

Abstract

The Food and Drug Administration introduced the Risk Evaluation and Mitigation Strategies (REMS) in response to the opioid crisis, aiming to educate and mitigate associated risks with opioid use. Pharmacists, often one of the last healthcare providers patients interact with before medication use, play a crucial role in the opioid space. However, limited research explores their views on REMS and its effectiveness.

Our cross-sectional study gathered input from community pharmacists to assess REMS understanding, barriers, and perceived effects on patient outcomes. We hypothesized that medication distribution would pose the biggest barrier, and that perceptions of burden would differ between common and less common opioids.

Analysis of surveys completed by 35 community pharmacists revealed healthcare professional (HCP) training as the primary perceived burden of REMS requirements. The secondary perceived burden of REMS was patient education. In addition, contrary to our hypothesis, both common and less common opioids shared similar rankings in perceived burdens.

Purpose

The purpose is to examine the perceptions of community pharmacists (LA City Area) regarding the effectiveness of REMS in mitigating opioid-related risks. Additionally, the study aims to explore how pharmacists' experience with REMS can indirectly influence patient safety, education, and accessibility to their opioid medications.

Background

- The FDA responded to the opioid epidemic in 2012 by implementing a Risk Evaluation and Mitigation Strategies (REMS) program for opioid prescribing which aimed to reduce the risks associated with opioid use^{1,2}.
- REMS program includes elements such as the distribution of educational materials, training requirements on proper opioid prescribing practices, and systems for monitoring and reporting adverse events related to opioid use. Additionally, it includes the development of tools and resources for healthcare providers to assess and manage patients' risk of opioid misuse or addiction, simultaneously promoting alternative pain management strategies when appropriate³.
- Although the REMS program was initiated, opioid-related harm continues to be a major public health concern and the effectiveness of the program is debated. While the program has increased awareness and knowledge among healthcare providers, it has not significantly reduced opioid prescribing or overdose rates. The goal is a balance between ensuring access to necessary pain management while minimizing the risks associated with opioid medications.
- Pharmacists are essential in ensuring the safe use of opioids and are often the last healthcare provider to interact with a patient before they receive their medications. However, there is limited research on pharmacists' perception of the REMS program and their role in implementing its requirements.
- A study needs to be done to investigate pharmacists' perspectives on the REMS program to evaluate its strengths, limitations, and opportunities for improvement.

Methods

Study Design

- Cross-sectional, survey study

Study Population

- Licensed Community Pharmacists practicing in Los Angeles City

Data Collection

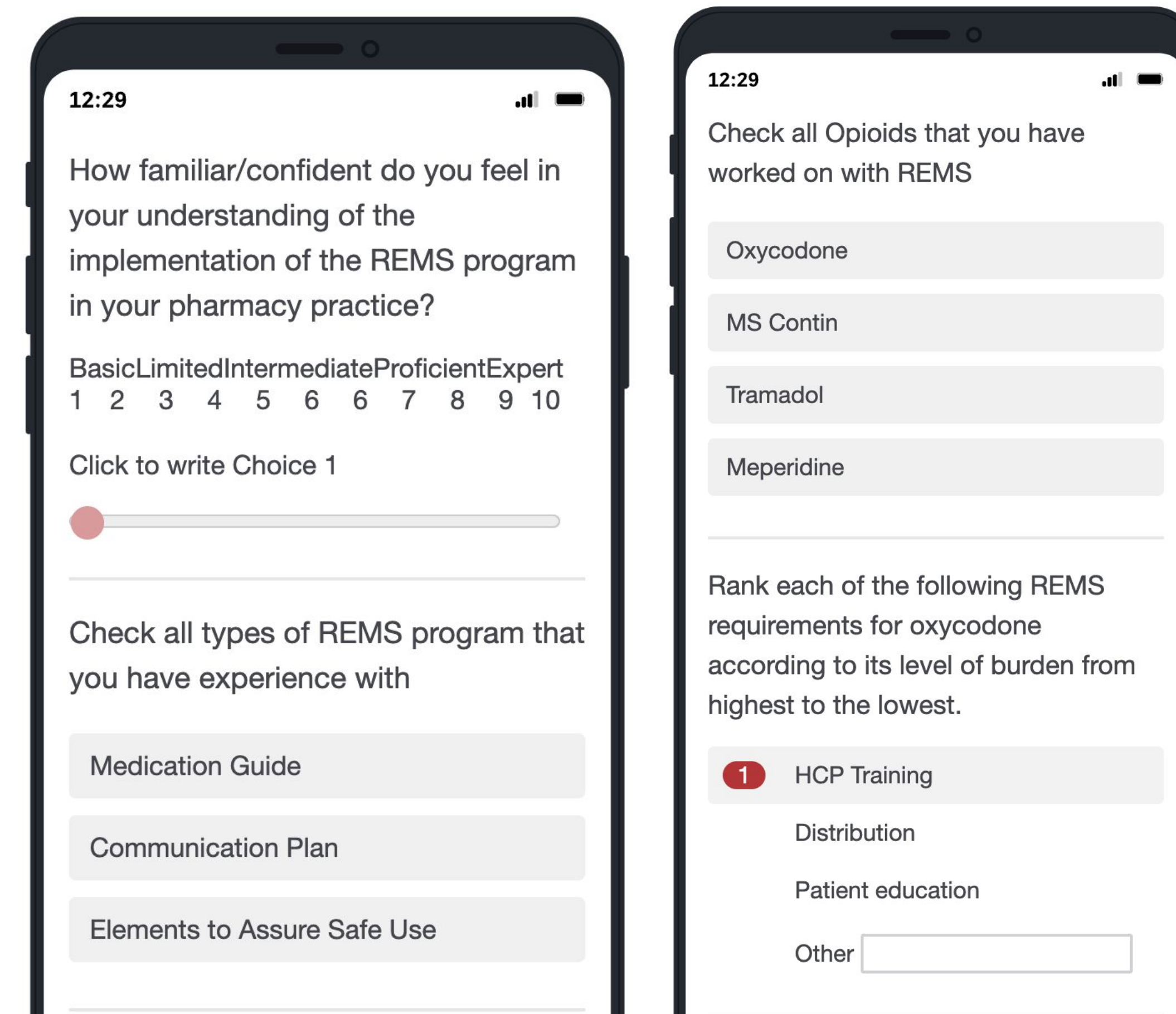
- Community Pharmacists were given a Qualtrics survey, either through QR code or link, with questions starting with consent and screening. They will move on to answer the questions about REMS for opioid use.
- Descriptive statistics was used to analyze the data.
- To protect participant privacy, surveys are fully anonymous.

Inclusion

- Professional Qualification (NPI#, PharmD.) practicing in Los Angeles City
- Experience with opioids
- Knowledge of REMS
- Availability and willingness to participate
- Informed consent

Exclusion

- Non-pharmacists
- Geographical constraints



Results

Do you believe that your company provides an adequate built-in program to submit REMS?

How do you feel about this statement? The risks, benefits, and effectiveness of the REMS program is discussed frequently within your pharmacy environment.

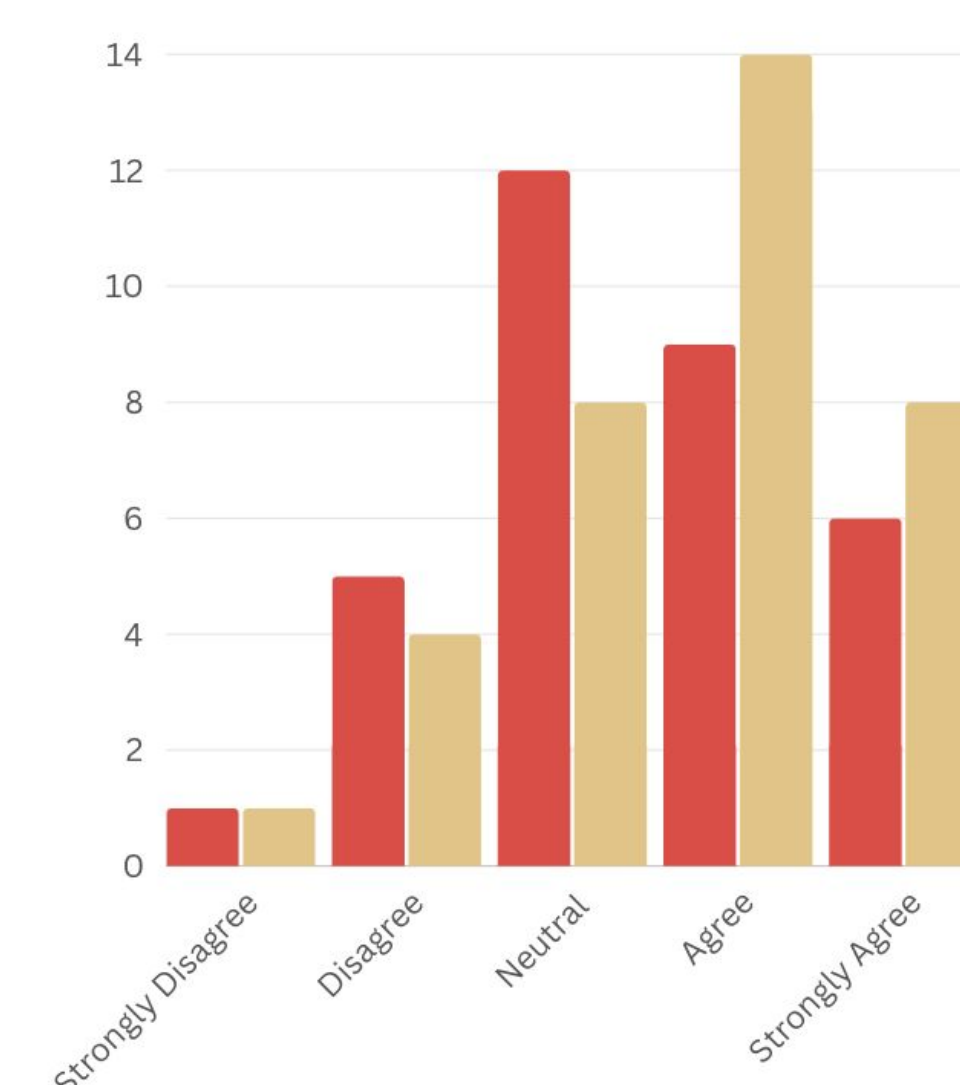


Figure 1: Survey Responses on Company Readiness for REMS Program Submission and Discussion Frequency in Pharmacy Settings

There are sufficient resources available for you to appropriately implement REMS

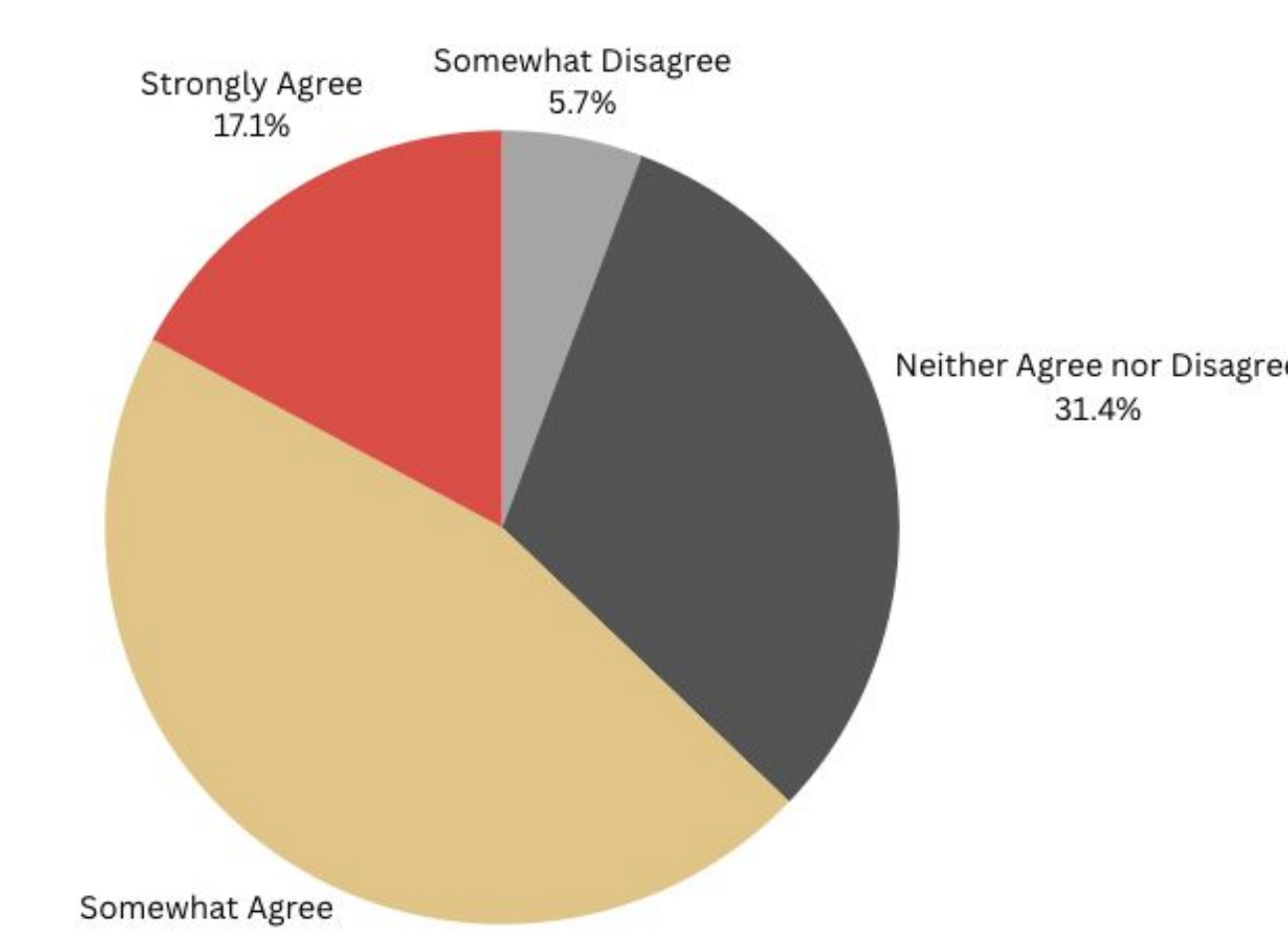


Figure 2: Perspectives on the Availability of Resources for REMS Implementation

Average Perceived Burden of REMS requirements

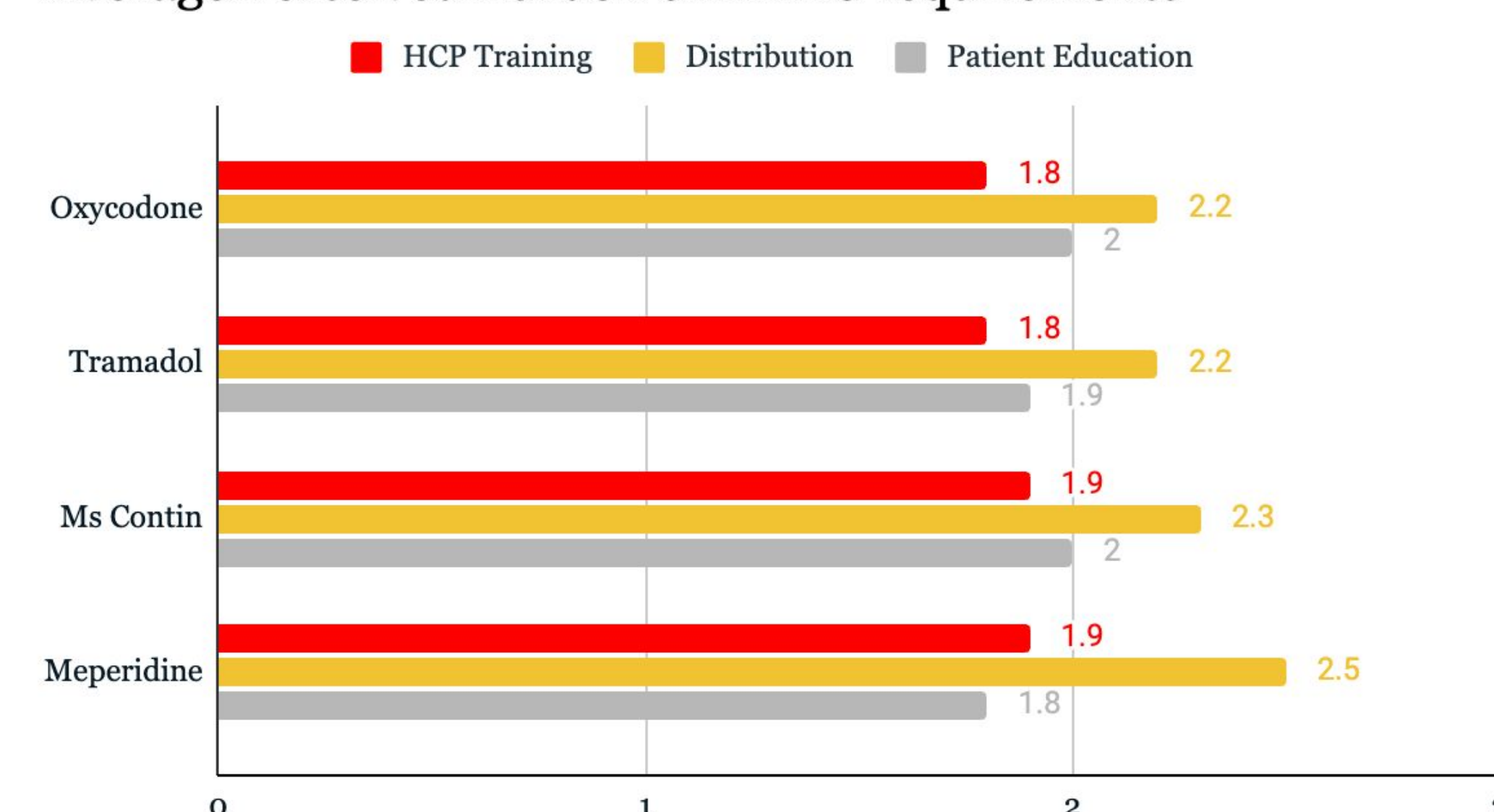


Figure 3: Averaged Perceived Burden of REMS Requirements

Time consuming which can lead to the possibility of decreasing patient care

Patients' understanding and education with the process. It can feel like busy work for the patient in order to receive meds, having them understand why the process is in place is the biggest hurdle.

Pharmacist training and consistent implementation across REMS programs is a significant challenge

Limited communication between healthcare providers makes it difficult to efficiently implement REMS

Figure 4: Open Feedback from Pharmacists

Discussion

- 34% held a neutral stance on whether their company provides an adequate built-in program to submit REMS
- 40% reported frequent discussions of the REMS program within their pharmacy environment
- 46% of pharmacists somewhat agreed that there were sufficient resources for them to implement REMS
- Primary burdens of REMS requirements were identified as healthcare professional (HCP) training and patient education
- Pharmacists' feedback noted challenges with REMS, perceiving it as time-consuming and potentially diverting attention from patient care. Patients' comprehension and education regarding REMS were seen as burdensome. Issues with pharmacist training, consistent implementation, and communication gaps among healthcare providers were mentioned.

Conclusion

Despite the FDA's proactive stance with the REMS program in addressing opioid-related risks, our study highlights persistent challenges within the community pharmacy setting regarding perceived burdens. This emphasizes the need for further research to enhance REMS implementation in community pharmacies.

Study Limitations

Recruitment of Participants: The process of identifying and recruiting community pharmacists for participation posed a significant challenge, primarily due to their busy schedules, making it difficult for them to allocate time for completing the survey.

Response Rate: Attaining a high response rate was crucial for securing a representative sample, and low response rates could have resulted in selection bias, potentially compromising the validity of our findings

External Validity: Surveys are anonymous, limiting our ability to verify if the individual completing meet the inclusion criteria

Future Research

Leveraging the research to provide suitable recommendations in the outpatient pharmacy environment, aiming to enhance pharmacists' comprehension and application of REMS for opioid use, and thereby maximizing patient health outcomes. More studies need to be done to investigate pharmacists' perspectives on the REMS program so that stakeholders can work together to develop strategies for enhancing the program to better address the opioid epidemic and promote safe medication use.

Acknowledgements

We would like to thank Dr. Eunjoo Pacifici and Dr. Terry Church for their guidance in developing and carrying out our research.

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