RATIONALIZING THE USE OF AUXILIARY LABELS FOR ORAL ONCOCOLOGY DRUGS

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Table 2. Usage of auxiliary labels: pre- and post-standardization

<table>
<thead>
<tr>
<th>Auxiliary label</th>
<th>Usage (N=150)</th>
<th>Pre-standardization</th>
<th>Post-standardization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not chew or crush, swallow whole</td>
<td>49</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Avoid grapefruit or grapefruit juice</td>
<td>38</td>
<td>15</td>
<td>2</td>
</tr>
<tr>
<td>May cause drowsiness/dizziness</td>
<td>26</td>
<td>N/A</td>
<td>26</td>
</tr>
<tr>
<td>Keep out of reach of children</td>
<td>10</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Avoid alcohol</td>
<td>7</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>May cause discoloration of urine</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Hazardous drug label</td>
<td>1</td>
<td>N/A*</td>
<td>1</td>
</tr>
</tbody>
</table>

* Potential recommendation of safe handling procedures with other hospitals in British Columbia.

Table 3. Inclusion criteria for commonly used auxiliary labels

<table>
<thead>
<tr>
<th>Label</th>
<th>Inclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not take if pregnant</td>
<td>Health Canada or Food and Drug Administration mandated pregnancy monitoring programs (e.g., methotrexate, talidomide)</td>
</tr>
<tr>
<td>Do not chew or crush, swallow whole</td>
<td>Crushing may affect bioavailability (e.g., enteric coating, modified release)</td>
</tr>
<tr>
<td>Take with plenty of water</td>
<td>Nephrotoxic, or with specific recommendations to consume large quantities of fluid (e.g., cyclosporine)</td>
</tr>
<tr>
<td>May cause drowsiness/dizziness</td>
<td>Strong cautions on somnolence or dizziness affecting functioning (confirm with BNF where possible)</td>
</tr>
<tr>
<td>Avoid alcohol</td>
<td>Evidence-based interactions (e.g., alcohol, disulfiram-like reaction)</td>
</tr>
<tr>
<td>Avoid grapefruit or grapefruit juice</td>
<td>Evidence-based interactions based on: - OPS product interaction section; - Product monograph cautions; or - Lexicomp® citing clinical cases</td>
</tr>
<tr>
<td>Avoid prolonged exposure to sun</td>
<td>Strong phototoxic reactions OR black box or other strong warnings (confirm with BNF where possible)</td>
</tr>
<tr>
<td>Avoid Aspirin</td>
<td>Documented interaction with aspirin</td>
</tr>
<tr>
<td>Do not take within 2 hours of antacids</td>
<td>Evidence-based interactions with antacids</td>
</tr>
</tbody>
</table>

BNF = British National Formulary, CPS = Compendium of Pharmaceuticals and Specialties

Phase IV

A list of standardized auxiliary labels was developed and adopted by all six centres in June 2014. Sources of information to support an auxiliary label included:
- Compendium of Pharmaceuticals and Specialties
- BC Cancer Agency Cancer Drug Manual
- British National Formulary
- Other resources as needed (e.g., Lexicomp®, AHFS DIl, Micromedex®)

Literature, including alerts from Health Canada and the US Food and Drug Administration.

After standardization:
- Number of auxiliary labels used was significantly reduced (table 2).
- The auxiliary label list was posted as part of the Cancer Drug Manual® on the website: [www.bcancer.ca/cancer]
- BC Cancer Agency pharmacy directive was developed.
- Staff was educated through two 30-minute inservices and an emailed document summarizing the frequently asked questions and answers.

Discussion

BC Cancer Agency has developed a systematic approach to standardize the use of auxiliary labels for oral oncology drugs dispensed for outpatients. The practice before standardization was highly inconsistent, similar to that reported in other studies.

Standardization has led to practice changes that may improve the safe administration of oral agents:
- Labels are consistently applied, independent of the practitioners
- Consistent messaging during patient counselling across professions
- Consistent assessment of similar cautions for similar situations for future drugs
- Label with multi-step instructions separated into labels with single-step instructions
- Consistent label (positioning) in applying the labels on the medication vial
- Provide auxiliary labels used by patients as the main information source (e.g., storage, proper administration)
- Reduced number of auxiliary labels
  - Improve clarity by focusing on the more significant cautions
  - Minimize alert fatigue

Conclusion

A systematic approach was developed to standardize and prioritize the use of auxiliary labels for oral oncology drugs to improve their safe administration at the BC Cancer Agency. The consistency of our practice has been significantly improved following the development and implementation of a harmonized list for all regional centres’ pharmacies.

References