

Balancing Access and Use of Opioid Therapy

MEETING REPORT

6th Annual Research Symposium
October 3, 2016



FOUNDATION

Gaylord National Hotel & Convention Center
National Harbor, Maryland

PRESENTATIONS

- ➔ KEYNOTE ADDRESS: OVERVIEW ON OPIOID PAIN THERAPY MISUSE AND ABUSE AND FEDERAL INITIATIVES
- ➔ MANAGED CARE PHARMACY'S LEADERSHIP AND OPPORTUNITIES IN CARA IMPLEMENTATION
- ➔ PATIENT PERSPECTIVE – ACCESS TO APPROPRIATE THERAPY
- ➔ PRESCRIBER PERSPECTIVES, CHALLENGES & RESPONSIBILITIES
- ➔ OPIOID USE MONITORING MEASURES
- ➔ MANAGED CARE AND HEALTH PLAN PERSPECTIVES
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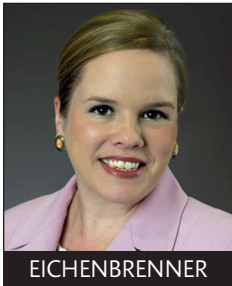
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OVERVIEW



The timely focus of the Academy of Managed Care Pharmacy (AMCP) Foundation’s 6th Annual Research Symposium – *Balancing Access and Use of Opioid Therapy* – discussed opioid pain therapies and related challenges confronting health plans, prescribers, pharmacists, payers and others. The topic aligned with the mission of the AMCP Foundation to advance collective knowledge about the myriad of factors that influence patient care. The Annual Research Symposium is designed to bring new data to light and offer novel insights on timely issues to optimize the practice of managed care pharmacy.

The statistics for this topic are grave with more deaths each year from opioid misuse and abuse than from traffic accidents in the United States.¹ Virtually all sectors of health care are in agreement that during the last decade, prescription drug misuse and abuse (especially of opioid analgesics) has been the fastest-growing substance abuse concern in the U.S.² The annual cost to hospitalize individuals with opioid abuse and related dependencies tripled over a 10-year period to nearly \$15 billion in 2012.³ Hospital admissions for those suffering from the effects of opioid use and misuse surged to 520,000, as reported by the Centers for Disease Control (CDC).³ Workplace costs for treatment and lost productivity is estimated to exceed \$50 billion.⁴ The Foundation’s Symposium contributed to and advanced the national dialogue around these

“One of the most confounding problems with the opioid epidemic, from a policy perspective, is that nearly every part of the health care system has aided and abetted the spread of the epidemic in some fashion.”

overwhelming statistics while remaining objective and solutions-oriented.

According to Paula J. Eichenbrenner, CAE, Executive Director of the AMCP Foundation, “This symposium will examine the present, but more importantly, look to the future, to the solutions that promise the greatest impact in stemming the opioid epidemic and to the research gaps that must be addressed to continue progress.”

Brett Norman, a reporter and health policy editor at POLITICO magazine, who is well known in both journalistic and health policy circles for his balanced and credible coverage of health care and pharma politics, moderated the symposium. Mr. Norman provided a unique perspective as a health care reporter who is watching the opioid epidemic unfold, stating that, “one of the most confounding problems with the opioid epidemic, from a policy perspective, is that nearly every part of the health care system has aided and abetted the spread of the epidemic in some fashion.”

Examples of these challenges within the health care system include fraudulent drug company marketing, federal drug policy emphasis on addressing pain management and subsequent incentives, and a culture of prescribing that embraced opioid medications without conceiving the downsides of addiction and overdose. Even in an era of “big data,” there are tremendous gaps in knowledge about what patients are taking, where they are getting their prescriptions, and what physicians are the outlier prescribers. Hospital policies, reimbursement strategies, patient advocacy groups, and other factors have also played a part in the problem. The backdrop of this epidemic is that there is a treatment gap and a need to significantly expand access to treatment. There is simply not enough capacity to care for those with substance use disorder, and

there is often limited insurance coverage for what treatment is available.

Mr. Norman shared that, “opioid use and misuse is one of the top health care issues in Washington because of the personal impact to grieving families, local community leaders, public health officials and first responders all over the country.” The confluence of issues, and the serious impact that this epidemic has had across the country, has resulted in very real and rapid action from the federal government, including the publication of the CDC Guideline for Prescribing Opioids for Chronic Pain (CDC Guideline) that provides strong warnings against routine prescribing of opioid medications for non-cancer, chronic pain patients, outlined rules to raise the caps on medication-assisted treatment (MAT), and engaged the U.S. Surgeon General to release the office’s first report on substance use and addiction, highlighting the issue as a disease and focusing on options for treatment and recovery.

States have also taken rapid action, requiring prescribers to check prescription drug monitoring databases (PDMPs) before prescribing opioids and other drugs with high risks of abuse and limiting the number of tablets or capsules that can be prescribed. These actions have not been without controversy and have faced opposition from medical groups. The American Medical Association (AMA) published new policies, and Congress passed an overhaul of the federal grant funding for substance treatment programs, the first major advancement in decades. Congress also passed the Comprehensive Addiction and Recovery Act (CARA) to provide some funding for many of these efforts. This Symposium continues these national efforts and will identify obstacles and opportunities for progress and areas of potential focus for future policy and programmatic action.



EXECUTIVE SUMMARY

The Academy of Managed Care Pharmacy (AMCP) Foundation's 6th Annual Research Symposium, *Balancing Access and Use of Opioid Therapy: Challenges Confronting Health Plans, Payers, Prescribers and Others*, provided a forum for representatives of key stakeholders to address key issues and strategies to reduce opioid use disorders. Symposium presentations aligned with the AMCP Foundation's core mission to advance collective knowledge about the myriad of factors that influence patient care, helping to advance the national dialogue around the opioid epidemic with a solutions-oriented agenda that identified obstacles and opportunities for progress and areas of potential future policy and programmatic action.

Addressing the Epidemic of Opioid Use Disorder

As the total number of opioid-related overdose deaths continues to increase, the topic of opioid use and misuse is one of the top health care issues in the country. Early identification of problematic opioid use and engagement in appropriate levels of treatment are critical in preventing morbidity and mortality. In response, federal drug policy efforts have been focused on opportunities to improve opioid prescribing, increase the use of naloxone to reverse opioid overdose, and expand the use of medication-assisted treatment for opioid use disorders.

Opioid use disorder is a substantial public health and public safety issue. There are many patients with pain that are not well managed, and they may not have access to the full complement of pain relief strategies and treatments. Concerns with prescribing trends include increases in dosages of opioids prescribed, longer durations of treatment, and

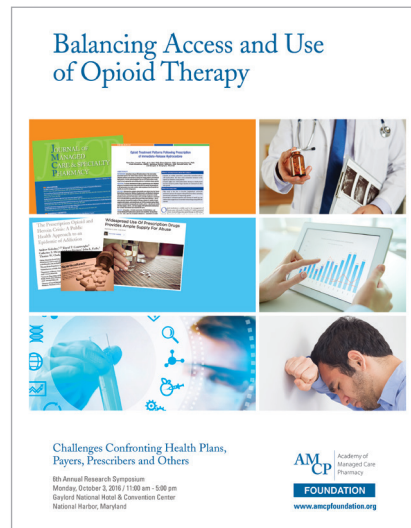
prescribing for conditions that do not benefit from the treatment of opioids. These issues are addressed within the new CDC Guideline. For patients that meet criteria for substance use disorders, there is a need to expand access to opioid use disorder treatment. The barriers to treatment are often significant, and for health care professionals, these barriers can be opportunities to discuss the benefits of treatment, and reinforce that opioid use disorder is a medical condition.

State-level efforts to expand access to naloxone are also increasing. Improving access is a critical component of risk reduction and expansion of naloxone access is an area where pharmacists can make a tremendous impact. Importantly, early identification of problematic

opioid use and engagement in appropriate levels of treatment are critical in preventing morbidity and mortality.

Patient Perspectives

Many people experience acute pain and chronic pain episodes in their lifetimes. Often, patients and providers may not appreciate that there are non-pharmaceutical treatment options for both acute and chronic pain. Health care providers frequently find themselves in a delicate balance to both reduce potential harm and effectively care for patients with pain. Tools such as prescription drug monitoring programs (PDMPs) and patient review and restriction programs (PRRs) are mechanisms that identify patients at risk for harm and help coordinate patient care and improve outcomes. Evidence shows that providing access to complete information about patient exposure to controlled substances may make providers more comfortable with prescribing and dispensing these medications. Research has shown that PDMPs and PRRs





are valuable tools to achieve harm reduction while ensuring patient access.

Provider Perspectives

From the perspective of a clinician, opioids are vital medicines for the relief of suffering at the end of life, for the treatment of acute pain, and for pain associated with active cancer. However, a sharp increase in opioid prescribing for chronic, non-cancer pain during the past two decades has been associated with large increases in opioid addiction and opioid deaths in the U.S. Prescribers are a very important piece of the puzzle in dealing with the opioid epidemic.

The opioid epidemic is a multidisciplinary issue. There are a number of principles of sound prescribing that support the safe and effective use of opioids for treatment of chronic pain. Currently, over 90 percent of primary care physicians do not routinely screen for substance use disorders. There is also a need to increase awareness across the entire spectrum of substance use disorders and appreciate that stigma is a significant barrier both within the general public and medical professionals. All health professionals should be trained on medications to treat substance use disorders, and pharmacists are key to the team to help address this epidemic.

Strategies to identify and support at-risk populations can be based on sophisticated patient-level analytic assessment, risk stratification and scoring that identifies patterns of use that suggest risk. There is ongoing work to develop a predictive

algorithm for opioid use disorder. Other initiatives are working to assess the effectiveness of wearable health technologies to improve treatment for patients with chronic pain. Additional opportunities for providers to improve patient safety and decrease diversion exist through formulary management, pharmacy based screening, and closer collaboration with other providers.

One way to advance medical care in treating substance use disorders is to properly align the payment incentives, requiring that resources be reallocated. From a managed care perspective, it is important to track the medical spend offset across silos. If physicians practice evidence-based medicine, addiction treatment will increase the pharmacy spend but will decrease emergency department utilization, decrease hospital admissions, decrease ICU stays, the length of stay, and 30-day readmission rates.

Providers are continually challenged with balancing the need for opioids for pain management with the management of risks, which creates the potential for naloxone to promote opioid safety discussions with prescribers and patients. Naloxone should be considered an opioid safety tool. The CDC Guideline recommends that prescribers “consider offering naloxone when prescribing opioids to patients at increased risk for overdose,” within the broader context of assessing other clinical variables. Pharmacies and pharmacists also have an increasing role in providing patient access to naloxone.

Managed Care Pharmacy’s Leadership

AMCP is working to take a leadership role in addressing the opioid epidemic, advocating for solutions and engaging managed care stakeholders. AMCP convened a Partnership Forum on Breaking the Link Between Pain Management and Opioid Use Disorder that specifically tasked AMCP to conduct continuing education programs for pharmacists and other providers on opioid use disorder and treatment, develop a best practices toolkit, and promote quality standards for opioid use disorder treatment and prevention.

AMCP was also encouraged to collaborate with other organizations representing addiction treatment experts and managed care to review current practices and identify areas for substantial improvements in patient outcomes. The subsequent establishment of the AMCP Addiction Treatment Advisory Group (ATAG) led to the development of Findings and Considerations for the Evidence-based Use of Medications Used in the Treatment of Substance Use Disorder, providing specific recommendations for managed care pharmacy.

Managed care plays a central role in addressing the opioid epidemic and is uniquely positioned to positively contribute to solutions through population management, appropriate medication selection, care coordination, and provider education. Health

plans can examine their coverage policies for both pain treatment and MAT and work to decrease the barriers to entry for both patients and providers. Managed care organizations are also encouraged to use data to risk stratify patients and inform providers about utilization issues. Data can also be leveraged to evaluate if implemented utilization policies are successful and to target patients that may be in need of medical intervention.

The U.S. society and our health care system will continue to seek solutions to the challenges of opioid use disorder. Managed care organizations can continue to focus on the role they can – and should – play in addressing this national health care emergency and developing meaningful solutions for patients, providers and payers.



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WITH APPRECIATION

The AMCP Foundation would like to express its appreciation to the organizations that provided support to the Symposium. The live meeting and the summary of its proceedings were made possible in part by Alkermes, Inc., Optum, Inc., Purdue Pharma L.P., and Teva Pharmaceuticals Industries Ltd.

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OVERVIEW ON OPIOID PAIN THERAPY MISUSE AND ABUSE AND FEDERAL INITIATIVES



Christopher M. Jones, Director of Division of Science Policy with the Office of the Assistant Secretary for Planning and Evaluation at the U.S. Department of Health and Human Services (HHS) provided the keynote

address for the session to provide a national perspective on the opioid crisis and how the federal government is evolving their response to the issues.

UNDERSTANDING THE EPIDEMIOLOGICAL TRENDS

The 2015 Substance Abuse and Mental Health Services Administration's (SAMHSA) National Survey on Drug Use and Health (NSDUH) reported on three indicators of misuse, including initiation, misuse, and use disorder and showed that prescription opioids are the most common substance that is initiated for misuse. For prescription opioids, more than 2 million people initiated use of opioids in 2015; 12 million people reported misuse within the past year, and more than 2 million people qualified as having prescription opioid use disorder.⁵ There appears to be some stabilization of opioid use over the past year in the U.S., with an increasing trend in heroin use.

The number of all opioid-related overdose deaths has increased dramatically since 1999.⁶ Policy and programmatic efforts to address the prescription opioid epidemic must be considered in the context of the misuse of opioids such as heroin and fentanyl. It has been shown the nonmedical use of prescription opioids is a significant risk factor for heroin use, with approximately 70-80 percent of heroin users reporting misuse of prescription opioids prior to initiating heroin.⁷ These statistics are influenced by economics and availability of these drugs, and people who demonstrate problematic behavior with nonmedical use of prescription opioids are the population at highest risk for initiating heroin.⁸

Figure 1: Nonmedical Use of Prescription Opioids is a Risk Factor for Heroin Use



3 out of 4 people who used heroin in the past year misused opioids first



7 out of 10 people who used heroin in the past year also misused opioids in the past year

There are multiple facets of the opioid epidemic that drive federal drug policy. Issues such as HIV and Hepatitis C infections linked to injection drug use, the impact of the opioid crisis on the foster care system, illicitly manufactured fentanyl, and the increasing incidence of neonatal abstinence syndrome are all examples of the complexity of the opioid problem.

“There are multiple facets of the opioid epidemic that drive federal drug policy.”

Federal Response to the Opioid Epidemic

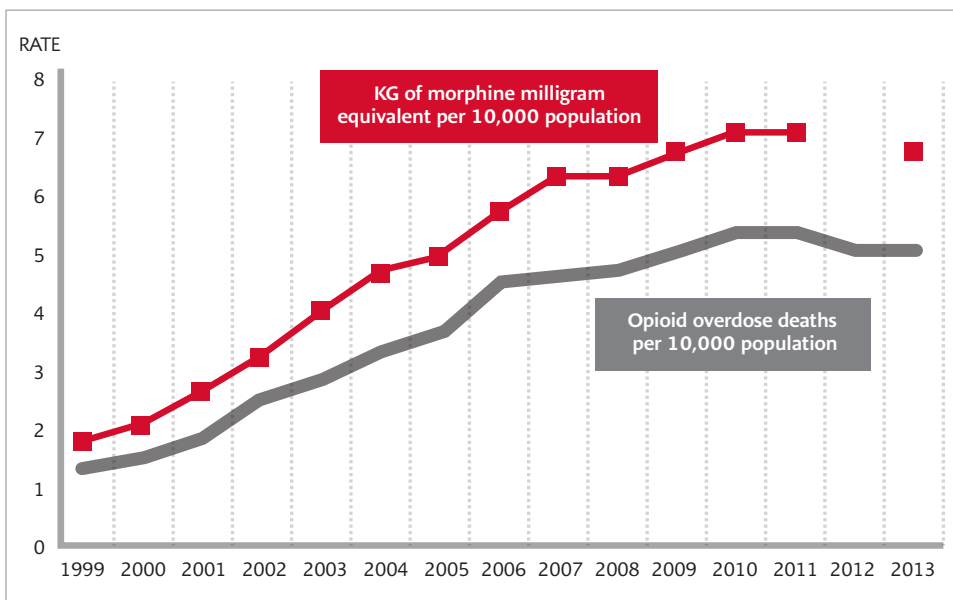
On an annual basis, the Office of National Drug Control Policy (ONDCP) issues a National Drug Control Strategy that outlines the blueprint to addressing the epidemiological issues.⁹ In 2011, ONDCP released a prescription drug abuse prevention program that specifically outlined activities within the federal government. In March 2015, under the direction of Secretary Burwell, the U.S. Health and Human Services (HHS) Division launched an initiative to be more targeted in the response to the opioid epidemic. This initiative has three focus areas, including improving opioid prescribing, increasing the use of naloxone to

reverse opioid overdose and expanding the use of medication-assisted treatment for opioid use disorders.

Improving Opioid Prescribing

One of the drivers of the current epidemic is that there were fundamental changes in the ways that opioids were prescribed. As demonstrated in Figure 2, as the availability of prescription opioids increased, there was a coinciding increase in the number of deaths from prescription opioid overdose.¹⁰

Figure 2 – Increases in prescription opioid prescribing coincide with increases in prescription opioid overdose death



The issue is not simply that there are more prescriptions for opioids, but also how these medications are being prescribed that is important. Prescribing trends include large increases in dosages of opioids prescribed, longer durations of treatment, and prescribing for conditions that do not benefit from the treatment of opioids. Patients often use multiple providers, multiple pharmacies and combine the use of opioids with benzodiazepines, alcohol and other sedating drugs. Studies show that these are all risk factors for opioid misuse and abuse.¹¹ Accord-

ing to Prescription Behavior Surveillance System (PBSS) data, opioid prescribing is concentrated within a small percentage of prescribers, with 10-20 percent of prescribers prescribing 60-80 percent of the opioids. This data allows for targeted policy responses to improve opioid prescribing.

HHS has been heavily focused on improving opioid prescribing and released the CDC Guideline in March of 2016. State-level funding has been allocated through the CDC for the Prevention for States Program, which funded activities such as surveillance programs and enhancing PDMPs. Educational programs for providers have been developed through the U.S. Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA). Other recent HHS actions include releasing a proposed rule

that delinks the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) pain related questions from value-based purchase reimbursement, decreasing the possible incentive to overprescribe opioids. The federal government is trying to lead by example by implementing policy within the Indian Health Service (IHS), which requires checking the PDMP prior to prescribing opioids for longer than seven days.

The implementation of the National Pain Strategy was launched as the first govern-

ment blueprint for how to advance pain care in the U.S. There are many patients with pain that are not well managed, and they may not have access to the full complement of strategies and treatments that could be used. The National Pain Strategy sets out the research agenda, policies that should be explored, and the data that is needed to inform improvement in these areas. The federal government has also been very focused on engaging with the health care professional community and bringing these stakeholders to the table.

Expanding Access to Opioid Use Disorder Treatment

There is a substantial gap in need and receipt of treatment for patients with opioid use disorders. There are almost 2.2 million people in the U.S. with an opioid use disorder; about 655,000 people received any treatment, and only about 500,000 people accessed this treatment at a specialty care setting.¹² For patients that meet criteria for substance use disorders, there are many reasons why they do not get treatment. Often, individuals lack awareness of the availability of treatment, do not feel that they need treatment, have stigma around treatment for substance use disorders, and are unable to pay for the costs of treatment or their lack of insurance coverage may be prohibitive.¹²

For health care professionals, these barriers can be opportunities to discuss the benefits of treatment and reinforce that opioid use disorder is a medical condition.

Currently, opioid abuse and dependence exceeds the capacity of physicians that can prescribe methadone, buprenorphine, and naltrexone in most states.¹² Studies have shown that when capacity for treatment is expanded, overdose deaths decrease.¹³ To address these challenges, HHS has implemented a number of activities to expand access to MAT, including publishing a final rule on buprenorphine to raise the maximum patient acceptance limit to 275 patients for certified physicians. The agency has also approved probuphine, the implant version of buprenorphine that provides an additional treatment option for opioid use disorder.

SAMHSA has worked to increase capacity for MAT at the state level through the provision of grants to states in both 2015 and 2016. HRSA provided \$94 million to improve access to MAT through community health centers, and AHRQ awarded \$49 million in research grants to study the provision of MAT in rural areas. Other initiatives include working toward parity in medication treatment, expansion of Medicaid to increase access and

implementation of CARA. Psychosocial treatment is also recommended in conjunction with pharmacological treatment of substance use disorders.¹⁴

Opioid use disorder is a substantial public health and public safety issue, and that priority has been reflected in the 2017 budget request for \$1.1 billion dollars to help address the opioid epidemic. SAMHSA has received \$920 million to expand access to MAT, increase capacity and make services more affordable, and build the systems that we need to treat opioid use disorders across the U.S.



Increasing Use of Naloxone

This is an area of policy that has rapidly changed, significantly increasing the number of states with naloxone access laws. As a result, there has been a meaningful increase in naloxone distribution through community pharmacies.¹⁵ Both the FDA and NIDA have also been working with drug manufacturers to develop new formulations of naloxone that are more easily used by laypeople. SAMHSA has developed an overdose toolkit, and there continue to be increases in funding for states and communities to purchase and distribute naloxone and train laypeople in its use. HHS also supports state-level efforts to expand access, which is an area where pharmacists can make a tremendous impact. Improving access is a critical component of risk reduction and continued expansion of naloxone is needed.

Importantly, early identification of problematic opioid use and engagement in appropriate levels of treatment are critical in preventing morbidity and mortality. These complicated issues will require a myriad of solutions and collaboration of key stakeholders. There are also specific opportunities for managed care to contribute to solutions that address the opioid crisis. Health plans can examine their coverage policies for both pain treatment and MAT and work to decrease the barriers to entry for both patients and providers. Managed care organizations are also encouraged to use data to risk stratify patients and inform providers about utilization issues. Data can also be leveraged to evaluate if implemented utilization policies are successful.

MANAGED CARE PHARMACY'S LEADERSHIP AND OPPORTUNITIES IN CARA IMPLEMENTATION



CANTRELL

Managed care pharmacy encompasses health care providers, patient advocates and others united to ensure that medication therapies are used safely and appropriately. Therefore, any issue that is a result of the inappropriate

use of medication is an issue for managed care stakeholders. There is a significant societal impact with over two million Americans that suffered from substance use disorders related to opioids and the estimated 500,000 people that are addicted to heroin.¹⁶ Overdose deaths from all opioids have increased over 200 percent in the last 10 years, with opioids involved in 61 percent of U.S. drug overdose deaths in 2014.¹

From a managed care perspective, a recent study showed that payment for opioid use disorder increased over 1,000 percent between 2011-2014, from \$32 million to \$446 million in 2015.¹⁷ Between 2007 and 2014, insurers saw a 3,200 percent increase in the number of claims for opioid dependence diagnosis, with insurers paying an average of over \$19,000 per patient for opioid use disorder diagnoses. This is a 563 percent increase in comparison to the \$3,435 in average claims paid for all patients.¹⁷ According to Susan A. Cantrell, RPh, CAE, who serves as the CEO of AMCP and the AMCP Foundation Chair, “the statistics are staggering and underscore the importance of this issue to managed care and our responsibility to help address these complex problems.”

Engagement of AMCP in Addressing the Opioid Epidemic

AMCP has worked to take a leadership role in addressing the opioid epidemic, advocating for solutions and engaging managed care stakeholders. In 2014, AMCP convened a Partnership Forum on Breaking the Link Between Pain Management and Opioid Use Disorder. AMCP partnership

forums address important emerging issues that impact managed care and bring together groups of multi-stakeholder participants for guidance on how AMCP can address the issue. The forum on Breaking the Link Between Pain Management and Opioid Use Disorder recommended that managed care:

- Advocate a holistic and evidence-based approach to pain management and opioid use disorder treatment,
- Recognize patients are a key part of the solution, it is critical to engage them in the decision-making process,
- Coordinate treatment approaches including pharmacy, medical providers, behavioral and mental health providers, and patients and their caregivers, and
- Support solutions with technology.

The Partnership Forum specifically tasked AMCP to conduct continuing education programs for pharmacists and other providers on opioid use disorder and treatment, develop a best practices toolkit, and promote quality standards for opioid use disorder treatment and prevention. AMCP was also encouraged to collaborate with other organizations representing addiction treatment experts and managed care to review current practices and identify areas for substantial improvements in patient outcomes.

The work of the Partnership Forum led AMCP to appoint an Addiction Treatment Advisory Group (ATAG) comprised of 20 diverse stakeholders in various settings, including behavioral health organizations, outpatient treatment centers, nonprofit advocacy groups, health plans, pharmacy benefit management companies, specialty pharmacies, employers, hospitals and manufacturers. The ATAG objectives are to:

- Identify and prioritize areas with the greatest potential to significantly improve patient outcomes,

- Develop recommendations to address barriers, improve processes and modify systems to improve outcomes,
- Serve as advocates in adopting recommended changes, and
- Support development of educational programs for managed care decision makers.

ATAG has developed Findings and Considerations for the Evidence-based Use of Medications Used in the Treatment of Substance Use Disorder. These specific recommendations for managed care pharmacy will be published in their entirety in the *Journal of Managed Care and Specialty Pharmacy*. The recommendations include the following guidance:

- Evaluate and update, as needed, managed care policies, processes, and benefit designs related to substance use disorders based on current evidence and an evolving understanding of substance use disorders as chronic health conditions,
- Enhance continuity of care for patients with substance use disorders by actively managing transitions of care between sites of care and between medical, pharmacy and mental health needs, and
- Improve health care professional and patient awareness of, and access to, medications used in the treatment of substance use disorders.

The ATAG also developed a three-part educational webinar series that has been presented throughout 2016.



AMCP has also been engaged in advocating for a number of provisions in CARA. CARA creates a framework for opioid abuse prevention and treatment and authorizes \$181 million in new spending to strengthen efforts at preventing and treating opioid abuse disorder. Importantly, the Act recognizes roles that pharmacists can play in addressing this epidemic. Efforts to engage pharmacists include appointing a pharmacy member to the pain management task force, providing grants to pharmacists to fund strategies to improve the provision of medications for both emergency treat-

ment and treatment of suspected overdoses, and engaging pharmacists in drug management programs. Pharmacists will also be involved in the HHS stakeholders group to provide input on the impact of drug management programs and defining at-risk populations.

CARA reauthorizes the National All Schedules Prescription Electronic Reporting Act (NASPERS) that provides grants to state PDMPs and encourages states to improve PDMPs by increasing interoperability and use of various health information technology strategies.

AMCP has engaged in a number of initiatives specific to CARA, including submitting a recommendation for a prominent pharmacist to serve on the Task Force for Pain Management, providing information on the differences within and between classes of opioids and the availability of abuse deterrent formulations, providing information on managing high-risk populations and prescribing best practices for those populations, and advocating evidence-based approaches to patient

Because of the central roles managed care organizations play in population management, appropriate medication selection, care coordination, and health care provider education, they are uniquely positioned to provide solutions to the complicated problems of addiction treatment.

– AMCP Addiction Treatment Advisory Group

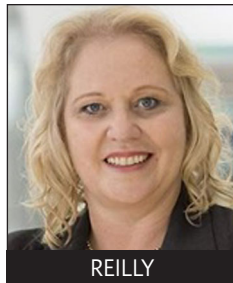
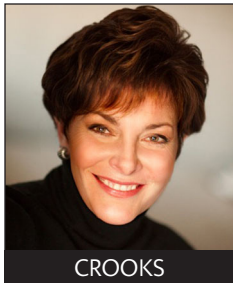
treatment. Additional activities include improving access to overdose treatment, participating in the development of clinical guidelines on overdose treatment, and providing information on the ability of pharmacists to provide MAT options and counseling.

AMCP has been active in NASPER reauthorization, supporting state legislation that allows health plans and PDMPs access to data, facilitating data sharing among PDMPs and across state lines, and developing real-time solutions for

PDMP data sharing that can be integrated into the workflow of pharmacists and prescribers. AMCP is also continuing to encourage states to include pharmacists that are authorized to prescribe naloxone as practitioners. AMCP believes that managed care plays a central role in addressing the opioid epidemic and is uniquely positioned to positively contribute to solutions through population management, appropriate medication selection, care coordination, and provider education.



PATIENT PERSPECTIVE – ACCESS TO APPROPRIATE THERAPY



Traveling the Path of Pain – Maze or Labyrinth?

Many people experience serious, acute pain and chronic pain episodes in their lifetimes. Often we don't think more broadly about the array of management strategies available for pain. Many patients and providers may not even appreciate that there are non-pharmaceutical treatment options for both acute and chronic pain. Pain management is often an art form.

Glenna Crooks, PhD, CEO, Strategic Health Policy International, Inc., spoke about the emotional and psychological impacts of pain management using the distinction between a labyrinth and a maze, a distinction that most people don't appreciate.

“Serious acute pain can rob people of any instinct beyond immediate relief. Enduring chronic pain can dead-end in addiction.”

A maze has dead-ends and blind alleys, and as a result, it is possible to get lost in a maze, and even, to die. Many people would say that this description “fits” their experience with pain. Serious acute pain can rob people of any instinct beyond immediate relief. Enduring chronic pain can dead-end in addiction. Intractable pain can test the capacity of patients to endure and their families to witness.

Any of these experiences can trigger anger, anxiety, helplessness, grief, fear, disillusionment, social

isolation, unemployment, addiction and early death. Once someone is lost in the maze, it is easy to get stuck, and it becomes hard to find a way out. A labyrinth, on the other hand, is a path without dead-ends. Though a traveler in a labyrinth can lose sight of what lies beyond the next turn, those who keep going always arrive at their destination. There is no way to get lost in a labyrinth. The only way to get stuck is to stop.

Ms. Crooks shared her personal story, describing her experience with both acute surgical pain and long-term traumatic injury chronic pain. Avoiding opioids and medications beyond those available over-the-counter, she embraced acupuncture, massage, reiki, mindfulness meditation, nutrition, wellness, sleep and a Zen practice known as “BigMind.” She has also studied neurosciences to learn how to use her brain to manage her pain. Despite the relief these alternatives provided, she acknowledges that they may not be affordable for patients who must pay out-of-pocket.

Her advice to managed care stakeholders is, “Don't build blind alleys or dead ends into the work that you are doing with your patients in pain. Don't create barriers that cause people to stop or get stuck.”

Balancing Risk Reduction with Patient Access

In relation to the opioid epidemic, The Pew Charitable Trusts, a non-profit, non-partisan research and policy organization, is focused on decreasing the inappropriate use of prescription drugs and expanding access to treatment for substance-use disorders. According to Cynthia Reilly, MS, BS Pharm, Director of The Pew Charitable Trusts Substance Use Prevention and Treatment Initiative, “pharmacists, prescribers, and drug benefit managers can utilize available tools to help reduce the incidence of potential harm while working with patients to reduce pain and suffering.

PDMPs are electronic databases that record dispensing of controlled substances to patients. Patient review and restriction programs (PRRs) are insurer-based mechanisms that identify patients at risk for harm and assign them to designated providers that coordinate their use of controlled substances. These tools are sometimes mischaracterized as being used solely to limit access to patient medications. However, when they are used effectively, the tools can be optimized to improve patient care and reduce harm.”

In some cases, health care providers find themselves between a rock and a hard place – being charged with reducing harm with the use of these drugs and caring for patients by mitigating their pain. We know that there is a need for caution in the use of opioid medications and that the risk-benefit profile is not favorable for the long-term use of these medications for pain.

There is evidence supporting thresholds that can identify patients at risk. A recent study followed patients that had overdosed when they were using opioids for chronic, non-cancer pain and found that 91 percent of these patients continued to receive opioids following their overdose and that 7 percent of those patients had a second overdose. Patient overdose rates were also more concentrated among those patients receiving higher doses of opioid therapies.¹⁸ As clinicians, we need to use tools that are available to minimize the risk of recurrent harm.

Another study looked at multiple provider episodes to obtain the same or similar opioid medications. The data shows that when the number of pharmacies a patient visits increases, the likelihood for the patient to have an overdose also increases. Additionally, there was an increased risk of overdose among patients that were using multiple doctors and pharmacies with less time between prescription fills.¹⁹

“Active use of PDMP data is one strategy to reduce harm and improve patient care. PDMPs are available in most states, but their use is currently suboptimal.”

Optimizing the Use of PDMP Data

Active use of PDMP data is one strategy to reduce harm and improve patient care. PDMPs are available in most states, but their use is currently suboptimal. Even when the use of PDMPs is required by state regulations, that mandated use may not mean the information is being optimally used to improve patient care. A recent study highlighted the potential benefits of using these databases. In response to PDMP data indicating that a specific patient was doctor shopping, 68 percent of prescribers used the information as an opportunity to discuss drug use with the patient, 32 percent screened the patient for substance-use disorders, and 13 percent used

the information as an opportunity to refer patients to treatment. Only 6 percent used the information as reason to discharge patients from their care.²⁰ Dismissing patients from any medical practice is not good patient care, resulting in patients searching for another provider, or foregoing care altogether and finding alternative, and often illegal, sources for prescription opioids.

There is evidence that as prescribers and pharmacists use PDMPs more frequently, it does not have an unintended, or chilling effect on access. In fact, access to complete information about patient’s exposure to controlled substances may make clinicians more comfortable with prescribing these medications. There are other challenges to using these databases effectively, including finding time within workflow and ensuring constructive patient communications. Health care professionals have been trained to share knowledge with patients and tell them what we think they need to know; however, first listening to the needs of the patient may be most effective. This may be particularly true when counseling patients with pain.

The Pew Charitable Trusts has been studying innovative practices in using PDMPs that have the potential to both increase prescriber use and

improve patient outcomes. The first example is prescriber-set thresholds. This is a variation of unsolicited reports, where the PDMPs send reports to prescribers based on pre-defined thresholds that may indicate that a patient is at risk of harm, as evidenced by a high dose or unusual combination of therapies. With prescriber-set thresholds, the prescriber sets the desired threshold for receiving this notification. This function can be especially useful if the prescriber and patient have entered into a pain management agreement. With this tool, the prescriber can set the threshold at “plus one” so that they are notified if the patient receives a controlled substance from another prescriber.

Maine was one of the first states to implement this practice, along with other changes to the PDMP to make the information more clinically relevant. The optimal use of this reported information is to engage in a dialog with patients, discuss why goals for pain management are not being met, and determine if a change in therapy may be warranted.

In a 2012 CDC report on PRRs, an expert panel found that these programs have the potential to reduce opioid usage to safer levels, save lives and reduce health care costs.²¹ The Pew Charitable Trusts has completed research to learn more about the characteristics and structures of PRRs and the impact of these programs. Part of the analysis determined whether or not the policies support or inhibit improvements in patient care. The Trusts conducted a literature review and a study of 38 fee-for-service Medicaid programs with PRRs. The study determined state-specific criteria used to identify and enroll patients (i.e., number of pharmacies, number of prescribers, number of prescriptions) across many states. Some states were also using more clinically-focused measures such as evidence of therapeutic duplication, concurrent use of an opioid and a benzodiazepine, and morphine equivalent dose (MED) thresholds.²² States are using multiple criteria to identify patients at risk, which allows for an opportunity to compare programs, determine best practices, and foster

“There is evidence that as prescribers and pharmacists use PDMPs more frequently, it does not have an unintended, or chilling effect on access. In many clinical settings, the effectiveness of opioids is overestimated, and the risks are underestimated. The most important thing clinicians can do is prescribe opioids judiciously and identify, intervene, and treat those with opioid use disorders. Providers need to appreciate that there is no conflict between improving quality of care for patients in pain and reducing our reliance on opioids.”

Another innovative practice is the inclusion of information in PDMP beyond the dispensing information. In 2016, Wisconsin began including information about overdoses that are reversed in the field (i.e., when a patient’s life is saved with naloxone). This information is now displayed in the PDMP profile where it can be useful to identify patients that may be at an increased risk of harm and allows providers to monitor patients more closely and potentially look for alternative therapies to effectively treat the patient’s pain.

PRRs, also known as lock-ins, are tools to better coordinate patient care and to improve outcomes.

program improvements. “Layering” multiple criteria along with the use of more clinical measures can help identify patients at risk and avoid false positives (i.e., patients who are identified but not appropriate for enrollment in PRRs).

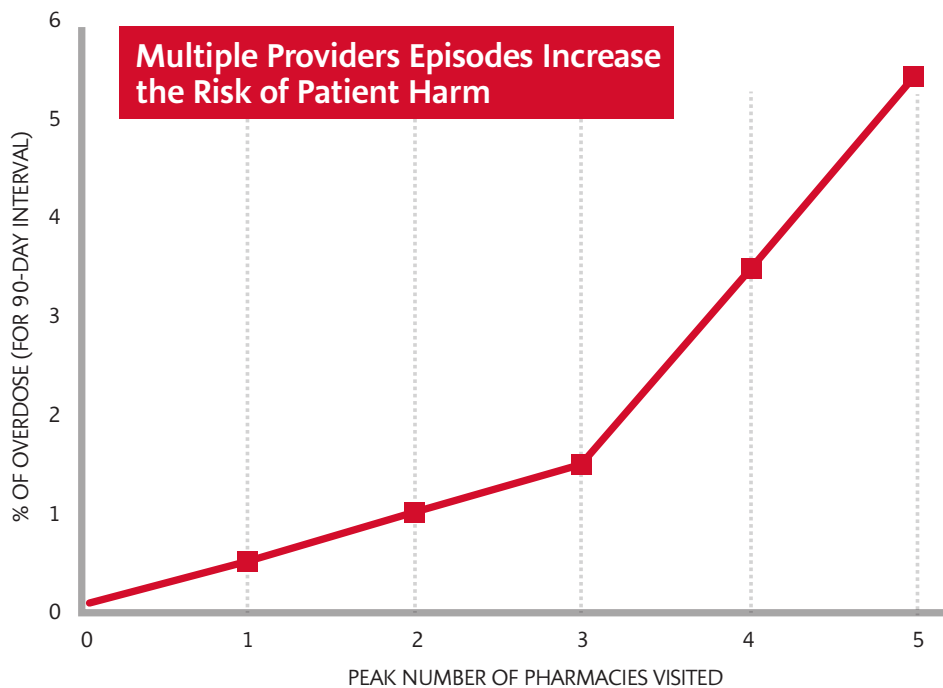
The Pew study also identified opportunities for improvement in PRRs. Currently, over 50 percent of programs are not offering patients additional services to manage their use of pain medications. Most state PRRs are providing case management, but just a handful of states are referring patients to treatment for substance use disorders, referring

patients to pain management specialists, or facilitating access to medication therapy management programs.

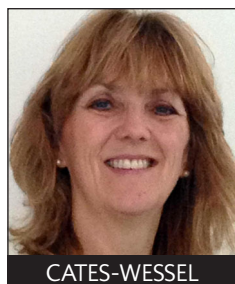
Another shortcomings of PRRs are that patients can circumvent the safeguards by going around assigned providers and paying cash for doctor visits and prescriptions. More than 50 percent of plans do not have access to PDMPs, often because state policies, laws, and regulations prohibit access. This is an opportunity for improvement; by removing these restrictions, insurers could see the complete picture of a patient's opioid use. In addition, only a few states have done any formal assessment of these programs and their effect on patient outcomes. For those that did have assessment programs, there was

evidence of reduced patient harm. There were a number of process measures that indicate possible reduction in patient harm, such as decreases in the number of pharmacies and prescribers visited, reductions in prescription volume and decreased emergency room use.²²

Research has shown that PDMPs and PRRs are valuable tools to achieve harm reduction while ensuring patient access. Opportunities remain to enhance the use of these tools and address barriers and concerns about their use. Continued research will better define impact, highlight best practices for these programs, and improve access to care for patients.



PRESCRIBER PERSPECTIVES, CHALLENGES AND RESPONSIBILITIES



Balancing Risk/Benefit from a Clinician's Perspective

From the perspective of a clinician, opioids are vital medicines for the relief of suffering at the end of life, for the treatment of acute pain, and for pain associated with active cancer. However, a sharp increase in opioid prescribing for chronic, non-cancer pain during the past two decades has been associated with large increases in opioid addiction and opioid deaths in the U.S. Prescribers are a very important piece of the puzzle in dealing with the opioid epidemic.

Although the focus of practitioners is often prescription opioids, illicit opioids also result in health risks for patients and provide an opportunity for physicians to intervene and provide appropriate care and referrals. "In many clinical settings, the effectiveness of opioids is overestimated, and the risks are underestimated. The most important thing clinicians can do is use opioids judiciously and identify, intervene, and treat those with opioid use disorders. Providers need to appreciate that there is no conflict between improving quality of care for patients in pain and reducing our reliance on opioids," stated Caleb Alexander, MD, MS, Co-director of the Center for Drug Safety at Johns Hopkins University.

The effectiveness and safety of opioids are very important issues in combination. When assessing the effectiveness of opioids, we know that they are more effective than placebo and better than non-steroidal anti-inflammatory drugs (NSAIDs)

for acute pain, but when it comes to evaluating long-term studies, this data is sparse, and the duration of follow-up has been limited. The few randomized clinical trials longer than 6 weeks have generally had poor results. Other studies have shown that long-term daily opioids worsen pain and physical functioning for patients.

The safety of opioids is where most focus has been placed. At least one-third of patients in many clinical studies stop opioids because of adverse effects. Importantly, the addictive properties of these medications are important to consider. Oxycodone and heroin molecules are highly similar from a structural perspective. The abuse liability of many prescription opioids is equal to or greater than that of heroin. Prescription opioids and heroin have very similar effects on the brain and the central nervous system, similar pharmacokinetics and pharmacodynamics. Therefore, the risk-benefit calculus for these products is extremely important to consider.

Often, the public discussion is focused on the behavior of abuse, rather than addiction as a disease. Therefore, it is important to appreciate how these complex issues are framed. A recent project with Johns Hopkins Bloomberg School of Public Health and the Office of the Assistant Secretary for Planning and Evaluation at HHS examined public and private insurance coverage for pharmacologic and non-pharmacologic alternatives to opioids and found that the formulary designs and coverage policies can make a significant difference on fostering access to safer, more effective treatments for chronic, non-cancer pain.²³

Sound Prescribing Practices

There are a number of principles of sound prescribing that should be paramount when prescribing opioids, including using higher doses with caution and using methadone and fentanyl with particular caution. Using trial periods, individualizing therapy and engaging multi-disciplinary pain management teams are useful strategies. Doses of opioids should be increased slowly, and doses should be reduced by 25-50 percent when switching among opioids to prevent against inadvertent overdose. Prescribers should also avoid the combination of benzodiazepines and opioids whenever possible. There are also sub-populations of patients that may be at increased risk, such as those using chronic opioids and benzodiazepines combined, those using chronic opioids alone and at high doses, and opioid shoppers.

There are a number of risk mitigation measures to monitor patients taking opioids, such as patient contracts, urine testing and unscheduled pill counts. However, there is limited evidence to demonstrate if these methods reduce injury and deaths, particularly in the long-term. It is important to remember that medications aren't inherently bad or good, dangerous or not dangerous; it depends on how they are used. This wisdom may be less true of opioids than other classes of medications because they are prone to overdose, addiction, and other adverse events.

Abuse Deterrent Formulations

Another strategy to reduce risk is the use of abuse deterrent formulations of opioids. However, these formulations are no less addictive than their counterparts. Abuse-deterrent formulations target the known or expected routes of abuse, such as crushing in order to snort or dissolving in order to inject. However, most non-medical opioid users take pills and swallow them whole.

Patients and prescribers may have misconceptions about the safety of these preparations. One-third of clinicians in a recent study erroneously reported the most common route of abuse was a method other than swallowing pills whole, and one-half erroneously reported that abuse-deterrent formulations were less addictive than their counterparts.²⁴ Abuse-deterrent formulations also may fuel aggressive marketing and promotional tactics that drive sales.

Risk Stratification Methods

One way to potentially minimize risk is through risk stratification methods, possibly developing a score that is as rigorous and robust for opioid use as the Framingham study is for heart disease.

Although there is interest in developing prospective and effective risk stratification methods, the current tools are limited and not very effective at differentiating risk. There are also challenges with incorporating any risk stratification methods into clinical practice.

Opioids are essential medicines for relieving pain and suffering at the end of life, for acute pain and for pain associated with active cancer, but their risk/benefit balance makes them unsuitable for many clinical settings where they have been widely used. This is a complex epidemic, and progress is being made to improve appropriate prescribing. With the number of stakeholders invested and the number of interventions that are being implemented and deployed, there will be continued improvement to ensure safe use of opioids.

Educating Providers on the Opioid Epidemic

Providing evidence-based data and information to providers is one of the primary needs in addressing the opioid crisis. There is a need to increase awareness across the entire spectrum of substance use

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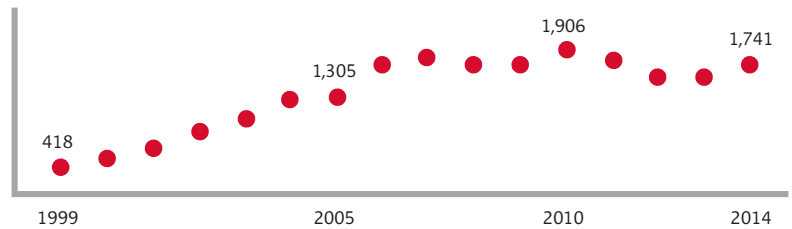
disorders and appreciate that stigma is a significant barrier both within the general public and medical professionals. According to Kathryn Cates-Wessel, Executive Director of the American Academy of Addiction Psychiatry and Principal Investigator and Project Director of the Providers Clinical Support System for Medication Assisted Treatment (PCSS-MAT) and Providers Clinical Support System for Opioid Therapies (PCSS-O), “training and mentoring programs have been developed for prescribers and health professionals and can be accessed at no cost. Every health care professional should be trained on how to prevent, identify, treat and/or refer patients to appropriate providers.”

The PCSS-MAT is a three-year grant funded by SAMHSA in response to the opioid overdose epidemic. PCSS-MAT has developed a national training and mentoring program to educate health care professionals on the use and availability of the latest pharmacotherapies. The overarching goal of PCSS-MAT is to make educational and training resources available on the most effective medication-assisted treatments for patients in a variety of settings, including primary care, psychiatric care, and pain management settings.

PCSS-MAT offers no-cost training activities with CME to health professionals through the use of webinars, online training modules, case vignettes, MAT waiver trainings, and one-on-one and small group discussions that provide coaching for clinical cases. In addition, PCSS-MAT offers a comprehensive library of resources including clinical guidance and other educational tools, community resources, and a PCSS Listserv that provides a “mentor on call” to answer questions about content presented through PCSS-MAT.

The PCSS-MAT Mentoring Program is designed to offer general information to clinicians about evidence-based clinical practices in prescribing medications for opioid addiction. This national network of trained providers has expertise in medication-assisted treatment, addictions and

More than 1,700 young adults, ages 18-24, died from Rx drug overdose in 2014 – a 4-fold increase since 1999... nearly 5 persons per day.



Among young adults, for every death due to Rx drug overdose, there were:



clinical education. The program uses a three-tiered mentoring approach, which allows every mentor/mentee relationship to be unique, and the relationship is designed to meet the specific needs of both parties.

Another available program is PCSS-O. Through education and colleague support, this national coalition of health care organizations is charged with developing training on the safe and effective use of opioids for treatment of chronic pain and opioid use disorders. The overarching goal of PCSS-O is to offer evidence-based CME training on the safe and effective prescribing of opioid medications in the treatment of pain and/or opioid use disorder.

The focus is to reach providers and/or providers-in-training from diverse health care professions, including physicians, nurses, dentists, physician assistants, pharmacists, and program administrators. The program currently represents over one million health professionals. PCSS-O offers training activities to health professionals through the use of webinars and online modules. In addition, PCSS-O offers clinical resources and coaching through clinical guidance and educational tools, coaching and peer support, and one-on-one, small

group discussions. The PCSS Listserv also provides an “Expert of the Month” to answer questions about content presented through the PCSS-O project.

The opioid epidemic is a multidisciplinary issue, and providers must work together to help each other and help patients in need. Engaging in local learning and mentoring opportunities is critical and offers an opportunity to build local learning collaboratives. All health professionals should to be trained on MAT and opioid therapies, and pharmacists are key to the team to help address this epidemic.

Managed Care Collaboration with Providers

In the current environment of opioid overdose as the leading cause of injury related deaths in the U.S., there are preconceived notions about the utilization of opioids for the treatment of both acute and chronic pain. In addition, prescribing habits of providers differ widely and in many ways may not be connected to improvements in patient outcomes. There are opportunities for providers to improve patient safety and decrease diversion through formulary management, pharmacy based screening, and closer collaboration with providers.

between the identification of patients who have addiction and providers that are not prepared to treat the disease of addiction and/or the pain that may precede the risk of addiction.

If we look at the primary drivers of the medical spend in the U.S., addiction is the number one cause of total cost. The top driver of medical spend is tobacco use disorder, an addictive disorder that causes heart disease and increased risk of diabetes. Second is obesity, which in a subset of patients, glucose acts like heroin in the dopamine boost provided to the reward system. Third is alcohol use disorder. The top three most expensive conditions that are treated in the U.S. are driven by addiction disorders, and this does not take into account those patients with opioid use disorder. As we look to implement good treatment systems, they must treat the totality of addiction as a disease, not just specifically opioid use disorder. And although much of the current focus is on opioid use disorder, marijuana use disorder and benzodiazepine use disorder are increasing in frequency.

“As physicians, we have to undo a lot of damage that has been done, often with good intentions. Physicians never want to do harm, but we have been complicit in one of the largest iatrogenically caused crises in the history of mankind with

“One of the fastest ways to advance medical care in treating substance use disorders is to properly align the payment incentives. In order to do that, resources must be reallocated. From a managed care perspective, it is important to track the medical spend offset across silos. If physicians practice evidence-based medicine, addiction treatment will increase the pharmacy spend but will decrease emergency department utilization, decrease hospital admissions, decrease ICU stays, the length of stay, and 30-day readmission rates.”

Currently, less than 10 percent of primary care physicians routinely screen for substance use disorders. Physicians have a fundamental lack of training on addiction and pain management, with medical school curriculums often requiring less than one hour of training throughout the entirety of a student’s medical education. There is a mismatch

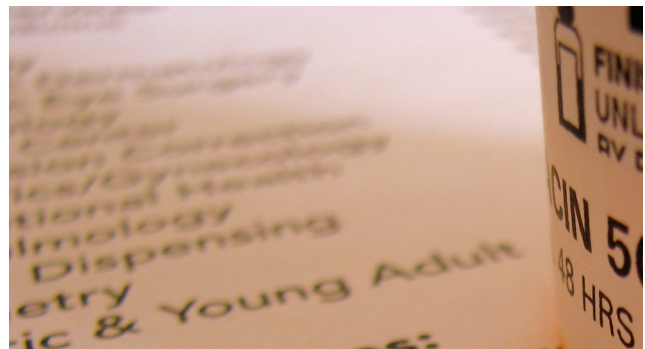
opioids. We need to own that and develop a pathway to solve the problems,” challenged Corey Waller, MD, MS, FACEP, DFASAM, American Society of Addiction Medicine.

One of the fastest ways to advance medical care in treating substance use disorders is to properly

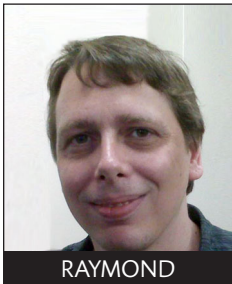
align the payment incentives. In order to do that, resources must be reallocated. From a managed care perspective, it is important to track the medical spend offset across silos. If physicians practice evidence-based medicine, addiction treatment will increase the pharmacy spend but will decrease emergency department utilization, decrease hospital admissions, decrease ICU stays, the length of stay, and 30-day readmission rates.

Formulary management strategies should focus on identifying patients who are at-risk using evidence-based criteria to set formulary limits and decreasing barriers to MAT. One example that could be effective is ensuring prescribed methadone for pain is classified as tier 3, not tier 1. Methadone is a significantly disproportionate killer when it is prescribed for pain, because it is inexpensive and prescribed in large quantities, so it is also a significant diversion risk. Methadone should never be the “fail first” option for pain. Another example is to increase access to the safest opioid, which is buprenorphine in many cases, because it has a significantly decreased risk of respiratory failure. The challenge is that it takes a long time to get approval for use, making its use for acute pain extremely difficult.

There are also a number of myths about opioids that we need to resolve to advance care. There is a real stigma associated with the use of medications like buprenorphine and methadone, which are appropriate medications for pain that are often safer and more effective than other options. Conversations with patients are necessary to understand their needs and make the best decisions to effectively treat both pain and suffering. Patients must be active participants in their own care and understand that treatment takes time.



OPIOID USE MONITORING MEASURES



RAYMOND



BURGESS

Prescription Drug Monitoring Programs

A recent review of state PDMPs showed that there are active PDMPs in every state and the District of Columbia, with the exception of the state of Missouri. PDMPs rely on prescribing and dispensing data from physicians and pharmacies. The data is accumulated on a state-by-state basis, and the state pays the full cost of these programs. No fees are charged to providers for reporting to or accessing data from PDMP programs. The basic information shared within these programs include the date the prescription is dispensed, the name of the pharmacy dispensing the medication, the drug name and quantity, the patient identity, and the prescriber identity. States typically identify patients differently (e.g., assigned number, algorithm of last name, etc.), and this can be problematic for providers that are trying to identify patients, particularly if they cross state lines to fill a prescription.

In general, PDMPs are effective; however, the degree of effectiveness depends on how states utilize the data from the programs. The data has to be accessed and utilized for it to be most effective. Some states proactively use data to reach out to physicians and patients to inform them about potential issues or concerns. Timeliness of PDMPs is improving, with daily reporting now required in 32 states. Philip Burgess, RPh, from the National Association of Boards of Pharmacy (NABP) shared, “one of the primary challenges to the use

In general, PDMPs are effective; however, the degree of effectiveness depends on how states utilize the data from the programs.

of PDMPs is provider inconvenience in accessing the database, often having to jump through several hoops to enter the database in a process that is outside of their normal workflow. Additional improvements like ‘one-click access’ are becoming more widely available and rapidly expanding.”

The biggest barrier to the effective utilization of PDMPs is that the data is not often shared between states, allowing gaps in reporting. To address this issue, NABP has developed PMP InterConnect®, a shared national database of PDMP data. The majority of states are engaged in the program, and other states are working toward connectivity. Each state has its own policies, laws and regulations that govern the use and transfer of this data, so legislative action is needed in some states before they can be part of PMP InterConnect®. In addition, only the state PDMP administrator or director controls the necessary permissions for sharing, and this

authority can vary by state. There are no costs for the prescriber or the pharmacies to access the national database. States are supporting the costs for their connectivity, and NABP has supported the development, maintenance, enhancements, and transaction fees for PMP InterConnect®.

PMP Gateway® is an interface that provides “one-click” access to a patient’s controlled substance prescription history from the PDMP into health IT systems. The interface provides health IT systems a single access point to multiple state PDMP data, thus saving health care providers the cost of individual integrations with each state PDMP. PMP Gateway® is live with implementations in 21 states and currently integrated with many leading EMR platforms (e.g., EPIC, Cerner, QS1). Two states (OH, MA) are providing “one-click access” for prescribers and pharmacists in their state.

Another challenge for PDMP programs is that there is no mandatory registration for prescribers;

therefore, the data inputs may be incomplete. Licensing boards are beginning to address this issue by integrating registration into medical and pharmacy license renewal. Managed care companies could also consider mandating that physicians register for the PDMP program if they want to be part of the network. Over half of states have requirements for prescribers and/or pharmacists to access PDMP information in certain circumstances, such as for certain medications. Other system and process enhancements include requiring practitioners and pharmacists to access the PDMP data prior to prescribing or dispensing a controlled substance, encouraging patients and providers to get smaller quantities of controlled substances for acute situations, and providing for medication therapy management by pharmacists for drug abuse treatment.

Using Naloxone to Improve Opioid Safety

The rate of overdose involving prescription opioids continues to be high. A recent study showed that 20 percent of chronic pain patients taking long-term opioids had experienced overdose or opioid induced respiratory depression.²⁵ In a sample of overdose patients, over 90 percent of patients with non-fatal opioid overdose received a new opioid prescription, and 7 percent had a repeated overdose.¹⁸ We simply haven't effectively addressed overdose risks inherent to prescription opioids. There are well-documented concerns regarding safety of long-term opioid treatment for chronic pain, and there are limitations of existing patient selection and risk mitigation strategies within clinical practice. Providers are continually challenged with balancing the need for opioids with the management of risks, which creates the potential for naloxone to promote opioid safety discussions with prescribers and patients.

Naloxone should be considered an opioid safety tool. Opioids will continue to be used for patients with both acute and chronic conditions. There is no imminent "next generation" of painkillers than can supplant the current use of opioids in the U.S. Even with this backdrop, the U.S. is lagging behind in prescribing and co-prescribing naloxone through the health care system. Naloxone is an FDA

approved opioid antagonist that treats overdose by restoring breathing. Naloxone has an excellent safety profile, and there are multiple formulations available for use, by both health care professionals and laypersons.

According to Daniel Raymond, Vice President of Policy for the Harm Reduction Coalition, "if the goal is to ensure where overdose occurs, the chance the overdose fatality is minimized, then we need to have individuals trained and prepared to deliver naloxone as near to the person who has overdosed as possible." As shown in Figure 3, there are four groups that can increase the access to naloxone in the community.

Figure 3: Four Quadrants Framework for Naloxone Access



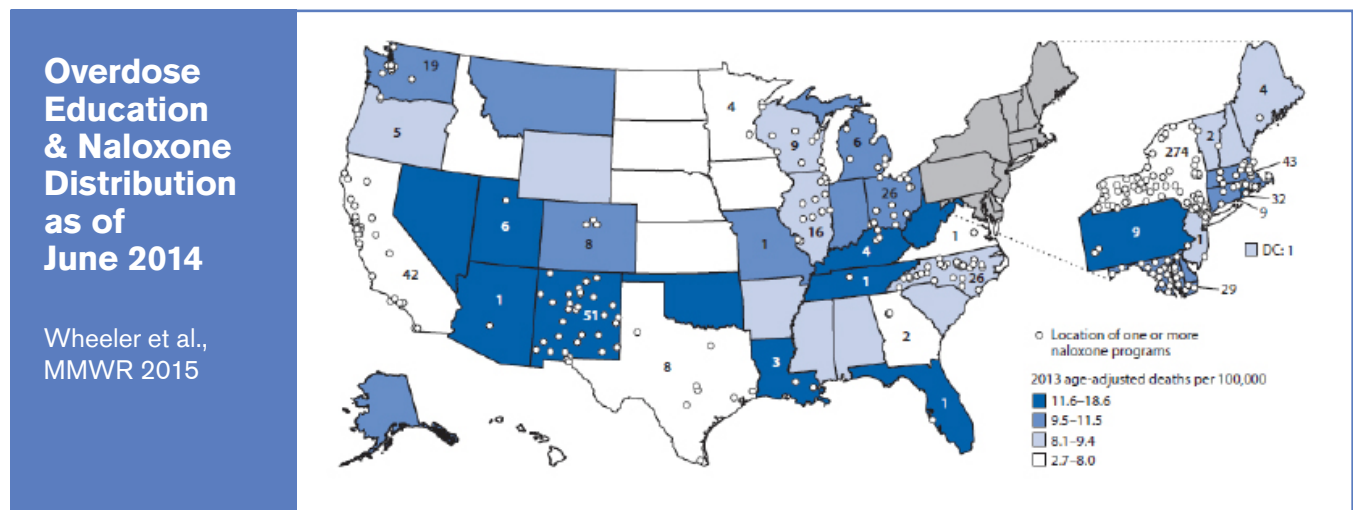
Community-based overdose education naloxone distribution (OEND) programs have emerged over the last 20 years and elevated the concept that naloxone could be used outside of hospital settings and specially trained EMS professionals. Naloxone administration is safe and simple and community laypeople can be trained to provide the rescue medication in overdose situations. Pilot studies and feasibility studies have contributed to the evidence-base demonstrating that laypeople can recognize

overdose, signs, symptoms, risk factors, and respond to an overdose event. Engaging these individuals can be a very effective public health strategy. Over 100 OEND programs have successfully trained individuals and distributed 150,000 naloxone kits and received reports of 26,463 overdoses.²⁶

In regard to first responders and law enforcement, there is recent recognition that basic emergency medical services (EMS) personnel did not possess naloxone but are often in the rural areas where there are more cases of overdose. There is now a move to equip basic EMS and law enforcement with naloxone. Traditional scope of practice has not allowed these professionals to administer medica-

co-prescribed naloxone to patients receiving opioids as part of a larger opioid safety and pain management protocol. Both patients and caregivers were trained and saw promising results.²⁷ This concept expanded to the Veterans Administration Opioid Overdose Education and Naloxone Distribution programs that have provided training and naloxone to over 12,000 veterans as of December 2015.²⁸

There has been an increase in the number of naloxone prescriptions written and filled; however, the absolute numbers are still low. There are ongoing efforts to advance prescribing. The CDC Guideline recommends that prescribers “consider offering naloxone when prescribing opioids to



tions; however, these rules are now shifting to allow for naloxone administration. There has also been rapid uptake of naloxone by law enforcement, supported by a Department of Justice toolkit and grant support through CARA.

Prescribing of naloxone is one of the most intriguing opportunities, but also the least developed. Originally, it was not envisioned that naloxone would be prescribed and dispensed, as it was developed for use in emergency departments or by anesthesiologists in the operating room. Now that the value of naloxone in the community is being recognized, it has generated questions about who could prescribe and increase access in the community. Project Lazarus in North Carolina was an early innovator that worked with doctors who

patients at increased risk for overdose,” within the broader context of assessing other clinical variables. The San Francisco Department of Public Health has also been working to improve naloxone co-prescribing through academic detailing. Pain doctors discount the likelihood of their patients being at risk for overdose. Patients tend to see opioid overdose as “happening to people with drug problems.” This project changes the dialog and frames the discussion around safety of opioids for all patients that are prescribed these medications and has developed an academic detailing guide discussing various scenarios that would resonate with chronic pain patients and their physicians. The results of the project show that by incorporating a safety message into the patient-provider discussion,

both sides better appreciate the risks of opioids, and almost 40 percent of patients received a naloxone prescription. After 6 months, those prescribed naloxone reported 47 percent fewer emergency department visits, and this percentage increased to 63 percent after 12 months.²⁹

Pharmacies and pharmacists also have an increasing role in providing patient access to naloxone. Naloxone remains a prescription drug but can be dispensed by pharmacists under some circumstances. Pharmacy access to naloxone is now allowable in many states under standing orders or collaborative practice agreements. Large pharmacy chains and independent pharmacies are moving quickly in many states to provide access to naloxone to their patients. There remains an ongoing dialogue at the FDA about whether naloxone could or should be available over-the-counter. This increased access has been helpful in addressing this public health crisis but highlights that prescribing for naloxone is still underutilized. There are provisions in CARA that will continue to facilitate and provide guidance for naloxone prescribing.

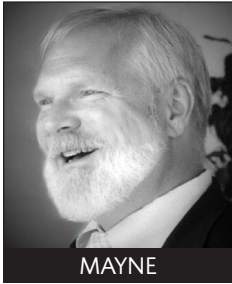
Within managed care, there needs to be additional clarity around coverage and formulary placement.

There are a number of different formulations of naloxone, routes of administration and price points for these products. Plans have implemented different strategies around tiering and prior authorization. There also remain questions about how to provide naloxone to parents and other caregivers who want to be trained and prepared to assist their loved-ones. Insurance often will not cover naloxone in these cases, which may need to be revisited by health plans so that these unnecessary barriers to providing care can be eliminated. In addition, there needs to be a continued professional dialog on the follow-up protocol after naloxone reversal.

There remain some unresolved questions about naloxone that need to be further explored. Should every chronic opioid patient receive naloxone? Should it be reserved for high doses?

Should naloxone be offered to patients that are also taking benzodiazepines? How should naloxone be used in patients with mental health, substance use disorders? All of these factors can place patients at an elevated risk for overdose and additional evidence, guidance and information on the use of naloxone in these populations is needed.

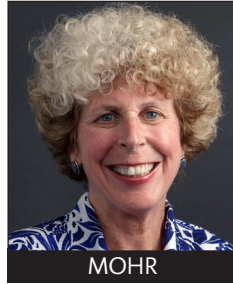
MANAGED CARE AND HEALTH PLAN PERSPECTIVES



MAYNE



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Pharma, Payers and Physicians as Partners to Address Opioid Abuse

Tracy Mayne, PhD, Executive Medical Director for Purdue Pharma shared, “all stakeholders have common goals in the opioid epidemic to reduce abuse and overuse of opioids and improve the lives of patients that are living with pain. As a pharmaceutical company, Purdue Pharma is working in partnership with others on several projects to address patient treatment and limit abuse. These projects have two goals. First is to develop a predictive algorithm to help identify patients at greatest risk for abuse and overdose, and second is to leverage wearable health technologies to address chronic pain.”

Developing a Predictive Algorithm for Opioid Use Disorder

One of the foundational elements for developing a predictive algorithm is to map extended release opioid use in the U.S. to determine normal use and outlying use. Treatment patterns of all non-cancer patients initiating an extended-release opioid were evaluated using the Truven database, a nationally representative database of over 98 million patients. Researchers took the first use of an extended release opioid and followed people over a 2-year period to better understand how these drugs are being used. During the study period, 18.2 million people were prescribed an opioid with 552,000 on extended release, most of who were also

“All stakeholders have common goals in the opioid epidemic to reduce abuse and overuse of opioids and improve the lives of patients that are living with pain.”

on an immediate release opioid. Approximately 20,000 patients in this population were only taking an extended-release opioid.³⁰

The study followed 71,000 of these patients to better understand prescribing patterns.

The results showed that patients fell into four groups regarding duration of use for opioids. Fifty percent of patients received a single prescription for less than a 30-day supply and never refilled the medication. Twenty two percent of patients had a single episode, defined as using a medication for a period of time and then discontinued long-acting use. Eighteen percent of patients experienced multiple episodes where there was evidence of medication use, a break, subsequent evidence of medication use, etc. Finally, 10 percent of the patient population used continuously over a 2-year period.³⁰

Those patients that used one agent continuously during the study period were further examined. The vast majority of these patients (75 percent) used only long-acting agents, 21 percent used two agents, and 8 percent used 3 or 4 different agents over the course of two years, with some pain physicians rotating long-acting opioids.

By examining the treatment patterns, researchers found that drug usage fell into two main categories, including titration, where the prescriber changes the original dose and prescribes a new dose for more than 60 days and excursion, where the prescriber temporarily increases or decreases the dose and then returns to the original, steady-state, dose. One-third of these patients never changed dose over the 2-year period. Among patients that did change dose, 9 percent had excursions, 25 percent had a mix of titrations and excursions, and 66 percent of patients were only titrated, with the majority of patients having 1 up-titration within the

time period. The result showed that 72 patients, or 2 percent of the population, had 3 or 4 sequential uptitrations over a 2-year period. These patients and prescribers fell outside of the standard deviation for normal prescribing and should be evaluated for appropriate use and potential risk for abuse.³⁰

These study results can be used by managed care to better define “usual prescribing” of opioids and to develop criteria to identify outlier patients and prescribers. The study also identified patients that consistently filled their opioid prescriptions early and had 100–200 extra pills at the end of the study. These patients were either not taking the medication as prescribed or could be actively diverting or creating a diversion risk. Payers could potentially use data to identify potential misuse and abuse by flagging escalation patterns, identifying pill collecting and conducting futility analysis.³⁰

Another recent study looked to quantify and characterize the incremental costs of opioid abuse, dependence, overdose, and poisoning over a 3-year period. The study examined 6.6 million patients with a first abuse, overdose, or dependence diagnosis and looked back over their claims history. Two cohorts were identified by propensity score matching on 200 variables over a 7–12 month period. The results showed that 5 or 6 months before the initial diagnosis, medical costs begin to increase. At diagnosis, there was a large increase in costs, and 6-months after diagnosis, these patients incur costs that are \$1,000 more a month compared to the control group.³⁰ The primary drivers of excess cost in this population were opioid dependence and poisoning; non-opioid drug abuse and dependence; and alcohol abuse and dependence. Cost increases were seen in inpatient settings, emergency departments, rehabilitation facilities, outpatient costs and prescription drug costs. Interestingly, these patients were in treatment for alcohol and non-opioid related substance abuse but may not have been evaluated for opioid abuse.³⁰

Leverage Wearable Health Technologies to Address Chronic Pain

There is ongoing work to assess the effectiveness of wearable health technologies to improve treatment for patients with chronic pain. There are numerous examples of wearable medical technology (e.g., Apple Watch, FitBit, chronic pain apps, smart pill bottles, wearable patches). These technologies are often interfaced with a smart device and connected to the cloud where the patient can view a dashboard showing the results. In the cloud, this data can merge with medical records and health care claims, providing health care professionals access to a patient’s dashboard. This allows for almost immediate population outcomes analyses, which can feed directly back into the patient’s device.

For example, a patient’s wearable technology could alert a care nurse that the patient is taking less steps, waking up earlier than normal, experiencing restless sleep and using more rescue medication. The nurse could proactively call the patient and recommend, based on data from the wearable device, that the patient take the long-acting opioid later in morning and that they see a physical therapist to do stretches in bed to help improve movement and decrease pain. The nurse may also more closely monitor rescue medication usage. Data provided by these devices may provide significant opportunities to increase quality of life for patients with pain.

Total Opioid Management within Managed Care

David Calabrese, RPh, MHP, Vice President and Chief Pharmacy Officer for OptumRx points out that the opioid epidemic knows no boundaries. It affects men and women, rich and poor, all ages, and every demographic. Unlike other challenges we have faced within our health care system, this one is unique in that it has largely been brought about by the well-intentioned, yet highly misguided efforts of our system to manage pain, as well as the well-documented over-promotion of opioid drugs for non-cancer related pain by select drug manufacturers.

The U.S. has the highest rate of death in the world due to opioid overdose, six times the world average.³¹ Seventy-eight Americans die every day of prescription opioid overdose,⁶ and there is almost \$80 billion in annual U.S. societal costs due to opioid misuse and abuse.³² There are over 700,000 inpatient admissions (\$28,000 - \$30,000 per episode) and over 500,000 ED admissions (\$5,000 per episode) per year. The U.S. has the highest per capita usage of opioid drugs in the world, consuming 80 percent of the world's prescription opioid supplies – with 250 million prescriptions issued in 2012; accounting for over 30 billion units of opioids.³³

In treating chronic pain, we know that opioid effectiveness is limited, side effects are significant, risks are substantial and effects on human function are small.^{34,35,36} A systematic review of the literature reviewed 2,000 studies between 1998 and 2012 and did not find a single study of non-cancer related pain, of at least a 3-month duration, that would be considered high-quality clinical evidence.³⁷

“Developing a program that provides total opioid management is a high priority topic for Optum Rx – a PBM component of Optum, the largest provider of health care services in the U.S. today. We have access to advanced technologies, analytics capability, behavioral health resources, pain management resources, systems, mobile and web-based tools to help address these complex issues,” explained Mr. Calabrese. Optum has developed a Total Opioid Management Program preliminarily entitled, Five for Life, that focuses on five domains for managed care to address the opioid crisis. These domains include prevention and education; minimizing early opioid exposure; providing aggressive measures of provider surveillance and intervention; identifying and supporting at-risk populations; and managing those with documented substance use disorders.

“Prevention and education strategies, at both the national and local levels, inform parents, patients, providers, and the community about the risks associated with the use of opioids. Conducting first-fill patient education can provide patients with an understanding of what an opioid is, what the risks are, if there are therapeutic alternatives, how to store the medication, and how to properly dispose of opioids.”

Prevention and education strategies, at both the national and local levels, inform parents, patients, providers, and the community about the risks associated with the use of opioids. Conducting first-fill patient education can provide patients with an understanding of what an opioid is, what the risks are, if there are therapeutic alternatives, how to store the medication, and how to properly dispose of opioids. Optum is partnering with network providers in development and promotion of “take-back” programs, providing instructions to patients on how they can return unused opioid medications to local pharmacy partners that have the capabilities to accept and properly dispose of these medications.

Provider education is also important, and a specific focus will entail actively promoting PDMP programs. The plan is considering utilization criteria that requires prescribers to affirm that they have utilized the PDMP before the prescription is filled, particularly for longer-acting agents and for continued prescribing of high-dose opioid therapy to individual patients. One out of every ten patients that starts an opioid will remain on the medication after 6

months, and one of every 550 patients that start an opioid will be dead of an overdose in a median of 2.5 years.³⁸ Minimizing first fill exposure and employing tighter drug utilization criteria, such as quantity limits, concomitant therapy (e.g., benzodiazepines), tighter refill window limits, and pregnancy screenings, may be particularly useful in curbing the indiscriminate prescribing and consumption of opioid medications. Other criteria that may be considered include requiring prior authorization for subsequent continuous fills, age edits, specialist limits, and requiring urine testing for more chronic therapy to be authorized.

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“It is well accepted that most physicians that write opioid prescriptions are doing so with well-intentioned purposes and want to do what is best to relieve a patient’s pain. However, that must be balanced with the clear risks and dangers of opioid therapy. Managed care should focus its efforts on education, monitoring, benchmarking and scoring prescribers, pharmacies and patients to identify patterns of utilization that indicate high risk and devise strategies to intervene quickly and aggressively.”

well-intentioned purposes and want to do what is best to relieve a patient’s pain. However, that must be balanced with the clear risks and dangers of opioid therapy. Managed care should focus its efforts on education, monitoring, benchmarking and scoring prescribers, pharmacies and patients to identify patterns of utilization that indicate high risk and devise strategies to intervene quickly and aggressively. Proactive collaboration and data sharing with state and federal licensing agencies and regulatory bodies can also decrease inappropriate prescribing and dispensing practices.

Strategies to identify and support at-risk populations can be based on sophisticated patient-level analytic assessment, risk stratification and scoring that identifies patterns of use that suggest risk. Patients can then be provided appropriate care and support, including behavioral health, case management support and MAT. Ensuring access to well-rounded pain management programming is also critical toward ensuring that those with true, chronic pain management needs are not abandoned and are properly supported to minimize dependency and overdose risk while still effectively delivering proper pain control.

Properly managing the afflicted population requires utilization of historic medical/pharmacy claims and EMR data to flag patients with recent or past history of opioid substance use disorder treatment. Studies demonstrate that our current lack of monitoring of these patients can result in a high number of them being re-exposed to opioid drugs soon after experiencing overdose or completing substance abuse

disorder treatment. Although controversial, when patients have been identified as having a use disorder, criteria can ‘lock-in’ patients to pharmacies, prescribers and/or specific drug and dosage regimens. Offering post-discharge relapse prevention support and MAT are extremely important, as patients are most vulnerable to relapse soon after discharge. Restricting access to opiates through prior authorization in those actively undergoing opiate abuse treatment can help to ensure success with such treatment. Physician guidance on proper naloxone prescribing for both the patient and the caregiver/family member is also a strategy that can help reduce overdose deaths. Managed care organizations are in a very unique position to help drive change in this area and have an important role to play, yet success in these efforts will require an openness toward partnership with other stakeholders that share accountability.

Figure 4: Accountable Stakeholders



Improving the Evidence Base

There are a number of health-system and payer approaches to better manage the opioid epidemic and improve patient outcomes. The Patient-Centered Outcomes and Research Institute (PCORI) is working to improve the evidence for effective solutions to manage this epidemic. PCORI has allocated over \$70 million in funding over the past two years to look at initial prevention of unsafe opioid prescribing and the management of long-term chronic pain patients. The organization is looking for real-world solutions that answer real-world questions that help patients make informed choices.

According to Penny Mohr, MA, Senior Program Officer for Improving Healthcare Systems at PCORI, “the opioid epidemic is an important focus of research for PCORI because opioid abuse results in a significant number of deaths in the U.S.; at the same time, there is significant concern by the pain advocacy community that there will be limits to legitimate patient access to opioids. PCORI is looking to fund research that strikes a balance to minimize abuse and ensure access to legitimate use.” Stakeholders have identified this as an important research question. Specifically, the National Association of State Medicaid Directors has shared concern about having to move quickly to put initiatives in place to stem the flow of opioids, but doing so without evidence-based strategies or effective ways to evaluate the impact of implemented interventions.

Before investing, PCORI looked at evidence gaps and evaluated systematic reviews and found that there is little evidence on safe prescribing, effective strategies to implement dose escalation and withdrawal strategies, and evaluation of comparative effectiveness of opioids versus

non-opioid therapies. Specific gaps that were identified include:

- Wide variation among states in opioid prescribing rates; indicating a lack of consensus about when to prescribe opioids³⁸
- Little evidence for how to improve safe prescribing of opioids³⁹
- No studies examined the comparative effectiveness of opioids vs. non-opioid therapies (pharmacological or non-pharmacological) for outcomes >1 year

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- Little available evidence on the effectiveness of dose escalation, withdrawal/tapering strategies, short/long acting opioids
- A number of strategies targeted to providers and/or patients to promote safe opioid prescribing have been developed but not rigorously evaluated⁴⁰
- Guidelines recommend use only when alternatives are ineffective³⁸

There are broad sets of initiatives across a number of federal agencies that are being rapidly implemented to address the opioid crisis (e.g., FDA Action Plan, IOM National Pain Strategy, the President’s Budget) without a strong evidence-base. There is a tremendous opportunity to add to the evidence-base in this regard.

The current PCORI portfolio related to opioids is small but very interesting. Researchers out of Group Health Cooperative in Washington State are determining best practices to stem the epidemic of opioid addiction and overdose that results from long-term use in treating chronic pain. The research will evaluate a health-plan initiative to reduce risks of long-term opioid use for chronic pain. The program includes reduced prescribing of high opioid doses and increased care planning and monitoring of chronic opioid therapy patients. The study will determine if the initiative influenced pain outcomes, patient-reported opioid

benefits and problems, and opioid-related adverse events. Early results show that the initiative did substantially reduce the number of opioid scripts and day supply. An assessment of the impact on reduction in pain and psychosocial outcomes is underway.

PCORI has had two major funding announcements around opioids. The first is focused on treatment strategies for managing and reducing long-term opioid treatment for chronic pain with the goal of managing patients with pain first while also reducing risks and harms of long-term opioid use. The study will focus on the following research questions:

- Among patients with chronic noncancer pain on moderate/high-dose, long-term opioid therapy, what is the comparative effectiveness of strategies for reducing/eliminating opioid use while managing pain?
- Among patients with chronic noncancer pain on moderate/low-dose, long-term opioid therapy, what is comparative effectiveness and harms of strategies used to limit dose escalation?

An example of the work being conducted with this funding award is a randomized controlled trial conducted by the University of Minnesota with 1,400 primary care patients at 9 VA sites that are receiving moderate to high-dose opioids. The research compares two systems of care strategies,

pharmacist-led telecare and an interdisciplinary pain management team, that differ substantially in comprehensiveness and resource intensity, to improve pain and reduce opioid use among Veterans. This includes a sub-study among patients on high-dose chronic opioid therapy to compare tapering with or without buprenorphine rotation. The research could provide evidence to support the use of a replicable strategy to improve pain and reduce opioid use.

The second funding opportunity focuses on strategies to prevent unsafe opioid prescribing in primary care among patients with acute or chronic non-cancer pain and will focus on potential new users of opioids, examine payer and health system strategies or patient- and provider- facing initiatives that will improve pain management, reduce harm from opioids, and improve knowledge, communication, shared decision making about alternatives treatments, and prevention of unsafe prescribing.

There will be additional, anticipated challenges in sustainability and adoption of these strategies. We need to better understand how we can adapt models that have proven to be successful in highly integrated systems into a more fragmented care delivery. Among these complex, multi-component systems approaches, we also need to study the most efficient ways to meet the dual goals of improving pain management and reducing unsafe opioid use.

TREATING CHRONIC PAIN WITH OPIOIDS: WHERE ARE WE?



Chronic pain is a prevalent chronic disease that impacts the daily lives of one-third of Americans over the age of 45, or 25 million, with daily chronic pain.⁴¹ This prevalence will continue to increase as the population ages. It is estimated

that the number of patients with chronic pain that are on opioids is 5-8 million.⁴² Chronic pain is different than acute pain, and the brain processes acute and chronic pain differently. Acute pain is primarily a sensory input, usually caused by tissue injury. Chronic pain engages a higher level processing response to pain that is expressed through thoughts and emotions.

Thus, chronic pain must be managed differently than acute pain, with analgesic medications being less important and the need to manage affective and cognitive components a more important aspect. For tissue injuries, there is an increased focus on physical restoration, such as exercise, physical therapy, stretching, yoga, and weight loss. Patients must also balance the affective and cognitive components of pain through activities such as cognitive behavioral therapy, mindfulness therapy and acceptance therapy. Overall function, including quality of life, is the key outcome for chronic pain patients.

Guidelines for Treating Chronic Pain

The CDC Guideline provides recommendations on when to initiate or continue opioids for chronic pain; opioid selection, dosage, duration, follow-up and discontinuation; and assessing risk and addressing harms of opioid use.³⁸ There are areas of consensus across the CDC Guideline and the ASAM criteria⁴³ and the Veteran's Administration/Department of Defense Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain.⁴⁴ It is important that patients are

effectively assessed and determinations are made to indicate that the patients' pain is opioid responsive or if the pain could be more responsive to other interventions.

Selecting which patients will do well on opioids using risk stratification approaches is particularly important. Proactively identifying patients that may have difficulty adhering to opioid therapy, including those with a history of substance use disorder can indicate patients that are at high risk for poor treatment response. There are a number of tools that have been designed and validated for this purpose such as the Screener and Opioid Assessment for Patients with Pain (SOAPP-R[®])⁴⁵, the Opioid Risk Tool (ORT)⁴⁶, and the Brief Risk Interview (BRI).⁴⁷ Determining predictive ability is difficult with any available tool, but they can be helpful in organizing and structuring assessments for patients at high risk.

There is also consensus across guidelines that there should be informed consent and a mutually agreed upon plan of treatment. Patients need to be active participants and clearly understand the risks and benefits of treatment. Ongoing assessment of pain, function, and adherence is necessary. Interventions for low-risk patients include random pill counts, random urine toxicology, PDMPs, and monitoring tools. Interventions for high-risk patients include increased visit frequency, shorter/smaller prescriptions, and access to additional addiction expertise. There are a number of monitoring tools that can be used to track patient adherence such as the Current Opioid Misuse Measure (COMM[™])⁴⁸, the Prescription Drug Use Questionnaire (PDUQ) and self-report version (PDUQ-p)^{49,50}, the Addiction Behaviors Checklist (ABC)⁵¹, the Pain Medicine Questionnaire (PMQ)⁵², and the Prescription Opioid Abuse Checklist (POAC).⁵³ These tools can identify people who are nonadherent, but that does not provide evidence of a substance use disorder.

The CDC Guideline also makes recommendations for risk mitigation strategies, including accessing the PDMP every 1-3 months, conducting urine drug testing at the initiation of therapy and at least annually thereafter, avoiding prescribing of opioid analgesics to those on benzodiazepines, and if opioid use disorder is present, referring to or arranging evidence-based treatment, including MAT. It is important to appreciate other risk factors for opioid toxicity such as respiratory insufficiency, pregnancy, renal insufficiency, patients over 65 years of age, and previous opioid overdose.

Risk mitigation strategies for these patients include the use of risk prediction instruments, treatment agreements, patient education, urine toxicology, use of the PDMP and other monitoring tools, pill counts, and abuse deterrent formulations. Although rational and practical suggestions, the data upon which the CDC Guideline was created are often insufficient or too limited to support any of the recommendations.

The CDC Guideline places an emphasis on responsible prescribing to minimize opioid exposure in the community, minimizing diversion, detecting and addressing misuse and abuse, referring to treatment,

and increasing focus on non-medication interventions. Opioid-sparing strategies that are recommended include tapering patients to the lowest dose possible, increasing vigilance, avoiding dose increases above 90 MME/day, limiting the length of prescription treatment following acute pain and utilizing non-opioid medications. There has been significant community concern that these guidelines will have a general chilling effect on opioid prescribing for patients with chronic pain.

Some patients on opioids can experience opioid induced hyperalgesia, or a decreased tolerance for pain. Opioid tapering can also increase hyperalgesia. We need to be mindful of withdrawal hyperalgesia and how that can complicate care. The CDC Guideline reinforces the importance of treating psychiatric symptoms. We know that chronic pain can worsen depression, is risk factor for suicide, and can cause psychological distress. Interventions that are often successful for patients with chronic pain are the same interventions effective for treating addiction, such as motivational interviewing, cognitive behavioral therapy, stress management, psychiatric assessment, and functional assessment.

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RESOURCES

There are a number of helpful resources that were shared during the Symposium that may be of use to individuals interested in this topic.

- American Society of Addiction Medicine. The ASAM Criteria. Access at <http://www.asam.org/quality-practice/guidelines-and-consensus-documents/the-asam-criteria>.
- College of Psychiatric and Neurologic Pharmacists. Naloxone Access: A Practical Guideline for Pharmacists. Access at <https://cpnp.org/guideline/naloxone>.
- College of Psychiatric and Neurologic Pharmacists. Opioid Use Disorders: Interventions for Community Pharmacists. Access at <https://cpnp.org/guideline/opioid>.
- U.S. Centers for Disease Control. Guideline for Prescribing Opioids for Chronic Pain – United States 2016. Access at <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.
- Johns Hopkins Bloomberg School of Public Health. The Prescription Opioid Epidemic: An Evidence-Based Approach. Access at <http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/opioid-epidemic-town-hall-2015/2015-prescription-opioid-epidemic-report.pdf>.
- National Association of Boards of Pharmacy. NABP PMP InterConnect. Access at <http://www.nabp.net/initiatives/pmp-interconnect/>.
- National Governor's Association. Finding solutions to the prescription opioid and heroin crisis: a road map for states. Access at <http://www.nga.org/files/live/sites/NGA/files/pdf/2016/1607NGAOpioidRoadMap.pdf>.
- National Institute on Drug Abuse. Trends and statistics: prescription drug abuse. Access at <https://www.drugabuse.gov/related-topics/trends-statistics>.
- Patient-Centered Outcomes Research Institute. Strategies to Prevent Unsafe Opioid Prescribing in Primary Care among Patients with Acute or Chronic Non-Cancer Pain, Access at <http://www.pcori.org/funding-opportunities/announcement/strategies-prevent-unsafe-opioid-prescribing-primary-care-among>.
- Prescribe to Prevent. Provides tools, resources, guides, forms on integrating naloxone into practice. Access at <http://prescribetoprevent.org/>.
- Provider's Clinical Support Systems for Medication-Assisted Treatment. Access at www.pcsmat.org.
- Provider's Clinical Support Systems for Opioid Therapies. Access at www.pcsmat.org.
- Substance Abuse and Mental Health Services Administration (SAMHSA). Medication-assisted treatment. Access at <http://www.samhsa.gov/medication-assisted-treatment>.
- White House Office of National Drug Control Policy. National Drug Control Strategy. Access at www.whitehouse.gov/ondcp.

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