ADAPT's Evidence-Based Practice (EBP) Spotlight Series

Safer/Competent Opioid Prescribing Education (SCOPE) of Pain

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Boston University School of Medicine | Boston Medical Center

ADAPT
A Division for Advancing Prevention & Treatment
CULTIVATING PREVENTION

Washington/Baltimore HIDTA
HIGH INTENSITY DRUG TRAFFICKING AREA

RESOURCE SUPPLEMENT

July 15, 2021

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ADAPT: A Division for Advancing Prevention & Treatment

Mission

ADAPT is a division within the Center for Drug Policy and Prevention at the University of Baltimore. The mission of ADAPT is to advance knowledge, skills, and quality outcomes in the field of substance use prevention while supporting successful integration of evidence-based strategies into communities.

Goals

1. Advance substance use prevention strategies through essential training and technical assistance services and resources.
2. Promote public health and public safety partnerships in substance use prevention.
3. Prepare the future public health and public safety workforces through student engagement in ADAPT operations and projects.

HIDTA Prevention

ADAPT supports the National High Intensity Drug Trafficking Area (HIDTA) Program by operationalizing the National HIDTA Prevention Strategy. ADAPT assists HIDTAs with implementing and evaluating substance use prevention practices within their unique communities. ADAPT also keeps HIDTA communities up to date with advances in prevention science. A variety of trainings and technical webinars to cultivate, nurture, and support hospitable systems for implementation are offered throughout the year.

Technical Assistance

Technical assistance is available to all HIDTA communities in the following domains:

1. Identification of Best Practices in Substance Use Prevention
2. Training
3. Implementation
4. Evaluation
5. Finance/Budgeting
6. Sustainability
7. Early Response

CONNECT WITH US ON SOCIAL MEDIA!

For frequent updates from ADAPT, be sure to *follow* and *like* us on the platforms below. These platforms provide an opportunity to share resources and connect with each other.

Platform	Direct Link
facebook	Like our Facebook page today: https://www.facebook.com/ADAPT-100681361632663/
LinkedIn	Follow our LinkedIn Company page for the latest insights and updates: https://www.linkedin.com/company/adapt-a-division-for-advancing-prevention-treatment
YouTube	Subscribe to our YouTube channel for informative video content! https://www.youtube.com/channel/UCbxhs3Kx69_OfAMw628PO7w/

For more information, email us at adapt@wb.hidta.org.

To be notified of upcoming webinars, products, and events, subscribe here!

ADAPT Recent Events

Concept Addressed	Fundamentals of Substance Use Prevention Technical Webinar Series	Date
Program Planning	Program Planning Fundamentals	**2/18/21** Archived on YouTube
Program Evaluation	Program Evaluation: Getting to Outcomes	**3/4/21** Archived on YouTube
Risk Factors	Interventions to Reduce Risk Factors for Substance Use	**3/23/21** Archived on YouTube
Protective Factors	Interventions to Promote Protective Factors for Substance Use	**4/8/21** Archived on YouTube
Persuasive Messaging	Persuasive Message Strategies in Substance Use Prevention	**5/6/21** Archived on YouTube
Persuasive Messaging Part II	EQUIP: A Model to Guide You in Constructing Persuasive Prevention Messages	**6/3/21** Archived on YouTube
Value Analysis	The Value of Prevention: Demystifying the Cost-Benefit Analysis	**6/15/21** Archived on YouTube
Appraising Evidence	Understanding Emerging, Promising, & Best Prevention Practices	**6/23/21** Archived on YouTube
What Works in Prevention	What Works (and Doesn't) in Drug Prevention	**7/14/21** Archived on YouTube

Announcing the
Evidence Based Practice Spotlight series.

SCOPE of Pain

A curriculum designed to help providers safely and effectively manage patients with acute and/or chronic pain, when appropriate, with opioid analgesics.

July 15, 2021
2:30-4:00pm EST

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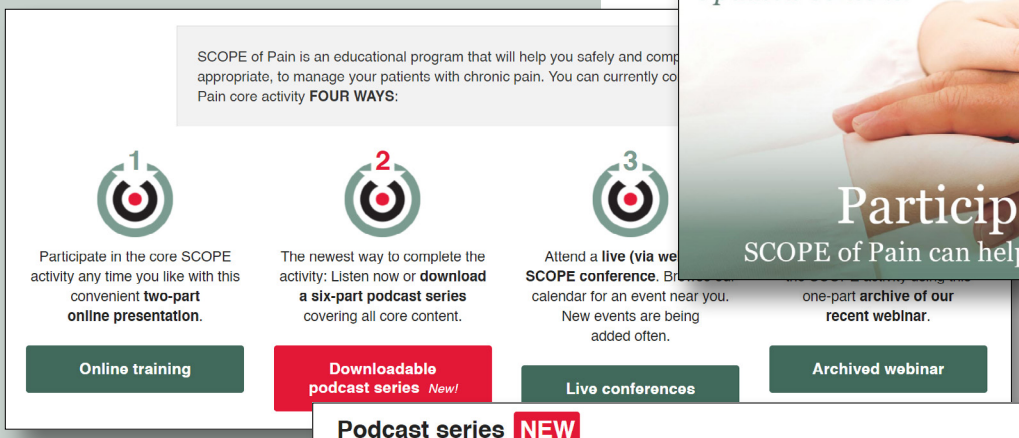
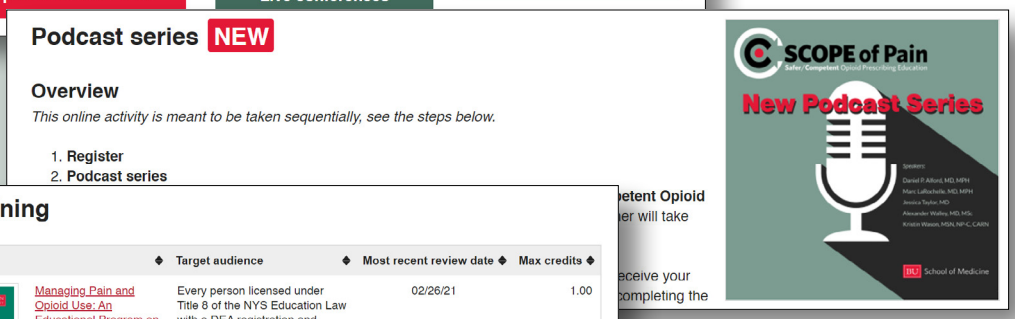
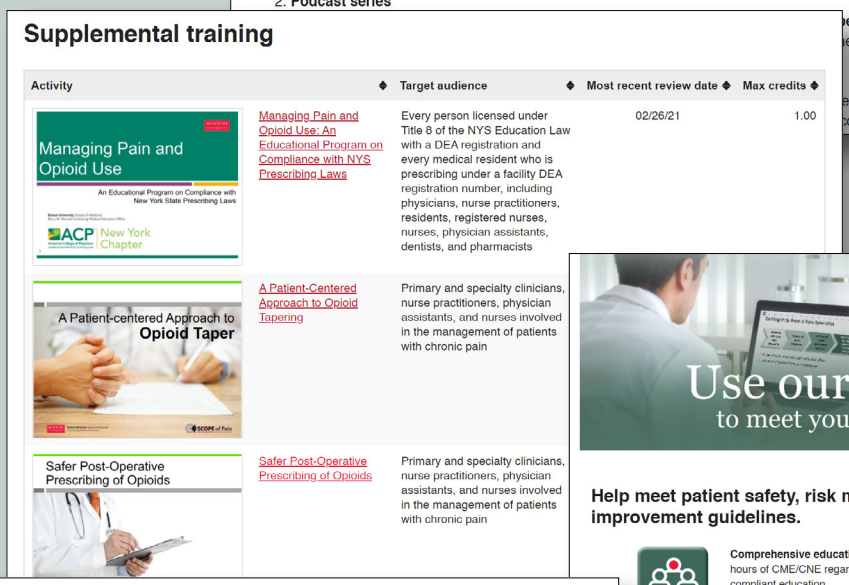
CULTIVATING PREVENTION

scopeofpain.org

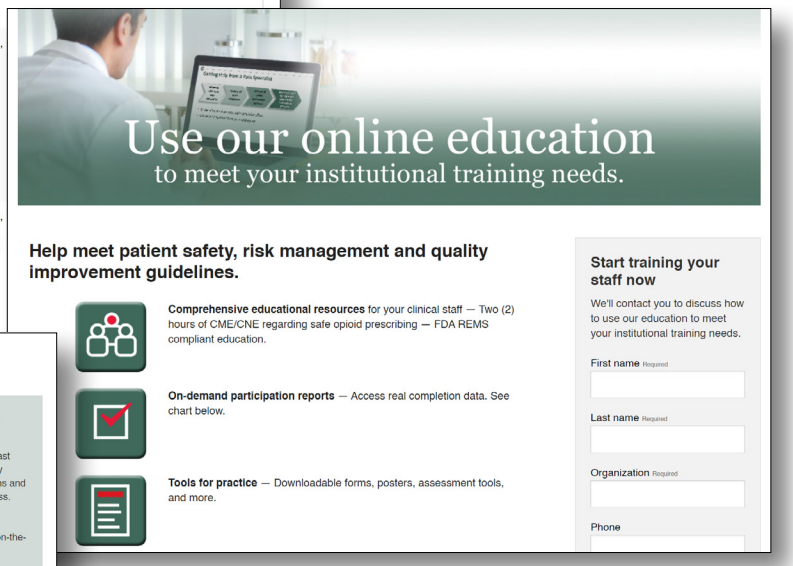
Core curriculum

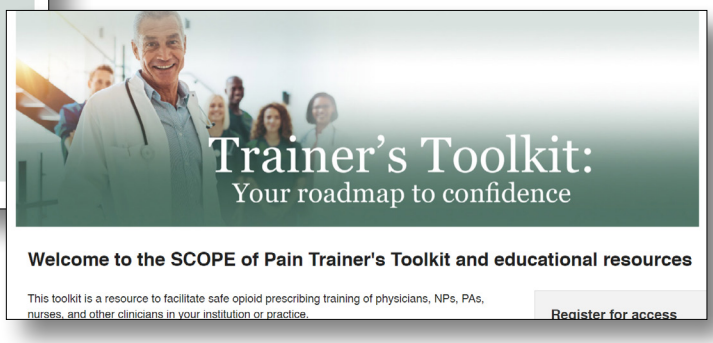






Train your organization





Safer/Competent Opioid Prescribing Education (*SCOPE of Pain*)

July 15, 2021

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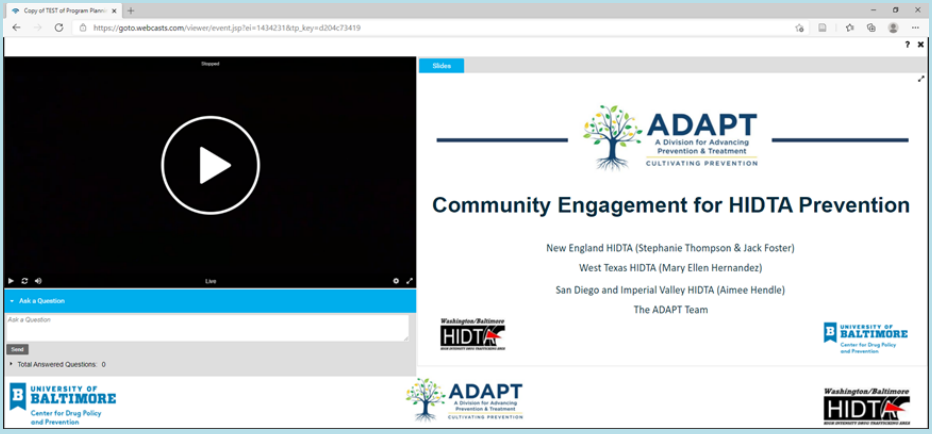
WASHINGTON / BALTIMORE HIDTA
HIGH INTENSITY DRUG TRAFFICKING AREA

Housekeeping



GoToWebcast Technical Support: 1-800-860-6814

ADAPT: adapt@wb.hidta.org

Daniel Alford, MD, MPH - Disclosures

- I serve as course director for safer opioid prescribing CME funded by an unrestricted educational grant awarded to Boston University by the REMS Program Companies as part of the FDA's Opioid Analgesic REMS program
- I have not received any direct payment from industry for these activities

Roadmap

- Background
- National Education Strategy
- Measuring Success
- SCOPE of Pain Program and Evaluation
- Additional Thoughts

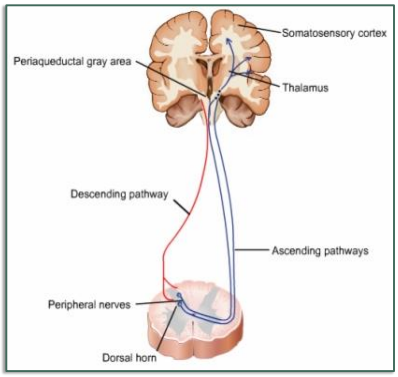
Background

Looking Back to Move Forward

- Joint Commission 2001 pain standards (“5th vital sign”), patient satisfaction surveys
- Pharma over-marketing
- Societal unrealistic expectations “painkillers”
- Lack of training for all healthcare providers
- Clinician confrontation phobia
- Financial misalignment favoring use of medications
- Lack of comprehensive pain management programs
- Difficult to measure subjective benefits and harms
- Difficult to distinguish inappropriate drug-seeking from appropriate pain relief-seeking
- Opioids as last choice with no analgesic ceiling resulting in high dose prescribing

Opioid Analgesics

- **Analgesia**
  - Turn on descending inhibitory systems
  - Prevent ascending transmission of pain signal
  - Inhibit terminals of C-fibers in the spinal cord
  - Inhibit activation of peripheral nociceptors
- **Variable response** (not all patients respond to the same opioid in the same way)
  - >1000 polymorphisms in the human mu-opioid receptor gene
  - Single nucleotide polymorphisms (SNPs) affect opioid metabolism, and activity at receptors and ion channels
- Activate the reward pathway



McCleane G, Smith HS. *Med Clin N Am.* 2007
Smith HS. *Pain Physician.* 2008
Ren Z et al. *Pain Physician.* 2015

Opioids and Chronic Pain

"The problem is, there's no evidence that opioids work for chronic pain, according to guidelines released in 2016 by the CDC"

Julia Lurie – reporter, *Mother Jones*, April 2018

Opioid Efficacy for Chronic Pain

Meta-analyses (**1-6 month** follow-up)

- **Opioids v placebo** *(high quality evidence)* Statistically significant improvements in pain[1,2] and functioning.[2]
- **Opioids v placebo** (neuropathic pain) *(low-mod quality evidence)* Clinically relevant pain relief and reduction of disability[3]
- **Opioids v nonopioids** *(low-mod quality evidence)* Similar benefits[2]

RCT[4] found **opioids not superior** to **nonopioids** for improving musculoskeletal pain-related function over 12 months

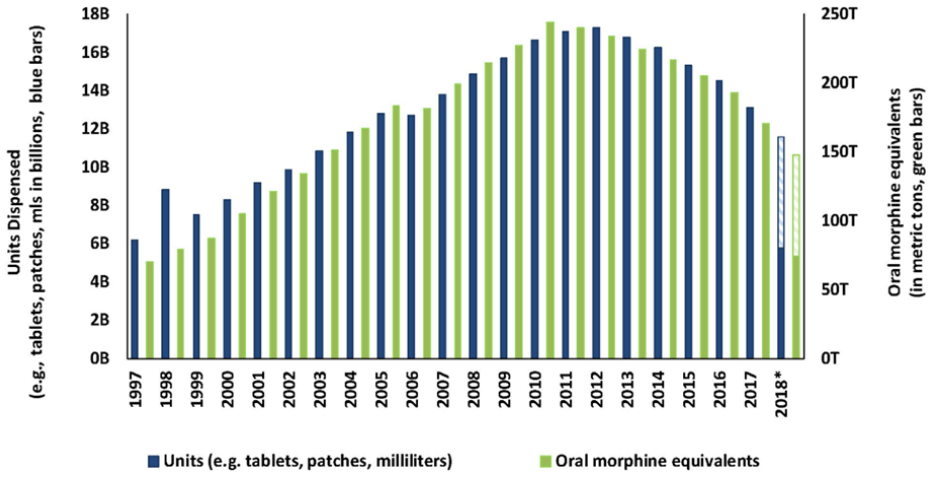
Study limitations:[5]

- *Excluded patients already on long-term opioids*
- *89% of eligible patients declined to be enrolled*

The efficacy and safety of <u>chronic</u> opioid therapy for chronic pain has been <u>inadequately studied</u>

1. Meske DS, et al. *J Pain Res.* 2018
2. Busse JW, et al. *JAMA.* 2018
3. Sommer C et al. *Eur J Pain.* 2020
4. Krebs EE, et al. *JAMA.* 2018
5. Webster L. *Pain Med.* 2019

Opioid Prescribing Trends



www.fda.gov, ONDCP 2019

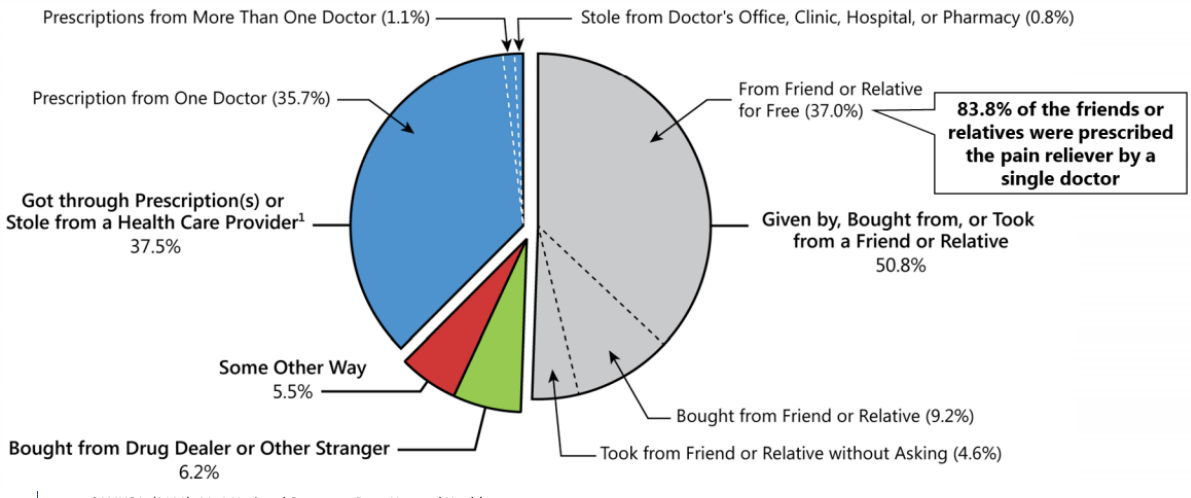
Opioid Overprescribing for Acute Pain

Emergency Department (McCarthy DM et al. *Pain Med.* 2021)

- opioid use for back pain, renal colic, fracture/dislocation, musculoskeletal injury
- **93% of patients had leftover pills**
- **52% of pills were unused**

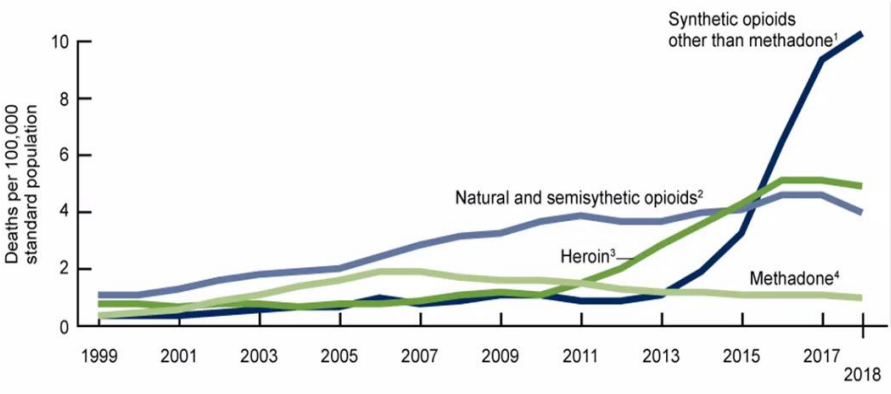
Surgery	Unused Opioids	Reference
Thoracic	**71%** taking **half or less**	Bartels et al. *Plos One.* 2016
C-section	**83%** taking **half or less**	Bartels et al. *Plos One.* 2016
Upper extremity	**77%** taking **half or less**	Rodgers et al. *J. Hand Surg.* 2012
General surgery	**71% of pills not taken**	Hill et al. *Annals Surgery.* 2016

Source of Prescription Opioids Misused



SAMHSA. (2020). 2019 National Survey on Drug Use and Health

Trends in Opioid Overdose Deaths



Overdose Deaths
6/2019-6/2020

- >83,000 deaths
- Highest number in 12-months
- 21% increase compared to previous year

Hedegaard H et al. *National Center for Health Statistics.* 2020

NCHS, *National Vital Statistics System.* 2021

Opioid Discontinuation Risks

- Study of 1.3 million US veterans with an outpatient opioid analgesic prescription over 2 years
- Opioid discontinuation was associated with an increased risk of death from overdose or suicide regardless of the length of opioid treatment
  - Risk increased with the longer the patient was prescribed opioids
  - Patients with SUD (HR, 2.48) and mental health diagnoses (HR, 1.54) were at most risk for overdose or suicide

Oliva EM, Bowe T, Manhapra A, et al. *BMJ.* 2020

"Universal Precautions" Prescribing Opioids

- Opioid misuse risk assessment
- Patient Provider Agreements (PPA)
- Medication Management
  - Opioids should not be 1st line, prescribe the lowest effective dose. (caution with any dose, if possible avoid doses >90 mg MME)
  - Avoid dangerous combinations (e.g., benzodiazepines)
- **Frequent face-to-face visits** (Document risks and benefits)
- **Risk mitigation, monitor for adherence, addiction and diversion**
  - Urine drug testing (UDT) and pill counts
  - Prescription Drug Monitoring Program (PDMP) data
  - Naloxone co-prescribing

Gourlay DL et al. *Pain Med* 2005
Dowell D et al. *MMWR* 2016

Complex Physician-Provider Communication

Opinion The New York Times

- Undertreating pain, we are admonished…it violates the basic ethical principles of medicine. On the other hand, we are lambasted for overprescribing pain medications… creating an epidemic of overdose deaths.
- For patients with chronic pain, especially those with syndromes that don't fit into neat clinical boxes, being judged by doctors to see if they "merit" medication is humiliating and dispiriting. This type of judgment, with its moral overtones and suspicions, is at odds with the doctor-patient relationship we work to develop

"As Mr. W. and I sat there sizing each other up, I could feel our reserves of trust beginning to ebb. I was debating whether his pain was real or if he was trying to snooker me. He was most likely wondering whether I would believe him…"

Danielle Ofri, MD, NYU and Bellevue Hospital, *August 2015*

Education Gap

- US Medical Schools average 10 hours of pain management education with only 30% offering opioid prescribing education
- 82% of primary care physicians rated their undergraduate medical education in chronic pain as insufficient
- 55% of primary care physicians rated their chronic pain training in residency as insufficient
- Only 34% of physicians felt comfortable in managing patients with chronic pain and only 1% found doing so satisfying

Loeser JD, Schatman ME. *Postgrad Med.* 2017
Mezei L et al. *J Pain* 2011
Morely-Forster PK et al. *J Pain Res* 2013
Upshur CC, et al. *J Gen Int Med.* 2006
Watt-Watson J et al. *Pain Res Manag* 2009
Watt-Watson J et al. *Pain* 2004
Yanni LM, et al. *J Grad Med Educ.* 2010

A National Education Strategy

Opioid Analgesics
Risk Evaluation and Mitigation Strategy (REMS)

A Unique REMS Program

- **Goal:** "…reduce serious adverse outcomes (addiction, unintentional overdose, death) from inappropriate [opioid] prescribing,…while maintaining patient access to pain medications"
- **Federal Government** – 2012: FDA mandated the class-wide Opioid REMS, developed the **curricular Blueprint**
- **REMS Program Companies:** manufacturers of opioid analgesics provided unrestricted educational grants to **accredited CME/CE providers**
- **Continuing Education Accreditors** – ACCME, ANCC, ACPE, AOA, AAFP responsible for auditing and capturing and reporting data

- **Manufacturers funding** of the education is **mandatory**
- **Prescriber participation** in the education is **voluntary**

FDA Curricular Blueprint

- Basics of Pain Management (mechanisms, assessment)
- Creating the Pain Treatment Plan
  - Non-pharmacologic
  - Pharmacologic (non-opioid, opioid)
  - Managing patients on opioid analgesics (acute and chronic pain)
    - Identifying and managing opioid use disorder
    - Opioid tapering
  - Addiction medicine primer

No limits or restrictions on what can be included as long as all elements of the FDA Blueprint are covered

Misinformation

"For opioid-makers, the [CE] courses for doctors "one of the most important marketing [tactics] that they have," says one pharmacology professor…It doesn't look like advertising. It doesn't look like promotion. It looks like education…"

Does Opioid REMS = Marketing?

NO! The hallmark of accredited CME is independence from promotion or marketing

- Accreditation Council for Continuing Medical Education (ACCME®) standards ensure that accredited CME is relevant, practice-based, and independent of commercial influence or bias
- Companies providing funding for accredited CME are prohibited from any influence over faculty or content; cannot pay attendees or faculty for travel, registration, or honoraria; and cannot influence who can attend

Commercial Bias?

For over 8 years,… **99.5%** (221,668/222,588) of *SCOPE of Pain* participants detected **NO commercial bias**

- Of the 0.5% who did…~20% erroneously clicked "yes" and wrote a comment such as "there is no bias in this presentation"
- Of those who did detect commercial bias, their comments fell into 3 themes…They reported bias because:
  - the topic was about prescribing opioids
  - opioids are never appropriate treatment for chronic pain
  - all pharma funded CME is implicitly biased

SCOPE of Pain
Safer/Competent Opioid Prescribing Education

Does CME Work?

- 5 systematic reviews concluded:
  - CME improves physician performance and patient health outcomes
  - Positive impact on physician performance more than patient health outcomes
- 8 systematic reviews concluded:
  - CME activities that are more interactive, use more methods, involve multiple exposures, are longer, and are focused on outcomes that are considered important by physicians lead to more positive outcomes

Cervero RM, Gaines JK. *J Contin Educ Health Prof.* 2015
Cervero RM, Gaines JK. *ACCME* 2014
Forsetlund L et al. *Cochrane Database Systematic Reviews.* 2009

Measuring Success: *The Ideal Outcomes*

- ✓ Decreases in overdoses
- ✓ Decreases in overdose deaths
- ✓ Decreases in ED visits related to opioids
- ✓ Decreases in opioid addiction
- ✓ Decreases in opioid diversion
- ✓ **Improvements in clinician performance**
- ✓ **Improvements in patient health outcomes** (decreased pain, improved function and quality of life)

Challenges to Measuring Success

- Inadequate data from CME participants
  - Limit burden to participants pre- and post-program
  - Limited access to participants for follow-up
- Difficulties in differentiating effects of the Opioid REMS from multitude of concurrent efforts:
  - Overdose education and naloxone distribution
  - Expanded treatment of opioid addiction
  - Prescription drug monitoring program use, law enforcement closing "pill mills"
  - National and state guidelines, insurers with dose limits

More Common Metrics *easier to measure…*

- ✓ Decreases in opioid prescribing, but…
  - ✓ What is the right amount? Based on what?
  - ✓ Are changes due to more judicious or fearful prescribing?
- ✓ Improvements in clinicians knowledge, attitudes, confidence
- ✓ Improvement in clinicians self-reported changes in practice

SCOPE of Pain

Program and Evaluation

Partnerships

- Partnered with over a 100 different local, regional, and national groups: Federation of State Medical Boards, Council of Medical Specialty Societies, academic medical centers, state boards, healthcare systems, public health organization, etc.
- **Beginning in 2013 partnership with NE HIDTA**, to collaborate on trainings throughout New England
  - Partnership arose through our collaboration with state medical boards, state police, and the DEA
  - Partnership resulted in a 2014 Outstanding Prevention Effort from HIDTA, ONDCP

2014 Outstanding Prevention Effort, HIDTA, ONDCP

SCOPE of Pain
Safer/Competent Opioid Prescribing Education

About *SCOPE of Pain*

Through the case presented participants learn:

How to…

Part 1

- Optimize safety when prescribing opioids for acute pain
- Determine when opioid analgesics are indicated for chronic pain
- Assess pain and prescription opioid misuse risk

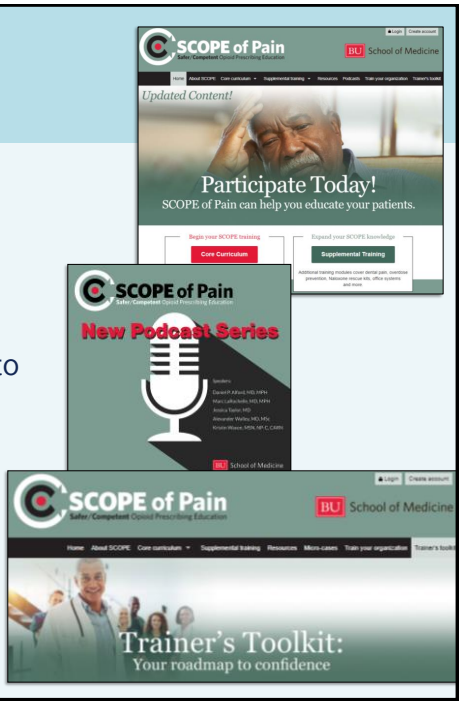
Part 2

- Educate patients about opioid risks and realistic benefits
- Monitor patients on opioid therapy for benefits and harms
- Assess and manage worrisome opioid-taking behaviors
- Safely taper long-term opioid therapy
- Identify and manage patients with an opioid use disorder

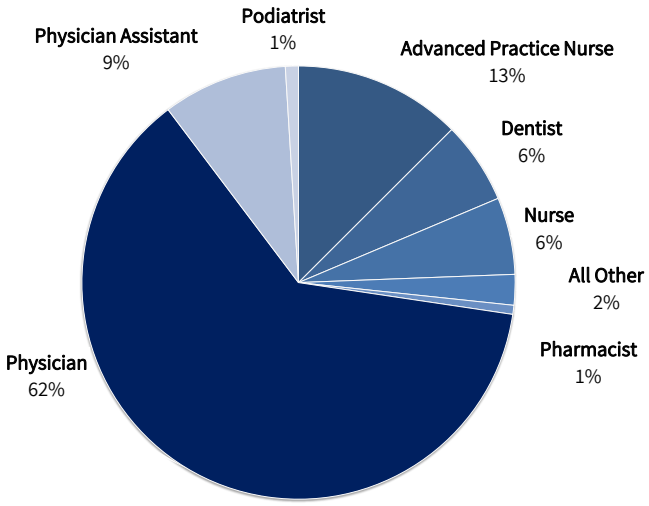
SCOPE of Pain Offerings*

- **Online Program:** 2-hours
- **Podcast:** Six 20-minute downloadable episodes
- **Live Meetings:** in-person or via webinar
- **Print:** downloadable PDF monograph
- **Train-the-Trainer:** Deliver SCOPE of Pain content to colleagues
- **Ancillary Materials:**
  - Trainer's Toolkit (videos, case studies, skills practice)
  - Audio micro-cases
  - Supplemental/complementary educational modules (e.g., tapering; setting up your practice)

*all offered at no cost at www.scopeofpain.org

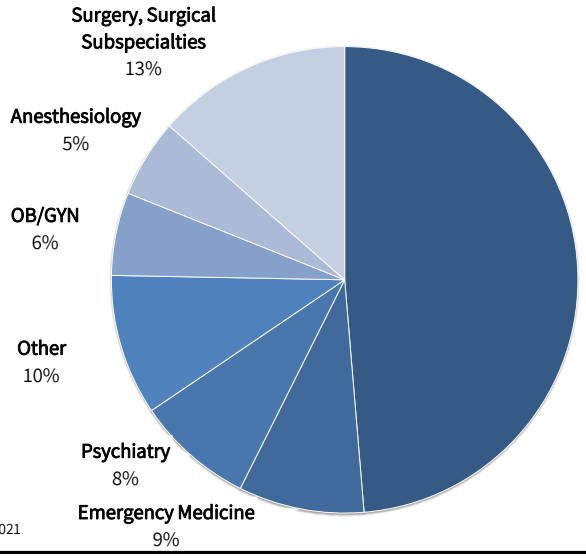


Completers by Profession (n=222,588)



March 1, 2013 through June 30, 2021

Completers by Specialty (n=222,588)



March 1, 2013 through June 30, 2021

SCOPE of Pain
Safer/Competent Opioid Prescribing Education

Scope of Pain Evaluation

Pre-Program Assessment (PRE):

1. **Knowledge** (20 items)
2. **Confidence** (6 items)
3. **Attitudes** (13 items)
4. **Clinical Performance** (7 items)

- **Socio-demographic data**

Participation *(live or online)* **3-hour** ***SCOPE of Pain*** **Program**

Immediate Post-Program Assessment (IMMED):

1. **Δ Knowledge** (20 items)
2. **Intention to implement change** (2 items)

2-Month Post-Program Assessment (2MO):

1. **Knowledge maintenance** (10 items)
2. **Δ Confidence** (6 items)
3. **Δ Attitudes** (13 items)
4. **Δ Clinical Performance** (7 items)
5. **Number of changes implemented** (1 item)
6. **Barriers to change** (1 item)

SCOPE of Pain
Safer/Competent Opioid Prescribing Education

Original Research Article

SCOPE of Pain: An Evaluation of an Opioid Risk Evaluation and Mitigation Strategy Continuing Education Program

- **Immediate post-program** (n=2,850)
  - 87% with intention to change toward guideline-based care
- **2-month post program** (n=476 [17% response rate but no significant differences in demographics to the entire sample])
  - Significant increase in correct responses to knowledge questions
  - 67% increased confidence in applying safer opioid prescribing care
  - 86% reported implementing guideline-based practice changes
  - Improvement in alignment of desired attitudes toward safer opioid prescribing

Alford DP, et al. *Pain Med* 2016

SCOPE of Pain Safer/Competent Opioid Prescribing Education

ORIGINAL RESEARCH OPEN

Safe and competent opioid prescribing education: Increasing dissemination with a train-the-trainer program

- 89 trainers were trained in 9 states
- 33% of the trainers conducted at least 1 training, with a total of 79 trainings educating 1,419 participants
- **Trainer-led** versus **Expert-led** participant outcomes
  - Immediate post-training, over 90% of both groups planned to make at least one change toward guideline-based safer opioid prescribing
  - 2-months post-training, there were **no significant differences** in improvements in knowledge, confidence, attitudes, and performance
  - Participants of the trainer-led programs were significantly more likely to be **practicing in rural settings**

Zisblatt L, et al. *Subst Abus* 2017

SCOPE of Pain Safer/Competent Opioid Prescribing Education

Additional Thoughts

Mandating Pain CME

46 State Medical and Osteopathic Boards require content on **pain management** *(FSMB 2021)*

We compared CME outcomes for mandatory versus voluntary training

CME outcomes collected **immediately post-training**

- **Satisfaction**
- **Knowledge**
- **Intent to change**
- **Perceived barriers to change**

Unpublished data

Analysis was run on the following sub-sample:

- Physicians, NPs and PAs
- Specialties likely managing chronic pain
- Opioid prescribing last 12 month

Mandatory group:

Completed *SCOPE of Pain* under the **NY state mandate**

2/2017 - 7/2017

Voluntary group:

Completed *SCOPE of Pain* **voluntarily (34 states)**

2/2013 - 7/2017, or until mandatory in their state

Mandatory versus Voluntary Training

- Mandated safer opioid prescribing training efficiently reached the target audience, attendees were less satisfied with the training, had slightly less correct knowledge answers and were less likely to endorse an intention to change than those who voluntarily completed the training
- There was a weak but significant correlation between satisfaction with the training and intention to change safer opioid prescribing practices

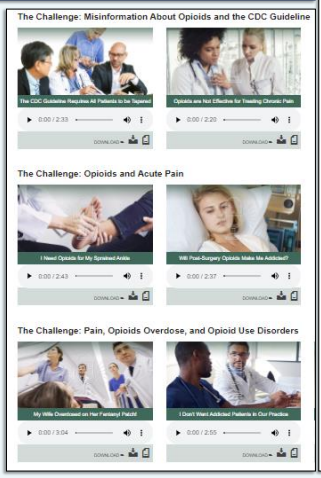
Unpublished data

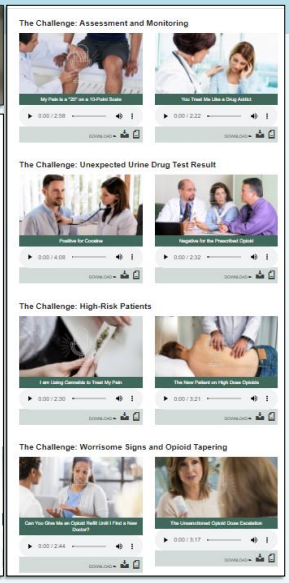
SCOPE of Pain
Safer/Competent Opioid Prescribing Education

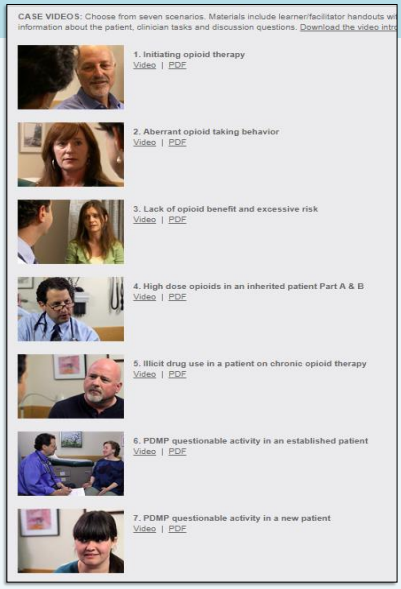
It cannot be limited to training prescribers

- Safer opioid prescribing is a lot of work
- Train (*and retrain*) and utilize other staff (*nurses, medical assistants, pharmacist, psychologists, social workers, front desk staff*)

Must Address Complex Conversations





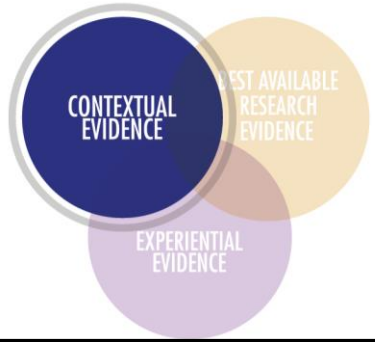


www.scopeofpain.org

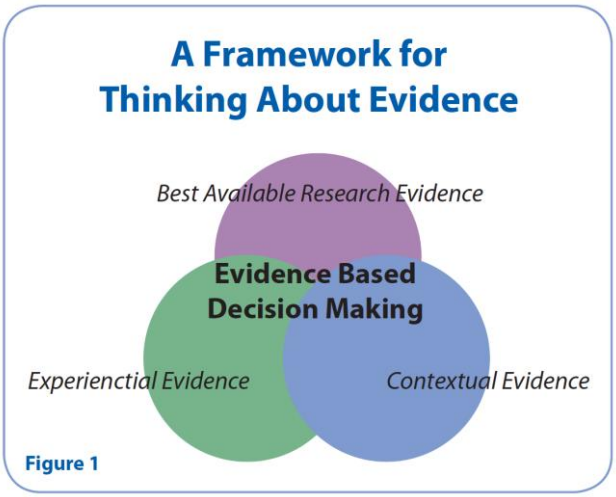
Upcoming Live Webinars

- 7/28/21 5:30 pm
- 8/23/21 6:30 pm

Understanding Evidence



Understanding Evidence

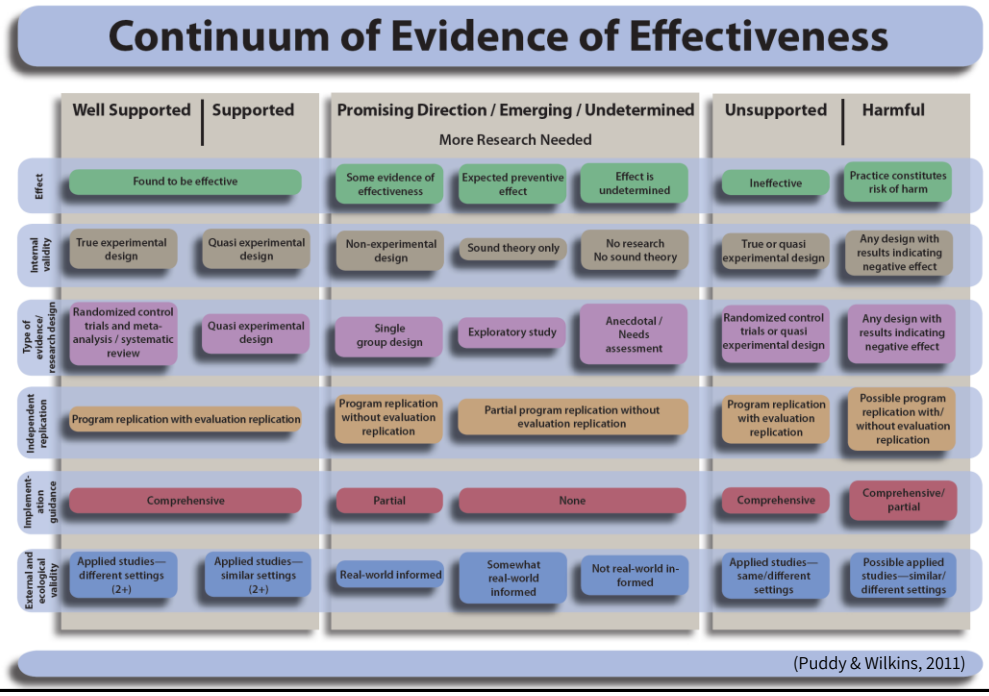


Feasibility

Acceptability

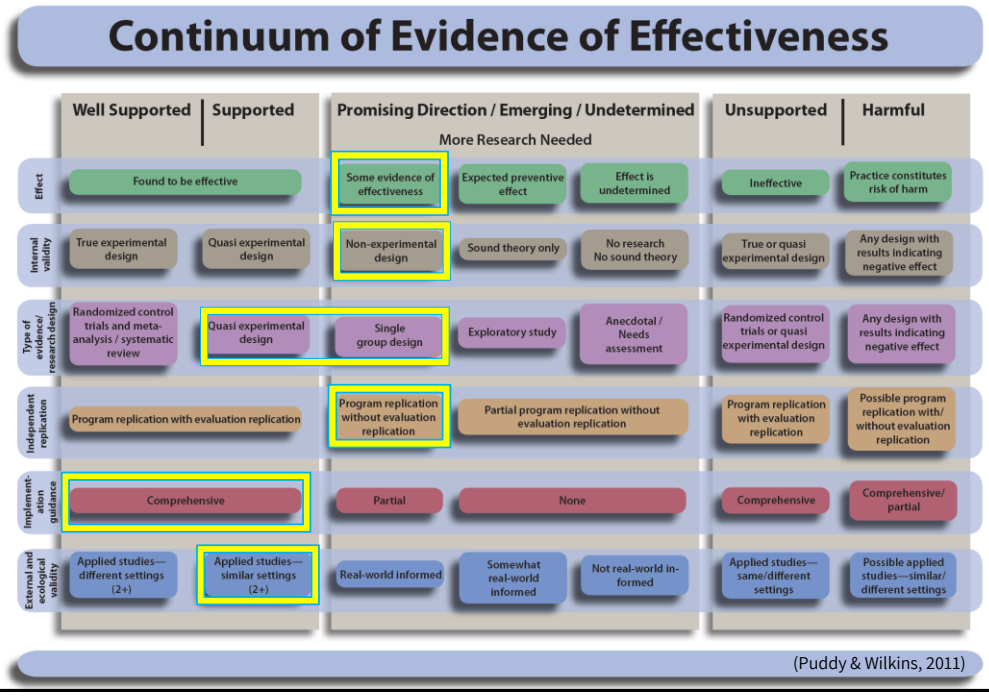
Utility

(Puddy & Wilkins, 2011)

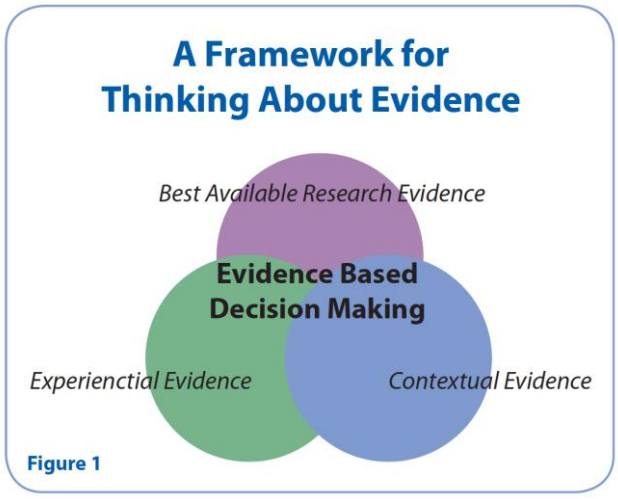


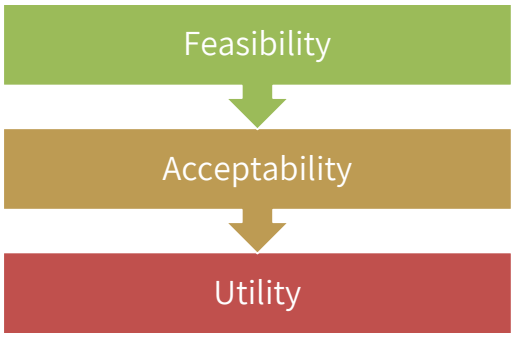
Review of Two Published Articles: *SCOPE of Pain*

- Alford, D. P., Zisblatt, L., Ng, P., Hayes, S. M., Peloquin, S., Hardesty, I., & White, J. L. (2016). SCOPE of Pain: An evaluation of an opioid risk evaluation and mitigation strategy continuing education program. Pain Medicine, 17(1), 52–63. http://dx.doi.org.mutex.gmu.edu/10.1111/pme.12878
- Zisblatt, L., Hayes, S. M., Lazure, P., Hardesty, I., White, J. L., & Alford, D. P. (2017). Safe and competent opioid prescribing education: Increasing dissemination with a train-the-trainer program. Substance Abuse, 38(2), 168–176. https://doi.org/10.1080/08897077.2016.1275927



Understanding Evidence





(Puddy & Wilkins, 2011)

Thanks!

Questions?

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SCOPE of Pain

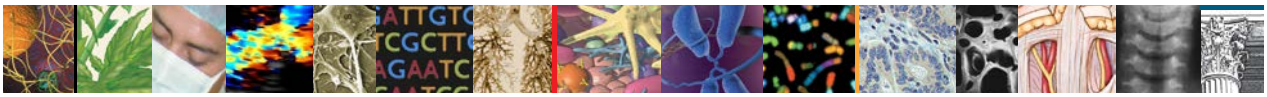
Resources Recommended by the Presenters

Resources (all articles are included in the Appendix)
Opioid Prescribing for Chronic Pain — Achieving the Right Balance through Education. - Alford DP. Opioid Prescribing for Chronic Pain--Achieving the Right Balance through Education. N Engl J Med. 2016 Jan 28;374(4):301-3. doi: 10.1056/NEJMp1512932. PMID: 26816007.
National Trends in Prescription Opioid Risk Mitigation Practices: Implications for Prescriber Education - Alford DP, Lazure P, Murray S, Hardesty I, Krause JR, White JL. National Trends in Prescription Opioid Risk Mitigation Practices: Implications for Prescriber Education. Pain Med. 2019 May 1;20(5):907-915. doi: 10.1093/pm/pny298. PMID: 30789651.
SCOPE of Pain: An Evaluation of an Opioid Risk Evaluation and Mitigation Strategy Continuing Education Program - Alford DP, Zisblatt L, Ng P, Hayes SM, Peloquin S, Hardesty I, White JL. SCOPE of Pain: An Evaluation of an Opioid Risk Evaluation and Mitigation Strategy Continuing Education Program. Pain Med. 2016 Jan;17(1):52-63. doi: 10.1111/pme.12878. PMID: 26304703; PMCID: PMC4718419.
Safe and competent opioid prescribing education: Increasing dissemination with a train-the-trainer program. - Zisblatt L, Hayes SM, Lazure P, Hardesty I, White JL, Alford DP. Safe and competent opioid prescribing education: Increasing dissemination with a train-the-trainer program. Subst Abus. 2017 Apr-Jun;38(2):168-176. doi: 10.1080/08897077.2016.1275927. PMID: 28418816.

SCOPE of Pain

Additional Web Resources

Organization	Resources
U.S. Food and Drug Administration	FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain - https://www.accessdata.fda.gov/drugsatfda_docs/rems/Opioid_analgesic_2018_09_18_FDA_Blueprint.pdf
Centers for Disease Control and Prevention (CDC)	Understanding Evidence Part 1: Best Available Research Evidence. A Guide to the Continuum of Evidence of Effectiveness. - https://www.cdc.gov/violenceprevention/pdf/understanding_evidence-a.pdf
ADAPT Fundamentals of Substance Use Prevention Webinar Series	Understanding Evidence in Substance Use Prevention - https://www.youtube.com/watch?v=0Ng46M_YnKQ&list=PLHYq4tqgyBBKov4HsixyR_zZYobFTDV_-&index=8&t=18s



The NEW ENGLAND JOURNAL of MEDICINE

Perspective

JANUARY 28, 2016

Opioid Prescribing for Chronic Pain — Achieving the Right Balance through Education

Daniel P. Alford, M.D., M.P.H.

In recent decades, the United States has seen a dramatic increase in opioid prescribing for chronic pain. That growth has been associated with increasing misuse of prescription opioids[1] and has led to increases in deaths due to unintentional opioid overdose and in the number of people seeking treatment for opioid-misuse disorders. There's probably 100% agreement that we, as a profession and society, have become overly opioid-centric in our management of chronic pain. Far more controversial are the role of long-term opioid therapy in managing chronic pain and the best strategy for ending the epidemic of prescription-opioid misuse.

Groups lobbying against prescribing opioids for chronic pain remind us that the effectiveness of long-term opioid therapy has been inadequately studied.[2] I believe that this is a case of absence of evidence rather than evidence of absence. As we await scientific evidence, questions remain regarding how best to address the epidemic of prescription-opioid misuse now. Groups advocating quick fixes believe that regulations that limit opioid availability are the best plan. This strategy is well intentioned and will certainly reduce opioid prescribing, but such blunt approaches will also limit access to opioids for patients who are benefiting or may potentially benefit from them.

Such an objection is not about protecting clinicians' autonomy, but rather about protecting access to opioids for our patients who are in severe pain. These regulations will lead some clinicians to refuse to prescribe opioids even when they're indicated, seeing it as too risky or too much work. They also create a climate of mistrust between patients and their health care teams. Clinicians are accused of both undertreating pain and overprescribing opioids, and patients with chronic pain who take opioids are viewed with suspicion. In addition, we don't know what impact indiscriminate reductions in access to prescription opioids will have on long-term clinical outcomes.

Prescriber education is a more finely tuned approach to addressing the opioid-misuse epidemic, allowing us to individualize care on the basis of a patient's needs after a careful benefit–risk assessment. That, after all, is the way we manage all chronic diseases. Education can empower clinicians to make appropriate, well-informed decisions about whether to initiate, continue, modify, or discontinue opioid treatment for each individual patient at each clinical encounter. Education has the potential to both reduce overpre-

scribing and ensure that patients in need retain access to opioids.

In July 2012, a national voluntary prescriber-education initiative was begun. The Food and Drug Administration (FDA) approved a single shared Risk Evaluation and Mitigation Strategy (REMS) requiring manufacturers of extended-release and long-acting opioid analgesics to fund accredited education on safe opioid prescribing based on an FDA curricular blueprint. Although this program has not yet trained the targeted number of prescribers, a recent evaluation suggests that REMS education can shift clinicians' self-reported practice toward safer, guideline-concordant care.[3] Comprehensive training in safe opioid prescribing is needed at all stages of medical education (undergraduate, graduate, and continuing), since training in this area has historically been lacking. This education must go beyond opioid prescribing to include comprehensive, multimodal pain management,[4] and it can be designed for the entire health care team: our nursing, pharmacy, and behavioral health colleagues have also been inadequately trained. This education can be coupled with enhanced clinical systems that support these new practices, including decision-support tools in electronic medical records.

Managing chronic pain is complex. Chronic pain is subjective and can present without objective evidence of tissue injury, which results in diagnostic uncertainties despite our most thorough assessments. Patients with chronic pain are desperately seeking immediate relief from their suffering; they tend to have unrealistic expectations regarding the potential benefits of opioids and not to fully appreciate the degree of risk conferred by escalating their own doses in a desperate (yet futile) attempt to obtain pain relief.

Clinicians have limited tools at their disposal to help these patients. Our reimbursement system favors the use of medications alone, despite evidence supporting multimodal care. Clinicians often have no easy access to nonpharmacologic therapies and cannot obtain pain consultations because there are too few pain specialists offering comprehensive pain care. Moreover, whereas clinicians can use objective measures to guide their management of other chronic diseases, here they must rely solely on the patient's (or family's) reports of benefits (such as improved function) and harms (such as loss of control). Clinicians are thus left basing treatment decisions on a brief subjective assessment of whether there's enough benefit to justify continued opioid therapy or enough harm to justify discontinuing it.

Many guidelines for safe opioid prescribing exist, and all include similar recommendations, including use of assessments of risk of opioid misuse, signed agreements that include informed consent, and monitoring strategies such as drug testing, pill counts, and prescription-drug–monitoring programs. But it's also essential for safe-opioid-prescribing education to include teaching of effective communication skills. How does one explain to a patient who's desperate for help that an opioid treatment must be discontinued despite the lack of alternative treatments? How does one deal with a new patient who is already taking high-dose opioids and insists that it's the only treatment that helps?

It's important for clinicians to judge the opioid treatment rather than the patient.[5] When opioid therapy is deemed too risky or inadequately beneficial, discontinuing it means abandoning not the patient but merely an inappropriate treatment. When a clinician changes the treatment approach with a patient who tests positive for an illicit drug, that response is not about punishing the patient, but about changing the treatment plan on the basis of a new risk and addressing a newly identified problem.

When a clinician determines that discontinuing opioid treatment is appropriate, the patient may disagree and express anger. Is such frustration attributable to an appropriate desire for pain relief, inappropriate drug seeking, or a combination of the two? Though a patient-centered approach is always preferred, there are times in managing opioid therapy for patients with chronic pain when the clinician's approach must be at odds with the patient's request but intended to keep the patient safe. Such an approach may be perceived as paternalistic and may threaten the therapeutic alliance. Although transparent communication leading to a patient-centered approach is important, it goes only so far when a patient with chronic pain also shows signs of opioid misuse (e.g., unsanctioned dose escalation), necessitating discontinuation of opioid treatment.

Addressing the crisis of prescription-opioid misuse has become a national priority. To judge from the progress of the REMS program for extended-release and long-acting opioids, voluntary prescriber education may be insufficient to address this problem. Mandatory education may be re-

quired. If so, it will be important to link mandated education to medical licensure to avoid having clinicians opt out — since that could lead to reduced treatment access, as well as burnout among the clinicians who opt in. Alternatively and ideally, we could mandate proof of clinical competence, allowing clinicians who are already well trained to test out of an education requirement. Unfortunately, it may be impossible to measure such skill-based competence on a national scale.

An audio interview with Dr. Alford is available at NEJM.org

I believe that the medical profession is compassionate enough and bright enough to learn how to prescribe opioids, when they are indicated, in ways that maximize benefit and minimize harm. Though managing chronic pain is complicated and time consuming and carries risk, we owe it to our patients to ensure access to comprehensive pain management, including the medically appropriate use of opioids.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

From the Boston University School of Medicine and Boston Medical Center — both in Boston.

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2. Chou R, Turner JA, Devine EB, et al. The effectiveness and risks of long-term opioid therapy for chronic pain: a systematic review for a National Institutes of Health Pathways to Prevention Workshop. Ann Intern Med 2015;162:276-86.
3. Alford DP, Zisblatt L, Ng P, Hayes SM, Peloquin S, Hardesty I, White JL. SCOPE of Pain: an evaluation of an opioid Risk Evaluation and Mitigation Strategy continuing education program. Pain Med 2015 August 25 (Epub ahead of print).
4. Fishman SM, Young HM, Lucas Arwood E, et al. Core competencies for pain management: results of an interprofessional consensus summit. Pain Med 2013;14:971-81.
5. Nicolaidis C. Police officer, deal-maker, or health care provider? Moving to a patient-centered framework for chronic opioid management. Pain Med 2011;12:890-7.

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Original Research Article

OXFORD

EDUCATION & TRAINING SECTION

National Trends in Prescription Opioid Risk Mitigation Practices: Implications for Prescriber Education

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Abstract

Objectives. To assess national trends in selected prescription opioid risk mitigation practices and associations with prescriber type, state-specific opioid overdose severity, and required pain education. **Methods.** Analysis of the national *SCOPE of Pain* registrants' baseline self-report of five safer opioid prescribing practices over three years (March 2013–Februrary 2016). **Results.** Of 6,889 registrants for *SCOPE of Pain,* 70–94% reported performing each of five opioid risk mitigation practices for "most or all" patients, with 49% doing so for all five practices. Only 28% performed all five practices for "all" patients prescribed opioids. There were few differences among three yearly cohorts. Advanced practice nurses reported performing practices for "all" patients more often than physicians or physician assistants. Clinicians from states with high opioid overdose rates reported significantly higher implementation of most practices, compared with clinicians from states with low rates. **Conclusions.** Prescribers report low levels of employing five opioid risk mitigation practices for all patients prescribed opioids before attending a safer opioid prescribing training. **Policy Implications.** Safer opioid prescribing education should transition from knowledge acquisition toward universal implementation of opioid risk mitigation practices.

Key Words: Opioids; Chronic Pain; Education; Continuing

Introduction

Over the past two decades, increases in opioid prescribing for chronic pain have been associated with increases in opioid-related morbidity and mortality in the United States [1]. In response to this national opioid crisis, consensus-based safer opioid prescribing guidelines have been published [2–5] and state laws regulating opioid prescribing practices have been enacted [6,7]. The Centers for Disease Control and Prevention's (CDC's) widely disseminated guideline state that there is "insufficient evidence to determine how harms of opioids differ depending on patient demographics or patient comorbidities" [2]. This statement supports the principle of "universal precautions," which assumes that all patients prescribed opioids are at risk for harm and that risk mitigation strategies should be applied to all patients prescribed opioids [8]. Although applying guideline-recommended practices universally is intended to lessen harm, applying them in clinical practice can be difficult [9–11]. These clinical challenges are in large part due to inadequate clinician training in pain management and safer opioid prescribing [12,13]. To help address this

training gap, the US Food and Drug Administration (FDA) approved in 2012 a single shared Risk Evaluation and Mitigation Strategy (REMS) requiring manufacturers of extended-release/long-acting (ER/LA) opioid analgesics ("opioid REMS") to jointly fund continuing education based on an FDA curricular, Blueprint for Prescriber Education [14,15]. The goal of opioid REMS prescriber education is to make opioid prescribing safer while maintaining access to opioid analgesics for those patients who are benefitting from them [16]. The first opioid REMS activity, entitled Safe and Competent Opioid Prescribing Education (*SCOPE of Pain*), was developed and launched in February 2013 by Boston University School of Medicine [17]. *SCOPE of Pain* is a two-hour live or online case-based lecture (available at www.scopeofpain.org). The curriculum covers assessing chronic pain and opioid misuse risk, safer opioid prescribing, and assessing and managing aberrant medication-taking behaviors. *SCOPE of Pain* has been shown to improve clinician safer opioid prescribing knowledge, attitudes, confidence, and self-reported clinical practices [18,19]. Although the FDA opioid REMS training is voluntary, some states have made pain and opioid prescribing continuing education mandatory [12,20]. The value of mandatory training has been the subject of much debate [21].

Although the severity of the national opioid overdose crisis varies [1], in states where the opioid crisis is more severe, it is unknown if there is an increased need for prescriber education, or if the crisis is due to factors outside of the prescriber's control. One hypothesis is that the opioid crisis is less severe in regions where more prescribers are performing the guideline-recommended clinical practices. Conversely, another hypothesis is that guideline-recommended clinical practices are performed more frequently in regions where the crisis is more severe due to increased prescriber awareness of the problem, resulting in increased motivation to seek solutions. This second hypothesis assumes that a more severe crisis in those states is due to factors beyond the prescriber's control, such as easy access to high-potency and inexpensive illicit opioids.

The implementation of the nationwide opioid REMS prescriber education program provides a unique opportunity to assess how the landscape for applying opioid risk mitigation practices has evolved over time. Thousands of health care providers nationwide have engaged in opioid REMS-supported educational activities, such as *SCOPE of Pain*, and have contributed to pre-activity self-assessments, which provide rich data by which to assess their baseline opioid risk mitigation practices to better inform future prescriber training needs [22].

This manuscript reports on the *SCOPE of Pain* registrants' baseline self-reported use of five selected opioid risk mitigation practices for three consecutive years, according to prescribers' professions (e.g., physician, advanced practice nurse, physician assistant). Associations between the degree of use of these prescription opioid risk mitigation practices and the severity of the registrant's state opioid crisis are also reported. State overdose rates (high or low) and the state's presence or absence of mandated continuing education requirements were taken as proxies for the severity of a state's opioid crisis.

Methods

An analysis was performed using data over three years (March 2013 to February 2016) from providers registering for the *SCOPE of Pain* program including their profession, specialty, years of practice, practice setting, and whether they refer patients to pain specialists. Registrants were also asked to provide their level of agreement (five-point scale: 1 = completely disagree to 5 = completely agree) with statements about managing patients with chronic pain including whether patients with chronic pain are able to provide accurate self-assessments of pain, whether managing patients with chronic pain is time-consuming and frustrating, whether it is the prescriber's responsibility to educate patients about not giving medications to relatives and friends, whether prescribers feel confident in assessing opioid misuse risk in patients with chronic pain, and whether prescribers would prefer to stop managing a patient who has misused his/her opioids.

All registrants self-reported their frequency of use of five selected guideline-based prescription opioid risk mitigation practices: 1) implement a Patient–Prescriber Agreement (including informed consent and plan of care); 2) inform their patients about taking prescription opioids exactly as prescribed (e.g., don't increase dose; don't crush tablets, etc.); 3) educate their patients about safe storage and disposal of prescription opioids; 4) counsel their patients about opioid-related risks of respiratory depression and overdose; and 5) explain to their patients the methods they use to monitor for prescription opioid misuse (e.g., urine drug tests, pill counts). These five clinical practices are universally recommended by published national safer opioid prescribing guidelines [2,3,5,23] and designed by experts in safer opioid prescribing, primary care and addiction medicine (DPA), in educational design (JLW, IH), and in outcomes assessments (PL, SM). For each practice item, registrants could select one of the following four nominal response choices: 1 = none of my patients, 2 = with my high-risk patients only, 3 = most of my patients, and 4 = all of my patients.

The analysis was restricted to the primary target group of the *SCOPE of Pain* program (in alignment with the objectives of the opioid REMS), which consisted of physicians, advanced practice nurses, and physician assistants who are licensed to prescribe opioid analgesics and are from one of the 13 specialties most involved in longitudinal management of patients with chronic pain (listed in Table 1). The analysis compares data from three different cohorts (year 1: March 2013–February 2014; year 2: March 2014–February 2015; year 3: March 2015–February 2016) in order to obtain a longitudinal

Table 1. SCOPE of pain registrant characteristics per year

	Year 1: Mar 2013–Feb 2014 (N = 2,317)	Year 2: Mar 2014–Feb 2015 (N = 1,884)	Year 3: Mar 2015–Feb 2016 (N = 2,688)	Total (N = 6,889)
Profession, No. (%) (significant difference between cohort distributions; chi-square $P < 0.001$)				
Physician	1,630 (70)	1,287 (68)	1,880 (70)	4,797 (70)
Advanced Practice Nurse	507 (22)	398 (21)	490 (18)	1,395 (20)
Physician Assistant	180 (8)	199 (11)	318 (12)	697 (10)
Specialty, No. (%) (significant difference between cohort distributions; chi-square $P < 0.001$)				
Family Practice	1,026 (44)	666 (35)	1,023 (38)	2,715 (39)
Internal Medicine	725 (31)	620 (33)	847 (32)	2,192 (32)
Anesthesiology	129 (6)	128 (6)	152 (6)	389 (6)
Hematology and Oncology	98 (4)	124 (7)	152 (6)	374 (5)
Physical Medicine and Rehabilitation	115 (5)	108 (6)	147 (5)	370 (5)
Orthopedic Surgery	63 (5)	107 (6)	136 (5)	306 (4)
Neurology	63 (3)	71 (4)	98 (4)	232 (3)
Pediatrics	29 (1)	21 (1)	39 (1)	89 (1)
Rheumatology	35 (2)	20 (1)	26 (1)	81 (1)
Obstetrics and Gynecology	17 (1)	21 (1)	35 (1)	73 (1)
Infectious Diseases	9 (0)	13 (1)	21 (1)	43 (1)
Sports Medicine	6 (0)	3 (0)	12 (0)	21 (0)
Adolescent Medicine	2 (0)	2 (0)	0 (0)	4 (0)
Years of practice, No. (%) (significant difference between cohort distributions; chi-square $P = 0.045$)				
0–5 y	572 (25)	490 (26)	748 (28)	1,810 (26)
6–10 y	350 (15)	295 (16)	415 (15)	1,060 (15)
11–20 y	651 (28)	504 (27)	760 (28)	1,915 (28)
≥21 y	718 (31)	576 (31)	750 (28)	2,044 (30)
Did not answer	26 (1)	19 (1)	15 (1)	60 (1)
Practice setting, No. (%) (significant difference between cohort distributions; chi-square $P < 0.001$)				
Urban	894 (39)	704 (37)	1,080 (40)	2,678 (39)
Suburban	816 (35)	702 (37)	1,067 (40)	2,585 (38)
Rural	559 (24)	438 (23)	484 (18)	1,481 (22)
Other	48 (2)	40 (2)	57 (2)	145 (2)

assessment of the uptake of these safer opioid prescribing practices. The Boston University Medical Campus Institutional Review Board (IRB) determined this evaluation to be exempt from further IRB review.

Analyses

For each clinical practice item, data were distinguished in two ways: by combining responses 3 = most of my patients and 4 = all of my patients as "most or all," and by isolating 4 as "all of my patients." Similarly, each attitudinal item was dichotomized by grouping those who answered 4 or 5 on the five-point scale. Frequencies and cross-tabulations were then calculated using IBM SPSS 22.0 software (IBM Corporation, Armonk, NY, USA). Chi-squares were calculated between the three yearly cohorts and between subgroups based on the registrants' professions and characteristics of their practice states. Pair-wise post hoc analyses were conducted between the three yearly cohorts and between the profession subgroups using a Bonferroni-adjusted alpha value needed for significance of 0.05/3 (as three pairs are being tested), or 0.0167. In all other cases, the statistical significance threshold level was predetermined at alpha = 0.05. In addition, the registrants' practice states were grouped in two different ways: 1) states with the 10 highest/lowest 2014 age-adjusted overdose death rates [24] and 2) states with/without opioid prescribing education requirements [12].

Results

Sample Description

Pretraining (baseline) assessment data from the 6,889 *SCOPE of Pain* program registrants in all 50 US states and the District of Columbia, representing the primary target group described above, were used for the purpose of this study (Table 1). This sample included 70% physicians, 20% advanced practice nurses, and 10% physician assistants, with 71% of the registrants practicing in family medicine or internal medicine. Fifty-eight percent of the registrants reported having more than 10 years of practice experience, with 39% in urban, 38% in suburban, and 22% in rural settings. Although the three yearly cohorts were significantly different by profession ($P < 0.001$), specialty ($P < 0.001$), years of practice ($P = 0.045$), and practice setting ($P < 0.001$), the absolute differences (up to 6%) do not appear to be meaningful. Fifty-four percent (3,749/6,889) of the total cohort reported referring only their "high risk" patients to pain medicine experts, whereas 13% (885/6,889) reported never referring their patients.

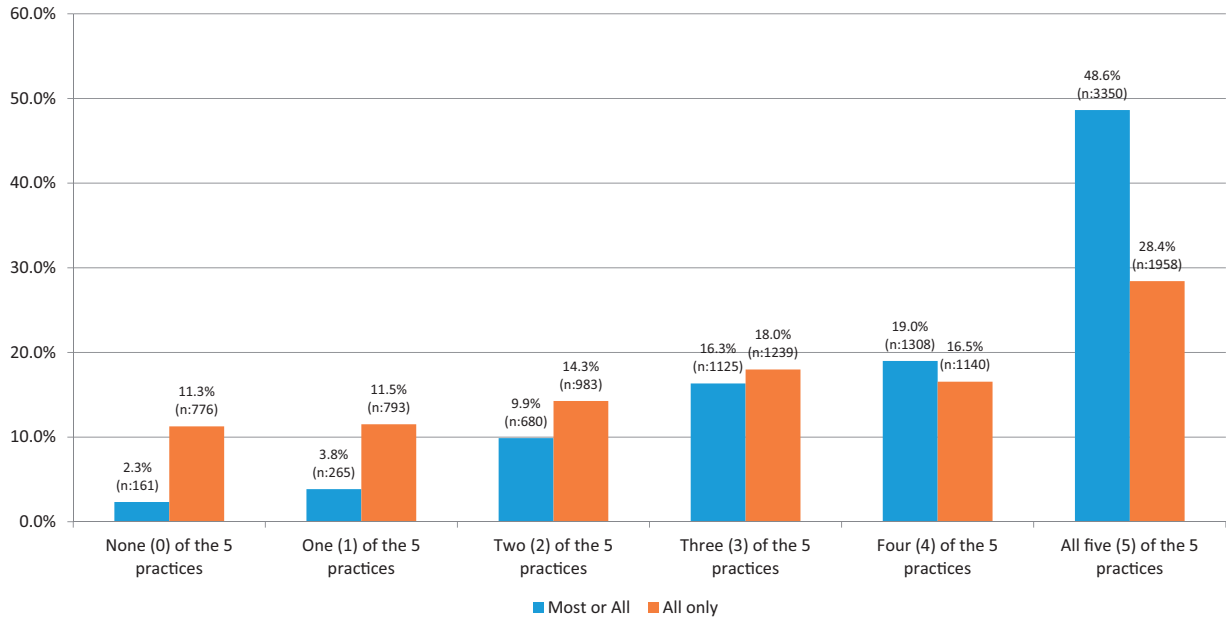

Figure 1. Number of opioid risk mitigation practices performed with "all or most" and with "all" patients (out of five).

Baseline Attitudes Regarding Managing Patients with Chronic Pain

At baseline, 68% (4,671/6,889) of registrants felt that treating and managing patients with chronic pain is time-consuming and frustrating; only 50% (3,456/6,889) agreed that most patients with chronic pain are able to provide an accurate self-assessment of their pain; 90% (6,212/6,889) agreed that it is their responsibility to discuss not giving away medications to relatives and friends; 43% (2,948/6,889) felt unsure about assessing for opioid misuse risk in patients with chronic pain; and 59% (4,053/6,889) would prefer to stop managing a patient who has misused his/her opioids.

Opioid Risk Mitigation Practices by Total Sample and Yearly Cohorts

Of the 6,889 registrants for *SCOPE of Pain* who met the criteria for the program's primary target group, 68% (4,658/6,889) reported performing at least four of the five opioid risk mitigation practices for "most or all" patients, whereas 49% (3,350/6,889) reported performing all five guideline-based practices for "most or all" patients (Figure 1, Table 2). Less than half (45%, 3,098/6,889) performed at least four of the practices with "all" patients, whereas only 28% (1,958/6,889) did so for all five practices.

Among all cohorts, 94% reported informing "most or all" of their patients about taking prescription opioids exactly as prescribed, and 79% did so for "all" of their patients. Eighty-seven percent reported counseling "most or all" of their patients about the risks of respiratory depression and overdose, and 66% did so for "all" of their patients. Approximately 70% of respondents reported performing the remaining three practices for "most or all" of their patients, including implementing a Patient–Prescriber Agreement (70%, including 54% for "all"), educating patients about safe storage and disposal (71%, including 51% for "all"), and explaining the methods used for monitoring for misuse (70%, including 53% for "all"). There were statistically significant differences between the three yearly cohorts for two of the five practices; however, there were no consistent temporal trends over three years.

Opioid Risk Mitigation Practices by Profession

All five safer opioid prescribing practices were reported as being carried out with "all" patients by a higher proportion of advanced practice nurses, compared with physicians and physician assistants (Table 2). Physicians performed two of the five practices with "most or all" of their patients significantly more often than the other clinical professions, whereas the remaining three were performed more often by advanced practice nurses.

Opioid Risk Mitigation Practices in States with vs without Pain-Specific Education Requirements

A significantly higher proportion of registrants practicing in states without pain-specific education requirements reported educating their patients about safe storage and disposal of prescription opioids "most or all" of the time than those with state education requirements (73% vs 69% $P = 0.001$) (Table 3). There were no significant differences found between states with and without mandatory pain-specific education in the remaining four opioid risk mitigation practices.

Table 2. Baseline self-reported opioid risk mitigation practices of SCOPE of pain registrants per year and by profession over three years

	Total Sample (N = 6,889)	Year 1: Mar 2013–Feb 2014 (N = 2,317)	Year 2: Mar 2014–Feb 2015 (N = 1,884)	Year 3: Mar 2015–Feb 2016 (N = 2,688)		Physician (N = 4,797)	Advanced Practice Nurse (N = 1,395)	Physician Assistant (N = 697)	
Safer Opioid Prescribing Practice	No. (%) Who Answered "Most or All of My patients" No. (%) Who Answered "All of My patients"				*P* Value (Chi-Square)	No. (%) Who Answered "Most or All of My Patients" No. (%) Who Answered "All of My patients"			*P* Value (Chi-Square)
Implement and cosign a Patient–Prescriber Agreement (including informed consent and plan of care)	4,807 (70) 3,693 (54)	1,645 (71) 1,223 (53)	1,327 (70) 1,063 (56)	1,835 (68) 1,407 (52)	0.085 0.015* Y2>Y3	3,436 (72) 2,586 (54)	932 (67) 762 (55)	439 (63) 345 (49)	<0.001** PH>APN, PH>PA <0.064
Inform my patients about taking prescription opioids exactly as prescribed (e.g., don't increase dose; don't crush tablets, etc.)	6,499 (94) 5,465 (79)	2,187 (94) 1,858 (80)	1,780 (95) 1,485 (79)	2,532 (94) 2,122 (79)	0.912 0.452	4,500 (94) 3,704 (77)	1,344 (96) 1,216 (87)	655 (94) 545 (78)	0.001** APN>PH <0.001** APN>PH APN>PA
Educate my patients about safe storage and disposal of prescription opioids	4,876 (71) 3,508 (51)	1,610 (69) 1,144 (49)	1,355 (72) 998 (53)	1,911 (71) 1,366 (51)	0.203 0.067	3,266 (68) 2,306 (48)	1,109 (79) 845 (61)	501 (72) 357 (51)	<0.001** APN>PH, APN>PA <0.001** APN>PH, APN>PA
Counsel my patients about risk of opioid-associated respiratory depression and overdose	5,997 (87) 4,533 (66)	2,024 (87) 1,510 (65)	1,628 (86) 1,261 (67)	2,345 (87) 1,762 (66)	0.620 0.459	4,134 (86) 3,056 (64)	1,260 (90) 1,022 (73)	603 (87) 455 (65)	<0.001** APN>PH, APN>PA <0.001** APN>PH, APN>PA
Explain to my patients the methods I use to monitor for prescription opioid misuse (i.e., urine drug tests and/or pill counts)	4,803 (70) 3,627 (53)	1,639 (71) 1,223 (53)	1,321 (70) 1,052 (56)	1,843 (69) 1,352 (50)	0.225 0.001* Y2>Y3	3,392 (71) 2,488 (52)	956 (69) 784 (56)	455 (65) 355 (51)	0.008** PH>PA 0.011** APN>PH

*Indicates which pairwise post hoc analysis showed a significant difference between year 1 (^{Y1}), year 2 (^{Y2}), and/or year 3 (^{Y3}) using a Bonferroni-adjusted α value needed for significance of 0.05/3 (as three pairs are being tested), or 0.0167.

**Indicates which pairwise post hoc analysis showed a significant difference between Physicians (^{PH}), Advanced Practice Nurses (^{APN}), and/or Physician Assistants (^{PA}) using a Bonferroni-adjusted α value needed for significance of 0.05/3 (as three pairs are being tested), or 0.0167.

Table 3. Baseline self-reported opioid risk mitigation practices of SCOPE of pain registrants by highest and lowest state-specific opioid overdose rates and by state-required pain education over 3 years

	State-Required Pain Education			State-Specific Drug Overdose Rate		
	With (N = 4,016)	Without (N = 2,780)		Among 10 Highest (N = 1,035)	Among 10 Lowest (N = 1,467)	
Opioid Risk Mitigation Practices	No. (%) Who Answered "Most or All of My Patients" No. (%) Who Answered "All of My Patients"		*P* Value (Chi-Square)	No. (%) Who Answered "Most or All of My Patients" No. (%) Who Answered "All of My Patients"		*P* Value (Chi-Square)
Implement and cosign a Patient–Prescriber Agreement (including informed consent and plan of care)	2,788 (69) 2,144 (53)	1,966 (71) 1,512 (54)	0.251 0.415	763 (74) 636 (61)	956 (65) 688 (47)	<0.001 <0.001
Inform my patients about taking prescription opioids exactly as prescribed (e.g., don't increase dose; don't crush tablets, etc.)	3,779 (94) 3,158 (79)	2,633 (95) 2,234 (80)	0.281 0.084	990 (96) 839 (81)	1,364 (93) 1,122 (76)	0.005 0.006
Educate my patients about safe storage and disposal of prescription opioids	2,775 (69) 2,008 (50)	2,028 (73) 1,440 (52)	0.001 0.145	764 (74) 555 (54)	978 (67) 706 (48)	<0.001 0.007
Counsel my patients about risk of opioid-associated respiratory depression and overdose	3,480 (87) 2,625 (65)	2,432 (87) 1,843 (66)	0.318 0.426	899 (87) 695 (67)	1,277 (87) 940 (64)	0.890 0.112
Explain to my patients the methods I use to monitor opioid misuse (i.e., urine drug tests and/or pill counts)	2,792 (70) 2,107 (52)	1,952 (70) 1,480 (53)	0.540 0.531	750 (72) 596 (58)	968 (66) 692 (47)	0.001 <0.001

Opioid Risk Mitigation Practices in States with High vs Low Drug Overdose Rates

Registrants whose clinical practice was in the 10 states with the highest drug overdose rates reported significantly higher use of four out of the five guideline-based practices for both "all" and "most or all" of their patients (i.e., implementing an agreement, informing patients to take opioids exactly as prescribed, educating patients about safe storage and disposal of opioids, and explaining to patients the methods used for monitoring for misuse) when compared with registrants whose clinical practice was in the 10 states with the lowest drug overdose rates (Table 3).

Discussion

Health care providers who registered for Boston University School of Medicine's Safe and Competent Opioid Prescribing Education (*SCOPE of Pain*) program over three years reported high levels of pretraining guideline-based opioid risk mitigation practices for "most or all" of their patients with chronic pain who were prescribed opioids, with a lesser proportion performing these practices with "all" of their patients. Although there were statistically significant differences between the three yearly cohorts for some practices, there were no consistent temporal trends.

Advanced practice nurses reported significantly higher levels of baseline safer opioid prescribing practices for "all" of their patients (except the item "implement and cosign a Patient–Prescriber Agreement," which was proportionately higher for advanced practice nurses but not statistically significantly so) when compared with the other two clinical professions analyzed (physicians and physician assistants). Higher adherence to guideline-based care among advanced practice nurse could be explained by differences in their training and view of guideline recommendations. Physicians are trained to consider deviating from consensus-based guidelines based on low-quality evidence when alternate approaches are deemed clinically appropriate for a specific patient, whereas nurses are trained to adhere to guidelines as literal standards and descriptions of mandatory professional practices [25–27]. Factors leading to physician nonadherence with guidelines have been described, including gaps in knowledge, attitudes, and behavior [28].

High reported use of the recommended practices with "most or all" patients suggests that clinicians are knowledgeable of the specific risk mitigation practices. However, the lack of universal application of the practices may be due to lack of knowledge or disagreement with the concept of universal opioid misuse risk. It may also be a result of the complexities of implementing these practices universally as it is time-consuming in clinical settings, where there are many competing priorities. Finally, lack of universal adoption of these practices may

be secondary to the lack of robust evidence supporting them. Providers are reluctant to follow guidelines if they do not believe that they will lead to consistent clinical benefits. These findings suggest that training needs to address the rationale for universal precautions when prescribing opioids and to address strategies for efficient implementation of opioid risk mitigation practices [29].

Only half of the registrants felt that patients with chronic pain could accurately self-assess their pain, and less than half felt comfortable assessing their patients for opioid misuse risk. The majority of registrants reported that managing patients with chronic pain is time-consuming and frustrating and that they would rather not continue to manage a patient who has misused their prescription opioid. These findings highlight the need for training beyond the guidelines to address providers' concerns and frustrations around managing patients with chronic pain such as trusting patients' self-assessments of pain with the development of an individualized treatment plan based on a careful risk and benefit assessment, setting up systems to support team-based care, and learning how to assess and manage patients' concerning behaviors suggestive of opioid misuse. Not surprisingly, the majority of respondents reported that they only referred their high risk patients to pain management specialists. This highlights the lack of appropriate comprehensive multimodal pain management referral options, which has been reported previously, along with limited insurance coverage for these services [30,31] and the reality that generalist clinicians often are left managing these very complex patients without benefit of expert consultation.

We used higher state drug overdose rates and the presence of state-mandated pain education as proxies for states with the most severe opioid crisis. In states with the highest drug overdose rates, four of the five opioid mitigation practices were performed significantly more frequently with "all" or "most or all" patients prescribed opioids. In states with mandated pain education, there were no practices performed at a higher rate for "all" patients than in states without education requirements. This suggests that in states with high overdose rates, as opposed to states with mandated pain education, providers may be more motivated to apply opioid risk mitigation strategies.

There is also a growing literature that looks beyond the safer opioid prescribing guidelines with a focus on the complexities and challenges of implementation and patient communication. Although a clinical practice may successfully follow national opioid risk mitigation guidelines (e.g., implementing Patient–Prescriber Agreements, urine drug monitoring), the implementation of these practices may be perceived as judgmental, stigmatizing, and punitive by the patient [32–34]. Clinicians describe complicated clinical relationships around the issues of opioids and chronic pain, which may prevent the development of a trusting relationship and result in antagonism between what the patient requests or demands and what the provider considers safe and appropriate [33]. Managing patients who use more opioids than prescribed and who continually request higher opioid doses involves particularly challenging clinical encounters. A qualitative study [35] of what opioid REMS educational activity registrants wanted to learn found a desire to understand how to maintain a positive provider–patient relationship while implementing safer opioid prescribing practices. Nicolaidis [36] described a patient-centered framework for chronic opioid management including staying in the clinician role and avoiding falling into the role of police officer or deal-maker. She described a benefit-to-harm approach that judges the opioid treatment and not the patient taking opioids. Published case discussions [9,37] have addressed the complexities of applying guideline-based care such as assessing and managing patients exhibiting aberrant opioid-taking behaviors (e.g., unexpected urine drug tests, requests for early opioid refills). If clinicians follow guidelines including urine drug monitoring but are unable to appropriately interpret the results, this can potentially adversely affect patient care [32,37]. If the Patient–Prescriber Agreement is written at a too high a reading level or is not reviewed periodically, it misses an important opportunity to educate the patient about safer opioid use. Looking forward, our results suggest that continuing education should transition from discussing what these guideline-based opioid risk mitigation practices are to why these practices are important and how to implement them efficiently and universally in clinical practice.

There are several limitations of this study. Since the clinical practice behaviors were self-reported, the answers of the registrants could be influenced by a social desirability bias. However this is less likely since these were baseline assessments in individuals who were registering to receive further training. Also participants were aware that the data collected would be aggregated and de-identified. In addition, data used were from registrants to a safer opioid prescribing educational program, and may not be generalizable to non-registrants. However, those seeking education may have the greatest perceived need. Differences between the demographic and clinical characteristics of the respondents in the three yearly cohorts may have had an impact on the comparisons that are able to be drawn between them. In terms of responses, there is an acknowledged possibility that some of the prescribers indicated that they did not engage in a particular practice because they knew another member of the team was doing it, rather than that practice being absent from their clinical setting altogether.

Conclusions

The prescription opioid morbidity and mortality crisis may have influenced clinician opioid risk mitigation practices, according to this analysis of pre-training self-reports from the opioid REMS *SCOPE of Pain* training program. This finding is in accordance with the

hypothesis that guideline-based clinical practices are performed more frequently in regions where the crisis is more severe, due to an increased motivation to seek solutions and education, although further studies are required to confirm this causality. Despite increased national dialogue about prescription opioid misuse from 2013 to 2016, we did not find any significant temporal trends in the use of opioid risk mitigations practices.

In September 2018 the FDA released a revised expanded REMS curricular blueprint which now includes acute and chronic pain management; nonpharmacologic and pharmacologic treatments for pain (both nonopioids and immediate-release and extended-release opioids); and content on addiction medicine [38]. The expansion of the opioid REMS program to include nonopioid pain treatments is essential as opioid prescribing decreases [39]. The inclusion of addiction medicine is important due to increases in opioid-related overdoses secondary to rises in heroin and illicit fentanyl use [40]. In addition to content expansion, it will be important for future trainings to go beyond improving provider knowledge. Based on our findings, future opioid REMS trainings should include content on optimizing pain management delivery systems and provider communication skills to ensure universally applied empathic, safe, and effective patient-centered care that better serves patients in pain and prevents frustration, burnout and cynicism in the providers taking care of them.

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OXFORD

EDUCATION & TRAINING SECTION

Original Research Article

SCOPE of Pain: An Evaluation of an Opioid Risk Evaluation and Mitigation Strategy Continuing Education Program

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Abstract

Objective. Due to the high prevalence of prescription opioid misuse, the US Food and Drug Administration (FDA) mandated a Risk Evaluation and Mitigation Strategy (REMS) requiring manufacturers of extended-release/long-acting (ER/LA) opioid analgesics to fund continuing education based on a *FDA Blueprint*. This article describes the Safe and Competent Opioid Prescribing Education (*SCOPE of Pain*) program, an ER/LA opioid analgesic REMS program, and its impact on clinician knowledge, confidence, attitudes, and self-reported clinical practice.

Method. Participants of the 3-h *SCOPE of Pain* training completed pre-, immediate post- and 2-month post-assessments.

Subjects. The primary target group (n = 2,850), and a subset (n = 476) who completed a 2-month post-assessment, consisted of clinicians licensed to prescribe ER/LA opioid analgesics, who care for patients with chronic pain and who completed the 3-h training between February 28, 2013 and June 13, 2014.

Results. Immediately post-program, there was a significant increase in correct responses to knowledge questions (60% to 84%, $P \leq 0.02$) and 87% of participants planned to make practice changes. At 2-months post-program, there continued to be a significant increase in correct responses to knowledge questions (60% to 69%, $P \leq 0.03$) and 67% reported increased confidence in applying safe opioid prescribing care and 86% reported implementing practice changes. There was also an improvement in alignment of desired attitudes toward safe opioid prescribing.

Conclusions. The *SCOPE of Pain* program improved knowledge, attitudes, confidence, and self-reported clinical practice in safe opioid prescribing. This national REMS program holds potential to improve the safe use of opioids for the treatment of chronic pain.

Key Words. Chronic Pain; Opioid Medications Continuing Education

Introduction

Chronic pain affects approximately 100 million in the United States, making it one of the most common reasons patients seek medical care [1,2]. Undertreated chronic pain causes reduced function and quality of life [3], and is associated with increased rates of suicidality [4,5]. However, more aggressive chronic pain management with opioid analgesics over the past two decades has been associated with an increase in prescription

opioid misuse including addiction, diversion, and overdose deaths [6–11]. Determinants for increased opioid-related mortality have been described including high-volume and high-dose prescribing [12]. Despite concerns over misuse, opioid analgesics remain an important treatment for some patients' chronic severe pain [1,13–15]. According to the Institute of Medicine report, "regulatory, legal, educational, and cultural barriers inhibit the medically appropriate use of opioid analgesics [1]." Numerous safe opioid prescribing guidelines have been published [16–21], however, recent reports show that adherence with these guidelines is low [22–24].

Clinicians struggle to balance the benefits and harms associated with opioid prescribing [4,25]. While pain management education remains inadequate [26–30], it is a key strategy to address the prescription opioid misuse problem [31]. In July 2012, the US Food and Drug Administration (FDA) approved a single shared Risk Evaluation and Mitigation Strategy (REMS) required of manufacturers of extended-release/long-acting (ER/LA) opioid analgesics to promote safe use of these medications [32]. While most FDA-mandated REMS programs include medication guides and communication plans and are associated with a single medication, this REMS requires all manufacturers to jointly fund accredited continuing education for the approximately 320,000 ER/LA opioid prescribers in the United States [33]. The FDA created the *Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics* ("FDA Blueprint") to define the content that must be included in REMS educational programs [34,35]. Boston University School of Medicine (BUSM), the first Continuing Medical Education provider to receive ER/LA opioid REMS funding, launched its Safe and Competent Opioid Prescribing Education (*SCOPE of Pain*) program on February 28, 2013.

As a new national strategy, the effectiveness of requiring manufacturers to contribute funds to support independent education based on an FDA Blueprint is unknown. The purpose of this study is to describe the *SCOPE of Pain* program and report on its impact on participants' knowledge, attitudes, confidence, and self-reported practice. As the first report on an ER/LA opioid REMS program, the data from this project can offer an initial assessment of effectiveness of this national strategy to improve practices.

Methods

SCOPE of Pain Description

SCOPE of Pain is based on the FDA Blueprint [36] and is offered as a 3-h live or online activity available at www.scopeofpain.org. The live programs included 20 half-day standalone meetings across the United States in 16 different states. The live and online curricula are identical and presented using a clinical case involving three separate visits: *initial visit*—assessing chronic pain and opioid misuse risk; *one week later*—initiating (continuing) opioid therapy safely and *months later*—assessing and managing aberrant medication taking behaviors. This allows participants to apply the ER/LA opioid REMS content to a common clinical scenario. *SCOPE of Pain* was created based on an existing online and live education program we developed in 2010 called "*Safe and Effective Opioid Prescribing for Chronic Pain*" (www.opioidprescribing.org) that had trained approximately 19,000 clinicians. A team of 13 faculty with expertise in pain management, addiction, primary care, and medical education created the original *Opioid Prescribing* program and a team of five experts tailored that content to cover all aspects of the FDA Blueprint to make the program REMS compliant. While the original content was well aligned with the FDA Blueprint, specific topics were expanded including opioid prescribing using a risk/benefit framework, effective communication skills for assessing and managing aberrant medication taking behaviors and strategies for team-based care. While the content was not formally tested, evaluation data from the over 5,000 participants of the original *Opioid Prescribing* program were used to inform the creation of the *SCOPE of Pain* program.

To ensure that the curriculum covered all FDA Blueprint elements, BUSM conducted both internal and external audit processes and an additional independent audit was conducted by the Accreditation Council for Continuing Medical Education (ACCME). The Boston University Medical Campus Institutional Review Board (IRB) determined this evaluation to be exempt from further IRB review.

Outcomes

A repeated measures design was used to assess the impact of *SCOPE of Pain* in changing clinicians' knowledge, attitudes, confidence, and clinical practice. Data were collected from participants at three time points: 1) pre-program (PRE), 2) immediate post-program (IMMED), and 3) 2-months post-program (2MO) (Figure 1). This design assessed changes over time with specific attention to increased alignment with practices described in the FDA Blueprint.

Items to assess participants' changes were designed by a multidisciplinary team including: a faculty expert in opioid prescribing, primary care and addiction medicine (DPA), experts in educational design (LZ, JLW, IH) and experts in outcomes assessments (SMH, SP, PN). Items were developed with the four key metrics of change that *SCOPE of Pain* targets: 1) twenty (20) items to assess improvements in *knowledge* (of which only 10 were repeated at 2MO to minimize respondents' burden and allow for additional questions about changes in performance), 2) six (6) items regarding change in

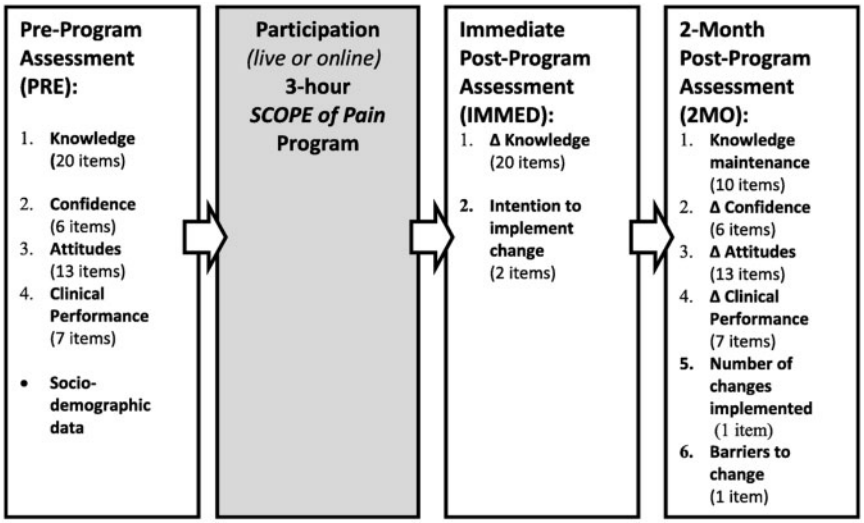


Figure 1 Evaluation of SCOPE of Pain: Data collection points and associated outcome metrics.

participant *confidence* to manage patients with chronic pain, 3) thirteen (13) items assessing change in *attitudes* (*motivation and willingness)* when treating patients with chronic pain and using guideline-based care; and 4) multiple items addressing changes in *clinical practice* including: a) two (2) items assessing intention to change clinical practice; b) seven (7) items assessing participants' reported changes in clinical performance; c) one (1) item assessing number of changes implemented; and d) one (1) item assessing barriers to implementing change in practice.

To be REMS compliant, the assessment was required to have knowledge-based questions from each of the six sections of the FDA Blueprint [36]. The course director (DPA) who specializes in primary care, pain management and addiction medicine and program education experts (LZ, IH, JLW) determined which elements from each section were best suited for knowledge-based questions and most relevant to practicing clinicians. Confidence and performance questions were based on guideline-based [17–21] safe opioid prescribing practices (e.g., risk and benefit assessments, monitoring and management strategies) and important communication skills. Each item was tested and retested for face validity, and linked explicitly to elements within the six sections of the FDA Blueprint for content validity. All questions were tested by primary care clinicians from general internal medicine and family medicine and pain and addiction medicine experts. The questionnaires used did not undergo validity testing as the evaluation was designed for a new educational program without a known gold standard or preexisting criterion by which to validate.

The PRE/IMMED/2MO items are quantitative using forced choice (drop-down) options. Knowledge-testing questions were a combination of multiple nominal choice responses (including dichotomous true/false questions and item-matching questions). Likert-type response formats were used for self-reported assessment of confidence, attitudes, and clinical practice.

Participant Recruitment

The primary target group included clinicians who manage patients with chronic pain longitudinally. This included primary care and other specialties that manage chronic pain such as hematology, oncology, rheumatology, rehabilitation medicine, sports medicine, neurology, orthopedics, and anesthesiology. While promotion for the program and collection of pre-assessment (PRE) and post-assessment (IMMED and 2MO) data extended beyond the primary target group, only participants whose specialty indicated a likelihood for managing chronic pain were included in this study.

All participants completed the pre-assessment on registration. Participants were required to complete the immediate post-assessment to receive continuing education credit. A drawing for an e-book reader was used to incentivize completion of the 2-month post-assessment. As an email address was collected for all participants, an email was automatically sent to all participants at 60 days, with a reminder at 63 days, and 66 days post-activity for those who did not complete the assessment.

Analyses

Using IBM SPSS 22.0 software (IBM Corporation, Armonk, NY), frequencies and cross-tabulations were calculated for each item. Paired *t*-tests were used to identify participant knowledge change (PRE vs IMMED) and knowledge maintenance (PRE vs 2MO). Paired *t*-tests were also used to compare participants' attitudes and clinical practice (PRE vs 2MO) to establish change in clinical practice two months after participation.

Table 1 *SCOPE of Pain* participant characteristics

	Primary Target Group (n = 2,850)	Completed 2-Month Post-Program Assessment (n = 476)
Profession n, (%)		
Physician	1,955 (69%)	288 (61%)
Advance practice nurse*	706 (25%)	154 (32%)
Physician assistant	189 (6%)	34 (7%)
Specialty n, (%)		
Family practice	1,179 (41%)	235 (49%)
Internal medicine	791 (28%)	117 (25%)
Anesthesiology	183 (6%)	26 (6%)
Pediatrics	159 (6%)	19 (4%)
Orthopedic surgery	105 (4%)	14 (3%)
Physical medicine and rehabilitation	115 (4%)	17 (4%)
Hematology and oncology	85 (3%)	12 (2%)
Obstetrics and gynecology	83 (3%)	12 (2%)
Neurology	63 (2%)	11 (2%)
Rheumatology	52 (2%)	5 (1%)
Infectious disease	25 (1%)	6 (1%)
Sports medicine	7 (0.2%)	1 (0.2%)
Adolescent medicine	3 (0.1%)	1 (0.2%)
Years of practice n, (%)		
1–5 years	659 (23%)	118 (25%)
6–10 years	405 (14%)	74 (16%)
11–20 years	783 (27%)	116 (24)
>21 years	950 (33%)	160 (34)
Other	21 (2%)	8 (1%)
Participant type n, (%)		
Online	2,203 (77%)	315 (66%)
Live	647 (23%)	161 (34%)

*Significant difference between the group that completed the *SCOPE of Pain program* and those that completed the 2-MO post-assessment at the $P = 0.05$ level.

Results

Participants

A total of 10,566 participants completed *SCOPE of Pain* between February 28, 2013 and June 13, 2014. Twenty-seven percent (2,850/10,566) were considered our primary target group (defined as being physicians, advanced practice nurses, or physician assistants licensed to prescribe opioid analgesics and a member of 13 specialties that routine manage patients with chronic pain (Table 1). The primary target group was made up of mostly physicians (69%), primary care specialties (75%), and clinicians practicing for greater than 10 years (60%). A majority of participants (77%) completed the training online rather than live. All 2,850 participants completed the PRE and IMMED assessments. Of those, 17% (476/2,850) completed the 2MO assessment. Table 1 presents the socio-demographics for the primary target group who completed *SCOPE of Pain* compared with the subset who also completed the 2MO assessment. The two groups were similar, except for a higher proportion of advanced practice nurses completing the 2MO assessment ($P < 0.001$).

The following section focuses on the findings divided into two sections 1) IMMED and 2) 2MO assessment. Findings are grouped by the type of expected impact of *SCOPE of Pain* on participants (knowledge, confidence, attitudes, and clinical practice).

IMMED: Immediate Post-Program Assessment (N = 2,850)

Knowledge. A significantly higher proportion of participants responded correctly to the 20 knowledge items in the IMMED compared with PRE, 84% vs 60% ($P \leq 0.02$), respectively.

Intention to Change. Immediate post-program, 87% of participants stated they were planning to make at least one change to align their practice with guideline-based

Table 2 Changes in confidence in performing guideline-based clinical practices

Statements	2-Months Post-Program Assessment (n = 476)		
	Rate your confidence in your ability to accomplish each of the following as you attended the program:		
	Increased	Remained the same	Decreased
Assess pain in a new patient?	65% (311)	32% (153)	3% (12)
Assess the potential benefit and risk of opioids for chronic pain in a new patient?	72% (341)	26% (126)	2% (9)
Communicate and collaborate with patients around opioid initiation?	71% (338)	28% (132)	1% (6)
Monitor patients on chronic opioid therapy for opioid misuse, including addiction and diversion?	63% (301)	34% (164)	2% (11)
Effectively and efficiently assess your patients for potential misuse of opioids?	67% (318)	32% (151)	1% (7)
Effectively communicate with your patients when treatment has shown no benefit	63% (300)	34% (160)	3% (16)

care. The most frequently stated changes were 1) to improve opioid prescribing documentation (56%); 2) to implement or improve opioid prescribing patient education or communication (53%); and 3) to institute or improve Patient-Prescriber Agreements (47%).

2MO: 2-Months Post-Program Assessment (N = 476)

Knowledge Maintenance. Compared with the PRE, the proportion of correct responses at 2MO was significantly ($P \leq 0.03$) higher for 7 out of the 10 knowledge questions on opioid misuse risk factors and risk assessment. While the improvement in correct responses in the 2MO (69%) compared with PRE (60%) was modest, it was significant.

Confidence. Approximately two-thirds of participants reported increased confidence in guideline-based opioid prescribing practices including assessing pain and opioid misuse risk and assessing, monitoring and discussing opioid benefits, risks, and harms with their patients (Table 2).

Attitudes. Participants reported on average an increase of 9% in alignment with increased trust in their patients and with guideline-based care ($P \leq 0.01$). For example, to the statement *I trust that available pain scales provide reliable assessment of pain in my patients*, 48% of participants responded 4 or 5 on the agreement scale (1 is completely disagree and 5 is completely agree) at 2MO, as compared with 31% at PRE, a 17% increase ($P < 0.01$). For the items for which a decrease in agreement was desired, the proportion of participants who reported being in agreement decreased on average by 7% ($P \leq 0.02$) (Table 3).

Clinical Practice (Patient Communication and Guideline-Based Care)

Patient Communication (Table 4)

Improvements were made in all seven recommended communication skills with a significant increase from PRE to 2MO in participants reporting performing these behaviors with most/all of their patients with chronic pain from an average of 64% to 78% ($P < 0.01$), respectively.

Guideline-Based Care (Table 5)

When presented with nine specific clinical practice changes at 2MO: 68% had either partially or fully improved their opioid prescribing documentation in patient medical records, 67% reported having implemented or improved patient education and communication relating to opioid prescribing and 52% reported having implemented/improved urine drug testing for monitoring opioid adherence and misuse. Approximately 60% reported partially/fully implementing four or more changes in their practice with 35% implementing 7–9 changes.

Barriers to Change

Eighty-three percent of participants reported at least one barrier to making practice change. The most significant barriers reported were patients' resistance to change (23%) followed by other providers' or institutional resistance to change (17%).

Table 3 Changes in attitude in managing patients with chronic pain (n = 476)

Statement	Desired Change	Percent (n) Reported ≥ 4 on the Agreement Scale Scale: 1-Strongly Disagree to 5-Completely Agree Pre-Program	2-Month Post-Program	% Change	*P* value
Statements that should have MORE agreement					
I trust that most of my patients with chronic pain are able to provide an accurate self-assessment of their pain	↑	48% (227)	50% (239)	+2%	0.314
I trust that available pain scales provide reliable assessment of pain in my patients	↑	31% (149)	48% (230)	+17%	<0.001
It is my responsibility and role to discuss with my patients not to give away their medications to relatives or friends	↑	92% (437)	96% (459)	+4%	0.001
I am comfortable responding to family calls about my patients' possible misuse of opioids	↑	50% (237)	62% (296)	+12%	<0.001
Statements that should have LESS agreement					
There is no reliable way to identify those of my patients who are drug-seekers	↓	29% (138)	21% (102)	−8%	0.020
Treating and managing patients with chronic pain is time-consuming and frustrating	↓	68% (326)	64% (304)	−4%	0.054
I will never prescribe ER/LA opioids to a patient with history of mental health issues	↓	16% (77)	17% (82)	+1%	0.564
I cannot get my patients to be truthful about illicit drug use	↓	29% (137)	22% (107)	−7%	0.004
I am uncomfortable communicating an unexpected urine drug test result to my patients	↓	24% (112)	20% (97)	−4%	0.187
I am unsure I am effectively assessing opioids misuse risk in my patients with chronic pain on ER/LA opioids	↓	48% (226)	31% (147)	−4%	<0.001
I suspect there is more I should be doing in the treatment and management of my patients who report chronic pain	↓	76% (360)	58% (275)	−18%	<0.001
I prefer to stop seeing/following a patient who has misused his/her opioid prescription	↓	57% (273)	51% (242)	−8%	0.007
I would only ask for a urine drug test from a patient that I thought was abusing the opioid prescription	↓	19% (90)	13% (63)	−6%	0.003

Discussion

SCOPE of Pain, an ER/LA opioid REMS program, resulted in improvements in knowledge and attitudes about safe opioid prescribing, as well as increases in self-reported confidence and implementation of improved communication skills and guideline-based opioid prescribing practices. There were increases in clinician trust in patients with chronic pain and in the tools available to assess patients' pain and to detect opioid misuse.

For the first time, an FDA REMS included the mandate for independent continuing education to be funded by commercial entities to help mitigate the risks of their medications. While education is a natural part of any REMS, whether you must teach about a mandated registry or how to document safe-use conditions (e.g., pregnancy tests), this REMS included an extensive, prescribed curriculum developed by the FDA and not the providers of the education. This is distinct from the usual process of how content for continuing education is created by the provider.

While the need for prescriber education is universally accepted, this REMS has been met with some skepticism [37]. This study is a first step in evaluating this national strategy of clinician continuing education as a way to improve safe opioid prescribing. The comparison among PRE, IMMED, and 2MO assessment data suggest that not only did clinicians learn more about safe opioid prescribing, but they have more confidence and

Table 4 Changes in patient communication (n = 476)

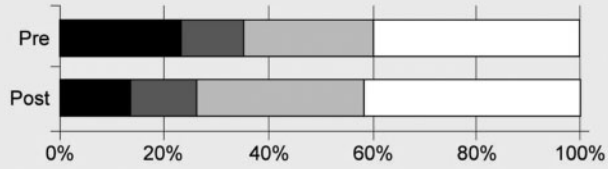
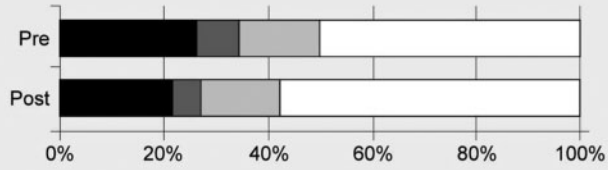
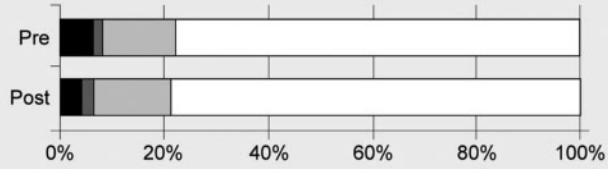
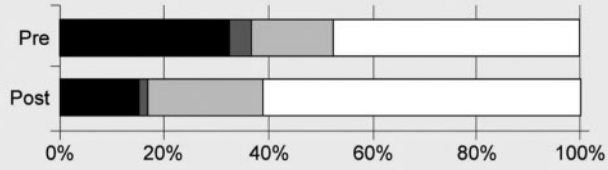
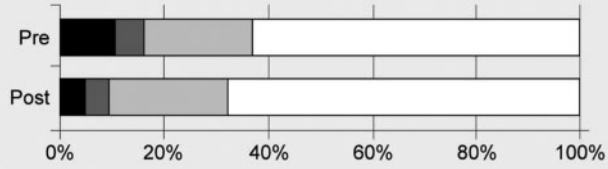
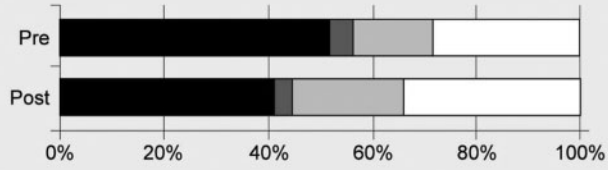
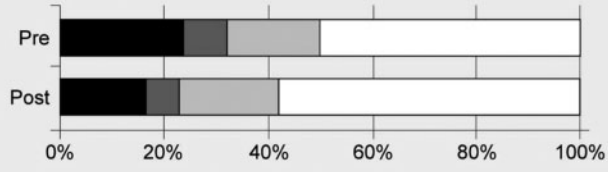
Clinical Performance Item	I am not currently performing this behavior in my practice / With my high risk pain patients only / With most of my pain patients / With all my pain patients
1 Talk with my patients' previous primary care providers and review prior medical records	
2 Implement and co-sign a Patient-Prescriber agreement (including informed consent and plan of care)	
3 Inform my patients about taking medication exactly as prescribed (e.g., don't increase dose; don't crush tablets, etc.))	
4 Educate my patient about proper storage and disposal of ER/LA Opioids	
5 Counsel my patients about risk of respiratory depression and overdose.	
6 Give my patients a patient counselling document and tools as part of the discussions with them when prescribing opioid analgesics	
7 Explain to my patient the methods I use to monitor opioid misuse (i.e., urine drug tests and/or pill counts)	

Table 5 Changes in guideline-based practices (n = 476)

	2-Months Post-Program Assessment		
	Have you made any changes in your practice, system care, and/or patient care as you participated the program entitled Scope of Pain: Safe and Competent Opioid Prescribing Education?		
Changes to Practice	% (n) who partially/fully implemented	% (n) who implemented before participating in this activity	% (n) who are planning on implementing in next 6–12 months or not planning to implement
Implement or improve ...			
Patient Prescriber "Agreements"	47% (225)	26% (143)	27% (128)
Informed consent procedures	45% (216)	18% (84)	37% (176)
Urine drug testing for monitoring	52% (246)	19% (92)	29% (138)
Pill counts for monitoring	43% (204)	10% (49)	47% (223)
Patient education or communication strategies	67% (319)	13% (63)	20% (94)
Office-wide policies/ procedures	49% (233)	18% (86)	33% (157)
Multidisciplinary team approach	48% (227)	14% (65)	39% (184)
Documentation in patient medical records	68% (325)	17% (80)	15% (71)
Register/begin using the Prescription Drug Monitoring Program	45% (214)	26% (124)	23% (108)

were able to make changes to align with guideline-based practices. While knowledge gain did decrease in the 2MO, it did not return to baseline, and in fact continued to be significantly higher than the PRE-assessment. Without repeated exposure deterioration of knowledge is an expected outcome in education studies.

While the evaluation of this REMS education is based on self-reported data and does not include objective measures (e.g., decreases in prescription opioid misuse) to demonstrate the effectiveness of the training, it does demonstrate that education based on content from the FDA, developed by continuing education providers, and funded by commercial interests can still yield a positive impact on self-reported changes in behavior.

There are a growing number of state policy, systems-level, and payer interventions being promulgated to address the prescription opioid misuse problem [31]. While these interventions appear to be efficient solutions to controlling prescription opioid misuse, such blunt instruments risk the unintended consequences of making opioids inaccessible for those that currently or potentially may benefit. In contrast, quality, targeted education can empower clinicians to make appropriate and informed clinical decisions about whether or not to initiate, continue, change or discontinue opioids for each individual patient suffering from chronic pain based on a careful benefit vs risk/harm assessment [38,39]. Educational approaches will maintain access for patients who do, or can, benefit from such medications while mitigating the potential risks to those who are not benefiting or are being harmed. While there has been considerable skepticism about continuing medical education's (CME) ability to improve clinicians' practices [40], recent meta-analyses have supported that, overall, CME, especially using serial educational interventions, is effective in changing clinician performance [41,42]. As opposed to regulations limiting clinician practice, education is a tool that can help clinicians develop the nuanced, informed approach necessary for individualizing patient care with regards to safe opioid prescribing.

Questions remain on next steps to enhance the current REMS education. This speaks to the need for a clinician awareness campaign regarding the availability of these REMS trainings. While the REMS program is mandatory

for the ER/LA opioid manufacturers, it is not mandatory for clinicians [37]. In one primary care survey [43], less than 10% of physicians were "very familiar" with the REMS education. Since the first announcement by the FDA regarding the opioid REMS program there has been debate as to whether clinician education should be mandated and linked to US Drug Enforcement Administration (DEA) licensure [44]. A training requirement is not unprecedented, as there is such a requirement within the Drug Addiction Treatment Act of 2000 [45] (DATA 2000) which limits the prescribing of buprenorphine for the treatment of opioid use disorders to those that have completed an 8-h training. While the DATA 2000 training requirement is highly supported by addiction medicine/psychiatry societies, only a small number of physicians have taken the training, which has resulted in limited access to this life-saving treatment for those who need it [46,47]. Thus, it would be important to link mandated opioid prescribing training to DEA licensure to avoid having clinicians "opt out" of this requirement leading to decreased treatment access and burn-out for those clinicians that "opt in." However, to make education mandatory there must be evidence that education would positively impact prescription opioid misuse without decreasing appropriate access to prescription opioids. Alternatively the goal could be mandatory demonstration of clinical competence allowing those clinicians well trained in this area to "test out" of the requirement. Finally, including practice-based performance improvement or quality improvement efforts following *SCOPE of Pain* education may lead to more robust clinical practice changes, but would require a more substantial investment in time and resources [48,49].

With any intervention, education or otherwise, it would be ideal to measure changes in clinical outcomes, such as fewer opioid overdoses and overdose deaths, and fewer emergency department visits. However, these important clinical outcomes would be difficult to attribute to any education alone as there are other concurrent efforts [31] that could also improve these outcomes including naloxone distribution [50], expansion of office-based opioid addiction treatment [51] with buprenorphine and naltrexone, and the availability of abuse-deterrent opioid formulations [52,53]. Evaluations focusing on decreasing the number of opioid prescriptions [54] are difficult to interpret as it is unclear what the correct amount of opioid prescribing should be to concurrently decrease opioid misuse while maintaining access to opioids for those who benefit.

The *SCOPE of Pain* evaluation has several limitations worth considering. Because our post-program assessments, with the exception of knowledge-testing questions, were self-reported by the participants there is risk of self-assessment bias and social desirability bias. To mitigate social desirability bias, participants completed their follow-up surveys anonymously to an independent evaluator. Program participants with a particular interest in the program objectives were potentially more likely to participate in the 2-month follow-up assessment. In addition, as this was a voluntary program, those that were interested in changing practice were more likely to enroll and, therefore, may have a greater change than the general population of practitioners. Therefore, there is the potential for participant self-selection bias. However, the demographics of those that completed the 2-month follow-up were similar to those that did not. The lack of a control group makes it difficult to attribute participant changes solely to *SCOPE of Pain*, however, many of the questions asked participants to attribute changes specifically to the program. While we found improvements in participant clinical knowledge, confidence, attitudes, and self-reported practice, we were unable by study design to detect if these improvements impacted patient care. Future research on ER/LA opioid REMS education should consider a more in-depth investigation on the impact on patients' care [55].

There were a few areas where this model did not succeed. First, the FDA Blueprint is very comprehensive and requires up to 2–3 hours of education. Some participants, particularly for the web-based activity, started the program but did not complete it. For the live activity, participants were required to pass a post-test to be counted as a program completer. As clinicians are not accustomed to completing a post-test for live activities, some participants attended the entire meeting, but could not be counted as completers of the education because they did not take the post-test.

In summary, the ER/LA opioid REMS training *SCOPE of Pain* improved clinician-level safe opioid prescribing outcomes, however, its impact on mitigating opioid misuse risk and harm while maintaining access to opioids for those that are or would benefit remains an unanswered question. While education cannot be the only strategy to combat this national crisis, it can help improve clinician behaviors and be a major part of the solution.

Acknowledgment

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Safe and competent opioid prescribing education: Increasing dissemination with a train-the-trainer program

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ABSTRACT

Background: Due to the high prevalence of prescription opioid misuse, the US Food and Drug Administration (FDA) mandated a Risk Evaluation and Mitigation Strategy (REMS) requiring manufacturers of extended-release/long-acting (ER/LA) opioids to fund continuing education based on an FDA curricular Blueprint. This paper describes the Safe and Competent Opioid Prescribing Education (*SCOPE of Pain*) train-the-trainer program and its impact on (1) disseminating the *SCOPE of Pain* curriculum and (2) knowledge, confidence, attitudes, and performance of the participants of *trainer-led* compared with *expert-led* meetings. *Methods: SCOPE of Pain* is a 3-hour ER/LA opioid REMS education. In addition to *expert-led* live statewide meetings, a 2-hour train-the-trainer (TTT) workshop was developed to increase dissemination nationally. The trainers were expected to conduct *SCOPE of Pain* meetings at their institutions. Participants of both the *trainer-led* and *expert-led SCOPE of Pain* programs were surveyed immediately post and 2 months post meetings to assess improvements in knowledge, confidence, attitudes, and self-reported safe opioid prescribing practices. *Results*: During 9 months (May 2013 to February 2014), 89 trainers were trained during 9 TTT workshops in 9 states. Over 24 months (May 2013 to April 2015), 33% of the trainers conducted at least 1 *SCOPE of Pain* training, with a total of 79 meetings that educated 1419 participants. The average number of meetings of those who conducted at least 1 meeting was 2.8 (range: 1–19). The participants of the *trainer-led* programs were significantly more likely to be practicing in rural settings than those who participated in the *expert-led* meetings (39% vs. 26%, $P < .001$). At 2 months post training, there were no significant differences in improvements in participant knowledge, confidence, attitudes, and performance between *expert-led* and *trainer-led* meetings. *Conclusions*: The *SCOPE of Pain* TTT program holds promise as an effective dissemination strategy to increase guideline-based safe opioid prescribing knowledge, confidence, attitudes, and self-reported practices.

KEYWORDS
Chronic pain; continuing education; opioid medications; train-the-trainer programs

Introduction

In the United States, there has been a dramatic increase in opioid prescribing for chronic pain, with an associated rise in unintentional opioid overdoses.[1] Prescriber education has the potential to both improve safe opioid prescribing practices and maintain access to opioid analgesics for those patients that may benefit from them.[2] In July 2012, the US Food and Drug Administration (FDA) approved a single shared Risk Evaluation and Mitigation Strategy (REMS) requiring manufacturers of extended-release/long-acting (ER/LA) opioid analgesics to jointly fund Continuing Education (CE) based on an FDA curricular *Blueprint for Prescriber Education*.[3] The FDA developed core messages to be communicated to prescribers in the Blueprint, published a draft for public comment, and considered the public comments when finalizing the Blueprint. It was approved as part of the ER/LA opioid analgesic REMS and is used by CE providers to develop the actual educational activity, which must be produced independent of commercial influence. The goal of this REMS was to educate through certified medical education at least 192,000 ER/LA opioid prescribers (60% of the 320,000 total active prescribers) within 4 years from the release date of the first REMS-compliant training.[3]

After the launch of the first REMS activity developed by Boston University School of Medicine (BUSM) in February 2013, the manufacturers of ER/LA opioids awarded 31 educational grants to accredited medical education providers in order to meet this goal. Each organization that received a grant was tasked with developing education to disseminate the ER/LA opioid REMS content to as many clinicians as possible. Although this REMS program has trained tens of thousands of prescribers, it has not yet achieved its target numbers of prescribers trained.[4]

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BUSM's ER/LA opioid REMS program entitled *Safe and Competent Opioid Prescribing Education* (*SCOPE of Pain*), the first funded program, has been found to be effective in improving knowledge, attitudes, confidence, and self-reported clinical practice in safe opioid prescribing.[5] The program was disseminated through a series of online modules, as well as live *expert-led* meetings. Although *expert-led* education is the traditional model of continuing medical education,[6] for this REMS initiative, where the content is predetermined by the FDA and there is a need for quick and widespread national dissemination, alternative modalities beyond *expert-led* live meetings are necessary. Online education was an obvious choice, but it is not optimal for the learner who prefers to learn in live settings and does not provide the same level of personal interaction with colleagues and faculty that live meetings can offer.[7–10] The question still remained how to disseminate this content efficiently and yet preserve the benefits of live meetings. With limited numbers of experts who are available to lead trainings at multiple small venues, a train-the-trainer (TTT)-type model could be optimal for expanding the reach of the programs beyond urban centers.[11,12] This study was designed to compare 2 different dissemination strategies of the ER/LA opioid REMS (*SCOPE of Pain*) education. We evaluated whether a trained trainer (*trainer-led*) would enhance program dissemination to a more rural audience and achieve similar educational outcomes as the *expert-led* education.

Methods

SCOPE of Pain *train-the-trainer (TTT) description*

SCOPE of Pain is a 3-hour live or online education available at www.scopeofpain.org and is based on the FDA curricular Blueprint.[3] In addition to the 20 *expert-led* live meetings and an online program that have been described in a previous publication,[5] a TTT model was developed to increase the reach of the program beyond the urban areas in which they are held. In this TTT model, all registrants of the *expert-led* sessions were sent e-mail invitations to apply to be a trainer for *SCOPE of Pain*. The TTT Web-based application included open-ended questions about their teaching experience, why they were interested in becoming a trainer, and who their proposed target audience was. In addition, each applicant uploaded their curriculum vitae and completed a disclosure form to capture any possible conflicts of interest. Appropriate candidates were selected based on their level of teaching experience, motivation to become trainers, and their lack of any relationships with commercial interests. Their motivation was measured by evaluating their answers to the question about how they would implement the training in their local area. Enthusiastic and well-thought-out plans were criteria used to gauge motivation to become a trainer.

The selected trainers attended a 2-hour TTT workshop that was held following the *expert-led* live *SCOPE of Pain* meeting. The TTT workshops focused on strategies to teach the *SCOPE of Pain* curriculum at their home institutions with the use of an Action Plan process to define their target audience, setting, timing, resources, and potential challenges to leading *SCOPE of Pain* meetings. The workshop was led by the *SCOPE of Pain* course director (D.P.A.), who is experienced in safe opioid prescribing education. Trainers were offered logistical support from the *SCOPE of Pain* staff to plan and run the live meetings along with a $300 honorarium per meeting. The support included a dedicated Web site to download educational materials (e.g., PowerPoint slides), a project coordinator available to help with scheduling, educational material printing, and participant outreach after the training was completed. In addition, *SCOPE of Pain* experts were available if trainers had any questions about the *SCOPE of Pain* content or needed assistance answering questions from their participants.

Outcomes

Measuring impact of expert-led *and* trainer-led *meetings*

Comparative evaluation of the *expert-led* and *trainer-led* meetings included 2 data collection time points: (1) immediate post program (IMMED) and (2) 2 months post program (2MO) (Figure 1). It was not possible to deploy a pre-post study design because participants of the *trainer-led* group did not preregister and logistically were unable to complete the pre-test on the day of the meeting. Multiple steps, described in a previous publication, have been taken to ensure the evaluation had face and content validity, was REMS compliant, and had clinical

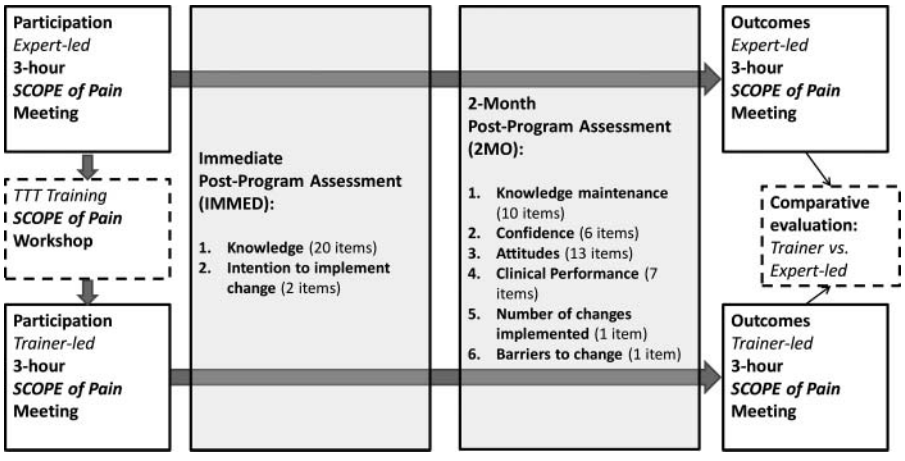

Figure 1. Comparative evaluation of *expert-led* and *trainer-led SCOPE of Pain*: structure, data collection points, and outcome metrics.

relevance to respondents.[5] The evaluation was designed to ensure assessment of changes in the participants' knowledge, attitudes, confidence, and clinical practice to demonstrate alignment with the best practices described in the FDA Blueprint. For the *trainer-led* meetings, since there was no pre-test, this was accomplished by asking participants to self-report their own changes in attitudes, confidence, and practice. For knowledge, a minimum standard of receiving a score of 70% or higher enabled the assessment of basic knowledge and comparison of IMMED and 2MO determined maintenance.

For both *expert-led* and *trainer-led* meetings, 4 key metrics (knowledge, confidence, attitudes, and clinical practice) were measured. These metrics are explicitly linked to the ER/LA opioid REMS FDA Blueprint, each including multiple quantitative items to fully cover the *SCOPE of Pain* content.

Participant *knowledge* (Key Metric 1) was assessed through 20 IMMED knowledge-testing items, 10 of which were repeated at 2MO. The 10 that were repeated at the 2MO facilitated assessment of participant clinical performance change, which can only be assessed effectively after participants have time to go back to their practices and implement changes. Knowledge-testing questions were a combination of dichotomous true/false questions, item-matching questions, and multiple nominal choice questions. Participant *confidence* to manage patients with chronic pain (Key Metric 2) was assessed with 6 self-report items with Likert-type response formats at 2MO. Items were based on common confidence issues faced by clinicians in the use of opioids when managing chronic pain. Participant *attitudes* when treating patients with chronic pain and using guideline-based care (Key Metric 3) were assessed using 13 self-report items with Likert-type response formats, including questions of motivation and willingness to treat patients with pain at 2MO. Finally, changes in participant *self-reported clinical practice* using guideline-based care (Key Metric 4) was assessed with 7 Likert-type response format self-report items about "commitment to change"[13] clinical performance (IMMED) and self-reported change (2MO), as well as 2 multiple nominal choice items about practice changes implemented and barriers to implementation (2MO). The BUSM institutional review board (IRB) determined this evaluation to be exempt from further IRB review.

Participant recruitment for expert-led *and* trainer-led *meetings*

Health care providers who manage patients with chronic pain and are licensed to prescribe opioids analgesics were the primary target group for the *SCOPE of Pain* program, and the audience of interest for the overall REMS initiative. This group included physicians, advanced practice nurses, and physician assistants licensed to prescribe ER/LA opioids practicing in primary care and specialties identified as managing patients with chronic pain. (See full list in Table 1.) Participants who were excluded from the study were either clinicians who do not manage chronic pain as part of their specialty practice (e.g.,

Table 1. *Expert-* and *trainer-led SCOPE of Pain* participant characteristics.

	Target audience for *SCOPE* (Physician/APN/PA, licensed to prescribe opioid analgesics)			
	IMMED		2MO	
Charscteristic	Expert ($n = 489$)	Trainer ($n = 424$)	Expert ($n = 128$)	Trainer ($n = 70$)
Profession, *n* (%)				
Physician	362 (74%)	322 (76%)	95 (74%)	46 (66%)
Advance practice nurse	93 (19%)	82 (19%)	26 (20%)	22 (31%)
Physician assistant	34 (7%)	20 (5%)	7 (6%)	2 (3%)
Specialty, *n* (%)				
Family practice	226 (46%)	216 (51%)	69 (54%)	44 (63%)
Internal medicine	172 (35%)	134 (32%)	40 (31%)	12 (17%)
Anesthesiology	16 (3%)	16 (4%)	3 (2%)	2 (3%)
Pediatrics	2 (0%)	0 (0%)	1 (1%)	0 (0%)
Orthopedic surgery	15 (3%)	16 (4%)	4 (3%)	4 (6%)
Physical medicine and rehabilitation	22 (5%)	22 (5%)	5 (4%)	5 (7%)
Hematology and oncology	10 (2%)	9 (2%)	1 (1%)	1 (1%)
Obstetrics and gynecology	5 (1%)	3 (1%)	0 (0%)	1 (1%)
Neurology	10 (2%)	1 (0%)	1 (1%)	0 (0%)
Rheumatology	7 (1%)	4 (1%)	1 (1%)	0 (0%)
Infectious disease	3 (1%)	1 (0%)	2 (2%)	0 (0%)
Sports medicine	1 (0%)	2 (1%)	1 (1%)	1 (1%)
Years of practice, *n* (%)				
1–5 years	114 (23%)	117 (28%)	33 (26%)	20 (29%)
6–10 years	59 (12%)	66 (16%)	16 (13%)	10 (14%)
11–20 years	126 (26%)	114 (27%)	28 (22%)	21 (30%)
≥21 years	186 (38%)	125 (30%)	51 (40%)	19 (27%)
Other	4 (1%)	2 (1%)	0 (0%)	0 (0%)
Practice setting, *n* (%)*				
Urban	181 (37%)	101 (24%)	56 (44%)	14 (20%)
Suburban	181 (37%)	150 (36%)	42 (33%)	19 (27%)
Rural	125 (26%)	163 (39%)	29 (23%)	36 (52%)
Other	2 (0%)	9 (2%)	1 (1%)	1 (1%)

*Distribution is significantly different (chi-square: $P < .001$ at IMMED, $P < .001$ at 2MO).

emergency medicine, psychiatry) or are not prescribers but worked with prescribers and were often responsible for creating and/or maintaining the systems needed for safe opioid prescribing (e.g., registered nurses, pharmacists). So although we felt that it was very important for these other health professionals to participate in *SCOPE of Pain*, generally it is the clinicians who prescribe opioids who would be the key respondents in determining the effect of the program. Given the focus of the REMS program, only the outcomes assessment completed by the aforementioned target group are included in the analyses for this paper.

For both the *expert-led* and the *trainer-led* meetings, completion of the IMMED was a requirement to receiving continuing education credit. For the 2MO assessment, an automatic e-mail was sent to all participants at 60 days using the e-mail address they had provided to the Web site either at registration or when claiming credit. Reminders were sent to noncompleters at 63 and 66 days. An incentive (entering a drawing for an e-book reader) was provided to encourage completion of the 2MO.

Analyses

Frequencies and cross-tabulations were calculated for each item using IBM SPSS 22.0 software (IBM Corporation, Armonk, NY). Comparison of *trainer-led* versus *expert-led* participants' responses was done using *t* tests for the continuous variables (percentage of correct answers to the knowledge questions, and number of changes intended/reported) and chi-squares for categorical variables (all other variables examined). In order to have sufficient statistical power to detect a difference between the *trainer-led* and *expert-led* groups, considering a medium effect size $w = .3$, an error $\alpha = .05$, and a statistical power $1 - \beta = .8$, a minimum of 133 respondents are required for the chi-square on the variable using highest number of potential values (5). Considering the same parameters, 82 respondents are required for the *t* test on the percentage of correct knowledge answers.

Results

TTT workshops and trainer-led *meetings*

During 9 months (May 2013 to February 2014), 89 trainers were trained during 9 TTT workshops in 9 states. Over 24 months (May 2013 to April 2015), 33% of the trainers conducted at least 1 training, with a total of 79 trainings training 1419 participants from the target group. The average number of trainings of those that conducted at least 1 training was 2.8, with a range of 1 to 19. At the same time, BUSM conducted 20 live *expert-led* meetings in 17 states educating 1742 participants from the target group.

Expert and trainer faculty description

The *SCOPE of Pain* expert faculty were all physicians who are experienced and accomplished educators in safe opioid prescribing for chronic pain, including experience presenting safe opioid prescribing education at national meetings and/or publishing on safe opioid prescribing and chronic pain in peer-reviewed journals. By contrast, the trainer faculty came from a variety of professions, including 50% physicians, 20% nurse practitioners, 12% pharmacists, and 10% physician assistants and with different levels of clinical pain expertise, ranging from

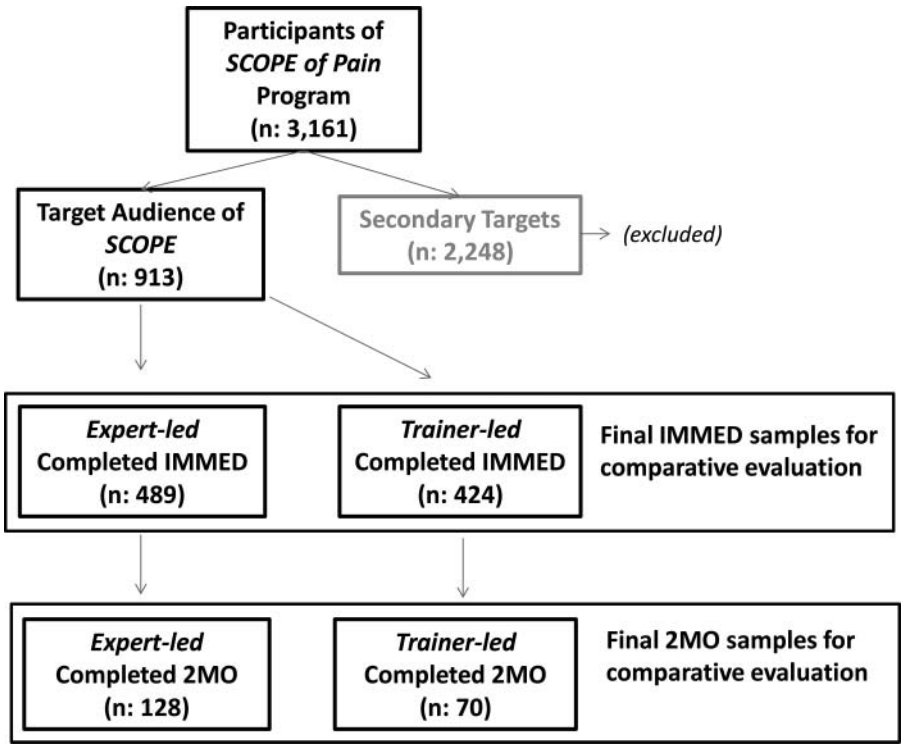

Figure 2. *Expert-* and *trainer-led SCOPE of Pain*: primary target group participants and evaluation sample.

Table 2. Knowledge assessment of *expert-* and *trainer-led SCOPE of Pain* participants immediate and 2 months post training.

		Average number of correct answers *n* (%)		
Assessment period	Assessment	Expert	Trainer	Difference*
IMMED (20 questions)	*n* (who completed all 20 questions)	457	404	$P = .091$ (n.s.)
	Average number of correct answers out of 20 (%)	18.4 (92%)	18.2 (91%)	
2MO (10 questions)	*n* (who completed all 10 questions)	119	68	$P = .538$ (n.s.)
	Average number of correct answers out of 10 (%)	7.7 (77%)	7.8 (78%)	

*n.s. = nonsignificant (*t* test).

none to fellowships in pain medicine. In addition, the trainers' level of experience as educators varied from none to extensive, with all having minimal to no experience training others in safe opioid prescribing for chronic pain. All the trainers had a strong commitment and a sense of responsibility to train others to simultaneously address both chronic pain and the prescription opioid misuse problems at their institutions and in their communities. Although we were unable to assess the trainers' competency, we did attempt to ensure content fidelity of their trainings by asking all trainers to sign a form committing to presenting all the Blueprint content. In addition, we were able to audit a random selection of *trainer-led* programs to assess that the entire *SCOPE of Pain* content was delivered.

Participants of trainer-led *and* expert-led *trainings* (Figure 2, Table 1)

A total of 3161 participants completed either the *expert-led* or *trainer-led SCOPE of Pain* meetings between February 28, 2013, and June 16, 2015. Twenty-nine percent (913/3161) were considered the primary target group for *SCOPE of Pain* (defined as being a physician, an advanced practice nurse, or a physician assistant from 1 of the 13 disciplines and specialties listed in Table 1 and being licensed to prescribe ER/LA opioid analgesics). Completion was defined as participants who completed the IMMED assessment after attending the *SCOPE of Pain* meeting.

The IMMED assessments were completed by 489 participants of the *expert-led* meetings and by 424 participants of the *trainer-led* meetings. Of those, 26% (128/489) of the *expert-led* and 17% (70/424) of the *trainer-led* groups completed the 2MO assessment. Table 1 presents the sociodemographics for the final samples of the comparative evaluation (primary target participants who completed *SCOPE of Pain* either through *expert-led* or *trainer-led* meetings). Demographic distribution between the 2 groups was significantly different with regards to their practice setting with 39% of participants (163) who attended the *trainer-led* meetings were from rural areas compared with only 26% (125) who attended the *expert-led* meetings.

The following section presents the findings divided into 3 sections: (1) Assessment of *knowledge* comparing *expert-led* and *trainer-led* IMMED and 2 MO assessments; (2) *Intention to change* comparing *expert-led* and *trainer-led* IMMED assessments; and (3) Assessments of *attitude, confidence*, and *practice* (*patient communication*, *guideline-based care*, and *barriers to change*) comparing *expert-led* and *trainer-led* in 2MO assessments.

Knowledge (Table 2)

The average proportions of correct responses in the IMMED were 92% for the *expert-led* group and 91% for the *trainer-led* group, whereas in the 2MO they were 77% for the *expert-led* group and 78% for the *trainer-led* group. The differences between the 2 groups were not significant (IMMED, $P = .091$; 2MO, $P = .538$).

Intention to change

Immediate post program, 93% of *expert-led* participants and 91% of *trainer-led* participants stated they were planning to make at least 1 change to align their practice with guideline-based care. There were significant differences between the 2 groups in the number of changes selected in the "*check all that apply*" list provided, with members of the *expert-led* group agreeing to 4.1 changes versus 3.5 changes for the *trainer-led* group ($P < .001$).

Confidence (Table 3)

For all 6 confidence items, approximately two thirds of the participants in each group reported increased confidence in guideline-based opioid prescribing practices. There were no significant differences between the 2 groups.

Table 3. Changes in participant confidence of *expert-* and *trainer-led SCOPE of Pain* at 2 months.

	Participants who reported increase confidence at 2MO *n* (%)		
Confidence item	Expert ($n = 128$*)	Trainer ($n = 70$*)	Difference**
Effectively and efficiently assess pain in a new patient	79 (62%)	42 (60%)	$P = .465$ (n.s.)
Efficiently assess the potential benefit and the potential risk of opioids for chronic pain in a new patient	99 (77%)	53 (76%)	$P = .398$ (n.s.)
Effectively communicate and collaborate with your patients around opioid initiation	92 (72%)	49 (70%)	$P = .781$ (n.s.)
Monitor patients on chronic opioid therapy for opioid misuse, including addiction and diversion	82 (64%)	47 (67%)	$P = .711$ (n.s.)
Effectively and efficiently assess your patients for potential misuse of opioids	89 (70%)	44 (63%)	$P = .285$ (n.s.)
Effectively communicate with your patients when treatment has shown no benefit	92 (72%)	49 (70%)	$P = .781$ (n.s.)

*Actual *n* for each item might vary slightly due to nonresponse. Percentages were calculated excluding nonrespondents for each item.
**n.s. = nonsignificant.

Attitudes (Table 4)

A majority of items showed no significant differences in the attitudes between the 2 groups, with 2 exceptions, the item "*It is my responsibility and role to discuss with my patients not to give away their medications to relatives or friends*" (97% agreement [*expert-led*] and 91% [*trainer-led*]; $P = .028$) and the item "*I cannot get my patients to be truthful about illicit drug use*" (13% agreement [*expert-led*] and 21% [*trainer-led*]; $P = .025$).

Clinical practice (patient communication, guideline-based care, and barriers to change)

Patient communication (Figure 3)

For the 7 clinical practice behaviors related to patient communication, although *trainer-led* groups reported slightly lower endorsements of guideline-based behaviors than the *expert-led* groups, no significant differences were observed between the groups. The item "*Give my patients a patient counseling document and tools as part of the discussions with them when prescribing opioid analgesics*" was the least reported behavior, as 59% of *expert-led* participants and 54% of *trainer-led* participants reported performing the behavior at all, and only 28% of *expert-led* and 29% of *trainer-led* performing the behavior with "*all pain patients*." At the other end of the spectrum, the item "*Inform my patients about taking medication exactly as prescribed*" was reported to be performed by 99% of *expert-led* and 94% of *trainer-led* and performed with "*all pain patients*" by 81% of *expert-led* and 73% of *trainer-led* of 2MO respondents.

Guideline-based care (Figure 4)

Between one third and two thirds of respondents for both the *expert-led* and *trainer-led* groups reported having either partially or fully implemented or improved the implementation of the 9 specific clinical practice changes at 2MO. The highest implementation/improvement rates were observed in regards to *documentation in patient medical records relating to opioid prescribing*: 70% of the *expert-led* group and 73% of the *trainer-led* group reported having fully or partially implemented a change following the program, whereas 20% of *expert-led* and 13% of *trainer-led* reported having already fully implemented before their *SCOPE of Pain* attendance. The lowest implementation/improvement rates were for *patient prescriber pain agreements* with patients (41% and 39% of the *expert-led* and *trainer-led* groups, respectively); however, this item was the item most often reported as already fully implemented before the program (45% and 49% of the *expert-led* and *trainer-led* groups, respectively). At least 4 partially/fully implemented changes were reported by 59% of *expert-led* and 60% of *trainer-led* respondents, and 28% of *expert-led* and 29% of *trainer-led* reported implementing 7 to 9 changes. The proportions reporting implementing none of the 9 changes were 13% (*expert-led*) and 7% (*trainer-led*). No significant difference was observed between the 2 groups for any of the 9 practice changes.

Barriers to change

All participants reported at least 1 barrier to making practice change. The most significant barriers reported were *lack of support staff* to help make these changes (48% *expert-led* and 44% *trainer-led*) and *patients' resistance to change* (37% *expert-led* and 37% *trainer-led*). No significant difference was observed between the 2 groups.

Discussion

This comparative evaluation assessed the educational outcomes for participants trained using the *SCOPE of Pain*

Table 4. Attitudes of participants of *expert-* and *trainer-led SCOPE of Pain* at 2 months.

Statement	Participants reporting ≥4 on the agreement scale[a]		
	Expert ($n = 128$*)	Trainer ($n = 70$*)	Difference**
Statements for which a high level of agreement is desirable			
I trust that most of my patients with chronic pain are able to provide an accurate self-assessment of their pain	58 (45%)	31 (44%)	$P = .842$ (n.s.)
I trust that available pain scales provide reliable assessment of pain in my patients	53 (41%)	22 (31%)	$P = .503$ (n.s.)
It is my responsibility and role to discuss with my patients not to give away their medications to relatives or friends	124 (97%)	64 (91%)	$P = .028$
I am comfortable responding to family calls about my patients' possible misuse of opioids	83 (65%)	38 (54%)	$P = .280$ (n.s.)
Statements for which a low level of agreement is desirable			
There is no reliable way to identify those of my patients who are drug-seekers	23 (18%)	9 (13%)	$P = .710$ (n.s.)
Treating and managing patients with chronic pain is time-consuming and frustrating	78 (61%)	43 (61%)	$P = .727$ (n.s.)
I will never prescribe ER/LA opioids to a patient with history of mental health issues	9 (7%)	8 (11%)	$P = .771$ (n.s.)
I cannot get my patients to be truthful about illicit drug use	16 (13%)	15 (21%)	$P = .025$
I am uncomfortable communicating an unexpected urine drug test result to my patients	28 (22%)	16 (23%)	$P = .410$ (n.s.)
I am unsure I am effectively assessing opioids misuse risk in my patients with chronic pain on ER/LA opioids	33 (26%)	19 (27%)	$P = .292$ (n.s.)
I suspect there is more I should be doing in the treatment and management of my patients who report chronic pain	70 (55%)	36 (51%)	$P = .898$ (n.s.)
I prefer to stop seeing/following a patient who has misused his/her opioid prescription	50 (39%)	24 (34%)	$P = .540$ (n.s.)
I would only ask for a urine drug test from a patient that I thought was abusing the opioid prescription	9 (7%)	6 (9%)	$P = .597$ (n.s.)

[a]Scale: 1 = Strongly disagree to 5 = Completely agree.
*Actual *n* for each item might vary slightly due to nonresponse. Percentages were calculated excluding nonrespondents for each item.
**n.s. = nonsignificant.

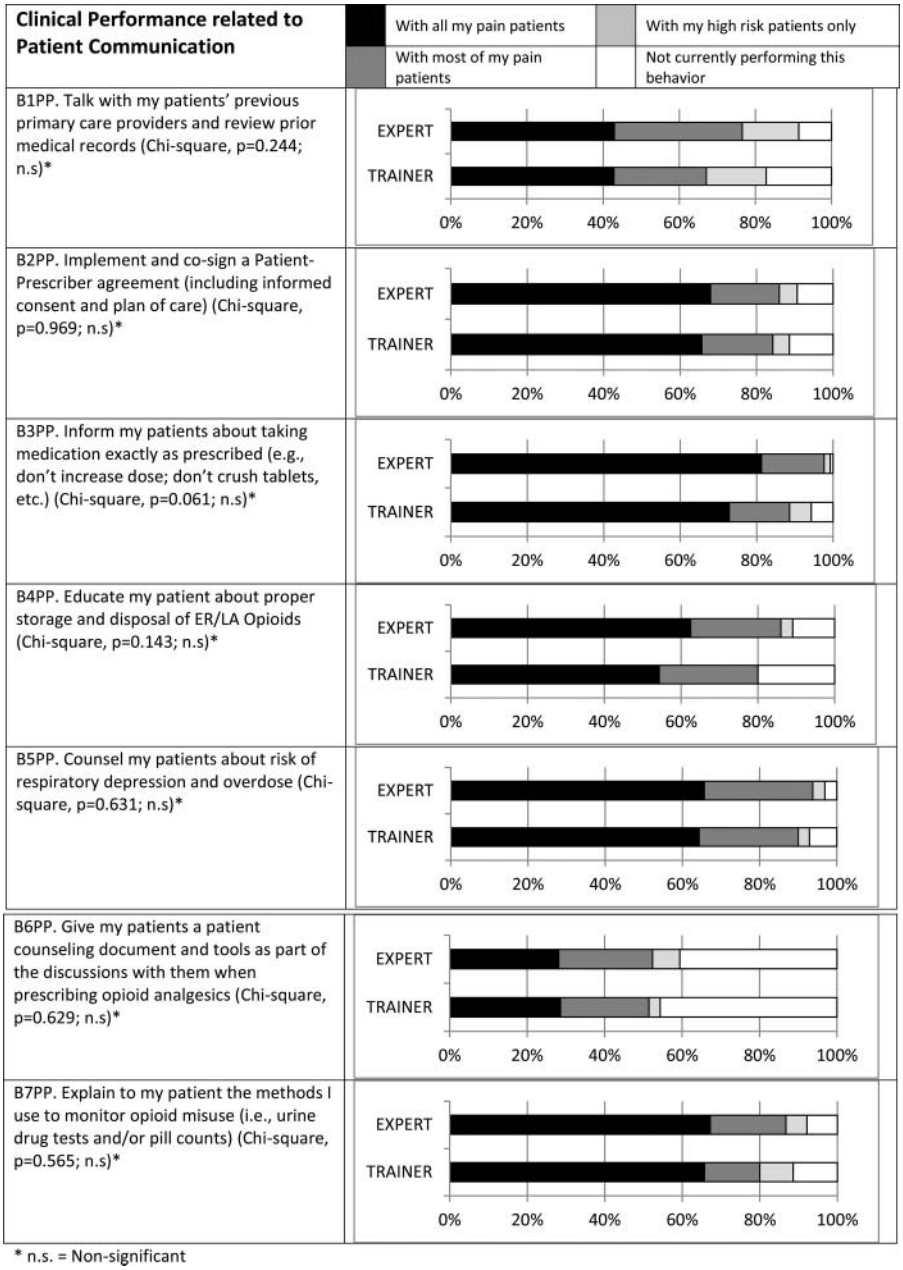

Figure 3. Self-reported patient communication strategies of participants of *expert-* and *trainer-led SCOPE of Pain* at 2 months

curriculum taught by either experts in safe opioid prescribing education *or* by trainers who participated in a 2-hour TTT workshop. This study demonstrates that selected trained trainers are able to achieve a similar level of learner impact as expert faculty while broadening the reach to more rural audiences. The ambitious goal set by the FDA for reaching 192,000 clinicians nationally in 4 years has spurned the need to develop scalable models for knowledge dissemination. The fact that the *trainer-led* meetings resulted in similar outcomes to *expert-led* meetings makes the TTT model appealing for public health initiatives, such as safe opioid prescribing, where widespread dissemination of information is needed.

Originally the TTT program was designed to enable the trainers to go back to their home institution and complete a single meeting for their colleagues. However, the fact that many trainers went on to complete more than 1 meeting (with one trainer completing 19 meetings) suggests that trainers were being identified as a resource in their regional community beyond their own institutions. In addition, once a trainer completed a meeting, they likely felt more confident conducting additional meetings.

The *trainer-led* education was more successful than the *expert-led* in reaching rural-based clinicians. This finding provides further evidence of the usefulness of the TTT model in reaching clinicians in less accessible locations.[14] Although this study had similar results to a study by Martino et al. by showing that the effects of the *trainer-led* education were the same as the *expert-led* education, more investigation is needed to determine if the TTT model could lead to more sustained changes due to the creation of local leaders. Since most of our trainers were not previously experts in safe opioid prescribing education, the

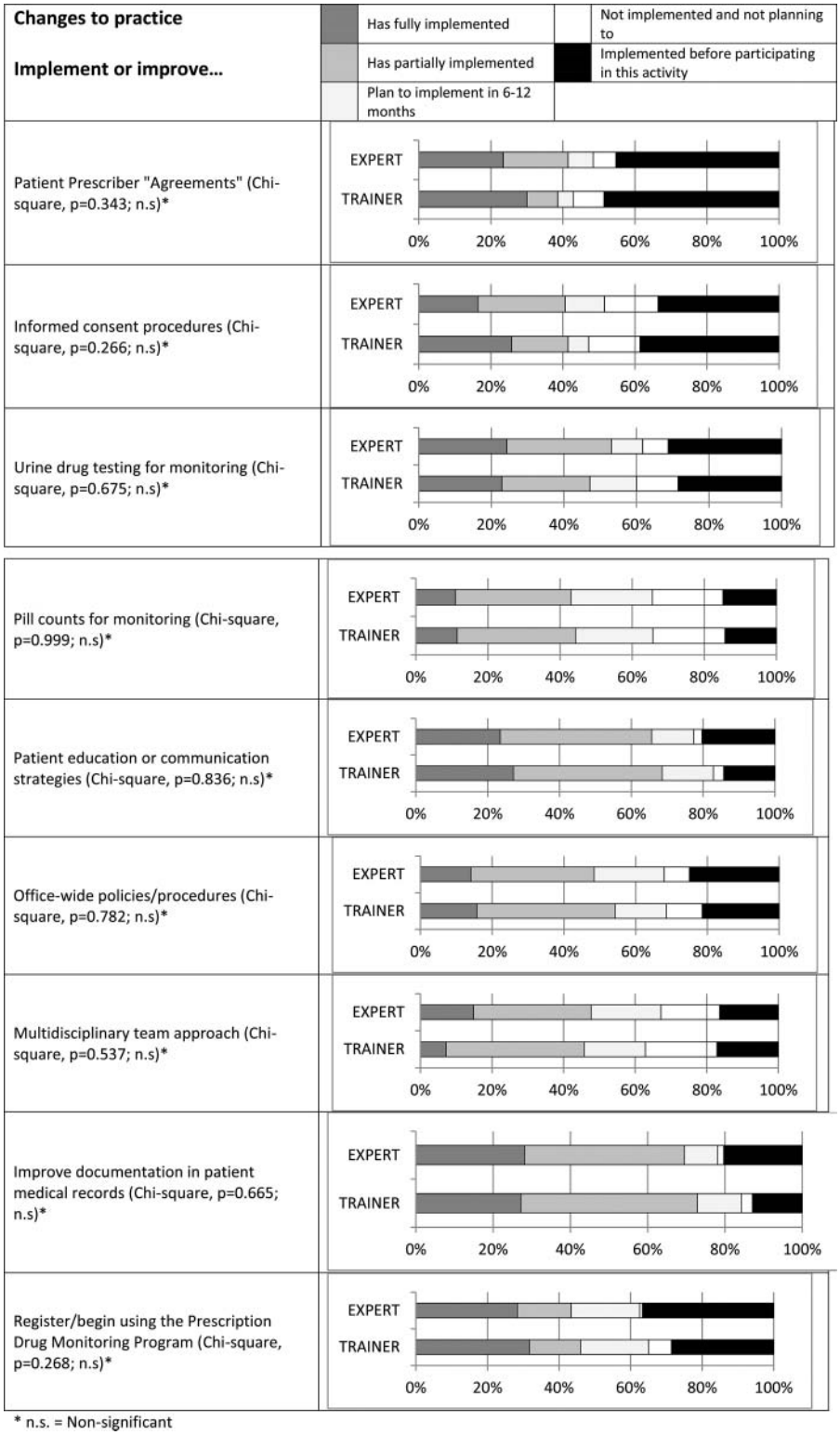

Figure 4. Changes in guideline-based practices at 2 months.

effects of having newly trained clinicians in these locations is unknown. The need to activate more members of the community in the fight against the opioid morbidity and mortality crisis is clear, and the TTT model has the potential to create local expert educators.

The education delivered to both groups was live and therefore sustained all the benefits of face-to-face education. It allowed the participants to ask questions of the trainers in real time, talk to colleagues about issues surrounding the content, identify local resources, and be removed from distractions as well as other commonly described disadvantages of online education, such as social isolation, difficulty of meaningful interaction, and de-individualized instruction.[8,9,10]

Two of the 13 attitude items had statistically significant differences between the groups (i.e., "*It is my responsibility and role to discuss with my patients not to give away their*

medications to relatives or friends," and "*I cannot get my patients to be truthful about illicit drug use*"). These 2 items focused on patient trust. It is possible that expert trainers were more skilled in teaching these more nuanced approaches to safe opioid prescribing that could be perceived by the patient as being judged. Further research is needed to test this hypothesis.

It is unclear why only a third of the trainers conducted their own trainings. There are likely numerous barriers to conducting trainings upon return to their home institution. It is possible that the external (BUSM) and/or internal (trainers' home institution) support provided to trainers was not adequate to conduct meetings. A 2-hour TTT workshop may be insufficient for some to feel that they have mastered of the content in order to train others. Further study is needed to determine how to best facilitate trained trainers as they plan their own educational meetings, as well as to determine what barriers they may face that prevent completing trainings.

The study has a few limitations to consider. This was a post-assessment-only design that did not allow for the assessment of baseline knowledge of both the *expert-led* and *trainer-led* groups. Although a pre-test/post-test design would have been preferable, it would have been logistically challenging to implement. As opposed to the *expert-led* sessions, participants of the *trainer-led* sessions did not preregister and therefore could not receive the pre-test before the activity. Due to the time constraints of typical *trainer-led* activities, the pre-test would have been too time-consuming to administer at the start of the activity. The changes in attitudes, confidence, and performance were self-reported and therefore open the risk for self-assessment bias and social desirability bias. The participants of the IMMED and 2MO post-assessments were self-selected and not randomly chosen, so it is possible that participants who found the education the most useful or had some changes to report were more likely to complete the assessments. However, this self-selection bias should apply equally to both groups. Without a control group, we cannot attribute changes exclusively to *SCOPE of Pain*. The high attrition in our study is consistent with other educational evaluation studies.[15] Our follow-up response rates were similar between our 2 comparison groups and likely limited by the same biases. In addition, the sample size was still above the minimum value calculated to be required a priori.

This study provides additional evidence of the effectiveness of education to promote guideline-based safe opioid prescribing and in particular how the TTT model can further disseminate this education to rural areas. With the ever-growing need to educate clinicians on the safe opioid prescribing practices for chronic pain, a model that does not rely on experts, who have limited time to train, is crucial. With the continued high prevalence of prescription opioid misuse, nontraditional models can help accelerate knowledge dissemination and possibly activate local leaders to help stem this growing crisis.

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Author contributions

All coauthors were involved in the writing or revisions of the manuscript. Dr. Zisblatt was involved in research conception and design, collection of data, analysis, and interpretation of the results. Dr. Alford was involved in research conception and design and interpretation of the results. Dr. Hayes was involved in research conception and design, collection of data, analysis, and interpretation of the results. Ms. Lazure was involved in data collection and analysis. Ms. White and Ms. Hardesty were involved in research conception and design and interpretation of results.

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