

# Participant Responses to a Web-Based, “Ready for REMS™” Educational Initiative

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## INTRODUCTION

- Risk Evaluation and Mitigation Strategies (REMS) are U.S. Food and Drug Administration (FDA)–mandated programs aimed at minimizing the risks associated with certain medications, including some opioids.<sup>1</sup>
- Because REMS are new to healthcare providers and patients, there has been general uncertainty about their purpose and impact on clinical practice.
- The results of a previous Web-based survey showed that healthcare providers are willing to be educated about REMS in order to maintain their ability to prescribe opioids.<sup>2</sup>
- Cephalon, Inc., in collaboration with leading pain experts, developed the “Ready for REMS” educational initiative to raise awareness of and prepare healthcare providers for FDA-mandated REMS for opioids.

## OBJECTIVE

- The objective of this report was to study healthcare providers’ understanding of and preparedness for REMS for opioids and their perception of the potential impact of REMS on their clinical practice.

## METHODS

- A 2-part educational series was developed for the “Ready for REMS” initiative.
  - **Part 1: The Necessity for REMS** presented information about the background of REMS for opioids.
  - **Part 2: Getting Ready for REMS** presented information about preparing for REMS.
- The series was hosted on the QuantiaMD® Web site. QuantiaMD is a Web-based provider of educational content for healthcare providers.
- Healthcare professionals who were members of the QuantiaMD community accessed the “Ready for REMS” educational series via a link on the QuantiaMD Web site.
- Before and after viewing the educational material, participants answered questions related to their understanding of and preparedness for REMS for opioids.

## RESULTS

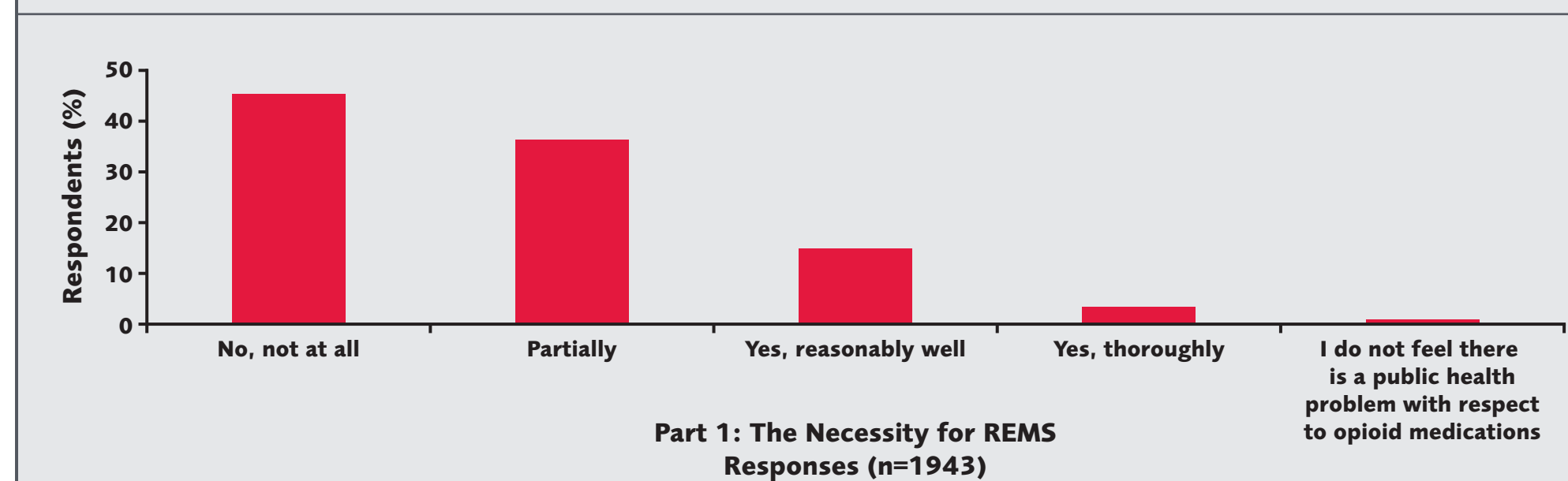
- As of July 14, 2010, the “Ready for REMS” educational initiative on the QuantiaMD Web site had 4634 page views:
  - 2371 for “The Necessity for REMS” program.
  - 2263 for the “Getting Ready for REMS” program.
- The specialties of the healthcare providers who viewed at least 1 program are presented in **Table 1**.

**Table 1. Specialties of Healthcare Providers Viewing the “Ready for REMS” Program**

Specialty	Healthcare Providers (%)
Family medicine	38
Primary care or internal medicine	33
Pain	8
Psychiatry	5
Oncology	2
Other	14

- Preprogram responses generally showed poor awareness and understanding of the need for REMS for opioids (**Figure 1**).

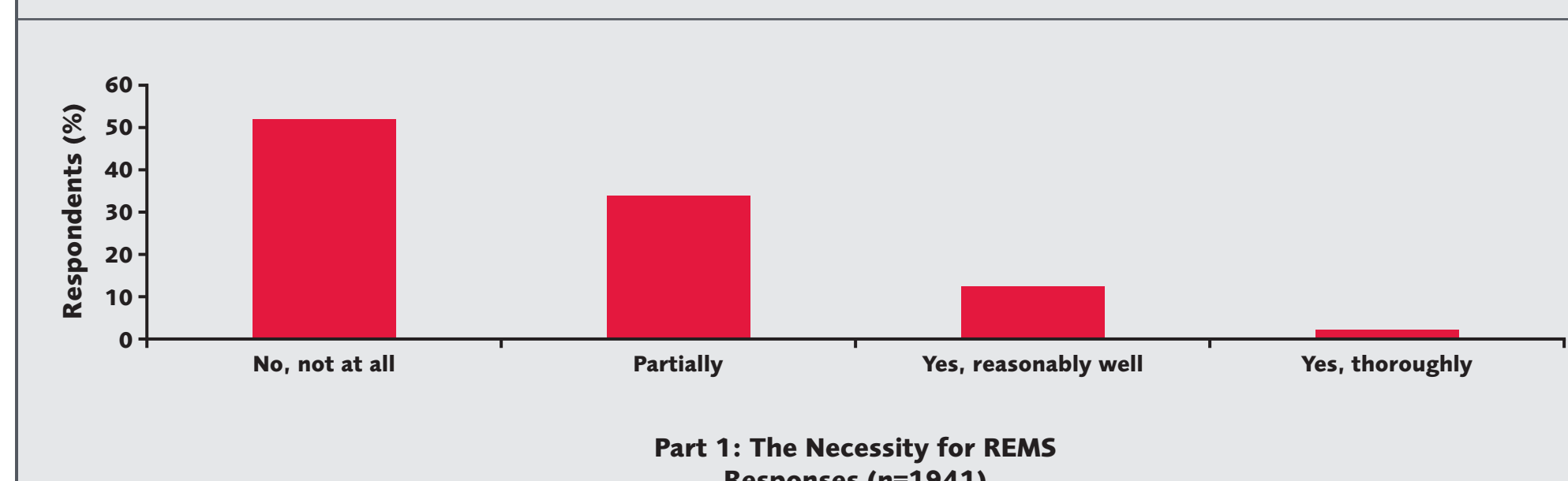
**Figure 1. Preprogram Question: Are you aware of the public health reasons behind the FDA’s decision to require REMS for some opioid medications?**



FDA=Food and Drug Administration; REMS=Risk Evaluation and Mitigation Strategies.

- Participants also felt unprepared for REMS (**Figure 2**).

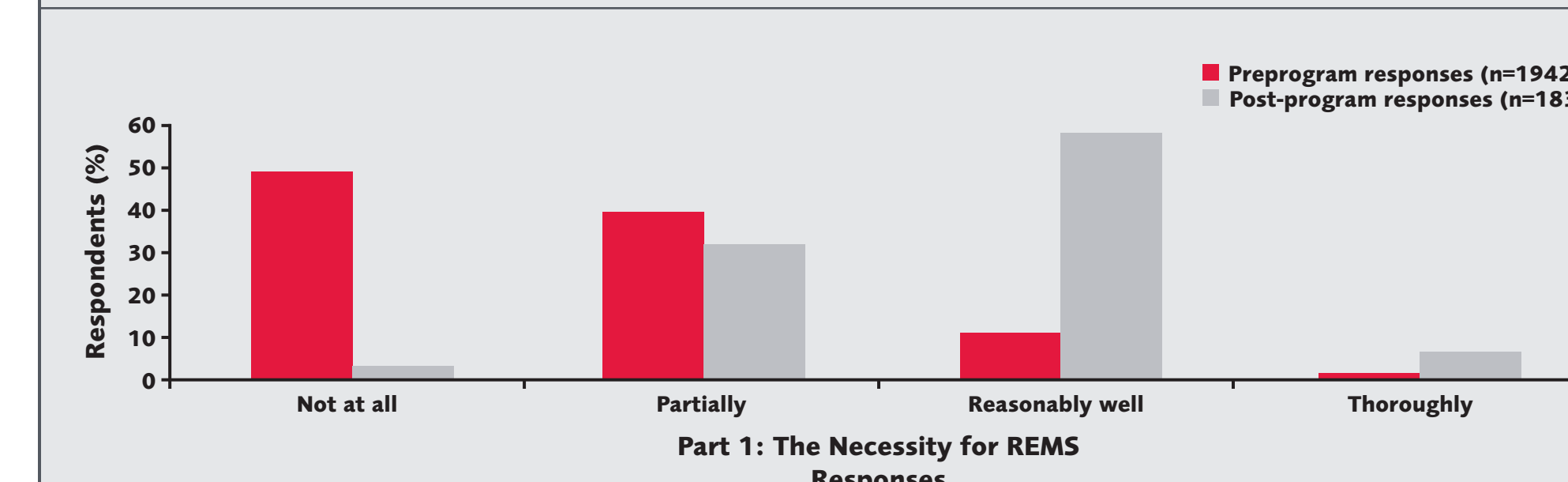
**Figure 2. Preprogram Question: Do you feel prepared for the introduction of REMS?**



REMS=Risk Evaluation and Mitigation Strategies.

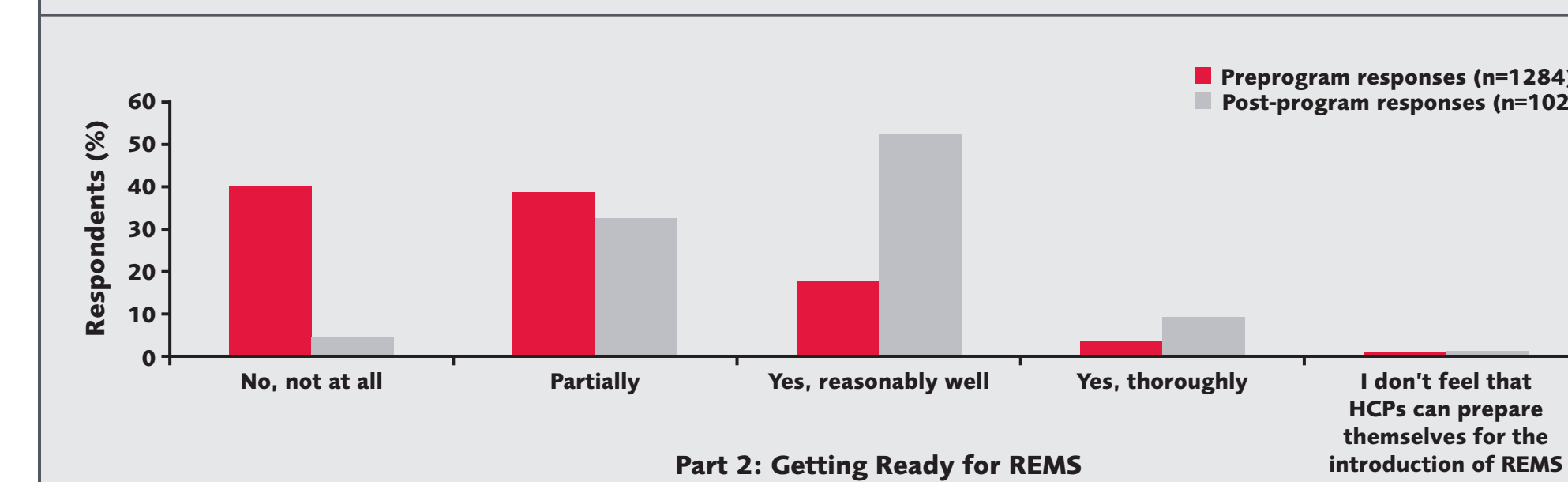
- Post-program responses showed a substantial shift toward a better understanding of REMS’ goals (**Figure 3**) and how to prepare for REMS (**Figure 4**).

**Figure 3. Preprogram and Post-program Question: How well do you feel you understand the goals of REMS for opioid medications?**



REMS=Risk Evaluation and Mitigation Strategies.

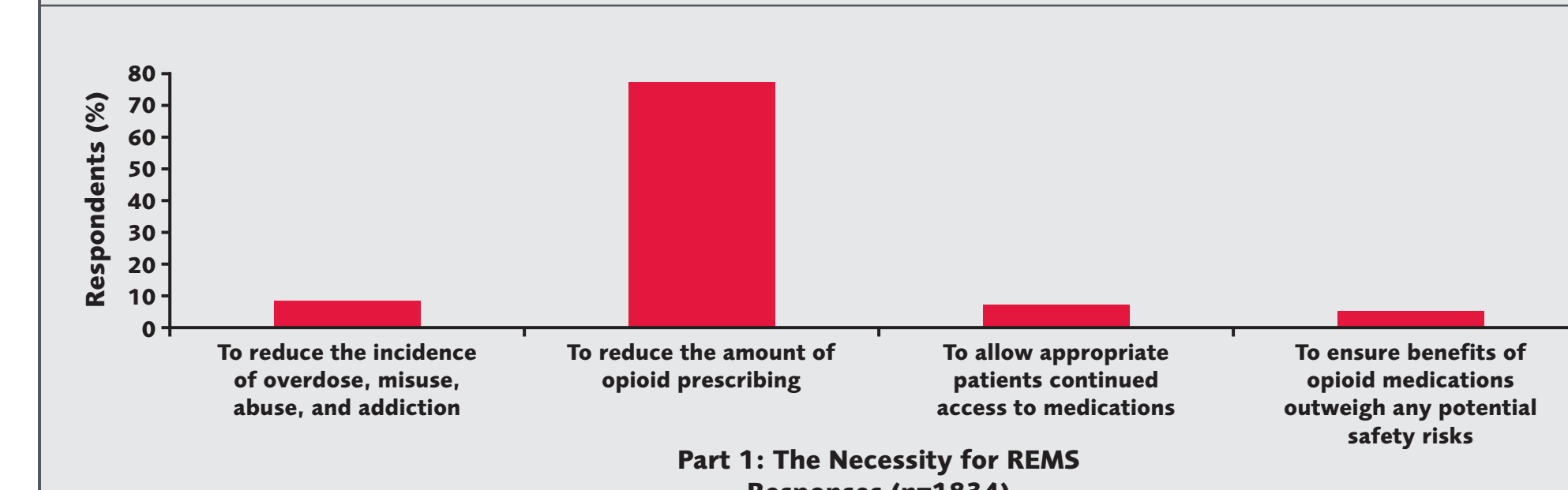
**Figure 4. Preprogram and Post-program Question: Do you understand how healthcare providers can prepare themselves for the introduction of REMS?**



HCPs=healthcare providers; REMS=Risk Evaluation and Mitigation Strategies.

- Importantly, after viewing the program, the majority of respondents (77.3%) recognized that reducing the amount of opioid prescribing is **not** one of the goals of REMS for opioids (**Figure 5**).

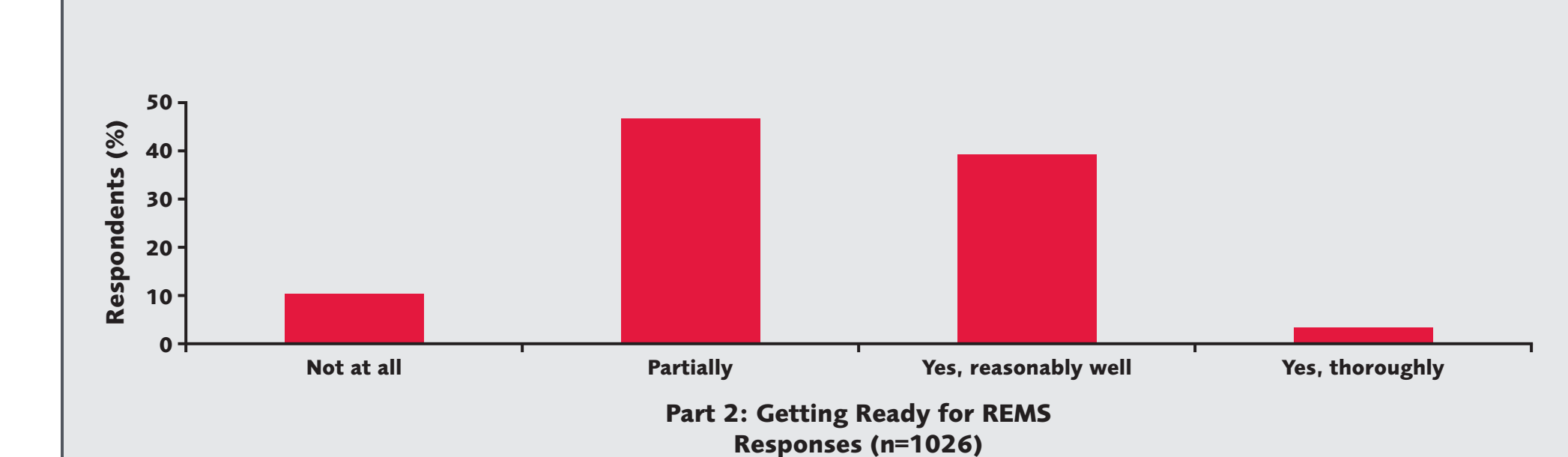
**Figure 5. Post-program Question: Which of the statements below is **not** one of the goals of opioid REMS?**



REMS=Risk Evaluation and Mitigation Strategies.

- Compared with the percentage before the program (**Figure 2**), a greater percentage of healthcare providers reported that they felt reasonably well or thoroughly prepared for the introduction of REMS after viewing the program (**Figure 6**).

**Figure 6. Post-program Question: Do you feel prepared for the introduction of REMS?**



REMS=Risk Evaluation and Mitigation Strategies.

- Some respondents participated in a post-program survey, which gave them the opportunity to provide comments in text boxes. Common themes in these responses were requests for more detailed information about:
  - How to implement REMS within the respondents’ practice.
  - Which drugs will have REMS.
  - Specific examples of the implementation of REMS.

## CONCLUSIONS

- Currently, healthcare providers appear to have a limited understanding and awareness of REMS for opioids.
- To prepare for the procedures that REMS will require, healthcare providers may benefit from education about the background and practical impact of REMS on their clinical practice.
- Based on responses before and after the program, the “Ready for REMS” educational initiative had a positive effect on healthcare providers’ understanding of REMS.
- Providing healthcare providers with education in advance may encourage them to participate in REMS and be better prepared to integrate REMS into their clinical practice.

## REFERENCES

1. Food and Drug Administration. *Guidance for Industry, Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications: Draft Guidance*. Rockville, MD: US Dept of Health and Human Services, Food and Drug Administration; 2009.
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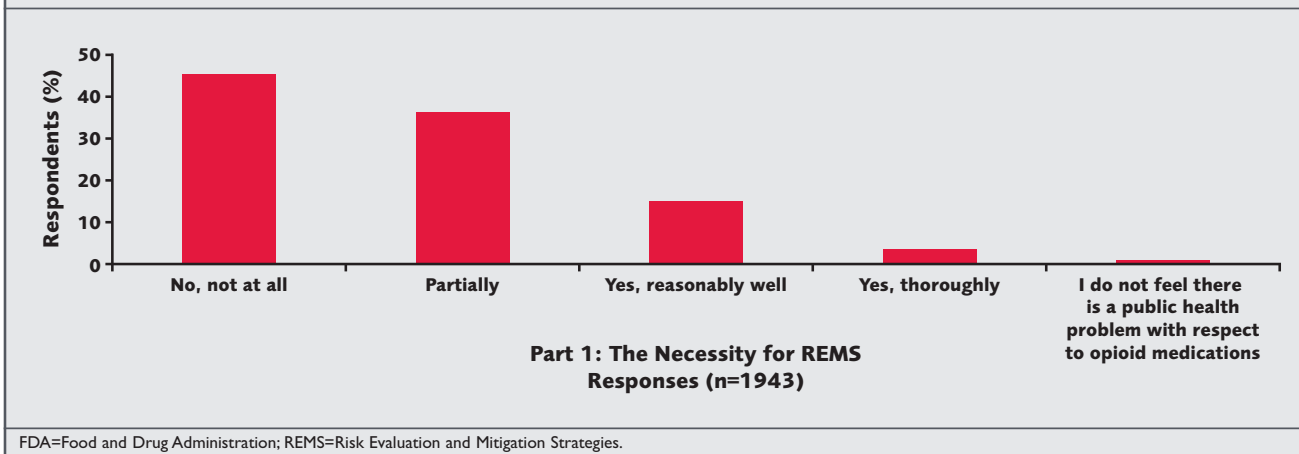
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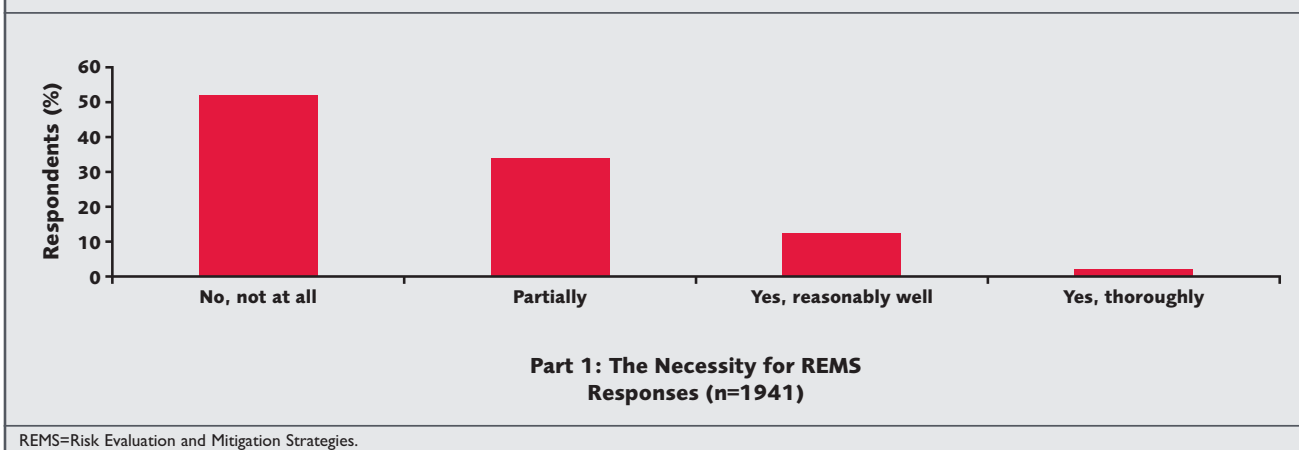
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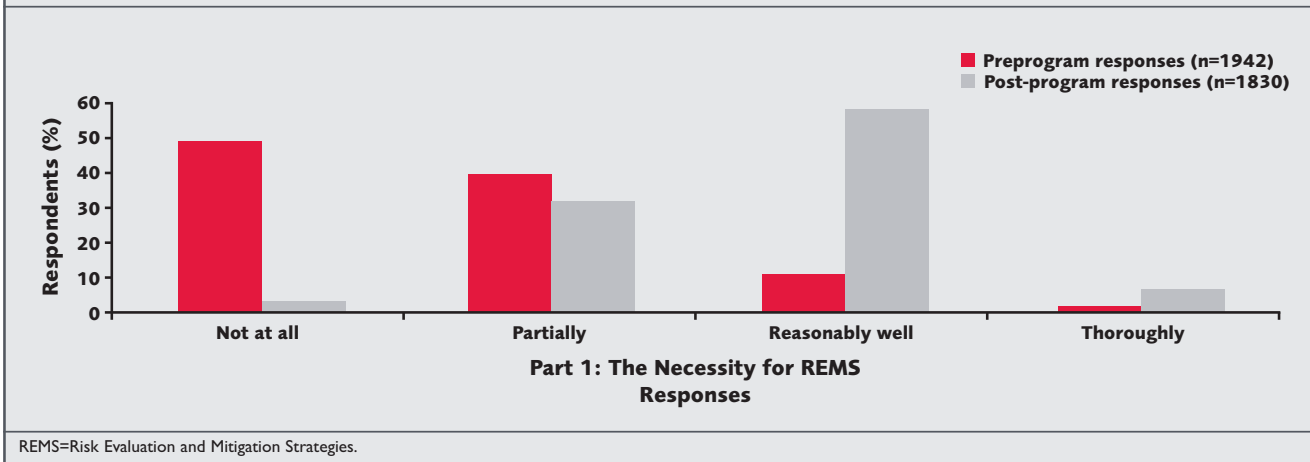
- Participants also felt unprepared for REMS (**Figure 2**).

**Figure 2. Preprogram Question: Do you feel prepared for the introduction of REMS?**

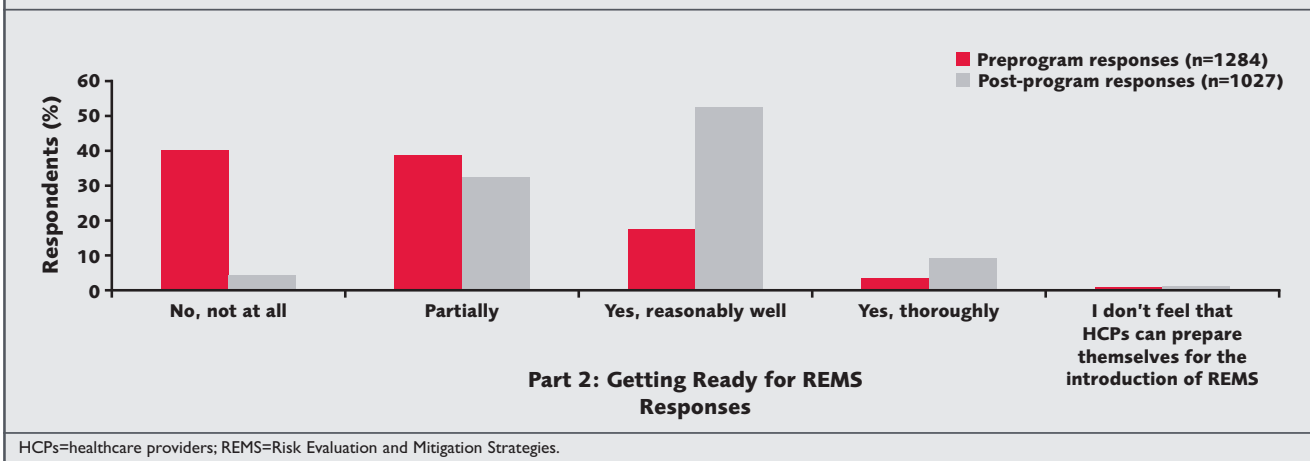


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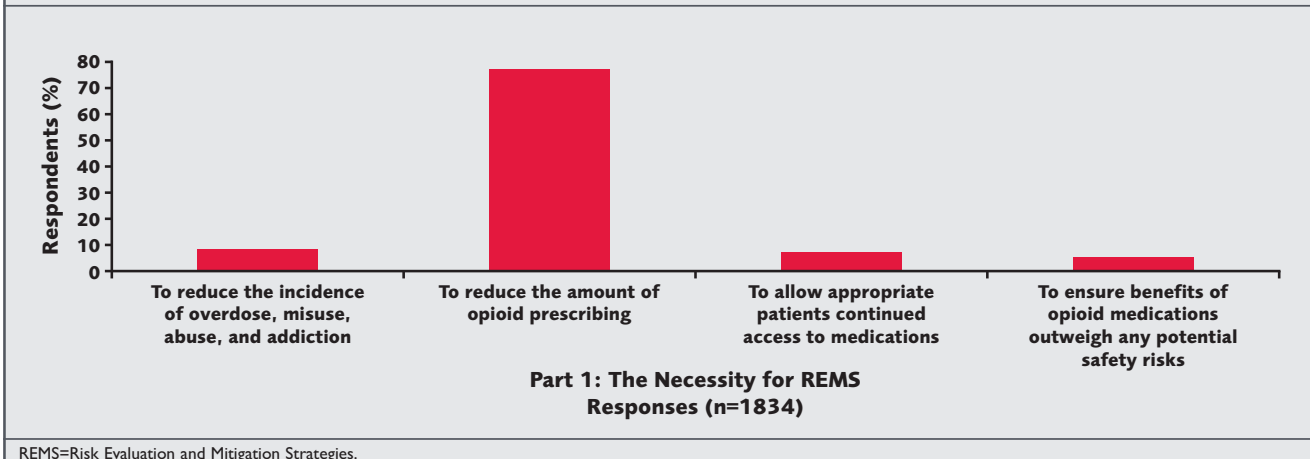


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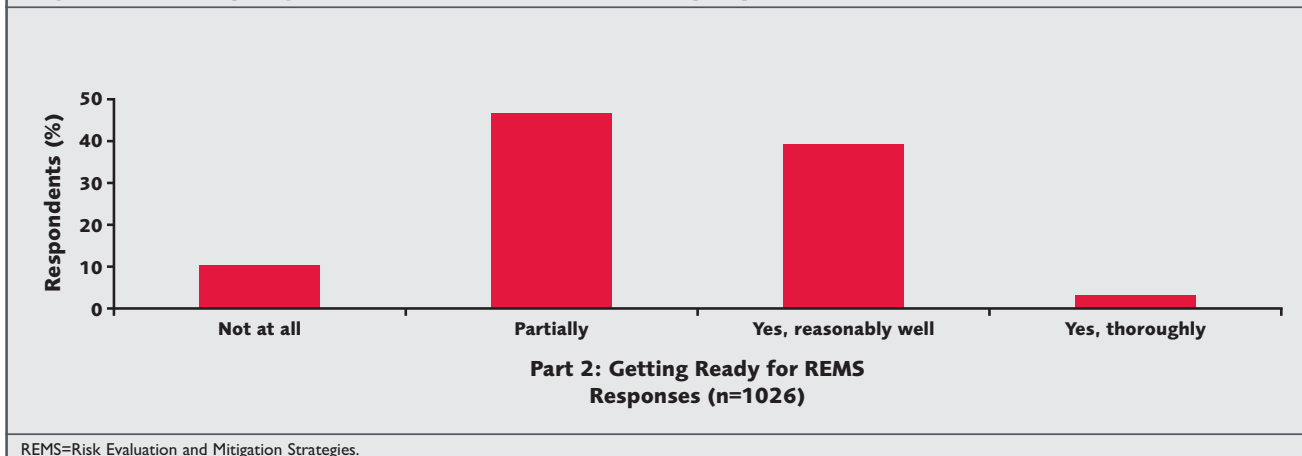
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