Title: Comparative effectiveness of post-discharge strategies for hospitalized smokers: study protocol for the Helping HAND 2 randomized controlled trial

Authors:

Zachary Z Reid (zreid@partners.org)
Susan Regan (sregan@partners.org)
Jennifer H.K Kelley (jkelley4@partners.org)
Joanna M Streck (jstreck@uvm.edu)
Thomas Ylioja (yliojat@upmc.edu)
Hilary A Tindle (hilary.tindle@vanderbilt.edu)
Yuchiao Chang (ychang@partners.org)
Douglas E Levy (dlevy3@partners.org)
Elyse Park (epark@partners.org)
Daniel E Singer (desinger@partners.org)
Kelly M Carpenter (Kelly.Carpenter@alere.com)
Michele Reyen (mreyen@partners.org)
Nancy A Rigotti (nrigotti@partners.org)

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Author’s response to reviews:

Dear Dr. Pafitis,

Enclosed please find our manuscript entitled “Comparative Effectiveness of Post-discharge Strategies for Hospitalized Smokers: Study Protocol for the Helping HAND 2 Randomized Controlled Trial,” which we are submitting for consideration for publication in BMC Public Health. Neither this manuscript nor any publication containing the results of this study has been published previously or are under review elsewhere.

This manuscript describes the protocol for an innovative, NIH-funded comparative effectiveness trial, testing two models for post-discharge smoking cessation treatment. This trial builds on the work of our recently-published smoking cessation trial that was shown to be effective for hospitalized smokers who want to quit smoking post discharge. The goal of the current trial is to move the research toward broad implementation by broadening eligibility criteria to include more vulnerable populations known to have high prevalence of smoking, by replicating the model in additional hospitals, and by streamlining the intervention itself to make it easier to implement in actual practice. The manuscript we are submitting addresses these differences as well as describing in detail the protocol of the new trial. Therefore, we believe that the manuscript will be of interest to readers of BMC Public Health.

This paper describes a protocol from a trial that is funded by an NIH/NHLBI R01
grant and has undergone peer-review by the funding body. It has Institutional Review Board approval. Per request, we have submitted the requested documentation to BMCSeriesEditorial@biomedcentral.com. The study status is currently ongoing. While study recruitment is complete, we are still collecting follow-up data from participants at the present time.

All authors have reviewed the manuscript and approve of its content. Dr. Rigotti receives royalties from UpToDate for chapters on smoking cessation and has served as an unpaid consultant for Pfizer and Alere Wellbeing, Inc. regarding smoking cessation. Dr. Park has a grant from Pfizer to supply varenicline for a clinical trial that is funded by NIH/NCI. No other contributing authors report any conflicts of interest related to this project to report.

Thank you for your consideration of our manuscript.

Sincerely,

Zachary Reid, BA