RESEARCH LETTER

Patient Information About Warfarin: An Assessment of Accuracy and Readability

Oral vitamin K antagonists, such as warfarin, are among the most commonly prescribed and potentially dangerous classes of medications. For many high-risk drugs, such as warfarin, there is a strong link between patient knowledge about the medication and their safe use. For warfarin, provision of high-quality education improves compliance, increases time in the therapeutic range, and leads to a reduction in complications. Patients are largely educated about warfarin through written information sheets provided by their pharmacies. Therefore, it is critical that these sheets are both accurate and understandable. The objectives of this study were to assess the content (accuracy and completeness) and reading level of patient education sheets (PES) about warfarin provided to patients by community pharmacies in Ontario, Canada, and by pharmaceutical producers of this high-risk drug.

Methods. A reference standard for content was developed based on a formal survey completed by 27 members of the Thrombosis Interest Group of Canada, a national group of thrombosis professionals. Five different warfarin PES (A, B, C, D, and E in the Table), distributed by 98% of the 3742 community pharmacies in Ontario (population, 12 million) were compared with the reference standard. The reading level was assessed using 2 standardized instruments, the SMOG and Flesch-Kincaid scales, and compared with the grade 5 to 6 reading level recommended for written patient information. Three patient booklets (X, Y, and Z in the Table), distributed by the commercial producers of warfarin, were also evaluated.

Results. Expert consensus identified 50 items that were rated as “essential” or “important” for patient education about warfarin. On average, the PES included only 63% of the recommended essential or important knowledge items (range, 22%-72%) (Table). On average, the sheets had 24 missing items, including the importance of laboratory monitoring or reference to the variable and individualized dose of warfarin required by different patients. None of the PES mentioned specific target ranges for the international normalized ratio (INR) value or the consequences of having an INR result above or below the target range. Only 1 PES mentioned a safe amount of alcohol that could be consumed or the advice to avoid binge drinking. The others recommended patients to avoid alcohol, an example of incorrect information that could lead to unnecessary lifestyle restrictions and could have an impact on adherence. The average reading level of the PES was grade 10 using the Flesch-Kincaid scale (grade 9 to 12) and grade 12 using the SMOG scale (grade 12 to 14). The mean word-to-content ratio of the PES was 67:1, meaning that for every 67 words of text, 1 relevant item was stated. The longer the document, the more likely it was to cover important content.

The 3 pharmaceutical patient booklets were generally of better quality, including an average of 69% of the essential or important items (range, 50%-81%) and missing an average of 15 items. These booklets also contained fewer incorrect or misleading statements than those distributed by the community pharmacies. The reading

<table>
<thead>
<tr>
<th>Warfarin PES or Information Booklet</th>
<th>Pharmacies Using PES, %</th>
<th>Content, % Essential or Important Items</th>
<th>Flesch-Kincaid Reading Level</th>
<th>SMOG Reading Level</th>
<th>Word Count</th>
<th>Word-to-Content Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PES</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>77</td>
<td>72</td>
<td>10.2</td>
<td>11.6</td>
<td>2043</td>
<td>57:1</td>
</tr>
<tr>
<td>B</td>
<td>17</td>
<td>22</td>
<td>8.7</td>
<td>11.0</td>
<td>502</td>
<td>46:1</td>
</tr>
<tr>
<td>C</td>
<td>3</td>
<td>58</td>
<td>9.5</td>
<td>13.0</td>
<td>1584</td>
<td>55:1</td>
</tr>
<tr>
<td>D</td>
<td>3</td>
<td>54</td>
<td>12.5</td>
<td>12.0</td>
<td>2462</td>
<td>91:1</td>
</tr>
<tr>
<td>E</td>
<td>0.2</td>
<td>50</td>
<td>9.5</td>
<td>13.8</td>
<td>2094</td>
<td>84:1</td>
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<td><strong>Manufacturers’ information booklets</strong></td>
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<td></td>
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<tr>
<td>X</td>
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<td>50</td>
<td>8.9</td>
<td>11.0</td>
<td>2238</td>
<td>90:1</td>
</tr>
<tr>
<td>Y</td>
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<td>76</td>
<td>7.7</td>
<td>11.1</td>
<td>1613</td>
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</tr>
<tr>
<td>Z</td>
<td>NA</td>
<td>81</td>
<td>8.0</td>
<td>11.7</td>
<td>3280</td>
<td>80:1</td>
</tr>
</tbody>
</table>

Abbreviations: NA, not applicable; PES, patient education sheet.
level of these booklets was grade 8 using the Flesch-Kincaid scale (range, grade 8-9) and grade 11 using the SMOG scale (range, grade 11-12). Their mean word-to-content ratio was 68:1.

Comment. The findings of this study reveal that patients prescribed warfarin are very likely to receive information sheets from community pharmacies that contain only 63% of the content important for its safe use as well as statements that experts believe are misleading or incorrect. Comprehension of these sheets is also limited by a reading level approximately 5 or 6 grade levels above that recommended for health information. The readability results found in this study are consistent with previous research reviewing drug-related patient education brochures, where the mean reading level was grade 11. In a study of warfarin therapy, more than half of patients were unable to comprehend health-related words at levels beyond grade 8, and an increased risk of bleeding and nonadherence has been reported in patients with low literacy.

The major limitation of this study is the absence of a gold standard for content of warfarin information; however, we relied on consensus from experts to create a reference standard. Although we reviewed PES distributed by Ontario pharmacies, the results are likely generalizable, since many community pharmacies across the country use information sheets obtained from the same small number of drug information databases. Since the drug information programs were produced by 5 different American and European software companies, our findings likely apply to warfarin PES at least across North America.

Appropriate and accurate information about warfarin is critical in helping patients make educated health care decisions. We suggest that standardization of the content of patient information about warfarin, developed with input from anticoagulation specialists and presented in a manner that is understandable by the majority of patients taking this medication, is an important patient safety priority. This approach to patient education must also be considered for other high-risk medications including the new oral anticoagulants and other medications with a narrow therapeutic index.

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INVITED COMMENTARY

Left Behind: Ensuring Clarity and Completeness of Our Educational Materials and Messages

Sometimes it seems that despite our best efforts to educate patients and families, we miss the mark. During internship, one of us (D.A.D.) sat down with the mom of a 2-year-old child to discuss the child’s condition and plan for care. After spending time “clearly” explaining things to her, the mom looked up with a bewildered yet calm look and said, “I have no idea what you just said.” This mom was lost. Thankfully, she had the courage to speak up. Often, we assume that we speak and write clearly and that our communication is effective; yet for various reasons, there is a gap between what patients know and what health care providers think they should know.

Failure to consider the literacy levels and learning needs of patients when designing educational messages is one way in which we leave our patients behind. An article by Diamantouros and colleagues1 assessed the accuracy, completeness, and reading level of 5 warfarin education materials provided by community pharmacies or pharmaceutical producers of warfarin. To do this assessment, the authors identified 50 “essential” or “important” knowledge elements (defined by clinical experts in warfarin management) and used tools to assess the reading level of the written materials. They found that the information contained between 22% and 81% of essen-