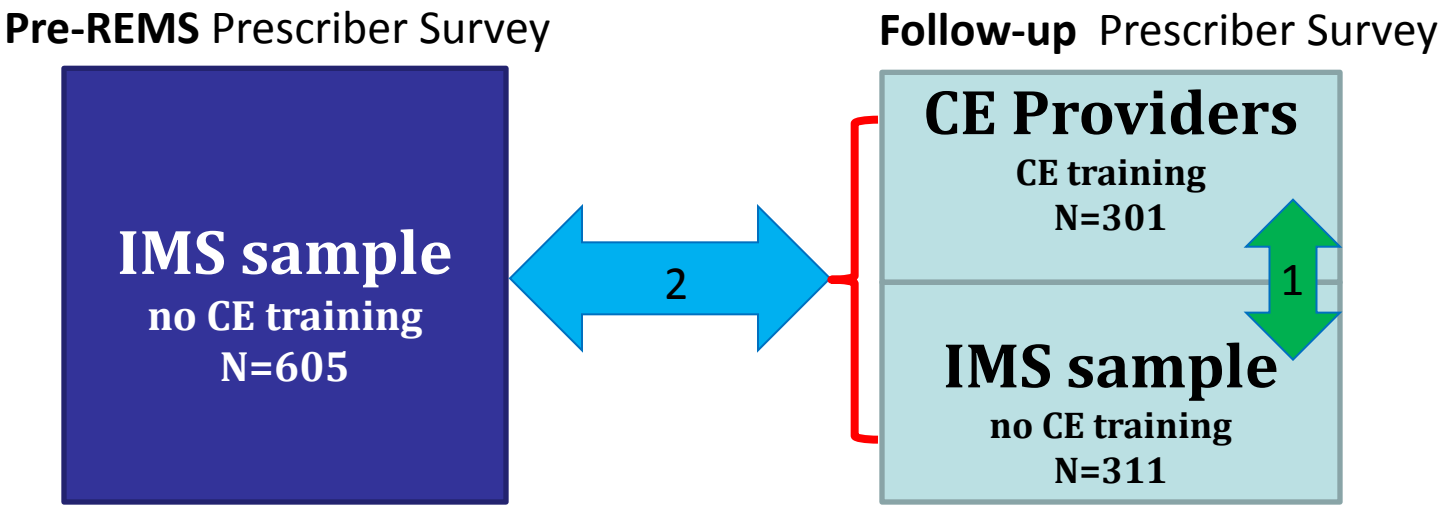
Comparability

Are populations similar?

Comparability



RPC compared Prescriber knowledge rates:

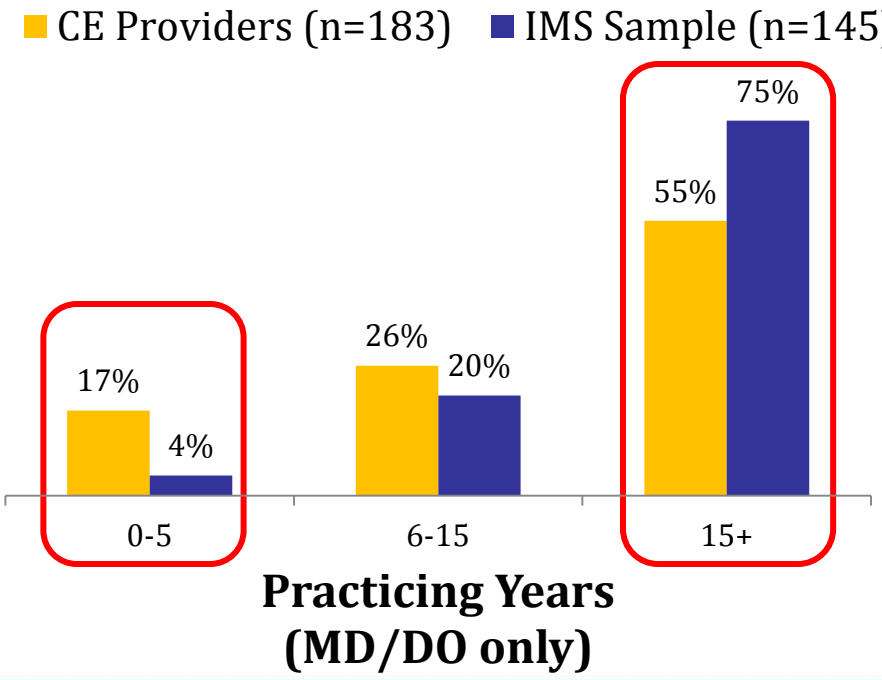
(1) CE Providers vs. IMS Sample

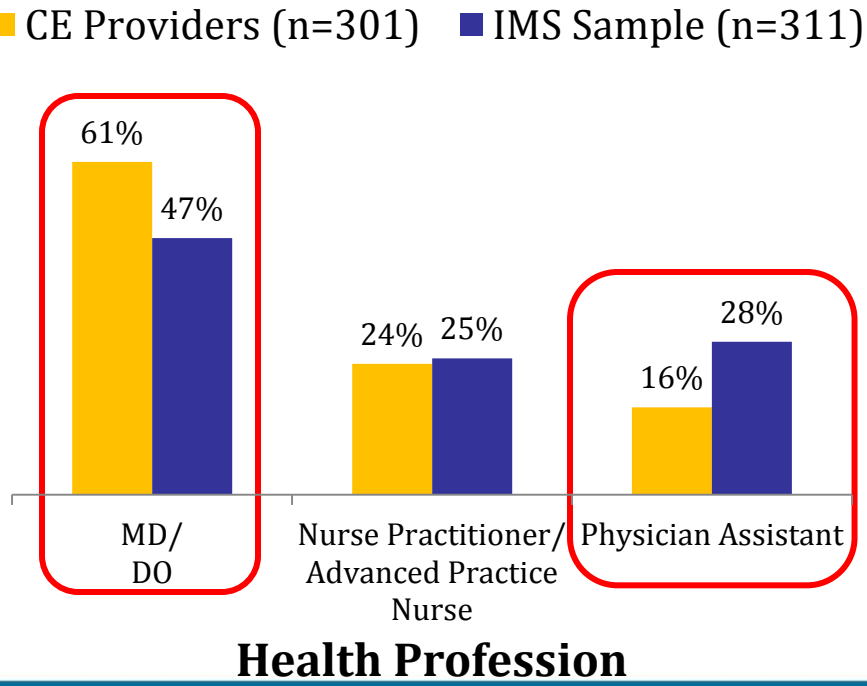
(2) Pre-REMS vs. Follow-up surveys

CE Providers vs. IMS Sample

Comparison of Prescriber Characteristics

- The two samples **are not comparable:** health profession, primary medical specialty, geographical region, past month prescription volume, practicing years
- Some of these characteristics could impact knowledge

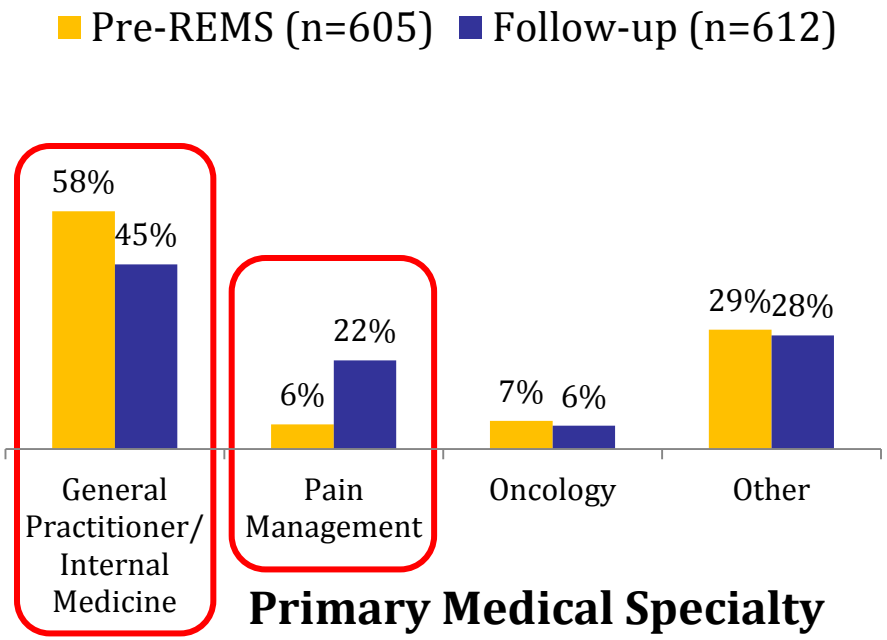




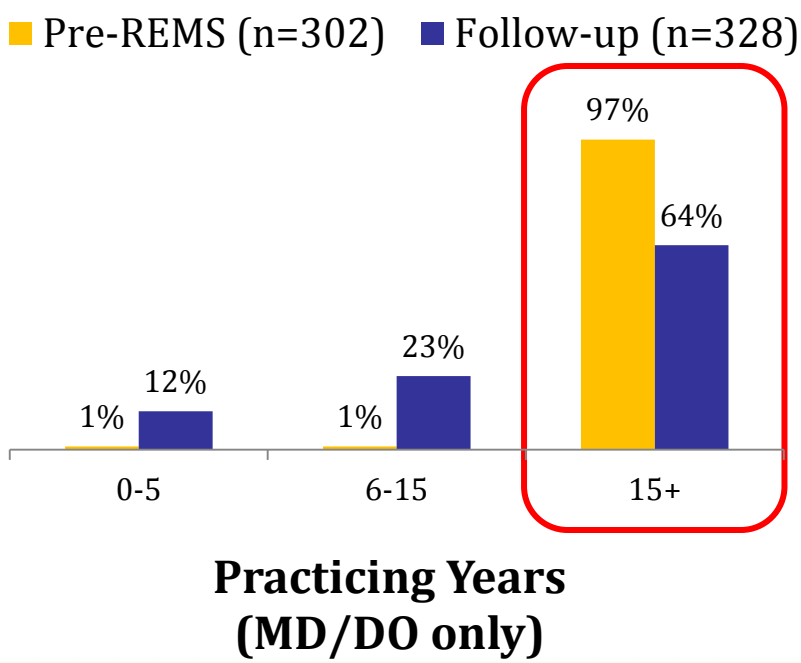
Pre-REMS vs. Follow-up Survey

Comparison of Prescriber Characteristics

- The two prescriber survey samples **are not comparable:** gender, primary medical specialty, geographical region, past month prescription volume, practicing years
- Some of these characteristics could impact knowledge



Primary Medical Specialty



Practicing Years (MD/DO only)

Validity

Are self-reported behavior accurate?

Validity

Self-reported behaviors in survey are not validated. For example,

- Number of prescriptions
- Frequency of performing urine drug screen test

Generalizability

Are survey results generalizable to the target population?

Generalizability

- Comparability
- Non-random sample
- Non response

Are Survey Samples Representative of the Target Population?

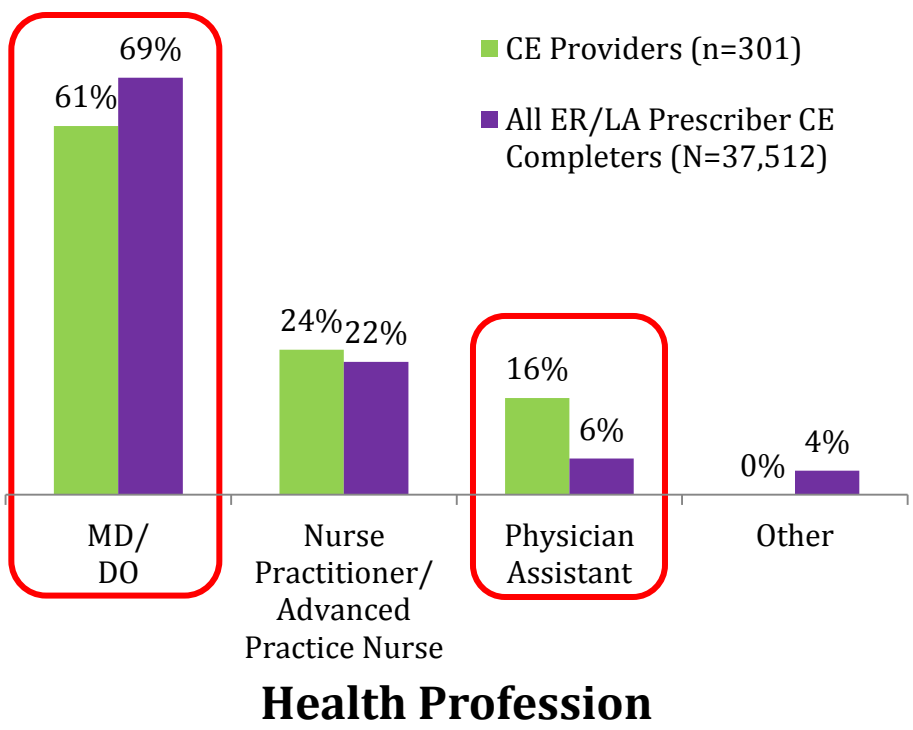
	Survey Samples	Target Population
1	CE Providers (follow-up Survey)	All ER/LA Prescriber CE Completers*
2	IMS Sample (follow-up Survey)	All ER/LA Prescribers**
3	Long-Term Evaluation (LTE) Survey	All ER/LA Prescriber CE Completers*
4	Patient Survey	Drug Use Data***

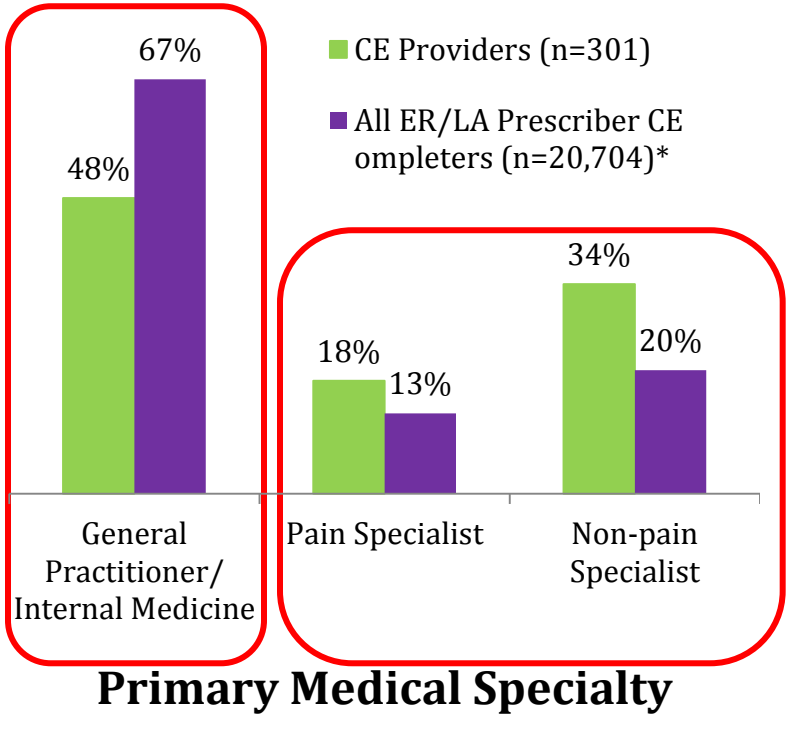
*RPC supported, accredited REMS-compliant CE completer (Feb 28, 2013-Feb 28, 2015)
**IMS database extracted in December 2014
***IMS projection from July 2013 to December 2014

CE Providers vs. All ER/LA Prescriber CE Completers

Comparison of Prescriber Characteristics

The survey sample **is different** from the target population: health profession and primary medical specialty



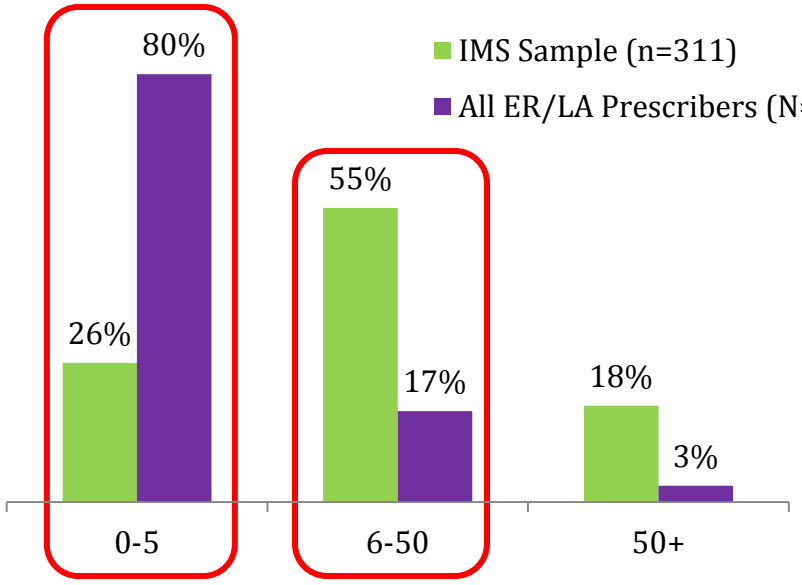


* This characteristic was captured by some CE Providers

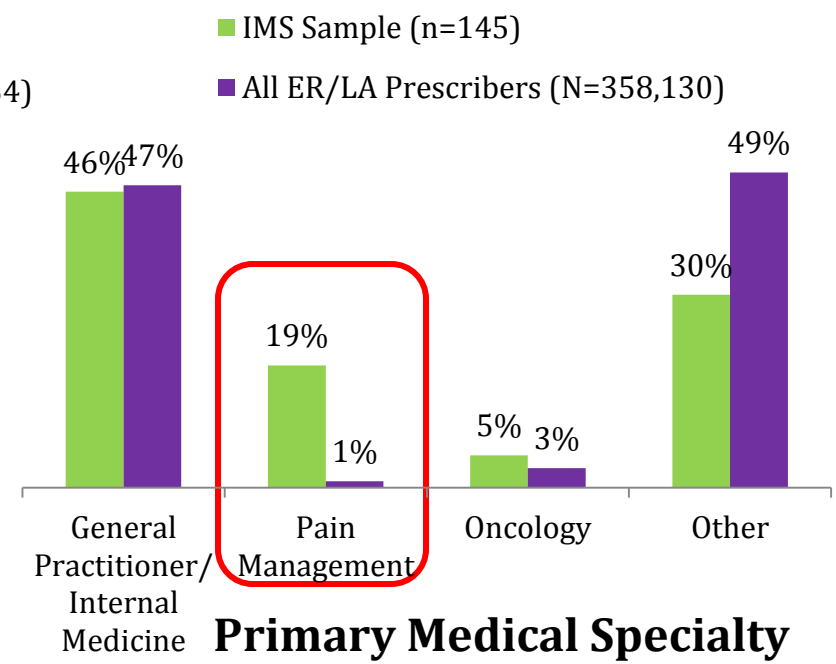
IMS Sample vs. All ER/LA Prescribers

Comparison of Prescriber Characteristics

The survey sample **is different** from the target population: past month prescription volume, primary medical specialty, health profession, region



Prescription Volume (Past Month)

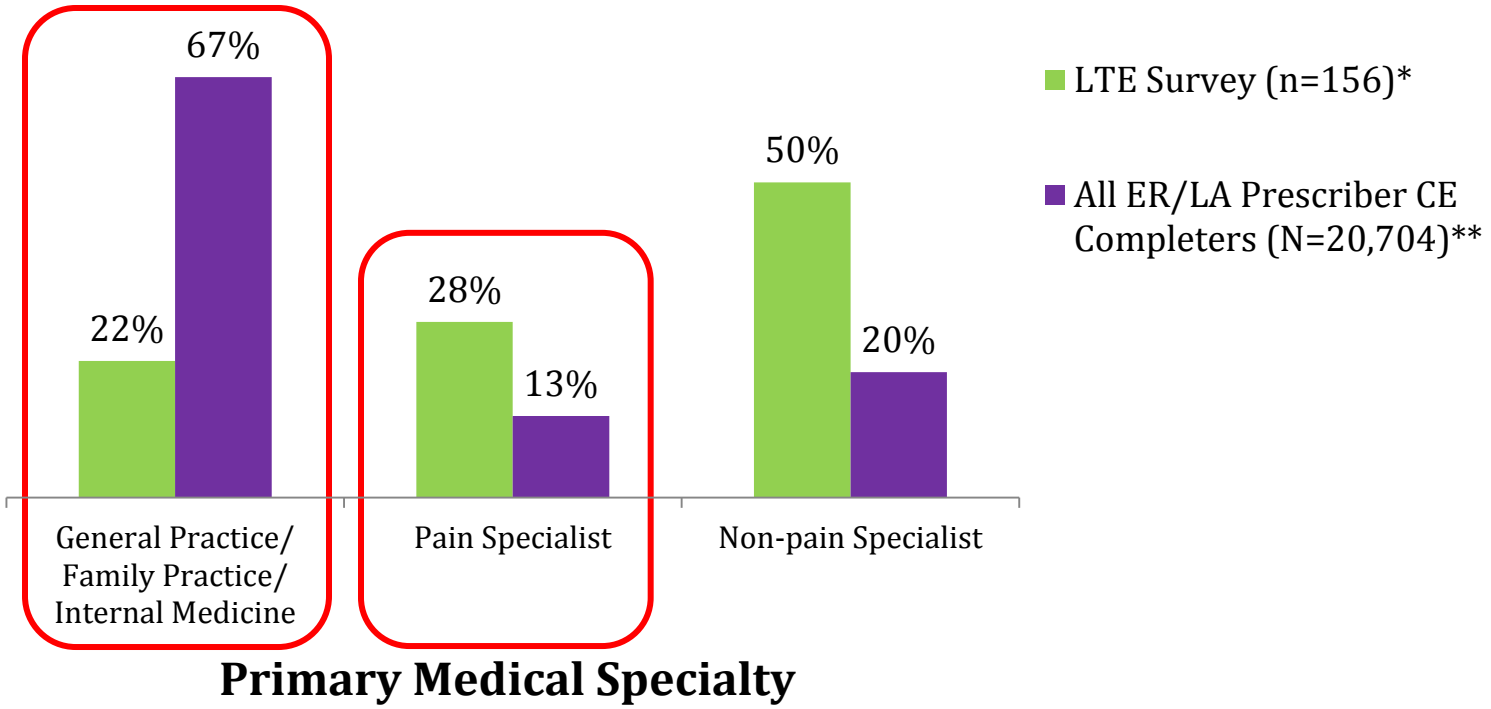


Primary Medical Specialty (MD/DO only)

LTE Survey vs. All ER/LA Prescriber CE Completers

Comparison of Prescriber Characteristics

The survey sample **is different** from the target population: primary medical specialty, health profession



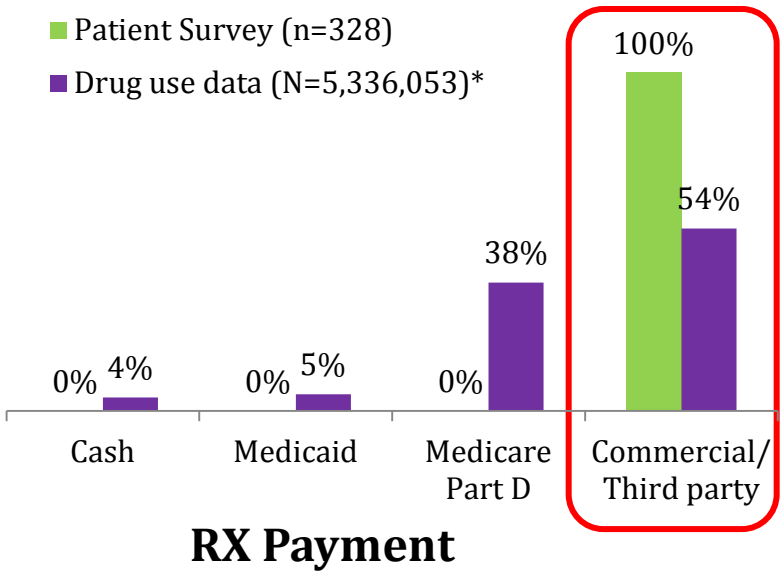
*Percentages are calculated based on the sample presented with this question because of skip logic in the survey
**This characteristic was captured by some CE Providers

Patient Survey vs. Drug Use Data

Comparison of Patient Characteristics

The survey sample

- **is not representative** of the target population: age, Rx payment, prescriber specialty
- may not be representative for race, income and education



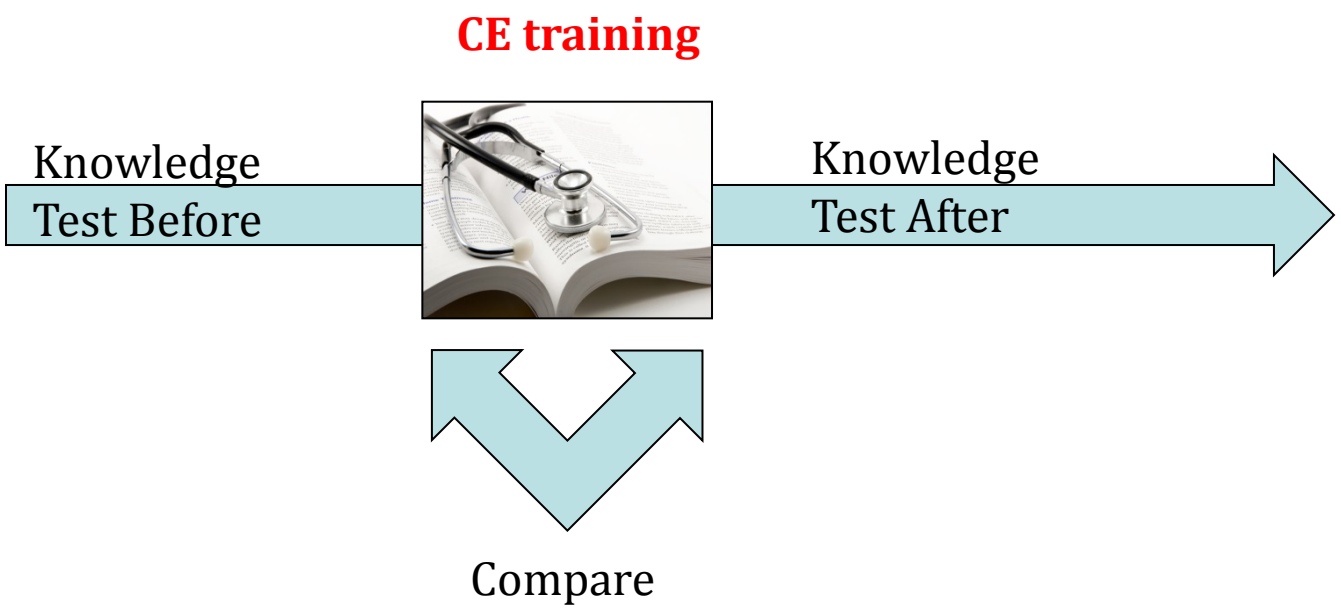
	Patient Survey (%)	Drug Use Data* (%)
Race Caucasian	94	**n/a**
Annual income at least 50,000	56	**n/a**
At least some college education	75	**n/a**

*IMS projection from July 2013 to December 2014

Considerations for Future Survey Designs

Assess the Impact of REMS CE

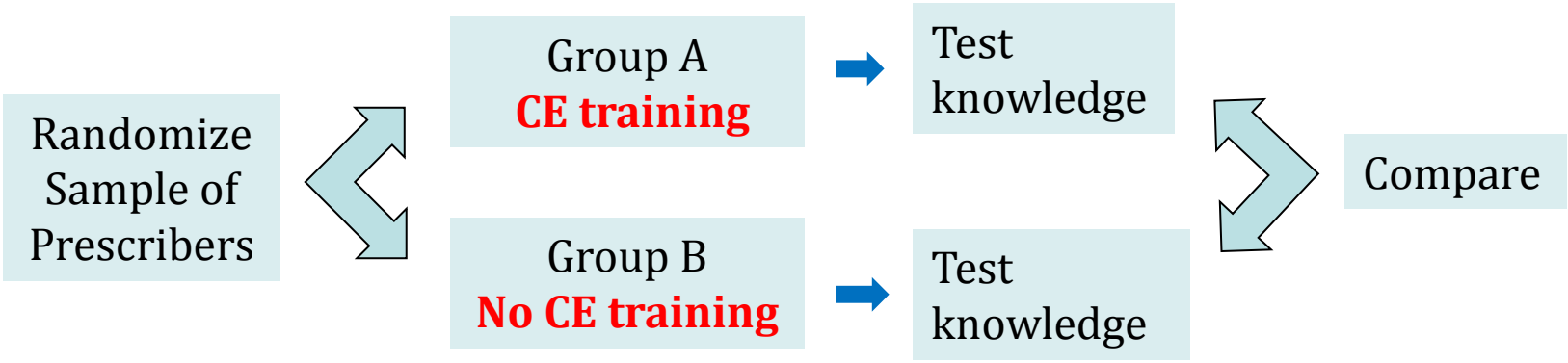
- Self-control survey on probability samples



Assess the Impact of REMS CE

continued

- Randomized experiment



Validate Self-Reported Behavior with Other Data Sources

Longitudinal database link to training data from before to after REMS CE training

- Electronic medical records
- Claims data

Generalize Survey Results to Target Population

Probability random samples

- measurable characteristics
- unmeasured characteristics

Statistical Evaluation Summary

- Survey results may have limitations of comparability, validity, and generalizability
- Prior FDA recommendations to RPC
  - Survey design and results should account for differences in baseline characteristics
  - Some survey results could be standardized to be more representative to target population
  - Additional data source for patient survey (e.g., Medicare, Medicaid)
- Considerations for future survey designs
  - probability random samples, self-control, randomized experiment, linkage to longitudinal database of behavior

Overall 36-Month Survey Review Conclusions

- In general, high knowledge rates for most of the six areas of the FDA Blueprint for both prescribers and patients.
  - Lower scoring items were most often in the domain of product-specific information and case-based scenario questions.
- Prescribers self-reported that they always or regularly conducted appropriate prescribing behaviors although patients reported a lower frequency of these same appropriate behaviors by their prescribers.
- While some prescribers reported changes in behaviors since the REMS, we are not sure why these changes occurred.

Overall 36-Month Survey Review Conclusions (2)

- Surveys have limitations.
  - Cross-sectional look at different prescribers and patients
  - Concerns about representativeness of the survey respondents
    - We have asked the RPC to provide more data on how survey respondents compare to the overall populations ER/LA prescribers, patients, and CE completers
  - The patient survey may over-estimate the effect of the REMS patient materials.
  - For the Year 3 Patient Survey, FDA recommended:
    - The use of different databases to recruit more representative populations (Medicare/Medicaid)
    - The inclusion of patient caregivers
  - Alternative survey designs should be considered.

End of Presentation