The Electronic Application of the Screening Tool of Older Persons'

potentially inappropriate Prescriptions (STOPP) versus the Beers Criteria in

Elderly Patients Presenting to the Emergency Center-

Effects on Medication Changes and Relapse Rates

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I have neither given nor received assistance with this work:

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Abstract

Objective: To demonstrate differences between two pharmacist-lead electronic medication review criteria applied at the point of geriatric patient EC discharge upon outpatient medication changes, and subsequent six-month EC readmission rates.

Study Design: A randomized, double-blind, retrospective-prospective, active control trial.

Setting: Suburban hospital ECs with a regional electronic patient record network accessible in the outpatient setting.

Subjects: Males and females aged 65 years and older presenting to a hospital EC, currently taking four or more medications. Subjects must not have obtained inpatient status, and must not have visited the EC within the past 12 months.

Intervention: 148 patients are electronically randomized into one of two experimental arms, prior to patient discharge. The active control arm features pharmacists applying the Beers Criteria, while the experimental arm will have the STOPP criteria implemented. Recommendations made are electronically flagged for review by PCPs in the outpatient setting.

Measurements and Main Expected Results: Data will be collected by pharmacists at EC discharge, one month post-discharge, and at the conclusion of the study. A comparison of the ratio of accepted medication changes made by PCPs one month post-discharge between the Beers and STOPP criteria will be assessed. Another analysis will determine if there is a significant difference in the ratios of six-month EC readmission rates between the treatment arms. Both assessments feature

a two sample unpaired student's t-test. This study expects to show that STOPP criteria will show a higher proportion of accepted medication changes made by PCPs, and a lower proportion of six-month EC readmission rates of patients as compared to using the Beers Criteria.

Conclusions: This study serves to demonstrate the comparative advantage of utilizing the STOPP criteria over Beers Criteria in an EC geriatric population. Limitations feature the exclusion of inpatient subjects. Future studies could implement STOPP criteria to a geriatric inpatient population, to assess how medication change recommendations affect readmission rates.

Key Words

Pharmacy, Geriatrics, Electronic Prescribing, Drug Therapy Assessment

Introduction and Background

Geriatric patients, aged 65 years and older, are more likely to frequent the emergency center (EC), and are at a higher risk for adverse health outcomes than younger patients during the first six months post-EC discharge.[1] Physiological changes, inappropriate prescribing, and polypharmacy in the geriatric population is readily addressed by pharmacists in the EC with specialized software. Notations for these electronic recommendations can appear in patient charts as an alert for outpatient primary care physicians (PCPs). However, it is unclear to what degree these recommendations ultimately impact changing medication profiles, or if these alerts impact EC readmission rates.

Tools are available to heighten awareness of potentially harmful drug interactions in the elderly population specifically. A systematic review of computerized order entry systems that provide interaction alerts has shown statistically significant improvements in prescribing behaviors.[2] The Beers Criteria has been a pharmacy staple for discovering and recording inappropriate prescribing in older populations.[3] Currently, the Beers Criteria contains 48 different medications and classes of drugs to generally avoid using in patients over 65 years old due to risk, derived from 20 diseases and conditions.[4] However, there are deficiencies in this model, primarily with the difficulty of interpreting and applying the criteria, inclusion of outdated medications, and omission of prevalent inappropriate prescribing situations.[3,5]

The recent European development of the Screening Tool of Older Persons' potentially inappropriate Prescriptions (STOPP), a comprehensive literature-supported review tool, has been shown to be more effective than the Beers Criteria in identifying inappropriate medications and adverse events in an inpatient setting.[3,6] STOPP consists of 65 criterion to detect unsuitable medication use in older patients, including descriptions of specific problems associated with medication use.[7] While the STOPP criteria has been implemented successfully at an American hospital, its comparative efficacy to the Beers Criteria has not been adequately studied.[3,8] Regardless of criteria used, there is a lack of conclusive evidence to assess whether electronic application of these tools results in increased PCP medication changes, or if these tools significantly affect rates of EC readmission.[3]

Hypothesis

The implementation of a pharmacist-lead electronic STOPP criteria medication review at the point of geriatric patient EC discharge will elicit a higher proportion of accepted medication changes made by PCPs in the outpatient setting, and will demonstrate a significantly lower six-month EC readmission rate for geriatric patients than when using the Beers Criteria.

Specific Aims

1. To determine and compare the ratios of accepted electronic drug change recommendations by PCPs within a month after pharmacist application of either Beers or STOPP criteria alerts. Pharmacists will perform data collecting in the inpatient setting, with an electronic assessment of patient records 30 days after each respective patient was discharged from the EC.

2. To determine and compare the ratios of six-month EC readmissions of patients that received either Beers or STOPP criteria electronic assessment and change recommendations at the point of initial patient EC discharge. Pharmacists will collect this data based on an electronic chart review at the conclusion of the study.

Study Design

This study will be designed as a randomized, double-blind, retrospective-prospective, active control trial. The study population will include males and females aged 65 years and older that present to a hospital EC, and are currently

taking four or more medications. This medication requirement is necessary to increase the likelihood that the application of either Beers or STOPP criteria will result in electronic medication change recommendations. The patient must not have acquired inpatient status during the initial EC visit, and must not have visited the EC within the past 12 months. These exclusion criterions are essential to establish readmission rates after a pharmacist-lead intervention that could possibly affect future EC readmission rates. The exclusion criteria also seeks to eliminate patients that present with conditions requiring more intensive and extensive monitoring, which could also confound readmission rates.

Qualified patients will be electronically randomized into one of two experimental arms once informed consent is obtained, preceding patient discharge from the EC. Patient medication regimens will be verified prior to the assessment to ensure accuracy of the electronic record. The pharmacists performing either type of electronic assessment will be blinded from knowing which program is implemented during the medication review. Also, the PCPs reviewing the medication change alerts will not know which criteria was used. The active control arm will feature the pharmacist applying the Beers Criteria during medication assessment. An active control is ethically necessary, and the Beers criteria is the current model used to assess geriatric patient risk to certain medication classes. The experimental arm will feature the STOPP criteria application to the patient's medication profile. Both types of criteria will require pharmacists to record at least one medication change recommendation into the patient's electronic chart for PCP review in the outpatient setting.

Pharmacists will collect data during the study. Data collection will occur at EC discharge, one-month post initial EC discharge, and at the conclusion of the entire study. Pharmacists and PCPs will not know which criterion is being utilized; therefore, this study is to be preformed as a double-blind trial. Standard HIPAA and IRB review protocol will be followed.

Data collected by the pharmacist at the point of EC discharge will include age, gender, race, contact and PCP information from the patient, after informed consent is received. The patient will be notified by technicians at the point of discharge to contact their PCP for a follow-up exam to be held within two weeks of discharge. Patients will be assigned a study participant number at this time, so that subsequent data assessment can be tied to the correct treatment arm.

At a time interval of 30 days (+/- one day) post-EC discharge for each patient respectively, pharmacists in the inpatient setting will review a participant's electronic patient records, as alerted electronically. **The primary outcome, comparison of the ratio of accepted medication changes by PCPs one-month post-discharge between the Beers and STOPP criteria, will be determined at this time**. The number of medication changes accepted by the PCP compared to the initial number of changes recommended by a pharmacist using a randomly assigned criterion will be recorded.

Final data collection by pharmacists will occur at the conclusion of the study. A secondary aim of this study is to compare the ratios of study participants in the treatment arms that presented to the EC within six months after initial EC discharge.

Pharmacists will obtain the six-month readmission status from a final electronic chart review, and record this information as tied to the study participant number.

Statistical Plan

The sample size will be 148 patients, with 74 patients in each treatment arm. This is based upon DSS research tool calculations that estimate an 85% power and alpha of 5%, a sample percentage value difference of 5% between groups, and a sample error of 8.1%.

Pharmacists in the inpatient setting, through electronic notifications, will collect all data. The primary outcome, a comparison of the ratios of accepted medication changes made by PCPs one month post-discharge between the two criterions, consists of continuous ratio data. A two sample unpaired student's t-test will be used to assess this information. This data will determine if the ratio of accepted medication changes is independent of the criterion used.

Another analysis will determine if there is a significant difference in the ratios of six-month EC readmissions between treatment arms, a secondary aim. This data is defined as continuous ratio data. Assessment will be performed by a two sample unpaired student's t-test. This will assess whether the ratios of six-month EC readmissions are independent of the criteria implemented.

All statistical assessment data will be provided in labeled tables, along with the calculated values of ratio statistical significance. A p-value of ≤ 0.05 will be considered significant. Multivariate regression analysis of the average age of the participants, as well as a count and percentage of the genders randomly allocated to

each of the treatment arms, will be provided to determine if any data could possibly be confounded by these factors.

Human Subjects

This study involves the use of human medical information. Since the interventional treatment deals with subjecting patients to a medication evaluation criterion not yet widely used in the United States, it is necessary to inform the patients that unforeseeable risk may exist. Data collected includes age, gender, contact and PCP information, percent of recommendation taken by the PCP one month after discharge, and six-month EC readmission status. Patient identification information is encoded after enrollment in the study.

Subjects feature patients that meet the inclusion criteria of males and females 65 years of age and older presenting to the EC, currently taking four or more medications. Pharmacists will recruit patients if the inclusion criteria is met. Excluded patients would include those that have attained inpatient status, or those who have presented to the EC within the past 12 months. Due to the advanced age of this population set, informed consent should be clearly explained orally by pharmacists to both the potential patient participants and their respective caretakers, if appropriate. Subsequent written consent must also be obtained prior to the pharmacist completing a criteria-lead medication review. Overall, this informed consent material will provide disclosure of all potential risks and benefits to the patient, and will follow standard informed consent protocol.

PCP involvement in the study will be limited to reviewing patient medical records for medication changes within a month of the patient's initial EC visit. Hospital network physicians, that use the software in their offices currently, will be informed about the study prior to its initiation.

A data safety monitoring plan will be followed to both protect patient data and reduce risk, due to the fact that STOPP data has not been widely used exclusively in the United States. This plan will be enabled to ensure that this population will not be put at additional risk of possible adverse drug events due to possible, but unlikely, medication review oversight. Technicians will review and obtaining PCP progress reports throughout the trial, and monitor readmission rates for both groups during the trial. These technicians are not associated with ultimate data collection, but will serve to monitor PCP feedback and concerns about differences in readmission rates if they arise.

The number of study participants totals 148 patients, with 74 patients in each study arm. Due to computerized randomization with the initial input of participant gender and age, treatment arms will contain a nearly equal proportion of men and women, with a similar average age as well in the treatment arms. Racial backgrounds will also be accounted for and will be evenly distributed between treatment arms.

Finally, although children are not involved, the elderly population included is indeed a population vulnerable to adverse medication events and hospital readmissions. As stated above, measures will be taken to ensure that the study is preformed in a manner that minimizes risk. The application of either criterion itself

serves to decrease the risk of adverse medication events occurring in this population due to medication mismanagement and polypharmacy.

Conclusion, Limitations and Future Directions

Due to evidence that suggests that the STOPP criteria potentially identifies more inappropriate medications than the Beers Criteria in geriatric patients, this study expects to show that application of the STOPP criteria will show a higher proportion of accepted medication changes by PCPs, and also a lower proportion of six-month EC readmission rates of patients as compared to using the Beers Criteria.

Limitations present in this study pertain to the exclusion of patients that have been admitted as an inpatient at the time of their initial EC visit. However, due to a high risk of medication mismanagement in this population, many of these patients will require inpatient medical attention. This exclusion criterion limits the application of the study results to the general geriatric patient population that attains inpatient status during an EC visit, since different medication review protocol will be preformed during the course of their stay.

Future studies preformed should identify a plan to implement the STOPP criteria to the geriatric impatient population at the hospital, and to assess how these medication change recommendations affect geriatric hospital readmission rates. Also, further studies could serve to assess PCP feedback to electronic STOPP criteria alerts, in order to increase the percent of accepted medication changes made in the outpatient setting.

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