

MUMPS study: Prospective Evaluation of a Medication Therapy Management Clinic versus Usual Medical Care in Patients Post Acute Coronary Syndrome

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BACKGROUND: The literature evaluating the role of clinical pharmacy specialists (CPS) in medication therapy management (MTM) for focused disease state management is abundant; whereas, for comprehensive coronary heart disease (CHD) management patient literature is limited.

PRIMARY OBJECTIVE: To evaluate the effectiveness of a CHD MTM collaborative practice involving a pharmacist compared to standard practice on the combined endpoint of blood pressure and lipid treatment at 32 weeks.

STUDY DESIGN: This is a single center, randomized prospective trial.

METHODS: Enrollees will be recruited from inpatients with ACS admitted to the medicine wards or critical care areas at the VA Tennessee Valley Healthcare System, Nashville Campus. Consented patients will be randomized according to blood pressure stratification with randomization occurring in proximity to discharge. Patients will receive either care in the MTM (cardiologist/pharmacist) cohort or the usual care cohort for up to 32 weeks following discharge. Patients in the intervention care group will be followed by their cardiologist and primary care (PCP) provider along with scheduled visits at specified intervals or more frequently as deemed clinically necessary with the MTM clinic. Patients in the usual care group will be scheduled to see a CPS, who is not involved in the intervention group, at 12-16 and 28-32 weeks following discharge. During usual care, the CPS will provide limited medication reconciliation (MR) and collect variables of interest. The usual care patients will be followed by their cardiologist and/or PCP as clinically deemed appropriate.

DATA COLLECTION PROCEDURES: Manual chart extraction from the Tennessee Valley Healthcare System (TVHS) computerized patient record system (CPRS) will be performed and data will be entered into a File maker Pro[®] database program created specifically for the MUMPS study.

PRIMARY ENDPOINT: Improvement in lipid and blood pressure control

ADDITIONAL ENDPOINTS: Secondary endpoints include the combined endpoint of morbidity and mortality, Morisky adherence for those who are hypertensive, and patient satisfaction with pharmacist services.

SAMPLE SIZE: We are in a position of a fixed sample size. Our focus will be on estimation of effect size (proportional odds ratio) and rates of achievement of one or both treatment goals (i.e. blood pressure and LDL) in the two groups.

STATISTICS: Descriptive analysis will include means (or medians for skewed data) for continuous variables and proportions for categorical data. Precision will be expressed using 95% confidence intervals. Effect size for the primary outcome will be measured as the proportional odds ratio using mixed-effect ordinal logistic regression to adjust for selected covariates as possible confounders. A mixed model will be utilized to account for missing data. Although the MTM group will have more visits, and thus more data, we will utilize only the baseline and 12-16 week and 28-32 week visit data in these analyses, in order to avoid bias. A life table will be used to estimate the morbidity and mortality endpoint. The within group comparison of subjective adherence will utilize ordinal logistic regression.