An Institutional Approach to Managing the Opioid Crisis

Halena M. Gazelka, MD; Casey M. Clements, MD, PhD; Julie L. Cunningham, PharmD, RPh; Holly L. Geyer, MD; Jenna K. Lovely, PharmD, RPh; Cheri L. Olson, MD; Lindsey M. Philpot, PhD; Steven B. Porter, MD; Terrence J. Witt, MD; Kathryn W. Zavaleta, MSHA; and Elizabeth B. Habermann, PhD

Abstract

The opioid crisis is a major concern of most health care institutions, including our large academic center. In this article, an organized approach to managing the epidemic institutionally is discussed. An Opioid Stewardship Program was instituted at our tertiary-care center with multiple sites and states of practice, which included diverse membership and expertise. Charges of the program included reviewing current practice, workflows, and external and internal guidelines and evaluating and standardizing prescribing practices. The development of an Opioid Stewardship Program resulted in: (1) an understanding of our diverse prescribing practices and the formation of patient- and procedure-specific guidelines to manage them, (2) education tools for our patients and providers, and (3) workflows and practice advisories within the electronic health record to support appropriate prescribing and monitoring of patients. This ongoing work continues to evolve in response to the needs of our patients, changing regulatory environments, and our improved understanding of our practices.


The opioid crisis in the United States has reached staggering proportions. In 2017, there were more than 47,000 overdose deaths from opioids, and these made up almost two-thirds of all overdose deaths.1 Given that opioids have led to approximately 200,000 deaths since the 1990s, the continued nearly exponential increase in overdose rates of the past several years portends one of the greatest iatrogenic epidemics in human history. Although many opioid overdoses are related to illicit drugs, in most abusers, substance use disorders develop after initial contact with a legitimate opioid prescription.2,3

In the early 1980s, the risk for addiction from long-term use of opioids was asserted to be low, with a 1-page letter to the editor in the New England Journal of Medicine reporting a risk of 1% based on a limited inpatient-only retrospective study.4 Unfortunately, this reported risk was much quoted but untested. Subsequent efforts to adopt pain as the “fifth vital sign” in the mid-1990s and public reporting of patient pain satisfaction scores and their inclusion in reimbursement calculations for hospital practices, combined with aggressive marketing of opioids, led to robust and unchecked prescribing in subsequent decades.5-7 The increase in opioid dependence led to further prescription requests by patients and ultimately to an increase in the use of illicit opioids as well.8

By the time the risks for addiction and overdose began to be well recognized, the number of prescriptions for opioids in the United States reached nearly 239 million per year, enough for each US citizen to receive an opioid prescription annually. Unfortunately, stemming the tide of opioid use and abuse has proved exceedingly difficult given the highly addictive nature of these medications.9-11
The opioid crisis has resulted not only in lost lives but also in astronomical costs to our society. It is estimated that the combination of care for overdose victims and addicts, lost productivity, care for the children of addicts, and fighting drug trafficking at our borders has cost more than $1 trillion. The cost of the opioid crisis is monumental, and managing it is likely to be very costly as well. Pitt et al discussed the effects that treating addiction (eg, no negative effect on society), decreasing the supply of opioids (eg, initial negative effect with increased use of heroin), and using other interventions may have on the epidemic. They noted that increased naloxone availability would most likely provide significant benefit in decreasing mortality rates related to opioid overdose.

In September 2018, President Donald Trump signed the opioid abuse Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (H.R. 6), a compilation of more than 70 bills focused on managing the effects of addiction and providing more than $8.4 billion of funding to related efforts. Although this may seem like an exorbitant sum, experts estimate that effectively curbing the opioid epidemic would cost $20 billion per year (the amount currently spent on efforts to combat human immunodeficiency virus infection/AIDS).

In response to these societal and financial costs, many states also have adopted legislation to curtail the epidemic regionally. Efforts have been multifaceted, with focuses on prescribing limits, enhanced patient screening, provider education (including continuing medical education [CME] requirements), and prescription drug monitoring program (PDMP) formation and use. As of October 2018, a total of 33 US states have passed opioid-related legislation as a direct response to the current crisis.

Many health care institutions, insurance companies, and organizations are increasing their efforts to address opioid-related issues such as quantity- or duration-specific prescribing limits, patient and provider education, the availability of nonopioid alternatives for pain management, and addiction services. It is clear that many patients with opioid use disorder will require medication-assisted therapy to achieve long-term abstinence. The 3 available treatments (methadone, buprenorphine, and naltrexone) all pose varying obstacles to delivery, including specialized training for providers (methadone and buprenorphine), the need for long-term follow-up and specialized treatment counseling, and often psychiatric care.

Our own institution, Mayo Clinic, has been active in:

- Working to understand the prescribing habits of our providers
- Establishing opioid prescribing guidelines after common surgical procedures
- Standardizing prescribing limits and monitoring patients taking opioids for chronic pain
- Producing written, video, and audio materials to educate both our providers and patients on appropriate opioid use
- Ensuring compliance with rapidly changing requirements in the 4 states in which we provide health care
- Instituting required education, as part of the curriculum, for our medical students regarding the proper use of opioids and options for management of opioid use disorder
- Engaging at both state and national levels to share our experience and to advocate for evolution of evidence-based approaches to mitigate the effects of the opioid epidemic
- Adapting our electronic health record (EHR) to standardize prescribing practices on the basis of institutional policies
- Encouraging the co-prescribing of naloxone for patients determined to be at increased risk for overdose (eg, higher-dose opioids and/or concomitant prescribing of benzodiazepines)

Here, we share our experience and present both our results and key lessons we have learned.

DEVELOPMENT OF THE INITIAL MAYO CLINIC OPIOID WORK GROUP

In 2016, it was clear that the opioid crisis had become an iatrogenic catastrophe and...
that concerted efforts were required not only to reduce risk but also to improve patient care. In multiple meetings, institutional leadership discussed the need to understand this epidemic and how it affected our patients, our providers, and our institution and also to contribute meaningful solutions to the complex issues affecting our practice.

Our charges were to:

- Assess the enterprise-wide risk for over-prescribing and diversion
- Review internal and external existing guidelines, policy, workflows, and controls governing opioid prescription processes
- Review and identify current-state best practices
- Define a standardization plan, starting with areas of highest risk
- Develop a timeline and implementation plan for instituting best practices

As a result, a Mayo Clinic Opioid Work Group was proposed. Dr Halena Gazelka, an anesthesiologist specializing in pain medicine, was named chair, and the search began for appropriate membership. In the first year, the group was composed of nearly 40 members and was truly multidisciplinary. Members included physicians (primary care, emergency medicine, addiction medicine, anesthesiology, and orthopedic surgery), pharmacists, an addiction medicine psychologist (and psychiatrist, on an ad hoc basis), experts in quality and surgical outcomes research, nursing leadership, a management engineer, an administrative lead, and representatives from the offices of compliance, government relations, and communications. Furthermore, all 4 states of practice were represented: Arizona, Florida, Minnesota, and Wisconsin. Many experts contributed substantially to our work when consulted, although they were not consistent members of our work teams.

Two important studies were conducted and published in the first year of our work. First, we surveyed our providers regarding their opioid prescribing habits, understanding of guidelines, PDMP enrollment, and opinions on standardizing our practice. The most profound piece of information gleaned was that 94% (903 of 961) of respondents believed that our institution should have a standardized approach to opioid prescribing. Second, an examination of our surgical practices showed significant variation in opioid prescribing at discharge after surgery. A follow-up survey of postdischarge surgical patients indicated that 63% (125 of 213) of the opioids prescribed for common surgical procedures were unused and 89% (2213 of 2486) of patients did not dispose of these unused medications.

With this important information regarding our current state, we began to address the rest of our charges. At the end of the first year, we renamed our workgroup the Mayo Clinic Opioid Stewardship Program to reflect the importance of these medications, our responsibility to our patients, and the long-term nature of our work.

**WHY OPIOID STEWARDSHIP?**

The term stewardship was selected by the group because it embodies the intent of primum non nocere (first, to do no harm). We also wanted to focus on ensuring safe effective pain management as related to opioid prescribing in our health care communities.

The multidisciplinary group subsequently formed 4 subgroups with chairs and members appropriate to the assigned tasks: short-term prescribing, long-term prescribing, education and tools development, and EHR-related issues. The following sections explain not only how we organized our efforts to accomplish the charges of our program but also the challenges of the work, some of which we solved and many with which we continue to struggle. We hope our experiences will both educate and inspire others also engaged in this important effort.

**OPIOID STEWARDSHIP PROGRAM ACTIVITY**

**Guideline Development**

A priority for the Mayo Clinic Opioid Stewardship Program Oversight Group (MCO-SPOG) was the development of enterprise
guidelines for short- and long-term opioid prescribing. A review of the Centers for Disease Control and Prevention (CDC) opioid guidelines and our 4 states’ legislation was completed and the results were compared and consolidated.\textsuperscript{25-29}

**Acute Prescribing Subgroup**

Patients taking opioids for acute pain are at risk for becoming long-term or persistent users of opioids. Although surgeons prescribe only 10% of the opioids prescribed in the United States (primarily to opioid-naive patients), an estimated 1% to 13% of these patients become long-term users of opioids after surgery.\textsuperscript{30} Furthermore, given the growing body of literature demonstrating the low ratio of consumed to supplied opioids, along with low disposal rates, millions of leftover opioids remain in surgical patients’ homes that are at risk for diversion to others and subsequent opioid misuse.\textsuperscript{23,30-33}

The Acute Prescribing Subgroup of MCOSPOG was composed of multiple specialty-specific teams representing general surgery, orthopedic surgery, neurologic surgery, urology, gynecologic surgery, otolaryngology, cardiovascular surgery, pediatric surgery, and the emergency department. Multidisciplinary teams were developed based on recommendations from leaders in each clinical specialty, which generally comprised the specialty’s practice chair or other physician leader, nurses, pharmacists, research scientists, and health care engineers. Teams met to review data and develop specialty-specific, procedure-specific, evidence-based guidelines for opioid prescribing at discharge from surgery.

The first step for each specialty was to review recent historical prescribing data to determine the range of opioids prescribed to their surgical patients at discharge, as well as the proportion of surgical patients who were already using opioids. These initial investigations demonstrated wide variation in prescriptions written to surgical patients, even when limited to opioid-naive patients, which led to calls by our surgical leadership for standardization.\textsuperscript{22}

A key issue in the completion of the short-term guidelines (Table 1) was acknowledging the lack of evidence-based literature to serve as the groundwork for dosing recommendations. Many short-term prescribing guidelines use daily limits for prescribing. However, this is fraught with many opportunities for misinterpretation and prescriber workarounds. In calculating

<table>
<thead>
<tr>
<th>Topic</th>
<th>Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider responsibilities</td>
<td></td>
</tr>
</tbody>
</table>
- Check the PDMP with each new or renewed prescription  
- If postoperative pain persists beyond normal expected healing, refer patient to primary care provider to discuss other pain management options  
- In managing acute pain related to a chronic condition, avoid prescribing or refilling opioids  |
| Patient selection |  
- Include appropriate documentation in the medical record (eg, patient history and physical examination findings, diagnosis, other therapies tried or considered, risk assessment)  |
| Dosing |  
- Prescribe opioids as part of a multimodal pain management plan  
- Use immediate-release formulations  
- Avoid prescribing >1 opioid at a time  
- Avoid prescribing concurrent benzodiazepines or sedative agents  
- In most circumstances, avoid prescribing more than a 3-d supply and limit the entire prescription to 100 MME  
- A 7-d supply may be appropriate for patients with high pain expectations; limiting the entire prescription to 200 MME is typically appropriate  
- If opioids cannot be avoided, consider prescribing naloxone for high-risk patients (eg, history of substance abuse, psychiatric illness, concomitant benzodiazepine use, history of overdose, sleep apnea, obesity, or major depression)  |

| MME | = morphine milligram equivalents; PDMP = prescription drug monitoring program.  |

\textsuperscript{MME = morphine milligram equivalents; PDMP = prescription drug monitoring program.}
a daily opioid dose, pharmacies generally use the maximum dose allowed. This can lead to very high total morphine milligram equivalents (MMEs) being prescribed while technically meeting criteria for a 1-day supply.

Example: Given a prescription of: “Oxycodone 5-mg tablets: Take 1 or 2 tablets every 4 to 6 hours as needed for pain,” this would allow #36 tablets for a 3-day supply (270 MME) and #84 tablets for a 7-day supply (630 MME).

Short-term prescribing by total MME is an important factor that contributes to chronicity of opioid use. Our guideline development team chose to use both a daily supply and a general MME maximum recommendation.

Our specialty-specific guidelines follow a tiered approach, initially conceptualized by our orthopedic surgical practice: approximately 10 to 20 procedures from each specialty were reviewed and sorted into “tiers” for prescribing. For example, for orthopedic surgery, procedures that were relatively less painful, such as carpal tunnel surgery, were deemed tier 1, with a recommended prescribing maximum of 100 MME, whereas procedures that were most painful, such as knee replacement, were deemed tier 4, with a recommended prescribing maximum of 400 MME. Examples of these tiered guidelines are available in our previously published studies. This approach allowed our short-term prescribing teams to both cover a breadth of procedures within each surgical specialty and form guidelines that were easier for clinicians to interpret and remember.

With guidance from our health care engineer, guidelines were rolled out within each specialty under a clinical leader, targeting prescribers and staff at all levels and roles. Guidelines are centrally located in our institution’s knowledge management database, AskMayoExpert, which is accessible to all providers. Overall, prescribers seemed open to advice on how much opioid to prescribe to patients. Two concerns were frequently raised: the potential effect on patient satisfaction scores and the increased need for refills, which can be difficult to provide to nonlocal patients. To date, we have seen no evidence that either of these counterbalances has been negatively affected.

Our first guidelines were implemented in orthopedic surgery in August 2017, with others implemented during the following year. Initial results from orthopedic surgery showed a 50% decrease in total opioid prescribing for total hip and total knee arthroplasty in the months immediately after implementation, with no increase in refill rates. Future work will assess continued adherence to guidelines, as well as modifications based on continued surveys of surgical patients regarding consumption, as a feedback loop. A recent study showed that the fewer opioids that patients are prescribed, the fewer they take, which suggests that our goal of optimizing opioid prescribing may not yet be fully realized. In addition, we continue to investigate the effect of intraoperative and in-hospital opioid use, as well as multimodal approaches to managing surgical pain.

Chronic Prescribing Subgroup

More than 11% of American adults have daily chronic pain, with an associated increase of approximately $5000 in average health care costs per person per year. Opioids are commonly prescribed for chronic noncancer pain despite a lack of understanding about their efficacy in long-term use. Additionally, long-term opioid therapy for nonpainful conditions, such as refractory restless legs syndrome, is recommended by some medical societies. The increasing number of patients requiring long-term opioid therapy, along with the increasing federal and state regulatory requirements intended to ensure safe opioid prescribing practices, necessitated the creation of institutional guidelines for patients in need of long-term opioid therapy.

Through an iterative process involving stakeholders from family medicine and primary care, emergency services, and specialty
practices, the MCOSPOG developed guidelines specific to these patients (Table 2). Information was gathered from national societies and federal agencies, federal and state regulatory bodies, and internal and external practitioners. After the long-term opioid guidelines were approved by clinical practice leadership, principal components were filtered into minimum practice standards for maintenance of patients on long-term opioid therapy.

The guideline development workgroup incorporated much of the work from the CDC for our long-term guidelines. However, within the long-term guidelines, additional consideration was given to the prescriber burden of required patient visits. Although an assessment is recommended every 3 months, no stipulation of who assesses the patient (physician, advanced practice provider, pharmacist, nurse, or other) was specified in the CDC guidelines. We believed that much of the administrative work of reviewing the PDMP, obtaining urine drug testing, administering appropriate screening tools, and assessing patients for adverse effects and functional status could be completed by clinic support staff within their scope of practice, provided that no state regulations offer further stipulations.

To facilitate conversation and engagement with leadership in clinical practice areas, prescribing data were derived from the EHR. To optimize prescribing safety for both patients and providers, all clinical departments with at least 1 patient qualifying as being on long-term opioid therapy were included on the contact list for awareness and discussion of best practices and needed workflows. Most patients on long-term opioid therapy were being treated in our longitudinal primary care practices, which had engaged in resource allocation and workflow development in parallel with the efforts of the MCOSPOG.

Initial conversations with physicians, advanced practice providers, clinical pharmacists, and nursing staff exposed the challenges of these front-line providers in treating patients with chronic pain. Difficulties identified with nonopioid alternative therapies included limited access, facilitating and arranging payment, patient time constraints to participate, and patient willingness to engage.

Despite the published evidence, providers also reported concerns with patient satisfaction scores if an opioid was not prescribed and shared personal accounts of the extents to which some patients will go to obtain opioids.

### TABLE 2. Chronic Opioid Guideline Summary

<table>
<thead>
<tr>
<th>Topic</th>
<th>Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient selection</strong></td>
<td>• Same as short-term guidelines with additional documentation recommendations (eg, opioid aberrant behavior/abuse assessment, depression, anxiety, functional status)</td>
</tr>
<tr>
<td></td>
<td>• Assess for appropriate referrals (eg, specialty practice, pain medicine, behavioral health/addiction medicine)</td>
</tr>
<tr>
<td></td>
<td>• Complete an opioid therapy agreement at start of long-term therapy, with third short-term prescription, or episodic use &gt;90 d</td>
</tr>
<tr>
<td><strong>Dosing</strong></td>
<td>• Follow dosing and duration guidelines from CDC</td>
</tr>
<tr>
<td></td>
<td>• Naloxone prescriptions—same as for short-term guidelines</td>
</tr>
<tr>
<td><strong>Provider responsibilities</strong></td>
<td>• Check the PDMP with each new or renewed prescription</td>
</tr>
<tr>
<td></td>
<td>• Clinical assessment</td>
</tr>
<tr>
<td></td>
<td>○ Evaluate benefits and harms within 1-4 wk of initiation or dose escalation</td>
</tr>
<tr>
<td></td>
<td>○ Reassess benefits and harms at least every 3 mo</td>
</tr>
<tr>
<td></td>
<td>○ Documentation at each reassessment of physical examination, pain intensity, function, adherence, adverse effects, and referrals</td>
</tr>
<tr>
<td></td>
<td>• Urine drug testing—at opioid initiation, at least once per y, and at any point if aberrant behavior is suspected</td>
</tr>
<tr>
<td><strong>De-escalation</strong></td>
<td>• Consider dose de-escalation or discontinuation at each visit</td>
</tr>
<tr>
<td></td>
<td>• Consider discontinuation and appropriate referrals with any aberrant behavior</td>
</tr>
<tr>
<td></td>
<td>• Individualize opioid taper regimen on the basis of patient scenario</td>
</tr>
</tbody>
</table>

CDC = Centers for Disease Control and Prevention; PDMP = prescription drug monitoring program.
Education and Tools Development Subgroup
A major component of our education subgroup’s efforts focused on change management. From a large survey of our prescribers performed before our interventions, we learned that nearly everyone believed that a consistent approach to opioid prescribing was needed and that nearly one-third of prescribers were not even aware of the CDC guidelines. Likewise, we identified gaps in the use of screening practices, safe prescribing practices, PDMP use, and recommendations for naloxone prescribing. However, we also lacked evidence about why our providers prescribe the types, routes, and doses of the medications used. To address this, we engaged focus groups to get input from stakeholders. Initial investigations were ad hoc in departments in which opioids are commonly prescribed, although later we conducted formal structured groups with representatives from across Mayo Clinic, assisted by an independent research group.

One of the first steps in our culture change was clarifying expectations, which was accomplished in the development of our prescribing guidelines. These guidelines then had to be disseminated. Because different people respond to various educational styles, several mediums were used. E-mail communications were delivered across the enterprise in 11 different instances when new recommendations or tools were available. Four different care process models were published as resources in our comprehensive guide for providers: (1) Ask-MayoExpert, a knowledge database for recommended care; (2) 2 mandatory computer-based educational modules, one designed and created for standardized training of all prescribers, pharmacists, and nurses across the enterprise to increase awareness of the guidelines and one designed to meet state-specific regulatory guidelines for our Arizona campus; (3) CME content, created using several short conversational podcasts for portability and accessibility; and (4) an Opioid Stewardship Intranet website with easy access to the policies, workflows, emerging research, and provider and patient educational tools developed by our team.

Focusing on the needs of the patient is a guiding principle of Mayo Clinic, and quality patient education is necessary as we consider changing how we assess and manage pain. Given that opioid prescribing is widespread and that one of our goals is enterprise-wide practice convergence, our patient education team foresaw the need for standardized language related to opioids. This will also be imperative in the future because specialty-, disease-, and procedure-specific patient education materials include information about opioids. Developing this common lexicon allows for consistent messaging throughout the enterprise. Five generic high-level materials were developed as pamphlets and patient handouts for: (1) general information about opioid medications; (2) treatment of acute pain; (3) information about the long-term use of opioid medications; (4) benefits, adverse effects, and risks of using opioids; and (5) a summary of why Mayo Clinic decided to change opioid prescribing practices. These 5 handouts provide a common base of information that can be applied in most patient care situations or adapted to other uses in subsequent materials.

We then developed videos for hospitalized patients to explain inpatient pain care at the time of admission, which help set expectations. We wanted to focus the patients’ attention on pain management as it relates to functional recovery, the potential role of opioids as part of multimodal therapy, and the likelihood that being “pain free” is neither a reasonable nor a safe expectation. A video is also available for use at discharge or in the outpatient setting for patients who are prescribed opioids to educate them about their proper use and disposal.

We also realize that our hospitals and clinics do not exist in a vacuum but rather are integrated within communities and that public messaging about the reasons and intent behind our opioid stewardship efforts is key. Personal and communal expectations of pain control, specifically the
use of opioids, are often well formed and deeply held, even before patients seek care. Helping patients and community members understand risks and processes before they come into the clinic or the hospital is important in establishing a shared vision for their care. Public messaging began before other interventions were implemented, with frank public commentary in the media about our research on our own wide variation in opioid prescribing and subsequent stories on Mayo Clinic’s intent to change our opioid prescribing practices. Representatives of our group have engaged with the media locally and nationally to improve public education regarding the opioid crisis and our work to manage it. Further public engagement efforts have included team members speaking at local events, coordinating improvements with government projects and law enforcement efforts, and hosting prescription drug take-back events on dates specified by the US Drug Enforcement Agency.

EHR-Related Issues Subgroup
At the same time that our original workgroup was established in 2016, work on an enterprise-wide EHR was in the early development phase. The goal of this undertaking was to allow for greater integration of all Mayo Clinic practices by using a unified EHR.

The use of EHR and opioid-related dashboards has been associated with greater adherence to prescribing guidelines. The timing of these 2 initiatives was seen as an opportunity to develop and use new tools for improving the care of patients on opioid therapy, increasing clinician adherence to opioid-prescribing guidelines, and allowing for further research in this area. The goals of the EHR Subgroup were to allow clinicians to easily access and use:

- Clinical data, including the patient’s opioid use history, risk factors for abuse/addiction, and results of safety assessments such as urine drug tests, opioid therapy agreements, and risk stratification tools
- Tools such as the individual state’s PDMP database, opioid-prescribing guidelines, MME calculators, and pertinent pharmacogenomics references
- Population metrics related to prescribing patterns and guideline adherence

This subgroup was composed of primary care and pain medicine clinicians, pharmacists, a pharmacy informatics specialist, systems engineers, and administrators. Some of the key features developed by the team and embedded in the new EHR included:

- Long- and short-term opioid prescribing registries; the inclusion of a patient in one of these registries is easily visible in the patient’s medical record
- A “Synopsis” profile that populates almost all EHR components and results related to long- and short-term opioid therapy
- “Best Practice Advisories” that prompt clinicians to complete opioid risk stratification tools, functional assessment tools, and opioid therapy agreements
- Direct links to “Mayo Clinic Care Process Models” for short- and long-term opioid therapy and our opioid prescribing guidelines
- An “Opioid Action Plan” function that allows for quick access to clinical information such as the indication for long-term opioid therapy, past and current therapies and medications used, and tapering plans
- “Single Sign On” capability for “1-click” access to each state’s PDMP without having to insert clinician credentials or patient biographical data
- Electronic prescribing of controlled substances, with defaults encouraging prescribing within legislated and guideline limits (Figure 1)
- A wide variety of reporting capability and dashboards related to opioid prescribing and adherence to prescribing guidelines at various levels from the individual prescriber level to all of Mayo Clinic.
CHALLENGES: MULTISTATE OPIOID STEWARDSHIP

Implementing an Opioid Stewardship Program presented some unique challenges to our practice. Operating as a unified clinical enterprise, Mayo Clinic practice locations exist in 4 states. Although federal efforts exist to manage the opioid epidemic, each state also has had a unique response to the opioid epidemic. In Minnesota, an opioid prescribing workgroup was convened in 2015 with guidelines published in 2018 to help the state’s Department of Human Services manage their Opioid Prescribing Improvement Program. In Wisconsin, after the creation of several laws known as the Heroin, Opiate Prevention, and Education agenda, the governor appointed an opioid task force in 2016. In Arizona and Florida, opioid-related deaths led the governors to declare states of emergency in 2017.

As of 2019, the 4 states have different restrictions on prescribing opioids (Table 3). Specific differences include the maximum duration per prescription of opioids for acute pain, the amount of opioid-related CME hours required for medical license renewal, the integration of each state’s PDMP into clinical practice, the integration of electronic prescribing of opioids, and the requisite documentation needed to administer and prescribe opioids.

This interstate variation presented tremendous challenges to our newly formed Opioid Stewardship Program. One way that Mayo Clinic responded to the different state-specific requirements was the creation of a podcast that met specific criteria for opioid-related CME requirements in Wisconsin and Arizona. Arizona’s Department of Health Services, Minnesota’s Department of Health and Department of Human Services, and Wisconsin’s Medical Examining Board have all issued clinical guidelines for opioid prescribing in an attempt to educate providers in those states on best practices for management of acute and chronic pain. Although we have remained cognizant of...

FIGURE 1. Electronic opioid ordering and defaults. MEDD = morphine equivalent daily dose; PRN = as needed.
<table>
<thead>
<tr>
<th>Factor</th>
<th>Florida</th>
<th>Arizona</th>
<th>Minnesota</th>
<th>Wisconsin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribing limits</td>
<td>3-d limit for acute pain; 7-d limit if deemed medically necessary</td>
<td>5-d limit for initial acute pain at &lt;90 MME/d; 14-d supply allowed postsurgery</td>
<td>100 MME or 7-d supply</td>
<td>Currently none in place or proposed</td>
</tr>
<tr>
<td>Exceptions to prescribing limit</td>
<td>Chronic pain, palliative care, cancer, terminal conditions, and traumatic injuries are exempted from the definition of “acute pain”</td>
<td>Chronic pain, cancer, traumatic injuries, hospice, palliative care, or burns</td>
<td>At provider discretion</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td>7-d prescription allowed if &gt;3 d are needed based on professional judgment of prescriber; “acute pain exception” is listed on the prescription, AND reason for exception is documented in medical record</td>
<td>&gt;90 MME/d is allowable IF confirmed by consultation with board-certified pain specialist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PDMP</td>
<td>Mandatory consultation of PDMP before prescribing or dispensing any CS, unless nonopioid Schedule V</td>
<td>Mandatory consultation of PDMP before prescribing or dispensing CS</td>
<td>Mandatory prescriber registration with PDMP</td>
<td>Mandatory consultation of PDMP before prescribing or dispensing CS for a duration &gt;3 d</td>
</tr>
<tr>
<td>Date of effect</td>
<td>7/1/2018</td>
<td>4/26/2018</td>
<td>7/1/2017</td>
<td>4/1/2017</td>
</tr>
<tr>
<td>CME</td>
<td>Board-approved 2-h CME on CS prescribing required for physicians</td>
<td>3-h CME related to opioid prescribing</td>
<td>2-h CME related to opioid prescribing</td>
<td>2-h CME related to opioid prescribing in each of 2 successive 2-y periods (beginning 2017)</td>
</tr>
<tr>
<td></td>
<td>Initial course must be completed by 1/31/2019, and then again before each subsequent licensure renewal</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CME = continuing medical education; CS = controlled substance; MME = morphine milligram equivalent; PDMP = prescription drug monitoring program.
these differences, standardization of opioid management has remained a high priority. Unification of the EHR has allowed for establishment of consistent tools for patient evaluation and pain management. One example is the development of an opioid therapy agreement, to be completed by both patient and provider, that encompasses the strict requirement for consent required by Arizona state law and is also applicable in Minnesota, Wisconsin, and Florida. Mayo Clinic continues to look for convergence on best practices related to opioid therapy while accounting for the different state-specific requirements.

LESSONS LEARNED AND ONGOING WORK

Regulatory compliance is a substantial driver of interventions targeting opioid prescribing. Although regulatory efforts have focused on the act of providing a prescription, prescriber-based interventions will inevitably fall short. A review by the Institute for Healthcare Improvement concluded that 75% of larger scale initiatives to address the opioid epidemic failed to consider a systems view. In particular, nurses and pharmacists have critical roles in the care of patients receiving opioid medications. Our work identified surprising gaps in knowledge and awareness of prescribing guidelines for providers, nurses, and pharmacists, which we have addressed through systematic communication plans, interprofessional leadership engagement, and professionally diverse workgroups. Further research will contribute to greater understanding of the knowledge, attitudes, and practice of caregivers and how both skills-based education and improvement initiatives can be better tailored to specific groups and settings. For example, training care teams how to talk to patients and tools for empathetic communication within safe practice may help address concerns about decreases in patient satisfaction.

Our experience also highlighted the range of clinical settings in which opioid medications are used. Evidence-based opioid prescribing applies to diverse settings, each with its own context and challenges. Despite this variation, our survey results and focus groups affirmed that the vast majority of prescribers welcomed a standardized approach. Future initiatives at Mayo Clinic will focus on understanding and tailoring interventions to the settings in which providers work. For example, important opportunities exist to optimize workflows within the EHR. The burden of operationalizing effective electronic workflows cannot and should not fall to individual providers. Instead, our team is actively working to create integrated operational processes that seamlessly incorporate EHR tools specific to a particular setting. A timeline of accomplishments and ongoing work is shown in Figure 2.

Although we face challenges from within, many challenges presented to us are outside our control. Medical insurance companies have proactively placed limits on opioid prescriptions for reimbursement, often with daily supply or MME maximums, which results in confusion. The subsequent burden of revising prescriptions, obtaining preauthorizations, and obtaining subsequent prescriptions falls to our providers, the pharmacy, and our patients.

Safe therapy must also address the challenges of integrating care for patients with mental health or substance use disorders. Providers consistently report difficulty managing transitions of care, particularly for patients needing short-term inpatient therapy. Responsible opioid prescribing for this subgroup of patients requires both the pursuit of nonopioid pain management options and concomitant treatment of mental health disorders. Organizations must simultaneously become more adept at identifying patients with substance use disorders, developing new strategies for treating patients with the most complex conditions, and improving coordination of care across settings.

We are keenly aware of the ongoing needs and challenges of our work in opioid stewardship. Although our focus was initially concentrated on opioid supply, we recognize further areas of need, which are increasingly becoming priorities. Focus on the management of opioid use disorder will
be particularly vital, including access to medication-assisted therapy such as buprenorphine, methadone, and naltrexone. Naloxone distribution and availability is a further focus, and we are working on methods to actively engage our staff in this effort, including best practice advisories in our EHR.

**GENERALIZABILITY TO OTHER INSTITUTIONS**

Although health care institutions vary considerably, many similarities exist that may contribute to the generalizability of our experience. The overarching legal implications of prescribing opioids do not vary from institution to institution, although they may, as we have learned, vary from state to state. It is therefore imperative that health care institutions not only heed their state laws but also participate in advocacy at the state and federal levels to ensure appropriate legislation. Furthermore, the mission of health care is clear: to deliver appropriate and timely care to patients. Not every institution will reproduce the research in this setting, but all can benefit from the results when formulating a plan for opioid management moving forward. As the opioid crisis has taken on significance in patient care, multiple commercially available EHRs have begun to produce opioid management tools.

**CONCLUSIONS**

The opioid epidemic plaguing the United States is partially iatrogenic, and the mission of health care to decrease human suffering compels us to act to mitigate the impact of this serious situation. The opioid crisis substantially affects our patients and our communities. Lest we forget, it also affects employee populations and the ability of an organization to retain a productive workforce. Despite this, opioids remain vitally important medications when used appropriately for both patient and diagnosis. Opioid stewardship must be adopted both individually and institutionally. Ideally, appropriate
Action at the local level may also mitigate the perceived need for results through often counterproductive regulations and excessive restrictions. The way forward reflects the critical role of health care governance, engagement of multidisciplinary care teams, and actionable performance metrics.

ACKNOWLEDGMENTS

We thank Trudi L. Lane, RPh, Registry and Med Mgt Informatician; Megan C. Sondreal, Epic Implementation; John M. Edwards, Epic Implementation; Andrew Sweeney, Epic Implementation; Cory J. Kudrna, Registry—Healthy Planet Consultant; Jason R. Buckmeier, Application Lead—Healthy Planet; Danny C. Whipple, MS, Management Engineering & Internal Consulting; and All other Mayo Clinic Opioid Stewardship Program Oversight Group members who are not coauthors. Editing, proofreading, and reference verification were provided by Scientific Publications, Mayo Clinic.

Abbreviations and Acronyms: CDC = Centers for Disease Control and Prevention; CME = continuing medical education; EHR = electronic health record; MCOSPOG = Mayo Clinic Opioid Stewardship Program Oversight Group; MME = morphine milligram equivalents; PDMP = prescription drug monitoring program

Potential Competing Interests: The authors report no competing interests.

Correspondence: Address to Halena M. Gazelka, MD, Division of Pain Medicine, Mayo Clinic, 200 First St SW, Rochester, MN 55905 (gazelka.halena@mayo.edu, Twitter: @hmgazelkamd).

REFERENCES


