




Florence
Nightingale
Foundation

Review of research
nursing and midwifery across
the UK and Ireland in 2017:

Structures, strategies and sharing

The Whitehouse Report
June 2018

Igniting leaders, fuelling potential.



“ For us who nurse, our nursing is a thing which unless we are making progress every year, every month, every week, take my word for it, we are going back... ”

Florence Nightingale

Claire L. Whitehouse, MSc, RN, PGC Research Methods, MRCN, IACRN, #WhyWeDoResearch Originator, Florence Nightingale Foundation Scholar (Research scholar 2010/11 & 2014/15, Travel scholar 2016/17)
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Notes by the author

In November 2016, I was awarded a Travel Scholarship from the Florence Nightingale Foundation (FNF) to investigate nursing and midwifery research structures and strategies across the United Kingdom (UK) and Ireland.

The Foundation awards scholarships to advance the study of nursing and midwifery and to promote excellence in practice. It raises funds to support clinical individuals to extend knowledge and skills, and promote innovation to improve patient care.

The purpose of the Scholarship project was to assist in the development of a nursing and midwifery research strategy at the James Paget University Hospitals NHS Foundation Trust (JPUH). Furthermore, it aimed to review nursing and midwifery research structures and strategies present in other organisations; to share working practices and processes; and to increase international research links.

The scholarship contract involved completion of a written report within three months of travel completion. This report is available through the FNF website at www.florence-nightingale-foundation.org.uk and as per the guidance provided, focused on the impacts made locally.

There has been no other platform of work completed in this way, therefore this second voluntary report provides an initial foundation to research nurse and midwife structures and strategies. Further publications based on individual themes will be released in professional journals throughout 2018. The project identified; positive working practices, issues to be addressed, gaps for future research, and celebrations.

This report focuses on nursing and midwifery research roles. It is a project which could be replicated easily, and I would happily share my approach should someone choose to take up the mantle for Allied Health Professionals (AHPs) and Clinical Support Officer/Trials Assistant based roles.

Many clinical trials and other studies would not run efficiently (or in some cases at all) without the expertise and specialism of clinical research nurses. I ask myself many questions: have we (CRN/Ms) unwittingly contributed to this viewpoint? Are we so busy that we are unable to describe what we do? Is it easy to describe the breadth of our roles? Do we contribute to the body of work 'out there' to demonstrate our impact? And is it demonstrated enough to show the true importance of CRN/M posts? There remains confusion between CRN/M and nurse/midwife researcher for example. Does this project and consequent report answer all the questions? Perhaps not. Does it assist in making a start? I hope so and for those who have acted as my critical friends (thank you), it appears to be useful from local and country-wide perspectives.

In the midst of undertaking this project, our site was allocated a substantial funding reduction which almost destabilised the department. I was fortunate, not only that we have a supportive Executive Team who took time to listen and assist us, but also that colleagues understood the value of this scholarship project; we were able to utilise some of the knowledge gleaned by that point towards the appeal work.

In ever changing economic times, I believe we as a CRN/M workforce should be showcasing working practices, clearly demonstrating and evidencing impact and having pride in the service we provide; recognising how much we impact patient's lives and experiences.

I feel a professional responsibility to share what I have learnt, not only because I have seen direct impacts from this type of information and work locally, but because so many organisations, sites and individuals voluntarily participated in this independent project and gave their views so freely and honestly.

This report seems the best way to say thank you, and to practice what I preach in contributing to the literature.



Claire Whitehouse, 2018
MSc, PGC Research Methods,
Intensive Care Spec. BSc. IACRN.

Collaborative foreword by formal contributors to the project

The essence of this project was collaborative enquiry to demonstrate gaps and celebrate impacts within the research nursing and midwifery world. It is therefore fitting that the foreword represents international collaboration and learning, with statements from country representatives and others with direct influence on the project.

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I am keen as Chief Nursing Officer for England to strengthen the involvement of nursing and midwifery staff in research and how nursing and midwifery staff can be supported in their roles with a focus on evidence-based practice. Therefore, I have been pleased to sponsor the Travel Scholarship for the author of this work and have been very interested in the results of this work.

Jane Cummings, Chief Nursing Officer for England

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I had the pleasure of being the midwifery representative for this project and am proud to have my name included in this report. Evidence-based care is seen as ‘the gold standard’ and research is one of the main ways to gather information to develop our knowledge, skills, how we care for patients and their families, drugs and medical devices. Research Nurses/Midwives are a vital resource in developing, leading and supporting research. Yet, we are, mainly, without strategies and structures to develop, lead and support the very staff that nearly all healthcare research relies on – nurses and midwives. We have the opportunity to build on the fantastic work done by Claire Whitehouse and I very much hope that our profession continues to grow and gain greater recognition for all that it achieves.

Hazel A Smith,
MSc, BSc, Communications Officer for the Irish Research Nurses Network and Research Coordinator (Clinical Midwifery Manager II for Research) for the Paediatric Intensive Care Unit in Our Lady’s Children’s Hospital, Crumlin, Ireland.

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The Irish Research Nurses Network (IRNN) were delighted and privileged to be involved in Claire’s project. It tapped into our own need to articulate the unique contribution of research nurses, and how the role bridges the divide between clinical practice and scientific research, and we were energised by Claire’s enthusiasm and dedication. It also highlighted that research nurses face the same challenges internationally, and that, through networking and collaboration, we can collectively develop our identity and visibility.

Deirdre Hyland
MSc, Chairperson Irish Research Nurses Network (Ireland)

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The UK and Ireland branch of the International Association of Clinical Research Nurses was established in 2016 to promote the role of the CRN and facilitate professional development and recognition. It is increasingly clear that in an environment where clinical research is a multinational endeavour, that CRNs can share resources and learn a great deal from international colleagues. The UK and Ireland branch of the IACRN act as a conduit for information; regularly organising Twitter chats to bring together the International CRN community. As a branch we commend this report and the growing body of information that sheds light on the vital importance of the CRN in Clinical Research.

Gordon Hill, MSc & Jennifer Allison, Co-Chair of the International Association of Clinical Research Nursing United Kingdom and Ireland Branch

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I had the privilege of being part of the interview panel for Claire's Florence Nightingale Foundation Research funding. Nursing Research like the modern profession of Nursing itself owes much to Florence Nightingale and her critical analysis of treatments and experiences at the English General Hospital Scutari Turkey during the Crimean War. Nightingale published an 800-page report using statistics to argue her case for improving sanitation and medical care in military and civilian hospitals. The death rate when she arrived at Scutari was almost 43%; six months later it had fallen to 2.2%, providing convincing evidence that her methods worked. Nightingale's detailed analysis gave birth to the field of Nursing Research which gradually came into its own as an independent field of investigation.



I would personally wish to congratulate all research nurses for the valuable ground-breaking work they have done over decades, however I would also wish to ask for people of influence, politicians, hierarchy of Nursing and Medical organisations to work alongside our Research Nurses, read, digest and implement their work, or openly discuss why not? As a former Parliamentary Under Secretary of State for NHS Services and a Registered Nurse, I was aware our nursing teams were always under pressure; speaking out with evidence is not always easy, I do not imagine Florence found her meetings all that welcoming but, a table statue of her is still in place when I last looked in The White Room in 10 Downing Street. She must wonder sometimes where we all are?

Continued Professional Education, open minds and hearts will save lives and resources. Thank you, Claire, for agreeing for me to be your mentor for this important work, I would still accept a role in your team!

”

Professor Ann Lloyd Keen R.N NDN.
Trustee Florence Nightingale Foundation, Fellow of Queens Nursing Institute. Hon.
Professor of Innovation Policy Practice Nursing Geriatric Care. Senior Scholar
Hartford Institute Geriatric Nursing New York University.

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The members of the Scottish Research Nurse and Coordinators Network (SRNCN) welcomed the opportunity to be part of a much wider scoping exercise by Claire; building a picture of the different research nursing structures in the UK and Ireland. We can become quite insular in our practices, but with this piece of work, an evidence base has been gathered so that we can understand how the differing structures impact on the research nurse workforce, and learn from each other, without having to reinvent the wheel.

”

Carole Edwards,
Chairperson Scottish Research Nurse and Coordinators Network (Scotland)
And Lead Research Nurse, NHS Grampian





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The Northern Ireland Clinical Research Network (CRN NI) were delighted to assist Claire in her review of research nursing and midwifery structures and sharing of learning across the UK and Ireland 2017. Prior to this, very little research/work has been conducted to assess the impact of different leadership and organisational structures on assuring and advancing teamwork and collaboration. This work is vital for our future research nurse workforce.

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Sonia McKenna, Staff Manager, Northern Ireland Clinical Research Network Staff Manager

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1. Executive Summary

Structures of CRN/M delivery teams varied by site and by country; there is currently no model which fits every organisation. Information identified within this project shows pitfalls to avoid for those in early stages of research team development, following experiences shared by those in larger departments. For more established research teams this project highlights good working practices to continue to develop and maintain a core CRN/M team. Smaller organisations demonstrated many good working practices which larger organisations were, and are, able to adopt.

Sites judge 'success' on team development, growth, progress and staff and patient experiences, alongside awareness, and where possible achievement of national targets and policies. Organisations/funding bodies base success on targets and policies as a priority to demonstrate quantitative evidence of impact. Many representatives within these organisations however, are moving towards other qualitative routes, recognising that not all impact is demonstrable through figures.

A meaningful oversight post with nursing/midwifery AND research background, as well as a strong patient focus, is critical to forging progress for CRN/M teams. This role also impacts the likelihood of active nursing/midwifery research within an organisation.

Engagement of Trust/Hospital Executive Teams and true commitment to research objectives and ambitions impacts team progress, structures and consequent availability of studies to patients.

Funding is a major issue with both positive and negative impacts however the link to Executive Teams and their understanding of, and active commitment to, research is viewed as an over-riding factor. This also relates to external funders having clear understanding of issues and celebrations at each site when allocating funds at annual timepoints.

Strategies for growth are viewed as essential by all organisations, however success or lack of strategy correlates with the success or lack of a clear research infrastructure.

Successful strategies are inclusive of those who they will impact at planning stages; full consultation exercises and opportunities to input ideas are essential. Strategies are unsuccessful or have a lack of 'buy in' from teams where the above processes do not occur or are implemented by individuals/groups whose roles are not strategic (or they are unaware of the detail within the roles they are altering).

Demonstrating impact and raising research awareness is high on all agendas from individuals to government bodies. To enable demonstration of impact, support must be available from all organisations and sites, led from the top. Nurses and midwives need to be encouraged, supported and given dedicated time away from the clinical environment to publish and disseminate their work.

Some excellent national events are held in all five countries which showcase work being undertaken by CRN/M teams and nurse/midwife researchers. There are also some exceptional local symposiums demonstrating effective impacts in improving awareness of the roles and patient care.

There appears to be a mis-match between national organisations and local sites around priorities, structures and level of progress. For example, nationally (all countries) there is a desire to implement nurse/midwife PI roles, however in many areas locally this has been happening for some time. Increased collaboration between organisations and improved communication routes may assist in sharing these working practices more freely and easily, preventing duplication.

Information gained through this scholarship has assisted in the development of the first Model for Developing Clinical Research Nursing and midwifery structures; The Whitehouse-Smith model (**Appendix six**).



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2. Introduction

The purpose of the Travel Scholarship (incorporating England, Ireland, Scotland, Wales and Northern Ireland) was to:

- ♥ **Review** the research nursing and midwifery structures and strategies present in organisations;
- ♥ **Review** how these structures and strategies were created;
- ♥ **Share** working practices and processes;
- ♥ **Increase** international research links; and
- ♥ **Assist** in the development of a research nursing strategy for The James Paget University Hospitals NHS Foundation Trust (JPUH).

2.1 Introduction to research nursing/ midwifery background

Local background

The authors' hospital site serves a population of around 230,000 residents as well as to visitors to the part of East Anglia, and is supported by a number of outreach clinics around the geographical area. The hospital has c500 inpatient beds located on the main hospital site, plus escalation beds where necessary for critical areas. The Trust employs >3000 staff, making it the largest local employer.

Four key values underpin the work that is conducted at JPUH:

- ♥ **Putting** patients first
- ♥ **Aim** to get it right
- ♥ **Recognise** that everybody counts
- ♥ **Do** everything openly and honestly.

Research activity within JPUH gradually increased throughout the last decade, with particular growth during 2006 and 2012. During 2015 an eight-post (staffing) business plan was submitted to the Trust to enable reinvestment from research income to both the clinical and non-clinical sides of the research team. The success of this plan directly influenced the next stage of growth.

Following the transition of the NIHR Clinical Research Networks in 2014 there was a subsequent landscape shift in and around 2016. This impacted directly on research nursing and resulted in the original business plan potentially no longer being the most appropriate or effective use of resources. It was recognised that a formal strategy was required which prior to this point had not been long-term.

To avoid a reactive approach to advertising these posts, it seemed more prudent to gain knowledge and experience from other sites to inform our decision; therefore, this project was created, and Travel Scholarship applied for.



UK and Ireland

Across these five countries, national commitments have been made to support research:

- ♥ **England** (NHS Constitution 2013 and 2015, Health and Social Care Act, 2012, NHS England 2013 and recently again in 2017)
- ♥ **Ireland** (Health Research Board 2016)
- ♥ **Northern Ireland** (Research for Better Health and Social Care Strategy 2016-2025)
- ♥ **Scotland** (Delivering Innovation through Research - Scottish Government Health and Social Care Research Strategy, Chief Scientists Office, 2015)
- ♥ **Wales** (Public Health Wales, 2015 and Health and Care Research Wales, 2015 & 2017).

The National Institute for Health Research (NIHR) (2017) have published a Clinical Research Nursing Strategy which recognises CRN/Ms place as 'visible leaders' and sets strategic goals for 2017-2020. This is the first focused strategy of its kind which acknowledges the research nursing and midwifery workforce for their skills, knowledge and unique leadership position in forging evidence-based change, as well as promoting areas where more work is required.

In terms of commitment to clinical research nursing and midwifery, it could be argued that we are behind in terms of evidencing the impact and importance of this role. CRN/Ms have recently described their roles through publication in attempt to raise the profile and awareness of the tasks they undertake, predominantly

through Journals with wide nursing-based audiences (Pick et al, 2011, Gibbs and Lowton, 2012*, Hamer, 2015, NIHR 2016 and Hyland and Clarke-Moloney, 2016); a number of blogs are also available (e.g. Gleason 2013, EMERGE 2014, Cancer Research UK, 2015, Bailey, 2016).

Elsewhere across the four nations, there is no specific national CRN/M strategy outside of developing home-grown research and working towards clinical-academic pathways. Whilst these are extremely important aspects of nursing and midwifery research and should certainly not be ignored, there appears to be a lack of focus on the large CRN/M workforce already in place who have excellent study delivery skills, and the potential to be developed further whilst remaining in the clinical environment. It would appear the notion of 'research nurse/midwife' versus 'nurse/midwife researcher' are still muddled by those unfamiliar with the differences (Jones, 2015); this could explain the lack of inclusion of the CRN/M delivery workforce in national strategies. It is important to evidence the value of these roles and this is a gap in the current literature.

Australia and New Zealand

Work on the role of the CRN/M focuses mainly on role content in Australia and New Zealand (Wilkes et al, 2012 and Barthow et al 2014). Reviewing the literature and job descriptions has shown that the role is slightly different when compared with the UK and has more combination of research nurse/midwife running hosted studies as well as conducting studies of their own, therefore arguably are not comparable for the purposes of this project alone.

Work has begun on evidencing knowledge and skills required of these roles across Australia with a prime example by Scott et al (2011), which designed, piloted and fully implemented a role-based questionnaire to 61 respondents focusing on the knowledge and skills of cancer clinical trials nurses. The results of this study showed the questionnaire as reliable and assisted in implementing a development programme for the local site.

America

The American Nurses Association (ANA) and the International Association of Clinical Research Nurses (IACRN) released the first Scopes and Standards for Clinical Research Nursing globally in October 2016 (IACRN, 2016). The Association worked over a number of years collating evidence to describe the types of roles and tasks undertaken by CRNs and scoped internationally both for literature and consultation exercises. All CRN publications from the UK were utilised in the document and this equated to under 5% of the literature.

The IACRN document displays the first ever acknowledgement of clinical research nursing as a speciality in its own right by a country's organisation representing the nursing profession. It is therefore a huge stepping stone towards formal recognition of research nursing as a specialism.

The UK and Ireland (as with other countries globally) are behind the ANA and IACRN in acknowledgement and/or recognition of the work undertaken by CRN/M staff. CRN/M's should contribute to the body of knowledge demonstrating their value by sharing their experiences, learning, expertise and team developments with others through publication and other formal dissemination routes if the role is to survive the economic climate.

3. Summary of the project

Planning

- ♥ As no previous review of nursing and midwifery research structures has been designed in this format, the project was undertaken as an enquiry/ service evaluation rather than as a protocol-focused research study. There was potential for growth within the project and the purpose was to glean and share information and working practices rather than work to a hypothesis.
- ♥ The initial plan was to visit sites from each country who were smaller than JPUH, around the same size (from a research perspective) and much larger, with the aim that strategies and structures be reviewed, learnt from and our own shared. Adult, mental health, paediatrics, community and secondary care sites were involved.

Networking

Initial identification of sites was through the **#WhyWeDoResearch** social media twitter campaign (www.whywedoresearch.weebly.com), the authors professional research networks and the Florence Nightingale Foundation Chairs network.

Participating sites

- **34 organisations** across five countries were involved. These included: Governments/ Government research representatives, National forums/groups, Clinical sites (e.g. NHS Trusts, Hospital Working Groups, Health Research Boards), Academic Institutions, and Cancer Research Networks/Centres. This was framed down further in to 44 separate research teams.
- **88 staff** were directly involved in the project and included: Lead Nurse/Midwife for Research (LRN/M), Research Matrons (RM), Clinical Nurse Managers (CNM), Clinical Midwifery Manager (CNM) Director and Associate Directors of Nursing/ Midwifery (DON/DOM), Chairman/woman, Chief Executives, Clinical Research Nurses and Midwives (CRN/MS) at various levels, physiotherapists, radiographers, Clinical Trials Assistants, Administrators.
- Meetings with sites generated discussion at international levels across the research field. Requests to meet with Governments, other National bodies and groups whilst in each country or prior to visiting showed the value they placed on building this foundation of work.

Geographical locations of sites



Practical arrangements and data collection

General

- ♥ Country-wide lead contacts were identified through the networking routes listed above
- ♥ A lead contact was identified at each participating site who was provided with a project synopsis
- ♥ All countries except England participated across set weeks (to assist with funding allocation and full-time LRN role)
- ♥ Visits included introduction to teams and tours of the research facilities
- ♥ Meetings were held either as groups/seminars or as 1-2-1 meetings - this was based purely on staff availability around clinical commitments. The site contacts pre-arranged timings and set agendas to allow any staff who wished to be involved the opportunity to do so
- ♥ In all cases, it was left to staff to choose whether they were happy for their line manager to be present
- ♥ At 90% of sites, the contact arranged additional meetings with representatives from their Executive Teams voluntarily.

Specific

- ♥ Each session (regardless of site or organisation) began by sharing the JPUH research structure and development charts (**see Appendices four and five**) and with justification for the project provided.
- ♥ Participants were free to discuss this however they wished. All sites immediately reflected upon their own structure (either by printing off organisational structures or explaining that there was no defined structure in place). This naturally developed into discussions around strategies, development for staff and opportunities for patients.
- ♥ Field notes were recorded throughout the discussion and a verbal summary provided at the end of the allocated time to ensure the main points had been captured.
- ♥ Where particularly poignant or passionate comments were made, quotes were recorded and confirmed by the individual as correct. Field notes were reviewed and completed in detail every evening to ensure completeness and allow reflection upon any arising themes.
- ♥ Any queries following visits were addressed through email or telephone.
- ♥ Participants were provided with contact details and were able to get in touch should they think of anything they wished to add following visits.
- ♥ As the year progressed, certain themes became clear regardless of country, therefore only at this point was the discussion guided in latter site visits to draw upon themes in more detail.
- ♥ Information from all sites was reviewed following the final site visit.
- ♥ Thematic analysis was utilised (despite being service evaluation/professional enquiry as opposed to formal research project) to establish themes.
- ♥ Themes were also reviewed on a country-specific basis where working practices, funding and stage of development varied.
- ♥ Major themes are demonstrated within this report. Further detail of themes will be published separately through a number of articles in professional journals during 2018.

Funding

- ♥ The project was awarded £3,500 in November 2016 and £3,484 was spent. A further £1,250 was generated by linking visits with invitations to speak at Conferences. Through designing this project to generate additional funds, it allowed a larger number of sites to participate.
- ♥ Nine conference and event presentations were made across all five countries; highlighting the work in this scholarship as it progressed, and about the #WhyWeDoResearch campaign (**see appendix two**).
- ♥ Over 6,150 miles were travelled over a nine-month period from November 2016. Public transport was utilised wherever possible (i.e. Trains and planes) and advanced booking for Hotels ensured reduced pricing.

Appendix One describes the project aims, mid-point status and outcome.

Appendix Two: Dissemination of project through Conference and Event presentations and tweekchats.

Appendix Three: Project challenges and opportunities

In November, the project
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4. Structures

4.1 Structures summary

At JPUH, 'structure' is a piece of work which has been a focus for the past five years across both the clinical and non-clinical sides of the research team. The structure has been reviewed twice in this period and was due a third time as we were about to expand the team further (**Appendix four**). It was interested to see how other sites were structured and what we could learn from and share with them. As Lead Nurse for Research, an additional focus was placed on development within the structure, including staff skills and opportunities for progression.

25% of sites were unsure how many CRN/Ms were working in their organisation. This was reflected across all countries

65% of sites showed organisational charts provided from their Executive teams which did not include Research and Development (R&D) Departments; often where research was included this was placed under 'Corporate' divisions/structures.

25% of sites demonstrated research as being under clinical divisions on organisational charts.

10% of Research, Development and Innovation (titles varied but were generally inclusive of these words) Departments had clear reporting structures for their teams overall and through to Chief Executive Officers and representation at Board level.

75% of the sites did not have a written structure in terms of development for CRN/Ms. Of the 25% that did, the content varied from informal charts, to others which were agreed and confirmed by Trust Executive Teams.

Fig 1. Hospital/Trust stats

- ♥ Where structures were present for research team staff, there was a segregated approach for delivery staff, ie CRN/Ms, and Nurse/Midwife Researchers ie those undertaking their own research. Country-wide differences were apparent here and are discussed later in the report (eg. There are no Research and Development (R&D) Departments in Irish Hospitals).
- ♥ There did not appear to be any correlation with the size of Trust/Hospital Group and likelihood of having a written structure in place. There was a slight tendency for smaller (research population-wise) Trusts to have structures documented in various forms demonstrating growth, than some of the larger hospital sites.
- ♥ A major factor as to whether documented structures for CRN/Ms was available, was if a LRN/M/RM/CNM/CMM was in post with responsibility for complete oversight of all research across the site. Where these were in post, current evidence, or evidence of working on structures was very clear, particularly when combined with a positive relationship with the DON. The impact of these roles and the type of person required became one of the projects key themes and is discussed later in the report.

Structures and reporting lines for CRN/Ms and nurse/midwife researchers varied amongst the following:

- ♥ No clinical line management alongside no 'dotted line' to clinical nursing/midwifery support.
- ♥ Direct report to a Consultant or medical colleague working on the same study, or in the same disease area with no input to the study being ran. No links to a wider research team within the organisation.
- ♥ Band 7 Senior Clinical Research Nurses (SCRN) - direct report to LRN/M/RM/CNM/CMM
- ♥ Nurse/Midwife researchers; usually sporadic with no clear link eg.
 - a) reporting to an academic supervisor with no clinical role;
 - b) reporting to a clinical supervisor with past experience in the disease area;
 - c) reporting to the hospital R&D office (with no set name/line manager) d) reporting to funder with no line management. One reported 'dotted line' line management to the LRN in their organisation.

4.2 Structures: Learning and themes

Structure requirements/formal reviews and perceptions

- ♥ Of the sites who did not have a formal, documented structure, it was evident that this inhibited some integration with the rest of the clinical staff in the Trust. A relationship between integration and Executive Team engagement was evident (discussed further within the 'Strategies' section).
- ♥ 80% of sites with demonstrable hospital structures in place, had had formal structure reviews in the past three years and generally felt these were useful in solidifying their place within the organisation. The other 2% had not experienced reviews but were happy with their structures and felt they worked well for staff and patient opportunities to participate in research.
- ♥ Some staff felt roles required review prior to any potential restructure as either they felt they were working above their banding/grade without acknowledgement, or did not understand some of the other roles within their team. Others felt the whole structure (documented or 'assumed') required a full review as it no longer reflected their current teams.
- ♥ There were clear view points from staff regarding role review and restructures (both positive and negative);

View 1 - "It's about time we had a clear structure, this way we can demonstrate to others what we do, where we fit in and why it's important for patients"

View 2 - "This is my opportunity to showcase exactly how much I do that goes unrecognised"

View 3 - "they want to down-grade us to change our role from nursing/midwifery, to one without professional qualification and give lower pay. Patients are not at the heart of these decisions".

There was a correlation between view point three expressed above and sites with negative team morale, poor Executive engagement and or lack of a LRN/M/RM/CNM/CMM role.

Sub-team structures

Multi-speciality teams (previously or sometimes still known as 'generic' teams)

- ♥ 70% of sites had either a multi-speciality team of CRN/Ms, or specific nurses who automatically provided cross-coverage for any study within their areas of knowledge.
- ♥ This was viewed as useful by most staff, allowing new CRN/Ms to have exposure to different types of studies and diseases; and later specialising further into one disease area.
- ♥ These staff often covered 3-4 disease areas at any one time.

Specialist research nurse teams

- ♥ 85% of sites had CRN/Ms who specialised in one disease area and covered around 6-10 studies each. Clinical knowledge was deemed essential

by all site staff with experience of running research studies when discussing successful study management.

- ♥ Issues arose where individuals organising the structures had not run a study before (described often as 'non-clinical'). These staff felt that clinical expertise in the disease area was not required. Whilst it was agreed by all that research skills were transferable; the general feeling was demonstrated through use of examples, eg. there had been safety concerns where less experienced staff, or non-clinical staff, were conducting tasks outside of their skill set.
- ♥ The onward impact of lack of clinical knowledge was increased pressure on the medical team members who had clinical responsibility for the patient, or where the non-clinical staff member did not pick up on an area of concern in results, thereby resulting in patient safety issues.

Other team members: Importance and concern

- ♥ 75% of CRN/M teams who had administrators and/or data managers in post, considered these roles essential to allow clinical staff to be able to undertake more nursing/midwifery specific tasks.
- ♥ Sites who had appointed administrative posts for clinical teams reported an increase in recruitment activity and availability of clinical resource to support current (or more) studies.
- ♥ CRN/Ms were keen to ensure appropriate training periods for Data Managers and Administrators. Essential criteria for these roles included understanding of the clinical pathways for the studies which they were supporting.
- ♥ All CRN/Ms supported Clinical Trial Associate (CTA)/Research Support Officer (RSO) roles where these had appropriate line management and accountability and a clear role where clinical tasks were required, eg. If taking blood samples they should be trained in the same way as phlebotomists, and all staff with a clinical aspect to their roles should undertake the Trust/Hospital Group clinical induction/mandatory training programmes, inclusive of basic life support.
- ♥ CRN/Ms voiced concern where CTA/CSOs were not considered appropriately line managed or trained to undertake tasks. Some reported being told 'you're just scared for your own job' when raising these concerns within their organisations. CRN/Ms were very keen in this project, to clarify their concern as being purely for patient and staff safety and wellbeing, if training and accountability was improper or inappropriate, and safety concerns arose.
- ♥ Some staff recognised that they have concerns for the CRN/M role generally however, due to lack of understanding by organisations of their impact or content. Some provided examples of CRN/M posts being replaced by lower grade staff with non-clinical qualifications or training, who were required to complete clinical tasks.

Team structure by funding stream

At some sites, CRN/M teams were split by funding stream, for example; NIHR CRN funded, NI CRN funded, Trust/Hospital funded, charitable funding, Health and Safety Executive (HSE), Clinical Research Facility (CRF) specific and commercially funded.

Whilst this appeared initially to be sensible, it was noted through reviewing field-notes that where this was the case in an organisation with no clinical oversight role, there was a real lack of community, cross-working, collaboration and sharing of working practices within the structure.

At some sites, clinical oversight roles had been present in the past, however when individuals moved on and were not replaced, the remaining staff lamented what was, and grieved for both the role and clinical leadership. As community etc broke down teams became fragmented, causing frustration, disappointment and lack of desire to remain in research roles. Interestingly at only one of these sites, did a team leader, eg SCRNs, persevere and raise concern through to Trust Board level.

There was not enough evidence within this project to confirm whether or not this structure was a benefit or otherwise, however there was an obvious positive difference in morale and sharing working practices where an oversight role was in place.

The project helped to connect staff within several sites, with the positive impact of establishing regular meetings between the SCRNs/Ms both for sharing practices and peer support.

During group meetings as part of the scholarship visits, an interesting thread arose across two-thirds of sites visited. Through discussion about structure and lack of contact between the teams, staff began to realise that the split by funding meant that they had different opportunities (some more, some less) to each-other, including but not limited to;

- ♥ Access to training and other educational courses;
- ♥ Variation in experience of working on observational versus interventional/academic versus pharmaceutical studies eg. additional requirements from pharmaceutical companies
- ♥ Knowledge around study set up and variations depending on type of study.

Resource allocation: Study number per full time member of staff

Extensive discussion at every participating site became the number of studies ran by CRNs/Ms.

Question themes raised (by participants) and discussed within their groups

- 'Should CRNs/Ms lead fewer studies each to enable them to manage, recruit and complete them to the best ability and achieve the targets?'
- 'Should the split be a larger number of observational studies per CRN/M versus a smaller number of interventional studies?'

- ♥ 'Should allocation be based on a mixture of the studies to encourage development and increase skills?'
- ♥ 'Should this be agreed and formally dictated as part of team structure and what happens when people will not listen to workload/resource concerns? Or should this be an informal decision made by the CRN/M/RM/CNM/CMM?'

Facts identified

- ♥ The average number per full time CRN/M involved was six studies.
- ♥ This number included a mixture of observational and interventional study types.
- ♥ The average remained whether reviewing a) a mixture of observational/interventional studies, b) solely focused on observational studies or c) solely focused on interventional studies.
- ♥ This took into account study complexity issues. For example

Observational studies may include 'one-off' visits, however there may be hundreds to undertake (and therefore a reflection in consequent paperwork completion thereafter)

Interventional studies may have fewer patients within the study, however be more complex in terms of workload (one patient visit may take one or two CRNs/Ms a full day to complete).

- ♥ Staff at all sites reported a lack of resource flexibility around sickness and annual leave due to consistently working to, or over, capacity. For example, should someone be taken unwell there was no space for workload to be reallocated to other staff without negative impact. The same occurred when staff took annual leave.

The results of this were varied:

1. Teams pulled together and other CRNs/Ms would complete patient visits so as not to let the patient down and to keep them on schedule (NB. Only possible where someone else was registered to do so on the delegation log)
2. Negative impact on the CRNs/Ms own workload by creating a backlog in time consuming administrative tasks.
3. Where no 'back-up' staff member was on the delegation log for the study and/or no other member of the study team was available due to other clinical commitments, patient visits were cancelled; leading to protocol deviations (or violations), decreased patient satisfaction, increased safety reporting workload and reduced reputation with the study Sponsor.
4. A smaller number of sites reported safety issues have arisen because of inability to conduct patient visits in these circumstances. These were reported through hospital safety mechanisms/systems. Some felt able to state over-work/capacity as reasons in the reporting system and some did not.

Shared decision making regarding studies

In structuring staff, departments and studies, participants were keen to express the importance of involving CRN/Ms who manage the studies daily.

Staff discussed the importance of considering current studies and their 'worth'. 80% of staff confided that they had taken on historical studies with lengthy closing dates. Issues arose with these particular studies where services had changed at site and no study review had been conducted, or the patient population was no longer available, therefore making further recruitment impossible.

Some staff reported being told by R&D departments that 'those studies can sit in the background' however CRN/Ms reported, the reality of day to day running means administrative work remains. This removes the CRN/Ms away from focusing on offering study opportunities to other patients. There was a lot of frustration in those instances and this was reflected across sites and countries.

The CRN/Ms were clear that they did not wish to close studies which were still active or had potential, but that they felt 'pigeon-holed' by facilitation or non-clinical staff, who assumed they wanted to close studies 'to make their lives easier', rather than it being an informed proposal based to their professional and experienced opinion.

Some sites who had recently received budget reductions had discussions around reducing the number of disease areas in which they were offering studies. The reporting of these discussions caused emotional reactions from the staff (tears in some cases) as they felt they were letting patients down by making such a decision. These staff were focusing on the bigger picture, which one summarised as

“

If we can reduce the number of disease areas we are offering studies in on a temporary basis, we can focus on the studies already open in areas where we have a large population. Some of those patients are already missing out as we are not able to resource studies properly staffing-wise and so can't offer them participation...by reducing the number of studies in quieter areas, we can still support patients in a different way and achieve the recruitment targets we're constantly being chased for. The idea is that this would hopefully be a temporary measure. We could demonstrate an increase in recruitment and as a result, funding should increase too, which means more staff, thereby allowing us to open more disease areas again but in a safer and more controlled way.

”

These same staff reported difficult conversations with their R&D departments/non-clinical line managers around the topic who were reported to be

- a) reluctant to reduce disease areas,
- b) reluctant to reduce the number of studies being conducted,
- c) unable to finance additional staff to take some of the burden, and
- d) unable to offer other potential solutions to assist the current situation.

This caused considerable distress to some CRN/Ms who felt that despite their best efforts, they were viewed as not trying hard enough. They reported being asked 'Why is it an issue?', 'What do you do all day?' and/or told 'Just make sure the cover is there; we need the numbers'.

In Ireland there are no R&D Departments therefore part of the CRN/M role includes identifying, setting up and reviewing studies as well as delivering them clinically. Advantages of this include (but are not limited to); appropriate studies can be sought directly by the CRN/M, and the individual has a multitude of research skills. The disadvantages include (but are not limited to); impact on ability to conduct studies and invite participants; additional administrative time of the CRN/M; a lack of time to promote and evidence the CRN/M roles.

Some sites had extremely good practices in place whereby all studies were reviewed on a six-month basis minimum; this review included all team members (clinical and non-clinical), as part of study oversight. Staff at these sites felt valued and that their opinions were considered.

These sites appeared to share a vision of patient focus, and in delivering this recognised the need for team-working and therefore shared decision-making practices. This is the recommended approach for harmonised working between R&D and clinical research teams where these currently work as separate entities.

Reactive Staff Recruitment

Staff recruitment in general was reactive in nature across most sites. The project identified that issues were due to the variation in funding streams (and associated criteria), development (job descriptions), post creation (banding/grading), and advertisement requirements.

Participants reported specific difficulties as;

- ♥ Criteria for releasing job adverts,
- ♥ Slow movement through the human resources (HR) department,
- ♥ Additional sign-off procedures which reflected Trust/Hospital Group processes where funds were coming from the NHS and not considered fit for purpose for external funding routes
- ♥ A study coming through sooner than anticipated, with current staffing resource already being over-capacity.
- ♥ Funding sources not releasing budgets to sites in a timely manner (some staff reported working a second year after a one-year fixed term without formal contracts in place).
- ♥ Enforced short/fixed term contracts eg 3 months.

Where teams were run through the R&D department with no clinical oversight post in place, there was a tendency for jobs to be automatically generated rather than as part of a pro-active planning discussion with the clinical research team regarding what might be the most effective role (eg. an administrative post for the clinical team rather than a nursing post).

The impact of reactive recruitment appeared to be negative for team structures and morale as well as causing direct impacts to patients.

Staff reported impacts as follows;

- a) inability to open studies in a timely manner,
- b) negative impact in opening studies in line with key performance indicators relevant to each country,
- c) negative impact on recruitment to national targets
- d) guilt from clinical staff at not being able to offer patients the opportunity to participate,
- e) impact on other clinical services and staff who had worked towards supporting a study but required the CRN/M to undertake the main day-to-day running. There was consequential impact on staff desire to remain involved in research in these instances because of perceived (or real) 'red tape'.

Pro-active Staff Recruitment

Some of the larger sites reported lengthy discussions (over the course of approximately a year), and eventual agreements with their Trusts/HR departments whereby if a research post was to be funded outside of the NHS/hospital funds, eg by Grant, they would not need to go through additional HR processes. Their route was through either a dedicated finance post allocated research within their portfolio, or by sign-off from the Director or Deputy Director of Finance. Sites reported this removing around four weeks from the standard recruitment process and reducing impacts from reactive recruitment.

A minority of sites confirmed they received Trust or Hospital funding and were treated as a 'core' service for example, similarly to Accident and Emergency, or Midwifery services. This provided them with a balance through which they could pro-actively recruit to posts with a view of covering studies in the pipeline.

If planned studies did not come to fruition, the post-holder supported the multi-speciality team until other studies came through the system, therefore effectively utilising skills and resource.

Mental health services tended to have good systems in place for reviewing which posts would be most suitable for upcoming studies ie whether this was a CTA/CRN/M, Psychologist etc. Discussions were held with all study team members and a collaborative decision made.

Staff at sites who followed pro-active recruitment procedures, also had substantive, or two-year minimum, research contracts, rather than short term versions (3-6 months).

Contracts

Contracts formed discussions throughout all organisations. It could fit in both the reactive and proactive sections above however its impact is large therefore a dedicated section to the topic has been included below.

In England the number of permanent research (CRN/M) posts has increased over recent years (though specific figures are unavailable), mainly due to NHS contracts confirming anyone on a fixed term post for over two years has the same employment rights as permanent staff. Some sites at the two-year point arrange for staff to move in to a substantive post, with the Trust taking responsibility should redeployment be required due to lack of research work.

Some staff reported being happy with fixed term contracts when they first entered research as it gave them a chance to experience the role and decide whether it was for them.

Others reported major difficulties with fixed term contracts in terms of obtaining mortgages or other banking requirements. Staff in this position were frustrated and considering leaving the role for a permanent nursing/midwifery post - this was reflected across all countries. Some CRN/Ms had been on rolling fixed term contracts for 4+ years and considered themselves permanent until this conversation came up as part of group discussion.

Discussions deepened when a number of CRN/Ms reported unease that often non-clinical research posts were automatically advertised as permanent and clinical staff more often as fixed term. The interpretation of this was lack of value of clinical knowledge, work and expertise. This feeling was represented in all countries, excluding Ireland, and with particular issue at the Research Delivery Manager (RDM) role in England.

The following list summarises feelings expressed by staff regarding fixed term contracts:

- ♥ Helpful for 'trying out' a new role
- ♥ Helpful for developing experience in different disease areas
- ♥ Perceived as a lack of commitment to research by the organisation where roles are not permanent; less value than other staff in the organisation.
- ♥ Undervalued and 'disposable'
- ♥ In Ireland, it was reported that some Hospital Groups or hospitals did not consider research staff as part of the clinical team, which created a lack of inclusivity and negative patient impacts.
- ♥ Difficulty in obtaining mortgages, or renewing mortgages already in existence

Requirements within contracts; findings.

- ♥ Research dedicated roles mean that patients participating in research are as important as all other patients receiving treatments in the organisation
- ♥ Some staff reported being regularly removed from research activity to support other clinical services (often in Ireland), thus patients in studies were cancelled or missed out on opportunities to be involved in research. This led to decreased job satisfaction as well as anecdotal reports of negative patient experiences, and knock-on funding impacts when targets were unable to be achieved
- ♥ Some CRFs did not have regular CRN/M staff, preferring to allocate short term contracts as required. This often caused delays in study set up, and sometimes loss of, studies where medics would request use of the facility and staff.

Identity: Uniforms

The topic of uniforms arose at all sites. Whilst it was not a major factor in discussions, it is necessary to report upon given its impact on staff perceptions on integration within the hospital/site (which was an over-riding theme).

CRN/Ms at 60% of sites wore a clinical uniform (inclusive of a small number of staff working in critical care areas who wore scrubs), 40% wore civilian clothing.

Staff reported three main uniform options,

- 1 - Clinical uniform to match grades and colours of others in the same profession within their organisation, plus different colour piping
- 2 - Clinical uniform of differing colour to others within their organisations
- 3 - Civilian clothing

The pros and cons as described by staff both for clinical uniform and for civilian dress-code are shown in Fig 2.

Reviewing available literature showed a paucity of evidence around the uniform issue for CRN/Ms (Albert et al, 2008, Timmons and East, 2011 and White, 2016). There is much evidence and literature regarding nurses and midwives wearing uniform and its relationship to professionalism, however minimal knowledge is known about the view from patients and other staff on the CRN/M uniform.

A paediatric study by Spry and Holdback (2015) reported parents preferred to be approached by research staff in uniform for reasons of; ease of identification, trust and professionalism. 31% of parents felt that what the nurse was wearing was likely to have influenced their decision. There was a preference for uniform to be worn however, within this study there was no agreement about what the uniform should be.

Interestingly, 85% of CRN/Ms across all sites within this scholarship project felt that a uniform was the most appropriate clothing for research teams. 8% said their minds had been changed from civilian clothing to uniform following the open discussions. 10% felt civilian clothing remained their preference.

Uniform

- ♥ Identity as a clinical individual
- ♥ Increased integration into the Trust/Hospital due to acceptance of being 'clinical'.
- ♥ A different colour uniform when establishing research in the organisation ie visibility, was cited as initially useful. The same organisations reported that once research had become established, moving into the same colour uniforms as clinical colleagues had better impact and showed research as truly integrated. On average this took around two years.
- ♥ Staff felt when wearing the same uniforms that this assisted in making research 'normal'. Some sites utilised coloured beading and/or research specific lanyards to assist in making themselves visible for patients and staff.
- ♥ Felt civilian clothing did not identify research staff as clinical (thus causing issues of credibility to other clinical staff)
- ♥ Felt 'being pulled away' from research work to support ward staff meant there was a bigger cultural issue to deal with and was not an issue specific to uniforms.

Civilian Clothing

- ♥ Demonstrate a difference between research and other staff
- ♥ Civilian clothing for clinical staff was acceptable by some hospitals and felt more comfortable for staff
- ♥ Wearing clinical clothing could result in being 'pulled away' from research work on to wards/ departments

Line Management for Senior Clinical Research Nurses/Midwives (SCRN/Ms)

The majority of sites had SCRNs in place for teams (eg by specialism), however, often those same SCRNs had no clinical reporting line upwards or were reporting to a Matron (or equivalent title) within the hospital who had no research delivery experience. Midwives were often managed under an SCRN or working alone.

Some SCRNs were reporting to R&D Managers who had research but no clinical experience and were not provided with a 'dotted line' accountability/support from a clinical member of staff to account for this. For nurses and midwives governed by the Nursing and Midwifery Council this provided concern around revalidation and professional accountability sign-off.

In Ireland it appeared common for CRN/Ms to be working in silos and officially line managed by the Consultant working within the same study. In these instances, many of those CRN/Ms felt isolated within their organisations. These same staff all cited the Irish Research Nurse Network (IRNN) as their route into the CRN/M network nationally and felt this contributed greatly to their learning, training, value and sense of community. Recent additional links with the Irish HRB also solidified this view.

In all countries, but particularly noted in Wales, Scotland and Ireland, staff reported a 'my nurse' syndrome with some of their medical colleagues, specifically where those CRN/Ms were directly employed by a medical Consultant. Staff described this as a 'condition' whereby medical colleagues felt they 'owned' that particular CRN/M.

In England this issue appears to be reducing, however some staff reported a remnant of similar concern when working in multi-speciality teams eg the CRN may cover ophthalmology, rheumatology and orthopaedics, however an ophthalmology consultant may raise issue with 'their nurse' covering other areas, without having an understanding of contracts, role or training requirements and/or funding stream.

Conversely a small number of CRN/Ms reported a preference to working with one medical colleague on his/her studies and working alone as it meant increased flexibility around working patterns and opportunities they felt they might not otherwise receive eg. Conference attendance. When meeting with teams as part of this scholarship project and becoming aware of other opportunities and working practices, some of these staff reported feeling scared that 'I don't know what I don't know'; a number of these were working with little training and guidance. Some also reported not having had updated Good Clinical Practice (GCP) or other training since they commenced in post and realised some of their work may not be up to current standards. All of these individuals said they had no idea how many other research staff were in their organisation.

Across all countries where a LNR/M/RM/CNM/CMM was in post and had complete oversight responsibilities, sites tended to have more clarity in terms of line management as well as overall structures. These leading individuals had either forged progress over recent years or were in the middle of doing so (including finding 'missing' or unidentified CRN/Ms). They were all able to account for NMC standards around revalidation and the workforce reported satisfaction with this approach.

Many established LRN/M/CNM/CMM's engaged closely with their HR departments to ensure that any clinical role with 'research' in the title was referred to them. This seems to have been received well by the research workforce who are then not only able to feel part of a community, but are able to welcome, support and train new staff to high standards, therefore reducing potential risk of harm to patients and/or research data.

75% of LRN/M/RM/CNM/CMMs entered their post with no clear line management in place regarding 'upward' reporting routes.

Each of these staff reported requesting meetings with their R&D counterparts/Clinical Directors for Research and DON/Ms as minimum to ensure that this was established as soon as possible. They stated this to have directly influenced organisational engagement in research as by default "it placed research at another senior member of the Executive team's door in portfolio terms". This equated to accountability and formal reporting measures which ultimately meant increased engagement.

Lead Research Nurse/Midwife/Research Matron/CNM – Impact upon structure

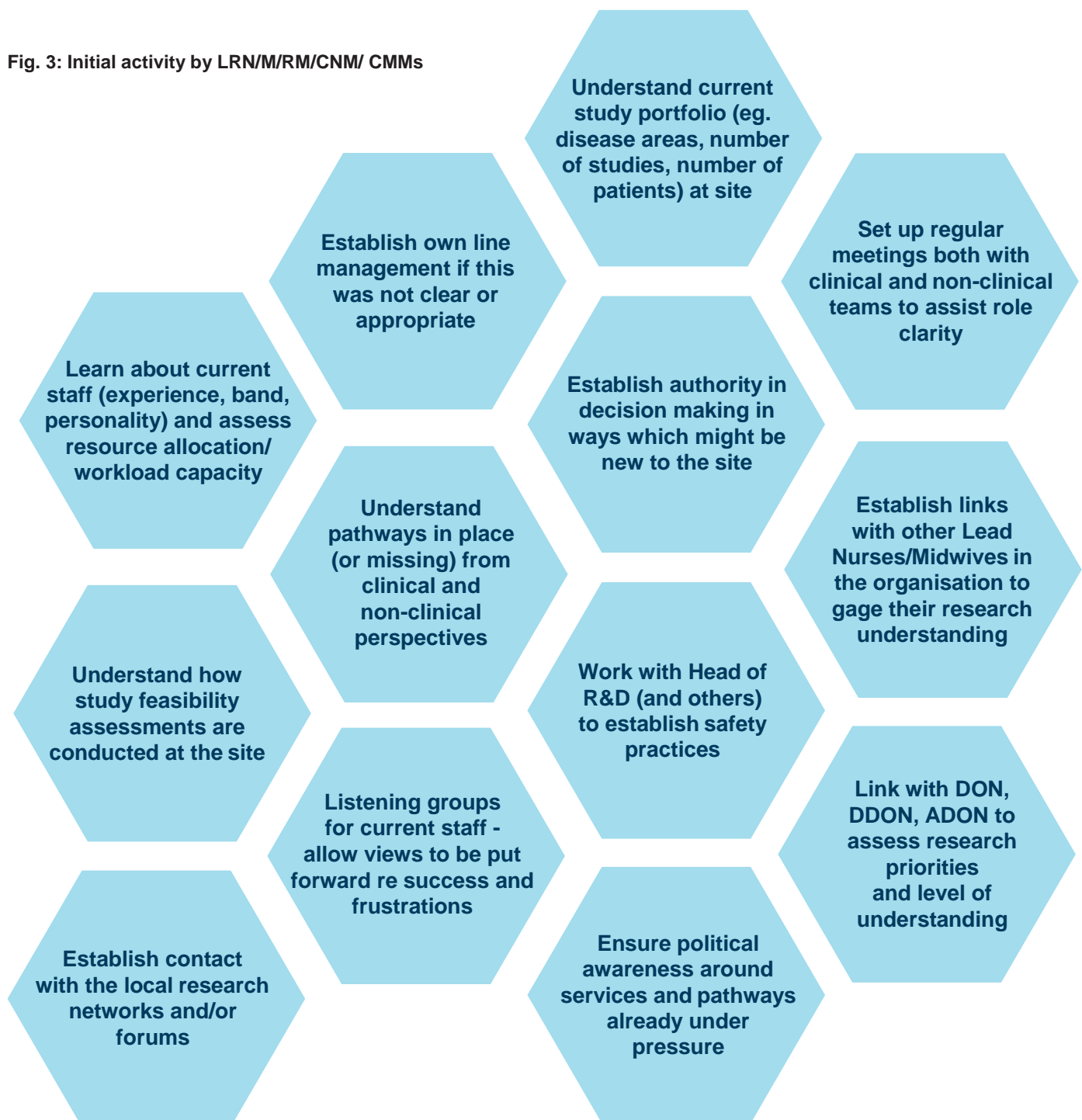
LRN/M/RM/CNM/CMMs with extensive research experience including study delivery, understanding and experience of study set up and in some cases, who had written, conducted and reported upon their own research, came across as informed, engaged, passionate and efficient leaders.

Their role to forge progress within the organisation, and assumption of responsibility for training and development of staff to ensure safe and efficient patient care, as well as positive patient AND staff experiences, was highlighted by themselves as paramount. These individuals were able to establish meaningful links with senior management within their organisations and with external agencies which improved engagement and understanding of research more widely.

Interestingly, the majority of individuals in these posts were the first person to take on the Lead role. Some reported immediate acceptance from the research workforce and others remember feeling isolated without any form of structure or support from both those above and below them (in banding/grading terms), as well as understanding what the role required.

Examples of initial activity undertaken by all of these individuals when entering their post were collated and are shown in Figure 3 (NB. This list is not exhaustive but details those tasks mentioned by all)

Fig. 3: Initial activity by LRN/M/RM/CNM/ CMMs



The tasks described in **Fig 3** were deemed essential in ensuring a full understanding of the workforce was available prior to discussions around structure/restructuring.

Where full understanding was not obtained, LRN/M/RM/CNM/CMMs reported unevidenced, and in some cases unnecessary, restructuring having taken place prior to their appointment within the organisations.

They also stated a role clarity, or alteration, exercise which included the whole team, may have sufficed to address problems arising and prevented an unsuccessful structural change.

Often structure changes were made;

1. Without representation or inclusion of those who would be directly affected,
2. By staff members whose roles were not strategic, or
3. By individuals who did not understand the roles they were restructuring.

This created further frustration, increased turnover of CRN/M staff due to feeling undervalued, as well as no improvement for patients (which was cited as the ultimate aim).

Where no clinical oversight role was in place at organisations, the level of staff dissatisfaction was higher and staff felt they had no voice when restructuring occurred.

At sites where a clinical oversight role was in place, the above issues were able to be addressed and (where appropriate), direct work was undertaken with the teams to identify a potential new structure, or a focus on role clarity. Staff within these organisations reported feeling valued, having an opinion which was listened to and felt part of a community working towards one joint vision.

Dr Helen Jones (2017) has explored how the CRN workforce has developed alongside growing National Health Service (NHS) research infrastructure in England, and recognised a lack of evidence concerning how best to structure CRN teams within acute trusts.

Jones (2017) recommendations relating to oversight and structure in particular included

- Organisations ensuring the CRN workforce is well led with the establishment of a Lead CRN post.
- R&D Departments should consider the timing of a full CRN workforce review

Recommendations as a result of this scholarship project echo these findings and further clarify that the workforce review should be led by the LRN/M/RM/CNM/CMM.

Importance of demonstrating impact, visibility and identity

CRN/Ms

Demonstrating impact to show value was high on agendas at research sites with a LRN/M/RM/CNM/CMMs in post. They were clear that this was an essential part of maintaining the CRN/M workforce having worked through the tasks, trials, tribulations and successes mentioned in the previous sections.

All LRN/M/RM/CNM/CMMs recognised that other clinical and non-clinical staff do not always recognise, appreciate or value the volume, complexity and knowledge of research held by CRN/Ms; nor the direct impact this has on the success (or otherwise) of the research studies they are managing. All reported having been asked during their research nursing/midwifery careers 'Why do visits take so long when you've got a protocol to follow' or 'What is it you do all day?'.

Some acknowledged that despite recognising the need for evidencing impact, they had not contributed so far to the body of literature publicly available which would reduce this type of enquiry.

All however, confirmed demonstrating impact was at the top of their agendas and had worked locally to resolve these issues, by inputting to annual Board reports implementing tools such as those shown in figure 4.

Fig 4. Impact tools



Research in progress by Linda Tinkler (2017) is an excellent example of this type of work. It explores the experiences of CRNs with an emphasis on factors that may have impacted on successful study delivery. The study noted additional perceptions in the wider context of professional identity such as role transition, altered relationships, peer perceptions of the role, emotional labour of patient approach and workload complexity, alongside ensuring duty of care for participants remains. Further work is currently underway to build upon these findings and will certainly be important for the CRN role in terms of contributing to the current research gap in the impact area.

Gordon Hill, a Senior Lecturer at Glasgow Caledonian University has been investigating 'gate-keepers' to patients for research and has demonstrated a link between CRN/Ms and clinical nurse specialist staff. This work will be published in the summer of 2018.

An additional recommendation from Jones (2017) study, related to impact and understanding; "Work should be taken to address the lack of understanding of research and the CRN role". It is hoped this project assists in forming the basis of that knowledge.

Nurse/Midwife Researchers

Examples of opportunities to undertake nurse/midwifery led research were demonstrated across all countries. Examples of those shared through project visits include (but are not limited to):

- ♥ **NHS Lothian Clinical Academic Careers Scheme (Scotland)** <https://www.ed.ac.uk/files/imports/fileManager/NHS%20Lothian%20NMAHP%20Clinical%20Academic%20Research%20Careers%20Scheme%20FINAL.pdf>
- ♥ **NIHR Fellowship Programme, England** <https://www.nihr.ac.uk/funding-and-support/funding-for-training-and-career-development/fellowship-programme.htm>
- ♥ **First into Research Fellowships (Research Building Capacity Collaboration), Wales** [file:///C:/Users/ruswh/Desktop/RCBC%20FiR%20Advert%202017_FINAL%20\(2\).pdf](file:///C:/Users/ruswh/Desktop/RCBC%20FiR%20Advert%202017_FINAL%20(2).pdf)
- ♥ **Research training fellowships for healthcare professionals, Ireland** http://www.hrb.ie/uploads/tx_hrbgrants/HPF_2016_Guidance_Notes.pdf
- ♥ **Health and social care R&D doctoral fellowship award scheme, Northern Ireland** <http://www.research.hscni.net/health-social-care-rd-doctoral-fellowship-award-scheme>

Clinical academic careers across the UK and Ireland are becoming more well-known and awareness of opportunities by people participating in this study was high. Dissemination of specific projects through publication were generously provided by participants.

Upon reflection, formal publication has been minimal in terms of demonstrating the impact of research programmes. Most experienced staff leading these programmes cited delays in write up to be due mainly to:

- ♥ Lack of time
- ♥ Pressures of new live projects
- ♥ Funding pressures to submit grants taking priority over previous work

Staff new to nursing and midwifery research cited other issues as barriers to publication:

- ♥ Lack of experience in writing for publication
- ♥ Perception of and discomfort with 'self-selling'
- ♥ Lack of understanding the publication process
- ♥ Fear of writing ability being sub-standard/lack of confidence
- ♥ Fear of criticism or rejection

All staff recognised publishing research to be important for providing an opportunity to share knowledge, skills and experiences, and having the potential to improve outcomes through changes in clinical practice. Publications mean avoiding repetition of studies, whilst at the same time allowing nurses or midwives the opportunity to contribute to their field; ultimately it also demonstrates impact.

Programmes witnessed through scholarship visits were usually University-led, in conjunction with a local healthcare establishment, or through a joint research post between the University and a Healthcare Trust/Hospital. All staff considered joint posts valuable in developing research criteria, particularly when in the early stages of establishing 'home-grown' research at clinical sites.

There was less focus on demonstrating the impact of the actual programmes of work which encourage, support and allow nurses and midwives to undertake their own research. These programmes have been very successful, (often repeated in consequent years), and with scope to be replicated elsewhere across the UK, Ireland and potentially globally.

Publications of the schemes would assist in the body of available literature and (as recognised by all involved in these discussions), increase establishment reputation through publication, as well as a potential increase in funding allocation and/or funding routes.

Staff were unanimous in supporting that nursing and midwifery research should be encouraged. In 2007, the UK Clinical Research Collaboration examined the role of nurse researchers and identified barriers that prevented them from pursuing research careers; this included a lack of sufficiently skilled staff to lead the programmes as well as dedication from funders.

The Association of UK University Hospitals (AUKUH) (2012) reports that key documents including Front Line Care (DOH, 2010a), Midwifery 2020: Delivering Expectations (DOH, 2010b), Council of Deans for Health (2012) and NES Scotland (2011) highlighted the need, value and desire to develop and sustain the clinical academic. The AUKUH Clinical Academic Careers Group for Nursing and Midwifery was set up.

Their scoping work included recognition that:

- CRN/M training over and above GCP was slow (this has since increased, particularly in England with NIHR courses, Wales through Health and Care Research Wales, and Ireland through the IRNN).
- Little evidence of CRN/Ms developing independent research skills and becoming research leaders in their own right
- Problems existed where CRN/Ms were employed by both Higher Education Institutions (HEIs) and the NHS.

The AUKUH (2012) report recommended that further local as well as national schemes for developing clinical academic careers were needed; the information discovered during this project shows these initiatives are growing, albeit sporadically across the five countries.

A decade later and national fellowships are in place to support nursing, midwifery and AHP researchers as well as a number of local University schemes. A number of publications reflect ongoing work in this arena; Carrick-Sen et al (2015), Coombs et al (2012), Holge-Hazelton et al (2015) and Strickland, K (2017).

A particular case study was described by Emma Munro and Sarah Bailey from University Hospital Southampton NHS Foundation Trust at the 2017 RCN International Research Nursing Conference (Munro and Bailey, 2017). Their presentation detailed the transition from research nurse to research nurse leader and provided the routes taken at their site to make this successful. Often CRN/Ms were leaving their posts and moving full time in to academic roles (a notion reflected across all countries). To reduce the impact of this and create other development opportunities three additional routes were created:

1. Joint clinical and research posts
2. Clinical academic career pathways and
3. New job descriptions for PhD nurses.

Benefits of this were; high quality staff attracted to the site, change in attitudes to research engagement, specific front-line study development and increased support for those in research roles.

In November 2016 the AUKUH released guidance on transforming healthcare through clinical academic careers and acknowledged environments to conduct research were not what they should be. They detailed complex gaps and lack of tools to expand existing programmes. Staff involved in the scholarship who discussed this aspect of impact reported a view that positive progress was slowly being made. Concerns remained however, that funding continued to be a major issue in the provision of places on these courses, and/or reduction in PhD funded places in some instances.

NHS England launched 'Leading Change, Adding Value' in 2016 and commitment 7 states "We will lead and drive research to evidence the impact of what we do'. Co-hosted by the Council of Deans of Health (CoDH) and the Chief Nursing Officer for England, a research round-table event was held as a call to action. CoDH has been working with professional bodies and others to strengthen the role of nursing, midwifery and AHPs in the next REF cycle 2021 and discussion points within this event covered increasing research in pre-registration curriculum; post registration course placing a greater focus on research and evidence, equipping nurses with the necessary skills to drive evidence-based practice forward (Peate, 2018).

'The Atlas of Shared Learning' is the culmination of the formal 3-year LCAV programme and aims to demonstrate how nursing, midwifery and AHP staff have led and contributed to narrowing the gaps existing in healthcare, funding and efficiency, as well inputting to the Five Year Forward View (NHS England, 2018).

The favoured route for assisting staff to look further into clinical academic careers when asked, was for Universities and healthcare organisations to create more dual-roles (as in the example of Munro and Bailey (2017)). Where this has been implemented and there are:

- a) clear reporting routes,
 - b) clear job descriptions and
 - c) availability of funding,
- success has been demonstrated.

Staff in the scholarship project viewed the CRN/M workforce based in healthcare establishments as a largely 'untapped' population of potentially high-quality researchers. In some cases, they were regarded as entirely invisible within the academic arena.

Whilst University staff recognised that there were areas where they could contribute further to the research nursing/midwifery literature, they also felt it was essential for CRN/Ms to demonstrate impact of their delivery work and importance of their roles, not just because of the economic climate (as was stated by CRN/Ms themselves), but to raise the awareness of the role and potentially open more opportunities for those wishing to undertake their own research either now or in the future.

Views of Research Nurses and Midwives on clinical oversight roles

The biggest theme in terms of 'structure' feedback was that clinical oversight had to be meaningful. Feedback confirmed oversight should be by a nurse or midwife with clinical research experience and responsibility for the whole clinical research team within an organisation.

In 2016, the ANA/IACRN utilised the domains of clinical research nursing (Adapted from NIH, 2009) (Fig 5) as a basis of framework provision regardless of study type, role or setting, in order to describe the roles of the CRN in more detail.

Fig 5: Domains of clinical research nursing



Participants in this scholarship project have contributed toward another 'slice' to build upon those in this NIH sphere when focusing on a meaningful oversight nursing/midwifery role. CRN/Ms had clear views on who their LRN/M/RM/CNM/CMM should 'be' and what they should be capable to 'do'. They were generous in describing these in detail.

Analysis of data gathered shows a further breakdown of this specific theme in to 'traits' and 'action'; the type of person fit for this role, and what they should be able to do effectively in order to be successful and forge positive change (see table 1).

The sphere from figure 5 could be expanded to include 'meaningful oversight' where it is being used to analyse or discuss the LRN/M/RM/CNM/CMMs role (Fig. 6). This slice would include; team management, leadership, teaching and education (both design and provision of), negotiations and enhanced research expertise.

There remains a paucity of literature on the views of CRN/Ms and having a lead oversight role to support their daily work and research delivery. CRN/Ms who had worked under an effective LRN/M/RM/CNM/CMM felt they had increased opportunities, a level of management between themselves and 'target setters', felt supported and were able to maintain patient focus and safety more readily than those without.

Misso et al (2016) undertook a clinical research engagement and leadership capacity building programme in a clinical setting, with little to no co-ordinated approach to clinical research leadership in Australia. Ensuring leadership from the front, by the right person, meant more staff were able to conduct and run clinical research, as well as identifying areas of clinical uncertainty to be addressed in the future. The leaders are essential to this programme's success in the same way as LRN/M/RM/CNM/CMMs are in clinical research delivery teams in the UK.

Evans (2014) investigated academic research leadership as perceived by those on the receiving end of it. Three specific features of research leadership were identified and examined:

1. To influence work that enhances people's capacity to make the right choices
2. To achieve requisite standards and
3. To effect processes, within research activity.

Participants in the scholarship project reported that LRN/M/RM/CNM/CMMs need to be multi-dimensional in terms of skills and knowledge in order to forge effective progress, deliver a successful department, and ensure the best opportunities are available for both patients and staff. This reflects the academic approach described by Evans (2014).

Fig. 6. Adapted domains of clinical research nursing

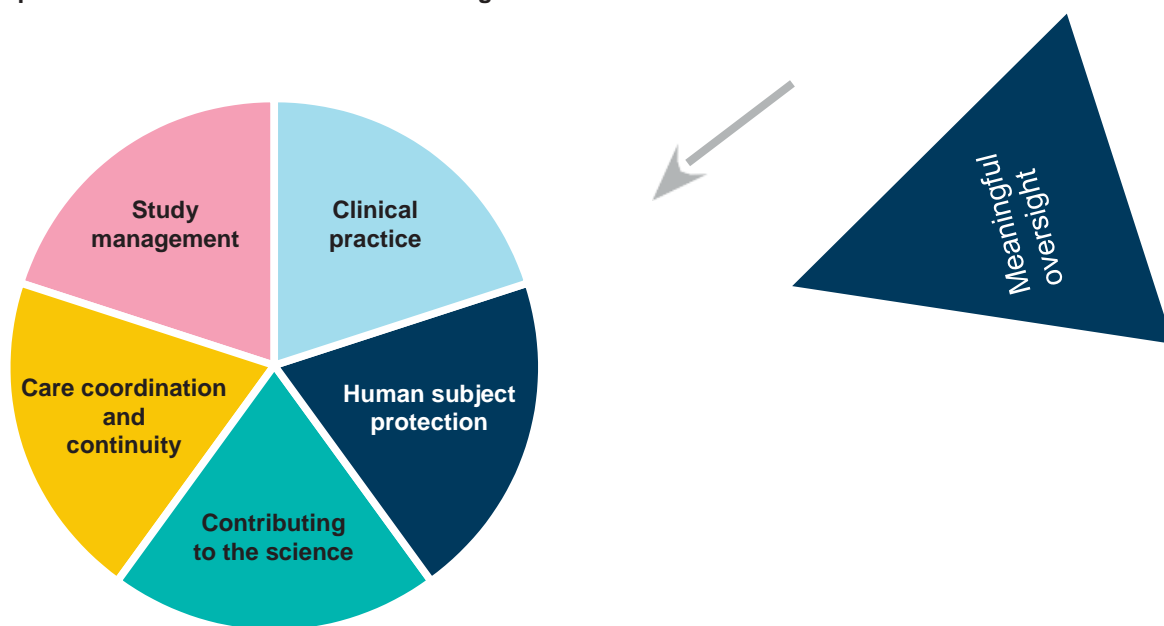


Table 1: Traits and actions of successful oversight roles

Traits	Action
<ul style="list-style-type: none"> ♥ Patient focused ♥ Honest and positive ♥ Political awareness/astuteness ♥ Able and confident to demonstrate value (self, individuals and team) ♥ Credible ♥ High standards ♥ Experienced in research delivery ♥ Able to lead a team and share a vision ♥ Inspirational ♥ Networker and communicator ♥ Able to appropriately challenge ♥ Clinically skilled to an advanced level ♥ Ability to teach ♥ Ability to embrace change and opportunity ♥ Nursing, Midwifery or AHP professional qualification (depending on the studies to be delivered and background required of the individual) 	<ul style="list-style-type: none"> ♥ Ensure patient centred approach to all work by all staff ♥ Have meaningful oversight at a Trust/Hospital level ♥ Ensure high standards ♥ Ensure role clarity ♥ Actively network ♥ Create links internally and externally ♥ Raise visibility ♥ Communicate effectively any changes or decisions and be realistic ♥ Raise awareness of roles and research ♥ Troubleshoot ♥ Provide expertise ♥ Forge progress ♥ Engage and encourage staff to own and share a vision ♥ Challenge the status quo where necessary ♥ Celebrate team and patient successes ♥ Keep up to date ♥ Engage, inspire and work with the team ♥ Make difficult decisions

5. Strategies

5.1 Strategies: The evidence

The evidence of this project in terms of strategy development both at sites and country-wide policy development were:

- ♥ Confusion in understanding the difference between nurse/midwife researcher and the CRN/M delivery workforce led to confused or complete lack of strategies.
- ♥ Executive Team Engagement and the opinion of research importance within the organisation impacted whether sites had a CRN/M/nurse/midwife researcher strategy in place (or development).
- ♥ Communication and understanding between both non-clinical and clinical sides of research delivery teams were paramount in successful creation of an onward strategy and shared vision.
- ♥ Where strategies were in place, these were initially separate for CRN/M workforce and the nurse/midwife researchers until establishment of an infrastructure was complete.
- ♥ Successful strategies for nurse/midwife researchers (as defined by study design, conduct, completion and dissemination of results) included a robust collaborative working relationship with a University (whether or not the University was local was not a factor).
- ♥ Organisations who engaged and involved patient's voices had clearer focus of goals for home-grown research.

5.2 Strategies: Themes

CRN/M vs Nurse/Midwife

Whilst both seek to improve patient care or demonstrate most effective treatments, the CRN/M and nurse/midwife researcher are different roles.

Funding criteria of the CRN/M workforce can be varied and very much direct how those individuals may (and may not) work. CRN/Ms generally run 'hosted' studies, ie. deliver research for others such as charities, pharmaceutical companies and studies with grant funding. For example, the NIHR CRN/M workforce may run a number of studies on the NIHR portfolio; the role is focused on recruitment of patients to studies and funding does not allow for undertaking one's own research alongside this. This is reflected in Wales and Northern Ireland, in most cases under alternative funding streams.

In Ireland the nature of the grant under which you are working has a specific impact upon your role content. For example, CRN/Ms may be hospital funded or funded through a national organisation where there is more emphasis on developing home-grown research. The nurse/midwife may be classed as a Clinical Nurse Specialist (CNS) or Advanced Nurse/Midwife Practitioner with a research aspect to their role whereby they are undertaking their own research project. There was confusion at some Irish sites to the benefit of a

CRN/M delivery role where the individual was hosting studies only for others (for example where CRN/Ms receive no authorship or public acknowledgement for their work). Working practices and examples were shared during the discussion and again afterwards via email.

The Irish Department of Health were very supportive of home-grown research by nurses and midwives and were open to developing a specific CRN/M workforce in the future. Connections were made with the IRNN who are already working on this.

In Wales the visits highlighted a unique and valuable role of the Head of Research Delivery (HRD). Three HRDs are employed by local Health Boards and have responsibility for North, South West and South East Wales regions. Two of the three have research nursing experience, with the third having front line research experience. Each HRD have Research Delivery Managers (RDM) who also all have frontline experience in research and a mixture of backgrounds. It was reported that England has an RDM role however it differs to that in Wales ie. often these individuals do not have clinical research delivery experience; the role also varies across the country in terms of content and support.

The Welsh HRD and RDM knowledge and expertise can assist towards development of evidenced and realistic research nursing and midwifery strategies. Their co-ordination and relationships are such that they are able to work with R&D departments to advise and guide structures as well as strategies.

A highlight within Wales is the close link with Welsh Government who have taken an active interest in developing the research agenda further across Health and Care research. The country was working through a transition at the time of scholarship visits therefore developments around this in terms of what it will look like remain underway.

Both Scotland and Northern Ireland visits highlighted a recognition of CRN/M and nurse/midwife researcher being two different roles. Work being led by Juliet McArthur at The University of Edinburgh and NHS Lothian works on a dual role whereby staff remain in clinical research practice, but also undertake an academic element, including working towards additional qualifications such as PhDs. A similar approach was seen in Glasgow through the Beatson West of Scotland Cancer Centre.

The NIHR in England hosts a Fellowship Programme which nurses, midwives and AHPs may apply for. Professor Greta Westwood (Florence Nightingale Foundation) has also reflected on developing successful home-grown research for nurses, midwives and AHPs at an NHS Trust (Westwood et al, 2018).

In Northern Ireland, Professor Vivian Coates at Ulster University (also Florence Nightingale Clinical Professor for Northern Ireland) was focusing on a supportive approach to developing home-grown nursing, midwifery

and AHP research by front-line staff, and ensuring that there was evidence of transferring both learning and research results into practice.

The Northern Ireland Clinical Research Network (NI CRN) support CRN/Ms to work within hospitals covering a variety of studies in numerous disease areas. Integration into the rest of the hospital teams and acceptance by hospital-funded staff was a recognised issue; this in part seemed to reflect some hospitals confusion over the CRN/M versus nurse/midwife researcher roles.

The NI CRN host regular educational days for all its staff. The combination of effective and well received training meant informed and engaged clinical research staff. These individuals focused on delivering hosted studies therefore a recommendation would be to continue developing and supporting CRN/Ms entering hospitals by linking in with the hospital funded teams and potentially the DON/M at each site to assist integration.

Overall there were varying levels of understanding of the difference of CRN/M/Nurse/Midwife researcher roles by individual, site, organisation and country-wide policy makers. There were varying levels of willingness to engage front line CRN/Ms and utilise skills and knowledge available from them when developing policy and strategies.

It was clear during the scholarship that confusion and engagement were the main causes of difficulty or success with certain policies and strategies whether local, regional or national.

Executive Team

Engagement of Trust and Hospital Executive Teams varied by site and by country.

The majority of visits throughout the scholarship included meetings with at least one member of the Executive Team; often the Director of Nursing (DON) or Director of Midwifery (DOM) the Chairperson, or the Chief Executive.

Whilst a request to meet Executive Team members had not been specified, site lead contacts all felt this was an important part of their agendas so built it in to the day(s). The following reasons were provided for this:

- ♥ To demonstrate the good working relationship between the research department and the Executive Team
- ♥ To demonstrate the importance of research within that Trust/Hospital amongst the Executive Team
- ♥ To raise research visibility with the Executive Team and demonstrate international engagement in CRN/M workforce development where it was felt this currently went unrecognised.
- ♥ To create the first link with the Executive Team at sites where this was yet to be established
- ♥ To utilise the visit as a high-profile event for the organisation and celebrating CRN/M roles in research, due to the Florence Nightingale Foundation reputation.

The approach with these members of staff was the same as with everyone else involved in the project; provision of background, justification of the project, and desire to assist in the growing body of literature around CRN/Ms and nursing/midwifery research. The staff were provided with the same platform to express their views and ways of working at their sites. Executive team engagement had a big impact on the progress of research departments at their sites (Table 2).

These 'activities' remained static whether research (medical, nursing, AHP, midwifery or a combination) was included in objectives or ambitions at these Trusts/hospitals or not. Most individuals described this situation as 'lip-service' ie. the wording was included in Trust/hospital literature. However, the input, engagement and commitment to research was not experienced or evident (both from a hosted-studies and home-grown studies perspective) to the teams.

Table 2: Executive Team Engagement and Impact of Research Delivery

Area of impact	Lack of engagement from Executive teams	Positive engagement from Executive Teams
Structure and strategy	No CRN/M structure and/or strategy in place (or development)	CRN/M structure evident, in development, or a sense of urgency around the need for an established structure
Visibility/Impact	No Clinical Director for Research OR the research was placed under someone else's 'portfolio' (often the Medical Director), therefore they were rarely present.	Clinical Director in post – with a good working relationship with the DON, LRN/M/RM/CNM/CMMs
Oversight/supervision	No clinical meaningful oversight role in place (LRN/M/RM/CNM/CMM)	Clinical oversight post in place - nursing or midwifery
Morale	An undervalued and frustrated CRN/M workforce	A happy and engaged workforce
Development	No development opportunities for staff	Development opportunities were shared with the CRN/M teams
Value	A feeling that research was not essential or valued within the organisation.	Research demonstrated through Trust/Hospital objectives and/or ambitions (and evidenced)
Integration	CRN/M denied access to essential clinical meetings	CRN/Ms actively involved in essential clinical meetings and embedded in specialism teams; usually a close relationship with Clinical Nurse Specialists
Progress	No opportunities for CRN/Ms to act as Principal Investigator (PI) or Co-Investigator (Co-I) for hosted studies	PI/Co-I opportunities in place (or a desire to) and active review of CRN/M PI/Co-I's as part of study feasibility assessments at study set-up stage.
Progress	No opportunity to design or undertake Nursing, Midwifery or AHP led research	Home-grown, nursing, midwifery and AHP research active – often supported directly by the DON or equivalent
Networking and progress	Minimal effective links with the adjoined (or any) University	Effective University links for academic support and in some cases PhD programmes.

The role of the DON/M on engagement and impact

With respect to nursing/midwifery research and CRN/M development and progress, there was a direct correlation to the DON/M view of research and the impact of CRN/Ms being able to integrate with the rest of the clinical staff on site.

Negative engagement - Case Study

One DON was actively against research despite it being evident in Trust/hospital objectives.

“

Nursing research is pointless and futile, sitting in cupboards reading papers all day is not nursing. Medical research uses nurses as odd-jobs for their own studies and our research team here are doing just that. No-one knows what they do.

”

Further probing into the DON's awareness of the research teams focus, priorities and work with external partnerships eg pharmaceutical companies/academia; showed, the individual was factually uninformed. The DON was unable to describe the team structure, upcoming plans or any successes (a number of which had been witnessed over the two days of the visit). They were also very unaware of the difference between nursing/midwifery research and CRN/M delivery roles.

Personal experience of the department and particularly the CRN/M delivery workforce was that they were; unsupported by the majority of their Executive Team; working incredibly hard under difficult circumstances; were struggling with budget restrictions (from an external funding body as there was no Trust/Hospital funding); but still had multiple celebrations to promote – some of which had been shared only a month before in the Hospital magazine.

The research team reported visibility exercises such as hospital-wide posters and hosting stalls during lunch breaks, which were both patient and staff facing, the previous week. They also reported having invited the DON to attend the department and meet some of the team; the DON did not arrive but confirmed he had other things to do when asked during the scholarship project meeting.

Whilst this is an extreme example of active disengagement, the themes within it were reflected at other sites where DONs had a lack of research understanding or were not engaged with the research nursing/midwifery workforce. The impact of this was detrimental to staff, both research specific and others, as well as the potential reduction in ability to offer patients equality to access of research opportunities

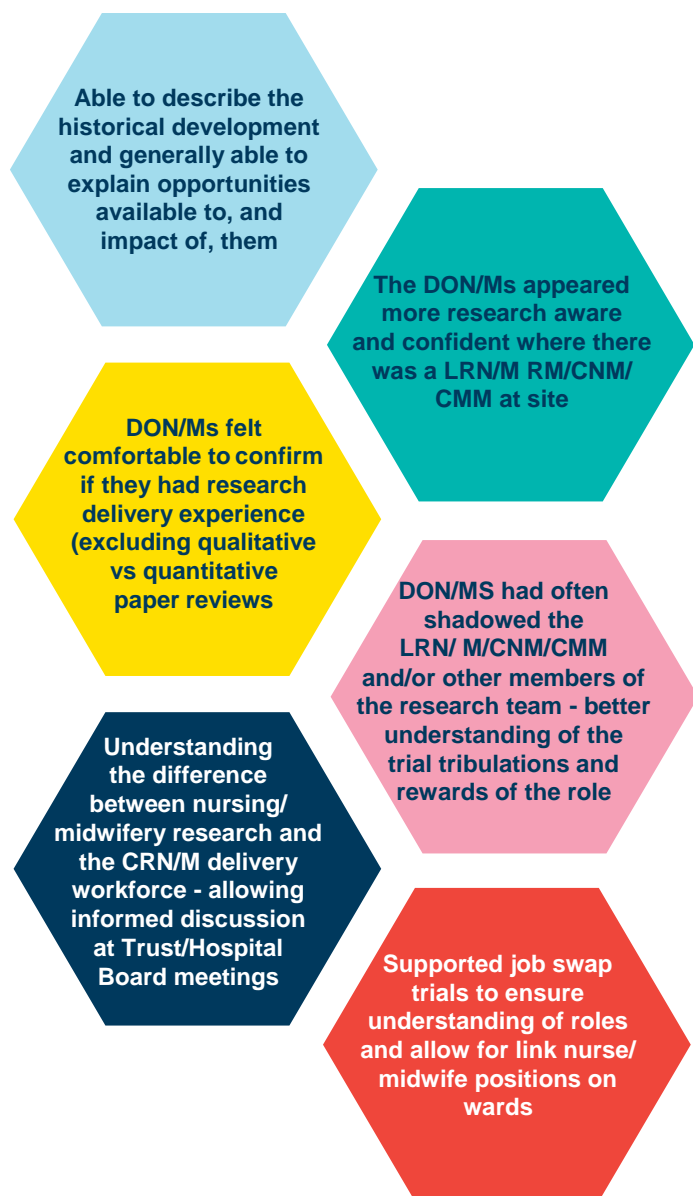
Summary of impacts by the DON/M – negative engagement:

- ♥ CRN/Ms were refused access to meetings where they may recruit potential participants eg multi-disciplinary team
- ♥ Staff on wards were disengaged with research; saw the CRN/Ms as non-clinical; viewed the CRN/Ms as 'not real' nurses
- ♥ Denied access to Nursing/Midwifery celebration events through lack of invitation to attend or present.
- ♥ Lack of progress with nursing/midwifery led research (home-grown or hosted studies)
- ♥ Lack of job satisfaction amongst staff and fewer opportunities for equality of access to research for patients.

Positive engagement

Where positive engagement was evident, DON/Ms demonstrated the attributes as described in Figure 7.

Fig. 7 Positive engagement with/by DON/Ms



DON/Ms with positive attitudes towards nursing and midwifery research with established strategies volunteered reflections on their own learning. These are shown in figure 8.

Fig 8: DON/M reflections



Summary of impacts by the DON/M – positive engagement

- ♥ Recognition and utilisation of enhanced skills held by CRN/Ms – often CRN/Ms were acting as PI/Co-Is for hosted studies
- ♥ Able to talent-map CRN/Ms who have clinical, project and leadership skills
- ♥ Shadowing opportunities for CRN/Ms with other staff and vice versa to assist in integration and understanding were available
- ♥ Positive research culture promoted amongst all staff and evident in Trust/hospital objectives/ambitions
- ♥ Where a LRN/M/RM/CNM/CMM was also present, a good working relationship between the two roles equalled trust. This related to increased research opportunities for staff and patients across the organisation.
- ♥ Clinical Nurse Specialists were involved in research
- ♥ Research was in (or being reviewed to be included) in all nursing and midwifery staff job descriptions.
- ♥ A team structure was evident and a strategy for growth was either in place or in development
- ♥ Clinical research meetings were led by the LRN/M/RM/CNM/CMMs (or the Senior CRN/M) in conjunction with the Clinical Director (where in post) and the Head of Research.
- ♥ Clear delineation between research roles was evident ie who is ultimately responsible for decisions relating to each area in relation to clinical and non-clinical targets/viewpoints.

Nurse/Midwife Principal Investigators

A huge area of interest from funding organisations as well as local sites was the development of the nurse/midwife PIs and/or Sub-Investigators (SI) for 'hosted' studies.

All staff recognised that some medical colleagues and pharmaceutical companies were reluctant for CRN/Ms to act as PI's for studies. They also confirmed that when challenging reasons for this, those staff/organisations were not able to provide solid explanation as to why. An interesting article by Spar et al (2009) cited physician time as a significant barrier to conducting clinical research. CRN/Ms confirmed this reflected their experiences (using obtaining signatures, and minimal input into the study delivery, as examples).

All CRN/Ms referred to the GCP guidelines during these discussions which state 'The Investigator should be qualified by education, training and experience to assume responsibility for the proper conduct of the trial...' (ICH-GCP, 1996). Some sites reported they had established Nurse/Midwife PIs already, or were in the process of doing so, often with a medic acting

as a SI for investigational studies as back-up. 10% of sites had actively updated feasibility standard operating procedures (SOPs) to ensure the question of who could act as PI was asked at the earliest stage. In Ireland, CRN/Ms who acted both as the clinical personnel and the facilitators were able to have these conversations themselves and 'allocate' the role accordingly.

100% of CRN/Ms/LRN/M/RM/CNM/CMMs/DON/Ms reported a desire to increase the number of nurse and midwife PI's. Country-wide organisations also confirmed a commitment in working towards this; nationally the notion was fairly new. There appeared to be a lack of awareness that in each country (albeit in 'pockets') this was already happening (or being planned); sites were already putting these roles in place where teams were established and experienced, as part of natural progression and staff development.

There was a desire by larger organisations and funders to create a PI checklist which could be utilised by CRN/Ms to prove their competence for the role. This was a conversation which stirred strong emotions amongst the CRN/M workforce with two responses:

- 1) Frustration and
 - 2) Offence
- ♥ The biggest contributing factor to a 'frustration' response was that medical PIs may have not undertaken any research since their medical training however by virtue of being a medic, were considered appropriately qualified by study Sponsors and local organisations. These PIs may not have run a study since qualifying, received any additional research training, or have any experience in trouble-shooting issues.
 - ♥ Offence was expressed also, and the reasons for this were cited to be that CRN/Ms often:
 - a) complete all day-to-day tasks, and lone visits with study participants were commonplace
 - b) medically qualified PIs are often just asked to provide signatures for oversight purposes
 - c) most trouble-shooting was undertaken by the CRN/Ms and when issues were raised from sponsor or monitors directly to the medical PI, they were often unable to provide an answer without checking the response of the CRN/M in the first instance.
 - d) CRN/Ms reported having received more recent research training as either compulsory parts of, or additions to, their role eg. Informed consent for research training and consequent competencies.
 - e) CRN/Ms were highly skilled in running numerous studies in parallel and therefore had more research delivery and leadership experience.

CRN/Ms acknowledged that it was entirely appropriate for medics to act as PI's for certain studies. None disputed that this should be the case for Clinical Trial of an Investigational Medicinal Products (CTIMP)

where they themselves did not have the clinical knowledge about all drug options (thus not fitting the aforementioned GCP criteria for PIs). Where they did have the knowledge and the Trust/hospital/Sponsor agreed, some still placed their role as SI, as opposed to PI, to cover accountability; others were firm in stating PI was their place in the team.

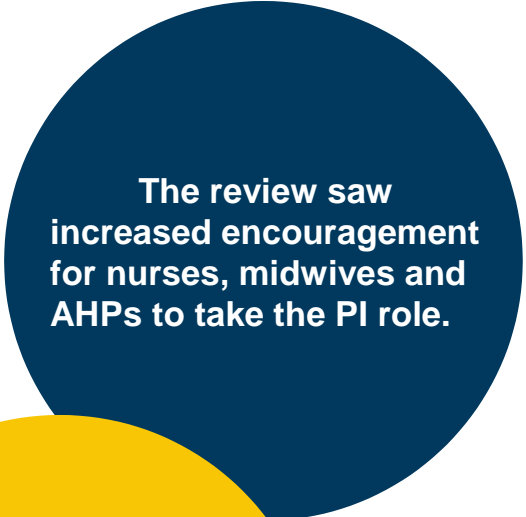
Over a decade ago, Rosenweig et al (2005) looked at published articles, anecdotal experience and completed research studies of nurses acting as PI for cancer research studies. Nurses in the study had; extensive oncology training in specific areas (usually by body-site), experience in having delivered clinical trials previously, and a full and complete understanding not only of the investigational drug, but of the alternative treatment options available to the group of patients. The study concluded that nurses can serve successfully as PIs for medication trials in cancer care.

More recently, Braidford and Terry (2015) investigated the nurse alongside the wording defining an individual as fit to be a PI for a research study. They spent 12 months on a mapping-exercise and identified only 4% of active studies had a nurse PI. 98% of open studies at that time had CRN involvement as contributors rather than leaders. Local strategic discussions led to a process whereby opportunities to lead on clinical studies were more widely shared. Ultimately the review saw increased encouragement for nurses, midwives and AHPs to take the PI role and acted as a trigger for R&D facilitators to ask the question from study set up.

CRN/Ms felt a checklist for PI criteria may potentially be of use, however they were clear to state that if this was implemented, it should not be specific to CRN/Ms; rather it should be for all PI's regardless of profession.

Participants in this project supported the move towards CRN/Ms to act as PIs. Undertaking the role for an observational study was viewed as a useful way to develop new nurse/midwife PI's in terms of confidence and building a portfolio of studies, whether these staff were dedicated CRN/Ms or nurses/midwives working on wards or in other departments which were research active.

More experienced CRN/Ms who were specialised in specific disease areas as well as research, cited acting as SI's was useful for demonstrating experience to sponsors. Acting as SI's for investigational studies (often commercial), allowed CRN/Ms to build a selection of studies on their CVs in a more visible lead role. In turn this made future study sponsors reconsider statements that only medical colleagues may act as PI for their studies.



The review saw increased encouragement for nurses, midwives and AHPs to take the PI role.



98%

of open studies at that time had CRN involvement as contributors rather than leaders.

6. Celebrations and visibility

- ♥ **England** - Annual FroNT group forum at the International RCN Conference. Annual NIHR Clinical Research Nurse Celebration Event (supported by the Department of Health) Annual regional NIHR celebration events
- ♥ **Ireland** - Annual Irish Research Nurse Network Conference (supported by Health Research Board Ireland)
- ♥ **Scotland** - Annual Research Nurse and Coordinators Network Conference (supported by Chief Scientists Office)
- ♥ **Wales** - Annual Health and Care Research Wales Event (supported by Welsh Government)
- ♥ **Northern Ireland** - Annual Northern Ireland Clinical Research Network Educational Event.
- ♥ **Universities** (regardless of geographical location) - Annual research symposiums/conferences

The SRNCN event includes a 'Research Nurse/Midwife' of the year award which has assisted in raising the profile not only of the individual and their work, but of research nursing in Scotland as a whole.

The NIHR and Department of Health in England celebrate clinical research nursing through hosting the 'Clinical Research Impact' category at the Nursing Times Awards annually. This, as in Scotland, has increased visibility and publications around celebrated work. The winners have also presented their work at the Department of Health as well as through other means of visibility raising, local media for example.

The Irish Research Nurse Network Conference now has a strong relationship with the Irish Health Research Board; something which came about when Dr Graham Love was Chief Executive and saw the IRNN tweeting about their event using #WhyWeDoResearch. After a lunch time visit to the event, a relationship was developed and this has led not only to increased understanding of the CRN/M role, but also to a funding stream specific to CRN/Ms in Ireland to assist with training, education and conference attendance.

Wales have had strong links between the research and Government worlds for some time. Their National events showcase work both nationally and internationally as well as holding break-out sessions which focus on specific examples of excellent work either being undertaken or that which has been completed and is transferrable to other clinical areas. These events continue to develop the existing relationship, ensuring all voices are heard and strategies can be developed accordingly.



The NI CRN host fantastic educational days which are designed by Sonia McKenna, Staff Manager. These are based on her knowledge and experience of working with CRN/Ms in the organisation and identifying gaps where more training is required. External speakers are invited to present which provides the staff with a wider perspective of the CRN/M role. Events are also utilised to showcase examples of excellent practice which have the ability to be replicated elsewhere.

All universities involved in the project reported hosting celebration/dissemination events. These tended to focus on the nurse/midwife researcher role and covered both original research and service evaluations. The size of these ranged from small seminar rooms to large auditoriums.

About half reported difficulties in getting nursing/midwifery research on to the annual research symposium/conference agenda.

Some Universities hosted specific nursing, midwifery and AHP conferences/symposiums. Reasons provided were:

- ♥ NMAHP research deserves dedicated space (the biggest viewpoint shared)
- ♥ Funding was available
- ♥ A specific event meant more people from those professions could attend – difficulty with space for larger audiences
- ♥ They could invite more organisations/programmes specific to NMAHP professions to host stalls in the lobby throughout the day
- ♥ Historical perspective on medical research events perceived as being 'boring' or 'not for NMAHPs' therefore a shared symposium may not attract NMAHP audiences.

Others reported persevering to ensure nursing, midwifery and AHP research was included in the main University research symposium. Reasons given for this were:

- ♥ The university should support NMAHP research equally to medical research (by far the biggest viewpoint shared)
- ♥ One multi-professional research symposium demonstrates a message from the establishment that it is a collaborative 'team'/department and not one which is viewed as separate (second largest viewpoint)
- ♥ Forced some medical colleagues unsupportive of NMAHP research to re-evaluate their perspectives once they heard the sort of work which was being undertaken and impacts it was having either locally or nationally (or more widely).
- ♥ Funding was unavailable for a second symposium in the same academic year and when challenged to host NMAHP symposium, requests were declined (smaller numbers)

Regardless of approach described above, representatives cited these events as directly responsible for improving awareness of nursing and midwifery research within their Universities. Where students or lecturers had conducted research and showcased it at these events, they were encouraged to disseminate further eg Nationally or internationally, through publication and/or conference routes.

The CoDH recently released 'Securing a Sustainable Future Strategic Plan; 2018-2021' (CoDH, 2017) which extends its commitment to strengthen the research agenda in relation to government policies and negotiate and secure research funding for all disciplines. Some university representatives have been in contact since the scholarship ended and since the publication of this strategy. They have confirmed that the CoDH (2017) plan should have a positive effect for them and that whilst it does not specifically discuss dissemination, many intend to use the document as ammunition to support publications, conferences and other sharing routes to ensure NMAHP research is heard and visible.

7. Country Showcases

England

- ♥ Research confirmed as 'core business' from Government level
- ♥ A specific CRN/M strategy launched October 2017
- ♥ NIHR Clinical Research Network and links to research sites
- ♥ Educational opportunities through charities, NIHR, Academia
- ♥ A number of sites with a LRN/M/RM in post
- ♥ Willingness to share learning and developments from large established sites through to those newly developed
- ♥ Nurses/Midwives as PIs/SIs becoming more commonplace.

Ireland

- ♥ IRNN community and output
- ♥ Engagement and collaborative work with the Irish HRB
- ♥ Support from DON/Ms regarding nursing/midwifery research approach within hospitals, inclusive of both funding for and expectations of, research within nursing and midwifery roles
- ♥ Support for nursing research from Chief Nursing Office at the DOH
- ♥ Desire to support Nurses/Midwives as PIs for hosted studies
- ♥ Development of Hospital Groups and inclusion of research midwife to the Steering Committee
- ♥ Good links with Universities.

Northern Ireland

- ♥ NI CRN as an organisation supporting development of the CRN/M workforce
- ♥ Annual educational training days well evaluated and leading to a workforce which has high standards of care and research delivery
- ♥ NI CRN supporting CRNs to support hospitals with research activity
- ♥ Staff Manager present within the NI CRN with ability to forge progress for nursing and midwifery delivery research
- ♥ Work to increase NMAHP led research within Universities and other organisations is increasing.
- ♥ Desire to support Nurses/Midwives as PIs.

Scotland

- ♥ SRNCN Network output and community
- ♥ Engagement work with the Chief Scientists Office (CSO)
- ♥ NMAHP research at The University of Edinburgh, University of Glasgow and Beatson West of Scotland Cancer Centre
- ♥ Work at student nurse level to increase awareness and understanding of the CRN/M roles
- ♥ Survey to the clinical workforce in Aberdeen; focus on awareness of research.

Wales

- ♥ Close links between Welsh Government (and therefore policy makers) and healthcare staff
- ♥ Desire to support Nurses/Midwives as PIs/SIs
- ♥ Regular annual events for CRN/Ms
- ♥ Cardiff & Vale multi-speciality delivery team which supports studies at various sites (fully set up with access with regards to competencies)
- ♥ HRD's all have frontline research delivery experience, therefore understand, value and can advise on the CRN/M roles
- ♥ Support for nursing research from Chief Nursing Office at Welsh Government.



8. Recommendations for CRN/M strategies and structures

- ♥ All sites should have a LNR/M/RM/CNM/CMM in post with meaningful oversight of the clinical research workforce.
- ♥ LNR/M/RM/CNM/CMM should lead development of structures for CRN/M teams.
- ♥ Where LNR/M/RM/CNM/CMM's report to a non-clinical individual eg Head of Research/Research Manager, arrangements should be made for a 'dotted line' to a (Deputy) Director of Nursing/Associate Director of Nursing (varying titles) to ensure clinical accountability and support.
- ♥ Appraisals for the LNR/M/RM/CNM/CMM should include the line manager and (where the Line Manager is a non-clinical member of staff) the dotted accountability individual in order to be effective.
- ♥ Where structures require review and no LNR/M/RM/CNM/CMM post is in place, this should be advertised and appointed to as soon as possible to ensure appropriate engagement, knowledge and experience is in place to manage the teams.
- ♥ CRN/Ms should be consulted regarding views on restructure for ideas and opinions at the earliest opportunity and provided with the opportunity to contribute.
- ♥ Decisions about strategy and structures should be made only by individuals with strategic aspects to their job roles and who understand the role(s) which are under review.
- ♥ Strategic decision-making meetings should include: Clinical Director for Research, Head of Research/Research Manager, (Deputy) Director of Nursing, LNR/M/RM/CNM/CMM (if in post, or otherwise all SCRNs leading sub-teams), and a finance representative (either from the organisation finance department or the R&D finance accountant if their role contains strategy and ability to confirm funds). Depending on the site, there may be other roles considered as essential attendance – this decision should be made by the Clinical Director.
- ♥ Permanent positions for CRN/Ms in CRFs should be considered in order to ensure a regular flow of studies through the department without unnecessary delays.
- ♥ Sites developing strategies to commence or increase home-grown research should implement an additional Lead Nurse/Midwife for Research role whose sole focus is developing relationships and research priorities at site and in conjunction with universities.

Appendix seven provides the basis of a strategy document for creating a research nursing strategy based on themes arising through this project.

9. Recommendations for future projects and research

9.1 Future projects – recommendation

- ♥ Identification of the full number of CRN/Ms across the UK and Ireland (regardless of funding route) would assist in understanding the scale of the CRN/M workforce
- ♥ Increase understanding of DON/Ms and Executive team members regarding the difference between nurse/midwife research and CRN/M delivery workforce roles
- ♥ Continue to increase the number of Nurse/Midwife PI's for hosted studies at sites.
- ♥ Repetition of the 2008 clinical research nurse report in Ireland to identify differences over the past decade
- ♥ Clarity over role content and titles within individual sites, would assist continuity across the country(ies)
- ♥ Funding/Government organisations to work to support raising the profile of CRN/Ms in addition to specific programmes of work
- ♥ Universities to increase publications of programmes of work which develop clinical-academics and hospital based nurse researchers
- ♥ A scoping exercise to identify the number of CRN/M PI's already in existence and the associated tools that are being used to confirm eligibility locally
- ♥ Investigation into the desire of a research nurse/midwife forum for England and Wales similar to those in Scotland, Northern Ireland and Ireland.

9.2 Future research - recommendations

- ♥ CRN/Ms should increase evidence within the literature of the impact of their roles through sharing working practices and outcomes in professional journals, conference presentations and other dissemination routes
- ♥ Work to understand other clinical workforce staff members within research teams: benefits and challenges alongside impact on data quality, impact on CRN/M/medics time, and patient experience.
- ♥ Research to identify understanding of CRN/M and nurse/midwife researcher roles by other clinical staff.
- ♥ Research to demonstrate the impact of dedicated roles for CRN'/Ms eg in CRFs, and benefits to patients and organisations.
- ♥ Research in to professional identity, including (but not limited to); uniforms, emotional resilience and role impact.

A cross-border group to establish collaborative approaches to sharing working practices and conducting research to benefit all across the UK and Ireland, would assist in international understanding and promotion of work conducted by both CRN/Ms and nurse/midwife researchers.

Appendix 1. Original Aims of project, status and mid-point and final outcome

Original Aim	Status (mid-end project)	Final outcome
<p>1. To identify a range of structures of research nursing/midwifery teams in the UK and Ireland</p>	<p>Merged with Aim 3. Many sites did not have specific structures in place; some were in development stages. There were differences between the understanding of the roles of research delivery nurses/midwives and those who were home-growing their own research, by site and by country - which in some cases hindered developing clear infrastructures, and therefore impacted on strategy development.</p>	<p>A range of structures and strategies were identified. Themes arising which assisted or hindered development of these are documented throughout this report. A suggested model of stages for developing a research team structure is available in appendix six.</p>
<p>2. To develop an awareness of the types of roles within clinical research delivery teams and the job remits/titles used</p>	<p>The review of nursing and midwifery research roles alone proved to be a large topic therefore the decision was made within the first trip to focus on these professions and step back from the AHP focused roles (see notes by the author on page 5).</p>	<p>The importance of a lead clinical oversight role was clearly demonstrated both through actions by the LRN/M/RM/CNM/CMMs themselves, and impacts as reported directly from the CRN/Ms under their charge.</p>
<p>3. To identify how research nursing strategies were developed at sites</p>	<p>Merged with Aim 1. Perhaps the biggest area of work within this project. This could now be termed 'how will research structures and strategies be developed?'</p> <p>Where LRN/M/RM/CNM/CMMs were in post with meaningful oversight of the whole team, and understood by Executive Teams and/or Directors of Research, progress was able to be forged around research nurse/midwife delivery roles, home-grown nurse/midwifery led research and development of all staff.</p>	<p>See outcome 1.</p> <p>Examples of themes identified in successful strategies are documented in appendix seven.</p>

Original Aim	Status (mid-end project)	Final outcome
<p>4. To create long term links across the home-countries which may lead to further collaborations in the future</p>	<p>A number of collaborations are already in place and with a variety of focuses. Some specific examples are provided below:</p> <p>Eg. 1. Linking of Government research ‘arms’ and forums across the home countries with a view to looking at increasing the number of nursing principal investigators for both hosted and home-grown studies</p> <p>Eg 2. Linking site contact from Darlington who is applying for a PhD with other sites from the project who were able to be recommended as fitting her proposed study.</p> <p>Eg 3. Supporting links between the Irish Research Nurse Network and the Irish Health Research Board</p> <p>Eg 4. Linking sites from different countries who are working on the same hosted studies (eg JPUH and Glan Clwyd Hospital, North Wales)</p>	<p>Additional collaborations continue to be made following various contacts made throughout this scholarship, whether with JPUH, or with other participating organisations/individuals.</p>
<p>5. To support development of nursing/midwifery research workforce pathways</p>	<p>It became evident early on that a large number of sites did not have a specific workforce plan in terms of development or pathways. Sites had excellent induction programmes and local teaching sessions available to both research and non-research employed staff. The JPUH workforce pathway was desirable to other sites.</p>	<p>A draft publication about the JPUH workforce development pathway creation is now underway and will be submitted to a Journal for peer review 2018.</p>
<p>6. To create evidence which may be used towards professional accreditation for clinical research nurses/midwives.</p>	<p>Locally JPUH have adopted the UK Clinical Research Forum Network (UK CRFN) consent competency document, and adapted the IACRN induction checklist to complement one already in place. The project identified a number of specific themes across all sites which impact the CNR/M role; it is important that CRN/Ms showcase their work and recognise the differences in their role when compared to other nursing and midwifery posts.</p>	<p>This project has formed the foundation for further research to be undertaken where previously little information has been publicly available. Recommendations are made at the end of the report.</p>

Appendix 2. Output

Conference/Event Presentations

- ♥ **Belfast City Hospital:**
Event hosted especially for the scholarship visit, Belfast, 7th November 2016
- ♥ **Irish Research Nurse Network International Conference:**
Dublin, 9th November 2016: Keynote
- ♥ **Northern Ireland Clinical Research Network Annual Education Event;**
Belfast, 12th December 2016
- ♥ **University Hospital Southampton NHS Foundation Trust Clinical Trials Associate Inaugural Conference:** Southampton, 3rd March 2017
- ♥ **Scottish Research Nurse and Coordinators Network Annual Conference;**
Dundee, 17th March 2017: Keynote
- ♥ **Welsh Government and Health and Care Research Wales National Event:**
Cardiff, 20th March 2017
- ♥ **Hinchingbrooke Hospital Annual Research Symposium, Hinchingbrooke Hospital, May 2017**
- ♥ **UK Forum for Trust/Health Boards Research Leads (FRoNT) Event:**
Darlington, 3th June 2017
- ♥ **UK Clinical Research Network Forum Annual Conference;**
Glasgow 6/7th July 2017. Two social media masterclasses with live tweetchats and Closing Plenary Session

TWEETCHATS via #WhyWeDoResearch International Twitter Community (1 hour in length)

- ♥ **“Midwifery research”**
Tuesday 16th May, 2017
- ♥ **“If and when to start research”**
Friday 19th May, 2017
- ♥ **“International Research”**
Friday 19th May, 2017
- ♥ **Careers for Clinical Trials Assistants/Clinical Support Officers”**
Monday 22nd May 2017
- ♥ **“Principal Investigators – who can be one and how do you choose?”**
Monday 22nd May, 2017
- ♥ **“Clinical Research Nurse: Professional Identity”**
Tuesday 23rd May, 2017
- ♥ **“Embedding research into clinical practice”**
Tuesday 23rd May 2017
- ♥ **“Scholarship opportunities for nurses, midwives and AHPs”**
Wednesday 24th May 2017
- ♥ **“Feasibility for research studies”**
Wednesday 24th May 2017
- ♥ **“Best practice in clinical research nurse/midwife induction”**
Thursday 25th May 2017
- ♥ **“What makes a good research environment?”**
Friday 26th May, 2017

All tweetchats had a reach of over 1 million impressions

Appendix 3. Challenges and Opportunities

Challenges

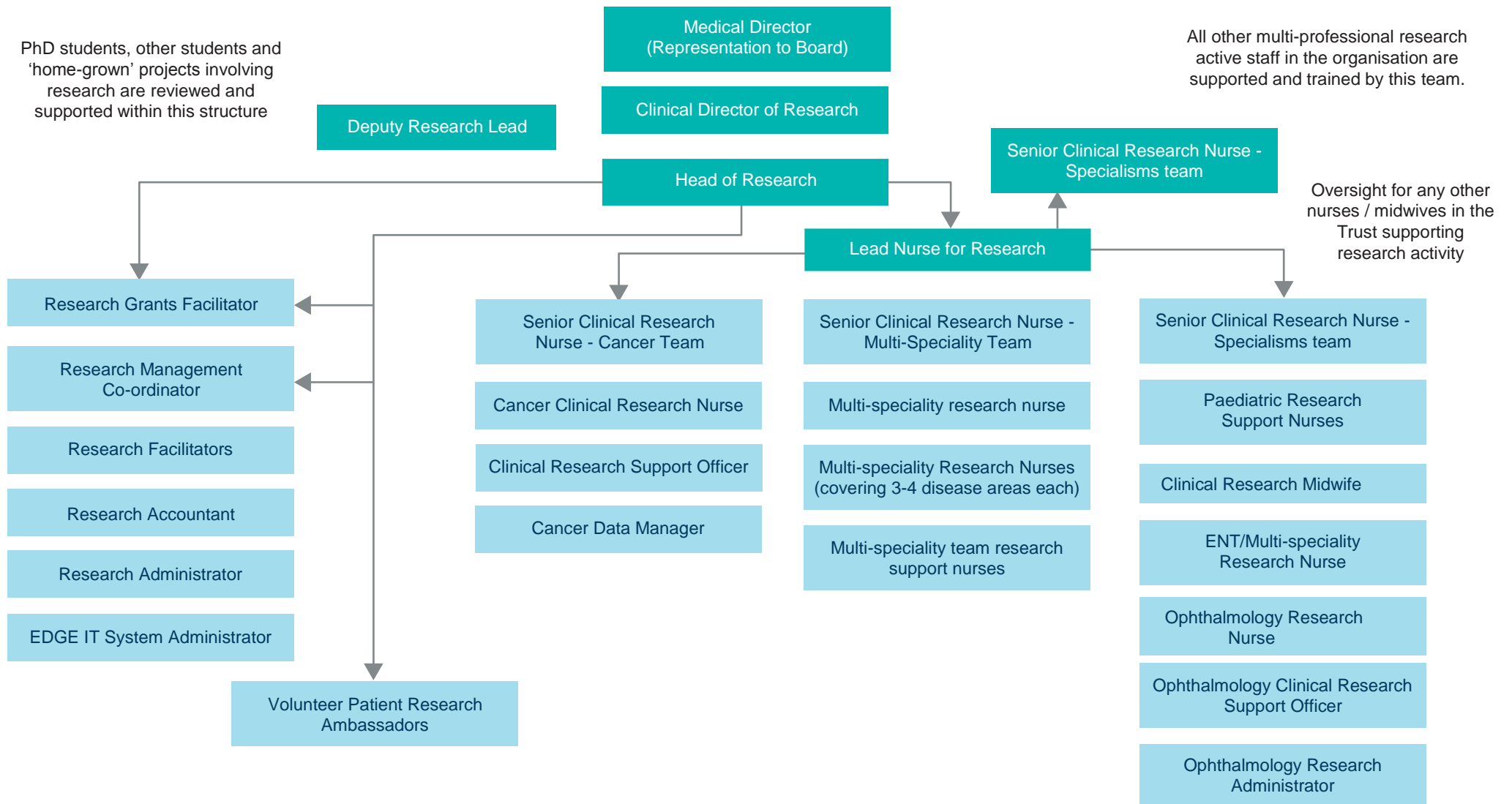
- ♥ The project grew far more than anticipated. Whilst this was positive, it meant some sites/organisations had to be turned down where they had made contact and requested to be involved over the year.
- ♥ The scholarship allowed four weeks as study leave (agreed by the Head of Research and Director of Nursing at application stage). A further 1.5 weeks of annual leave was utilised to allow more sites/organisations to participate and ensure an equal spread across each country.
- ♥ The write up has been (and publications continue to be) entirely in my own time. The support from colleagues, those staff and sites involved internationally in the project, and my husband, kept me focused when things were difficult.
- ♥ The scholarship provided £3,500. Whilst funding and time allocation were limiting factors, this assisted in keeping the project focused and still allowed for more site involvement than anticipated.

Opportunities

- ♥ Participating sites were an incredible strength to this project. Every site and CRN/M gave their time freely, openly and honestly. Without their openness this project would not have developed as it has.
- ♥ Having the support of Hazel A. Smith as Midwifery advisor on this project has been invaluable. She has assisted in my understanding of the midwifery research role and differences in structures and strategies.
- ♥ The funding for this project allowed face to face conduct of groups/seminars/121s. Whilst skype for example is a valuable tool, there are times when face to face cannot be replaced. In this instance, face to face meant that discussions were more open, people were able to understand clearly the reasoning behind the project and what I truly wished to achieve.
- ♥ With advanced planning and preparation this report shows that it is possible to conduct a large project with £3,500.
- ♥ This was a scholarship-based project and therefore it is entirely independent. Any individual at each site regardless of funding stream, was able to be involved.
- ♥ #WhyWeDoResearch provided the opportunity to network, develop and maintain relationships with visiting sites and provide updates on the project. It also allowed those involved and observing the project to provide their feedback and thoughts throughout the study period.
- ♥ This project demonstrates both the scope and hunger for a larger scale version to be undertaken in the future.

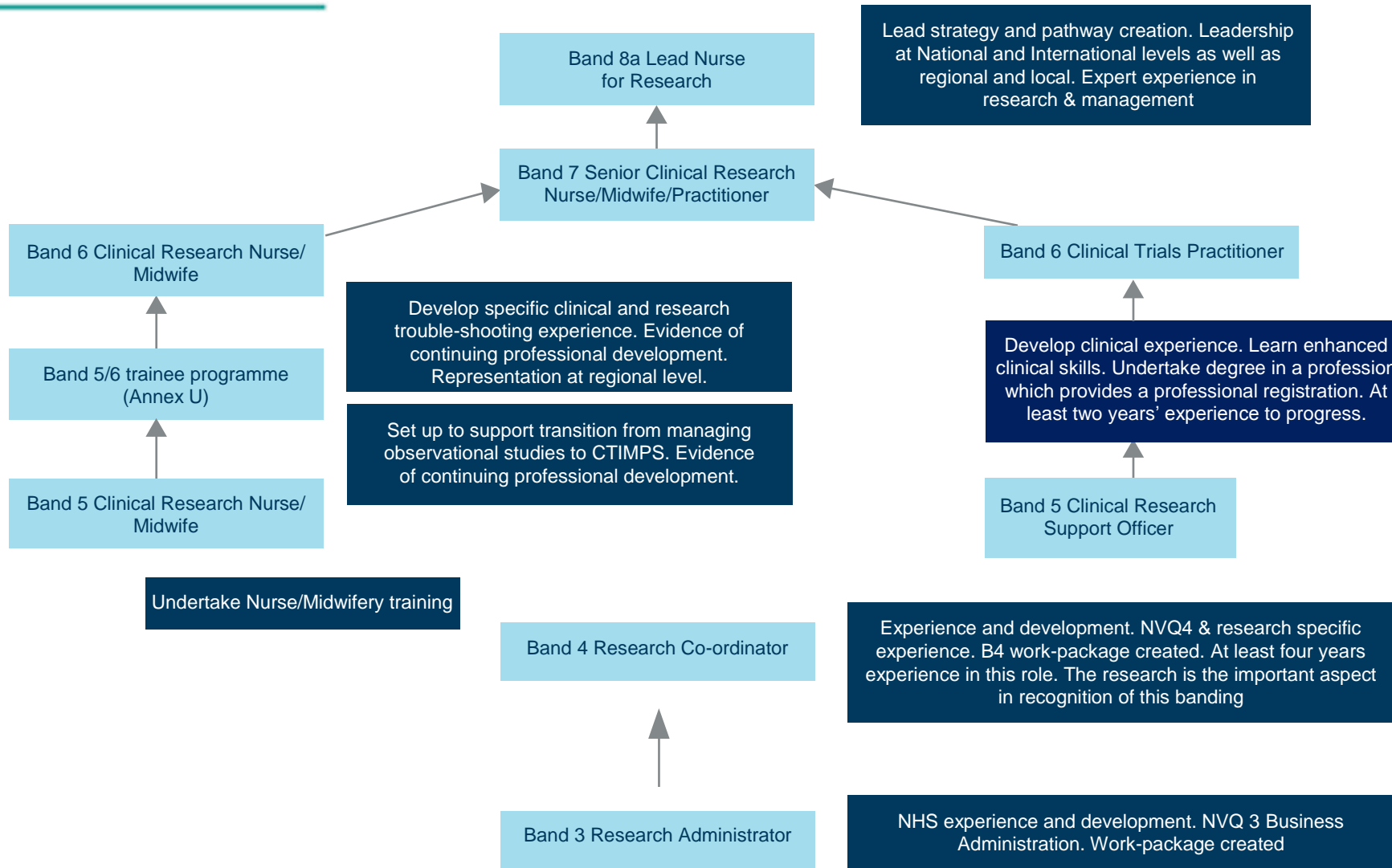
Appendix 4.

The core structure within the R&D Department at JPUH clearly states roles and reporting lines from entry to Board Level. The team works as one large team split by clinical and non-clinical sides, rather than as separate entities. I have provided a diagram showing the JPUH structure as requested by several sites who wished to replicate it.



Appendix 5.

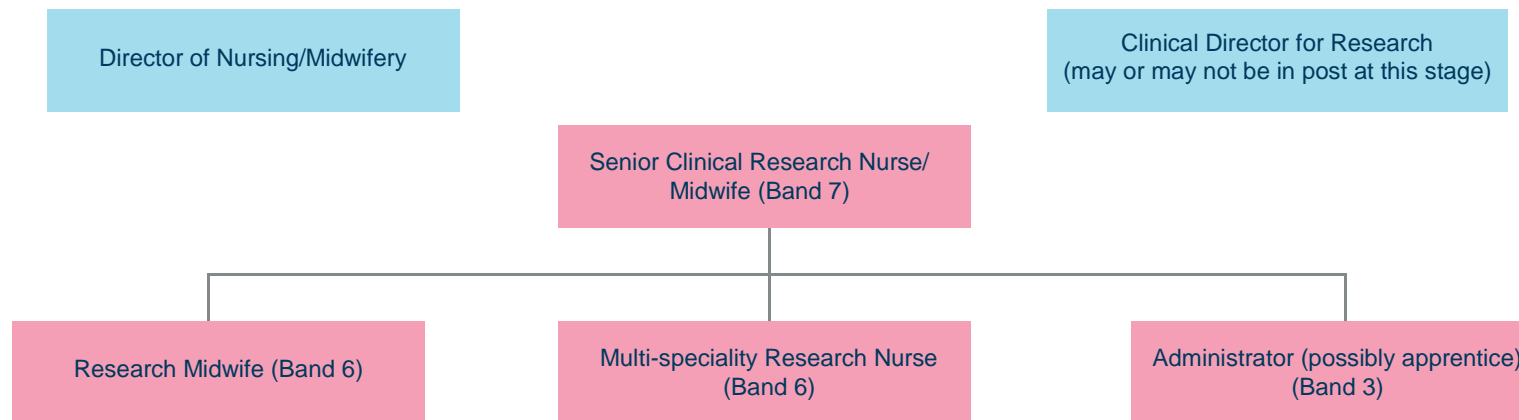
The development pathway for staff at JPUH also became desirable for other sites therefore an overview of this is provided below.



Appendix 6. Whitehouse-Smith (2018) model for developing clinical research teams

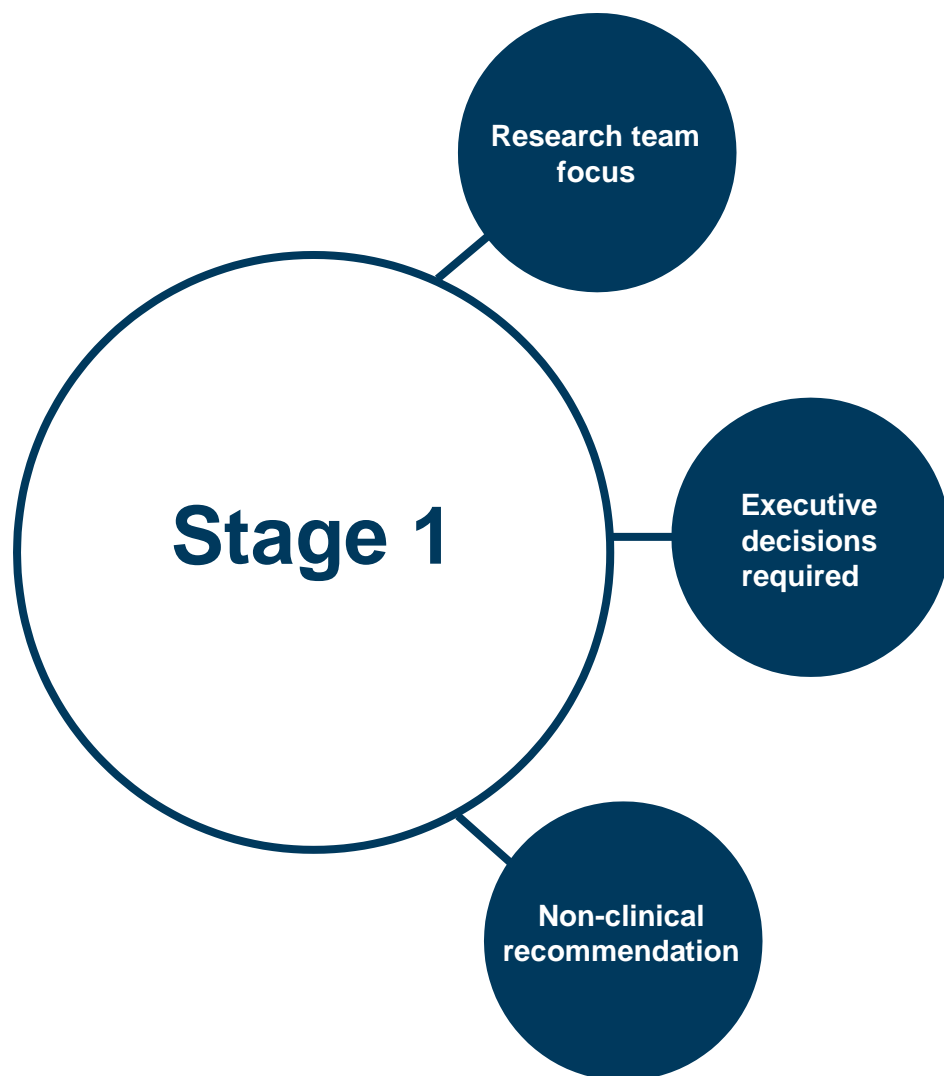
The organisational charts within this appendix describe a proposed model of stages for building a clinical research nurse/midwifery team from a basis of no research activity. It is constructed with order of role implementation in the first instance and based on the review of structures throughout this project. It does not represent the 'how', however suggestions are made regarding questions which should be asked and answered at each stage prior to moving to the next.

Each stage is represented by an organogram of the clinical side of the research team, followed by an infographic providing further considerations and suggestions for team set up based on a) Clinical delivery team b) Executive team and c) Non-clinical team. Timeframes for working through each stage will vary depending on the site/organisation.



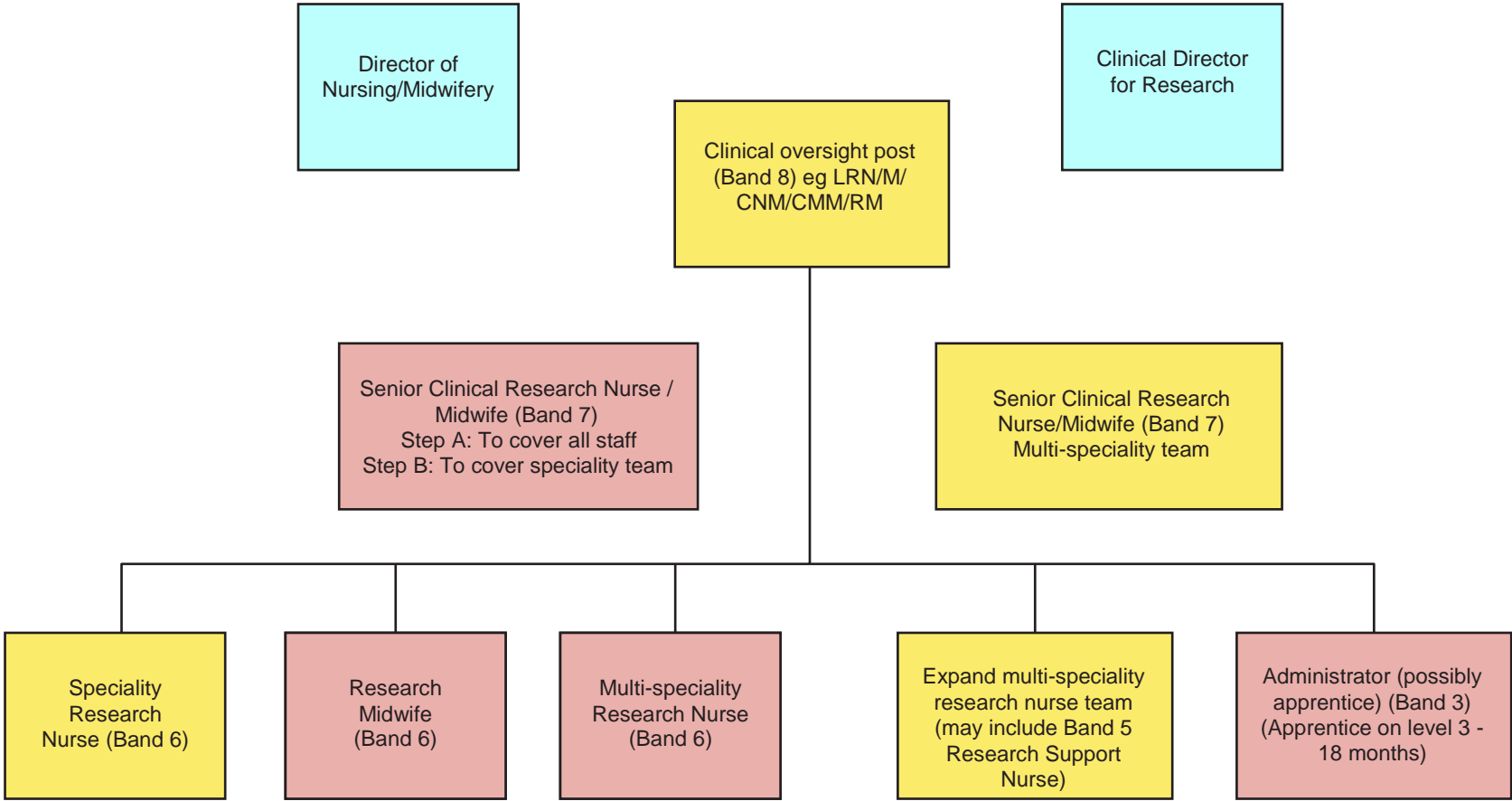
Executive decision to be made (from the outset): Is the Trust/Hospital going to 'pump prime' the team utilising funding from within their organisation? Are there other funding routes available within the country eg NIHR research networks – England, Health and Care Research Wales – Wales, NI CRN – Northern Ireland, Chief Scientists Office – Scotland, HRB/HSE – Ireland. What are the criteria for these funding routes? Will staff contracts be fixed term? Permanent? Will a research accountant be required/who will have research on their finance portfolio? Is there suitable accommodation to locate the team, files and the study equipment?

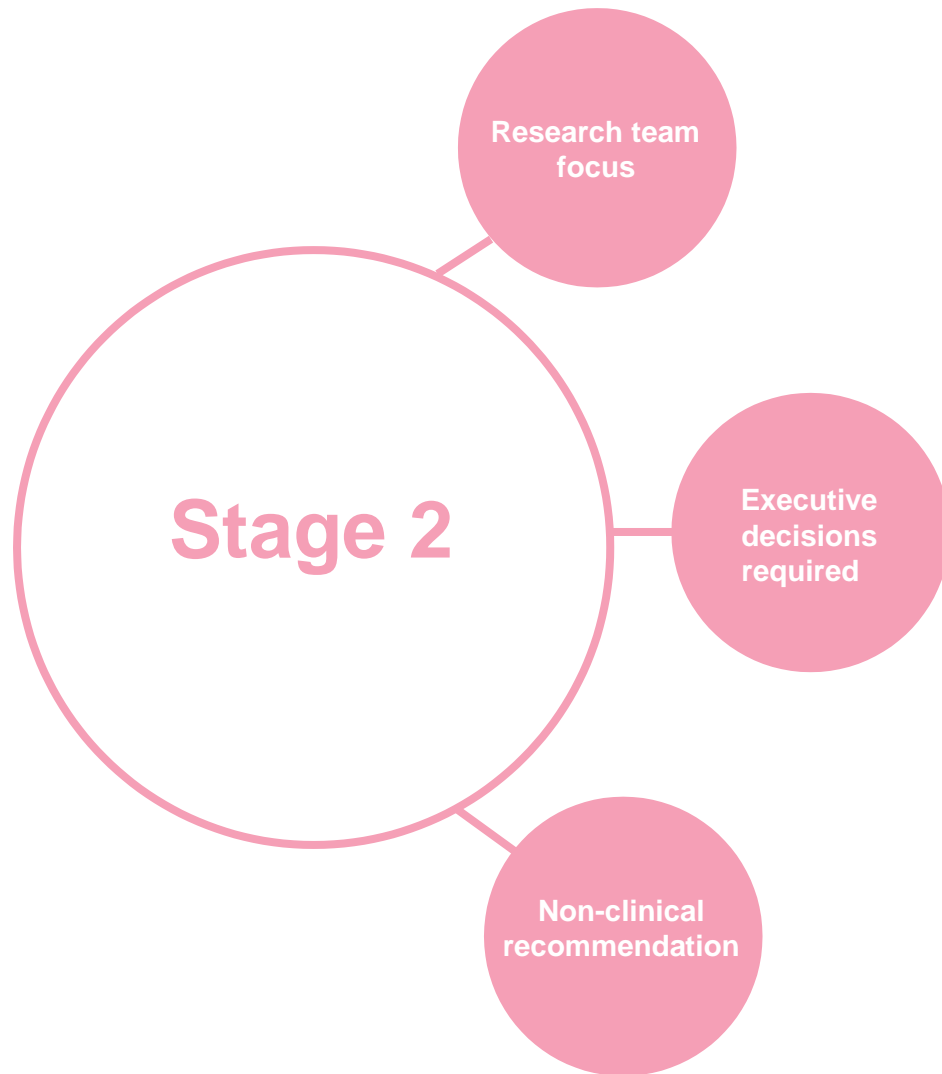
Most importantly, is there a commitment and shared vision to support hosted research within the organisation and has this been discussed/reviewed with all other management within the organisation (eg middle management including clinical and non-clinical staff. Will some awareness/promotional work be conducted to inform staff within the organisation that research is going to be an option for patients soon?



- **CRN:** Clinical areas where there is demonstrated interest from clinical teams. This could be a mixture of disease areas eg. Ophthalmology, orthopaedics and rheumatology (multi-speciality)
- **CRM:** The midwifery post may commence as part time whilst studies are sought and the portfolio within that arena with healthy volunteers
- **Oversight role:** Set at band 7 initially: maintain a full awareness of clinical areas engagement and which areas may be interested in developing; lead in to the next stage with a plan, mindful of clinical service ad targets to be achieved.
- The project identified that some clinical areas are reluctant to engage in hosting research studies. At this early stage of team development, a decision must be made between trying to engage research in areas with reduced interest, and/ or putting additional efforts and resource in to supporting those areas who are already immersed. The latter is the recommended approach for stage 1.
- All: Focus on raising awareness of research to all other staff within the organisation and teaching for lead nurses/midwives and matrons/charge nurses with little research experience
- There may or may not be a Head of Research or Clinical Director for Research at this point.
- If one or both are present, the SCR/M will work closely with them regarding next steps of development
- If there is not, the SCR/M will be discussing this with the DON/M. The DON/M should work with the Executive Team regarding plan awareness and implementation, ensuring Executive Team engagement remains effective.
- Consideration of potential research focuses for NMAHP research; co-ordinate work with audit/transformation teams to ensure evidence is available ahead of developing the nurse/midwife researcher roles (and prevent reactive approaches)
- Further consideration to accommodation: does it require review of relocation prior to team expansion?
- It is useful at stage 1 to have a Research Facilitator post in place.
- This individual will be responsible for the study set up and act as a point of contact for the Sponsor
- They will review documents, work on completion of expression of interest/feasibility forms, arrange site visits when applicable, review approvals (country-variations should be taken in to account here) and co-ordinate the set-up of the study.
- Once the study is running, they may provide support with Sponsor liaison
- The post requires research knowledge and understanding of the study set-up pathway within the country in which they are working, therefore is generally viewed as a band 5 role.
- The placement of this role at this stage allows the clinical staff to focus on clinical tasks and offering studies to patients. In turn, this increases ability to achieve country-wide targets both from a clinical and non-clinical perspective, for example, in England study set up times (Research Facilitator) and 'First patient, first visit' (FPFV) (Clinical Teams).

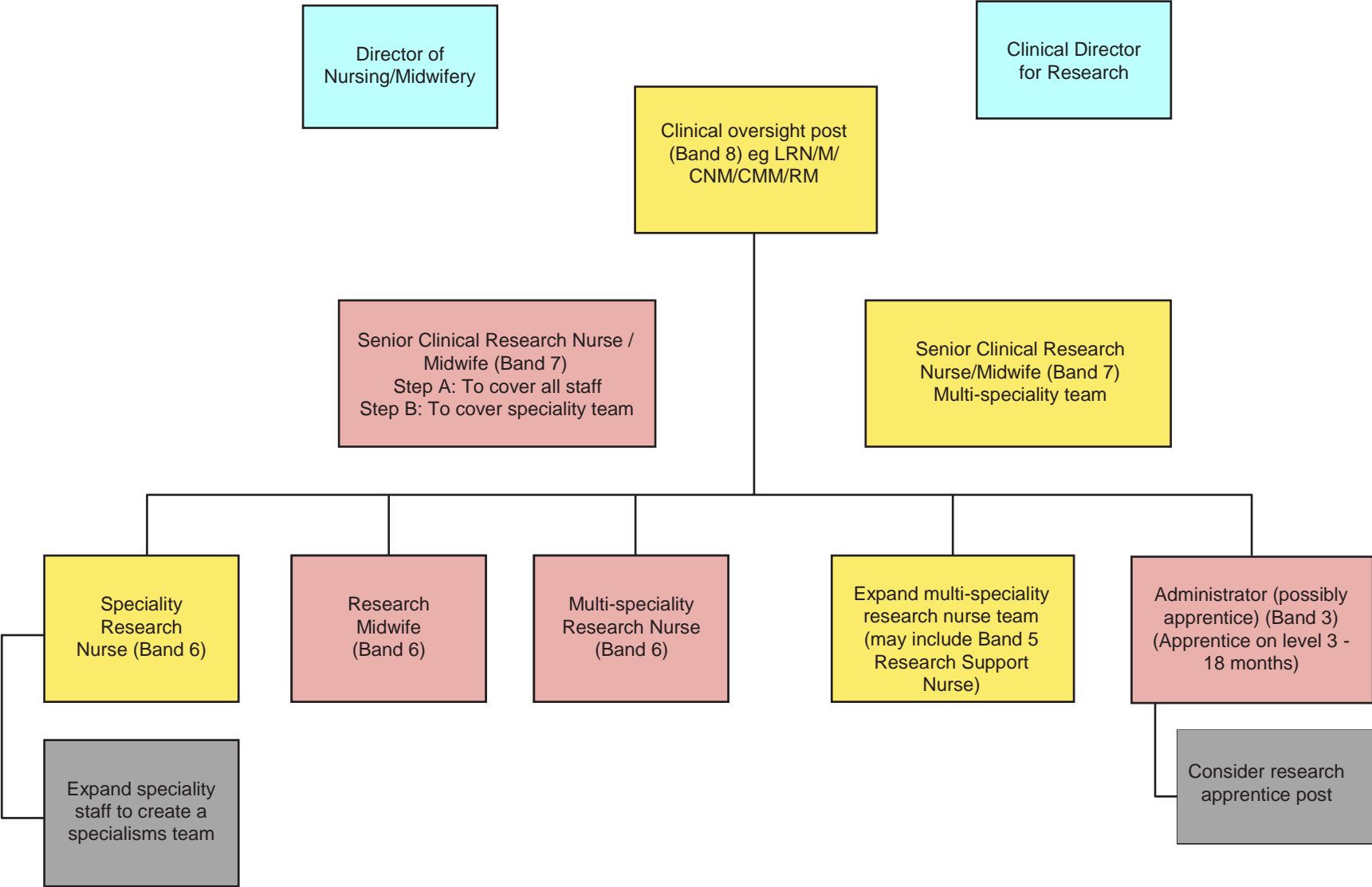
Stage 2 - Recognising areas for development, expanding the multi-speciality team and reviewing oversight.

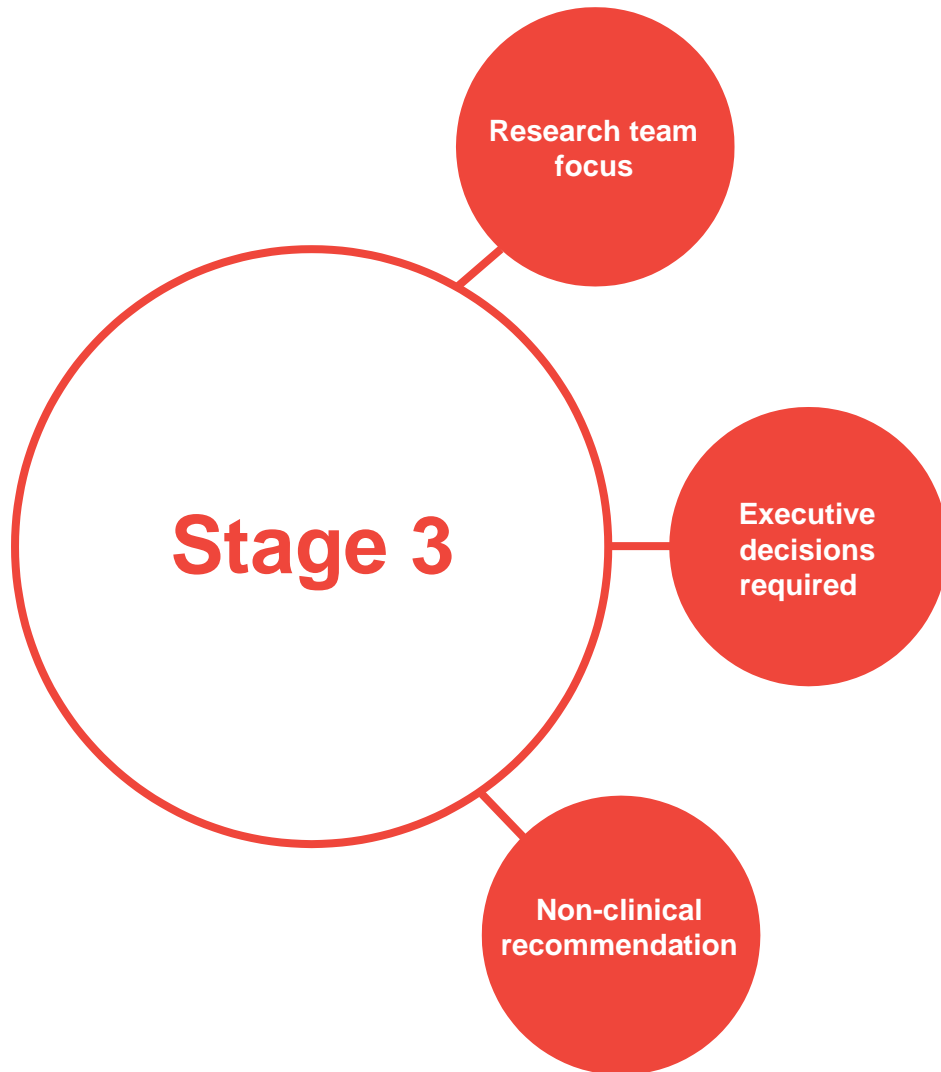




- Expansion of CRN multi-speciality posts to allow further growth of studies and resource to safely deliver them. Expansion in stage 2 may include band 5 Research Support Nurse posts or Clinical Trials Assistants depending on the types of studies coming through the pipeline.
 - Consider increasing CRM post to full time if portfolio of studies is growing effectively, or adding another post should there have been a large influx of studies, or more in the pipeline.
 - Appoint a second oversight post whose role would encompass line management of the multi-speciality team. Original oversight role to retain line management of the speciality nurse, midwife, administrator, reduce their study portfolio and focus further on strategy development.
 - Continued focus on raising awareness of research to all other staff within the organisation and teaching for lead nurses/midwives and matrons/charge nurses with little research experience.
 - Continued focus on training and development to increase skill set and support new staff.
-
- Depending on rate of growth, funding availability and other visionary factors, consider advertising for a strategic oversight post at Band 8 (level within this banding should reflect the size of the workforce).
 - Should point 1 occur, the SCRNI, Band 7 post should be altered eg take back a portfolio of studies and line management, and reduce the amount of strategic direction
 - Consideration of developing NMAHP 'home-grown' research - review of audit and transformation work in place
 - Consideration of grant routes
 - Review of accommodation – does this require review or relocation prior to further team expansion?
-
- Depending on the rate and growth of studies, a second or part time Research Facilitator post may be required at stage 2
 - A Research Manager should be appointed to lead the research facilitation and study management side of the team (which may include research accountant, data managers)
 - The Research Manager is responsible for all non-clinical study set up oversight, leading the team with awareness, monitoring and achievement of National targets, and supporting the strategic direction of the department
 - Banding of the Research Manager post depends on the size of the workforce, amount of strategic requirements within the role and vision of the organisation

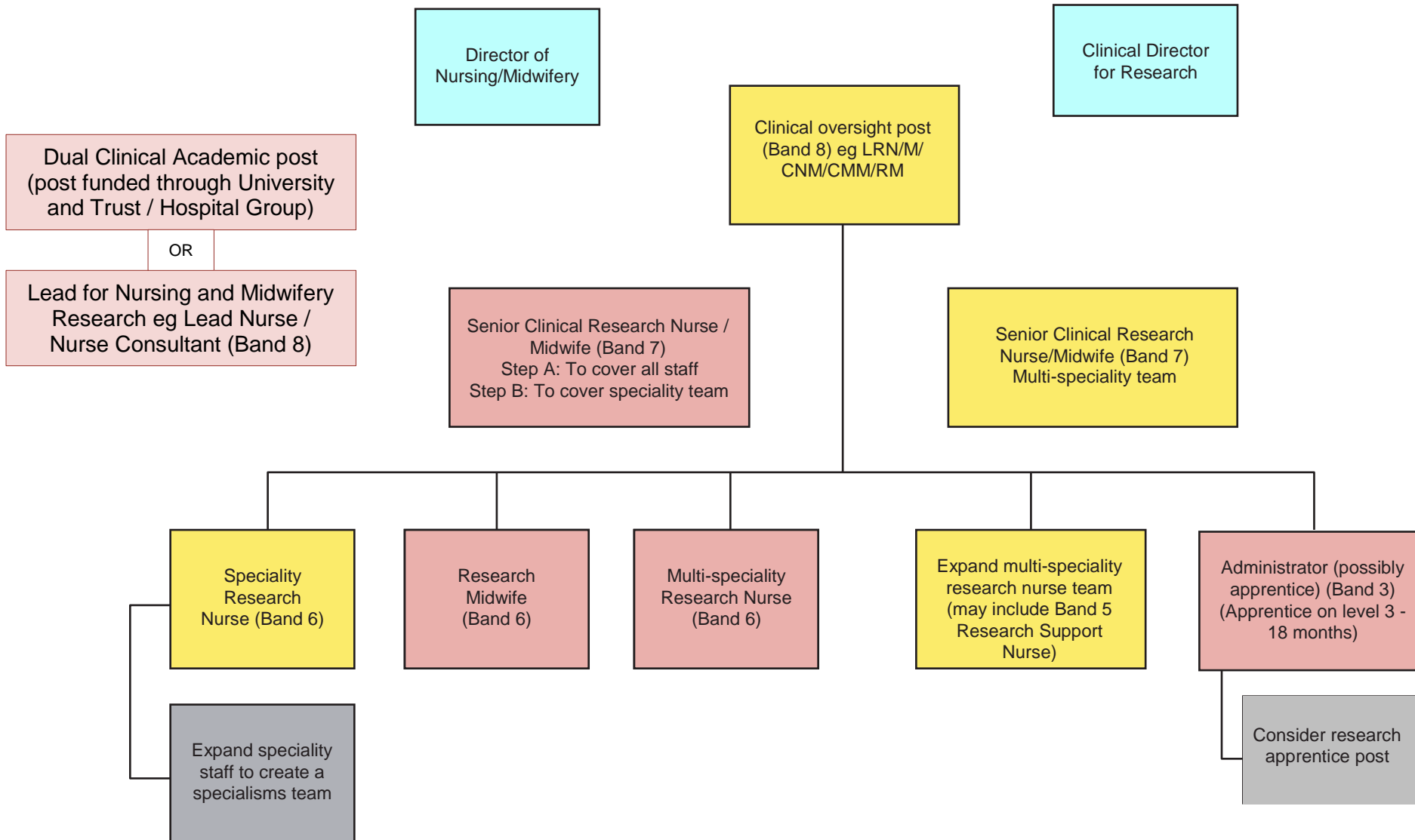
Stage 3 - Continued expansion of the team; specialism, administrative support and clinical oversight





- Expansion should include development of speciality CRN/M posts based on the strategic direction taken by the oversight post in stages 1 and 2
- Consideration of additional administrative support. Research Apprentice administrator appointments have been made at sites previously and proven successful
- Continued training and development for all staff
- Continued focus on raising awareness of research to all other staff in the organisation
- Lead nurses/midwives and matrons/charge nurses actively involved and engaged with research activity in their area: supportive of their staff identifying potential participants
- Contribute to the body of publicly available literature around delivery roles, and where appropriate demonstrating impact through case studies, posters, conferences, publication and other routes
- If Band 8 strategic clinical oversight post (level within this banding should reflect the size of the workforce) was not fulfilled at stage 1 or 2, it must be implemented at stage 3 if the organisation wishes to develop research further in a safe manner.
- If the organisation wishes to commence 'home-grown' research by NMAHPs, an additional post should be created to lead on this. The post holder would develop relationships with Universities, lead their own research and develop other staff within the organisation to build upon the audit and transformation work commenced in stages 1 and 2.
- Review of accommodation – does it require review or relocation prior to further team expansion?
- A review of financial processes may be required at this stage. If the research portfolio was placed under a member of the Trust/Hospital finance team who also had other services to cover, stage 3 may be the time to review the effectiveness of this. A separate post may be required to adequately manage the income and expenditure of the department alongside reporting to external funders.
- Continued training and development for staff.

Stage 4 - Research delivery team established, research awareness and positive research culture throughout the organisation



Research delivery workforce

The research delivery workforce (pictured above left) will continue to grow, expand and develop based on the continued review of strategies of stages 1 - 3 and with the oversight of the lead post.

Home-grown research development

To develop home-grown research by NMAHPs, it is essential to appoint a dedicated lead post for this to be successful. Two suggested forms this role could take are described in the red boxes representing stage 4. Differences between these appointments demonstrated in the project are described below.

Lead for Nursing and Midwifery Research



Nurse Consultant (Research) - Dual Clinical-Academic post



These posts will work to:

- ♥ Establish research priorities.
- ♥ Utilise joint working relationships to develop research projects
- ♥ Apply for research grants
- ♥ Support nurses and midwives within clinical ward and departmental based roles to write and conduct research
- ♥ Support clinical teaching of research (both in Universities and healthcare establishments) to increase research capacity and capability
- ♥ Increase number of PhDs available to nurses and midwives; support application for and undertaking of these courses
- ♥ Increase the number of nursing and midwifery publications through encouragement, support and guidance.
- ♥ Challenge existing practice and contribute to a research rich environment which leads towards achieving excellence in health outcomes.
- ♥ Share and disseminate best practice techniques.

An exemplar institution working to this stage is University Hospital Southampton NHS Foundation Trust: Munro E and Allison J 2018 Ensuring effective research delivery through innovative workforce development. In press; Nursing Times, publication date 14 June 2018.

Stage 5 - Embedding of staff to clinical areas (if appropriate for the organisation)

Within the project, embedding of staff in to clinical areas has been demonstrated as effective in a small number of organisations.

Once a positive research culture has been established and research has been normalised as part of patient care pathways, it may be appropriate to embed CRN/Ms in to the clinical areas in which they are working, both in terms of line management and geographically by location (particularly with the specialism teams).

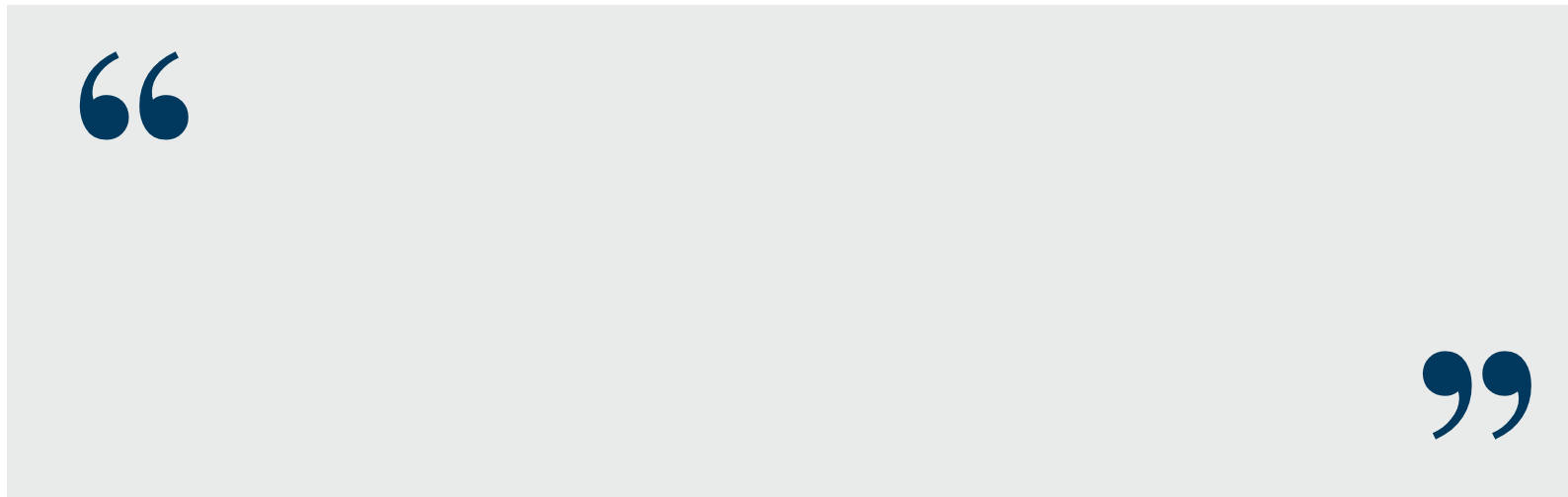
The Lead Nursing/Midwifery posts in these areas will have a firm understanding of the research delivery team and the CRN/M roles which will enable effective line management. A multi-speciality CRN team may remain in place with a SCRN supervision and support. Appraisals and objectives will be dual hosted by the line manager and the SCRN to ensure all opportunities, development areas and understanding and achievement of national targets and performance measures are included, as well as celebrations of success.

The Lead for Nursing and Midwifery Research or Nurse Consultant (Research) will continue to support staff within clinical areas to develop home-grown research studies. Provision of support should include nurses and midwives working at all levels, from entry through to senior nursing/midwifery management.

Appendix 7. Themes to be included within a research nurse/ midwife strategy and examples of objectives.

The purpose of developing a research strategy is to provide a clear and coherent focus for research leadership with an organisational overview that promotes co-ordination of health care research for nurses and midwives. It should relate clearly to local and National priorities and ambitions, as well as contain an element of flexibility allowing response to rapid changes in those priorities.

A generally agreed strategic aim within this project was confirmed as:



Themes described by sites with successful strategies are described below. Example objective wording has been included to demonstrate the type of content within the theme.

Theme	Example of objective
1. Evidence	To provide care to patients and families which is consistent with the best available evidence.
2. Capability	To increase research capability in the Trust through raising research awareness and promoting a research culture.
3. Patient and public involvement	To promote research collaborations through patient and public involvement at all stages of the research process.
4. Infrastructure	To build infrastructure that will support a research active environment.
5. Development	To develop a high-quality programme of multi-professional research with particular emphasis on health services interventions, outcomes and patient and family experiences e.g. patient voices.
6. Capacity	To increase research capacity through increasing the number of research publications, research projects, and the amount of funding gained for research.
7. Collaboration	To encourage intra-disciplinary and multi-disciplinary collaborations.
8. Governance	To ensure that the research conducted adheres to Good Clinical Practice and is ethically reviewed.
9. Raise profile	To raise the profile of research conducted by nurses in the Trust to internal and external organisations.
10. Value	To create an environment that supports and values the development of research skills and experience.

Examples of timeframes associated with each objective were identified within the project however are not described within this appendix as they varied greatly depending on the organisation engagement and vision.

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