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Evolution of the Research Workforce

Nicolas Aldridge – Lead Nurse R&D

Clinical Research at UHCW

Background: 2015/16

- 4500 recruited patients per year

- 66 wte Clinical Research Staff (Delivery Team)
- 53 Nurses/Midwives
- 7 Assitant Research practitioners
- 6 Research Administrators
- 2.69 Research Data Clerks

- 27 specialities

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Challenging Times

- Centre for Workforce Intelligence (2014) – predicted 47500 fewer nurses by end 2016

- The RCN estimated that in 2014 around 10,000 nurses and health care support workers made up the research workforce

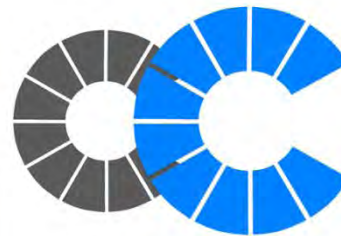- Difficulty to recruit to Research Nurse posts

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Right person for the right job !

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"A method to determine the percentage of time nurses spend delivering direct patient care"

CareClox

"I am delighted to see how the innovation and collaboration of nursing and IT staff have produced a fantastic product that gives greater clarity and management information to better plan safe and sustainable staffing. The tool was developed from a manual system, that whilst very useful was time consuming for the nurses to complete. This was counter to the approach of releasing time for nurses to spend with their patients. The development of this app has been a phenomenal technical achievement and now has captured over 7000 hours of clinical time, highlighting how teams spend their time with patients. This has saved over 76k of resources and significant hours of nursing and care time."
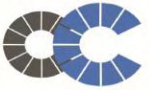
Professor Mark Radford
Deputy Director of Nursing, NHSi

Adapted for our research teams

Direct Care	Indirect Care	Non Patient Activity
Medicines	Research Documentation	Protocol Review
Patient Communication	Data Entry	Feasibility
Nursing/Clinical Procedures	Data Queries	Study Set up
Patient Data Collection	Screening	Monitor Meetings
Recruitment	Data Collection	Professional Communication
	Sample Handling	Administrative

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CareClox
Setting a new benchmark for determining Direct Contact Time with patients.

An electronic solution for **data collection and real-time reporting**, CareClox makes analysis of clinical activity quick and easy, offering an unparalled level of insight which can ultimately lead to an increase in time spent directly with patients.

10 Teams over 2 weeks
3,100 hrs data collected

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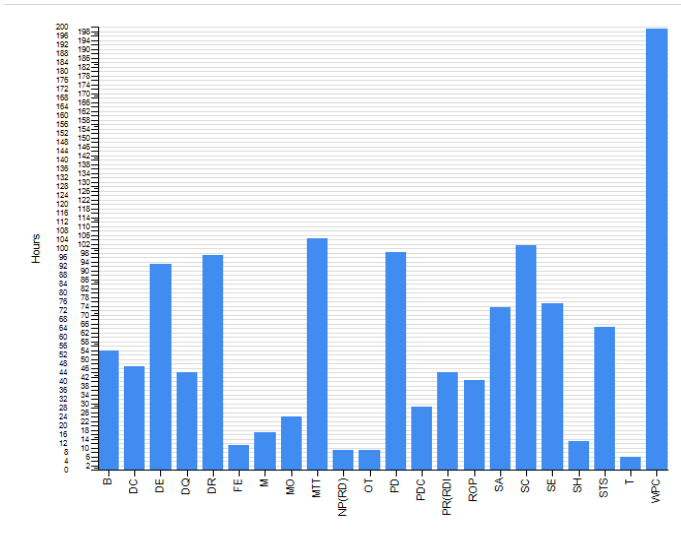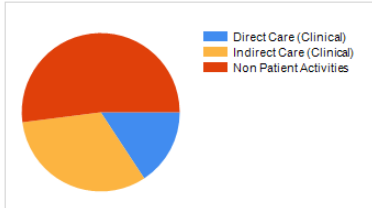NHS Trust

Research Nurse All Tasks

Time Spent on Tasks by Job Titles
11/1/2016 12:00:00 AM to 8/31/2017 12:00:00 AM

Job Title: Registered Nurse (R)

Category	Hours	Percentage
Direct Care (Clinical)	197.00	15.71 %
Indirect Care (Clinical)	404.67	32.27 %
Non Patient Activities	652.42	52.02 %
	1254.09	100.00 %

Direct Care (Clinical)
Indirect Care (Clinical)
Non Patient Activities

Category	Task Code	Task	Hours	Percentage
Direct Care (Clinical)	M	Medicines	17.17	1.37 %
Direct Care (Clinical)	NP(RD)	Nursing Procedures	9.17	0.73 %
Direct Care (Clinical)	PD	Patient Communication	98.25	7.83 %
Direct Care (Clinical)	PDC	Patient Data Collection	28.42	2.27 %
Direct Care (Clinical)	PR(RDI)	Recruitment	44.00	3.51 %
Indirect Care (Clinical)	DC	Data Collection	46.75	3.73 %
Indirect Care (Clinical)	DE	Data Entry	93.08	7.42 %
Indirect Care (Clinical)	DQ	Data Queries	44.25	3.53 %
Indirect Care (Clinical)	OT	Ordering tests	9.17	0.73 %
Indirect Care (Clinical)	DR	Research Documentation	97.00	7.73 %
Indirect Care (Clinical)	SH	Sample Handling	13.08	1.04 %
Indirect Care (Clinical)	SC	Screening	101.33	8.08 %
Non Patient Activities	B	Breaks	53.92	4.30 %
Non Patient Activities	FE	Feasibility	11.08	0.88 %
Non Patient Activities	MTT	Meetings	104.33	8.32 %
Non Patient Activities	MO	Monitor Visits	24.25	1.93 %
Non Patient Activities	WPC	Professional Communication	199.25	15.89 %
Non Patient Activities	ROP	Review of Protocols	40.42	3.22 %
Non Patient Activities	SE	Staff Education	75.08	5.99 %
Non Patient Activities	SA	Study related admin	73.50	5.86 %
Non Patient Activities	STS	Study Set up	64.75	5.16 %
Non Patient Activities	T	Travel	5.83	0.47 %

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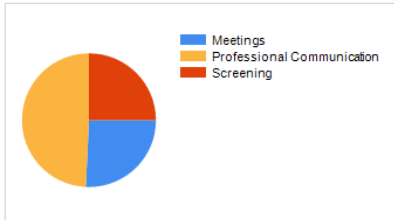NHS Trust

Research Nurse
Top 3 Tasks

Top Three Time Spent on Tasks by Job Titles
11/1/2016 12:00:00 AM to 8/31/2017 12:00:00 AM

Job Title: Registered Nurse (R)
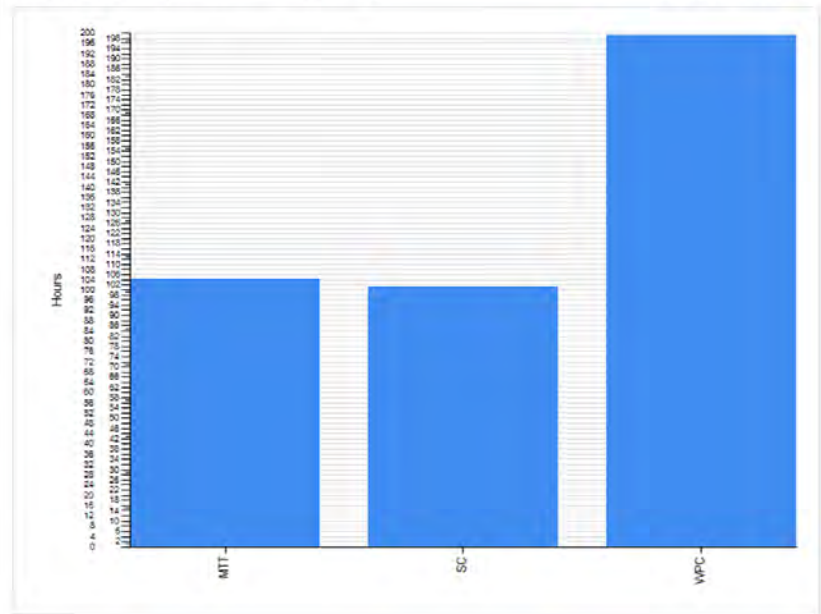
Category	Hours	Percentage
Direct Care (Clinical)	197.00	15.71 %
Indirect Care (Clinical)	404.67	32.27 %
Non Patient Activities	652.42	52.02 %
	1254.09	100.00 %

- Meetings
- Professional Communication
- Screening

Category	Task Code	Task	Hours	Percentage
Non Patient Activities	WPC	Professional Communication	199.25	15.89 %
Non Patient Activities	MTT	Meetings	104.33	8.32 %
Indirect Care (Clinical)	SC	Screening	101.33	8.08 %

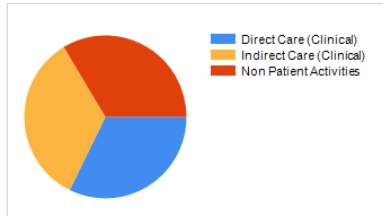| Category	Task Code	Task	Hours	Percentage
Non Patient Activities	WPC	Professional Communication	199.25	15.89 %
Non Patient Activities	MTT	Meetings	104.33	8.32 %
Indirect Care (Clinical)	SC	Screening	101.33	8.08 %

Research Assistant Practitioner All Tasks

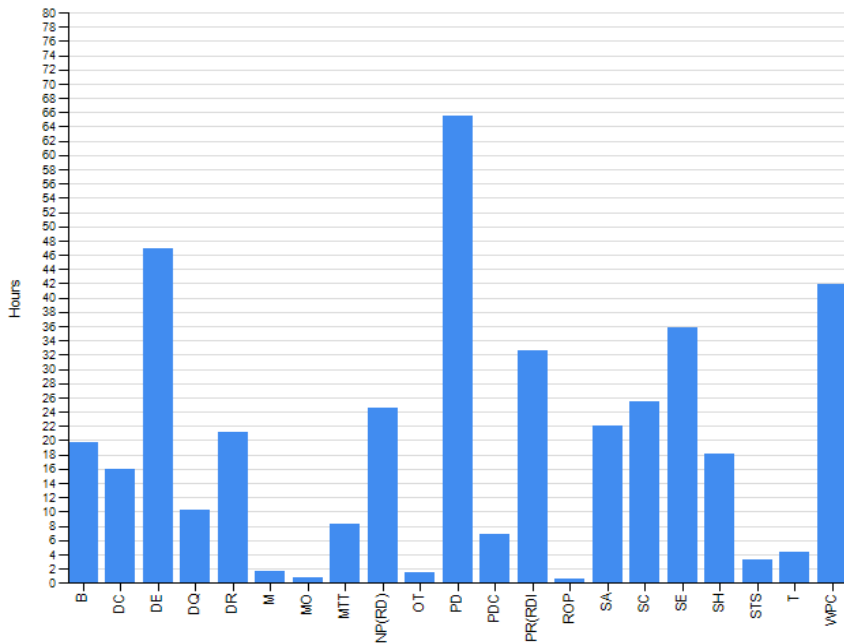### Time Spent on Tasks by Job Titles
11/1/2016 12:00:00 AM to 8/31/2017 12:00:00 AM

Job Title: Research Assistant Practitioner (R)

Category	Hours	Percentage
Direct Care (Clinical)	131.33	32.26 %
Indirect Care (Clinical)	139.08	34.17 %
Non Patient Activities	136.67	33.57 %
	407.08	100.00 %

- Direct Care (Clinical)
- Indirect Care (Clinical)
- Non Patient Activities

Category	Task Code	Task	Hours	Percentage
Direct Care (Clinical)	M	Medicines	1.67	0.41 %
Direct Care (Clinical)	NP(RD)	Nursing Procedures	24.58	6.04 %
Direct Care (Clinical)	PD	Patient Communication	65.58	16.11 %
Direct Care (Clinical)	PDC	Patient Data Collection	6.92	1.70 %
Direct Care (Clinical)	PR(RDI	Recruitment	32.58	8.00 %
Indirect Care (Clinical)	DC	Data Collection	15.92	3.91 %
Indirect Care (Clinical)	DE	Data Entry	47.00	11.55 %
Indirect Care (Clinical)	DQ	Data Queries	10.17	2.50 %
Indirect Care (Clinical)	OT	Ordering tests	1.42	0.35 %
Indirect Care (Clinical)	DR	Research Documentation	21.08	5.18 %
Indirect Care (Clinical)	SH	Sample Handling	18.08	4.44 %
Indirect Care (Clinical)	SC	Screening	25.42	6.24 %
Non Patient Activities	B	Breaks	19.75	4.85 %
Non Patient Activities	MTT	Meetings	8.25	2.03 %
Non Patient Activities	MO	Monitor Visits	0.83	0.20 %
Non Patient Activities	WPC	Professional Communication	41.83	10.28 %
Non Patient Activities	ROP	Review of Protocols	0.67	0.16 %
Non Patient Activities	SE	Staff Education	35.75	8.78 %
Non Patient Activities	SA	Study related admin	22.00	5.40 %
Non Patient Activities	STS	Study Set up	3.25	0.80 %
Non Patient Activities	T	Travel	4.33	1.06 %

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Research Assistant Practitioner Top 3 Tasks

Top Three Time Spent on Tasks by Job Titles
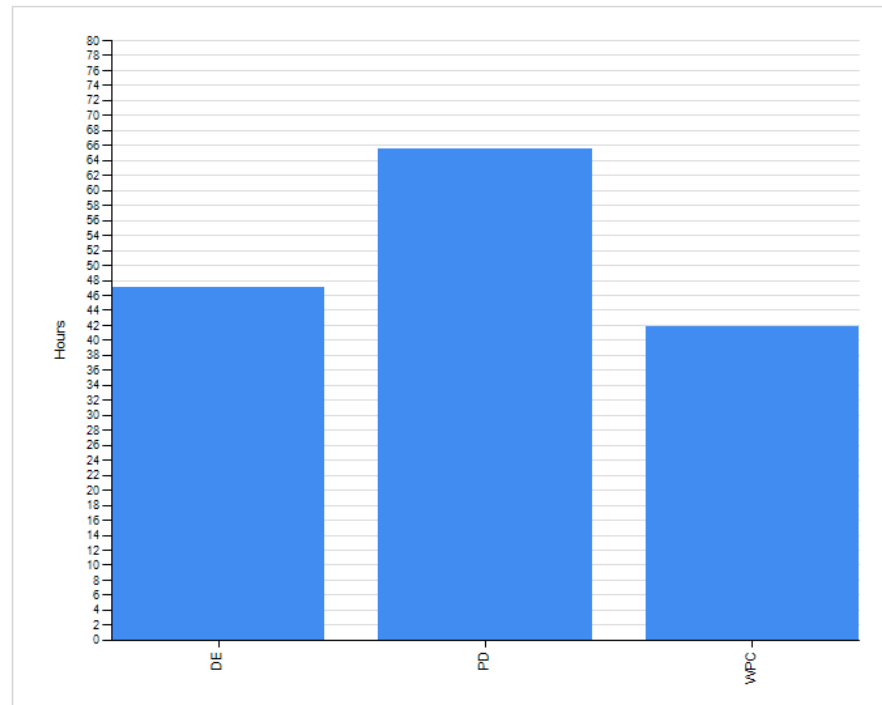11/1/2016 12:00:00 AM to 8/31/2017 12:00:00 AM

Job Title: Research Assistant Practitioner (R)

Category	Hours	Percentage
Direct Care (Clinical)	131.33	32.26 %
Indirect Care (Clinical)	139.08	34.17 %
Non Patient Activities	136.67	33.57 %
	407.08	100.00 %

Data Entry
Patient Communication
Professional Communication
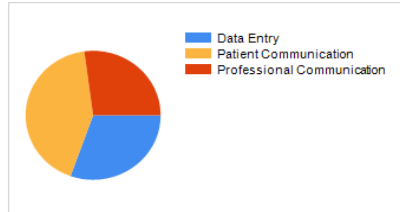
Category	Task Code	Task	Hours	Percentage
Direct Care (Clinical)	PD	Patient Communication	65.58	16.11 %
Indirect Care (Clinical)	DE	Data Entry	47.00	11.55 %
Non Patient Activities	WPC	Professional Communication	41.83	10.28 %

Category	Task Code	Task	Hours	Percentage
Direct Care (Clinical)	PD	Patient Communication	65.58	16.11 %
Indirect Care (Clinical)	DE	Data Entry	47.00	11.55 %
Non Patient Activities	WPC	Professional Communication	41.83	10.28 %

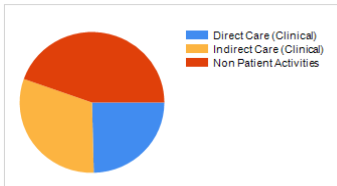University Hospitals
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Research Midwife All Tasks

Time Spent on Tasks by Job Titles
11/1/2016 12:00:00 AM to 8/31/2017 12:00:00 AM

Job Title: Registered Midwife (R)

Category	Hours	Percentage
Direct Care (Clinical)	57.50	24.61 %
Indirect Care (Clinical)	72.00	30.81 %
Non Patient Activities	104.17	44.58 %
	233.67	100.00 %

Direct Care (Clinical)
Indirect Care (Clinical)
Non Patient Activities

Category	Task Code	Task	Hours	Percentage
Direct Care (Clinical)	M	Medicines	2.25	0.96 %
Direct Care (Clinical)	NP(RD)	Nursing Procedures	6.58	2.82 %
Direct Care (Clinical)	PD	Patient Communication	25.33	10.84 %
Direct Care (Clinical)	PDC	Patient Data Collection	3.58	1.53 %
Direct Care (Clinical)	PR(RDI	Recruitment	19.75	8.45 %
Indirect Care (Clinical)	DC	Data Collection	5.25	2.25 %
Indirect Care (Clinical)	DE	Data Entry	23.17	9.91 %

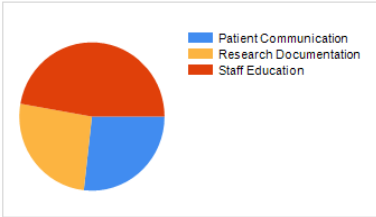| Category	Task Code	Task	Hours	Percentage
Direct Care (Clinical)	M	Medicines	2.25	0.96 %
Direct Care (Clinical)	NP(RD)	Nursing Procedures	6.58	2.82 %
Direct Care (Clinical)	PD	Patient Communication	25.33	10.84 %
Direct Care (Clinical)	PDC	Patient Data Collection	3.58	1.53 %
Direct Care (Clinical)	PR(RDI	Recruitment	19.75	8.45 %
Indirect Care (Clinical)	DC	Data Collection	5.25	2.25 %
Indirect Care (Clinical)	DE	Data Entry	23.17	9.91 %
Indirect Care (Clinical)	DQ	Data Queries	9.67	4.14 %
Indirect Care (Clinical)	OT	Ordering tests	0.33	0.14 %
Indirect Care (Clinical)	DR	Research Documentation	24.58	10.52 %
Indirect Care (Clinical)	SH	Sample Handling	3.67	1.57 %
Indirect Care (Clinical)	SC	Screening	5.33	2.28 %
Non Patient Activities	B	Breaks	9.17	3.92 %
Non Patient Activities	FE	Feasibility	0.50	0.21 %
Non Patient Activities	MTT	Meetings	15.83	6.78 %
Non Patient Activities	MO	Monitor Visits	2.08	0.89 %
Non Patient Activities	WPC	Professional Communication	21.25	9.09 %
Non Patient Activities	ROP	Review of Protocols	1.33	0.57 %
Non Patient Activities	SE	Staff Education	44.67	19.12 %
Non Patient Activities	SA	Study related admin	5.08	2.18 %
Non Patient Activities	STS	Study Set up	1.00	0.43 %
Non Patient Activities	T	Travel	3.25	1.39 %

Research Midwife Top 3 tasks

Top Three Time Spent on Tasks by Job Titles
11/1/2016 12:00:00 AM to 8/31/2017 12:00:00 AM

Job Title: Registered Midwife (R)

Category	Hours	Percentage
Direct Care (Clinical)	57.50	24.61 %
Indirect Care (Clinical)	72.00	30.81 %
Non Patient Activities	104.17	44.58 %
	233.67	100.00 %

Pie chart legend:
- Patient Communication
- Research Documentation
- Staff Education

Category	Task Code	Task	Hours	Percentage
Non Patient Activities	SE	Staff Education	44.67	19.12 %
Direct Care (Clinical)	PD	Patient Communication	25.33	10.84 %
Indirect Care (Clinical)	DR	Research Documentation	24.58	10.52 %

Category	Task Code	Task	Hours	Percentage
Non Patient Activities	SE	Staff Education	44.67	19.12 %
Direct Care (Clinical)	PD	Patient Communication	25.33	10.84 %
Indirect Care (Clinical)	DR	Research Documentation	24.58	10.52 %

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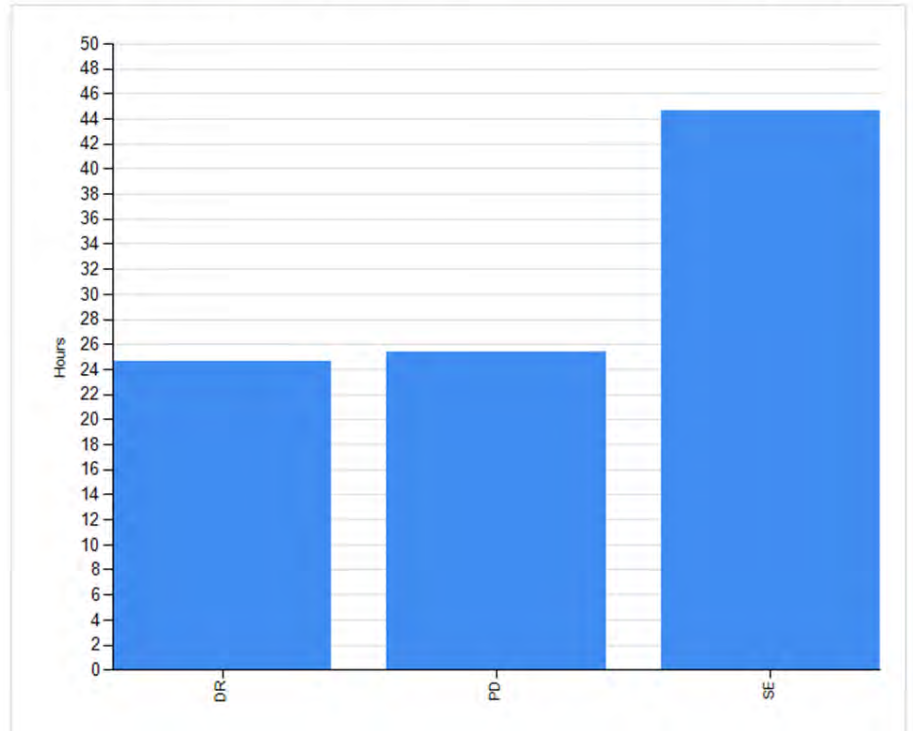
Results

Research Nurses and Midwives spend ¼ of time on direct care, ½ time on patient related activities and remaining time on non-patient activities.

Research assistant practitioners spent a total of ¾ of their time on patient related activities.

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Do We Need Nurses ?

RIGHT PEOPLE. RIGHT SKILLS. RIGHT NOW.

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Changes

New Posts Created : Clinical Trial Co-ordinator (B5)

Replacements not like for like

Increased Data support

Increased ARP

Implementation

Before CC codes	After CC codes
53 nurses/midwives	49 nurses/midwives
7 ARP	12 ARP
6 research administrators	6 research administrators
2.69 Data	4.69 Data
	3 clinical Trial Co-ordinators
Total – 68.69 wte	Total- 74.69 wte
	Difference: increase by 6 staff

732 hrs increase per month in nurse time from existing workforce

318 hrs increase from new roles

HOW ?

Data Staff now take 300 hrs per month

5 ARP (3 replaced other posts) 2 new posts = 300 hrs per month

3 new CTC = 450 hrs per month

Total – 1050 hrs

732 hrs previous work now releases nurse/midwives

Remainder 318 hrs additional

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Cost

Difference in staffing cost + £64k per year

Cost Saving – To increase nursing team
by 732 hrs per month £186k per year

186k – 64k = Total Saving £122k

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Increased Value and Opportunity

Increased patient facing time- value for patient & staff

Increased R&D people power

Opportunity to explore new talent sources

Value £$£$

Addresses workforce challenges

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Thank You

Acknowledgements:

Julie Jones

Judith Smith

Jane Rush

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RCN International Nursing Research Conference 2018

The unique role of the research nurse in delivering clinical research

Fiona Kinnaird, Lead Research Nurse,
Royal Marsden NHS Foundation Trust, London

Kay Walker, Clinical Research Nurse Manager,
Ninewells Hospital & Medical School, Dundee

Introduction

- The role of the clinical research nurse (CRN) within the NHS.

- An overview of how this role links nursing, science and medicine.

- Impact of demand for research delivery staff on job roles and titles.

- The recognition of the role as a speciality.

- Lack of clarity around roles and responsibilities.

- Expansion of the role to streamline care delivery.

- Difficulties faced by CRNs to identify their unique contribution.

Setting the scene

1981:

- the quality of clinical therapeutic studies improved when CRNs were involved;

- CRN role has evolved since then (influenced by the needs of pharma for support with drug development programmes).

- Increase in demand for CRNs with subsequent growth in the variety of roles and titles

Definition

The International Association of Clinical Research Nurses - Definition 2012:

"Clinical Research Nursing is the **specialized** practice of professional nursing focused on maintaining equilibrium between **care of the research participant** and fidelity to the research protocol. This specialty practice incorporates human subject protection; care coordination and continuity; contribution to clinical science; clinical practice; and study management throughout a variety of professional roles, practice settings, and clinical specialties."

International Association of Clinical Research Nurses. (2012) "Enhancing Clinical Research Quality and Safety Through Specialized Nursing Practice". Scope and Standards of Practice Committee Report.

NIHR 2017-2020 Clinical Research Nurse Strategy

Improve awareness and understanding of the specialty of clinical research nursing and its contribution and impact.

Develop leaders to share best clinical research nursing practice locally, nationally and internationally.

Promote innovation in research delivery practice to include the use of digital technologies to improve data quality and enable novel ways of using resources.

Create a clinical research culture that is patient and public focused

NIHR 2017-2020 Clinical Research Nurse Strategy

Strategy emphasises the role played by Research Nurses (Nursing Times)

- **CRNs to read strategy and think "this is the direction I wish to go";**

- Trusts to embrace strategy as it will have an impact on patient care;

- NHS to recognise research nurses as an incredibly important workforce.

Roles and responsibilities - confusion

Clinical research nurse or nurse researcher…

Clinical Research Nurse	Nurse Researcher
Advanced clinical skills too enable coordination and management of one or more clinical trials	Academic career path- **Master's degree or PhD.**
Adherence to study protocols and procedures, research governance requirements and patient safety.	Baseline knowledge of research methodologies.
Role is based around supporting other **people's** research ideas.	Develop own ideas into robust research questions and projects.
Monitoring the health status of 'their patients'.	Complete design of research and relevant documents.

Jones, H. (2015) Clinical research nurse or nurse researcher? Nursing Times; 111: 19, 12-14.

Roles and responsibilities - evolution

➤ Clinical Research Nurses - seen as cost effective as they were able to undertake tasks that crossed boundaries including:
- set up clinical trials;
- process blood samples;
- enter data;
- deliver drugs, care for patients.

➤ Increase in research activity in the NHS has helped new roles emerge to streamline this activity including trial co-ordinators and laboratory staff.

➤ Workforce shortages, increasing patient acuity - introduction of staff to take on routine tasks including clinical trial administrators and health care assistants.
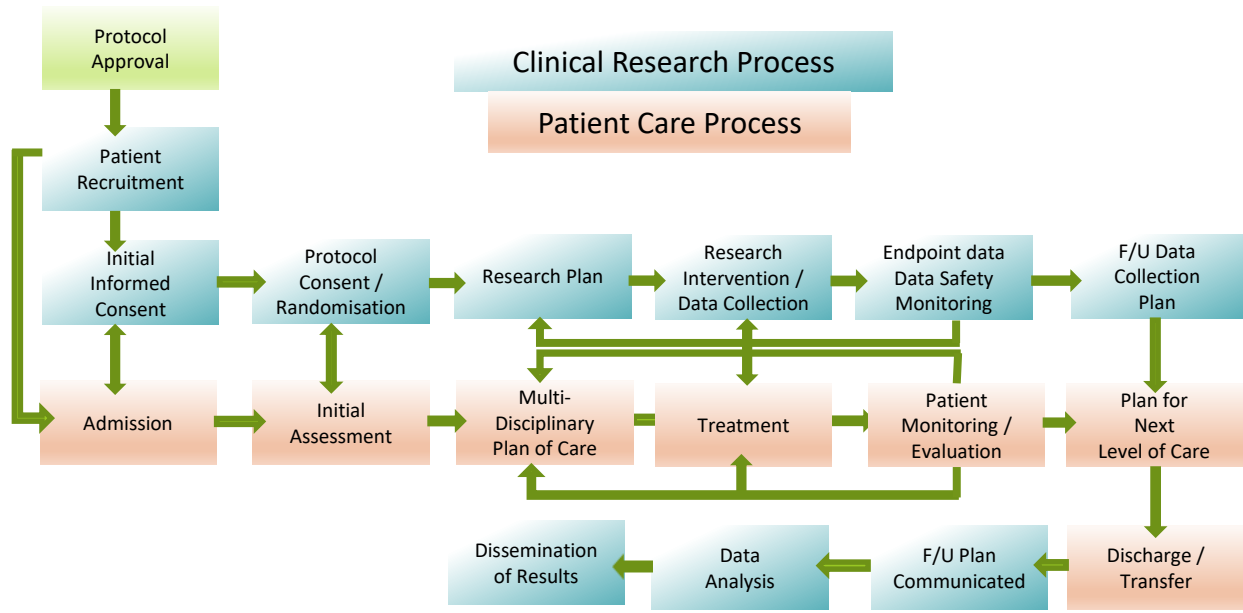
OUTCOME: Increase in research capacity

Maximising Skills-the participant journey
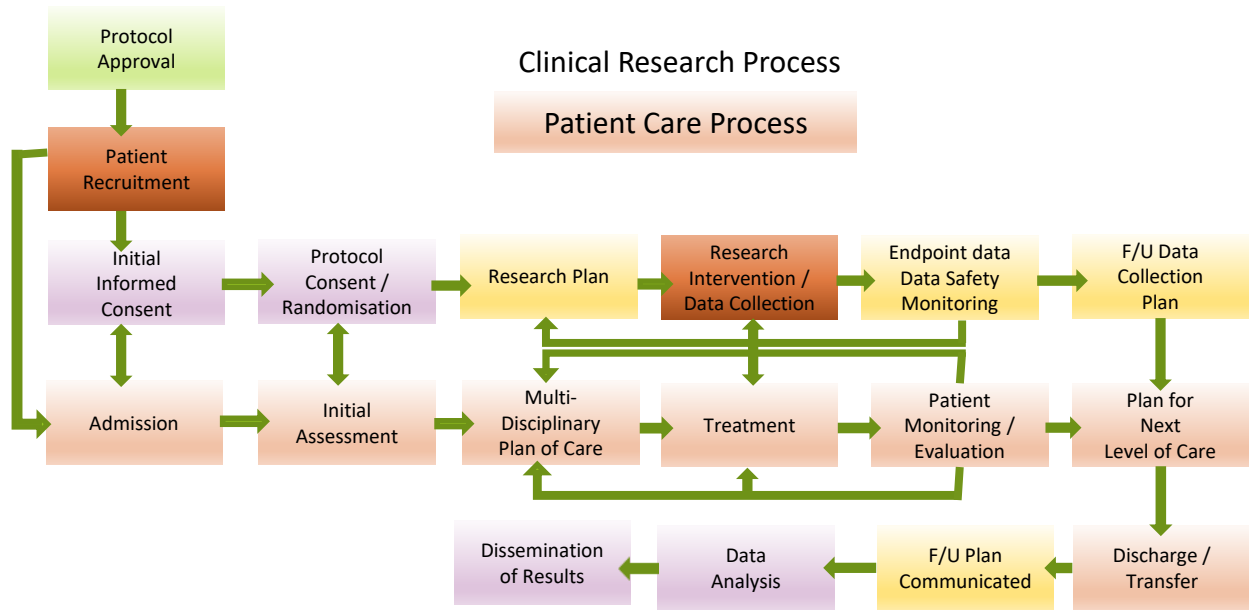
Adapted from: Hastings, C., Fisher, C. and McCabe, M. (2012) 'Clinical research nursing: A critical resource in the national research enterprise'. *Nursing Outlook*, 60 (3), pp. 149 - 156.

Capturing Uniqueness - impact of the CRN role

Legend:
- R &D
- Nurse
- Patient

Clinical Research Process (Nurse)
Patient Care Process (Patient)

Clinical Research Process (top row):
Protocol Approval → Patient Recruitment → Initial Informed Consent → Protocol Consent / Randomisation → Research Plan → Research Intervention / Data Collection → Endpoint data Data Safety Monitoring → F/U Data Collection Plan

Patient Care Process (middle row):
Admission → Initial Assessment → Multi-Disciplinary Plan of Care → Treatment → Patient Monitoring / Evaluation → Plan for Next Level of Care

Bottom row:
Dissemination of Results ← Data Analysis ← F/U Plan Communicated ← Discharge / Transfer

Adapted from: Hastings, C., Fisher, C. and McCabe, M. (2012) 'Clinical research nursing: A critical resource in the national research enterprise'. *Nursing Outlook*, 60 (3), pp. 149 - 156.

Why is there a need to defining the unique role of the CRN?

- CRNs often have difficulty in describing their role to others

- Need to clarify the role of the CRN in the multidisciplinary research team

- Inform decisions regarding accountability and delegation of work within the team

- Inform decisions regarding research delivery workforce and skill mix

- Ensure that research participants receive the right care, in the right place at the right time from the right person

- Participants have an the right to know what they can expect from a registered nurse

Do you need a CRN?

Nursing is…..

"…**use of clinical judgement in the provision of care to enable people** to improve, maintain, or recover health, and to achieve the best **quality of life whatever their disease or disability until death.**"

Royal College of Nursing (2014), Defining Nursing, London RCN

"…**autonomous and collaborative care of individuals of all ages,** families, groups and communities, sick or well and in all settings. Nursing includes the promotion of health, prevention of illness, and the care of ill, disabled and dying people. Advocacy, promotion of a safe environment, research, participation in shaping health policy and in patient and health systems management, and education are also key nursing roles.

International Council of Nurses (2002) The ICN Definition of Nursing. Geneva:ICN

Defining Characteristics
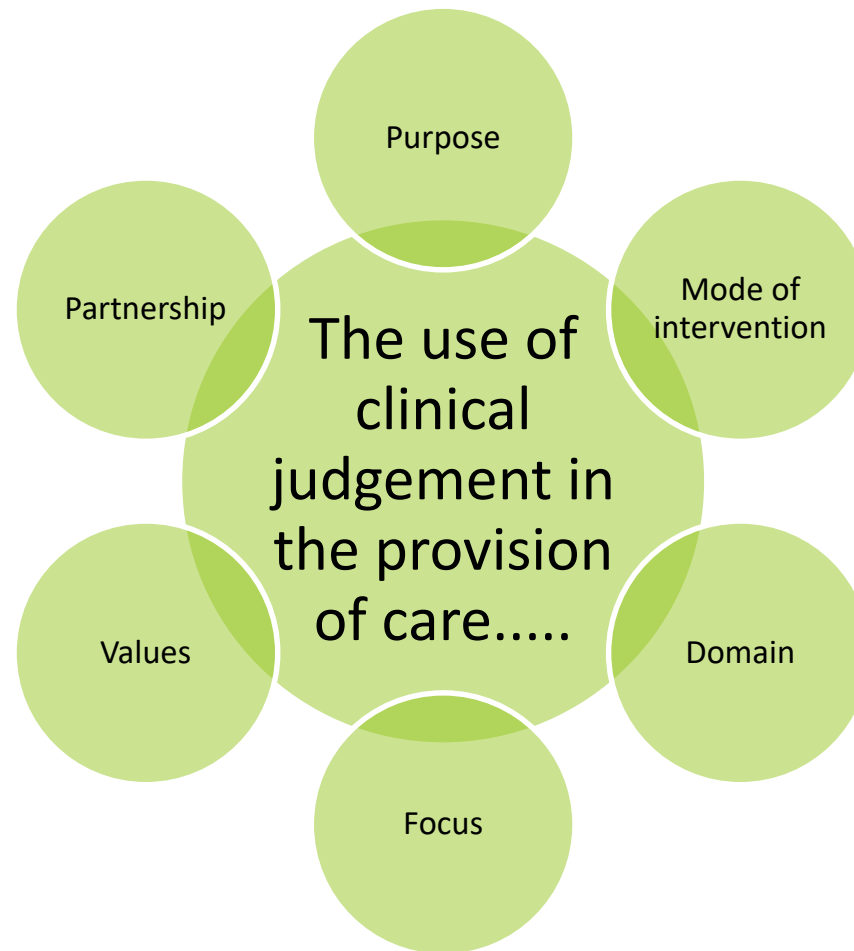
Domains of clinical research nursing practice
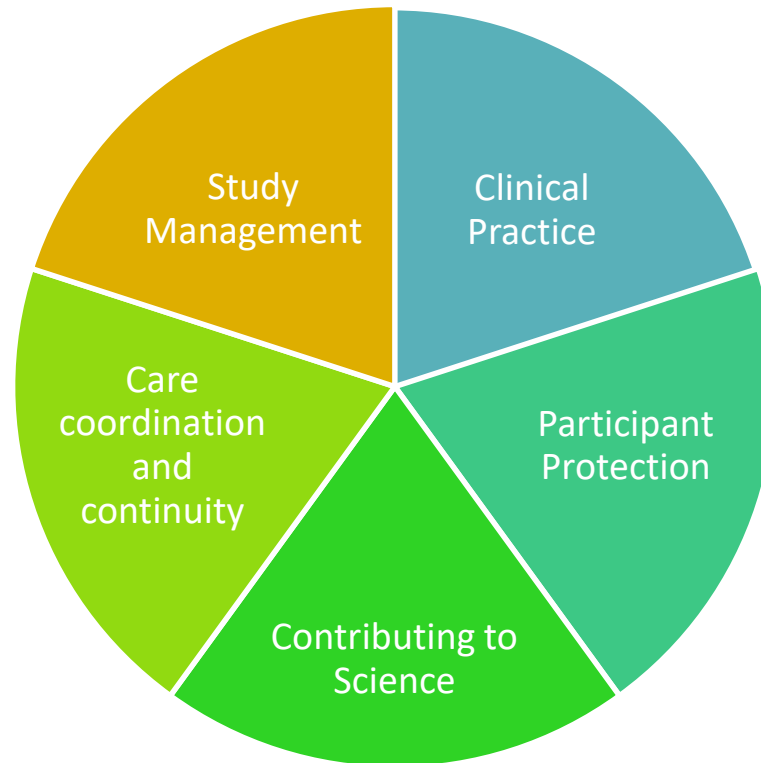
International Association of Clinical
research Nurses (2012), Enhancing clinical
research quality and safety through
specialised nursing practice, Scope and
standards of practice committee report

14

Case study

Role of the CRN coordinating a drug trial for patients with a diagnosis of Idiopathic Pulmonary Fibrosis.

The research delivery workforce is evolving

- Increase in the development of roles that do not require clinical professional registration

- Development of the clinical research practitioner role as an integral part of the research delivery workforce

- Blurring of boundaries between CRN and other patient facing roles often encompass responsibilities previously the remit of the CRN

- Myriad of titles, roles and NHS AfC Banding describing non-registered roles

- **New Posts advertised with the job title as "Research Nurse/Clinical Trial Practitioner"**

Professional Identity - Extended role

"I am a direct care-giver, advocate and clinician"

"The role encompasses academic, financial, managerial and administrative boundaries"

"I have core clinical values in which I balance between caring for participants and delivering clinical research "

"I have a range of skills, regularly practising with a high degree of autonomy in decision making and problem solving".

"I give compassionate care"

"I use intuition and clinical judgement when recruiting to studies"

"I use clinical instinct to guide my decisions"

Raja-Jones, H. (2002) 'Role boundaries – research nurse or clinical nurse specialist? A literature review'. *Journal of Clinical Nursing*, 11: 4, pp. 415 - 420.
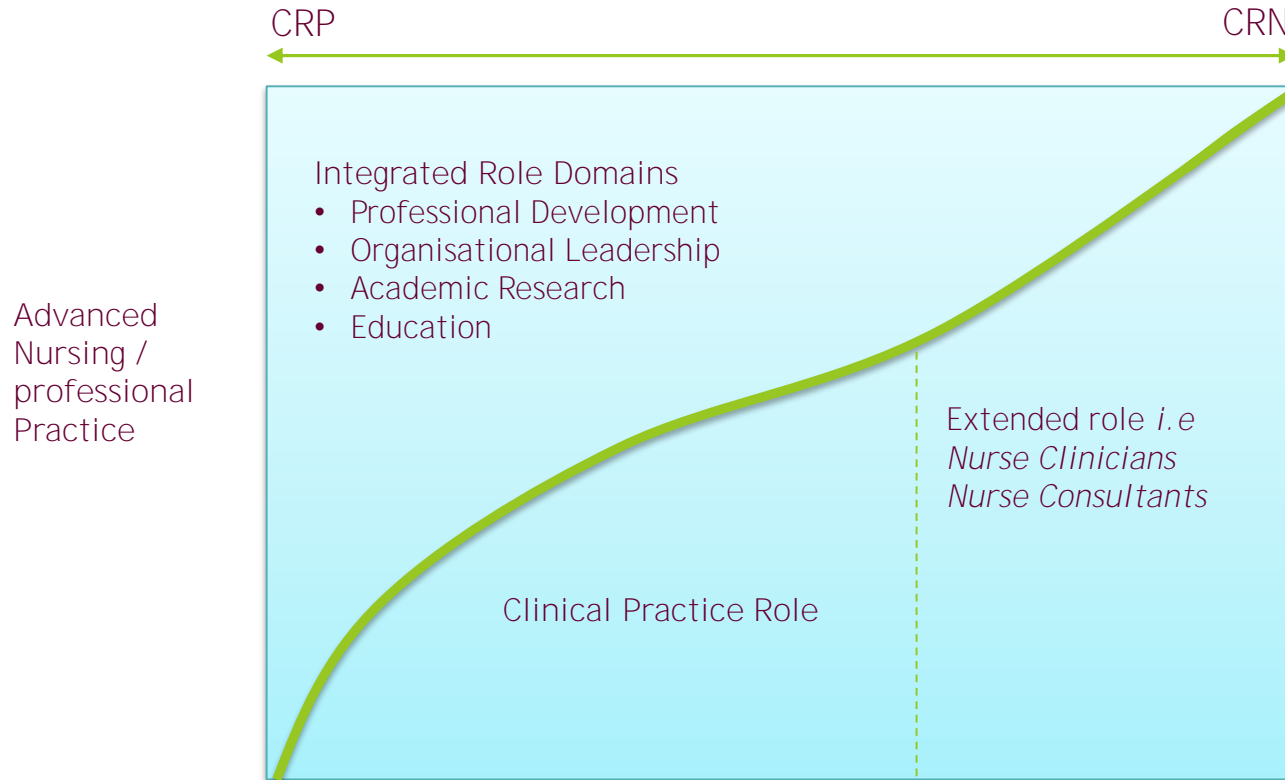
Tinkler, L., Smith, V., Yiannakou and Robinson, L. (2018) 'Professional identity and the Clinical Research Nurse: A qualitative study exploring issues having an impact on participant recruitment in research'. *Journal of Advanced Nursing*, 74, pp. 318 - 328.

Professional Identity - CRN contribution

Clinical Research Nurses

Clinical Research Practitioners (CRP)

Clinical Research Staff

Advanced Nursing Skills - Extended Role
Influence change to improve patient health
(clinical, educational, professional development,
organisational and research activities)

Competency Training in Research
Health Science Degree
Allied Health Professional
On going professional development

Competency Training in Clinical Research
Variety of roles and responsibilities

Professional Identity

Continuum of Clinical Research Role

CRP ⟷ CRN

Advanced Nursing / professional Practice

Integrated Role Domains
- Professional Development
- Organisational Leadership
- Academic Research
- Education

Extended role *i.e Nurse Clinicians Nurse Consultants*

Clinical Practice Role

Adapted from Bryant-Lukosius, D. *et al.* (2004) 'Advanced practice nursing roles: development, implementation and evaluation'. *Journal of Advanced Nursing*, 48: 5, pp. 519 - 529.

Nurses do not want to lose their identity within clinical research but to have an acknowledgement that their value and contribution is important.

References

Barnes, G. (1981) 'The nurse's contribution to the Medical Research Councils trial for mild hypertension'. *Nursing Times;* 77: 29, pp. 1240-1245.

Bryant-Lukosius, D. *et al* (2004) 'Advanced practice nursing roles: development, implementation and evaluation'. *Journal of Advanced Nursing*, 48: 5, pp. 519 - 529.

Hastings, C., Fisher, C. and McCabe, M. (2012) 'Clinical research nursing: A critical resource in the national research enterprise'. *Nursing Outlook*, 60 (3), pp. 149 - 156.

International Association of Clinical Research Nurses. (2012) "Enhancing Clinical Research Quality and Safety Through Specialized Nursing Practice". Scope and Standards of Practice Committee Report.

International Council of Nurses (2002) The ICN Definition of Nursing. Geneva:ICN

Jones, H. (2015) 'Clinical research nurse or nurse researcher?' *Nursing Times;* 111: 19, 12-14.

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