American Society of Addiction Medicine

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Treat Addiction ● Save Lives

May 20, 2015

Richard G. Frank, PhD
Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Assistant Secretary Frank,

As you know, today Senator Markey announced the introduction of the Safe Prescribing of Controlled Substances Act, which would require that prescribers who are applying for a DEA license to prescribe controlled substances complete mandatory education approved by the Secretary of Health and Human Services. As a member of the CO*RE collaborative, one of the approved providers of extended-release long-acting opioids risk evaluation and mitigation strategy (aka ER/LA REMS) training, the American Society of Addiction Medicine (ASAM) would like to provide input to the development of mandatory prescriber education that draws upon our experience as an ER/LA REMs education provider. The remainder of this letter provides background on CO*RE along with information that can be helpful as this legislation is considered.

CO*RE Collaborative Background:

CO*RE is a collaboration of ten professional societies, started in 2010, whose mission is **to promote individual and population health and public safety through timely, evidence-based, outcome-oriented and interprofessional education related to the comprehensive management of pain, addiction, and their co-morbidities.** The organizations that comprise the CO*RE partners represent more than 713,000 clinicians in a wide spectrum of clinical specialties and subspecialties and who work in a variety of clinical practice settings**.** The ten CO*RE member organizations include the following:

- American Academy of Hospice and Palliative Medicine
- American Academy of Physician Assistants
- American Association of Nurse Practitioners
- American Osteopathic Association
- American Pain Society

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- American Society of Addiction Medicine
- California Academy of Family Physicians
- Healthcare Performance Consulting
- Interstate Postgraduate Medical Association
- Nurse Practitioner Healthcare Foundation

Also working with the CO*RE member organizations are several key strategic partners including Medscape, Physicians Institute for Excellence in Medicine (working with 15 state medical societies), American College of Emergency Physicians and the American Academy of Family Physicians. More information about CO*RE is available here. CO*RE has been an approved provider of ER/LA REMS training since 2013. It offers a standard curriculum which offers credit for physicians (MDs and DOs), nurse practitioners and physician assistants. The curriculum is delivered in several different formats including live sessions at national and state meetings and through online formats. The two-hour curriculum is supplemented with an optional 3-hour version, as well as modules with additional in-depth content (e.g., pain and addiction), and additional resources (e.g., patient counseling, forms, etc.). CO*RE is the single largest provider of this training reaching more than 75,000 clinicians in just over two years. The FDA blueprint is the basis for this curriculum. This blueprint provides a well-vetted outline for a curriculum that could be easily expanded to cover short-acting opioids as well. A link to this curriculum is available here. Information about ASAM's offering of the CO*RE REMS program is available here including copies of slides and links to the online format of the program.

Recommendations:

Mandatory Education and Preferred Credit Hour Options

In 2011, CO*RE conducted a needs assessment to help plan its ER/LA REMs educational offering (a complete copy of this report is included with this letter). A key component of this needs assessment was a clinician survey to assess educational and behavioral needs – including preferred credit hour options. The assessment was an online survey disseminated by each of the CO*RE member organizations to their membership. A response rate of 21% was achieved (calculated on surveys completed divided by emails opened) and reflected a total of 2,306 completed surveys.
One of the questions asked respondents their attitudes about being required to complete educational activities in order to continue prescribing opioids. Only a very small percentage (6% of primary care respondents and 2% of specialists) indicated that they would stop prescribing rather than comply with educational requirements (see chart on page 56 of the attached report). The most common response from specialists was "I don't need it, but I will endure it," while the largest group of primary care providers indicated that "I need it anyway, so this is a good reason to do it."

Respondents were also presented with a set of options and asked to select the "best option" and the "worst option" with the respect to tying DEA licensing to successful completion of opioid education (see chart on page 59 of the attached report). Based on the analysis of the options that were presented, it was determined that the combination

of 2 credits immediately, and 2 credits over 2 years was the most preferred option (28% of respondents). Interestingly, the second most preferred option was very close, with 3 credits at 23% and 3/3 (3 credits in the first year followed by 3 credits over 2 years). This indicates that respondents will tolerate a significantly higher number of credits if they are not all required in the first year.

Count Completion of Qualified Training Toward the Mandatory Education Requirements

It is recommended that the Secretary consider accepting CME/CE documentation from clinicians who have completed qualified educational programs. Clinicians may be more willing to accept a national requirement if they can count already completed trainings that meet federal requirements. It is also recommended that ER/LA REMS training be considered as meeting these requirements. All of the approved ER/LA REMS providers have to develop programs that match the curriculum defined in the FDA blueprint and as described earlier, that provide a minimum of 2 hours of CME/CE credit, that test learners' knowledge acquisition based on the training program, and that are assessed for absence of bias by national accrediting organizations. To date, CO*RE has reached more than 75,000 clinicians with its program, and taking into account the other approved providers it is likely that well over 100,000 clinicians have already completed approved ER/LA REMS trainings. Given the time that clinicians have taken to complete these programs and the quality of the trainings, it is recommended that a nationally mandated program accept CME/CE documentation from clinicians who have completed ER/LA REMS training from approved providers.

Consider Including a Test-Out Option

To date, it has been difficult to get a significant number of clinicians to participate in the ER/LA REMS training even though it is free and provided in a variety of delivery formats. It is believed that a significant number of clinicians have chosen not to complete an ER/LA REMS training because they believe they have sufficient knowledge and training on pain management. To ensure that these clinicians can demonstrate their knowledge, it is recommended that a federally mandated program offer a "test-out" option. CO*RE has explored this option. It recently conducted a survey with a total of 675 responses that documented positive response to this option with preliminary results summarized below.

- *Clinicians who wish to prescribe opioids should be required to demonstrate knowledge and competence for prescribing these medications.* ***86% agree or strongly agree***
- *If there was a requirement (licensing, maintenance of certification, state regulations, etc.) to participate in education around safe use of opioids, would you be in favor of a "Test-out" process, by which you could take a test and receive credit for your knowledge and competence in lieu of the required education?* ***71% YES***
- *Regardless of whether you agree with such a test, what would be an appropriate amount of time for a test, assuming you would receive CME/CE credit for the amount of time spent taking the test?* ***39% - 60 minutes; and 28% 30 minutes***
- *Testing is an effective way to assess knowledge and competency on the topic of safe use of opioids.* ***80% agree or strongly agree***
- *I would participate in such a test even if it was not a requirement for me.* ***65% agree or strongly agree***

CO*RE has developed a proposal to implement a validated test for clinicians who want to “test-out” of a mandatory CME/CE program associated with the ER/LA REMS curriculum. CO*RE has not yet received funding to implement this program; however, if there is federal receptivity to this option (including support from the FDA), then we believe it would be feasible to secure funding to implement this option.

While the ER/LA REMS program is a voluntary education program, we believe that there have been important learnings from this program that can inform the legislative process. ASAM and its CO*RE partners are willing to continue to serve as a resource to provide insight based on our experience with the ER/LA REMS program.

Sincerely,

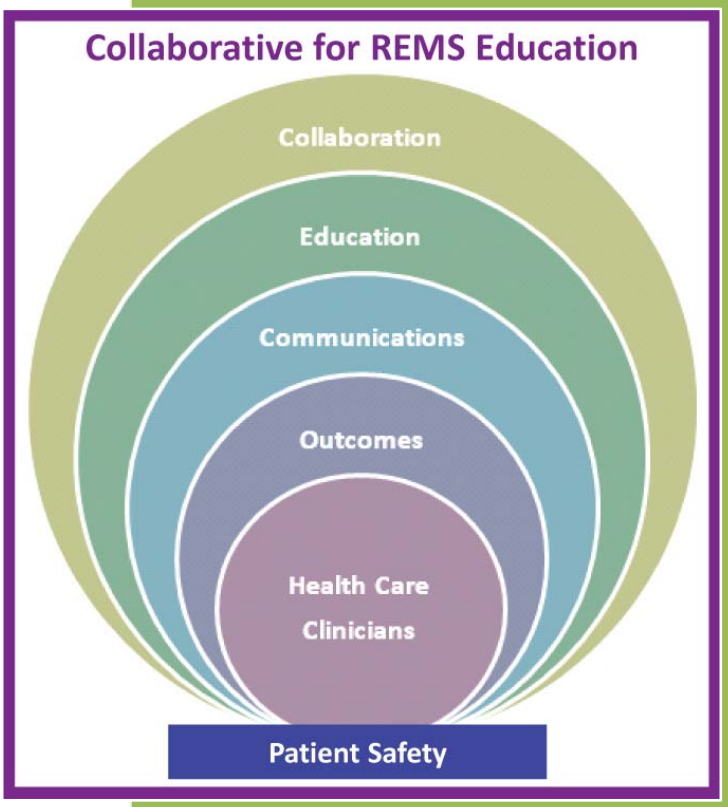
R. Jeffrey Goldsmith, MD, DLFAPA, FASAM

President, American Society of Addiction Medicine

Enclosure: CO*RE Needs Assessment Report 2011

2011

Needs Assessment and Educational Design Report
Long-Acting and Extended Release Analgesic Opioids REMS



Submitted by
CO*RE Partners
August 9, 2011

Executive Summary

*While it is true that pain is a universal human experience, it is never true that one can feel another's pain. The effort to protect the public from inadvertent harm through use of strong analgesic medications must never supersede the importance of providing comfort to those who suffer. The core tenets of the CO*RE initiative are simply these: to protect those who suffer, as well as those who do not.*

– Katherine Galluzzi, DO, family physician, geriatrician and pain specialist

Primary care providers, pain management, addiction and palliative care specialists, and clinicians representing all arenas of the health care system struggle to successfully manage their patients' pain. For many patients, long-acting and extended-release opioid medications constitute an effective and valuable element in the pain management plan. However, opioid prescription involves many complex issues of misuse, abuse, addiction, adverse effects, and fear of legal and regulatory action. In order to address risk and safety concerns, reduce serious adverse outcomes, and simultaneously ensure that persons with pain maintain necessary access to opioids, the U. S. Food and Drug Administration (FDA) has requested from the Industry Work Group (IWG) a Risk Evaluation and Mitigation Strategy (REMS) plan that applies to all long-acting and extended-release opioid analgesic medications.

In response to the REMS program's emphasis on prescriber education, a group of professional organizations has come together to create the Collaborative for REMS Education, or CO*RE. This partnership of eight professional organizations represents a significant portion of all opioid prescribers and individuals who will be affected by REMS. Individually and collectively, the CO*RE partners are deeply committed to providing continuing education that results in optimal pain management and optimal care for all patients.

Initiated in June 2010, the CO*RE partners have taken steps to systematically research and understand the practice issues, barriers to care, and safety concerns involved in pain management with opioids. CO*RE's intentions are twofold: 1) that findings will benefit the national long-acting and extended-release analgesic opioid REMS; and 2) that CO*RE itself will use these findings to inform the design, delivery, and evaluation of the education that forms part of the solution to this complex and challenging situation.

To this end:

- Content experts worked with prescribers and CO*RE leadership to identify a detailed list of core competencies necessary to assess safe and effective use of opioids in pain management.
- An in-depth quantitative and qualitative educational needs assessment was conducted, including a) 40 interviews with prescribers; b) a practice and attitude survey distributed to more than 50,000 individuals; and c) a comprehensive education and literature review.

- Nationally recognized educational experts provided insight and guidance into best educational design built on evidence-based adult learning principles.
- Clinical experts, educational experts, and the CO*RE leadership came together to participate in two educational summits. This group worked to summarize, discuss, and analyze findings to create a set of important implications and preliminary recommendations for REMS education as the program moves forward.

Insights

The four-armed needs assessment project provided CO*RE partners with baseline knowledge about clinicians' perceived and actual practice gaps, concerns about treating persons living with pain, barriers to optimal care, and attitudes toward REMS and voluntary or mandatory education. This baseline knowledge was instrumental in understanding the implications of this project going forward.

CO*RE partners learned that clinicians — specialists and primary care providers alike — acknowledge need and educational gaps across the continuum of care for persons living with pain. These needs include the initial assessment of the patient, development of a treatment plan, assessment of risk for abuse, and ongoing reassessment of the patient.

Additionally, clinicians perceive many barriers to best practices. Both primary care providers and specialists expressed concern about accidental overdose and patients' concerns that they may become dependent or addicted. Primary care providers also listed among the top barriers the limited access to pain specialists for consultation or referral.

Although pain is a significant and genuinely challenging issue for clinicians, CO*RE found that evidence-based education rooted in clinical competencies will help ensure the safe and effective prescribing of opioid medications.

Ideal REMS education will meet the spectrum of individualized learner needs and will focus on patient care within teams, practices, and health care systems. In addition to the identified core competencies, content must address patient-prescriber communication and clinician fears about prescribing opioids.

Partners held initial concern about learners' tolerance for education; we feared clinicians would stop prescribing rather than participate in mandated education. Encouragingly, needs assessment data reveal that most clinicians are interested in participating in REMS education.

While the number of hours or credits has yet to be determined, and the amount of content that could be included in a curriculum is vast, clinicians in the CO*RE survey revealed a preference of four to six hours over a two-year period (two to three hours annually, for two years) as an optimal amount of time to devote to opioid education.

Recommendations

Traditional continuing professional education does not always progress beyond clinical knowledge to address competence and performance that will affect patient health. The CO*RE partnership strongly believes that in order to reduce the risk of opioid abuse, misuse, and addiction, and to make a difference

in the lives of persons living with pain, REMS education must go further than to simply meet a set of prescribed educational requirements.

Understanding that a portion of learners may already possess some level of competence, CO*RE recommends a foundational program of self-assessment that will guide prescribers to and through educational interventions that address each person's unique needs. A detailed outcomes strategy, including continuous assessment and monitoring, must be developed along with the program curriculum.

Given the voluntary nature of REMS education and preliminary findings about preferred educational modalities and venues, CO*RE recommends a thoughtfully constructed modular educational design that incorporates the best principles of live, print, and online learning. These modules, supporting the clinician's journey from knowledge to competence to performance, must be designed to maximize the time frame that learners will devote to voluntary education and to meet their motivations for initiating and completing the journey.

CO*RE recommends a comprehensive model of competency-based education — envisioned and implemented within a foundation of evidence-based adult education principles — which will deliver REMS education that truly affects practice, safety, and patient health; we do not believe this approach is at odds with the equally important task of ensuring a wide learner reach.

In short, CO*RE recommends an educational program that:

- Employs a competency-based curriculum rooted in evidence-based principles of adult learning.
- Educates and guides a learner and his/her team across the full cognitive and behavioral continuum from knowledge to competence to performance.
- Incorporates self-assessment and allows the learner to progress logically from predisposing to enabling to reinforcing phases.
- Implements efficient, modular and diversified learning modalities presented in venues which will best encourage learner participation under voluntary engagement.
- Balances the need for effective education with education that must have a wide audience reach.
- Respects the time parameters that busy clinicians are willing to meet to voluntarily engage in education.

> *Treating patients with chronic pain is one of the more frustrating experiences in a primary care practice. It's time-consuming, with a low success rate, and you seem to be constantly balancing on a very thin line between undertreating pain and overprescribing narcotics. Many of our current practices are not serving anyone well: patients are not satisfied, prescribing clinicians are frustrated, and addiction/overdose rates are increasing. We can — and have got to — do better. It will take a concerted effort, involving all members of the health care team, as well as patients, but we can do it.*
>
> *– Carol Havens, MD, family physician and addiction medicine specialist*

Our Promise

CO*RE is committed to designing and delivering appropriate, high quality education, rooted in evidence-based adult learning strategies; meeting the unique educational, practical, and structural needs of the individual learner; and changing clinician behavior in the short- and long-term.

Effective education — delivered in an engaging format that applies directly to practice — results in safe and effective pain management that ensures the best care possible for all patients.

Acknowledgement

CO*RE acknowledges the work of our writing team Amy Holthusen and Mary Ales from IPMA, led by Shelly Rodrigues, CAFP, and thanks all the partners and advisors who participated extensively in the review process.

The CO*RE Partners and Associates have been engaged in this discussion since June 2010, meeting regularly by conference call, communicating with leaders and members, participating in national meetings, and supporting the work as it moved forward – all as a function of their commitment to the educational needs of the prescribing community and the patients they serve.

We respectfully submit this paper for your information and consideration.

CO*RE Partners

American Academy of Hospice and Palliative Medicine (AAHPM)
American Academy of Nurse Practitioners (AANP)
American Academy of Physician Assistants (AAPA)
American Osteopathic Association (AOA)
American Pain Society (APS)
American Society of Addiction Medicine (ASAM)
California Academy of Family Physicians (CAFP)
Nurse Practitioner Healthcare Foundation (NPHF)

CO*RE Associates

American Pharmacists Association (APhA)
Interstate Postgraduate Medical Association (IPMA)
Healthcare Performance Consulting (HPC)

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Since the fall of 2009, the CO*RE partners have progressed from a group of eight discrete organizations to a unified collaborative partnership that is committed to advancing best education in pain management and safe use of long-acting opioid medications. Collectively, the group has undertaken countless hours of research, discussion, expert advice, stakeholder input, and analysis to determine the most salient lessons for the development, implementation, and evaluation of long-acting opioid REMS curriculum and programming. Like all stakeholder groups, CO*RE understands that the request to educate 650,000 or more prescribing clinicians on this complex topic on a voluntary basis will be challenging. Yet CO*RE, representing key prescribers across multiple disciplines, remains committed to participating in a manner that will make a difference for our members, all prescribers, and the patients they serve.

The most recent phase of CO*RE's learning process culminated in a summit on July 19th, 2011. Based on review of the literature, an in-depth needs assessment, and expertise of partners and clinicians, we have arrived at the following set of key implications for consideration by all who are involved in the planning and implementation of this and future REMS education.

Pain is a significant and challenging issue in health care.

Pain is one of the most common clinical challenges faced by health care providers; in the United States, anywhere from two to 40 percent of the adult population will suffer from moderate to severe chronic pain.[1] Severe chronic pain has a devastating effect on patients; it affects every aspect of their lives, from mental health to employment to daily activity and function.

A June 2011 report from the Institute of Medicine outlines the current state of science, health care, and research related to pain. The report reveals significant knowledge gaps in both society and the health care environment and recommends redesigned education programs that "foster an understanding among patients, the public, and health care providers that there are complex biological and psychosocial aspects to pain. [Education should address] the nature of pain; ways to use self-help strategies to prevent, cope with, and reduce pain; and available treatments for pain."[2] The report also notes that "improving education is especially important for primary care providers, given their key role in pain management."

Every health care professional who treats patients with pain faces a set of unique challenges and barriers to optimal care. While long-acting and extended-release opioid therapy can be an effective component of a successful pain management plan, these medications involve significant concerns regarding patient safety, the potential for abuse and addiction, regulatory processes, and the best strategies to successfully manage persistent pain while ensuring the safety of all patients.

Competency-based education is key to ensuring safe and effective prescribing of opioid medications.

We recognize that stakeholders involved in all levels of the FDA's REMS program exhibit varying degrees of confidence in continuing education efforts. The CO*RE partnership is convinced that

evidence-based education should be targeted to the competency levels of individual learners and designed and implemented in accordance with proven adult learning principles. We are also convinced that this type of education plays a fundamental role in changing clinician behavior and ensuring best practice, resulting in optimal patient outcomes and patient safety.

While we acknowledge that education may begin with a one-time interaction or engagement, we believe that it must consist of more than that single knowledge-level activity to be successful. Based on the principles of effective education, CO*RE's REMS education plan will provide a multifaceted opportunity to change prescriber behavior and support learner engagement along a continuum from knowledge to competence to performance. We aim to design and implement excellent evidence-based education that will be clinically applicable and will meet and exceed the FDA's requirements.

Clinician education must focus on patient care.

In continuing education and discussions of pain-related risk management, the needs and perspective of the pain patient are often overlooked as efforts focus on the prescriber.

The CO*RE partners recognize that the REMS program has been implemented not for the benefit of the prescriber, but for the care and safety of the patient; this philosophy of better pain care forms the foundation for CO*RE's goals, processes, strategies, and educational curriculum. Reflecting this emphasis on the individual needs of the patient living with pain, special populations may have different requirements for their pain management. Such considerations will also be addressed in the educational curriculum.

> *Improving a patient's quality of life by managing pain and other distressing symptoms of a serious illness is what those in hospice and palliative medicine do each day. Being able to address all types of pain across all settings and for diverse populations – while also managing the risk for diversion and misuse – requires a delicate balance that the experts within CO*RE are uniquely suited to provide.*
>
> *– Ron Crossno, MD, family physician and palliative medicine specialist*

Patient-prescriber communication must be a central component of education.

A program grounded in patient needs and perspectives highlights the importance of patient-prescriber communication. CO*RE's in-depth research into gaps in clinical practice surrounding the opioid management of pain, and the educational needs that address those gaps, reveals that communication issues emerge within almost every clinical competency — from obtaining an accurate history and comprehensive physical exam, to discussing therapy goals and expectations, to managing risk and safety.

While CO*RE's evaluation to date has illuminated the prescriber's perspective on patient communication, research that fully acknowledges the patient perspective on this topic, including the inclusion of current understanding of shared decision-making, must also be considered in the future design and focus of REMS programming.

The bottom line on misuse/diversion/abuse from the physician's perspective is that if a clinician has the slightest inkling that a patient presenting with severe pain has an ulterior motive for wanting pain control interventions, the clinical encounter becomes a 'no win' scenario. If he prescribes an opiate, he'll be staring at the ceiling in the middle of the night wondering if the opiate is being sold on the street. If the clinician doesn't prescribe an opiate, he'll be staring at the ceiling wondering if he caused a patient to needlessly endure ongoing pain.

– Paul Grossman, MD, family physician

Opioid REMS education will affect a broad spectrum of learners.

The CO*RE partners represent a heterogeneous population of opioid prescribers and dispensers. As such, we recognize the diversity of the learner population and their educational needs. Learners that will be affected by REMS education include primary care providers and specialists; physicians, physician assistants, advanced practice nurses, and other health care professionals; and people from a range of practice settings, locations, patient populations, and levels of interaction with other providers. Within these groups, individuals bring differing levels of knowledge, skill, competency, and expertise. Additionally, different learners possess different learning styles and preferences. Effective REMS programs will acknowledge learner diversity and allow for individualized education based on specific need. Methods for learners to self-assess their educational needs and select the most appropriate interventions to meet those needs will be an important element of this curriculum.

Health care happens within teams and systems.

Research on health care provider behavior reveals that patient care is provided within the context of a team, practice and system; moreover, behavioral change often occurs on a team or system level as well. Nevertheless, most needs assessment data and most continuing education focuses on the individual prescriber rather than on the team or system.

CO*RE aims to move beyond the traditional educational model of individual self-assessment. The best practices model for REMS education will incorporate interprofessional, team-based, systems-oriented, and performance-based education which includes self-assessment and links directly to practice and patient care.

Clinicians are fearful about the repercussions of prescribing opioids.

Prescribers who manage pain practice in continual fear of regulatory and legal repercussions stemming from prescribing opioids. This 'fear factor' is a major distinction between pain and other disease conditions and contributes to the challenging character of pain management. As one prescriber put it, "(Clinicians) are scared to death to do what is right, and consequently, they're practicing poor medicine."

It is important for REMS education to acknowledge this fear in an open manner through a frank discussion of learners' competence and confidence and actual and perceived risk of legal and regulatory action. Use of tools, strategies to direct practice, and clinical guidelines in pain

practice will reduce the risk of adverse legal or regulatory action while ensuring safe and effective patient care.

> *I wish I had more time, more tools, and more standardized protocols for dealing with [pain patients]. It would help with liability. I am fearful of losing the therapeutic bond I have with my patients when I have to play policeman. I want to treat chronic pain like any other medical condition.*
> *– Family physician and opioid prescriber*

Education can address structural barriers to optimal care.

CO*RE's educational needs assessment process identified, and quantified, a list of the most significant barriers to optimal care. While traditional medical education focuses on clinician-centered factors, in reality most of these barriers are related to systems factors such as reimbursement, access to care, and regulation. We recognize that the power of continuing education to address these issues at their source is limited; notwithstanding, the CO*RE partnership strongly believes that providing prescribers with the tools and resources to effectively mitigate these barriers will significantly reduce the impact of structural barriers on patient care.

Technology will play a major role in future pain management.

The past 10 years have seen an increase in computer-based health management systems for billing and patient health records. The prevalence of electronic health records (EHR) was reflected in CO*RE's needs assessment survey; 69% of respondents indicated that they are using EHRs in their practice. The Institute of Medicine Report *Crossing the Quality Chasm: A New Health System for the 21st Century* highlights the important role that information technology and electronic medical records play in quality improvement and patient care.[3]

Electronic systems carry the potential to track health information such as diagnosis, test results, prescribed therapy, guidelines, and insurance information. These systems can be invaluable in tracking billing and managing individual patients; however, understanding and managing the patient population, referrals, out-of-network care, and confidential health status varies considerably within EHRs. Questions remain about the integration of EHRs into practice, CMS requirements for use, connections within and between health care systems and settings, and integration into a systems approach to care. While further research will reveal the best role for information technology, EHRs will be integral in the context of long-acting opioid use and chronic pain management.

The Value of Evidence- and Individual Needs-Based Education

> *Education is being able to differentiate between what you do know and what you don't … It's knowing where to go to find out what you need to know; and it's knowing how to use the information once you get it."*
>
> *– William A. Feather (1889-1981), American publisher/author*

The CO*RE partnership holds strong conviction in the efficacy of well-designed competency-based education and its role in translating research; augmenting clinician knowledge, skills, and practice; changing attitudes and behavior; and confronting barriers to best care.[4] Each of these elements is key to ensuring that every patient receives the best possible care. In short, the role of education in patient safety and health outcomes must not be underestimated.

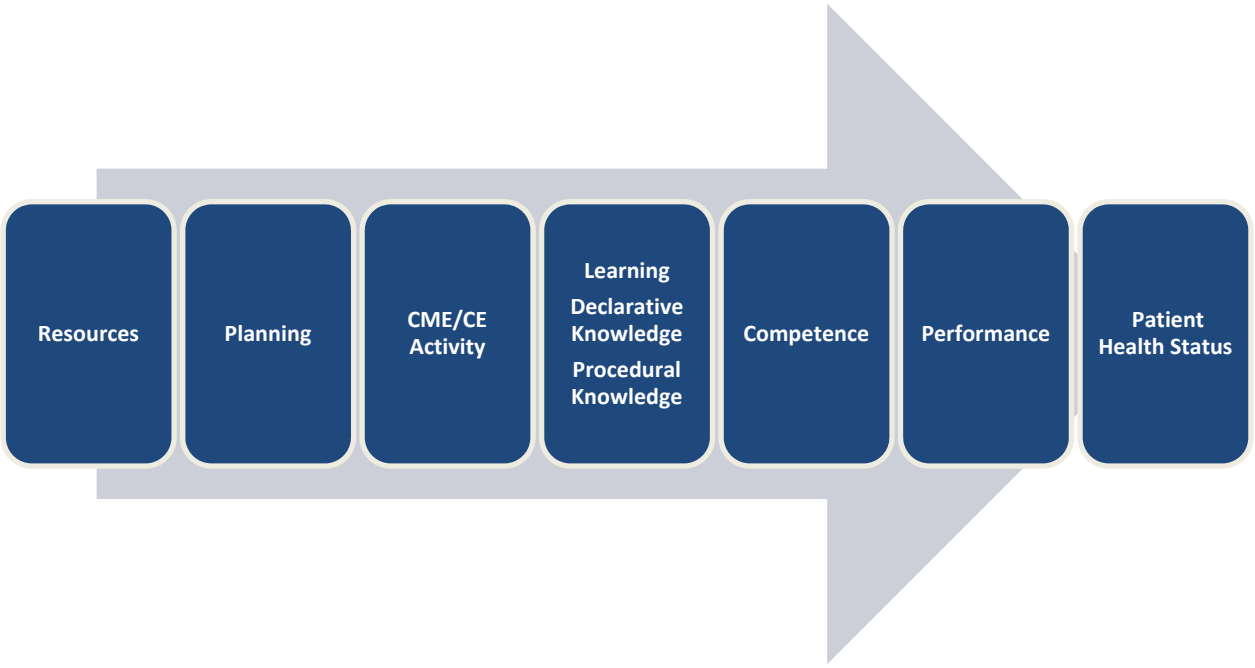
This conviction is not at odds with education that must have a wide learner reach. The fact that the CO*RE partners represent a significant constituency of targeted learners will be important in the successful staging of our initiative as we move learners across a spectrum of education.

Each CO*RE partner is accredited to provide quality continuing professional education; each subscribes to the educational standards set forth by their accrediting bodies. As part of this accreditation, the CO*RE organizations strive to include in their programs activities that move clinicians along a continuum from knowledge to competence to performance. The CO*RE initiative design will reflect this approach.

At one end of the continuum, CO*RE education will enhance clinical knowledge: the activities will deliver new information or knowledge to learners via a variety of vehicles, from live to online to enduring. During the next stage, competence (which denotes capability or skill), learners will have the opportunity to enhance applications (for example, skills in interpreting urine drug testing results for patients using opioids) as they move through the middle of the education spectrum. At the far end is performance, where learners put their competence into practice. Learners' individual and collective educational needs span the full continuum of knowledge, competency, and performance; a comprehensive education strategy must address each of these areas in order to address the entire set of learner practice gaps (See Figure 1 on page 11).

This approach will be augmented by creating additional predisposing, enabling, and reinforcing strategies aimed at promoting better understanding, application, and retention of the educational message. Programming will be developed to meet not only the clinicians' continuing education interests and needs, but also, in the case of physicians, their Maintenance of Certification requirements as well. In the case of nurse practitioners, this programming will meet the certification and licensing requirements for identified pharmacology content.

Figure 1: Progression Through Educational Outcomes. Don Moore, PhD.



A significant body of research exists on the principles of adult learning and the most effective content, format, and delivery strategies for continuing education. Seven key attributes for effective education have been described by Robert Fox:[5]

1. Based on needs
2. Simulates application
3. Interactive with teachers, materials and colleagues
4. Provides anonymous, accurate feedback
5. Allows for reflection on practice
6. Allows learners some control over the experience
7. Leads to verifiable outcomes

The Institute of Medicine report, "Health Professions Education: A Bridge to Quality," states, "… a new vision for clinical education in the health professions . . . is centered on a commitment to, first and foremost, meeting patients' needs."[6] The new vision reads: "All health professionals should be educated to deliver patient-centered care as members of an interdisciplinary team, emphasizing evidence-based practice, quality improvement approaches, and informatics."

This vision statement – a result of work completed in 2002-2003 by a series of IOM committees – has been adopted by CO*RE as the basis of the REMS educational plan. This model incorporates needs assessment, best evidence, and best practice. Additionally, the CO*RE partners recognize the five IOM core competencies that all clinicians should possess, regardless of discipline, professional degree or practice setting:

- **Provide patient-centered care**. Identify, respect, and care about patients; understand differences, values, preferences, and expressed needs; listen to, clearly inform, communicate with, and educate patients while sharing decision making, care management and patient safety.

- **Work in interdisciplinary teams.** Teams can cooperate, collaborate, communicate, and integrate care.
- **Employ evidence-based practice.** Incorporate best research with clinical expertise and patient values for optimal care.
- **Incorporate approaches based on proven quality improvement techniques.** Address errors and hazards in care using basic safety design principles, such as standardization and simplification; design and test interventions to change processes and systems; and measure outcomes in terms of performance improvement.
- **Employ informatics and technology.** Use technology to communicate, manage knowledge, and support decision making.

Meeting and Exceeding FDA Requirements

The stated goal of the REMS program as written by the Food and Drug Administration (FDA) is as follows:

> *Reduce serious adverse outcomes resulting from inappropriate prescribing, misuse and abuse of extended-release (ER) and long-acting (LA) opioids while maintaining patient access to pain medications. Adverse outcomes of concern include addiction, unintentional overdose, and death."*[7]

Components of the required REMS programs, outlined in the FDA's notification letter released in April 2011, include a medication guide; elements to ensure safe use (prescriber education, training providers to educate patients, and informing prescribers of REMS requirements); and a timetable for submission. The REMS program must also include a plan for program assessment which evaluates the following:

- Number of prescribers educated;
- Quality of educational materials;
- Prescribers' and patients' understanding of risk factors;
- Patterns of opioid abuse, misuse, and addiction;
- Patterns of drug utilization; and
- Changes in clinician prescribing behaviors.

Appendix A of the REMS notification letter explicitly outlines the content of the elements to ensure safe use. The required content covers general prescribing information, such as patient selection, assessment of risk, long-term pain management using opioids, dose initiation and modification, and ongoing monitoring. Other required topics include product-specific drug information and patient counseling guidance.

As ongoing dialogue continues between the Industry Working Group, the FDA, and other stakeholders, the required REMS content — including program criteria, hours, content, accreditation issues, and emphasis on safety— may continue to undergo further revision.

CO*RE partners are membership organizations or organizations directly affiliated with active clinical prescribers. As such, it is our vested interest and responsibility to our members to move them as far along the learning continuum as is possible. To that end, almost all the competencies developed by

CO*RE in June of 2010 exceeded those detailed in the Appendix A of the April 2011 REMS letter. [CO*RE does not address product specific package information.] CO*RE partners believe a baseline of education is appropriate, with additional offerings that exceed the baseline. CO*RE also appreciates the need to implement a staged approach that is consistent with, and supportive of, the final 'blueprint' to be released/approved by the FDA.

> *Physicians who prescribe long acting opioids for chronic pain patients must have a state-of-the-art understanding of the indications, risks, and counter-indications for these powerful medications and be exceedingly thoughtful about when and how they are prescribed. Specialists in addiction medicine have worked for many years with our colleagues in pain management to develop and deliver education on the "common threads" between pain and addiction.*
>
> *– Herbert Malinoff, MD, addiction medicine specialist*

Phase One | First Summit: June 11, 2010

In June 2010, the American Pain Society (APS) and the California Academy of Family Physicians (CAFP) invited key stakeholders to join them for a gathering titled *REMS Summit: Impact on Primary Care Prescribers*. The participating organizations worked under the firm belief that consistent, competency-based educational programming, in conjunction with a uniform evaluation methodology, would positively impact prescriber behavior, thus addressing FDA concerns while ensuring continued patient access to best pain care. The summit's primary purpose was to identify the essential competencies needed to safely and effectively prescribe opioids to manage pain.

The group agreed to define competencies as the measurable or observable knowledge, skills, abilities, and behaviors critical to successful job performance (in this context, opioid prescribing). Participants also agreed to focus on the larger body of prescribers rather than on a single specialty, with the understanding that any educational curriculum would by necessity be tailored to meet a specific audience's needs: from primary care to subspecialist care, from urban academic settings to small rural practices, and with consideration for differing patient populations, practice teams, referral resources, and payment options. It was understood that programs would also need to address the educational and practice implementation needs required by students, interns and residents, and practicing clinicians; e.g., advanced practice nurses, physician assistants and physicians, pharmacists, and interprofessional practice teams.

In addition, secondary focuses of the meeting included:

- Promoting better recognition of the opioid drugs REMS program and advancing stakeholder collaboration to develop responsible educational solutions;
- Envisioning potential strategies and tools for use by prescribing and dispensing individuals and organizations;
- Creating a communication strategy that ensures that information is directed to, and considered by, the right audiences (e.g. pain community, the public, legislators); and
- Identifying metrics by which educational efforts can be evaluated.

The CO*RE Approach to Competency-Based Education

Competency-based education has emerged as a leading format for clinician education at all levels. This educational model focuses on achieving desired outcomes in clinical behavior as a result of engaging in a broad spectrum of educational activities, including practice-level education. Rather than simply outlining curricular content, the CO*RE partners have identified a series of practice-based competencies as a direct avenue to engage clinicians in clinical practice improvement.[8 9 10]

At the June 2010 Summit, CO*RE Partners articulated three assumptions forming the foundation of our educational approach to safe and effective opioid prescribing:

1. Opioid prescribing competencies are expected to improve prescribing for all classes of opioids and for both acute and chronic pain.
2. The defined competencies should be relevant to all of the approximately 650,000 prescribers of opioids.
3. Development of competencies is ideally initiated in undergraduate training, but should be provided as continuing education and quality improvement to practicing professionals.

After coming to agreement on these items, the CO*RE group considered several existing opioid-related curricula as a basis for outlining broad topics to be used in defining core competencies. They ultimately chose to collapse the seven chapter topics in Dr. Scott Fishman's book *Responsible Opioid Prescribing: A Clinician's Guide* into four areas.[11] Using these topics, guidelines from leading professional organizations, other evidence-based research, and clinical practice experience, the partners broke into four work groups to define competencies in each area. They then reconvened to discuss and debate recommendations and ultimately agreed on a series of core competencies for safe and effective care outlined on the following page.

CO*RE Competencies: To safely and effectively prescribe opioids to manage pain, a clinician/prescriber will demonstrate knowledge, skills, abilities and behaviors that enable him/her to:

A. Develop an integrated treatment plan based on a comprehensive evaluation. Specific components include:

1. Gather appropriate information through:
   a. Review of medical records.
   b. Perform/Review history with special attention to relevant past medical history, pain hx, and pain related information
   c. Identify risk factors for misuse of opioids

2. Screen for risks of substance misuse and psychiatric co-morbidity using available evidence-based tools

3. Gather relevant objective data:
   a. Perform appropriate physical examination to:
      1. Assess pain
      2. Identify findings suggestive of substance abuse or mental health conditions that augment opioid risk
   b. Obtain appropriate testing to:
      1. Define etiology of pain (e.g., imaging studies, EMG, laboratory data, etc.)
      2. Identify factors associated with the risk of opioid abuse:
         a. Serologic data
         b. Toxicology screens
         c. Screen for depression or anxiety disorder

4. Formulate a working diagnosis of pain and other relevant conditions

5. Create an individualized treatment plan, based on comprehensive assessment that balances benefits and risks for the patient and accounts for the patient's goals and preferences
   a. Describe the needs of special populations, including people with the disease of addiction, the elderly, children, women, and cultural and ethnic minorities
   b. Document the evaluation, objective data, diagnosis and treatment plan

B. Implement a trial of opioid therapy. Specific competencies include:

1. Engage in a meaningful informed consent process that educates the patient, family, and caregivers
   a. Know important potential risks and benefits of opioid therapy
   b. Communicate and document the risks and benefits of opioid therapy supported by relevant patient education materials.

2. Develop a mutually understood and agreed upon plan for clinical care which includes:
   a. Goals for treatment
      1. Communicate these goals to the healthcare team and other support systems patient has designated
   b. Dosing and access to medications
      1. Reduce quantity of opioids for patients at higher risk for abuse, when appropriate
      2. Be familiar with tamper resistant, abuse deterrent formulations available for patients at risk for abuse

c. Instruct patients regarding safe drug storage (locking up) and proper disposal of all medications
d. Expectations with respect to other treatments (anxiolytics), substance use (ETOH, THC), and behaviors (taking more than prescribed, or more often than prescribed, or for other reasons than prescribed)
e. Initiate a Patient Provider Agreement (PPA) that includes education & discussion of:
1. Goals of treatment
2. Dosing and access to medications
3. Safe medications use, storage (locking up) and disposal

3. Expectations with respect to other treatments, substance use and behaviors

4. Utilize a *system of documentation* that includes
a. Initial evaluation and relevant diagnoses
b. Treatment plans (including prescriptions)
c. Informed consent and agreement
d. Results of referrals and consultations
e. Objective testing: radiology and lab data (including urine drug testing)
f. Appropriate follow-up relating to clinical progress and medication management considering both positive effects (e.g., analgesia or functional improvement) and negative effects (e.g., side effects or aberrant behaviors)

5. Utilize and teach appropriate office protocols for requesting, receiving, dispensing, administering, storing and destroying medications in the work setting which meet all state and Federal regulations and documentation requirements of your discipline and practice.

C. Periodically review and revise treatment as indicated, including referral. Specific competencies include:

1. Understand and implement important elements of re-evaluation of opioid therapy, including assessment of:
a. Adherence to the treatment plan (includes checking prescription monitoring program and computerized records)
b. Pain
c. Activities of daily living and other valued functions
d. Presence or absence of adverse effects of opioid therapy
e. Recognition of behaviors that may be associated with aberrant behavior and misuse of opioids
f. Monitor for potential overdose
g. Stability of relevant co-occurring conditions
h. Vigilance for emerging or alternative diagnoses
i. Reconcile medications at each visit
j. Access the state's Prescription Monitoring Program prior to prescribing

2. Use toxicology screening appropriately
a. Describe the rationale for toxicology screening in opioid therapy
b. Interpret common toxicology findings
c. Know resources for assistance in interpretation of unexpected toxicology findings

3. Demonstrate competent pharmaco-therapeutic management including multimodal analgesia.
a. Use good clinical judgment to determine the quantity of the prescription

b. Monitor all patients receiving opioids for pain across all settings
c. Educate patients and caregivers about medication side effects, potential medication interactions (i.e., alcohol, other drugs), and precautions while taking these medications (e.g., falls, working with heavy machinery, etc).
d. Modify opioid dosing, including:
    1. Titration to effect, guided by safety and patient tolerability
    2. Converting from one opioid to another
        a. Convert from immediate-release product to extended-release and long-acting products
        b. Converting from one extended-release and long-acting product to another
    3. Tapering/termination of medication
    4. Counsel patients about missed doses.
        a. Advise dosing schedules that fit into patient's lifestyles to reduce likelihood of missed doses.
        b. Suggest strategies to avoid missed doses.
e. Recognize opioid tolerance and introduce appropriate strategies for management
    1. Identify the potential for opioid-induced hyperalgesia and strategies for managing pain when this occurs.

4. Address opioid misuse appropriately
    a. Determine a differential diagnosis of opioid misuse
    b. Recognize the signs of opioid misuse through systematic evaluation as noted above in C1, C2 and
    c. Refer and follow-up when consultation is necessary

5. Recognize when discontinuation of opioids is indicated and how to initiate and follow through a taper schedule
    a. Know appropriate reasons for opioid discontinuation
    b. Apply therapeutic and appropriate strategies for opioid discontinuation
    c. Continue care for pain and other clinical conditions when opioids are discontinued

6. Identify appropriate referrals when condition warrants
    a. Facilitate coordination of care through effective documentation and communication
    b. Document plans for coordination of care
    c. Communicate with members of the healthcare team
    d. Document all opioid prescriptions regardless of format (e.g., verbal order, written prescription, call-in to pharmacy)

D. Act in compliance with relevant laws and policies

1. Follow appropriate office protocols for requesting, receiving, dispensing, administering, storing and destroying medications in the work setting which meet all state and Federal regulations and documentation requirements

2. Know elements of the Federal Controlled Substances Act relevant to opioid prescribing, including:
    a. Necessity of holding a current and valid DEA license to prescribe Controlled Substances
    b. Rationale for drug scheduling and the legal responsibilities associated with each relevant schedule
    c. Unique features of prescribing/managing patients on either methadone or buprenorphine
    d. Appropriate and legal writing of a series of prescriptions for controlled substances to lessen the likelihood of duplication or diversion

3. Know state legislation, regulations, rules, and unofficial policy statements relevant to opioid prescribing in the state(s) in which the prescriber practices.

4. Know the purpose and intent of prescription drug monitoring programs (PMPs)
   a. If the state in which the prescriber practices has a PMP, utilize the PMP

5. Maintain security of prescription pads, electronically submitted script data and scheduled medications

6. Access DEA guidance/handbooks on prescription and drug safety

7. Instruct patients in safe drug storage (locking up) and proper disposal of all medications

8. Describe the roles and responsibilities of the members of the health care team with respect to opioid prescriptions. Be aware of documentation of opioids called into pharmacy

9. Comply with FDA's opioid REMS requirements
   a. Describe legal responsibility for educating patients on medication guides.

E. For specific products (existing products and new products as they become available):

1. State the pharmacokinetic and pharmacodynamic properties of opioid medications

2. State the product-specific toxicity

3. List the requirements for opioid tolerance for specific long-acting and extended release products

4. Describe the mechanism of action, usual dosing (including titration, conversion, tapering), side effects, tolerance/addictive potential, toxicity, safe storage and disposal of each of the following specific medications:
   a. Fentanyl transdermal system
   b. Hydromorphone ER
   c. Methadone
   d. Morphine ER
   e. Oxycodone ER
   f. Oxmorphone ER
   g. Buprenorphine
   h. New products

5. Instruct patients and their significant supports to recognize, report, and seek care for signs and symptoms of adverse effects/overdose

Phase Two | Needs Assessment Project

While the competencies identified during the first summit provide a foundation for REMS education in opioid prescribing and pain management, the CO*RE partners fully acknowledge that such efforts will have little effect unless they target the specific educational needs of the learner population. The CO*RE group designed an in-depth needs assessment to clearly define the following elements:

- Current metrics and standards of care related to pain management and opioid prescription
- Current gaps in the body of pain-related literature

- Clinician attitudes, barriers to change, and barriers to best practice in pain management
- Perceived needs of clinicians
- Gaps in patient health
- Gaps in clinician knowledge, skills, and attitudes (KSA)
- Mechanism by which clinician KSA gaps contribute to clinician performance and patient/population health
- Tools and resources that are most useful to opioid prescribers
- Clinician learning styles, preferences, and desirable formats
- Clinicians' level of tolerance for REMS education based on CE/CME credit hours
- Clinician behavior and responses to existing initiatives similar to REMS

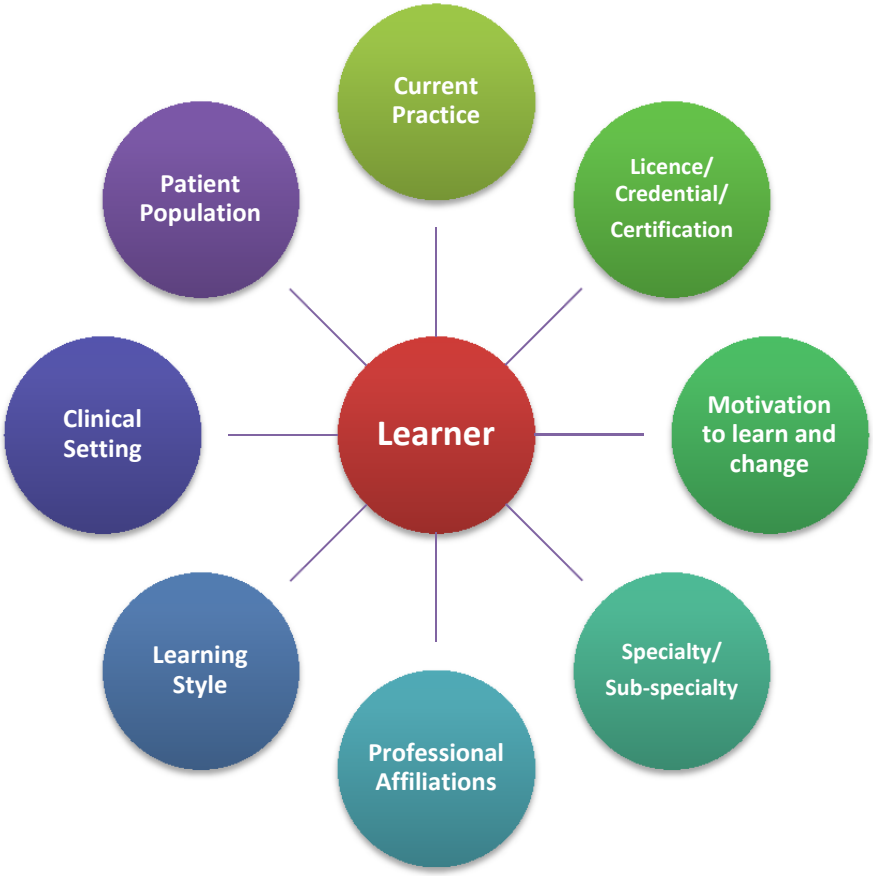


Figure 2: Factors that Influence the Impact that Education has on the Learner

The careful systematic collection and consideration of practitioner responses ensures them a strong voice in the educational design process. By assessing needs and determining desired outcomes, the process remains focused on the clinical issues and improvement of patient health.

The process and methodology of the clinician-focused needs assessment recognizes the importance of learning in altering clinical practice. It also recognizes the importance of motivation to learn and change as an essential element to successful behavior and practice change. Additionally, clinician behavior depends not only on skill and knowledge, but also on the clinical environment and the forces at play

within that environment. For clinicians to change their clinical practices, educational design must take into account the systems and stakeholders that impact these practices. Finally, all needs assessment methods were designed to reflect the diversity of the clinician and patient populations, including geographic, economic, and demographic factors.

There were four arms to CO*RE's needs assessment process:

- One: Educational Review: The CO*RE educational review incorporated an assessment of existing published literature as well as other available information on the needs of clinicians relating to pain management, the use of opioids, and REMS. This information serves as a basis of comparison to the perceived needs identified through qualitative interviews and quantitative survey. The complete educational review is included as Appendix 2, page 62.

The following needs assessment methods were designed to reflect the diversity of the adult patient population and clinical practices in pain management and opioid utilization. The scope of this study suggests that both a qualitative and quantitative approach to data collection and analysis was appropriate.

- Two: In-Depth Interviews: The CO*RE partners conducted 40 in-depth telephone interviews with stakeholders, including physicians, nurse practitioners, physician assistants and pharmacists representing family medicine, primary care, pain management, hospice and palliative care, addiction medicine, and pharmacy. The 60-90 minute interviews provided insight into the problems that clinicians face with managing patients with pain; they also identified learner needs and generated the competencies and barriers which informed the quantitative portion of the needs assessment.

- Three: Change Readiness Inventory: To quantify learners' educational and behavioral needs, a Change Readiness Inventory was administered to family physicians, general internal medicine physicians, pain specialists, hospice and palliative medicine, and addiction specialists. This assessment, completed through an online survey sent to more than 50,000 CO*RE partner members, gauged competencies and barriers that affect change in clinical practices. Clinicians also rated each of the CO*RE competencies according to their present and desired levels of ability, thereby revealing the perceived needs of the target learners. Although the results are not included in this report, a similar survey was sent to more than 10,000 American Pharmacists Association members to access needs of dispensers. A total of 2,306 surveys were completed, a 21 percent response rate.

- Four: Clinical Practice Assessment: The Clinical Practice Assessment, disseminated online together with the Change Readiness Inventory, was composed of a series of statements — developed by clinical experts — that represent particular actions critical to obtaining optimal outcomes in pain management and opioid prescribing. These statements allowed a comparison between perceived needs and actual practice needs based on current clinical performance.

The above needs assessment elements are described in full detail in the *Needs Assessment Research and Analysis* document included in Appendix 1, page 40.

*Nurse practitioners are the only discipline increasingly choosing primary care over specialty care. It is critical that these clinicians, who are on the front line of patient management, have the knowledge, skills and confidence to both identify and manage patients with chronic pain. CO*RE has the potential to provide the depth and breadth of education needed. The input of professional societies from primary care and specialty areas is critical to the development of content appropriate across the spectrum of practice.*

– JoEllen Wynne, FNP, family medicine clinician

Needs Assessment Results

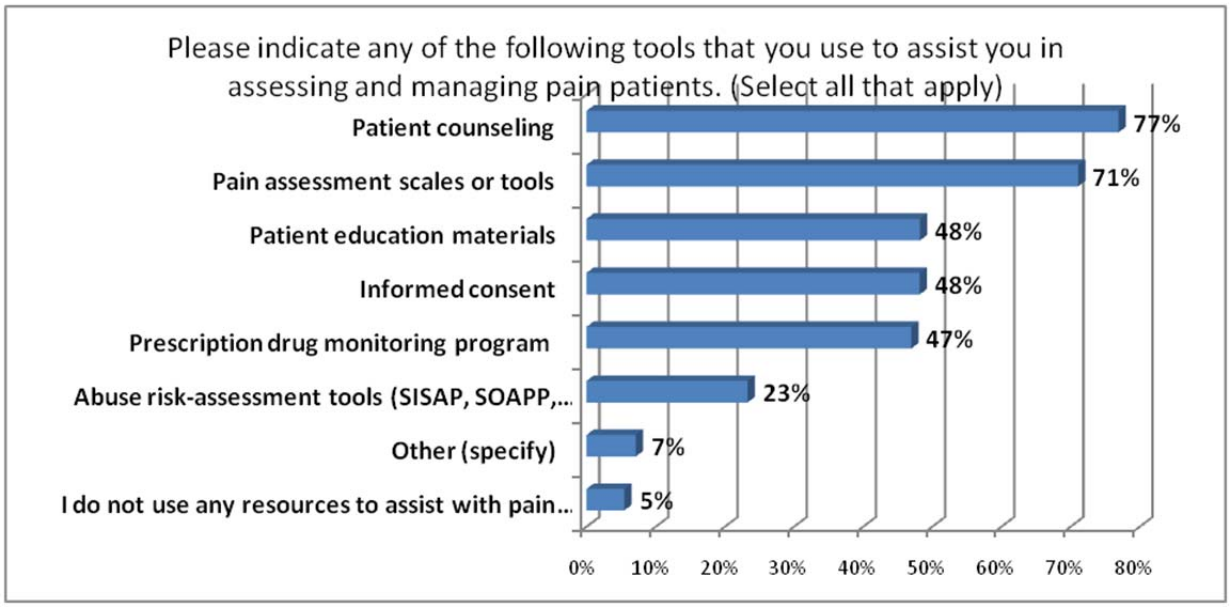
The in-depth needs assessment revealed that clinicians perceive significant need across the continuum of care for persons living with pain. These needs include the initial assessment of the patient, development of a treatment plan, assessment of risk for abuse, and ongoing reassessment of the patient.

Additionally, clinicians perceive many barriers to best practices. Both primary care providers and specialists expressed concern about accidental overdose and patients' concerns that they may become dependent or addicted. Primary care providers also listed among the top barriers to this care the limited access to pain specialists for consultation or referral. The fear of abuse and need to recognize potential diversion were identified as major concerns for clinicians who prescribe opioids.

Furthermore, the needs assessment findings suggest that few clinicians will stop prescribing opioids due to REMS educational requirements. Clinicians in the survey indicated a need to participate in education around opioid prescribing with a preference of four-six hours of CE/CME spread over a period of two years. Respondents are most likely to participate in activities at local, state, and national society meetings.

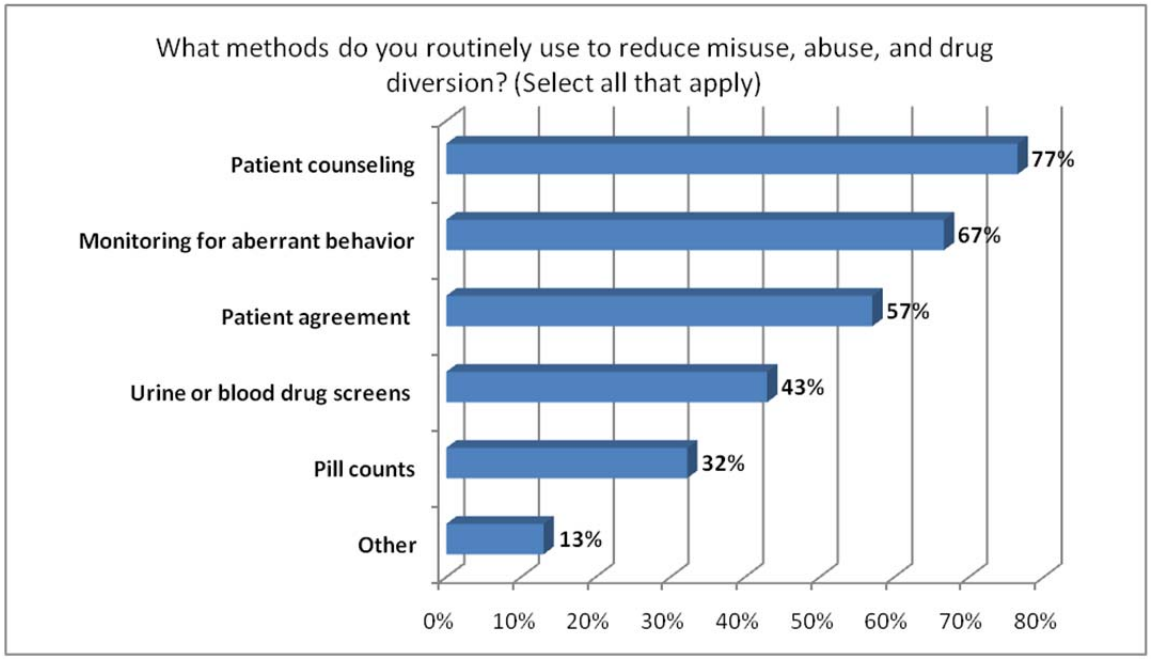
Graphs representing select key findings are included below; rating scales are based on 1-5, 1=low and 5=high.

Figure 3: Tools to Assess and Manage Pain Patients



The most commonly used tools to assess and manage pain patients included patient counseling and assessment scales or tools (Figure 3). Approximately half of respondents also used patient education materials, informed consent, and prescription drug-monitoring programs (also known as PDMPs or PMPs). Only 5percent of respondents used no resources in the assessment and management of pain patients.

Figure 4: Methods to reduce misuse, abuse, and drug diversion



The survey queried respondents about the methods that they used to reduce misuse, abuse, and drug diversion (Figure 4). The most common response was patient counseling, used by 77 percent of clinicians. Other methods used by more than half of respondents included monitoring for aberrant behavior and patient agreements.

Respondents were asked to rate their current skill level and desired skill level for each competency item. The next two graphs (Figure 5, Figure 6) represent the current present competencies (represented by the blue left-hand bar) and desired competencies (the red right-hand bar) of primary care providers and specialists. Both groups of respondents consistently demonstrate a high desired level of ability for each of these competencies, with none averaging lower than 4.4 on the 5-point scale. Ratings for present abilities exhibit more variation.

The difference, or gap, between the clinicians' ratings for *present ability* and *desired ability* represent the perceived need for that particular competency. In other words, this number represents the difference between "what is" and "what ought to be." A gap of 0.5 is presumed to be important, with gaps of 1.0 - 2.0 considered ideal. Gaps smaller than 0.5 indicate low motivation to learn and change, while gaps higher than 2.0 represent an unattainable or impractical level of change.

Figure 5: Present and Desired Abilities of Primary Care Physicians

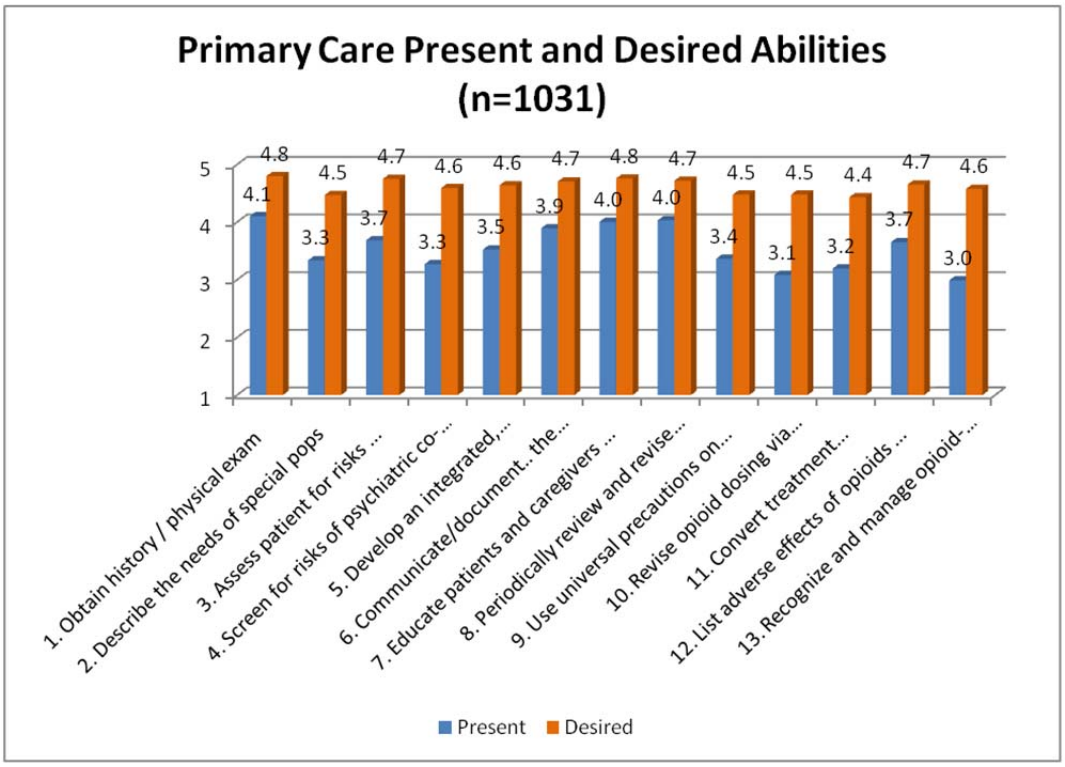
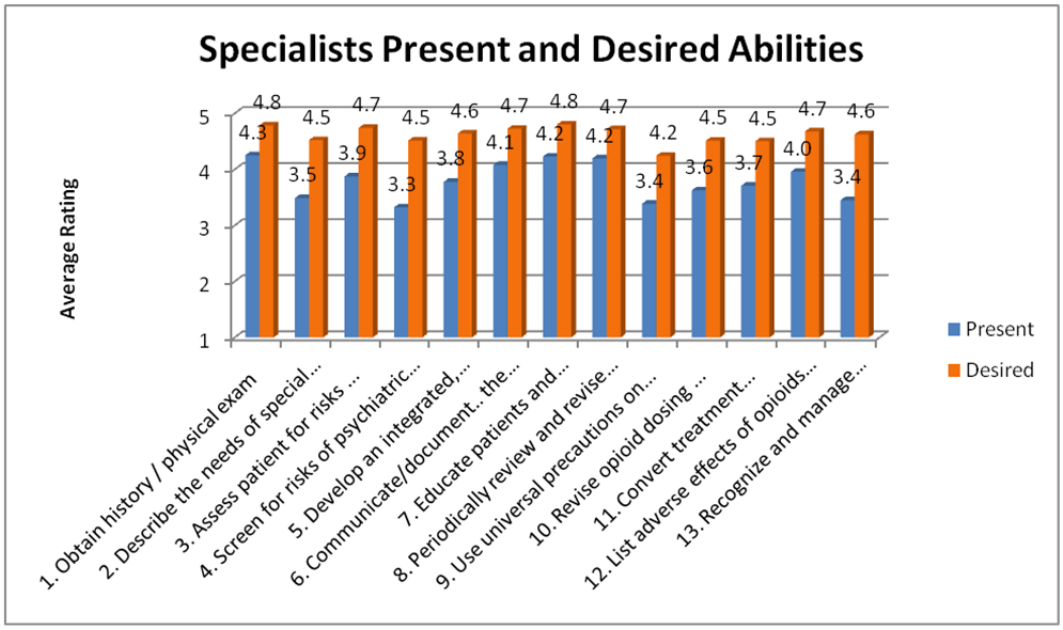
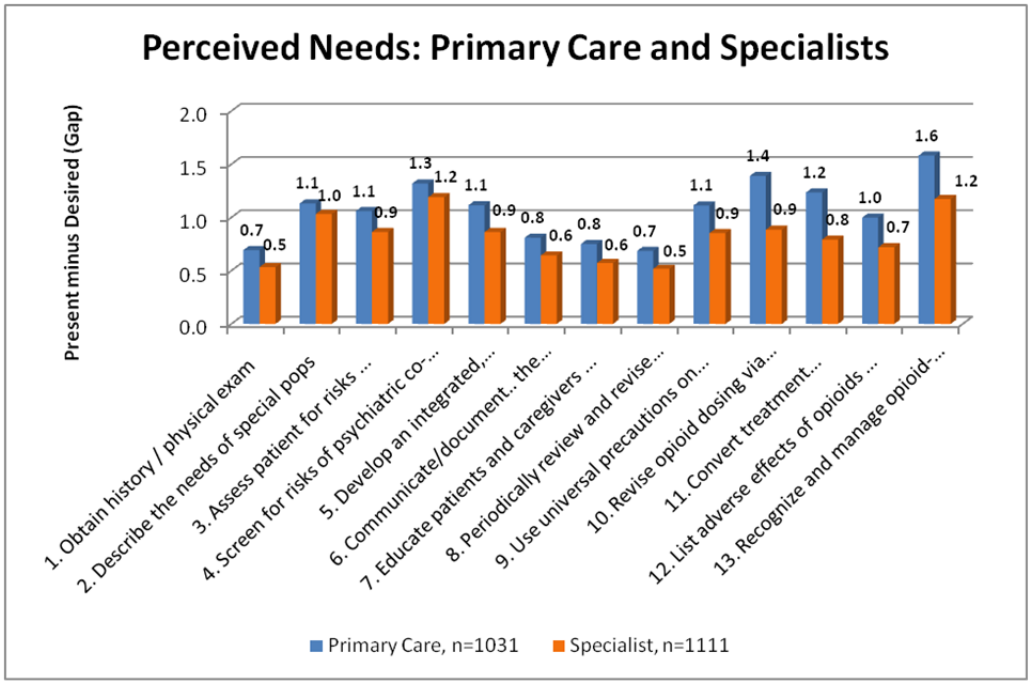


Figure 6: Present and Desired Abilities of Specialists



The following chart (Figure 7) details perceived competency gaps for both primary care providers and specialists.

Figure 7: Primary Care and Specialist Competency Gaps



Survey respondents were also asked to rate the following statements based on the extent to which each presented a barrier to best care in pain management with opioid medications.

Barriers Expressed by Survey Respondents

1. I am concerned that my patients may become dependent on or addicted to opioids.
2. Some patients are concerned that they may become dependent on or addicted to opioids.
3. I am concerned that patients may accidentally overdose.
4. I don't like the regulatory scrutiny that comes with prescribing opioids.
5. Pain patients do not adhere to a treatment plan.
6. I am concerned about potential diversion of opioids when I prescribe them.
7. Managing pain patients takes too much time and disturbs the workflow in my office.
8. Clinical guidelines on appropriate use of opioids are unclear.
9. I am not reimbursed adequately for managing pain patients.
10. Pain patients are sometimes unpleasant to deal with.
11. I have limited access to pain specialists for consultation and referral.
12. My patients do not have access to providers of non-pharmacological therapy (cognitive-behavioral, physical therapy, alternative, etc.)
13. The cost of non-pharmacological therapy is too high for my patients.

Figure 8: Barriers to Best Practices

Barriers were higher overall for those in primary care than in pain specialty practices (Figure 8). The three highest barriers for primary care were:

1. I am concerned that my patients may become dependent on or addicted to opioids.
6. I am concerned about potential diversion of opioids when I prescribe them.
10. Pain patients are sometimes unpleasant to deal with.

For those in specialty practices, the highest barrier was:

2. Some patients are concerned that they may become dependent on or addicted to opioids.

Further graphs are included in the full report of needs assessment findings; see Appendix 1, page 40.

Eighty-nine percent of respondents to the Change Readiness Inventory and Clinical Practice Assessment were identified based on their membership in one of the eight CO*RE organizations. The remaining 11 percent consisted of independent clinicians, unaffiliated with the CO*RE organizations, who served as a comparison group. Analysis revealed no significant differences between the responses of the two groups; consequently, CO*RE partners believe that needs assessment results are representative of all potential REMS learners, not simply those in the CO*RE membership.

Phase Three | Second Summit: July 19, 2011

In July 2011, the CO*RE partners assembled to review the needs data and translate the perceived needs, barriers, and attitudes into educational practice gaps, thereby beginning the process of "backwards planning".[12] By first identifying the optimal population health outcomes, planners can develop an overall educational framework that focuses on measurable and relevant public health needs. This critical analysis ensured that the needs were evaluated using desired clinical and educational attributes. The overall goal of the summit was to translate the real and perceived needs into practice gaps to inform the instructional design. Clinicians will be drawn to education that is grounded in their practice as expressed through clinical problems and patient needs. These attributes will provide credibility, applicability and relevance beyond just passing a test.

Each of the eight organizations sent at least one clinician representative and one educational staff member to the summit; most organizations had two staff members in attendance. In addition, representatives from the American Pharmacists Association, Healthcare Performance Consulting, Interstate Postgraduate Medical Association — all CO*RE Associates — were in attendance as presenters and participants. Finally, the Education Advisory Panel (EAP), Nancy Bennett, PhD, Marcia Jackson, PhD, and Don E. Moore, Jr., PhD, were active participants. The session was facilitated by Carol Havens, MD. In total, 35 individuals were engaged in the day's activities.

Likening our work on the REMS initiative to building an airplane while it is flying, Cynthia Kear and Catherine Underwood, CAE, MBA, representing the CAFP and APS, welcomed the participants to Chicago, summarized the work completed since the first summit, and outlined the tasks to be accomplished at the meeting. The summit provided a forum for diverse groups and individuals to work together toward a common statement of what is needed for clinician education and patient benefit in the arena of long-acting opioid prescribing and management.

As an opening for the meeting, attendees engaged in an interactive process to confirm the characteristics of good education. Reflecting on the experiences of educational activities that they believed were successful, positive, made a difference, or were "intellectually challenging," the participants agreed that the optimal education is based on needs and simulated application. Best education is individualized to the learner, provides feedback and allows for reflection on practice, allows for personal connection to the content, and allows learners a modicum of control over the experience.

With these characteristics of education in mind, APS' Steve Biddle, MEd, led the group though a backward imaging session and discussed the concept of *Good … Better … Best* in developing a continuum of educational activities for the learning population of this initiative.

Tom McKeithen and Chris Larrison from Healthcare Performance Consulting presented the results of the CO*RE needs assessment (described in the previous section). They presented the education literature review, 360° interviews, and survey findings on clinicians' perceived and actual practice gaps. Barriers to treatment of patients with pain, patients with addiction and dependence issues, special populations, and barriers to the completion of REMS education were also discussed. Subsequently, the Education Advisory Panel presented their own comments on the needs assessment and provided guidance on how the revealed concepts might link to potential educational design within the initiative. Discussion points prompted by the EAP included:

1. Issues of payment and limited access must be addressed; answering these questions, including questions of finances or coverage, may further define barriers to care.

2. The first two barriers are very closely aligned to gaps or perception of gaps. It should be noted that guidelines are available to address these barriers.

3. Eight barriers relate to patients; however, the needs assessment did not incorporate the patient perspective. Follow-up patient-centered research will present a more complete picture of these barriers.

4. Both the social aspect (barriers that make the encounter difficult; i.e., systems issues) and the technical aspect (barriers of information; i.e., history/physical, drug titration, testing, etc.) of the clinical encounter are amenable to education.

5. Incorporating learner self-assessment is vital in stratifying the needs of specific learners and directing the educational experience across a spectrum from primary care to subspecialties such as palliative care or addiction medicine.

6. Summit participants cautioned against assuming that largest perceived practice gaps represent the greatest need or the most-needed intervention. More analysis should be done to ensure that these gaps are relevant to the learners.

7. Our data is clearly focused on the individual clinician; we will be challenged to apply findings to clinician teams as we move forward with education design and implementation.

Using this information as a basis, the participants divided into four work groups to develop recommendations about the education required to meet — and exceed — the gaps in 13 competency

areas (the summarized competencies used in the needs assessment). This shorter list was developed to allow learners to see succinct statements of competency needed for optimal management of the chronic pain patient. This list was reviewed by the partners and by clinical experts; and in some cases, slight edits were made to clarify or broaden language.

Two of the groups represented primary care; the other two represented subspecialty care. Each group contained a facilitator from the work team, an Education Advisory Panel member for expertise, and a recorder/reporter. The 13 competencies/gaps were broken into two sets, so each group addressed half the gaps; consequently, each gap was addressed by one primary care group and one subspecialty group.

The work groups were asked to answer three questions for each assigned gap:

1. On a 5-point scale, what does a 5 (or, the best in performance/competence) look like in practice?
2. What are the attributes of the education that would help clinicians to attain a 5? (Included educational format; for example, self-assessment, standardized patient, case vignette, work team with colleagues, etc.)
3. Based on the needs assessment data presented, what path would a learner take to get to a 5?

The Education Advisory Panel was invaluable in guiding the small group process. Participants agreed that in some cases, gaps are small and that clinical change as a result of learning will make 5 easier to reach; in other areas, the larger gap based in performance will make progress more challenging. Summit participants also agreed that not all gaps apply to all learners. Other key discussion points included potential educational strategy, overall framework of educational design, turning identified needs into deliverables, bridging the gap between learners' diverse needs and the FDA's end goals, and attaining results within realistic timelines. We asked groups how to account for the fact that desired and indicated educational content and format will differ considerably among learner population.

The table below outlines a summary of the findings from the small group sessions:

What Does a "5" Look Like?	Attributes of the Education	Comments and Notes
1. Take a relevant history and physical exam of patients with chronic pain.		
The H/P is completed to determine whether indication/need for LA opioid therapy exists. This is an important step in understanding the medical diagnosis of the pain condition being treated.	H/P is a skill that requires practice and feedback, active listening and communication and should be taught including a watch and evaluate (right vs. wrong) segment.	Clinicians may need greater motivation because most think that they know how to do a good H/P. The best H/P might also reveal a condition not needing an LA opioid.
1A. Use diagnostic testing, including radiologic and laboratory data, to define etiology of pain and to assess risk of opioid misuse.		
Following and appropriate H/P, select correct diagnostic test – radiologic or lab – to confirm medical diagnosis.	Knowing when to use what test in which patient, and which patients are susceptible to potential abuse with non-determined pain is a skill that improves with practice.	Clinicians and patients will have the benefit of better treatment outcomes and treatment planning and will have more accurate information for a baseline that results in safe and accurate prescribing.

2. Describe the needs of special populations, including people with the disease of addiction, cultural and ethnic minorities, pregnant women and those at the extremes of age.		
Delineate the clinical issues of patients with pain who also have co-morbid conditions, for example age, end-of-life, or other special needs. Understand and engage the patient with cultural, ethnic, or language-related needs.	Systems-based education that includes the practice team. - Define roles and responsibilities of office staff - Awareness of differences for special populations (including health literacy) - Empower the team to lead - Knowledge of different population needs - Skills in working with patients of difference culture/age	You can't get an accurate H/P unless you have complete information on patients. Clinical indications could be changed and patients harmed and the ability to effectively communicate with patients is key.
3. Assess patient for risks of problem/aberrant behaviors, opioid misuse, substance abuse and addiction.		
Become fluent with the tools for screening including use and analysis, and appropriate use with patient at hand, including which and when to use them. Determine patient specific risk factors for opioid abuse including aberrant behaviors.	Knowledge and competence education that could be scenario-based, focusing on constancy of use (pick one and use it well; tools that form a comfortable foundation for practice) K – What tools are available K – What resources are available (state databases, pharmacy records). Systems can work with full care team including pharmacy C – Role play of clinician and standardized patient C – Observation and feedback C – Distinguish drug-seeker, quick-fix, unintentional misuse, legitimate under-treatment of pain	There may be a fear factor at play, and clinicians need to be assured that appropriate assessment will assist with "Do no harm." This will encourage clinician empowerment to make appropriate treatment plans to treat the whole patient.
4. Screen for risks of psychiatric comorbidity using available evidence-based tools.		
Use of appropriate tools for screening. Combine use of tools for comorbidities i.e. depression, diabetes, etc. Recognition of barriers for care of mental health patients; barriers include $, time, coverage, access, adherence. Patient stratification for appropriate placement	Case scenarios with vignettes that include application of risk stratification tool focusing on "if this … then that" decision making support.	Personalizing treatment to the patient's needs is key; planning for these patients will improve care and outcomes.
5. Develop an integrated, individualized treatment plan including pharmacologic and non-pharmacologic therapy		
Address multi-modal analgesia with an upfront, individualized assessment and treatment plan that includes: - Not over or under? - Right quantity of drugs - Team based MMA in practice - Access or knowledge of available tools	Skill – Motivational interviewing curriculum will be valuable here. Content should include: - What is MMA? - Algorithm - What does the patient experience look like?	Role play will assist in learning. Use knowledge and practice with feedback (e.g. simulated scenarios) Help learner understand what's in it for them – take some pressure of the prescriber by including non-

We must help clinicians determine how to measure success for each patient (function, patient satisfaction, patient definitions), including getting prescriptions from one source if possible, and having an exit plan.	- What non-pharma exists - What pharma exists - What pharmacology is available - Personalized to patient context - Identify patient-centered goals incorporating function - Follow-up	pharmacological therapy.
6. Communicate and document the risks and benefits of opioid therapy		
Content should include: - Informed consent - Ask, tell, ask - Side effects - Safe medicine storage - Individualized to patient and caregiver - Patient questions - Effective documentation Finding the balance between reassurance and uneasiness will be important.	K – Standardized medication documents that assist clinicians with communication C – Practice communication with case scenarios and role play P – Chart review	This section will help address with provider fear and may have benefit with malpractice carriers.
7. Educate patients and caregivers about medications side effects, potential medication interactions, and precaution while taking opioid analgesics.		
Content should include: - Informed consent - Transfer of knowledge to patients - Ask, tell, ask Relay safe medication management (storage, administration and disposal) Assess patient health literacy and cultural competence. What are cultural values related to opioids?	Tools: Standardized medication documents that list risks - Medication storage, administration and disposal - Information on drug-drug interactions K – The difference between dependence and addiction and helping patients overcome fear of opioids - Patient centered component: does the HCP teach the patient about risk? Review misuse/abuse.	Modeling video for ask-tell-ask Role play with other clinicians or standardized patients can assist. Health literacy tools
8. Periodically review, revise and document treatment as indicated including referral		
This section includes: - Use of a registry - Objective evidence of improved or diminished function - Review side effects - Availability of referral - Exit plan	Registry K – What must be documented in a chart and developing treatment plan goals C – Documenting C – Case based developing exit plan	Patient and caregiver review of plan
8A. Document all relevant diagnostic, treatment, and follow-up information		
- Accurate and complete medical record including prescription fill (note: these don't cross state lines or VA) - Templates, patient agreements, communication tools, contracts, etc. 4 As: Analgesia, Aberrant behavior, ADLs, and Adverse effects	Medico-legal aspects of record keeping will be addressed. Office team requirement and sample documentation would be helpful as well.	Didactic sessions, with chart review/feedback, matching the documentation to the treatment goals. Check for accurate documentation to mitigate legal issues. Integrated records reflect an integrated team.

Electronic Health Record Dissemination of information across all disciplines (ER, pharmacy)		
9. Use universal precautions on all patients receiving opioid treatment		
Not evaluated in workgroups.	Not evaluated in workgroups.	Not evaluated in workgroups.
10. Revise opioid dosing via titration, rotation (using equianalgesic dosing), or tapering/termination of medication		
ID patient risk behaviors Knowledge of various agents Knowledge of addiction, dependence and tolerance Knowledge of tools for determining equianalgesia of agents	K – Know how, when, and why to test C – How to interpret and communicate results Knowledge of revising dosing; relationship between dosing and failure of opioid therapy and asking why does treatment fail?	Case studies Use therapeutically – tell patient that you will randomly drug test
11. Convert treatment from immediate-release products to extended-release and long-acting products		
Content could include qquianalgesic dosing, safe medication management, and length of treatment. Refer back to competency #8	Knowledge of equianalgesic principles, pharmacokinetics, pharmacodynamics. Knowledge of indications – when and how to convert, recognized limitations, how to make the transition safely.	Didactic Case based Case studies and vignettes, mentors, and role-playing.
12. List adverse effects of opioids (sweating, nausea, low testosterone)		
Outline drug drug interactions List of adverse effects with symptoms Likeliness of occurrence	K – Knowledge of adverse effects K – How to effectively communicate to patients K – What should patient do if they have reaction C –Effectively communicate without compromising pts taking drugs	Didactic for knowledge- may be place Will there be an option to “test out” Case vignettes, standardized patients, monitor feedback for effectiveness in communicating.
13. Recognize and manage the failure of opioid therapy, including, but not limited to, opioid-induced hyperalgesia		
Primary care says this is purview of specialists, and that appropriate referral plans are needed.	Patient communication: prepare them for this possibility at the outset.	There is a lack of agreement about the definition of hyperalgesia
**** Also Discussed by Workgroups: Identify underlying psycho-social problems that may be associated with chronic non-malignant pain.**		
Ensuring that you ask the questions and engage the patient to get the most complete information available	Include motivational interviewing Case vignettes Practice based system work	Without this information you are practicing blindly.

After the work groups presented their reports, the EAPs then again commented on the process and identified where to address educational design issues as we proceed in curriculum development.

Summit attendees focused their design on best or “level-5” education, not simply better care. There was general consensus that curriculum would include self-assessment that focused on learners’ specific practice, team and system needs. Relevant materials and resources would be presented in an interactive

format, including examples and demonstration that reflect real clinical problems and allow learners to practice desired knowledge and skill. Learner self-assessment and feedback played a key role in the small group discussions. One group worked to design a framework for designing the curriculum (Figure 10) that incorporates this spectrum of self-assessment to performance improvement. The framework mirrors the clinician learner engagement paradigm as discussed by Moore, Green, Gallis (Figure 9).[13]

Figure 9: Learner Engagement Paradigm

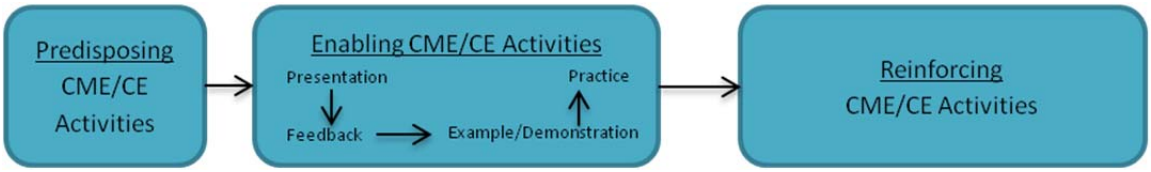


Figure 10: Curriculum Framework

STAGE	Predisposing →	Enabling →	Reinforcing
HOW	Self Assessment	Resource Center of Excellence Case Based Vignettes →	PI-CME/CE Year 1 Pilot Year 2 Scale Up
WHO	Individual	Individual/Team	Practice
ASSESSMENT	Self compared to peers	Continuous Assessment	PDMP Measure and System Data
DELIVERY	On-line	Live Conference, Web, Enduring etc.	In Practice/Community

This overall model supports behavior changes as part of a process rather than as a result of a single event. Patient care is increasingly influenced by team management as well as individual practice; this model supports both individuals and teams in a process of comparing current practice to optimal performance through self-assessment. A variety of learning activities and resources (for example, case-based vignettes or PI-CME/CE), hosted in a resource center of excellence, will directly address the identified needs. Continual evaluation through both formative and summative assessment will result in a living resource that is continually updated. Specific learning activities will be designed to match

variations in learner needs, specialty, learning format preferences, practice setting and patient needs as represented in the figure below. Learning activities will be directly presented; resources supporting "train the trainer" component will provide broad reach. Departmental conferences, small groups, and professional meetings may choose to use the objectives, content, questions, and assessments as part of their educational strategy. Non-educational strategies will provide on-going clinician support. Over time, performance improvement activities for individuals and practice could be designed and offered.

The summit concluded with a discussion of next steps, outlined later in this report (see page 36). A small working team met after the summit to review the day's activities, the work groups' reports, and summaries of comments. They then consolidated the information into a series of recommendations, an outline for this report, and a work plan going forward to proposal submission.

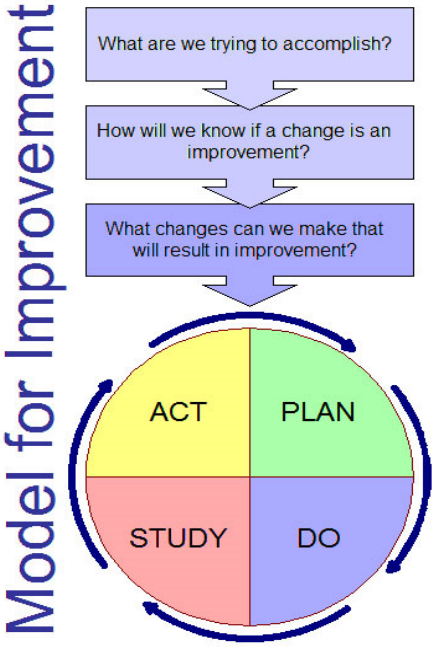
CO*RE Preliminary Recommendations on Educational Design

Based upon work done in Phases One, Two and Three, and understanding that the final 'blueprint' will ultimately influence actual development, CO*RE recommends an educational design that:

- Employs a competency-based curriculum rooted in evidence-based principles of adult learning.
- Educates and guides a learner and his/her team across the full cognitive and behavioral continuum from knowledge to competence to performance.
- Incorporates self-assessment and allows the learner to progress logically from predisposing to enabling to reinforcing phases.
- Implements efficient, modular and diversified learning modalities presented in venues which will best encourage learner participation under voluntary engagement.
- Balances the need for effective education with education that must have a wide audience reach.
- Respects the time parameters that busy clinicians are willing to meet to voluntarily engage in education.

Continuous Assessment

In addition to the above recommendations, CO*RE is committed to continuous assessment of its processes and products. This process will give us detailed and specific data on the impact of CO*RE activities and the evidence will be used to track program effectiveness and make changes as needed. (See Right: ***Figure 11: Plan-Do-Study Act Model for Improvement***.)



We will engage in a methodical, continuous assessment to routinely and rigorously monitor our efforts, comparing and contrasting actual results versus goal. We intend to incorporate the Plan-Do-Study-Act (PDSA) model for assessment, pausing after each critical phase to assess the efficacy of our plan and adjust accordingly.[14] This adjustment could manifest in redirecting efforts or in redoubling efforts.

The same PDSA philosophy will be included in practice-based educational activities as well. For example, we will also develop tools — such as the American

Academy of Nurse Practitioners' in-office flip chart, used in its very successful COPD (chronic obstructive pulmonary disease) initiative — to be tested for decision support and patient engagement.

Education Advisory Panel

To ensure that all CO*RE material is grounded in evidence-based adult educational strategies that are proven to change clinician behavior, CO*RE has engaged a group of nationally-recognized experts in educational design, clinical education, and CME/CPD.

Nancy Bennett, PhD	Assistant Professor of Psychiatry Massachusetts General Hospital Boston, Massachusetts
Marcia Jackson, PhD	President, CME by Design Santee, South Carolina
Donald E. Moore, Jr., PhD	Director, Division of Continuing Medical Education Professor of Medical Education and Administration Vanderbilt University Nashville, Tennessee
Carol Havens, MD	Family Medicine and Addiction Medicine Kaiser Permanente, Sacramento Medical Center Department of Chemical Dependency Regional Director for Clinical Education Northern California Permanente Medical Group Sacramento and Oakland, California

While continuing education in health care regularly involves experts in clinical content, few initiatives make similar use of experts in adult education. To date, the Education Advisory Panel has provided invaluable feedback on educational strategies and programming. CO*RE will continue to work closely with these individuals as the partnership moves forward with designing educational curriculum, format, and delivery. Combining clinical expertise with educational expertise ensures maximum effectiveness of the overarching educational design as well as each individual educational modality.

Our Promise

CO*RE is committed to designing and delivering appropriate, high-quality education, rooted in evidence-based adult learning strategies; meeting the unique educational, practical, and structural needs of the individual learner; and changing clinician behavior in the short- and long-term.

Effective education – delivered in an engaging format that applies directly to practice – results in safe and effective pain management that ensures the best care possible for all patients.

Next Steps

The completion of the needs assessment and educational design summit is just the beginning of the next phase of CO*RE work. There are many tasks ahead as the partnership moves forward to respond to the FDA's REMS and the requests for proposals that may be forthcoming. Future tasks include:

Presenting this report: CO*RE will send this report to Pfizer Medical Education Group and Purdue Pharma LLC, supporters of Phases Two and Three of this work, and to the IWG and FDA for review and comment. We would be pleased to present the findings via web or conference call.

Finalizing the infrastructure of CO*RE: Each organization has signed a letter of intent and participation agreement. An infrastructure document, with roles and responsibilities, has been distributed; the next steps include the assignment of working committees, including an operations committee, finance committee, grant writing work group, and communications committee. A Clinical Advisory Board will also be appointed; the EAPS will continue to work with CO*RE as we move forward.

Preparing for proposals/grants: CO*RE's proposal writing team has begun work on the review of this material and the Scope of Proposal document submitted to the IWG and FDA in October 2010. The group will prepare a new proposal to address the educational and outcomes needs of the REMS, including content development and delivery, technology and communications, outcomes measurement, and implementation along the continuum from self-assessment to performance improvement. Educational design, metrics and budgets will be included; and the writing team is working to have this proposal complete as soon as possible after the FDA release of the 'blueprint' document.

The CO*RE partners wishes to thank all the participants in this process and looks forward to the next steps in in its work to address this important public health and education initiative.

About the CO*RE Partnership

The eight CO*RE partners and three CO*RE associates are committed to ensuring effective, evidence-based education to change clinician behavior and promote best patient care.

CO*RE Partners

- American Academy of Hospice and Palliative Medicine (AAHPM)
- American Academy of Nurse Practitioners (AANP)
- American Academy of Physician Assistants (AAPA)
- American Osteopathic Association (AOA)
- American Pain Society (APS)
- American Society of Addiction Medicine (ASAM)
- California Academy of Family Physicians (CAFP)
- Nurse Practitioner Healthcare Foundation (NPHF)

CO*RE Associates

- American Pharmacists Association (APhA)
- Interstate Postgraduate Medical Association (IPMA)
- Healthcare Performance Consulting (HPC)

Further information on each organization is available in Appendix 5, page 93.

Background and History of the CO*RE Collaboration

CO*RE began as a group of individual organizations, each considering the potential trajectory of opioid REMS programs. Over the past two years, the partners have come together into a formal united collaboration that is dedicated to improving patient care through REMS education.

- In September of 2009, CAFP leaders first met with Marsha Stanton, PhD, RN, formerly of King Pharmaceuticals and currently with Pfizer, to discuss issues in REMS. CAFP brought a request for approval to investigate to its Board of Directors in November 2009, and in January 2010 launched a survey about pain management, REMS, the FDA and DEA to members of CAFP and eight other state chapters. At the same time the APS was completing work on its pain management and opioid use guidelines.
- Simultaneously, CAFP reached out to the APS — an organization also deeply engaged in issues and policies connected to pain management and in development of guidelines for opioid use — to inquire about an opportunity to work together. Other organizations were recommended by the APS based on their roles in pain care and a demonstrated willingness to enter into a collaborative.

- On June 10, 2010, representatives from 12 organizations attended the first CO*RE summit in Chicago. The group developed the CO*RE competencies for safe and effective pain management and opioids prescription. The competencies were adopted by all of the organizations.
- During the summer following the first summit, CAFP and APS led the organizations through a series of exercises to develop the *Scope of Proposal* document, which outlined work to be done to meet and exceed the soon-to-be-released REMS. The document delineated the partnership's infrastructure, roles, responsibilities, and educational activities with budgets. It was submitted to the IWG and FDA on October 18, 2010.
- Meanwhile, CAFP worked to secure letters of intent from each organization. The group met face-to-face and via teleconference early October 2010 to finalize the Scope. At that time, the American Academy of Pain Medicine, the American Society for Pain Management Nursing and the American Academy of Pain Management withdrew from the initiative.
- During the first quarter of 2011, CAFP worked on the infrastructure documents necessary to formalize the CO*RE relationship, including a Participation Agreement and Addenda. All eight partners have signed the agreement.
- In March of 2011, CAFP submitted grant proposals to Pfizer, Purdue, Endo, and Janssen to support a needs assessment and educational design summit. CO*RE received approval from Pfizer and Purdue in May of 2011 and worked in earnest to complete the needs assessment and host the design summit on July 19, 2011.

Throughout the process, the CO*RE partners have held regular conference calls and reported progress to their respective boards. Select CO*RE partners have presented and attended FDA, ACCME, IWG, and other REMS-focused events.

The CO*RE partnership brings together a unique array of experiences, skills, expertise, learner representation, and commitment to education. Partner memberships represent clinicians from the entire spectrum of prescribers and dispensers; CO*RE's potential to access these individuals directly is unparalleled.

All eight partner organizations are responsible for, and deeply committed to, improving patient outcomes through evidence-based, practice-changing education. Many of the partners and associates have previous experience in successful large-scale collaborations. Moreover, all eight partners have come together at the two summits described above to set a collaborative framework for planning a superlative educational initiative.

Learner Representation and Access

The membership of the eight partner organizations represents the full spectrum of targeted prescribers and dispensers, ranging from primary care physicians, nurse practitioners, physician assistants, and pharmacists to cutting-edge researchers, addiction, palliative and pain specialists, and expert opinion leaders. These organizations' members also practice in the continuum of settings, from academic centers to solo offices and small facilities, and from urban centers and chain pharmacies to rural communities.

Because each partner represents the voice of the targeted constituencies, the partnership offers a unique capability to build learner/prescriber/dispenser awareness through highlighting the critically important health crises inherent in the management of acute and chronic pain.

The eight organization members of CO*RE have immediate access to 392,000 clinician members; with the outreach of member associations and commercial education organizations, CO*RE can reach approximately 667,000 prescribers and dispensers. Each partner will employ its internal and external communication vehicles —including magazines, e-newsletters, social media outlets and websites —to reach members and learners.

Skill and Experience in Certified Education

All eight organizations are respected and accredited providers, fully conversant in the requirements and methodology of today's complex and varied educational environments. As accredited providers, content developed by this group will be given the full range of certification necessary to elicit learner participation, including *AMA PRA Category 1* ^{TM}, AOA Category 1, AAFP Prescribed, AANP, ANCC, AAPA credit and ACPE credit.

Organizational Support and Leadership

All eight organizations enjoy the full support of their elected and staff leadership to move forward in this innovative collaboration. Boards of directors, education committees, and other leadership bodies are committed this issue, adding multiple perspectives to the project. Each of the organizations has signed a formal CO*RE Participation Agreement.

Background in Collaboration

Because the majority of the eight partners have experience in medium-to-large scale collaboration, this model has been selected as the basis of operation for the CO*RE partnership. Many collaborative and operational processes have been adapted from a highly visible, successful, and award-winning collaboration: Cease Smoking Today (CS2day), which was designed to address another public health crisis of tobacco use. The eight-partner CS2day collaboration has worked together since 2007, reaching more than 50,000 clinician learners, and has been financial steward for grants totaling $17,000,000. The best practices of the CS2day collaboration will be brought to bear fully upon the CO*RE initiative.

CO*RE Pain Management and Opioid REMS

Needs Assessment Research and Analysis

The following clinician-focused needs assessment methodology was designed to inform the development of educational interventions which will have an optimal impact on educational, behavioral, and clinical outcomes. The process recognizes the importance of learning in the process of changing clinical practices. It also recognizes the importance of motivation to learn and change as an essential element to successful planned change.

Systematically collecting and considering the responses of practitioners, gives practitioners a voice in the process. By assessing needs and determining desired outcomes, the process remains focused on the clinical issues and improvement of patient health. In this case, all needs assessment methods were designed to reflect the diversity of the clinicians and patient populations, including geographic, economic, and demographic factors.

Clinician behavior depends not only on skill and knowledge but also on the physician's clinical environment and the forces at play within that environment. For clinicians to change their clinical practices, they must take into account the systems and stakeholders that impact their practices. This ***needs assessment research*** has been designed to answer the following research questions:

- What gaps currently exist in the knowledge, skills and attitudes (KSA) of clinicians with respect to pain management and the use of opioids?
- How do the KSA gaps contribute to gaps in clinician performance as well as patient and population health?
- What are the perceived needs of opioid prescribers as described by self-assessed clinical competency gaps?
- What is the level of tolerance of clinicians for Risk Evaluation and Mitigation Strategies (REMS) compliance in terms time allocation, based on CE/CME credit hours.
- What are the most desirable formats for delivering REMS education?
- What tools and resources are most useful to opioid prescribers?
- What are the barriers to best practices in pain management?

Methods

The needs assessment methods were designed to reflect the diversity of the adult patient population and clinical practices in pain management and opioid utilization. The scope of this study suggests that both a qualitative and quantitative approach to data collection and analysis was appropriate.

Educational Review: The CO*RE educational review incorporated an assessment of existing published literature as well as other available information on "real needs" of clinicians relating to pain management, the use of opioids, and REMS. It was designed to identify, synthesize and summarize data from any and all sources that would give insight into specific educational needs, barriers to best practices, and barriers to implementation of REMS or other regulatory controls over clinician prescribing. The information developed in this review serves as a basis of comparison to the perceived needs as identified in the qualitative interviews and quantitative survey.

In-depth interviews: As part of the CO*RE needs assessment, Healthcare Performance Consulting conducted in-depth interviews with stakeholders including physicians, nurse practitioners and physician assistants from family medicine, pain management, hospice and palliative care, addiction medicine, hospitalists and pharmacists. The interviews were conducted as part of the overall needs assessment to gain insight into the problems clinicians face with managing patients with pain as well as the perceived needs of the learners. These interviews generated the competencies and barriers which inform the quantitative portion of this assessment.

Participants were recruited from the target populations by CO*RE member associations and a provider panel. Selection criteria required specific specialties and an active outpatient practice. The interviews were conducted by telephone and lasted approximately one hour. Interviewees were compensated $250 for their time.

The interviews started with a general disclosure describing the project and proceeded to identification of the participant's responsibilities, thoughts and concerns about pain management and opioids. Interviewees were asked to identify problems associated with managing patients with pain and list the causes of those problems. As the interviews progressed, competency statements derived from best practices and refined by specialists were discussed with clinicians and validated for use in the Change Readiness Inventory (CRI). Interviewees were also asked to describe recent changes in practice, the reasons for making those changes, and barriers that may have impeded them.

Change Readiness Inventory: To quantify the educational and behavioral needs, a Change Readiness Inventory was administered to the clinician target audiences (family medicine, general internal medicine, pain management, hospice/palliative care, and addiction specialists). This assessment was an on-line survey that gauged competencies and barriers that affect change in clinical practices. The assessment was based on current theories of how and why clinicians change behavior (Fox RD, Mazmanian PE, Putnam RW. *Changing and Learning in the Lives of Physicians*. New York: Praeger Publishers; 1989), and is specific to clinicians. Experts in pain management and addiction medicine aided in developing the assessment; then clinicians from the targeted learner population helped to validate specific items in the survey. The assessment included competencies and barriers that are specific to pain management and the use of opioids. The competencies were developed using a variety of resources, including the FDA Post-Approval REMS Notification letter of April 2011, the CO*RE Competency Statements, and published clinical guidelines from the American Pain Society and American Academy of Pain Medicine. The competencies were further refined through the learner interviews and

expert opinion. In the assessment, clinicians rated these competencies according to their *present* and *desired* levels of ability. Because the assessment gathered self-reported data, it revealed *perceived* needs of the target audience. Actual needs were determined by expert opinions and the current literature on pain management and opioid utilization. Results from the clinical practice assessment (CPA) portion of the survey provided additional information on actual needs.

Clinical Practices Assessment (CPA): The CPA was composed of statements directly related to the competencies for pain management and opioid utilization. Clinical experts developed these statements to represent the particular actions or clinical decisions critical to obtain optimal outcomes in this clinical area of medicine. These statements allowed a comparison between perceived needs and actual practice needs based on current clinical performance.

Confidentiality

Participants in the needs assessment process were and shall remain anonymous. No personally identifiable information (e.g., contact information) was collected in this project, except for the purpose of compensating interview respondents for their time.

Analysis

Each of the components listed above was analyzed independently. This report summarizes findings and recommendations for all components. Qualitative data were transcribed into an Excel spreadsheet from notes taken during the interviews. Themes were derived from the data and presented to faculty for interpretation and inclusion in the quantitative assessment. Quantitative data were analyzed in order to establish significance of gaps, barriers, and clinical practices.

Results

Interviews

Interviews were conducted with 40 stakeholders with great diversity in geography, years of practice, and practice setting. All target audiences were interviewed. The information obtained in the interviews guided survey development, and helped to interpret the survey results. Both primary care and pain specialty clinicians were interviewed. Interviewees appreciated the opportunity to reflect on their current practices considering how and why they do what they do. Several themes emerged as the interviews progressed. In primary care, there is a strong recognition of the importance managing pain appropriately, but a general lack of confidence in doing so, and a perception of high barriers that prevent best practices.

Educational needs for clinicians that emerged from the interviews include:

- A better understanding of the pathophysiology of pain and the basic science of opioids
- Using appropriate tools and techniques to assess pain in the absence of pathology
- Assessing for the psychiatric components of pain and managing them holistically as part of pain management.
- Using appropriate tools and techniques to assess patients for the risk of abuse
- Applying guidelines or algorithms for utilizing opioid therapy
- Knowledge of how and when to adjust doses and revise treatment regimens
- Increased ability to define and recognize abuse, dependence, addiction, etc.

Specific barriers that emerged as themes from the interviews include:

- The legal and regulatory climate around opioid prescribing that may inhibit appropriate use
- The fears of both prescribers and patients regarding addiction potential of opioids
- Diversion of opioids
- The extra time required to appropriately diagnose, assess for risks, and manage chronic pain patients
- The cost and/or lack of access to specialists or other resources needed to manage the patient with chronic pain
- The cost and/or lack of availability of non-pharmacologic, complementary or alternative therapies to manage pain
- A perception that pain patients in general are difficult to deal with and consume time/energy that is disproportionate with the rewards of taking care of them

Change Readiness Inventory/Practice Assessment

The assessment was disseminated as an online survey. Each of the CO*RE partner organizations sent an email to all or part of their membership containing a link to the online survey. Larger organizations sent emails to a random sample of 10,000 members, while smaller organizations sent the email to all members. A total of more than 50,000 emails were sent inviting members to complete the survey. The survey link was also sent to a supplemental list of 200 family physicians nationwide. The purpose of this supplemental recruiting was to give a broader geographic spread of the family medicine target audience – balancing the large number of California physicians recruited through the California Academy of Family Physicians.

The survey response rate was calculated on surveys completed divided by emails opened. A response rate of 21% was achieved, which is comparable to past surveys conducted by CO*RE partners with their membership. A total of 2306 surveys were completed. One-hundred fifty-seven surveys were not used because they were completed in less than ½ the average completion time. After deleting these responses, the average completion time of the valid surveys was 13 minutes.
The survey questions are grouped into 5 domains including demographics, practice assessment, perceived needs, barriers to best practices, and learning preferences. Each of these domains is described below.

Demographics

Respondents to the survey represented all of the targeted organizations and the population of opioid prescribers in the U.S. By degree, about 39% were physicians including both MDs and DOs, 41% nurse practitioners, 16% physician assistants (Figure 1). A separate survey for pharmacists is currently under analysis. The 1% PharmDs represented in this data are separate from the pharmacist survey.

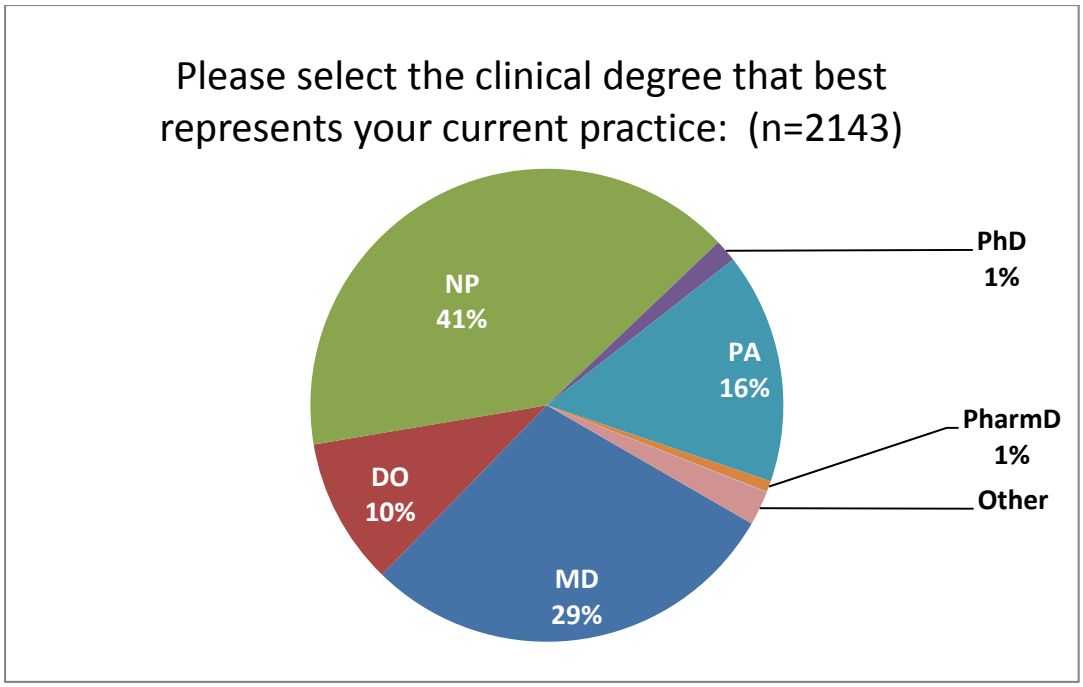


Figure 1. Responses by clinical degree

Participants were asked to select their clinical practice type. About 43% indicated that they are in a primary care practice, while 25% selected various pain specialties (Figure 2). A large group of "Other" responses includes hospitalists, psychiatrists, and various surgical and medical specialties (Table 1).

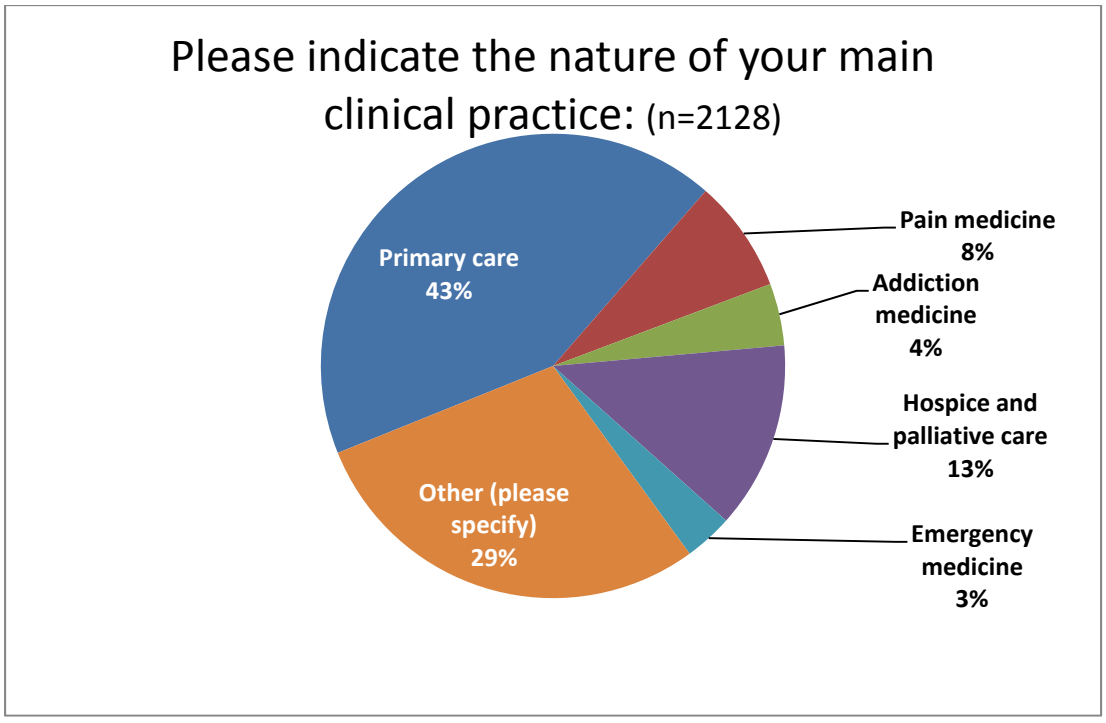


Figure 2 Responses by clinical practice

Specialty	Number of Responses	Specialty	Number of Responses
Hospitalists	64	Occupational Medicine	16
Orthopedics	36	OB/GYN	15
Oncology	27	Geriatrics	14
Psychiatry	25	Long-term Care	13
Surgery	24	Hematology/Oncology	12
Urgent Care	22	Pulmonology	11
Acute Care	21	Neurosurgery	10
Cardiology	21	>50 additional specialties	286

Table 1 Responses by clinical practice "Other"

There was an even representation of rural, urban, and suburban practices represented among the respondents (Figure 3).

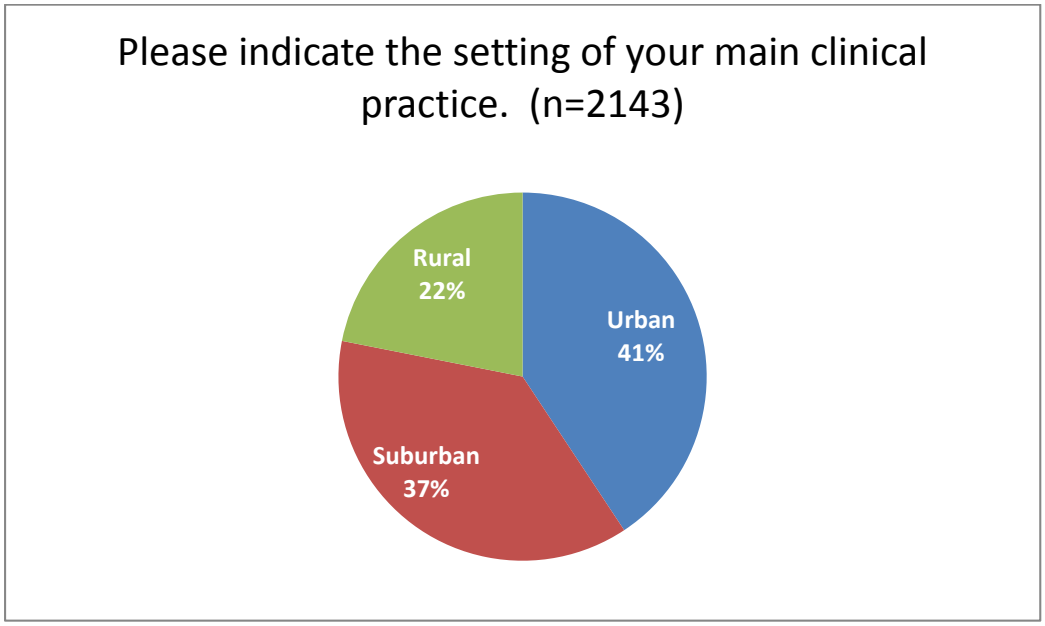


Figure 3. Responses by setting

Practice Assessment

Sixty-nine percent of the participant reported that they use an electronic health record (Figure 4). This is well over the national average for office-based physicians, 50.7%, as reported by the CDC (http://www.cdc.gov/nchs/data/hestat/emr_ehr_09/emr_ehr_09.htm). This may reflect the greater diversity of clinicians included in the CO*RE data, and/or the fact that clinicians responding to an online survey may be more technology-oriented and utilize EHRs to a greater extent than the overall population of clinicians.

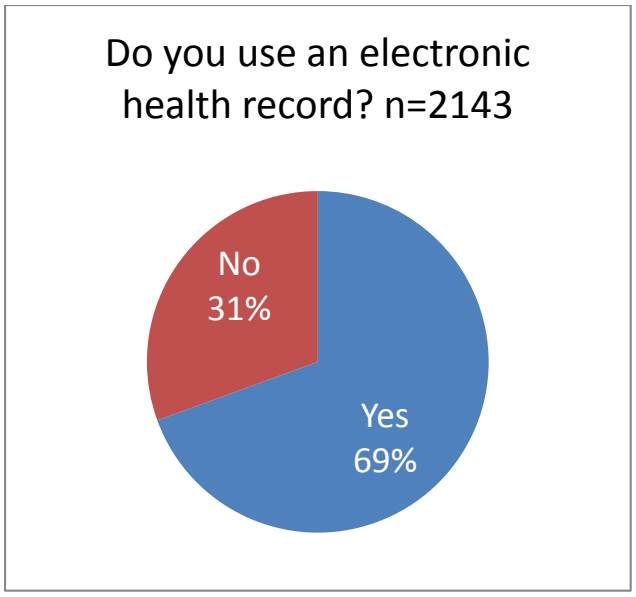


Figure 4. Responses by type of health records

Fifty-two percent of the respondents indicated that they have access to or are part of a multi-disciplinary pain management team (Figure 5). When asked to select the elements of this team, pain specialists and pharmacists were the most frequently selected items (Figure 6).

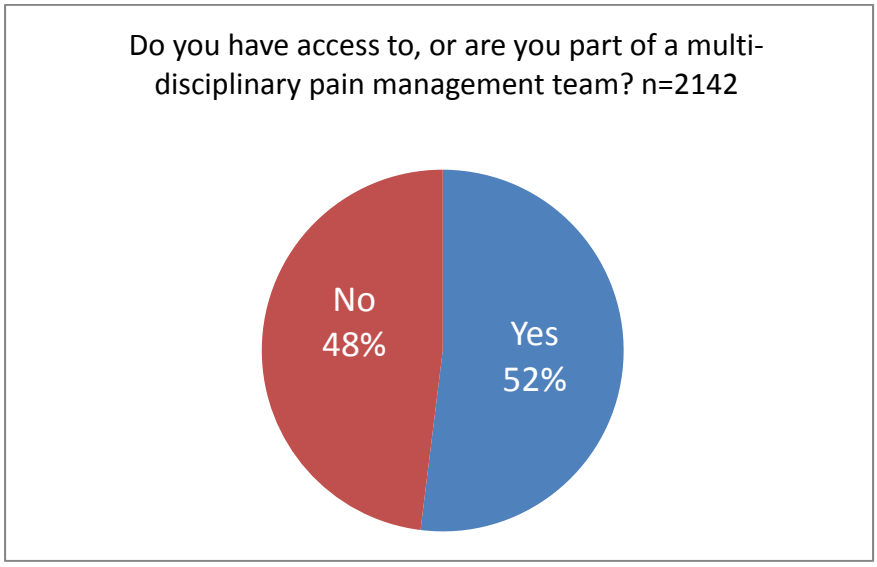


Figure 5. Reponses by access/participation in a team

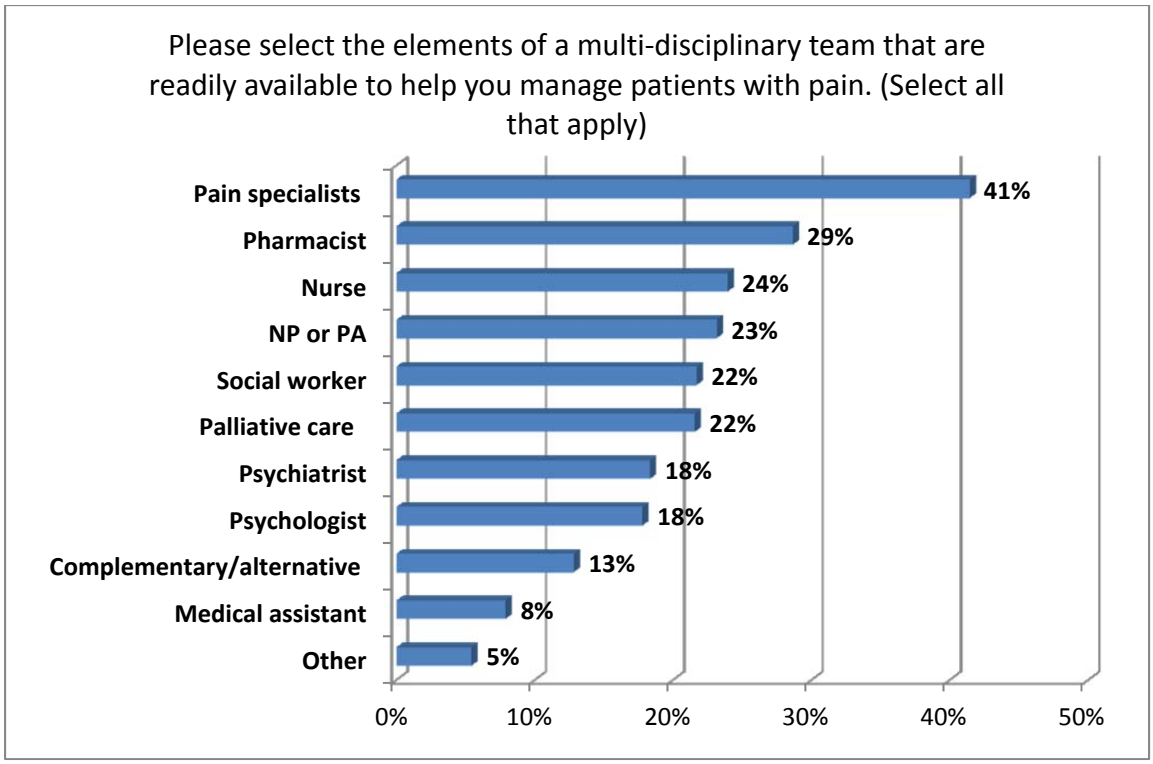


Figure 6. Responses to elements of the team

Respondents indicated that they utilize a broad variety of tools and resources to help manage their pain patients (Figure 7). The most widely utilized were patient counseling and pain scales, with over 70% of respondents selecting each these items. Also widely utilized are patient education materials, informed consent, and prescription drug monitoring programs.

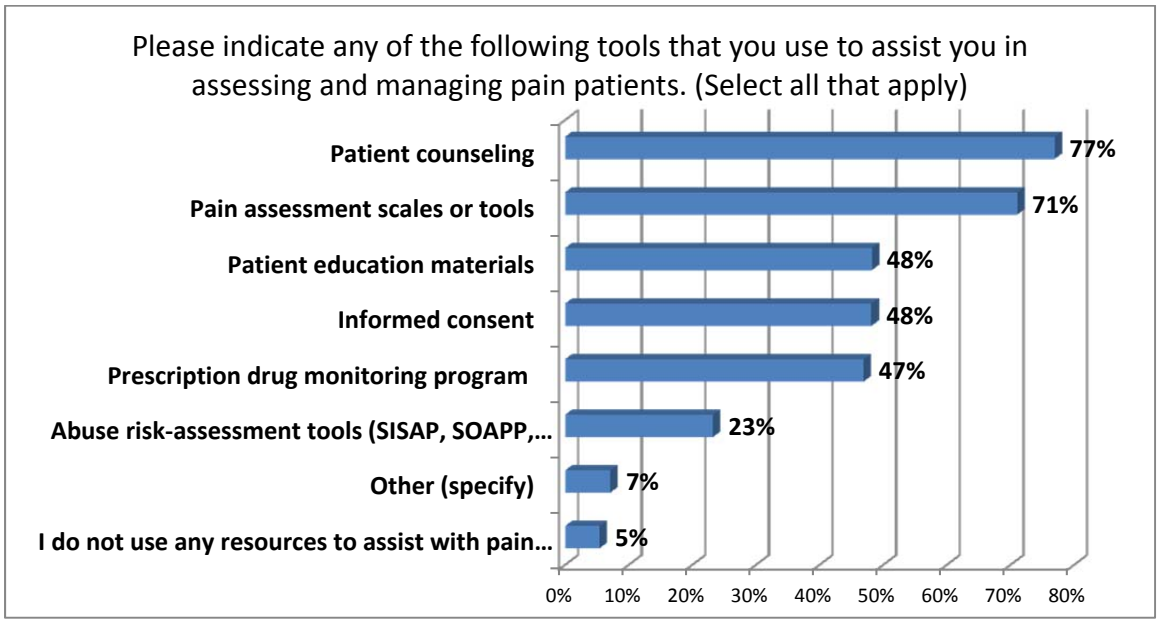


Figure 7. Responses to tool utilization

When asked about resources used to reduce drug abuse or diversion, the most commonly selected item was patient counseling at 77% (Figure 8). Sixty-seven percent said that they monitor for aberrant behavior, while 57% use a patient agreement to reduce abuse and diversion (Figure 8).

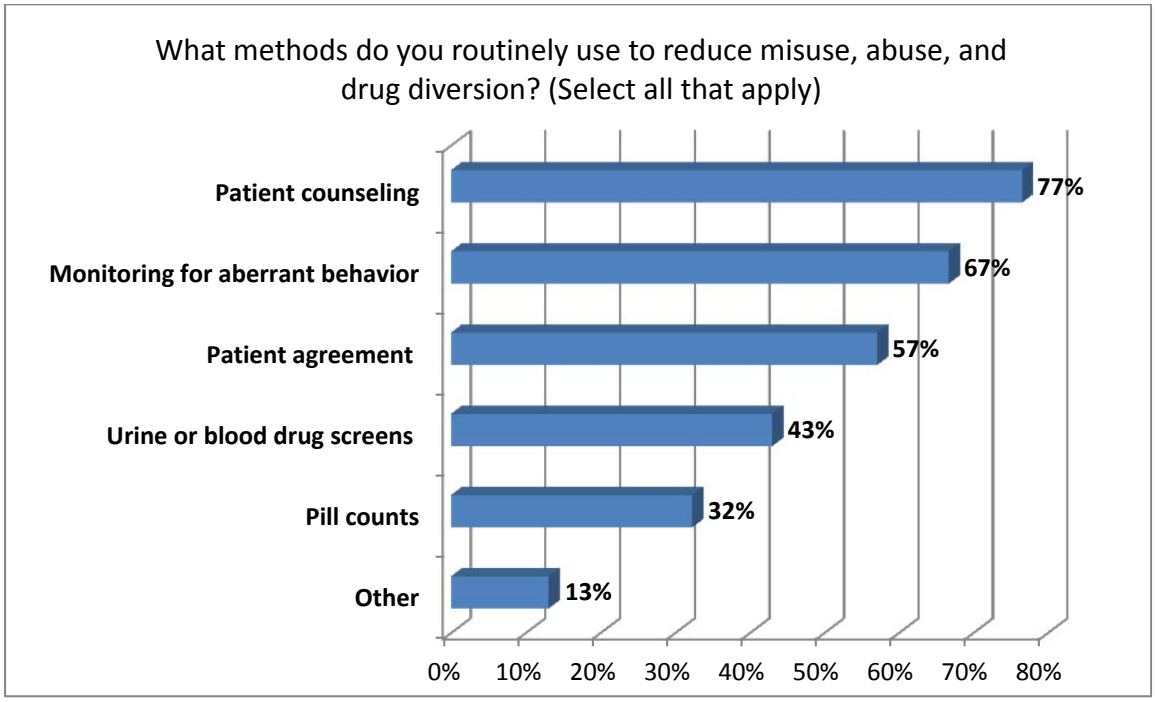


Figure 8. Responses by methods used

Two questions were asked regarding opioid utilization for managing pain. When asked to select their 3 most commonly prescribed opioids, there were marked differences between primary care clinicians and those in pain specialty practices (Figure 9). Among the more often used medications, there were glaring differences in the use of hydrocodone, morphine, tramadol and codeine.

When asked to estimate the number of their patients currently taking opioids, more than 50% of the respondents indicated that they have 25 or fewer (Figure 10). While specialists and primary care clinicians showed a similar pattern of distribution among the categories, significantly more specialists selected “More than 100” on this question.

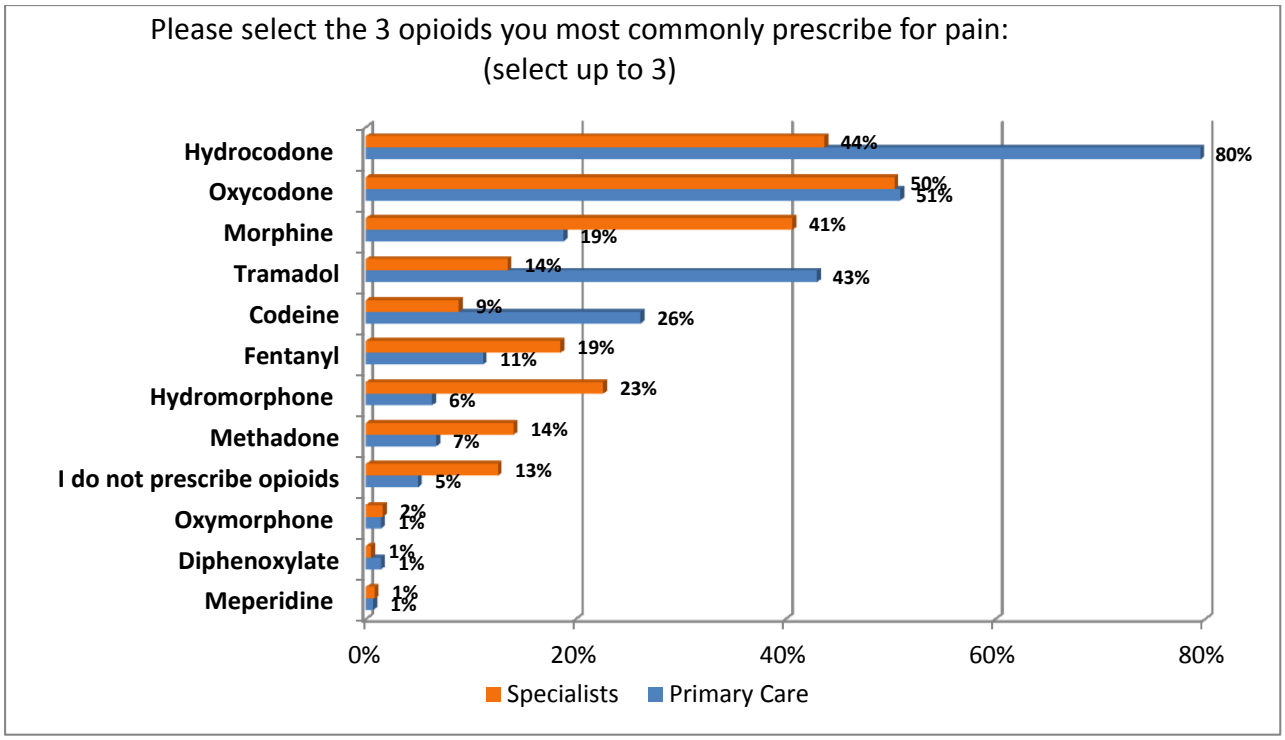


Figure 9. Responses on opioid selection

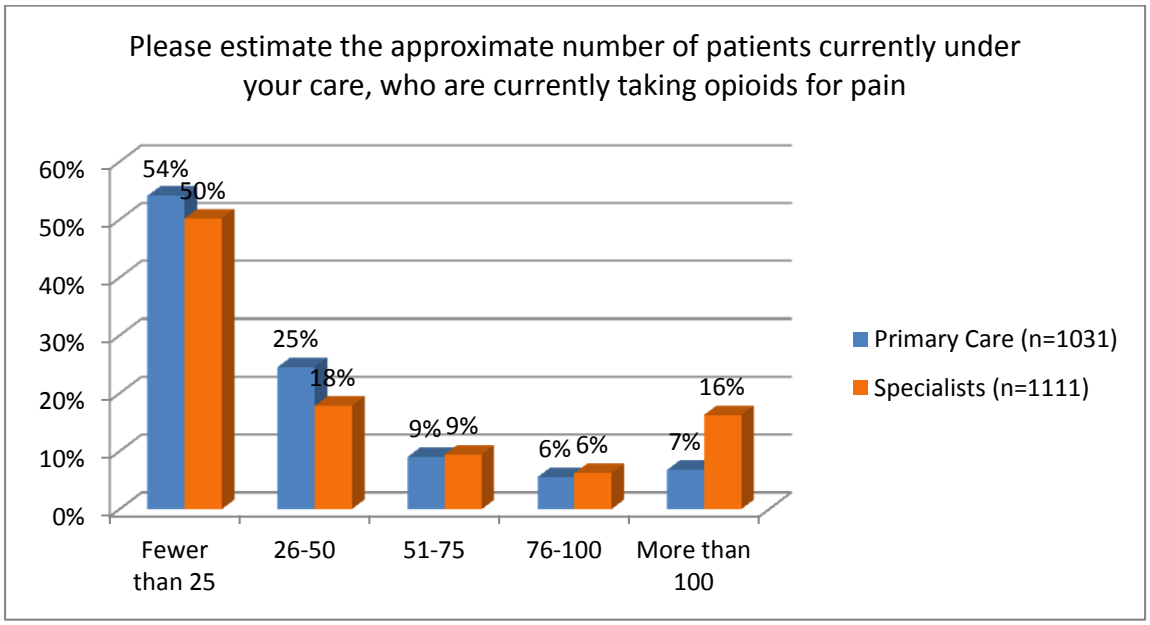


Figure 10. Responses to number of patients on opioids

Clinical Competencies

The competencies are a series of statements that represent the abilities clinicians need to successfully manage patients with chronic pain. These competencies were developed from clinical guidelines, current literature, and expert opinion. Clinicians were asked to consider the following statements, and

then indicate their *present ability* and their *desired ability* on a 5-point scale (from 1-*low* to 5-*high*) in performing each task.

Please rate your *present* and *desired* ability to:

1. Obtain a relevant history and physical exam to determine the etiology of patients' pain.
2. Describe the needs of special populations, including pregnant women, adolescents, cultural/ethnic minorities, and those at the extremes of age.
3. Assess patient for risks of problem/aberrant behaviors, opioid misuse, substance abuse and addiction.
4. Screen for risks of psychiatric co-morbidity using available evidence-based tools.
5. Develop an integrated, individualized treatment plan including pharmacologic and non-pharmacologic therapy.
6. Communicate and document the risks and benefits of opioid therapy.
7. Educate patients and caregivers about medication side effects, potential medication interactions, and precautions while taking opioid analgesics.
8. Periodically review and revise treatment as indicated, including referral if needed.
9. Use universal precautions on all patients receiving opioid treatment (drug testing, pill counts, etc.)
10. Revise opioid dosing via titration, rotation (using equianalgesic dosing), or tapering/termination of medications.
11. Convert treatment from immediate-release product to extended-release and long-acting products.
12. List adverse effects of opioids (sweating, nausea, low testosterone, etc.)
13. Recognize and manage opioid-induced hyperalgesia.

The *desired* ability represents the importance the respondents place on that particular clinical competency statement. Primary care clinicians consistently demonstrate a high *desired* level of ability for each of these competencies, with none averaging lower than 4.4 on the 5-point scale (Figure 11). This indicates that all of these competencies are deemed important for successfully managing chronic pain patients. The *present* ability ratings showed more variation, with several competencies averaging just over the midpoint, 3 on the 5-point scale.

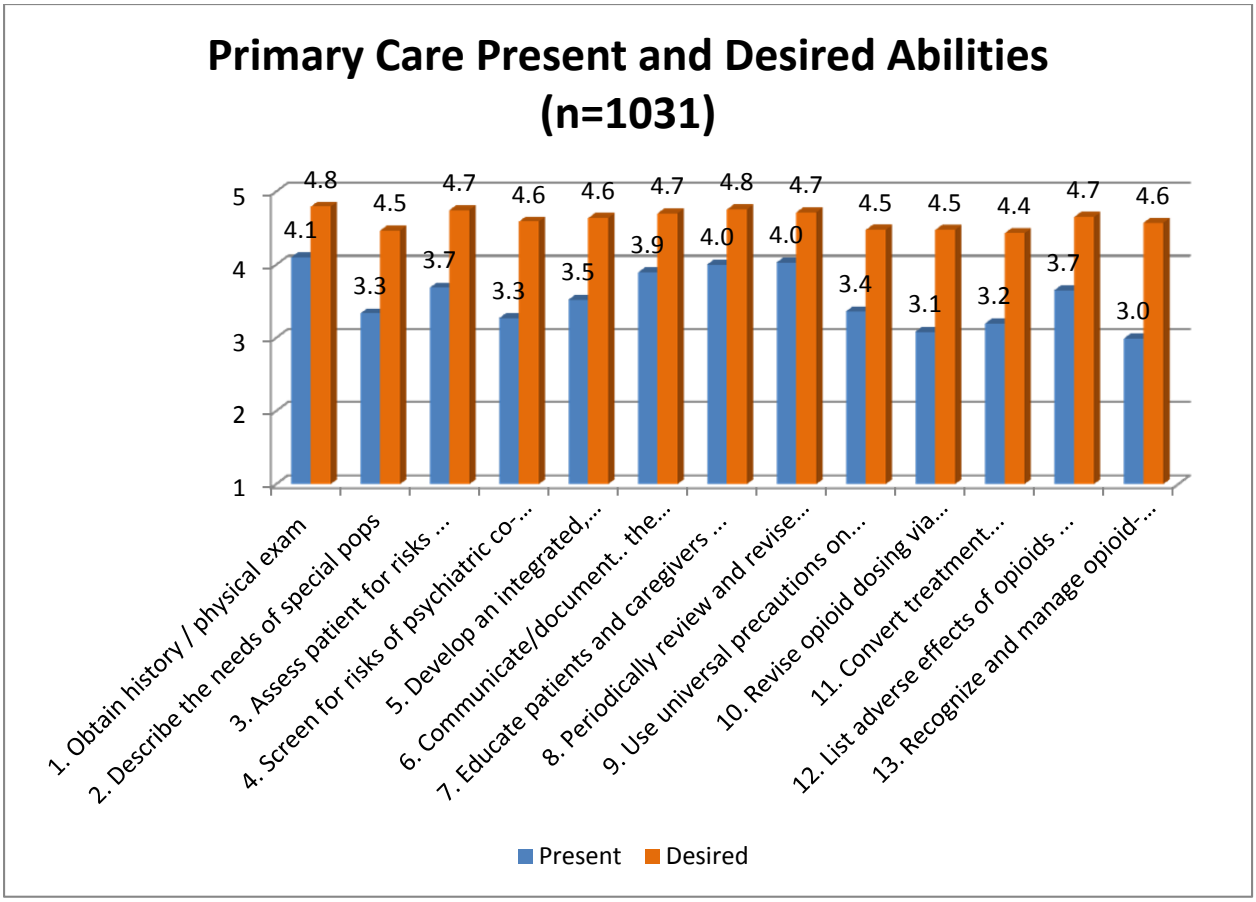


Figure 11. Competency Ratings- Primary Care

The pain specialists rated their present/desired abilities on the same set of competencies (Figure 12). Their desired abilities showed a similar pattern to the primary care group, with most competencies averaging between 4.5 and 4.8. They rated themselves somewhat higher on present abilities, but still indicated a number of present abilities in the 3.3-4.0 range.

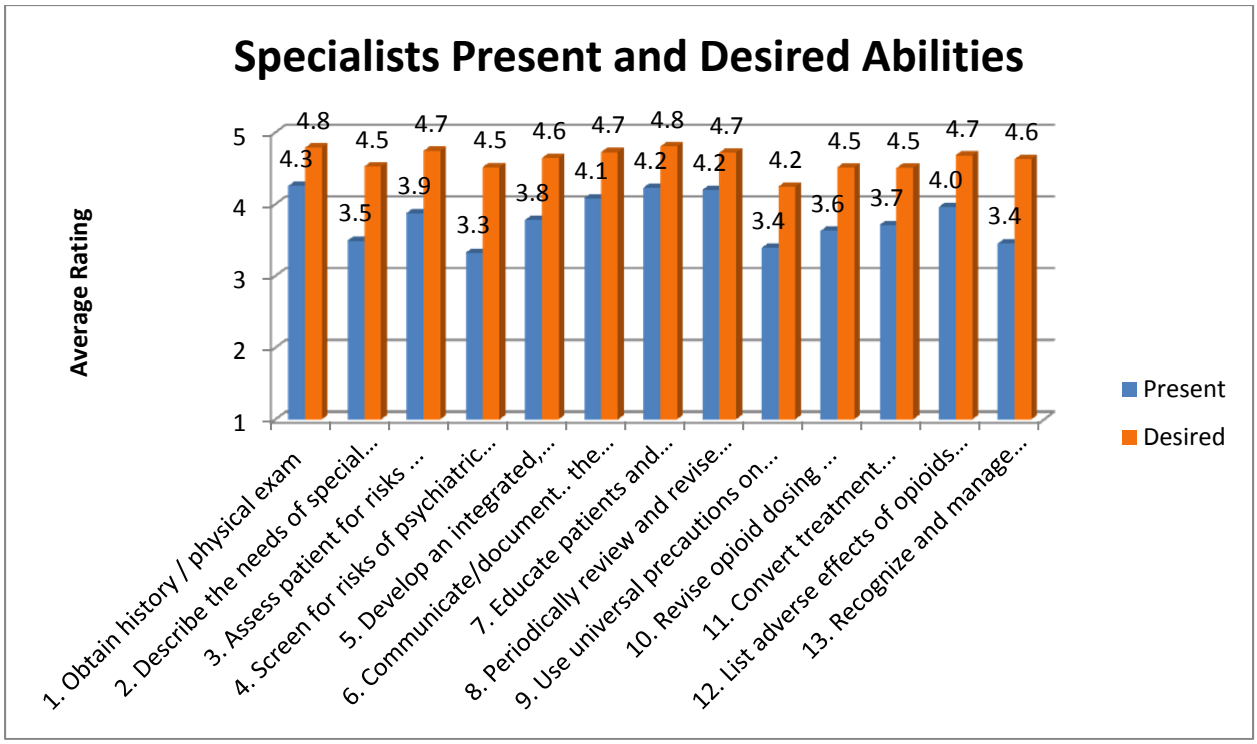


Figure 12. Competency Ratings- Specialists

Perceived Needs (Competency Gaps)

The difference, or gap, between the clinicians' ratings for *present ability* and *desired ability* represent the perceived need for that particular competency. In other words, this number represents the difference between "what is" and "what ought to be." A gap of 0.5 is presumed to be important, with gaps of 1.0 - 2.0 considered ideal. Gaps smaller than 0.5 indicate low motivation to learn and change, while a gap higher than 2.0 may represent a level of change that the physician believes to be unattainable or impractical. Figure 13 illustrates the perceived need (gap) for each of the competencies, broken out by type of practice.

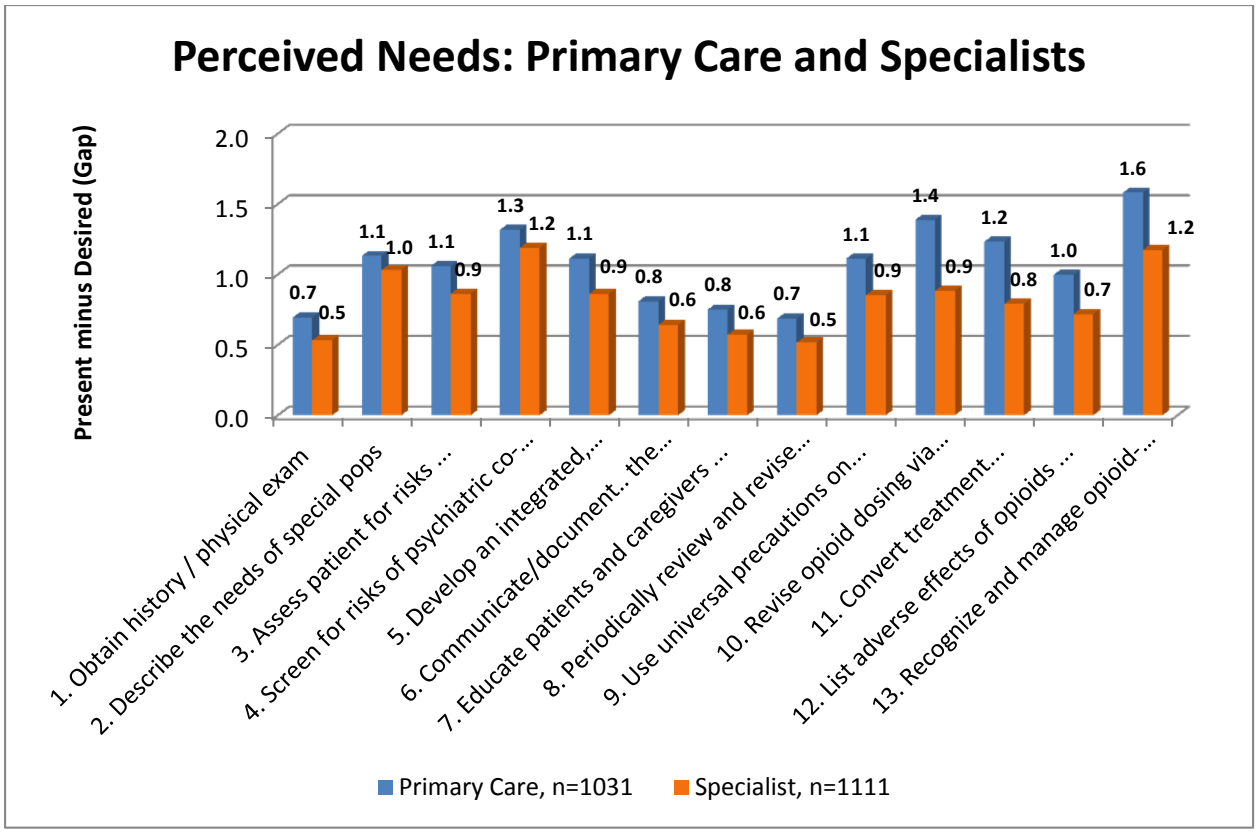


Figure 13. Perceived needs

All ten of the perceived competency gaps are important to both primary care and pain specialists. Several are in the ideal range, between 1.0 and 2.0. Overall, the gaps were higher for those in primary care than in pain specialties, as would be expected. Clinicians realize that change is needed in this area of medicine and are motivated to make practice changes. Two areas of high perceived need are shared by both groups of clinicians, and are:

4. Recognize and manage opioid-induced hyperalgesia.
13. Screen for risks of psychiatric co-morbidity using available evidence-based tools.

Clearly, there are several areas of pain management where clinicians are not presently performing at their *desired* levels of ability. Additionally, statistical analysis shows that there is a significant correlation between competency gaps. This indicates that when a physician indicates a gap in one competency, there is a higher likelihood of perceiving gaps with other competencies.

Barriers

Barriers to change are real or perceived issues that may prevent clinicians from applying best practices. Knowledge of the nature and magnitude of these barriers helps educational designers address them within the scope of the interventions, thereby facilitating changes in clinician performance as compared to changes in knowledge. The barriers were derived from the qualitative interviews, expert opinion, and the literature on pain management and opioid use.

The barriers section contained the following statements. Respondents indicated their level of agreement with these statements by rating from 1, low to 5, high.

Reflecting on your own experience, please rate the following statements according to your extent of agreement with each of these as barriers to best practices in managing pain patients with opioids.

1. I am concerned that my patients may become dependent on or addicted to opioids.
2. Some patients are concerned that they may become dependent on or addicted to opioids.
3. I am concerned that patients may accidentally overdose.
4. I don't like the regulatory scrutiny that comes with prescribing opioids.
5. Pain patients do not adhere to a treatment plan.
6. I am concerned about potential diversion of opioids when I prescribe them.
7. Managing pain patients takes too much time and disturbs the workflow in my office.
8. Clinical guidelines on appropriate use of opioids are unclear.
9. I am not reimbursed adequately for managing pain patients.
10. Pain patients are sometimes unpleasant to deal with.
11. I have limited access to pain specialists for consultation and referral.
12. My patients do not have access to providers of non-pharmacological therapy (cognitive-behavioral, physical therapy, alternative, etc.)
13. The cost of non-pharmacological therapy is too high for my patients.

Barriers were higher overall for those in primary care than in pain specialty practices (Figure 14). The 3 highest barriers for primary care were:

1. I am concerned that my patients may become dependent on or addicted to opioids.
6. I am concerned about potential diversion of opioids when I prescribe them.
10. Pain patients are sometimes unpleasant to deal with.

For those in specialty practices, the highest barrier was:

2. Some patients are concerned that they may become dependent on or addicted to opioids.

There is an interesting comparison between the specialist and primary care barriers on addiction in that the specialists feel that *patient* concern about addiction (barrier 2) is a high barrier, while primary care clinicians are *themselves* concerned about addition as a barrier (barrier 1). Nevertheless, there are a large percentage of both specialists and primary care clinicians that rated all of these barriers at a 4 or 5, so all need to be considered when designing educational activities.

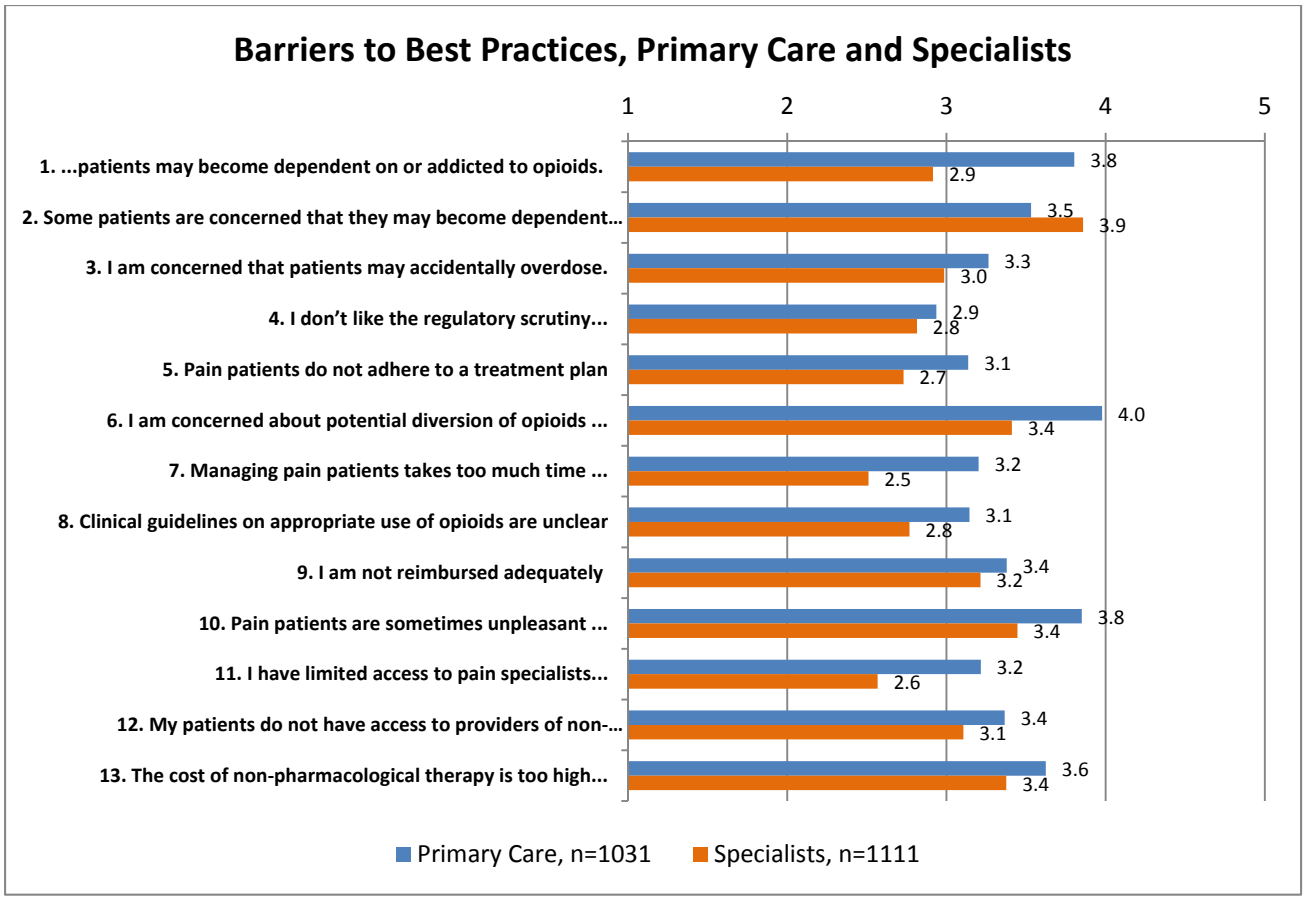


Figure 14. Barrier ratings

Learning Preferences

The first question in this section deals with attitudes of clinicians about being required to complete educational activities in order to continue to prescribing opioids (Figure 15). A small percentage indicated that they would stop prescribing opioids rather than comply with educational requirements. Those who said they would stop prescribing were more likely to be rural (5.5%) or suburban (5.3%) clinicians than urban clinicians (3.1%). The most common response from specialists was "I don't need it, but I will endure it...", while the largest group of primary care indicated that "I need it anyway, so this is a good reason to do it". The "Other" responses (6% and 11% for primary care and specialists respectively) were mostly variations on the listed responses or complaints about REMS.

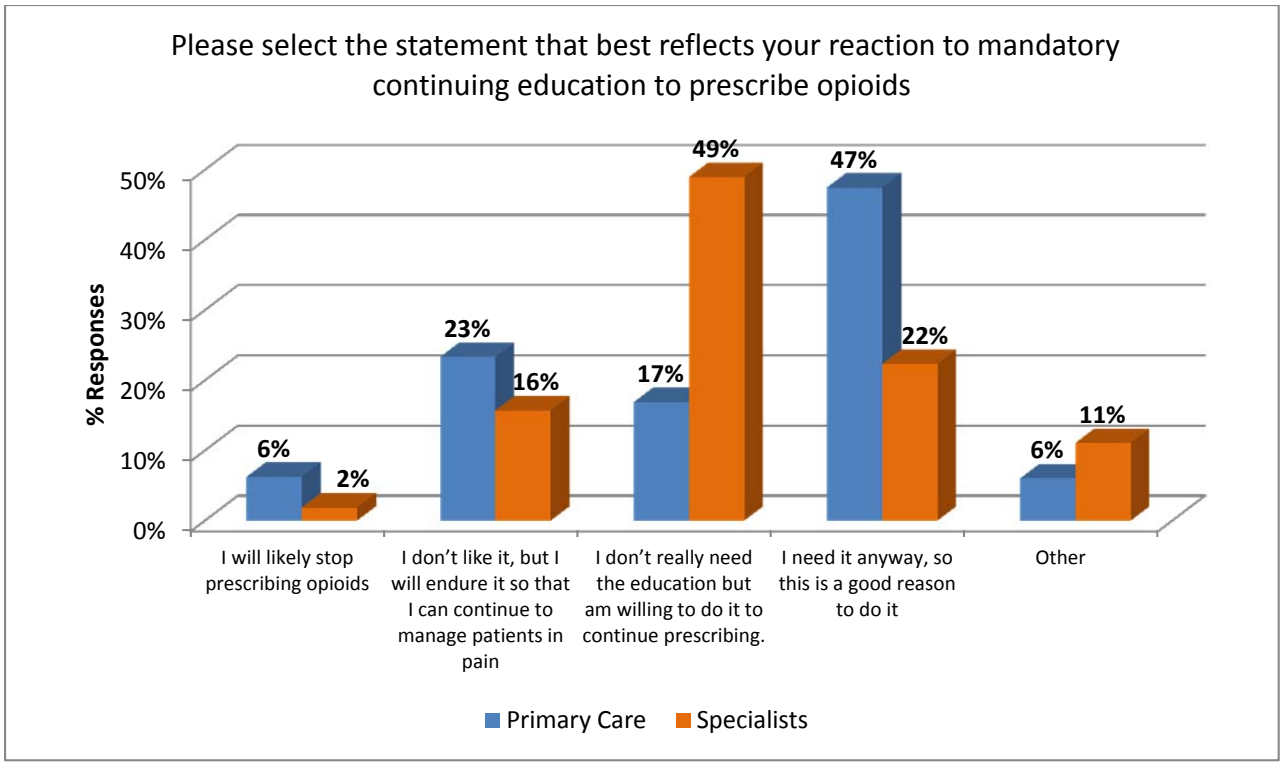


Figure 15. Attitudes toward REMs

A key research question for this needs assessment was the level of tolerance that clinicians would have for REMS requirements. We assessed their tolerance in terms of credit hours required by using a technique called Max-Diff. Max-Diff is a technique derived from market research, and is considered to give more useful information by requiring respondents to choose between different combinations of attributes. In this assessment, we were primarily concerned with the number credits that clinicians would be required to complete, and whether these required credits would be needed immediately to continue prescribing, or would be spread out over a period of years.

The survey respondents were presented with 3 randomly selected options from the list of 7 below. They were then asked to select the "Best option" and the "Worst option."

If DEA licensing is eventually tied to successful completion of opioid education, please indicate your best and worst options for various scenarios of required educational credits (CE/CME/ACPE,etc.). (NOTE: 2 choices should be selected, 1 best, 1 worst)

Best option	Attributes	Worst option
[]	3 credits immediately to continue prescribing opioids	[]
[]	2 credits immediately to continue prescribing opioids, 2 more over 2 years	[]
[]	5 credits immediately to continue prescribing opioids	[]
[]	3 credits immediately to continue prescribing opioids, 3 more over 2 years	[]
[]	7 credits immediately to continue prescribing opioids	[]
[]	4 credits immediately to continue prescribing opioids, 4 more over 2 years	[]
[]	Quit prescribing opioids for my patients in pain	[]

It is instructive to note that the choices offered are arranged in increments of 1 credit, ranging from 3 credits to a total 8 credits. They vary alternatively from immediate credits (3, 5, 7) to a combination of immediate and long-term credits over a period of 2 years (2/2, 3/3, 4/4). This supplies data in 2 dimensions, measuring the total credit hours desired as well as the timeframe in which they may be implemented. An additional choice offered was to "Quit prescribing opioids." This final choice was clearly the worst option for respondents as shown in Figure 16 below.

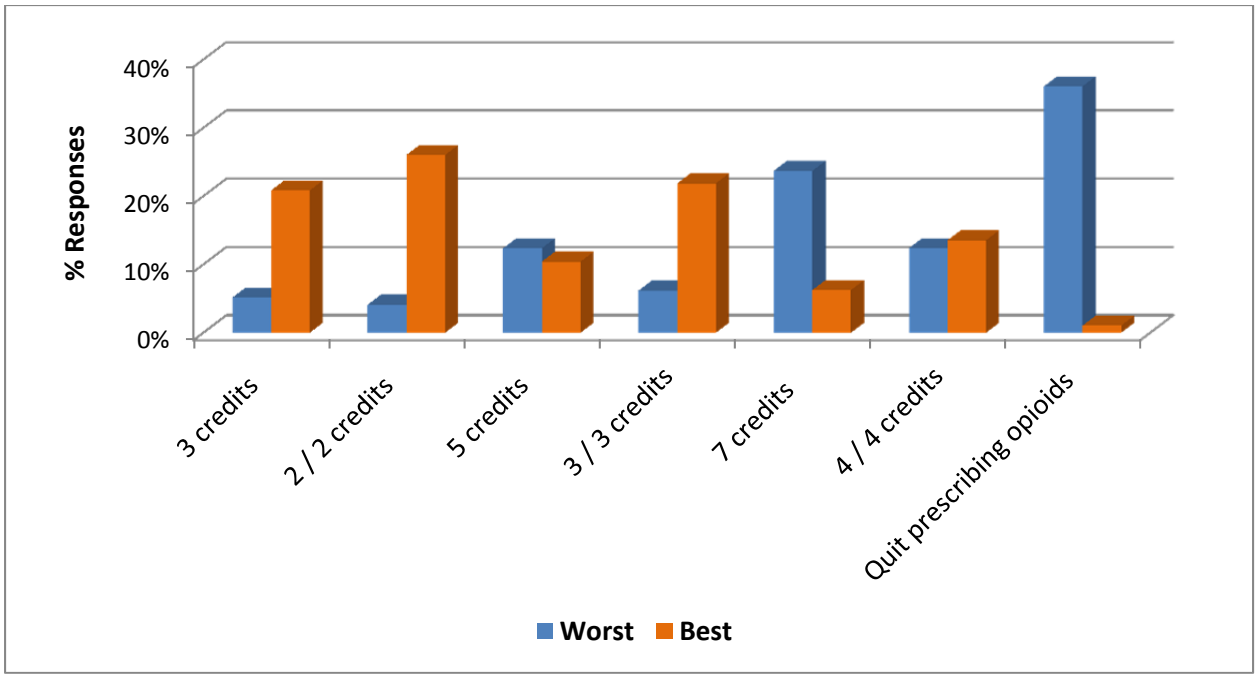


Figure 16. Preferred credit options

The "best option" as selected by the respondents, varies widely among the choices presented. A better way to summarize the data is in calculation of "share of preference", as shown in Figure 17. Share of preference is calculated from both the "best" responses and the "worst" responses. It is clear that the combination of 2 credits immediately, and 2 credits over 2 years, provides the largest share of preference at 28%. Interestingly, the second highest share of preference was very close, with 3 credits at 23% and 3/3 credits at 22%. This indicates that participants will tolerate a significantly higher number of credits if they are not all required in the first year.

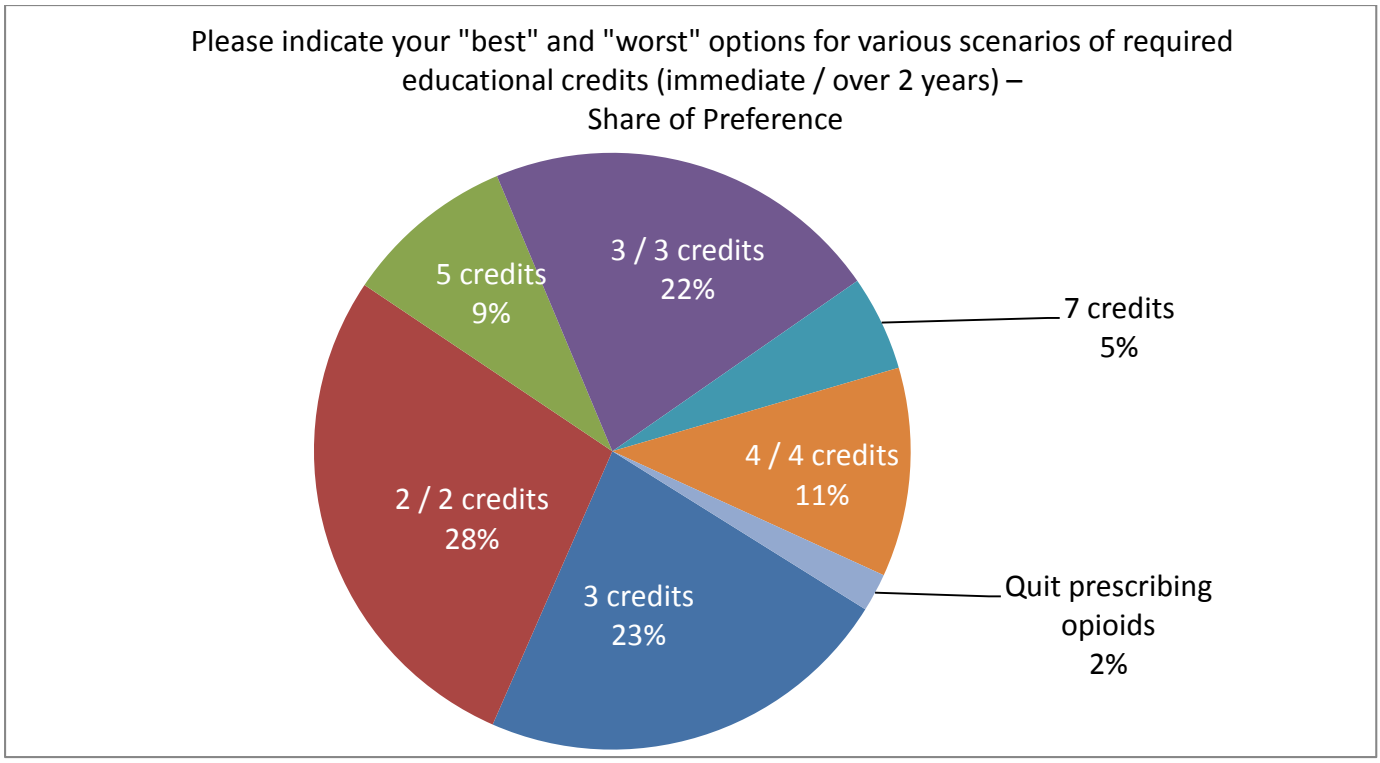


Figure 17. Educational Credits, Share of preference

Respondents were asked to rate various attributes of continuing education on a 5 point scale (1=not important, 5=very important. The ratings were fairly even across 3 of the attributes, while "speaker or author" was rated lower than the others (Figure 18).

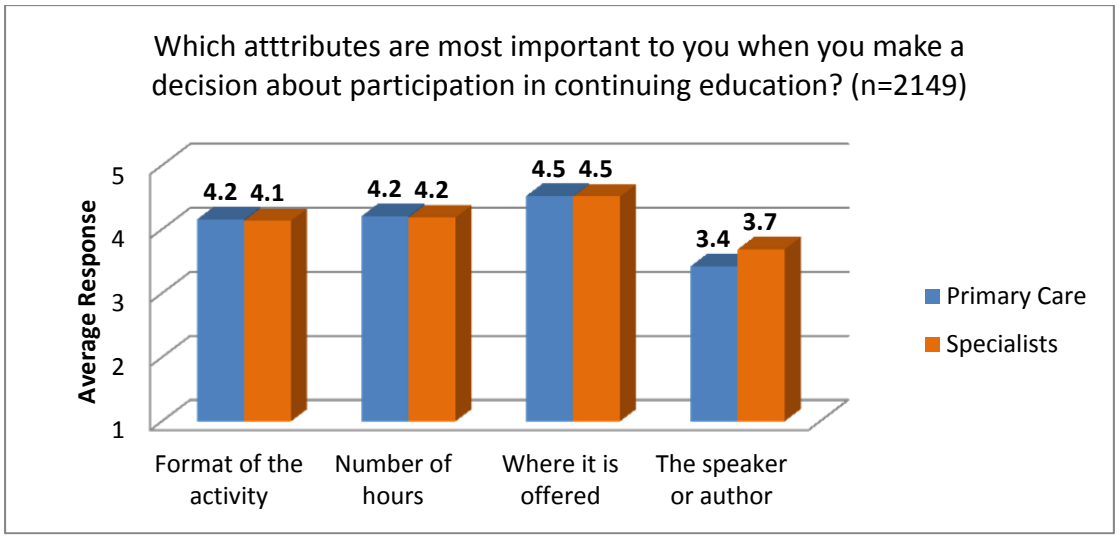


Figure 18. Attributes of education

Survey respondents were also asked to indicate the most recent educational activity for which they received credit. The choices incorporated both the location and format of educational activities (Figure

19). The responses here were very similar between those in primary care and specialty practices. Both indicated by a large margin that they most recently received credit for state or national medical society meeting.

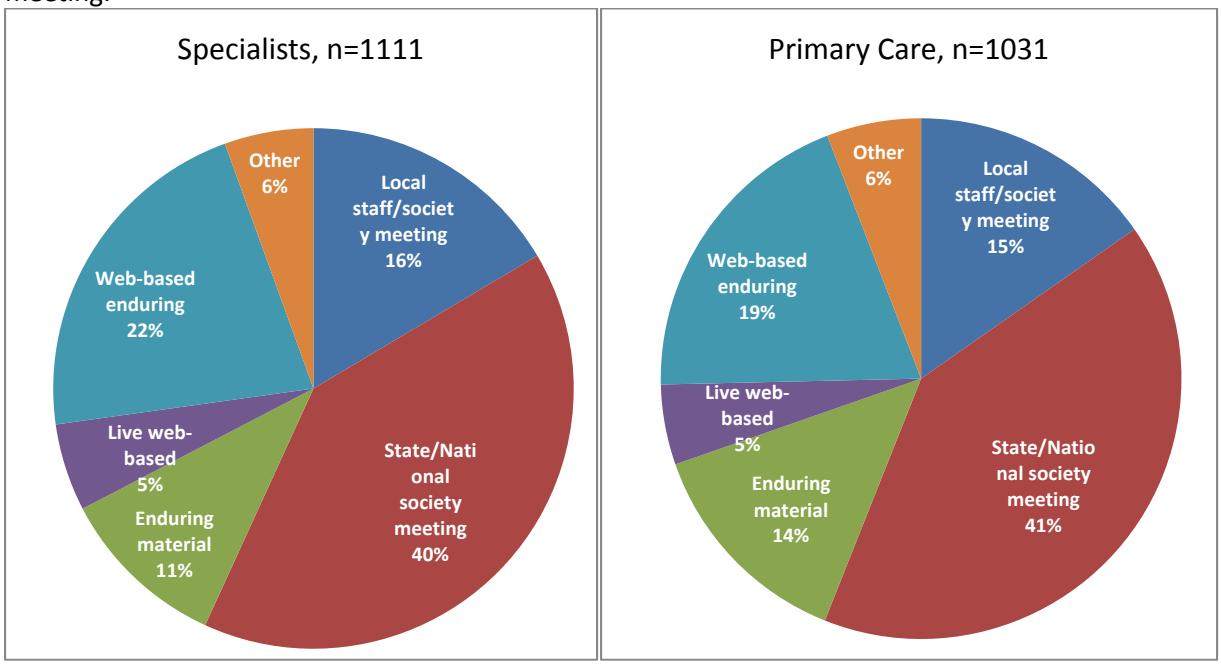


Figure 19. Recent educational activities

Finally, participants were presented a list of 17 clinical topics related to pain management and opioid utilization. They were asked to select up to 5 topics that are most important to them. They were not allowed to select more than 5 topics.

Using a calculation of "Total Unduplicated Reach and Frequency", the 6 topics listed below would attract the highest number of participants.

- **Pain assessment**
- **Risk factors for aberrant behavior**
- **Conversion of different medications**
- **Managing special populations**
- **Patient monitoring**
- **State or federal guidelines/regulations for opioid use**

Findings

The educational survey and practice assessment served to quantify perceived needs, barriers, and learning preferences of the targeted clinical audiences. The key findings from this survey are as follows:

- Clinicians have high perceived needs across the continuum of care for chronic pain patients including the initial assessment of the patient, development of a treatment plan, assessment of risk for abuse and ongoing reassessment of the patient. The highest perceived needs reported included:

- Appropriate diagnosis and management of pain using opioid therapy
- Managing psychiatric comorbidities associated with chronic pain

- Clinicians perceive many barriers to best practices. The fear of abuse and identifying potential diversion were identified as major concerns. Tools to aid in identification of risk are not generally used in primary care offices. Even the lowest rated barrier had 31% of primary care clinicians rate it high (4 or 5 on the 5 point scale). The specific barriers rated the highest include:
  - Patient and clinician fear of addiction to opioids
  - Diversion or other abuse of opioids
  - Extra time and energy required to manage patients with chronic pain

- Specialists, although familiar and implementing many best practices, perceive needs around pain management and the use of opioids. This may be a case of the "worried well", but should be beneficial when presenting education on this topic.

- Few clinicians will quit prescribing opioids due to REMS educational requirements

- Clinicians are willing to participate in education around opioid prescribing with a "sweet spot" of 4-6 credits of CE/CME spread over a period of 2 years.

- Clinicians are most likely to participate in activities at local, state, and national society meetings.

- Selected topics and sub-topics as listed above are most likely to attract clinicians to educational activities.

- REMs education should demonstrate the benefit to the practicing clinicians including increasing safety of the providers themselves by lowering the risk of abuse and diversion.

Summary

Continuing Clinical Education for primary care clinicians is needed in the area of pain management. This needs assessment research has revealed and illuminated both real and perceived needs of clinicians in this clinical area. Both types of needs should be addressed in program content, formats, and promotion of educational activities. Activities should allow learners to see how the educational activity relates to their perceived needs while addressing real needs.

Clinicians have a strong desire for competency in utilizing opioid therapy to manage chronic pain. They recognize the value in education around these issues, even while sometimes dissatisfied with what some perceive as more regulation around their clinical practices. Finally, the regulatory and legal environment around opioid prescribing necessitates a "safe" environment for learning.

Physician Needs Underlying Successful Implementation of REMS for Opioids

CO*RE Literature Review | July 2011

Introduction

In the mid-1990s, the use of prescription opioids traditionally reserved for treating cancer and acute pain expanded to include treatment of other chronic pain conditions, heretofore referred to as chronic non-cancer pain or CNCP. In part, this change resulted from ethical concerns related to the under-treatment of chronic pain. State medical boards and legislatures changed regulations, ending a prohibition on opioid use for CNCP. However, there was (and remains[1]) only very limited clinical data to support this use for CNCP.[2] Directives and guidelines from state and national medical boards supported these changes and resulted in new policies that encouraged the use of opioids for long-term pain control. Following this change, a dramatic increase in opioid prescriptions was seen; paralleling the increased use of these drugs for CNCP has been an increase in deaths due to drug poisonings and hospitalizations.[2] In 2011, prescription opioid drug abuse, misuse, and addiction are considered an epidemic and a significant public health problem.[3]

In response to a 2006 Institute of Medicine (IOM) report on drug safety,[4] the Food and Drug Administration Amendments Act (FDAAA) was signed into law in 2007; this gave the FDA authority to require risk evaluation and mitigation strategies (REMS), which evolved from the previous risk minimization action plans (RiskMAPs), to have an increased focus on drug safety and post-marketing surveillance.[5] The impetus behind any REMS is to ensure that the expected benefits of a medication exceed potential risks for specific patients and medical circumstances. REMS may include tactics such as the development of medication guides for patients, communication plans for healthcare providers, and elements to assure safe use (ETASU), which may include special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, or use of patient registries. By July 2009, 52 drugs had approved REMS[6]; a year later, 130[7]; and, in July 2011, 212.[8] In April 2011, the FDA mandated that manufacturers of long-acting opioids develop a class-wide REMS through a single, shared system to address the growing problems associated with opioid misuse. The central component of the REMS for long-acting opioids is an education program for prescribers.[9]

A large body of literature exists on the use of opioids in specific medical situations, as well as their risks and how to mitigate those risks, including those associated with addiction, abuse, and overdose. Numerous health care professional and other national and international organizations have published position statements, white papers, and similar documents containing their recommendations around balancing opioid access for individuals with medical needs and the broader public health and safety

issues.[10-13] Many recommendations fall outside the healthcare provider realm and involve system changes such as health/societal policy, public health education, payer systems, monitoring by states or other institutions, and law enforcement. The focus of this literature review is to summarize what can be determined about physician learning needs related to successful implementation of REMS for opioids.

Gaps in Utilization of Opioids for Treatment of Pain

Using the model of backwards planning,[14] one starts by examining gaps at the level of community health before tracing back to gaps in patient health and physician performance, competence, and knowledge. Incorporating the model of discrepancy analysis,[15] one compares "what ought to be" with "what is" in order to frame the problem. These models are applied in the following examination of gaps in appropriate use of opioids in the treatment of pain.

Community and Patient Health

The problems of pain and misuse of pain treatments are well documented.[13,16] At the community health level, pain is prevalent and costly. In 2006, approximately 76 million people in the US had chronic pain.[17] In terms of financial impact, large corporations pay about $2 million per employee with chronic pain to cover absences, lost productivity, short-term disability, and healthcare costs.[13] With regard to diversion of opioids in particular, the National Drug Intelligence Center (NDIC) estimated the costs to public and private insurers to be $72.5 billion per year. The misuse of opioids has become the most common form of poisoning treated in US emergency departments (EDs).

At the patient health level, numerous clinical reports suggest that chronic pain remains undertreated;[18-23] the percentage of patients receiving appropriate and adequate treatment has been reported to be as low as 10-25%.[24-27] Patients with chronic pain have difficulty finding physicians who can effectively treat their pain, with nearly 50% of patients changing physicians at least once, and nearly 25% making at least three physician changes.[28] In response, the Healthy People 2020[29] initiative includes an explicit objective to "reduce the proportion of patients suffering from untreated pain due to a lack of access to pain treatment."

In addition to under-treatment, there are gaps in safety related to opioid use. Opioids now exceed cocaine and heroin in causing unintentional overdose deaths, having increased from causing 2901 deaths in the US in 1999 to 11,499 in 2007 (see Figure 1). There are geographic disparities in drug overdose deaths, with the five highest rates occurring in West Virginia, New Mexico, Utah, Louisiana, and Nevada (Figure 2).

Figure 1.[16]

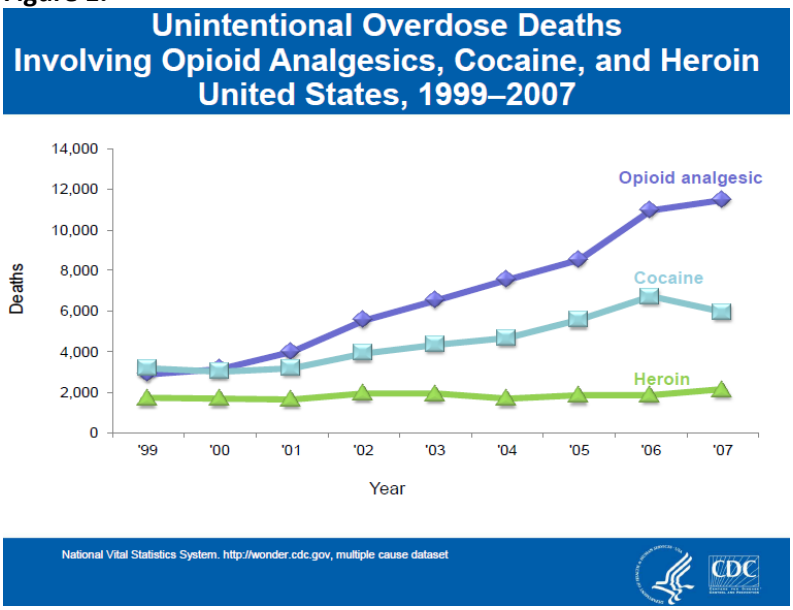
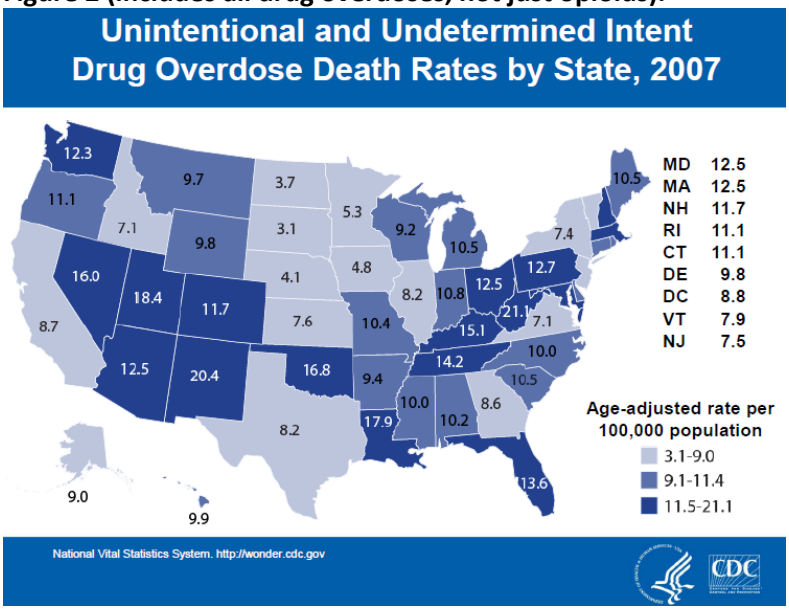
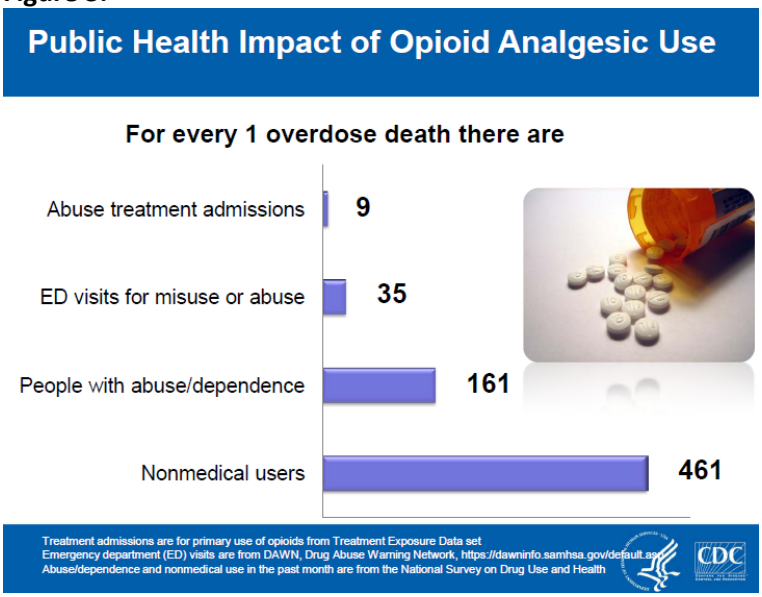


Figure 2 (includes all drug overdoses, not just opioids).[16]



But the number of unintentional deaths is just the tip of the iceberg of opioid misuse statistics, as reflected in Figure 3.

Figure 3.[16]



To further quantify the scope of the problem as it has grown over the last decade

- 257 million prescriptions for opioids were dispensed in 2009—a 48% increase compared with figures for 2000[30]
- There was a 111% increase in ED visits involving nonmedical use of prescription opioids, including hydrocodone, oxycodone, and methadone, between 2004 and 2008[13]
- From 1998 to 2008 there was a 400% increase in substance abuse treatment program admissions among people ages 12 and older who reported any pain reliever abuse[30]

Consequently, there are also Healthy People 2020 objectives for the following safety-related metrics[29]:

- Reduce the number of non-FDA approved pain medications (from 575 to 518)
- Reduce serious injuries from the use of pain medicines
- Reduce deaths from the use of pain medicines

Physician Performance

The use of chronic opioid therapy to treat CNCP, including common conditions such as back pain, osteoarthritis, fibromyalgia, and headache,[31] remains controversial due to the lack of consistent evidence. Although a recent meta-analysis indicates CNCP management with opioids in well-selected patients can lead to long-term pain relief with a very small risk of developing addiction, abuse, or other serious side effects,[32] and other reviews support this use,[33,34] opioids are not always effective. In addition, there is uncertainty about long-term benefits and potential harms of opioid use for CNCP.[35,36] Thus, there are challenges with regard to "what ought to be" in the use of opioids for CNCP.

<u>Relevant Healthcare Professionals</u>

The problems associated with pain treatment and opioid use in particular are especially important to primary care physicians (PCPs), physician assistants (PAs), and nurse practitioners (NPs), who are on the front line in terms of managing patients with chronic pain.[1,13] Other clinicians who have a role in caring for these patients include those in the following specialties: emergency medicine, pain medicine, hospice and palliative care medicine, physical medicine and rehabilitation, anesthesiology, neurology, psychiatry, obstetrics/gynecology, orthopedic surgery, hematology/oncology and radiation oncology,

hospital medicine, and long-term care. Specialists may be more likely to prescribe extended-release opioids than nonspecialists.[37] In addition, pharmacists, dentists, and prescribing psychologists are sometimes involved in the care of patients with pain.

What Ought to Be?

Ideally, clinical decisions should be informed by high-quality evidence, but in reality, this is difficult to follow. Published randomized trials focus primarily on the evaluation of short-term benefits of opioids vs placebo in highly selected populations.[33,34] In addition, sufficient evidence is sparse on areas such as risk assessment, initiating and titrating opioids, monitoring patients on chronic opioid therapy, using high-dose opioids, and treating high-risk patients. Most existing guidelines for judicious use of opioids in appropriately selected patients with CNCP were developed using a consensus process, in part due to a lack of strong evidence.[36] For example, the American Pain Society (APS) and the American Academy of Pain Medicine (AAPM) partnered to develop an evidence-based guideline on the use of opioids for CNCP which included a systematic evidence review that addressed 37 key questions that a multidisciplinary expert panel believed to be critical to answer in order to develop evidence-based recommendations. However, almost all of the randomized trials of opioids for CNCP found were short-term efficacy studies, and, for virtually every "key question," the findings identified important research gaps. Thus, it was concluded that there remain critical research gaps on use of opioids for CNCP, which are summarized as follows:

- *Lack of effectiveness studies* on long-term benefits and harms of opioids (including drug abuse, addiction, and diversion)
- *Insufficient evidence* to draw strong conclusions about optimal approaches to risk stratification, monitoring, or initiation and titration of opioid therapy
- *Lack of evidence* on the
    - Utility of informed consent and opioid management plans
    - Utility of opioid rotation
    - Benefits and harms specific to methadone or higher doses of opioids
    - Treatment of patients with CNCP at higher risk for drug abuse or misuse

Consequently, clinical decisions regarding the use of opioids for CNCP can only be based on weak evidence; this applies to policy decisions as well. Unfortunately, this deficit will result in continued uncertainty regarding best practices, and could contribute to unnecessary harms.[36]

In addition, guidelines also differ in their scope and focus (eg, pain type/location and/or treatment type), complicating matters for clinicians (see Table 1).

Table 1. Sampling of Guidelines for Pain Treatment

Pain Type	Treatment Type	Guideline Author
General pain	Opioids	Webster & Fine[38]
CNCP	Opioids	Interagency (Washington State Agency Medical Directors)[39]
CNCP	Opioids	APS/AAPM[31]
Low back pain	Multiple	APS[40]
Chronic pain	Multiple	Institute for Clinical Systems Improvement[41]
Multiple	Opioids	Federation of State Medical Boards[42]

Although the delineation of "what ought to be" for physician performance is not rooted in evidence of as high a quality as one would like, some of the best practices that emerge from currently available guidelines, position papers, and other sources (including learner interviews reported on elsewhere in this project), are shown in Table 2 (left column) contrasted with some evidence of "what is" in terms of performance and some of the factors underlying performance (right column). The IOM 2011 report[1] notes that there is a drive toward competency-based education and suggests that "recognizing pain management as part of the core competency of internal medicine could substantially improve the ability of a large group of physicians to manage pain." These statements can be used as a competency model, or framework, within which to assess learning needs, plan educational content, and assess outcomes of interventions.

Table 2. Gap Analysis

What Ought to Be Done (Desired)	What Is Being Done (Actual)
Obtain a relevant history and physical exam to determine the etiology of patients' pain. Describe the needs of special populations, including pregnant women, adolescents, cultural/ethnic minorities, and those at the extremes of age.	In busy primary care practices, a thorough diagnosis of the cause and type of pain is often difficult to achieve. The result is that often pain therapy is based not on science but on intuition or hearsay, and ends up aggravating rather than ameliorating prescription pain medication abuse and addiction.[43] 43% of physicians do not ask about prescription drug abuse when taking a patient's health history.[43] There is a "… lack of information about the patients who come to see us. We need a national monitoring program for controlled drug patient prescriptions with information accessible to the provider."[44] HIPAA regulations have made it more difficult to obtain records from a patient's previous physician.[43] Patients may not report pain due to stigma or stoicism associated with knowledge or cultural attitudes.[1]
Assess patient for risks of problem/aberrant behaviors, opioid misuse, substance abuse, and addiction. Screen for risks of psychiatric comorbidity using available evidence-based tools.	One-third of physicians do not regularly call or obtain records from the patient's previous (or other treating) physician before prescribing controlled drugs on a long-term basis.[43] A retrospective chart review of CNCP management practices in an internal medicine clinic indicated that only 39% of CNCP patients' charts had any information regarding illicit substance use; patient legal history was documented in only 32% of charts; and prior medical records were obtained only 39% of the time.[45] A 2000 study found that only 6.2% of PCPs identified substance abuse as one of their five diagnoses when presented with a hypothetical patient with clear early symptoms of alcohol abuse.[46] In another case, only 1% of the physicians surveyed offered substance abuse as a possible diagnosis.[47]

	In contrast to some of the other findings, a Center on Addiction and Substance Abuse (CASA) survey found that most physicians (80.0%) feel qualified to diagnose prescription drug abuse and addiction, and most physicians (81.9%) and pharmacists (86.6%) are confident of their ability to know when a person is seeking controlled prescription drugs for purposes of abuse and/or diversion; those who had received training/instruction in dispensing controlled drugs, identifying prescription drug addiction, and/or preventing diversion were significantly more likely than those without such training/instruction to be confident of their ability to detect diversion and abuse.[48]
Develop an integrated, individualized treatment plan including pharmacologic and non-pharmacologic therapy.	In busy primary care practices, a balanced, multifaceted pain treatment program is often difficult to achieve.[49] The percentage of patients receiving appropriate and adequate treatment has been reported to be as low as 10%-25%.[24-27] There is significant variability in treatment selection and application across clinical settings and considerable evidence to suggest that PCPs in particular are not utilizing treatment guidelines to assist them in their chronic pain management.[45,50-56] There is limited understanding among clinicians of how to select patients for opiate trials, the optimal end points for determining treatment success, and identifying those likely to benefit from long-term use of opioids.[57] The majority of physicians do not know that patients seeking pain relief for CNCP often have underlying psychosocial problems and need psychological or rehabilitation services, or would respond well to other non-drug interventions.[49]
Communicate and document the risks and benefits of opioid therapy. Educate patients and caregivers about medication side effects, potential medication interactions, and precautions while taking opioid analgesics. List adverse effects of opioids (sweating, nausea, low testosterone, etc).	Better communication skills are needed to build therapeutic relationships with their patients (which increases the likelihood that patients will follow physicians' advice).[58] CASA's *Missed Opportunity* study found that 46.6% of PCPs find it difficult to discuss prescription drug abuse with patients for whom they prescribe the medications.[46] Such lack of patient education may lead to under- or overuse of potentially addictive medications.[48]
Periodically review and revise treatment as indicated, including referral if needed.	A survey of CNCP management in an internal medicine clinic revealed that clinicians lacked adequate knowledge in management of CNCP, which resulted in lack of clinical confidence.[45]

Revise opioid dosing via titration, rotation (using equianalgesic dosing), or tapering/termination of medications. Convert treatment from immediate-release product to extended-release and long-acting products. Recognize and manage opioid-induced hyperalgesia.	A lack of knowledge among physicians and/or people with pain regarding the field of pain care medicine was identified as one of the top barriers to adequate pain care at a 2009 American Medical Association (AMA) Summit.[1] Reasons cited by patients who change physicians include that they perceive their physician as having a lack of knowledge about pain.[28] According to a needs assessment for a performance improvement education activity, clinicians "need more education on evaluating pain, developing and implementing appropriate risk management strategies, as well as understanding adverse effects of analgesic medications and adjusting and appropriately monitoring drug levels to increase confidence in treating chronic pain with opioids."[59] The majority of physicians do not know that the long-term safety and effectiveness of opioids for management of nonmalignant pain have not been substantiated.[49]
Use universal precautions on all patients receiving opioid treatment (drug testing, pill counts, etc).	A retrospective chart review of CNCP management practices in an internal medicine clinic indicated that, in terms of monitoring, only 18% of patients had urine drug screens and 25% of patients had fewer than four physician visits during a year of treatment.[45] Few PCPs prescribing opioids for CNCP appear to be using urine testing or other strategies to reduce the risk of opioid abuse.[60]

Why Are There Gaps? Barriers to Optimal Pain Treatment

Suboptimal pain treatment has been found to be due to several clinician-related factors, including gaps in clinical knowledge, inadequate pain assessment skills, negative attitudes toward patients with chronic pain, fear of the abuse and diversion potential of prescribed narcotics, and fear of regulatory scrutiny.[18,19,25,61-65] Underlying many of these is a consistent theme of inadequate training. Barriers are summarized in Table 3, expressed as statements from a physician's perspective (left column) and corresponding evidence of knowledge, attitude, or skill barriers. Clinicians' barriers statements were obtained from qualitative interviews with prescribers.

Table 3. Barriers

Barrier Category and Statements	Examples of Evidence Supporting the Barrier
Abuse/addiction likelihood • I am concerned that my patients may become dependent on or addicted to opioids	• Substantial evidence indicates the knowledge level of PCPs regarding the concepts of addiction and other closely associated concepts such as dependence, tolerance, and pseudoaddiction is woefully inadequate and influences their clinical decision making[51,56,61,62,66-68]

• Some patients are concerned that they may become dependent on or addicted to opioids • I am concerned that patients may accidentally overdose	• Numerous studies have found that a majority of PCPs incorrectly believe treatment of CNCP with opioids will inevitably lead to abuse and/or addiction[18,61-63,66,69] (in reality, the risk of addiction is negligible in appropriately selected patients[70]) • There are continued misperceptions about misuse and abuse of opioids[71,72] • Most physicians and pharmacists (in the CASA survey) would be interested in receiving additional education or training in o Prescribing or dispensing controlled drugs (61.2% of physicians, 67.6% of pharmacists) o Identifying prescription drug abuse/addiction (69.4% of physicians, 79.9% of pharmacists) o Identifying prescription drug diversion (70.9% of physicians, 81.0% of pharmacists)[48]
Legal/regulatory • I don't like the regulatory scrutiny that comes with prescribing opioids	• Surveys show that clinicians have a poor or limited understanding of the laws, regulations, and other policies that govern the prescribing, dispensing, or administration of controlled substances, including opioid analgesics[66,73] • Little research has been conducted to determine the extent that clinicians' knowledge of policies impacts healthcare practice and patient care; however, clinicians are more vulnerable to regulatory investigation or discipline if they fail to comply with practice standards or regulations[48] • 5.8% of physicians and 9.0% of pharmacists inaccurately thought it was not lawful to prescribe opioids to patients with chronic pain who have a history of substance abuse; 18.4% of physicians and 16.5% of pharmacists did not know whether it was lawful[48] • Physicians report regulatory concerns, long-term safety and durability of response concerns, and the possibility of peer scrutiny as reasons for resistance to treating CNCP with opioids[18,20,62,63,66,74-77] o Federal and state drug abuse prevention laws, regulations, and enforcement practices have been considered impediments to effective pain management since 1994[1] o 29% of PCPs and 16% of pain specialists report they prescribe opioids less often than they think appropriate because of concerns about regulatory repercussions[78] o In a California Academy of Family Physicians (CAFP) survey regarding barriers to prescribing long-acting opioids, fear of abuse/addiction/diversion was the top barrier; fear of liability was also a barrier[44]
Patient factors • Pain patients do not adhere to a treatment plan • Managing pain patients takes too much time and	• Patient compliance: better communication skills are needed to build therapeutic relationships with patients (which increases the likelihood that patients will follow physicians' advice)[58] • Health professionals may hold negative attitudes toward people reporting pain and may regard pain as not worthy of their serious

disturbs the workflow in my office • Pain patients are sometimes unpleasant to deal with	attention, especially for some minority groups[1]; in fact, reasons cited by patients who change physicians are their perceptions that their physicians were not willing to treat their pain aggressively enough and did not take their pain seriously[28] • Negative emotions (frustration, guilt, lack of appreciation) also plague some primary care practitioners; despite feeling confident of their ability to treat pain, 73% of primary care clinicians said patients with chronic pain are a major source of frustration[61] • Patient expectations and preferences o Some patients desire more aggressive treatment than the physician is willing to give
Diversion • I am concerned about potential diversion of opioids when I prescribe them	• Most physicians and pharmacists (in the CASA survey) would be interested in receiving additional education or training in identifying prescription drug diversion (70.9% of physicians, 81.0% of pharmacists)[48] • Without a patient-centered approach to managing chronic pain, the provider may be in a position of a police officer or judge, or making deals/bargaining with patients, which can weaken the therapeutic relationship[79]
Lack of quality evidence/guidelines • Clinical guidelines on appropriate use of opioids are unclear	• There is a lack of guidelines for use of opioids in the ED[3] • There are no evidence-based protocols to guide practitioners in facilitating self-management and patient education in this area[1] • There is interdisciplinary disagreement on management principles of chronic pain; because "pain management is spread out over many clinical specialties, there is confusion about who is 'in charge' of developing, documenting, and reporting best practices and pain care guidelines"[1]; competing, overlapping, and sometimes conflicting efforts of various organizations mean there is no single-party ownership of the pain medicine specialty • There is also a lack of clinical role models (specialists treating chronic pain) in most academic medical centers[1] • There is inconsistency and lack of coordination of federal guidelines and funding; where national guidelines are linked to reimbursement and, thus, access to care, it is imperative that guidelines be aligned with current best practices and the latest evidence[13] • As described in a previous section, most guidelines were developed by consensus in the absence of strong evidence to guide recommendations[36]
Cost/reimbursement • I am not reimbursed adequately for managing pain patients • The cost of nonpharmacological therapy is too high for my patients	• Payer policies o Preferred drug lists o Lack of reimbursement for longer patient counseling visits, self-management programs, and nontraditional therapies o Differences in patient insurance

Interdisciplinary care access • I have limited access to pain specialists for consultation and referral • My patients do not have access to providers of nonpharmacological (cognitive-behavioral, physical, alternative, etc) therapy	• Interdisciplinary team approaches are not consistently used in pain care, and there is limited access to quality pain specialists[1]

Clinician confidence, which may be impacted by many of the knowledge and other barriers above, is also noted as a barrier:

- A survey of CNCP management in an internal medicine clinic revealed that clinicians lacked adequate experience in management of CNCP, which resulted in lack of clinical confidence[45]
- Only 34% of PCPs at academic medical centers felt comfortable treating people with CNCP[75]
- Many primary care practitioners at community clinics felt inadequately prepared to treat pain and had low satisfaction with providing pain care, despite the fact that nearly 40% of their adult appointments were patients with chronic pain complaints[56]
- As noted in the IOM report section on education challenges, physicians' beliefs about their ability to manage pain do not always match their actual competence; "there is no correlation between physicians' confidence in their knowledge and abilities to manage pain and their ability to make good treatment decisions; better self-assessment tools are needed to help physicians understand and remediate their knowledge and skill deficits"[1]

Finally, **inadequate training** is frequently cited as a critical underlying factor of the gaps in pain treatment. Pain receives insufficient attention in virtually all phases of medical education.[1] Results of a November 2009 AMA Pain Medicine Summit found that "training was seen as poor or 'not leading to competency' at both the undergraduate and residence levels in all suggested areas of pain treatment."[80] Medical school education provides students with pharmacology information, but often does not adequately address issues of pharmacotherapy, such as the use of combination drugs, drug interactions, compliance issues, dosage reductions in the elderly, and how to appropriately prescribe psychoactive drugs.[16] In addition, training in addiction and related disorders is very limited and inadequate at the graduate and postgraduate levels.[61,68,81-83]

Primary care providers often receive little training in the assessment and treatment of complex chronic pain conditions, In a survey of PCPs, 20% of respondents stated they received no training in the management of CNCP, and an additional 32% stated they received "limited" training.[75] Similarly, a survey of internal medicine residents revealed that 57% rated their training in chronic pain management as only "fair" or "poor."[45] Attending physicians rated their medical school education (81.5%) and residency training (54.7%) regarding chronic pain management as inadequate. In the same study, the mean rating for chronic pain education for NP and PA programs was 0.5 on a scale of 0 (not at all satisfied) to 4 (very satisfied).[56] The need for improved education on prescribing controlled substances in medical schools is largely unmet.[48]

Strategies to Address Gaps in Pain Treatment

Numerous educational strategies have been implemented and/or recommended to address gaps in pain treatment; of those that have been implemented, data on physician change or improved patient outcomes are available for some and not for others. However, several sources note that education alone is not enough to attain/maintain continued competency in this complex area of practice[1,84,85]; new ways of ensuring that healthcare professionals understand the proper use of opioids are needed,[13] and education will be ineffective in the absence of systems that permit or encourage clinicians to act on their knowledge, including changing reimbursement policies.[1] Information about strategies is summarized below according to whether they are predominantly educational or system related.

Educational Strategies

Physician and Pharmacist Preferences

The CASA survey asked physicians and pharmacists to indicate their most valuable sources of knowledge about controlled prescription drugs; results are shown in Table 4. For physicians, work experience ranks well above other methods, whereas a majority of pharmacists agreed that continuing education courses were also valuable, although the remainder of sources ranked relatively low.

Table 4. Most Valuable Sources of Knowledge About Controlled Prescription Drugs (percent agreeing)[48]

Source of Knowledge	Physicians	Pharmacists
Work experience	83.7	90.0
Colleagues	50.6	46.6
Internship/Residency/Fellowship	43.1	11.5
Journal articles	42.6	39.6
Continuing education courses	39.1	66.8
Pharmacology course	27.5	36.3
Reference books	17.0	20.2
Information from drug product manufacturers	16.6	19.8

Continuing Medical Education (CME) Modules/Interventions (sampling)

- In Tennessee, physicians who are deemed "overprescribers" must take a CME course on proper prescribing practices[86]; the Robert Wood Johnson Foundation teamed with Vanderbilt University to create a program specifically focusing on physicians who are reportedly misprescribing controlled substances[87]; the course allows practitioners (physicians and dentists) to discuss their prescribing practices and learn how to avoid future problems
- The AMA has a popular 12-hour Pain Management CME program that has issued over 200,000 certificates since its launch in 2004; it was revised in 2007 and further revisions and enhancements are planned[11]
- The AMA is providing assistance to the US Department of Health and Human Services (DHHS) Center for Substance Abuse Treatment to develop an online CME activity[11]
- The AMA, in collaboration with medical schools funded by the National Institute on Drug Abuse (NIDA), has coordinated the research and development of education modules for use with undergraduate medical students and residency programs, with intentions to convert them to courses for practicing physicians[11]
- Sessions are being devoted to pain management and REMS at conferences (eg, AAFP's 2011 Scientific Assembly, September 14-17, 2011, in Orlando)[30]

- Performance improvement CME is offered on this topic[59]

Student Training

Health Professional Students for Substance Abuse Training (HPSSAT) is a project of the Physician Leadership on National Drug Policy that aims to impact the education of students throughout the array of health professions and to increase and improve health professional student training and education in substance abuse prevention and treatment. The goal of HPSSAT is that all graduating health professional students have the skills to appropriately screen, diagnose, and provide intervention for patients with substance abuse problems. HPSSAT members help to identify and understand the core requirements for adequate substance abuse prevention and treatment training and serve as advocates for local and national educational reform.[88]

Guideline Development and Dissemination Educational Pilot in Washington State[2,16]

The Interagency Workgroup on Practice Guidelines collaborated with pain management providers in Washington State to develop a guideline on opioid use for chronic pain and, in April 2007, published the *Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain: an educational pilot to improve care and safety with opioid treatment*.[39] The guideline was developed as an educational tool for primary care providers and offers recommendations for managing patients with CNCP. The main emphasis is on preventing future cohorts of high-dose patients. One unique feature is a "yellow flag" threshold, which calls for the healthcare professional to stop and, if needed, get a one-time pain management consultation from a healthcare professional certified in pain, neurology, or psychiatry when a patient's dose reaches 120 mg MED (morphine equivalent dose).

In 2009, an interim evaluation of this strategy was conducted; results and subsequent recommendations and steps are shown in Table 5.

Table 5. Evaluation Findings and Recommendations from Pilot in Washington State[2]

Interim Evaluation Finding	Recommendations and Planned Changes
There is frequent reported use of some best practices including assessment of mental health and substance abuse history, and use of opioid agreements, but low reported use of tools to assess pain and function, or urinalysis.	Continue and improve dissemination of the guideline. Develop or identify patient education or decision aid tools since many providers surveyed noted use of the guideline as a patient-education tool and a need for patient decision aids to help patients understand treatment choices for CNCP.
Many providers cite access or quality concerns related to use of pain specialists.	Evaluate and address potential access and quality concerns related to specialty pain consultations. It was found that there were not enough pain specialists; this was addressed by conducting advanced training for primary care to increase their proficiency (thereby reducing need for specialist referrals) and also by establishing telemedicine consultations and Webinar trainings with pain specialists and PCPs. Public payers are working on payment codes to incentivize these activities.

Overall lessons learned from the Washington State educational pilot are that

1. Prescriber education requires appropriate tools and dosing guidance.

2. Prescriber education alone is not adequate.
3. A more comprehensive approach to effectively treating chronic pain must be developed.
4. Statewide change through collaboration is needed.
5. New state regulations are needed to ensure best practices and to prevent worst practices.

Thus, a combination of having appropriate clinical guidelines in place, education of prescribers, and system changes to facilitate and incentivize guideline adherence seem to be the ingredients for success.

Peer/Physician Mentoring Programs

Physician behaviors are most likely to change when prompted and assisted by other physicians.[11] Mentoring programs have resulted in enhanced knowledge, skills, and confidence.[89] For these reasons, a peer mentoring model was used to develop a Physician Clinical Support System for buprenorphine (PCSS-B), managed through a collaboration of medical societies and the AMA. It is a clinical mentoring program that has trained and provided assistance to hundreds of physicians through telephone, e-mail, in-person support, a Web site, clinical guidances, a "warmline," and outreach to primary care and specialty organizations.[90] Although impact on care quality or buprenorphine treatment expansion is not quantified, anecdotal information supports an interpretation that buprenorphine treatment was facilitated and likely more consistent with guidelines for those who accessed the system, in addition to demonstrating the feasibility of implementing such a system. A similar program exists for methadone (PCSS-M) and for primary care (PCSS-PC) that is focused on addressing alcohol, tobacco, and drug screening interventions and treatment.[91]

Other Education Recommendations

- Make pain training more comprehensive, incorporating the needs of the primary care practitioner and the pain care specialist alike[1]
- Promote the shared care concept by expanding interdisciplinary education so that more care can be delivered by a primary care team instead of having to be handled by an individual physician[1]
    - This has been done with hypertension management and is in line with the trend of medical homes that use teams to provide chronic care, as well as the development of accountable care organizations
- Use positive incentives to encourage physicians to complete educational requirements (eg, waivers)[11]
- Develop physician guidelines on opioid prescribing in the ED[3,92]
- Start with a pilot before disseminating more broadly

System Strategies

Prescription Drug Monitoring Programs[3,13,16]

In an effort to curb diversion of prescription medications, many states have implemented prescription drug monitoring programs (PDMPs)—electronic databases that record and track prescribers and recipients of controlled medications. Many groups call for increased effectiveness and improved use of PDMPs.

Shared Care: Opioid Renewal Clinics

Similar to the interdisciplinary care concept, a structured opioid renewal program for managing patients with CNCP has been run by a nurse practitioner and clinical pharmacist and supported by a multispecialty team in a primary care setting.[93]

Other System Recommendations[16]

- Track the rate of use of multiple providers and high dosage
- Use single copy, serialized, tamper-resistant paper prescription or e-prescribing forms[92]
- Restrict selected patients to one provider and one pharmacy (by Medicaid and others insurers)
- Insurers can restrict payment for inappropriate use, eg, use of long-acting opioids for short-term pain
- Improve legislation and enforcement of existing laws, including
    - Prevent doctor shopping (laws exist in 33 states)
    - Reduce "pill mills" and other fraud through licensure and inspection laws (3 states)
    - Require physical exams before prescribing (32 states)
    - Stop drug distribution to "pill mills"
    - Require identification at dispensing (11 states)
- Expand use of overdose harm reduction programs
    - Including more widespread distribution of the opioid antidote, naloxone
    - Expand use of buprenorphine for treatment of opioid dependence

The Role of REMS in Addressing Gaps in Pain Treatment

Since the REMS mechanism was formally launched in 2007, the FDA has required REMS for a number of drugs, including several individual opioids. The REMS for each agent differ and include a range of tactics, some of which require healthcare providers to complete special education and certification processes in order to prescribe the drugs. In April 2011, the FDA announced a class-wide REMS requirement for long-acting and extended-release opioids (those already approved and those yet to be approved); manufacturers are asked to collectively arrive at a single shared REMS plan for the class of agents. Such work is underway via an Industry Working Group that is in communication with the FDA and other stakeholders in an effort to develop a REMS that meets the fundamental purpose of improving patient safety while maintaining access to appropriate prescription opioids according to standards of medical practice.[94]

Current parameters of REMS for opioids include[95]

- The FDA has decided not to require the REMS for all opioids; the agency concluded that there is a disproportionate safety problem associated with the extended-release and long-acting opioids which must be addressed, and will incorporate a step-wise approach to focus first on educating prescribers of these types of opioids
- The central component at this time is the creation of an education program for prescribers[9]; this education will include information on weighing the risks and benefits of opioid therapy, choosing patients appropriately, managing and monitoring patients, and counseling patients on the safe use of these drugs; additionally, prescribers will learn how to recognize evidence of and potential for opioid misuse, abuse, and addiction
- Participation in the education system is voluntary at this time for healthcare professionals, though it is mandatory that manufacturers offer the education; however, the FDA and the Obama Administration intend to pursue legislation for a mandatory educational requirement linked to Drug Enforcement Agency (DEA) registration requirements for healthcare professionals

Outcomes Base of REMS

Like many of the guidelines for pain treatment, REMS is limited in the extent of evidence and outcomes that link strategies to improved physician performance and patient outcomes. Groups have warned that caution should be exercised in the implementation of REMS until better evidence is available to guide decision making.[96] This is particularly true for some of the ETASU components: "None of the new REMS with ETASU, and very few of the older RiskMAP programs, have been retrospectively reviewed, so the science base on which to judge the effectiveness of ETASU is virtually nonexistent."[12] There is concern that unintended consequences may occur and that ETASU may not be appropriate, especially in opioid REMS (see section on barriers to compliance below for more information).[12]

Patient-Provider Agreements

For example, the approved REMS for a transmucosal fentanyl tablet for breakthrough cancer pain require the use of patient-provider agreements. In a literature review of opioid agreements used in the treatment of CNCP published in 2010,[60] only four studies were found that compared outcomes of patients with and without opioid agreements. All were retrospective and observational, and none evaluated clinical outcomes on addiction and overdose. Thus, despite the perception that these agreements are legal and binding, there is no evidence that they change behavior.[97] An *American Journal of Bioethics* panel also outlined a number of unintended consequences associated with the use of opioid agreements.

Positions of Physician Groups on REMS

As with the position and concerns expressed in the AMA report, other professional organizations have also issued statements concerning REMS. Many echo similar concerns, although there is disagreement between some on whether the REMS should cover all opioids or only long-acting ones.

- The American Psychiatric Association, American Osteopathic Academy of Addiction Medicine, and the American Academy of Addiction Psychiatry all issued statements of support following the April 2011 FDA decision[9]
- The American Academy of Pain Management recommended that any new REMS plan should cover the entire class of opioids, not just long-acting[9]
- The APS also advocates for covering all opioids, and emphasizes that the opioid REMS would be the first of many necessary steps to improve the problems associated with opioid misuse[98]
- The American College of Physicians, together with 15 other physician specialty groups, does not support extending REMS to all opioids (this was issued in 2009, prior to the April 2011 FDA decision)[11]

Within their statements, some of these groups suggested barriers and facilitators to physician compliance and ultimate effectiveness of REMS, as noted in the sections below.

Barriers to Physician Compliance With REMS

Although the current opioid class REMS is still in development and new education or other requirements for physicians are not mandatory at this time, some surveys have been conducted to gauge anticipated physician reaction to potentially required components of REMS.[10,44,99-101] These survey outcomes, in conjunction with information available on outcomes of REMS for other drugs or regulatory actions, suggest that there will be barriers to physicians complying with various aspects of REMS, as outlined in Tables 6 and 7. Primary care practitioners who prescribe most of the analgesics are most likely to see REMS as a barrier.[96]

Table 6. Barriers to Physician Compliance With REMS: *Specific REMS Components*

Category	Extent of Anticipated Barrier
Physician education	Physicians were surveyed on various scenarios of amounts of education; they are generally willing to complete limited education, for example: • 48% of PCPs were willing to complete no more than 2 hours of local training to continue prescribing opioids,[99] but 47% of PCPs who currently prescribe transmucosal fentanyl products would **discontinue** prescribing them if required to participate in a 2-hour training session; 45% of PCPs said they would **discontinue or are likely to discontinue** prescribing opioids if required to complete 4-8 hours of training followed by 2 hours of pain-related CME every 2 years[99] • Surveyed clinicians preferred shorter intervals to longer ones, desiring 2 hours every 3 years (39%) compared to every 6 (30%) or 9 (21%) years[44] • 61% of pharmacists also support prescriber education (out of 59 respondents to an American Pharmacists' Association "Pulse" survey)[101]
Patient education	Most PCPs are willing to complete mandatory patient education, and 70% of pharmacists support patient education for opioid REMS, but 12% of PCPs would **discontinue** prescribing long-acting opioids if required to complete mandatory patient education, and only 24% of the pharmacists recommend a medication guide as part of opioid REMS.[99,101] Some feel strongly: "Focusing on medication and communication guides is wasted effort. Such guides have not been shown to change prescribing behavior."[102] Medication guides tend to be lengthy, which can contribute to information overload for patients (especially those with limited literacy or for whom English is not their primary language), and he process for modifying them is paperwork intensive for both the FDA and manufacturers.[6,10]
Patient registry	50% of PCPs were willing to register patients on a 6-month basis,[99] but 18% would **discontinue** prescribing opioids if required to register each patient in a registry and have the patient reregistered every 6 months. The pharmacists perceive this as one of their top challenges; while 66% recommend patient registration for opioid REMS, a substantial 22% recommend against them.[101]
Documentation	With opioid REMS, there would be a need for extensive record-keeping across the continuum of care.[6] Documentation can be challenging for pharmacists and other healthcare practitioners. Hence, 32% of PCPs would **discontinue or are likely to discontinue** prescribing opioids if required to document ongoing monitoring of therapy, including efficacy and safety, and monitoring for aberrant, drug-related behavior.[99] However, 66% of pharmacists recommend verification/documentation of patient education, and whereas many oppose mandatory agreements[11,103] (see above), 93% of pharmacists recommend using them.[101]
Certification tied to DEA registration	Many physician groups support that this "should only be used as a last resort to keep high-risk products with very unique and important benefits on the market when no other approach is sufficient to allow continued marketing of a drug product."[11] When surveyed, 79% of PCPs said they would opt in to this to continue to prescribe and 11% said they would not; however, it's unclear what was involved in certification requirements).[99]

Table 7. Barriers to Physician Compliance With REMS: *General Concerns and Unintended Consequences*

Category	Examples
Hassle/ burden competes with obligation to care for patients	• Mandatory requirements in general are barriers; less intrusive elements should be tried first (positive incentives would be better)[11] • As risk-management programs proliferate, patient care could be driven by compliance with paperwork instead of individual patients' clinical needs[7] • Time and workflow burden may be disruptive to other patient care[104] • Although the FDAAA requirement (for REMS) is to *not* be unduly burdensome on patient access to the drug and to minimize the burden on the healthcare delivery system,[11] there is a perception that requirements are logistically burdensome[44] • There is already an administrative burden on keeping up with all the special CME required to maintain licenses in other areas (domestic violence, HIV, medical errors, maintenance of certification, etc)[44]
Circumvention/ manipulation	For some severe conditions, physicians have misrepresented facts to circumvent cumbersome appeals processes regarding insurance company restrictions on what they believed to be a healthcare benefit[105]; greater utilization restrictions in the healthcare system are likely to increase physicians' manipulation of reimbursement rules to obtain coverage for services they perceive as necessary.[106]
Patient access/ delays in care	REMS could result in reduced access for some patients with legitimate medical needs, particularly those in underserved communities, to medically necessary drugs.[11] For example, physicians opting out of prescribing Schedule II controlled substances will leave fewer PCPs willing to manage patients with chronic pain. More patients will come to emergency rooms for pain relief—even though time-release opioids are rarely prescribed in the emergency room,[11] guidelines are lacking, and chronic pain is perceived to have a low priority in the ED.[76] Further, patients may be admitted to the hospital with an outpatient REMS drug that is not available through the hospital, or requires a new process for access, and a designated or certified prescriber or pharmacist must be contacted and all required paperwork must be in place before the drug can be dispensed.[6,7]
Beliefs/ attitudes	Although over 80% of pharmacist survey respondents think REMS will address abuse and misuse,[101] others think REMS will not solve the problems associated with misuse.[9] REMS is not intended to directly address diversion; other coordinated approaches are needed (eg, prescription monitoring programs [PMPs])[11] for that. It is expected that there will be continued fear of abuse, addiction, diversion, and liability,[44] and concern about resurrection of widespread opioid phobia among physicians.[11]
System challenges	Finally, there are some additional implementation challenges of having FDA regulate a category/class of drugs (due to number of drugs, patient volume, etc),[6] and challenges for those who cannot easily collaborate with others (eg, in a health system) to share the burden of REMS among various healthcare professional team member roles. The lack of a searchable database of certified providers or a central clearinghouse of REMS information also presents challenges.[104]

Examples of Unintended Consequences in Other Clinical/Regulatory Areas

We know from experience in other areas that restrictions for Schedule II products have led to physicians opting out of prescribing, reducing patient access to medically necessary drugs, and fostering a shift to Schedule III products.[11] These effects were seen

- When New York mandated government-issued serialized forms for benzodiazepines
- In states with PMPs that track only Schedule II substances
- In states that have 'proactive' vs 'reactive' PMPs
- When highly restrictive limitations were placed on solo and group practices equally for providing methadone maintenance and prescribing buprenorphine

In all instances, the policy greatly limited patient access and physicians' desire to provide opioid treatment and maintenance.

Facilitators of Physician Compliance With REMS

Factors facilitating physician compliance with REMS parallel some of the educational and system strategies and recommendations noted in a previous section on addressing gaps in pain treatment; they also contrast with some of the barriers mentioned above. Facilitators include:

REMS Development Strategies[7,10-12,96,101]

- REMS should be standardized with general templates that drugs could be "slotted in to"
- Frontline healthcare providers (prescribers, pharmacists), as well as patients, should have input in the development of REMS
- Communication and awareness about REMS programs and requirements should be improved
- Achievable metrics should be developed to assess efficacy of REMS programs and modify the programs accordingly
- A clearinghouse should be developed for all REMS information
- Strategies should be piloted before nationwide implementation

Education Strategies[11,102,101,107]

Pharmacists cite education (of prescribers, pharmacists, and patients) as a top element to incorporate into opioid REMS. Consistent with adult learning principles, education should be based on understanding how best to change prescribing behavior. It should be unique, creative, multifaceted, and allow for measurement of outcomes. Recommended strategies include

- Using interactive cases
- Academic detailing, in which nonindustry experts offer tailored instruction to clinicians[1]
- Make education relevant to the providers' practices
- Develop and implement physician/peer mentoring programs (eg, PCSS-B), because physician behavior is most likely to change when prompted and assisted by other physicians
- Focus content on areas of greatest need and impact, such as factors contributing to overdoses, inappropriate patient selection or prescribing, and pathways to nonmedical use

System Strategies[6,7,11-13,44,107]

Without the support of systems, changes in behavior and outcomes are impeded. Systems recommendations include:

- Use PMPs
- Integrate REMS into the existing infrastructure of hospitals or long-term care centers, including electronic medical record systems
- Modify workflow and staffing structures to facilitate implementation of REMS and ensure patient access to medications

- Within a health system, team roles and processes can be determined that integrate REMS requirements into current processes; collaborative efforts could help reduce workload
- Advocate transition from paper-based to electronic processes
- Develop referral and consultant list
- Utilize positive and financial incentives to encourage physicians to complete education, eg, medical malpractice premium reductions

Conclusion

At the crossroads of evolving risk management plan requirements and increasing challenges in the treatment of pain is an opportunity to use best practices in risk mitigation and education to improve effective use of opioids for legitimate medical purposes and to curtail what has become an epidemic of opioid abuse, misuse, and addiction. In a July 2009 presentation by the Tufts Health Care Institute on Opioid Risk Management, Nathaniel Katz, MD, MS, provided a succinct summary of what will make for successful REMS:[108]

- Root cause analysis of the problem
- Clear determination of exactly what we want prescribers to do
- Clear determination of exactly what we want patients to do
- Clear determination of exactly what we want pharmacists to do
- Efficient and effective method to shape behavior
- Efficient method to assess training status prior to dispensing
- A credible method for evaluating positive and negative impact of programs

This literature review addresses the above success elements at the level of meeting physician learning needs. The identified gaps, barriers, and recommended strategies can inform the development of national educational efforts or can serve as a foundation for exploring root causes with specific audiences and locales to better tailor interventions. The competency model, though it may be impacted and refined as future research helps to fill gaps in evidence, represents what healthcare providers should do and provides a framework for evaluating program impact. The strategies to address gaps in pain treatment and facilitators of physician compliance with REMS suggest methods to most effectively shape behavior.

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Appendix 3: REMS Background

Clinicians, lawmakers, and drug manufacturers have long recognized that the potential risks of some medication classes necessitate specific risk management strategies. The FDA has long been involved in efforts to ensure patient safety while maintaining access to necessary medications. The Risk Evaluation and Mitigation Strategies (REMS) program is the most recent, involved, and comprehensive iteration of federally mandated risk management programs.

For decades, various measures have been implemented by the U.S. government and drug manufacturers to reduce patient risk from potentially harmful medications. For example, in 1990 the "no blood, no drug" system for clozapine required patients to obtain regular blood cell counts to screen for agranulocytosis; in 1998, a program was implemented to prevent fetal exposure to thalidomide.[1] In 2005, the Federal Drug Administration released a series of three Risk Management Guidance Documents, one of which outlined the design, creation and implementation of Risk Management Action Plans, or RiskMAPs.[2,3,4] The Risk Management Guidance Documents were recommendations only – they were not required or legally enforceable.[5]

RiskMAPs – a "strategic safety program designed to meet specific goals and objectives in minimizing known risks of a product while preserving its benefits"[6] – were the first standardized pharmaceutical risk management program. By February of 2007, 30 medications were covered by a RiskMAP program, most centered on education and outreach.[7] The philosophy and elements of these programs formed the basis for the development of REMS.

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[1] An overview of RiskMAPS: Office of Surveillance and Epidemiology. FDA. 2007. Accessed at: http://www.docstoc.com/docs/573628/An-Overview-of-RiskMAPs.

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Risk Evaluation and Mitigation Strategies (REMS)

On September 27, 2007, President George W. Bush signed the Food and Drug Administration Amendments Act (FDAAA) into law. This act amended the Federal Food, Drug and Cosmetic Act to create section 505-1, which authorizes the FDA to require drug manufacturers to submit a plan for a Risk REMS if the FDA deems it necessary to ensure that the risks of the drug do not outweigh its benefits.[8] In February of 2009, the FDA sent letters to manufacturers of extended-release opioid analgesics, informing that REMS would be required in order for opioids to remain on the market. The list included fentanyl, methadone, morphine, and oxycodone.[9]

In the midst of a series of meetings soliciting input from stakeholders, industry, and the public, the FDA released a preliminary guidance document for REMS in September of 2009.[10] In April of 2011, a letter was released to manufacturers of long-acting and extended-release opioid medications outlining the elements of the required REMS program, which include a prescriber education component. The following month, representatives from manufacturers of affected medications met with the FDA and the IWG to discuss plans for implementing a large-scale, comprehensive REMS program.

State Requirements for Pain Management

Seven states, including Tennessee, California and West Virginia, have enacted specific legislation mandating that physicians undergo certified pain management and/or controlled substance education as part of their medical license renewal process.[11] California's requirements are representative of a statewide legislative attempt to address continuing medical education for pain and end-of-life care. Signed in 2001, *AB 487: Pain Management and the Appropriate Care and Treatment of the Terminally Ill* requires California physicians to complete 12 credits of pain-related CME.[12] The California legislation did not include a systematic assessment of the need, the development of a uniform and appropriate curriculum, or a standardized method by which to capture, measure, and assess outcomes that evaluate the effectiveness of the mandated 12 credits of education.

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[8] 21 USC §355-1. SEC. 505-1. Risk Evaluation and Mitigation Strategies.

[9] Opioid Drugs and Risk Evaluation and Mitigation Strategies (REMS): FDA to Meet with Drug Companies about REMS for Certain Opioid Drugs. U.S. Food and Drug Administration. Accessed at: http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm.

[10] U.S. Department of Health and Human Services et al. Guidance for Industry Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications. September 2009.

[11] American Medical Association. Continuing Medical Education for Licensure Reregistration. Located at: http://www.ama-assn.org/resources/doc/med-ed-products/continuing-medical-education-licensure.pdf. 2011.

Appendix 4: FDA Crosswalk

PROPOSED REVISED COMPETENCIES	FDA MATCH
To safely and effectively prescribe opioids to manage pain, a prescriber will demonstrate knowledge, skills, abilities, and behaviors that enable him/her to:	1
A. Develop an integrated treatment plan based on a comprehensive evaluation. Specific competencies include:	1, 1a
1. Gather appropriate information through: a. Review of medical records b. *Perform*/*Review* history with special attention to relevant past medical history, pain hx, and pain-related information	1a
c. Identify risk factors for misuse of opioids	1aii
2. Screen for risks of substance misuse and psychiatric co-morbidity using available evidence-based tools	1aii
3. Gather relevant objective data:	1a
a. Perform appropriate physical examination to: (1) Assess pain (2) Identify findings suggestive of substance abuse or mental health conditions that augment opioid risk	1a, 1aii
b. Obtain appropriate testing to: (1) Define etiology of pain (eg, imaging studies, EMG, laboratory data, etc.) (2) Identify factors associated with the risk of opioid abuse: (a) Serologic data (b) Toxicology screens (c). Screen for depression or anxiety disorder	1a, 1aii
4. Formulate a working diagnosis of pain and other relevant conditions	
5. Create an individualized treatment plan, based on comprehensive assessment, that balances benefits and risks for the patient and accounts for the patient's goals and preferences	1ai, 1ci
a. Describe the needs of special populations, including people with the disease of addiction, the elderly, children, women, and cultural and ethnic minorities	1a
b. Document the evaluation, objective data, diagnosis and treatment plan	
B. Implement a trial of opioid therapy.	1di
1. Engage in a meaningful *informed consent process* that educates the patient, family, and caregivers	3a, 3bii, 3gi, App B1b
a. Know important potential risks and benefits of opioid therapy	1b, 3a, 3f, 3gi, 3h, App B5, App B6a, App B7
b. Communicate and document the risks and benefits of opioid therapy supported by relevant patient education materials.	1b, 3a, 3f, 3h, App B 1b, App B5, App B6a, App B7
2. Develop a mutually understood and agreed upon plan for clinical care which includes: a. Goals for treatment (1) Communicate these goals to the healthcare team and other support systems patient has designated	1a, 1ai, 1ci, 1cii,3b, 3bi, 3bii, 3d, 3g, 3gi, 3h, App B1a, App. B3, App B6, App B7,

b. Dosing and access to medications (1) Reduce quantity of opioids for patients at higher risk for abuse, when appropriate (2) Be familiar with tamper resistant, abuse deterrent formulations available for patients at risk for abuse c. Instruct patients regarding safe drug storage (locking up) and proper disposal of all medications d. Expectations with respect to other treatments (anxiolytics), substance use (ETOH, THC), and behaviors (taking more than prescribed, or more often than prescribed, or for other reasons than prescribed) e. Initiate a Patient Provider Agreement (PPA) that includes education and discussion of: (1) Goals of treatment (2) Dosing and access to medications (3) Safe medications use, storage (locking up) and disposal 3. Expectations with respect to other treatments, substance use and behaviors	1biii,1biv
4. Utilize a *system of documentation* that includes a. Initial evaluation and relevant diagnoses b. Treatment plans (including prescriptions) c. Informed consent and agreement d. Results of referrals and consultations e. Objective testing: radiology and lab data (including urine drug testing) f. Appropriate follow-up relating to clinical progress and medication management considering both positive effects (eg, analgesia or functional improvement) and negative effects (eg, side effects or aberrant behaviors)	
5. Utilize and teach appropriate office protocols for requesting, receiving, dispensing, administering, storing and destroying medications in the work setting which meet all state and Federal regulations and documentation requirements of your discipline and practice.	
C. Periodically review and revise treatment as indicated, including referral.	**1e, 1ei, 1f**
1. Understand and implement important elements of re-evaluation of opioid therapy, including assessment of: a. Adherence to the treatment plan (includes checking prescription monitoring program and computerized records) b. Pain c. Activities of daily living and other valued functions d. Presence or absence of adverse effects of opioid therapy e. Recognition of behaviors that may be associated with aberrant behavior and misuse of opioids f. Monitor for potential overdose g. Stability of relevant co-occurring conditions h. Vigilance for emerging or alternative diagnoses i. Reconcile medications at each visit j. Access the state's Prescription Monitoring Program prior to prescribing	1biii or 1biv, 1cv, 1e, 1ei, 1ciii, 1civ, 3biv, 1fi
2. Use toxicology screening appropriately	1fii
a. Describe the rationale for toxicology screening in opioid therapy	1fii
b. Interpret common toxicology findings	1fii
c. Know resources for assistance in interpretation of unexpected toxicology findings	1cv, 1fii
3. Demonstrate competent pharmaco-therapeutic management including multimodal analgesia. a. Use good clinical judgment to determine the quantity of the prescription	1bi
b. Monitor all patients receiving opioids for pain across all settings	1bi

c. Educate patients and caregivers about medication side effects, potential medication interactions (ie alcohol, other drugs), and precautions while taking these medications (eg, falls, working with heavy machinery, etc).	
d. Modify opioid dosing, including: (1) Titration to effect, guided by safety and patient tolerability. (2) Converting from one opioid to another (a) Convert from immediate-release product to extended-release and long-acting products (b) Converting from one extended-release and long-acting product to another (3) Tapering/termination of medication (4) Counsel patients about missed doses. (a) Advise dosing schedules that fit into patient's lifestyles to reduce likelihood of missed doses. (b) Suggest strategies to avoid missed doses.	1dii, 1dii1,1dii2, 1diii, 1div
e. Recognize opioid tolerance and introduce appropriate strategies for management (1) Identify the potential for opioid-induced hyperalgesia and strategies for managing pain when this occurs.	1eii, 1aiii
3d. Address opioid misuse appropriately	1bii, 1fiii
3di. Determine a differential diagnosis of opioid misuse	1bii, 1fiii
3dii. Recognize the signs of opioid misuse through systematic evaluation as noted above in C1, C2 and 3diii.	1bii, 1fiii
3diii. Refer and follow-up when consultation is necessary	1bii
3e. Recognize when discontinuation of opioids is indicated and how to initiate and follow through a taper schedule	1g
3ei. Know appropriate reasons for opioid discontinuation	1g
3eii. Apply therapeutic and appropriate strategies for opioid discontinuation	1g
3eiii. Continue care for pain and other clinical conditions when opioids are discontinued 1. Identify appropriate referrals when condition warrants	1g
3f. Facilitate coordination of care through effective documentation and communication	
3fi. Document plans for coordination of care	
3fii. Communicate with members of the healthcare team	
3fiii. Document all opioid prescriptions regardless of format (eg, verbal order, written prescription, call-in to pharmacy)	
D. Act in compliance with relevant laws and policies	
1. Follow appropriate office protocols for requesting, receiving, dispensing, administering, storing and destroying medications in the work setting which meet all state and Federal regulations and documentation requirements	
2. Know elements of the Federal Controlled Substances Act relevant to opioid prescribing, including: a. Necessity of holding a current and valid DEA license to prescribe Controlled Substances b. Rationale for drug scheduling and the legal responsibilities associated with each relevant schedule c. Unique features of prescribing/managing patients on either methadone or buprenorphine d. Appropriate and legal writing of a series of prescriptions for controlled substances to lessen the likelihood of duplication or diversion	
3. Know state legislation, regulations, rules, and unofficial policy statements relevant to opioid prescribing in the state(s) in which the prescriber practices.	
4. Know the purpose and intent of prescription drug monitoring programs (PMPs)	1fi
a. If the state in which the prescriber practices has a PMP, utilize the PMP	1fi

5. Maintain security of prescription pads, electronically submitted script data and scheduled medications	
6. Access DEA guidance/handbooks on prescription and drug safety	
7. Instruct patients in safe drug storage(locking up) and proper disposal of all medications	3g, App B6, App B7
8. Describe the roles and responsibilities of the members of the health care team with respect to opioid prescriptions. Be aware of documentation of opioids called into pharmacy.	
9. Comply with FDA's opioid REMS requirements	
a. Describe legal responsibility for educating patients on medication guides.	
E. For specific products (existing products and new products as they become available):	
1. State the pharmacokinetic and pharmacodynamic properties of opioid medications	2a
2. State the product-specific toxicity	2b
3. List the requirements for opioid tolerance for specific long-acting and extended release products	2c
4. Describe the mechanism of action, usual dosing (including titration, conversion, tapering), side effects, tolerance/addictive potential, toxicity, safe storage and disposal of each of the following specific medications:	2d
a. Fentanyl transdermal system	2di
b. Hydromorphone ER	2dii
c. Methadone	2diii
d. Morphine ER	2div
e. Oxycodone ER	2dv
f. Oxmorphone ER	2dvi
g. Buprenorphine	2dvii
h. New products	2dviii
5. Instruct patients and their significant supports to recognize, report, and seek care for signs and symptoms of adverse effects/overdose	App B1c, App B2
6. Provide evidence-based, culturally appropriate counseling and education to patients/families/caregivers, taking into account health literacy levels	App B1
7. Teach patients/caregivers how to taper/discontinue medications in concert with treatment plan. Provide written instructions for the patient. Place copy of written instructions in the medical record.	App B4
8. Provide each patient with a Patient Treatment Agreement that specifies: purpose and goals of therapy; therapy/therapies to be used; instructions for use; risks, benefits, side effects, & adverse effects; patient responsibilities and how they are monitored; provider responsibilities. Also include expectations if monitors indicate abuse, misuse, or diversion	App B8
9. Provide additional educational resources to patients/families/caregivers as needed, including links to web sites, print resources, etc.	App B9

CO*RE Partners

American Academy of Hospice and Palliative Medicine – 4,000 members
Their mission is dedicated to expanding access of patients and families to high quality palliative care, and advancing the discipline of Hospice and Palliative Medicine. Palliative medicine relieves the pain and other symptoms patients suffer due to serious illness. Hospice focuses care that relieves symptoms and supports patients as they approach the last stages of life. A multidisciplinary team of experts address the physical, psychological, spiritual and practical burdens of illness and provides support to and works in partnership with the doctor. Care is offered in hospitals, long-term care facilities, hospices or at home.

American Academy of Nurse Practitioners – 28,600 individuals/154 groups or 140,000 practicing NPs
AANP represents the interests of the more than almost 140000 nurse practitioners currently practicing in the U. S. and continually advocates at local, state, and federal levels for the recognition of NPs as providers of high-quality, cost-effective, and personalized healthcare. AANP promotes excellence in NP practice, education, and research; shapes the future of health care through advancing health policy; and builds a positive image of the NP role as a leader in the national and health care community.

American Academy of Physician Assistants – 43,000 members
The American Academy of Physician Assistants (AAPA) is the only national professional association that represents all PAs across all medical and surgical specialties in all 50 states, the District of Columbia, Guam, the armed forces, and the federal services. AAPA provides comprehensive support and advocacy for physician assistants so that they may, in turn, provide patients with increased access to quality, cost-effective health care. Founded in 1968 to support the growing PA profession, AAPA works to increase the professional and personal growth of the more than 73,000 PAs in practice today through a range of information, advocacy and services.

American Osteopathic Association – 90,000+ members
Founded in 1897 by a group of students from the American School of Osteopathy in Kirksville, Mo., the American Osteopathic Association aimed to organize the efforts of individual physicians and colleges to advance the osteopathic medical profession. AOA's membership includes more than 33,000 practicing primary care osteopathic physicians. The AOA's mission is to advance the philosophy and practice of osteopathic medicine by promoting excellence in education, research, and the delivery of quality, cost-effective health care within a distinct, unified profession.

American Pain Society – 3,000+ members
The American Pain Society (APS) is a multidisciplinary community that brings together a diverse group of scientists, clinicians and other professionals to increase the knowledge of pain and transform public policy and clinical practice to reduce pain-related suffering. APS core areas of emphasis include research, education, treatment, and advocacy. The American Pain Society is a national chapter of the International Association for the Study of Pain (IASP) – the largest multidisciplinary international association in the field of pain, bringing together scientists, clinicians, health care providers, and policy

makers to stimulate and support the study of pain and to translate that knowledge into improved pain relief worldwide.

American Society of Addiction Medicine – 3,000 members
The American Society of Addiction Medicine is an association of physicians dedicated to improving the treatment of alcoholism and other addictions, educating physicians and medical students, promoting research and prevention, and enlightening and informing the medical community and the public about these issues to promote the appropriate role of the physician in the care of patients with addiction. ASAM seeks to enhance the quality and increase the availability of appropriate health care for people affected by the addictions.

California Academy of Family Physicians – 7,000+ members
The California Academy of Family Physicians, founded in 1948, champions the role and practice of family physicians collectively and individually to enhance the health and well-being of Californians. The Academy advocates positions that strengthen and streamline California's primary care infrastructure to help family physicians manage the staggering rise in chronic illness and provide all Californians with a medical home where they can access comprehensive and affordable care. CAFP has vast experience in continuing medical education and professional development and has worked in collaboration with several medical associations, foundations, medical schools, and community organizations to further primary care education.

Nurse Practitioner Healthcare Foundation
The Nurse Practitioner Healthcare Foundation works to improve health status and quality of care for all patients through nurse practitioner innovations in research to improve health outcomes, education to enhance NP leadership in health care, facilitate health policy to eliminate health care disparities and improve health care delivery systems, and philanthropy.

CO*RE Associates

American Pharmacists Association – 60,000 members
The American Pharmacists Association (APhA) is the organization whose members are recognized in society as essential in all patient care settings for optimal medication use that improves health, wellness, and quality of life. Through information, education, and advocacy APhA empowers its members to improve medication use and advance patient care, and working toward transformation of their profession from one focused on the drug product to a clinical service focused on the patient.

Interstate Postgraduate Medical Association (IPMA)
The mission of Interstate Postgraduate Medical Association (IPMA) is to disseminate medical knowledge and elevate the standards of continuing medical education to improve physicians' ability to prevent, detect and treat disease. Since its inception in 1916, IPMA has remained dedicated to this goal. Operating as a not-for-profit 501 (c)(3) educational association, IPMA creates educational and change strategies that transform health care practices to improve patient health. The IPMA is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education (CME) for physicians since 1994, and received accreditation with commendation in 2007.

Healthcare Performance Consulting (HPC)

Healthcare Performance Consulting develops and implements strategies to drive behavior change in clinicians, patients and others within health care systems in order to attain specific and measurable quality and cost outcomes for clients. The core competency of HPC is its ability to assess current behavior of physicians and other health care practitioners, analyze forces and barriers behind that behavior, and develop strategic approaches that will change the behavior; where it is ethical and medically appropriate to do so. This is accomplished by taking a systems approach to changing behavior. The HPC consultants each have over 25 years of experience in the health care system and have presented their expertise at national meetings of CME educators and researchers of physician behavior change. HPC has consulted on projects in a variety of clinical areas. HPC experience and core competencies include: needs analysis and outcomes measurement, medical education, training and education, organizational development, management and quality improvement.

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