Active Pharmacovigilance and Health Care Utilization

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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

IVRS

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

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

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

Target Drugs

<table>
<thead>
<tr>
<th>Class or indication</th>
<th>Medication Names</th>
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<tbody>
<tr>
<td>Insomnia</td>
<td>Zolpidem (Ambien) Eszopiclone (Lunesta)</td>
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<td>Erectile dysfunction</td>
<td>Tadalafil (Cialis) Vardenafil (Levitra)</td>
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<td>Angiotensin receptor blockers (ARB)</td>
<td>Losartan (Cozaar) Valsartan (Diovan) Irbesartan (Avapro) Aliskiren (Tekturna)</td>
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<td>Asthma</td>
<td>Montelukast (Singulair) Fluticasone-Salmeterol (Advair)</td>
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<td>Smoking cessation</td>
<td>Varenicline (Chantix)</td>
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<td>Hypertension</td>
<td>Ramipril (Altace) Lisinopril (Prinivil) Captopril (Capoten) Enalapril (Vasotec)</td>
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<td>Diabetes</td>
<td>Rosiglitazone (Avandia) Pioglitazone (Actos) Exenatide (Byetta) Sitagliptin phosphate (Januvia)</td>
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<tr>
<td>Psychiatric</td>
<td>Risperidone (Risperdal) Olanzapine (Zyprexa) Quetiapine (Seroquel) Aripiprazole (Abilify) Modafinil (Provigil) Duloxetine (Cymbalta)</td>
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<td>Other</td>
<td>Raloxifene (Evista) Infliximab (Remicade) Etanercept (Enbrel) Trasplastin (Sancarco) Ibandronate (Boniva)</td>
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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

Outcomes among participants with/ without symptoms

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% vs. 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