Drug and patient safety studies: methods and implementation

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ABSTRACT

- **Background:** The majority of healthcare is delivered in ambulatory care settings, where fragmented care, and high medication use prevalence may compromise patient safety. In particular, hypoglycemic diabetic agents lead to adverse drug events (ADE) among patients treated in outpatient settings.
- **Objective:** The goals of this project are to: 1. identify sources of confounding and bias in safety studies; and 2. design a study for implementation and evaluation of pharmacy-based strategies to improve safety in ambulatory care settings.
- **Method:** To achieve the first goal, I have planned a workshop in collaboration with the FDA. This workshop explores creative methods to address confounding and bias in pharmacoepidemiology safety studies. With respect to the second goal of this project, I will plan to assess the joint impact of a pharmacist-lead intervention to patients and physicians, aimed at identifying and resolving drug therapy problems in high risk elderly patients on insulin and/or oral hypoglycemic agents. Ultimately, this study will provide an updated and contemporary medication safety framework for care in ambulatory settings, which practices can readily adopt and which future studies can use to devise and implement further actionable strategies to improve patient safety.

INTRODUCTION

- The prevention of adverse drug events (ADEs) is an important patient safety priority as ADEs account for over 280,000 hospital admissions annually.
- Older adults have multiple chronic conditions and thus are at high risk for ADEs: reports show that 57-59% of older adults take 5-9 medications and 17-19% take 10 or more over the course of a year.
- A significant proportion of the ADEs among the elderly in both inpatient and outpatient settings are due to hypoglycemia resulting from insulin administration and/or oral anti-diabetic agents.
- Retrospective observational post-approval studies may be helpful at improving safety in ambulatory settings by analyzing large existing electronic healthcare databases but may be limited by the absence of information on important risk factors or health behaviors necessary to adequately evaluate the drug-outcome relationship.
- Treatment regimens for diabetic patients are inherently complex to manage and administer. Pharmacist interventions have been shown to reduce medication errors by providing education and medication counseling, and by engaging patients for shared decision making.

STRATEGIC GOALS

- **Strategic goal 1:** Because observational studies are increasingly utilized as evidentiary sources for regulatory decisions, ensure that findings from observational research are minimally influenced by unmeasured or inadequately measured confounding factors.
- **Strategic goal 2:** Develop a study incorporating the role of the pharmacist and successful elements of previous interventions I have led of engaging patients and providers in the management of diabetes such as the Maryland Men's Cardiovascular Promotion (MVP), Peer-to-Peer Social Networks in Diabetes (P2P), NIH-funded Baltimore Partnership to Educate and Achieve Control of Hypertension (BPTEACH), the award-winning Maryland's Patients, Pharmacists Partnerships (P3) Program, the Transitions of Care in Diabetes Study, and the PCORI-funded University of Maryland-based infrastructure PATIENTS.

CURRENT PROGRESS

- In collaboration with the FDA and University of Maryland Center for Excellence in Regulatory Science and Innovation, I have organized a public workshop entitled *Addressing Inadequate Information on Important Health Factors in Pharmacoepidemiology Studies Relying on Healthcare Databases: Public Workshop*.
- The purpose of the public workshop was to engage in constructive dialogue regulators, academicians, pharmaceutical industry, clinicians, other stakeholders and the general public on potential strategies to improve availability of information on important health factors in pharmacoepidemiology studies that rely on electronic healthcare databases to evaluate the safety of pharmaceutical products in the post-approval setting.

The topics covered included the discussion of:

- *How to supplement data with surveys and linkages via the use of*
  - external information to evaluate comparability of cohorts
  - surrogate measures
  - mobile devices to enhance information on electronic medical records
- *How to make greater use of the data at hand by*
  - text and data mining strategies
  - covariate measurement error and differential covariate measurement across treatment groups
  - improving the reliability, transparency, and reproducibility of database research without transmitting patient-level databases

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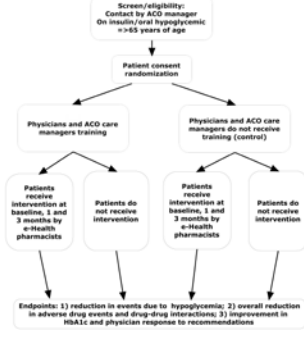
FUTURE PLANS

- The next step: development of a holistic, patient and provider-driven synergistic adaptations of a pharmacist comprehensive medication therapy management, for improving medication-related safety in ambulatory care settings with high-risk patients on insulin and oral hypoglycemics, with a special focus on reducing adverse drug events related to hypoglycemia as well as other preventable adverse drug events, including ADE-related hospitalization and emergency department admissions.
- Patients in the intervention group will receive medication management services by e-health tools administered by pharmacists. Each patient's adverse drug events will be recorded for 6 months.



DISCUSSION

- The proposed study aligns with the National Action Plan for Adverse Drug Event Prevention to provide a multidisciplinary approach involving patient-centered interventions provided by pharmacists for patients and physicians, including educational outreach to physicians, to resolve medications safety concerns associated with diabetes agents among priority populations.
- This study is novel in assessing the joint impact of an e-health pharmacist-education-counseling-intervention on both patients and physicians in ambulatory settings. The study challenges the typical paradigm of clinical practice and care delivery, capitalizing on the cognitive role of the patient and the pharmacist It is innovative as it designs a collaborative team care approach maximizing the use of e-health technologies.