

Active Pharmacovigilance and Health Care Utilization

JS Haas, E Klinger, L Marinacci,
P Brawarsky, EJ Orav, GD Schiff, DW Bates
ISQua 2012



IVRS

- Interactive Voice Response System
 - Systematic
 - Cost-effective way to contact populations
 - Standard interview
 - Opportunity for immediate notification
 - Interoperate with EHR



Protocol

- Eligible adult patients (n = 1,591):
 - PCP visit
 - Target drug
 - English
 - No opt-out
- Called 2 – 6 weeks post-visit.
 - Asked about adherence and 29 pre-specified ADEs
- Note in EHR
- Email PCP if: (1) stopped medication intended for chronic use and not discussed with provider, (2) a pre-defined list of symptoms that were of clinical concern or (3) requested that we send an email to their provider

Background

- Safety of prescription drugs is a major public health concern
- Limits of passive surveillance
- While capacity for active surveillance using electronic medical records (EMRs) and claims data is expanding, these data do not capture patient experience, as clinicians often fail to document a patient's symptoms

Objective/ Hypothesis

- Is participation in this type of systematic monitoring system associated with subsequent changes in medication management or health care utilization?
 - Patients who participated and completed the IVRS would
 - be more likely to have their medications stopped
 - have more planned outpatient visits
 - have fewer unplanned acute visits

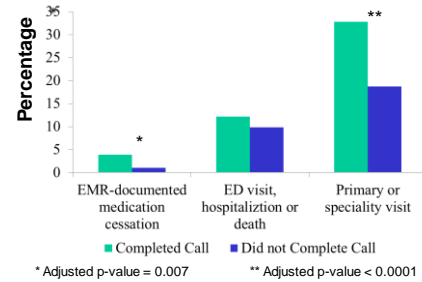
Target Drugs

Class or Indication	Medication Names	
Insomnia	Zolpidem (Ambien)	Eszopiclone (Lunesta)
Erectile dysfunction	Sildenafil (Viagra or Revatio) Vardenafil (Levitra)	Tadalafil (Cialis)
Angiotensin receptor blockers (ARB)	Losartan (Cozaar) Valsartan (Diovan)	Irbesartan (Avapro) Aiskiren (Tekturna)
Seizure	Gabapentin (Neurontin)	Pregabalin (Lyrica)
Asthma	Montelukast (Singulair)	Fluticasone-Salmeterol (Advair)
Smoking cessation	Varenicline (Chantix)	
Lipid lowering	Rosuvastatin (Crestor)	Ezetimibe-simvastatin (Vytorin)
Diabetes	Rosiglitazone (Avandia) Pioglitazone (Actos)	Exenatide (Byetta) Sitagliptin phosphate (Januvia)
Psychiatric	Risperidone (Risperdal) Olanzapine (Zyprexa) Quetiapine (Seroquel)	Modafinil (Provigil) Aripiprazole (Abilify) Duloxetine (Cymbalta)
Other	Raloxifene (Evista) Infliximab (Remicade) Etanercept (Enbrel)	Tropium (Sanctura) Ibandronate (Boniva)

Outcomes

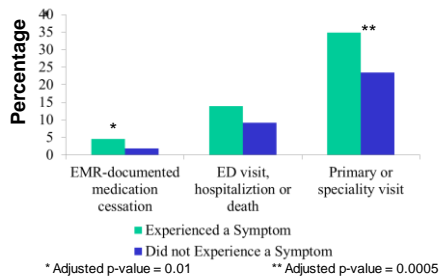
- Assessed 6 months following enrollment
- Primary:
 - Documentation in EHR that medication was stopped
 - Visit to a PCP or specialist physician (planned care)
 - ED visit, hospitalization or death (unplanned care/ outcome)
 - No opt-out
- Secondary:
 - Self-reported medication cessation vs. EMR documentation
 - Primary outcomes for those who reported/ did not report a symptom

6-month Outcomes



Adjusted and clustered models adjusted for age, sex, race/ethnicity (categorized as white, black, Hispanic or other), median income, primary care clinic, number of comorbid conditions, drug class and ED visits or hospitalization and primary care or specialist visits within one year prior to enrollment date.

Outcomes among participants with/ without symptoms



Adjusted and clustered models adjusted for age, sex, race/ethnicity (categorized as white, black, Hispanic or other), median income, primary care clinic, number of comorbid conditions, drug class and ED visits or hospitalization and primary care or specialist visits within one year prior to enrollment date

Assessment of Whether Symptom Medication Related

- 799 participants with ≥ 1 symptom
 - 22% attributed symptom to drug
 - 51% thought not related
 - 27% not sure
- Those who thought medication related to symptom more likely to stop medication (13.1% s. 1.5%, $p < 0.001$)

Limitations/ Considerations

- Exploratory study, non-randomized design
- Limited set of medications

Conclusions

- Pharmacovigilance was associated with documented medication cessation and a decline in unanticipated health care
- EMR documented cessation substantially lower than that noted by patients
- Quarter of patients with a symptom think may be related to medication
- Ascertaining symptom information from patients crucial to prevent potential morbidity and improved adherence