NI CRN
CLINICAL RESEARCH NETWORK

NORTHERN IRELAND CLINICAL RESEARCH NETWORK ANNUAL REPORT

2016/17

NICRN
CLINICAL RESEARCH NETWORK

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1.0 EXECUTIVE SUMMARY

Clinical research is essential for better understanding of disease processes and for the development of new tests, treatments and interventions. The purpose of NICRN is to provide and manage the infrastructure necessary to support high quality clinical research in the Health and Social Care (HSC) Trusts and in primary care across N. Ireland. NICRN currently supports research through twelve Clinical Specialty Groups : Cardiovascular, Child Health, Critical Care, Dementia, Diabetes, Gastroenterology, Mental Health, Renal medicine, Respiratory Health, Stroke , Primary Care and Vision. NICRN deploys 45.33 Whole Time Equivalent staff across the HSC and primary care

In 2016/17 all five HSC Trusts and 84 out of 339 (25%) general practices were actively involved in supporting NICRN adopted studies. Over this period there were 205 active research studies and a total of 2814 patients were recruited to NICRN adopted research studies in N. Ireland. NICRN aims to support a broad spectrum of high quality clinical research studies including national publically funded studies, commercially sponsored research and which incorporate a range of study methodologies (Randomised Controlled Trials, observational studies, qualitative research. evaluation of tests etc.). The study portfolio remains well balanced as regards both sponsorship and study type: 40% of studies were commercially sponsored and 54.6% were of randomised controlled trial design.

There was evidence of increased efficiency of working across the network with the ratio of patients screened: recruited falling from 9:1 to 3.25:1. Furthermore the median percentage recruitment target attained has risen to 90.5%.

NICRN is keen to foster close collaborative working with the life and health sciences commercial sector and the Director and Senior Manager have held a series of meetings with pharmaceutical industry companies and clinical research organisations to raise the profile of NICRN and to encourage the siting of more clinical trials in N. Ireland. The NICRN steering committee has been reconstituted to include representation from the Association of the British Pharmaceutical Industry and also a clinical research organisation.

NICRN remains committed to ensuring that patient and public involvement (PPI) is integrated into its research activities. The Steering Committee was reconstituted to include two PPI representatives. NICRN staff employed at each of the five HSC Trusts participated in participated in public engagement events on International Clinical Trials Day to raise the profile of clinical research and to encourage patients, carers and the public to ask their health professional about research opportunities ('OK to ask'} that might be available to them.

2016/17 has been a busy and productive year for NICRN and I commend all NICRN staff, investigators and the clinical specialty groups for their hard work and dedication to clinical research. I particularly wish to thank all those patients and members of the public who have contributed to NICRN either in an advisory capacity or as research participants who have given so generously of their time and energy.

Dr Maurice O'Kane

NICRN Director

Northern Ireland Clinical Research Network

2 BACKGROUND

The Northern Ireland Clinical Research Network (NICRN) was established in 2008 to support the staff and service users of the five Health and Social Care (HSC) Trusts and the primary care sector to participate in high quality clinical research studies. Clinical research is essential to improve understanding of disease processes and the development of new tests and treatments. From a patient perspective, involvement in clinical research offers the opportunity of prioritising research questions of most relevance to patients or carers and the possibility of contributing to and participating in high quality research studies. For health care organisations active participation in clinical research helps foster an organisational ethos of intellectual rigour and enquiry all of which go and in hand with excellence in the delivery of care.

NICRN comprises 12 Clinical Speciality Groups (CSGs) which are focussed on areas of existing excellence in clinical research: Cardiovascular, Child Health, Critical Care, Dementia, Diabetes, Gastroenterology, Mental Health, Primary Care, Renal, Respiratory Health, Stroke and Vision.

The NICRN infrastructure comprises 66 highly trained research staff (including clinical research nurses, Allied Health Professionals [AHPs] along with and managerial and administrative staff). Each staff member is trained in key research areas such as Good Clinical Practice, Informed consent, recruitment and retetention, data quality and management.

Figure 1: Operational structure of NICRN

NICRN is organised on a hub and spoke design (Figure 1), with the NICRN Co-ordinating Centre providing management and administrative support to ensure effective management and co-ordination of regional activity with good communication and connectivity between the stakeholders throughout N. Ireland. The NICRN Co-ordinating Centre is hosted by the Belfast Trust and comprises the NICRN Director, Senior Manager, Senior Nurse and administrative staff.

Each CSG is overseen by a management group comprising research active clinical staff from across N. Ireland, including HSC Trusts, Queens University and Ulster University. There may also be patient and public representation. The primary responsibility of the management group is to prioritise and adopt new studies onto the CSG portfolio taking into account study quality, local capacity and capability.

The NICRN places patient needs at the centre of its activities. NICRN staff act as patient advocates within the research process and the NICRN steering committee and CSGs benefit from direct Patient and Public Involvement (PPI) which provides guidance and direction.

NICRN has developed close links with the pharmaceutical industry and clinical research organisations to allow more effective collaborative working and to increase clinical trial activity in N. Ireland.

3 MAJOR DEVELOPMENTS IN REPORTING YEAR

3.1 STAFFING

The NICRN currently deploys 66 staff members (45.33 Whole Time Equivalents [WTE] over the 5 Health and Social Care [HSC] Trusts and primary care structures). The primary care team, which supports studies throughout N. Ireland, is employed by the Belfast HSC Trust. Staffing levels have remained relatively constant over the last 3 years. A significant development in the reporting period was the appointment of a research officer to the Mental Health group; this is the first staff appointment in mental health and is anticipated that it will have a major impact in allowing the Mental Health CSG to adopt and support clinical research studies.

The NICRN team includes 31.8 WTE research nurses, 5.0 WTE staff at the NICRN Co-ordinating Centre (including the NICRN senior manager and senior nurse), 2.5 WTE physiotherapists attached to the Respiratory Health clinical specialty group, 1.0 WTE optometrist and 1.0 WTE imaging technician (both attached to the Vision clinical specialty group) and 4.0 WTE administrators providing support to specific clinical specialty groups **(Table 1**).

CSG	WTE	POSTS
Cardiovascular	6	8
Child Health	3.5	5
Critical Care	5.8	7
Dementia	2	3
Diabetes	4	7
Gastroenterology	0.5	2
Mental Health	2	1
Primary Care	2.5	3
Renal	3.53	6
Respiratory Health	6.5	8
Stroke	4	6
Vision	5	10
Total	**45.33**	**66**

Table 1. Staff resource supporting each of the Clinical Specialty Groups [CSG].

(WTE: Whole time equivalent)

Of the NICRN total staff complement, 57% are based in Belfast HSC Trust and 43% in the other HSC Trusts (**Table 2**). The NICRN co-ordinating Centre staff and the Primary Care team staff are employed by the Belfast HSC Trust but provide support to NICRN adopted studies across N. Ireland.

HSC Trust	WTE
Belfast	**26**
Western	**5**
Northern	**5**
South Eastern	**4.8**
Southern	**4.53**
TOTAL	**45.33**

Table 2 Staff resource allocation across the five HSC Trusts. WTE: Whole Time Equivalents.

The Clinical Specialty Group leads are given in Appendix 1

3.2 STAFF TRAINING AND EDUCATION

NICRN provides training for NICRN and other research active HSC staff. Over 2016/17 two full training days were delivered by Professor Allan Gaw [Associate Director of Education, Quality Standards at the NIHR CRN in Leeds].The topics covered in training days included : Good Clinical Practice, Informed consent (Paediatric and adult),: Using the Integrated Research Application System (IRAS), Recruitment and retention strategies in clinical trials, data management in clinical trials, preparation for MHRA inspection, working effectively with Industry, good Research Practice for non-drug studies and time management.

In addition two in-house training sessions were delivered by the NICRN Co-ordinating Centre to the NICRN clinical staff team on a range of topics including the NIHR Portfolio Management System, EDGE database and the NIHR research study intensity tool.

3.3 PORTFOLIO ACTIVITY: ADOPTED STUDIES

The number of active network studies has increased year on year from 174 adopted studies in 2014/15 to 207 in 2016/17 [**Tables 3a, b and c**]. It should be noted that the Gastroenterology Clinical Specialty Group only became active in the reporting year. The Mental Health Clinical Specialty Group appointed a research officer in early 2016 and has not yet been in a position to adopt any studies but has identified a pipeline of studies which may be suitable for adoption in 2017/18.

Year	**Cardiovascular**	**Child Health**	**Critical care**	**Diabetes**	**Dementia**	**Gastroenterology**
2014/15	27	15	18	14	4	-
2015/16	35	18	13	16	5	-
2016/17	39	16	17	17	7	1

Table 3a. Number of active studies by Clinical Specialty Group

Year	Primary Care	Renal	Respiratory Health	Stroke	Vision
2014/15	16	24	21	12	23
2015/16	13	23	33	15	27
2016/17	13	22	31	14	28

Table 3b Number of active studies by Clinical Specialty Group

Year	Total active studies across NICRN Portfolio
2014/15	174
2015/16	198
2016/17	205

Table 3c. Total number of active studies across the NICRN portfolio

A major aim of NICRN is to ensure that patients throughout N. Ireland have an opportunity to participate in clinical trials and clinical research. All five HSC Trusts actively recruited into NICRN adopted studies over the reporting period. The participation of individual Trusts in particular studies is dependent on the patient population served, local clinical research expertise, local access to clinical investigation modalities which may be required as part of the study protocol (e.g. medical imaging) and capacity. The Belfast HSC Trust accounts for almost 50% of the total active study sites delivering the NICRN portfolio, Northern HSC Trust 12%, South Eastern HSC Trust 11%, Southern H SC Trust 14% and Western HSC Trust 14.5% **(Table 4).** The greater activity at Belfast HSC Trust reflects a number of factors which include the size of the Trust, the co-location of the Medical School with research active academic staff and the fact that it offers a range specialist regional clinical services not delivered at the other Trusts. Patients from throughout N. Ireland receiving care from a regional specialty service in the Belfast Trust will therefore have the opportunity to participate in clinical trials.

Of the 339 general practices in N. Ireland, 84 (24.7%) have hosted NICRN adopted clinical studies.

HSC Trust	2014/15	2015/16	2016/17
Belfast	119	138	133
Northern	34	28	35
South Eastern	33	27	32
Southern	39	41	40
Western	43	43	41

Table 4 The number of NICRN adopted studies active in each HSC Trust

3.4 PORTFOLIO ACTIVITY: PATIENTS SCREENED AND ACCRUED

Recruitment into a clinical research study requires initial screening to ensure that the potential participant fulfils the required study inclusion and exclusion criteria. Screening may be a time consuming process for both patients and staff. NICRN has been supporting the direct clinical care team in ensuring that screening procedures are as efficient as possible. This has been reflected in a reduction in the ratio of screened to recruited research participants from 9 : 1 in 2014/15 to 3.25 : 1 in 2016/17, indicating a more efficient use of patient and staff time **(Figure 2).**

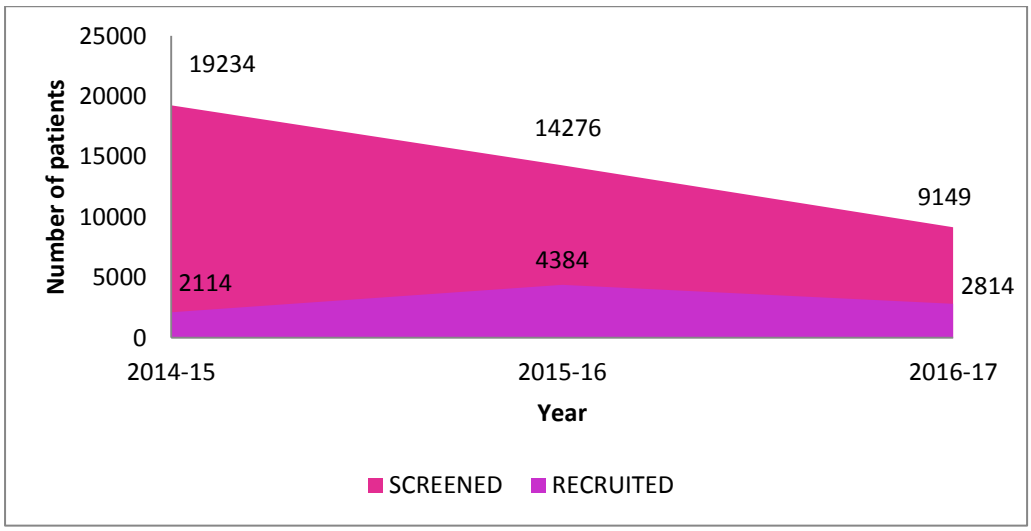

Figure 2. The numbers of patients screened and recruited over the period 2014 to 2017

Over the reporting period a total of 2814 patients in N. Ireland were recruited to NICRN adopted studies across the range of Clinical Specialty Groups **(Tables 5a,b and c**). The numbers within a specific CSG may rise or fall on annual basis depending on what new studies become available either from academic or commercial sources. Furthermore individual research studies may differ markedly in complexity i.e. from relatively low intensity observational studies to complex, high intensity intervention studies.

	Cardiovascular		Child Health		Critical Care		Diabetes		Dementia		Gastro – enterology	
	S	**R**	**S**	**R**	**S**	**R**	**S**	**R**	**S**	**R**	**S**	**R**
2014 /15	1528	384	354	146	4090	445	681	317	81	81	-	-
2015 /16	856	404	190	138	2365	220	2148	382	255	2	-	-
2016 /17	825	553	196	75	1723	479	1136	287	689	412	6	0

Table 5a Number of patients Screened [S] and Recruited [R] in each of the NICRN Clinical Specialty Groups over the last 3 years

	Primary Care		Renal		Respiratory Health		Stroke		Vision	
	S	**R**	**S**	**R**	**S**	**R**	**S**	**R**	**S**	**R**
2014 /15	7204	281	680	257	1457	95	2878	35	281	73
2015 /16	4049	2587	696	337	2145	101	1389	94	183	119
2016 /17	1175	111	247	213	1439	154	1320	205	393	325

Table 5b Number of patients Screened [S] and Recruited [R] in each of the NICRN Clinical Specialty Groups over the last 3 years

	Total activity across all Clinical Specialty Groups	
	Screened	**Recruited**
2014/15	19 234	2114
2015/16	14 276	4384
2016/17	9 149	2814

Table 5c Number of patients Screened [S] and Recruited [R] in each of the NICRN Clinical Specialty Groups over the last 3 years

3.5 PORTFOLIO ACTIVITY: RECRUITMENT TO TARGET

At the commencement of any clinical research study, each participating site will agree a target number of participants to be recruited. This figure will be based on a range of factors including the study design, the target patient population and local capacity to deliver the studies. For some studies requiring stringent inclusion and exclusion criteria or which are seeking to access difficult to reach patient groups or where the study protocol is complex and labour intensive for the research team, recruitment may be challenging. For the overall success of a study it is important that recruitment targets at individual sites are realistic and feasible so that the study sponsor can ensure that a sufficient number of study sites have been enrolled. The ability to estimate and attain realistic treatment targets is an import skillset of the site research team which is based on research experience, efficient participant screening and recruitment.

Over the 2016-17 period NICRN portfolio achieved a median Recruitment to Target (RtT) of 90.5% (range 40-106%) , up almost 10% from 2015/16 **(Tables 6a, 6b, 6c)**. Note that Gastroenterology was excluded from the analysis as the group had just been established with only one study adopted and recruitment ongoing during the reporting period. The low median percentage recruitment target attained by the Dementia Clinical Specialty Group reflected one particular study to which recruitment proved very difficult and which was subsequently withdrawn by the study sponsor.

For individual HSC Trusts the median recruitment value varied from 57% to 98.5% **(Table 7)**.

	Cardiovascular	**Child Health**	**Critical Care**	**Dementia**	**Diabetes**
2014/15	104%	61%	100%	57%	92%
2015/16	90%	50%	80%	2%	110%
2016/17	97%	40%	77%	100%	100%

Table 6a Median percentage target recruitment attained within each of Clinical Specialty Groups

	Primary care	Renal	Respiratory Health	Stroke	Vision
2014/15	102%	82%	96%	60%	75%
2015/16	105%	67%	82%	71%	88%
2016/17	106%	84%	100%	77%	80%

Table 6b Median percentage target recruitment attained within each of Clinical Specialty Groups

	Total NICRN Portfolio
2014/15	86.6%
2015/16	80.8%
2016/17	90.5%

Table 6c Median percentage target recruitment attained across the total NICRN study portfolio

HSC Trust	2014 /15		2015/16		2016/17	
	No of active studies	Median % recruitment target	No of active studies	Median % recruitment target	No of active studies	Median % recruitment target
Belfast	119	80%	138	69%	133	90%
Northern	34	80%	28	73%	35	78.3%
South Eastern	33	90%	27	93%	32	86.4%
Southern	39	84%	41	100%	40	57%
Western	43	87.1%	43	78%	41	98.5%

Table 7 The median % recruitment target attained across the portfolio of studies at each HSC Trust

3.6 PORTFOLIO BREAKDOWN: COMMERCIAL V. NON –COMMERCIAL SPONSORSHIP

NICRN recognises the essential role the commercial sector plays in developing new therapies and interventions. While NICRN prioritises high quality, national publicly funded studies (e.g. NIHR, MRC etc.) it does seek to strike a balance between commercial and non-commercial sector studies. The NICRN Director and Senior Manager have held a series of meetings with senior representatives of the major pharmaceutical industries in the UK and with Clinical Research Organisations to raise the profile of NICRN, to encourage the setup of more clinical trials of investigational medicinal products in N. Ireland and to ensure that NICRN better understands and is responsive to industry requirements. To support better collaborative working the NICRN steering committee has been reconstituted to include representation from both the Association of the British Pharmaceutical Industry and a clinical research organisation.

Each Clinical Specialty Groups agrees a target proportion of commercial sector studies on its portfolio with the NICRN director at a 6 monthly objective setting meetings. Generally, the balance is set at around a 40%:60% (commercial: non-commercial) split, but will vary between CSGs and over time depending on the relative availability of high quality commercial and non-commercial studies at any given time. **Figure 3** and **Table 8,** show the commercial: non-commercial breakdown across the entire NICRN portfolio over the last 3 reporting periods. **Tables 9a** and **9b** show the portfolio breakdown in individual Clinical Specialty Groups**.**

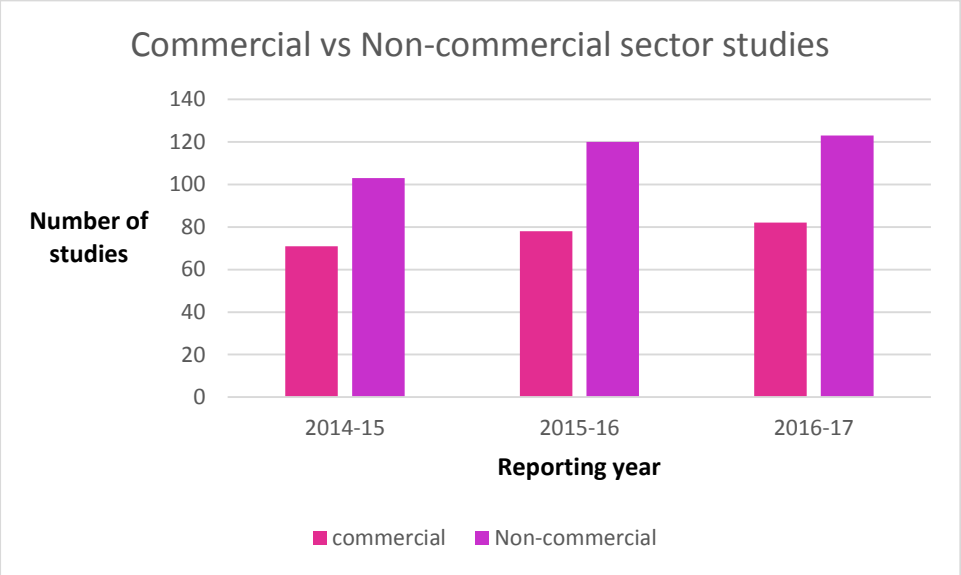

Figure 3. The commercial versus non-commercial breakdown of entire NI portfolio over last 3 years

	Commercial	Non-commercial	% commercial
2014/15	71	103	41%
2015/16	78	120	39%
2016/17	82	123	40%

Table 8 Breakdown between commercial and non-commercial contract studies over the last 3 years across the entire NICRN portfolio

	Cardiovascular	Child Health	Critical Care	Dementia	Diabetes	Gastro-enterology
2014 /15	51.9%	6.7%	11.1%	50%	57.1%	-
2015 /16	54.3%	16.7%	7.7%	80%	62.5%	-
2016 /17	56.4%	18.8%	5.9%	85.7%	82.4%	0&

Table 9a Percentage of commercial studies in each of the Clinical Specialty Group portfolios

	Primary Care	Renal	Respiratory Health	Stroke	Vision
2014 /15	31.3%	41.7%	66.7%	8.3%	60.8%
2015 /16	30.8%	21.7%	57.6%	13.3%	51.9%
2016 /17	38.5%	13.6%	58%	21.4%	42.9%

Table 9b Percentage of commercial studies in each of the Clinical Specialty Group portfolios

3.7 PORTFOLIO BREAKDOWN: RANDOMISED CONTROLLED TRIAL (RCT) V. NON-RCT

Different types of clinical study design may be deployed to answer clinical research questions. A Randomised Controlled Trial (RCT) is a trial in which participants are randomly assigned to one of two or more groups (interventional [test] group and control [comparison] group). This design is commonly used (particularly in studies of investigational medicinal products) for determining the effect of a clinical intervention. However the RCT design may not be a suitable approach for answering other types of research questions such as those looking at identifying disease risk factors, evaluating diagnostic tests or studies using qualitative methods to assess patient/carer experience. To ensure that all types of high quality clinical research studies can be supported it is important that the NICRN portfolio incorporates studies employing a range of study designs. The breakdown of portfolio studies by RCT v. non-RCT is therefore monitored; a 50:50% RCT v. non-RCT split probably represents a reasonable if somewhat arbitrary nominal target. The exact breakdown will vary between Clinical Specialty Groups depending on the types and quality of studies becoming available and will also vary with time.

For the reporting period the .percentage RCTs across the Clinical Specialty Groups ranged from 27.3% (Renal) to 78.6% i (Stroke), **Tables 10a, 10b**.

For the total NICRN study portfolio the percentage RCTs was 56.9%, 53% and 54.6% for the three reporting periods 2014/15, 2015/16 and 2016/17 respectively (**Table 11**).

	Cardiovascular	Child Health	Critical Care	Dementia	Diabetes	Gastro-enterology
	% RCTs	% RCTs	% RCTs	% RCTs	% RCTs	% RCTs
2014/15	40.7%	53.3%	66.75	50%	64.3%	-
2015/16	42.9%	55.65	61.5%	40%	68.8%	-
2016/17	48.7%	68.85	70.65	28.65	76.5%	100%

Table 10a Randomised Controlled Trials (RCTs) as part of the study portfolio for each of the Clinical Specialty groups

	Primary Care	Renal	Respiratory Health	Stroke	Vision
	% RCTs	% RCTs	% RCTs	% RCTs	% RCTs
2014 /15	56.3%	41.7%	71.4%	83.3%	56.5%
2015 /16	46.2%	26.1%	66.7%	86.7%	44.4%
2016 /17	46.2%	27.3%	54.8%	78.6%	50.0%

Table 10b Randomised Controlled Trials [RCTs] as part of the study portfolio for each of the Clinical Specialty groups

Reporting year	RCTs as % of total portfolio
2014/15	56.9%
2015/16	53%
2016/17	54.6%

Table 11 Randomised Controlled Trials (RCTs) as part of the entire NICRN study portfolio

3.8 PORTFOLIO ACTIVITY: TIME FROM STUDY SET UP TO FIRST PATIENT VISIT

The time interval from study set up to first patient visit is an important measure of performance as it indicates the speed with which research teams can recruit patients to the study. The clock only starts when a study has received all relevant approvals to proceed (research ethics and local Trust research governance approval) and when the study sponsor has put in place all other arrangements necessary for the study to commence (e.g. the provision of study medication, study specific training etc). The First Patient First Visit (FPFV) time is a performance measure that is of particular interest to commercial contract studies. Accordingly NICRN now monitors FPFV times broken both by Clinical Specialty Groups and the host HSC Trusts.

Across the Clinical Specialty groups the median FPFV time varies between 19 and 171 days **(Tables 12 and 13**). The variability reflects in part challenging inclusion and exclusion for particular studies that made recruitment difficult. However NICRN recognises the importance of reducing these considerably and is working with NICRN support staff and Clinical Specialty Groups on this.

To align with the National Institute for Health Research Clinical Research Networks (NIHR CRN) High Level Objectives, NICRN will report the % of studies attaining a FPFV of $\leq$ 30days. For 2016/17 **36%** of our total commercial portfolio had a FPFV within 30 days.

	Cardiovascular	**Child Health**	**Critical Care**	**Dementia**	**Diabetes**
2016 /17	40	171	56	21	81.5
	Primary Care	**Renal**	**Respiratory Health**	**Stroke**	**Vision**
2016/17	Not Available	152	30	19	64

Table 12 First **patient first visit intervals expressed as median number of days for each interest group in 2016/17**.

HSC Trust	**First patient first visit [days] median**
Belfast	60
Northern	19
South Eastern	52
Southern	31
Western	18

Table 13 First patient first visit intervals expressed as median number of days for the study portfolio at each HSC Trust in 2016/17

4. NICRN STEERING COMMITTEE

The NICRN steering met on one occasion during the reporting period (29 November 2016) under the chairmanship of the new NICRN Director. It was proposed and agreed that the steering committee should be reconstituted with a new terms of reference and membership to better reflect the strategic objectives of NICRN. In particular there was recognition of the need for stronger patient and public representation on the steering committee. In addition it was proposed that there should be representation from the commercial sector, to include both the pharmaceutical industry and clinical research organisations. It was agreed that the primary aim of the steering committee should be to provide strategic direction for NICRN rather than simply to provide oversight of operational management.. The first meeting of the reconstituted steering committee was scheduled for 15 May 2017.

5 PATIENT &PUBLIC ENGAGEMENT

In line with HSC Research and Development Division policy, NICRN wishes to ensure that Patient and Public Involvement (PPI) is integrated into the research cycle so that researchers prioritise topics that are important to service users and carers and formulate questions, processes and outcomes that are meaningful to people rather than just theresearcher.

The NICRN Steering Committee has been reconstituted to include two PPI representatives. For each of the Clinical Specialty Groups, the management committee must be able to demonstrate appropriate Personal and Public Involvement (PPI) in the decision making process but there is no mandated approach to PPI and committees are free to choose the most appropriate way to involve patients, carers and the public. Five of the 12 Clinical Management Groups currently have PPI members and have full voting rights as regards study adoption.

On International Clinical Trials Day teams of NICRN staff based in each of the HSC Trusts participated public engagement events to raise the profile of clinical research and to encourage patients, carers and the public to ask their health professional about research opportunities ('OK to ask'} that might be available to them and remind health and social care professionals to be research aware.

6. UPDATES FROM THE CLINICAL SPECIALTY GROUPS

This section provides brief updates on the major achievements and challenges experienced by the individual clinical specialty groups in the reporting period.

- **Cardiovascular**

  Leads: Professor Donna Fitzsimons and Dr Patrick Donnelly

The Cardiovascular group remains extremely active with 39 adopted studies and a total of 553 patients recruited in the reporting period. The study portfolio is broadly balanced d as regards RCT.v. non-RCT and commercial v. non-commercial sponsorship. The median recruitment target attained was 97%.

- **Child Health**
  Leads: Dr David Sweet and Dr Anthony McCarthy

The Child Health Clinical Specialty Group continues to be successful in international studies with high levels of recruitment. BHSCT was the international top recruiter in a commercially sponsored study of a new surfactant; the lead author in the resulting publication was from the Belfast team (see below)[1]. Recruitment to the Australian Placental transfusion study and Prednos study also compared very favourably to other international sites.

[1]A first-in-human clinical study of a new SP-B and SP-C enriched synthetic surfactant (CHF5633) in preterm babies with respiratory distress syndrome . David G Sweet,1 Mark A Turner,2 Zbyněk Straňák,3 Richard Plavka,4 Paul Clarke,5 Ben J Stenson,6 Dominique Singer,7 Rangmar Goelz,8 Laura Fabbri,9 Guido Varoli,9 Annalisa Piccinno,9 Debora Santoro,9 Christian P Speer10

Arch Dis Child Fetal Neonatal Ed 2017;0:1–7. doi:10.1136/archdischild-2017-312722

- **Critical Care**
  Lead: Professor Danny McAuley

The Critical Care group remains extremely active with a large and diverse portfolio of studies. NICRN supported studies have yielded high impact journal publications (see below). [1,2] Of these, the REVIVE Trial was jointly supported by the NICRN Respiratory group.[2]

Critical Care studies either led by NICRN members or involving NICRN members as co-applicants were successful in securing >£5m NIHR funding for the following studies:

- **NIHR EME (MRC funded) programme** **£1,570,833** **2017-2021**

  STudy into the REversal of Septic Shock with Beta Blockade (STRESS-BB) 14/150/85.

- **NIHR HTA programme*** **£1,611,095** **2017-2021**

Antifungal stewardship opportunities with rapid tests for fungal infection in critically -ill patients (The AStop Study) (15/116/03)

- **NIHR HTA programme** **£1,881,302** **2017-2019**

Sedation and weaning in children (SANDWICH trial) (15/104/01)

- **NIHR HTA programme** **£1,590,629** **2017-2021**

Biomarker-guided duration of antibiotic treatment in hospitalised patients with moderate or severe sepsis (ADAPT-SEPSIS)(15/99/02)

[1]Levosimendan for the Prevention of Acute Organ Dysfunction in Sepsis
A.C. Gordon, G.D. Perkins, M. Singer, D.F. McAuley, R.M.L. Orme, S. Santhakumaran, A.J. Mason, M. Cross, F. Al-Beidh, J. Best-Lane, D. Brealey, C.L. Nutt, J.J. McNamee, H. Reschreiter, A. Breen, K.D. Liu, and D. Ashby. **N Engl J Med 2016;375:1638-48**

[2]Effectiveness of an exercise programme on physical function in patients discharged from hospital following critical illness: a randomised controlled trial (the REVIVE trial). Kathryn McDowell,1 Brenda O'Neill,1 Bronagh Blackwood,2 Chris Clarke,3 Evie Gardner,4 Paul Johnston,5 Michaeline Kelly,6 John McCaffrey,7 Brian Mullan,8 Sally Murphy,8 T John Trinder,9 Gavin Lavery,8 Daniel F McAuley,2,4,8 Judy M Bradley2 McDowell K, et al. **Thorax 2016;0:1–10. doi:10.1136/thoraxjnl-2016-208723**

- **Dementia**

Leads: Professor Peter Passmore and Dr Stephen Todd

The Dementia specialty group showed a sharp increase in activity with seven studies adopted, recruiting 412 patients and overall the median percentage recruitment target attained was 100%. Two of the seven portfolio studies were RCTs.

- **Diabetes**

Leads: Professor Vivien Coates and Dr Hamish Courtney

The Diabetes group study portfolio continues to increase with a high proportion of commercially sponsored studies and RCTs reflecting the recent development of new classes of antidiabetic drugs.

In conjunction with Diabetes UK, the group has further developed partnerships with patients by establishing a patient group be involved in the development and review of research proposals

Co-lead Prof VE Coates represented NICRN Diabetes group at Diabetes UK Development Group and is a member of Clinical Study Group 5: Long term self-management and glycaemic control.

Co-Lead Prof VE Coates attended the World Congress Clinical Trials in Diabetes and presented a poster 'Building a Clinical Research Network to support clinical trials in Diabetes in N. Ireland'

- **Gastroenterology**

Leads: Dr Peter Watson and Dr Patrick Allan

The Gastroenterology group commenced activity during the reporting period and adopted one study. A promising pipeline of commercial sponsored and other studies has been identified and a sharp increase in activity is anticipated for 2017/2018

Mental Health
Leads: Professor Gerry Leavey and Dr Ciaran Mulholland

Although the Mental Health network did not formally adopt any studies in the reporting period, a research officer was appointed which will act as a significant enabler for future study adoption. The Mental Health Clinical Management Group has now representatives from all five HSC Trusts and also a clinical trainee representative. The leads have been active in promoting the Mental Health network, engaging with the pharmaceutical industry and attendance at national meetings to identify a pipeline of studies for adoption in 2017/18

- **Primary Care**
  Leads: Mrs Claire Leathem. Co-lead post is currently vacant

Professors Margaret Cupples and Carmel Hughes who were co-leads of the Primary Care team for a number of years have stood down. The NICRN management team wishes to acknowledge and thank them for their leadership in developing the Primary Care group so successfully to its current high level of activity across N. Ireland to the extent that of the 339 general practices in N. Ireland, 84 (24.7%) have been active in supporting to NICRN adopted studies. Mrs Claire Leathem has taken over as a co-lead. The second co-lead post remains vacant at the time of writing.

In collaboration with direct clinical care staff in individual general practices, NICRN and the Primary Care team are addressing challenges in the processes for patient screening to assess suitability for entry to NICRN adopted studies.

- **Renal**
  Leads: Professor Peter Maxwell and Dr Neal Morgan

The Renal group retains an active portfolio of studies. The relatively small proportion of commercially sponsored studies (13.6%) compared to previous years reflects a diminished pipeline of new pharmaceutical products in this disease area. Despite this activity levels remain high with observational studies and studies addressing quality of life issues contributing to the portfolio. The ratio of patient screened to recruited is extremely high at 1 : 1.16 , indicating very efficient screening and recruitment processes.

- **Respiratory Health**
  Leads Professor Judy Bradley and Dr Lorcan McGarvey

The Respiratory Health group recruited 154 patients to 31 research studies in the reporting period. Recruitment was extremely successful across the portfolio of studies with a median percentage recruitment

target attainment of 100%. Recruitment was particularly high for the EMBARC and EMEE-TIPAC studies and with the N. Ireland team among the highest recruiters for a large EU grant funded study. A study co-ordinator was invited to present at an international meeting to showcase and share best practice in patient recruitment.

The Knowledge Exchange project team were invited to present at The Association of Chartered Physiotherapists in Respiratory Care and have had an abstract accepted for the World Bronchiectasis Conference

- **Stroke**

Leads: Dr Michael Power and Mrs Carolee McLaughlin

The Stroke group remains active with 205 patients recruited to 14 research studies in the reporting period. The lower proportion of commercial studies (21.4%) reflects a reduced pipeline of new investigational medicinal products being developed in this disease area. However this has been compensated by an increase in the number of qualitative and observational studies. Patient recruitment is high with a median percentage target recruitment attainment of 77%.

- **Vision**

Leads: Professor Julie Silvestri and Professor Jonathan Jackson

The Vision group recruited 325 patients to 28 studies over the reporting period. The study portfolio is balanced with 42.9% commercially sponsored and 50 % of RCT design. The median percentage recruitment TARGET attained was 80%. Currently all research activity in the Vision group is based in the Belfast HSC Trust and the Leads will liaise with colleagues in the Ophthalmology service in the Western HSC Trust and the Optometry Department at Ulster University's Coleraine campus to explore the possibility of opening NICRN adopted studies in the north west.

APPENDICES

APPENDIX 1

Clinical Specialty Group	Clinical Lead
Cardiovascular	Professor Donna Fitzsimons (QUB) / Dr Patrick Donnelly (SEHSCT)
Child Health	Dr David Sweet (BHSCT) / Dr Anthony McCarthy (BHSCT)
Critical Care	Professor Danny McAuley (QUB)
Dementia	Professor Peter Passmore (QUB) / Dr Stephen Todd (WHSCT)
Diabetes	Professor Vivien Coates (UU) / Dr Hamish Courtney (BHSCT)
Gastroenterology	Dr Peter Watson (BHSCT) / Dr Patrick Allan (SEHSCT)
Mental Health	Professor Gerry Leavey (UU) / Dr Ciaran Mulholland (NHSCT)
Primary Care	Mrs Claire Leathem (BHSCT) /To be confirmed)
Renal	Professor Peter Maxwell (BHSCT) / Dr Neal Morgan (SHSCT)
Respiratory Health	Professor Judy Bradley (QUB) / Dr Lorcan McGarvey (QUB)
Stroke	Dr Michael Power (SEHSCT) / Mrs Carolee McLaughlin (BHSCT)
Vision	Professor Julie Silvestri (BHSCT) / Professor Jonathan Jackson (BHSCT)