Editorial

Leveraging Technology in Risk Evaluation and Mitigation Strategy Programs

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Abstract

Description

Medication safety is improved through REMS programs. Multidisciplinary teams and front-line staff are vital in setting up a REMS program and should be included in any discussions surrounding REMS programs. Certain components of the REMS requirements may be replaced with CDS screens. Utilizing technology can help advance patient safety and aid in regulatory compliance.

Keywords

medication safety; drug safety; risk mitigation; pharmacy technology; REMS; FDA

There are numerous regulatory agencies and professional organizations that have established guidelines to improve medication safety. One such regulation is the Risk Evaluation and Mitigation Strategy (REMS) Program that was established by the Food and Drug Administration (FDA) Amendments Act in 2007. With the provision, the FDA gained the authority to require REMS for medications or biological products in order to ensure the benefits outweigh the potential risks.[1] REMS programs provide a more comprehensive and enforceable approach than previously used Risk Minimization Action Plans (RiskMAPS). Through REMS programs the FDA can require the manufacturer to develop medication guides and Elements To Assure Safe Use (ETASU), such as mandatory certification of pharmacists to dispense or practitioners to prescribe certain medications. Furthermore, the manufacturer is also expected to submit regular assessments of the REMS to the FDA for evaluation. Consequences for not meeting REMS requirements could include the FDA imposing warnings, fines, and even the seizure of products.[1]

REMS programs are designed to prioritize patient safety by ensuring standard practices for medications with additional safety risks. They can be required by the FDA either during the approval process for the drug or after approval, if surveillance identifies any safety concerns.[2] Multiple studies have shown the benefits REMS programs have provided. A study by Quffa et al showed improved compliance with monitoring parameters based on the REMS for dofetilide.[3] In another study by Brandenburg et al the effectiveness of education to the patient for both thalidomide and lenalidomide was evaluated and showed the mandated REMS program was an effective tool.[4] The study found that patient understanding was increased due to the REMS requirements, and patient safety was ultimately enhanced through birth control compliance.[4] While there are studies that have shown benefits, other studies have shown a need for improvement with some REMS programs. In a study by Chan et al, 77 REMS programs were reviewed for actionability, understandability, and readability.[5] Thirty percent of the programs utilized educational documents to communicate risks

to patients, resulting in 27 documents for analysis.[5] The analysis showed that the reading level was at a 9th-grade level or higher, with 49% being actionable and 89% meeting the understandability criteria.[5] This study showed that there is an opportunity for improving patient educational material.

Operational challenges can arise due to numerous documentation and/or monitoring requirements for each REMS program. REMS programs are challenging for healthcare team members as there is a lack of standardization and the programs continue to grow with additional required components.[6] By leveraging technology, procedures and processes can be developed in order to facilitate REMS program compliance. For instance, mandatory fields within the electronic health record can ensure documentation in accordance with the REMS program. Many organizations have implemented clinical decision support (CDS) systems that are customized to enhance medication safety.[2] CDS screens should be individualized for each drug as REMS programs are specific to the medication. Requiring a forcing function will help ensure all the elements of the program are being followed. The forcing function is an aspect of design within the CDS system that will prevent the healthcare team member from ordering the medication without consciously considering all the information.[7]

An example of a CDS screen for alvimopan is provided in **Table 1.** For each CDS screen, the individual attesting provider (eg, the pharmacist) may vary based upon the REMS requirements. For instance, in this CDS screen, the inquiry related to education is intended to remind the pharmacist to validate that the provider and the nurse have been educated prior to verifying the medication order. The actual tracking system for proper education may be documented via an online learning portal or another mechanism. Other technology can also be utilized in collaboration with a CDS screen. For example, with alvimopan the electronic medication administration record can include comments and defaults to a maximum of 15 doses as it is indicated for only short-term use while the patient is hospitalized. A CDS screen can further assist in validating the quantity if a second order is inadvertently placed. Other inquiries in the CDS screen are built to provide key information and reflection on the requirements. As this is only 1 example and other drugs have distinct REMS requirements, the CDS screen can be tailored to what is necessary. For instance, if there is a drug that requires a REMS patient enrollment number or an authorization number, the CDS could require a response to capture that data.

When setting up technology such as a CDS tool, a multidisciplinary team can assist to ensure all elements are present and incorporated into the tool. This proactive step will hopefully aid in decreasing manipulations and multiple revisions to the program. This step is especially important as the REMS algorithms can be time-consuming, complex, and impact the facility financially.[2] Maintaining the CDS tool is also vital in order to optimize the safety and care of patients.[2]

The FDA requires REMS programs on various drugs when there are additional safety con-

Table 1. Example of Mandatory Fields for Specified REMS Medication

REMS Program Inquiry	Response
Education has been provided for the healthcare team members responsible for dispensing, ordering and administering alvimopan. (Confirm)	
No more than 15 doses have or will be dispensed for the patient while inpatient. (Confirm)	
No medication will be dispensed for outpatient use. (Confirm)	
No medication will be transferred to another hospital that is not enrolled in the E.A.S.E. Entereg REMS Program. (Confirm)	

cerns, which assists in ensuring the benefits outweigh the risks to patients. Individual entities have a certain level of freedom in deciding how the required elements are implemented and compliance is monitored. Leveraging technology can assist in advancing patient safety and aid in regulatory compliance.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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