Identification of name confusion medication errors in the US FDA’s Sentinel System

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Disclosure statement

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▪ The authors have no relationships to disclose.
Background

- Look-alike, sound-alike (LASA) medication errors are of concern to the US FDA

- July 2015: FDA drug safety communication regarding medication errors in prescribing or dispensing due to brand name confusion with the antidepressant Brintellix (vortioxetine) and the antiplatelet Brilinta (ticagrelor)
May 2016: Brintellix renamed Trintellix
Objective

- To assess whether name confusion medication errors could be identified in the US FDA’s Sentinel System by assessing the presence and absence of on- and off-label indications in claims data.
Methods

- Sentinel: FDA’s post-market medical product safety surveillance system utilizing electronic claims and medical record data
- Identified new users of Brintellix, and separately of Brilinta, 183 day washout; 9/30/2013 – 9/30/2015
- Members from 16 health plans enrolled with medical and pharmacy coverage for ≥365 days prior to dispensing date
- Post-exposure enrollment of 30 days
Assess on- and off-label indications in -365 days through +30 days

- No Brintellix indication (dx codes)
- Yes Brilinta indication (dx codes)

Incident Brintellix dispensing

No prior Brintellix dispensing in -183 d

Assess on- and off-label indications in preliminary claims profile review at 1 DP

- No Brintellix indication (dx codes) and no use of drugs in same class (NDCs)
- Yes Brilinta indication (dx codes)
Assess on- and off-label indications in -365 days through +30 days

- **No** Brilinta indication (dx codes)
- **Yes** Brintellix indication (dx codes)

Incident Brilinta dispensing

No prior Brilinta dispensing in -183 d

Assess on- and off-label indications in preliminary **claims profile review at 1 DP**

- **No** Brilinta indication (dx codes) and **no** use of drugs in same class (NDCs)
- **Yes** Brintellix indication (dx codes)
Methods

**Brintellix**
- Indication:
  - Depression
- Off-label indications:
  - Schizophrenia
  - Episodic mood disorders
  - Anxiety disorders
  - Personality disorders
  - Bipolar depression
  - PTSD
  - Chronic pain

**Brilinta**
- Indications:
  - Acute coronary syndrome
  - Myocardial infarction
- Off-label indications:
  - Peripheral arterial disease
  - Unstable angina
  - Stroke
  - Stent
# Results – Brintellix users

<table>
<thead>
<tr>
<th></th>
<th>New Users</th>
<th>Dispensings</th>
<th>Eligible Members</th>
<th>New Users / 1K Eligible Members</th>
<th>Dispens. / User</th>
<th>% of Total Users</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All Brintellix Users</strong></td>
<td><strong>18,793</strong></td>
<td><strong>57,549</strong></td>
<td><strong>46,474,433</strong></td>
<td>0.40</td>
<td>3.06</td>
<td></td>
</tr>
<tr>
<td><strong>Indication for Brintellix</strong></td>
<td><strong>16,639</strong></td>
<td><strong>51,266</strong></td>
<td><strong>9,295,731</strong></td>
<td>1.79</td>
<td>3.08</td>
<td><strong>85.2%</strong></td>
</tr>
<tr>
<td><strong>Indication for Brintellix and no indication for Brilinta</strong></td>
<td><strong>15,766</strong></td>
<td><strong>48,654</strong></td>
<td><strong>8,668,254</strong></td>
<td>1.82</td>
<td>3.09</td>
<td><strong>80.7%</strong></td>
</tr>
<tr>
<td><strong>Indication for Brilinta and no indication for Brintellix</strong></td>
<td><strong>71</strong></td>
<td><strong>178</strong></td>
<td><strong>2,016,969</strong></td>
<td>0.04</td>
<td>2.51</td>
<td><strong>0.4%</strong></td>
</tr>
</tbody>
</table>
Brintellix Results

71 Potential erroneous **Brintellix** dispensings

17 Members at health plan doing profile review

5 No dx codes or dispensings in same drug class to indicate Brintellix

12 Evidence suggestive of appropriate treatment
## Results – Brilinta users

<table>
<thead>
<tr>
<th></th>
<th>New Users</th>
<th>Dispensings</th>
<th>Eligible Members</th>
<th>New Users / 1K Eligible Members</th>
<th>Dispens. / User</th>
<th>% of Total Users</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All Brilinta Users</strong></td>
<td>19,936</td>
<td>80,725</td>
<td>46,471,030</td>
<td>0.43</td>
<td>4.05</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Indication for Brilinta</strong></td>
<td>19,537</td>
<td>79,395</td>
<td>2,679,321</td>
<td>7.29</td>
<td>4.06</td>
<td>98.0%</td>
</tr>
<tr>
<td><strong>Indication for Brilinta, no indication for Brintellix</strong></td>
<td>13,654</td>
<td>57,885</td>
<td>2,011,492</td>
<td>6.79</td>
<td>4.24</td>
<td>69%</td>
</tr>
<tr>
<td><strong>Indication for Brintellix, no indication for Brilinta</strong></td>
<td>90</td>
<td>224</td>
<td>8,669,435</td>
<td>0.01</td>
<td>2.49</td>
<td>0.5%</td>
</tr>
</tbody>
</table>
Brilinta Results

90 Potential erroneous Brilinta dispensings

21 Members at health plan doing profile review

8 No dx codes or dispensings in same drug class to indicate Brilinta

13 Evidence suggestive of appropriate treatment
Discussion

- Automated tools + claims profile review can identify potential name confusion medication errors
- This approach narrowed down likely name confusion errors that could be confirmed by medical chart review if necessary
- Strength of claims: dx codes captured across care locations, unlike EHR
- Algorithm can be refined to improve specificity
  - Include history of drugs in same class as potentially incorrect drug
  - Algorithm has not been validated
Conclusions

▪ We have developed a claims-based algorithm for identifying potential name confusion medication errors in Sentinel using a combination of routine tools and claims profile review

▪ Our approach may be useful for similar types of medication errors – and similar data sources
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- Elizabeth Dee
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- Kevin Haynes
- Fang Tian

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Extra slides
Work by others

- Basco et al 2010
  - Examined prescription **dispensing patterns** to screen for LASA errors in pediatric outpatient setting
    - Pairs of drugs where 1 was common in peds, 1 uncommon; looked for dispensing of second drug among those who usually received the first drug

- Rash-Foanio et al 2017
  - Developed automated detection algorithm using medication orders and diagnostic codes in claims data
    - Similar overall approach to Sentinel analysis
    - Utilizes natural language processing – not based on known pair