Assessing the performance and effectiveness of a Risk Evaluation and Mitigation Strategy (REMS) is a requirement of every approved REMS program. However, measuring the effectiveness of a REMS program is challenged by limitations in interpreting the relative performance of the assessment survey results.

Pharmaceutical manufacturers with a REMS faces difficulty is stating subjectively stating the effectiveness of the REMS in achieving its goals and the need if any for corrective actions.

ASSESS (Awareness Safety Surveys for Evaluative Studies and Statistics) is a novel registry and analytical tool used for:
- Examining the influence of multiple variables on influence REMS assessment scores
- Determining if normal ranges exist and if appropriate performance benchmarks can be established
BioTrak developed analytical methods and tools to answer “What variables are most highly correlated to, or most influence, the assessment score with patients?"

The influence of program-specific variables on “overall assessment score” as the dependent variable output was examined. Variables included:

- Therapeutic class
- Disease category
- Level of safety risk (lower, moderate, higher)
- Disease presentation (acute, chronic)
- Type of REMS
- Number of Serious Risk Messages in REMS
The influence of program-specific (inter-program) variables was also examined.

- Normalized assessment scores in order to test respondent-specific variables (intra-program). This allows “pooling” of data from different REMS assessment surveys.
- Three types of normalization techniques were developed:
  - T-Score (lacks sensitivity)
  - Distance from the Mean (can be influenced by outliers)
  - Distance from the Median (preferred)
- Respondent-specific variables included:
  - Receipt of Medication Guide
  - Receipt of Counseling on the Medication Guide
  - Method of patient recruitment
  - Any and all demographic questions
Results

Medication Distribution Rates by Source (N=1,463)

- Receipt of MG (HCP): 42.1%
- Receipt of MG (Pharma): 62.7%
- Receipt of MG (Other): 3.6%
- Receipt of MG (I don't recall): 6.4%
- Receipt MG from 1+ source: 84.8%
Results

Medication Distribution Rates by Source (N=1,271)

<table>
<thead>
<tr>
<th>Source</th>
<th>Prevalence Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offered MG Counseling (Dr. Office)</td>
<td>56.7%</td>
</tr>
<tr>
<td>Offered MG Counseling (Pharmacy)</td>
<td>26.8%</td>
</tr>
<tr>
<td>Offered MG Counseling (Don't recall)</td>
<td>1.6%</td>
</tr>
<tr>
<td>Offered MG Counseling (any source)</td>
<td>74.9%</td>
</tr>
</tbody>
</table>
Results

Rx Dispensing Channels Used (N=976)

- Large Chain Retail Pharmacy: 59%
- Small Pharmacy Store: 21%
- Mail Order Pharmacy: 14%
- Doctor's Office: 3%
- Hospital Pharmacy: 2%
- Other: 1%
- Other: 1%
Results

Survey Taker (N=1,463)

- Patient: 89%
- Caregiver: 11%
Results

Respondent Gender (N=1,463)

- Male: 59%
- Female: 41%
Results

Rx Dispensing Channels Used (N=1,183)

- College Graduate: 29%
- Some College: 30%
- High School Graduate: 19%
- Post-Grad/Professional Degree: 19%
- Less than High School Diploma: 3%
Results

Effect of Medication Guide Distribution on Distance from the Median Assessment Score (N=1,463)

- Yes (all): 1.1%
- Yes (HCP & Pharm.): 1.5%
- Yes (HCP or Pharm.): 0.9%
- Did not receive: -4.0%
Results

Effect of Patient Counseling on Distance from the Median Assessment Score (N=1,268)

- HCP only: 0.3%
- Pharmacy only: 2.8%
- HCP & Pharmacy: 4.5%
- None: -0.4%
Results

Age vs. Distance from the Median Assessment Score
(N=1,463)
Results

Effect of Number of Serious Risk Messages on Overall Assessment Score

- 1 - 2 Serious Risks (N=865) - 64.8%
- 3 or more Serious Risks (N=598) - 49.0%
Key Takeaways

• Receipt of a Medication Guide from an HCP, pharmacist or both increases patient knowledge of the key risks messages associated with a REMS. However, the relative increase the mean assessment score is small (~1%).

• Counseling of patients about the REMS key messages has a positive influence on knowledge about these risks. When both HCP and pharmacists provided counseling, the mean assessment score increased 4.5%.

• There is not a correlation between patient age and assessment knowledge scores for all programs analyzed.

• The number of REMS key risk messages greatly influences knowledge scores. The mean overall assessment score for programs with 1-2 key risk messages was 65% compared to 49% for REMS with 3 or more key risk messages.
For More Information

• We hope you found this research summary interesting. To learn more or to discuss your REMS program, please contact:

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