The Clinical Research Associate Retention Study: A Report From the Children's Oncology Group

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Abstract

Pediatric medicine often struggles to receive adequate research funding for its small, yet vulnerable population of patients. Remarkable discovery in pediatric oncology is credited in large part to the collaborative structure of its research community. The Children's Oncology Group conducts studies supported by the National Cancer Institute. The clinical research associate (CRA) discipline comprises professionals who support administrative duties, regulatory duties, subject management, and data collection at individual research sites. The purpose of this study was to identify factors associated with CRA retention, as the group continues to have high turnover and position vacancy. A cross-sectional survey design was used to characterize the most frequently cited reasons CRAs gave when considering leaving or staying within their position. Results suggest that low salary, unmanageable workload, lack of career advancement and professional development, and lack of research commitment from the medical team were associated with intent to leave CRA positions. The most frequently cited reasons for staying at their job were the meaningfulness and interest in the work, a supportive principal investigator, and enjoyment working with colleagues. CRAs reported serious but eminently solvable issues that can be addressed using practical and low-cost solutions to improve job satisfaction and retention.

Keywords

healthy work environment, retention, clinical trials, quality improvement

Introduction

On the tail of a major global economic recession and the largest U.S. health care overhaul in history, resources to conduct research are scarce and require careful preservation. The Children's Oncology Group (COG) is the National Cancer Institute's only pediatric clinical trial network. COG is made up of more than 7500 pediatric oncologists, subspecialists, nurses, and allied health team members located at more than 200 leading cancer centers, universities, and children's hospitals. These facilities offer diagnosis, treatment, and care services, as well as investigation of cancers in children and adolescents (Adamson, 2013b; COG, 2016). An essential part of the research team is the clinical research associate (CRA) discipline, but the group struggles with high turnover and position vacancy rates (S. Stork, personal communication, April 10, 2013). CRA leadership reports the discipline currently turns over about one-fourth of its membership annually (S. Jones, B. Shepperd, & J. Bradley, personal communication, June 14, 2017).

It is widely accepted that a high rate of voluntary turnover is associated with organizational ineffectiveness, or the inability of an organization to achieve its goals (Griffeth & Hom, 1995). The goal of COG is to "cure all children and adolescents with cancer, reduce the short- and long-term complications of cancer treatments, and determine the causes and find ways to prevent childhood cancer" (COG, 2016). The steady loss of qualified CRAs

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continues to stress the limits of available human resources. Translational discovery has led to intricate study design, frequent use of investigational new drugs, and the collection of highly detailed data (Adamson, 2013a). The National Clinical Trials Network infrastructure has become an extremely complex environment as CRAs work with multiple groups including COG operations and administration, other collaborating research sites, regulatory authorities, multiple institutional review boards/research ethics boards, and industry partners. In an environment of increasing complexity, the importance of qualified CRA retention is a major concern.

Methods and Materials

Literature Review

The primary aim of the CRA retention study was to identify and share the reasons CRAs gave for why they would plan to stay within or leave their current job. A literature review was performed in preparation of creating the survey. The following databases were searched: Ovid Medline, CINAHL, Cochrane, EMBASE, PsychINFO, and Google Scholar, to identify relevant articles published between 2005 and 2012. Key words used include personnel turnover, health care, retention, intent to stay or intent to leave, and organizational commitment. A total of 1139 article abstracts were reviewed for pertinent themes; 16 articles were considered to be relevant to CRA retention and retained for this review. Few studies specific to research professional retention were identified; however, literature regarding the retention of nurses, allied health professionals, and nonprofit employees was identified and included.

Theoretical Framework

There are many well-studied theoretical models of turnover research (Hinshaw & Atwood, 1983; Irvine & Evans, 1995; Mobley, 1982; Price & Mueller, 1981). In his seminal work on the causes and consequences of employee turnover, Mobley (1982) theorized that the determinants of employee turnover can be grouped into 4 categories: (a) organizational variables, (b) individual nonwork variables, (c) individual work-related variables, and (d) external economy (Mobley, 1982). These factors were used to build the elements of the CRA retention survey.

Salary and financial incentives can help with employee recruitment and retention, though conflicting information exists on the effect of compensation on retention. Price (2001) defines pay as money and its equivalents, which employees receive for their services to the employer. Financial considerations are not the only variable

affecting the decision of an allied health employee to stay within or leave an organization (Buykx, Humphreys, Wakeman, & Pashen, 2010; Hayes et al., 2006). Research does suggest the *dissonance* between pay and level of responsibility may negatively affect the retention of nursing staff (Cowin, 2002; Coomber & Barriball, 2007).

Other organizational variables that promote positive retention include benefits, contingent rewards (eg, bonuses or promotion), and a positive culture that promotes appreciation and recognition. A leadership model that promotes adherence to an institution's core values, fosters individual growth and development, and advocates for staff is an important consideration in employee retention (Peace, 2008). Throughout the literature, leadership models that empower and promote collaborative decision making are linked to high employee retention. Relationally focused leadership is reported to result in a quality work environment (Cowden, Cummings, & Profetto-McGrath, 2011). Positive work environments also focus on and provide support toward individual employee goals and needs.

Important individual, nonwork variables noted in the literature are the presence of work-life balance, the degree of family-work conflict, and promotion by employer of flexibility (DePanfilis & Zlotnik, 2008; Hayes et al., 2012; Peace, 2008). Stress, burnout, and repetitiveness of task increase turnover through their negative impact on job satisfaction (Westlund & Hannon, 2008). Stress has a strong relationship with intent to leave, and factors such as low autonomy, low recognition, and poor communication with colleagues are described as frequent causes of this stress (Coomber & Barriball, 2007). Price identifies 4 types of stress: resource inadequacy (lack of means to perform a job), role ambiguity (unclear job obligations), role conflict (inconsistent job obligations), and workload (amount of effort required by job; Price, 1997). In a meta-analysis, Spector (1986) found strong positive associations with heightened work performance and satisfaction among employees with more perceived control over their work life, such as self-sufficiency in meeting everyday challenges and participation in the decision-making process. Open and transparent two-way communication between employee and employer is an important consideration (Peace, 2008) and can be used to avoid stress and eventual burnout.

Findings related to individual variables of retention have been fairly consistent. Positive factors that improve retention include belief in the values and vision of the organization, mission attachment/alignment, a sense of belonging, and a willingness to pursue the organization's goals. Each of these factors nurtures a desire to help others and contribute to a community, which promotes a sense of shared purpose (Hayes et al., 2006; Peace, 2008; Pepe, 2010). When an employee has the opportunity for

achievement, stimulation, responsibility, and advancement (Pepe, 2010), both the perception of the position and work-life become enriched. On the other hand, a poor understanding of one's workplace role and duties, ambiguity of responsibility, and poor recognition of achievement can result in demoralization. Hayes et al. (2012) report that role ambiguity is associated with conflict on nursing units, which can contribute to higher turnover rates.

Other external factors on employee retention include real or perceived availability of other opportunities and advancement of career (Hayes et al., 2012). Studies on the availability of other jobs and the effect on turnover are conflicting. Price and Mueller (1981) stated that when the job market is hiring, turnover increases, and when hiring slows, turnover does as well. Another study states that employment opportunities are a relevant factor in areas with a higher population (Bloom, Alexander, & Nichols, 1992), though admittedly inconsistent. Research professionals working in nonprofit research have the allure of for-profit employment opportunities, which typically offer higher compensation, bonus structures, robust staffing support, and opportunities for advancement.

Turnover: Measurement and Acceptable Rates

An acceptable level of turnover is not straightforward. Some turnover is healthy, as low-performing employees not only contribute little to the organization but can even negatively influence productivity and workplace morale. Not all employee turnover is voluntary (retirement, dismissal), and employer/employee separation can be necessary for legal and ethical reasons. In 2013, based on a survey of over 40 000 organizations, BenchMarkPro Survey reported voluntary turnover in health care as 12.5% and total turnover as 16.8% (Bares, 2016). For comparison, all industries reported had an average voluntary turnover of 10.4% and total turnover of 15.1% (Bares, 2016).

Steel, Griffeth, Hom, and Lyons (2002) stated in article, "The fact is often overlooked, but the reasons people stay are not always the same as the reasons people leave" (p. 152). Based on this, COG CRAs were asked to choose the top five reasons influencing their decision to stay within (intent to stay) their current position and the top five reasons influencing their decision to leave their current position (intent to leave). Elements provided for both intent to leave and intent to stay were based on the factors identified in the literature review.

The CRA Retention Survey

A cross-sectional survey was open to all members of the COG CRA discipline (970 members) for a duration of 3

weeks (July 2013 to August 2013). The survey was hosted on SurveyMonkey, a fee-based SSL-encrypted online survey tool. Survey Monkey was used to create the survey, collect data, and analyze results.

Since data are not gathered when a CRA leaves COG, the perception of high CRA turnover was based on personal report from the CRA Steering Committee and not prospective data. To validate the perception, an element was added to the survey asking participants whether they were (a) hired as a replacement for a previous CRA, (b) were hired within a newly created CRA position, or (c) were unsure.

It is important to note that studies conducted by several teams found that turnover intentions represent a reliable indicator of actual turnover and are heavily influenced by job satisfaction (Allen, Shore, & Griffeth, 2003; Cohen, 1993; Griffeth & Hom, 1995). The survey asked participants how likely they were to leave their position with the next 6 months (*very likely, likely, don't know, unlikely, very unlikely*). Participants selecting "don't know," "likely," and "very likely" were considered as at risk for leaving their position. Demographic elements collected include nominal data, such as gender, and ordinal factual data, such as salary ranges and highest level of education attained.

Results

The overall response rate of the survey was 47% (N = 456). The great majority of respondents were female (93.51%), and about half (46.26%) reported being certified in clinical research by the Society of Clinical Research Associates or the Association of Clinical Research Professionals. Most respondents reported working full-time (88%), while the remainder reported a part-time work schedule (12%). Table 1 includes salary ranges for all CRAs in U.S. dollars; after adjusting to include full-time CRAs only (N = 399), annual salary was reported as follows: less than \$30 000 (N = 10), \$30 000 to 39 000 (N = 48), \$40 000 to 49 000 (N = 88), \$50 000 to 59 000 (N = 111), \$60 000 to 69 000 (N = 81), more than \$70 000 (N = 52), and did not answer (N = 9; Table 1).

The reported direct supervisor for CRAs ranged from clinical research manager (N = 123), COG site principal investigator (PI; N = 98), lead COG CRA (N = 78), director/assistant director of research (N = 43), administrator (N = 38), nurse manager (N = 34), division chief (N = 11), and other (not specified; N = 30). The option "Other: please specify" was added in case the supervisory role was not listed in the given options. Survey respondents entered an additional 30 supervisor roles in the free text space provided.

Seventy-five percent of respondents report holding a bachelor's or master's degree. About ¼ of respondents

Table 1. COG CRA Discipline: Compensation, Work Experience, Training, and Educational Background.

	%	N
Highest level of education (completed degree)		
Bachelor's degree	47	216
Graduate degree	28	126
Associate degree/diploma	17	77
High school or GED	8	35
Skipped	—	2
Are you a nurse?		
No	74	331
Yes	26	118
Skipped	—	7
Work effort		
Full-time	88	399
Part-time	12	56
Skipped	—	1
Gender		
Female	94	418
Male	6	29
Skipped	—	9
Annual monetary compensation including overtime, US\$		
<30 000	5	24
30 000-39 000	14	64
40 000-49 000	22	99
50 000-59 000	27	118
60 000-69 000	19	83
>70 000	13	58
Skipped	—	10
Previous research experience (years) when hired as a COG CRA		
None	39	177
<1	7	33
1-3	21	95
4-6	14	64
7-9	7	30
≥10	12	55
Skipped	—	2
As a new CRA, how much training did you receive at your site?		
None	19	87
<1 month	35	159
1-2 months	20	90
3-4 months	12	57
5-6 months	7	30
≥7 months	7	30
Skipped	—	3
Are you certified in clinical research (CCRP or CCRC)?		
No	46	210
Yes	54	244
Skipped	—	2

Abbreviations: COG, Children's Oncology Group; CRA, clinical research associate; CCRP, Certified Clinical Research Professional; CCRC, Certified Clinical Research Coordinator.

identified themselves as nurses (26%). Around forty-two percent (42%) of CRAs reported having 0 to less than 1 year of clinical research experience when hired, and 74% received no training (19%) to less than 2 months (55%) of training as a new COG CRA. Seventy percent of respondents reported that they were replacements for previous CRAs (N = 319).

Thirty-seven percent of respondents chose "very likely," "likely," "don't know" when asked whether they would leave their position within 6 months. Sixty-four percent of respondents reported they were "very likely" or "likely" to stay in the job at least through the next 6 months. Factors that were most frequently chosen for leaving their current position were low salary (N = 286), unmanageable workload (N = 271), lack of career advancement (N = 259) and professional development (N = 181), and lack of research commitment from the medical team (N = 190). The most frequently cited reasons for staying at their position were the meaningfulness of the work (N = 346), interest in the work (N = 279), having a supportive PI (N = 238), and enjoyment working with the medical team (N = 232) and fellow CRAs (N = 216; see Table 2).

Discussion

Turnover Risk

Thirty-seven percent of respondents were categorized as "at risk" of leaving their position within 6 months ("very likely," "likely," "don't know"). This is a troubling rate as compared to the health care industry turnover rate of 16%. Seventy percent of respondents reported themselves as a replacement for a previous CRA; this provides modest evidence to support concerns of high turnover and asserts new CRA applications represent poor CRA retention rather than expansive hiring of new CRAs at member sites.

Factors Contributing to Positive and Negative CRA Retention

Compensation. Low salary was the most frequently cited contributing factor for negative CRA retention. Reported salary varied from less than \$30 000 to over \$70 000 US\$ annually for full-time CRAs (N = 399). The CRA role can differ site to site, and this may always result in a wider range of salary; however, a range of less than \$30 000 to more than \$70 000 annually for full-time individuals is significant. This may be accounted for by a wide range of educational backgrounds and training among CRAs. If an individual is a registered nurse, he or she may also be responsible for patient care duties, which would affect compensation. To confirm that CRA positions are classified and compensated appropriately, a revamped analysis

Table 2. Factors Influencing CRA Retention, Likelihood of Leaving COG CRA Job Within 6 Months, and Replacement Versus New Position at the Time of Hire.

What makes you want to leave your COG position?	
My salary is too low.	286
Unmanageable workload.	271
Lack of career advancement opportunities.	259
Lack of research commitment from the research team.	190
Lack of support for professional development.	181
What makes you want to stay at your COG position?	
My work is meaningful.	346
My work is interesting.	279
Principal Investigator is supportive.	238
I enjoy working with the medical team.	232
I enjoy working with my fellow CRAs.	216
How likely are you to leave your COG position in the next 6 months?	
Very unlikely	39% (174)
Unlikely	25% (109)
Don't know	19% (86)
Likely	7% (32)
Very likely	10% (43)
Skipped	(12)
Were you hired as a replacement for a previous CRA or hired into a brand-new CRA position?	
Replacement	70% (319)
New position	26% (116)
Don't know	4% (19)
Skipped	(2)

Abbreviations: COG, The Children's Oncology Group; CRA, clinical research associate.

of compensation using role-specific market data and input from human resources, investigators, and management is imperative. The Society of Clinical Research Professionals (SoCRA) has published 3 detailed salary surveys since 2004 to guide research professional compensation (DePaulo, 2015).

Job satisfaction and retention are negatively affected when the complexity of role, workload, and the level of responsibility required are not commensurate with compensation. The second most frequently cited reason affecting CRA attrition after low salary was unmanageable workload. A site with a large number of enrollments, an experimental therapy program, or other factors that increase clinical research complexity and workload should factor those considerations into CRA compensation.

Professional Development. Both lack of career opportunity and professional development were cited as problems. Continuing education should be a mainstay of the clinical research program. Staff development through education

and professional association provides an opportunity to solidify and expand knowledge and share expertise with other professionals. Working with other research professionals could benefit CRAs, as the group reported enjoyment working with their peers as a positive factor in retention. Professional development creates a space for autonomy, a proven positive factor in increased job satisfaction (Price, 2001). Other opportunities for CRA professional growth include regional, national, and international involvement with professional organizations and research groups. CRAs should receive site-funded support for professional membership fees, research professional certification, and travel for scientific and professional meetings. Career ladders specific to research professionals are another valuable tool for managers that has proven effective in the retention of nurses (Drenkard & Swartwout, 2005). Ladders present an objective and customizable career path to those interested in growing within their research role.

Education and Training. Key to the issue of CRA satisfaction seems to be the process of training new staff members. CRAs are often relied on as an essential team member in pediatric oncology. They are expected to have a reasonable level of knowledge about many types of childhood cancer and a strong understanding of research regulations, operations, subject management, health information privacy laws, policies and procedures of sponsors, good clinical practice and site-specific knowledge. According to our survey, 75% of CRAs have higher education but almost 40% have no previous research experience. Thirty-three percent reported 4 or more years of previous research experience, but the experience was not necessarily specific to oncology. This suggests a well-educated population is being recruited but poorly equipped; new COG CRAs are being given little to no training at an institutional level (74% report receiving no training to less than 2 months of training at hire).

Current employee and investigator mentoring coupled with national and international resources can provide comprehensive, low-cost, and reasonably accessible training to new CRAs. Since CRAs reported enjoyment in working with the medical team and other CRAs as a positive factor in retention, training materials and instruction could be created and given by investigators, clinical staff, and senior research staff. PIs can support this by providing new and senior CRAs time to give and receive appropriate training. As volume and complexity of research objectives are expanded, the experience, knowledge, and breadth of the research office must grow in tandem. Nursing retention studies show that poor role differentiation and ambiguity can lead to a negative atmosphere that contributes to attrition, so it is important to explicitly state job duties and measure progress objectively. For new staff, demonstrated

competencies through the use of shadowing and skill checklists confirm that CRAs are properly equipped.

Leadership and Outside Job Opportunities. In Westlund and Hannon's (2008) study, the "supervision" variable had the highest mean score with relation to turnover intention. Though compensation was the most frequently cited reason for negative retention in this survey, leadership is an important factor relating to both intent to leave and intent to stay in the literature and this survey. CRAs cited PI leadership, working with the medical team, and working with fellow CRAs as positive factors influencing their decision to stay. The survey provided 7 unique supervisor roles and a section for free text under "Other," which collected 30 additional specified supervisor roles. Though supervision variability is clear and investigators might feel they do not have direct power over decisions affecting CRA worklife, we suggest PI leadership is an important influencer of CRA job satisfaction and retention.

Through a delegation of authority log, investigators delegate many essential clinical research duties to their research staff (Speicher et al., 2012). Delegation does not relieve the investigator of accountability; in accordance with the Code of Federal Regulations, it is always the responsibility of the PI to fulfill his or her duties as PI (Code of Federal Regulations: Subpart D—Responsibilities of Sponsors and Investigators, 2015). It is likely that outstanding sites not only have the oversight legally required but are led by relationship-centric investigators who educate, support, empower, and reward individuals in a supportive environment built on shared purpose. Leadership cannot always "fix" every issue but can exert positive influence on the working lives of staff dedicated to supporting their research work. Excellent clinical research professionals have employment opportunities in for-profit medical research through pharmaceutical companies, contract research organizations, and other commercial organizations. Strong leadership will maximize resources to improve the worklife of their staff to reduce the likelihood CRAs seek and accept industry positions.

Mission Alignment. Critical to the success of our group is that CRAs report strong alignment to the mission of COG. The belief in the values and vision of an organization is known to have a positive impact on retention as it promotes a sense of belonging, a shared purpose, and a willingness to pursue the organization's goals (Hayes et al., 2006; Peace, 2008; Pepe, 2010). Coupled with strong leadership to address some of the serious, but fixable, workplace issues discussed above, investigators have a chance to build a successful research program firmly cemented in the shared goal of curing childhood cancer.

Limitations

This study included a convenience sample from one cooperative group, and results were based on self-reported data. There is a possibility that responses could be skewed if participants perceived the data to be identifiable, such as linking responses to institutional sites. The survey was hosted by a third-party provider in an effort to minimize bias. Self-selection bias is also a possibility—it may be that the participants felt strongly about leaving or staying within their role and that our survey missed a moderate set of the population in our data. Respondents might also support adult or other nononcology research and individual negative or positive experiences with those non-COG groups could influence the data of this survey. There are also other factors such as a lack of employer paid leave, which may lead to CRA turnover.

Implications for Practice

This study identifies the need for leaders to assess the compensation of CRAs as they relate to the duties, size, and complexity of the research program. Site-provided initial training and continuing education are vital. Sites should strongly consider implementing professional development tools, such as career ladders, and supporting professional development activities (eg, professional certification and travel support) to keep new and experienced personnel engaged.

Conclusions

A truly robust research program comprises qualified investigators and staff members who have the support to achieve individually and collectively toward shared goals. Sites and research cores able to preserve their professional work force through active leadership are better equipped to meet the challenges presented by a field that continually balances on the precipice of discovery. Strategies for retention discussed in this article could be applied to adult oncology and nononcology research professionals. Since much of our literature was based on nursing retention and a quarter of COG CRAs are nurses, there may be common challenges and solutions applicable to the retention of pediatric oncology nurses and other allied health members.

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