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Improving Nurse Education on Research Informed Consent

Tina Rasooli
trasooli@dons.usfca.edu

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University of San Francisco

Abstract

As the number of human participants in clinical trials continues to grow, it is increasingly imperative that research nurses are educated about valid research informed consent to improve patient outcomes. As patient advocates, nurses must be aware of the components and principles of valid informed consent in order to protect the rights, safety, and wellbeing of their patients as human subjects. The research nurse must also be aware of their available resources and who to contact if they suspect a problem or a lack of patient comprehension of the study. In order to address these needs, an evidence-based performance improvement project was created as part of a Clinical Nurse Leader Internship on the Clinical Research Unit of an urban teaching hospital. This unit did not have any formal training on research informed consent for their nursing staff. An evidence-based education tool was created to train new nurses on the unit about research informed consent to increase nurse competency in valid informed consent and improve patient outcomes. An assessment was used to evaluate the staff's knowledge on Research Informed Consent. After the implementation of the education tool, this assessment was repeated and presented a thirty-two percent improvement in the staff's knowledge on Research Informed Consent.

Problem Statement

There is a lack of nurse competency in Research Informed Consent due to the absence of formal training on the subject at the general clinical research unit of an urban teaching hospital. This not only challenges the patient's safety and basic human rights, but it also poses a threat to the clinical trial participant's autonomy. As there is no formal educational tool or training on informed consent for newly hired nurses on the unit, nurses currently have to educate themselves about the subject either through the Internet or asking colleagues for information. This poses a safety issue for patients participating in clinical trials and challenges their basic human rights because they may not understand the treatment they are receiving or they may not have accurately consented to it. In order to protect clinical trial participant's safety and autonomy and improve patient outcomes, an evidence-based education tool was created to educate and train new nurses about the principles and components of Research Informed Consent.

Rationale

A thorough needs assessment and root cause analysis was conducted on the general clinical research unit that led to the proposed improvement project (see Appendix A). The root cause analysis presented a lack of research nurse knowledge surrounding the informed consent components, process, and the role of the Institutional Review Board (IRB) in clinical trials as a result of no formal training on these topics. This leads to a safety issue in regards to the patient's health, basic human rights, and autonomy.

Interviews were conducted with the nurse managers and staff nurses who identified this issue as their top safety concern for the unit. In addition, assessments were provided to both the day and night shift nurses to evaluate their knowledge of the Research Informed Consent process, the IRB, how to contact the IRB at the hospital, who to contact if the patient has a

question about the study protocol, and how to assess if the patient understands the study protocol (see Appendix B). The results of the assessment showed sixty percent of nurses correctly identified the components of the Research Informed Consent and fifty percent correctly described the role and purpose of the IRB in relation to research studies. Fifty percent of the nurses correctly identified how to contact the IRB at the hospital and eighty percent correctly described whom to contact if the patient has a question about the study protocol. Furthermore, fifty percent correctly described how to assess if the patient understands the study protocol. The results of the assessment showed quantitative significance to the lack of knowledge surrounding the informed consent process and the need for an evidence-based education tool to improve unit based orientation to Research Informed Consent (see Graph A).

Literature Review

A thorough literature review was conducted to support the need for this project. Pick (2013) describes informed consent as the process by which a patient agrees to undergo a treatment, procedure, or clinical trial after receiving all the information needed to make the decision. A patient's consent is valid if they have the capacity to understand the information, are accurately informed, and have not been pressured or coerced to participate. Within the context of clinical research, patients are considered a vulnerable group whether they are healthy volunteers or those with a particular illness. As patient advocates, nurses need to be aware of the components and principles of valid informed consent in order to protect the rights, safety, and wellbeing of their patients. A fundamental ethical standard for medical research includes treating human participants with respect, protecting their health and human rights, and supporting them in making an informed decision. A crucial component to obtaining informed consent is assessing the patient's capacity to comprehend the information. Patient's who may be vulnerable or lack

the capacity to consent include children, patients with learning disabilities, or those who are not fluent in English. Within the context of Research Informed Consent, the non-research nurse must still be able to assess the patient's comprehension of the research trial and collaborate with the research team if they feel the patient does not understand the study or has not provided consent.

Ross and Krebs (1999) found that the research nurse role has evolved from the traditional role of supporting the clinical research to acting as the principal investigator or collaborative partner. With this evolution, the nurse's role in the informed consent process has increased. If nurses are educating their patients during the informed consent process, they must have a clear comprehension of the six critical components it contains. First the patient must be informed of the purpose of the study, procedures, therapies, the duration, and rationale for the study. Secondly, the patient must understand the possible risks and discomforts associated with the study and how they may be ameliorated. The third element involves a description of the benefits associated with the study. It is vital that the patient understand there may or may not be direct medical benefit with the trial. The nurse must educate the patient about the risks to benefits ration even once the therapy has begun. The fourth component addresses the need to disclose alternative procedures or treatments before signing any informed consent form. Additionally the possibility of being randomized to standard therapy or placebo should be made clear to the patient if it is a randomized control trial. The fifth element includes patient confidentiality and who will have access to the information related to the study. Component six includes the conditions regarding medical treatment and compensation in the case of injury related to the clinical trial. It is essential that the nurse reiterate that that patient may withdraw from the study at any time and it will not effect their treatment in any way.

Cresswell and Gilmour (2014) report that many participants in randomized control trials do not understand at least some aspects of the trial or the randomization component even after signing the informed consent. They 'reported that 70% of a 207 participant oncology randomized control trial did not know their treatment was not the best proven treatment for their cancer. Often the randomization is not understood by patients and should be made clear by the clinical research nurse to ensure patient safety and autonomy.

Murff et al. (2006) conducted a national survey of General Clinical Research Center (GCRC) nurses to determine their feelings, beliefs, and actions regarding the informed consent process. They surveyed 902 nurses at 90 different GCRC's around the Unites States. Among their results they found that 17% of nurses reported being regularly present during the informed consent process, however, 78% regularly assessed the participants' comprehension of the study they consented to. Forty-one percent of nurses reported they had assisted in a trial where the patient did not fully understand the information in the consent document but was enrolled in the study regardless, and 9% had assisted in a protocol where their patient underwent a study procedure despite having unanswered study-related questions. Twenty-seven percent had assisted in a protocol where they believed the participant did not understand that their treatment was for research purposes only. Eleven percent of nurses believed they had assisted in a protocol where their patient had been coerced into participating. Twenty-eight percent of nurses reported having contacted a study investigator over the past six months concerning a patient's understanding of the consent process or study and 13% had refused to assist in a study intervention. Ten percent of nurses reported they never or rarely contact a study investigator if they suspect a problem with the informed consent process. These barriers in communication may be due to a fear of losing

research participants, the investigator's reaction, or a lack of nurse comprehension of the informed consent components or process.

Kotzer and Milton (2007) describe that nurses and healthcare professionals often do not have knowledge about the role and purpose of the Institutional Review Board (IRB) due to a lack of education surrounding IRB policies, procedures, and guidelines. The IRB's primary goal is to monitor, review, and approve responsible research protocols while protecting the rights and wellbeing of human research subjects. The IRB process has played a major role in identifying risks undetected by researchers and developing safety protocols for human research subjects. Healthcare professionals are often intimidated by the IRB and federal regulations because of a lack of formal education on the fundamental IRB procedures and federal guidelines.

Billings (2000) applies the use of technology in nursing education to increase the efficiency and effectiveness of teaching and learning in the busy clinical setting. Web-based courses have resulted in positive outcomes in nursing education because it meets the needs for access and convenience for healthcare professionals with complex work schedules. Furthermore, web-based courses are available 24 hours-a-day, seven days a week, and do not require a classroom, instructor, or commuting.

Levine (2001) describes six basic principles to guide educators of adult learners in the clinical setting; (i) begin by telling the adults what you are about to tell them; (ii) organize your presentation in a logical manner; (iii) do not feel the need to tell them everything; (iv) understand what you want the adult learner to do with the information you provide them; (v) know when to teach and when to learn; and (vi) help the adult relate the information to their own practice. These straightforward principles can aid when teaching adult learners and organizing instructional presentations on clinical concepts.

Cost Analysis

The solution to the problem includes creating an evidence-based education tool about Research Informed Consent for new nurses to use during their unit orientation. This educational tool is a web-based course and does not require a classroom, instructor, or additional resources. The unit already has computers that the new nurses can use to complete the education tool, or they can access the tool at home on their own computers. The education tool was created on PowerPoint and will be uploaded to the hospital's staff web page.

While there are limited costs to creating the education tool, the nurses being trained will be receiving their hourly wages during the training process. The education tool will take approximately thirty minutes to complete and the starting salary for a newly hired nurse at this hospital is approximately fifty dollars per hour. This unit hires approximately eight new nurses per year who will go through the training process. Therefore, the cost of training new nurses on this education tool is approximately two hundred dollars per year. This educational tool will not only increase patient and nurse satisfaction by improving patient outcomes, but it can also save potential costs. This training can prevent potential costs due to hospital-acquired injuries and lawsuits, which could result if a patient is erroneously or improperly consented to a research trial.

Methodology

The entire project was conducted over the coarse of three months (see Appendix C). In order to plan the change strategies in the unit setting and gain support from other members of the interdisciplinary team, Havelock's Theory of Change was used throughout the course of the project. According to Lane (1992), Havelock's Change Theory is comprised of six simple steps. The first step requires establishing a rapport with the other unit members and members of the

interdisciplinary team who will be involved with the change. The second step involves identifying the problem in the setting that requires the change. The third step requires investigating the problem, researching the literature, and gathering resources. The fourth step involves selecting the interventions that will be used to create change and address the problem. Step five involves supporting the staff in establishing and accepting the change. Once the change is successful, step six requires maintaining the change in the system setting and preventing relapse into old habits.

After establishing a positive rapport with the nursing team and managers, a thorough unit assessment was conducted. This included a microsystem analysis, communication assessment, unit observations, interviews, data collection, literature review, and collaboration with the unit managers and staff in the creation of the evidence-based education tool. In addition, a communication board was created and placed in the nurses' break room to facilitate communication between the staff and project facilitators, update staff on the project, and provide a place for staff to return their assessments if they preferred to remain anonymous.

A microsystem assessment tool was used over the course of two weeks to assess the "Five P's" of the microsystem, which includes the purpose, patients, professionals, processes, and the patterns of the unit. The data was collected for the microsystem assessment through observation, staff and manager interviews, patient interviews, and assessments. The "purpose" assessment investigates why the inpatient unit exist and what role it plays within the hospital. The "patients" assessment collects patient demographics, the top diagnoses on the unit, what resources they use, and how patients view the care they receive. The "professionals" assessment creates a comprehensive picture of the unit by distinguishing what role every individual plays on the unit, if tasks are being delegated to the right people, and whether or not roles are being

optimized. The "processes" assessment investigates how things get done in the microsystem, the step-by-step processes, potential delays, and how long the care process takes on the unit. The "patterns" assessment investigates the leadership and social patterns on the unit, how often the microsystem meets to discuss patient care, and how communication is disseminated on the unit.

Interviews with unit managers included questions regarding their top safety concerns on the unit, how the process of change occurs on the unit, patterns of communication on the unit, and the inpatient unit profile. Interviews with staff covered their top safety concerns and where they would like to see change on the unit. The assessments, which were distributed to the day and night shift nursing staff, evaluated their knowledge of the Research Informed Consent process, the IRB, how to contact the IRB at the hospital, who to contact if the patient or nurse had a question or concern about the study protocol, and how to assess the patient's comprehension of the study. In addition, a communication assessment was conducted to investigate the overall noise level on the unit, manager-staff communication, staff-patient communication, report/handoff, social support for nurses/staff, conflict resolutions, and interdisciplinary communication (see Appendix D).

Nursing Relevance

This project clarifies the purpose and components of the Research Informed Consent and its role in protecting patients' basic human rights. It clarifies the research nurses role in the study protocol process and highlights their role as patient advocates. This project contributes to the unit's mission of assisting the research community in translating safe clinical research ideas into successful clinical studies. Furthermore, this project will help uphold the general clinical research unit's standards of protecting patients, conducting responsible clinical research, and producing reliable study results.

Summary Report

The microsystem assessment revealed that the patient population consists of predominantly adults between the ages of 19-50 years of age and the top diagnoses consist of Glioblastoma, Leukemia, Alzheimer/Dementia, and Liver Transplant. The patient population census consists of 10-15 outpatients and 6-8 inpatients per given day. The staff population consists of two unit leaders during the day shift, four registered nurses per shift, one technician per shift, and one research coordinator per clinical trial. The Primary Investigator of the given clinical trial is available on call during all research trials. The unit is small compared to the other units of the hospital, consisting of eight rooms and ten beds. This also contributes to the patterns observed in the unit, as it is a quiet unit with few call lights and high patient and staff satisfaction.

The design of the evidence-based education tool consisted of a PowerPoint learning module. The PowerPoint contained information on what a Research Informed Consent is, the six main components of the informed consent, the IRB, the IRB specific to the hospital, the key players in the clinical trials, who to call if there is a problem, and how to assess if the patient understands the informed consent and clinical trial. Most of the information in the PowerPoint was retrieved from the information in the Literature Review.

The education tool was presented to the unit managers and registered nurses during a weekly staff meeting. The staff was given the same assessment given before the implantation of the intervention after the presentation. The post-intervention assessment results were tremendously higher after seeing the PowerPoint presentation. The results of the assessments showed eighty percent of nurses correctly identified the components of the Research Informed Consent and ninety percent correctly described the role and purpose of the IRB in relation to

research studies. Eighty percent of the nurses correctly identified how to contact the IRB at the hospital and a hundred percent correctly described whom to contact if the patient has a question about the study protocol. Furthermore, a hundred percent correctly described how to assess if the patient understands the study protocol. The results of the assessment showed quantitative significance to the improvement of knowledge surrounding the informed consent process and the effectiveness of the PowerPoint as a training tool (see Graph B). Overall the nurses had a thirty-two percent improvement in their assessment results after the implementation of the education tool.

The nurses and managers on the unit received the information very well as reflected in the post-intervention assessment results. The managers and nurses were very pleased with the end result and expressed that they are looking forward to using the PowerPoint as a training tool for newly hired nurses on the unit. The only redesign of the PowerPoint after the presentation was adding the references for each slide of the PowerPoint and a reference list at the end of the PowerPoint.

The overall experience of the project was very positive. It was very eye opening to go through each individual step of the assessment process all the way through to the intervention, implementation, and evaluation. In order to have a successful change on a unit it is imperative to go through each step. In order to maintain this change on the unit the managers must implement it into their training program and stay up to date with the best practices in Research Informed Consent as stated by the literature. Healthcare is always evolving and as new information is discovered, it is essential for healthcare personnel to stay up to date and implement best practices to improve patient outcomes.

References

Billings, D. (2000). A framework for assessing outcomes and practices in Web-based courses in nursing. *Journal Of Nursing Education*, *39*(2), 60-67.

Cresswell, P., & Gilmour, J. (2014). The informed consent process in randomized controlled trials: Anurse-led process. *Nursing Praxis In New Zealand*, *30*(1), 17-28.

Kotzer, A., & Milton, J. (2007). An education initiative to increase staff knowledge of Institutional Review Board guidelines in the USA. *Nursing & Health Sciences*, *9*(2), 103-106.

Lane, A. J. (1992). Using Havelock's model to plan unit-based change. *Nursing Management*, 23(9), 58-60.

Levine S. (2001). The challenge of helping adults learn: Principles of teaching technical information to adults. Retrieved from: http:// eric.ed.gov/ERICDocs/ data/ericdocs2/ content_storage_01/ 0000000b/80/24/2b/1c.pdf.

Murff, H. J., et al (2006). General clinical research center staff nurse perceptions and behaviors regarding informed consent: Results of a national survey. *IRB: Ethics and Human Research*, 28(4), 8-12.

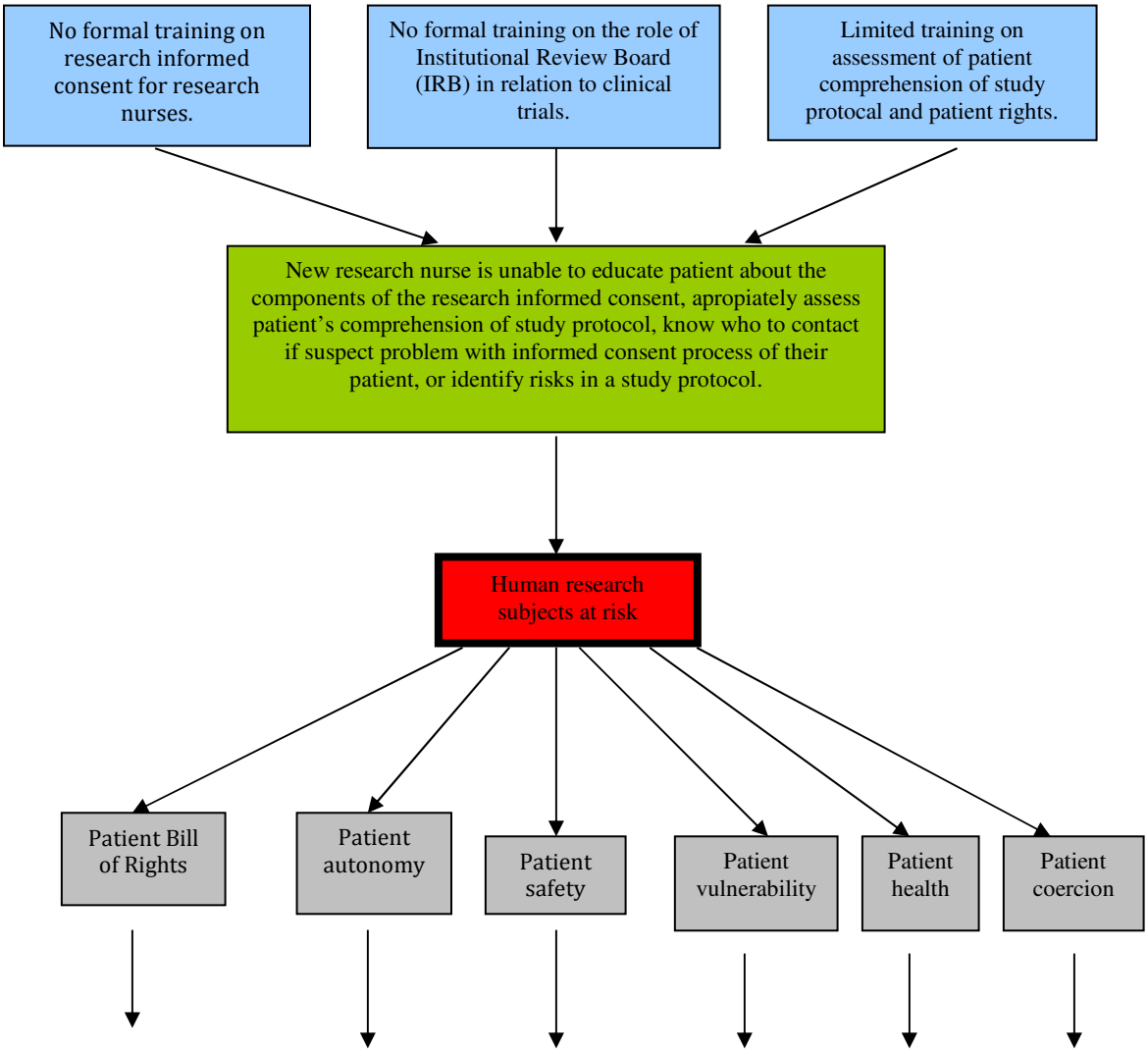
Pick, A., Berry, S., Gilbert, K., & McCaul, J. (2013). Informed consent in clinical research.

Nursing Standard, *27*(49), 44-47.

Rosse, P. A. & Krebs, L. U. (1999). The nurse's role in the informed consent process. *Seminars in Oncology Nursing*, 15(2), 116-123.

Appendix A

Root Cause Analysis



Solution:
Evidence-based electronic educational tool for training research nurses. Learning module will include information about the purpose and components of the research informed consent, role of the IRB, assessment of patient comprehension of informed consent and study protocol, and what do if suspected problem with informed consent

Appendix B

Assessment

1. What are the 6 main components of the research informed consent?

2. What is the IRB and what do they do?

3. What is the name of the IRB at this hospital and how do you contact them?

4. Who should you call if the patient has a question about the study protocol?

5. How can you assess if the patient understands the study protocol for the day? What kinds of questions should you ask?

Thank you for your participation!

Appendix C

Project Timeline

9/9/14 – Communication Board

9/10/14 – Microsystem Assessment

9/16/14 – Questionnaires

9/30/14 – Literature Review

10/15/14 – Project Prospectus

10/21/14 – Root Cause Analysis

11/24/14 – Project Summary/Final Report

12/3/14 – Project Abstract and Poster

12/10/14 – Poster Presentation

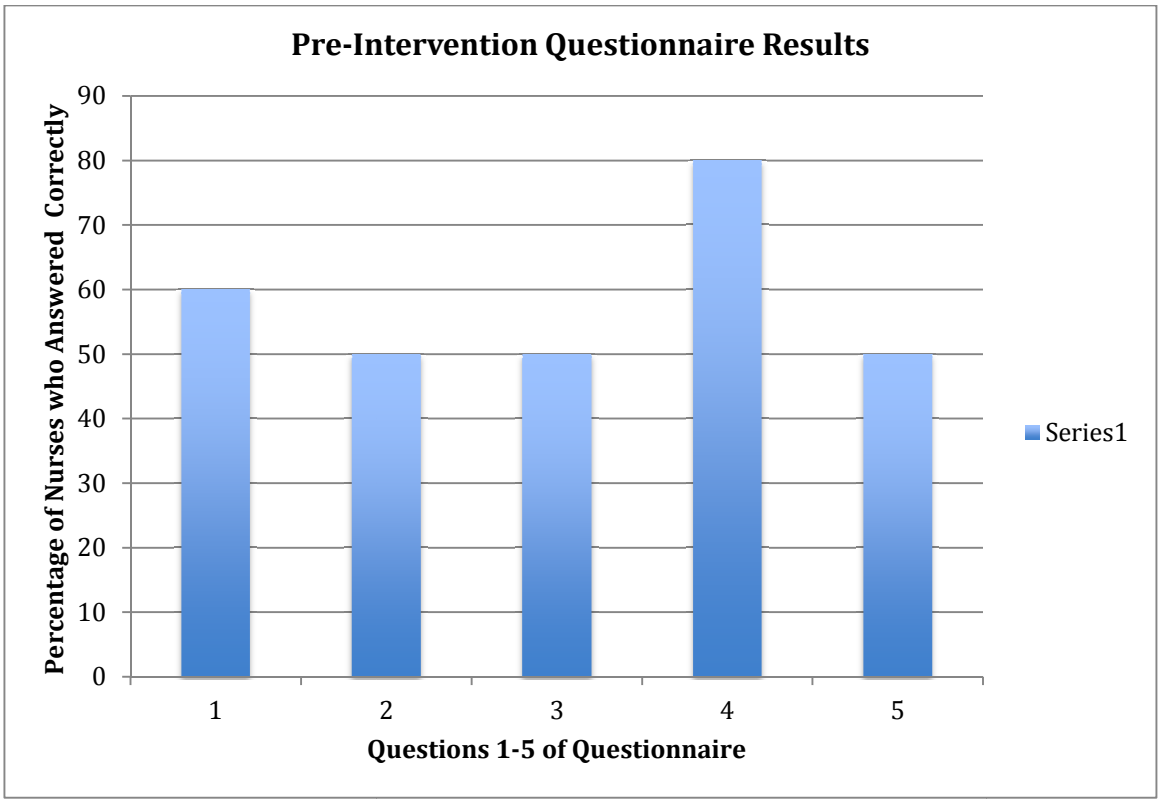
Appendix D

Unit Communication Assessment Tool

Unit Characteristics	**Assessment**
Noise level on the unit	Low
Manager: • Visibility of manager, staff • Communication pattern from manager to staff • Receptiveness of manager to staff concerns	Managers are visible and communicate with staff throughout the day (mostly from the Assistant Patient Care Manager). Communication with staff predominantly through emails going to all staff, morning and evening huddles, and weekly staff meetings. Managers are receptive to staff concerns.
Report/handoff: Method of delivery (face-to-face)? Systematic?	Morning and Evening Huddles. Face-to-face handoff.
Nurse-patient communication – are RNs making the plans of care for the day together with patients, is it respectful communication, are RNs attending to patients needs in a timely manner, is the call light answered promptly?	Yes, RNs make the plans of care for the day together with patient in terms of ADL's. (protocol schedule in place) Respectful communication. RNs attend to patients needs in a timely manner, call lights answered promptly.
Gossip – is it noticeable, what s the subject of it, who engages in gossip?	Minimal
Social support for nurses, who provides support? Is staff welcoming to new RNs and floaters?	Yes, social support from managers, colleagues, and study coordinator. Staff is welcoming to new RNs and floaters.
Conflict resolution – how is it resolved? Are managers involved?	Most often resolved amongst each other. Mediation services through the hospital if conflict. Manager involved if performance issue or unprofessional behavior.
Communication between physicians and staff	Start up meeting for study protocol between the nurses and physicians (primary investigator). Collaborative practice meeting for OMFS – talk about issues/change in practice. Pager box.

Graph A

Pre-Intervention Questionnaire Results



Graph B

Post-Intervention Questionnaire Results