Assessing the Performance of FDA Risk Evaluation and Mitigation Strategies (REMS)

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Presentation Overview

❑ 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

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ASSESS Research Methodology

❑ 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:

- o Therapeutic class
- o Disease category
- o Level of safety risk (lower, moderate, higher)
- o Disease presentation (acute, chronic)
- o Type of REMS
- o Number of Serious Risk Messages in REMS

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ASSESS Research Methodology

❑ 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
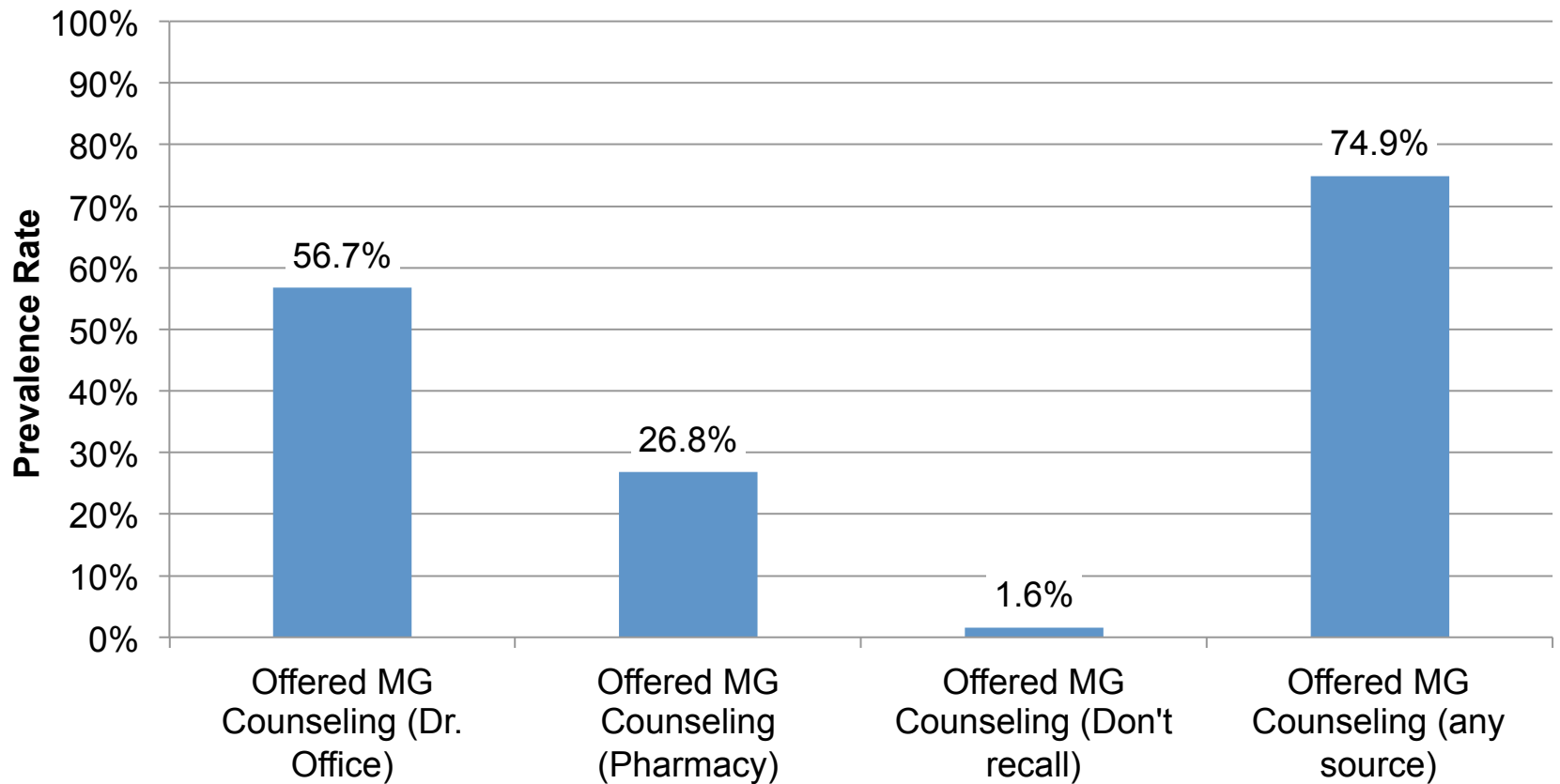 - Any and all demographic questions

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Results

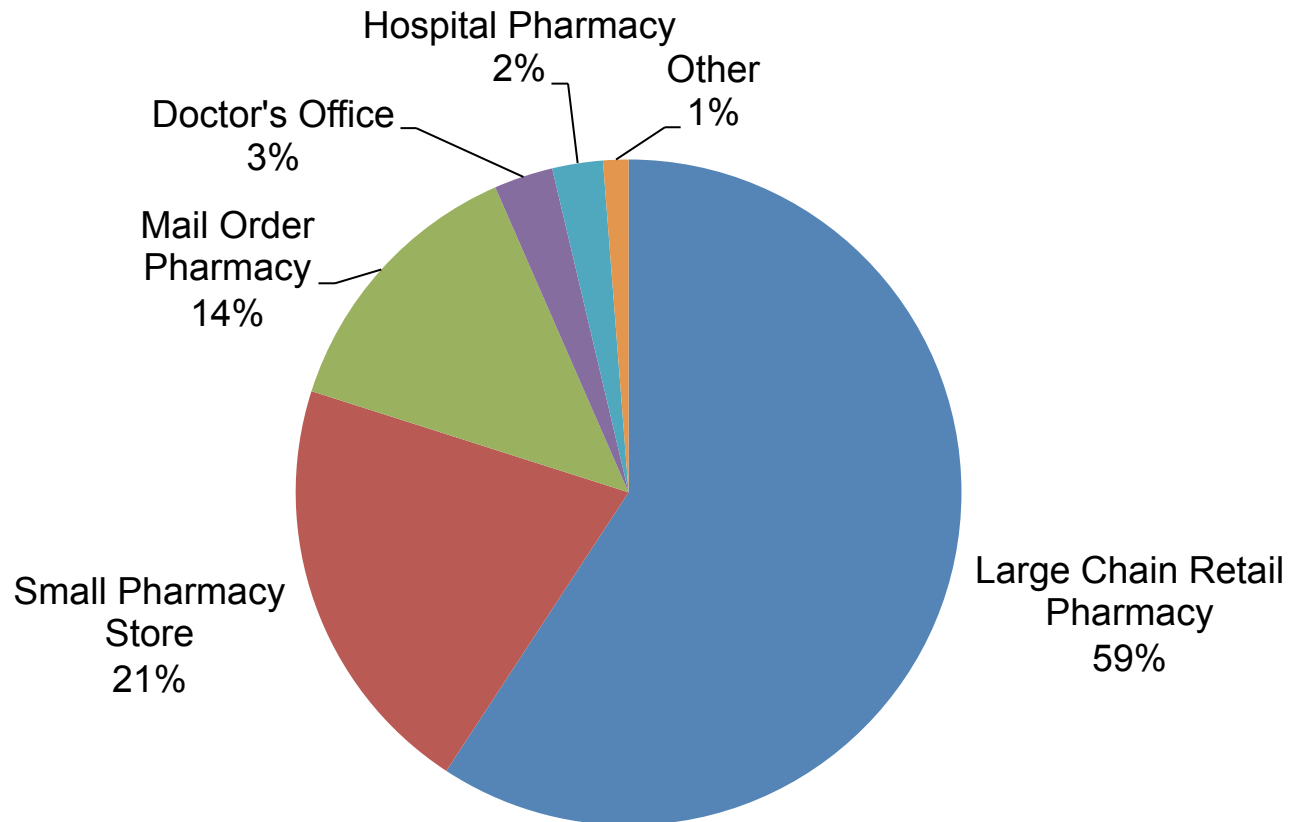**Medication Distribution Rates by Source (N=1,463)**
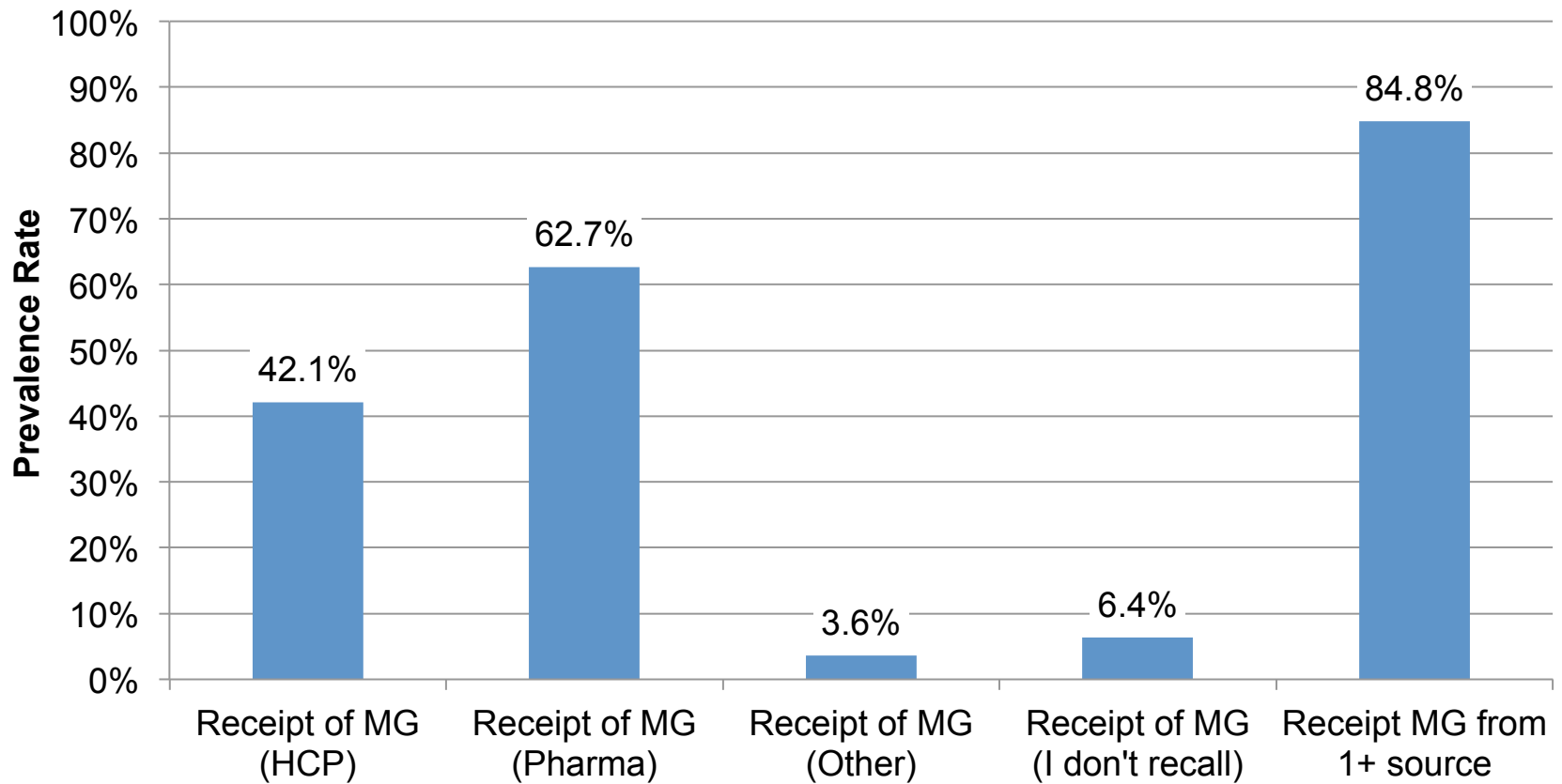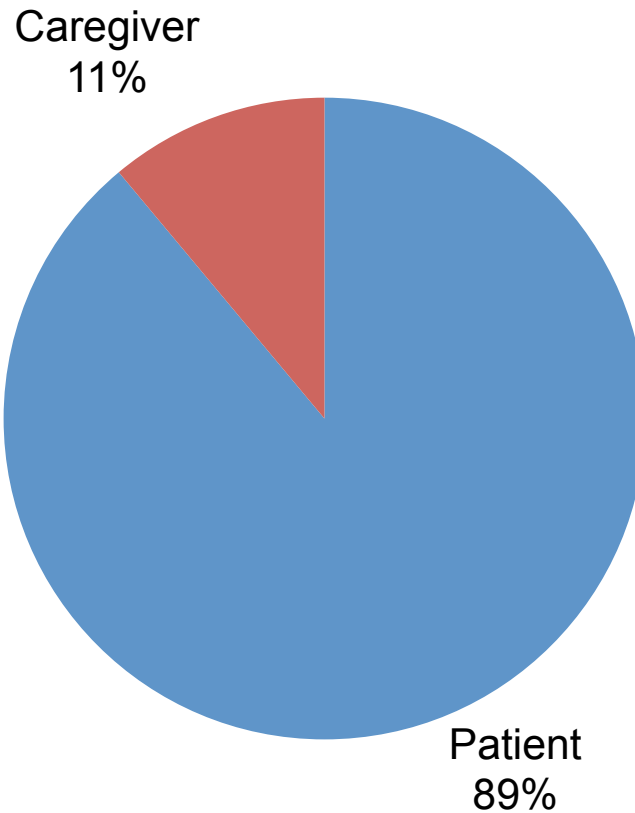
Results

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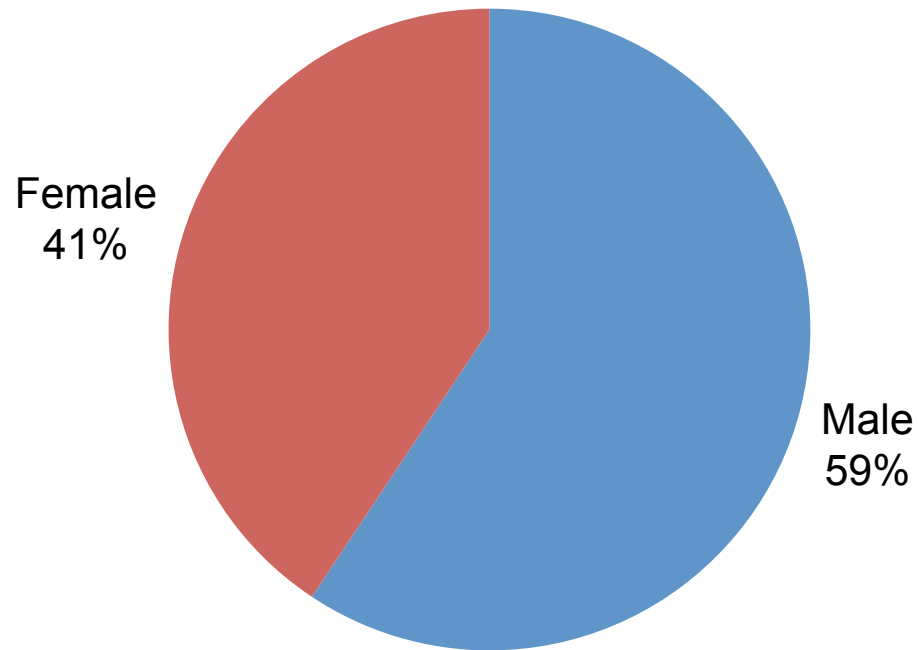
Results

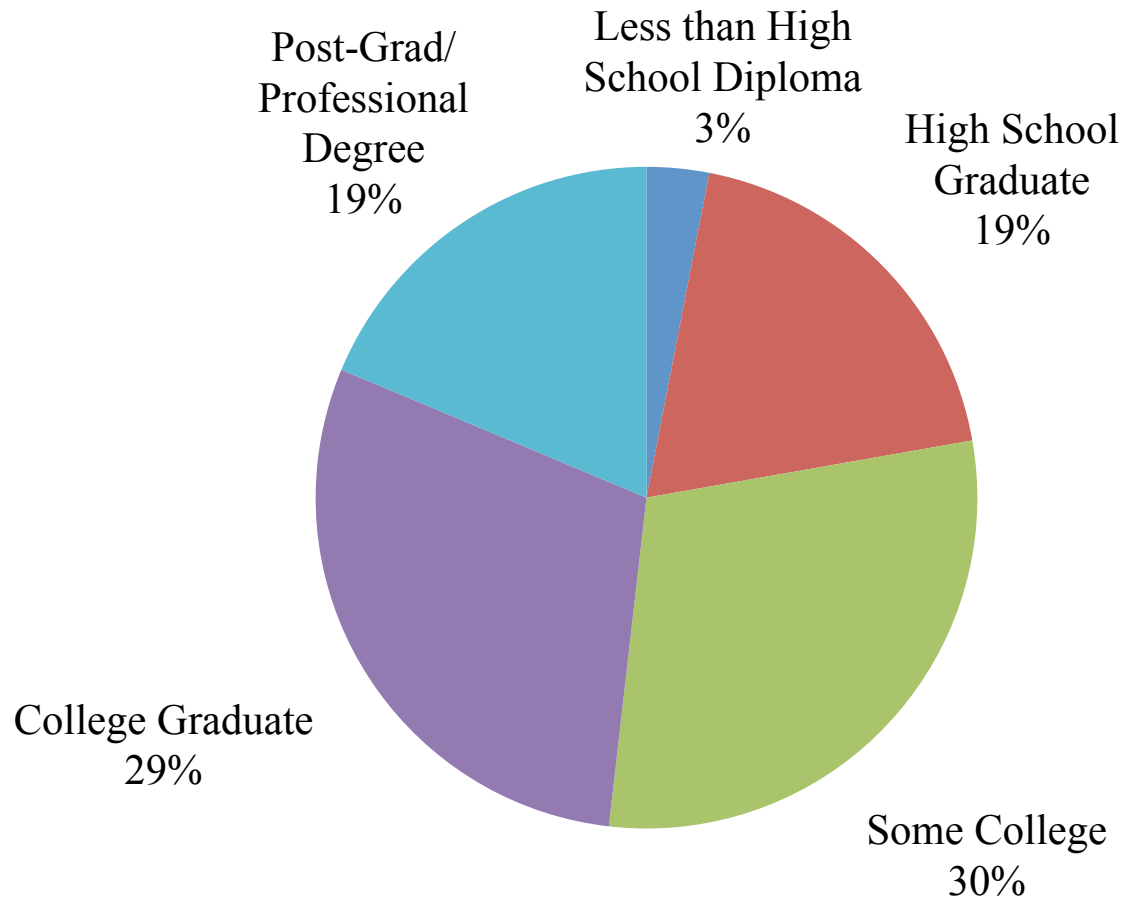**Rx Dispensing Channels Used (N=976)**

Results

Survey Taker (N=1,463)

Caregiver 11%

Patient 89%

Results

Respondent Gender (N=1,463)

Results

Rx Dispensing Channels Used (N=1,183)

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

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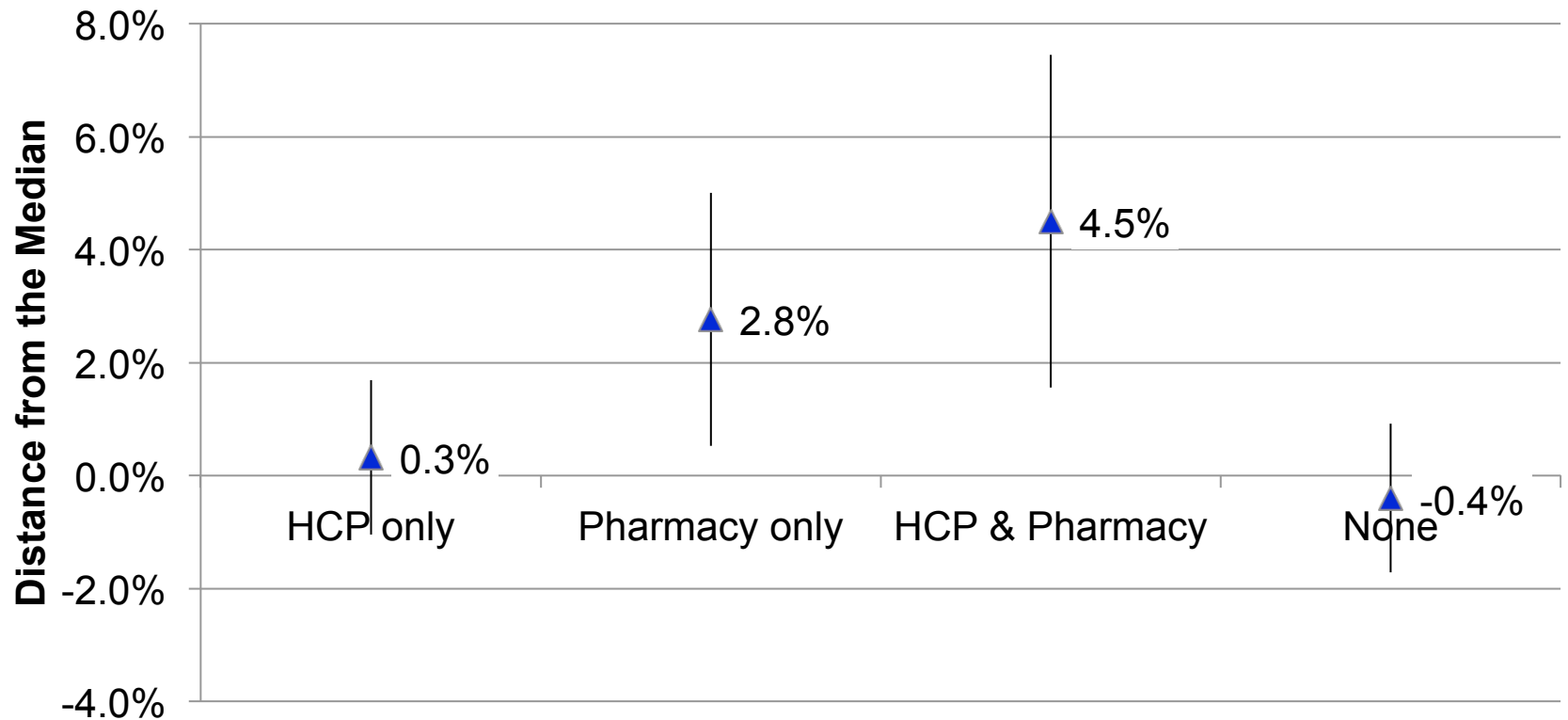
Results

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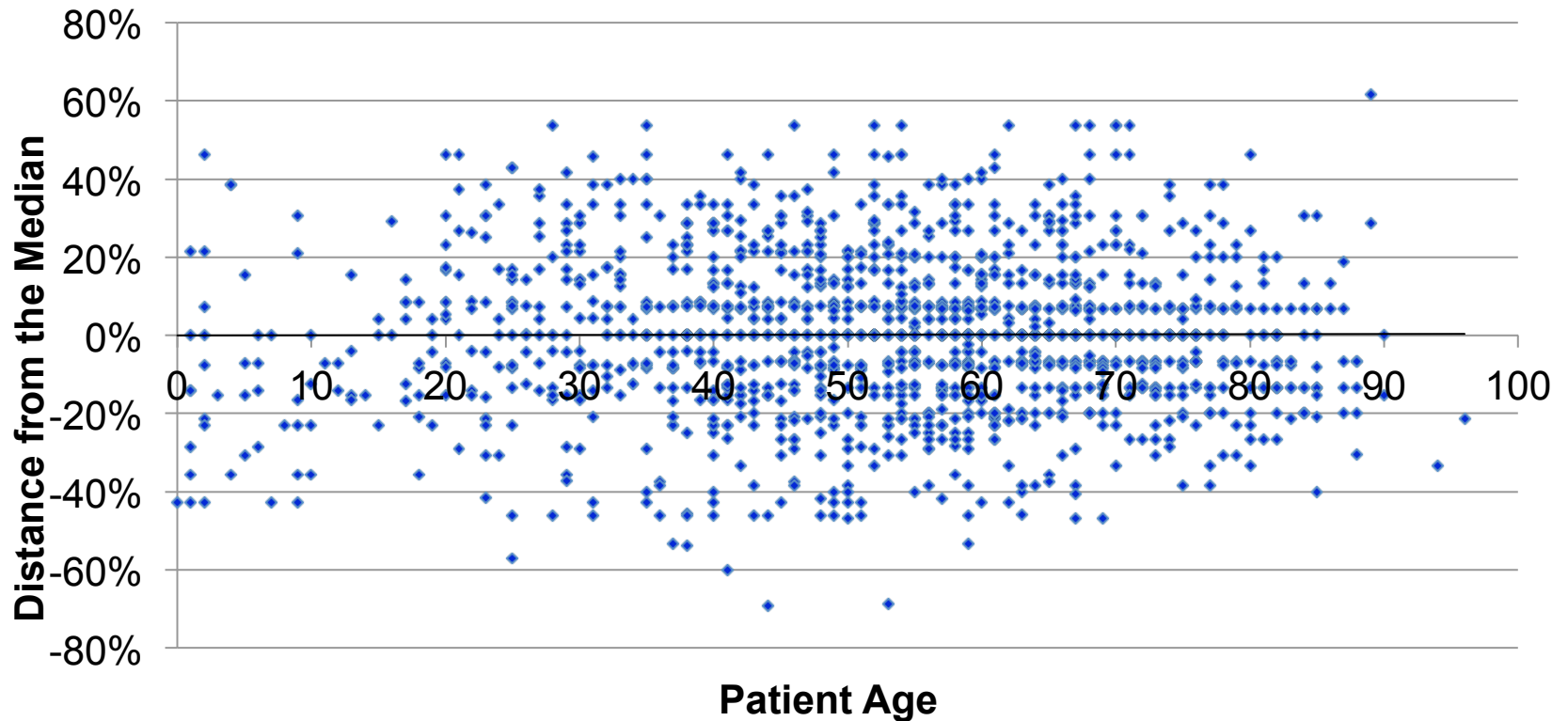
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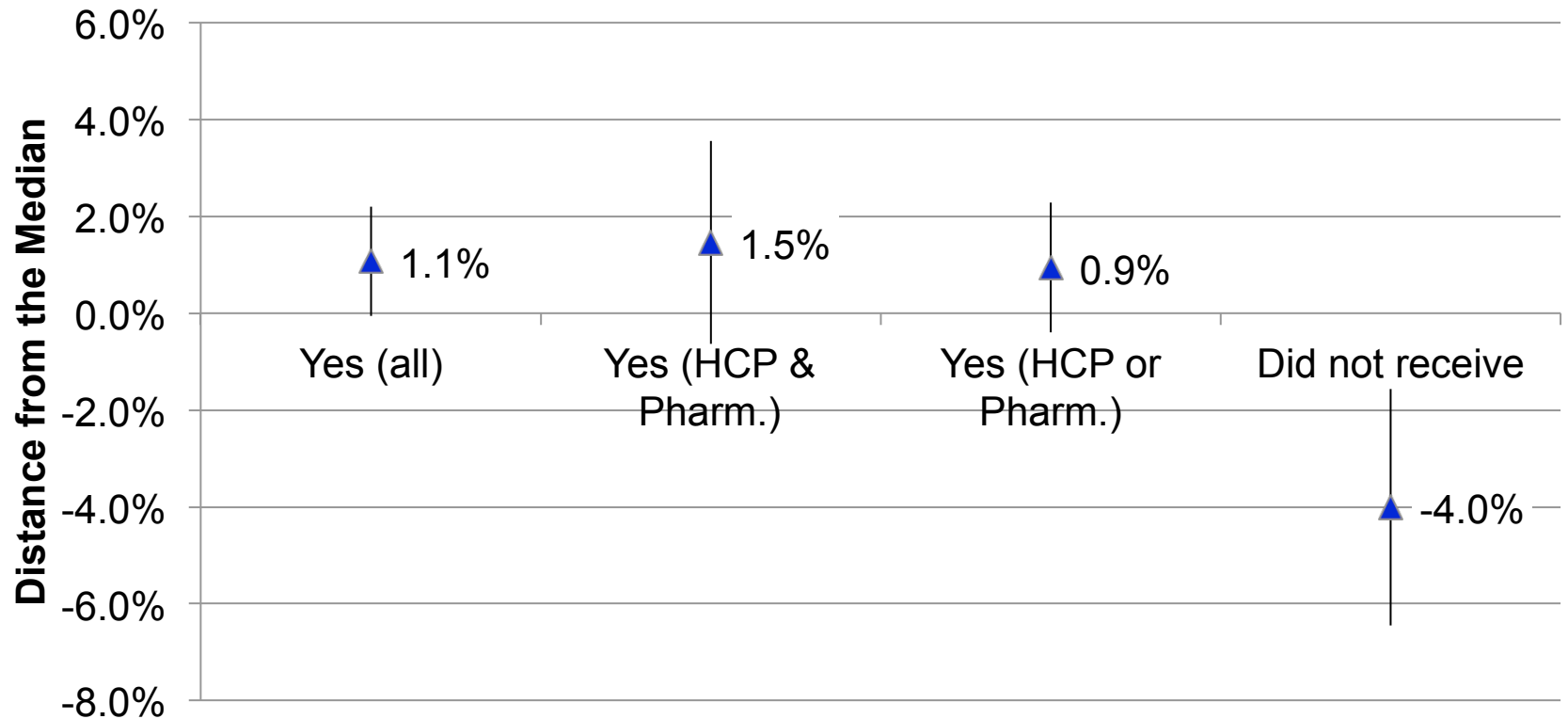
Results

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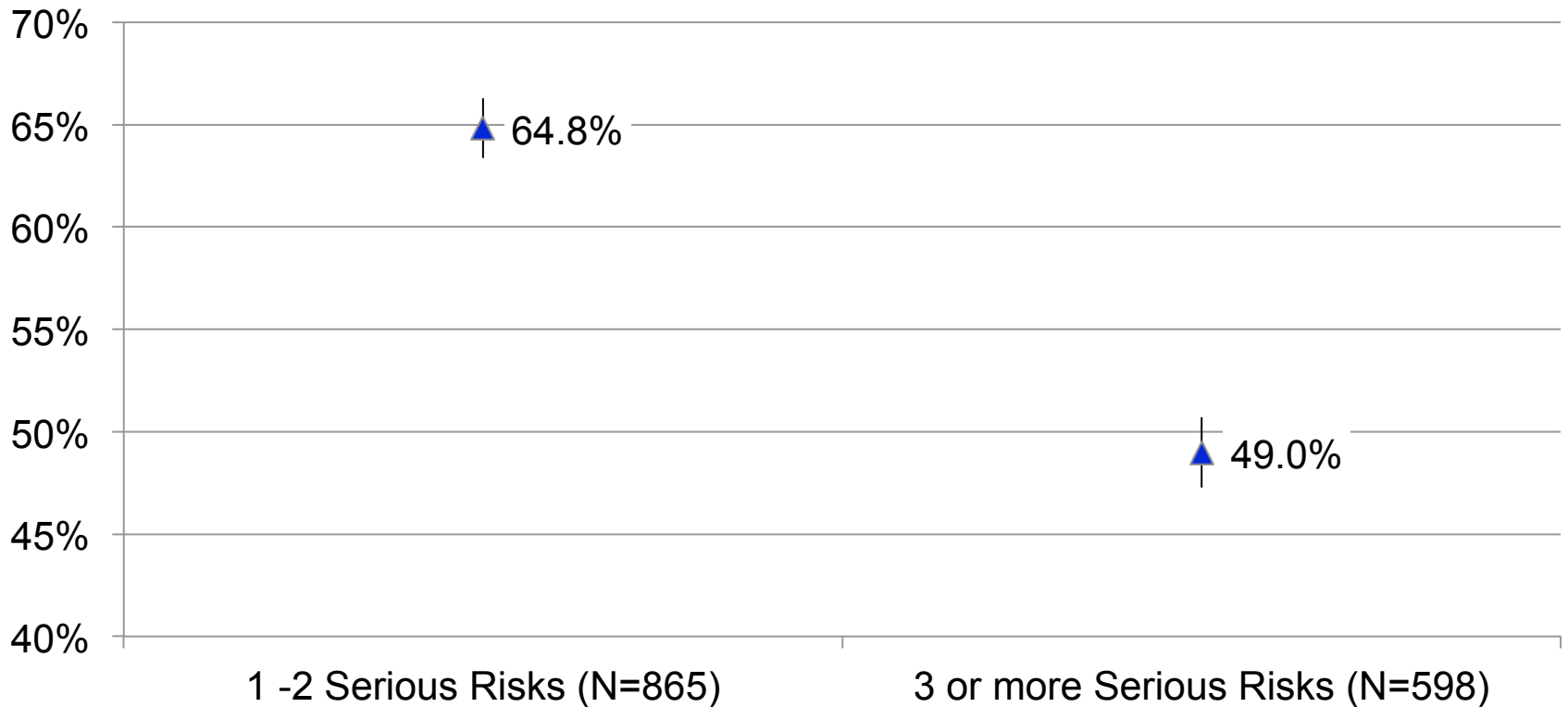
Results

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

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Results

Effect of Number of Serious Risk Messages on Overall Assessment Score

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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.

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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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