MORAL DISTRESS IN CLINCIAL RESEARCH NURSES

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DEDICATION

For my late parents, Ora O’Neal and James O’Neal. They were my biggest fans, and I know they are somewhere cheering me on.

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ABSTRACT

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MORAL DISTRESS IN CLINICAL RESEARCH NURSES

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Clinical research nursing is the nursing specialty that focuses on the care of research participants and the management of clinical trials. Clinical research nurses (CRNs) experience unique challenges in the context of their role related to informed consent, dual obligations, and organizational support. These ethical challenges can lead to conflict, which may lead to moral distress. While moral distress has been examined in many areas of nursing and non-nursing healthcare specialties, it has not been studied in clinical research nursing. A descriptive, quantitative design was used to examine moral distress experienced by CRNs and explore the relationship between moral distress scores and demographic characteristics of CRNs.

CRNs (N = 322) were recruited using digital flyers, emails through professional organizations, social media, and snowball recruitment. The Measure for Moral Distress – Health Care Professionals (MMD-HP) was administered electronically to measure moral distress in CRNs. Sample characteristics were recorded using a nine-item demographic form. Mean scores were calculated to obtain the overall moral distress score, as well as individual item scores. Pearson's product-moment correlations, independent t-test, and

one-way ANOVA were performed to explore differences among the demographic variables.

The analysis demonstrated that CRNs experience moral distress (M = 79.58, SD = 64.27) and that moral distress scores varied by participant demographics. Levels of moral distress were negatively correlated with CRN age (r = -.156, $p < .05$). CRNs who had previously left a job or considered leaving a job due to moral distress had significantly higher levels of moral distress than those who had not ($F_{2,239}$ = 14.26, p = .000). Further, the moral distress scores for CRNs currently considering leaving their position due to moral distress were significantly higher than CRNs not considering leaving (t = 6.42, p = .00). Good reliability of the MMD-HP and four subscales with the sample was demonstrated.

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CHAPTER I

INTRODUCTION

Clinical research nursing is the specialty nursing practice focused on the care of research participants and the management of clinical trials. In 2016, the American Nurses Association (ANA) recognized clinical research nursing as a nursing specialty and published the scope and standards of practice for the clinical research nurse (CRN) in collaboration with the International Association for Clinical Research Nursing (IACRN). Although clinical research nursing is a rapidly emerging specialty and the numbers of CRNs are increasing, clinical research nursing remains a relatively unknown and misunderstood area of nursing outside of the clinical research arena (Kunhunny & Salmon, 2017; Larkin et al., 2017).

Successful clinical trials require extensive collaboration and coordination with multidisciplinary research teams. At the center of that team is the CRN. From initial protocol development to final study close out, and all points in between, the CRN plays an integral role. The CRN is responsible for the day-to-day management of the clinical trial as well as providing and coordinating research related care to the research participant. As the primary point of contact and advocate for the research participant, the CRN has a vital role in ensuring participant safety, maintenance of informed consent, and safeguarding the human subjects' rights of the research participant. Additionally, the integrity and fidelity to implementation of the research protocol, along with the collection

and recording of research data, are within the purview of the CRN role responsibilities. Performing these duties, all the while ensuring human subjects' protections are being adhered to, often place the CRN in a precarious position balancing the clinical needs of the participant and the requirements of the research (Kunhunny & Salmon, 2017). According to Oberle and Allen (2006), nurses involved in the conduct of clinical trials encounter ethical dilemmas or conflicts when attempting to balance moral obligations versus methodological issues in the care of the patient. Ethical dilemmas related to the risk/benefit of trial participation for the research participant, informed consent, and participant recruitment have also been reported. The ethical dilemmas faced while maintaining equilibrium between care of the research participant and fidelity to the research protocol can lead to ethical conflicts. These conflicts may potentially lead CRNs to experience the phenomenon known as moral distress (Larkin et al., 2017; Oberle & Allen, 2006).

Moral distress is the painful feeling that occurs when a nurse knows the right thing to do but is unable to act due to real or perceived constraints (Corley, 2002). It has been portrayed in the literature as a primary ethical issue facing the nursing profession and has been described as a threat to nurses' integrity and quality of patient care. Further, moral distress has been linked to job dissatisfaction, burnout, and turnover (Barlem & Ramos, 2015; Hiler et al., 2018). Since moral distress was identified and described in the 1980s (Jameton, 1984), several studies have examined moral distress in the area of critical care, end-of-life issues, and medical/surgical nursing, as well as in ancillary areas

across the healthcare spectrum (Oh & Gastmans, 2015). Although limited, literature describes the impact of moral distress on quality of care given citing nurses' avoidance of patients, increased pain, longer stays, and inappropriate care (Corley, 2002). While the concept of moral distress has been researched in multiple nursing and non-nursing areas (Oh & Gastmans, 2015), moral distress in clinical research nursing has yet to be explored.

Problem of Study

CRNs experience unique ethical challenges in the context of their role (Höglund et al., 2010; Larkin et al., 2017). Although research is limited, ethical conflicts concerning the dual obligation of the CRN to the research protocol and the patient, as well as role conflicts, have been described in the literature. What is not known is whether these ethical conflicts lead to moral distress in the CRN.

Rationale for Study

The purpose of this study was to examine moral distress as experienced by CRNs in the context of their role. There is a paucity of literature on the specialty of clinical research nursing, and less on the impact of ethical challenges and moral distress among CRNs. Issues related to informed consent, conflicted allegiances, and organizational support appear consistently in the limited literature on the subject, suggesting the need for further in-depth studies in this area (Höglund et al., 2010; Larkin et al., 2017). The day-to-day ethical challenges and possible associated moral distress confronting the CRN merits investigation. Research is needed to not only describe the nature of moral distress

in CRNs, but also to determine possible patient impact of moral distress in the research setting. Additionally, in order to develop interventions and processes to minimize moral distress in the clinical research setting, the nature of the phenomenon of moral distress in this area must first be explored. By identifying and measuring moral distress in the CRN, this study laid the foundation for future examination of the potential impact of moral distress on research participant care and interventions to manage moral distress in the research setting.

Theoretical Framework

The theoretical framework selected for this study was the moral distress theory developed by Mary Corley (2002). The theory was designed to elucidate what happens when a nurse is either unable to act or feels unable to act as a moral agent for the patient and as a result, experiences moral distress. The context of the theory speaks to the internal and external perceptions of the nurse. The external perceptions concern the work environment, situations that create the ethical conflict and perceived constraints. According to the moral distress theory, institutional constraints are a primary factor contributing to moral distress. The internal perceptions relate to the nurses' psychological responses, such as perceived powerlessness or self-doubt. The moral distress theory describes how these internal and external perceptions lead to either moral distress or moral intent to act using moral concepts to navigate moral situations encountered in the healthcare environment (Corley 2002; Wilson, 2017).

Theoretical Concepts

The two assumptions of the moral distress theory presuppose nursing as a moral profession and nurses as moral agents. The theory defines eight integrated, non-linear moral concepts that relate to the internal or nurses' perceptions: commitment, sensitivity, autonomy, sense-making, judgment, conflict, competency, and certainty. Although presented individually, the concepts interact with other concepts within the theory. How the concepts and interrelationships of the concepts influence behavior and outcomes is described as propositions within the theory. A detailed description of each of the moral concepts of the theory follows (Corley, 2002).

Moral Conflict

Moral conflict, as defined in the model, is a situation that involves a discordance of the nurses' values regarding the morally right action to take. The six essential features of this concept include choice, advocacy, autonomy, pain and suffering, values and relationship (Corley, 2002).

Moral Commitment

Moral commitment describes the loyalty of the nurse to patient care and the principles involved. Further, moral commitment intimates a willingness of the nurse to stand up or take risks for the patient based on moral convictions. High levels of moral commitment are associated with the development of moral competency and lower levels of moral distress (Corley, 2002).

Moral Sensitivity

Moral sensitivity is the ability of the nurse to identify a moral conflict and have the insight to distinguish the ethical consequences on behalf of the patient. It is suggested in the moral distress theory that nurses with a high level of moral sensitivity are more apt to develop moral competency and experience low levels of moral distress (Corley, 2002).

Moral Sense-Making

Similar to sensitivity, the concept of moral sense-making is the ability of the nurse to structure a meaning or make sense of a moral situation or encounter. Nurses who have high levels of moral commitment, competency, and sense-making are likely to experience less moral distress (Corley, 2002; Wilson, 2017).

Moral Autonomy

Moral autonomy is defined as the freedom and the right to make choices on behalf of the patient. The feeling of moral autonomy may cause the nurse to feel a sense of responsibility to take the morally correct action on behalf of the patient (Corley, 2002).

Moral Judgment

The concept of moral judgment is the ability to integrate the ethical considerations, weigh both sides of the moral situation and determine the best course of action to take. A nurse with a high level of moral commitment, competency, and sense-making is more likely to effect sound moral judgment and consequently experience less moral distress (Corley, 2002; Wilson, 2017).

Moral Competency

Moral competency is in effect a culmination of a few of the concepts and is defined as the nurses' ability to make moral sense of situations, use moral judgment and act in a morally appropriate manner. Nurses with high levels of moral competency feel they are making the best choice based on their moral judgment (Corley, 2002).

Moral Certainty

The concept of moral certainty is the feeling of absolute conviction what is the best course of action to take in an ethical situation. Moral certainty can lead the nurse to put self at risk personally and professionally in order to act on the sense of conviction (Corley, 2002).

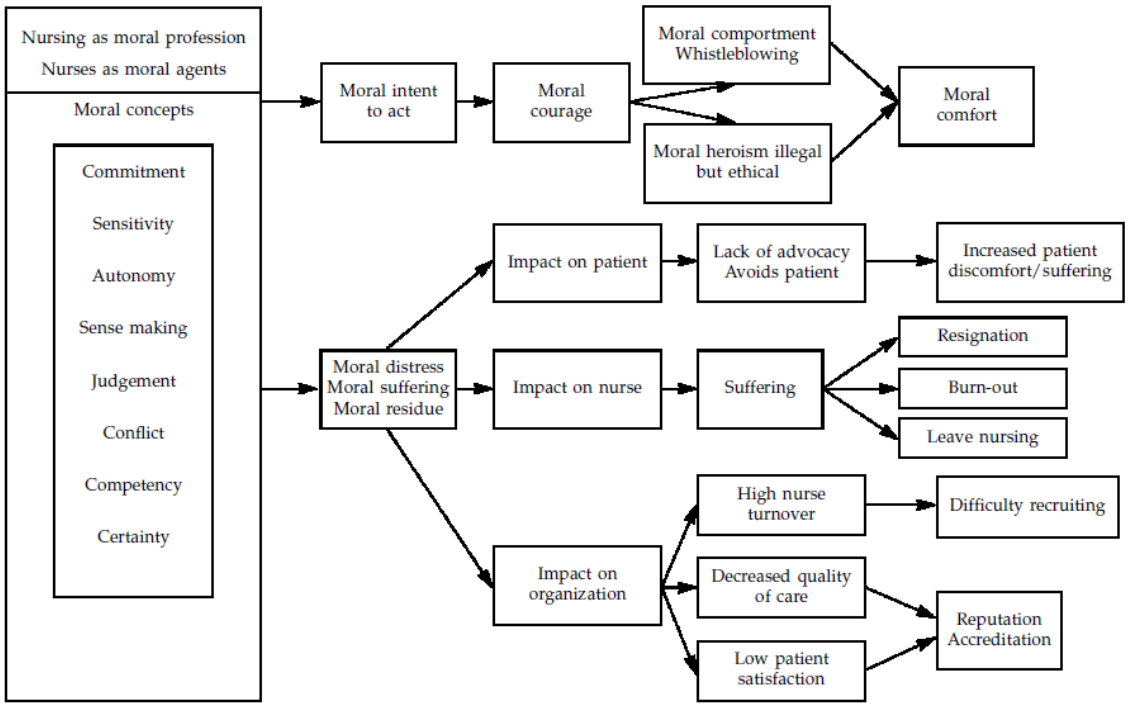
The relationships among the theoretical concepts may be complex and interactive, and the model of the theory (see Figure 1) visually depicts how when presented with a moral question or situation, the interplay among the concepts determines whether the situation progresses to moral comfort or moral distress (Corley, 2002).

As mentioned, the theory posits that institutional constraints are a major contributor to moral distress. While the organizational perspective is not extensively addressed in the theory, propositions from the organizational perspective are presented. Nurses who are satisfied with the ethical work environment, and those with good relationships with peers, managers and administration will have lower levels of moral distress. Nurses working in organizations without clear policies to guide practice or

mechanisms for addressing conflicts will have higher levels of moral distress (Corley, 2002).

Figure 1

Model for Theory of Moral Distress Adapted from "Nurse Moral Distress: A Proposed Theory and Research Agenda," (Corley, 2002)



Assumptions

The moral distress theory was selected to guide this study as it clarifies the process and concept of moral distress, the outcome to be measured (Corley, 2002). As

previously mentioned, the assumptions of the moral distress theory presuppose nursing as a moral profession and nurses as moral agents. Applied to this investigation, clinical nurses are moral agents and when faced with a moral or ethical dilemma, the dynamic interrelationship of the moral concepts held by the CRN will influence the outcome of either moral distress or moral comfort.

Research Questions

The following research questions were addressed in this study:

1. Do CRNs experience moral distress in the context of their role?
2. What is the relationship between moral distress scores and demographic characteristics of CRNs?

Definition of Terms

The following conceptual and operational definitions were used in this study:

1. Clinical research nurse was conceptually defined as those nurses working in the specialty of clinical research nursing, the "specialized nursing practice focused on maintaining equilibrium between care of the research participant and fidelity to the research protocol" (ANA & IACRN, 2016, p. 3). Clinical research nurse was operationally defined as registered nurses who are actively managing clinical trials or providing nursing care exclusively to patients participating in clinical trials.
2. Moral distress was conceptually defined as the painful feeling that occurs when a nurse knows the right thing to do but is unable to act due to real or perceived

constraints (Corley, 2002). Moral distress was operationally defined as the score of the Measure for Moral Distress – Health Professionals (Epstein et al., 2019).

Limitations

As with all research, this study had limitations. The Measure of Moral Distress – Health Professionals, the instrument used in this study, was designed for use in the clinical setting (Epstein et al., 2019). Because CRNs have unique roles, the initial concern was that the instrument would not adequately capture moral distress in this population. However, the instrument demonstrated good reliability in the pilot study, indicating that moral distress was indeed consistently measured. Additionally, with an anonymous, web-based, self-report study, the status of respondents cannot be confirmed and is vulnerable to inaccurate response rates based on poor recall or response bias.

Summary

Clinical research nursing is a specialty nursing practice with the sole focus on the care of research participants. The unique role responsibilities of the CRN can lead to ethical conflicts and potentially to moral distress. This study examined moral distress in the CRN. The research questions answered with this investigation were:

1. Do CRNs experience moral distress in the context of their role? and
2. What is the relationship between moral distress scores and demographic characteristics of CRNs?

Corley's (2002) moral distress theory was used to guide the study. Conceptual and operational definitions used in the study were defined. Identification and description of

the occurrence of moral distress in CRNs is significant in that it is the first step needed to establish the potential patient impact of moral distress in the research setting.

CHAPTER II

REVIEW OF THE LITERATURE

This chapter presents a review of the literature related to moral distress in the CRN. Because there are no published studies specifically examining moral distress in the role of the CRN, the review includes research related to ethical challenges or dilemmas in the CRN. Additionally, studies were included that explored ethical issues or moral stress non-nursing research roles that function similarly to the CRN.

Conduct of the Literature Review

The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement guidelines were utilized to guide this systematic review (Moher et al., 2009). The review included original research related to the experience of moral distress, ethical dilemmas, or moral stress in CRNs or clinical research staff. Research with non-nursing clinical research staff was included, as research nurses frequently function under non-nursing titles as well as the similarity in the functions of non-nursing roles. Studies that examined other aspects of the CRN role that contained findings related to ethical issues or conflicts were also included. Eligible studies must be published in peer-reviewed journals. Non-English language, non-research role, literature reviews, and expert opinion articles were excluded. No date limitation was imposed due to the dearth of the available literature on the topic.

Search Strategy

A comprehensive search was performed utilizing Academic Search Premier, CINAHL, PsycARTICLES, and MEDLINE electronic databases. The following terms were used for the search: research nurse, research nursing, clinical trials nurse, study coordinator, research coordinator, and clinical research combined using the Boolean operator "and" with moral distress, moral stress, ethics, ethical dilemma, ethical issues, and ethical challenges. Titles and abstracts of the resultant articles were reviewed for relevance and eligibility prior to conducting a full text assessment of the pertinent articles. Additionally, reference lists of selected articles were hand-searched to find pertinent articles not identified in the database search.

Data Extraction and Synthesis

A data extraction tool was created to index the authors, publication year, purpose of study, study design, study sample and setting, level of evidence, strengths and limitations, and key findings. The data was extracted independently by hand. Key findings were summarized and synthesized narratively. A content analysis was performed to identify themes present in the study findings and to establish connections between the reviewed articles. A thematic analysis approach was utilized.

Search Results

The search yielded a total of 305 articles utilizing the previously mentioned search terms. Once duplicates were removed, titles and abstracts of 298 articles were screened, and 274 were excluded due to lack of relevance to the aims of the review.

Twenty-four full text articles were assessed, and 13 were excluded. Of those, four expert opinion and three literature review articles were excluded due to lack of original research. Five articles were excluded because the research was not related to the ethical aspect of clinical research nor addressed the ethical challenges faced by the CRN, and one was excluded because it examined ethical competency rather than ethical challenges of the CRN. The remaining 11 articles met eligibility and were included in the review. Figure 2 depicts the flow diagram of the study search and selection according to the PRISMA methodology. Characteristics of the selected studies and key findings of each are described in Table 1.

Level of Evidence

All studies were non-experimental; three were quantitative and eight were qualitative. According to the Johns Hopkins nursing evidence-based practice model levels of evidence, all of the studies were level III evidence (Dang & Dearholt, 2017).

Risk of Bias

No publication bias was noted across studies. Larkin et al. (2017) noted a possible risk for bias related to participant selection, as recruitment and eligibility was for CRNs who had experienced an ethical dilemma. Two studies (Fisher et al., 2013; Fried & Fisher, 2016) included the Marlowe-Crowne Social Desirability Scale Short Form to assess response bias among respondents.

Rigor

Qualitative studies were evaluated for evidence that Lincoln and Guba's (1985) criteria for trustworthiness were followed. Of the eight qualitative studies, only one (Höglund et al., 2010) explicitly addressed how Lincoln and Guba's criteria for trustworthiness (1985) were met for the study. The remaining seven qualitative studies described the qualitative analysis processes in varying degrees of detail, which allowed for inference as to what criteria for trustworthiness were followed (see Table 1).

Figure 2

PRISMA Flow Diagram

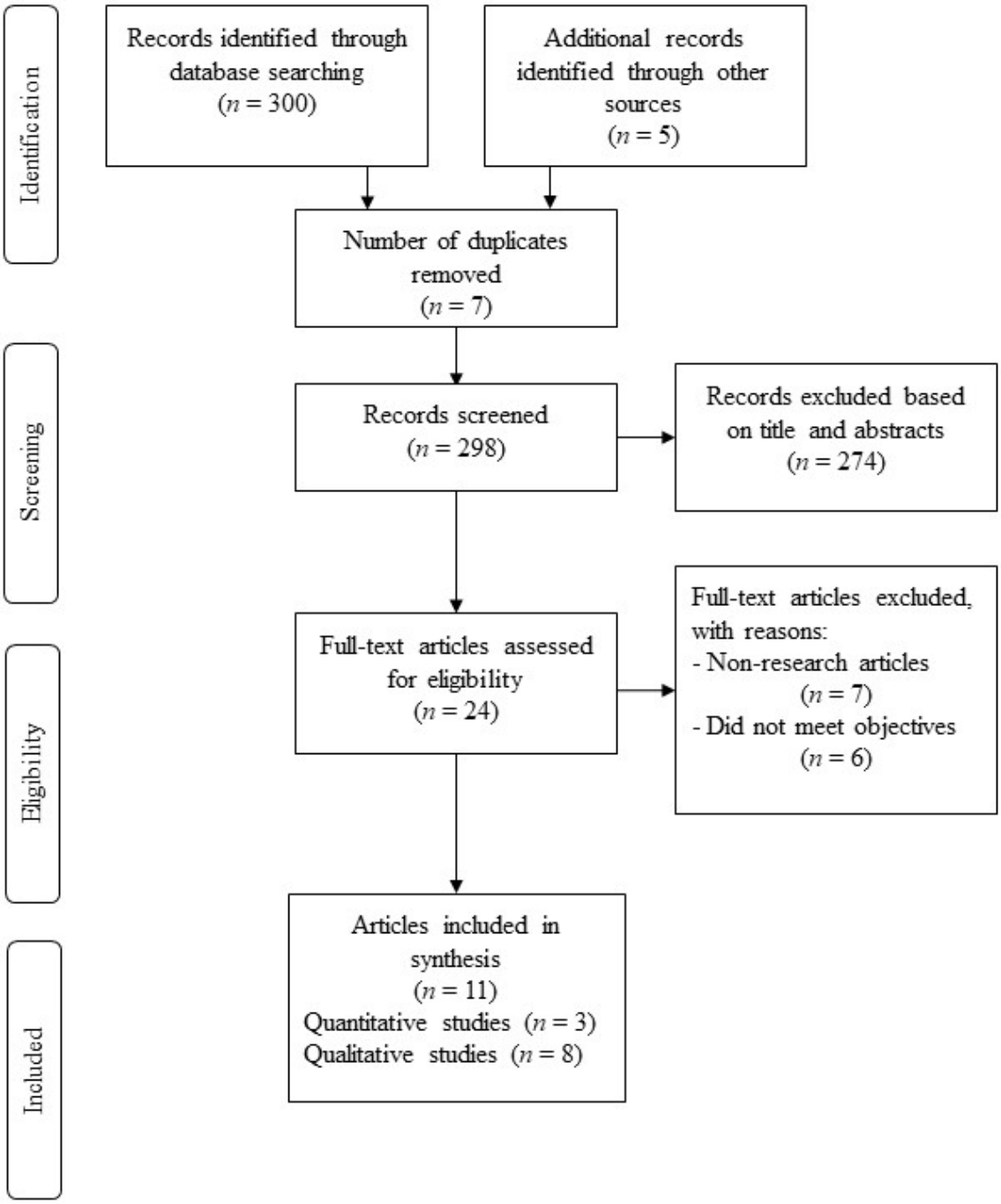


Table 1

Summary of Literature of Ethical Challenges in CRNs and Clinical Research Personnel

Author & Year	Purpose of Study	Research Methods/ Instruments	Sample and Setting	Key Findings	Limitations/ Rigor
Cantini & Ells, 2007	Describe the role of clinical trial nurses (CTN) in the informed consent (IC) process and explore conflicts of interest and ethical dilemmas encountered by nurses fulfilling that role	Descriptive Quantitative 50-item questionnaire developed by authors to address the variables, 2/3 items closed-ended (Likert, yes/no, multiple choice). 1/3 items open ended.	*N* = 65 Clinical trial nurses in Quebec	- 75% involved in IC process - 56% expressed it was both PI and CTN responsibility to assess comprehension of info - 56% reported conflict of interest between obligation to participant and to the research project - frequency varied - Ethical dilemmas caused by unclear policies, job description - Conflicts: research participants lack full comprehension and implications of study participation, alternatives not offered to patients, patients refused to read consent due to trust in PI - CTNs with more research ethics education and more experience reported more conflict.	Limitations: - no reliability or validity data for questionnaire - small sample size limited sample (one hospital system) Rigor: - Used VanKaam's method for open ended questions

Author & Year	Purpose of Study	Research Methods/ Instruments	Sample and Setting	Key Findings	Limitations/ Rigor
Davis et al., 2002	Assess how study coordinators shape the ethical conduct of research and how their multiple roles affect protection of subjects	Qualitative Seven 90 minute focus groups in which coordinators responded to vignettes related to job description and ethical issues	*N* = 45 69% (*n* = 31) of coordinators were nurses Academic medical center, federal research institution, and private organizations in the US	Study coordinators described 19 skills required of their role. Consistently described complex and conflicting obligations as a part of their role and identified three critical roles: 1) Patient advocacy 2) Subject advocacy 3) Study advocacy It is the job of coordinator to balance these. Primary advocacy is patient advocacy. Workplace influenced outcomes. Study sites that were more research focused, such as NIH and private sector, emphasized subject and study advocacy. The more clinical sites emphasized patient advocacy.	Limitation: - Minimal description of procedures for trustworthiness. Rigor: - Lincoln & Guba's Criteria of trustworthiness (1985) evidenced: - Dependability - described data collection and analysis, validated by three authors - Transferability - thick description of the complexities of the themes and subthemes, triangulation of data source using two vignettes

Author & Year	Purpose of Study	Research Methods/ Instruments	Sample and Setting	Key Findings	Limitations/ Rigor
DeBruin et al., 2011	Identify and describe the ethical and professional concerns encountered by nurses during their work in clinical trials	Qualitative Seven semi-structured focus groups	*N* = 37 Variety of research settings in Midwest and West Coast	Ethical concerns identified related to: - dual obligations - informed consent - workload - dual obligations between investigator and sponsor - conflict related to informed consent and assuring voluntariness - job role had more impact on ethical concerns	Rigor: criteria of trustworthiness evidenced - Credibility – process to review transcripts and compare with other reviewers - Transferability - thick description of concepts and themes, triangulation of analysts - Confirmability - independent auditor of transcript and preliminary analysis

Author & Year	Purpose of Study	Research Methods/ Instruments	Sample and Setting	Key Findings	Limitations/ Rigor
Fisher et al., 2013	Explore how attitudes and experiences of research staff working on community-based drug research and organizational work climates affect levels of moral stress	Quantitative - Six scales (110 item Likert type items) measuring moral stress, research moral dilemmas, perceptions of organizational support and organizational climate - Demographics questions: - Gender - Ethnicity - Age - Education - Years experience - Drug use studies - Personal history of drug use - Most frequent studies - Most frequent drugs - Meeting with PI - Hours worked per week	*N* = 275 Non-nursing research staff working with community-based drug protocols	Approx. 50% reported moderate levels of moral stress ~33% feel overburdened Organizational climate mostly positive and associated with strong research commitment and lower levels of moral distress Age (r = -23, p<.001) and frequency meeting with PI (r = -23, p<.001) negatively correlated with moral stress scores. Strong research commitment (r = -.16, $p \leq .01$) and positive organizational support (r = -72, p < .00) negatively correlated with moral distress 40% endorsed items indicating that job did not provide counseling for job related stress and unrealistic demands for recruitment numbers, multiple staff roles	Scales developed with content, construct and internal reliability. Cronbach's alpha for the six scales ranged from .66 - .91 Limitations: - Anonymous, web based, self-report scales do not have ability to confirm status of respondents and may be vulnerable to inaccurate response rates due to poor recall or response bias

Author & Year	Purpose of Study	Research Methods/ Instruments	Sample and Setting	Key Findings	Limitations/ Rigor
		- Current salary - Salary as part of total income - Current financial situation - Lived in same community as study participants - Job health benefits - Most frequent duties - Most frequent participants - Marlowe-Crowne social desirability scale to control for bias Scales developed by authors based off of responses focus group and adapted from other questionnaires			

Author & Year	Purpose of Study	Research Methods/ Instruments	Sample and Setting	Key Findings	Limitations/ Rigor
Fisher & Kalbaugh, 2012	Identify how research coordinators manage role and ethical conflicts within clinical trials	Qualitative Observation and semi structured interviews	*N* = 18 research coordinators Medical research organizations in southwestern US	Common theme identified was altruism in how research coordinators describe purpose and meaning for their work. The three functions or sub-themes of altruism identified were (a) to motivate patients to be compliant, (b) to minimize tensions between research and care, (c) to contest the undervaluation of their role.	Rigor: - Criteria for trustworthiness evidenced by: Credibility - allowed participant to edit transcript prior to analysis, prolonged engagement - Dependability - thorough description of data collection and data analysis, multistaged process of coding field notes and interviews for core and emerging categories. Coding was multistaged to revisit the data multiple times.

Author & Year	Purpose of Study	Research Methods/ Instruments	Sample and Setting	Key Findings	Limitations/ Rigor
Fisher, 2006	Describe how coordinators experience and contend with conflict between research and care in clinical trials industry	Qualitative Institutional ethnography 12 months of observation and semi structured interviews	*N* = 21 60% (*n* = 15) nurses Multiple research organizations in southwestern US	Ethical conflicts identified included: coordinating drug trials, resolving role conflict through ethics, patients lack of understanding, placebos, get to spend a lot of time with patients, bad studies	Limitation: - No description of analysis or procedures to ensure trustworthiness

Author & Year	Purpose of Study	Research Methods/ Instruments	Sample and Setting	Key Findings	Limitations/ Rigor
Fried & Fisher, 2016	Explore the nature of moral stress and its relationship to job burnout among research staff members conducting face to face research tasks for empirical studies on anxiety and mood disorders, and test hypothesis that perceived organizational support for general and ethics specific research responsibilities serve as protective factors for stressors	Quantitative Moral Stress Scale - Clinical Research - 54 item Likert type scales measuring research moral stress, perceptions of organizational support and research ethics climate - Demographics - Gender - Ethnicity - Last time worked on research study - Number of mental health studies as research worker - Experience - Authored publications - Hours worked per week	*N* = 125 Non-nursing mental health research staff	Endorsement of concerns about potential harms and adequacy of human subjects protections Cumulative job stress 18%, but endorsement of job stress items 5-42% 54% at least low levels of burnout 74% - 96% positive research ethics 41% - 90% positive climate org 55-59% too much pressure on enrollment and staff to take on multiple roles Higher levels of moral stress and job burn out negatively correlated with organizational support ($p <. 01$)	Limitations: - Risk of bias associated with online surveys - Potential lack of representativeness of participants

Author & Year	Purpose of Study	Research Methods/ Instruments	Sample and Setting	Key Findings	Limitations/ Rigor
		- Work as part of graduate assistantship - Formal training in mental health counseling - Education - Age - Percent time of direct participant contact - Presentations - Income - Marlowe-Crowne Social Desirability Scale to control for bias			

Author & Year	Purpose of Study	Research Methods/ Instruments	Sample and Setting	Key Findings	Limitations/ Rigor
Godskesen et al., 2018	Investigated ethical challenges experienced by nurses in onc/hem when nursing care and research overlap - and how nurses handle such challenges	Qualitative Semi-structured interviews Demographics collected: - Gender - Age - Education - Working years in onc/heme - Practice setting - Phase of trials familiar with - Country	*N* = 39 nurses Sweden, Denmark and Finland	Themes identified: 1) Patient related challenges - informed consent - balance risk and benefits - hope 2) Workplace challenges: - workload - competence - patient safety - being subordinate 3) Strategies of dealing with challenges - finding support from colleagues	Rigor: Criteria for trustworthiness evidenced by - Dependability - description of data collection and data analysis, transcripts analyzed and discussed multiple times by authors - Transferability – thick description of the themes and complex challenges

Author & Year	Purpose of Study	Research Methods/ Instruments	Sample and Setting	Key Findings	Limitations/ Rigor
Höglund et al., 2010	Describe and explore ethical dilemmas experienced by Swedish research nurses in day-to-day work in clinical research	Qualitative Part of a larger comparative study between how doctors and research nurses engaged in ethical dilemmas within clinical trials Semi-structured interviews	*N* = 6 research nurses Four Swedish hospitals	Themes identified: 1) ethical dilemmas: research vs patient interests, conflicting roles 2) ethical reasoning: feeling responsible, working patient centered, and 3) attitudes toward research nurses and their work: ethical disagreements with PI, 'invisible' profession, not encouraged to develop ethical competence.	Limitation – Authors cited small sample size as a limitation. Saturation was not addressed. Rigor: Followed Lincoln & Guba criteria for trustworthiness: - Credibility - thorough in data collection and analysis - Dependability - consistency in research process - Confirmability - results grounded in the material by use of quotes - Transferability - results are readily communicated and used in other contexts

Author & Year	Purpose of Study	Research Methods/ Instruments	Sample and Setting	Key Findings	Limitations/ Rigor
Larkin et al., 2017	Describe the nature of ethical challenges experienced by CRNs within context of their practice	Qualitative Semi-structured interviews Demographic data collected: - Age - Gender - Race - Ethnicity - Education level - Years of experience as a research nurse - Type of practice setting in role of CRN	*N* = 12 Registered nurses or Nurse practitioners with at least one year experience in clinical research role Recruited from northeast outpatient/ inpatient and clinical research center	Two major themes: 1) Inability to provide a known or probable good/do no harm, 2) Conflicted allegiances and/or dual professional obligations	- Limitations: Possible bias in participant selection, call out for research nurses who had experienced ethical dilemma - Small sample size cited by authors; however, sample size was determined by data saturation Rigor: Criteria for trustworthiness evidenced - Dependability - detailed description of data analysis - Confirmability - reflexivity during process - Transferability - thick description of complex concepts and themes

Author & Year	Purpose of Study	Research Methods/ Instruments	Sample and Setting	Key Findings	Limitations/ Rigor
Loh et al., 2002	Explore the views of data managers concerning the nature, challenges and rewards of their role and the similarities and differences between their role and that of the physician in obtaining informed consent	Qualitative Four focus groups held, individual group sizes unidentified	*N* = 21 data managers working in cancer or pain trials 67% (*n* = 14) nurses 3 large teaching hospitals	Themes identified 1) Different roles: Information provision, quality assurance and patient advocacy, ongoing support during trial 2) Barriers to their effectiveness: inconsistent messages from team members, level/lack of support, conflict when pressure to maximize recruitment was compromising patient care 3) Difficulties and training needs: basic research and ethics education, health professional-patient communication education, patients entering trial for wrong reason, language/cultural barrier and informed consent, trial disadvantageous to the patient	Rigor Criteria for trustworthiness noted: - Credibility - thorough description of data collection and analysis - Dependability - consistency in research process - Confirmability - results grounded in the material by use of quotes - Transferability - results are readily communicated and used in other contexts

Discussion

The articles selected for review consisted of eight qualitative and three quantitative studies. Two quantitative studies evaluated moral stress in non-nursing research staff, and one examined the role of the CRN in the informed consent process. The qualitative studies explored ethical challenges or issues of the CRNs and other clinical research staff in their roles. Upon analysis of the articles, three main themes emerged: 1) dual obligations/role conflicts, 2) informed consent and enrollment, and 3) workplace issues. It is important to note that although a variety of titles are used in the following review of literature, the functional roles are consistent with the CRN.

Dual Obligations/Role Conflicts

Maintaining equilibrium between the care of the research participant and integrity of the research protocol is the cornerstone of the CRN role. Preserving that balance can lead to ethical conflicts related to the dual obligation of care of the study participant and obligation to the research protocol. This conflict essentially sets the role of the CRN in opposition to the role of the nurse within the same individual (Larkin et al., 2017). The ethical issues of dual obligations and role conflicts are a predominant theme in this literature.

Höglund et al. (2010) conducted a qualitative study of research nurses in Sweden (n = 6) in which participants were asked what ethical dilemmas they experienced in their daily role as a research nurse. The two primary types of situations involved role conflict. Respondents reported concerns about patient interests versus research interests as well as

conflicts between their role as a nurse and a research assistant. One respondent described how urging participants to stay in the study was his "duty" (Höglund et al., 2010, p. 244) as a CRN, but also felt this was discordant with his nursing beliefs, as continuing in the study involved extra burdens for the patient.

Similarly, in a qualitative study examining ethical challenges, Larkin et al. (2017) interviewed CRNs (N = 12) who self-identified as having experienced ethical challenges in the context of their role. Participants frequently asserted the sentiments of dual professional obligations or conflicted allegiances and expressed feeling "caught in the middle" (Larkin et al., 2017, p. 7) between the patient and the protocol. Participants reported questioning their identity as being a nurse first. The respondents also described feeling pressure to enroll participants and be "loyal to the team and the principal investigator" (Larkin et al., 2017, p. 8) even if the nurse felt that the patient was not a good fit for the trial. One participant characterized the feeling as "serving two masters" (Larkin et al., 2017, p. 9). Another participant stated, "you want to do the right thing for everybody…and you're torn in two different directions…" (Larkin et al., 2017, p. 9). Further, nurses reported feeling conflicted or concerned that the patient was receiving a placebo.

In an ethnographic study conducted over a 12-month period, Fisher (2006) sought to discover how study coordinators experience and cope with the conflict between research and care in the context of their position in the clinical trial industry. Of the 21 coordinators who took part in the study, 10 were nurses. Participants described being torn

between their obligation to the sponsor and to the patients. One participant expressed how difficult it is to enroll a patient to a study that is “not a good option” (Fisher, 2006, p. 685). Another coordinator convinced her investigator to stop accepting certain studies because she felt her role was to help “mankind” (Fisher, 2006, p. 685), but that the investigational drugs were worsening the symptoms.

Another study by Fisher and Kalbaugh (2012) combined observation and semi-structured interviews to identify how research coordinators manage role and ethical conflicts within clinical trials. Each of the 18 research coordinators were interviewed individually for the study. Respondents reported the most distress about “therapeutic misconception” (Fisher & Kalbaugh, 2012, p. 146) of the research participants. The coordinators expressed doubt that the research patients are able to differentiate between being a part of a study and having standard medical care. One participant gave an example of a research patient with severe psoriasis on a placebo-controlled study. Although the patient read the informed consent and it had been explained to him, the patient did not understand why he was not selected to get the active medication because his psoriasis was “so bad” (Fisher & Kalbaugh, 2012, p. 146). Additionally, participants admit to grappling with prioritizing the goals of research over the care of the patient, specifically pointing out the difficulty of observing patients’ conditions fail to improve or worsen due to participation on the clinical trial.

Davis et al. (2002) investigated the role of the study coordinator in the ethical conduct of clinical trials using seven focus groups at three different types of facilities. Of

the 45 coordinators who took part in the study, 68% had nursing backgrounds. Analysis of the data indicated the centrality of the coordinator position in the clinical trials and suggested complex relationships and role expectations with potential for conflict between the roles. Participants consistently described their positions as potentially conflicting obligations to various parties and identified three critical roles: 1) patient advocacy, 2) subject advocacy, and 3) study advocacy. Balancing the three advocacies is complicated by the competing objectives of each and knowing that one advocacy may impede the advancement of another. Deciding which one of these to focus on and which one to defer was a primary ethical challenge of the study coordinator position.

Fisher et al. (2013) evaluated factors contributing to moral distress in non-nurse research workers (N = 275) conducting community-based drug user research. A series of six surveys (110 items total) developed by the authors were administered via the Internet to measure moral stress (Research Moral Stress Scale), ethics climate (Research Ethics Climate Scale), organizational support (Organizational Research Support Scale), research ethical dilemmas (Research Moral Dilemma Scale), attitudes toward research (Research Mistrust Scale), and dedication to research (Research Commitment Index). Approximately half of respondents experienced at least low levels of moral stress, with scores in the "somewhat agree" range. Pearson correlations yielded significant negative correlations between moral stress and age (r = -.23, p = .001) and moral stress and frequency of meeting with the principal investigator (r = -.23, p = .001). Some concerns

related to challenges assuring human subjects protections and perceived conflict between study compliance and caring for research participants' needs were described.

Fried and Fisher (2016) used a similar study design to examine moral stress and job burnout among non-nurse research staff conducting clinical trials with mental health patients ($N = 125$). Results suggested that although overall research stress was low, participants experienced conflicts related to dual responsibilities of producing scientifically valid research while providing clinically appropriate care to the patient. Similar to the Fisher et al. (2013) study, age was negatively correlated with research job burnout scores ($p < .01$).

Informed Consent and Enrollment

Informed consent is a foundational element of protection of human participants' rights in clinical research. Ethical issues and dilemmas surrounding the informed consent process and study enrollment was a prevalent theme in the reviewed articles. In one study, participants expressed concern of threats to patient autonomy during the informed consent process. One research nurse reported trepidation when being rushed to obtain informed consent document and the uncertainty of whether the patient had full understanding. Another participant described the challenge of older patients who will do whatever the healthcare professionals recommend, and therefore enter the study without full consideration of the implications (Höglund et al., 2010). These concerns are pervasive. In their study, Larkin et al. (2017) reported nurses worrying about how well informed the participant is about the research, citing situations in critical care areas where

a family has little time to fully read the informed consent document and make an informed decision about study participation**.**

Fried and Fisher (2016) describe research workers' concerns about participants enrolling in mental health research, including worries related to participant confusion and difficulty understanding the difference between prescribed treatments and an intervention research study, concerns that patients will provide false answers in order to meet eligibility, and fears that research risks will be disregarded when money is used as patient compensation or inducement for enrollment. Participants in another trial expressed unease as they felt that patients often gave false information about their drug use in order to be enrolled in the trial (Fisher et al., 2013).

A study by Cantini and Ells (2007) performed in Montreal explored the practice of CRNs in the informed consent process. A convenience sample of clinical trial nurses (N = 65) completed a 50-item questionnaire about their role in the informed consent process. Five concepts were examined and measured: disclosure of information, comprehension, voluntariness, conflict of interest, and ethical dilemmas. A large percentage (75%) of participants reported being involved in the informed consent process before, during, and after consent was obtained. Over 90% of respondents reported that they participated in providing information about the research study to the potential research subject and assessing the patient's willingness to participate in the study. More than half of the participants (56%) reported conflict of interest related to their role in the informed consent process. Specific conflicts included: research participants lacking full

comprehension or implications of the study; alternatives to study participation not offered; patients declined to read the informed consent document because of trust in the physician; and investigator insistence on enrolling a patient irrespective of the ineligibility of the patient.

Godskesen et al. (2018) had similar findings in a qualitative study using individual interviews with hematology/oncology research nurses (N = 39) in Sweden, Denmark and Finland to investigate the ethical challenges that occur when nursing care and research overlap in clinical trials. Participants reported that the informed consent process was challenging due to a variety of reasons. Some nurses expressed concern about patient autonomy and whether the decision-making process is free of persuasion. Some felt that patients will sign the informed consent document without adequate understanding. One participant described how the trust of healthcare and desire to be agreeable will determine the patient's decision to participate rather than full understanding of the implications. Some participants expressed unease when the physician essentially "sold" (Godskesen et al., 2018, p. 478) the protocol to the patient by representing it as more effective than what was supported by the evidence.

Loh et al. (2002) conducted a qualitative study examining issues of ethical informed consent. Data managers working with cancer trials at three institutions in Australia were invited to participate in focus groups regarding their role in the informed consent process. Of the 21 participants, 14 had nursing backgrounds. Participants reported experiencing a range of ethical dilemmas in their role in the informed consent

process. Some participants felt they had to go behind the physician and balance out or correct aspects of information provided by the physician that could be perceived as coercive. For example, one participant asserted that physicians are prepared to "bend the truth" (Loh et al., 2002, p. 2417) about eligibility criteria and minimize the impact of the side effects to the potential research participant. Another ethical issue expressed is that of the patient who appears to enter the study with false hopes of receiving a "wonder drug" (Loh et al., 2002, p. 2419). Finally, data managers voiced ethical concerns about enrolling patients in trials that are potentially detrimental and that they do not support.

Finally, in a qualitative study conducted by DeBruin et al. (2011), 37 nurses working in clinical research participated in seven focus groups in the Midwest and the West Coast. This study focused on the ethical challenges faced by nurses in the day-to-day work in clinical trials, specifically those that cannot be resolved by the current ethical oversight mechanisms, such as the institutional review board. The nurse participants were employed in a variety of settings, including academia, the pharmaceutical industry, and private practice. Consistent with previous studies, participants worried about the legitimacy of the informed consent and how much the patients understand the trial to which they are agreeing to participate. One participant shared an example of being pushed to enroll a patient who had just been diagnosed with a life-threatening illness and was not equipped to make a decision to participate on a trial at the time. The nurse described it as an "emotional, difficult process" (DeBruin et al., 2011, p. 133). Pressure to enroll research patients was another challenging area reported by the participants. Two

participants gave examples in which the physician or other members of the research team became angry when consent was not obtained and patients were not enrolled, albeit for valid reasons.

Workplace

Several of the studies cited the lack of role specific training or ethical competence education as a factor impacting ethical challenges of their role (Fisher, 2006; Godskesen et al., 2018; Höglund et al., 2010; Loh et al., 2002). Additionally, workload and organizational support contributed to the ethical issues that the respondents experienced (DeBruin et al., 2011; Fisher et al., 2013; Fried & Fisher, 2016).

Organizational Issues

In the study by Fisher et al. (2013), organizational climate was rated positively overall; however, approximately 40% of respondents endorsed items indicating unrealistic demands for recruitment numbers and a lack of counseling offered by their organization for work-related stress. Positive attitudes toward organizational climate were associated with lower levels of moral stress. Fried and Fisher (2016) found that work environment with research ethics policies in place and general job support served as a protective factor against research moral stress and job burnout; however, many participants reported feeling overburdened with multiple responsibilities. Although organizational support was not directly mentioned, research nurses reported feeling ‘invisible’ and unknown at the hospital. Further, participants reported seeking more information about their work and role (Höglund et al., 2010, p. 246).

In the study by Godskesen et al. (2018), nurses cited patient safety issues related to high work pressure, lack of time, and not having adequate information on the investigational agent. A heavy workload and insufficient time were reported as significant challenges of the nurse. Another study pointed to the "sheer workload" (DeBruin et al., 2011, p. 131) posing ethical challenges and impacting the nurses' ability to protect the rights of the research participants.

In their study, Davis et al. (2002) saw little variation between the role of the study coordinator across the sites; however, some differences of emphasis of the advocacies was noted. For example, the academic site focused more on the patient advocacy versus the government and private sector sites focused more on the subject and study advocacy. The different approaches or emphasis influenced coordinators' ability to balance their roles.

Ethical dilemmas were experienced by two thirds of respondents in the study by Cantini and Ells (2007) as a result of their role in the informed consent process. Commonly cited reasons were lack of clear guidelines and policies related to the nurses' role in the informed consent process, the fact that the principal investigator was their employer, and the lack of a job description.

Training Issues

Respondents in one trial suggested that further training in foundational clinical research content as well as the ethical and legal responsibilities of the trial manager would be beneficial. Additionally, participants proposed the benefit of health

professional-patient communication training related to topics such as how to talk about trial funding, equipoise and randomization, and assessing understanding (Loh et al., 2002). Despite acknowledging their need for further development of ethical competence due to their autonomous role and tendency to be faced with difficult situations without support, research nurses in Sweden were discouraged from attending ethics training or classes. When asked about attending an ethics class, a principal investigator told one participant, "that's not necessary…you don't have to think about that." (Höglund et al., 2010, p. 246).

In another study, half of the respondents (50.8%) reported needing more education to adequately fulfill their role in the informed consent process. Specifically, the participants reported needing education in the topics of legal obligations and implications related to obtaining informed consent and liability of the CRN in the informed consent process (30.8%). Twenty percent of respondents endorsed the need for general education on the informed consent process. Interestingly, correlational data showed that nurses with more experience and ethics training had an increased tendency to report conflict. This suggests that research ethics training and years of experience sensitize the CRN to ethical dilemmas rendering them better able to identify potential and actual ethical conflicts (Cantini & Ells, 2007).

Summary

In summary, the literature demonstrates that ethical challenges and conflicts are prevalent in nurses and non-nurses working in the clinical research arena. Studies showed

that a primary ethical conflict experienced by the CRN is the issue of dual obligations or research versus patient care. Participants reported feeling torn between doing what is right for the patient and doing what is right for the study. Maintaining the balance between the two often creates dilemmas for the nurse (Davis et al., 2002; Fisher, 2006; Fisher et al., 2013; Fried & Fisher, 2016; Höglund, et al., 2010; Larkin et al., 2017). The CRN plays a significant role in the informed consent process in research which contributes to ethical dilemmas. Several studies demonstrated the concern that research participants did not fully understand the research study or the implications of participation even after consenting to the study (Cantini & Ells, 2007; DeBruin et al., 2011; Fisher et al., 2013; Fried & Fisher, 2016; Godskesen et al., 2018; Höglund et al., 2010; Larkin et al., 2017; Loh et al., 2002). Although not as frequently reported, organizational issues including heavy workload and lack of adequate support is reported to impact patient safety (Cantini & Ells, 2007; Davis et al., 2002; DeBruin et al., 2011; Fisher et al., 2013; Fried & Fisher, 2016; Godskesen et al., 2018; Höglund et al., 2010). Finally, ethical dilemmas and the struggle coping with ethical conflicts were partially attributed to the lack of educational opportunities and training in ethics pertaining to clinical research in a few studies (Cantini and Ells, 2007; Höglund et al., 2010; Loh et al., 2002).

This review illustrates the unique challenges facing nurses and non-nurses in their work in clinical trials. The literature also acknowledges the importance of the CRN to the conduct of the clinical trial as well as demonstrating that the majority of the work in

clinical trials is performed by the CRN. It is problematic that so little research is focused on the role and ethical issues encountered while working in the role. Furthermore, what has not been studied is the presence of moral distress in the CRN role.

CHAPTER III

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

A descriptive quantitative study design was applied to measure the level of moral distress in CRNs. A one-time measure of the variable, moral distress, was obtained to address the first research question, do CRNs experience moral distress in the context of their role? Demographic characteristics of the participants were collected to examine the relationship between individual demographic features and moral distress score to answer the second research question, what is the relationship between moral distress scores and demographic characteristics of CRNs?

A descriptive research design is used when the aim of the study is to observe, describe, and document a situation or phenomenon. This design is suitable for use in examining topics or problems of which little is known or there is limited literature (Polit & Beck, 2017). A descriptive research design was appropriate for this study because no studies have been identified in the literature that examine moral distress in CRNs.

Setting

The instrument used to collect data for this study was administered electronically using Qualtrics (https://www.qualtrics.com). Participants were able to complete the online questionnaire in any location, on any computer or mobile device that had internet access.

Population and Sample

The target population of this study was registered nurses working in the capacity of the CRN. The eligibility criteria consisted of registered nurses who were: (a) actively managing clinical trials or providing nursing care exclusively to patients participating in clinical trials, (b) 18 years of age or older, and (c) able to read the English language. Because nurses performing the function of CRN often have varying professional titles, the eligibility criteria for this study defined the role by function rather than title in order to capture all registered nurses working in the capacity of a CRN.

Participants were recruited through the use of digital and hard copy flyers (see Appendix A); email lists from professional organizations, including the IACRN and the Society of Clinical Research Associates (SoCRA); social media, including Twitter, Facebook, LinkedIn; and snowball recruitment from other participants. Nurses both nationally and internationally were included.

A power analysis to determine sample size was conducted running G*Power. The sample size calculation was based on Research Question 2: What is the relationship between moral distress scores and demographic characteristics of CRNs? A moderate effect size of 0.25 (f), alpha of 0.05, power of 0.8, and group number of 6 were used for one-way analysis of variance (ANOVA). The group number was set to 6 based on the level of education demographic question, which has the most levels of the demographic characteristics collected. The resulting sample size was 216, and in order to allow for incomplete data and attrition, a sample size of 300 was determined.

Protection of Human Subjects

The Institutional Review Board (IRB) at Texas Woman's University approved the research study in July 2019 (see Appendix B). The risk to confidentiality was minimal, as the online questionnaire was anonymous and identifiers were not collected. A consent statement was included at the beginning of the survey that provided information about the purpose of the study, a description of time commitment and that participation is voluntary. Completion of the questionnaire was construed as informed consent. Participants were encouraged to discontinue taking the survey and seek assistance from their institutional Employee Assistance Program (EAP) or Human Resources Department if any of the questions were upsetting.

Instrument

Two instruments were used to collect data: (a) a demographic data form and (b) the Measure for Moral Distress – Health Professionals (MMD-HP; Epstein et. al, 2019).

Demographic Data Form

The demographic form (see Appendix C) was employed to describe and identify demographic characteristics of the sample. The form included basic demographic information on age, gender, country, and state. Other demographic characteristic questions included job title, level of nursing education, years of nursing experience and clinical research nursing experience, and whether the participant's CRN role was primarily that of a coordinator or bedside nurse. These sample attributes were collected to explore the relationship of moral distress scores and demographic characteristics.

Measure for Moral Distress – Health Professionals

The MMD-HP (see Appendix C) was utilized to measure the level of moral distress. The instrument was developed and tested by Epstein et al. (2019), and is the result of a substantial, evidence-based revision of the widely used Moral Distress Scale – Revised (MDS-R; Hamric et al., 2012). The MMD-HP was developed to more thoroughly capture the team and system level root causes of moral distress, as well as to simplify its use (Epstein et al., 2019).

The Moral Distress Scale (MDS), introduced by Mary Corley et al. in 2001, is a 38-item measure of the cumulative aspect of moral distress in intensive care nurses (Corley et al., 2001). The MDS-R was created in 2010 when the MDS was revised by Hamric et al. (2012) in order to shorten the instrument to 21-items and increase applicability to all health care providers. The MDS-R has six versions for different types of healthcare providers and has been extensively used with good reliability and validity. Epstein et al. (2019) noted that recent studies have suggested additional root causes that are not captured by the MDS-R. Further, the six versions of the MDS-R could be condensed into one instrument; therefore, Epstein et al. (2019) revised the MDS-R and developed the MMD-HP.

The MMD-HP is a 27-item instrument that uses a 0-4 Likert type scale to measure the frequency and intensity of moral distress. Each of the 27 items is a root cause situation that is scored based upon how often it occurs (frequency) and how distressing it is (intensity). For example, the first root cause situation is “Witness healthcare providers

giving “false hope” to a patient of family” (Epstein et al., 2019, p.1). Participants rate on a Likert scale how often the situation occurs (frequency: 0 = *never*, 4 = *very frequently*) and how distressing it is when it occurs (distress: 0 = *none*, 4 = *very distressing*). The composite item score (fxd) is created by multiplying the frequency (f) and distress (d) for each item (range 0-16). The overall MMD-HP score is obtained by summing the item composite scores (range 0 – 432). Higher scores indicate higher levels of moral distress (Epstein et al., 2019).

The MMD-HP also provides space to write in and rate additional situations in which the respondent has experienced moral distress. Further, the following three additional situations specific to the CRN role were included:

- Feel pressured to enroll patient on clinical trials even though you feel they are not eligible
- Experience conflict between obligation to provide care that is best for the patient and compliance with the study protocol
- Be required to enroll patients on clinical trials even though you know that the treatment is not working

The responses and scores to the additional CRN items and any write-in situations were analyzed separately. The MMD-HP concludes with two additional items to measure whether the participant has ever left a job due to moral distress and if they are currently considering leaving due to moral distress (Epstein et al., 2019).

Reliability

According to Epstein et al. (2019), reliability testing for the MMD-HP was conducted with nurses, physicians, and other health care clinicians at two academic medical centers. Clinicians working both in inpatient units and outpatient clinics were invited to participate. A total of 653 surveys were included in the final analysis: 440 nurses, 123 physicians, and 90 other direct-care providers. The MMD-HP demonstrated good reliability for the overall sample with a Cronbach's alpha of 0.93 as well as for each provider group: nurse 0.931, physician 0.901, and other 0.936. Item to item correlations were calculated, and no problematic items were identified.

Validity

Epstein et al. (2019) evaluated the construct validity for the MMD-HP by testing the four following hypotheses: (a) nurses would have higher levels of moral distress than physicians, (b) participants who were considering leaving their position due to moral distress would have higher MMD-HP scores than those not considering leaving, (c) higher MMD-HP scores would be associated with poorer perceptions of workplace ethical climate, and (d) the MMD-HP would have a three-level structure (patient, team, and system). The first hypothesis was confirmed by analysis indicating that MMD-HP scores for nurses (M = 112.3) were significantly higher than scores for physicians (M = 96.3). The second hypothesis was supported with higher scores for participants considering leaving a position due to moral distress (M = 168.4) compared to scores of those not considering leaving (M = 94.3). To test the third hypothesis, scores of the

Hospital Ethical Climate Survey (HECS), which was administered concurrently with the MMD-HP, were compared with scores of the MMD-HP. As hypothesized, MMD-HP and HECS scores were negatively correlated (r = - 0.55, $p < 0.001$).

Exploratory factor analysis (EFA) was employed by the Epstein et al. (2019) to confirm the fourth hypothesis for construct validity. The eigenvalue criterion of > 1.0 was used, and four factors were identified and tested using principal components extraction and promax rotation. Several factor structures were evaluated, but the researchers settled on the four-factor solution. The four root level factor clusters include: (a) primarily system-level causes, (b) clinical root causes at patient level, (c) team level causes involving compromises to integrity occurring within a team, and (d) team-level causes related to breakdown in team interactions with patients and families. The four-factor solution accounted for 54.3% of the model variance.

Data Collection

The MMD-HP (Epstein et al., 2019), was administered online via Qualtrics (https://www.qualtrics.com), a secured online survey platform. The URL link to the survey and QR code were included in recruitment flyers and emails. The digital flyer was posted on the IACRN discussion forum and was emailed by the organization to all members. The local chapter of SoCRA emailed the digital flyer to members. The URL link to the survey was posted on social media sites such as Twitter, Facebook, and LinkedIn. Further data was collected via snowball method from participants.

Pilot Study

A pilot study was conducted in order to test the methodology. The study was approved by the Texas Woman's University IRB in June 2019. Pilot study participants were recruited using digital flyers via email and Facebook as well as snowball recruitment from participants. A total of 42 CRNs completed the survey, and four were deleted due to finishing less than half of the survey. Further, three other cases did not complete all the questions and were not included in the overall MMD-HP scores. Reliability of the MMD-HP was demonstrated with an overall Cronbach's alpha of 0.96. The subscales also showed good reliability with Cronbach's alpha ranging from 0.84 – 0.93. Analysis revealed that the MMD-HP scores for the entire sample had a mean of 96.36 (*SD* = 66.24) and median of 85, with a range of 1-216. Although the instrument does not yet have values to indicate what scores constitute high versus low levels of moral distress (Epstein et al., 2019), the results demonstrate that CRNs do experience moral distress in the context of their role. Significant correlations were not demonstrated between MMD-HP scores and demographic characteristics.

The primary modification for the larger study was to increase the completion rate. A progress bar was added to the survey so that participants could gauge their progress as they took the survey. Additionally, to prevent skipping questions, all appropriate items were rendered required in order for the participant to continue to the next question. Overall, the pilot study was fairly smooth as far as implementation, and the revisions were minor.

Treatment of Data

Data was analyzed using Statistical Package for Social Sciences (SPSS) software. Descriptive statistics were obtained to include measures of central tendency, frequency distribution, and standard deviation of the MMD-HP scores. An independent *t*-test and a one-way ANOVA were performed explore the individual differences among the demographic variables. A content analysis was conducted on write-in items. Level of significance set at $\alpha = 0.05$.

CHAPTER IV

ANALYSIS OF DATA

The purpose of this study was to examine moral distress as experienced by CRNs in the context of their role and to identify relationships, if any, of moral distress scores and demographic characteristics. The MMD-HP (Epstein et al., 2019) was used to assess the level of moral distress experienced by CRNs. A demographic data form was utilized to identify sample characteristics, and descriptive statistics were used to summarize the distribution demographics in the sample. Moral distress scores and associated data were summarized using descriptive statistics and analyzed using Pearson's correlation, independent *t*-test, and one-way ANOVA. Additionally, internal consistency reliability was estimated by calculation of Cronbach's alpha for the total instrument, the four subscales, and the three additional CRN specific items.

Description of the Sample

A total of 322 CRNs took the questionnaire. Sixty-four cases were deleted due to completing less than half of the survey, and one case was deleted due to ineligibility. Fifteen cases did not complete all the questions and were not included in the overall MMD-HP scores.

The sample was predominantly female (n = 241, 93.8%) with one CRN classifying their gender as "do not identify." Participants ranged in age from 22 years to

73 years with a mean age of 47 years (*SD* = 12.15). Overall years of nursing experience ranged from 1 year to 53 years (*SD* = 12.89), and clinical research nursing experience ranged from less than a year to 40 years (*SD* = 9.00; see Table 2).

More than half of the CRNs held a baccalaureate nursing degree (*n* = 148, 57.6%). The CRNs were largely employed in the United States (*n* = 218, 84.8%) and chiefly working in the coordinator/study manager role (*n* = 180, 70%; see Table 3).

Findings of the Study

A one-time measure of moral distress was assessed using the MMD-HP (Epstein et al., 2019). Recruited CRNs completed the survey to evaluate moral distress in the context of their role. The MMD-HP is a 27- item self-administered Likert type scale that presents root cause situations scored according to how often they occur and how distressing they are, so that each item has a frequency and a distress measurement. Frequency and distress are multiplied for each item to obtain the individual item score (fxd), and the item scores are summed to create a composite score. A higher score indicates a higher level of moral distress, with a scale range of 0 – 432.

Table 2

Distribution of Gender, Age, Nursing Experience, and CRN Experience of the Participants

Variable	*n*	%
Gender		
Female	241	93.8
Male	15	5.8
Do not identify	1	.4
Age (years)		
20 – 29	29	11.3
30 – 39	49	19.1
40 – 49	61	23.7
50 – 59	77	30
60 years and older	41	16
Years Nursing Experience		
0 – 2	23	8.9
3 – 5	22	8.6
6 – 10	42	16.3
11 – 20	55	21.4
> 20 years	114	44.4
Years CRN Experience		
0 – 2	57	22.2
3 – 5	56	21.8
6 – 10	43	16.7
11 – 20	66	25.7
>20 years	33	12.8

Table 3

Distribution of Highest Nursing Education, Country Employed, and CRN Role of the Participants

Variable	*n*	%
Highest Nursing Education		
Diploma	7	2.7
Associate degree	21	8.2
Baccalaureate	148	57.6
Master's Degree	58	22.6
Doctoral Degree	13	5.1
Other	10	3.9
Country Employed		
United States	218	84.8
United Kingdom	34	13.2
Republic of Ireland	2	.8
Australia	1	.4
Canada	1	.4
South Africa	1	.4
CRN Role		
Coordinator/study manager	180	70
Bedside	23	8.9
Combination of both	24	9.3

Moral Distress Scores

To address the first research question, do CRNs experience moral distress in the context of their role, the mean, median, and standard deviation of the MMD-HP scores were calculated for the total sample, as well as by demographic groups. The mean MMD-HP composite score for the entire sample was 79.58 (n = 242, SD = 64.27), and the

median was 67 with a range of 0 – 354. Mean moral distress composite scores varied by participant demographics.

The youngest participants had the highest levels of moral distress amongst age groups. Participants aged 20 – 29 years had a mean score of 99.65 (*SD* = 58.89), and those aged 30 – 39 years had a mean score of 97.82 (*SD* = 75.01). Conversely, CRNs over age 60 years reported the lowest levels of moral distress with a mean of 57.68 (*SD* = 42.23). Participants with 3 – 5 years of nursing experience had the highest scores (*M* = 93.25, *SD* = 57.73), while CRNs with greater than 20 years nursing experience had the lowest scores (*M* = 73.19, *SD* = 60.10). Nurses with 6 – 10 years of CRN experience reported the highest levels of moral distress with a mean of 100.34 (*SD* = 68.87), and those with greater than 20 years of CRN experience had the lowest, with a mean of 70.33 (*SD* = 58.88; see Table 4).

CRNs working in the bedside role had higher levels of moral distress (*M* =108.04, *SD* = 81.92) than CRNs working in the coordinator role or a combination of both. Associate degree nurses had the lowest moral distress with a mean score of 56.95 (*SD* = 48.40). Participants who are considering leaving their current position due to moral distress (*M* = 135.56, *SD* = 74.72) had higher levels of moral distress than those who are not considering leaving (*M* = 68.82, *SD* = 56.19; see Table 5).

Table 4

Mean Moral Distress scores for Overall sample, Gender, Age, Years of Nursing Experience, and Years of CRN Experience

Variable	*M*	*SD*	*n*
Total	79.58	64.274	242
Gender			
Female	77.87	64.817	228
Male	87.69	56.185	13
Do not identify	135	-	1
Age (years)			
20 – 29	99.65	58.89	26
30 – 39	97.82	75.01	44
40 – 49	63.67	59.51	57
50 – 59	85.69	67.55	75
60 years and older	57.68	42.23	40
Years Nursing Experience			
0 – 2	77.90	64.56	20
3 – 5	93.25	57.73	20
6 – 10	89.69	60.81	39
11 – 20	82.49	77.08	51
> 20 years	79.88	60.10	111
Years CRN Experience			
0 – 2	75.76	71.51	51
3 – 5	77.65	52.66	51
6 – 10	100.34	68.87	41
11 – 20	77.34	65.73	64
>20 years	70.33	58.88	33

Table 5

Mean Moral Distress scores for Education, CRN Role, Country Employed, Left Position Due to Moral Distress, and Considering Leaving Due to Moral Distress

Variable	*M*	*SD*	*n*
Highest Nursing Education			
Diploma	74.43	104.92	7
Associate Degree	56.95	48.40	20
Baccalaureate Degree	80.14	57.34	138
Master's Degree	93.87	76.42	54
Doctoral Degree	83.85	78.66	13
Other	37.9	36.06	10
CRN Role			
Bedside nursing	108.04	81.92	23
Coordinator/study manager	75.95	59.18	165
Combination of both roles	77.37	73.20	24
Country Employed			
United States	77.99	60.70	205
United Kingdom	86.21	82.82	33
Republic of Ireland	67	-	1
Australia	20	-	1
Canada	134	-	1
South Africa	205	-	1
Have you ever considered leaving clinical position due to moral distress?			
No, I have never considered leaving or left a position	52.37	57.72	90
Yes, I considered leaving but did not leave	95.14	56.58	83
Yes, I left a position	96.35	69.71	69
Are you considering leaving your position now due to moral distress?			
Yes	135.56	74.72	39
No	68.82	56.19	203

Individual item scores (fxd) were calculated and ranked. The scale range for individual item scores is 0 – 16. The mean item score was 2.99 (*SD* = 2.40) with a range of 0 – 16. The highest ranking individual item was, “be required to care for more patients than I can safely care for” (*M* = 4.63, *SD* = 4.98), while the lowest ranked item was “participate in care that I do not agree with, but do so because of fears of litigation” (*M* = 1.28, *SD* = 2.74). The four root level subscales of the MMD-HP include (a) system-level root causes, (b) clinical root causes, (c) team level – integrity causes, and (d) team level – interaction causes. The mean item scores were calculated for items within each subscale, and the subscale with the highest mean item score was the team level – interaction causes.

The three CRN specific items were calculated separately from the group. The highest mean item score of the CRN specific items was “dual obligation” (*M* = 4.13, *SD* = 4.71; see Table 6).

Table 6

Mean Item Scores by Subscale

Variable	*M*	*SD*
System Level Root		
16. Be required to care for more patients than I can safely care for	4.63	4.98
19. Have excessive documentation requirements that compromise patient care	4.12	4.83
18. Experience lack of administrative action or support for a problem that is compromising patient care	3.82	4.57
4. Be unable to provide optimal care due to pressures from administrator or insurers to reduce costs	3.54	4.68
17. Experience compromised patient care due to lack of resources/equipment/ bed capacity	3.31	4.16
22. Be required to work with abusive patients/family members who are compromising quality of care	2.52	3.56
7. Be required to care for patients who I do not feel qualified to care for	2.46	3.47
23. Feel required to over-emphasize tasks and productivity or quality measures at the expense of patient care	2.45	3.85
Clinical Root		
2. Follow the family's insistence to continue aggressive treatment even though I believe it is not in the best interest of the patient	4.22	4.56
1. Witness health care providers giving "false hope" to a patient or family	3.41	3.84
3. Feel pressured to order or carry out orders for what I consider to be unnecessary or inappropriate tests and treatments	3.35	3.83
8. Participate in care that causes unnecessary suffering or does not adequately relieve pain or symptoms	2.72	3.50
5. Continue to provide aggressive treatment for a person who is most likely going to die regardless of this treatment when no one will make a decision to withdraw it	2.48	3.35
10. Follow a physician or family member's request not to discuss the patient's prognosis with the patient/family	2.33	3.42

Variable	*M*	*SD*
Team Integrity Root		
20. Fear of retribution if I speak up	3.42	4.70
25. Work within power hierarchies in team, units, and my institution that compromise patient care	2.72	4.18
21. Feel unsafe/bullied among my own colleagues	2.47	3.88
11. Witness a violation of a standard of practice or a code of ethics and not feel sufficiently supported to report the violation	1.99	3.12
27. Work with team members who do not treat vulnerable or stigmatized patient with dignity and respect	1.48	2.98
6. Be pressured to avoid taking action when I learn that a physician, nurse, or other team colleague has made a medical error and does not report it	1.35	2.66
12. Participate in care that I do not agree with, but do so because of fears of litigation	1.28	2.743
Team Interaction Root		
14. Witness low quality of patient care due to poor team communication	4.49	4.61
9. Watch a patient suffer because of a lack of provider continuity	4.35	4.68
15. Feel pressured to ignore situation in which patients have not been given adequate information to ensure informed consent	2.72	3.89
26. Participate on a team that gives inconsistent messages to a patient/family	2.55	3.481
24. Be required to care for patients who have unclear or inconsistent treatment plans or who lack goals of care	2.31	3.67
Clinical Research Nurse Specific Items		
29. Experience conflict between obligation to provide care that is best for the patient and compliance with the study protocol	4.13	4.71
28. Feel pressure to enroll patient on clinical trials even though you feel they are not eligible	3.94	4.55
30. Be required to enroll patients on clinical trials even though you know that the treatment is not working	3.85	4.77

Relationship to Demographic Characteristics

To address the second research question, what is the relationship between moral distress scores and demographic characteristics of CRNs, Pearson's correlations, independent *t*-test, and a one-way ANOVA were performed to examine the statistical significance of relationships between demographic characteristics and levels of moral distress.

Pearson's product-moment correlations were conducted to examine the relationship between age, years of nursing experience, and years of CRN experience with moral distress. As shown in Table 7, there was a small, negative correlation between age and moral distress scores. The relationship between moral distress and years of nursing experience and CRN experience were not statistically significant.

Table 7

Pearson's Product-Moment Correlations for Age, Years of Nursing Experience, Years of CRN Experience With Moral Distress Composite Score

Variable	*r*	*p*
Age	-.156	.02*
Years of Nursing Experience	-.083	.20
Years of CRN Experience	-.053	.41

*$p < .05$

To examine differences of moral distress scores by gender, highest nursing degree, and intent to leave current position due to moral distress, independent samples *t*-tests were conducted. Although mean scores were higher for males (M = 87.69, SD = 56.19) than females (M = 78.87, SD = 64.82), there was no significant difference in the scores. Participants who indicated that they are considering leaving their jobs had significantly higher moral distress scores (M = 135.56, SD = 74.72) than those who are not considering leaving (M = 68.82, SD = 56.19). A large effect size (d = 1.01) was demonstrated (Cohen, 1988). Results of the *t*-tests and effect sizes are listed in Table 8.

Table 8

Means and Standard Deviations for Moral Distress Scores by Gender, Highest Nursing Degree and Intention to Leave Position

Variable	*n*	*M*	*SD*	*t*	*p*	*d**
Gender Ψ				-.480	.63	.15
Female	228	78.87	64.82			
Male	13	87.69	56.19			
Highest Nursing Education Ψ				-1.59	.12	.24
Undergraduate	173	75.18	58.80			
Graduate	68	91.44	75.89			
Considering leaving due to MD				6.42	.00**	1.01
Yes	39	135.56	74.72			
No	203	68.82	56.19			

Ψ Equal variances not assumed statistics reported
*Cohen's $d = (M_2 - M_1) / SD_{pooled}$
**$p < .05$

One-way ANOVA was conducted to explore the impact of country employed, CRN role, and previous history of leaving a position on moral distress scores. There was a statistically significant difference at the $p <$. 05 level in moral distress scores of CRNs who had previously left a position or considered leaving a position due to moral distress and CRNs who had not left a position due to moral distress. The calculated effect size using eta squared was .10, indicating that the difference in means was moderate to large (Cohen, 1988). Post-hoc comparisons using Games-Howell indicated that the mean moral distress score for CRNs who had not previously left a position due to moral distress (M = 52.37, SD = 57.72) was significantly different from CRNs who had previously left a position (M = 96.35, SD = 69.71) and CRNs who had considered leaving, but did not (M = 95.14, SD = 56.58). There was no significant difference in mean moral distress scores of CRNs who had previously left and CRNs who considered leaving but did not leave. The mean scores between groups in CRN roles and country employed were not statistically significant (see Table 9).

Table 9

Means and Standard Deviations for Moral Distress by Country Employed, CRN Role, and Previously Left Job Due to Moral Distress

Variable	*SS*	*MS*	*F*	*p*	*d*
Country Employed					
Between	4871.54	2435.77	.588 (2, 239)	.556	.00
Within	990741.47	4145.36			
CRN Role					
Between	20930.21	10465.10	2.588 (2, 209)	.078	.02
Within	845253.09	4044.27			
Left Job Due to MD					
Between	106158.19	53079.10	14.263 (2, 239)	.000*	.10
Within	889454.82	3721.57			

*$p < .05$

Write-In Items

In addition to the questionnaire items, the MMD-HP provides space for participants to write in and score additional situations in which they have experienced moral distress. A total of 52 write-in items were analyzed for themes and concepts. There was a wide variety of concepts within the items. The following six themes were identified, (a) system, (b) human subjects' protections, (c) research integrity, (d) communication, (e) patient/clinical, and (f) inappropriate delegation. The system theme had by far the most items (22), with inappropriate delegation (3) the fewest (see Table 10).

Table 10

Themes for Write-in Items

Theme (number of items)	Item Examples
System (22)	Providers continue enrollment despite severe staffing shortages
	Delays with study coordination impacting patient's care
	Lack of transparency of administrators regarding the impact of Covid-19 pandemic
	No one listens to us
Human subjects' protections (8)	Consenting a patient who is unsure about their own goals of care
	Investigator mentioning a trial and not emphasizing risk
	Dangerous protocol
Research integrity (7)	Asking for waivers for eligibility for clinical trials for patients who are not appropriate for the trial
	PI saying adverse events were not related, but they clearly were
Communication (6)	Clear consistent instructions from leadership, i.e. recruit patients over current work
Patient/clinical (6)	Having clinical trial subjects and patients
	Insurance company denies patient participation on a clinical trial
Inappropriate delegation (3)	Investigators require study coordinators to determine treatment decisions and oversee trials with little input
	PI delegating MD tasks to CRN

Reliability of the MMD-HP

Reliability coefficients were estimated for the overall MMD-HP scale and the four subscales using Cronbach's alpha coefficient. The total instrument had good internal consistency, with a Cronbach's alpha coefficient of .93. The subscales also demonstrated good reliability with Cronbach's alpha coefficients ranging from .80 – .86 (see Table 11).

Table 11

Reliability Estimates for MMD-HP and Subscales

	Number of Items	Cronbach's Alpha
Total Instrument	27	.93
System Root	8	.86
Clinical Root	6	.84
Team Integrity Root	7	.80
Team Interaction Root	6	.85

Summary of the Findings

A total of 322 nurses participated in this descriptive, quantitative study to examine moral distress in CRNs. Levels of moral distress were measured with the MMD-HP (Epstein et al., 2019). Sample characteristics were recorded using a nine-item demographic form.

In order to evaluate the first research question, do CRNs experience moral distress in the context of their job, moral distress composite scores were computed. To examine the relationship between moral distress scores and demographic characteristics, data from the MMD-HP was analyzed using Pearson's correlations, *t*-tests, and a one-way ANOVA. The analysis demonstrated that CRNs experience moral distress and that there is a significant negative correlation between age of the CRN and moral distress scores. CRNs who had previously left a job or considered leaving a job due to moral distress had significantly higher levels of moral distress than those who had not. Further, the moral distress scores for CRNs currently considering leaving their position due to moral distress were significantly higher than CRNs not considering leaving. Good reliability of the MMD-HP and four subscales was demonstrated.

CHAPTER V

SUMMARY OF THE STUDY

Clinical research nursing is the nursing specialty that focuses on the management of clinical trials and the care of patient participants. Literature, although limited, has demonstrated that CRNs face unique ethical challenges in the context of their role. Ethical challenges and conflicts can lead to moral distress, which has been identified as a leading ethical threat to nurses. This study was designed to determine if CRNs experience moral distress and to examine relationships between levels of moral distress and demographic characteristics. Mary Corley's (2002) moral distress theory provided the conceptual framework for this study. This chapter provides a summary of the study, discussion of the study findings, conclusions, implications for practice, and recommendations for further research.

Summary

A descriptive, quantitative design was used to explore the concept of moral distress in CRNs. Participants were recruited using digital flyers and emails distributed by professional organizations, including the IACRN and the local chapter of SoCRA. Social media, including Twitter, LinkedIn, and Facebook, as well as snowball sampling were also employed. A one-time measure of moral distress using the MMD-HP via an online platform was taken by a total of 322 participants. The first research question, which addressed whether CRNs experience moral distress, was examined using measures

of central tendency, namely the mean composite moral distress scores. The second research question which explored relationships between moral distress scores and demographic characteristics, was analyzed using Pearson correlation, one-way ANOVA, and independent *t*-test. Reliability of the MMD-HP was estimated using Cronbach's alpha.

Discussion of the Findings

The moral distress theory (Corley, 2002) provided the conceptual framework for this study. The theory posits that moral distress or moral comfort is the outcome of ethical challenges and the interrelationships of moral concepts in managing those challenges. The research questions investigated in this study were:

1. Do CRNs experience moral distress in the context of their role?
2. What is the relationship between moral distress scores and demographic characteristics of CRNs?

This study applied the principles of the theory to determine whether the dynamic interrelationship of the moral concepts held by the CRN influenced the outcome of moral distress or moral comfort.

Moral Distress Scores

In order to answer the first research question and explore the levels of moral distress in CRNs, the means were calculated for the overall sample and for demographic characteristics. Additionally, item scores were analyzed individually and by subscale. Because the MMD-HP is a recently revised instrument, scores that constitute high versus

low levels of moral distress have not yet been elucidated. One suggestion by the author is to calculate the mean moral distress scores for those participants considering leaving their position now due to moral distress and for those not considering leaving their position now due to moral distress. Individuals intending to leave due to moral distress should have higher levels of moral distress than those who are not considering leaving; therefore, providing a guide for what indicates high and low scores. The CRNs that were considering leaving their current position due to moral distress had a mean score of 135.56 (*SD* = 64.72, *n* = 39). Those who are not had a mean moral distress score of 68.82 (*SD* = 56.19, *n* = 203). Using the benchmark scores of 136 as a high level of moral distress and 69 as low levels of moral distress, the overall mean score of the sample (*M* = 79.58, *SD* = 64.27) suggests that CRNs do experience moral distress. Further, by using a score of 136 as an indicator of high levels of moral distress, it can be extrapolated that nearly 20% (*n* = 47) of the CRNs experience high levels of moral distress.

Two other studies used the MMD-HP to measure moral distress in nurses. Epstein et al. (2019) conducted initial validation studies of the MMD-HP and explored moral distress scores in clinical nurses, as well as physicians and others patient-facing health care professionals. In another study, Latimer et al. (2020) used the MMD-HP to measure moral distress in mechanical circulatory support nurses. Compared with the mean moral distress scores in the Epstein et al. (2019) and Latimer et al. (2020) studies, the CRNs demonstrated lower mean moral distress scores, but similar ranges in scores (see Table 12).

In their study with non-nursing research staff, Fisher et al. (2013) reported that although the scores were not high, approximately 50% of the participants endorsed moderate levels of moral stress. While the MMD-HP was not the instrument used, and it was moral stress as opposed to moral distress, it is notable to mention.

Table 12

Comparison of Mean Moral Distress Scores in Other Studies

	M	*SD*	Range	*n*
Latimer et al., 2020				
Ventricular Assisted Device Nurses	126	75.4	2 – 334	36
Epstein et al., 2019				
Nurses (Inpatient, ICU, ER, OR)	112.3	73.2	0 – 359	440
Current study				
Clinical research nurses	79.6	64.3	0 – 354	242

The moral distress theory postulates that institutional constraints are the foremost reason for moral distress. This position is corroborated in this study, as the system level root had the highest mean item scores among the subscales, and the system theme for the write-in items had by far the highest number of items attributed to it. The highest scoring item, “be required to care for more patients than I can safely care for,” is consistent with the write-in items that indicate high workload as a cause of moral distress. Workload issues were also among key findings in the reviewed literature (DeBruin et al., 2011;

Godskesen et al., 2018). This item was the third highest scored item in the Epstein et al. (2019) study, proving that patient load is an ever-present problem in nursing.

Although the added CRN items did not rank highest among item scores, the item that addressed the feeling of dual obligations, “experience conflict between obligation to provide care that is best for the patient and compliance with the study protocol,” which is frequently cited in the literature as a primary cause of ethical conflict (DeBruin et al., 2011; Fisher & Kalbaugh, 2012; Höglund et al., 2010; Larkin et al., 2019; Loh et al., 2002) had the fifth highest item score. The other two added CRN items that focused on pressures to enroll patients scored on the mid-high level. Notably, pressure to enroll patients for various reasons made up 10% of the write in items.

It is unclear why CRNs had lower moral distress scores than nurses in the comparative studies. Many factors may have influenced the results. As cited as a limitation of this research, the MMD-HP was designed for use in the clinical setting, and as such, the items may not have captured unique ethical situations of the CRN. If that was the case, however, it would be presumed that the added CRN items would have had the highest item scores.

Another possible explanation for the low mean moral distress score may be related to the methodology and use of an online questionnaire. It was noted that nine participants (3.5%) entered straight zeros, which could be an indicator that the participants did not read the questions, did not understand the instructions for the questions, or simply straightlined. Straightlining is a term that describes the behavior

when a respondent to a questionnaire uses the same response for all items in that set (Kim et al., 2019). Certainly, the other explanation for the comparatively lower moral distress scores is that moral distress is not experienced at as high a level or incidence by CRNs as clinical nurses.

Demographic Characteristics and Moral Distress

The second research question addressed the relationship between moral distress scores and demographic characteristics. In previous studies of moral distress, significant relationships between age, years of experience and education have been inconsistent. Research has demonstrated both positive, negative, and no correlation to years of experience and age (Allen et al., 2013; Ameri et al., 2016; Elpern et al., 2005; Rice et al., 2008; Sirilla, 2014). In this study, age had a small negative correlation with moral distress scores in this study, with the lowest moral distress scores from CRNs who are 60 years of age and older. In a study with non-nursing research staff, a negative correlation between age and moral stress scores was also demonstrated (Fisher et al., 2013). An explanation might be that an older nurse would have had more ethics training or had developed better coping skills; however, the lack of significant correlation and findings related to years of nursing and CRN experience contradict that thinking. Although the differences were not statistically significant in this study, it is interesting that the highest scores among years of nursing experience and years of CRN experience fell in the 3 – 5 year range and 6 – 10 year range, respectively.

While not significantly different, CRNs who work at the bedside reported higher mean moral distress scores than those who work in the coordinator position. The moral distress scores of the bedside CRNs (M = 108.04, SD = 81.92) was comparable to the scores of the nurses in the Epstein et al. (2019) study (M = 112.3, SD = 73.2). Possible explanations are that bedside CRNs experience more moral distress or, as previously mentioned, the MMD-HP has more of a clinical focus and captures the issues more associated to a clinical nurse.

Consistent in previous studies is the correlation between moral distress scores and history of leaving a job or intent to leave current job due to moral distress (Allen et al., 2013; Latimer et al., 2020; Sirilla et al., 2017; Whitehead et al., 2015). This study supported that finding. CRNs who had previously left a position or had considered leaving a position due to moral distress had significantly higher moral distress scores than those who have not left or considered leaving as a result of moral distress. Similarly, moral distress scores of CRNs who are considering leaving are significantly higher than those who are not.

Reliability of the MMD-HP

In this study, the entire MMD-HP as well as the four subscales demonstrated reliability coefficient estimates of .80 or above, with the total instrument estimate at .93. These estimates are consistent with the Epstein et al. (2019) study.

Conclusions and Implications

Based on the results of this study of moral distress in CRNs, the following conclusions were established:

1. CRNs experience moral distress as indicated by scores on the MMD- HP.
2. Older CRNs experience less moral distress than their younger counterparts.
3. CRNs who had previously left, considered leaving or are considering leaving their current job due to moral distress experienced significantly higher levels of moral distress than those with no intent to leave or had not considered leaving or left.
4. The MMD-HP performed well psychometrically with this sample of CRNs.

The following implications for nursing were determined based on the findings of this study:

1. CRNs experience moral distress, and some experience it at high levels. Causes that led to the highest levels of moral distress were related to system or institutional issues. Mechanisms and processes must be established or improved to identify, reduce, and prevent the situations that lead to moral distress.
2. Research and ethics education are inconsistent at best and non-existent at worst among CRNs. Educational infrastructure must be instituted to provide CRNs the tools to evaluate and cope with the unique ethical challenges faced in their role.

Recommendations for Further Study

Based on this study, the following recommendations for further research were established:

1. This study should be repeated using a mixed methods triangulation design in order to use multiple methods in order to comprehensively understand the phenomenon in CRNs.
2. This study should be replicated using a moral distress measure that is designed for the research population.
3. This study should be replicated with more clarification regarding the CRN role and title in the demographics section.
4. Further research on moral distress should be conducted with both nursing and non-nursing research personnel. Non – nursing research personnel often perform the same role as the CRN and are, as of late, being hired into roles that nurses were exclusively hired into in the past.
5. Further research is needed in the methodology of online questionnaires regarding completion rates and straightlining.

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APPENDIX A

Recruitment Flyer and Email

Dear Clinical Research Nurse:

I am a student at Texas Woman's University – Houston (TWU), and I am conducting a study titled Moral Distress in Clinical Research Nurses. The purpose of the study is to examine moral distress as experienced by clinical research nurses in the context of their role.

The anonymous online survey takes about 10-15 minutes to complete and is voluntary and confidential.

Eligible participants are:

- Registered Nurse
- Actively managing clinical trials **or** providing nursing care exclusively to patients participating in clinical trials
- Can read the English language
- Age 18 and over

To take the survey, click HERE or copy and paste the link below into your address bar.

https://www.URLLINK TO SURVEY

If you have any questions about this study, please email me at boneal@twu.edu or call at 832-689-2071. Thank you for sharing your experiences of moral distress.

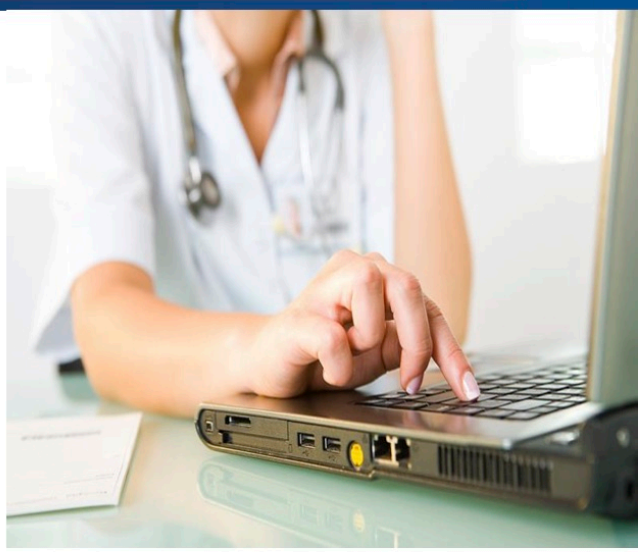
Sincerely,

Brandi Showalter, MS, RN, CCRP
Doctoral Nursing Student
PhD Nursing Science Program,
Texas Woman's University – Houston
6700 Fannin Street, Houston, TX 77030
Email: boneal@TWU.edu
Phone: 832-689-2071

Recruiting Clinical Research Nurses

for Research Study

Moral Distress in Clinical Research Nurses



The purpose of this study is to examine moral distress as experienced by clinical research nurses in the context of their role.

The anonymous online survey takes about 15 minutes to complete and is voluntary and confidential

Are you eligible?

- Registered Nurse
- Actively managing clinical trials **or** providing nursing care exclusively to patients participating in clinical trials
- Can read the English language
- Age 18 and over

To take the survey, click HERE, follow the below link or scan the QR code to participate.

https://singuserbd4374d3.sjc1.qualtrics.com/jfe/form/SV_1SIMqqLGH6ydEqN

For more information or any questions, please contact the researcher:

Brandi Showalter, MS, RN, CCRP
Doctoral Nursing Student
PhD Nursing Science Program,
Texas Woman's University – Houston
6700 Fannin Street, Houston, TX 77030
Email: boneal@TWU.edu
Phone: 832-689-2071

APPENDIX B

IRB Exemption Letter

Texas Woman's University
Institutional Review Board (IRB)
irb@twu.edu
https://www.twu.edu/institutional-review-board-irb/

July 22, 2019

Brandi Showalter
Nursing - Houston

Re: Exempt - IRB-FY2019-325 Moral Distress in Clinical Research Nurses

Dear Brandi Showalter,

The above referenced study has been reviewed by the TWU IRB - Houston operating under FWA00000178 and was determined to be exempt on July 19, 2019. If you are using a signed informed consent form, the approved form has been stamped by the IRB and uploaded to the Attachments tab under the Study Details section. This stamped version of the consent must be used when enrolling subjects in your study.

Note that any modifications to this study must be submitted for IRB review prior to their implementation, including the submission of any agency approval letters, changes in research personnel, and any changes in study procedures or instruments. Additionally, the IRB must be notified immediately of any adverse events or unanticipated problems. All modification requests, incident reports, and requests to close the file must be submitted through Cayuse.

On August 26, 2020, this approval will expire and the study must be renewed or closed. A reminder will be sent 45 days prior to this date.

If you have any questions or need additional information, please contact the IRB analyst indicated on your application in Cayuse or refer to the IRB website at http://www.twu.edu/institutional-review-board-irb/.

Sincerely,

TWU IRB - Houston

APPENDIX C

Demographics Form and Measure of Moral Distress- Healthcare Professional

Block 8

COMPLETION OF THIS QUESTIONNAIRE WILL BE CONSTRUED AS INFORMED CONSENT

Dear Participant,

You are invited to take part in a survey as a part of Brandi Showalter's dissertation study at Texas Woman's University - Houston (TWU). The purpose of this study is to examine moral distress as experienced by clinical research nurses in the context of their role. The survey will take approximately 10-15 minutes to complete. Your participation is voluntary. You may withdraw from the study at any time. There are minimal risks from completing the survey. If you become upset by any of the questions, discontinue taking the survey and seek assistance from the Employee Assistance Program (EAP) or Human Resources Department at your institution. Your answers will be completely anonymous and confidential. All of the data will be sent to one database and the results will be reported as aggregate data rather than by a single participant.

There are 2 sections to the survey: a demographic section followed by a survey asking questions about moral distress. **Please complete both sections. If you have questions about the survey, please contact Brandi Showalter at boneal@twu.edu or call 832-689-2071.**

Thank you for your time,

Brandi Showalter, MS, RN, CCRP

Block 10

DEMOGRAPHIC SECTION

Please answer all items.

Age in years:

Gender:

- ○ Female
- ○ Male
- ○ Transgender
- ○ Do not identify

Country in which you are employed:

If you live in the US, state in which you are employed:

What is your job title?

Highest educational level in nursing:

- ○ Diploma
- ○ Associates Degree (ADN)
- ○ Bachelor's Degree (BS/BSN)
- ○ Master's Degree (MS/MSN)
- ○ Doctoral Degree PhD/DNP
- ○ Other (please specify)

Years of experience as a nurse:

Years of experience as a clinical research nurse:

Is your role as a clinical research nurse a bedside nursing role or coordinator/study manager role?

- ○ Bedside nursing
- ○ Coordinator/study manager
- ○ _____ Other

Default Question Block

Measure of Moral Distress - Healthcare Professionals (MMD-HP)

Moral distress occurs when professionals cannot carry out what they believe to be ethically appropriate actions because of constraints or barriers. This survey lists situations that occur in clinical practice. If you have experienced these situations they may or may not have been morally distressing to you. Please indicate how frequently you have experienced each item. Also, rank how distressing these situations are for you. If you have never experienced a particular situation, select "0" (never) for frequency. Even if you have not experienced a situation, please indicate how distressed you would be if it occurred in your practice. Note that you will respond to each item by checking the appropriate column for two dimensions: *Frequency* and *Level of Distress*.

Epstein, E.G., Whitehead, P.B., Prompahakul, C., Thacker, L.R., & Hamric, A.B. (2019). Enhancing understanding of moral distress: The measure of moral distress for healthcare professionals. *AJOB Empirical Bioethics 10*(2), 113-124 https://doi.org/10.1080/23294515.2019.1586008.

	Frequency					Level of Distress				
	Never				Very frequently	None				Very distressing
	0	1	2	3	4	0	1	2	3	4
1. Witness healthcare providers giving "false hope" to a patient or family.	○	○	○	○	○	○	○	○	○	○
2. Follow the family's insistence to continue aggressive treatment even though I believe it is not in the best interest of the patient.	○	○	○	○	○	○	○	○	○	○
3. Feel pressured to order or carry out orders for what I consider to be unnecessary or inappropriate tests and treatments.	○	○	○	○	○	○	○	○	○	○
4. Be unable to provide optimal care due to pressures from administrators or insurers to reduce costs.	○	○	○	○	○	○	○	○	○	○
5. Continue to provide aggressive treatment for a person who is most likely to die regardless of this treatment when no one will make a decision to withdraw it.	○	○	○	○	○	○	○	○	○	○

MMD - pg 2

Click to write the question text

	Frequency					Level of Distress				
	Never				Very frequently	None				Very distressing
	0	1	2	3	4	0	1	2	3	4
6. Be pressured to avoid taking action when I learn that a physician, nurse, or other team colleague has made a medical error and does not report it.	○	○	○	○	○	○	○	○	○	○
7. Be required to care for patients whom I do not feel qualified to care for.	○	○	○	○	○	○	○	○	○	○

	Frequency					Level of Distress				
	Never				Very frequently	None				Very distressing
	0	1	2	3	4	0	1	2	3	4
8. Participate in care that causes unnecessary suffering or does not adequately relieve pain or symptoms.	○	○	○	○	○	○	○	○	○	○
9. Watch patient care suffer because of a lack of provider continuity.	○	○	○	○	○	○	○	○	○	○
10. Follow a physician's or family member's request not to discuss the patient's prognosis with the patient/family.	○	○	○	○	○	○	○	○	○	○

MMD pg 3 11-15

Click to write the question text

	Frequency					Level of Distress				
	Never				Very frequently	None				Very distressing
	0	1	2	3	4	0	1	2	3	4
11. Witness a violation of a standard of practice or a code of ethics and not feel sufficiently supported to report the violation.	○	○	○	○	○	○	○	○	○	○
12. Participate in care that I do not agree with, but do so because of fears of litigation.	○	○	○	○	○	○	○	○	○	○
13. Be required to work with other healthcare team members who are not as competent as patient care requires.	○	○	○	○	○	○	○	○	○	○
14. Witness low quality of patient care due to poor team communication.	○	○	○	○	○	○	○	○	○	○
15. Feel pressured to ignore situations in which patients have not been given adequate information to ensure informed consent.	○	○	○	○	○	○	○	○	○	○

MMD items 16-20

	Frequency					Level of Distress				
	Never				Very frequently	None				Very distressing
	0	1	2	3	4	0	1	2	3	4
16. Be required to care for more patients than I can safely care for.	○	○	○	○	○	○	○	○	○	○
17. Experience compromised patient care due to lack of resources/equipment/bed capacity.	○	○	○	○	○	○	○	○	○	○
18. Experience lack of administrative action or support for a problem that is compromising patient care.	○	○	○	○	○	○	○	○	○	○
19. Have excessive documentation requirements that compromise patient care.	○	○	○	○	○	○	○	○	○	○
20. Fear of retribution if I speak up.	○	○	○	○	○	○	○	○	○	○

MMD 21-25

Click to write the question text

	Frequency					Level of Distress				
	Never				Very frequently	None				Very distressing
	0	1	2	3	4	0	1	2	3	4
21. Feel unsafe/bullied amongst my own colleagues.	○	○	○	○	○	○	○	○	○	○
22. Be required to work with abusive patients/family members who are compromising quality of care.	○	○	○	○	○	○	○	○	○	○
23. Feel required to overemphasize tasks and productivity or quality measures at the expense of patient care.	○	○	○	○	○	○	○	○	○	○
24. Be required to care for patients who have unclear or inconsistent treatment plans or who lack goals of care.	○	○	○	○	○	○	○	○	○	○

	Frequency					Level of Distress				
	Never				Very frequently	None				Very distressing
	0	1	2	3	4	0	1	2	3	4
25. Work within power hierarchies in teams, units, and my institution that compromise patient care.	○	○	○	○	○	○	○	○	○	○

MMD 25 - 27 + research

Click to write the question text

	Frequency					Level of Distress				
	Never				Very frequently	None				Very distressing
	0	1	2	3	4	0	1	2	3	4
26. Participate on a team who gives inconsistent messages to a patient/family.	○	○	○	○	○	○	○	○	○	○
27. Work with team members who do not treat vulnerable or stigmatized patients with dignity or respect.	○	○	○	○	○	○	○	○	○	○
28. Feel pressured to enroll patients on clinical trials even though you feel they are not eligible.	○	○	○	○	○	○	○	○	○	○
29. Experience conflict between obligation to provide care that is best for the patient and compliance with the study protocol.	○	○	○	○	○	○	○	○	○	○
30. Be required to enroll patients on clinical trials even though you know that the treatment is not working.	○	○	○	○	○	○	○	○	○	○

Write in options

If there are other situations in which you have felt moral distress, please write in and score them.

	Frequency					Level of Distress				
	Never				Very frequently	None				Very distressing
	0	1	2	3	4	0	1	2	3	4
Additional situation	○	○	○	○	○	○	○	○	○	○
Additional Situation	○	○	○	○	○	○	○	○	○	○

Have you ever left or considered leaving a clinical position due to moral distress?

- ○ No, I have never considered leaving or left a position.
- ○ Yes, I considered leaving but did not leave.
- ○ Yes, I left a position.

Are you considering leaving your position now due to moral distress?

- ○ Yes
- ○ No

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