



# ***Effective Patient Communication: Improving on Medication Guides***

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# *FDAAA Sets Higher Bar for Medication Guides*



**REMS assessment  
is elevating interest  
in effectiveness of  
Medication Guides  
for patients**



# *Are Medication Guides Sufficiently Effective?*

**Three points of evidence suggests the need to augment Med Guides to effectively communicate safety messages:**

- I. Comprehension study of a Medication Guide
- II. Study of a drug facts box to communicate medication benefits and risks
- III. Literature defining adult learning principles

# *I. Comprehension Study of Medication Guide*

## ■ Objectives

- Evaluate patient comprehension of product safety messages
- Identify ways to improve comprehension

## ■ Interviews of patients conducted at multiple locations

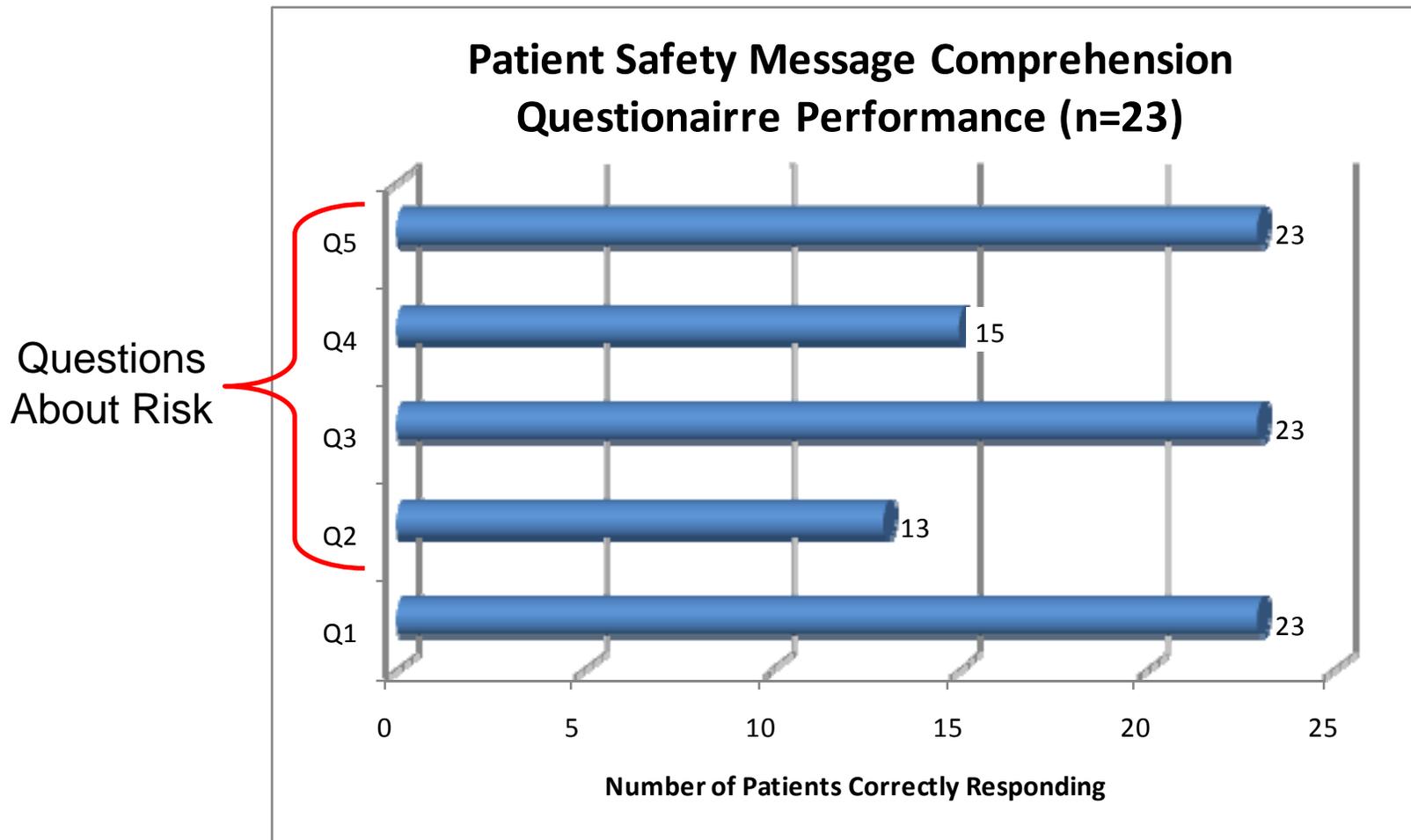
## ■ Patient Cohort (n=23)

- Individuals diagnosed with condition for which product is indicated

## ■ Assessment

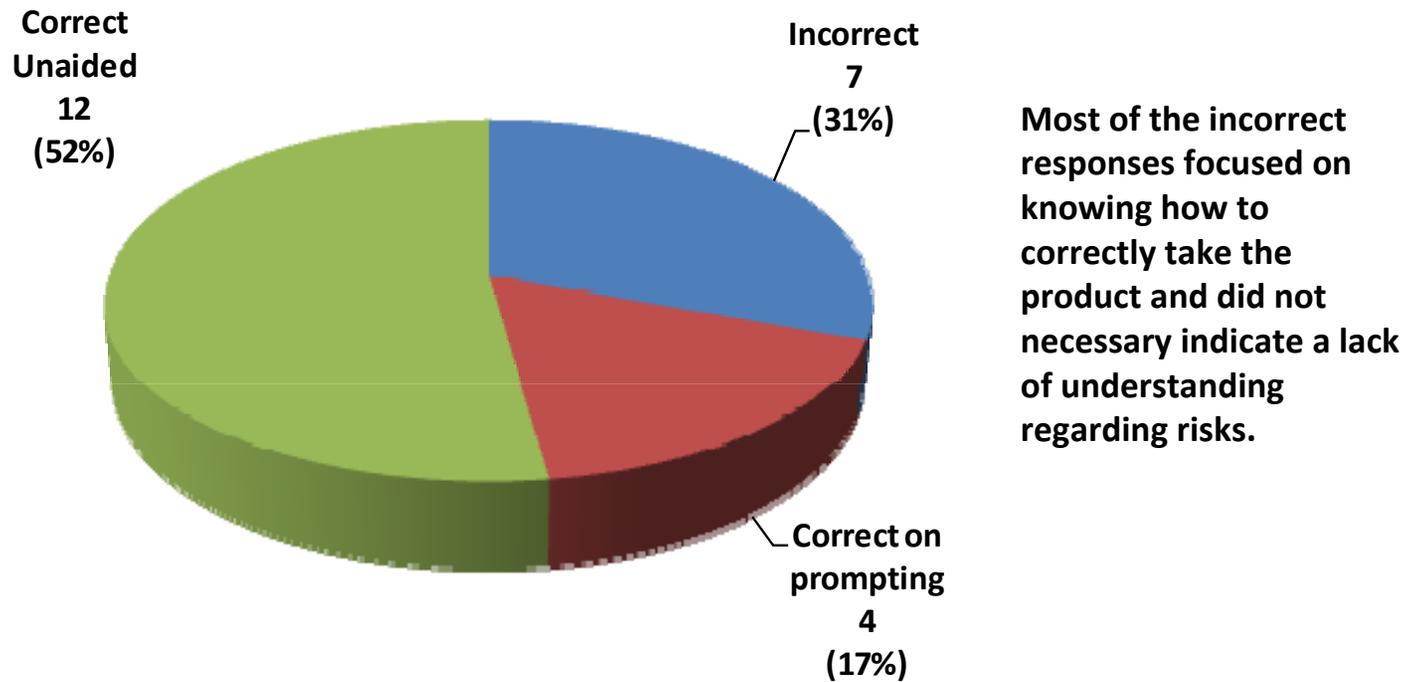
- Reviewed product Medication Guide
- Administered written test
- Interviewed by research associate

# Questionnaire Performance



# Safety Message Recall

**Question 6: What is the most important information you should know about the product?**



**The interviews indicated there were some misunderstandings**



# ***Patient Recommendations to Improve the Guide***

- **Start Med Guide with description of medication, indication for use, and benefit**
  - This was conveyed repeatedly as very important
  - Patients want to know what the drug is and how it might benefit them before they are presented with the risks
- **Place key risk statements in a summary box on first page then expand on it later in the Med Guide**
  - Keep all risk statements in one area of the Med Guide
- **Use callout boxes and other format and graphical methods to emphasize the most important information**

## ***II. Communicating Drug Benefits and Harms with a Drug Facts Box: Two Randomized Trials***

### **■ Objective**

- Determine if drug safety box improves knowledge and affects judgment about prescription medications

### **■ Study involved 231 adults nationwide**

### **■ Two DTC drug ads for each of two indications**

- Control
- Brief summary replaced by “Drug Facts Box” providing side-by-side description of benefits and risks

### **■ Assessment**

- Choice of correct drug for indication
- Accurate perception of benefits and side effects

# *Findings*

- **“Drug Facts Box” improved patient knowledge**
  - Contains fewer elements presented in structured format
  - Better choices between drug and symptoms
    - ◆ Patients able to choose the superior drug
  - Corrected overestimation of benefit in prevention setting
    - ◆ Patients demonstrated accurate perception of drug benefits and side effects
- **Focused reader’s attention and minimized cognitive burden**

### *III. Study Findings Are Consistent With Theory*

- **Adult learning principles define elements of effective learning:**
  - **Curriculum** – a clear plan for presenting required information
  - **Enablers** – tools that enable the learner to use the knowledge in their personal situations
  - **Application** – learners are shown how to use the knowledge
  - **Interactivity** – information is presented in a variety of ways that address diverse learning styles



# *Summary of Insights for Risk Communications*

- **Patients qualitatively prefer:**
  - Knowledge of benefit as a context for understanding risk
  - Formatting and callout boxes to aid comprehension
- **Drug Fact Box describing benefits and risks improved patient knowledge and choices**
- **Enabling tools such as checklists help to apply knowledge to behavior change**
  - Provides an opportunity for improvement if REMS assessments determine Med Guides are insufficient to achieve goals



# References and Acknowledgements

## References

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