Title

Challenges in REMS compliance.

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Challenges in REMS compliance

The risk evaluation and mitigation strategies (REMS) program is a medication safety program implemented by the US Food and Drug Administration (FDA). While FDA allows manufacturers to market high-risk medications, it was given the authority to implement REMS for these medications in 2007.[1] The REMS program strives to improve patient safety by increasing the likelihood that benefits outweigh risks in patient populations. REMS may require manufacturers to communicate risks in multiple ways, which include supplying a medication guide.[2] REMS provide specific information and dictates activities to patients, providers, and pharmacists receiving the medication. These activities are medication specific and individualized to address safety concerns. While the roles of REMS participants can have similarities across medications, responsibilities for each medication can differ. Examples of responsibilities, or "elements to assure safe use (ETASU)," include requiring the prescriber and pharmacist to be REMS certified, documenting a safe condition via laboratory test(s), and having patients use 2 methods of birth control while on the medication.[1,3]

REMS can be required for a specific medication or medication class, such as opioid analgesics used in an outpatient setting.[4,5] Developing a standardized method to meet all REMS requirements for every medication is challenging for many hospitals due to the increase in the number of REMS. As of 2020, there were 59 medications or medication groups that required REMS,[6] and at our institution, 30 of them are listed on the formulary. Our electronic health record system is configured to alert providers and pharmacists about REMS requirements when they order or dispense medication. Internally created REMS information sheets, which summarize REMS requirements specific to each formulary REMS agent, are accessible to all staff electronically. Because each medication has unique requirements, these sheets are different for each REMS medication.

To identify process gaps, we conduct internal audits and host external audits of REMS medications each year. Between 2017 and 2020, we completed 12 internal audits and 5 external audits. Audit findings consist of missed regularly scheduled training, missing documentation of training, and difficulty in confirming patient enrollment outside of regular hours. This lack of training and inability to gather information when necessary are risks to patient care because they present challenges to safely dispensing a patient's medication.

After our internal evaluation, we aimed to understand how REMS worked at other hospitals. We posted a Qualtrics survey (Qualtrics, Provo, UT) in the Vizient community to gather information. Fourteen hospitals (eg, academic medical centers, specialty hospitals, and nonprofit hospitals) across the nation responded over 3 weeks. Our survey findings showed that there are common barriers to REMS compliance (Table 1). Among those surveyed, 86% of hospitals reported that they do not have processes defined for all the required REMS medications.

External auditing can help many hospitals continually try to improve their processes. External audits are conducted by third-party auditing companies hired by the manufacturers of REMS medications to ensure that requirements are being followed. Interestingly, 43% of the survey respondents were not externally audited for any of their REMS medications in the past year. Fifty percent of respondents were audited only for 1 or 2 REMS medications in the past year.

Creating a standardized process for the medications could be a challenge, as no 2 medications have the same requirements. However, both a standardized REMS training toolkit and a set of documentation guidelines would help mitigate medication safety risks. These materials could be incorporated into orientation training for people involved and tracked electronically. Overall, we continue to find it challenging to keep track of all the REMS medications and their restrictions, but we hope to resolve some of these issues as we open the dialogue with other institutions.

REMS is a program that ensures proper prescribing and use of medications; however, its processes are becoming more complicated, making it hard to uphold program

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Table 1. REMS Compliance Challenges Identified by Survey Respondents (n = 14)

Barrier to REMS Compliance	No. (%) of Hospitals Identifying Barrier
Lack of standardization of the REMS program	10/14 (71)
Complexity of the REMS program	10/14 (71)
Lack of defined processes for successful implementation of REMS	8/14 (57)
Lack of a defined process for consistent evaluation and improvement of REMS compliance (ie, internal audits)	8/14 (57)
Lack of a responsible person for REMS oversight	5/14 (36)
Lack of pharmacy oversight in the continuum of care: purchasing, storage and handling, prescribing, verifying, administering, monitoring	4/14 (29)

Abbreviation: REMS, risk evaluation and mitigation strategy.

requirements. While the aforementioned survey was not a random sample and inherently contains a voluntary response bias, it does demonstrate that the number of medications or medication groups with a REMS label has increased in the years since the inception of the REMS program in 2007. Additionally, it is reasonable to theorize that hospitals seem to agree on the aspects of REMS that are difficult to implement. Hospital collaboratives, state societies, or national societies should consider establishing operational standards for REMS medications and developing shared toolkits for training. They might also consider establishing the position and duties of a REMS coordinator who oversees pharmacy processes relating to REMS medications and tracks documentation mandated by FDA. The REMS program continues to grow as more medications are identified as high risk, creating a sense of urgency for each institution to have a better command of the REMS medications and operational challenges.

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