SOCIAL/BEHAVIORAL/EDUCATIONAL RESEARCH PROTOCOL
UNIVERSITY OF MISSOURI

Project Title: A Next Generation, Low Cost Tracking System for Healthcare Process Validation
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I. Research Objectives/Background

The purpose of the project is to develop a new way to understand patient care data analytics by using a real-time location system (RTLS). We will deploy the RTLS-based nursing activity analysis system at an ICU at the University Hospital, University of Missouri Health Care in Columbia, Missouri. We will validate location system performance against manual observation of nursing activity. We will correlate nursing activity metrics against patient outcomes as measured by Sequential Organ Failure Assessment (SOFA) score.

Real-Time Location Systems (RTLS) identify and locate tagged assets, staff, or patients as they move through a hospital. RTLS can address a variety of other practical problems in healthcare such as inventory management and patient tracking and monitoring. Most RTLS employ some flavor of Radio Frequency (RF) angle-of-arrival, time-of-flight, time-difference-of-arrival, or Received Signal Strength Indicators (RSSI). However, these techniques have several significant disadvantages. Among these are confusion from multipath and environmental clutter, line-of-sight operation, need for synchronization, range restrictions, and expense. Furthermore the human body, composed mainly of salt water, occults high frequency signals making fading a serious problem. Wi-Fi tracking, in particular is, limited to an accuracy of 10-20ft and cannot provide the precision data required for high-fidelity applications in healthcare such as workflow management.

In the current study, we will validate location system performance against manual observation of nursing activity. We will correlate nursing activity metrics against patient outcomes as measured by SOFA score. The anticipated outcome is actionable, location-based data to describe, analyze, or validate healthcare processes with a maximum error of 5% relative to manual observation. Also, we will identify specific location-based metrics useful in monitoring nursing activity. We will deploy and test the system in a medical ICU at the University Hospital ICU. The anticipated outcome is a real-time statistical quality control chart capable of monitoring nursing processes and detecting anomalies with user-configurable statistical power.

II. Recruitment Process

Prospective participants will receive an individual email from co-investigator explaining study including the need for participants willing to wear two location tags for the duration of their shift. The Informed Consent form and Demographic Question will be attached to this email. Those willing to participate will also be asked to send the completed Demographics Questionnaire attached to their email response. Receipt of the completed Demographics Questionnaire will signify their consent to participate.
The co-investigator will explain in the individual email that this study is to solely gain knowledge regarding their workflow as they deliver patient care and is not an evaluation of their performance or clinical judgment. Their participation in the study will not be revealed to their manager unless the participant wishes. The co-investigator will explain that participation is voluntary, they can withdraw at any time without risk to their employment and all aspects of their participation will be confidential.

III. Consent Process

A Waiver of documentation of consent form will be attached to the individual's email as well as the Demographic Questionnaire. The Waiver of Documentation of Consent form will provide an overview of the study. They will be informed both in the form and in the text of the email that the return of the completed Demographic Questionnaire signifies their consent to participate in the study and that participation is voluntary and confidential. They will be provided with the co-investigator's contact information should they have questions or concerns.
In addition, information from the EMRs of patients assigned to the nurse participants will be abstracted retrospectively under the Waiver of Consent after the patients have been transferred from the ICU. Patient factors will be used to help interpret the nurse participant data. However, concurrent patient data abstraction is not necessary for data analysis in this research project as there will be no intervention introduced that would impact the patient data. Further, patients in this ICU are usually unable to provide informed consent due to the presence of mechanical ventilation and continuous sedation.

IV. Inclusion/Exclusion Criteria

Inclusion criteria include English speaking, RN or LPN licensure.
Exclusion criteria include nurses helping to provide care but not having a patient assignment and nurse managers.

V. Number of Subjects

The study design is prospective, observational. The subject population is medical intensive care unit (ICU) nurses at University Hospital, MU Health Care. The anticipated number of subjects is 20. Normally, there are 10 nurses in each ICU per day shift (7:00 AM – 7:30 PM). During the data collection, the research team will monitor one designated medical ICU for 4 months (80 observation days).

VI. Study Procedures/Study Design

Recruited nurses will receive two RTLS location tags prior to their shift from trained undergraduate industrial and manufacturing systems engineering (IMSE) students who will keep a log of the nurses' name and tag identification. The nurses will carry the tags for the duration of their shift and then return the tags to the students. While they carry the RTLS tags, IMSE students will stand at the corner of the nurse's station in each pod to record the nurses' activities and the time spent in these activities using a data collection form previously developed during earlier pilot work when IMSE students collected time-motion data regarding ICU nursing care activities. If any special events occur during the observation period, they will record a description of these events, which include but not be limited to unscheduled medical activities or admission of a new patient to the ICU from the Emergency Department (ED). The RTLS location tag distribution and nurse observation will occur four to five days per week until a total of 80 days of location and observation data is obtained. For each patient that is assigned to an observed ICU nurse, data will be extracted retrospectively from their EMR. The abstracted data will include: age, gender, hospital admitting diagnosis, medical ICU admitting diagnosis, past medical diagnoses, laboratory values occurring during, or 24 hours prior to observation time, neurological status, mean arterial pressures during observation time, intravenous medications administered during observation time, any diagnostic studies performed outside of the ICU during the observation time, and any in-room procedures performed during the observation time.

VII. Potential Risks

There is minimal risk to the participants in this study. There are no potential risks or discomfort for the participant as there will be no change in their work process. Methods to avoid inadvertent coercion in the recruitment process will be deployed.

VIII. Anticipated Benefits

Analyzing the ICU nurse's workflow can furnish an understanding of the causes of delayed and missed care delivery. The findings from this research will highlight opportunities to improve the workflow management design. Such information can guide future workflow management to reduce the ICU nurse's workload and the risk of delayed or missed care in the ICU resulting in improved patient outcomes.

IX. Compensation

Each participant will be given a gift card ($10). If they participate multiple times, then they will receive multiple gift cards. For example, if a nurse participates this study on five day shifts, then he or she will receive a five $10 gift cards.

X. Data Safety Monitoring Plan

The data to be collected in this research project is from observation and tracking of the participants' movements using location tracking technology as they engage in their normal work routine. The Principal Investigator (PI) will provide data and safety monitoring through the following processes:

1. Each participant will be assigned a study code by the co-investigator (Co-I). A key linking the participant to their study code will be kept in an electronic file that is stored in an account that has a HIPAA-compliant security rating and can only be accessed by the PI and Co-I.
2. The username used to access the study subject's electronic medical record event log data will be removed from the data and replaced with the subject's study code by the principal investigator and the co-investigator. Only de-identified event log data will be used in the analysis.
3. Informatics specialists will de-identify patient data using the Safe Harbor method and assign a unique code to each patient's data. They will export the deidentified data to a secure account provided by the University of Missouri for data analysis. Only research team members will have access to this account. To anticipate the possible need to re-identify the patient, the informatics specialists will export a key connecting the medical record number with the unique code to a separate account that has a HIPAA-compliant security rating and can only be accessed by the PI and Co-I.
4. The first case and every tenth subsequent case will be reviewed by the PI and Co-I for compliance with IRB requirements and conformance with informed consent requirements.
5. Weekly research team meetings to review the data collected and resolve any issues encountered during the data collection session
6. A log will be kept whereby the research team member distributing the location tags to the participants for the data collection session will enter the tag identification number; the co-investigator will enter the study code of the subject receiving the tag into the same log. In the event that there is an issue with the signal produced by the tag, the tag will be removed from service and substituted with another using the same log entry procedure. The removed tag will be inspected and tested by the PI and/or manufacturer. It will only be returned to service if the issue is resolved. Such events will be reported to NINR by the PI.
7. We will monitor the test on at least a daily basis looking for potential adverse events in compliance with existing The University Hospital policies and procedures. Adverse events may include:
    a. Adverse patient outcomes attributable to the test
    b. Statistically significant changes in patient outcomes
    c. Any other unanticipated problems with the study
8. We will provide details to NINR and the IRB, including:
    a. Details of the event
    b. Any recommendations arising out of the study
    c. Any actions taken as a result of a potential adverse event
9. As per the University of Missouri Health Sciences Institutional Review Board (IRB) Core Standard Operating Procedure for Event Reporting and the Standard Operating Procedure for Unanticipated Problems, the Principal Investigator will be responsible for:
    a. Reporting to the University of Missouri Health Sciences IRB within 5 business days of the investigator becoming aware of unanticipated problems that meet <u>all</u> of the following criteria:
        i. **unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-

approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

ii. **related or possibly related** to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

iii. suggests that the research places subjects or others at a **greater risk of harm** (including physical, psychological, economic, or social harm) **than was previously known or recognized.**

b. Unanticipated problems reported to the University of Missouri Health Sciences IRB will be done using the IRB's Case Report Form

c. The Principal Investigator will maintain a log, database, or other tracking system for trends

10. Potential adverse events may include:

a. Data privacy violations: Our HIPAA-compliant plan will anonymize personal data and store it in a secure fashion, so a data privacy problem is unlikely

b. Electromagnetic Interference (EMI): Dr. Kim employed an earlier generation of tracking devices that showed exhibited no interference or incompatibility with other ICU electronic devices. However, the researchers will be alert to the potential problem and remove any interfering tags from service

XI. Multiple Sites

NA

XII. References

NA