The Effects of a Formal Organizational Program on Nursing Supervisor Self-Perception of Leadership

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The Effects of a Formal Organizational Program on Nursing Supervisor Self-Perception of Leadership

Jonathan Judy-del Rosario

UNM College of Nursing

Scholarly Chair: Christine Delucas, DNP, MPH, RN, NEA-BC

Scholarly Committee Member: Michael J. Chicarelli, DNP, MSN, RN

Date of Submission: April 7, 2022
“The Effects of a Formal Organizational Program on Nursing Supervisor Self-Perception of Leadership”

Jonathan Judy-del-Rosario

Chair: Christine Delucas, DNP, MPH, RN, NEA-BC

(Member)
Abstract

Nursing house supervisors oversee hospital operations during evenings, nights, weekends, and holidays, yet many feel disconnected from others in the nursing leadership team. These individuals work as the sole leader on duty, having limited interaction with the daytime leaders and often lack formal leadership development. This quantitative, quasi-experimental study explored the effects of implementing a formal educational and team building program on the perception of the supervisor’s leadership skills as well as collaboration with the leadership team. The Leadership Practices Inventory and the Collaborative Behavior Scale – Shortened were the two surveys administered to assess the effects of this program. The initial results following the program did not demonstrate overall increases in their leadership practices or perceived collaboration, but the limited participants in the two-month follow up had non-statistically significant increases in all categories. While the statistical significance of the findings was limited by the number of participants, the clinical significance of the study demonstrated the benefit of education, leadership development, and collaboration. Investment in the nursing supervisors can increase engagement, improve effectiveness, positively impact quality of work, and improve job satisfaction and retention of these critical leaders.

Keywords: nursing house supervisor, nursing supervisor, leadership, collaboration, formal education, team building, leadership practices, leadership team disconnect.
Dedication

This scholarly project is dedicated to the nursing supervisors who protect, support, and lead our nurses around the clock to provide excellent and safe care to hospitalized patients. Their leadership during evenings, nights, and weekends is instrumental to acute care hospital operations.
Acknowledgements

I am greatly appreciative for the guidance and support for my DNP project by Dr. Delucas, who was there for me every step of the way. I am thankful for the patience and explanation provided by Blake Boursaw who made me really enjoy statistics. My classmates were like family throughout the challenges of our simultaneous doctorate program and worldwide pandemic. And finally, I cannot say enough about the support I received from my husband, Kurt, who encouraged me along the way and kept the kids out of my hair so I could always have dedicated time to my studies.
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<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tr>
<td>American Organization of Nurse Executives (AONE)</td>
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<tr>
<td>Collaborative Behavior Scale – Shortened (CBSS)</td>
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The Effects of a Formal Organizational Program on Nursing Supervisor Self-Perception of Leadership

INTRODUCTION AND BACKGROUND

For nearly a century, the nursing supervisor served as the clinical lead and administrator on duty in U.S. hospitals during the evening, night and weekend shifts. Although they fill a vital role in hospital operations, there is often no formal training that occurs in their roles. In addition, as a representative of hospital and nursing leadership during these off-shifts, the nursing supervisor carries through the vision of the nursing management and leadership team. Despite this, nursing supervisors often feel disconnected from the nursing leadership team and view themselves more as shift lead than a nursing leader (Weaver & Lindgren, 2017).

Problem Statement

While nursing supervisors play a significant role in hospital operations, their interaction and collaboration with the daytime nurse managers, directors and other leaders are limited due to their schedules. There are few recent quantitative and qualitative studies that examine specifics of the role of the nursing supervisor throughout their shift, but research is lacking on the perspective of their leadership practices or ability as well as their collaboration with the other nurse leaders within the organization. Additionally, there is only one published study that describes the collaboration between nursing supervisors and unit-based nurse managers.

Study Purpose

Effective communication, collaboration and leadership are key in creating optimal conditions for patient safety. It is imperative that the nursing leadership function as a cohesive team. Transparency, open and honest communication, trust and integrity all contribute to a
highly reliable organization. The off-shift nursing supervisor oversees hospital operations during the off-shifts when the traditional weekday leadership structure is not present, yet they feel disconnected and do not always view themselves as leaders. The purpose of this scholarly project is to determine if a formal organizational program for nursing supervisors, focused on education and team building, will improve nursing supervisor self-perception of their leadership skills and collaboration with the rest of the nursing leadership team.

**Study Aim and Objectives**

The study will examine the effect of an educational and team building intervention on a group of nursing supervisors. The overall effectiveness of the intervention will be measured using a pretest/posttest evaluation of each nursing supervisor’s self-perception of their leadership practices and their perceived collaboration with the nursing leadership team. The objectives of this study include: (1) measure self-perception of leadership practices or behaviors before and after the intervention, (2) measure perceived collaboration before and after the intervention, (3) provide a standardized approach to educate and support the nursing supervisor staff.

**Scope of the Study**

The study focuses on creating a standardized educational program that is focused on the specific learning and growth needs of the nursing supervisors. Additionally, the nursing supervisor team will have opportunities to meet, interact and team build with the other nursing leaders in the organization. The study will encompass the nursing supervisor and nursing leadership group of one organization that spans a total of three campuses and assess their perception collaboration with the entire leadership team as well as their perception of themselves as leaders.
Assumptions

The main assumption of this scholarly project is that the nursing supervisors are not perceived by themselves or others as leaders within the organization. Secondly, it is assumed that the nursing supervisors lack collaboration with the overall nursing leadership team and feel a sense of disconnect with them. This includes a lack of inclusion in operational meetings and communications. Finally, it is assumed that the nursing supervisor team has lacked formal education or training on leadership aspects of their role.

Significance of the Study

This study will expand on two areas that are limited in the current published data. The first is examining how nursing supervisors view themselves as leaders. A second area will assess how the nursing supervisors perceive their collaboration with the other nursing managers and leaders within the organization.

REVIEW OF THE LITERATURE

A literature search was conducted using PubMed and CINAHL. Keywords used during the search included, but were not limited to ‘nursing supervisor,’ ‘administrator supervisor,’ or ‘house supervisor,’ and ‘leadership and management.’ Articles were limited to those published between 2015 and 2020. Initial search revealed 100 articles. Article selection was further limited to articles written in English and published in the United States, and articles related nursing supervisor roles outside of an acute care hospital were excluded, leaving 41 articles remaining for review. Additionally, articles of interest were identified within the references of the initially selected articles.
Collaboration with the Nursing Leadership Team

A review of the literature to find research examining the collaboration between nursing supervisors and the nursing management team with whom they work revealed only one article. A quantitative, cross-sectional descriptive study conducted at several mid-Atlantic acute care hospitals demonstrated a statistically significant relationship ($p<0.01$) between collaboration scores and job satisfaction of nursing supervisors and unit-based nurse managers (Weaver et al., 2019). Additionally, those with higher levels of collaboration had lower intent to leave the organization. These findings are important as it is the first study that suggests improved collaboration leads to better job satisfaction and less turnover.

Another finding in the study relates to the demographics of the participants in the study. Nursing managers that were both younger in age and newer in their positions perceived higher collaboration with the nursing supervisors. This may be important when examining relationships across other organizations.

This study used the Collaborative Behavior Scale-Nurse Manager to survey participants. One limitation to the study is that this scale measures the perceptions of collaboration, but not actual collaboration itself. The study was also conducted in 9 mid-Atlantic hospitals, many of which are Magnet® certified facilities. This could be a threat to external validity, as these hospitals may have additional resources that others do not. Finally, participation rate was only 55% for nursing supervisors and 48% for nurse managers. Results may be skewed if less motivated or engaged staff did not complete this voluntary survey.

Roles and Responsibilities

Several studies, both qualitative and quantitative, looked at the roles and responsibilities of the nursing supervisor. Role clarity is an important aspect in effective management.
Successfully carrying out a nursing management role requires collaboration with others on the team and contributes to both nurse and patient safety.

An early qualitative, exploratory study was conducted to better understand how administrative or nursing supervisors perceive their roles (Weaver & Lindgren, 2016). In this study, a single interview lasting 30-60 minutes was conducted with 10 participants, guided by the objectives of the American Organization of Nurse Executives (AONE) competencies for nurse managers. One of the key findings is that management workflow and supervisor decision making on the off-shifts is done differently than those by the usual daytime leadership team. Secondly, the study described significant categorizations of their work, including staffing, patient flow, and crisis management. Finally, the supervisor’s role of being available to staff—both from an emotional and supportive standpoint to their ability to physically get what they need was outlined.

This study validated many of the well-known aspects of the nursing supervisor role. But there were also a few limitations to this study. The purposive sample was limited in size and diversity, as all participants were female and geographically located in the northeast part of the United States. In addition, practice standards were not established, and further evaluation of the effectiveness of the supervisor in their roles is needed.

In 2017, Weaver and Lindgrin completed a qualitative, focused ethnographic study to better understand the roles and responsibilities of the nursing supervisor. Two major sub themes were found in the study: 1) defining roles and responsibilities of the nursing supervisor around staffing, patient flow, crisis management, and 2) being a hospital representative, in addition to their contributions to nurse and patient safety because of their role.
The findings of this study are important because it is the first to clearly outline aspects of defined roles and expectations for nursing supervisors and their linkage to nurse and patient safety. It also outlined the need to further explore leadership between the off-shift nursing supervisors and the remainder of the leadership team. A limitation of the study was the purposive sampling, as participants were volunteers from an AONE newsletter, and these participants may represent a more engaged group than others not involved with this professional organization.

Given the lack of documented insight into the specifics of the role of the nursing supervisor, a study was conducted to describe a sample of nursing supervisors, as well as their role. In 2019, Glasofer and Lapinsky completed a research investigation to better understand three main aspects of the nursing supervisor role: 1) nursing supervisor characteristics, 2) development of a role delineation questionnaire, and 3) assessing the feasibility of conducting a role delineation study. This mixed methodology study, used an exploratory design based on the American Nurses Credentialing Center’s framework for role delineation studies.

Through convenience and snowball sampling, the study examined a sample of 50 nursing supervisors in New Jersey. Some of the major findings in demographics were that the participants were mostly white females, mostly within 10 years of retirement, less than half had advanced degrees, and their reporting structures were inconsistent. The author considered the initial description of a nursing supervisor’s work as the main contribution of this study (Glasofer & Lapinsky, 2019). Some major factors of their work included administrative presence, leadership, focus on patient safety, advocacy for patients and hospital throughput. This study set the stage for future research in other geographic areas. Finally, threats to external validity due to sampling (small sample size in a single state), as well as missing data points after participants failed to complete all 109 survey questions, are other limitations to this study.
In 2020, Morelock conducted a study to explore the perceived increase workload of the nursing supervisor. In this qualitative exploratory analysis, data was collected for 12 months from a Magnet® facility to examine the number of physical steps taken each shift, as well as the number of phone calls to understand the significance between those two factors and hospital and emergency department (ED) census. The author found that phone calls peaked in the afternoon from 5:00 pm to 7:00 pm and rose sharply again before change of shift at 7:00 am. The nightshift nursing supervisor averaged more steps Monday through Friday, but the daytime nursing supervisor had slightly more on the weekends, with no statistically significant difference.

There was a positive correlation between the total number of steps with each of the following: total calls \( r = 0.40, p = 0.00 \), midnight census \( r = 0.50, p = 0.00 \), patients holding in the ED \( r = 0.44, p = 0.00 \), and 24-hour ED census \( r = 0.42, p = 0.00 \). There were also strong correlations between midnight census and midnight census \( r = 0.71, p = 0.00 \) and between midnight census and 24-hour ED census \( r = 0.70, p = 0.00 \).

This is the first known study to quantify the measures outlined. Further research is needed to understand how these findings compare in other facilities as well as how it impacts the nursing supervisor role or patients within the hospital. The author also suggested that optimizing chain of command in certain situations would be effective in minimizing calls to the nursing supervisor.

**Leadership Team Disconnect**

Nursing supervisors are present within the hospital at times that are not traditionally covered by the majority of hospital leadership. While the evening shift supervisor may overlap slightly with the daytime leadership team and the nighttime supervisor may overlap during the morning with the daytime leadership team, there is rarely much more time that the teams spend
collaborating. In the study by Weaver and Lindgren (2017), a third sub theme was discovered: nursing supervisors not only felt disconnected from the daytime nursing leadership team, but also did not associate as part of that team. This disconnect can contribute to a lack of cohesiveness between members of hospital leadership.

Additional research shows that nursing supervisors perceived a less-collaborative relationship with the nursing unit-based managers (Weaver et al., 2019). Further findings in this area are limited and Weaver suggested that additional research is warranted to better understand why the team members feel that the relationship is less than collaborative between the two groups.

Patient and Staff Safety

A nurses’ primary responsibility is caring for and providing a safe environment for their patients. The nursing supervisor’s role promotes safety for both patients and staff. To further explore the themes and processes used by nursing supervisors to promote safety during their shift, a qualitative, focused ethnographic study was completed to categorize how these evening, night and weekend supervisors achieve these goals. Weaver et al. (2017) conducted semi-structured phone interviews with 30 administrative supervisors from 20 states as well as focus groups with 39 RNs from 7 different hospitals to better understand how the nursing supervisors lead to ensure safety throughout the hospital and their shift. The participants of the study were chosen through purposive sampling.

The nursing supervisor is the go-to person for any patient or staff safety concern that comes up during the shift. Staff escalate clinical concerns to the nursing supervisor and expect to receive guidance or resources to address these concerns. They are often seen as the clinical expert or the person most knowledgeable to find the right answer on policies, procedures or
during urgent or emergent situations. The supervisors consistently thought that establishing trust with the staff was imperative for open communication and transparency. The supervisors are constantly aware of their surroundings and maintain a safety mindset during rounds.

In the review of literature, the concept of the nursing supervisor’s contribution to safety was present in two other studies. Weaver and Lindgren (2017) also identified nurse and patient safety as a subtheme in their analysis when exploring the nursing supervisor’s role perception. In creation of their role delineation questionnaire, Glasofer and Bertino Lapinsky (2019), one of the significant findings used to create the tool included the supervisor’s contribution to patient safety and experience.

**Leadership Programs**

Leadership programs are often used to help individuals understand their particular leadership styles and provide training and education on various topics, providing opportunities to promote growth and development. These programs are often used with those with a wide range of experience and leadership styles.

In a recent study, investigators conducted a program on crisis management for nursing supervisors which also examined the participant’s leadership styles and the relationship with job satisfaction. Weaver, et al. (2019) completed a quantitative study using 56 nursing supervisors from 26 different hospitals that described leadership style and measured perceived competence of the subjects during an emergency. The Multifactor Leadership Questionnaire 5X short form was used to measure leadership style, while the Nurses Assessment of Readiness (NAR) scale was used to measure perceived competence during an emergency.

The findings in the study demonstrated that nursing supervisors at Magnet® hospitals with higher transformational leadership scores had greater job satisfaction ($r = 0.48$, $p < 0.05$).
Second, nursing supervisors in non-Magnet® hospitals with higher transformational leadership scores had been in their positions longer than those with other leadership styles \((r = 0.49, p < 0.05)\). Of note, there was not statistically significant difference in transformational leadership scores between the Magnet® and non-Magnet® hospitals. Third, those with passive-avoidant leadership styles were newer in their roles \((r = -0.45, p < 0.01)\). Overall, all the respondents felt prepared to respond in disasters and while the Magnet® hospital supervisors felt more prepared than the non-Magnet® hospital supervisors, the finding was not significantly different.

This study provided research on role-specific training for the nursing supervisors that is lacking in the literature. Since nursing supervisors oversee hospital operations for the majority of the day and are expected to respond and often lead a response to a crisis, this type of training is important to their role. This also contributed to the realm of job satisfaction with the nursing supervisors, which is also lacking in the literature.

A second study that examining nursing leadership and the effect on staff was conducted by Manning in 2016. This quantitative, descriptive correlational design investigated the influence of nurse manager leadership style on staff nurse engagement. In this study, 441 RNs in 3 different acute care hospitals completed a Multifactor Leadership Questionnaire 5X short form to access leadership style of their manager as well as the Utrecht Work Engagement Scale to assess engagement. Findings in this study were similar to findings in previous research.

All transformational leadership style factors had a positive impact on staff engagement \((p < 0.001)\). Transactional leaders had significant findings, both positive and negative. Passive management by exception had a negative impact on staff engagement \((p < 0.001)\) while active management by exception and contingent reward had a positive impact \((p < 0.001)\). Passive-avoidant leaders had a significant negative impact on staff engagement \((p < 0.001)\).
This study highlights the importance of having leaders that are transformational leaders to fully engage staff, or at least focusing on the strengths of the transactional leaders. Given these findings, programs that develop nursing leaders, including nursing supervisors, could help accomplish this goal. Limitations of this study include the use of a convenience sample, as well as the one-time use of this survey.

Finally, a quantitative and qualitative study was completed to understand the effects of a nursing leadership perspectives program on leadership and professional behavior (Abraham, 2011). A total of 15 RN participants completed the 32-hour course of didactic and experimental learning. The Leadership Practices Inventory (LPI) was completed to measure leadership behavior as well as the Nursing Activity Scale (NAS) to measure professional behavior. The LPI and NAS were done pre- and post-intervention, along with a written evaluation and narrative at the end of the program. Additional data was collected at 6 months.

Data analysis with the Wilcoxon Sign-Rank test showed the intervention to be statistically significant in both leadership behavior ($p = 0.01$) and professional behavior ($p = 0.001$). Additionally, in the study, it was noted that there was an improved promotion rate and a 100% retention rate in the study group.

This study suggests that formal learning for a group of nurses can improve leadership and professional behavior and lead to increased promotions into larger roles. Limitations to this study include the small sample size in addition to the convenience sampling used to obtain participants.

THEORETICAL MODEL AND METHODOLOGY

Theoretical Model

The Kouzes’ and Posner model for functional leadership provided the theoretical framework for this study. Initially in *The Leadership Challenge*, the theoretical model focused
on five leadership practices and ten commitments that were desired in effective leaders (Kouzes & Posner, 1987). Over time, their work evolved to create the Leadership Challenge Model, or the Five Leadership Practices Model. Throughout the years of their work, Kouzes and Posner learned that those leaders that make extraordinary things happen in their organizations engage in practices and behaviors that they describe as The Five Practices of Exemplary Leadership® (Kouzes & Posner, 2017). The current model describes five key leadership concepts for practice with examples of key behaviors to support those concepts.

The five leadership practices of this model consist of: model the way, inspire a shared vision, challenge the process, enable others to act, and encourage from the heart. Modeling in the way represents commitment to shared values and leading by example. Encouraging others to join in these shared values and aspirations inspires a shared vision. In challenging the process, a leader seeks challenges, contests the status quo, takes risks and looks for ways to improve and innovate. When enabling others to act, the leader creates an atmosphere of trust, treats others with respect and involves others in all aspects to reach the goal. And finally, encouraging from the heart recognizes and praises a job well-done, celebrates milestones and gives the team support and appreciation.

As this study aims to improve leadership self-perception as well as the perception of collaborative behavior in the nursing leadership team, this framework will guide the focus and interventions needed to improve the nursing supervisor’s leadership practices. The model provides a structure of practices and key behaviors that are applicable at all levels of leadership.
Methodology

This quantitative, quasi-experimental study used a pretest-posttest design to assess if an educational and team-building intervention impacted the nursing supervisor’s self-perception of leadership as well as their perception of collaboration with the nurse manager group. The participants completed an initial short demographic survey (Appendix A), as well as the Leadership Practices Inventory (LPI) (Appendix B) and the Collaborative Behavior Scale-Shortened (CBSS) (Appendix C). The demographic questions were chosen to describe the characteristics of the group. The LPI is a 30-question, reliable and validated tool for assessing leadership practices and behaviors (Posner, 2016). The CBSS is an 8-question, reliable and validated tool used to assess collaborative behavior between groups (Stichler, 2013). At the end
of the program, the participants were also asked three additional qualitative questions about the program (Appendix D).

**Ethical Issues**

This study does not present any known ethical concerns. While the interventions for the study were used for all the nursing supervisors, participation in the study was voluntary. Confidentiality was ensured as the data from the surveys were automatically de-identified by using participant numbers instead of names. The data collection program, REDCap, maintained their assigned numbers as they completed subsequent surveys.

**Setting**

Prior to the collection of study data, Institutional Review Board (IRB) permission was obtained from the University of New Mexico Health Sciences Center (Appendix E). The study was conducted at a quaternary, acute-care, multi-campus, non-profit academic medical center in Northern California. The licensed bed count of the medical center is 562 beds. There are 3 acute-care campuses that each have a nursing supervisor on duty for evenings, nights and weekends.

**Study Population**

The study population consisted of nursing supervisors employed full-time, part-time or per diem. The participants had at least 1 year of experience in a supervisory role. The minimum 1-year supervisory requirement was chosen to ensure adequate experience in their role. At the start of the study, there were a total of 22 nursing supervisors that were employed within the department. All of the 22 nursing supervisors met the 1-year supervisory experience requirement and were eligible to participate.
Research Design

Quantitative, quasi-experimental pretest-posttest design to evaluate the effectiveness of the intervention. Prior to the start of the study, participants were asked to complete the demographics survey, the LPI and the CBSS. Following the initial assessments, the nursing supervisors participated in an educational program that focused on leadership development that was particular to their role (Appendix F). The program engaged the group in a variety of topics including managing complexity with difficult conversations, collaboration, inspiring and motivating, and leading and enabling a team.

During the program, the nursing supervisors were integrated into more of the operational functions of the overall nursing leadership team. Given the ongoing operational demands of the medical center during COVID-19 surges on top of periods of high census, the nursing supervisors often met with senior nursing leaders for additional planning calls during the off-hours. In addition to these measures, the Chief Nursing Executive or Senior Nursing Executive attended each of their monthly staff meetings.

Within the 14 days following the completion of the program, the nursing supervisors completed both the LPI and CBSS, as well as three qualitative questions regarding the program. To assess the sustained effects of the program on the nursing supervisor’s self-perception of their leadership practices and collaborative behaviors with the entire nursing leadership team, the LPI and CBSS were repeated at 2 months post completion of the program.

Statistical Analysis

Given the small sample size, non-parametric statistical testing was used for the data analysis. The Wilcoxon Signed-Rank test was used to compare ranks between the pre- and post-tests for the LPI and the CBSS. A sensitivity power analysis using G*Power was conducted prior
to the start of the study. A Wilcoxon Signed-Rank test with an estimated 15 participants would be sensitive to effects of Cohen’s $d = 0.80$ with 80% power ($\alpha = 0.05$, two-tailed). Therefore, any statistically significant findings in the study would need an effect size of 0.80 or greater.

Additionally, descriptive statistics for the demographic data will be presented.

**Budget**

The costs associated with this project were absorbed within the hospital operating budget for the nursing supervisors. Each of the supervisors were compensated from their education time for participation in both the self-learning modules and group discussions. The LinkedIn Learning modules were provided as part of a subscription already held by the organization. Facilitation of the group discussions were conducted by salaried employees within the organization.

**RESULTS AND DISCUSSION**

**Results**

This study had an initial participation rate of 86% with a small sample size ($n=19$). Following the program, only 45% of the participants completed the post-program surveys ($n=10$). At 2 months following the program, those 10 participants were invited to complete the 2-month follow-up surveys with a participation rate of 23% ($n=5$).

The demographics of the group are presented in Table 1. Seventy-nine percent of the sample were female ($n=15$), while 21% ($n=4$) were male. The ages of the supervisors ranged from 30-64 years old, with 26% of the group falling in the 45-49 year range. Approximately 37% were less than 45 years and 37% were older than 49 years of age.
Table 1

Demographics

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The group’s experience in nursing ranged from less than 10 years to greater than 40 years. Five of the supervisors (26%) had been a nurse less than 10 years. More than half of the group (63%) had been a nurse less than 20 years. The remaining 7 supervisors (37%) had been a nurse more than 20 years, with one of them being a nurse for more than 40 years.

When analyzing the pretest/posttest scores of the LPI, the scores of the 10 participants completing both surveys were analyzed within the five categories of the scale. Posttest mean scores decreased in 3 of the 5 subscales. ‘Challenges the Process’ and ‘Encourages the Heart’
both had small effect sizes while the decrease of ‘Models the Way’ had a medium effect size.

Minimal mean increases were seen ‘Inspiring a Shared Vision’ and ‘Enabling Others to Act’ with small effect size. All observed T statistics were larger than the critical value for T, indicating no statistically significant differences in any of the subscales (see Table 2).

Table 2

Pre-Post Comparisons for the Collaborative Behavioral Scale-Shortened (CBSS) & the Leadership Practices Inventory (LPI)

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
<th>Pre/post difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M</td>
<td>SD</td>
<td>M</td>
</tr>
<tr>
<td>CBSS (n = 9)</td>
<td>23.22</td>
<td>7.38</td>
<td>21.67</td>
</tr>
<tr>
<td>LPI (n = 10)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Challenges the Process</td>
<td>21.7</td>
<td>3.59</td>
<td>21.1</td>
</tr>
<tr>
<td>Inspiring a Shared Vision</td>
<td>20.8</td>
<td>4.49</td>
<td>21</td>
</tr>
<tr>
<td>Enabling Others to Act</td>
<td>24.5</td>
<td>2.42</td>
<td>24.6</td>
</tr>
<tr>
<td>Models the Way</td>
<td>24.2</td>
<td>2.82</td>
<td>22.6</td>
</tr>
<tr>
<td>Encourages the Heart</td>
<td>23.3</td>
<td>3.23</td>
<td>22.5</td>
</tr>
</tbody>
</table>

<sup>a</sup>Wilcoxon T statistic
<sup>b</sup>Critical value for Wilcoxon T statistic
*<i>p</i> < .05, **<i>p</i> < .01, ***<i>p</i> < .001

For the CBSS, there was 90% participation in both the pre- and post-surveys of the 10 participants. There was an overall decrease in mean score from 23.22 to 21.67 with medium effect size (r=0.33). The T statistic was larger than the critical T value, indicating no statistically significant findings.

The comparison of the post-program and 2-month follow up scores were analyzed using the five categories of the LPI. The mean score of each subscale increased in the 2-month follow up, although none of the findings were statistically significant. ‘Inspiring a Shared Vision’ had the smallest increase with a small effect size. The ‘Challenges the Process’ subscale had a
medium effect size, while the remaining three, ‘Enabling Others to Act,’ ‘Models the Way,’ and ‘Encourages the Heart’ all had large effect sizes.

Table 3

Post/2-month post Comparisons for the Collaborative Behavioral Scale-Shortened (CBSS) & the Leadership Practices Inventory (LPI)

<table>
<thead>
<tr>
<th></th>
<th>Post</th>
<th>2 months post</th>
<th>Post/2m post difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M</td>
<td>SD</td>
<td>M</td>
</tr>
<tr>
<td>CBSS (n = 5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Challenges the Process</td>
<td>20.6</td>
<td>4.1</td>
<td>23.4</td>
</tr>
<tr>
<td>Inspiring a Shared Vision</td>
<td>20</td>
<td>3.94</td>
<td>21.6</td>
</tr>
<tr>
<td>Enabling Others to Act</td>
<td>23.6</td>
<td>3.51</td>
<td>25.4</td>
</tr>
<tr>
<td>Models the Way</td>
<td>22.2</td>
<td>3.7</td>
<td>24.8</td>
</tr>
<tr>
<td>Encourages the Heart</td>
<td>21.6</td>
<td>4.51</td>
<td>25.4</td>
</tr>
</tbody>
</table>

*a Wilcoxon T statistic  
*b Critical value for Wilcoxon T statistic  
*p < .05, **p < .01, ***p < .001

In reviewing the 2-month post-program comparison, there was an overall increase in CBSS mean score from 20.6 to 23.4 with a large effect size (0.73). Given the low response rate to the follow up survey, the sample size was not large enough to yield any statistically significant results.

During the analysis of the qualitative comments post intervention, the most common theme observed was related to the participants satisfaction with taking the time to meet and collaborate with their colleagues. Comments regarding the content of the video was mixed, both positive and constructive. One user wrote, “The online LinkedIn Learning classes was a great educational tool. It was nice to see different point of views regarding leadership.” Another user wrote, “Some of the content and examples didn’t apply to healthcare.” Most of the nursing supervisors were able to articulate specific practices that they were able to change following the
education to better their practice. Some of these changes included acknowledging staff, listening, being more empathetic and active problem solving.

**Findings**

The initial results following the program indicated that there was no statistically significant difference in the nursing supervisor’s self-perception of their leadership practices as well as collaboration with the nursing leadership team. Scores on the CBSS as well as three of the five scales of the LPI had decreases following the educational intervention. Both ‘Inspiring a Shared Vision’ and ‘Enabling Others to Act’ both had slight increases that were not statistically significant. Despite no statistically significant findings, there were some other observed themes in the study.

The nursing supervisors had the highest rated scores in the themes of treating others with respect and practicing the values that they believe. Other high scoring leadership practices included asking what can be learned as well as creating an atmosphere of trust. The lowest scores in the leadership practices were in sharing future dreams, enlists a common vision, and excitement for the future.

In the 2-month follow up, despite low participation, the scores in each of the categories increased in both the LPI and the CBSS. While these findings were encouraging, the $n$ was too small to determine any statistically significant findings. Despite this, these increases may be clinically significant for the nursing supervisors. Some of the largest overall increases seen 2 months after the program was in celebrating milestones and wins, enlisting a common vision, and telling others about their group’s work.
Discussion

The role of the nursing supervisor is critical to hospital operations during the evening, night, and weekend shifts. To carry out the mission and vision of nursing, the nursing supervisors must collaborate well with the rest of the nursing leadership team. Additionally, understanding the roles and responsibilities of the nursing supervisor may clarify expectations and improve collaboration between the nursing supervisors and nursing managers.

There is existing research describing the roles and responsibilities of the nursing supervisors, as well as their commitment to patient and staff safety (Weaver & Lindgren, 2016; Weaver & Lindgren, 2017; Glasofer & Lapinsky, 2019; Weaver, et al., 2017). There is also research describing leadership programs for this population (Weaver, et al., 2019; Manning, 2016; Abraham, 2011). This study aimed to fill in a gap of limited research examining both the nursing supervisor role as well as collaboration between the nursing supervisors and nursing management team. While this project demonstrated some qualitative benefits of structured education and team building, there are a number of factors that may have contributed to the lack of statistically significant findings to apply to future practice.

Implications for Practice

Both the quantitative and qualitative findings of the study validate the need for ongoing development activities and education for nursing supervisors. This is especially important for this group of leaders that have not only been isolated throughout the COVID-19 pandemic, but also inherently isolated due to the nature of their work schedules, as they are often present when other nursing leaders are not working. The shorter duration of the intervention in this study may have contributed to the lack of statistically significant findings, so a program of a longer duration may be more effective. Additionally, lengthening the program along with added follow up and
mentoring might increase buy-in and have the supervisors more participative than a brief program.

Given that collaboration and leadership skills are valuable to the success of individual leaders as well as the organization, expanding this type of program to any leaders in the organization may be beneficial.

**Strengths and Limitations of the Study**

A primary strength of this study is that it may be one of the first studies to assess nursing supervisor’s self-perception of their leadership skills and collaboration with the leadership team before and after an educational intervention. Additional strengths include validated instruments were used for data collection. The study was easy to conduct as it occurred at three sites of one single organization. Using self-paced modules and flexible group meetings allowed more flexibility for supervisor participation. The qualitative feedback for the study was overall positive and the supervisors were appreciative of the focus on professional development of their group.

Limitations of the study include the small number of participants. While easy to complete, conducting the study at one site limited the total number of possible participants. The small number of participants in addition to findings that are not statistically significant are threats to external validity. Another limitation, related to the COVID-19 pandemic, was the inability to conduct in-person education and follow-up groups, which may have had a negative impact on the supervisor’s ability to relate to and collaborate with other members of the team. Finally, the use of LinkedIn Learning modules provided generalized education of the various leadership topics but were not specifically focused on healthcare leadership.
Suggestions for Further Research

This study could be reproduced in a similar format at a future time when in-person educational sessions and follow up could be conducted to allow the participants to have face-to-face time with their colleagues. Given that improvements in leadership practices and collaboration often take longer periods of time, it may be valuable to conduct a similar study with education and follow up over a longer period, such as a full year. Another opportunity is to conduct the study at multiple sites to ensure a larger sample size to examine the effects of the education. Further research is also needed to understand the effects of these type of virtual educational and team building programs over an extended period of time.

The study can also be replicated in a variety of settings, both inside and outside of healthcare. Leadership and collaboration skills are required for the success of businesses and other organizations. Finally, leadership training and team building can be applied across all levels of leadership, from front line managers to executives in the c-suite.

Concluding Remarks

Nursing supervisors play a critical role in hospital operations and are a vital part of the leadership team. Providing opportunities for growth and an environment of cohesiveness is required to improve collaboration between leaders. Investing in educational programs to develop their leadership skills can increase engagement, effectiveness, quality of work, job satisfaction and retention. A highly functioning and collaborative team with strong leadership skills is essential in creating a highly reliable organization that provides safe, high-quality care to our patients and community.
References


Appendix A

Demographics Survey

1. What is your sex?
   a. Male
   b. Female
   c. Prefer not to answer
2. What is your age?
   a. 25-29
   b. 30-34
   c. 35-39
   d. 40-44
   e. 45-49
   f. 50-54
   g. 55-59
   h. 60-64
   i. 65 and over
3. Number of years in nursing:
   a. <10
   b. 10-20
   c. 21-30
   d. 31-40
   e. >40
4. Number of years as a nursing supervisor:
   a. <5
   b. 5-10
   c. 10-20
   d. 21-30
   e. 31-40
   f. >40
5. Highest level of education:
   a. Associates degree
   b. Diploma
   c. Bachelor’s degree
   d. Master’s degree
   e. Doctoral degree
## Appendix B

<table>
<thead>
<tr>
<th>Leadership Practice Statement</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 I look for opportunities that will test my skills and abilities.</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>2 I describe the kind of future I want my team to create.</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>3 I involve the team in planning the action we will be taking.</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>4 I am clear about my own philosophy of leadership.</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>5 I take time to celebrate when project milestones are reached.</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>6 I stay up to date on new developments in my field or in my organisation.</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>7 I appeal to others to share my dream of what the future can be like.</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>8 I treat all members of my team with dignity and respect.</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>9 I break projects down into manageable chunks.</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>10 I recognise individuals for their contribution to the success of the team’s work.</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>11 I challenge the way people do things at work.</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>12 I communicate clearly a positive and hopeful outlook for the future of the organisation.</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>13 I give people a lot of discretion to make their own decisions.</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>14 I make sure that people stick with the values that have been agreed on</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>15 I praise people for a job well done.</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>16 I look for innovative ways the team can improve what is done for the organisation</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>17 I show others how their long term future interests can be realised by investing in the common vision</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>18 I develop co-operative relationships with the people I work with</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>19 I let others know my beliefs on how to run the team I lead.</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>20 I give team members lots of appreciation and support for their contributions</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>21 I ask ‘what can we learn’ when things do not go as expected</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td></td>
<td>Statement</td>
</tr>
<tr>
<td>---</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>22</td>
<td>I look ahead and forecast what I expect the future to be like</td>
</tr>
<tr>
<td>23</td>
<td>I create an atmosphere of mutual trust in the projects I lead</td>
</tr>
<tr>
<td>24</td>
<td>I am consistent in practising the values I believe in</td>
</tr>
<tr>
<td>25</td>
<td>I find ways to celebrate team accomplishments</td>
</tr>
<tr>
<td>26</td>
<td>I take risks with the way things are done even if there is a risk of failure</td>
</tr>
<tr>
<td>27</td>
<td>I am contagiously excited and enthusiastic about future possibilities</td>
</tr>
<tr>
<td>28</td>
<td>I get others to feel a sense of ownership for the projects they work on</td>
</tr>
<tr>
<td>29</td>
<td>I make sure that the work group sets clear goals, makes plans and establishes milestones for the projects I lead</td>
</tr>
<tr>
<td>30</td>
<td>I make a point of telling the rest of the organisation about the good work of my team</td>
</tr>
</tbody>
</table>
Appendix C

**NURSE-MANAGER COLLABORATIVE BEHAVIOR SCALE – Shortened Version**

**Directions:** The purpose of this scale is to determine the extent of collaboration behaviors which generally exist between you and the managers with whom you work. (For each statement check (✓) the one box that indicates how often you believe that each behavioral statement occurs.) There are no right or wrong answers. Please answer each item as best as you can.

<table>
<thead>
<tr>
<th>Rarely</th>
<th>Sometimes</th>
<th>Often</th>
<th>Nearly Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. We trust each one another.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. My opinions are listened to.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. I feel that my input is truly valued.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. There is a feeling of mutual regard and respect.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. We share information openly with one another.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. We recognize the need to have a sense of “give and take” in the relationship.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. We recognize our interdependence with one another to meet the unit’s goals.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. We are committed to the process of working together to meet the unit’s goals.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix D

Additional Post-Program Survey Questions

1. What did you find most beneficial about the program?

2. What did you find to be least helpful about the program?

3. How has the program changed your practice?
Appendix E

Human Research Protections Program

September 13, 2021
Christine Delucas
ADelucas@salud.unm.edu

Dear Christine Delucas:

On 9/13/2021, the HRRC reviewed the following submission:

Type of Review: Initial Study
Title of Study: The Effects of a Formal Organizational Program on Nursing Supervisor Self-Perception of Leadership
Investigator: Christine Delucas
Study ID: 21-331
Submission ID: 21-331
IND, IDE, or HDE: None

Submission Summary: Initial Study

Documents Approved: • CBSS Survey - Judy-del Rosario
  • Course Outline - Judy-del Rosario
  • Demographics Survey - Judy-del Rosario
  • Judy-del Rosario - Consent
  • Judy-del Rosario - Letter of Support
  • Judy-del Rosario - Post Survey Emails
  • Judy-del Rosario - Protocol
  • Judy-del Rosario - Recruitment email
  • Judy-del Rosario - Reminder Recruitment email
  • LPI Survey - Judy-del Rosario
  • Post-Survey Questions - Judy-del Rosario

Review Category: EXEMPTION; Categories (2)(i) Tests, surveys, interviews, or observation (non-identifiable)

Determinations/Waivers: Employees.
Provisions for Consent are adequate.
HIPAA Authorization Addendum Not Applicable.

Submission Approval Date: 9/13/2021
Approval End Date: None
Effective Date: 9/13/2021

The HRRC approved the study from 9/13/2021 to inclusive. If modifications were required to secure approval, the effective date will be later than the approval date. The
Human Research Protections Program

“Effective Date” 9/13/2021 is the date the HRRC approved your modifications and, in all cases, represents the date study activities may begin.

Because it has been granted exemption, this research is not subject to continuing review.

Please use the consent documents that were approved by the HRRC. The approved consents are available for your retrieval in the "Documents" tab of the parent study.

If the study meets the definition of an NIH Clinical Trial, the study must be registered in the ClinicalTrials.gov database. Additionally, the approved consent document(s) must be uploaded to the ClinicalTrials.gov database.

This determination applies only to the activities described in this submission and does not apply should you make any changes to these documents. If changes are being considered these must be submitted for review in a study modification to the HRRC for a determination prior to implementation. If there are questions about whether HRRC review is needed, contact the HRPO before implementing changes without approval. A change in the research may disqualify this research from the current review category. You may submit a modification by navigating to the active study and clicking the “Create Modification/CR” button.

If your submission indicates you will translate materials post-approval of English materials, you may not recruit or enroll participants in another language, until all translated materials are reviewed and approved.

In conducting this study, you are required to follow the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library.

Sincerely,

Thomas F. Byrd, MD
HRRC Executive Chair

Abbreviated Investigator Responsibilities

NOTE: For a full unabridged version of the Investigator Manual, please visit the HRPO website at https://hsunm.edu/research/hrpo.

What will happen after HRRC review?
Human Research Protections Program

The HRPO will provide you with a written decision indicating that the HRRC has approved the Human Research, requires modifications to secure approval, or has disapproved the Human Research.

- If the HRRC has approved the Human Research: The Human Research may commence once all other organizational approvals have been met. HRRC approval is usually good for a limited period of time which is noted in the approval letter.
- If the HRRC requires modifications to secure approval and you accept the modifications: Make the requested modifications and submit them to the HRRC. If all requested modifications are made, the HRRC will issue a final approval. Research cannot commence until this final approval is received. If you do not accept the modifications, write up your response and submit it to the HRRC.
- If the HRRC defers the Human Research: The HRRC will provide a statement of the reasons for deferral and suggestions to make the study approvable, and give you an opportunity to respond in writing. In most cases if the HRRC’s reasons for the deferral are addressed in a modification, the Human Research can be approved.
- If the HRRC disapproves the Human Research: The HRRC will provide a statement of the reasons for disapproval and give you an opportunity to respond in writing.

In all cases, you have the right to address your concerns to the HRRC directly at an HRRC meeting.

What are my obligations after HRRC approval?
1. Do not start Human Research activities until you have the final HRRC approval letter.
2. Do not start Human Research activities until you have obtained all other required institutional approvals, including approvals of departments or divisions that require approval prior to commencing research that involves their resources.
3. Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
   a. Delegate responsibility to the research staff in accordance with the staff’s training and qualifications.
   b. Assure that all procedures associated with the research are performed, with the appropriate level of supervision, only by individuals who are licensed or otherwise qualified to perform them under the laws of New Mexico and policies of The University of New Mexico Health Sciences Center.
   c. Monitor the research study and perform quality management activities to ensure the protection of participants and the quality of the research data.
4. Obtain the legally effective informed consent from human participants or their representatives, using only the currently approved informed consent documents, and
Human Research Protections Program

provide a copy to the participant, if applicable. a) Ensure that only HRRC-approved investigators obtain informed consent from potential participants.

5. If unavailable to conduct the research personally, as when on sabbatical leave or vacation, arrange for another HRRC-approved investigator on the study to assume direct responsibility or notify the HRRC of alternate arrangements.

6. Maintain accurate and complete research records, including but not limited to, original signed informed consent and authorization documents, and retain these records according to HRRC policy and the applicable regulatory retention terms.

7. Fully inform the HRRC of all locations in which human participants will be recruited for this project and obtain and maintain current HRRC approvals/letters of cooperation when applicable.

8. Ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.

9. Update the HRRC office with any changes to the list of study personnel.

10. Personally conduct or supervise the Human Research.

   a. Conduct the Human Research in accordance with the relevant current protocol as approved by the HRRC.

   b. When required by the HRRC, ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the HRRC.

   c. Do not modify the Human Research without prior HRRC review and approval unless necessary to eliminate apparent immediate hazards to participants.

   d. Protect the rights, safety, and welfare of participants involved in the research.

11. Submit to the HRRC:

   a. Proposed modifications as described in this manual. (See “How do I submit a modification?”)

   b. A continuing review application as requested in the approval letter. (See “How do I submit continuing review?”)

   c. A continuing review application when the Human Research is closed. (See “How Do I Close Out a Study?”)

12. Report any of the information items listed in Appendix A-1 to the HRRC within five business days.

13. Submit an updated disclosure of financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

14. Do not accept or provide payments to professionals in exchange for referrals of potential participants (“finder’s fees.”)

15. Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments.”)

16. See additional requirements of various federal agencies in Appendix A-2 through A-9 of the Investigator Manual. These represent additional requirements and do not override the baseline requirements of this section.
Human Research Protections Program

If the HRRC directs or your study is selected for an onsite post-approval review, cooperate with HRPO Quality Improvement program staff to complete it.

Research Data and Study Records
Researchers and staff should have systems or practices for maintaining the essential Research Records that they create in order to be able reasonably to support research findings, justify the uses of research funds and resources, and protect any resulting intellectual property.

During the life of a study and beyond its closure, many information security and storage policies pertain to the maintenance and archival of study documents and research data. These policies and procedures include those of the researcher’s department, UNM HSC, the State of New Mexico, Federal privacy laws (such as HIPAA, FERPA, FOIA, New Mexico IPRA), Federal regulations (FDA, OHRP, DHHS, etc) as well as the data confidentiality requirements associated with research funding (e.g. National Institutes of Health, Department of Defense (DOD), etc.).

PI responsibilities for document and data security are particularly critical during times of study transition, as when a PI is leaving UNM HSC, is transferring PI responsibilities or is closing a study. Be prepared ahead of time and discuss transition and/or long-term storage plans with your department Chair/ Research Chair. Assure that information regarding these plans are documented in a standard place and are using an established process, so that an incoming PI and department personnel can find, understand and follow it.

Appendix A-1 Reportable New Information
Report information items that fall into one or more of the following categories to the HRRC within 5 business days. Reference SOP: New Information (HRP-024).

1. Information that indicates a new or increased risk, or a new safety issue, for example:
   a. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
   b. Protocol violation that harmed participants or others or that indicates participants or others might be at increased risk of harm.
   c. Complaint of a participant that indicates participants or others might be at increased risk of harm or at risk of a new harm.
   d. An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk.
   e. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.
Human Research Protections Program

f. Changes significantly affecting the conduct of the clinical trial or increasing the risk to participants.

2. Harm experienced by a participant or other individual, which in the opinion of the investigator are unexpected and related or possibly related to the research procedures.
   a. A harm is "unexpected" when its specificity or severity are inconsistent with risk information previously reviewed and approved by the HRRC in terms of nature, severity, frequency, and characteristics of the study population.
   b. A harm is "related or possibly related" to the research procedures if, in the opinion of the investigator, the research procedures more likely than not caused the harm.

3. Non-compliance with the federal regulations governing human research or with the requirements or determinations of the HRRC, or an allegation of such non-compliance.

4. Failure to follow the protocol due to the action or inaction of the investigator or research staff.

5. Change to the protocol taken without prior HRRC review to eliminate an apparent immediate hazard to a participant.


7. Complaint of a participant that cannot be resolved by the research team.

8. Premature suspension or termination by the sponsor, investigator, or institution.

9. Incarceration of a participant in a study not approved by the HRRC to involve prisoners.

10. Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g., FDA Form 483).

11. Written reports of study monitors.

12. Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of participants).

13. Unanticipated Problems Involving Risks to Subjects or Others, including any event or problem that is serious, unexpected, and related to the research, where "related" means the event or problem might reasonably be regarded as caused by, or probably caused by, the research.

14. Disciplinary action against the investigator or research staff by federal, state, and local regulatory agencies.
Appendix F

Course Outline

1. Collaboration

2. Managing Complexity

3. Inspires and Motivates

4. Leading and Enabling the Team
   b. Leading from the Middle  https://www.linkedin.com/learning/leading-from-the-middle/build-relationships-and-trust?u=44911804