

Author's response to reviews

Title: A Controlled Trial of Value-Based Insurance Design: The MHealthy: Focus on Diabetes (FOD) Trial

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Author's response to reviews: see over



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Martin Eccles
Editor-in-Chief
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Brian Mittman, PhD
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Title: "A Controlled Trial of Value-Based Insurance Design: The MHealthy: Focus on Diabetes (FOD) Trial"

Dear Dr. Eccles and Dr. Mittman,

Thank you for your helpful comments on our manuscript entitled, "A Controlled Trial of Value-Based Insurance Design: The MHealthy: Focus on Diabetes (FOD) Trial." We have revised the manuscript in response to the suggestions raised by you and the two anonymous reviewers. The specific modifications are outlined below.

I believe the changes have substantively strengthened the manuscript and hope you will now find it suitable for publication in *Implementation Science*. Please do not hesitate to contact me should any additional questions or suggestions arise. Thank you for your consideration of this manuscript.

Sincerely,

Allison B. Rosen, MD, ScD

Responses to Referee 1's comments:

Point 1. MPR is a more flawed measure of medication adherence than you have discussed in your limitations paragraph on MPR (first full paragraph on page 21). Because the intervention should have a direct effect on pill-buying but only an indirect effect on pill-taking (that is, it should only increase true adherence in those patients for whom ability to purchase medications is a barrier to adherence) MPR is likely to modestly overestimate actual adherence, by causing some unknown number of patients to buy but not take their medications. It is still the correct outcome of the study-- this is a limitation, not a flaw-- but the paragraph should be revised to make this limitation more explicit.

We have made the following addition (underlined) to the last paragraph on p.20:

“Fourth, adherence is estimated using medication possession ratios, which assume that the supply of medication dispensed is an adequate proxy for patient adherence. However, because the intervention should have a direct effect on pill-buying but only an indirect effect on pill-taking, MPR is likely to modestly overestimate actual adherence, by causing some unknown number of patients to buy but not take their medications.”

Point 2. It is quite confusing to have the study setting where it is in the manuscript. The 3 paragraphs on study setting should be moved to the methods section, between hypotheses and study population identification.

Done.

Point 3. The last of those 3 paragraphs states that, "because chronic disease management programs are so prevalent, the presence of a disease management program, common to both the intervention and the control groups, increases study generalizability without compromising the comparability of the two groups." This is naive; far fewer patients are in disease management programs than are not. The sentence should be removed.

We have deleted this sentence.

Point 4. Least importantly, I would consider taking the statistical model and placing it in a figure so as not to disrupt the flow of the manuscript on page 17.

Done. The statistical model is now provided in Figure 2.

Response to Referee 2's comments:

Point 1. 1. What is the baseline use of the targeted medications in the two groups of patients? What is their average number of medications per month pre-intervention? This is important baseline information to put into Table 2 and bottom of pg 18 and will give some idea of the magnitude of medication use and change.

We have added baseline medication use to Table 2 and to the text on page 18.

Point 2. I think the authors primary outcome of medication use and adherence and secondary outcome of health utilization and costs is appropriate, however, the real and essential impact of the benefit change is if it improves patient health outcomes. The authors mention this in the discussion section on pg 19, however do not include information about health outcomes in their study. In administrative data there is information about intermediate endpoints (A1C, lipid panel, creatinine) and health events (MI, stroke, renal failure), and I am not clear why the authors did not decide to examine these outcomes.

Our decision not to examine these endpoints was one of necessity rather than choice. Examination of intermediate outcomes was complicated by incomplete laboratory data in the pre-period. In turn, the study was not sufficiently powered to explore health events.

Point 3. In Table 1 where the authors list the drug classes receiving co-payment reduction, I was confused that insulin was not on the list, particularly because the authors chose their cohort based on any diabetic medication use, including insulin. Was this deliberately left out? If so why?

We have added a footnote to Table 1, noting that Insulin was not included in the intervention because M-CARE already waived copayments for insulin.

Point 4. MHealthy: Focus on Diabetes is not described in the abstract under methods and I was a little confused trying to figure out what MHealthy meant/stood for.

We have made this change in the abstract.

Point 5. In the abstract methods section the authors should set up that this article introduces the intervention and provides baseline data. This is not clearly spelled out and I was looking for the results of the trial.

We have revised the abstract background section to read, "we describe the design and implementation of MHealthy: Focus on Diabetes, a prospective, controlled trial of targeted co-payment reductions for high value, underutilized therapies for individuals with diabetes" and the methods section to include, "individual patient-level baseline data are presented".

Point 6. Pg 11 beginning of the Hypotheses section "We hypothesize" should be changed to "We hypothesized".

Revision made.

Point 7. Pg 13 Study Design – Please note here how stable this population is – is there a lot of employee turnover? How will this affect the study?

We have added on page 12 that “UM employee turnover is low.” We also note, though, that the intervention population is not static. “Both new UM employees with pre-existing diabetes and current employees newly diagnosed with diabetes are automatically enrolled in the intervention upon having an eligible pharmaceutical claim filed.”

Point 8. It was not clear until the top of pg 18 that the author's analyses will be at the individual patient level (although that was what I had assumed). Please clarify this in the study design section and possibly the abstract.

We have added to the first paragraph of the study design section (on page 13) that the “unit of observation is the patient-quarter.”

Point 9. The legend of Figure 1 includes the information that the intervention group is composed of UW employees in any health plan and the control group is only non-employee M-CARE enrollees. This is an important point and not mentioned in the manuscript.

We have added the following text on page 17: “In turn, because there may be important differences between UM employees who enroll in M-CARE and those who enroll in other health plans, analyses will be repeated with and without the small subset enrolled in other health plans.

Point 10. Figure 1 doesn't have enough contrast, especially in the white circle, and is difficult to read in black and white.

Figure 1 has been revised.

Point 11. Seems to me a limitation of the study not address is that individuals over age 65 are excluded from the analysis, although I understand the rationale that multiple medication benefit changes were happening with Part D.

We acknowledge on page 21 that generalizability is limited to the ‘non-elderly U.S. population [that] has employer-based coverage.’

Point 12. Pg 12, 3rd paragraph – Are UM employees who want to opt in to the program given the discount in the same drug classes?

Yes. We now note on page 12 that these ‘opt-in’ individuals are “eligible for the full intervention.”