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Implementing an Intervention to Reduce Seclusion and Restraints in an Inpatient Psychiatric Hospital

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By

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Abstract

The need to enhance nursing staff's knowledge, perceptions and attitudes around alternatives to seclusion and restraint has been well validated in the literature. Seclusion and restraint use in the inpatient psychiatric setting are highly dangerous physical interventions, used to control the behavior of a mentally ill patient who is a danger to self or others. Seclusion and restraint events have the potential to cause emotional trauma, physical injury to patients or staff and the possibility of patient death. The purpose of the capstone project was to implement an evidence-based education program to, improve nursing staff's (RN, LPN, MHA and SRNA) knowledge and attitudes of alternatives to seclusion and restraint in an inpatient psychiatric setting. As part of annual mandatory education requirements for the agency, thirty-five nursing staff (MHA,SRNA, LPN, and RN) participated in the project and completed the 3 hour course, *CPI: "How To" Strategies for Intervening With Challenging Individuals;* including pre and post measures, CPI Knowledge Assessment and Reducing Seclusion and Restraint Organizational Questionnaire (RSROQ); assessing perception and attitudes. Results of the project indicated, significant increases in knowledge of alternatives to seclusion and restraint in MHA/SRNA's and RN/LPN's from baseline. RN/LPN's had significant increases in the attitude subscore of the RSROQ and total RSROQ score.

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Implementing an Intervention to Reduce Seclusion and Restraints in an Inpatient Psychiatric Hospital

Seclusion and restraint use in the inpatient psychiatric setting are highly dangerous physical interventions, used to control the behavior of a mentally ill patient who is a danger to self or others. Seclusion and restraints are considered a last resort when de-escalation interventions by staff have not succeeded in controlling a patient's behavior. Seclusion and restraint events have the potential to cause emotional trauma (Freuh, Knapp, Cusck, Grubaugh, Sauvegeot, Cousins, Yim, Robins, Monnier & Hiers, 2005), physical injury to patients or staff and the possibility of patient death (Azeem, Aujila, Rammerth, Binsfeld & Jones, 2011).

Context of the Problem

Seclusion and restraint are currently, universally viewed as a high-risk practice, although widely used throughout history (Lewis, Taylor & Parks, 2009). The National Association of State Mental Health Directors (NASMHD) and the Research Institute (NRI) data from 2002 - 2009, reported data from approximately 200 facilities identifying in any given month approximately 3.5% to 4.0% of patients were restrained and 2.2% to 2.8% were secluded (NRI, 2010). It is estimated that each year in the United States, 50 to 150 individuals die as a result of being in seclusion or restraints in mental health inpatient facilities with many more injured or traumatized by these events (Weiss, Altimari, Blint & Megan, 1998).

Scope of the Problem

The need for the reduction and elimination of the use of seclusion and restraint is not a new issue of concern. The use of seclusion and restraint was brought to national attention after a Sentinel Alert was issued in 1998 by the Joint Commission regarding the use of seclusion and restraints in the behavioral health setting. The Sentinel alert prompted many state and federal

agencies to examine the rules and regulations around the use of restraints and a subsequent push from the federal government and the Joint Commission and the National Association of State Mental Health Program Directors (NASMHPD) to eliminate the use of seclusion and restraints in the psychiatric setting (Joint commission, 2002; Substance Abuse and Mental Health Services Administration, 2006). Although the risks of psychological and physical harm associated with the use are known, seclusion and restraint continue to be used.

Consequences of the Problem

Seclusion and restraints were once viewed as an intervention that created a safe and secure environment for patients and staff, though the literature contradicts this viewpoint. The economic burden of seclusion and restraints use is extremely high for both the patient and staff member. Multiple studies have found seclusion and restraints inflict psychological harm, physical injury and death for not only the patient who is being subjected to the intervention but the staff applying the intervention, while providing no therapeutic benefit (Weiss et al., 1998; Huckshorn, 2006; NASMHPD, 2009, Happell & Harrow, 2010; Moylan & Cullinan, 2011). Staff are at risk for personal injury, psychological effects, and even death (Pollard, Yanasak, Rogers & Tapp, 2007). Injuries to staff members of all types, including psychological, have the potential to contribute to organizational disruptions and workforce instability, including recruitment and retention (Unruh, Joseph & Strickland, 2007). The potential for the risk of injury during a seclusion and restraint event increases stress and anxiety levels in staff. Staff may also be unprepared emotionally to deal with seclusion and restraint events. According to Bonner, Lowe, Rawcliffe and Wellman (2002), staff members often feel personal discomfort and distress in implementing physical restraint that can be described as traumatic. Staff members in physical restraint situations are not only forced to deal with their own, often strong emotions,

including fear but their need for self-preservation (Bigwood & Crowe, 2008). The psychological and emotional impact after an incident may even reach the level of post-traumatic stress disorder in some staff members. According to Moylan and Cullinan (2011), the traumatic impact of such events, as seclusion and restraint remains underreported, undetected and undertreated. Staff members have reported both positive and negative feelings after events of seclusion and restraint. Negative feelings of frustration, guilt, anger and a sense of failure have been reported but conversely positive feelings of satisfaction in helping the patient and maintaining control of the ward have been reported (Happell & Koehn, 2010).

Patients who are secluded and restrained may be traumatized or re-traumatized as a direct result of the experience, which can result in longer lengths of stay (Frueh et al., 2005; Calkins & Corso, 2007). Patients who have experienced seclusion and restraint have recounted the event as traumatic (Frueh, et al., 2005).The cost to the patient can go beyond the effects of trauma and have further effects on interpersonal relationships, mistrust of the health care system and care providers. Additionally the time and attention of staff consumed by the patient in seclusion and restraints decreases the time available to care for other patients (NASMHPD, 2009). The decision by staff to seclude and restrain a mentally ill patient whose behavior has become uncontrollable must involve the balance between the potential traumatic nature of seclusion and restraint, the restriction of the patient's autonomy, with the need to maintain a safe environment for all patients and staff in the milieu (Hellerstein, Staub & Lequesne, 2007).

In behavioral health settings, exceedingly high rates of patients with trauma histories have been reported among psychiatric patients. Goodman, Rosenberg and Mueser (1997) report ninety percent of public mental health clients have been exposed and experienced multiple exposures of trauma. The majority of clients served in public mental health have histories with

sexual abuse, physical abuse, including child abuse and neglect, and the witnessing of interpersonal violence in childhood onward (Rosenberg, 2011). Mental health professionals inadvertently perpetuate the cycle of trauma for psychiatric patients by responding to the escalation of behavior though the use of seclusion and restraints often re-traumatize individuals (National Association of State Mental Health Program Directors, 2009).

Evidence-based Intervention

A systemic approach should be used which ensures all people who come in contact with the behavioral health system receive services sensitive to the impact of trauma (Rosenberg, 2011), with emphasis on the use of interventions, rather than the use of seclusion and restraint. The literature supports a multitude of interventions, with a key focus on the reduction of seclusion and restraint. The implementation of staff training, based on concepts around the trauma-informed approach from the National Association of State Mental Health Directors, utilizing the six core strategies in reducing seclusion and restraint, have been implemented in a number of studies with great success in decreasing the incidence of seclusion and restraint (Ashcraft & Anthony, 2008; Barton, et al., 2009; Azeem et al., 2011; Borckardt, Madan, Grubaugh, et al, 2011).

Purpose of the Project

The purpose of this project was to implement an evidence-based education program specific to the use of seclusion and restraints in an inpatient psychiatric setting. The objectives of the program were:

1. To improve nursing staffs (RN, LPN, MHA & SRNA) knowledge of alternatives to seclusion and restraint in an inpatient psychiatric setting and,

2. To improve nursing staff's attitudes of alternatives to seclusion and restraint in an inpatient psychiatric setting.

Theoretical Framework: The Theory of Planned Behavior

Nurses, including those in psychiatric nursing are faced with making educated decisions on a daily basis in the assessment and care of their patients'. The theory of planned behavior proposed by Icek Ajzen (1985) links an individual's beliefs with an individual's behavior. The theory of planned behavior is an extension of the theory of reasoned action, proposed by Martin Fishbein and Icek Ajzen (1975). The theory of planned behavior became necessary due to the limitations of the theory of reasoned action in dealing with behaviors over which people have incomplete volitional control.

According to the theory, human behavior is guided by three considerations; beliefs about the likely consequences of the behavior (behavioral beliefs), beliefs about the normative expectations of others (normative beliefs), and beliefs about the presence of factors that may facilitate or impede performance of the behavior (control beliefs). Behavioral beliefs produce a favorable or unfavorable attitude toward the behavior. Normative beliefs result in subjective norm. Control beliefs effect perceived behavioral control. The culmination of attitude toward the behavior, subjective norm and perceived behavioral control, lead to the development of behavioral intention. According to Ajzen (1991), the more favorable the attitude toward the behavior and subjective norm and the greater the perceived behavioral control, the stronger should be the person's intention to carry out the behavior in question.

When the individual is given a sufficient degree of actual control over the behavior, the individual is expected to carry out their intentions when the opportunity arises. Therefore, intention is assumed to be the immediate precursor of behavior. However, because many

behaviors pose difficulties of execution that may limit volitional control, it is important to consider perceived behavioral control in addition to intention.

Organizing Framework: The Public Health Prevention Model

The Public Health Prevention Model's (PHPM) primary areas of focus are disease prevention and health promotion which are a logical fit and effective approach to reducing the use of seclusion and restraints (NASMHPD, 1999; Huckshorn, 2004). The concept of identifying risk factors for conflict and violence and early intervention strategies, makes this model applicable to seclusion and restraints. This model addresses minimization of conflicts, identification and resolutions of situations as they occur and knowledge acquisition of prevention strategies after incident analysis when incidents do occur.

The PHPM framework constructs of primary, secondary and tertiary prevention interventions guide in framing reduction activities (NASMHPD, 1999; Huckshorn, 2004). Primary prevention addresses the development of the treatment environment, both administrative and clinical. The focus of primary prevention is to minimize the potential for conflicts to occur, including policies and procedures, early risk assessments and principles of care that are trauma-informed (Huckshorn, 2004).

Secondary prevention addresses, the effective use of early interventions to ease conflict or aggression when they occur. Interventions include, staff training in areas of de-escalation techniques or methods, training focused on attitudes and behaviors when faced with a conflict situation, comfort rooms and individually developed crisis plans for the patient to assist with emotional self-management (Huckshorn, 2004, NETI, 2005).

Tertiary prevention interventions address the most effective way to minimize the harm done to consumers, staff and others witnessing a seclusion or restraint event. Interventions

include, granting the earliest possible release from seclusion or restraints, event debriefings with both the staff involved and the patient, patient comment cards and problem solving activities as well as identification of those who may require treatment for trauma (LeBel, et al., 2004; Huckshorn, 2004). According to the National Executive Training Institute (2003), prevention is the essential focus of the Public Health Prevention Model, to seclusion and restraint reduction. For the purposes of this project, the evidence-based education intervention will focus on primary and secondary prevention interventions.

Review of Literature

Initiatives to Reduce Seclusion and Restraints

Ashcraft and Anthony (2008), conducted a 58-month retrospective comparative analysis of an initiative to eliminate seclusion and restraints from the crisis center operation at two crisis centers based in Arizona, operated by META Services, from January 2000 to October 2004. The primary areas were monthly incidence of seclusion and restraints, staff time lost from injury, and chemical restraint data post-implementation.

Ninety-five staff from both centers participated in a twelve-hour training (a three-hour session each week for 4 weeks), developed by META Services. The training, based on the strategies for seclusion and restraint reduction, was devised using the training and organizational change manual developed by META Services. It is important to note, the strategies used by META Services are similar to the seclusion and restraint reduction strategies outlined by the National State Mental Health Program Directors. The strategies included as part of the initiative are (1) strong leadership direction, including policy and procedural change; (2) staff training on specific issues: Fear, hopelessness, prejudices and negative attitudes and, (3) debriefing regarding the consumer (Ashcraft & Anthony, 2008).

Training included a three-hour session on the principles of recovery, with the next three, three-hour sessions focused on the core elements of how to implement recovery into practice. Areas of focus were assisting people who were experiencing trauma and those experiencing issues related to substance abuse, using language of recovery in strength-based conversations and, ways to build resilience through self-directed treatment planning. Staff were trained on methods to empower each consumer versus having staff striving for compliance and control and giving patients as much control and responsibility as possible for their own lives and behavior as a key to eliminating seclusion and restraint (Ashcraft & Anthony, 2008).

Reduction in seclusion and restraint use was documented for both centers with a significantly greater reduction in the smaller center. The smaller center also achieved significant reduction in staff injuries related to patient seclusion and restraint (15 to 5), while the larger one remained relatively unchanged (9 to 8). There was no increase in chemical restraint usage observed following the initiative implementation. The authors concluded, the development, implementation, and evaluation of this initiative suggests that elimination is of seclusion and restraint, rather than reduction is a legitimate goal (Ashcraft & Anthony, 2008).

Borckardt, et al. (2011), conducted a randomized control study to examine the effect of a systematic implementation of behavioral interventions on the rate of seclusion and restraint in an inpatient psychiatric hospital over a 3.5 year period (total of 89,783 patient-days). Utilizing the engagement model (an adaptation from the work of Sandra Bloom), components of the intervention included trauma informed care training, changes in rules and language, patient involvement in treatment planning and changes to the physical characteristics of the therapeutic environment. Five inpatient units were randomly assigned to implement the intervention components at different stages.

All unit staff attended a half-day training seminar for each of the components in the intervention with focus on the nature of trauma and the effects on the patients' experiences, physiology, and psychological processes with direction on how to minimize engaging in behaviors that could exacerbate trauma related reactions from patients, the effect of rules and language on patients' perceptions, the rationale for and the clinical benefits of involving patients in the treatment planning. Outcome measures included perceptions of the physical environment, trauma sensitivity of the staff, and involvement of the patient in treatment planning process. Data were collected before and after each phase of the intervention rollout via the Quality of Care (QOC) measure developed by Danielson, et al. (Borckardt, et al., 2011). The rate of inpatient psychiatric seclusion and restraint (per patient day) was tracked continuously during the 3.5-year period by the investigators.

Study findings included and 82.3% reduction in use of seclusion and restraints ($p=0.008$) between the baseline phase (January 2005 through February 2006) and the follow-up, post intervention phase (April 2008 through June 2008). Unlike other interventions, changes to the physical environment were associated with reductions in seclusion and restraint rates, independent of date introduced (Borckardt et al, 2011).

Azeem, Aujla, Rammerth, Binsfeld and Jones (2011), evaluated the effectiveness of six core strategies based on trauma-informed care, developed by the National Association of State Mental Health Program Directors, in reducing the use of seclusion and restraints with hospitalized youth. A comparative study using retrospective medical file review of seclusion and restraint incidents for 458 inpatient youths compared with the 12-month post-implementation of the six core skills training program for staff.

The hospital staff received training in the six core strategies that are based on trauma informed care. The six core strategies for the staff training included using primary prevention principles, including awareness of the patient's trauma history, utilizing safety plans and comfort rooms, diversional activities, and de-escalation techniques (Azeem et al., 2011).

Findings supported a downward trend in number of seclusion and restraint edisodes and present change among hospitalized youth after implementation of National Association of State Mental Health Program Directors six core strategies based on trauma informed care (Azeem et al., 2011).Barton, Johnson and Price (2009), evaluated the effectiveness of using trauma-informed care principles, patient-centered care and the Mental Health Recovery Model in eliminating restraint use on a 26 bed-adult behavioral health unit in a 248 bed private, non-community hospital in Pennsylvania. Two team members from the community hospital attended the three-day National Executive Training Institute (NETI) program for the reduction of seclusion and restraint. NETI training became the basis for implementation timeline (18 months) and staff training presentations. The presentations included childhood trauma, trauma theory, statistics of trauma cases, neurobiological effects of trauma and changing culture. (Barton et al., 2009).

Retrospective audits of patient related data on rates of restraint and administration of sedative-hypnotic medications were obtained across a 3 year period with audits pre-training (2001-2002) and continuing into 2004-2005 and post training (2007-2008). The investigators found the incidence of restraint reduced from 19 in 2001-2002 (pre-training) to 9 in 2004-2005, and to zero for 2007-2008 audits (post-training). The investigators concluded, through the application of person-centered, recovery-oriented, and trauma informed care principles by unit

staff makes the goal of a restraint free environment possible. They also concluded it appears to reduce the need for sedative-hypnotic medication to control behavior (Barton et al., 2009).

Wisdom, Wenger, Robertson, Van Bramer and Sederer (2015), evaluated the outcomes of the Positive Alternatives to Restraint and Seclusion (PARS) project with the goal of reduction of the use of seclusion and restraints. Three facilities participated in an in-depth intervention that included staff training, on-site mentors, peer specialists, and on-site consultation from the National Association of State Mental Health Program Directors (NASMHPD) Office of Technical Assistance. The intervention included implementation of NASMHPD's Six Core Strategies to Reduce the Use of Seclusion and Restraint. The main area of focus was leadership toward organizational change with leaders partnering with staff and youths to implement the other core strategies: workforce development, devising tools to prevent use of restraint and seclusion, consumer involvement, use of data to inform change, and post-event debriefing (Wisdom et al., 2015).

The intervention included the facility leaders receiving extensive training on the Six Core Strategies to Reduce the Use of Seclusion and Restraints with development of an action plan. The NASMHPD provided two-day training sessions focused on the core strategies for all disciplines, including nursing, psychiatry, psychology, social work, and paraprofessional staff. Topics covered during the training included, identification of risk factors, understanding aspects of trauma and trauma-informed care, recovery oriented and person-centered care, strategies for changing interactions between staff members and patients from coercive to collaborative, proactive violence prevention, and use of sensory modulation and comfort rooms. Facility 2 staff received training in dialectical behavior therapy and the sanctuary model as well.

Linear regressions determined the strength of the rate of restraint and seclusion episodes per 1,000 client-days against time (2007–2011), to determine whether episodes declined during the intervention period. Based on analysis of the data, the use of restraint and seclusion was significantly reduced at all three sites over the course of the project. Facility 1, showed a decrease of 62%, from 67 to 25 (R2=.27, p=.019) in the number of incidents per 1,000 client days; Facility 2, a decrease of 86%, from 63 to 7 (R2=.50, p=.001); and Facility 3, a decrease of 69%, from 99 to 13 (R2=.29, p=.007) (Wisdom et al., 2015).

Lewis, Taylor and Parks (2009), evaluated an evidenced-based Crisis Prevention Management (CPM) program at The Henry Phipps Psychiatric Clinic, an 88 bed facility with five units, at The Johns Hopkins Hospital. The program focused on changing the culture of patient care, believed to be a necessity for seclusion and restraint reduction efforts.

A departmental committee was developed with nurses from all inpatient units. Through discussion, a vision for patient care delivery was developed. Cultural change activities included focus groups with staff to examine clinical practice, their response to patient requests, and aggression. Several nurses from each unit championed the Public Health Prevention Model reinforcing seclusion and restraint hinder patient recovery efforts and empowered their peers to become more proactive and creative with their interventions. All department staff attended a 1-day workshop with the goal to facilitate cultural change. Methods included presentations, discussion, and staff input into the development of various aspects of the model. Each program component was piloted on the five different units to reveal various design flaws and to allow staff to become more familiar with the program.

Study findings indicated a cumulative reduction in the actual hours of seclusion and restraint from 2004 through 2006 on the units. Each unit experienced a decrease in the use of

restraint ranging from 20–97%. Three of the four units had a decrease in the use of seclusion ranging from 30–63%. Outcome data reflected a reduction of 75% in the use of seclusion and restraint overall. The investigators also found there to be no increase in patient or staff injuries since the implementation of the Public Health Prevention Model (Lewis et al., 2009).

Nurses Experiences with Seclusion and Restraint

Moran, Cocoman, Scott, Matthews, Staniuliene and Valimkai (2009) utilized a qualitative research approach to examine the emotions and feelings experienced by psychiatric nurses working in Ireland in relation to incidents of seclusion and restraint. Purposive sampling identified psychiatric nurses on four wards which used seclusion and restraint as eligible participants. Twenty-three nurses participated in three focus group interviews utilizing open-ended questions.

Based on the interviews, three themes were created from the data analysis, (1) the last resort-restraint and seclusion; (2) emotional distress and; (3) suppressing unpleasant emotions. The investigators interpreted these themes as, nurses utilize seclusion and restraint as a last resort when dealing with and managing aggressive and violent patients. Nurses thus experience significant emotional distress when they are thrust into unpleasant interventions and subsequently suppress their distressing emotions to get through incidents of seclusion and restraint (Moran et al., 2009).

Bigwood and Crowe (2008) used qualitative phenomenological approach to examine mental health nurses' experiences with physical restraint in a 65 bed acute psychiatric inpatient setting. Seven nurse volunteers were guided by semi-structured interviews to respond to the following: "Describe an experience of working with a patient you have been involved in physically restraining". Supplemental questions were also used as a structure for the interview,

"Please tell me about the most recent instance where you were involved in physically restraining a patient"; "Please tell me about the first time you were involved in physically restraining a patient"; "Please tell me about the best instance of physically restraining a patient you have been involved in"; and "Please tell me about the worst instance of physically restraining a patient you have been involved in" (Bigwood & Crowe, 2008).

Study findings indicate, mental health nurses are very uncomfortable with physical restraint, although they see it as an integral part of their role. With physical restraint, the nurses experienced both conflict and fear with the restraint and would take preference to utilization of alternative de-escalation techniques if possible. The nurses also felt conflict in, the need to control, maintaining therapeutic relationships and feelings of being scared in situations where they no longer felt in control. Personal values, feelings and professional beliefs were problematic for the participants and they identified physical restraint as sometimes traumatic. The participants were aware of the detrimental effects physical restraint had on patients and themselves (Bigwood & Crowe, 2008).

Suen, et al. (2006) employed quantitative methods to examined levels of knowledge, attitudes and staff practices in the use of restraints in rehabilitative settings, and the direct and indirect effects of factors that influenced these practices. A convenience sample composed of 80% of the licensed nurses and healthcare assistants (HCAs) employed at two rehabilitation centers in Hong Kong was recruited (N=209). A questionnaire was used to assess levels of knowledge, attitudes and practices of staff regarding physical restraints (Suen et al., 2006).

Study findings indicated inadequate knowledge (mean = 5.93, median = 6.00, SD = 1.99) related to risks and outcomes of restraint use. A score of 11 represented 100% correct responses. Negative attitudes results, ranged from 21 to 39, with a maximum possible score of 48, (median

= 31.00, SD = 3.41) with many realizing a loss of dignity for persons when restraints are applied. Nursing staff believed that good alternatives to restraints are not available and they underestimated the physical and psychological impact of restraints on patients. The investigators also found nursing staff attitudes with clinical experiences had positive direct effects on restraint use. Nursing staff's level of knowledge and clinical experience had a positive indirect effect on practice by influencing attitudes (Suen et al., 2006).

Patient experiences with Seclusion and Restraint

Soininen et al. (2013) explored patients' perceptions of their treatment in the hospital after a seclusion or restraint episode at three hospitals in Finland. Patients who met inclusion criteria (between 18-65, Finnish language spoken, secluded or restrained during their current hospital stay and written informed consent). Of the 307 patients secluded or restrained, 149 meet inclusion criteria and 90 questionnaires were eligible for analysis (55 men, 35 women). Results indicated patient's overall dissatisfaction with treatment following a seclusion and restraint episode. Although patients perceived enough attention from staff and their opinion could be communicated, patient communications were not taken into consideration (Soininen et al., 2013).

A similar qualitative study by Kontio et al. (2012) explored inpatient psychiatric patients' experiences and suggestions for improvement in seclusion/restraint practices. Patients from Six acute closed wards in two psychiatric hospitals in Southern Finland were recruited for the study if restrained or secluded during the study period (120 of 789 total patients). Thirty one patients met study criteria and consented to respond to open ended interview questions. The results from 30 interviews were analyzed. Findings supported the patient perspective of insufficient attention during seclusion/restraint episodes, including not receiving enough information about their situation, treatment and plans for what would happen next. Patient suggestions for improvements

and alternatives focused on being provided humane treatment by all clinical staff even during seclusion/restraint and alternatives with a focus on empathetic patient-staff interactions.

Larue et al. (2013) also described the perceptions of patients regarding application of the seclusion and restraint protocol in a psychiatric hospital in Montreal with additional focus on circumstances and conditions the patient perceived as either helpful or harmful in the seclusion and restraint process. Twenty-eight of the 50 patients restrained and included in the study indicated staff did not offer alternatives to seclusion and restraint. Patients also noted three categories of preventive interventions prior to loss of control could reduce the incidence of SR: relational interventions between patient and staff, pharmacological interventions, and environmental interventions. Patients' perceived that the health care team did not follow-up (1.61, SD = 1.08), with the patients after the experience. Follow-up is essential for piecing together a confusing event (Larue et al., 2013).

The literature identifies negative physical and emotional experiences for patients, nurses and staff with implementation of seclusion and restraint in impatient psychiatric care environments. Evidence-based education programs specific to the use of seclusion and restraints have resulted in increased knowledge of alternatives to seclusion and restraint use and a reduction in use of seclusion and restraints post educational intervention. This project implemented an evidence-based education program based on the six core strategies in reducing seclusion and restraint from the National Association of State Mental Health Directors, to improve nursing staff's (RN, LPN, MHA and SRNA) knowledge and attitudes of alternatives to seclusion and restraint in an inpatient psychiatric setting.

Agency Description

Setting

The capstone project was implemented at a 239- bed, inpatient acute psychiatric hospital in the east south-central region of the United States. The agency is the second oldest psychiatric hospital in the United States. The agency provides recovery-focused, individualized acute care mental health services for adults (age 18 and over) with severe and persistent mental illness who live in the 50 counties surrounding and including Fayette County, Kentucky. The agency is comprised of 7 acute care units, 5 of which are currently in use and a 2-unit, Long Term Care Facility. The geriatric unit provides care for adults age 55 or older who exhibit a disturbance in functioning that requires both 24-hour supervision and management and intense, skilled nursing care and stabilization. The acquired brain injury unit provides individualized, holistic, compassionate rehabilitation for individuals age 18 and over who have suffered an acute brain injury. The agency has a maximum patient capacity of 239 patients.

The mission of the agency is, to provide a full range of acute psychiatric inpatient services in the least restrictive way through, assessment, evaluation, treatment and educating patients in accordance with the best practices and evidence based standards as they exist; providing humanitarian treatment that respects the dignity and rights of each individual; extending treatment that is least restrictive to the liberty of the patients; and maximizing patients' opportunities for return to the community and community involvement. The vision of the agency is to create an environment of care that promotes hope and expeditious recovery from symptom burden; to emphasize each patient's strengths and improve their success in overcoming the challenges of mental illness; and to maximize each client's social adjustment, satisfaction with life, and freedom of choice.

Target Population

The population for this project was nursing staff at the agency who provide direct patient care. Roles included in the population are registered nurses (RN), licensed practical nurses (LPN), mental health associates (MHA) and state registered nurse aides (SRNA). The ESH nursing department utilizes a team nursing approach with 2-3 nurses (at minimum, 1 RN to supervise) on a unit and a variable number of MHA's dependent on day-to-day patient needs. Day-to-day care is provided by both nurses and MHA's. For the purposes of this project, RN's, LPN's, MHA's and SRNA's hired prior to January 1, 2016 were recruited, as all nursing roles provide support and intervention during patient crisis situations with the potential for seclusion and restraint. CPI recertification is an annual requirement for staff hired prior to January of each year. Staff hired after January 1, 2016 completed an initial 8-hour training during hospital orientation in 2016.

Project Design

The evidence-based practice project utilized a pre-and-post- test design. The project included CPI Knowledge questionnaire and an Organizational Questionnaire for Reducing Seclusion and Restraint (RSROQ). The organizational questionnaire was used to assess nursing staff's perceptions of use of seclusion and restraint and the activity agency has implemented to reduce and/or eliminate seclusion and restraint use.

Project Methods

Description of Evidence-Based Intervention

Current Nursing staff at the agency hired prior to January of 2016, were required to complete a 3-hour re-certification on a selected topic in *CPI: Non-Violent Physical Crisis Intervention* with 1 ½ hours dedicated to didactic and 1½ hours dedicated to the non-violent

physical intervention techniques. Continued certification is a requirement of continued employment at the agency. The topic for the re-certification class was selected by CPI certified instructors at the agency based on areas identified as needing education for current clinical and nursing staff. Attending the course and completing a pre and post-test are required components of the program, to receive credit for completion. Although it was a requirement for employment to attend the course and complete the required tests, it was not a requirement for employment to allow the project leader to collect and analyze data for use in the evidence based project.

The focus of this project was the 3-hour re-certification course for current nursing staff, with the focus on *CPI: Non-Violent Physical Crisis Intervention* with the chosen topic of *"How to" Strategies" for Intervening with Challenging Individuals*. The didactic content was provided by the Crisis Prevention Institute with supplemental content developed by the agency education department and taught by the project leader. The supplemental content focused on trauma-informed care. The agency provided the workbooks for each participant of the class who has registered. The project leader was granted permission to use the CPI copyrighted training materials including the DVDs.

IRB Approval.

Exempt approval by the University of Kentucky, Institutional Review Board (IRB) was granted on July 11, 2016; prior to initiation of the capstone project (Appendix B). Once IRB approval was granted from the University of Kentucky, the approval letter and required documents were submitted to the Eastern Kentucky University IRB and an authorization agreement with Eastern Kentucky University was granted.

Recruitment.

Nursing staff were offered 21 opportunities during the project timeline to schedule the required class through the electronic training system provided by the agency. The available dates were sent to staff via flyer postings on their units and through information provided in the hospital weekly newsletter. The project leader sent an e-mail to those who had registered for the sessions, inviting them to participate in the evidence-based project including the consent cover letter. The e-mail was sent 5 days and 2 days prior to the scheduled session.

Pre/Post Intervention.

Nursing staff were handed an envelope including the IRB approved consent cover letter, a CPI participant workbook, a CPI Knowledge pretest, the pre-RSROQ and the post-RSROQ. The CPI Knowledge post-test is included as part of the participant workbook. The trainee was given the option to either participate or not participate in the project. Attending the course and completing a pre/post-test were required components of the program, to receive credit for completion. Participation in the data analysis for the evidence-based project was voluntary. Project data collection instruments were labeled with a unique number on a removable white label. The labels on the pre/posttest were placed over the name field. The participant number on the pre-tests matched the number on the post-tests. Trainees choosing not to participate in the project were asked to draw a line through the participant number on the data collection instruments. Submission of the packet to the project leader with the numeric coding intact implied consent to participate in the project.

Intervention.

Trainees participated in training lead by the PI: *CPI: Non-Violent Physical Crisis Intervention* with the chosen topic of *"How to" Strategies" for Intervening with Challenging*

Individuals. The project leader is a CPI certified instructor. The didactic content, DVD's and workbooks were purchased from Crisis Prevention Institute, for use at ESH. Trainees follow the workbook as a guide for the PowerPoint and DVD guided lecture content.

Procedures

Measures and Instruments.

"How to" Strategies" for Intervening with Challenging Individuals Pre/Post Test

The pre/post-test knowledge assessment, included as part of the *CPI* re-certification program, *"How to" Strategies for Intervening with Challenging Individuals* was created by the research and development team at *CPI* as part of this program and was included in the program purchased by the agency. The measure was developed by the statistical experts and creators of the *CPI: Non-Violent Crisis Intervention* program. The measure consists of 7 items; 3 questions requiring a written response from the participants, 2 True/False questions and 2 multiple choice questions. The post-test developed for this program will serve as the pre and post assessment of knowledge. Permission was granted by CPI for the copying of the post-test for use as a pre-test. The assessment measure is an established component of the CPI program

The Reducing Seclusion and Restraint-Organizational Questionnaire

The Reducing Seclusion and Restraint-Organizational Questionnaire is designed to assess constructs that influence organizational culture and climate including: Staff perceptions of organizational efforts to reduce seclusion and restraint and staff attitudes toward the use of seclusion and restraint. This instrument is in public domain and may be used without the permission of the authors. The questionnaire is composed of 41 items which are categorized by concepts into six different constructs for measuring the organization's efforts in reducing or

eliminating seclusion and restraint; leadership-management support, staff development, assessment and treatment planning, patient involvement, debriefing and staff attitudes.

Construct and content validity of the items was established through multiple reviews by clinicians, pretesting in multiple facilities and review by graduate students (Colton & Xiong, 2010). Reliability for the questionnaire was established through pretesting at 3 agencies with revision following the first agency. Cronbach's alpha ranged from 0.53 to 0.91 for the six constructs. This value suggests the items are good measures for the six constructs. Cronbach's alpha for constructs are reported as follows: Leadership-management support (0.732); staff development (0.903), assessment and treatment planning (0.911); consumer involvement (0.534), likely due to only 2 items in this construct; debriefing (0.759) and attitudes (0.624). Indicating the questionnaire meets the criteria for a valid and reliable tool of assessment of organizational activities to reduce seclusion and restraint (Colton & Xiong, 2010).

Implementation.

The project leader, provided a 3-hour re-certification course, entitled, *"How to" Strategies for Intervening with Challenging Individuals,* with 1 ½ hours dedicated to didactic and 1½ hours dedicated to the non-violent physical intervention techniques. The didactic portion of the course was divided into 3 parts; Understanding Goals, Power and Relationships, "How To" Strategies for Intervening with Challenging Individuals and Practice Scenarios.

Results

Data Analyses

Data were analyzed using the Statistical Package for Social Sciences (SPSS) version 21. Baseline characteristics of participants were described using frequencies and percentages for nominal and ordinal variables. Differences in baseline nursing staffs' knowledge (CPI

knowledge assessment), perceptions (leadership/management, staff development, assessment and treatment planning, consumer involvement and debriefing), attitudes, post CPI knowledge assessment and total RSROQ scores were examined using paired sample t-tests (2-tailed); comparing the mean difference pre to post intervention. Changes in nursing staffs' knowledge, perceptions, attitudes and RSROQ were examined using the paired sample t-test (2-tailed) and stratified by job role. An alpha level of .05 was used to determine significance in all analyses.

Sample Description

Table 1

Role

	Frequency	Percent	Valid %	Cumulative %
MHA/SRNA	19	54.3	54.3	54.3
RN/LPN	16	45.7	45.7	100.0
Total	35	100.0	100.0	

Note: N=35

Table 1 and Table 2 present the specific role and years of service for participants within the agency. A total of 16 RN/LPN's and 19 MHA/SRNA's, (N=35) participated in the capstone project. The majority of participants were MHA/SRNA's (54.3%). Analysis of years of service for all participants indicated the majority had worked at the facility for between one to five years (68.6%).

Table 2

Years of Service with Organization

	Frequency	Percent	Valid %	Cumulative %
Less than 1 yr.	4	11.4	11.4	11.4
1-5 yrs.	24	68.6	68.6	80.0
6-10 yrs.	5	14.3	14.3	94.3
11-15 yrs.	2	5.7	5.7	94.3
Total	35	100.0	100.0	

Note: N=35

Table 3

Changes in Knowledge, Perceptions and Attitudes in Total Sample

	Total Pre		Total Post		Change			
	M	SD	M	SD	Mean Diff	*t*	*df*	*P*
CPI Knowledge Assessment	4.6	1.1	5.7	0.6	1.1	6.3	34	<.0001*
Leadership Sub Score	6.9	1.7	7.2	1.8	2.3	1.3	34	.186
Staff Development Sub Score	5.2	1.4	5.2	1.3	0.0	0.0	34	1.000
Treatment Planning Sub Score	6.4	1.9	6.6	1.8	0.2	1.0	34	.324
Consumer Involvement Sub Score	1.8	0.5	1.9	0.4	0.1	0.4	34	.711
Debriefing Sub Score	2.7	0.5	2.8	0.5	0.1	0.5	34	.600
Perception Sub Score	26.1	5.3	27.0	5.5	0.9	1.9	34	.071
Attitudes Sub Score	7.7	2.0	8.5	2.5	0.8	2.8	34	.008*
RSROQ Score	33.8	6.3	35.5	6.5	1.7	2.7	34	.010*

Note: M=Mean, SD=Standard Deviation, *t*=paired t-test statistic, *df*= degrees of freedom, *Indicates, $p \leq 0.05$

Table 4

Changes in Knowledge, Perceptions and Attitudes Stratified by Job Role

	MHA Pre		MHA Post		Change				RN/LPN Pre		RN/LPN Post		Change			
	M	SD	M	SD	Mean Diff	*t*	*df*	*p*	M	SD	M	SD	Mean Diff	*t*	*df*	*p*
CPI Knowledge Assessment	4.4	1.1	5.6	0.8	1.2	4.7	18	<.0001*	4.8	1.0	5.8	0.4	1.0	4.1	15	.001*
Leadership Sub Score	6.8	2.0	6.9	2.1	0.1	0.4	18	.695	7.1	1.3	7.4	1.5	0.4	1.9	15	.083
Staff Development Sub Score	5.2	1.3	5.2	1.3	0.0	0.0	18	1.000	5.2	1.5	5.2	1.5	0.0	0.0	15	1.000
Treatment Planning Sub Score	6.2	2.1	6.3	2.1	0.1	0.4	18	.695	6.7	1.7	7.0	1.2	0.3	1.0	15	.333
Consumer Involvement Sub Score	1.7	0.6	1.8	0.5	0.1	1.0	18	.331	1.9	0.3	1.9	0.3	0.1	0.6	15	.580
Debriefing Sub Score	2.8	0.4	2.7	0.6	0.1	0.8	18	.429	2.6	0.6	2.9	0.5	0.3	1.5	15	.164
Perception Sub Score	25.7	5.9	26.4	6.2	0.6	0.9	18	.360	26.6	4.7	27.8	4.7	1.1	1.8	15	.095
Attitudes Sub Score	8.3	1.8	8.7	2.6	0.4	1.1	18	.288	7.0	1.9	8.3	2.3	1.3	3.1	15	.007*
RSROQ Score	34.0	6.7	35.0	7.3	1.1	1.2	18	.228	33.6	6.0	36.0	5.9	2.4	2.7	15	.016*

Note. M=Mean, SD=Standard Deviation, *t*=paired t-test statistic, *df*= degrees of freedom, * Indicates, $p \leq 0.05$

Change in Knowledge, Perceptions and Attitude Scores

The total scores in the knowledge, perceptions and attitude questionnaires are presented in Table 3. Mean scores in both questionnaires increased in the total sample from pre to post measure. However these increases were significant in CPI knowledge assessment (mean pre-test score=4.6 vs. mean post-test score=5.7, $p<.0001$), the eta squared statistic (.54) indicated a large effect size; attitude sub score of the RSROQ (mean pre-test=7.7 vs. mean post-test 8.5, $p=.008$), the eta squared (.19) indicated a large effect size; and in the total RSROQ (mean pre-test=33.8 vs. mean post-test=35.5, $p=.010$), the eta squared statistic (.18) indicated a large effect size.

Table 4 provides the stratified analyses of changes in knowledge, perception and attitudes by job role. At pre-test/pre-measure, RN/LPN's had higher scores than MHA/SRNA's, in CPI knowledge assessment and the leadership/management, treatment planning, consumer involvement, perception sub scores of the RSROQ, and total RSROQ score; however these differences were not significant. At post-test/measure, RN/LPN's also had non-significant higher scores in the leadership/management, treatment planning, consumer involvement, debriefing, perception sub scores of the RSROQ, and total RSROQ score. MHA/SRNA's had higher, albeit, non-significant scores on attitude sub scores of the RSROQ at baseline and the attitude sub score of the RSROQ at post measure. RN/LPN's had significantly greater increases in CPI knowledge assessment (mean pre-test score=4.8 vs. mean post-test score=5.8, $p=.001$), the eta squared statistic (.53) indicated a large effect size; attitude sub score of the RSROQ (mean pre-test=7.0 vs. mean post-test 8.3, $p=.007$), the eta squared (.39) indicated a large effect size; and in the total RSROQ (mean pre-test=33.6 vs. mean post-test=36.0, $p=.016$), the eta squared statistic (.33) indicated a large effect size.

Among MHA/SRNA's there was only a significant increase in CPI knowledge assessment (mean pre-test=4.4 vs. mean post-test 5.6, $p<.0001$), the eta squared statistic (.55) indicated a large effect size.

Discussion

Seclusion and restraint in inpatient psychiatric settings are high-risk practices which place patients and staff at risk for personal injury, psychological effects and even death (Pollard, Yanasak, Rogers & Tapp, 2007). Nursing staff working in the psychiatric setting can benefit from education and training on techniques to safely manage patient behaviors; to avoid use of seclusion and restraints. Evidence for the implementation of and success of education and staff training, based on the concepts around strategies in reducing seclusion and restraint are well documented in the literature (Ashcraft & Anthony, 2008; Barton, et al., 2009; Azeem et al., 2011; Borckardt, Madan, Grubaugh, et al, 2011).

The findings of this capstone project are well supported by the literature. Staff training, based on the six core strategies for the reduction of seclusion and restraint, developed by the NASMHPD have been implemented with great success in increasing knowledge of alternatives to seclusion and restraint, thus decreasing the incidence of seclusion and restraint (Ashcraft & Anthony, 2008; Barton, et al., 2009; Azeem et al., 2011; Borckardt, Madan, Grubaugh, et al, 2011). The results of this project indicate the intervention utilizing, *CPI: "'How to" Strategies for Intervening with Challenging Individuals,* showed a statistically significant increase in knowledge for both groups, MHA/SRNA's and RN/LPN's. RN/LPN's results demonstrated statistically significant differences in the attitudes sub score of RSROQ and the total RSROQ score with regard to perceptions and attitudes toward reducing seclusion and restraints. When stratified by role, both RN/LPN's and MHA/SRNA's benefited from the intervention with regard

to increase in knowledge from baseline to post test scores. RN/LPN's benefited more from the program than MHA's/SRNA's with regard to changes in perceptions and attitudes toward reducing seclusion and restraints. Although not statistically significant for either group, the agency can benefit from looking at 2 construct areas that affect staff perceptions about organizational factors that influence use of seclusion and restraint; leadership and treatment planning. A secondary outcome that can be expected following the intervention would be a decrease in seclusion and restraint rates.

The sustainability of this intervention is likely due to the support of the agency and the continued support for strategic initiatives for alternatives to reduce and maintain seclusion and restraint. The support is based on the identified need for further education for nursing staff on alternatives to seclusion and restraint. The RSROQ could be used by the agency on a yearly basis to assess staff attitudes and perceptions and to measure if organizational changes are taking effect.

Limitations

A limitation of this project is the small sample size of 35 participants. This may be partially explained by the restriction of class size to 25 participants and the inclusion of other clinical disciplines in the class. An additional limitation is participants self-selected to participate or not participate in this project. The project also utilized self-report data collection instruments.

Implications

Education on interventions to reduce seclusion and restraints are important in the inpatient psychiatric setting. Knowledge is the beginning step in establishing competent methods to reduce seclusion and restraint use by nursing staff. Education and staff training, based on the concepts and strategies to reduce seclusion and restraint support increased

knowledge and seclusion and restraint episode reductions. The annual CPI review offers an opportunity to assess competence for all nursing staff who has been employed for over 1 year at the agency. Due to the nature of the inpatient psychiatric setting, it is vital to maintain competency in skills and assessment through education and staff development. Although the physical skills taught in the mandatory annual CPI recertification may not be utilized on a daily basis by nursing staff, the verbal intervention techniques presented in this program/intervention are used daily. The annual training offers nursing staff, the opportunity to review and increase their knowledge specific to interventions reducing seclusion and restraint use and enables nurses to draw from the education provided to implement interventions when needed throughout the year following recertification. Assessment of perceptions and attitudes toward reducing seclusion and restraint will assist the agency to identify areas needing improvement. Data from this project will assist the agency to target specific areas of education, procedure or policy changes to support nursing staff caring for patients.

Summary/Conclusion

Results of this project demonstrated education for nursing staff on alternatives to seclusion and restraint can be an effective method for increasing knowledge, perceptions and attitudes toward alternatives to seclusion and restraint. This is consistent with the literature, with a focus on education as an intervention for alternatives to seclusion and restraint. After participating in the education, nursing staff at the agency had a significant increase in knowledge related to alternatives to seclusion and restraint. RN/LPN’s had a significant increase in attitudes and total RSROQ score with regard to perceptions and attitudes toward seclusion and restraint reduction.

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APPENDIX A

Statement of Mutual Agreement for Capstone Project

I. General Information

Student Name: Amanda Lykins, MSN, RN, DNP student

Project Title: Alternatives to the Use of Seclusion and Restraints: An Intervention in an Inpatient Psychiatric Hospital

Agency: Eastern State Hospital-Managed by UK Healthcare

Agency Contact: Marc Woods, BSN, RN-Assistant Chief Nurse Executive
Chizimuzo Okoli, PhD, MPH, MSN, RN-Director of Tobacco Treatment Services and Evidence-Based Practice at Eastern State Hospital

II. Brief description of the project

- The purpose of the project is to implement an evidence-based education program for nursing staff, to improve staff knowledge and attitudes in use of alternatives to seclusion and restraint for mental health patients in an inpatient psychiatric setting at Eastern State Hospital. The principal investigator will provide interactive training for licensed/registered nurses, mental health associates and State Registerd Nurse Aides utlizing the program, *CPI: "How To" Strategies for Intervening With Challenging Individuals,* as part of the mandatory annual recertification requirement for Eastern State Hospital. The program consists of 1 ½ hours of didactic content and 1 ½ hours of nonviolent physical crisis intervention techniques.

- All nursing staff are required as a condition of employment to complete the training and pre-test and post-test. Nursing staff are not required as a condition of employment to participate in this project. Data collection forms of nursing staff choosing to participate in the project will be collected and copies prior to any identifying information being entered on the form to help assure confidentiality of the participant's individual data. The pre-test and the Organizational Questionnaire for Reducing Seclusion and Restraints will be distributed, completed and collected prior to the didactic portion of the intervention. Participants will then receive 1½ hours of interactive training utilizing the program, *CPI: "How To" Strategies for Intervening With Challenging Individual.*

- Following the didactic portion of the intervention, participants will be asked to complete the post-test and the Organizational Questionnaire for Reducing Seclusion and Restraints. The post-test will be identical to the pre-test. Post-tests will be collected and the forms of nursing staff electing to participate in the project will be photo-copied and returned to the participant for review of correct responses and later become a component of the employee record as documentation of program completion.

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The participant will then participate in the 1 ½ hour portion dedicated to the non-violent physical crisis intervention techniques.

- The implementation site of this project will be Eastern State Hospital-Managed by UK Healthcare.

- Any products produced from collaboration with the agency must be discussed with the student, Capstone Advisor, and appropriate agency representative.

- The ownership of intellectual property rights to data obtained from this project will be to Amanda Lykins. Privileges will be granted to Eastern State Hospital, in use of the final analyzed data.

On-site activities

- Five days and 2 days prior to the project implementation, a list of nursing staff who have registered for the course will be obtained from the link blue system. An e-mail will be sent to the registered participants inviting them to take part in the project. The information sent in the e-mail will be the information from the IRB approved consent cover letter.

- Nursing staff choosing to participate in the project will be asked to complete a pre-test and questionnaire prior to the educational intervention; the Organizational Questionnaire for Reducing Seclusion and Restraints. An educational intervention will be utilized to provide education for licensed/registered nurses, mental health associates and State Registerd Nurse Aides utlizing the program, *CPI: "How To" Strategies for Intervening With Challenging Individuals,* as part of the mandatory annual recertification requirement for Eastern State Hospital. Following the didactic portion of the intervention, participants will be asked to complete the post-test and the Organizational Questionnaire for Reducing Seclusion and Restraints. The participant will then participate in the 1 ½ hour portion dedicated to the non-violent physical crisis intervention techniques.

Agreement of written and oral communication

- Administrator's at Eastern State Hospital-Managed by UK Healthcare grant, Amanda Lykins, DNP student permission to disseminate the aggregate data obtained from this project in a presentation for her DNP Capstone Project at Eastern Kentucky University.

Student Name: Amanda Lykins, RN, MSN, DNP student

Project Title: Alternatives to the Use of Seclusion and Restraints: An Intervention in an Inpatient Psychiatric Hospital

- Administrator's at Eastern State Hospital-Managed by UK Healthcare grants, Amanda Lykins, DNP student permission to disseminate the data obtained from this project for publication at a later date following agency review and approval.

- The ownership of intellectual property rights to data obtained from this project will be to Amanda Lykins, DNP student. Privileges will be granted to Eastern State Hospital-Managed by UK Healthcare, in use of the final analyzed data.

- Reference to Eastern State Hospital-Managed by UK Healthcare, utilized in the implementation of the project; in student's academic work, publications, and presentations will be referred to as:

    - Eastern State Hospital, an acute inpatient psychiatric hospital in southeastern Kentucky, in the student's final report and on-campus capstone presentation.
    - A 239 bed, inpatient acute psychiatric hospital, in the east south-central region of the United States in the executive summary or abstract.
    - A 239 bed, inpatient acute psychiatric hospital in the east south-central region of the United States in professional presentations.
    - A 239 bed, inpatient acute psychiatric hospital in the east south-central region of the United States in professional publications.

- Formal agency approval will be obtained prior to any publicly shared findings.

IV. Required Signatures:

_____	_____
Student	Date
_____	_____
Capstone Advisor	Date
_____	_____
Agency Representative	Date

Approved ____ (Date) _____

APPENDIX B

Office of Research Integrity
IRB, IACUC, RDRC
315 Kinkead Hall
Lexington, KY 40506-0057
859 257-9428
fax 859 257-8995
www.research.uky.edu/ori/

EXEMPTION CERTIFICATION

MEMO: Amanda Lykins, MSN,RN
815 Rock Way
Richmond, KY 40475
PI phone #: (270)300-7625

FROM: Institutional Review Board
c/o Office of Research Integrity

SUBJECT: Exemption Certification for Protocol No. 16-0562-X1B

DATE: July 11, 2016

On July 11, 2016, it was determined that your project entitled, *Alternatives to the Use of Seclusion and Restraints: An Intervention in an Inpatient Psychiatric Hospital*, meets federal criteria to qualify as an exempt study.

Because the study has been certified as exempt, you will not be required to complete continuation or final review reports. However, it is your responsibility to notify the IRB prior to making any changes to the study. Please note that changes made to an exempt protocol may disqualify it from exempt status and may require an expedited or full review.

The Office of Research Integrity will hold your exemption application for six years. Before the end of the sixth year, you will be notified that your file will be closed and the application destroyed. If your project is still ongoing, you will need to contact the Office of Research Integrity upon receipt of that letter and follow the instructions for completing a new exemption application. It is, therefore, important that you keep your address current with the Office of Research Integrity.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research" from the Office of Research Integrity's IRB Survival Handbook web page [http://www.research.uky.edu/ori/IRB-Survival-Handbook.html#PIresponsibilities]. Additional information regarding IRB review, federal regulations, and institutional policies may be found through ORI's web site [http://www.research.uke.edu/ori]. If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at (859) 257-9428.