Encouraging Mail Order Pharmacy Use to Improve Outcomes and Reduce Disparities

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CLINICAL TRIAL PROTOCOL

Abbreviations:
CVD: cardiovascular disease
HPHC: Harvard Pilgrim Health Care Institute
IVR: automated telephone call (interactive voice response)
KP: Kaiser Permanente
KPNC: Kaiser Permanente Northern California
KPHI: Kaiser Permanente Center for Health Research, Hawaii
LDL: Low-density lipoprotein
PDC: Proportion of Days Covered

OBJECTIVE:

In this study, we seek to determine whether targeted, patient-centered interventions to encourage mail order pharmacy use will result in greater rates of mail order pharmacy use as well as improvements in medication adherence. We conducted a randomized encouragement trial to encourage use of the existing mail order pharmacy among diabetes patients with poor adherence to CVD risk factor medications who use only retail pharmacies and examined whether the intervention's impact differs across key subgroups. The specific aims of this clinical trial are to:

Aim 1: To test whether outreach strategies to encourage mail order pharmacy use will increase rates of mail order pharmacy use (Primary Outcome) in diabetes patients at high risk for poor health outcomes.
Aim 2: To examine whether encouraging the use of mail order pharmacy services to deliver cardiometabolic medications results in greater medication adherence, and to assess differences in the impact of the intervention across key subgroups.

BACKGROUND:

There is an urgent need for effective, sustainable interventions to improve diabetes medication adherence. Good medication adherence is associated with improved control of CVD risk factors, fewer hospitalizations, and lower mortality in patients with diabetes mellitus. However, only about 50-70% of patients with chronic conditions such as diabetes are adherent to their regular medications. In response to this problem, literally hundreds of interventions to improve adherence have been evaluated and published over the last 60 years. Traditional interventions almost always require substantial investments of personnel, time, and/or financial resources. However, they generally show only modest improvements in adherence, which dissipate completely once the active intervention phase concludes. Recent approaches such as medication therapy management are expensive to implement and limited to small subgroups of patients (e.g., Medicare Part D enrollees with multiple chronic diseases and multiple medications). These types of resource-intensive interventions will be challenging to disseminate and implement more widely and are unlikely to reach large numbers of adults with diabetes. Disparities in medication adherence are prevalent among patients with diabetes. The underlying reasons for these disparities in adherence are multifactorial, and include inability to afford prescribed medications, low health literacy and low health numeracy, low patient self-efficacy, inadequate patient-provider communication, and difficulty accessing pharmacies. Since poor medication adherence is linked to poor diabetes outcomes, improving adherence among minority and low-SES patients is critical in any effort to improve health care outcomes for these populations. There is only limited evidence that broadly targeted quality improvement efforts such as diabetes registries and care reminders impact disparities in diabetes care.

Evidence is growing that voluntary mail-order pharmacy use is linked to better adherence and outcomes. While the majority of efforts to improve adherence are focused on changing behavior at the individual level, recent studies have examined the role of pharmacy choice as a determinant of adherence. One recent multi- level analysis found that the between-pharmacy variation in medication adherence was significant and represents an independent pharmacy-level effect on adherence not explained by individual-level factors. This study also found that voluntary use of a mail-order pharmacy as compared to a retail pharmacy was associated with an 8-percentage point improvement in adherence to antidiabetic medications. Investigators on our study team have replicated this finding in several analyses using observational data for different chronic conditions, employing statistical approaches to mitigate selection bias. These studies show not only improved medication adherence with mail-order pharmacy use, but also lower LDL cholesterol among statin users and a decrease in racial disparities in adherence to antihypertensive medications. There is an urgent need for a well-designed, randomized trial to test strategies for improving mail order pharmacy use in diabetes patient at risk for poor health outcomes.

STUDY SETTING:

Research activities took place at the (3) locations listed below.

1. Kaiser Permanente Northern California (KPNC), Division of Research, Oakland, California
2. Kaiser Permanente Center for Health Research (KPHI), Honolulu, Hawaii
3. Harvard Pilgrim Health Care (HPHC) Institute, Boston, Massachusetts

STUDY DESIGN:

This study conducted a randomized encouragement trial to encourage use of the existing mail order pharmacy among diabetes patients with poor adherence to CVD risk factor medications who use only retail pharmacies. Subjects were randomized to (2) arms: 1) the intervention arm and 2) the usual care arm. Those randomized to the intervention arm, at all sites, received encouragement to use mail order pharmacy services by receiving an outreach letter, which includes information about the benefits of mail order pharmacy use, and information on how to enroll in mail order pharmacy services at their individual site. In addition, those randomized to the encouragement at KPNC and KPHI received an encouragement outreach email (secure message) and a pre-recorded phone message. Since phone and email contact with patients is not standard of care with HPHC, they received letter-only encouragement outreach. There was no outreach follow-up. Observational EHR data was used to examine the impact of the intervention on mail order use and medication adherence. Those patients randomized to the usual care arm did not receive any form of encouragement outreach from the study team.

STUDY POPULATION:

a. NUMBER OF SUBJECTS

63,012 total participants

b. INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria:

- Age 18 years or older
- Have a diagnosis of diabetes as indicated by EHR
- Have active health plan membership in the past 12 months
- Non-adherent (PDC <80%) to at least one oral CVD risk factor medications in the past 12 months
- Have no evidence of mail order pharmacy use to refill oral CVD risk factor medications.

Exclusion Criteria:

- Pregnancy or Dementia/Traumatic Brain Injury diagnosis in the past 12 months
- Hospitalized, in Skilled Nursing Facility, Hospice, or Home Health at the time of randomization

WAIVER OF INFORMED CONSENT and HIPPA PRIVACY RULE AUTHORIZATION:

A waiver of informed consent and HIPPA Privacy Rule Authorization was granted from KPNC IRB (IRB of record for this study) for participants in the study intervention. The only known risk is disclosure of confidential information. Safeguards were be put in place to prevent the loss of privacy and to prevent breaches of confidentiality. This study represented no more than minimal risk participants.

STUDY PROCEDURES:

Eligible patients were randomized into (2) arms: 1) an intervention arm and 2) a usual care arm. Those randomized to the intervention arm, at all sites, received encouragement to use existing mail order pharmacy services by receiving an outreach letter, which includes information about the benefits of mail order pharmacy use, and information on how to enroll in mail order pharmacy services at their individual site. The instructions on how to enroll in the existing mail order pharmacy services came directly from health plan operations materials. In addition, those randomized to the encouragement arm at KPNC and KPHI also received an encouragement outreach email (secure message) and pre-recorded phone message. Since phone and email contact with patients is not standard of care with HPHC, they received letter-only encouragement outreach. The letter and email outreach will be delivered only once. The Interactive Voice Response (IVR) system was programmed to make up to the IRB approved maximum attempts to contact eligible participants via phone to play the approved pre-recorded message: If a call is answered, the message begins. No PHI was disclosed in the outbound message. At the end of the call patients were given the opportunity to be transferred to their local mail order pharmacy phone line. Eligible members can hang up at any time and were not re-dialed. Those patients randomized to the usual care arm did not receive any outreach from the study team.

DATA ANALYSIS:

To examine the relationship of encouraging MOP use with MOP use and adherence, we estimated the differences in MOP use and CVD medication adherence at follow-up between the two arms using Chi-square tests in an intent-to-treat (ITT) analysis. Differences in the percentages of CVD drug fills delivered by mail were estimated using T-Test. To determine whether MOP use differed by race/ethnicity we calculated risk ratios using modified Poisson regression comparing the effect of treatment on outcomes within each group. We used Chi-square tests to compare the percent of patients with a hospitalization or emergency department visit during follow-up between the intervention and control arm and compared the number of primary care visits between arms using the Kruskal-Wallis test. Patients who died or who disenrolled from their health plan during follow-up were excluded from the analysis. In addition, those who did not have a CVD medication fill during the follow-up period were also excluded since we were unable to assess whether they used MOP. Sensitivity analysis was conducted to assess the impact of those without CVD medication fills during follow-up by including them in the analytic population as non-users of MOP at follow-up. All analyses were further stratified by site and results from both the KP sites were collapsed based on the similarity of study results in the two sites, and because their pharmacy distribution structure and health care systems were also similar in comparison to HPHC.