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Trouble for trials - The worrying state of the research nurse workforce

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Trouble for Trials - The Worrying State of the Research Nurse Workforce

Abstract

Clinical research nurses (CRNs) are a specialty of Registered Nurses that are highly trained to support the breadth of clinical trial operations and manage participant care in community settings new to research. CRNs are uniquely equipped with a scope of practice that permits product administration, participant assessments, and data management. As clinical trials and their management expand beyond traditional, site-based operations models to decentralized or remote models, the need becomes great to ensure adequate staffing of experienced research professionals, such as CRNs. However, the *2020 National Nursing Workforce Survey* reported consecutive contractions in the number of CRNs practicing in the U.S in both 2017 and 2020 surveys when compared to previous reports in 2013 and 2015. The Society of Clinical Research Associates *2020 Salary Survey* further described much of the current CRN workforce as nearing or at retirement age, raising concern for additional reductions. This workforce contraction tangents one of the highest volumes of clinical trial starts in modern history, prompting concern for adequate staffing of CRNs to facilitate continued examination of novel therapies and devices. Complex investigative products and evolving safety profiles coupled with an increased focus on community participant enrollment requires CRN involvement in heightened safety monitoring and interdisciplinary communication among clinical providers and research collaborators. This paper examines the contributory factors of the CRN workforce contraction and response efforts at professional and organizational system levels.

As a former clinical research nurse (CRN) and clinical trial manager, I have always found clinical trials fascinating. Each trial is the embodiment of the human spirit and drives us to explore the unknown crevices and corners of the corpus in order to enhance quality of life and even cure diseases. In my role as a CRN, I witnessed the birth of new treatments, watched new devices save lives, and developed longitudinal relationships with participants and their families, bonded through the unpredictable adventure of the new and unknown. I 'grew up' in my early nursing career as a research nurse and have since transitioned to the roles of nursing faculty and nurse scientist. However, looking over my shoulder, who will be there to replace me in the role of research nurse? There is a multitude of clinical trials that need research nurses, and yet, the emerging generation of our nursing workforce is not aware of opportunities to participate in the specialty of research nursing or the significance of the role of the research nurse as it relates to the continued generation of new drugs and devices for the patients of tomorrow.

Therapeutic research and development priorities and clinical trial coordination strategies shifted with the COVID-19 pandemic, prompting 800 different clinical trials of vaccine-based therapeutics [1]. Most trials during the pandemic were delivered as remote or decentralized trials, which are clinical trials that partially or fully incorporate digital tools (wearable technology, sensors, devices) to facilitate investigational procedures in a participant's home or community setting [1,12]. Research programs already underway in 2020 bounced back from pandemic-derived recruitment disruptions or freezes, with an overall 8% increase in clinical trial starts and 8,000 drugs in various stages of viability examination [1]. Despite this rebound, staffing research programs and ensuring optimal trial conduct has proven challenging. For example, diseases such as cancer require clinical trial staff with well-developed participant management skills to support complicated safety reporting and the emerging digital health aspects of modern trial design (such as remote data capture from participant-worn

devices) [9]. Within Southwest Oncology Group (SWOG), 80% of the affiliated research programs reported staffing shortages due to the COVID-19 pandemic [9]. The lead-time to train new personnel in the complexities of clinical trial management may take upwards of one year or more, which may spark additional delays in research progress and participant enrollment [9,11].

To facilitate appropriate staffing, The Joint Task Force for Clinical Trial Competency (JTF) developed a guiding framework comprised of eight domains of clinical competencies related to optimal trial management as a research professional, which spans communication, teamwork, research design, and data management components [5]. The *Scope and Standards for Practice* for CRNs encapsulates and expands upon these domains by including clinical practice, contribution to science, and participant care coordination with continuity of care as of paramount importance [8]. Furthermore, the *Scope and Standards for Practice* lends definitions to the different nomenclature used to describe the role of a CRN dependent upon setting and function: a *research nurse* provides participant care and contributes to science within clinical research settings while a *nurse researcher* contributes to science through independent research and a focus on new knowledge generation within the professional body of nursing [8]. However, modern trial designs and expansion of research nursing into non-traditional settings and roles (Clinical Research Associates, or monitors, for example) as well as nurses conducting research has blended these titles, particularly given nurse researchers are generating new knowledge in adjacent fields like psychiatry and medicine [13].

The 2022 IQVIA Institute *Global Trends in R&D* report highlights two significant takeaways related to the future projections of novel therapeutics advancement (1) historically high clinical trial activity and (2) increased utilization of remote/decentralized trial models [1]. These trends will undoubtedly require research nurses with heightened trial management skills to support complicated safety reporting and changes with participant status related to trial procedures within remote/decentralized trial models. Unlike home health nursing, CRNs administer investigational

products with largely unknown safety profiles, which requires a unique skillset to monitor for what may otherwise be seen as benign changes in participant health status when the changes are early warning indicators of impending, more life-threatening issues. Coordinators do not have the same medical training and skillset as nurses, which creates a gap in participant safety management and duties that can be delegated to coordinators [5]. For example, an intermediate research coordinator would demonstrate an ability and/or understanding of the elements of participant safety while a CRN is trained to identify safety issues and predict future challenges related to potential participant injury given the nursing assessment skillset [5,8].

Compounding the increased trial activity and shift in trial setting are the changes seen in the nursing workforce at-large: increased numbers of nurses leaving the workforce and/or retiring. Research nurses, given nursing specialty designation from the American Nurses Association in 2016, comprise approximately 15,545 nurses (0.5%) of the total nursing workforce (as extrapolated from the *2020 National Nursing Workforce Survey* as ‘nurse researcher’), shown in Figure 1[2]. Other estimates cite lower numbers, potentially as low as 10,000 research nurses in the United States and 12,000 in the United Kingdom [3, 13]. However, the quantification of the CRN workforce is challenging due to the lack of definitions related to *research nurse* versus *nurse researcher* in the survey design (such as with the *2020 National Nursing Workforce Survey*) and the lack of state-level reporting of this specialty [2]. Research nurses tend to also be of advanced age, with 12% of research nurses reported to be age 55 years or older on the Society of Clinical Research Associates (SoCRA) *2020 Salary Survey* and have a mean age of 49.1 years [4]. The median salary of a research nurse in 2020 was \$82,083 compared to lower salaries of clinical research coordinators (\$58,599) [4]. This differential in salary between research nurses and research coordinators has dissuaded the hiring of research nurses in favor of coordinators [3].

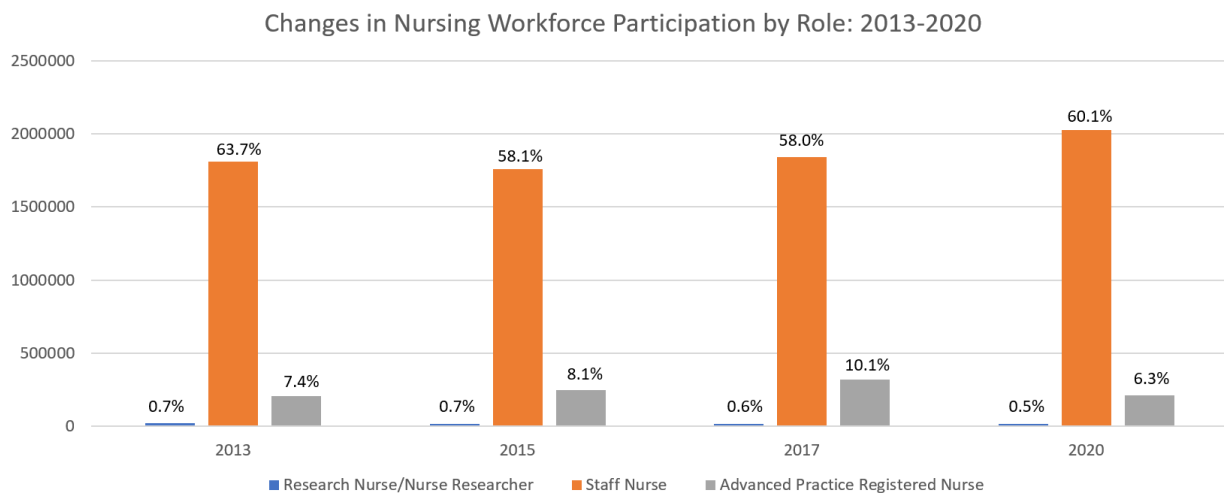


Figure 1. Changes in Nursing Workforce Participation by Role from 2013-2020. Derived from Smiley RA, Ruttinger C, Oliveira CM, Reneau KA, Silvestre JH, Alexander M. The 2020 National Nursing Workforce Survey. *Journal of Nursing Regulation* 2021; 12(1): S1-S96.

However, as the industry shifts to bringing clinical trials into the milieu of participants' homes, research nurses are quickly becoming a priority role necessary for accurate remote data collection and safe participant management. Nursing scope of practice affords Sponsors, sites, and participants consistent and consolidated delegation of trial duties [8]. For example, research nurses can administer investigational products, collect biospecimens, initiate or maintain access lines, and conduct participant assessments. Research nurses also are vocal in their enthusiasm to blend nursing care and approach to the latest in exploratory treatments and devices [4]. Research nurses are agile, with a majority being trained in at least two different therapeutic areas, permitting investigators to incorporate research nursing to a diverse set of participants [4].

However, with the rapid adoption and rollout of decentralized trials, research nurses have shouldered unforeseen burdens to their wellbeing, such as their safety translating research to home environments as well as stress and anxiety related to digital delivery of trial information or procedures [11]. Training that is focused on decentralized clinical trial delivery is not widespread nor tailored to the nursing role or body of knowledge, creating unsettling gaps in organizational support of the research nurses delegated to these unique, remote, or hybridized trials [11]. Research nurses were furloughed en

masse during the height of the COVID-19 pandemic due to on hold or cancelled studies, and those who remained on staff found themselves balancing multiple roles in order to continue managing active trials [10, 11]. One research program in the Midwest experienced a 40% turnover over the course of two years within their research nurse workforce, the largest in the program's history [11]. Loss of research nurse workforce is particularly devastating to community practices and research programs given the smaller employment pool, fixed financial resources, and potential lack of larger system-based resources if unaffiliated from a larger health center [11].

The steady decline of those nurses describing themselves as nurse researchers or research nurses sparks worry - are there enough research nurses to support the investigational products currently in development? [1] Research nurses are needed now more than ever to lend their skills and unique experience to keep participants safe and trial conduct in compliance. [1] However, there is a glaring lack of cultivating this specialized workforce in nursing school curricula. Very few nursing schools describe research nursing as a potential career, creating a workforce-wide lack of awareness [6]. Research nurses have described stumbling into the specialty rather than having a facilitated career change from clinical nursing [6].

The significant efforts to expand access and opportunities for trial participation via remote trial models and legislative support (Clinical Treatment Act, DIVERSE Trials Act) means more trials requiring research nursing support. The majority (almost 60%) of research nurses work in hospital or academic medical center settings, but what organizational support or infrastructure can be built to develop a research nurse workforce [4]? The International Association of Clinical Research Nurses (IACRN) created a curriculum for nursing school adoption and integration of research nursing within accredited programs [7]. Education-based modules have been developed to generate awareness among undergraduate nursing curricula as to the specialty [6]. How might these initiatives be refined to reflect the changing

landscape of the nursing workforce to meet current and future research nurse needs and adapted trial designs?

Just as there is a focus to retain clinical nurses, the research nurse workforce requires attention in order to continue the rapid pace of novel drug and device approvals. While largely unsung in the media, research nurse support was a significant component of the expedited COVID-19 vaccine development and roll-out. This historical achievement would not have been possible without the contribution of thousands of research nurses logging safety reports, administering vaccines, and monitoring participants. The decline of the research nurse workforce without an established presence of this specialty during the early years of a nurse's career spell trouble for Sponsors, physician investigators, and participants alike. Given the impact of personnel shortage across the continuum of clinical trial operations, from regulatory to legal review timelines, Dizon and colleagues concluded that the persistence of the staff shortage issue in clinical trials, including research nurses, will warrant 'an immediate national response.[9]' It's time to amplify the awareness and recognition of this critical specialty that infuses their passion and care in the participants of the present and the future.

References

1. Global Trends in R&D 2022. IQVIA Institute, February 2022.
(<https://www.iqvia.com/insights/the-iqvia-institute/reports/global-trends-in-r-and-d-2022>).
2. Smiley RA, Ruttinger C, Oliveira CM, Reneau KA, Silvestre JH, Alexander M. The 2020 National Nursing Workforce Survey. *Journal of Nursing Regulation* 2021; 12(1): S1-S96.
3. Jones CT, Griffith CA, Fisher CA et al. Nurses in clinical trials: Perceptions of impact on the research enterprise. *Journal of Research in Nursing* 2022; 27(1-2): 50-65.

4. Society of Clinical Research Associates [SoCRA] 2015 salary survey: Summary report. DePaulo PJ, December 2015.
<https://www.socra.org/assets/migrated/Uploads/PDFs/2015-SOCRA-Salary-Survey-Results-160127.pdf?vid=2>.
5. Sonstein SA, Jones CT. Joint Task Force for Clinical Trial Competency and Clinical Research Professional Workforce Development. *Front Pharmacol*. 2018;9:1148. doi:10.3389/fphar.2018.01148
6. Capili B, Baker L, Thangthaeng N, Legor K, Larkin ME, Jones CT. Development and evaluation of a clinical research nursing module for undergraduate nursing schools: expanding Clinical Research Nurses' outreach. *Journal of Research in Nursing*. 2022;27(1-2):68-77. doi:10.1177/17449871211070972
7. McCabe M, Ness E, eds. Clinical research nursing core curriculum. Mullica Hill, NJ: *International Association of Clinical Research Nurses*; 2021.
8. American Nurses Association and International Association of Clinical Research Nurses. Clinical Research Nursing: Scope and Standards of Practice. Silver Spring, MD: *American Nurses Association*; 2016.
9. Dizon DS, Szczepanek CM, Petrylak DP, et al. National impact of the COVID-19 pandemic on clinical trial staff attrition: Results of the SWOG cancer research network survey of oncology research professionals. *Journal of Clinical Oncology*. 2022;40(16_suppl):11049-11049. doi:10.1200/jco.2022.40.16_suppl.11049

10. Chan G, Bitton J, Allgeyer R, Elliott D, Hudson L, Moulton Burwell P. The impact of covid-19 on the Nursing Workforce: A National Overview. *OJIN: The Online Journal of Issues in Nursing*. 2021;26(2). doi:10.3912/ojin.vol26no02man02
11. Pennell NA, Szczepanek C, Spigel D, Ramalingam SS. Impact of workforce challenges and funds flow on cancer clinical trial development and conduct. *American Society of Clinical Oncology Educational Book*. 2022;(42):874-883. doi:10.1200/edbk_360253
12. Van Norman GA. Decentralized clinical trials: The future of medical product development? *JACC Basic Transl Sci*. 2021;6(4):384-387. Published 2021 Apr 27. doi:10.1016/j.jacbts.2021.01.011
13. Tinkler L, Smith V, Yiannakou Y, Robinson L. Professional identity and the Clinical Research Nurse: A qualitative study exploring issues having an impact on participant recruitment in research. *J Adv Nurs*. 2018;74(2):318-328. doi:10.1111/jan.13409