Biostatistics Scope of Work Agreement

General Information

Investigator	Joshua Denson Joshua.denson@ucdenver.edu	**Date**	7/13/2017
Project Number	P1222Denson		
Project Title	Implementation of standardized transition of care protocol for medical residents		

Project Cost and Milestones

Project Type: Custom - CEPS Study Design Consulting and Average Data Analysis/Publication

Billing Phase and Milestone	Cost
Phase 1: Project Start Up Discuss and review project materials, establish timelines, deliverables, and data structures with biostatistician.	$ 450
Phase 2: Small Design and Exploratory Analysis of Retrospective Data Consult as needed on study design and exploratory analysis of retrospective data.	$ 1890
Phase 3: Exploratory Analysis of Prospective Data Establish preliminary analysis dataset, run descriptive statistics and graphics, and create a report.	$ 2470
Phase 4: Comprehensive Analysis Report on Initial Intervention Complete comprehensive analysis and present a report.	$ 1760
Phase 5: Follow-up Analysis Report on Subsequent Intervention Complete follow-up analysis and present a report on subsequent intervention.	$ 1760
Phase 6: Project Complete Complete final analysis and publication quality figures.	$ 450
Total Cost	$ 8780
Discount – Cost paid by your department	$ -3780
Total Due	**$ 5000**

Understanding of Project

Project Description

Medical errors resulting in patient harm are a leading cause of death among Americans, and are an increasingly recognized result of miscommunication during transitions in care. Emerging data suggest the effects of a more substantial care transition, termed the end-of-rotation transition in care (or service transition), may be detrimental to patient care. During this care transition, housestaff communicate information for up to 14 patients to a new resident who have never previously met the patients. Unlike shift handoffs, where the original physician resumes care, this care transition is permanent – the resident signing out has no further contact with these patients or their new care team. This transition has been associated with increased lengths of stay, costs, and mortality, yet an evidence-based intervention that reduces these risks has yet to be developed, and best practices are lacking. In our initial meetings with housestaff, residency leadership, and individual block directors, we have found the end-of-rotation transition process at the University of Colorado Internal Medicine Residency Program is not standardized, characterized by variable elements of written, verbal, and in-person signout, despite a residency program recommendation for in-person service transitions for all Intensive Care Unit (ICU) patients. Therefore, we believe an iterative approach to development of an end-of-rotation handoff strategy with a demonstrated ability to improve outcomes is needed to guide residency programs and hospital systems as they try to address this area of vulnerability for patients.

The overall goals of this project are to implement a structured handoff system and improve patient safety during end-of-rotation transitions in care. We will use available evidence and residency feedback to develop a patient-centered intervention that demonstrates acceptability and adoption by housestaff, improves patient outcomes, and reduces costs related to end-of-rotation transitions in care. The specific objectives for this project are the following:

- By December 2017, develop a pragmatic service transition process adapted from available evidence and housestaff feedback that can be feasibly and reliably implemented into clinical practice using a bedside transition checklist and a patient-centered, multi-disciplinary approach.
- By the end of April 2018, improve rates of resident use of the standardized handoff system from 25% to 75% and to reduce ICU length of stay (and associated bed-day costs) among medical patients who are not on hospice or comfort measures in the University of Colorado Hospital (UCH) Medical ICUs by 10%. We will measure a number of pre-specified patient outcomes (ICU-free days, mortality, etc.) to determine if our intervention improves patient care and safety.
- We aim to refine and improve this health system initiative through iterative PDSA cycles using resident and staff feedback, patient outcome measures, and cost-saving estimations. These process improvements if successful may allow dissemination to residency programs outside of the University of Colorado.
- We aim to improve housestaff knowledge of safe care transitions.

This project has been awarded a Clinical Effectiveness and Patient Safety (CEPS) award to evaluate the above objectives. The CBC will work with the investigator to finalize study design details and conduct data analysis on patient and resident factors.

Timelines/Deadlines

The investigator plans to begin the intervention in September, with the first TOC opportunity occurring at the end of that month. The first round of interventions will take place over 3 or 4 months (TBD), after which an initial analysis will be conducted. A second round of interventions will take place, and the analysis will be repeated. Note that all outcomes and analyses will be defined for the first analysis, and the second analysis will consist only or a repeat of the first. Below is a list of action items and associated timeframes.

- Assist with pre-post survey development: August, complete by August 31
- Review REDCap database: August, complete no later than August 31
- Summarize retrospective data and calculate ICU free days: This will take between 2-4 weeks following receipt of retrospective data pull – tentatively scheduled for September
- Power calculation to determine whether 3 or 4 months of intervention should occur – same timeframe as retrospective data summary
- Analysis of initial intervention data – this will take approximately 4-6 weeks upon receipt of the data. Note that this is dependent on how much notice we have on the data, as well as timing (during December student RAs have finals and abstract commitments, and analysis may take more time).

Study Design

This study will consist of an intervention targeted at the medical ICU (mICU) at University Hospital during the Fall / Winter of 2017/2018. Each month, the mICU has 4 teams of resident/intern pairs, and transition of care handoffs occur after the end of each 28 day rotation. Thus, for 3 months, there will be 3 opportunities of handoffs between 4 teams. The investigator plans a 4-pronged intervention which will consist of an education session, a bedside face-to-face handoff, a checklist handoff, and a targeted daily medication review. Based on pilot data, the investigator estimates that 25% of handoffs happen as they should, and this study is designed to demonstrate improvement in those rates, as well as improved patient outcomes. Patient and resident outcomes will be evaluated for a 3 or 4-month phase immediately after implementation. After 3 months, changes to the intervention will be made as appropriate, and another 3 months of evaluations will occur. Results will be compared to post-intervention data.

Anticipated Sample Size

The study population will consist of any patient in the mICU on day of transition at 7 am. The investigator anticipates there will be between 90-120 patients meeting this criteria. There will be 4 residents per month, for a total of 12-16 residents (plus interns) for each 3-month evaluation cycle.

Descriptive Statistics Desired

Patient demographics in pre and post intervention groups (standard Table 1), and summarization of resident and intern characteristics as needed.

Hypothesis

Primary

Hypothesis	The intervention will improve patient outcomes
Outcomes	Main: ICU Free Days Additional: Hospital LOS, ICU LOS, Mortality, Readmission, ventilator free days, rapid response calls
Explanatory Variable	Intervention

Secondary

Hypothesis	The intervention will improve resident handoffs and adherence to a standardized system
Outcome(s)	Main: Proportion of face-to-face handoffs Additional: Checklist completion (checklist is completed per patient), time to complete handoff, ratio of perceived value to extra effort
Explanatory Variable	Intervention

Additional Notes

- The biostatisticians should work with the investigator to identify the best control group (or groups); specifically, the retrospective window to use, and whether other units in UCHealth or at DHHA may serves as good comparators.
- Should seasonal factors may need to be considered when evaluating this data; e.g., people tend to be sicker and have worse outcomes in the winter?
- Analyses of the secondary hypotheses will require some discussions and planning with the investigator; for example to evaluate the proportion of face-to-face handoffs, a control / pre group may not be available, and a one-sample test comparing the proportion observed in the intervention against a set value (e.g. 30% or 50%) may be more appropriate. For other outcomes, such as the perceived value to extra effort, pre-post survey may be used to allow pre-post comparisons.

Approval of Agreement

By approving this Scope of Work Agreement, you are acknowledging that you have read and agree to the project costs and milestones, timelines, project details, and terms and conditions outlined in this document.

To approve this Scope of Work Agreement click the button below.

Approve Scope of Work Agreement ▸

(If you don't agree with this Scope of Work Agreement or would like to withdraw your request for CBC services, please send us an email to cbc.project@ucdenver.edu with a brief explanation.)

Terms and Conditions

Clean data requirements - ready for analysis

The data are assumed to be cleaned and ready for analyses unless otherwise agreed upon, and a data dictionary should be provided to the analyst. We strongly encourage the use of REDCap as a data collection and management tool.

Report writing, abstract and manuscript preparation and revision

A final report will be created with an introduction, statistical methods, and results section. These sections will be close to publication ready. The CBC biostatistician will edit the methods and results section for publication and read the final version of the manuscript prior to submission. Assuming the biostatistician has provided significant contribution to the manuscript in terms of performing analyses and contributing to the results and methods sections, the biostatistician shall be a co-author on the publication, acknowledging the intellectual contribution of the work.

Assuming no substantial new analysis is needed, the CBC biostatistician will assist with writing a response to reviewer's statistical questions, make revisions to the paper and review the final version of any revised manuscript. If substantial new analysis is required, a new scope of work will be created and with costs agreed upon by both parties.

CBC Authorship Guidelines

The CBC abides by the International Committee of Medical Journal Editors (ICMJE) guidelines concerning authorship. Visit our CBC website to learn more about CBC's authorship policies.

Specific CBC guidelines include:

- The biostatistician performing the analysis will be a co-author on the publication to acknowledge the intellectual contribution to the work. Statistician co-authors will use their primary appointment affiliation on manuscripts and abstracts.
- To maintain study and statistical integrity, data collected for publication and abstracts will only be analyzed after study completion.
- The CBC biostatistician performs the analysis, collaborates in the structuring of the presentation of the results, and writes the "statistical methods" section of the paper.
- The biostatistician reviews the publication and any revisions prior to submission.
- The biostatistician will assist with revisions, keeping in mind your revision deadlines.

CBC's right to cancel or close out a project

Please approve the Scope of Work (SOW) within 15 days (or prior to anticipated start of work, if less). SOWs not approved within 30 days will be closed. Projects which remain inactive for over 60 days will be closed unless prior arrangements have been made, and a final bill will be sent for work completed.

CCTSI subsidized projects

If the project cost is subsidized by the Colorado Clinical and Translational Sciences Institute (CCTSI), you are required to cite the CCTSI grant in posters and publications. Please review the CCTSI's Citation and CTSA grant language.