From Contributor to Leader: How a Nurse can Undertake the Role of Principal Investigator (PI) in Clinical Research in the UK

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Abstract - **Under UK law, an investigator is defined as an "authorised health professional responsible for the conduct of a trial at a site, and if the trial is conducted by a team of authorised health professionals at a trial site, the investigator is the leader responsible for that team" [1]. Whilst the umbrella term "authorised health professional" encompasses registered nurses, midwives and allied health professionals, in addition to medics, research currently tends to be medically led (ie, whereby the Principal Investigator is a doctor). At Chelsea and Westminster Hospital (CHW), a 12 month activity mapping exercise highlighted that only 4% of clinical research studies opened had a PI who was a nurse. However a more in-depth review highlighted that 98% of all clinical research studies opened during that same time period had involvement of nurses as contributors as opposed to leaders. Resultantly a local strategic decision was taken to encourage engagement of, and to enhance opportunities for, nurses to lead on clinical research studies, as appropriate. Collaboration with the existing multi-professional research forum and steering group at CWH facilitated open discussion regarding the key reasons why more nurses (along with midwives and allied health professionals) were not leading on clinical research studies. Three key explanatory factors resulted from this, and a systematic action plan followed to boost the number of nurse PIs. Many individual and organisational benefits were recognised as a result of this programme of work. The experience at CWH confirms that nurses are more than capable of acting as PIs on clinical research studies providing that appropriate support and monitoring are in place. It is therefore the recommendation of this paper that nurses are encouraged and developed to transition from the role of contributor to leader in clinical research.**

Keywords - Principle Investigator, nurse, research, leader, contributo, workforce development

I. INTRODUCTION

Chelsea and Westminster Hospital (CWH) is a leading healthcare organisation located in South West London, United Kingdom. As a constituent organisation of the National Health Service (NHS), national strategic directives to encourage the delivery of research through the NHS are adopted locally to transform healthcare, service provision and patient experience. Given the drive for research to form a core aspect of standard care [1] a programme of work has implemented to develop the workforce to encourage research leadership, with a particular focus upon nursing staff whom are the largest single professional workforce at CWH.

A. Regulatory perspective

Under law applicable to the United Kingdom, an investigator is defined as an "authorised health professional responsible for the conduct of a trial at a site, and if the trial is conducted by a team of authorised health professionals at a trial site, the investigator is the leader responsible for that team" [2].

Whilst the umbrella term "authorised health professional" encompasses registered nurses, midwives and allied health professionals, in addition to medics, research currently tends to be medically led (ie, whereby the Principal Investigator is a doctor).

B. Activity mapping

At CWH, over a 12 month period (2013/2014), during an activity mapping exercise, it was noted that of the 78 clinical research studies opened during that year, only 7 had a PI who was not a doctor. Of those, only 3 were nurses. Given that CWH employs no less than 102 clinical nurse specialists and 3 nurse consultants (all of whom have research as a component of their job description), the proportion of nurse led research studies was surprisingly low. However a more in-depth review highlighted that 98% of all clinical research studies opened during that same period had involvement of nurses as contributors as opposed to leaders.

Resultantly a local strategic decision was taken to encourage engagement of and enhance opportunities for nurses to lead on clinical research studies, as appropriate.

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II. Information Gathering

A. Multi-professional research forum

Collaboration with the existing multi-professional research forum and steering group at CWH facilitated open discussion regarding the key reasons why more nurses (along with midwives and allied health professionals) were not leading on clinical research studies.

The forum, which at this time had been in existence for 18 months, was led by the Lead Research Nurse at CWH, with the objectives of:

- Providing a venue for sharing advice and support on all aspects of research.
- Maximising opportunities for partnership, networking and sharing of information.
- Receiving local, regional and national research updates.
- Raising awareness of studies being undertaken.
- Sharing research issues and challenges as well as innovative methods to improve research uptake by multi-professionals.
- Providing an environment to identify and provide relevant research education and training.

B. Steering group

The steering group was led by the Deputy Chief Nurse at CWH with the objectives of:

- Promoting, monitoring and directing research in line with the corporate objectives of CWH.
- Promoting and maintaining links with Higher Education Institutions (HEIs) including key local stakeholders such as Kings College London (KCL).
- Appraising effectiveness in research activity as a component of performance review.

The insights and information gleaned within these fora provided a foundation to address the under-utilisation of senior, and in many cases specialist, nursing expertise to lead within the research field.

III. Key Explanatory Factors

A. Perceptions

Firstly there was a widespread perception at CWH that clinical research studies, particularly those involving a clinical intervention, must be led by a doctor. When asked about the basis of this perception, nurses, midwives and allied health professions regularly made reference to the requirement for a physical examination, the confirmation of eligibility and the decision to dose to be undertaken by a medically qualified individual. Qualitative interviews found the following quotation to be a common theme of perception: "Clinical research studies, particularly those involving a clinical intervention, must be led by a doctor."

B. Competence

Secondly, concerns were expressed in relation to nurses lacking the relevant skills and knowledge of research processes and leadership to allow them to demonstrate appropriate PI oversight. This was in spite of research being a feature of their job description and "excellence in research" being a local corporate objective. The complexity of the research process was highlighted as a key reason for nurses preferring to take a contributory role, rather than leadership.

C. Value

Thirdly nurses reported that they found it difficult to engage in research (as a contributor or leader) if it wasn't deemed to be important or appeared to lack value within their department and/or by management. This linked closely to fiscal restraint, time restrictions and the de-prioritisation of research whereby research was frequently perceived to be a burden and additional to clinical care.

Central to these key explanatory factors was the theme of culture and the requirement for cultural change at an organisational level.

IV. Actions Undertaken

It was recognised that a systematic approach was required to address the key issue of the lack of nursing leadership of research at CWH. This resulted in the following programme of work:

A. Actions to address perception

Clinical research was incorporated into the CWH induction of nursing staff, with the aim to instil, from day one, an understanding and recognition that nurses can lead on research and that a wide range of support is available at CWH to aid this. Since the launch of this incorporation, more than 300 new nurses have been exposed to this research induction, with 10% self-referring themselves at a later date to the research department for additional training to act as a local ambassador for research in their clinical area.

For longstanding employees of CWH, who would not attend the revised induction, departmental clinical research sessions were delivered, with the aim to instil this same understanding. These departmental clinical research

sessions were tailored to the needs of the department and lead nurse and clinician. At a minimum, each session is facilitated by the organisational research manager and a senior nurse, and incorporates International Conference on Harmonisation Good Clinical Practice (ICH-GCP) training, protocol specific training for on-going studies, informed consent training, and open dialogue to answer questions and disseminate best practice. Since the launch of the training programme, diverse clinical departments have received training for all staff grade nurses and above, from ophthalmology, obstetrics, sexual health and emergency department.

B. Actions to address competence

The clinical research process at CWH was mapped out specifically for this multi-professional group, using simple terminology, serving as a step-by-step guide to outline the pathway from having an initial idea through to potentially a change in clinical practice. Since dissemination of the progress map, this has been downloaded 240 times and been widely shared at all training sessions.

To develop research confidence and competence, a new researcher training programme with specific relevance to nurses was implemented. This included a one stop research workshop (which included 8 segments covering all aspects of research from funding, patient involvement to engagement with life science industry partners), facilitated ICH-GCP training, informed consent for research and a drop in clinic for generic queries. Since the launch of the workshop, over 150 employees have been trained with 98% anticipating change to their daily practice as a result.

Nurse researchers from HEI's were invited to work in partnership with CWH to develop the nurse-led research portfolio, evidencing the feasibility of nurses as PIs. At least 5 novel research projects are in development as a direct result of this engagement.

Highlighting strategies to encourage nurses to lead on their own research, and also proactively finding multicentre studies for a nurse PI.

C. Actions to address value

Reporting of research activity and associated barriers to the CWH executive board to gain high level research buy in from management and to ensure the prioritisation of research activity. Reports are posted on a tri-yearly basis, with monthly short reports to all relevant stakeholders.

Demonstration of potential cost savings made by research to managers, along with an emphasis upon improvements in patient satisfaction and experience resulting from participation. Excess treatment savings are key method of achieving continuous cost improvement programme targets imposed upon clinical departments.

Risk assessment packages were developed to support case-by-case review of the feasibility and desirability of a nurse PI, dependent on the nature of the study, the patient population, the expertise of the nurse and the availability of medical oversight.

V. BENEFITS OF NURSE PIS

A. Benefits to the individual

For the individual (the nurse), benefits of being a PI include personal and professional growth, development of clinical leadership skills, a sense of empowerment and parity with medical colleagues and the knowledge that they are contributing to the evidence base within their clinical specialty. Many of these individuals progress to having their work published at international conferences and in peer reviewed journals. These benefits are realised regardless of whether the research project forms part of an educational degree or not. Feedback from such nurse PIs comprised the following:

> "Leading on my own research was fulfilling experience and one that I didn't think I'd have the opportunity to do as a nurse, especially with it being an RCT."

> "It was never clear in my head how I would be able to meet the 'research' requirement of my job description and neither was it challenged in my appraisal. When I was made aware of a study I could act as PI for I went for it and I have learned so many new skills and this is reflected on my CV and in my daily practice."

> "At first running a research study was unnerving but the ongoing support and a clear pathway made it achievable and enjoyable."

B. Benefits to the organisation

For the organisation, benefits include additional capacity and capability to safely support research, improved caliber of nursing staff, retention of these staff through improved role satisfaction and translation of research into local practice to improve patient care.

VI. RECOMMENDATIONS

It should be recognised that it is not always feasible for a nurse to act as a PI as some research studies have heavy medical involvement. In all cases, each individual research study should be risk assessed, for example by reviewing local standard operating procedures and relevant frameworks and legislation applicable to individual countries/territories. In a large majority of

instances the benefits of a nurse acting in a leadership role, as opposed to solely in a contributory role outweigh the risks. The experience at CWH confirms that nurses are more than capable of acting as PIs on clinical research studies providing the appropriate support and monitoring are in place.

It is therefore the recommendation of this paper that nurses are encouraged and developed to transition from the role of contributor to leader in clinical research.

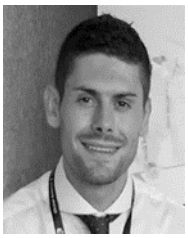
REFERENCES

[1] NHS Constituion for England, 2013.

[2] The Medicines for Human Use (Clinical Trials) Regulations, 2004, No. 1031. Part 1, Regulation 2.

AUTHOR'S PROFILES

Laura Braidford currently works as the Lead Research Associate Nurse at Chelsea and Westminster Hospital, managing a team of nurses, midwives and research assistants who deliver both commercial and non-commercial research studies across the organisation. With extensive clinical and managerial experience in both the public and private sectors, Laura strives to promote multi-professional research and is passionate about workforce development and clinical leadership. Laura is looking forward to completing her Masters' in Public Health this summer and aspires to do a PhD sometime in the future.



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