

Burnout in Clinical Research Coordinators in the United States

Clement K. Gwede, PhD, MPH, RN, Darlene J. Johnson, MBA, CCRA,
Cleora Roberts, PhD, and Alan B. Cantor, PhD

Purpose/Objectives: To assess burnout among clinical research coordinators (CRCs) and to determine which personal and job-related factors are associated with burnout.

Design: Random, stratified, cross-sectional mail survey.

Setting: CRCs from membership lists of clinical research organizations.

Sample: 252 CRCs in the United States. To be included in the study, participants must have been in their current position longer than six months and involved in clinical trial coordination or data management. Of 2,770 records, 900 CRCs were mailed questionnaires; 35% (316) responded, and 252 of those were eligible for analysis. Eligible respondents were Caucasian (86%), female (94%), and employed full-time (92%) in an oncology setting (71%).

Methods: Respondents completed mailed self-administered questionnaires measuring burnout, job satisfaction, personality characteristics, perceived work overload, and selected personal- and employment-related data. Data analyses included descriptive, univariate, and multivariate statistics.

Main Research Variable: Burnout.

Findings: About 70% of respondents were satisfied with their job, and 74% would still choose the clinical research profession. Approximately 44% reported high emotional exhaustion, a component of burnout. Factors independently associated with high emotional exhaustion burnout were low satisfaction with job ($p < 0.0001$), high perceived daily workload ($p < 0.0001$), and low endurance personality ($p = 0.002$).

Conclusions: Burnout is prevalent in CRCs. Job dissatisfaction, perceived daily work overload, low endurance, and nurturance personality traits were associated with high burnout.

Implications for Nursing: Nurses are involved significantly in clinical trial coordination. High burnout rates have potentially negative implications for data quality and productivity in clinical trial data management—important values for nursing and the clinical research profession.

Although healthcare work settings can be highly stimulating and rewarding environments, certain work-related stressors have been documented. Previous research has shown that job-related stress and burnout are associated with high levels of demand placed on healthcare workers, especially in situations where a worker's influence is low (van Servellen & Leake, 1993). In addition to the overall emphasis on cost containment and the underlying demand for quality, healthcare occupations are faced with chronic shortages of staff and the expectation "to do more with less." Several factors may contribute to the development or amelioration of occupational stress and burnout among clinical research coordinators (CRCs). CRCs, many of whom are nurses, are responsible for coordinating, managing, and implementing diverse and challenging clinical trial activities such as regulatory processing of the clinical trial protocol;

Key Points . . .

- ▶ Burnout among clinical research coordinators (CRCs)—many of whom are nurses—is not well documented.
- ▶ Oncology and nononcology CRCs report significant burnout, especially among those who report high dissatisfaction with their jobs, work overload, and low endurance or nurturance personality traits.
- ▶ Burnout in CRCs is comparable to levels reported by other healthcare professionals, and most CRCs are satisfied with their jobs and motivated to remain in the profession.

identifying, recruiting, and enrolling patients; monitoring and assessing patients during active treatment and follow-up; and data collection and submission (completion of case report forms) at investigative sites. Recognizing the complexity and challenges of this position, some institutions have undertaken additional structural and role delineation initiatives to create specialty functions such as regulatory specialist, clinical trial nursing ladder, and data manager positions (data collection function only) to simplify the complex CRC role. However, many CRCs still do it all and continue to be faced with the potential distress associated with a broadly defined and overwhelming position. Furthermore, the role of CRCs often is not well understood by other healthcare workers, thus leading to ineffective interactions with other well-established disciplines and providers, such as nurses, physicians, pharmacists, or laboratory personnel. Other distressful factors may include having various personal characteristics, working with patients with acute or life-threatening conditions, dealing with heavy daily workload, and experiencing a variety of stressors in the work environment or the uncertainty of the job itself (e.g., organizational restructure and the associated fear of job loss) as reported in other healthcare occupations (Beaudoin & Edgar,

Clement K. Gwede, PhD, MPH, RN, is an assistant professor and Darlene J. Johnson, MBA, CCRA, is a programs/research administrator, both in the Department of Interdisciplinary Oncology at the H. Lee Moffitt Cancer Center and Research Institute in Tampa, FL; Cleora Roberts, PhD, is a professor in the School of Social Work and Alan B. Cantor, PhD, is a professor in Interdisciplinary Oncology, both at the University of South Florida in Tampa. (Submitted December 2004. Accepted for publication February 21, 2005.)

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2003; Denton, Zeytinoglu, Davies, & Lian, 2002; Gabassi, Cervai, Rozbowski, Semeraro, & Gregori, 2002; Johnson, Roberts, Trotti, & Greenberg, 1998; Peteet et al., 1989; Seago & Faucett, 1997; Vachon, 1987; van Servellen & Leake). For example, one study found that radiation therapists with achievement-oriented personality traits and nurturing qualities were protected from burnout (Johnson et al.). Beaudoin and Edgar showed that hassles related to interdepartmental relations, working conditions, and organizational and physical environment prevent nurses from performing patient care and increase nurse dissatisfaction. These issues have not been evaluated for CRCs in the United States.

The desire to hire and retain qualified CRCs has prompted interest in the factors associated with work-related distress. However, clinical research and clinical trial nursing, unlike other healthcare professions, is a relatively young specialty, and efforts to understand job-related stress among CRCs are compounded by inherent variations in work settings, diversity in employment practices, and lack of professional standards and clear role delineation. These issues have been discussed in recent literature (Ehrenberger & Lillington, 2004; Gwede, Johnson, & Daniels, 2001; Gwede, Johnson, & Trotti, 2000a, 2000b; Roche et al., 2002), but a dearth of literature addresses burnout in clinical research. Previous efforts have focused on descriptive analyses in three related areas, including (a) clinical research infrastructure, resource management, and role delineation at investigative sites (Ehrenberger & Lillington; Fowler & Thomas, 2003; Gwede et al., 2001; Hancock, Wiland, Brown, Kerner-Slemons, & Brown, 1995); (b) workload measurement issues (Gwede et al., 2000a, 2000b; Roche et al.); and (c) nontreatment costs of conducting clinical trials (Emanuel, Schnipper, Kamin, Levinson, & Lichter, 2003; Fowell & Wilson, 2002; Johnson, 2003; Wright & Levine, 2003). These studies have raised questions and identified the challenges facing clinical research sites and CRCs regarding workload burden and potential for burnout, but none has addressed burnout and professional satisfaction of CRCs directly.

The primary aims of this study were to assess and describe the patterns of burnout in CRCs and to determine which personal characteristics (e.g., age, marital status, personality type) and work-related factors (e.g., perceived work overload, area of specialty, years of work experience, type of studies managed, job satisfaction) are associated with burnout in this sample.

Methods

Study Design, Setting, and Participants

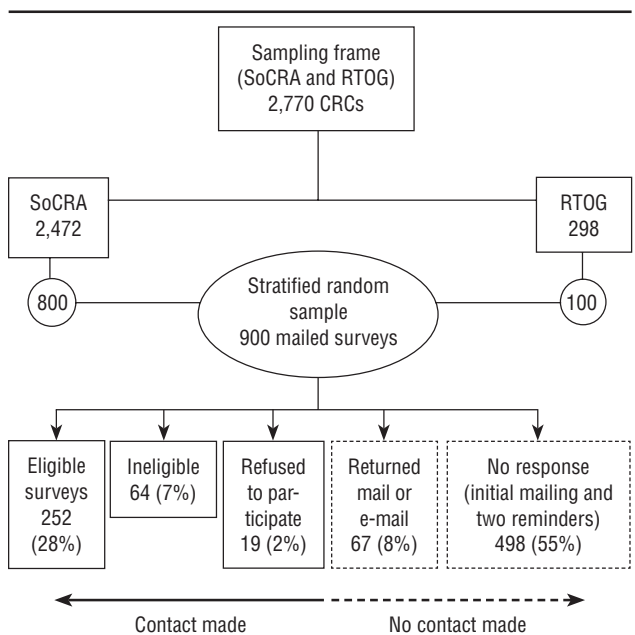
A random, stratified, cross-sectional mail survey design was used to identify and recruit potential respondents. CRCs working in oncology or nononcology settings at investigative sites in the United States were eligible to participate if they

- Currently were involved in clinical trial coordination or data management (i.e., enrolling or following patients or collecting data or completing case report forms)
- Had been employed longer than six months at the current position. People with fewer than six months' employment may not have an adequate appreciation of the scope of their work environment and associated distress because they still may be in training.

Of six clinical trials organizations approached to obtain mailing addresses for CRCs, only two—the Radiation Therapy Oncology Group (RTOG) and the Society of Clinical Research Professionals (SoCRA)—provided membership lists containing postal mailing addresses and e-mail addresses (when available). The two electronic databases were merged and sorted to identify and remove duplicate records. A total of 2,770 records were available for sampling (see Figure 1). The random sampling program (stratified by professional society) was designed to sample 100 CRCs from RTOG and 800 from SoCRA. A total of 900 CRCs were mailed a cover letter, three standardized surveys, and a demographic and employment questionnaire with a goal of obtaining 420 completed responses. After the initial mailing, two reminders were sent either by e-mail (majority) or postcard (Fowler, 1993). As shown in Figure 1, 316 (35%) of 900 CRCs responded by mailing back a completed questionnaire. After the questionnaires were checked for eligibility, 252 (28%) respondents were found eligible and were analyzed further. The most common reason cited for refusal to participate was “too busy.” The most common reason for ineligibility was “changed role, no longer doing data management.”

Procedures for Protection of Participants

Approval to conduct the study was obtained from the University of South Florida Institutional Review Board with a waiver of informed consent. In the database containing response data, code numbers were used to identify participant records to protect confidentiality. Only one member of the research team had access to the master file linking the code numbers to participants' postal and e-mail addresses—linkage of records was necessary for the purposes of re-mailing. Participants were not paid or compensated for their involvement.



CRC—clinical research coordinator; RTOG—Radiation Therapy Oncology Group; SoCRA—Society of Clinical Research Associates

Figure 1. Study Schema Showing Sampling Strategy and Participation Rates

Outcome Measures

Burnout: The Maslach Burnout Inventory (MBI) (Maslach & Jackson, 1986) is a 22-item questionnaire assessing three components of burnout: emotional exhaustion, depersonalization, and personal accomplishment. The emotional exhaustion subscale contains nine items such as “I feel like I am at the end of my rope.” The depersonalization subscale contains five items such as “I have become more callous toward people since I took this job.” The personal accomplishment subscale consists of eight items such as “I have accomplished many worthwhile things in this job.” Respondents were instructed to answer each question according to how often it occurred. A 7-point response scale is used for each item: 0 = never, 1 = a few times a year, 2 = once a month or less, 3 = a few times a month, 4 = once a week, 5 = a few times a week, and 6 = every day.

The MBI provides three scores that represent the sum of the individual items included in each of the three subscales. The three subscale scores are used separately as individual outcome variables and are interpreted separately. For example, a high degree of burnout is reflected by high scores on the emotional exhaustion and depersonalization subscales and low scores on the personal accomplishment subscale. Internal consistency reliability as measured by Cronbach’s alpha for the entire sample in this study was 0.91, 0.81, and 0.72, for the emotional exhaustion, personal accomplishment, and depersonalization subscales, respectively. These psychometric properties are consistent with findings from other samples (van Servellen & Leake, 1993).

Predictor Variables

Personality variables: The Personality Research Form (PRF) (Jackson, 1984) measures personality traits of people with normal, rather than pathologic, functioning. Participants were asked to respond to each statement as “true” if it describes them or “false” if it does not. Of the 14 subscales in the PRF, four were used in this study because they are commonly used in studies of this nature.

- Abasement: readily accept criticism and blame and tend to be self-effacing
- Achievement: maintain high standards and willing to put forth effort to attain excellence
- Endurance: willing to work long hours and persevere in difficult situations
- Nurturance: sympathetic and interested in caring for ill people

Each subscale has 16 questions that are answered “true” or “false.” To compute a subscale or trait score, eight questions should be answered “true” and the other eight should be “false” for that trait. A total score representing the sum of the responses to the 16 items (maximum score is 16) was constructed for each subscale. Each subscale score was used as a separate variable in analysis.

Professional satisfaction: The Professional Satisfaction Questionnaire (PSQ) (Buck, 1987; Johnson et al., 1998) was adapted to solicit opinions on a number of categories important to CRCs. These categories include items related to job responsibilities; relationships with patients, physicians, and other staff; and control over and importance of job and emotional stress. The response was obtained based on a five-point scale of 1 (strongly agree) to 5 (strongly disagree). For some

of the analysis, these response options were collapsed into agree or strongly agree, undecided, or disagree or strongly disagree, or they were dichotomized into agree versus undecided or disagree. For multivariate analyses, selected PSQ items were used as individual predictors or outcome variables.

Sociodemographic, employment, and study variables: Respondents’ sociodemographic and job-related characteristics were collected using standard structured questions and response formats. These data included age, gender, ethnicity, marital status, number of children and adults in household, annual income from clinical research job(s), professional training, highest level of education, employment status (full-time versus part-time), number of hours worked, employment setting (oncology versus nononcology), years of experience in clinical research, number of employers, number of years working for the current employer, and predominant type and phase of studies managed (i.e., industry or pharmaceutical versus cooperative group, and phase II or III studies).

Data Analysis

All data were analyzed using SAS® version 8.2 statistical procedures (SAS Institute, Inc., Cary, NC). First, descriptive analyses were performed to assess distribution (frequencies, means, standard deviations) of all variables. Then bivariate associations of predictor (sociodemographic, personality, employment, study type) variables and dependent (burnout and professional satisfaction) variables were examined using correlational analyses (Pearson product-moment correlation coefficient or Spearman), chi-square analyses, and t tests as indicated to assess relationships of variables as well as comparability of subsamples (e.g., oncology versus nononcology). To evaluate as many potential predictors as possible, any variable found to be approaching statistically significant bivariate associations ($p < 0.1$) with the two burnout subscales (i.e., emotional exhaustion, personal accomplishment) were used as predictors in multivariate hierarchical linear regression analyses to identify factors independently associated ($p < 0.05$, two-sided) with two burnout variables (i.e., emotional exhaustion, personal accomplishment). Depersonalization was not used as a dependent variable in regression analysis because (a) it had a strong correlation with emotional exhaustion ($r = 0.50$), (b) it generally is regarded as a final extension of emotional exhaustion burnout (van Servellen & Leake, 1993), and (3) it had the least association with predictor variables in this sample.

Results

Descriptive Analyses

Demographic, employment, and study information: Respondents were predominantly Caucasian (86%), female (94%), married or living with a partner (71%), a college graduate or higher (77%), employed full-time (92%), and working in the oncology specialty (71%). Demographic information is presented in Table 1. The mean age was 43.8 years. About half (52%) of respondents had been employed in clinical research for more than five years, but most (68%) had been in their current position for five years or fewer. A notable number (45%) had nursing training, compared to 21% whose background was clinical research and 34% who had other backgrounds. Overall, the type of studies managed by the CRCs was balanced by sponsor type and phase of study. However, as expected, for both phase II and phase III studies,

Table 1. Distribution of Selected Demographic and Employment Variables

Variable	n	%
Age (years)		
\bar{X} = 43.8	–	–
SD = 9.7	–	–
Median = 44.4	–	–
Range = 24.7–68.9	–	–
Race		
Caucasian	217	86
Gender		
Female	234	94
Marital status		
Married	162	64
Current living relationship		
Married or living with partner	179	71
Education		
Less than college graduate	59	24
College graduate	133	53
Graduate degree or higher	59	24
Employment status		
Full-time	231	92
Working second job		
Yes	29	12
Working more than one clinical research job		
No	239	96
Salary (\$)		
≤ 30,000	49	20
30,001–50,000	126	50
> 50,000–100,000	75	30
Number of years in current position		
≤ 1	33	13
2–3	84	34
4–5	54	22
6–10	50	20
> 10	26	11
Professional background		
Nursing	113	46
Clinical research	53	22
Other	80	33
Focus area in which currently employed		
Oncology	179	71
Other	72	29
Predominant type of studies managed^a		
Industry		
Phase II or I/II	56	44
Phase III	72	56
Cooperative		
Phase II or I/II	60	41
Phase III	87	59

N = 252

^a Some clinical research coordinators reported comparable volume of industry and cooperative trials and were included in both categories.

Note. Because of rounding, not all percentages total 100. Percentages were calculated based on number responding; missing data were not included.

oncology CRCs reported predominantly cooperative group studies. For phase II studies, oncology CRCs reported 50% cooperative versus 28% pharmaceutical, compared to 13% versus 63%, respectively, for nononcology CRCs. Similarly, for phase III studies, oncology CRCs reported 60% cooperative versus 28% pharmaceutical, compared to 12% versus 68%, respectively, for nononcology CRCs. No differences

were noted between oncology and nononcology CRCs in comparisons of demographic and employment variables.

Professional satisfaction: Professional satisfaction was high. At least 69% of respondents said that they were satisfied with their jobs, and at least 74% indicated they would still choose the clinical research profession if they had to make the decision again. A majority (94%) of CRCs felt strongly that their jobs were important, and 77% indicated strongly that they would encourage others to go into this profession. CRCs working in the oncology setting were more likely to be concerned about high daily workload compared to CRCs working in nononcology settings (55% versus 37%, $p = 0.008$). Although a handful of other comparisons were approaching statistical significance, the two groups generally were comparable in all other aspects of professional satisfaction.

Burnout and personality variables: The mean scores and standard deviations for burnout and personality variables are summarized in Table 2 by focus area (comparing oncology CRCs to nononcology CRCs) as well as for the entire sample. No statistically significant differences existed in the subgroup comparisons of burnout and personality variables by specialty area. No differences were found in comparisons by employment status (full-time versus part-time). Compared to a mixed sample of healthcare professionals ($N = 1,104$) provided by the MBI test manual (Maslach & Jackson, 1986), CRCs in this study reported comparable levels of burnout in two (emotional exhaustion and personal accomplishment) of the three subscales (see Figure 2). However, CRCs reported lower burnout in the depersonalization subscale.

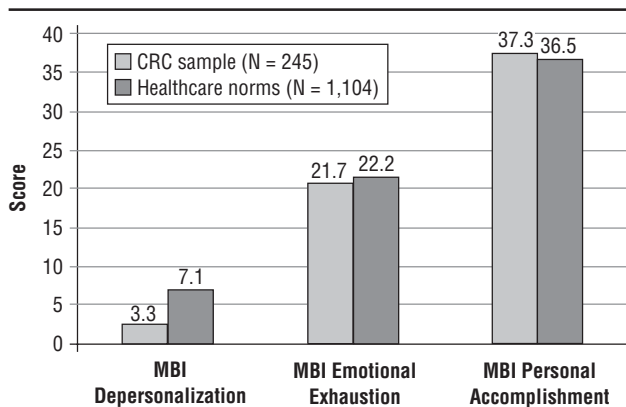
Correlational Analyses

Overall, emotional exhaustion and personal accomplishment burnout had the most meaningful correlations only with personality and professional satisfaction variables. For example, Table 3 shows that satisfaction with job is strongly correlated with the level of emotional exhaustion burnout ($r = 0.60$, $p < 0.0001$). Respondents who were satisfied (lower

Table 2. Distribution of Mean Scores for MBI and PRF Variables by Specialty (Oncology Versus Nononcology) Area

Variables	Oncology (N = 172)	Nononcology (N = 73)	p	All CRCs (N = 245)
	\bar{X} (SD)	\bar{X} (SD)		\bar{X} (SD)
MBI				
Depersonalization	3.5 (4.2)	3.0 (3.5)	NS	3.3 (4.0)
Emotional exhaustion	22.3 (11.5)	20.3 (12.4)	NS	21.7 (11.8)
Personal accomplishment	38.0 (8.7)	40.2 (6.9)	NS	37.3 (8.2)
PRF				
Abasement	7.4 (2.8)	7.8 (2.7)	NS	7.6 (2.8)
Accomplishment	12.0 (2.2)	12.0 (2.0)	NS	12.0 (2.4)
Endurance	11.5 (2.4)	12.1 (2.5)	NS	11.7 (2.5)
Nurturance	11.9 (2.9)	11.6 (2.3)	NS	11.8 (2.7)

CRC—clinical research coordinator; MBI—Maslach Burnout Inventory; NS—not statistically significant (i.e., $p > 0.05$) (t tests for differences between mean scores for oncology and nononcology CRCs); PRF—Personality Research Form



CRC—clinical research coordinator; MBI—Maslach Burnout Inventory
 Note. Higher scores for depersonalization and emotional exhaustion and lower scores for personal accomplishment reflect worse burnout.

Figure 2. Maslach Burnout Inventory: Comparison of Clinical Research Coordinators With Norms Based on a Sample of Healthcare Workers

score) with their jobs reported lower burnout (lower score) compared to those who reported dissatisfaction (higher score). Similarly, satisfaction with job was moderately correlated ($r = -0.36, p < 0.0001$) with personal accomplishment burnout. Respondents who reported greater satisfaction with their job (lower score) reported more personal accomplishment (higher score).

Regarding personality variables, endurance personality traits were negatively associated with depersonalization and emotional exhaustion, as expected. These data suggest that individuals who rated high in endurance personality traits reported less burnout (lower scores) in these two areas. On the other hand, higher endurance personality traits were positively correlated ($r = 0.30, p < 0.0001$) with higher personal accomplishment burnout, as expected.

Multivariate Analyses

After controlling for employment status (full- versus part-time), number of hours worked per week, and professional background (nurse versus non-nurse), the authors examined the relationships of predictors to burnout variables. Beta weights (standardized regression coefficients) were reviewed to assess the relative importance of selected variables in predicting burnout. The results in Tables 4 and 5 suggest that 54% of the variance in emotional exhaustion burnout is explained by the linear combination of the predictors included in regression model 1. Based on the beta weights (β), job satisfaction had the greatest influence on emotional exhaustion burnout and all coefficients were in the expected direction.

Factors strongly associated with emotional exhaustion burnout were satisfaction with job ($\beta = -0.31, p = 0.0001$), daily workload ($\beta = -0.30, p = 0.0001$), and endurance personality traits ($\beta = -0.20, p = 0.002$). In regression model 2, 34% of the variance in personal accomplishment burnout was explained by the linear combination of the predictors included in the model. Among these predictors (based on β), job satisfaction had the greatest influence on personal accomplishment burnout. Factors independently associated with personal accomplishment burnout were satisfaction with job ($\beta = 0.36,$

$p = 0.0001$), endurance personality traits ($\beta = 0.23, p = 0.01$), emotional satisfaction ($\beta = -0.22, p = 0.007$), and nurturance personality traits ($\beta = 0.20, p = 0.02$).

Post-Hoc Comparisons

Based on cutoffs derived from the MBI manual (Barrett & Yates, 2002; Johnson et al., 1998), respondents were grouped in categories reflecting low, medium, or high burnout on each subscale. For interpretation, a high degree of burnout is reflected by high scores on the emotional exhaustion and depersonalization subscales and a low score on the personal accomplishment subscale. For emotional exhaustion ($N = 189$), 52% reported low burnout (≤ 16), 4% reported medium (17–26), and 44% reported high (≥ 27). For depersonalization ($N = 226$), the distribution was 91% low burnout (≤ 6), 4% medium (7–12), and 5% high (≥ 13). Finally, for personal accomplishment ($N = 192$), 64% reported low burnout (≥ 39), 2% indicated medium

Table 3. Intercorrelations Among MBI Subscales and Correlations of MBI Variables With PRF and PSQ Variables

Variable	MBI Depersonalization	MBI Emotional Exhaustion	MBI Personal Accomplishment
MBI			
Depersonalization	–	0.51***	–0.33***
Emotional exhaustion	–	–	–0.36*
Personal accomplishment	–	–	–
PRF			
Abasement	0.21	–0.02	0.07
Accomplishment	–0.05	–0.02	0.23**
Endurance	–0.21*	–0.22**	0.30***
Nurturance	–0.19	–0.06	0.34***
PSQ			
My daily workload is too high for me to be able to perform my job to the best of my ability.	–0.16	–0.56***	0.13
I get emotional satisfaction working with patients.	0.19	0.04	–0.38***
I am satisfied with my job.	0.32***	0.60***	–0.36***
The current shortage of staff is very stressful.	–0.13	–0.49***	0.10
If I had the decision to make over again, I would still go into this profession.	0.19	0.35***	–0.26***
I have no doubt that my job is important.	0.04	0.11	–0.10
The daily challenges of the profession are the reasons I remain.	0.05	0.26***	–0.18

* $p < 0.003$, ** $p < 0.001$, *** $p < 0.0001$

MBI—Maslach Burnout Inventory; PRF—Personality Research Form; PSQ—Professional Satisfaction Questionnaire

Note. PSQ response scale: 1 = strongly agree, 2 = agree, 3 = undecided, 4 = disagree, 5 = strongly disagree

Note. For MBI subscales, higher scores for Depersonalization and Emotional Exhaustion indicate worse burnout and higher scores for Personal Accomplishment indicate less burnout.

Table 4. Factors Associated With Maslach Burnout Inventory Emotional Exhaustion Burnout After Controlling for Employment Status, Weekly Hours Worked, and Professional Background

Variable	\bar{X} (SD)	β Weights ^a		
		β	t ^b	p
My daily workload is too high for me to be able to perform my job to the best of my ability ^c .	2.75 (1.27)	-0.30	-4.1	< 0.0001
I get emotional satisfaction working with patients.	1.71 (0.81)	-0.02	-0.3	0.75
I am satisfied with my job.	2.29 (1.05)	0.36	5.5	< 0.0001
The current shortage of staff is very stressful.	2.29 (1.20)	-0.13	-1.8	0.07
I would still go into this profession.	2.06 (0.96)	0.11	1.8	0.07
Abasement personality	7.56 (2.79)	0.05	0.9	0.38
Accomplishment personality	11.99 (2.36)	0.06	0.9	0.37
Endurance personality	11.69 (2.49)	-0.20	-3.1	0.002
Nurturance personality	11.80 (2.73)	-0.07	-1.2	0.23

N = 194

R-square = 0.54 (proportion of variance in the dependent variable explained by all variables [all together] included in the model)

^a Beta weights are standardized multiple regression coefficients obtained when each Maslach Burnout Inventory variable was regressed on all predictors in the model.

^b For t tests that tested significance of the beta weights

^c Response scale for all ordinal items on the Professional Satisfaction Questionnaire were 1 = strongly agree, 2 = agree, 3 = undecided, 4 = disagree, and 5 = strongly disagree.

(32–38), and 35% reported high (≤ 31). These findings suggest that emotional exhaustion burnout (44%) is more prevalent in this sample followed by personal accomplishment burnout (35%).

Figures 3–5 show the relationship among selected measures of professional satisfaction and emotional exhaustion burnout. In general, the results show that those who reported high levels of burnout were more likely to report dissatisfaction with their profession. Conversely, the conclusion could be made that individuals who reported greater dissatisfaction with profession were more likely to report higher burnout. The nonoverlapping error bars in Figures 3–5 suggest that the differences between the low and high categories (for burnout scores) are consistently statistically significant.

Discussion and Implications

This is the first study of CRCs in the United States designed specifically to examine the prevalence of burnout and professional satisfaction and the extent to which personal- and employment-related characteristics were associated with burnout. Except for perception of workload burden and predominant type of studies managed (by sponsor type), no statistically significant differences were found between oncology CRCs and nononcology CRCs with regard to demographics, personality, employment characteristics, professional satisfaction, and burnout. Although Roche et al. (2002) found that sponsor type and study phase were associated with workload burden, the current study found no

association of these factors with burnout and professional satisfaction in this study.

When looking at overall burnout scores, the current study findings showed that CRCs report similar levels of burnout when compared with other healthcare workers, with the exception of depersonalization. The current sample scored lower in depersonalization, indicating lower levels of this aspect of burnout. A study of 45 radiation therapy technologists in Florida evaluated the influence of personality characteristics on job satisfaction and burnout (Johnson et al., 1998). Despite the small sample size and low response rate (40%), this study found less burnout, and conversely greater job satisfaction, compared to a normative sample of healthcare professionals. The current study's data are consistent with previous findings (Barrett & Yates, 2002; Beaudoin & Edgar, 2003; Johnson et al.; Peteet et al., 1989).

The current study found associations of personality characteristics with burnout. Specifically, high endurance personality trait was independently associated with lower levels of emotional exhaustion ($p = 0.002$) and higher levels of personal accomplishment ($p = 0.01$) in multivariate analyses. Similarly, nurturance personality trait was independently associated with lower personal accomplishment burnout ($p = 0.02$). The findings suggest that CRCs who possess high endurance and nurturance personality qualities seem to be somewhat protected from burnout. These findings are consistent with other studies. For example, Johnson et al. (1998) found a strong positive correlation between the achievement personality trait and personal accomplishment subscale of the MBI ($r = -0.56$, $p < 0.001$), suggesting that achievement orientation promotes greater feelings of personal accomplishment.

The current study's researchers found that perceived daily workload and job satisfaction were correlated with emotional exhaustion burnout (see Table 3) and these relationships also were evident in multivariate analyses (see Tables 4 and 5).

Table 5. Factors Associated With Maslach Burnout Inventory Personal Accomplishment Burnout After Controlling for Employment Status, Weekly Hours Worked, and Professional Background

Variable	\bar{X} (SD)	β Weights ^a		
		β	t ^b	p
I get emotional satisfaction working with patients ^c .	1.71 (0.81)	-0.22	-2.8	0.007
I am satisfied with my job.	2.29 (1.05)	-0.31	-4.2	< 0.0001
Abasement personality	7.56 (2.79)	-0.03	-0.4	0.66
Accomplishment personality	11.99 (2.36)	-0.08	-0.9	0.39
Endurance personality	11.69 (2.49)	0.23	2.6	0.01
Nurturance personality	11.80 (2.73)	0.20	2.4	0.02

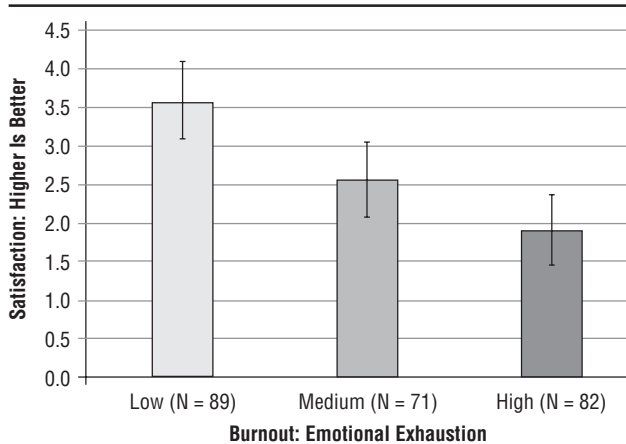
N = 138

R-square = 0.34 (proportion of variance in the dependent variable explained by all variables [all together] included in the model)

^a Beta weights are standardized multiple regression coefficients obtained when each Maslach Burnout Inventory variable was regressed on all predictors in the model.

^b For t tests that tested significance of the beta weights

^c Response scale for all ordinal items on the Professional Satisfaction Questionnaire were 1 = strongly agree, 2 = agree, 3 = undecided, 4 = disagree, and 5 = strongly disagree.

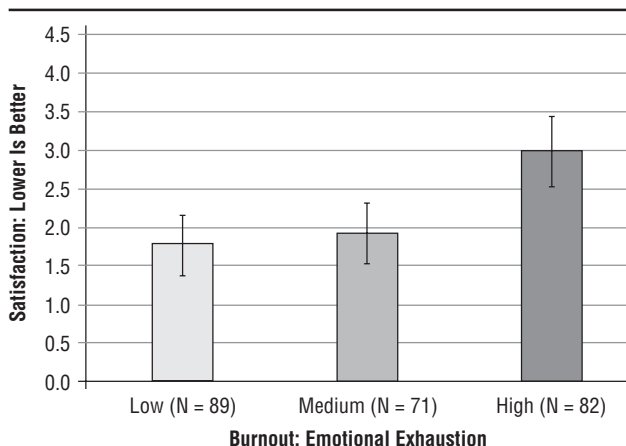


Note. Response scale: 1 = strongly agree to 5 = strongly disagree
 Note. Higher scores for emotional exhaustion reflect worse burnout.

Figure 3. My Daily Workload Is Too High for Me to Be Able to Perform My Job to the Best of My Ability

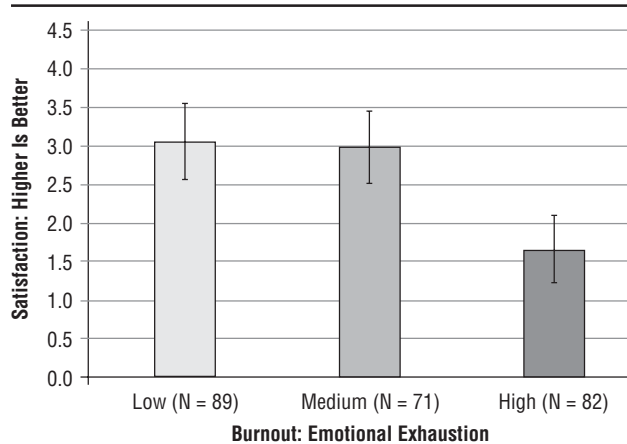
Although this is a cross-sectional study and the causal associations are unclear, the findings support the assertion that job satisfaction predicts the level of burnout and vice versa. Understanding the relationship between job satisfaction and burnout is an important goal in a young profession faced with the challenges of diversity, rapid growth, and ever-changing work-related demands and environments. Although professional dissatisfaction and burnout rates were lower in the current sample, clinical research managers and study sponsors should implement strategies that can increase CRCs' job satisfaction and reduce burnout, thereby enhancing the retention of qualified and experienced CRCs. Furthermore, staff burnout may affect productivity and patient satisfaction (Barrett & Yates, 2002; Garman, Corrigan, & Morris, 2002).

Nurses are significantly involved in clinical trials coordination. Nurses and other professionals who move into clinical trial management should be encouraged by the study findings. First, these data suggest that CRCs experience burnout at



Note. Response scale: 1 = strongly agree to 5 = strongly disagree
 Note. Higher scores for emotional exhaustion reflect worse burnout.

Figure 4. I Am Satisfied With My Job



Note. Response scale: 1 = strongly agree to 5 = strongly disagree
 Note. Higher scores for emotional exhaustion reflect worse burnout.

Figure 5. The Current Shortage of Staff Is Very Stressful

levels comparable to other healthcare professionals. Second, CRCs currently report high levels of job satisfaction and many are motivated to remain in this young profession. Third, the researchers have identified factors that may contribute to the development or amelioration of burnout. Simply put, CRCs who report work overload are unhappy with their jobs, and those low in endurance or nurturance traits are more likely to report high burnout. However, no simple or pragmatic solutions exist for translating these preliminary findings into effective strategies to reduce burnout. Left unmanaged, high burnout has potentially negative implications for data quality and productivity in clinical trials data management—important values for nursing and the clinical research professions.

Limitations

The current study yields important findings but has notable limitations in sampling frame and generalizability. First, the sample was drawn from the membership of two organizations, thus excluding potential respondents affiliated with other clinical research organizations. For example, SoCRA membership generally represents a significant proportion of CRCs who work in oncology at large academic medical centers but may not capture CRCs who work at small research sites or nononcology settings. Second, the generalizability of the findings is hampered by a low response rate—a common problem in survey research (Barrett & Yates, 2002; Fowler, 1993; Garman et al., 2002). The most common reason for refusal to participate was “too busy.” Given that perceived daily workload significantly correlated with emotional exhaustion, CRCs who were too busy to complete a survey may have had a greater tendency toward higher emotional burnout. Nevertheless, the study results contribute new findings to the literature because no studies have documented burnout among CRCs in the United States.

Conclusions

Overall, the results suggest that CRCs experience levels of burnout comparable to levels reported by other samples of healthcare professionals. Although the researchers found that

job satisfaction and certain personality qualities are associated with burnout, the underlying causes of burnout are not known from these data. Further research is needed. Understanding the patterns and causes of burnout may help in developing strategies to reduce job-related distress. Nevertheless, the current findings facilitate the following conclusions and recommendations.

- Emotional exhaustion and personal accomplishment burnout are prevalent among CRCs in the United States.
- Burnout is associated with perceived daily work overload, job dissatisfaction, and low endurance and nurturance personality traits.
- Comprehensive and effective strategies to improve daily workload and job satisfaction may help ameliorate burnout. Thus, the findings of this study have potential implications

for improving the professional work environment for CRCs. The findings also could assist administrators at investigative sites and study sponsors (industry and government) in appreciating the economic impact of job dissatisfaction and burnout in relation to recruitment and retention of CRC personnel. Professional societies also have obligations to help develop workload standards and role delineation to reduce job-related stress. Ultimately, job dissatisfaction and burnout are important areas of study in clinical trial management because of financial, data quality, and the potentially damaging physical and psychological impacts of burnout.

Author Contact: Clement K. Gwede, PhD, MPH, RN, can be reached at gwede@moffitt.usf.edu, with copy to editor at ONFEditor@ons.org.

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