Opportunities for Improving the Use of Cancer Registry Data in Drug Safety Studies: Factors Influencing Interview Response Rates

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RTI Health Solutions

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Presentation Objectives

• Provide background on the study and source of data used for analysis

• Assess the impact of various factors on successfully completing a patient interview
  – Lag time
  – Differing patient access pathways
  – Access and availability of updated contact information

• Identify opportunities to improve the interview rate
In a preclinical rat toxicology study, Forteo (teriparatide), a drug used to treat osteoporosis, caused an increase in the incidence of osteosarcoma.

No such signal has been seen in clinical experience.

FDA required a postapproval surveillance study as a condition of drug approval.

- A 15-year study was initiated in 2002 and is currently ongoing.
Study Background, Continued

- **Primary objective**
  - Identify approximately 33% of newly diagnosed cases of osteosarcoma among men and women aged 40 years and older
  - Determine incident osteosarcoma cases, if any, who have a history of Forteo treatment

- 15 cancer registries are currently providing data for the study

- Cases include 12 ICD-O-3 codes for osteosarcoma plus 5 additional ICD-O-3 codes for sarcoma, NOS and other specified cancers where site equals bone

- Interview patients (or proxies if patient is deceased) regarding prior exposure to Forteo
Methods

• We assessed the impact of various factors on completing a successful patient interview:
  – Lag time between diagnosis and reporting to RTI-HS
  – Complexity of patient-access pathways
  – Access and availability of updated contact information
Lag time is defined as time between date of diagnosis and date reported to RTI-HS with contact information.

Factors impacting lag time:
- Time for complete case ascertainment
- Patient access pathway
- Year the registry joined the study

The longer the lag time, the more difficult it becomes to interview:
- Greater chance the patient has died
- Patient or proxy has moved from address at diagnosis
- Patient or proxy may no longer remember specifics about medication usage or cancer diagnosis
Impact of Lag Time on Interview Rate
## Interview Rate by Lag Time

<table>
<thead>
<tr>
<th>Lag Time</th>
<th>Total Identified</th>
<th>Total Interviewed</th>
<th>Interview Rate&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-1 Year</td>
<td>486</td>
<td>229</td>
<td>47%</td>
</tr>
<tr>
<td>1-2 Years</td>
<td>430</td>
<td>149</td>
<td>35%</td>
</tr>
<tr>
<td>2-3 Years</td>
<td>171</td>
<td>53</td>
<td>31%</td>
</tr>
<tr>
<td>3+ Years</td>
<td>196</td>
<td>50</td>
<td>26%</td>
</tr>
</tbody>
</table>

<sup>a</sup> Interview rate = (number interviewed)/(number identified by participating registries). Data as of March 31, 2011, for cases diagnosed 2003-2009.
# Interview Rate by Year Registry Added

<table>
<thead>
<tr>
<th>Year Registry Added (No.)</th>
<th>Total Identified</th>
<th>Total Interviewed</th>
<th>Interview Rate $^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004 (4)</td>
<td>654</td>
<td>263</td>
<td>40%</td>
</tr>
<tr>
<td>2005 (3)</td>
<td>434</td>
<td>181</td>
<td>42%</td>
</tr>
<tr>
<td>2006 (3)</td>
<td>421</td>
<td>172</td>
<td>41%</td>
</tr>
<tr>
<td>2007 (2)</td>
<td>222</td>
<td>83</td>
<td>37%</td>
</tr>
<tr>
<td>2008 (2)</td>
<td>239</td>
<td>55</td>
<td>23%</td>
</tr>
<tr>
<td>2009 (2)</td>
<td>151</td>
<td>45</td>
<td>30%</td>
</tr>
</tbody>
</table>

$^a$ Interview rate = (number interviewed)/(number identified by participating registries). Data as of March 31, 2011, for cases diagnosed 2003-2009.
Impact of Patient-Access Pathway on Interview Rate
Patient-Access Pathways

• **General Types**
  - MD notification required
  - Patient release required
  - MD notification and patient release required
  - MD permission to contact patient required
  - MD permission to contact patient and patient release required
Example: Simple Patient-Access Pathway, Physician Notification

Registry identifies eligible patient

- Registry sends record to RTI; RTI contacts MD and patient directly
Example: More Complex Patient-Access Pathway, Physician Permission and Patient Release

Registry identifies eligible patient

Registry sends to MD a lead letter and permission form

MD permission

No

Registry may not contact patient

Yes

Registry sends to patient a lead letter, brochure, and release form

Wait 3 weeks

Patient refusal, no contact

Patient provides permission

Registry attempts telephone contact with patient

Wait 3 weeks

Registry sends record to RTI

Registry sends to patient a lead letter, brochure, and release form
## Patient-Access Pathways

<table>
<thead>
<tr>
<th>Process Required to Obtain Patient Information</th>
<th>Number of Registries</th>
</tr>
</thead>
<tbody>
<tr>
<td>MD notify only</td>
<td>4</td>
</tr>
<tr>
<td>Patient release only</td>
<td>4</td>
</tr>
<tr>
<td>MD notify and patient release</td>
<td>3</td>
</tr>
<tr>
<td>MD permission</td>
<td>4</td>
</tr>
<tr>
<td>MD permission and patient release</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>16</strong></td>
</tr>
</tbody>
</table>

Includes MD Anderson Cancer Center separately because it has a pathway different from that of the Texas Cancer Registry. Note that Texas Cancer Registry is categorized as ‘MD Permission’; recently in Dec. 2010 the pathway changed to ‘MD Notify only’.
### Patient-Access Pathway and Interview Rate

<table>
<thead>
<tr>
<th>Registry</th>
<th>Type of Patient Access Pathway</th>
<th>Total Identified</th>
<th>Total Interviewed</th>
<th>Interview Rate(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>North Carolina</td>
<td>MD notify only</td>
<td>121</td>
<td>71</td>
<td>59%</td>
</tr>
<tr>
<td>New York</td>
<td>MD notify and patient release</td>
<td>231</td>
<td>108</td>
<td>47%</td>
</tr>
<tr>
<td>CA - LA SEER</td>
<td>MD notify only</td>
<td>81</td>
<td>36</td>
<td>44%</td>
</tr>
<tr>
<td>California (exc. LA)</td>
<td>MD notify only</td>
<td>323</td>
<td>141</td>
<td>44%</td>
</tr>
<tr>
<td>Michigan</td>
<td>MD notify and patient release</td>
<td>122</td>
<td>51</td>
<td>42%</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>Patient release only</td>
<td>183</td>
<td>70</td>
<td>38%</td>
</tr>
<tr>
<td>Arizona</td>
<td>MD notify only</td>
<td>36</td>
<td>13</td>
<td>36%</td>
</tr>
<tr>
<td>Harvard &amp; Hopkins</td>
<td>MD permission</td>
<td>111</td>
<td>40</td>
<td>36%</td>
</tr>
<tr>
<td>MD Anderson</td>
<td>Patient release only</td>
<td>154</td>
<td>51</td>
<td>33%</td>
</tr>
<tr>
<td>Missouri</td>
<td>Patient release only</td>
<td>63</td>
<td>21</td>
<td>33%</td>
</tr>
<tr>
<td>New Jersey</td>
<td>MD permission and patient release</td>
<td>67</td>
<td>22</td>
<td>33%</td>
</tr>
<tr>
<td>Florida</td>
<td>Patient release only</td>
<td>269</td>
<td>86</td>
<td>32%</td>
</tr>
<tr>
<td>Ohio</td>
<td>MD permission</td>
<td>100</td>
<td>32</td>
<td>32%</td>
</tr>
<tr>
<td>Minnesota</td>
<td>MD notify and patient release</td>
<td>88</td>
<td>24</td>
<td>27%</td>
</tr>
<tr>
<td>Texas</td>
<td>MD permission</td>
<td>172</td>
<td>33</td>
<td>19%</td>
</tr>
</tbody>
</table>

\(^a\) Interview rate = (number interviewed)/(number identified by participating registries). Data as of March 31, 2011, for cases diagnosed 2003-2009.
Access and Availability of Updated Contact Information
Qualitative Factors Affecting the Ability to Complete an Interview

• Missing or out-of-date contact information
  – Patient
  – Proxy
  – Physician

• Limited access by some registries to commercial databases to update contact information

• Some registries are unable to send RTI cases if they were unable to contact MD or patient
Conclusions

• **Interview rates decrease as complexity of the patient access pathway increases**
  – Interview rates trended lower at registries where MD permission was required

• **Interview rates decrease as lag time increases**
  – Year registry began participating appeared related to interview rate; however, registries with less complex requirements were recruited first (confounds lag time)

• **Missing or out-of-date contact information can adversely affect interview rates**
Collaborative Efforts to Improve Interview Rates

• RTI-HS met with 10 participating registries in November 2010 to discuss ways to increase interview rate
  – Registries shared efforts undertaken to improve data
  – Registries shared what processes they can and cannot change

• Since meeting with the registries three amendments were submitted in two states resulting in simplification of patient access pathway
Thank You!

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