

Improving Time to Palliative Care Review With Predictive Modeling: Study Protocol for a Stepped-wedge, Pragmatic Randomized Controlled Trial

Patrick Wilson (✉ wilson.patrick@mayo.edu)

Mayo Clinic Minnesota <https://orcid.org/0000-0002-6604-444X>

Lindsey Philpot

Mayo Clinic Minnesota

Priya Ramar

Mayo Clinic Minnesota

Curtis Storlie

Mayo Clinic Minnesota

Jacob Strand

Mayo Clinic Minnesota

Alisha Morgan

Mayo Clinic Minnesota

Shusaku Asai

Mayo Clinic Minnesota

Jon Ebbert

Mayo Clinic Minnesota

Vitaly Herasevich

Mayo Clinic Minnesota

Jalal Soleimani

Mayo Clinic Minnesota

Brian Pickering

Mayo Clinic Minnesota

Study protocol

Keywords: Palliative care, electronic medical record, artificial intelligence, AI, pragmatic clinical trials, stepped wedge trials

Posted Date: March 25th, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-55430/v1>

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Abstract

Background: Palliative care is a medical specialty centered on improving the quality of life (QOL) of patients with complex or life-threatening illnesses. The need for Palliative care is increasing and with that the rigorous testing of triage tools that can be used quickly and reliably to identify patients that may benefit from palliative care.

Methods: To that Aim we will conduct a two-armed stepped-wedge cluster randomized trial rolled out to two inpatient hospitals to evaluate whether a machine learning algorithm accurately identifies patients who may benefit from a comprehensive review by a palliative care specialist, and decreases time to receiving a palliative care consult in hospital. This is a single-center study which will be conducted from August 2019 to November 2020 at Saint Mary's Hospital & Methodist Hospital, Mayo Clinic, Rochester, Minnesota. Clusters will be nursing units which will be chosen to be a mix of complex patients from Cardiology, Critical Care and Oncology and had previously established relationships with palliative medicine. The stepped wedge design will have 12 units allocated to a design matrix of 5 treatment wedges. Each wedge will last 75 days resulting in a study period of 12 months unless otherwise specified. Data will be analyzed with Bayesian hierarchical models with credible intervals denoting statistical significance.

Discussion: This intervention offers a pragmatic approach to delivering specialty palliative care to hospital patients in need using machine learning, thereby leading to high value care and improved outcomes. It is not enough for AI to be utilized by simply publishing research showing predictive performance; Clinical trials demonstrating better outcomes are critically needed. Furthermore, the deployment of an AI algorithm is a complex process that requires multiple teams with varying skill sets. To evaluate a deployed AI, a pragmatic clinical trial can accommodate the difficulties of clinical practice whilst retaining scientific rigor.

Trial registration NCT03976297 (ClinicalTrials.gov), registered on June 6, 2019 prior to trial start.

Background

Palliative care is a medical specialty centered on improving the quality of life (QOL) of patients with complex or life-threatening illnesses through the prevention and management of pain and other problems, be it physical, psychosocial and/or spiritual [1].

As patient populations in western countries are aging and becoming more complex, often requiring care from multiple specialties, there is a growing recognition of the need for specialty palliative care teams to engage with patients earlier in their disease course. A consequence of this increased demand is exemplified by the growing mismatch between clinical care and patient preferences at the end-of-life. For example, research has demonstrated that most people prefer to die at home despite the majority dying outside of the home (nursing home or hospital) [2–3]. Palliative care specialists excel in goals of care and patient preference discussions. Unfortunately, palliative care expertise is often an underutilized

resource, and the current model of care and incentives may relegate palliative care as a “last resort” after all attempts at cure have been exhausted [4]. This delay can lead to suboptimal symptom management for pain, lower quality of life, and even reduced survival [5–8]. In addition to these unrealized benefits, palliative care has been shown to be inversely associated with aggressive medical interventions and emergency room (ER) visits, hospital and intensive care unit (ICU) admission and death in the last weeks of life, all of which are indicative of low value care [9–11]. Demand for appropriate palliative care will and should increase, and with that policy initiatives and referral triage tools that lead to timely high-quality palliative care services will need to be implemented [12]. Triage tools can be used quickly and reliably to identify patients that may benefit from palliative care, thereby leading to high value care and improved outcomes.

Risk Scores

The development of risk stratification and triage tools for palliative care services has an extensive history with early methods such as The Palliative Prognostic Score (PaP) [13, 14]. Although a complete enumeration of scores in this space is out of scope, there are three aspects of palliative care scoring that are important to mention. First, many palliative care tools often use proxies for palliative care need. For example, mortality tends to be the most common proxy usually in the form of the Surprise Question - “Would I be surprised if this patient died in the next 12 months?” Although straightforward, mortality as a proxy is substandard, because many patients who are at risk of mortality do not necessarily need palliative care and many patients can benefit from palliative care interaction, even if their risk of short term mortality is low. Other scores have modeled proxies such as use of hospice services but still limit care to end of life and not the entire spectrum of palliative care needs [15, 16]. Second, palliative care tools often have a targeted timeframe or specified population. For instance, early palliative care scores were focused on patients with cancer, whether late stage or early stage [17]. Subsequently, scores have been developed specifically for inpatient, either general floor or ICU units or community based [18–20]. Although these scores have greater utility, they limit the ability to transfer to other populations which may limit legitimate palliative care need. Third, the complexity of a score is often an important consideration. Earlier models have utilized scores that were simple and easy to calculate, and could be done through clinical examination. Recently with the advent of artificial intelligence (AI) and near universal adoption of electronic medical records (EMR), scores are now being developed that utilizes large and complex types of routinely collected data for predictions. Avati et al. developed a deep learning algorithm on EMR data utilizing a model with 13,654 features predicting mortality, and Jung et al. developed an outpatient mortality prediction algorithm utilizing 1,880 features and using gradient boosting machines (GBMs) [20, 21].

Development of Integrated Palliative Risk Score Algorithm

Informed by these considerations, a machine learning algorithm trained on EMR data and fully integrated into an IT solution focusing on the identification of patients who may benefit from early palliative care review was developed on inpatients from a large academic medical center. The solution, known as

Control Tower, pulls disparate data sources centered on a machine learning algorithm which predicts the need for palliative care in hospital. The algorithm along with other key patient indicators was integrated into a graphical user interface (GUI) which allows a human operator, known as the Control Tower Operator (CTO) to review the algorithm predictions and subsequently record the operator's assessment.

Evaluation of AI

Despite the large number of published risk scores in the literature for palliative care needs, to the best of our knowledge, there has been a lack of research assessing wide scale *evaluation and implementation* of palliative risk scores into clinical practice. Often scores are tested based solely on predictive performance with validation consisting of clinical review. As hypothesized by Spiegelhalter, it is not enough for algorithms to be trusted by simply publishing research showing predictive performance (Phase I) or clinical assessment (Phase II); two additional phases are needed. First, there should be field testing with clinical trials demonstrating an impact on clinical outcomes (Phase III) as well as an infrastructure to ensure prospective monitoring during routine use [22]. There have been some encouraging and notable exceptions nonetheless; In Courtright et al. the authors published an EHR algorithm for palliative care with a pre-post evaluation on frequencies of consults, advance care planning (ACP) documentation, home palliative care and hospice referrals, code status changes, as well as length of stay [23].

Aims of the Study

The objective of this study is to evaluate whether the Control Tower solution accurately identifies patients who may benefit from a comprehensive review by a palliative care specialist, and decreases time to receiving a palliative care consult in hospital. By creating an algorithm that automatically screens and monitors patient health status during their hospitalization, the hypothesis being tested is that patients will receive *needed* palliative care earlier than under the usual course of care.

Trial Design

To accomplish the primary aim we will use a two-armed stepped-wedge cluster randomized trial rolled out to both inpatient hospitals in Mayo Clinic, Rochester. Trial units will receive a computerized assessment of patients in the hospital identified to be at risk of needing palliative care services where control units will receive the usual source of care.

Methods/design

Study Setting

This is a single-center study which will be conducted from August 2019 to November 2020 at Saint Mary's Hospital & Methodist Hospital, Mayo Clinic, Rochester, Minnesota. The nursing units chosen for the study have a mix of complex patients from Cardiology, Critical Care and Oncology and had previously established relationships with palliative medicine.

Eligibility Criteria

The recruitment and enrollment is broad and is designed to mimic the actual use of the Control Tower in practice. To be included in the trial, patients will need to be admitted to either inpatient facility during the study period. Patients will need to have a risk score of at least 7 (out of 100) from the algorithm. Patients will be excluded from review if they are under the age of 18, previously seen by palliative care during the current hospital encounter, currently enrolled in Hospice or currently followed by a palliative care team. In addition, patients with an expected discharge in the next 24 hours and patients who do not provide research authorization to review their medical records for general research studies in accordance with Minnesota Statute 144.335 will be excluded from the study.

Intervention

Interventions: A full description of the Control Tower interface can be learned through Murphee et al. [24]. Briefly, the Control Tower is a workstation and software tool that extracts medical data, processes the prediction algorithm, and presents the results through an ordered patient list. Currently the algorithm is running on all inpatients in both study hospitals in an automated monitored process. A screenshot of the interface can be seen in Fig. 1. In addition to the algorithmic score, additional data on comorbidities, laboratory values and hospital events are available and presented to give the score context. Patients receive scores from the Control Tower (0-100; higher score indicating increased need) for palliative care and are subsequently ranked from highest to lowest need with each score colored into tertiles: Red (7 or greater), yellow (less than 7, greater than or equal to 4), and white (less than 4). Patients with previous palliative care in their hospital stay have their scores labeled green.

The Intervention will include a CTO who will interact with the inpatient palliative care consult service at both study sites. The CTO will monitor the Control Tower during weekday normal business hours (Monday through Friday; 8am – 5pm) and select once a day, a cohort of patients with the highest need who may benefit from palliative care review. The operator will assess for any additional exclusion criteria in developing the final list. After all screening is finished the CTO will select the top 12 patients to be sent to palliative care in a file through email. The number 12 was agreed upon to match the expected capacity of the palliative care team and to maintain regularity throughout the trial. The file will consist of the patient identifying information, along with the algorithmic score indicating probability of needing palliative care, and contextual factors such as the hospital unit they are in and what factors in the model are driving the score. The palliative care team member who is on service will also assess the need for each patient through the daily report and record whether they agreed with the algorithm's conclusion or not. For those agreed upon patients who are also in the intervention arm, the palliative care team will approach the attending clinical team to suggest a palliative care referral for the patient.

The utilization of a new tool such as the Control Tower to identify patients appropriate for palliative care can be disruptive to standard clinical workflows and processes. To help ensure proper dissemination of these new referral patterns, we engaged with a communications specialist and worked directly with area practice leaders to set up a communication plan.

Patients who are not in an intervention period will receive the standard of care. This is feasible given we can easily control the communication between the palliative care team and the attending teams to prevent any contamination between clusters. Furthermore as stated above, we calibrated the prediction model and the Control Tower review to match the average capacity of the palliative care service, knowing that they will still receive palliative care consults through the traditional pathway i.e. the attending care team consulting palliative care directly. This additional measure increases the likelihood the control group gets the usual source of care.

Outcomes

For all study outcomes, data will be collected through either the electronic medical record or administrative billing system at trial completion. The primary outcome will be timely identification for need of palliative care as measured by the electronic record of a consult by the palliative care team in the inpatient setting. Data will go through quality checking quarterly, at each step during the burn in period, and before finalization.

The secondary outcomes are as follows:

1. The number of inpatient palliative care consults - Measured by the rate of palliative care consults in the inpatient units of interest.
2. Timely identification for need of palliative care per unit - Measured as time in hours from admission to the electronic record of consult by the palliative care team in the inpatient setting for each of the 12 nursing units.
3. Transition time to hospice-designated bed - For all patients with Medicare insurance the time from admission until transferred to a hospice-designated bed.
4. Time to hospice designation - Measured as time in hours from admission to the electronic record of consult by the hospice care team in the inpatient setting.
5. Emergency Department visit within 30 days of discharge - Measured by the number of study participants who upon discharge from the inpatient setting are readmitted to the Emergency Department at any Mayo Clinic facility within 30 days (excluding inpatient readmissions through the Emergency Department).
6. Hospitalization or readmission within 30 days of discharge - Measured by the number of study participants who upon discharge from the inpatient setting are readmitted to an inpatient unit at any Mayo Clinic facility within 30 days (excluding transfers and planned readmits).
7. ICU transfers - Measured by the number of study participants who transferred to an ICU during their inpatient stay.
8. Ratio of inpatient hospice death to non-hospice hospital deaths - Measured by the number of deaths of study participants in hospice designated beds by the number of deaths in non-hospice beds.
9. Rate of discharge to external hospice - Measured by the number of participants whose electronic health record indicates discharge to external hospice.

10. Inpatient length of stay - Measured as time from admission to discharge from hospital for all study participants.

Participant timeline

In the stepped-wedge design clusters, in this case floor units, cross over randomly (computer generated) from the control or standard of care condition to the intervention condition in a staggered fashion. The stepped wedge design will have 12 units allocated to a design matrix of 5 treatment wedges. Each wedge will last 75 days resulting in a study period of 12 months unless otherwise specified. The first step will be a baseline period in which no intervention is administered; where in the last step all clusters will be treated [Table 1]). At the start of each wedge there will be two weeks of burn-in to allow the clinical team to integrate the intervention with their workflow. Due to the pragmatic nature of the design we are unable to blind providers to whether they were in the intervention unit or control unit.

Data Analysis Plan

Summarized patient data will be characterized by age, sex, and baseline covariates entered into the machine learning algorithm. All patients will be analyzed on an intention to treat status; this principle will be extended to the cluster status in the event of transfers between intervention and control units.

For all study outcomes Bayesian estimation to account for design features in the stepped design will be used. Specially, time-to-event modeling to assess the effects of the intervention will be used to model timely palliative care and other time to event or count outcomes. The chosen model consists of a hierarchical regression treating the time-to-event as a heterogeneous Poisson process, allowing for adjustment to the event rate due to secular time effects and unit clustering. Unit clustering will be treated with normal random effects and the secular trend will be modeled with autoregressive prior of order 1. Statistical tests will be based on 95% credible intervals. For secondary binary outcomes logistic regression will be used with the same design features.

Stepped-wedge cluster randomization trials typically have more statistical power than other cluster randomized designs when clusters are correlated, because each cluster is able to serve as its own control. Because of the complex nature of the design, we estimated statistical power using Monte Carlo simulation [25]. Our model for the simulation consisted of a hierarchical Poisson regression with the outcome being time to palliative care. Random effects for cluster as well as a time series autoregressive model for secular trend were integrated to correctly specify the wedge design. To estimate reasonable parameters for this model we collected pilot data for all Mayo Rochester inpatient admissions in 2017 with palliative care consult status. With estimates of the intra-correlation of clusters, and secular trend estimated from data we have at least 80% power in several scenarios for the 12 month timeframe to detect Incident rate ratios (IRRs) of 1.25 or greater. See Fig. 1 for the power curves; we tested various scenarios with varying number of clusters and time windows. We choose the 12 month time frame and opted for scenario 2 because it is a good compromise between the power of the test (assuring we could detect a reasonable effect) and implementation (palliative care wanting to make sure they could set up a

well-defined and accepted process on each of the selected intervention units to ensure intervention fidelity).

Data Management

All data for all study outcomes, model covariates and process measures will be collected through three principal means:

1. All input predictors and model predictions from the machine learning model are logged every time the algorithm is called and our stored in a study database.
2. Study outcomes will be collected through electronically pulling administrative billing data or data from the health systems EHR.
3. Process measures (number of palliative care accepts and reasons for rejection) will be collected through the daily logs transferred between the CTO and Palliative care team

For each variable pulled electronically we will do a validation study to make sure that it is measuring the appropriate concept.

Data Monitoring

The proposed intervention does not exceed the threshold of minimal risk so no data monitoring committee (DMC) will be created. Pursuant to this there will be no interim analyses or stopping rules for ending the trial early. Risks of this study to patients are expected to not differ from those encountered during routine clinical care. Patient safety will be maintained through the clinical staff adhering to the standards of clinical care. Study logs will be audited on a quarterly basis for reporting purposes but no statistical analyses will be done and there will be no decisions made on the data to stop or continue the trial.

Confidentiality

Patient's participation is only through the utilization of hospital services with no additional contact or visits needed; therefore the hospital's policies and procedures for maintaining patient privacy with respect to data will be in place. All patient data are securely stored behind an electronic firewall and will be stored on separate, password-protected, secure servers; only study personnel will have access to these data. For report purposes we will use the Centers for Medicare and Medicaid Services (CMS) data protocol; all results will be reported in aggregate with no cells size smaller than 10.

Dissemination policy

Every attempt will be made to have our work published in the literature regardless of outcome and trial summary results will be submitted to ClinicalTrials.gov following the completion of the trial. The team will follow any standard authorship requirements as specified in journals we attempt to publish in.

A checklist of recommended items to address in a clinical trial protocol according to the "Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013" guidelines is also provided [see

Additional file 2].

Discussion

This study investigates the effect of a machine learning algorithm integrated into a healthcare delivery model to bring timely palliative care to patients in the hospital.

Significant knowledge gaps exist about how risk algorithms routinely perform in practice settings due to the complex nature of the task. Building an algorithm, creating the infrastructure to deliver it in real time, and developing a healthcare model that integrates the algorithm into healthcare delivery and improves outcomes require a large interdisciplinary team. Not surprisingly, the development of such a team is often difficult to create and maintain. In the current paradigm of scientific funding and recognition it may often be a risky decision to engage in team science vs. research which focuses on smaller scale efforts that lead to more research publications [26, 27].

Given the nature of this pragmatic clinical trial there are several strengths and limitations that are worth noting. As this trial is imbedded into the clinical practice, the patient population is well represented with very few exclusion criteria and a waiver for both patient and provider consent. Additionally this trial has considerably less burden, as the number and complexity of study visits, study procedures, and questionnaire burden are non-existent and the assessments carried out by study staff are intrinsic to the healthcare model, meaning that if implemented they would be a part of an intervention and are minimal as to not disrupt the usual source of care.

However pragmatic research is not without its limitations. Principally the trial relies on routinely collected data and exclusively uses EHR data for study outcomes. Take our primary outcome as an instance; the choice of timely palliative care is largely a pragmatic measure due to the routine storage of specialty consults in the EHR. Although seemingly more important measures such as unnecessary utilization or quality of life could be ascertained, we opted to target a measure that had adequate power and could be routinely collected throughout the trial without too much burden to practice. In addition the ability to validate EHR measures is limited; the ability to do small validation studies is feasible for key measures but full adjudication is not possible.

Abbreviations

Table 1
List of Abbreviations

QOL	Quality of Life
ICU	Intensive Care Unit
ER	Emergency Room
AI	Artificial Intelligence
EMR	Electronic Medical Record
PaP	Palliative Prognostic Score
GBM	Gradient Boosting Machine
GUI	Graphical user interface
CTO	Control Tower Operator
ACP	Advanced Care Planning
IRR	Incidence Rate Ratio
CMS	Centers for Medicare and Medicaid Services
MB	Mary Brigham Unit of Saint Mary's Hospital
EI	Eisenberg Unit of Methodist Hospital

Declarations

Ethics approval and Consent to Participate

The protocol for this study was approved as a minimal risk study by the Mayo Clinic Institutional Review Board (IRB) (No. 19-002315). The IRB waived the requirement to obtain individual patient consent and provider consent due to the pragmatic nature of the design. All protocol amendments will be subjected to IRB approval and will be updated subsequently in the clinical trial registry.

Consent for Publication

Not applicable

Availability of Data and Materials

De-identified datasets will be available to qualified investigators through communication of reasonable requests with the PI after primary results manuscripts are accepted.

Competing Interests

The authors have no conflicts of interest or competing interests to disclose.

Funding

This study is funded by the Kern Center for the Science of Health Care Delivery and the Clinical Practice Committee (CPC) at Mayo Clinic. The content is solely the responsibility of the authors and does not necessarily represent the official views of the Kern Center or the CPC.

Author Contributions

P.M.W, C.B.S., PR, and LP developed the study design and drafted the study protocol. P.M.W, C.B.S., PR, LP, and S.W.A developed the analytic and statistical plan. J.S and A.M. provided contributions to the Palliative medicine literature and B.P, J.S, and V.H provided insight on the clinical informatics. All authors will be actively engaged in the implementation of the study protocol. All authors have read, submitted comments and revisions, and approved the final version of this manuscript.

Acknowledgments

We thank the Center for Palliative Medicine, the IT analysts who developed and monitored the Control tower, and all the patients who participated in our study.

Trial Status

The protocol published here is version 1.3 dated May 5, 2020. The study began on Aug 19, 2020. Study recruitment commenced on that day and is expected to continue until November 17, 2020. Three events occurred that required a change to the protocol:

1. A logging error was discovered on 12/25/2019 which lead to two units not being included in Control Tower: Mary Brigh (MB) 6 D/E and Eisenberg (EI) 4-4. This required one unit MB 6 D/E to be re-randomized because they were already in the intervention and would not have been able to contribute data in the control arm otherwise. EI 4-4 was entered into the trial on 11/25/2019; MB6 D/E was entered into the trial on 12/03/2019.
2. On 3/18/2020 the clinical trial was paused due to the COVID-19 pandemic. During this time there were no staff available to continue the trial. This pause was ended on 05/04/2020 and there was one week of burn in to allow staff to reorient to the control tower process.
3. An error was discovered in which the algorithm was not correctly calculating scores due to missing data. This delay was further exacerbated by IT furloughs due to the COVID-19 pandemic. As such we decided to remove data during this period (06/05/2020-07/15/2020) and added an additional month of follow up to the last wedge period.

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Figures

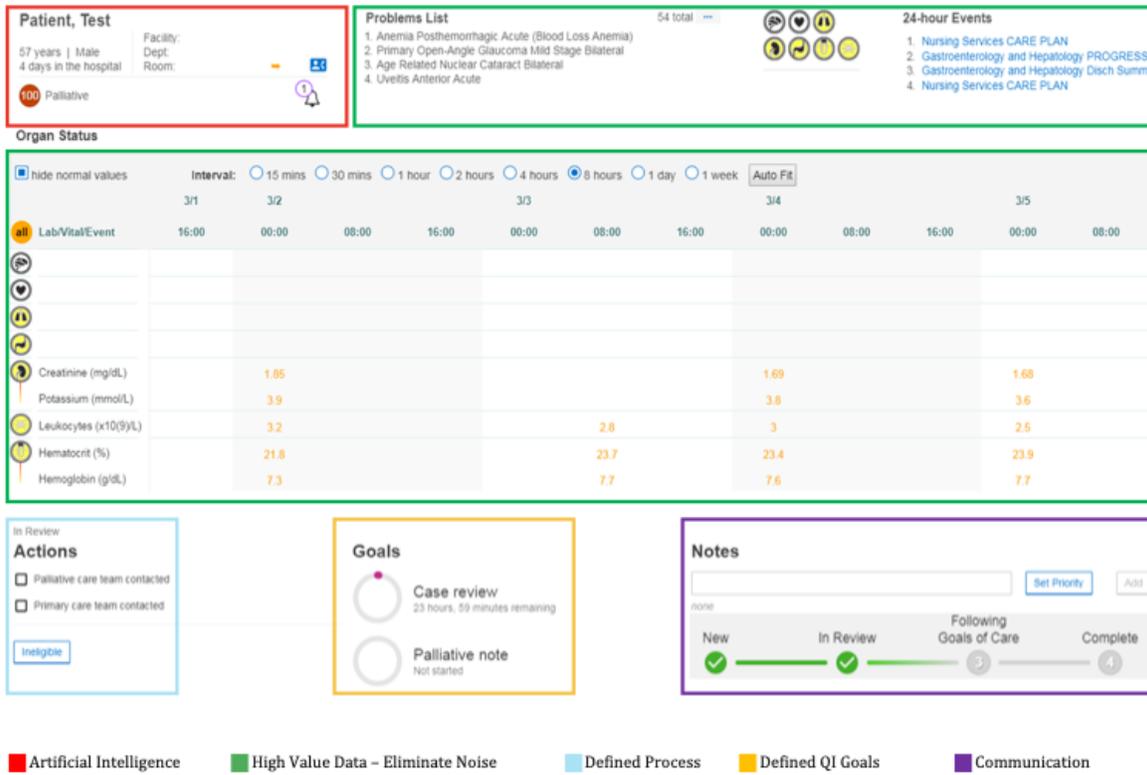


Figure 1

Screenshot of the Control Tower User Interface

Cluster List	Baseline Aug 19-Oct 31		Time 1 Nov 01-Jan 13		Time 2 Jan 14-May 20		Time 3 May 21-Aug 2		Time 4 Aug 3-Nov 16		Close Nov 17
ET 7					X			X			
EI 10-3/10-4					X			X			
MB 5 B/G					X			X			
MB 6 D/E	X	XXXXXX	XX		X			X			
Unit 4-3					X			X			
ET 5					X			X			
ET 4					X			X			
ET 6					X			X			
EI 4-4	X	XXXXXX	XX		X			X			
Data Collection											
Model Log Data	O	O	O		O			O		O	
Process Measures	O	O	O		O			O		O	
Study Outcomes											O

The trial will be conducted over 12 months with 12 inpatient units crossing from control to intervention in 75 day steps. Each cluster will have a burn-in period of 2 weeks at the start of the trial and when they receive the intervention. White cells denote usual source of care, and grey cells are intervention periods. The Xs signify when the intervention was silent, and Os indicate period when data collection occurs.

Figure 2

Stepped wedge design

Power for Various Evaluation Scenarios (Varying Number of Units)

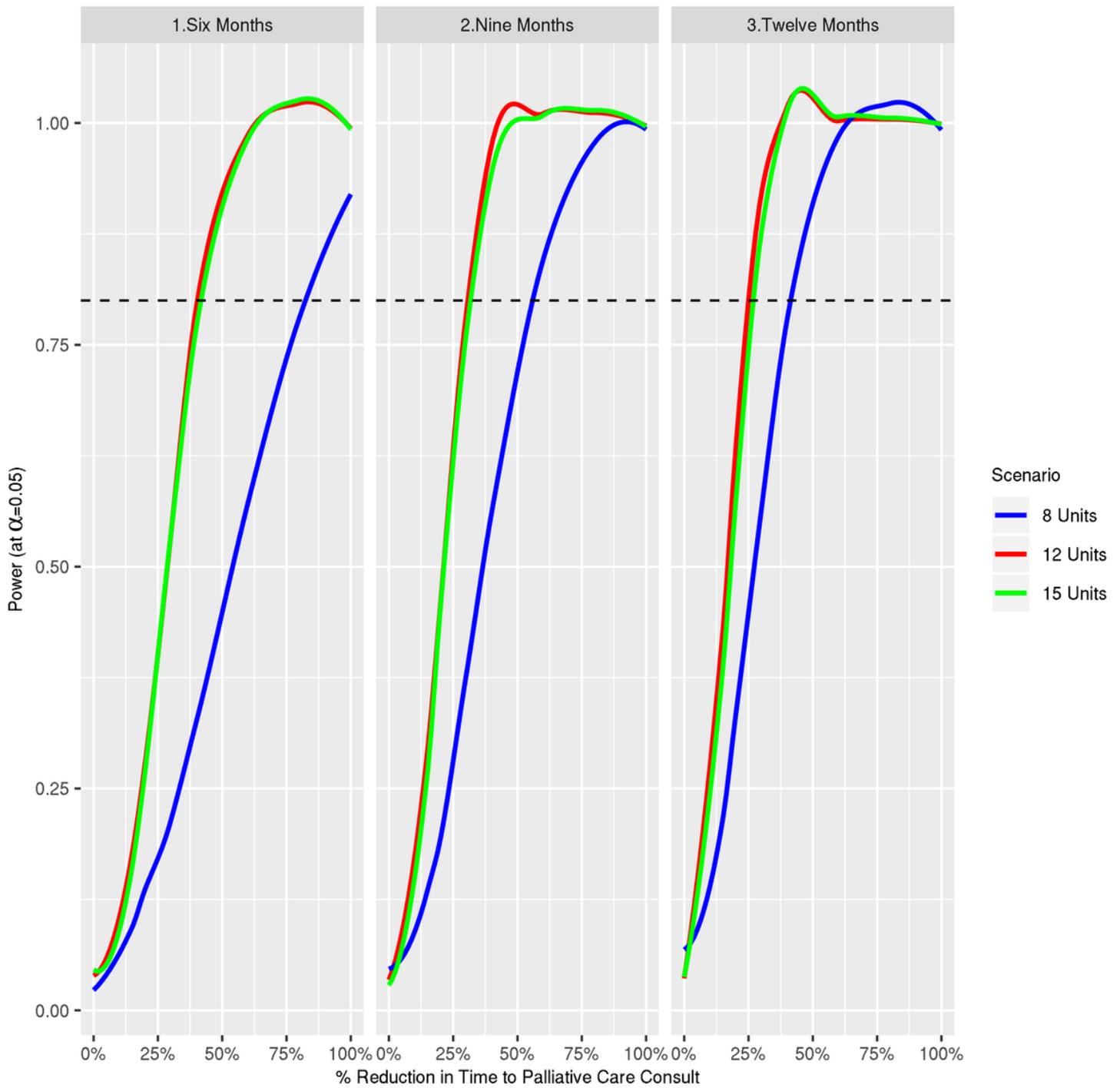


Figure 3

Stepped Wedge Design Power Curves

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SPIRITCTchecklistv2.doc