Background

- Risk Evaluation and Mitigation Strategy (REMS) is a risk management communication plan that applies risk minimization strategies beyond basic professional labeling. It is designed to achieve specific goals to mitigate risks associated with the drug, ensuring that the benefits of the drug outweigh the risks.

- A REMS may include a medication guide, patient package insert, elements to assure safe use, implementation system, and/or communication plan (which only applies to New Drug Applications (NDA) and Biologic License Applications (BLA) only).

- Drug sponsors design and develop REMS programs and then the FDA reviews and approves them. REMS programs can be designed for a single drug or a class of drugs. Each REMS has specific safety measures unique to the safety risks associated with a particular drug or class of drugs.

- In 2011, FDA created the REMS Integration Initiative in order to determine how to design REMS that can be better integrated into the existing and evolving healthcare system and improve future REMS assessments.

- Due to the variations in requirements and possible restrictions, REMS can add burden to the healthcare delivery system and may unintentionally create barriers to patient access to potentially life-saving medications.

- Measuring outcomes to assess risk mitigation may be difficult and complicated REMS could potentially create barriers to access for select patients.

Objective

- To identify and assess key factors impacting pharmaceutical industry development and healthcare provider (HCP) communication of REMS materials.

- To identify barriers to patient comprehension and determine the impact from pharmaceutical industry and HCPs.

Methods

- Following a review of the available literature, we propose several phases of assessment to evaluate the development and implementation of REMS programs.

Phase 1

Industry

Determine typical practices within the pharmaceutical industry for development of REMS

Phase 2

HCP

Assess HCP behaviors and communication styles while interacting with REMS patients

Phase 3

Patients

Qualitatively evaluate patient comprehension of REMS materials

Methods (continued)

- Phase 1, 2, and 3 of this project will evaluate various time-points of the healthcare continuum (industry, HCPs and patients) to assess their impact on the effectiveness of REMS programs.

- These phases will be conducted in one specific disease state.

- Statistics: Descriptive statistics will be utilized to describe data

Discussion

- REMS is an important tool that provides patients with safe access to medications that would not otherwise receive FDA approval.

- A recent publication evaluated patient understanding of medication guides and demonstrated the need to improve patient-directed materials and the methods of assessing them.

- Understanding the process by which REMS materials are developed, communicated, and ultimately interpreted by the patient is crucial for identifying possible gaps within the REMS program.

- This study should be conducted in a population of a single disease state to maintain internal validity.

- Conducting this research will help to identify these barriers to patient comprehension and better outcomes associated with risk mitigation.

- Increased patient understanding has the potential to lead to earlier detection and management of AEs which may be associated with improved patient outcomes.

References


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Disclosure

The authors have nothing to disclose.