Author's response to reviews

Title: Design, rationale, and baseline characteristics of a cluster randomized controlled trial of pay for performance for hypertension treatment

Authors:

Laura A Petersen (laurap@bcm.tmc.edu)
Tracy Urech (tracy.urech@va.gov)
Kate Simpson (kate.simpson@va.gov)
Kenneth Pietz (pietz.kennethc@va.gov)
Sylvia J Hysong (sylvia.hysong@va.gov)
Jochen Profit (profit@bcm.tmc.edu)
Douglas Conrad (dconrad@u.washington.edu)
R. Adams Dudley (adams.dudley@ucsf.edu)
Meghan Z Lutschg (meghan.zimmer@va.gov)
Robert Petzel (robert.petzel@va.gov)
LeChauncy D Woodard (lwoodard@bcm.tmc.edu)

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Editors
Implementation Science
c/o BioMed Central
c/o BioMed Central
236 Gray’s Inn Road
London WC1X 8HB
United Kingdom

Dear Editors,

Thank you for the opportunity to revise the article entitled “Design, Rationale, and Baseline Characteristics of a Cluster Randomized Controlled Trial of Pay for Performance for Hypertension Treatment.” Our study is ongoing. We anticipate starting data collection for the post-washout performance period this September. We have included an explicit timeline of the study’s activities in this resubmission as Figure 4.

We have uploaded to the journal’s website an updated version of the manuscript as well as the completed CONSORT checklist for reporting cluster RCTs. Since this is a study protocol article that does not report results from the intervention period, we do not feel the CONSORT checklist items 13-22 (Results and Discussion of results) are appropriate at this time, and we do not address these in this response. Please find attached a point-by-point summary of the revisions. All changes in the manuscript are noted in bold

We look forward to hearing from you concerning our revised manuscript.

Best regards,

Laura A. Petersen, MD, MPH
Professor of Medicine
Chief, Section of Health Services Research
Baylor College of Medicine

Laura A. Petersen, MD, MPH
Professor
Chief, Section of Health Services Research
Department of Medicine
Baylor College of Medicine
Summary of revisions

Manuscript: Design, Rationale, and Baseline Characteristics of a Cluster Randomized Controlled Trial of Pay for Performance for Hypertension Treatment
Corresponding author: Laura A. Petersen

Abstract: We added the following text to the Methods/Design section on page 2 to address item 1 (allocation to intervention) on the CONSORT checklist, “All participants at the hospital (cluster) were assigned to the same study arm.”

Introduction
- We added a section on page 6 to address CONSORT checklist item 2 (rationale for cluster design). Since this section includes a new citation, we updated the reference numbers accordingly.

Design of Trial
Since our goal was to evaluate the impact of financial incentives on individual physicians as well as primary care provider groups, we implemented a cluster randomized controlled design and clustered at the facility level [12].

- We removed the following text on page 8 from the last paragraph of the Introduction section, “We have also structured our study to evaluate the persistence of the effect of financial incentives after the intervention ceases and to identify any unintended consequences of these explicit financial incentives on patients, providers, and the health care organization.” The new “Study objectives” section in the Methods includes this information

Methods/Design
- We added a section on page 8 to address item 5 (objectives) on the CONSORT checklist:

Study objectives
The goals of this study were to: (1) determine the effect of physician-level financial incentives on processes and outcomes of care for outpatients with hypertension; (2) assess the impact of group-level financial incentives; (3) ascertain whether there are additive effects of physician- plus group-level financial incentives; (4) evaluate the persistence of the effect of financial incentives; and (5) identify any unintended consequences of these explicit financial incentives.

- We revised the language in the section called “Study sites.” We changed the section title to “Study sites and constrained randomization.” Starting on page 9, we updated the text in the 1st paragraph to address CONSORT checklist items 3 (cluster eligibility) and 10 (randomization implementation). The underlined text in the 1st paragraph is not new to the manuscript but was moved from another location. In the 2nd paragraph starting on page 10, we revised the text to describe sequence generation, allocation concealment, and randomization implementation (items 8, 9, and 10 on the CONSORT checklist).

Study sites and constrained randomization
We partnered with 5 Veterans Affairs (VA) regional networks to implement the study. Within these networks, hospital-based VA outpatient clinics that could conduct human subjects’ research and had 8 or more eligible primary care physicians were potential study sites. Of the 22 potential study sites, only 12 met the requirements for study implementation: hospital director assent; Institutional Review Board (IRB) and VA
Research and Development (R&D) approval; having a credentialed individual willing to serve as the site’s PI; and having at least 5 consented physician participants at time of randomization. We stratified these 12 study sites on the following characteristics expected a priori to be associated with responses to financial incentives and the study outcomes of interest: teaching status, geographic location, participation in the ALLHAT study [4] (a very large trial of various medications used to treat hypertension in both VA and non-VA settings that included intensive education regarding hypertension control and use of evidence-based hypertension treatment at participating sites), and the degree of clinic geographic proximity within the primary care setting at each study site. We identified a hospital as a teaching facility if it was listed in the Association of American Medical College’s (AAMC) Council of Teaching Hospitals (COTH) directory or if the American Medical Association’s (AMA) Fellowship and Residency Electronic Interactive Database (FREIDA) listed the VA facility as having a “major” affiliation with a medical school. To determine geographic region, we used US Census Bureau information to identify the corresponding Census Division for each site. Study site investigators provided clinic layout information, and we designated sites as being integrated if the layout was amenable to group cohesion (e.g., the primary care clinic offices were located on the same floor at the study site).

We randomized at the cluster (hospital) level. To ensure that hospitals of the same type would not be concentrated in the same arm, we employed the following constraints: (a) all non-teaching hospitals could not be in the same arm; (b) all non-ALLHAT sites could not be in the same study arm; (c) no arm could have 2 sites from the same geographic location; and (d) at least 2 sites per arm had to meet the criteria for geographic integration (Figure 1). Using SAS version 9.1.3 (SAS Institute Inc, Cary, NC), a data analyst on the study team who was not involved in the processes of site selection or subject recruitment assigned a uniform random number to each of the possible allocations and selected the allocation sequence with the highest random number. The study team reviewed the resulting sequence to prepare for non-physician recruitment at the 6 sites randomized to the 2 group arms. Table 1 lists the characteristics of the study sites.

- We added text to the 2nd paragraph and revised paragraph 3 of the “Power and sample size” section to address item 6 (sample size) on the CONSORT checklist. In the 2nd paragraph starting on page 11, we added the sentence, “Using these data, we estimated values of the intraclass correlation of 0.39 for appropriate medication and 0.14 for BP control.” We updated the 3rd paragraph of this section to describe the number of clusters and cluster size:

We provide power calculations for the process and outcome measures. We calculated effect sizes for various values of the difference in percentage use of appropriate medication and BP control we could detect between the study arms with 80% power using a 2-sided t-test with 95% significance. Greater increases in power result from increasing the number of clusters than by increasing the number of cases within clusters [18]. However, it is much more difficult and costly to recruit more hospitals. We chose to use 3 hospitals per study arm with 5 physicians per hospital and 40 patient charts per physician. We determined that we could detect a difference of 17 percentage points between the mean proportions of appropriate medications in the arms for an effect size of 1.59. Similarly, for BP control, we determined we could detect a difference of 15 percentage points between the mean proportions in the study arms for an effect size of 1.30.
For the section “Baseline characteristics of study participants,” we revised the 2nd sentence in the 1st paragraph (page 12) to indicate who obtained information consent from the physician participants. In regards to CONSORT checklist item 9 (allocation concealment), we also added the following text in the 1st paragraph (page 13) to clarify the physician recruitment process, “Following randomization of study sites to study arms, we continued to consent eligible physician participants as necessary to meet our recruitment goal of 7 physicians per site (see Power and sample size section).” In the 2nd paragraph, starting on page 13, we revised the 3rd sentence to indicate who obtained informed consent from the non-physician participants.

In the “Audit and feedback” section (page 14), we made the following minor edits to the 1st sentence: added “of 5” before the word “data” and added the clause “approximately 4 months apart” at the end of the sentence.

We made minor edits to the 1st sentence in the “Financial incentives” section (page 14) to improve sentence structure and flow. We removed the 2nd sentence in the paragraph since the information is discussed in the “Study outcomes” section. We also edited the 2nd to last sentence (page 14) in the paragraph that discusses when and how participants received incentive payments.

In the “Data collection” section, in the 1st paragraph we clarified in the 2nd sentence (page 16) that data collection is being done by abstractors located at the Houston coordinating center. We added this per item 3 on the CONSORT checklist (notes to describe locations where data were collected). In the 2nd paragraph, we added the following text (page 17) to address item 11 (blinding), “Also, we blinded chart abstractors to the study’s objectives and to study arm assignments to ensure impartiality in the data collection process.”

In the “Washout period and post-washout period data collection” section, we added the following sentence to reference Figure 4 (new), “A timeline of the study’s activities, from physician recruitment to post-washout data collection, is presented in Figure 4.”

In the “Data analysis” section, we added the word “cluster” to describe facility in the 2nd to last sentence of the paragraph (page 19).