Biostatistics Scope of Work Agreement

General Information

Investigator	Christopher Schifeling christopher.schifeling@ucdenver.edu	**Date**	July 24, 2018
Project Number	P1351Schifeling		
Project Title	Missed and delayed diagnoses of palliative care in terminal hospitalizations		

Understanding of Project

Project Description

The study is a retrospective evaluation of electronic health data (EHR) to evaluate the rate of missed and delayed diagnoses of palliative care for people who are terminally hospitalized. Studies indicate that palliative care has benefits during the end of life process at least 3 months prior to patient death, however, it is more common that patients are provided these services within their last month of life. In this study, we will assess the rates of palliative care diagnoses within the UC Health system and describe patterns of care among different patient populations.

Description of data: Data will be pulled from Health Data COMPASS. Patients who were terminally hospitalized (died in-patient or within a week of discharge), who were not pregnant, or did not have a traumatic or sudden death (based on ICD10 codes) between 2015 to summer of 2018 will be included in the cohort. The investigator anticipates a few thousand patients will meet inclusion criteria during the study timeframe. COMPASS will pull patient and hospitalization data, as well as all prior encounters in the UC Health system within the prior year before death. The dataset will include the following:

- Patient characteristics and demographics (age, gender, race, ethnicity, etc)
- Chronic diseases (binary yes/no for several diseases)
- Zip codes as a marker of SES
- Encounter data in year prior to death (e.g. specialist vs pcp, count of visits)
- Palliative care order: Binary – was a palliative care order placed by a provider
- Palliative care order date: Date first palliative care order placed
- Type of palliative care (in-patient consult, out-patient clinic, home based)
- Date of death
- Cause of death

Detailed Analysis Plan: CIDA will conduct descriptive analyses to describe the rate of palliative care diagnose and trends within the data. Descriptive statistics will be generated for the following information:

- Table 1: demographic and patient characteristics of the study population
- Rate of palliative care orders and % of individuals who were not prescribed care
- Rate of delayed palliative care (definition of delay needs to be confirmed with investigator)
- Mean / median time between first palliative care order and death
- Rate of in-hospital, at-home, SNF, and hospice deaths within this population by disease state
- Mean / median number of encounters in year prior to death; we will estimate overall rates, as well as rates stratified by whether an order was placed

In addition, CIDA will conduct limited hypothesis testing for between 3-5 hypotheses. Tentative hypotheses are:

- Is the time between palliative care order and death date significantly less than 3 months?
- Does time between palliative care to death date differ significantly between patients with different diagnoses or diseases?
- Is the rate of missed diagnoses for palliative care different between different diagnoses / causes of death?

Deliverables:

- **Exploratory Report:** The exploratory report will consist of descriptive statistics outlined above.
- **Comprehensive Report:** Upon review of this report for completeness and data quality, CIDA will conduct hypothesis testing and provide the investigator with a comprehensive report containing a near-publication ready statistical methods section and results section including descriptive tables, figures, and hypothesis testing results.
- **Abstract and Manuscript Preparation:** Assuming the CIDA biostatistician's work contributes to the intellectual content of the study, the CIDA biostatistician will be included as a co-author on all submitted abstracts and manuscripts pertaining to this work. They will review the abstract and provide input, as well as assist with conference materials (poster or talk) if the abstract is selected. They will review the paper, assist with the methods and results sections, and assuming no substantial new analysis is needed, assist in revisions to the paper / response to reviewers.

Anticipated timeline: The investigator anticipates COMPASS will complete the data pull by end of August or early September, and will provide an update in mid-August regarding data status. Once data are available, CIDA will assign a biostatistical team and a kick-off meeting will be set up, tentatively by October 1, 2018. Assuming there are no data issues or other unforeseen delays, data analysis will take between 4-6 weeks from the kick-off meeting.

Note: the investigator hopes to submit an abstract in mid-December. Assuming data are available (clean and no unforeseen dealys) by November 1, CIDA will complete the analysis no later than December 10.

Other notes for the analyst: From the provided data, CIDA will calculate the time between the first palliative care order and death date, and create indicator variables for missed and delayed diagnoses. CIDA should work with the analyst to identify the most appropriate way to handle missed diagnoses (e.g. set to missing) for hypotheses testing and clearly specify each population to be included within a hypothesis test; e.g. to evaluate time between palliative care and death by diagnoses only for those who received palliative care.

Project Cost and Milestones

Project Type: Pilot Analysis, No 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: Pilot Analysis Complete pilot analysis and present a report. Additional changes to analysis are anticipated and part of the Project Complete phase.	$ 3,525
Total Due	**$ 3,975**

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 CIDA services, please send us an email to cida@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 CIDA 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 CIDA 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.

CIDA Authorship Guidelines

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

Specific CIDA 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 CIDA 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.

CIDA'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.