# 2014/15

# ANNUAL REPORT

NICRN CLINICAL RESEARCH NETWORK

NICRN Co-ordinating Centre

Northern Ireland Clinical Research Network

2014/15

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# Overview and Development of the Network

## 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 (appendix 1) is built around a hub and spoke design to facilitate easier 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 2014 to 31st March 2015.

## Core performance targets

Each group is expected to achieve targets set in line with predicted activity, strategic direction and core staffing. This is to maximise productive health and financial returns on core funding in terms of numbers of patients and health care professionals engaged with locally placed clinical trials and other high quality research projects. This enables the development of a high quality local portfolio and regional approach to conducting research. Each group's leads meet with the director to agree targets set around the number of studies adopted, minimum % recruitment to target, the % of commercial involvement, the proportion of clinical trials especially Clinical Trials of Investigational Medicinal Products (CTIMPs) and the development of a regional collective approach to study adoption.

## Network development over reporting period

Table 1 summarises some core data from the groups and compares this year's activity against the previous 3 years.

| Interest group | Total active studies<br>**14/15**(13/14)(12/13)(11/12) | No. Studies Adopted<br>**14/15**(13/14)(12/13)(11/12) | Total Patients screened<br>**14/15**(13/14)(12/13)(11/12) | Total Patients Accrued<br>**14/15**(13/14)(12/13)(11/12) |
|---|---|---|---|---|
| Cardio | **27**(31) (17) (16) | **10**(12)(4) (3) | **1582**(1641)(900) (2744) | **384**(1116)(291)(541) |
| Children's | **15**(16)(19) (22) | **0**(5)(1)(7) | **354**(1026)(462)(360) | **146**(241)(162)(360) |
| Critical Care | **18**(23)(10)(10) | **2**(15)(4)(3) | **4090**(3707)(2797)(1816) | **445**(623)(127)(479) |
| Dementia | **4**(2)(1)(4) | **1**(1)(1)(0) | **81**(162)(102)(239) | **81**(151)(97)(66) |
| Diabetes | **14**(15)(10)(13) | **4**(7)(6)(7) | **681**(798)(462)(1458) | **317**(415)(53)(406) |
| Primary Care | **16**(15)(12)(11) | **5**(6)(5)(7) | **7204**(6515)(2294)(2952) | **281**(1344)(532)(1173) |
| Renal | **24**(22)(15)(NA) | **3**(8)(15)(NA) | **680**(207)(231)(NA) | **257**(82)(179)(NA) |
| Respiratory | **21**(19)(15)(27) | **6**(6)(4)(9) | **1457**(1370)(430)(1448) | **95**(146)(206)(150) |
| Stroke | **12**(9)(9)(8) | **5**(3)(2)(0) | **2878**(2921)(5961)(4058) | **35**(55)(106)(104) |
| Vision | **23**(18)(19) (17) | **13**(4)(4) (8) | **281**(223)(223) (146) | **73**(230)(151)(146) |
| **TOTAL** | **174**(170)(127) (128) | **49**(67)(46) (44) | **19288**(18580)(13862) (15221) | **2114**(4403)(1904)(3425) |

As can be seen from table 1 & 2 the general trend over 14/15 has been maintained at a steady state across the entire portfolio compared to the same time period last year with 174 active studies running regionally in 14/15 versus 170 for 13/14. The total number of studies adopted was down by 18 however more patients were screened with a total of 19288 screening actions to recruit 2114 participants. This recruitment figure is down on 13/14 by over 50%, though still in line with 12/13 figures. Some of this reduction can be attributed to significant reductions in recruitment across the cardiovascular and primary care groups as compared to 13/14. This is more related to make up of their respective portfolios in 13/14. Cardiovascular portfolio hosted 13 observational studies in 13/14 as

compared to 4 in 14/15. These studies recruited higher numbers of participants with much reduced study intensity. The primary care group hosted a large observational study in 13/14 which successfully recruited 1010 participants and this is partly responsible for this reduction in overall recruitment.

Other notable points were the success of the cardiovascular and vision group's in securing 23 new studies over this reporting period which equates to almost 47% of total regional adoption.

The renal group also significantly increased its recruitment in 14/15 by over 300% whereas all the other groups showed either maintenance or a reduction in recruitment as compared to recent years.

The children's group did not secure the adoption of any new studies over this reporting period. This was in part due to the group's small staffing compliment and capacity being impacted significantly by extended periods of absenteeism which resulted in their staffing compliment being reduced by almost 33% over the year (table 3).

Table 2 summarises some core data from the group's objectives and compares this year's activity against the previous 2 years along with each group's percentage of target recruitment.

| Interest Group | Commercial 14/15(13/14)(12/13) | Randomised 14/15(13/14)(12/13) | Multi-centre 14/15(13/14)(12/13) | % Recruitment to target |
|---|---|---|---|---|
| **Cardiovascular** | 17(11)(6) | 11(11)(11) | 6(5)(5) | **95** |
| **Childrens** | 1(1)(2) | 8(5)(10) | 9(8)(6) | **76** |
| **Critical Care** | 2(1)(0) | 12(12)(6) | 9(11)(3) | **92** |
| **Dementia** | 2(1)(0) | 2(1)(0) | NA | **57** |
| **Diabetes** | 8(4)(0) | 9(7)(6) | 7(8)(3) | **85** |
| **Primary Care** | 5(4)(2) | 9(8)(4) | 12(11)(9) | **102** |
| **Renal** | 10(8)(9) | 10(7)(6) | 15(11)(7) | **78** |
| **Respiratory Health** | 14(11)(9) | 15(11)(9) | 3(5)(2) | **106** |
| **Stroke** | 1(1)(1) | 10(8)(7) | 8(8)(8) | **70** |
| **Vision** | 14(10)(12) | 13(10)(11) | NA | **86** |
| **Totals** | **74(52)(41)** | **90(80)(70)** | **69(67)(51)** | |

In terms of each group's objectives, table 2 clearly illustrates that across 3 notable objectives namely number of commercial partnerships, Randomised controlled trials (RCT's) and regional sharing of studies all showed a steady increase in each versus previous years. We have increased our commercial portfolio by 33 studies since 12/13, an increase of almost 46%. This is especially marked in the cardiovascular, respiratory health and vision groups who participated in 45 commercially sponsored studies over 14/15. This increase in commercial activity is essential for the future development of the network. Funding is limited and so this income is needed for reinvestment for expansion.

The number of RCT's has increased by 22% since 12/13 illustrating an increase in the overall quality of our portfolio. A similar increase in the regional aspect of study delivery was seen in 14/15 with 18 (26%) more studies being undertaken at 2 or more NI sites.

These positions illustrate increases in local investment, quality and shared delivery across the network. Of particular interest is the NICRN's ability to deliver to target. Of those studies that closed across 14/15, the % recruitment to target data clearly indicates that we are particularly good at delivery of studies. It has been agreed that all studies should recruit to a minimum of 80% of contracted target to be defined as successful. Over 14/15, 60% of groups achieved this figure with a further 20% being within a 5% tolerance limit. Of note is primary care and respiratory health group's ability to secure additional recruitment over and above original agreements from sponsors. Competitive recruitment is an essential point of planning a study and deciding on site placement. These figures provide study sponsors with additional confidence that study targets will be met and hence should aid NI in securing additional studies.

## Local Portfolio Management System

As reported in our annual report for 13/14 the NICRN needed to develop a portfolio management system which was fit for purpose for local stakeholders as well as enabling UK wide collation and reporting. The original proposition was a national portfolio to which each Devolved Nation (DN) would have authorisation and upload responsibilities. This however never materialised and each DN has had to develop systems, relevant and appropriate to their needs and available resource whilst still enabling UK wide working.

Our sister network, the Northern Ireland Cancer Trials Network, had been led by the UK Cancer Research Network's use of the EDGE portfolio management system as their preferred option. This informed the local decision and following a period of discussion between HSC RDD and their UK partners and between NICRN and Trust R&D structures it was agreed to deploy EDGE regionally.

Much of the workflows which would inform a system, of value to all users, were defined via a collective approach between the NICRN portfolio manager, NICTN coordinators, Trust R&D managers, HSC R&D Division programme manager and the NI Gateway. A staggered release across potential users was agreed and the initial roll out across the 2 NI networks and the Gateway was achieved by the start of 1st quarter of 14/15. The BHSCT as the lead NI R&D site followed shortly thereafter. The remaining 4 NI HSC Trusts would come on line following a testing phase within BHSCT. One of the core benefits of EDGE as a LPMS is the role of the supporting staff to enter their recruitment data live. This enables clinical teams to review their sites activity live via the web and allows for core documents to be stored and available over any participating site. To facilitate this movement of patient data across platforms and Trusts Data Access Agreements needed to be established across sites. To date the role of the EDGE systems has proved itself as a suitable tool for local project management and reporting. Over 15/16 this will be further developed to allow other service groups such as Trust finance to build their workflows into this regional system.

## Staffing

Over 13/14 the HSC R&D division, confirmed that no additional funding would be available for existing interest groups. Newly established groups such as mental health would still be considered for core staff funding in line with business plans.

This position dictates that groups now must use their generated income to reinvest in their group's development. However to date no agreement has been established to confirm a regional approach to income management. This will be a priority for all stakeholders during 15/16.

Table 3 illustrates the agreed staffing compliment across NICRN Interest groups and the WTE in post in 14/15.

Table 3

| Interest Group | WTE Funded | WTE in post | Comment |
|---|---|---|---|
| Cardiovascular | 6.0 | 5.25 | Maternity |
| Childrens | 3.25 | 2.25 | Maternity and absenteeism |
| Critical care | 5.8 | 6.9 | Used Income to increase capacity |
| Dementia | 2.0 | 1.7 | Retirement |
| Diabetes | 4.1 | 3.55 | Maternity |
| Primary care | 2.5 | 2.5 | |
| Renal | 3.1 | 2.85 | Vacant post |
| Respiratory Health | 6.5 | 9.1 | Used Income to increase capacity |
| Stroke | 4.5 | 3.8 | Maternity |
| Vision | 5.0 | 4.75 | Vacant post |
| Total | 42.75 | 38.95 | Variance of 3.8 WTE |

Table 3 also illustrates that the network operated with a variance of almost 4 WTE over 14/15 this equates to an absenteeism rate of 8% which is slightly above the local Trust target of 5%.

The scale of the NICRN means that absenteeism has a significantly larger potential for negative impact as compared to our larger Devolved Nation (DN) partners. This is most notable in the Children's group which operated over 14/15 with a reduction in capacity by almost 33% and their inability to adopt any new studies over this reporting period (table 1).

The co-ordinating centre has been engaged in developing strategies to try and alleviate this lack of flexibility firstly by working with BHSCT nursing bank structures to establish a clinical research nurse bank. Under spend has been redirected to this programme and enabled groups like Children's to use short term approaches to support study delivery. Over 14/15 the network supported approximately 105 additional hours within the Children's group. This strategy will be further developed over 15/16 and it would be anticipated that as the

principal loss of staff is via maternity leave, and therefore planned, that the impact on study deliver will be reduced.

Staff capacity is now the major decider in whether a study can be adopted or rejected. To inform this decision the NICRN coordinating centre has developed the role of an amended version of the UK Clinical Research Facilities intensity tool. This is simply a formulated Excel spread sheet that calculates the WTE required to deliver the defined study actions. The formulae build's in productive working times and as it is completed by the staff who will be delivering said functions hence the outputs are as accurate a descriptive of delivery requirements as can pragmatically be defined.

The intensity tool will be further developed over 15/16 to form a core document in the NICRN adoption process (appendix 2) and will clarify the actual working level for the staff compliment per group/site etc.

The staff component makes up approximately 77% of total spend and as the central pillar of the network, the staff have always been supported in their training and education allocation over and above standard practice. Over 14/15 we supported all our appropriate staff in attending 25 standard mandatory training events across the 5 HSC Trusts. This was augmented with a further 23 non mandatory events including 4 NICRN specific training events provided by Professor Allan Gaw. On top of this allocation each groups specific training will be presented within the interest groups dedicated section in annual report.

## 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 achieved through the senior manager in 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 40% is placed on all staff salaries within the Coordinating Centre.

Also 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 14/15 the total costs for the network equated to spend of **£2,111,096** which equates to an increase in spend of 3.5% over this reporting period. The majority **£1,626,597** (77%) is on core CRN and AHP staff, whilst the co-ordinating centre accounted for **£180,219** (8.5%) of staff spend, plus a Goods and Service budget of **£46,274.** Due to existing agreements re hosting of network co-ordinating centre an overhead of 40% is provided to the BHSCT which amounts to **£72,088** per annum. The clinical leads 0.1 or 0.2 PA costs accounted for the remaining **£258,006** (12%).

## Interactions

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, University of Ulster, Invest NI, our Devolved Nation partners and the commercial sector.

One key development over 14/15 was the successful delivery of a local NI Clinical Innovations conference. This took place on the 15th and 16th of September 2014 when scientific and medical personnel from 19 Global Pharmaceutical companies gathered in Belfast for a 24 hour visit to Northern Ireland to meet with leading local Clinical Researchers and discuss how Northern Ireland can best position itself to increase levels of collaboration around clinical research with Industry.

The visit was organised by a steering group representing Northern Ireland's Health & Social Care R&D Division, ABPI NI Innovation Group, HSC Innovations, NICRN, Queen's University, University of Ulster and Invest NI. It was organised as an opportunity for medical and scientific staff from global pharmaceutical companies to engage with key Government, Health & Social Care and Academic stakeholders in Northern Ireland. The goal of the event was "to to build relationships between the Northern Ireland and Pharmaceutical industry Clinical researchers with a view to increasing collaborative research.".

The feedback was excellent with an overall rating of 4.3 and I include a vignette from an attendee below.

*Dear Steve,*

*I felt compelled to drop you a line to congratulate you on what was a fascinating meeting. You, and those involved in organising the meeting, deserved the thanks and recognition received at the end of the event. The spirit of openness and discussion is promising for the development of an on-going dialogue and the attraction of more investment into Northern Ireland.*

*Thanks again,*

# Section 3

## Topic Specific Reports

### Cardiovascular Interest Group


Co clinical leads Professor Donna Fitzsimons and Dr Patrick Donnelly

#### Introduction

NICRN-CV in year 2014-15 has enjoyed significant development. Building on their SWOT analysis from last year the group agreed their strategic objectives and set out a vision as to how these would be achieved. It is significant that each of the PIs contributed to this plan and that it has been endorsed by the NICRN Director. Key objectives within the vision are to attract funding that facilitates capacity building and to work more closely with local industry and charitable and statutory bodies to achieve this. In line with this the NICRN-CV has conducted a series of face to face meetings with NICHS, BHF, BSO, R&D Office, Philips and KANOS to name but a few. Discussions have advanced a number of separate initiatives aimed at attracting investment in cardiovascular R&D and the intention is to develop these into funding applications or studies that demonstrate capability to integrate large datasets and address clinically important issues.

This year there has been consolidation of the cardiovascular research portfolio, with 50 studies in the overall portfolio and the number of active studies and sites remaining fairly constant at 27 and 33 respectively. In particular, there was a significant increase in patients throughout NI involved in research. In total 1528 NI citizens were screened for participation in CV research, with 384 of these recruited to network adopted clinical trials. This represents a reduction by 732 participants, however as highlighted in Network overview this reduction is related to the differences in portfolio make up. Screening was also reduce by 113 screening function as compared to same period last year but again this is related to the make-up of portfolio, i.e. more intensive studies with smaller volume through-put. It does however mean that over the last five years almost 8000 people in Northern Ireland have been screened for participation in NICRN-CV research and almost 3500 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 non-commercial portfolio remains critical to the development of this group given that it is a conduit for knowledge generation and transfer bringing cutting-edge developments in CV

care to NI. Many of these studies have been successful in achieving international peer reviewed presentations and publications and have promoted Northern Ireland as a dynamic and successful research hub. Importantly these non-commercial studies generate a platform for on-going collaborations with local industry, academia and healthcare trusts that is vital to the Network.

### Cardiovascular staff

Table 4 illustrating NICRN Cardiovascular staffing component funded versus in post

| HSC Trust | POSITION/BAND | R&D FUNDED | ACTUAL WTE |
|---|---|---|---|
| BHSCT | BAND 6 NURSE | 1.0 | 1.0 |
| BHSCT | BAND 6 NURSE | 1.0 | 0.5 (WENT ON MAT LEAVE 30/09/2014) |
| SEHSCT | BAND 6 NURSE | 1.0 | 1.0 |
| SEHSCT | BAND 4 | 1.0 | 0.75 (Started 1/11/2014) |
| SHSCT | BAND 6 NURSE | 0.5 | 0.5 |
| SHSCT | BAND 6 NURSE | 0.5 | 0.5 |
| WHSCT | BAND 6 NURSE | 1.0 | 1.0 |
| B6 = 5.0WTE<br>B4 = 1.0WTE | | B6 = 4.5 WTE<br>B4 = 0.75WTE | |

The group staff were directly supported to attend 25 mandatory training programmes and a further 23 non-mandatory events, in addition to these events the network budget supported a further 4 events specific to cardiovascular staff over the reporting period.

## Childrens Interest Group

The Children's group lead was unavailable to draft their section therefore as per our annual report guidance; the raw data is included only.

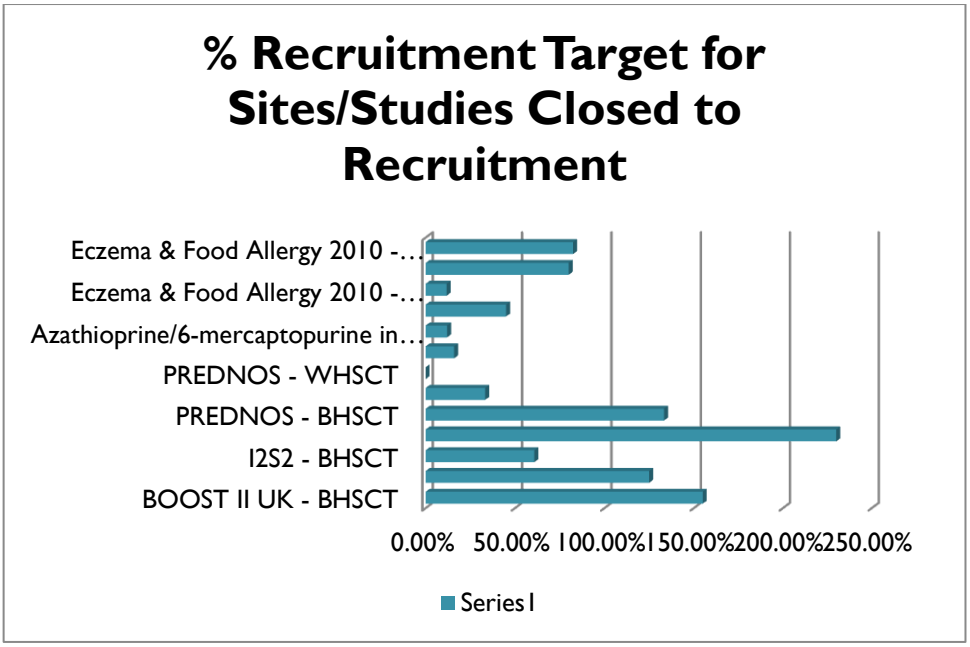
Table 5

| Active Studies | Active Sites | Commercial | Randomised | Multicentre |
|---|---|---|---|---|
| 15 | 28 | 7% | 53% | 60% |

As per table 5 above, although no new studies were adopted over the reporting period the group was fully engaged in the delivery of 15 studies from previous year, 60% of which were conducted at 2 or more sites. Over half were RCT's however only 1 (7%) was industry sponsored.

The group achieved a % recruitment to target figure of 75% which, although below the accepted threshold of 80%, is still just within local tolerance limits of 5%.

Figure 1 showing the NICRN Children's group recruitment to target figures




## Children's staffing

The group was severely hampered in its capacity over 14/15 due to a series of maternity leaves and a long period of unplanned absenteeism. Within such a small group, such losses make it difficult for the group to develop in any way.

Table 6 illustrating the NICRN Childrens staffing compliment (funded versus in post)

| HSC | POSITION/BAND | R&D FUNDED | ACTUAL WTE |
|---|---|---|---|
| BHSCT | BAND 6 NURSE | 1.0 | 0.5 (Absenteeism) |
| BHSCT | BAND 6 NURSE | 0.75 | 0.75 |
| SHSCT | BAND 6 NURSE | 0.5 | 0.0 (Mat Leave) |
| SHSCT | BAND 6 NURSE | 0.5 | 0.5 |
| WHSCT | BAND 6 NURSE | 0.5 | 0.5 |
| B6 = 3.25WTE | B6 = 2.25WTE | | |

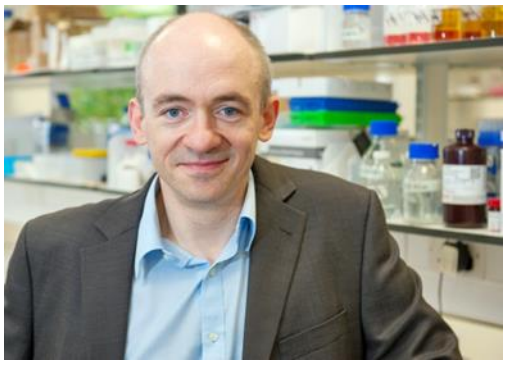
As can be seen in table 6 above, the childrens group did suffer from a reduced workforce over 14/15. Through a mixture of maternity leave and unscheduled absenteeism the group essentially only had 2.25 WTE available throughout this period. Staff still needed to avail of their mandatory and additional training as per other groups. They also attended study and group specific training as per below.

Table 7 Illustrating the NICRN Children's training provisions supported by coordinating centre

| | |
|---|---|
| 01/04/2014 – 31/03/2015 (Staff attended throughout) | Hyponatraenia/ Regional Paediatric Fluid Balance/ |
| 01/04/2014 – 31/03/2015 (Staff attended throughout) | Neo natal resuscitation |
| 19th August 2014 | SIFT Study Specific Training |
| 27th May 2014 | Management of IV Fluids<br>Management of IV Medication |

| | |
|---|---|
| 20th May 2014 | Neo-Natal Resuscitation |
| 22nd January 2015 | Belfast MBRACE - UK |
| 15th March 2015 | Bayley's Scales of Infant and Toddler Development |
| 19th June 2014 | British Paediatric Neurology Association – PET 1 (Glasgow) |

## 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
2) Develop protocols which are led by local researchers which attract NIHR and other 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 and recruitment

Tables 8 and 9 details the current portfolio. Only a limited numbers of studies have been adopted in the past year due to the large number of existing studies (15) from the previous year. There is a pipeline of major trials expected in the next year which the NICRN (critical care) will support. The network continues to successfully deliver our portfolio on time and target as highlighted by the data that the average accrual to target was 91%. We have a balanced mix of clinical research. One of the challenges nationally in critical care has been the limited number of commercial studies available, however our commercial has increased in the past year. Professor McAuley as SG lead is actively working with major companies including GSK, Bayer, Boehringer as well as small biotech companies to increase the commercial portfolio.

Table 8 summarising the critical care portfolio

| Active Studies | Active Sites | Commercial | Randomised | Multicentre |
|---|---|---|---|---|
| 18 | 40 | 11% | 67% | 50% |

Table 9 illustrates the breakdown of portfolio study design

| | | | |
|---|---|---|---|
| Clinical Trial of a Invest Medicinal Prod. | CTIMP | **44%** | **8** |
| Clinical Trial (other) or Clinical Investigation | CT Other | **28%** | **5** |
| Study using questionnaire/interview/mixed methods inc. quantitative | Quantitative Mixed Methods | **11%** | **2** |
| Study using Qualitative methods only | Qualitative Methods only | **6%** | **1** |
| Study limited to Tissue, Biological samples and/or data | Tissue, Biological samples / data | **11%** | **2** |

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. This work has been presented as a late breaking abstract at the American Thoracic Society and as a plenary session at the Canadian Critical Care Forum.
3) Sites in the network consistently recruit above average. For example the NHSCT and BHSCT are consistently the 2nd and 3rd highest recruiting sites in LeoPARDS (a study of levosimendan in critically ill patients with sepsis) in the UK together recruiting approximately 14% patients of the patients recruited in the UK to date. Dr Anthony Gordon, CI for the study commented "the NI sites have been great in LeoPARDS".
4) The NIHR HTA £2.1M funded REST study to determine whether veno-venous Extracorporeal Carbon Dioxide Removal and ultra-protective mechanical ventilation in patients with acute hypoxaemic respiratory failure decreases mortality will be undertaken in 40 sites in the UK, and is being led from NI as a collaboration with

BHSCT and QUB (co-leads McNamee and McAuley). The support from the Critical care network sites in NI will be key to the success of the trial.

5) As well as the NIHR HTA funded REST study, 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 sepsis diagnostic study, LeoPARDS, BREATHE, VAPRapid).
6) Investigators in NI are continuing to lead or be co-applicants for a series of national studies which are currently under review eg NIHR HTA commissioned call for Biomarker-guided duration of antibiotic treatment in hospitalised patients with moderate or severe sepsis (co-applicants McMullan and McAuley); NIHR HTA commissioned call for Antifungal Stewardship opportunities from rapid testing in ICU - The A-Stop Study (lead McMullan; co-applicant McAuley); NIHR EME application for a STudy into the REversal of Septic Shock with Beta Blockade - STRESS-BB (co-applicant McAuley) and the Wellcome Trust HICF application for Repair of Acute Respiratory Distress Syndrome by Mesenchymal Stromal Cells – REALIST (lead McAuley)
7) Highlighting our commitment to build research infrastructure which supports critical care research across the Island of Ireland, the HRB recently funded the Irish Critical Care Clinical Trial Network (on which McAuley was a co-applicant).

### Interaction with other Research Infrastructure

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

Specific recent examples of this related to critical care are the NIHR HTA funded REST study and the TSB funded sepsis diagnostic study which are managed by the NI CTU

Professor 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.

Professor McAuley was acting Director of the NI CRF until July 2015. 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.

Professor McAuley and Dr 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 REST, the PPI representative Mr Barry Williams will sit on the Trial Steering Committee for the study.

## Capacity building

Demonstrating the success of the critical care network in building research capacity in NI, the REVIVE study formed the basis of a successful PhD for Kathryn McDowell who was also awarded a prize for this study as one of the best abstracts in Rehabilitation at the European Respiratory Society annual congress 2016. In addition Dr Murali Shyamsundar was was successful in obtaining a prestigious NIHR clinician scientist award (only the 3rd awarded to critical care in over 10 years this scheme has been running), and was appointed as a new clinical senior lecturer in ICM between the RVH and QUB. His PhD (funded by the NI HSC R&D office) was supported by the NICRN and delivery of his current clinical trial programme will be supported by the NICRN, of which he is now a member.

The network continues to support HSC R&D funded PhD fellowships where the project involves a clinical trial.

## Infrastructure

Professor 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 facility is a collaborative project between the BHSCT and QUB and will open in September 2016. 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 calls for Biomarker-guided duration of antibiotic treatment in hospitalised patients with moderate or severe sepsis and Antifungal Stewardship opportunities from rapid testing in ICU.

Professor McAuley and Dr McMullan are currently sitting on HTA funding panels.

## Collaboration across networks

The REVIVE trial was an example of successful collaboration with the respiratory health network which together successfully delivered this trial.

## Staffing and Training

Table 10 illustrating the NICRN Critical care groups staffing compliment (funded versus in post)

| HSC | POSITION/BAND | R&D FUNDED | ACTUAL WTE |
|---|---|---|---|
| BHSCT | BAND 6 NURSE | 0.5 | 1.0 |
| BHSCT | BAND 6 NURSE | 1.0 | 1.0 |
| BHSCT | BAND 6 NURSE | | 0.5 (MAT Leave 19/9/14) |
| BHSCT | BAND 4 | 1.0 | 1.0 |
| BHSCT | BAND 6 NURSE | | 0.1 |
| SHSCT | BAND 6 NURSE | 0.5 | 0.5 |

| | | | |
|---|---|---|---|
| WHSCT | BAND 6 NURSE | 1.0 | 1.0 |
| NHSCT | BAND 6 NURSE | 1.0 | 1.0 |
| SEHSCT | BAND 6 NURSE | 0.8 | 0.8 |
| B6 = 4.8WTE<br>B4 = 1.0WTE | B6 = 5.9WTE<br>B4 = 1.0WTE | | |

The staff allocation was increased over 14/15 by the addition of study specific funded posts being brought into the network structure. This supported the team whilst members of staff were off on extended leave.

Table 11 shows that in addition to the standard 25 mandatory training events staff were released to attend they were also supported to attend 22 non mandatory training events and the additional 6 group specific events as well.

Table 11 showing the additional group specific events, training and education supported by NICRN funding

| | |
|---|---|
| 23rd Jan 2015 | NICS/Critical Care Review Meetings |
| 26/27TH June 2014 | UK CCRF – Cardiff |
| 13th June 2014 | Bi Annual CC Conference |
| Sept 2014 | Effective Presentation Skills |
| December 2014 | Foundation of Nursing Studies course on Practice Development |
| On going | Practice Development Module at University of Ulster |

## Dementia Interest Group

Co clinical leads Professor Peter Passmore and Dr Stephen Todd

The dementia interest group have had four studies in the portfolio: one commercial, multi-centre, randomised clinical trial of a novel investigational medicinal product was newly adopted in 2013/14, and an extension study for this agent has continued. There is a locally designed and led observational study of delirium in elective hip and knee surgery patients which has completed recruitment to target and within the estimated timescale. Much of the effort within the group has centred on a study into subcortical ischaemic vascular dementia. This study is examining the hypothesis that a commonly used calcium channel blocker, amlodipine, can benefit patients with this type of dementia. The study acronym is AFFECT. The clinical lead for NICRN (Dementia) is the PI for the AFFECT study which is jointly funded by the Alzheimer's Society and British Heart Foundation (£2.25m). This study is managed through Queen's University Belfast and the Belfast Health and Social Care trust are study sponsor. The NICRN nurses provided much of the input into the study set up, advising the trial manager on many practical issues. Two of the nurses provided all of the national training for the clinical trial sites involved in the study. This reflected their extensive experience in clinical trial work and knowledge of the assessments used in dementia (20 years). This study is now ready to recruit in N Ireland. While the assessments will take place in Belfast Trust, all Trusts in N Ireland are PIC sites and can provide details of patients who are interested in taking part in the study. Thus patients from all over N Ireland can participate if eligible.

There have been a number of approaches in relation to commercial clinical trials that plan to recruit. Due to issues with availability of PET scanning for research two studies cannot be performed here. There are ongoing discussions about one further commercial trial which does seem feasible. There are a few other funded studies which we propose to adopt. These relate to research programmes with Pharmacy and also with respect to research in retinal measures in dementia.

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. There is also a background of great difficulty in recruitment to trials in dementia within the UK where most studies do not reach their planned recruitment targets. The Alzheimer's Society and AR-UK are well aware of this problem and are striving through various initiatives to improve this situation.

During the year the two most experienced research nurses retired. This left a huge gap for a period but two excellent replacements have been appointed. They have already made an impact. They have publicised the NICRN Dementia network more widely and have made great efforts in anticipation of recruitment to AFFECT.

### 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

Table 12 summarises the NICRN Dementia group portfolio for 14/15

| Active Studies | Active Sites | Commercial | Randomised | Multicentre |
|---|---|---|---|---|
| 4 | 4 | 50% | 50% | 0% |

Table 13 shows the Dementia groups portfolio breakdown

| | |
|---|---|
| Total Active Studies 2014/15 | 4 |
| Total Active Sites 2014/15 | 4 |
| Total Studies in Overall Portfolio | 10 |

## Staffing

Table 14 Dementia staffing, funded versus in post

| HSC | POSITION/BAND | R&D FUNDED | ACTUAL WTE |
|---|---|---|---|
| BHSCT | BAND 6 NURSE | 1.0 | 1.0 |
| BHSCT | BAND 6 NURSE | 0.5 | 0.35 (LEFT 31ST DEC 14) |
| BHSCT | BAND 6 NURSE | 0.5 | 0.35 (LEFT 31ST DEC 14) |

The group's ability to deliver on their portfolio was curtailed by the loss through retirement of its 2 longest serving staff members. Both had over 2 decades of experience and this experience and skill set undoubtedly will be sadly missed in the future. However 2 excellent new members of staff were quickly recruited and they have been very focussed and proactive in developing their skills to date. The team did avail of all mandatory training and attended an additional 23 non mandatory training events however no group/study specific training was requested in this reporting period.

## Patient and Public Involvement

NICRN Dementia have had PPI from the outset. We are fortunate to have been involved in PPI since 1990 and before NICRN set up. We have thus been able to have the support of Gordon Kennedy in particular. Gordon is nationally known for his work with the QRD in the Alzheimer's Society. He and his local colleagues have always helped with development of research proposals at the earliest stage, providing vital advice on research priorities and the construct of proposals. Gordon has also significantly helped the local R&D office with their PPI programme. This is one of the major success stories of NICRN (Dementia). Gordon has provided more information below on his role.

## PPI involvement – a personal story Mr Gordon Kennedy

*My introduction to PPI began under another name. My wife Phyllis was diagnosed with Alzheimer's disease over 20 years ago. This led to Phyllis being invited to participate in the clinical trial of a drug called Aricept, the first possible drug treatment for the disease, which was being carried out by Prof Passmore's team at Queen's. This led a few years later to Phyllis participating in further research projects into the illness. One such project was being funded by the Alzheimer's Society and it involved their newly formed Volunteer Research Network. The Network is made up of people either with dementia, or who have direct experience of caring for people with dementia. As Network members, we prioritise the aspects of the disease which the Society should be funding, score the four page lay summaries which all grant applicants are required to submit and sit on appointment panels. In addition, three Network members are appointed to all successful research proposals as monitors. Because of this requirement, Prof Passmore invited me to be one of the Society's monitors for his new project, which was rather back to front, as it was because I was asked to be a monitor that I joined the Network, rather than the other way round!*

*That invitation was the beginning of a 15 year journey as a lay participant in dementia research, a journey which I have found to be both enlightening and personally rewarding. It has also led me into a broader PPI journey. When the concept of involving service users in all aspects of the health service, was being introduced across the UK, the Health & Social Care R&D Division was looking at how Personal and Public Involvement (PPI), could be introduced into the field of research in Northern Ireland. This led about 5-6 years ago, to a steering group from a broad range of disciplines being set up under the leadership of Dr Gail Johnston. As the work which the Alzheimer's Society's Volunteer Research Network had been doing, was in effect PPI in action, I was invited to participate in the steering group. That too has been a privilege, in sharing and learning how properly implemented PPI can be of real benefit not only to the users, but also to the researchers, as they seek to find cures and at the same time, improve the care and treatment of all users of the Health Service.*

*One recent, very positive development of the PPI role, has been in meeting with researchers at the formative stage of their research proposals. There is a real risk that involving service users in research can simply be seen as putting a contact name in the PPI section of the grant application form! People with the specific illness being studied, and those caring for them, have unique insights and experiences which, if tapped into, can enable researchers to better focus and develop their*

*projects. Early involvement with PPI representatives can allow this to happen, thus leading to better research and better outcomes. That, in my opinion, is what PPI is seeking to achieve.*

*Most recently I have participated in the public announcement of the Join Dementia Research register, which has been set up in Northern Ireland to enable more people to participate in clinical trials. Research is an exciting journey with new technologies enabling new discoveries and insights to be made across a broad range of disciplines on an ongoing basis. As a lay person, it has been my privilege over the last 15 years to participate in some small way in that journey.*

## Diabetes Interest Group

Co clinical leads Professor Vivien Coates and Dr Hamish Courtney

### Portfolio

In 2014/15, the group was involved in 14 active studies running across 26 sites, 5 of which were adopted during the year 2014/15. The active studies comprise 7 investigations that are currently open and recruiting, 5 that have completed recruitment and are in follow-up, 2 have closed and 1 study (Intense) is open in 2 sites (NHSCT & SHSCT and in set up in BHSCT (Table 15).

Of those 5 studies which have completed their recruitment phases, 2 studies recruited 100% or more of the recruitment target (CANVAS, PAIGE), 1 study (REWIND) recruited 100% in NHSCT but <100% in other sites), 1 study (Glycated intestinal peptides) achieved recruitment of 83% and 1 study (CANVAS-R) recruited 75% of target. In additional the SNAC study, which is closed, achieved a recruitment of 114% (Figure 1).

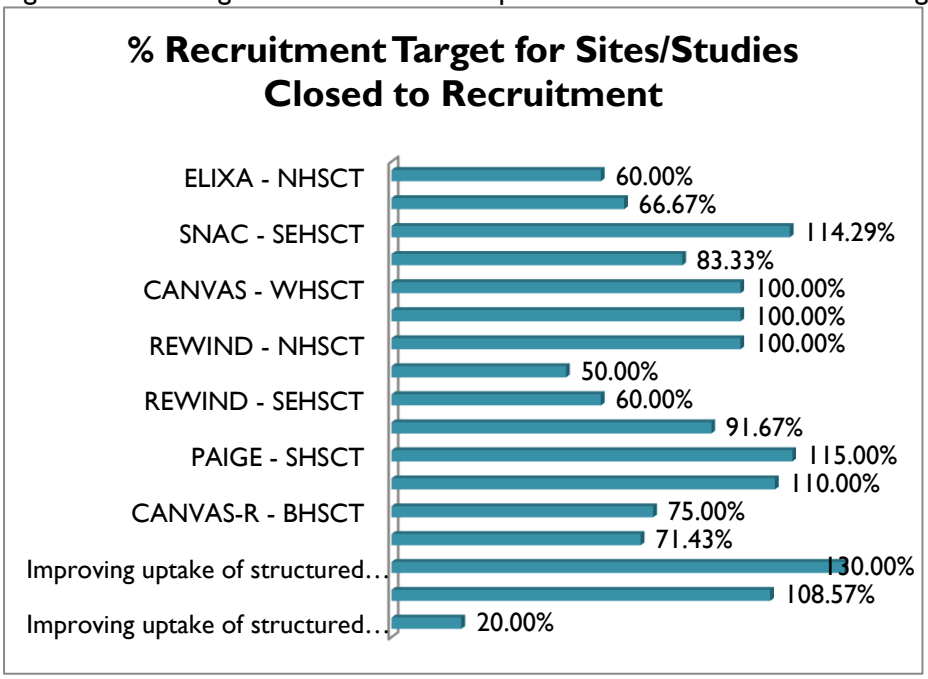
Table 15 summarises NICRN Diabetes portfolio active over 14/15

| Active Studies | Active Sites | Commercial | Randomised | Multicentre |
|---|---|---|---|---|
| 14 | 26 | 57% | 64% | 50% |

Table 16 illustrates the NICRN Diabetes group portfolio breakdown

| | | | |
|---|---|---|---|
| Clinical Trial of a Invest Medicinal Prod. | CTIMP | **43%** | **6** |
| Clinical Trial (other) or Clinical Investigation | CT Other | **14%** | **2** |
| Study using questionnaire/interview/mixed methods inc. quantitative | Quantitative Mixed Methods | **29%** | **4** |
| Basic science study involving procedures with human participants | Basic science study | **7%** | **1** |
| Study limited to Tissue, Biological samples and/or data | Tissue, Biological samples / data | **7%** | **1** |

Figure 2 illustrating the NICRN Diabetes portfolio and its recruitment to target




Of the 14 active studies, 8 had commercial involvement and the remainder were funded through research councils, charities and R&D sources.

The breakdown of the design of the studies is as follows: 6 CTIMP, 2 CT, 4 were studies using questionnaire/interview or mixed method design, 1 study was a basic science study involving procedures with human participants and 1 study was limited to tissue samples (see Table 16).

## Staffing

Table 17 showing NICRN staff allocation; funded versus in post over reporting period

| HSC | POSITION/BAND | R&D FUNDED | ACTUAL WTE |
|---|---|---|---|
| BHSCT | BAND 6 NURSE | 0.6 | 0.8 |
| BHSCT | BAND 6 NURSE | 1.0 | 0.25 (RETURN TO 0.5WTE - BACK FROM MAT LEAVE 22/09/2014) |
| SEHSCT | BAND 6 NURSE | 0.5 | 0.5 |
| SHSCT | BAND 6 NURSE | 0.5 | 0.5 |
| NHSCT | BAND 6 NURSE | 0.5 | 0.5 |
| WHSCT | BAND 6 NURSE | 1.0 | 1.0 |
| B6 = 4.1WTE | | B6 = 3.55WTE | |

Table 18 shows the diabetes group specific training supported over 14/15

| | |
|---|---|
| 3rd March 2015 | MHRA – GCP symposium London |
| 25th March 2015 | Pathways for Progress in Diabetes Nursing |
| 25th Sept 2015 | Innovations and Advances in Diabetes Care |
| 21st May 2015 | Diabetic UK: Care and connect campaign |
| 21st Oct 2014 | ECG recording and supervision |
| 14th Jan 2015 | Renal impairment in acute care setting |

The Diabetes Interest Group is co-led by Professor Vivien Coates and Dr Hamish Courtney, and currently has 4.1 WTE staff funded with 3.55 active/available throughout reporting period. This is spread across 5 HSC trusts (1.6 WTE in BHSCT, 1.0 in WHSCT, 0.5 WTE in NHSCT, 0.5 WTE in SEHSCT and 0.5 WTE in SHSCT) (TABLE 17). These posts are all Band 6 Research Nurses and all funded by NICRN.

The CRN committee includes diabetologists from each Trust, plus representation from dietetics, nursing, patient involvement and the charity Diabetes UK. The CRN Committee meets three times a year in various locations around N. Ireland.

Most of the new studies during the past year have been commercially funded, partly due to the work of Dr Courtney in establishing links with the companies and lobbying them to include N Ireland in their trials. There have been no new multi-site investigator led studies adopted in the last year reflecting difficulties with securing funding for large clinical trials. Efforts continue to forge links between researchers in the Universities and the Trusts. Prof Coates, attended the Diabetes Clinical Studies Groups - Development Group Meeting, as co-chair of the NICRN, the aim of which was to identify priority areas for research in diabetes.

### Interaction with other research infrastructures

There have not been any UK Network meetings relating to diabetes as far as we are aware. The co-chairs would be keen to attend such an event should the opportunity arise.

### PPI

Mr Martin Adams represents the views of people with diabetes at our meetings. He is a founding member of the Diabetes UK lay research group and communicates the views of this wider group at our meetings. Diabetes UK works closely with Dr Gail Johnston in order to offer training of lay members regarding their input to the research agenda.

### Other initiatives

At the last CRN meeting Dr Roberto Scarano from the pharmaceutical company Eli Lilly presented 'Clinical Research in Lilly 'to indicate future studies that might be adopted in N. Ireland and also to promote links between the company and the CRN Diabetes Group.

## Mental Health Interest Group

Co clinical leads Professor Gerry Leavey and Dr Ciaran Mulholland

The mental health group have experienced a number of HR difficulties recruiting staff to post. These were principally local HR issues which took a considerable amount of time to resolve. Following several rounds of recruitment and selection the first Mental Health CRN was successfully secured and would take up post in first quarter 15/16. It would be hoped that the additional staff required to deliver a regional model will be in post through 15/16.

## 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 Manager, two clinical research nurses (one has recently tendered her resignation and will leave her post on November 13th 2015) 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 the 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 and studies 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), 2013/14 (n=15) and 2014/15 (n=15). In 2012/13, the majority of studies were observational (58%); in 2013/14, this decreased to 33%, with a commensurate increase in the contribution of CTIMP studies (17% 2012/13; 33% 2013/14). In 2014/15, the distribution across CTIMP, 'CT Other' and 'Other' categories has remained consistent. There is a preponderance of studies which focus on the management of long-term conditions, across a range of disease areas. There has also been an increase in the number of commercial studies which have been adopted (n=2 in 2013/14; 4 in 2013/14; 5 in 2014/15).

Recruitment has been excellent, with the vast majority of studies exceeding target numbers (See Table 19, e.g. GARFIELD and Polypharmacy 2). 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 2014/15) required screening of 2196 patients in order to recruit seven. A similar effort was required for SNAC and the Vitamin D studies.

Two studies which applied for support were not adopted, 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 our offices in close proximity to the clinical leads who are both from QUB. The staffing component is 1.0 WTE band 7 Clinical Trials Manager and 1.5 WTE band 6 CRNs. The staff have been highly productive in terms of collecting high quality data and developing research in new sites and other disciplines within primary care, including dentistry. As noted earlier, one of the band 6 CRNs (0.5FTE) has recently tendered her resignation, and will leave her Network post on November 13th. It is imperative that recruitment can proceed promptly to appoint a replacement in order to maintain the capacity of the Primary Care Interest Group.

Table 20 illustrates the staffing allocation for NICRN Primary Care group. Funded versus in post over 14/15

| HSC | POSITION/BAND | R&D FUNDED | ACTUAL WTE |
|---|---|---|---|
| BHSCT | BAND 7 NURSE | 1.0 | 1.0 |
| BHSCT | BAND 6 NURSE | 1.0 | 1.0 |
| BHSCT | BAND 6 NURSE | 0.5 | 0.5 |
| B7 = 1.0WTE<br>B6 = 1.5WTE | B7 = 1.0WTE<br>B6 = 1.5WTE | | |

During 2014-15, the NICRN Primary Care Group has engaged with 15 PIs, 57 general medical practices and three dental practices, with a total of 1735 patients who have participated in studies. Many of the PIs are known to the Network staff, and great emphasis is placed on ensuring that PIs, health care professionals and patients experience the highest quality of service from Network staff. This accounts for a number of PIs seeking study

adoption on a recurrent basis, and health care professionals who are ready to consider participation in further studies.

## Education and Training

Outside of mandatory training and the NICRN dedicated training events, NICRN did not support any additional dedicated training, so no additional cost or time was required.

Table 21 shows the primary care group specific training supported over 14/15

| | |
|---|---|
| 4th April 2014 | RCN Research Conference – University of Glasgow |
| 7th Oct 2014 | Atrial Fibrillation – University of Birmingham |
| 6th March 2015 | Primary Care CPD- Centre for Public Health |
| 25th Feb 2015 | Type 2 diabetes update |

## 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 the National Institute for Research (NIHR) Clinical Research Network (CRN).

## 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 best represent primary care patients' interests. As mentioned above, the 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, it is ensured that the studies supported include active patient participation within their planning and management.

## Other Initiatives

All Network staff have continued to actively engage 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 workstreams 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

Network staff organised 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 most recent event was held on 7th October, 2015. It was attended by approximately 45 health and social care professionals and academics with interests in primary care research and from a range of locations across NI. Feedback indicated that the Forum overwhelmingly met the expectations of delegates, the quality of the presentations was excellent, and the organisation of the event was outstanding.

## Primary Care Activity Report

For such a small unit the Primary Care Group is one of the networks which has been 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 a committed workforce who have developed excellent skill sets and knowledge of their particular environment and site capabilities.

The portfolio increased overall by having 15 active studies over 2014/2015, an increase of 33% from 2012/2013 (Table 19). Six new studies were adopted over the current year, easily meeting the target objective. Accrual is also excellent.

**Table 19 Overview of studies from the Primary Care Portfolio 2014/15**

| Study Name | Commercial | Randomised | Multi-Centre | Design | Phase | Adopted in 14/15 | Accrual Status | Trust | NI / Site Accrual Target | Patients Screened (2014/15) | Patients Recruited (2014/15) | Total Screened to end of Mar 15 | Total Recruited to end of Mar 15 | Recruitment as % of Target |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| HEAT | N | Y | Y | CT other | IV | Y | Open | NI | 100 | 125 | 0 | 125 | 0 | 0% |
| Baby Hearts | N | N | Y | Other | II/III | Y | In setup | NI | 0 | 0 | 0 | 0 | 0 | 0% |
| PREFER in VTE REGISTRY | Y | Y | Y | CTIMP | N/A | N | Closed | NI | 1 | 3 | 0 | 5 | 0 | 0% |
| GARFIELD | Y | N | Y | Observational | N/A | N | Open | NI | 45 | 97 | 34 | 264 | 123 | 273% |
| MOSAICC Pilot | N | N | N | Observational | Pilot | N | Closed | NI | 50 | 308 | 26 | 308 | 26 | 52% |
| SNAC NN-9924-790 | Y | Y | N | CTIMP | II | N | Closed | NI | 2 | 1250 | 0 | 1250 | 3 | 150% |
| Live:Life | Y | N | N | Observational | N/A | Y | Follow-up | NI | 1 | 16 | 2 | 16 | 2 | 200% |
| POLYPHARMACY(P1) | N | N | Y | CT other | Pilot | N | Closed | NI | 10 | 37 | 4 | 79 | 10 | 100% |
| POLYPHARMACY(P2) | N | N | Y | CT other | Pilot | N | Closed | NI | 40 | 830 | 50 | 830 | 50 | 125% |
| Vitamin D Study | N | Y | N | CTIMP | N/A | N | Closed | NI | 20 | 719 | 1 | 1350 | 3 | 15% |
| REWIND H9x-MC-GBDJ | Y | Y | Y | CTIMP | II/III | N | Closed | 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% |
| Team-Med | N | Y | Y | Observational | N/A | Y | Closed | NI | 6 | 1133 | n/a | 1133 | n/a | 100% |
| WILDA | N | N | Y | Observational | N/A | Y | Open | NI | 6 | 33 | 1 | 33 | 1 | 17% |
| | 31% | 56% | 75% | | | 31% | | | **1741** | **7204** | **281** | **10700** | **1735** | 100% |
| | 5 | 9 | 12 | | | 4 | | | | | | | | |

Of the six newly adopted studies, two were commercial and all were of good quality, consistent with the Network's remit and group objectives.

Recruitment to target is exemplary (one of the highest in NICRN) with a mean across the year of 102%, which again easily meets the target set as an annual objective (Figure 3).

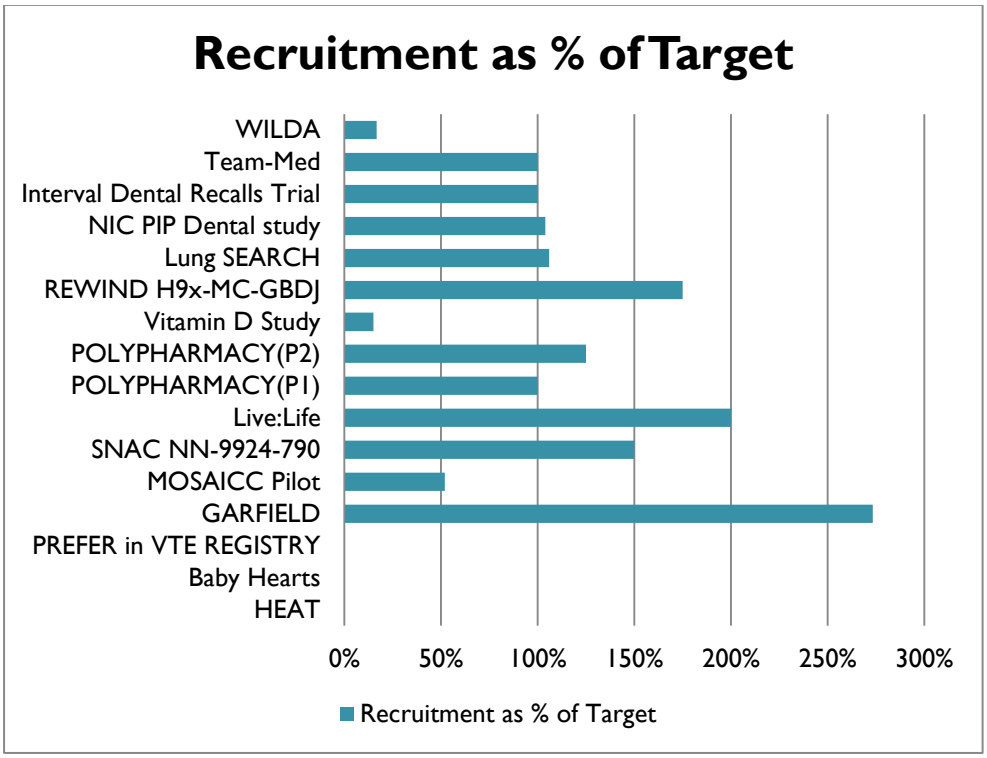



**Figure 3 Recruitment as a percentage of target for studies adopted in 2014-15**

In terms of portfolio balance, during 2014/2015, clinical trials accounted for 63% of the portfolio, of which 32% were categorised as CTIMP and 31% as other clinical trials; 31% were observational studies (Figure).

## Renal Interest Group

### Co leads Professor Peter Maxwell and Dr Neal Morgan

### Introduction

Now in its third year of operation the NICRN Renal portfolio has continued to expand and develop as evidenced by a further 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, 50% studies multicentre) and in 2014/15 there were 24 active studies (across 55 active sites, 63% studies multicentre) reflecting the excellent engagement from researchers across the network.

We have a broad research portfolio with a balance of commercial (42%) and non-commercial (56%) 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 maintains 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 2014/2015 averaged 78% across both commercial and non-commercial studies.

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 , PIVOTAL, PD-CRAFT 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 Renal Association and Kidney Research UK are now working with investigators, industry and patient groups to develop a UK Renal Research Strategy. Northern Ireland renal medicine investigators have contributed directly to this national strategy

The portfolio in 2014/15 includes studies in persons with chronic kidney disease (including polycystic kidney disease, membranous nephropathy and diabetic nephropathy). Individuals with ESRD remain a high priority for clinical trial activity. There are active studies in renal transplantation, haemodialysis, peritoneal dialysis and conservative management of ESRD. For instance, a Kidney Research UK supported study assessing Epigenetics and Outcomes in Renal Transplantation efficiently recruited to overall target aided by three active sites.

We recognised 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 now an area of emerging strength in NI aided by an academic collaboration with researchers at University Hospital Birmingham.

There are continued challenges negotiating (in a timely fashion) the various research ethics committee and individual 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 Northern Ireland Renal network is co-led by Prof Peter Maxwell in BHSCT and Dr Neal Morgan in 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 are present). Highlighting the depth of engagement across our specialty, of the 24 consultant nephrologists in post 50% are currently acting as local PIs/co-PIs for portfolio studies.

Table 22 shows the NICRN core funded staffing allocation

| HSC | POSITION/BAND | R&D FUNDED | ACTUAL WTE |
|---|---|---|---|
| BHSCT | BAND 6 NURSE | 0.5 | 0.5 |
| BHSCT | BAND 6 NURSE | 0.5 | 0.5 |
| SEHSCT | BAND 6 NURSE | 0.5 | 0.5 |
| SHSCT | BAND 6 NURSE | 0.6 | 0.6 |
| NHSCT | BAND 6 NURSE | 0.5 | 0.25 (STARTED 8/10/14) |
| WHSCT | BAND 6 NURSE | 0.5 | 0.5 |
| B6 = 3.1WTE | | B6 = 2.85WTE | |

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.

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.

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) provides 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 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 training 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.

## 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 presented an overview of the NICRN Renal interest group to UKCRN colleagues at the December 2014 meeting. This platform served to highlight achievements of the network, strengthen established links and will broaden the scope of our network's collaboration within the next 12 months.

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 and then HSC R&D Division 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).

Publications have been generated from many of the adopted studies including the NIHR PACKS study design (BMC Nephrol 2015 Jul 11;16:104) , multiple papers from the Kidney Research UK Epigenetics and Outcomes of Renal Transplantation (Transplant Res. 2014 Sep 24;3:18; Am J Nephrol. 2014;39(4):297-305; J Am Soc Nephrol. 2014;25(5):1037-49; Transplantation. 2014; 15;98(3):e19-20) and ATTOM (Nephrol Dial Transplant. 2014;29(11):2144-50).

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. This need to showcase the networks success and optimise effective exposure for the network with key stakeholders (industry partners and PPI) was a key topic of discussion at our network strategy meeting in March 2015.

## Renal Activity Report

The portfolio as illustrated in table's 23 through 24, over this reporting period, had 24 active studies. During 2013-15 NICRN Renal adopted 8 studies (Membranous nephropathy, EQUAL, PD-Craft, Aki Biomarkers, ALPHA, PIVOTAL, SONAR and EARNEST) of these studies PD-Craft closed to recruitment with an average recruitment to target figure of 96.66% across three sites.

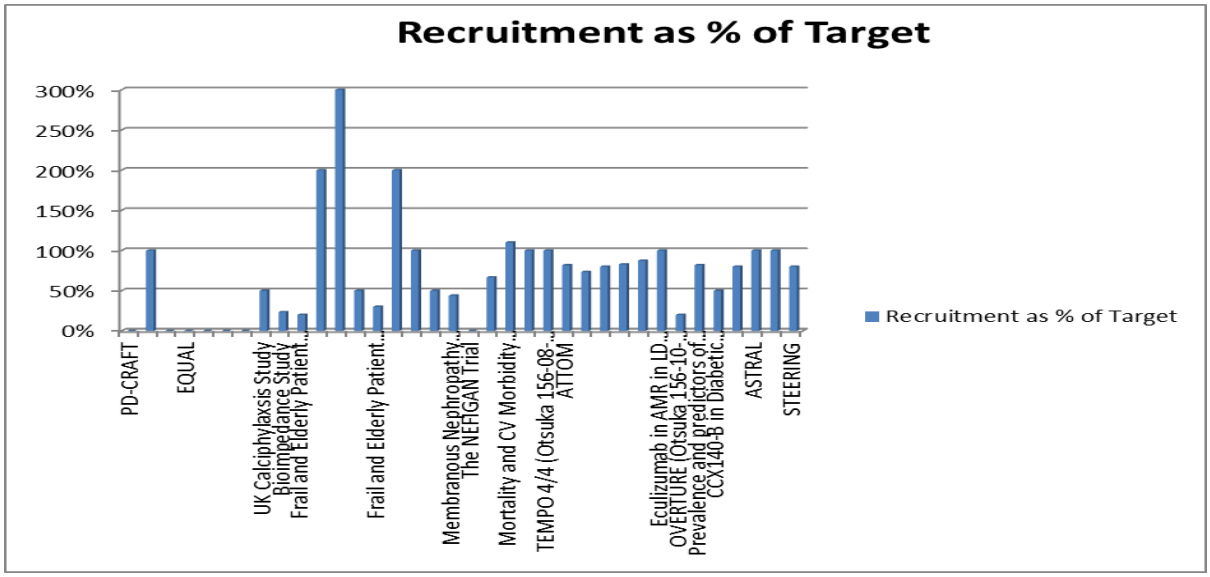
Table 23 summarises the NICRN Renal group portfolio for 14/15

| Active Studies | Active Sites | Commercial | Randomised | Multicentre |
|---|---|---|---|---|
| 24 | 55 | 42% | 42% | 63% |

Table 24 illustrates the NICRN Renal group portfolio breakdown

| | | | |
|---|---|---|---|
| Clinical Trial of a Invest Medicinal Prod. | CTIMP | **38%** | **9** |
| Clinical Trial (other) or Clinical Investigation | CT Other | **13%** | **3** |
| Study using questionnaire/interview/mixed methods inc. quantitative | Quantitative Mixed Methods | **17%** | **4** |
| Basic science study involving procedures with human participants | Basic science study | **8%** | **2** |
| Study limited to Tissue, Biological samples and/or data | Tissue, Biological samples / data | **25%** | **6** |

Figure 4 shows the NICRN Renal groups recruitment to target figures



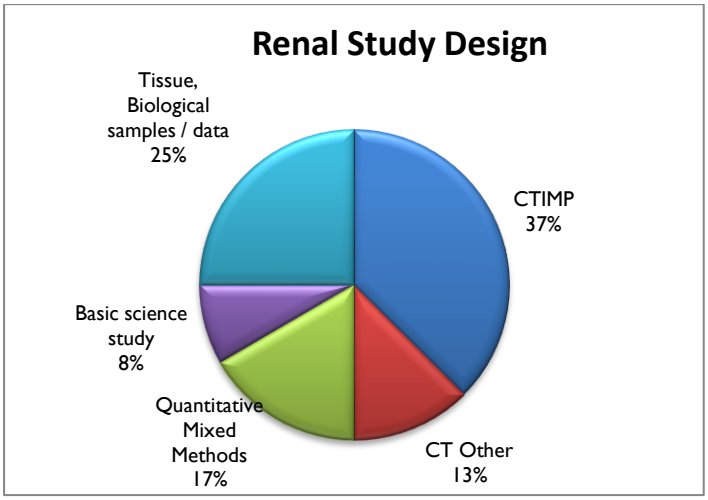
Screening and accrual figures are for 2014/15 are substantially increased compared to 2013/14. Absolute screening numbers were up by >400 overall and accrual is up by 175. As studies from 14/15 have moved from actively accruing to follow up then we would expect to see such a reduction and the new studies in set up will start accruing over first quarter 15/16.

The group has met its target on regional working with >50% of overall portfolio occurring at more than one NI site. There were 2 commercially sponsored studies adopted in 14/15 (SONAR and PIVOTAL), three UK Renal Registry linked studies (PD-Craft, EQUAL and EARNEST) and an MRC sponsored study (Membranous Nephropathy) as compared to 1 in 13/14 (table 23).

The NICRN Renal portfolio has maintained a very solid record in terms of mean accrual to target at 78% figure 4 and table 2

In terms of the balance across the portfolio we have increased the percentage and volume of commercial studies during 2014/15 which represented 50% of the study designs Table 23.

Figure 5 illustrates the renal portfolio design breakdown



## Respiratory Health Interest Group

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

### Introduction

The Respiratory Health Group continues to have a large and dynamic initiative within NICRN. The group is Co-led by Professor Judy Bradley (QUB) and Dr. Lorcan McGarvey (BHSCT and QUB).

We have over 35 high quality publications from our group to date (Impact factors >5; n=17; Impact 2-4 n=10; other 8) in which PIs have had key authorship roles reporting results of studies supported by NICRN Respiratory Health.

2014/15 has seen a number of key achievements:

ECF CTN (Elborn/Bradley/Downey) remain in upper quartile across the following performance measures: Total number recruited, Time from SIV to 1st patient, Overall site performance evaluation score.

In terms of competitive recruitment: We were top UK recruiter for Respire study; we were also the highest recruiting site to the Xention study.

In terms of new therapies: Quinsair was approved in 2014- we were a key site for the clinical trials; we are also providing support to evaluate the roll out of other new therapies into clinical practice e.g. Mannitol.

In terms of significant grant income: RASP-UK - Queens / Belfast Trust lead on ca £15 million programme of work on severe asthma....all of work being done in / with support of Respiratory Network.

Our co-ordinators are actively involved in external conferences: For example one of our co-ordinators (K. McDowell) was awarded best abstracts in Rehabilitation and Chronic Care at the European Respiratory Society Congress September 2015; other coordinators have presented at European training days (for example D Cosgrove and V McClenaghan received excellent feedback at the 2014 ECFS CTN training day).

Respiratory continue to invest time and resources capturing income for future investment. For this reporting period investments include co-ordinator staff, CF fellowship; staff training. It has been agreed that future investment will include an additional Staff Nurse, Band 7 quality improvement post and also additional Fellowship as well as support for clinician PI time.

### Portfolio

In this reporting period the Respiratory Health Interest Group continues to deliver on a large portfolio of Phase 2 proof of concept and phase III studies in carefully characterised patient cohorts in Severe Asthma, Cystic Fibrosis, Chronic cough, Bronchiectasis and COPD. It is notable that principal investigators in our group are participating both as national/international Chief Investigators as well as local Principal Investigators for many of the studies in our portfolio.

Table 25 summarises the NICRN Respiratory Health group portfolio for 14/15

| Active Studies | Active Sites | Commercial | Randomised | Multicentre |
|---|---|---|---|---|
| 21 | 27 | 67% | 71% | 14% |

Table 26 illustrates the NICRN Respiratory Health group portfolio breakdown

| | | | |
|---|---|---|---|
| Clinical Trial of a Invest Medicinal Prod. | CTIMP | **67%** | **14** |
| Clinical Trial (other) or Clinical Investigation | CT Other | **19%** | **4** |
| Study limited to Tissue, Biological samples and/or data | Tissue/Bio Samples, Data | **10%** | **2** |
| Combined Trial (IMP & IMD) | Combined IMP & IMD | **5%** | **1** |

In this reporting period the group has 21 active studies, of which 14 studies are CTIMP commercial studies (67%) (Table 25 & 26), the remainder of the portfolio are funded investigator led studies using various methodologies. The majority of the studies in the portfolio are long term RCT with many studies lasting >1 year. Several of our long term RCT have been followed by open label phases which are important bridging studies to

ensure that patients have the option to continue on trial medication until the drugs are licenced and available within the NHS. Additionally the nature of our trial portfolio (e.g. increasing number of early phase studies) means that the majority of study visits across our portfolio are long (majority visits > 4 hours per visit with some studies eg those studies in Vertex CF portfolio having visits up to 13 hours). The intensive nature of studies obviously impacts on the total number of patients we can recruit overall.

We conduct in depth feasibility assessment for all studies proposed unto the network and this along with an excellent high performing research teams has resulted with average recruitment of 105% target recruitment in this reporting period.

### Workforce

Our current group includes 5 active clinician PIs (Dr Lorcan McGarvey, Dr Damian Downey, Prof Stuart Elborn, Prof Liam Heaney, Dr Martin Kelly and ) and 2 non-clinician PI (Prof Judy Bradley and Dr Brenda O'Neill) however a key objective for the next reporting period is to encourage new PIs to bring studies in new areas to the group in order to widen our current portfolio. At a recent strategy meeting we reviewed the constitution of our Clinical Management Group and have now expanded this to include additional PIs (Dr. Nick Magee, BHSCT; Dr Claire Butler, BHSCT; Dr Stephen Rowan, SEHCT). These appointments will help Respiratory Health achieve its objective of expanding its portfolio to include other respiratory disease areas including Lung Cancer and Idiopathic Pulmonary Fibrosis.

Respiratory Health is one of only two groups which currently employ AHPs within the workforce but this has resulted in a very dynamic workforce, many of whom are trained to PhD level.

Table 27 illustrating the NICRN Respiratory Health staffing compliment (funded versus in post)

| HSC | POSITION/BAND | R&D FUNDED | ACTUAL WTE | ADD WTE |
|---|---|---|---|---|
| BHSCT | BAND 6 NURSE | 1.0 | 1.0 | |
| BHSCT | BAND 6 NURSE | 1.0 | 1.0 | |
| BHSCT | BAND 6 NURSE | 0.5 | 1.0 | 0.5 (CAPACITY) |
| BHSCT | BAND 4 | 1.0 | 0.5 (started 1/9/14) | |
| BHSCT | BAND 6 PHYSIO | 1.0 | 0.3 | |
| BHSCT | BAND 6 PHYSIO | 0.0 | 1.0 | 1.0 (CAPACITY) |
| BHSCT | BAND 6 PHYSIO | 0.0 | 1.0 | 1.0 (CAPACITY) |
| BHSCT | BAND 6 PHYSIO | 0.0 | 1.0 | 1.0 (CAPACITY) |
| BHSCT | BAND 6 PHYSIO | 0.5 | 1.0 | 0.5 (from R&D) |
| BHSCT | BAND 6 AHP | 1.0 | 1.0 | |
| WHSCT | BAND 6 NURSE | 0.5 | 0.5 | |
| B6 = 5.5WTE<br>B4 = 1.0WTE | | B6 = 8.8WTE<br>B4 = 0.5WTE | | |

Core Staff funded by PHA in this reporting period: 3FTE nurses (2.5FTE BHSCT, 0.5FTE Western); 2.5FTE AHPs (BHSCT); 1FTE administrator (BHSCT). This is supplemented in this reporting period by capacity: 0.5FTE nurse, 2.5FTE AHP). We have had several staff challenges and periods of unfilled posts in this reporting period however due to the excellent teamwork and support by CC, PIs and experienced coordinators we have maintained a highly performing portfolio.

We appointed the first Clinical Trial Fellowship (Dr. Charlotte Addy) who commenced her 3 year programme of Research at QUB in September 2015. Dr Addy will provide specific clinician support to the network, alongside her research component which will have a specific CF focus.

We have also secured funding for a second Clinical Trial Fellow which will be aligned with the MRC funded programme in severe asthma (RASP-UK) and is due to be appointed in early 2016. These Fellowship posts provide additional clinician support to the network and also provide a platform to young researchers to gain advanced research training in clinical trials. It is a key objective of the group to continue to support these training opportunities.

## 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. It is notable that this group uses there income generation collectively to supports a number of coordinator staff as well as staff training and research opportunities

## Education and Training

As per Table 27 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.

Table 28 shows the Respiratory Health group specific training supported over 14/15

| | |
|---|---|
| 15th Dec 2014 | Introduction to Microsoft Excel |
| 6th Oct 2014 | Advanced Microsoft PowerPoint |
| 5th March 2015 | LCI (Lung Clearance Index) 2 Day training programme |
| 3rd December 2014 | British Thoracic Society Conference – 3 days |
| 4th-6th December 2014 | BTS Winter Meeting |
| 01/04/2014 – 31/03/2015 | (All Staff attended throughout)<br>Additional Training –<br>• LCI<br>• ECG<br>• SPIROMETRY<br>• CANNULATION<br>• SWEAT TRAINING |

| | |
|---|---|
| | • NPD<br>• VENEPUNCTURE |

### Interaction with other Research Infrastructure

The respiratory group continue to be one of the primary users of the NICRF and in this reporting period the majority of their commercial and funded portfolio are now carried out in NICRF as such the respiratory group are an important source of income for NICRF (income to NICRF over 50,000 in this reporting period).

## 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. This has continued over the years the network has been in place. There has always been strong input from Allied Health Professionals who have made strong impacts as co-directors of the network, most recently Carolee McLaughlin who has particular expertise in swallowing problems post stroke and outlines below her involvement in some very important research. 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.

### Summary of 2014/15

A total of 35 patients were recruited to all stroke studies requiring 2878 to be screened. Significantly more patients were recruited to RCTs than in 13/14. 67% of the studies were multi-centre RCTs. CROMIS-2 (Clinical Relevance of Microbleeds in Stroke -Intracerebral Haemorrhage) recruited well in 4 trusts with all sites had recruiting 80 participants against a

combined NI target of 86(RTT 93%). BIG-CACTUS has now been adopted and is led in N.I. by Carolee McLaughlin (see below). There were 5 new studies opened during this period:

The following studies closed to recruitment: DARS and AVERT. 59 patients in total were recruited to AVERT, 1 in 14/15 before the study closed to recruitment. This was a landmark study looking at the outcomes with earlier rehabilitation input post stroke. These studies were key studies looking at specific aspects of acute care and rehabilitation

### Big successes:

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

The IRIS study is now in the follow-up phase. The IRIS Study 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 dysphasia post stroke .

The Belfast Trust was 1 of only 2 European sites chosen to take part in the ESCAPE study, a landmark stroke interventional study in the hyperacute phase of stroke. This study along with 5 other similar studies conclusively demonstrated the potential benefits of clot retrieval as an interventional treatment in the first few hours post stroke onset. The ESCAPE study was published in the NEJM with Dr Paul Burns (neuroradiologist RVH) listed as one of the principle authors.

Furthermore, the stroke network has struggled with numbers of recruitment last year. We are pleased to say in comparisons from last year we have almost *doubled the number* of patients in the same time frame this year. Screening numbers continue to be high showing the complexity of the client group. Additionally, a key achievement is the adoption of the *commercial study* GLORIA which is open in the Western Trust.

### Challenges

There have been challenges for the network during the year 14/15 year because of a significant lack of suitable stroke studies but also because of ongoing staffing challenges. Recruitment to stroke studies is particularly challenging because of the complexity of acute stroke but also the delays in accessing stroke units as their ward of first admission in the different Trusts. Because of the pressures on acute medical beds direct stroke unit access for acute stroke patients is falling resulting in more difficulty recruiting these patients to acute stroke studies. It is extremely challenging to recruit and randomise patients to trials outside of organised stroke services. We will therefore be aiming to increase the % of rehab studies and patients recruited in 15/16. We will also examine ways to measure screening numbers relevant to each study.

### Opportunities

There were on-going discussions with Randox about initiating a N.I. study to help identify the Strokes sooner and possibly enable a more accurate indication of who might be suitable for thrombolysis. Considerable time and effort have been invested in this potential project by both medical and nursing staff in the network and by Randox staff but progress has been

very slow. Further discussion with Randox is required to determine how to take things forward from here.

## Current portfolio

**Studies that were open last year and are currently open include;**

i. **ESCAPE**- study ran From May 14 to October 14 inclusive, within this time period 32 patients were assessed as potential patients and 4 were randomised. The trial was stopped early because of efficacy. Results showed a 25% absolute benefit in the amount of patients achieving functional independence when endovascular therapy was used. This is pioneering treatment offered only in Belfast Trust currently in NI and is a landmark study in the progression of stroke treatment. Belfast PI were co-authors of the published paper in *NEJM*.

ii. **GABS**- a physiotherapy lead rehabilitation study is being conducted locally in SE Trust. It was adopted at the end of this reporting period and we look forward to recruiting to this local study.

iii. There were 5 new studies adopted onto the portfolio in 14-15.

1. **TICH-2** a hyper acute stroke with the aim of testing whether it is possible to give tranexamic acid to patients in the first few hours after haemorrhagic stroke and to find out if it reduces the chances of dying and being left with disability. Numbers are small with the recruitment target set at 6-12 per year, again highlighting the challenges faced with hyper-acute studies. Currently 3 patients have been recruited in this reporting period.

2. **MADE** Trial examines the effects of two years of minocycline treatment on deterioration in cognitive function and activities of daily living in patients with early Alzheimer's disease assessed and managed within NHS Memory Services. If minocycline can be shown to have efficacy in the trial, this would rapidly pave the way for effectiveness trials and ultimately availability of a low cost and safe treatment for this common and devastating condition. This is open in the Northern Trust.

3. **RESTART** – restart or stop antithrombotic drugs post haemorrhage. This study is another acute trial aiming to recruit 720 patients following brain haemorrhage looking to determine the beneficial effects of antiplatelet drugs such as aspirin on the risk of heart attack, stroke and other clotting problems as well as their effect in the risk of a brain haemorrhage. This study is recently opened in 4 Trusts. It is recognised that recruitment numbers will be small.

4. **GLORIA**- The GLORIA™-AF Registry Program is a large, international, prospective registry program designed to characterize newly diagnosed patients with

non-valvular atrial fibrillation at risk for stroke in different regions of the world. This study is in Set up currently. This commercial study will provide income generation for the Network.

The pattern of the studies adopted has moved to include rehabilitation studies. We have added a speech & language therapy rehabilitation study as outlined;

5. **BIG CACTUS**; this opened in Belfast and Northern Trust in early 2015. This is a speech and language therapy study. Big CACTUS is a pragmatic randomised controlled trial (RCT) to compare outcomes for people with persistent aphasia using computerised speech and language therapy at home with those having usual care (standard speech and language therapy provision or general daily communication activity), or attention control (daily completion of puzzle book activities. The recruitment target set is 15 per site and currently we are on target to meet these goals.

One study was not adopted to the portfolio following an intensity tool analysis of the clinical need required by the research nurses. It was a dementia study called **AFFECT.** A RCT of calcium channel blockade with amlodipine for the treatment of subcortical ischaemic vascular dementia.

## Workforce

Stroke network has enjoyed a close collaboration between all the nurses. This is certainly strength of this network.

Table 29 shows the NICRN Stroke core funded staffing allocation (Funded versus in post over 14/15

| HSC | POSITION/BAND | R&D FUNDED | ACTUAL WTE |
|---|---|---|---|
| BHSCT | BAND 6 NURSE | 1.0 | 0.3 (RETURN TO 0.5WTE - BACK FROM MAT LEAVE 03/08/2014) |
| NHSCT | BAND 6 NURSE | 0.5 | 0.5 |
| NHSCT | BAND 6 NURSE | 0.5 | 0.5 |
| SEHSCT | BAND 6 NURSE | 1.0 | 1.0 |
| SHSCT | BAND 6 NURSE | 1.0 | 1.0 |
| WHSCT | BAND 6 NURSE | 0.5 | 0.5 |
| B6 = 4.5WTE | | B6 = 3.8WTE | |

Most of 14-15 realised a vacant 1.0WET post in Belfast Trust as a result of maternity leave. Currently this post remains .5 WTE vacant. This is the only reduction in staffing this year.

## Education and Training

All stroke research nurses attended the UK stroke forum. All nurses attended and presented a PR stand at the NIMAST stroke forum. Trials 2 further studies were proposed for adoption following these conferences.
Table 30 shows the Stroke group specific training supported over 14/15

| | |
|---|---|
| 03/09/2014 | Restart or Stop Antithrombotics Randomised Training Modules |
| 05/09/2014 | NIH Stroke Scale Certification |
| 14/09/2014 | Tranexamic acid for IntraCerebral Haemorrhage (TICH-2) Training Certification |
| 21/01/2015 | Study day on hyper acute nursing in stroke care |
| 20/02/2015 | Northern Ireland Stroke Conference NIMAST/UKSF |
| 06/04/2014 | Multi-Disciplinary Stroke Training Session |

## Interaction with other Research infrastructure

2 co-chairs have attended the national stroke network meetings and have forged links with sub group specialities.

Dr Power has had an initiation visit of the clinical research facility in BCH.

## Patient and Public Involvement

Stroke network has benefited form close PPI involvement with an established and committed representative Prof Philip Reilly who attends all CMG meetings and actively contributes to these.

Philip has been an important part of the stroke research network in N.I. and has voiced the views of users and carers very ably. He has previously worked in the health service and more importantly knows the challenges stroke patients face as he himself suffered a stroke in recent years (2008). He has recently been offered a place on the Council of the Stroke Association (UK) having gone through an interview process by NIHR.
> He is very dedicated to ensuring that the voice of users and carers are heard and is a valued member of the network.'

**Other initiatives**

- ✓ All research nurses and PIs are trained in EDGE and update this database as required.
- ✓ All nurses attended NIMAST stroke forum with the aim of promoting awareness raising of stroke research – following this the Mirror box study was successfully adopted.
- ✓ Carolee McLaughlin has been involved with the dysphagia research network UK and has attended portfolio writing groups and has submitted applications for funding with this network.

- ✓ Carolee has been involved in Phagenyx product evaluation and feasibility of use of the product an acute ward. This product is currently used within the STEPS RCT for the intramuscular stimulation for swallowing.
- ✓ Additionally, Carolee has been actively involved in updating the MAPS data base system for Phagenyx.
- ✓ Further dysphagia initiatives include presentations at national conferences on swallowing research studies (UK 14.)
- ✓ Finally, carolee is co-author in conjunction with SRN which has been accepted for the international journal of stroke, IJS.

## Vision Interest Group

**Dr Giuliana Silvestri &Associate Professor Jonathan Jackson Clinical Leads**

### Introduction

2014/5 was another great year for the Vision NICRN Group. In this report we will highlight the breadth and depth of the portfolio of disease studies that the group has been involved in during the 2014/5 year. This represents a healthy mix of commercial and non-commercial studies and illustrates how members of the group have responded to the opportunities available through regional and national collaboration. The portfolio overview (TABLE 31) highlights the position of the group in terms of recruitment to target.

Table 31 summarises the NICRN Vision group portfolio for 14/15

| Active Studies | Active Sites | Commercial | Randomised | Multicentre |
|---|---|---|---|---|
| 23 | 23 | 61% | 57% | 0% |

Established in 2008 the NICRN Vision Group had initially been led by both Dr Giuliana Silvestri and Associate Professor Jonathan Jackson who shared managerial responsibility for the Group until 2011 when Jonathan took up a position at the Australian College of Optometry in Melbourne Australia. At that time Giuliana assumed the role of sole Clinical Lead. In mid-2014 Jonathan returned to Northern Ireland to resume his role as Head of Optometry at the BHSCT and in December he was re-appointed as co-lead of the Group. Jonathan has a track record of involvement in clinical research and states that he *is "very excited and enthusiastic about re-engaging with the R&D community, NICRN Vision Group members and Dr Silvestri as Co-Chair, and that he hopes that his enthusiasm will encourage many others from a wide range of professions, from across the academic and clinical communities, to get involved in clinical research."* The Staff Team working within NICRN Vision continues to grow and their skill set expands as studies in other ophthalmic sub-specialities are adopted. The core staff, of which there are now 10, includes a number of individuals funded by Professor Chakravarthy. In addition the Vision NICRN Group have made an internal arrangement whereby each PI will donate 10% of their personal capacity fund to a central capacity fund for reinvestment in the Vision NICRN Network. The group plan to invest available monies in additional optometry and ophthalmology sessions in 2015-2017 as this will increase our capacity to carry out a diverse range of studies throughout the full working week.

## Staff

Table 32 illustrating the NICRN Vision group's staffing compliment (funded versus in post)

| HSC | POSITION/BAND | R&D FUNDED | ACTUAL WTE | ADD WTE |
|---|---|---|---|---|
| BHSCT | BAND 6 NURSE | 1.0 | 1.0 | |
| BHSCT | BAND 6 NURSE | 1.0 | 1.0 | |
| BHSCT | BAND 4 | 1.0 | 1.0 | |
| BHSCT | B7 IMAGING TECH | 1.0 | 1.0 | |
| BHSCT | B7 OPTOM | 0.4 | 0.05 | |
| BHSCT | B7 OPTOM | 0.4 | 0.1 | |
| BHSCT | B7 OPTOM | 0.2 | 0.4 | |
| BHSCT | B7 OPTOM | 0.0 | 0.2 (STARTED 6/6/14) | 0.2 (funded from light study) |
| B7 = 2.0WTE<br>B6 = 2.0WTE<br>B4 = 1.0WTE | | B7 = 1.75WTE<br>B6 = 2.0WTE<br>B4 = 1.0WTE | | |

In addition to the core publically funded staff shown in Table xxx above the group is also supported by Professor Chakravarthy' s release of her own funded staff to support activity as and when required. This adds greater capacity to group and is very much appreciated.

All of our staff have specialised in the field of ophthalmology and hold responsibilities that extend beyond those normally practiced within the conventional clinical environment. Our staff are dedicated to provide the best possible specialised patient centred care and to working together as a team.

The Groups nursing team Miss Rebecca Denham and Mrs Georgina Sterrett continue to do a fantastic job at liaising with potential study sponsors and coordinators, as new studies are proposed and adopted by the group. They have become skilled multi-taskers, keen negotiators, and have helped consolidate activities during this, our most successful period yet. Our ability to engage with commercial organisations and provide high level support with the process of adoption is a significant contributor to our success as a group. Our nursing staff are very versatile and pro-active and play a major role in both patient recruitment and many of the clinical procedures undertaken by those participating in studies. Georgina and Rebecca are now routinely producing "Study Alert Cards" for newly adopted studies.

Our Imaging Technicians Mr Vittorio Silvestri and Mr Graham Young, having gained global accreditation from a number of International Image Reading Centres (ie: DIRC, DUKE, VIENNA, Network UK) continue to develop and use their extensive expertise in imaging a wide range of structures within the eye and visual system. They have also acquired many new skills including those necessary to test and evaluate visual fields and have trained staff from the CRF to use imaging equipment. Vittorio has written imaging protocols for a number of studies (ie Leavo, Clarity) and regularly interacts with external sites to quality control imaging protocols. Graham Young also teaches students and grades images for a variety of studies.

The optometric staff cohort is made up of an enthusiastic group of individuals ( Dr Deidre Burns, Mr Paul Wright,, Dr Lesley Boyle and Ms Katie Graham) all of whom have evolved from a background in clinical hospital and university based practice. The Optometric teams responsibilities extend well beyond those normally practiced as conventional core optometry skills and this has contributed to their commitment to the service. All have learnt how to read protocols, have been accredited by a number of Optometry certifiers(ie Etonwood, and Certififeyed), taken part in clinical research audits, collated data, gained more experience in reading OCTs and Fluorescein Angiograms, learnt how to do micro-perimetry and co-ordinate several studies.

Smooth running of the system is facilitated through involvement of the groups dedicated and hardworking administrator Miss Louise Scullion without whose careful oversight the Co-Chairs would find managing the evolving workload very difficult.

An indication of the contribution the Team makes to clinical research in Northern Ireland can be drawn from a recent comment made by one of the Networks most senior PIs, Professor Augusto Azuara-Blanco. *"NICRN has recently adopted a NIHR-funded study for glaucoma and I had the chance of working with the NICRN team. I have been very impressed with the professionalism of the research nurses and admin staff. I must also mention the excellent personal skills that are critical to support patients during their experience as participants."* Ms Sarah Wilson a PI on the Light study reiterates these sentiments and expresses her thanks to the *team: "Thank you for your support and dedication to LiGHT. As you know recruitment finished just prior to Christmas, with a very respectable 30 patients."*

## Facilities

NICRN Vision benefits from a fully functional Clinical Research Suite at the RVH Ophthalmology Department (BHSCT). Our current accommodation facilitates easy communication with clinical staff within Ophthalmology and assists with patient recruitment. Patients feel comfortable and reassured when consenting to take part in studies carried out

within an environment that they are familiar with. The group does however also has the opportunity to use the Clinical Research Facility (QUB) for non-interventional studies and has throughout the current year also made use of facilities at the Glaucoma unit at Shankill Health and Wellbeing Centre. We are however in some respects victims of our own success with facilities and space become very pressurised. As we head into 2015/6 plans are in progress for relocation within a custom made facility in the Department of Ophthalmology and to undertake more of our activity at Belfast Trust and University locations off site. Miss Silvestri in her role as Clinical Director has secured agreement from the Trust for the provision of extra space for the relocation. The Vision Research Suite is fully equipped with the following facilities, instrumentation and equipment:

- eCRF facilities
- Visual Acuity and Contrast Sensitivity vision testing lanes
- Refraction equipment and accredited protocols
- Colour fundus cameras including Topcon, Nidek and Canon Instruments
- Fluorescein Fundus Angiography equipment
- MAIA Microperimetry & Visual field testing instrumentation
- Corneal endothelial cell count facilities
- Slit lamp Biomicroscopes
- A 2RT Lazer
- A Clean room for Intravitreal injections
- A Spectral Domain OCT: Heidelberg Spectralis

## Principal Investigators

The nature of the studies recruited to the portfolio reflects the specialist clinical and academic interests of the PIs. Whereas the PIs responsible for many of our early studies had specialist interests in diseases of the retina and visual disability (Usha Chakravarthy, Giuliana Silvestri, Jonathan Jackson) more recently the number of PIs has expanded to include those with a broader range of clinical interests. (Dr Heping Xu, Dr Michael Williams, Dr Tanya Moutray, Professor Noemi Lois, Professor Augusto Azuara-Blanco, Miss Sarah Wilson, Mr Murali Upendran, Mr Stuart McGimpsey, Dr Ruth Hogg). The range of diseases under study has expanded to include retinal vascular occlusive diseases, diabetic maculopathy and glaucoma and we envisage this expanding further to include paediatrics and refractive error over the next few years.

## Collaboration with other Networks

Our group continues to support portfolio studies within the Cancer Network. Since returning from Australian Professor Jackson has taken over responsibility for linkage with the studies from the Cancer Network and our staff provide both pre study screening investigations and safety monitoring for a number of important studies adopted by the Cancer Group. These studies could not proceed without the collaboration of the Vision Network. Jonathan and Giuliana would particularly wish to convey their thanks to all on the team for facilitating the important work undertaken by the Cancer Group.

## NICRN Vision Portfolio Metrics

Since 2008, the Vision Network has provided support for 43 studies in total. Of these 24 are closed; 8 are open; 6 are in follow-up and 5 are in set-up. During the course of the current year patients taking part in the portfolio of studies attended a total of 450 clinical visits, the vast majority of which involved multiple clinical assessments.

On a separate yet related note an additional 13 studies are, as of the start of the 2015/16 year, in pre-authorisation and Leads are deliberating on feasibility and capacity before deciding if we have sufficient resource to adopt.

The ratio of commercial to non-commercial studies being facilitated by the Group during the course of the current year was approximately 3:2 (~60% Commercial), in closed or open phase. In terms of meeting recruitment targets our closed studies have achieved an impressive recruitment figure of 85.7 %.

Commercial Companies with whom we have been involved include:

Alcon Laboratories

Allergan

Bayer Healthcare

Bayer Schering

Roche NeoVista Inc

Novartis

Oraya Therapeutics

Pfizer

Quark Pharmaceuticals Inc

Santen Inc

Psividia Corp

Almeria Sciences

Vision Care Inc

Emmes

The value attributed to the work of the Network and its dedicated team of staff is illustrated by the comments made by representatives from several of the commercial companies we have partnered with during the current year. Mr Tom Miller from Novartis (The TREND study) responding to a protocol enquiry states: *"Apologies!!, I should have known the dream team would be on top of things ".* Dr Negin Sarafraz-Shekary from the King's Clinical Trials Unit (The CLARITY study) says ***"****It was really lovely working with you all and thank you very much for all your efforts for the study"*

## Strengths of the Vision Network Group

As indicated above one of the group's greatest strengths is the knowledge and enthusiasm of our dedicated team of PIs and staff who provide the expertise and skill necessary to both attract and facilitate a diverse portfolio of studies. In addition to clinical skills our staff have developed skills in assessing the needs of new protocols, attributing time required to undertake a very varied range of research activities, and also in using the new Intensity Costing Template.

The Group has continued to benefit from Professor Usha Chakravarthy's on-going appointment as the Clinical Lead for the UKCRN Ophthalmology Specialty Group. Although Usha has stepped down from this post in March she has agreed to continue to oversee the group until a new chair has been appointed in June. This 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

Staff within the NICRN Vision Network have continued to use all available opportunities to work closely in collaboration with our colleagues at the Centre for Experimental Medicine (CEM) and the Central Angiographic Reading Facility at QUB. The Ophthalmology Programme within (CEM) is multidisciplinary in nature and pioneers translational research in basic cell and molecular biology, pathophysiology of disease, genetic analysis, protein chemistry, retinal imaging, patient-based phenotyping/genotyping and the co-ordination of multi-national clinical trials. This new Centre, which has, at its core three themes consisting of ophthalmology, diabetes and genomics research, opened in January 2015.

During the course of 2015/6 we hope to expand our collaborative approach to do more with our colleagues at the University of Ulster.

## Challenges

During the course of the year the Network has faced challenges many of which, it could be argued, were a direct result of our initial success. As more and more studies are proposed for adoption our nursing team have been required to process increased numbers of adoption forms and intensity tools. Our imaging team have been required, not only to undertake complex and time consuming imaging investigations on patients recruited to our own studies, but also to those adopted by the Cancer Network. Our Optometrists have been called to undertake a broader range of visual function and functional vision assessments across multiple sites. In like manner as the workload increased so too did pressures on facilities with all staff having to exercise creativity in sharing both clinical and administrative space. A continued challenge facing the team is that of "Trust Processes" however the dedicated team in the NICRN office (Dr Paul Biagioni, Mrs Sonia McKenna, Mr Shane Jackson, Mrs Ciara McKenna and Miss Roisin Kerr) have worked consistently to help us through these. Our thanks to Paul, Sonia, Shane and the team are very sincere. The addition of new disease areas in our portfolio has been very welcome but has brought additional challenges as training for new techniques was required.

The work of the Network continues to be Belfast-centric and this is a challenge that we hope to work on in the incoming year. Whereas we have tried to encourage participation from the only other large Ophthalmic Unit in Northern Ireland, the Western Trust, progress has been limited. We will however continue to make the Vision Network Group staff available on a sessional basis to those wishing to initiate studies either in the Western Trust area or at the University of Ulster. Importantly the CMG membership includes representation from both 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.

Recruitment targets have been improving steadily over time however the group has learnt some important lessons from earlier studies. Some investigator-led studies struggle to recruit patients particularly if protocol requirements differ markedly from routine clinical practice. Recruitment was particularly difficult in studies which were heavily dependent on patient identification and input from other specialties. We are however now mindful to assess potential more stringently.

## Specific Challenges

The TABUL study, in which 2 diagnostic approaches to Giant Cell Arteritis were to be evaluated (Temporal Artery Biopsy vs Ultrasound), was a case in point. Although 29 suitable cases were identified only 6 proved suitable and amenable to recruitment. The ROSA study: A randomised controlled trial of continuous positive airways pressure (CPAP) in patients with impaired vision due to diabetic retinopathy and concurrent Obstructive Sleep Apnoea (OSA), illustrated an alternative challenge. This study, initiated by the Respiratory Team, required recruitment from within Ophthalmology. The consensus view, noted on reflection, was that this study was very problematic to deliver as it required additional time from a sleep technician to conduct the procedure.

Throughout the year a regular challenge has been the acquisition of sufficient Medical cover to support the broad range of studies submitted for adoption. As this was never a core funding function the team lacks a dedicated R&D funded member of staff.

In summary the NICRN Vision Network is a vibrant, active and dedicated group with excellent recruitment and accrual 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.

## Education and Training

The staff attended all provided training, 25 mandatory events and 23 non-mandatory events over 14/15 and the optometrists were supported over a number of other additional training programmes as agreed. Table 33 illustrates the training events supported by the NICRN for the vision group, including the national vision speciality group which was chaired by Professor Usha Chakravarthy and facilitated by Ms Louise Scullion as administrator.

Table 33 illustrating the training events specific to NICRN vision

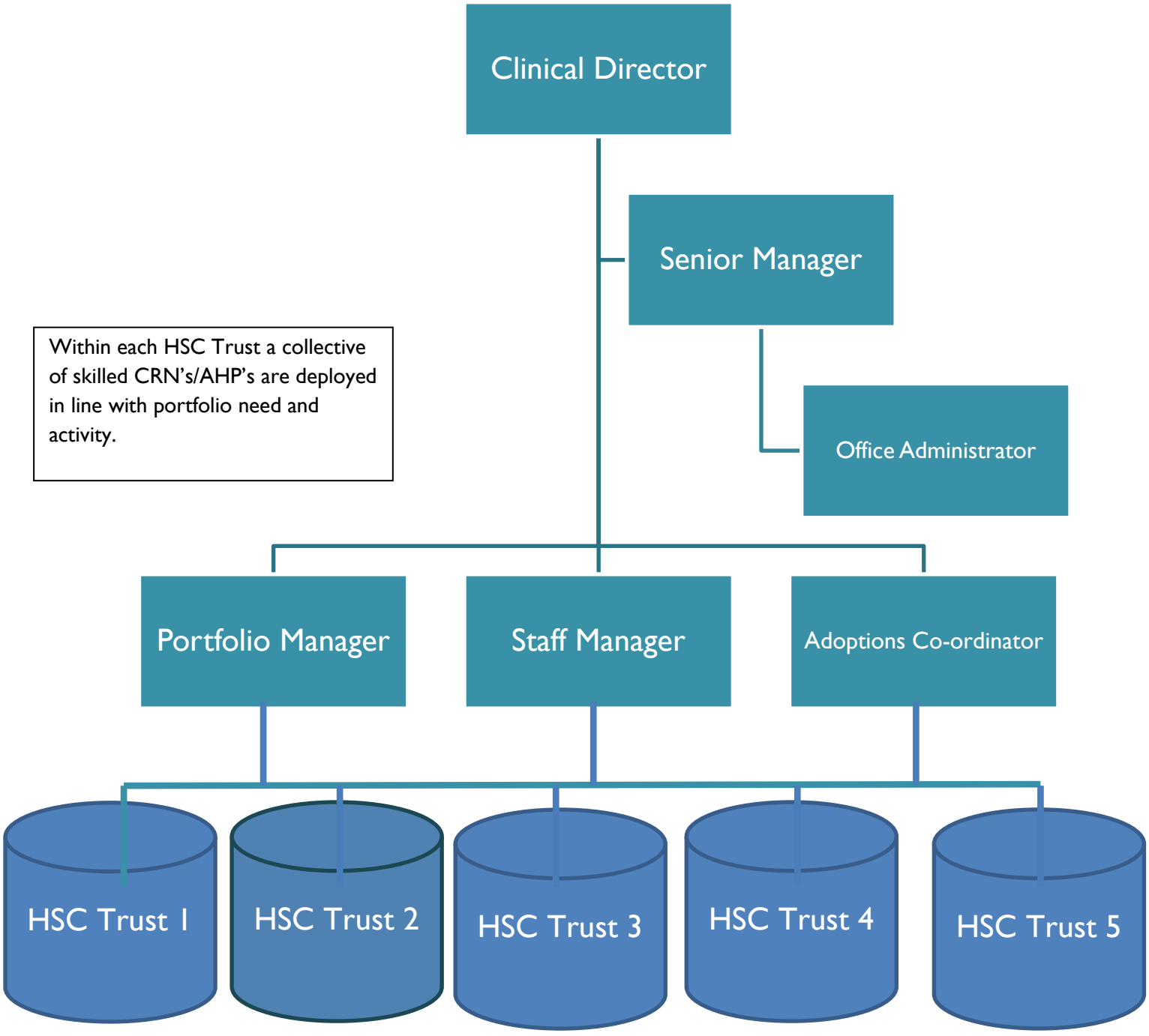
| | |
|---|---|
| 01/04/2014 – 31/03/2015 (Staff attended throughout) | Ophthalmology speciality Group Meetings – London |
| 14th Nov 2014 | Ophthalmic Training Day |
| 16th Nov 2014 | Improving the care of the Diabetic In-Patient |
| 12th Feb 2015 | TOPCON Maestro 3D OCT |
| 6th Sept 2014 | Update of Anti VEGF therapies Symposium |

## Section 4

## Appendices

### Appendix 1

### NICRN Co-ordinating centre Organisational structure



Appendix 2

NICRN Adoption process

# NICRN Adoption Process