Official Title: A feasibility study of a novel mHealth clinical decision support application to enable community health workers to manage hypertension with remote physician supervision

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A. COVER PAGE

Project Title: mHealth to Enable Task Sharing for Hypertension Care in LMIC	
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Human Subjects: Yes **HS Exempt:** NA **Exemption Number:** **Phase III Clinical Trial:** NA	**Vertebrate Animals:** No
hESC: No	**Inventions/Patents:** No

4.3 Statistical Design and Power

As this aim is focused on determining the feasibility of CHW-led hypertension management, power analyses were not performed. The main outcome of interest for this aim is the agreement of CHWs and physicians with the CDS application's recommendation for antihypertensive medications. Based on our experience with a similar diabetes program and published results of other CHW interventions, we have set an agreement threshold of 90%. In order to account for application updates during the early stages of the study, agreement will be assessed in the last 3 months of the feasibility study. Agreement will be summarized as the raw proportion of visits for which both the CHW conducting the visit and the physician reviewing post-visit data agreed with the antihypertensive recommendations provided by the application. As a secondary analysis, we will also calculate agreement individually for CHWs and the supervising physician to examine any discrepancies.

Other continuous outcomes will be summarized using means and standard deviations, both at baseline and 6 months after enrollment. Paired measures will be assessed for change using mean change and standard deviation of change. These changes will be assessed statistically versus a null hypothesis of no change using paired t-tests or Wilcoxon signed-rank tests on the paired differences. The continuous outcomes include systolic and diastolic blood pressure, CDS application usability score,[65] patient weight, LDL, HDL, total cholesterol, triglycerides, fasting glucose, Hypertension Self-care Activity Scale (H-SCALE) subscores,[66,83] Patient Assessment of Chronic Illness Care (PACIC) subscale score and overall score,[64] and serum creatinine. Outcomes of study visit duration and physician review and care coordination time will be summarized over the whole length of the study, and examined for trends with respect to progression of the study, both with respect to calendar time, and time from patient enrollment.

Other dichotomous outcomes will be summarized using proportions; time of assessment depends upon the outcome. For outcomes that are measured at baseline and 6 months after enrollment, the raw proportions will be reported for both periods, and association between the outcome and the two periods will be statistically assessed versus a null hypothesis of no association using McNemar's test. Outcomes to be assessed for change from baseline include systolic blood pressure <= 140mmHg, systolic blood pressure <= personalized goal, adherence to self-care activities as indicated by established H-SCALE cutoffs, and global patient satisfaction with hypertension care. Outcomes to be reported over the last 3 months of the trial include agreement of CHWs and physicians with various CDS application recommendations (atorvastatin and aspirin prescription, and referral recommendations). Outcomes to be reported throughout the whole trial include visit completion, medication adherence, incorrect CDS recommendations and application errors and malfunctions, complications of hypertension or hypertension treatment, and referral recommended by CHWs that are completed. For the outcomes assessed over the whole trial, or in the last three months, the raw proportions and occurrence counts will be reported for these periods. Additionally, instances of these outcomes / frequency of occurrence will also be examined versus calendar time, or time since subject enrollment, for potential trends. Patient retention will be determined by proportion of original patents that participated in a follow-up visit 6 months or longer from their initial visit.