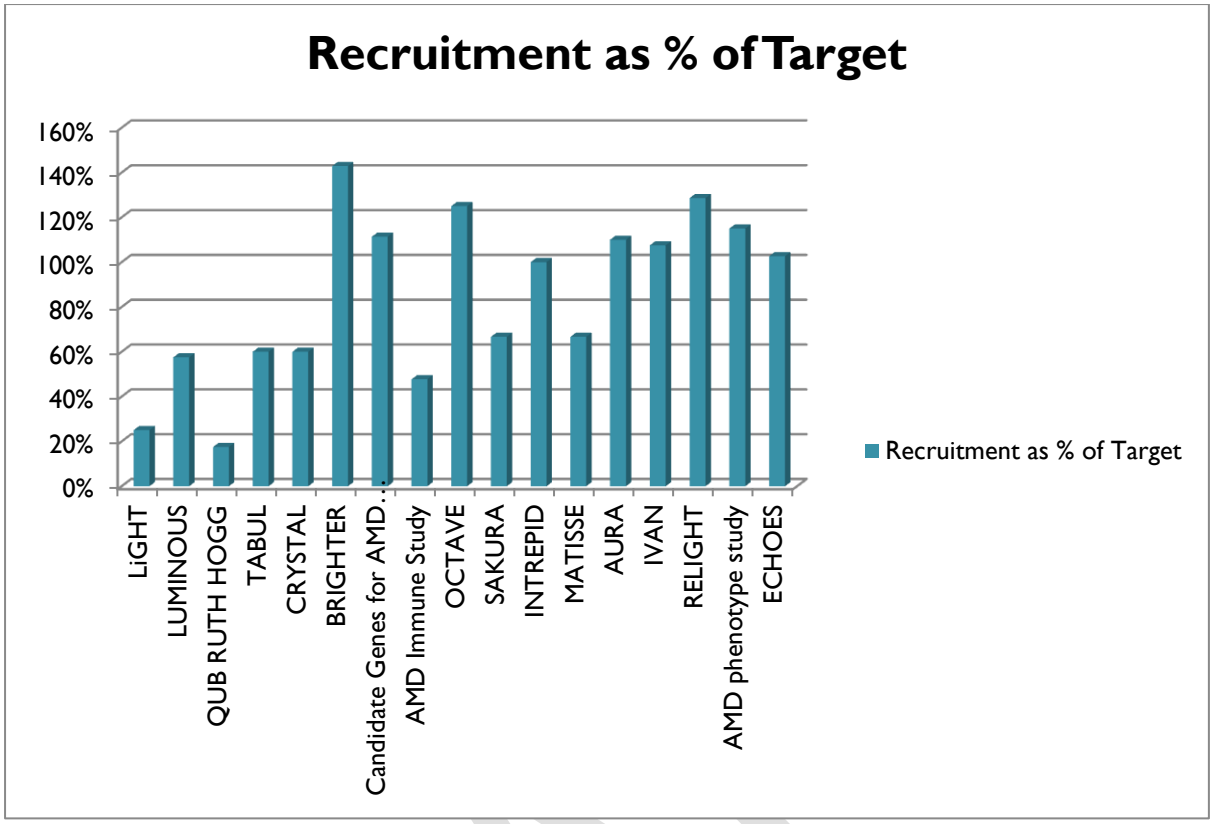
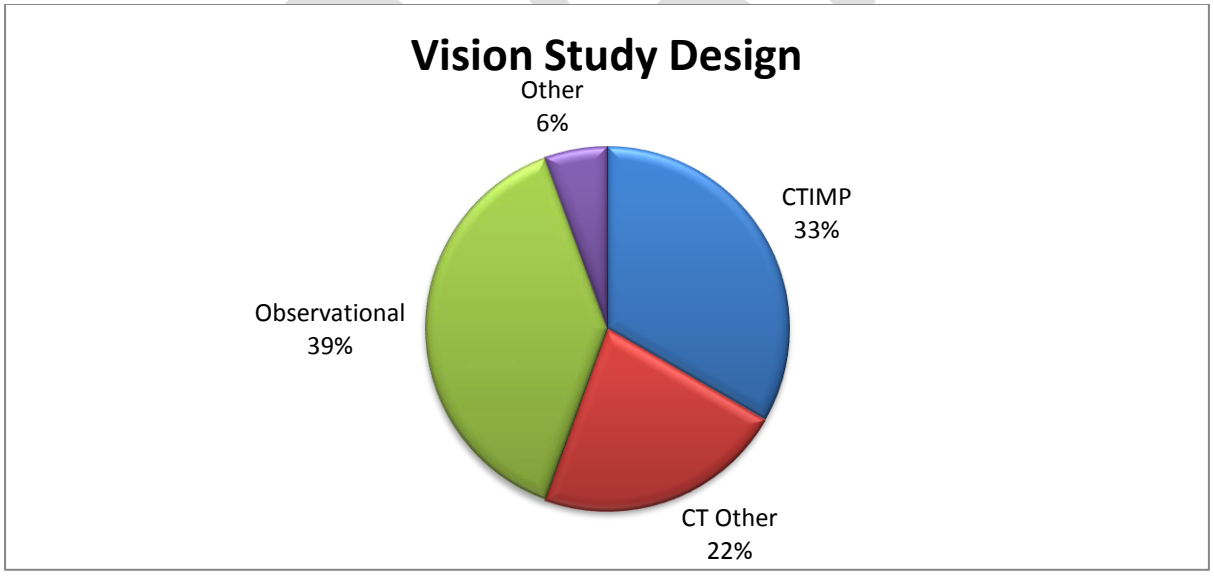

Recruitment as % of Target
160%
140%
120%
100%
80%
60%
40%
20%
0%
LiGHT
LUMINOUS
QUB RUTH HOGG
TABUL
CRYSTAL
BRIGHTER
Candidate Genes for AMD...
AMD Immune Study
OCTAVE
SAKURA
INTREPID
MATISSE
AURA
IVAN
RELIGHT
AMD phenotype study
ECHOES
Recruitment as % of Target

Figure 19

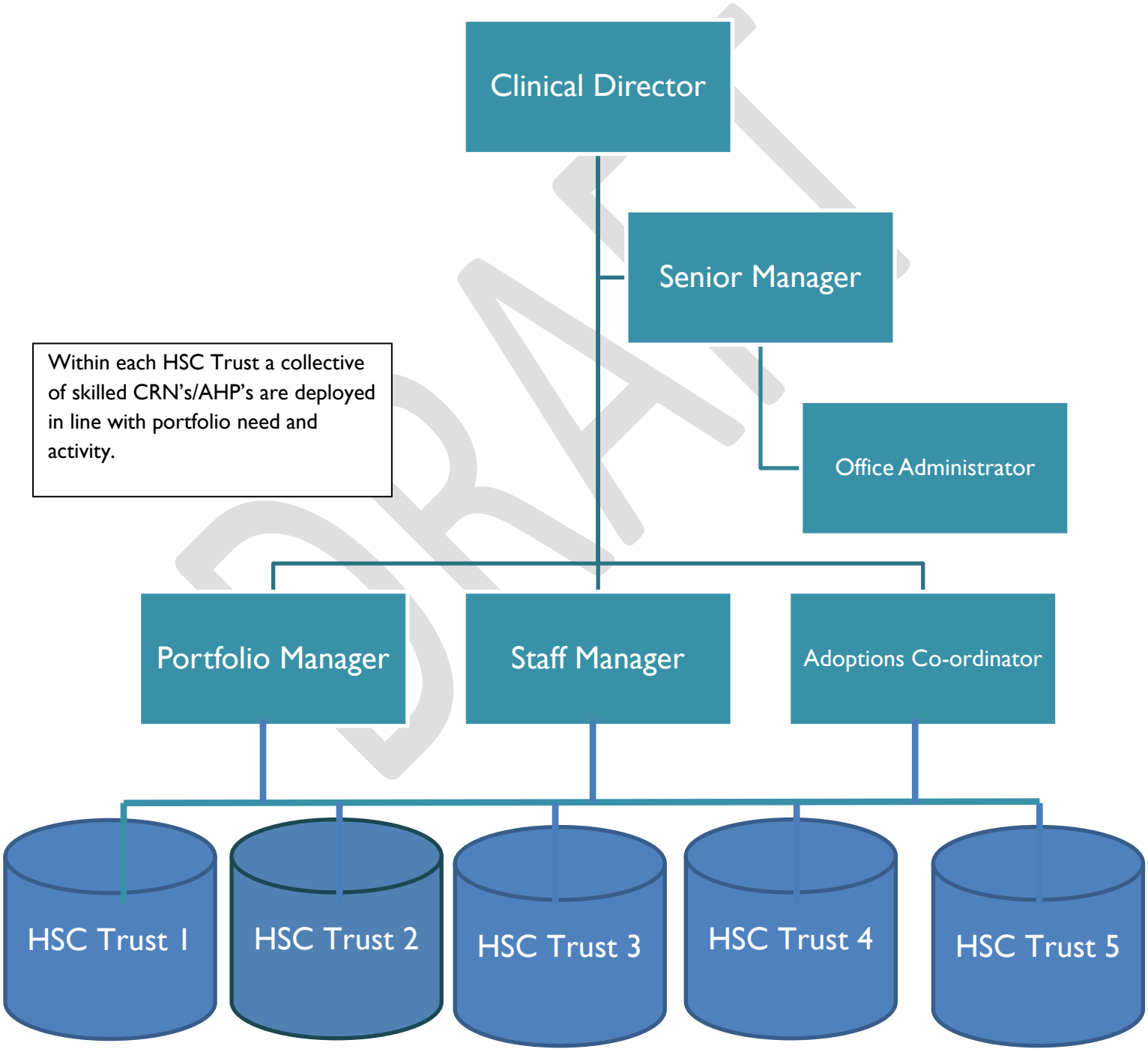

Vision Study Design
Other
6%
CTIMP
33%
Observational
39%
CT Other
22%

Section 4

Appendices

Appendix 1

NICRN Co-ordinating centre Organisational structure



Within each HSC Trust a collective of skilled CRN's/AHP's are deployed in line with portfolio need and activity.

Appendix 2

Table of group objectives

Objective		Comment	Groups
1. Portfolio			
1.1	Number of studies adopted	Normally set around 3-6 per year. On-going levels of activity will be considered when setting target each year	All Groups
1.2	Percentage of commercial studies	As market can vary this metric is principally for Info gathering. Future development of groups staffing will be informed by level of commercial partnership and investment	All Groups
1.3	Percentage of studies at two or more clinical nodes	Normally set at between a target of 15% - 50% to demonstrate shared networking approach. Dependant on node feasibility	Except Vision, Dementia and Respiratory groups
1.4	Percentage of studies for each of five Trusts	Info gathering to illustrate regional approach and evidence of all NI community access	All Groups
1.5	Percentage of RCT's	Info gathering for support design quality of portfolio	All groups
2. Accrual			
2.1	Percentage of studies meeting/exceeding target recruitment	50% target. Both the monthly and cumulative recruitment will be recorded.	All Groups
2.2	Numbers of people recruited to studies	Info gathering to be tied to annual increase metrics if appropriate	All Groups
3. Speed			
3.1	Completion of recruitment on or ahead of schedule	50% target	All Groups

Appendix 3

Complete staff training review for 2013/14

DATE	DETAILS	FACILITATOR
Thursday 2nd May 2013	Clinical Research Nursing Challenges and Opportunities	Prof Debra Moser
Thursday 13th June 2013	NICRN Training Day • Update of Clinical Trials Legislation • Clinical Trial Monitoring Workshop • Presentation re Gateway • 'Finders, Keepers: Recruitment and Retention in Clinical Trials' • Recruitment, Problem, Literature, Solution	Prof Allan Gaw Alison Murphy Paul Biagioni
Tuesday 17th September 2013	Informed Consent Training adult and children's	Prof Allan Gaw
Thursday 24th October 2013	Record Management Presentation	Catherine Rogan
Thursday 27th March 2014	NICRN Training Day • Introduction to Clinical Research Session • Time Management Session	Prof Allan Gaw
01/04/2013 – 31/03/2014 (Staff attended throughout)	NIHR GCP	
01/04/2013 – 31/03/2014 (Staff attended throughout)	NICRN Induction Programme	Sonia McKenna
01/04/2013 – 31/03/2014	Clinical Supervision	

(Staff attended throughout)	
01/04/2013 – 31/03/2014 (Staff attended throughout)	Appraisals
Mandatory Training 01/04/2013 – 31/03/2014 (Staff attended throughout)	Administration of Medicines and the Medicines Code Infection Control Safeguarding Vulnerable Adults Medical Devices Child Protection Awareness Adult Informed Consent Training Adult in Hospital Life Support Anaphylaxis and PGD Awareness Data Protection Awareness Archive Training Workshop Adverse Incident Reporting PPI training Fire Safety and Environmental Awareness and RQIA Update in Patient Handling Immediate Life Support Recertification How to manage and resolve conflict Equality Training for Staff Venepuncture Training HRPTS – Employee Self Service Awareness Session Display Screen Equipment Training Medical Gasses HIV Training Intravenous Cannulation

01/04/2013 – 31/03/2014 (Staff attended throughout)	Research Appreciation
01/04/2013 – 31/03/2014 (Staff attended throughout)	Presentation / Facilitation Skills Study Day
01/04/2013 – 31/03/2014 (Staff attended throughout)	It's OK to ASK Campaign.
01/04/2013 – 31/03/2014 (Staff attended throughout)	RCN Annual Conference
01/04/2013 – 31/03/2014 (Staff attended throughout)	KSF: Attribute Overview
01/04/2013 – 31/03/2014 (Staff attended throughout)	Lone worker
Monday 20th May 2013	International Clinical Trials Day
01/04/2013 – 31/03/2014	Clinical Trials Module QUB

(Staff attended throughout)	
01/04/2013 – 31/03/2014 (Staff attended throughout)	IATA
01/04/2013 – 31/03/2014 (Staff attended throughout)	EDGE Training
01/04/2013 – 31/03/2014 (Staff attended throughout)	Intensity Tool Training
01/04/2013 – 31/03/2014 (Staff attended throughout) March 2013	Trust policies and SOP'S Euro Heart Care (Glasgow)
01/04/2013 – 31/03/2014	30th Annual Cardiology Update
Wednesday 23rd January 2013	Delivering Neo Natal studies on the NIHR Portfolio
01/04/2013 – 31/03/2014	Planet2 Study Day
Thurs 7th/Fri 8th Feb 2013	Bayley scales of Infant Development (Bayley III training)
Thurs 4th/Fri 5th July 2013	UKCCRF – London

Monday 21st Oct 2013	Delirium Conference
October 2013	"Nicola" Interviewer Training – 2 days
Thursday 10th Oct 2013	NI Conference of the Primary Care Diabetes Society • Enabling healthcare professionals to better manage Diabetes
6th Dec 2013	Endocrinology Clinical Cases Day

29th/30th April + 7th/8th May 2013	Airway Clearance Masters Module – UU	
24th Sept – 24th Jan 2013	Single Masters Level Module – Oxford Brookes University	
01/04/2013 – 31/03/2014 (Staff attended throughout)	Additional Training – • LCI • ECG • SPIROMETRY • CANNULATION • SWEAT TRAINING • NPD • VENEPUNCTURE	
01/04/2013 – 31/03/2014	UK Stroke Forum – Harrogate	
December 2013	NIMAST Annual Conference	
March 2013	SPAF Academy Meeting	
September 2013	Clinical Trials Module - QUB	
20th May 2013	Royal College of Ophthalmologists Congress: Retina Day in Liverpool	
9th March 2013	Optical Coherence Tomography Course	
6th Sept 2013	Update of Anti VEGF therapies Symposium	
April 2013	Gonioscopy Course for Research Optometrist – Moorfields Eye Hospital, London	
February 2013	Ocular pharmacology and therapeutics (postgraduate level module) – Aston University, Birmingham	