Randomized Controlled Trial of Enhanced Pharmacy Care in Older Veteran Outpatients

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BACKGROUND / RATIONALE:

Complications resulting from medications, or adverse drug events (ADEs), are prevalent and are a major source of excess morbidity and costs. ADEs are particularly problematic in older patients because of their higher burden of co-morbidity and diminished physiologic reserve. In addition, older patients are more likely to be exposed to polypharmacy, a major risk factor for ADEs. While ADEs may be idiosyncratic, many result from medical errors and inadequate systems for ensuring the safe and effective use of medications.

The goal of the proposed study is to test the efficacy of a potentially potent intervention to improve the use of medications in older outpatients enrolled in Veterans Affairs (VA) primary care clinics. The intervention-Enhanced Pharmacy Care-involves a formal, multi-dimensional evaluation of patients' medication regimens by a trained clinical pharmacist and board-certified geriatrician.

OBJECTIVE (S):

The study has the following six aims: 1) Compare changes in prescribing practices-as measured by medication appropriateness, number of medications, and cost of prescribed medications-between baseline and follow-up in patients randomized to Enhanced Pharmacy Care and patients randomized to usual care; 2) Compare other medication-based endpoints in the two groups, including the occurrence of potential ADEs, medication compliance, and patient knowledge of medications; 3) Compare changes in health-related-quality-of-life in the two groups; 4) Compare patient perceptions of the quality of VA outpatient care in the two groups; 5) Compare health care utilization during the one-year study period in the two groups; and 6) Examine attitudes of primary care providers (PCPs) about the intervention.

METHODS:

Patients were eligible for the trial if they were 65 years and older and receiving prescriptions for > 5 medications in a VA primary care clinic. Patients were randomized to usual care or to the intervention, which included a structured medication history and medical records review. For intervention patients, therapeutic recommendations were developed and presented to primary care providers. Baseline and 3-month measures were obtained and change was assessed by analysis of covariance.

FINDINGS / RESULTS:

The following represent results from the initial 493 patients enrolled in the trial. Patients (mean age, 74 years; 98% male) were taking a mean of 13.7 ± 4.9 medications at baseline. At 3 months, the mean number of medications had decreased slightly in both intervention and control patients (1.0 vs. 0.1; p=. 08); 22% of patients in both groups reported one or more ADEs (p=. 97). No differences (p>.1) were observed between the groups in health-related quality of life (as measured by the SF-8), symptoms, self-reported health, patient satisfaction, medication knowledge, monthly drug costs, or VA and non-VA healthcare utilization. Surveys of providers indicated the intervention was well accepted by 80%, and 77% indicated that they would refer patients to such a service. Patients did not differ in their overall satisfaction with health care between the two groups, however the intervention group was more likely to want to schedule time with a pharmacist to review medications and felt the time spent discussing medications was appropriate.

STATUS:

493 patients have been enrolled in the trial and 12-month follow-up has been completed on over 95% of patients. Preliminary results have been evaluated and abstracts have been submitted to national meetings, including the 2004 VA Health Service Research & Development and 2004 SGIM Annual Meetings where it will be presented as an oral presentation. We are completing all the data cleaning and will be performing final analyses on the data, with manuscript preparation. Final outcome assessment using the Medication Appropriateness Index is in the final stage.

IMPACT:

Although well accepted by patients and providers, a collaborative PharmD/MD intervention to improve prescribing resulted in no significant impact on the occurrence of ADEs, healthcare utilization, drug costs, and other endpoints at three months. The lack of measurable effect may reflect the one-time nature of the intervention or concurrent institutional patient safety initiatives. These negative findings suggest that more intensive interventions to improve medication prescribing in high risk elderly veterans may be necessary or specific high-risk populations may be more likely to obtain benefit.

PUBLICATIONS:

Conference Presentations / Abstracts

1. Carter BL, Hoth AB, Rosenthal GE, Kaboli PJ. A single, global intervention for mediation-related problems does not improve blood pressure control. American Society of Hypertension Annual Meeting. New York, NY 2003.

2. Kaboli P, Hoth AB, Carter BL, Chrischilles E, Schorr R, Bhattacharyya A, Ness J, Rosenthal GE. The VA enhanced pharmacy outpatient clinic (EPOC) study: a randomized controlled pharmacist-physician intervention trial. Society of General Internal Medicine 27th Annual Meeting / Journal of General Internal Medicine. Chicago, IL 2004; 19: 114.