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Margolis-FDA Workshop: Identifying Key Competencies for Opioid Prescriber Education

Virtual Public Workshop
April 4, 2022 | 1:00-5:00 p.m. ET
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Research Primer: Current Knowledge on Core Competencies and Practice Gaps for Managing Patients with Pain

Introduction

In recent years, the opioid and substance use crisis has continued to worsen, leading to over 100,000 overdoses annually as of October 2021. In contrast to prior waves of the opioid epidemic, which were driven primarily by prescription opioid analgesics, recent increases in overdose deaths have primarily been driven by illicit synthetic opioids, including fentanyl and its analogues. Stimulants such as cocaine and methamphetamine have also been identified in increasing proportions of drug overdose deaths. However, with prescription opioids continuing to play a role in some overdose deaths, a wide range of policy interventions, including continuing education for prescribers of opioid analgesics, have been instituted with the goal of improving the safety and appropriateness of opioid analgesic prescribing.

As the opioid and substance use crisis continues to evolve, there is increasing recognition that prescriber and other health care provider (HCP) education efforts, such as the continuing education through the Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS)[1], may need to be updated to better address public health needs. For example, concerns from HCPs and patients that efforts to reduce opioid analgesic prescribing have resulted in inadequate pain management for patients suffering from chronic pain have prompted increasing calls for prescriber and HCP education efforts to be expanded to include additional information on multimodal approaches to pain management, including non-pharmacological and non-opioid pharmacological treatment options. Similarly, continued gaps in access to evidence-based Medications for Opioid Use Disorder (MOUD) and the increasing involvement of stimulants and polysubstance use in overdose deaths may underscore the need for additional training to support HCPs in better recognizing and intervening with patients at risk of substance use disorders (SUDs).

Over the past several years, federal agencies, state medical boards, licensing organizations, health systems, and graduate educational institutions have all implemented their own prescriber and HCP education efforts. There is widespread consensus that prescriber and HCP education can help support providers in reducing opioid-related risks and improving health outcomes for their patients. However, many experts point to a lack of consistency, harmonization, and alignment in these educational efforts that has contributed to persisting gaps in HCP knowledge and practice. Given the urgent need to address professional practice gaps that can adversely affect patient outcomes, additional action is needed to ensure that these efforts are effectively targeted at overcoming existing knowledge gaps that may contribute to poor patient outcomes such as inadequately managed pain or opioid use disorder (OUD).

[1] The U.S. Food and Drug Administration's OA REMS program requires that manufacturers of opioid analgesics to offer training for all HCPs who are involved in the management of patients with pain. To meet this requirement, drug companies with approved opioid analgesics will provide unrestricted grants to accredited continuing education providers for the development of education courses for HCPs based on the FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain.

To better understand the landscape of existing HCP education efforts across federal, state, and health system settings, this research primer summarizes recent research, policy statements and guiding frameworks related to a) core competencies for education and training of opioid prescribers and other HCPs involved in the treatment and monitoring of patients with pain; and b) current gaps in HCP knowledge and practice on key competencies related to management of acute and chronic pain, opioid prescribing, and treatment of SUDs. Specifically, this primer highlights key themes from recent grey and white literature, as well as policy documents and stakeholder resources from professional societies, provider education organizations, education accreditation organizations, accreditation councils, and licensing boards.

Core competencies for health care providers for the management of patients with pain

In the context of prescribing opioid analgesics for the management of pain, "core competencies" refers to a set of essential skills and knowledge, derived from existing evidence and best practices, that HCPs should possess to successfully manage a patient's pain while mitigating opioid-related risks. The authors of a December 2021 special publication by the National Academy of Medicine's (NAM) Action Collaborative on Countering the U.S. Opioid Epidemic on harmonizing interprofessional education approaches to address the opioid epidemic recommend establishing "*minimum* core competencies" for HCPs in pain management and treatment of SUDs. The authors suggest this set of minimum core competencies could form a common foundation of knowledge and skills across health professions and enable greater interprofessional collaboration while preserving "flexibility reflective of scope-of-practice and setting-specific needs." The Action Collaborative intends to release a comprehensive, interprofessional core competency framework in spring 2022, which will aim to close practice gaps and improve patient- and family-centered care for pain and SUD.

A substantial number of frameworks and curricula have been designed to educate opioid prescribers and other HCPs involved in the treatment and monitoring of patients with pain on how to provide safe and effective care for their patients, including through the use of non-opioid and non-pharmacologic therapies. They have been put forward by a variety of government agencies, accrediting and licensing bodies, and graduate and professional educational organizations, and are often intended to meet needs specific to those organizations' membership and audiences. The content included varies, but these frameworks and curricula commonly emphasize some of the same core competencies. Many aim to ensure HCPs understand the mechanisms of pain and how to assess pain; opioid and non-opioid or non-pharmacological treatments for pain; and best practices for safely prescribing opioid analgesics, monitoring patients who take them, and tapering opioid analgesics. In addition to principles of pain management, many also include content on OUD and in some cases other SUDs, focusing on how to recognize signs of these disorders; guidance on avoiding language that can perpetuate harmful stigma historically associated with OUD; and instructions on referring patients for treatment. A better understanding of commonalities across these frameworks could help illuminate where there may be consensus on critical skills for all HCPs and support future efforts to foster harmonization and collaboration across stakeholders. This section summarizes several particularly relevant and useful examples.

FDA REMS Blueprint

The goal of the Opioid Analgesic (OA) REMS is to educate prescribers and other HCPs (including pharmacists and nurses) on the treatment and monitoring of patients with pain. Through better education, the healthcare team will have an improved understanding of how to manage pain and the role of opioid analgesics along with nonpharmacologic and non-opioid analgesics in pain management. The education must provide information about the risks of opioids and use of other therapies and is intended to assist HCPs to "reduce serious adverse outcomes" associated with "inappropriate prescribing, misuse, and abuse" of opioid analgesics. The OA REMS requires all manufacturers of opioid analgesics to make accredited continuing education (CE) courses available for opioid analgesic prescribers and HCPs who participate in the management of patients with pain. The OA REMS Blueprint details topics that should be covered in REMS-compliant CE courses. The Blueprint states that upon completion of REMS-compliant educational activities, HCPs should be knowledgeable about the following topics:

- Understanding definitions and mechanisms of pain, including acute and chronic pain;
- Properly assessing patients' pain;
- Creating an effective treatment plan for pain management using treatment options including non-pharmacologic treatments, non-opioid medications, and opioid analgesics as appropriate based on the risks and benefits of these treatment options;
- Managing patients on opioid analgesics throughout the course of the treatment plan, from initiating treatment for acute or chronic pain to long-term management, monitoring for and intervening in case of OUD, and safely tapering opioid analgesics if needed; and
- Understanding principles of addiction and OUD, including best practices for reducing stigma.

Accreditation Council for Graduate Medical Education (ACGME) Recommendations for All Medical Residents and Fellows

ACGME's 2021 GME Stakeholders Congress on Preparing Residents and Fellows to Manage Pain and SUD identified three categories for core competencies in which all medical residents and fellows should be educated or trained: pain management, communication, and SUD and OUD. Core competencies for pain management include properly assessing pain and considering multimodal approaches to pain management, including non-opioid pain management alternatives (both pharmacological and non-pharmacological). For cases in which opioid analgesics are appropriate, the core competencies emphasize safe opioid prescribing practices such as how to select opioid analgesic medications, how to calculate appropriate dosages and durations for therapy, and, if necessary, how to taper patients off of opioid analgesics. The report also outlined core competencies in communication covered both provider-patient communication and communication between HCPs. Opioid prescribers and other HCPs should be trained in communicating options for pain management to patients, as well as the risks and benefits of opioid and non-opioid pain treatments, via methods free of stigmatizing language that can create barriers to pain treatment and treatment for SUD. Finally, the report recommends HCPs be educated on how to recognize signs of SUD and OUD, as well as how to use medication to treat OUD and/or where to refer patients for such treatment.

Department of Veterans Affairs Opioid Safety Initiative (OSI) and Academic Detailing Program

Within the Department of Veterans Affairs (VA), the Veterans Health Administration (VHA) established the OSI to guide VHA HCPs toward offering safer and more effective treatment for patients with pain. In addition to a Clinical Practice Guideline, the OSI Toolkit Materials include provider guides detailing best practices and supporting evidence for acute pain management and chronic pain management. Another provider guide focuses on identifying and managing OUD. These educational materials are used in the VA's academic detailing program, in which clinician detailers provide "individualized, face-to-face outreach" to other VA HCPs "to encourage evidence-based decision making to improve Veteran health outcomes." Academic detailing has been found to be an effective approach to changing provider behavior.

Both the acute and chronic pain provider guides emphasize the risks of prescribing opioid analgesics and encourage alternative therapies. Both recommend a stepwise approach to treating pain in which HCPs use non-pharmacologic treatments first, prescribe non-opioid pharmaceutical treatments if needed, and prescribe opioid analgesics only as the final "step" if all other treatment options have proven ineffective. The guides offer extensive information on and evidence for non-pharmacological, non-opioid, and multimodal approaches to treating pain. The chronic pain guide also includes strategies for communicating with and mitigating risk for patients who have been taking longer-term, higher-dose opioid prescriptions, such as educating them on the risk of overdose and co-prescribing naloxone, per the recommendations of the VA Opioid Overdose Education and Naloxone Distribution (OEND) Program.

The acute and chronic pain guides also provide essential information on identifying and treating OUD, which the OUD-specific guide expands on further. This guide begins with recommendations for avoiding stigmatizing language, before providing information on how to recognize OUD, assess a patient who may be suffering from OUD, and begin treatment using MOUD – including details on buprenorphine, methadone, and naltrexone formulations and dosages.

Providers Clinical Support System Curricula

The Providers Clinical Support System (PCSS) is a SAMHSA-funded program composed of a coalition of associations led by the American Academy of Addiction Psychiatry that offers training focused on treating chronic pain and OUD for primary care providers. PCSS offers a wide range of courses on these topics, most notably their Chronic Pain Core Curriculum and their SUD 101 Core Curriculum. The organization also provides mentoring services from experts in pain management and OUD treatment for HCPs to seek answers to specific clinical questions or to receive in-depth one-on-one guidance to supplement the curricula.

The Chronic Pain Core Curriculum begins with the basics of understanding chronic pain and pain management, including social, psychological, and biological mechanisms of pain, how to assess pain, and common pharmacological and non-pharmacological treatment options. Courses then cover the evidence regarding opioid analgesic medications for chronic pain, associated risks, and best practices for starting, monitoring, and discontinuing opioid therapy. The curriculum content also covers risk mitigation strategies such as assessing risks of and monitoring for OUD, co-prescribing naloxone, and how to treat pain in patients with OUD, including the use of MOUD. The curriculum strongly emphasizes the importance of provider-patient communication as a core competency critical to effective chronic pain and OUD treatment.

The SUD 101 Core Curriculum covers OUD along with Alcohol Use Disorder (AUD) and Tobacco Use Disorder (TUD). The content includes training on avoiding stigmatizing language related to SUDs as well as tools to assess whether a patient suffers from a SUD and how to initiate treatment interventions if necessary. Courses train HCPs in using different MOUDs (methadone, buprenorphine, and naltrexone) and how to integrate ongoing treatment for OUD into primary care. Again, provider-patient communication is strongly emphasized, with a focus on "patient-centered communications skills" to enable HCPs to help patients through the process.

Health care provider knowledge and practice gaps related to the management of patients with pain

The NAM report defines a professional practice gap (PPG) as "the difference between health care processes or outcomes observed in practice, and those potentially achievable on the basis of current professional knowledge." The Accreditation Council for Continuing Medical Education (ACCME) abides by the same definition of PPGs. The NAM report suggests that understanding PPGs allows education providers to "identify possible contributors to those gaps, and to design and evaluate education to close the gaps." In other words, an effective assessment of PPGs can guide educational interventions and content to better train HCPs, and ultimately improve outcomes for patients.

The literature review included in the NAM report found opioid prescribing and tapering to be by far the most prominent PPG, followed by other areas of practice such as monitoring patients, screening and assessment, and non-pharmacological treatments. The authors cited gaps in clinical knowledge and HCP attitudes and bias as the leading contributors to these most common PPGs. The report's survey of 62 accrediting, certifying, licensing, and regulatory organizations found that less than half had educational requirements on acute and chronic pain management, and less than one-third had educational requirements on SUDs. A large 2021 survey of primary care providers specifically intended to assess knowledge related to the core principles included in the OA REMS Blueprint identified similar gaps. Responses to that survey "indicated profound and persistent gaps in knowledge, particularly in definitions and mechanisms of pain, general principles of pharmacologic analgesic therapy, and specific aspects of opioid analgesic therapy and addiction." Respondents also "expressed limited confidence in their abilities to incorporate patient engagement techniques…or develop a treatment plan for a patient with chronic pain." The following section of this research primer further explores some of these specific areas where knowledge and practice gaps persist.

Non-Opioid Alternatives

HCPs who care for patients with acute or chronic pain may be over-reliant on opioid analgesics due to a lack of knowledge about non-opioid alternatives for pain management. These alternatives can include non-opioid analgesic medications as well as behavioral and physical therapies. Non-opioid pain management strategies may be underutilized in part due to health care system factors such as limited reimbursement, but there is a connection with HCP knowledge as well. From 2013 to 2015, "safe alternatives to opioids" was one of the most common topics for providers' questions during REMS-compliant opioid prescriber education trainings offered by the Boston University School of Medicine. More recently, a 2020 study of 186 primary care providers via academic detailing sessions found "uncertainty about safe non-opioid treatments for patients with pain and common comorbidities" to be a commonly cited knowledge gap. In a cross-sectional study of over 10,000 physicians, between 2015 and 2017 those in the highest quartile of performance on knowledge assessments were significantly less

likely to prescribe opioid analgesics to patients with new onset back pain than those in the lowest quartile.

Safe Opioid Prescribing

Some knowledge and practice gaps still persist around fundamental principles of safe opioid prescribing. These gaps exist throughout the process of prescribing opioid analgesics and monitoring and caring for patients who take these medications – both the NAM report and the findings from ACGME's Stakeholders Congress discuss gaps in training and in practice related to these topics.

Choosing appropriate dosage and duration for opioid therapy is one key area in which prescriber knowledge may be insufficient. For example, opioid prescribing following common surgical procedures is widely variable, even among patients who undergo the same procedures, and often excessive. One study of post-operative opioid prescriptions found that over 80% of patients who reported no post-operative pain were still prescribed opioids. Some prescribers still report difficulties calculating morphine milligram equivalents (MMEs), a key metric for standardizing and calculating opioid dosages across different opioid medications. Many prescribers also lack the necessary skills to reduce or discontinue opioid therapy appropriately and to treat opioid use disorder (OUD); both of these topics are discussed in the following sections.

Tapering

Patients who are prescribed higher doses of opioid analgesics, or who are prescribed opioid analgesics for longer periods of time, may need to be tapered off of these medications or onto lower doses. Abrupt discontinuation of opioids, especially for individuals with high-dose and longer-term treatment, has been shown to be associated with increased rates of illicit opioid use, opioid-related hospitalizations, mental health crises, and risk of suicide. More rapid or immediate discontinuation may increase the risk of these outcomes.

Research indicates that many prescribers of opioids may lack the necessary knowledge and skills to safely and effectively taper patients' opioid treatment and mitigate those adverse outcomes. One study of over 200,000 patients prescribed high-dose, long-term opioid therapy (≥90 MMEs for ≥90 consecutive days) in North Carolina found that "the combined rates of discontinuing and rapid tapering were much higher than the rate of gradual tapering" in this patient population both before and after the implementation of new state medical board policies intended to discourage overprescribing, leading the researchers to recommend "better policy communication and prescriber education regarding opioid tapering best practices." That study found discontinuation, rapid tapering, and gradual tapering all increased following the change in state medical board policy. This trend is mirrored nationwide, as a wide range of policies discouraging inappropriate and excessive opioid prescribing have led more prescribers to taper patients off of high doses or long prescriptions. A cohort study of nearly 100,000 patients with long-term opioid prescriptions found that from 2008 to 2017, the percentage being tapered nearly doubled, from 12.7% to 23.1%, but that more than one-quarter of those patients were being tapered too quickly relative to CDC recommendations, further underscoring the impact of prescriber knowledge gaps on this topic.

SUD and OUD Treatment

HCPs may also lack sufficient knowledge around identifying patients at risk of developing a SUD or delivering FDA-approved MOUD for treatment of opioid use disorder. Despite the effectiveness of buprenorphine and methadone in reducing risk of overdose and other adverse opioid-related health outcomes, MOUD "remain[s] highly underutilized." A variety of barriers contribute to underuse of MOUD, including waiver requirements for prescribers and lack of reimbursement, but HCP knowledge likely plays a role as well. One survey study of more than 100 family physicians in primarily rural areas found that while 80% of physicians regularly saw patients with OUD and 70% felt primarily responsible for treating those patients' OUD, only 10% were buprenorphine prescribers. Nearly 90% cited inadequately trained staff as a key barrier to prescribing buprenorphine. In open-ended survey responses, some physicians also mentioned "mistrust" of patients with OUD or patients using buprenorphine to treat OUD, highlighting the fact that the persistent stigma surrounding MOUD creates further barriers to access.

Beyond improving understanding of addiction and recognition of signs that a patient may suffer from a substance use disorder, HCPs may also lack knowledge on how to refer patients to treatment for these disorders and how and where patients may be able to access treatment. Another survey study, this one capturing about 100 emergency department physicians, found that a majority of attending physician respondents and an even larger proportion of resident respondents were unaware of any MOUD providers in their communities. Fewer than one-third of attending physicians had ever referred a patient to such a clinic, and an even smaller proportion of residents had done so.

Prescribing or dispensing naloxone is one more key part of mitigating harm from opioid use and OUD with which some HCPs may lack familiarity. Naloxone is a safe and effective medication that can immediately reverse an opioid overdose, and the CDC recommends people struggling with OUD, or people taking high doses of opioid analgesics, should carry naloxone and keep it in the home. FDA has also recommended that HCPs consider prescribing naloxone to patients who are prescribed opioid analgesics and are at increased risk of opioid overdose, as well as patients who are prescribed MOUD. In 2020, FDA began requiring manufacturers of opioid analgesics and MOUDs to include recommendations about co-prescribing naloxone to the prescribing information on their labels.

Yet some opioid prescribers have expressed concerns about prescribing naloxone. One study of the VA Overdose Education and Naloxone Distribution (OEND) Program found that participating HCPs voiced concerns about a lack of knowledge, familiarity, and comfort with naloxone distribution, along with concerns that naloxone prescribing could lead patients to use more opioids (though evidence suggests that dispensing naloxone is not associated with differences in substance use). That VA OEND study, along with other evidence on prescriber education interventions related to naloxone prescribing, shows that prescriber education on this topic can substantially increase providers' understanding of naloxone and their naloxone prescribing rates.

Provider Communication and Stigma

There are also a number of less technical skills that HCPs may lack related to safe and effective pain management and opioid prescribing. It is difficult to quantify practice gaps in these skills, such as provider-patient communication, HCP confidence in having difficult conversations around substance use, or knowledge of team-based approaches that can support multi-modal approaches, but research

indicates they are important and gaps do exist. Many pain patients – in some samples, a majority of them – report negative or less than optimal experiences with provider visits for pain care. These difficulties are reported on both sides of the provider-patient relationship, with HCPs being far more likely to report chronic pain patient visits as "difficult" compared to general primary care visits.

The effects appear to be even more pronounced for patients struggling with OUD. A survey of over 3,500 patients with OUD who'd received primary care from the Veterans Health Administration (VHA) found that these patients were significantly less likely than comparator patients without OUD to report negative care experiences related to provider communication. These findings are consistent with other research findings suggesting that patients with OUD face stigma that can reduce access to and quality of care. Systemic racism and sexism contribute to further disparities in access to pain care and OUD treatment, with people of color and women being less likely to have access to both.

HCPs may also lack knowledge and skills related to interprofessional communication (i.e., communicating and coordinating with other HCPs who care for the same patient). "Communication with other members of the care team" was among the PPGs identified in the NAM report's literature review, with one study citing "no clear documentation of interdisciplinary collaboration of pain assessment and management" for patients with acute pain as an area where professional practice diverges from guidelines for best practices. As described in the previous section on SUD and OUD treatment, many HCPs also lack the knowledge necessary to perform what is sometimes referred to as a "warm handoff" – directly connecting patients with SUDs to appropriate treatment options at the point of care.

Conclusion

While existing research, guidance, and policies from a variety of key stakeholders offer some level of consensus on the core competencies that are essential for opioid prescribers and other HCPs involved in the treatment and monitoring of patients with pain, HCP knowledge and practice gaps still persist in some of these areas. This may be in part due to a lack of alignment and harmonization among the many educational materials offered by a wide range of stakeholder organizations. There is clear potential for interprofessional and intergovernmental collaborations to make improvements in provider education. Efforts like the NAM Action Collaborative on Countering the U.S. Opioid Epidemic, as well as the Opioid Regulatory Collaborative, an organization composed of state dental, medical, pharmacy, and nursing boards aiming to align opioid-related guidance and policies, represent encouraging steps toward such effective collaborations. Further collaboration on and harmonization of education for HCPs can help ensure that they are better prepared to meet the ongoing need for safe and effective pain management and SUD treatment.