Development and Testing of Health Literate Patient Labeling

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Objective

• Purpose
  – Maximize comprehension of patient labeling for all audiences, including those with limited health literacy

• New process developed by an innovative industry-academia partnership
  • Merck:
    – Legal, Health Literacy, Regulatory Policy, Marketing, Marketing Research, Chief Medical Officer
  • Academia: National health literacy experts and teams
    – Dr. Ruth Parker (Emory)
    – Dr. Michael Wolf (Northwestern)
Merck’s Past Approach to Testing

• Historically, Merck has done comprehension testing of patient labeling
• Merck’s past approach included conducting research across a broad range of education levels; however, few respondents presented with limited health literacy
  • Harder to locate and less likely to participate
  • Directionally, limited health literacy respondents had lower comprehension scores than those with adequate health literacy
Updated Approach to Testing

- Elimination of requirement for desktop computer
- Recruitment at literacy centers, senior centers
- Inclusion of health literacy assessment
  - One question phone screener (*How confident are you filling out medical forms by yourself?*)
  - Newest Vital Sign assessment done at the end of the interview
  - Schlesinger database began to add health literacy assessment
- In-person research to increase likelihood of participation by respondents with limited health literacy
  - Moderators who are knowledgeable of and sensitive to health literacy
- Combination of open and closed book assessment
- Aim for 25% of respondents with limited health literacy
Process Overview: Patient Labeling Development and Testing

**Health Literacy Review**
- Merck creates draft of patient labeling
- Northwestern/Emory apply best practices
- Merck reviews, with few changes

**Focus Groups**
- Focus groups in Chicago and Atlanta
- Patient labeling revised and sent to Merck
- Merck reviews, with few changes

**Comprehension Testing**
- Qualitative research with limited and adequate health literacy respondents
- Debrief with Merck, Northwestern, and Emory
- Labeling revised as necessary
Results

- High comprehension by respondents with both adequate and limited health literacy

<table>
<thead>
<tr>
<th>Average Comprehension Scores Across Literacy Levels (n=548)*</th>
<th>Patients (n=249)</th>
<th>Caregivers (n=145)</th>
<th>Gen Pop (n=154)</th>
<th>Overall (n=548)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limited Health Literacy</td>
<td>88%</td>
<td>94%</td>
<td>87%</td>
<td>89%</td>
</tr>
<tr>
<td>Adequate Health Literacy</td>
<td>94%</td>
<td>96%</td>
<td>92%</td>
<td>95%</td>
</tr>
<tr>
<td>Overall</td>
<td>92%</td>
<td>96%</td>
<td>90%</td>
<td>93%</td>
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</tbody>
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Both adequate and limited health literacy respondents stated they would be likely to:

- Read the information
- Keep information as a reference
- Have a clear understanding of how to correctly use medication
- Have a clear understanding of risks
- Ask questions of their providers
Contact Information

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