Duke | MARGOLIS CENTER for Health Policy

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

Virtual Public Workshop

April 4 & 5, 2022

Meeting Summary

Introduction

The Duke-Margolis Center for Health Policy, with support from the U.S. Food and Drug Administration (FDA), convened a virtual public workshop on April 4 and 5, 2022, entitled "Identifying Key Competencies for Opioid Prescriber Education." Building on a previous Margolis-FDA workshop from October 2021, which explored the potential value of mandatory prescriber education under the Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS), April's workshop focused on the content of education for opioid prescribers and other health care providers (HCPs) involved in the treatment or management of patients with pain. Workshop participants represented a wide range of stakeholder groups — federal government agencies, provider associations, educational institutions, licensing and accrediting bodies, and patient advocacy organizations. Discussions covered core competencies for HCP education, gaps in HCP knowledge and clinical practice, lessons learned from existing educational interventions, and future policy actions to improve HCP education on opioid analgesics, pain management, and substance use disorders (SUDs). These discussions included topics currently in the REMS-compliant education, but also considered the broader landscape of HCP education programs.

Key takeaways from this workshop included:

- Core competency frameworks for HCP education can be useful in establishing a baseline level of knowledge for all HCPs at every level of academic and professional education. To account for the diversity of HCPs (e.g., provider types, specialties, practice settings), educational programs should be flexible to meet HCP practice and education needs.

- Practice and knowledge gaps persist among HCPs in areas identified as important core competencies in both pain management and opioid use disorder (OUD) treatment. These include best practices for assessing pain; choosing appropriate pharmacologic or non-pharmacologic treatments; initiating, monitoring, and discontinuing (tapering) of opioid analgesics if appropriate; and evidence-based screening for OUD and referral to treatment for OUD if necessary. Provider-patient communication and inter-provider communication were also identified as key practice gaps.

- There is significant variation and fragmentation in the landscape of HCP educational offerings. Interprofessional and intergovernmental collaborations may be a useful approach to further aligning and harmonizing the content of these various educational initiatives and sharing best practices from interventions that prove effective.

- Translating knowledge into clinical practice remains challenging, in part due to system-level barriers that cannot be changed through education alone. Certain education delivery methods such as academic detailing, which closely engage HCPs, may be effective, but they are also costlier. Assessments and data collection can also help refine educational interventions and target them to HCPs who have significant knowledge gaps. But other health care system factors — notably insurance coverage (or lack thereof) for different treatments for pain — will affect HCP behavior regardless of knowledge levels and may require further policy action.

FDA Presentations

The workshop opened with two presentations from FDA reviewing key takeaways from the October 2021 workshop, laying out FDA's current thinking on HCP education under the OA REMS, and reviewing the Blueprint that forms the basis for OA REMS Education. Dr. Patrizia Cavazzoni, Director of the Center for Drug Evaluation and Research at FDA, provided opening remarks beginning with an overview of the opioid and substance use crisis. Next, Dr. Cavazzoni laid out FDA's commitment to addressing the crisis, and FDA's vision for how prescriber education can advance that commitment.

Drawing on the previous workshop's discussions, Dr. Cavazzoni reviewed the current landscape of opioid prescriber education, noting the range of available educational programs and their inconsistencies in content, scope, and depth in opioid analgesic education. In addition to the high variability in content, educational requirements differ across institutional, state, and federal levels, leaving an opportunity for improvement by instilling consistent core competencies for HCPs nationwide. To address the potential gaps in opioid prescriber and HCP education, Dr. Cavazzoni presented FDA's vision for prescriber education: a core curriculum that would form the basis for a national-level required educational program offering consistent, evidence-based content on pain management and the treatment of OUD for all HCPs. That core curriculum would be intended to provide foundational HCP knowledge which additional education or trainings could build on with more information tailored to provider specialties and evolving public health needs. Implementing the core curriculum could be achieved through multiple vehicles. The OA REMS is one vehicle by which the FDA could implement a single, unified curriculum, with the advantage of a nationwide reach. However, there are concerns that required education under the REMS might not be sufficiently flexible to allow for tailored education and that the OA REMS may face skepticism due to drug manufacturer funding. An alternative option for implementing a nationwide educational standard could be tying an educational requirement to Drug Enforcement Administration (DEA) registration and renewal. FDA is also considering further alternatives involving collaborations with other federal agencies and professional and medical societies.

FDA's CDR Mark Liberatore then presented the current FDA Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain and reviewed its most recent updates. The original Blueprint was approved under the Extended-Release and Long-Acting (ER/LA) REMS in 2012 and included an outline for REMS-compliant continuing education (CE) content development by CE providers. When the ER/LA REMS was established, the Blueprint covered only ER and LA opioid analgesics, and was intended to educate only prescribers of opioids, primarily about the safe use of those products. In 2018, the REMS was modified to include all opioid analgesics intended for outpatient use and the education was expanded to target all HCPs involved in the management of

patients with pain. Along with the 2018 modification, the Blueprint was broadened. Product-specific information was replaced with an outline of information on many areas of pain management. As a result of the 2018 modifications, the current Blueprint now lays out specific content that must be covered within two focus areas: the basics of pain management and creating the pain treatment plan. Within the pain treatment plan, the Blueprint outlines general principles of non-pharmacologic and pharmacologic analgesic therapy, as well as the management of patients on opioid analgesics. Finally, while the Blueprint does not cover addiction medicine in detail, it does contain an addiction medicine primer.

CE providers of REMS-compliant education courses must cover the key points laid out in the Blueprint, but they do have some flexibility in designing and presenting the material. The Blueprint is an outline of core CE content, and neither FDA nor the companies subject to the REMS directly control or design the resulting CE content. FDA is now considering enhancements to the Blueprint based on a range of ongoing and parallel initiatives (e.g., FDA Safety Labeling Changes, updated CDC guidelines, FDA MME workshop) and sources of feedback, including the Duke-Margolis workshop in October 2021 and this workshop.

SAMHSA Presentation

Dr. Yngvild Olsen, Acting Director of the Center for Substance Abuse Treatment at the Substance Abuse and Mental Health Services Administration (SAMHSA), reviewed several SAMHSA training efforts related to SUDs. SAMHSA provides grant support, technical assistance, and other educational resources to train HCPs nationwide. This presentation highlighted five examples of SAMHSA educational initiatives:

1. The Providers Clinical Support System (PCSS) – a grant program offering free training for HCP students at academic institutions on prevention and treatment of chronic pain/OUD/SUDs.
2. The Opioid Response Network – coordination of local consultants in every state to provide technical assistance and education on SUDs to HCPs and individuals, tailored to state, locality, or community needs.
3. The Rural Opioid Technical Assistance Program – regional expert grantees providing technical assistance and training materials to support rural communities in addressing opioid use disorder (OUD) and other SUDs.
4. Addiction Technology Transfer Centers – 13 locations across the country offering trainings in a variety of formats designed to be accessible for HCPs as well as a central resource for relevant research on addiction medicine.
5. The Evidence-Based Practices Resource Center – a central repository of SUDs educational contents and practical tools to incorporate evidence-based practice across health care settings.

Examining Core Competencies for Opioid Prescriber Education

Diving deeper into HCP education efforts, the first panel discussion session opened with a presentation focused on two core competency frameworks, one developed by the National Academy of Medicine's (NAM) Action Collaborative on Countering the U.S. Opioid Epidemic based on a recent special report by the same group, and the other by the Accreditation Council for Graduate Medical Education's (ACGME) 2021 Stakeholders Congress. While the content of the two frameworks shares some similarities, the

frameworks are intended for different audiences. The NAM framework is intended to form the basis of education for practicing HCPs across different provider types and specialties, and the ACGME framework is tailored for physicians in residency or fellowship training.

The NAM core competency framework laid out three broad HCP performance domains – Core Knowledge, Collaboration, and Clinical Practice. Performance in these three domains is intended to reflect overall provider competence. Knowledge, skills, and abilities in six core competency domains form the basis for overall competence and performance. Those six domains are: 1) baseline knowledge; 2) applied knowledge; 3) patient-centered practices; 4) team-based care; 5) health systems and environment; and 6) professionalism. Each of the six competency domains includes specific skills HCPs should possess related to treating pain and SUDs, which are intended as minimum core competencies to be built upon based on provider type or specialty. Similarly, ACGME's core competency framework lays out three broad categories of competencies – Pain Management, SUD, and Communication – with specific skills that should be taught within each broad competency and additional considerations for various specialties.

Following the overview of the two competency frameworks, panelists largely agreed that HCPs should be trained on core competencies highlighted in the presentation, such as the fundamentals of assessing acute and chronic pain; how to choose an appropriate therapy for pain, including but not limited to opioid and pharmacologic therapies; and how to monitor patients with pain throughout treatment. HCPs should be able to use evidence-based screening tools to identify OUD or other SUDs in patients and refer them to treatment if necessary. Several speakers mentioned the importance of treating pain management and addiction medicine, including OUD treatment, as separate topics in education. Covering both fields of medicine in a brief course could lead to either or both being taught inadequately. Others worried this combined approach might also contribute to stigma surrounding pain care by implicitly suggesting all pain patients are at higher risk of developing SUDs.

Flexibility in a core competency framework was a common theme. Panelists encouraged tailoring education to specific needs across different provider types, specialties, or settings. Provider-patient communication was another core competency panelists emphasized, stating the importance of training providers in communication strategies that reduce the bias and stigma associated with both pain and OUD to build trust and allow for truly patient-centered care. Panelists supported early educational interventions during medical, pharmacy, physician assistant, or nursing school. Yet they also acknowledged the impact of that education will be diminished if best practices are not modeled by other, established, practicing HCPs — especially during residencies or fellowships. This underscores the need for these core competencies to be implemented in CE as well.

Professional Practice Gaps in SUD and Pain Management and Related Gaps in Current Prescriber Education

Participants next considered where gaps may still exist in HCP knowledge and clinical practice, including on some of the core competencies from the previous session. This session began with another presentation based on the NAM Action Collaborative's special report, this one summarizing the findings from an extensive literature review. In a comprehensive review of 310 articles on clinical practice and

knowledge gaps related to opioids, pain management, and SUDs, researchers found significant gaps, particularly in prescribing and tapering opioid analgesics. Gaps were found as well in monitoring and assessing pain and screening for SUDs. Communication again rose as a prominent theme: communicating with patients and other providers was a commonly cited practice gap. The identified practice gaps were most often attributed to a lack of knowledge on best practices, provider attitudes and biases, and a lack of evidence-informed tools and resources. Significant variation in prescribing practices was identified, which may be related to fragmentation and variation in HCP education across provider types and specialties. Since a wide variety of provider associations and CE providers develop and deliver education to HCPs, content covered and resulting knowledge and practice may vary accordingly.

Throughout the following discussion, provider-patient communication emerged as one of the most significant clinical practice gaps. Panelists emphasized the need for clear, honest, and culturally appropriate communication between the provider and patient in applying best practices for pain management, such as assessing and monitoring patients' pain, setting appropriate goals for pain management therapies (particularly for chronic pain), and tapering opioids if necessary. A multimodal pain management strategy, including non-opioid and non-pharmacologic therapies, was supported as these options may be underutilized in practice. But the panel stressed that HCPs in many cases may lack the skills to communicate with patients about how those non-opioid therapies can help address pain and how patients can navigate common barriers to accessing them, such as a lack of insurance reimbursement.

Communication between HCPs on the care team emerged as another critical gap, as some panelists expressed concerns that HCPs lack knowledge or skills necessary to communicate with others who provide care to the same patient in a different setting, or even the pharmacist who fills the patient's prescriptions. Some gaps in fundamental knowledge were identified as well. Panelists felt some HCPs may lack knowledge on how to identify and assess acute and chronic pain, distinguish between the two, and set out appropriate treatment plans. Similarly, HCPs may lack the skills to monitor and perform an evidence-based screening for OUD. For both pain patients and patients with OUD, panelists felt HCPs should be better trained on when and how to refer patients to specialists in pain care, medication for opioid use disorder (MOUD), or mental health who might be able to better address their needs.

Panelists also discussed how personalized, tailored approaches to education may be more effective in influencing provider behavior and suggested longitudinal assessment strategies to move toward a system of continual improvement in which HCPs can receive ongoing feedback and training targeted toward persistent practice gaps. The discussion stressed the importance of assessments of HCP knowledge and of the impact of educational interventions to ensure knowledge is being translated into practice as intended.

Identifying Lessons Learned from Provider Education and Continuing Medical Education Initiatives

The next session showcased lessons learned from some effective educational programs that have had some success in instilling core competencies and addressing knowledge or practice gaps. These HCP education initiatives covered a range of topics, from opioid prescribing for chronic pain to medications

for OUD, and utilized multiple delivery formats and methods, from online modules to in-depth, one-on-one academic detailing.

The importance of an interdisciplinary approach to education was discussed extensively. Panelists described how their respective educational programs aim to engage not just physicians, but also nurses, physician associates, and even staff who work in health care settings but are not generally considered HCPs (such as front desk staff). This ensures the entire care team shares common foundational knowledge and can coordinate and communicate effectively to provide better care. The issue of reducing stigma arose again in this context: panelists described how the entire care team, from a lead physician to a receptionist who initially greets the patient, should be educated on the importance of using destigmatizing communication strategies to ensure patients feel comfortable seeking the treatments they need. Panelists in this session also echoed comments from earlier speakers recommending education be engaging and tailored to HCPs' needs in order to generate real impact. They suggested that education that is too basic or "one-size-fits-all" can be frustrating or burdensome for HCPs. To better target educational needs, panelists discussed using strategies such as personalized academic detailing, realistic patient scenarios, and easily accessible mentorship networks for quick questions or more in-depth advice. Several panelists also described using assessments and data-based tools to monitor HCP knowledge and provide further education to providers with room for improvement on the content where knowledge gaps persist.

Future Directions and Next Steps for Shaping Prescriber Education Efforts

This final discussion of the workshop focused on policy recommendations for a variety of stakeholders involved in HCP education. Discussion underscored the importance of tailoring education to HCPs' needs, including a recommendation that FDA provide greater flexibility in the Blueprint to allow CE providers to offer more targeted education, rather than covering the entire set of topics in the Blueprint. Test-out options, allowing HCPs to move past content with which they are already familiar and focus more on topics where they need additional training, were also mentioned. Panelists' remarks on the need for further flexibility referred not just to REMS education, but also to educational requirements for state licensure, which some said are unduly restrictive and not always well-aligned with HCP needs. Panelists generally supported pursuing existing national collaborations among licensing boards across states and across provider types, or establishing further collaborations, to streamline and align these educational requirements. Several panelists suggested further funding to promote and expand existing educational interventions that have been effective, or to spread the lessons learned from those models to other organizations involved in training HCPs. The use of data analytics to guide HCPs in practice or to shape and target educational interventions was recommended, echoing earlier remarks on the value of such strategies.

Conclusion

Over the course of this two-day public workshop, panelists considered how HCP education on pain management and SUDs can be improved to better prepare prescribers and other HCPs to provide safe and effective care for patients. Panelists discussed the importance of instilling core competencies regarding pain management and SUD care, while balancing the need for flexibility and tailoring

education to different HCPs' particular circumstances. Many persistent knowledge and practice gaps were identified in fundamentals of acute and chronic pain care as well as treatment for OUD. Strategies that have been effective in addressing practice gaps target HCPs' educational needs with engaging methods of delivery and involve the entire care team with interdisciplinary approaches. In the final session, participants recommended providing greater flexibility in education, better aligning the content of education, and promoting or extending the reach of existing educational programs that have proven effective to better address identified knowledge and practice gaps.

FDA and Duke-Margolis thank the workshop participants and attendees for their contributions to and interest in addressing these critical issues. Feedback shared in this workshop will inform FDA as it continues work on addressing the opioid and substance use crisis.

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