

Executive Summary to UM Benefits Office

October 2005

Principle Investigators

Hae Mi Choe, Pharm.D., CDE
Clinical Assistant Professor/Clinical Pharmacist
College of Pharmacy

James Stevenson, PharmD, Ph.D.
Pharmacy Director, UMH Pharmacy Administration and Associate Dean for Clinical Sciences
and Professor of Pharmacy, College of Pharmacy

Benefits Office Contacts

Keith Bruhnsen
Pharmacy Plan, Manager

Dawn Parsons, RPh, MBA
Clinical Pharmacist

Impact of pill-splitting on economic and pharmacologic outcomes

Significance

Controlling pharmaceutical costs is one of the major objectives for the University of Michigan. Thus, opportunities must be identified to control the escalating pharmaceutical costs while maintaining the quality of care. The proposed study evaluated the impact of pill splitting on economic and pharmacologic outcomes, as well as patient satisfaction. Cholesterol lowering agents known as “statins” were used in the study since the effects of pill splitting (i.e., changes in low-density lipoprotein, LDL, etc.) can be measured objectively. Also, they are some of the most commonly prescribed agents in the U-M Prescription Drug Plan. The findings of this study will serve to further establish the safety, efficacy, and medication cost-savings of pill splitting programs. In addition, these findings will help to explain the impact of pill splitting on patient adherence to therapy and the impact of pill splitting on patient-reported satisfaction. If the pill splitting is shown to reduce medication costs while maintaining clinical outcomes and patient satisfaction, then these results will help justify broader utilization of pill-splitting as a cost-containment measure at the University of Michigan.

Specific Aims

1. To evaluate the effect of financial incentive on patients medication use and cost.
 - a) To estimate the percentage of patients willing to split pills in those with and in those without financial incentive.
 - b) To estimate the percentage of patients reverting back to whole pill after pill-splitting was initiated.
 - c) To assess medication compliance by reviewing medication refill rate.
2. To assess low-density lipoprotein (LDL)-lowering achieved using subject-split statins to that previously achieved using an equivalent dose administered as a whole pill.
3. To assess subject-reported satisfaction associated with splitting medications.

Study Methods

This was a prospective randomized study funded by the Benefits Office and approved by the University human subject review committee. A letter explaining the study, consent forms, Initial Survey, and \$5.00 for completion of the survey were mailed to the patients. Those who agreed to participate in the study were randomized to groups with or without co-payment reduction.

The patients randomized to the co-payment reduction group received a 50% discount on their co-payment for the prescription. For example, \$14 co-payment was reduced to \$7. All other patients received no co-payment reduction for pill splitting. All participants received a free pill cutter with instructions for use. At the end of 6 months of pill splitting, patients completed the satisfaction survey to determine their perspectives on this form of cost-containment strategy.

Patients' LDL cholesterol levels were evaluated before and after implementation of pill-splitting to determine whether there is any change in clinical response.

Preliminary Results

Three hundred and two patients participating in the U-M Prescription Drug Plan with primary care physicians at East Ann Arbor Health Center were identified as patients who received a prescription for atorvastatin (Lipitor), pravastatin (Pravachol), or simvastatin (Zocor). Out of 302 patients, 54 patients were excluded for discontinuation of statin drug, changed health center or insurance company, or unable to contact. Out of 248 eligible participants, 111 agreed to participate in the study (45%). There were 7 interested patients who could not enroll in the study because they were already splitting or only wanted to be in the copay reduction group. Fifty-six patients were randomized to no copay reduction group and 55 patients were randomized to copay reduction group.

In the no copay reduction group, 5 patients withdrew from the study. One patient developed side effect to the statin, 1 patient did not like pill splitting, and 3 patients withdrew due to no copay reduction. In the copay reduction group, 3 patients withdrew from the study due to discontinuation of the statin or leaving the health center.

After the study was completed, all participants were offered a 50% copay reduction for pill splitting until end of the calendar year. Out of 97 patients who returned the final survey, 88 patients wanted to continue pill splitting (91%). Out of 9 patients who stopped pill splitting after the study was over, 7 patients were willing to continue pill splitting if we dropped the copay completely. There are 14 patients who have not returned the final survey yet.

Study preliminary results indicate:

Satisfaction - (Out of 97 surveys) "The extra effort to split the pill is no big deal."

- 47 strongly agree
- 32 agree
- 8 neutral
- 8 disagree
- 2 strongly disagree

Compliance – (Out of 97 surveys) "Since I started pill splitting, I missed more doses per month."

- 3 strongly agree
- 1 agree
- 4 neutral
- 19 disagree
- 71 strongly disagree

LDL changes: LDL levels have decreased since tablet- splitting in 52 patients and increased in 44 patients. Whether these changes are statistically significant has not yet been fully evaluated. Preliminary impressions are that LDL control was not clinically altered, but until the statistical analysis is complete, we cannot say with any certainty.

Preliminary study results indicate that pill splitting with statins is both a safe and effective method for reducing member and prescription drug plan expenses. This study provides the University empirical evidence that adopting pill splitting for a wider population of statin uses is a viable approach in pharmacy plan management.