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Commentary on: Spilsbury K, Petherick E, Cullum N, Nelson A, Nixon J & Mason S (2008) The role and potential contribution of clinical research nurses to clinical trials. *Journal of Clinical Nursing* 17, 549-557.

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Recent decades have witnessed an overwhelming push for evidence-based practice both in the nursing profession and the health sector as a whole. This demand for evidence has resulted in a dramatic increase in the number of research projects being undertaken, and in turn, strong workforce demands for professionals to undertake research and thus generate evidence.

Nurses have answered the call for health researchers in many ways. In Australia, the annual survey of all registered nurses reports at least one in every 100 RNs works predominantly in research, and that nurses working in research have increased by 21% over the last five years (Australian Institute of Health and Welfare 2006). These numbers reflect the international trend for higher numbers of nurses working in research roles.

Nurses work in a variety of research contexts and employment settings. With large-scale randomised controlled trials the 'gold standard' required for new healthcare interventions, large numbers of nurses now specialise in coordinating these complex clinical trials. Spilsbury *et al.* (2007) offer valuable insights into this growing and important group.

The title 'Clinical Research Nurse' (CRN) used by Spilsbury *et al.* to describe the role is currently popular in the UK. The UK Clinical Research Collaborative's Subcommittee for Nurses in Clinical Research (Workforce) recently defined a CRN as 'a nurse who is employed principally to undertake research within the clinical environment', and specifically includes nurses working under the direction of medical researchers, those supporting research in a major facility, and those undertaking their own research (UKCRC Sub Committee for Nurses in Clinical Research (Workforce) 2007a). Current UK datasets do not capture the numbers or nature of these positions, although five Wellcome Trust Clinical Research Facilities and their associated NHS Trusts, reported about 600 CRN-type posts in 2005 (actual position titles varied considerably) (UKCRC Sub Committee for Nurses in Clinical Research (Workforce) 2007a). The title 'CRN' is also commonly referred to as 'Clinical Research Coordinator' or 'Clinical Trial Coordinator' (Ahern *et al.* 1993, Kellen *et al.* 1994, Mueller & Mamo 2002, Rickard *et al.* 2007a, Rico-Villademoros *et al.* 2004).

The exact number of CRN-type positions worldwide is unknown. Some indication is provided by the international Association of Clinical Research Professionals who have examined and certified 11,700 Clinical Research Coordinators from 13 different countries since 2002 (Association of Clinical Research Associates (ACRP) 2007). Despite the large number of nurses in CRN-type positions, the role has received limited attention. There are predominantly anecdotal reports in the literature but few rigorous investigations (Roberts & Rickard 2005). It seems an omission and anomaly that so little is known about CRNs, who have a pivotal role to play in the research and development of healthcare. The paper by Spilsbury *et al.* is, therefore, a welcome addition to increase awareness and knowledge of the role.

It is a matter of debate why specialist research roles for nurses have failed to attract much interest by researchers or policy makers. To redress this issue we nominate three priorities for action. Firstly, agreement and consistency of titles and terms; secondly, better understanding of the role as it is currently and appropriate models of support for CRNs. Thirdly, improved recognition by the nursing profession.

An obvious factor limiting visibility of the CRN role is inconsistent terminology. We observed the most common title to be 'Research Coordinator' in a survey of Australasian intensive care units; although in total the 49 respondents reported 21 different job titles (Rickard *et al.* 2007a)! The title CRN is appealing as it recognises that the majority of incumbents are nurses. Should we embrace the term CRN and encourage its use internationally? Although Research Coordinators are usually nurses, we have also observed pharmacists, physiotherapists, and medical doctors ably fulfill the role. If we insist on disciplinary backgrounds in researchers' titles, will we see a future workforce of 'Clinical Research Pharmacists', 'Clinical Research Social Workers' and so on? In this era of multidisciplinary research and shifting professional boundaries, the generic term 'Clinical Research Coordinator' or even a new term such as 'Clinical Researcher' might be more appropriate.

Regardless of title, the CRN role is relatively new, and requires further study. Previous surveys in Australasia, North America and Spain have highlighted the generally positive experience of performing the role, and its value to the wide spectrum of nursing and patient care (Ahern *et al.* 1993, Kellen *et al.* 1994, Mueller 2001, Mueller & Mamo 2000, 2002, Rickard *et al.* 2007a, b, Rico-Villademoros *et al.* 2004, Roberts *et al.* 2006). Spilsbury *et al.* have, for the first time, surveyed a UK cohort and report positive aspects of the role to be autonomy, developing research and other skills, being part of a research team, educating clinical staff, using nursing knowledge and skills, and facilitating improved patient care via research. Difficulties identified included: hostile or non-cooperative clinical colleagues, isolation, and patient recruitment difficulties. The role clearly has a heavy clinical base, with clinical knowledge and skills utilised. The ability to lead, educate, motivate and communicate with multiple clinical staff and departments is also apparent. Spilsbury *et al.*'s results have many consistencies with previous international research. This supports the validity of their results, and provides evidence that CRN roles are an international phenomenon. They also show us that by adding a CRN sub-study to the main clinical trial, value is added to understand the results and their context. CRNs may be a vital link in explaining discrepancies between 'efficacy' (it works under trial conditions) and 'effectiveness' (it works in the real world). As such, Spilsbury *et al.*'s methods

should be considered in the design of all clinical trials, including pharmaceutical trials.

Clear messages of support and inclusiveness for nurses who choose to specialise in clinical research are sorely needed from nursing professional bodies. Because many CRNs work on projects where the principle investigator is a medical doctor, the role is sometimes criticised by nursing colleagues as ‘not really a nurse’, or as limited intellectually, ‘collecting data for doctors’. This provokes the interesting question: is working as a CRN on a clinical trial of a nursing intervention inherently different to working on a trial investigating a medical intervention? Spilsbury *et al.*’s study is groundbreaking as for the first time it focuses on the contribution of CRNs working on a nursing RCT. Their findings about the CRN role and the experience of performing it, are extremely consistent with numerous anecdotal reports as well as previous studies of CRNs managing non-nursing trials (Ahern *et al.* 1993, Kellen *et al.* 1994, Rickard *et al.* 2007a, b, Rico-Villademoros *et al.* 2004, Roberts *et al.* 2006). Interestingly, Spilsbury *et al.*’s CRNs still experienced hostility from clinical nursing staff, despite the fact that they were working on a ‘nursing’ trial. It seems that it is not the type of trial, nor the discipline of the principal investigator, but rather the specialist clinical research focus that best defines the CRN role.

The global clinical research workforce, including CRNs, has expanded exponentially with increases in research activity and regulatory complexity. It is timely that governments and professional groups collect reliable data on the size and state of the clinical research workforce. In conjunction, there is a need for reforms to allow appropriate training and employment conditions for clinical researchers. A recent UK report recommends a flexible career structure, training and award scheme to encourage nurses to develop as researchers (UKCRC Sub Committee for Nurses in Clinical Research (Workforce) 2007a). However, caution has been raised that reforms must not focus on academic nurses to the exclusion of the majority who will prefer to support the research of others, rather than lead research projects (UKCRC Sub Committee for Nurses in Clinical Research (Workforce) 2007b). Not all clinical nurses desire to be nurse practitioners, nor all unit managers to be directors of nursing. Similarly not all CRNs will aspire to professorial positions, instead choosing their valuable role in managing complex clinical research projects. They will do this in teamwork with chief investigators from nursing, medical, and other varied backgrounds, and we should value and support them in this.

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